NICK ASSINK

PERSONALIZED TREATMENT FOR TIBIAL PLATEAU FRACTURES

Towards 3D-assisted fracture assessment, surgery, and outcome prediction

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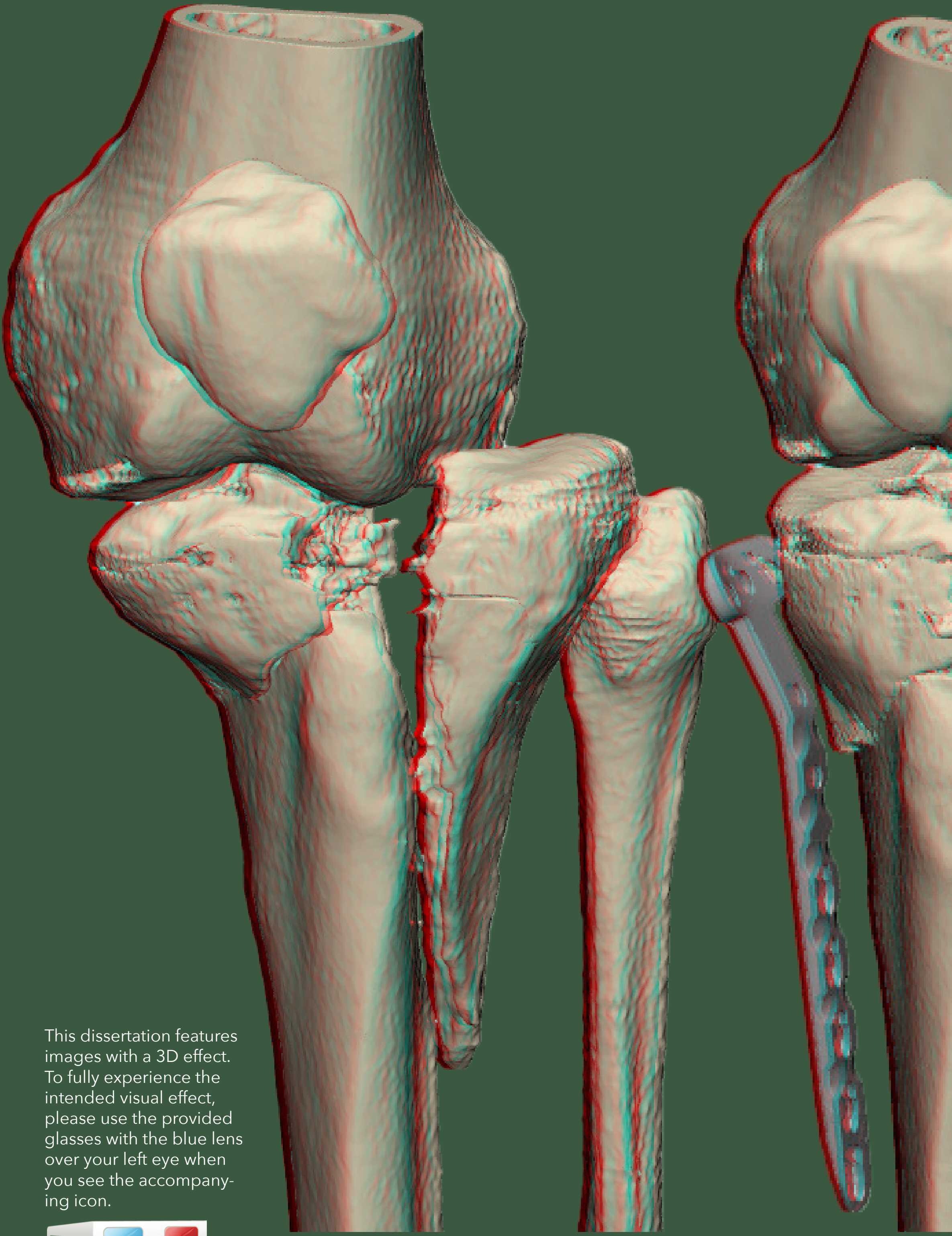

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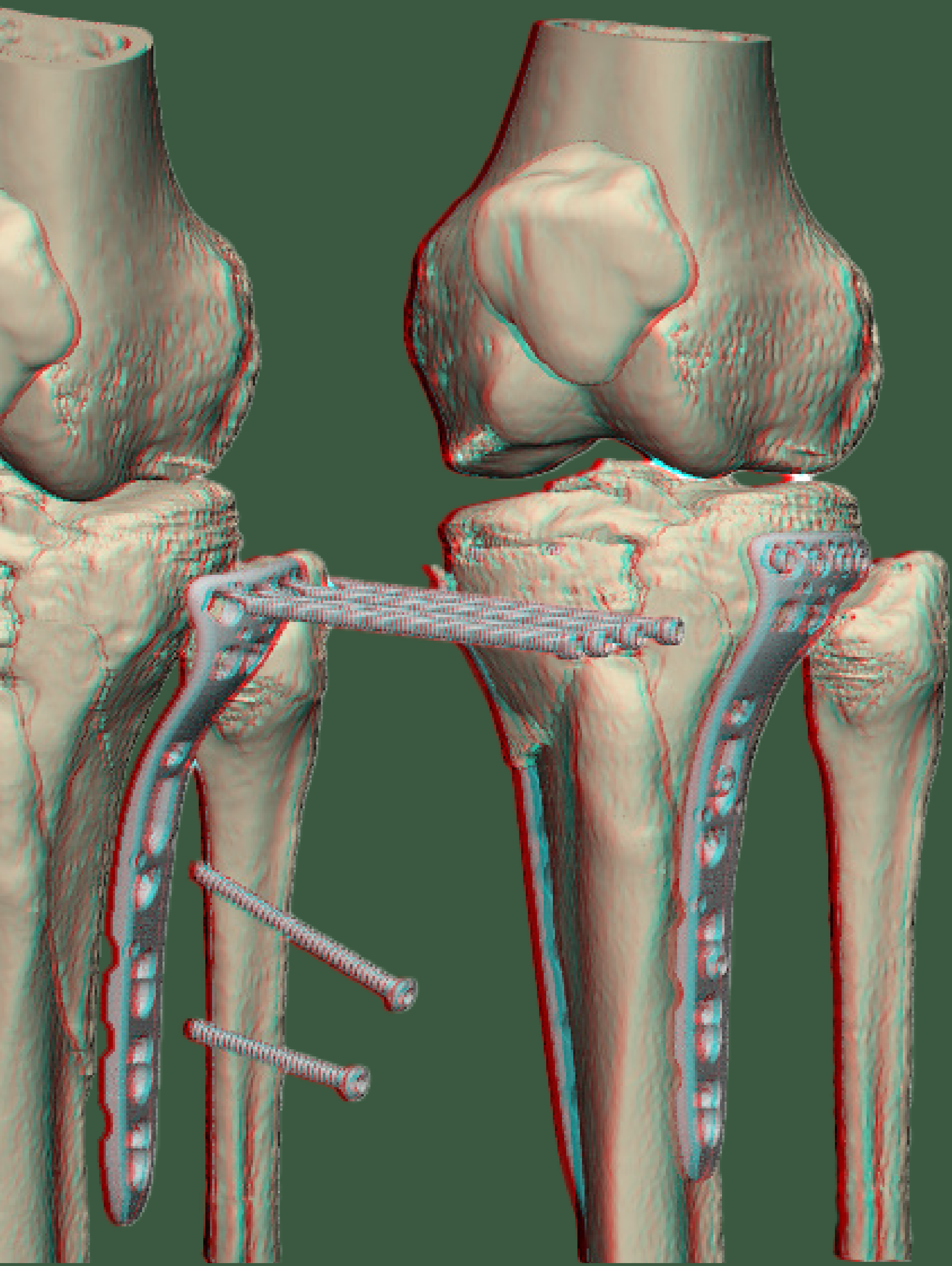

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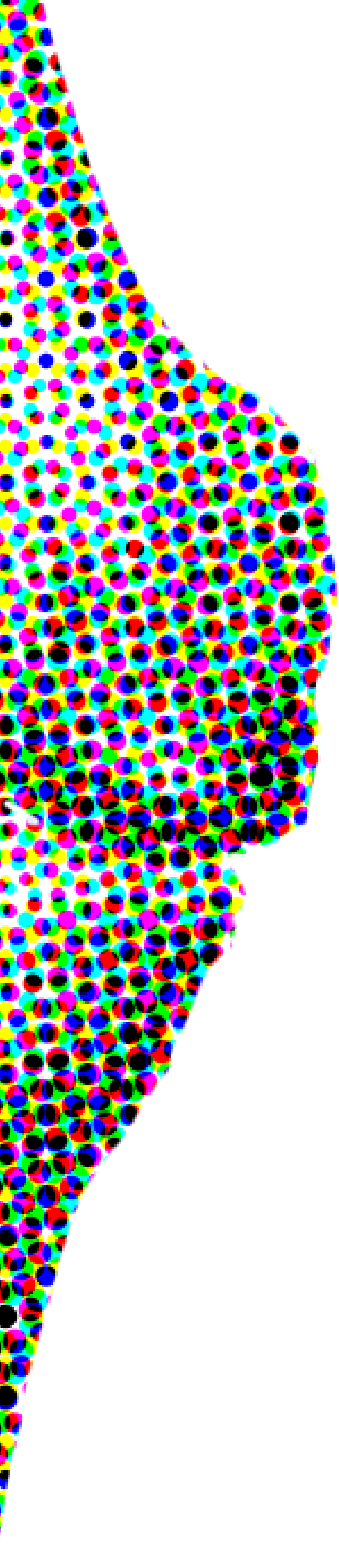
CHAPTER 1



GENERAL INTRODUCTION

PREFACE

Most children possess an imagination that knows no boundaries. I was no exception. As a little boy, my adventures took me to the most spectacular places. From historical castles, to planets far beyond what is known. Growing up, this imagination usually fades out because of daily routine. Yet, in July 2022 reality brought me back to my imagination when NASA revealed the first stunning images from the James Webb Space Telescope which captured the universe in breathtaking detail. One image, a sharply focused ultradeep field view, revealed an universe older than we have ever seen. The observations of the James Webb telescope are only one example in which advancement in technology allows us to measure and analyze previously inaccessible data, providing new insights and opportunities for innovation. In medical imaging, new advancements also allow for visualizing parts of the human body in unprecedented detail. The newest high spatial resolution CT-scanners allow for detailed 3D reconstructions, whereas increased computing power allows to process and analyze big datasets, paving the way for innovations that could significantly improve both diagnostics and treatment.

Technology has also transformed various aspects within our current daily routine. From how we consume information to how we access goods and services. Most of these aspects take place on the small screen of our mobile device, through which we are constantly connected to the rest of the world. The use of sophisticated algorithms has enabled a high degree of personalization across various industries. The content we see on our screens, whether it be news articles, products, or music recommendations, is increasingly tailored to our individual tastes and preferences. This trend not only enhances our experiences as consumers but also holds immense potential for healthcare. By leveraging technology to gain a deeper understanding of patients, healthcare providers can deliver treatments that are customized to each individual's unique characteristics and needs. This shift towards more patient-centered care has the potential to revolutionize healthcare and improve outcomes for patients, but also set expectations straight by tailoring patient-specific predictions. As technology continues to evolve, the possibilities for personalized healthcare are endless, promising a future where patients receive the right care at the right time, every time.

Over the past four years, this PhD research has focused on using novel (3D) techniques to improve measurement methods, customize patients' treatment, and provide patient-specific outcome predictions. All with the goal to use gained knowledge for the development and application of **patient-tailored solutions in the treatment of tibial plateau fractures.**

TIBIAL PLATEAU FRACTURE

Fractures have been a part of human existence since time, with evidence of bone-setting techniques discovered at archaeological sites in Egypt. It was only in the early nineteenth century, however, that medical literature began to differentiate between shaft and intra-articular fractures, notably in Sir Ashley Cooper's book titled *"A Treatise on Dislocation and on Fractures of the Joints"* [1]. The description in this book of 'oblique fractures of the tibial head which are fractured into the knee-joint' was one of the early medical documentations of fractures of the tibial plateau, being published in 1825. Fractures of the tibial plateau are fractures which involve the articular surface of the tibial part of the knee. Since the knee is one of the most loadbaring parts of the body, fractures around this joint highly impact patients' mobility, severely restricting their ability to engage in social activities and work [2,3]. Tibial plateau fractures typically occur from either a varus (inward) or valgus (outward) force applied to the knee, often accompanied by an axial (downward) load [4,5]. Depending on the nature of the force and the knee's position at the time of injury, the resulting fracture patterns varies from simple split fractures to complex multi-fragmentary fractures of lateral, medial or bicondylar types [6–8]. The cause of these fractures generally depends upon age and activity: low-energy incidents such as falls from a small height are more common in older, predominantly female, populations, while younger, mostly male individuals tend to suffer these injuries from high-energy impacts like vehicle collisions or falls from significant heights [9–11]. Tibial plateau fractures are relatively rare as they account for 1-2% of the fractures in adults and 8% in the elderly population [10,12]. Though with reported incidences of tibial plateau fractures between 10-25 per 100.000 anually [9,11], this would accumulate up to 4500 patients in the the Netherlands per year, and even up to 2 million patients worldwide, representing a significant healthcare burden.

Fracture assessment

For successful treatment of a fracture, a detailed understanding of its nature is required. Visualization and characterization of the fracture are therefore essential in order to determine how to treat a fracture. One of the first classification methods was proposed by Marchant in the first half of the 19th century [13]. Based on radiographs of the knee, he distinguished these fractures into three different types: split, depression or combined. Currently, at least 38 different classification tools to classify tibial plateau fractures have emerged based on either radiohaphs or more detailed Computed Tomography(CT)-imaging [14]. Among these, the AO/OTA (Fig. 1), Schatzker and Three-column classifications are most commonly used [15–17]. In addition to classifying a fracture pattern, one could quantify the fractures' severity by measuring fracture displacement in terms gap and step-off (Fig. 2), tibial widening, or alignment of the tibial axis in coronal or sagittal plane. These measurements, which can be determined using plain radiographs or CT-scans, provide a comprehensive understanding of the injury's extent. Based on the combination of the fracture's classification, displacement

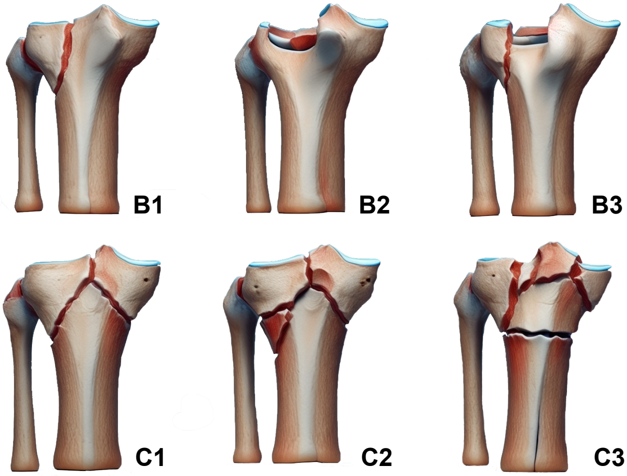


Figure 1: Based on fracture characteristics, the AO/OTA classification classifies intra-articular tibial plateau fractures into different types of fractures: partial articular fractures (B1:pure split, B2: pure depression, B3: split-depression) or complete articular fractures (C1: simple articular and metaphyseal, C2: articular simple and metaphyseal multifragmentary, C3: articular multifragmentary)

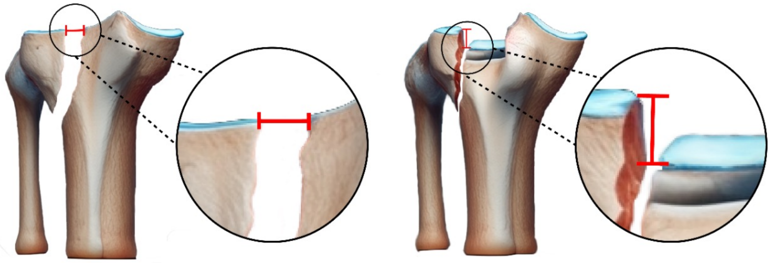


Figure 2: Displacement of tibial plateau fractures could be measured in terms of gap(left) and step-off(right) both before and after treatment. Gap is defined as the separation of fracture fragments along the articular surface. Step-off is defined as the separation of fracture fragments perpendicular to the articular surface.

and patient characteristics (e.g. age, comorbidities) one could opt for nonoperative or operative treatment. Surgical intervention is generally recommended for fractures with a gap or step-off greater than 2 mm, a metaphyseal-diaphyseal translation exceeding 1 cm, or an angular deformity greater than 10 degrees [18]. This decision-making underscores the significance of a detailed fracture analysis, ensuring that the chosen treatment plan aligns with both the nature of the fracture and the patient's overall health situation.

Treatment

Nonoperative management usually involves immobilization techniques, such as a knee brace or long-leg cast, for several weeks to facilitate bone healing. Alternatively, operative treatment consists of open fracture reduction followed by fixation using plate and/or screws [20–22]. The main goals of operative treatment in tibial plateau fractures are to reestablish joint stability, achieve normal limb alignment, and restore the articular surface [18,19]. This could be achieved through Open Reduction and Internal Fixation (ORIF) of the fractures, which allows for realignment and stabilization of the fracture fragments. Various surgical approaches are available for exposing the tibial plateau, depending on the characteristics of the fracture. Following exposure, the different fragments of the fracture are typically realigned, and the reduced position is secured using osteosynthesis materials including screws and plates. Treatment techniques have been changing throughout the years (Fig. 3). Nowadays around two out of three patients receive operative treatment for their tibial plateau fracture. Though, for most time in history, people were reliant on closed reduction techniques, and splinting or casting to retain the reduction. It wasn't until the late 19th century that the first techniques of operative treatment with osteosynthesis plates emerged [20,21]. With the discovery of antisepsis, the emergence of X-ray, more knowledge regarding tissue reaction to metals, and improved surgical techniques for internal fixation, closed methods of treating fractures faced more critical reevaluation. The introduction of compression plates by Danis in 1947 [22], established the concept for the osteosynthesis plates and further popularization of these plates occurred with the Arbeitsgemeinschaft fur Osteosynthesefragen (AO) group in the 1960s [23]. Since then significant advancements have been made including the introduction of locking plates and screws, which facilitates more stability in fractures in osteoporotic bone or those with high comminution. These locking plates and screws provide a significant advantage over traditional fixation methods by creating a stable, fixed-angle construct that does not depend as heavily on the bone's condition for stability [21]. Further developments led to the currently used anatomically shaped locking compression plates which combines both compression and locking into one plate [24,25]. Latest developments consist of the use of patient-specific implants which are tailor-made for the specific anatomy and fracture morphology of a patient [26]. This latest development does not only illustrate the significant progress in fracture treatment throughout the years, but also highlights the personalized direction in which orthopaedic-trauma care is heading, aiming for personalized solutions for each patient.

Functional outcome

Functional recovery after a tibial plateau fracture varies significantly between different patients and depends on several factors. After a fracture, the majority of patients reports an initial decline in functional outcome, followed by a steep increase from 6 to 12 months follow-up [27]. Yet at one year follow-up, there is usually still significant

Historical perspective of Tibial Plateau Fractures: Diagnostics & Treatment

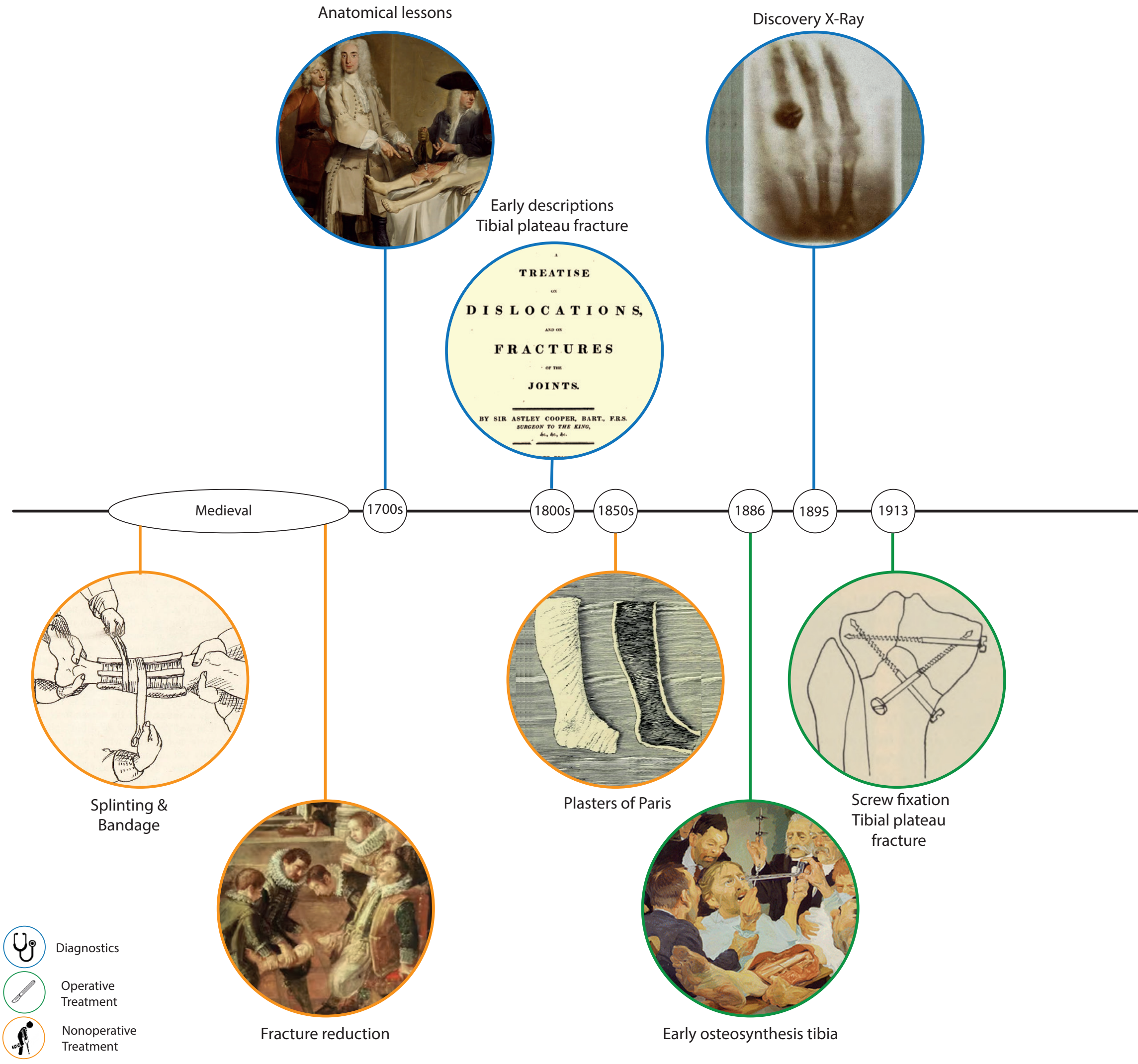
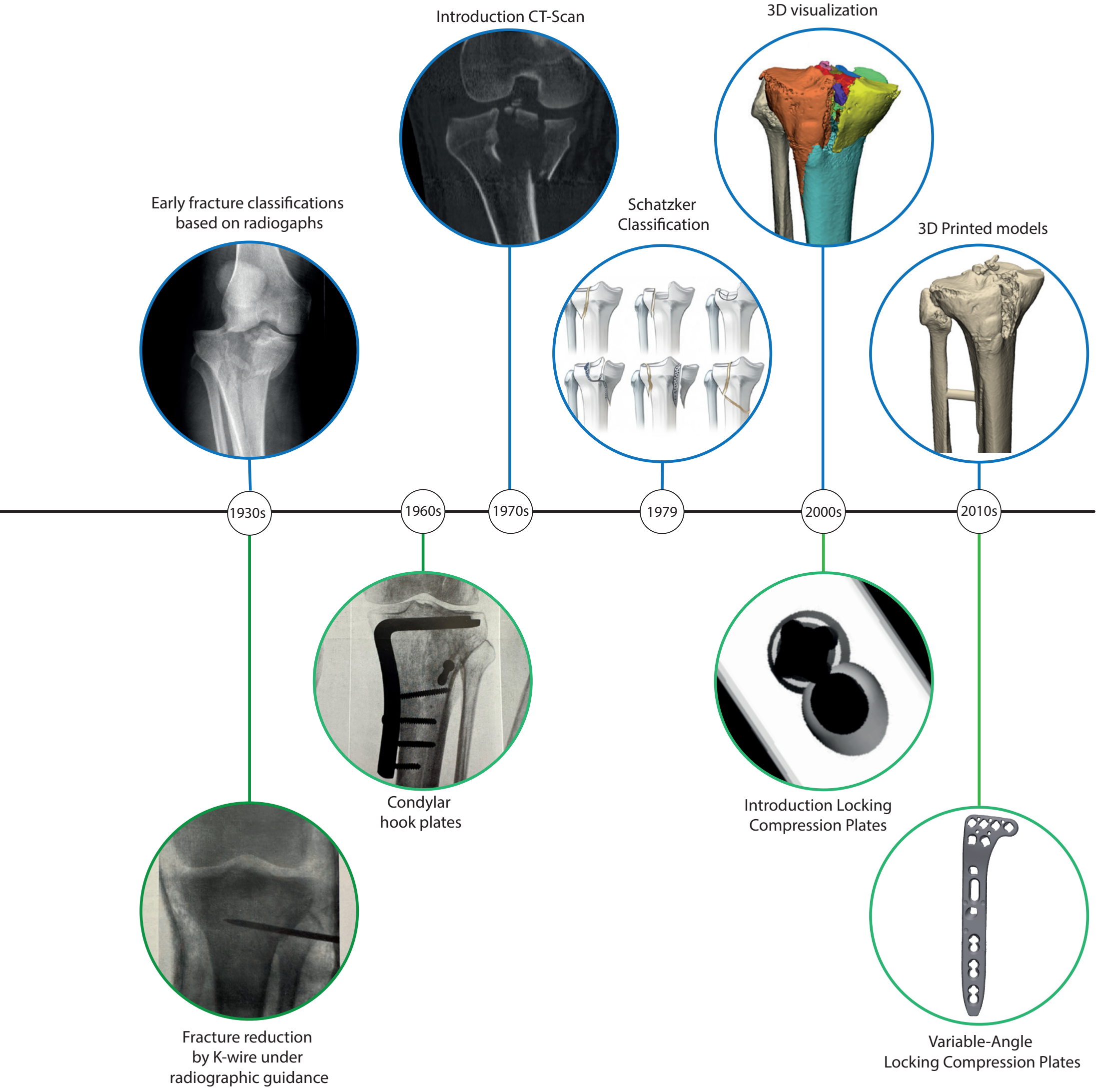


Figure 3: Global overview of milestones in the historical advancements in diagnosis, operative and nonoperative treatment.


Introduction CT-Scan
3D visualization
Early fracture classifications based on radiogaphs
Schatzker Classification
3D Printed models
1930s
1960s
1970s
1979
2000s
2010s
Condylar hook plates
Introduction Locking Compression Plates
Fracture reduction by K-wire under radiographic guidance
Variable-Angle Locking Compression Plates

impairment of movement and muscle function and the majority of patients have not fully recovered [28]. Small increase in function is still observed until five years after injury, but the average recovery does not reach the level of functionality before injury [27]. Patients especially report poor abilities to perform sports. More than 30% of the patients will not return to performing sports, whereas from the patients who do return to sport up to 40% will not reach their pre-injury level [3].

It is generally believed the quality of articular reduction, restoration of the tibial axis, and patient characteristics such as age and gender impact functional outcome [29,30]. Yet, the exact impact of each parameter remains unclear. Early reports supported the idea that achieving anatomical reduction with <2 mm articular displacement as measured on radiographs is essential for achieving good functional outcome [19,31]. Yet, within current literature there is little rationale for claiming that accurate articular reduction of tibial plateau fractures, especially within tolerances of less than 2 mm, is critical to achieving a good clinical outcome [32]. Ever since its introduction, the 2 mm cut-off has been self-propagated, despite numerous research with contradicting findings [33]. Even though clinical decision-making is currently performed with CT, this cut-off based on plain radiographs is still used today. The first part of this thesis addresses whether the current indications for surgery are justified and assessed the association between different radiographic features and risk on a knee prosthesis, as well as patient-reported outcome **[PART I]**. Within the second part of this thesis, a machine learning based prediction model was created which included both radiographic as patient characteristics to provide a patient-centred outcome prediction tool **[PART II]**. Both part I and part II of this thesis are based on conventional, widely available, imaging modalities. In the subsequent parts of this thesis novel applications based on more advanced 3D imaging in tibial plateau fracture treatment will be explored.

Three-dimensional fracture visualization

Medical imaging has made significant improvements throughout the years. The discovery of X-rays in 1895 was a groundbreaking moment, fundamentally changing the medical landscape. For the first time, physicians could look inside the human body without surgery, allowing direct visualization of fractures. This capability marked a departure from an era in which reliance was solely on physical examinations and clinical judgment. Despite that radiographs are confined to a 2D projection, they remain valuable tools in fracture assessment today due to their ease of accessibility and minimal radiation. The introduction of the CT-scan in 1971 further enhanced diagnostics by providing cross-sectional images of the body. This allowed physicians to "scroll" through different layers of tissue and bone providing clinicians with a multi-dimensional view of injuries, enabling a more accurate assessment of fracture patterns, displacement, and associated injuries. The subsequent development of MRI scanners further enhanced diagnostics by facilitating the visualization of other (soft) tissues including cartilage, cruciate ligaments and muscles. Utilization of three-dimensional volume rendering techniques has enabled direct visualization of fractures as a 3D object on the computer screen. These rendering techniques for fractures were initially documented in the late 80s, with reports highlighting the creation of 3D images for acetabular fractures [32]. Subsequently, in the 90s, these techniques were also applied to tibial plateau fractures [33]. With improvements in quality of the CT scans and enhanced computing power in the last two decades, these 3D virtual reconstructions are increasingly accessible and used. Additionally, these virtual renderings can be 3D printed to create a tangible model of a fracture which further increases the understanding of complex fractures [34,35]. 3D printing, also known as additive manufacturing, is a process of creating three-dimensional objects by layering or depositing material in a sequential manner based on a digital model. This technique found its origin in the early 80s, whereas 3D printing industry experienced rapid growth and widespread adoption in the last decade including in the field of healthcare. Figure 3 provides an overview of these different imaging modalities for fracture assessment and their place in historical context with respect to available treatment techniques. One of the most recent developments in facture visualisation consist of quantitative 3DCT (Q3DCT). Q3DCT is a promising technique which adds a quantification tool to the 3D rendering and could provide a valuable tool in addition to classic measurements (e.g. gap and step-off) [36]. In the third part of this thesis, Q3DCT measurements will be developed and applied on tibial plateau fractures to further improve fracture assessment **[PART III]**.

VIRTUAL SURGICAL PLANNING

3D assisted surgery in acute fracture care

An important adage emphasized in surgical training is *"plan your operation, and operate your plan"* [37]. The utilization of 3D technology can substantially enhance surgical planning by allowing for virtual preparation of various surgical steps including fracture reduction strategy, implant sizing and placement, and establishing screw positions and lengths [38]. Surgeons can employ these 3D renderings to simulate specific aspects of the surgical procedure within a virtual environment, enabling them to anticipate on challenges and optimize the surgical plan. The virtual plan facilitates real-time adjustments, ensuring alignment among the whole team involved in the operative procedure. Further translation of this virtual strategy into the operating theatre can be achieved through the utilization of techniques such as 3D printing. Patient-specific instrumentation including 3D printed surgical guides are increasingly used for various surgical applications and offer several benefits, including improved accuracy shorter operation times, and greater predictability in terms of surgical outcomes [34,35].

The process of 3D-assisted surgery starts with segmentation of the medical imaging into a 3D model (Fig. 4; left). Within the field of bone-related surgery, the consensus is that a CT-scan offers best quality images for 3D reconstruction. Segmentation is based on global thresholding which uses a cut-off for the grey values representing a certain type of tissue (i.e. bone). Additionally, when dealing with fractures, each fragment can

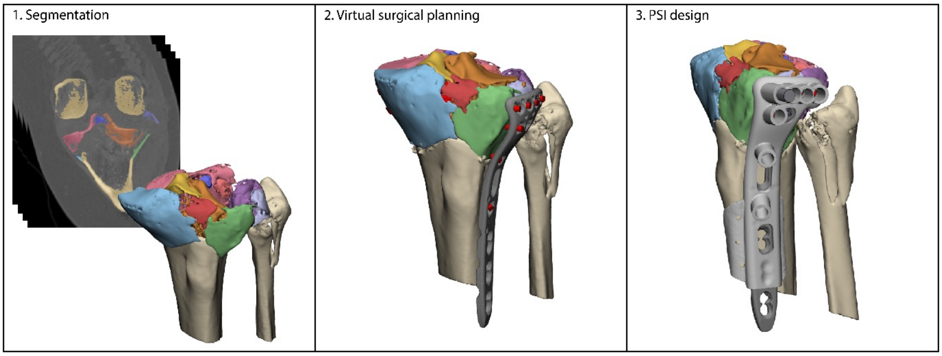


Figure 4: Process of 3D-assisted surgery: segmentation, virtual surgical planning and Patient-Specific Instrumentation (PSI) design and manufacturing.

be segmented separately based on either connecting pixels or manual input. The second stage consist of performing parts of the intended surgery virtually including fracture reduction, plate fitting, screw positioning, cutting planes or bone resections [38]. After establishing a final plan, this plan could be shown virtually in the operating theatre increasing the surgeons' perception of the surgical procedure. Also, other tools such as computer navigation, 3D printed patient-specific surgical guides, or custom-made implants could be used to translate the virtual surgical plan into the procedure, leading to a more predictable outcome. Modern 3D software tools allow for designing of these tools. The fourth part of this thesis will focus on the use of different tools such as surgical guides and custom-made implants to translate the virtual patient-specific surgical plan into the operating theatre **[PART IV]**.

3D-assisted surgery for posttraumatic malunions

Despite extensive preoperative planning, surgical treatment of tibial plateau fractures might still lead to a suboptimal result in a substantial number of patients due to complex fracture patterns, associated fracture comminution, and soft tissue injury [39]. Patients with severe malunited tibial plateau fractures often endure significant physical impairment. In the young active population, treatment options are limited, with corrective osteotomy surgery being one of the few available choices. Revision surgery presents significant challenges for the orthopaedic trauma surgeon, but provides a good option for these cases when carefully planned [40–42]. 3D printed surgical cutting and reduction guides provide an accurate tool for planning the osteotomy enhancing predictability of postoperative results [43]. The last part of this thesis will cover the use of 3D planned corrective surgery in malunited fractures **[PART V]**.

AIMS OF THE THESIS

The overall aim of the research presented in this thesis is to work **towards a more patient-tailored approach in the treatment of tibial plateau fractures**.

The specific aims are:

- To assess what sizes of gaps and step-offs could be accepted for the nonoperative treatment of tibial plateau fractures **[Chapter 2]**.
- To compare functional outcome after non-operative and operative treatment in minimally displaced fractures with the aim to address whether current indications for surgery are still justified **[Chapter 3]**.
- To assess the association between different radiographic features and risk on prosthesis following surgical treatment of tibial plateau fractures **[Chapter 4]** .
- To develop and internally validate a clinical prediction model using machine learning algorithms to predict functional outcome following a tibial plateau fracture **[Chapter 5]**.
- To develop a Q3DCT measurement to quantify intra-articular displacement **[Chapter 6]**.
- To assess the association of the developed Q3DCT measurement with patient-reported outcome and conversion to total knee arthroplasty **[Chapter 7 & 8]**.
- To assess the relationship between the different unique tibial plateau injury mechanisms and the functional recovery at follow-up **[Chapter 9]**.
- To provide a complete and comprehensive overview of the currently used concepts of 3D-assisted surgery in patients receiving surgical treatment for their tibial plateau fracture **[Chapter 10]**.
- To assess whether 3D-guided surgery is feasible and can be used to facilitate optimal screw trajectories in tibial plateau fracture surgery **[Chapter 11]**.
- To assess whether it is feasible to fabricate and use patient-specific implants for medial tibial plateau fracture surgery **[Chapter 12]**.
- To assess whether our alternative two-step method for 3D-guided patient-specific extra-articular osteotomies is feasible and accurate **[chapter 13]**.
- To develop a novel technique for 3D-guided patient-specific intra-articular osteotomies **[Chapter 14]**.

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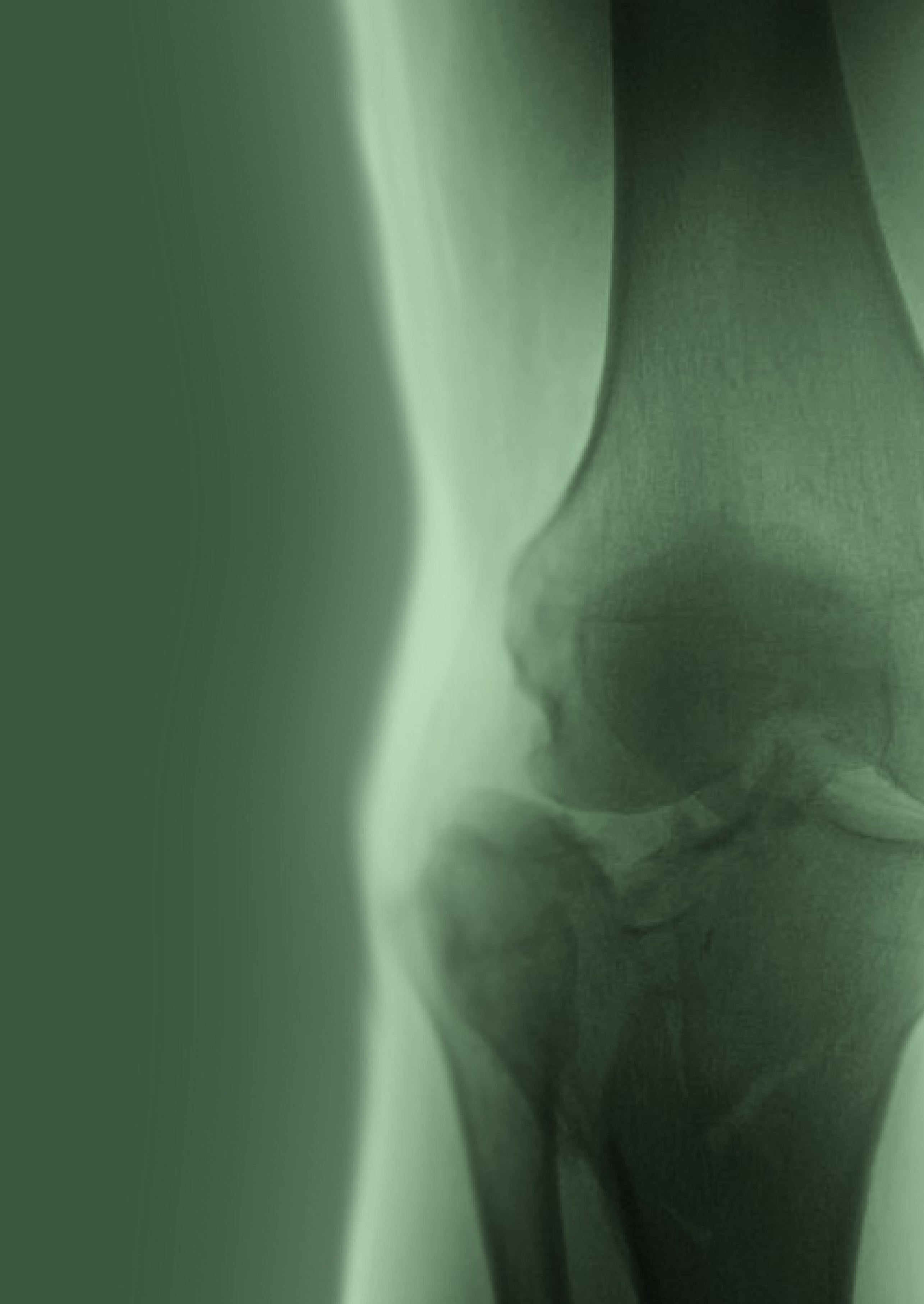

CONVENTIONAL FRACTURE ASSESSMENT

PART I

CHAPTER 2

Functional Outcome After Nonoperative Management of Tibial Plateau Fractures in Skeletally Mature Patients: What Sizes of Gaps and Step-offs Can be Accepted?

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images were reassessed, fractures were classified, and gap and stepoff measurements were taken. Nonresponders did not differ much from responders in terms of age (53 ± 16 years versus 54 ± 20 years; p = 0.89), gender (70% [142 of 203] women versus 59% [142 of 242] women; p = 0.01), fracture classifications (Schatzker types and three-column concept), gaps (2.1 ± 1.3 mm versus 1.7 ± 1.6 mm; p = 0.02), and stepoffs (2.1 ± 2.2 mm versus 1.9 ± 1.7 mm; p = 0.13). In our study population, the mean gap was 2.1 ± 1.3 mm and stepoff was 2.1 ± 2.2 mm. The participating patients divided into groups with increasing fracture displacement based on gap and/or stepoff (< 2 mm, 2 to 4 mm, or > 4 mm), as measured on CT images. ANOVA was used to assess whether an increase in the initial fracture displacement was associated with poorer functional outcome. We estimated the survivorship of the knee free from conversion to total knee prosthesis at a mean follow-up of 5 years using a Kaplan-Meier survivorship estimator.

Results: KOOS scores in patients with a less than 2 mm, 2 to 4 mm, or greater than 4 mm gap did not differ (symptoms: 83 versus 83 versus 82; p = 0.98, pain: 85 versus 83 versus 86; p = 0.69, ADL: 87 versus 84 versus 89; p = 0.44, sport: 65 versus 64 versus 66; p = 0.95, QOL: 70 versus 71 versus 74; p = 0.85). The KOOS scores in patients with a less than 2 mm, 2 to 4 mm, or greater than 4 mm stepoff did not differ (symptoms: 84 versus 83 versus 77; p = 0.32, pain: 85 versus 85 versus 81; p = 0.66, ADL: 86 versus 87 versus 82; p = 0.54, sport: 65 versus 68 versus 56; p = 0.43, QOL: 71 versus 73 versus 61; p = 0.19). Survivorship of the knee free from conversion to total knee prosthesis at mean follow-up of 5 years was 97% (95% CI 94% to 99%).

Conclusion: Patients with minimally displaced tibial plateau fractures who opt for nonoperative fracture treatment should be told that fracture gaps or stepoffs up to 4 mm, as measured on CT images, could result in good functional outcome. Therefore, the arbitrary 2-mm limit of gaps and stepoffs for tibial plateau fractures could be revisited. The survivorship of the native knee free from conversion to a total knee prosthesis was high. Large prospective cohort studies with high response rates are needed to learn more about the relationship between the degree of fracture displacement and functional recovery after tibial plateau fractures.

INTRODUCTION

The World Health Organization recommends taking 10,000 steps a day to stay healthy [22], which equates to approximately 3 million steps per person each year. A tibial plateau fracture may have a major impact on a patient's mobility, social activities, and ability to work. Adequate treatment is crucial to minimize the risks of progressive posttraumatic arthritis and patient disability [1, 5, 10, 11]. Assessment of fracture displacement is essential to choose the best treatment strategy for tibial plateau fractures [8]. Gap and stepoff measurements, which provide information about fracture displacement, are used for clinical decision-making when choosing between operative or nonoperative treatment. Nonoperative management usually consists of a knee brace or long-leg cast for several weeks and is considered a good option for the treatment of minimally displaced tibial plateau fractures [5, 10, 11].

A frequently reported indication for nonoperative treatment of tibial plateau fractures includes minimal displacement with an articular fracture gap and/or stepoff of less than 2 mm [12, 13]. However, in a review of previous studies, Giannoudis et al. [4] reported that articular gaps and stepoffs up to 10 mm are well tolerated and could be accepted for nonoperative treatment. However, we are not aware of any evidence regarding fracture displacement and the functional outcome after nonoperative treatment of tibial plateau fractures. Most studies of tibial plateau fracture treatment are focused on functional outcomes after surgery [7, 19, 21]. Moreover, few studies have primarily focused on the correlation between initial fracture displacement and functional outcome [7, 15, 16, 18]. Additionally, several studies [4] have used standard radiographs to assess fracture displacement, whereas over time, clinical decision-making has become increasingly based on CT images. CT images have been shown to increase the accuracy of assessing fracture displacement [12]. There seems to be no consensus on the impact of minimal fracture displacement on functional outcome. Because the degree of fracture displacement is important for patient counseling regarding the indications for surgery and prognosis, it is crucial to assess what sizes of gaps and stepoffs could be accepted for the nonoperative treatment of tibial plateau fractures.

We therefore asked: (1) In patients treated nonoperatively for tibial plateau fractures, what is the association between initial fracture displacement, as measured by gaps and stepoffs at the articular surface on a CT image, and functional outcome? (2) What is the survivorship of the native joint, free from conversion to total knee prosthesis, among patients with tibial plateau fractures who were treated without surgery?

PATIENTS AND METHODS

Study Design and Setting

A multicenter cross-sectional study was performed in patients who were treated nonoperatively for a tibial plateau fracture between January 2003 and December 2018 at the University Medical Center Groningen (The Netherlands), Isala (The Netherlands), University Hospitals Leuven (Belgium), and Martini hospital (The Netherlands). These include, respectively, three Level 1 trauma centers and one Level 2 trauma center.

Participants

Patients with a preoperative (diagnostic) CT scan and follow-up of at least 1 year were eligible for inclusion. A gap and/or stepoff of more than 2 mm, as measured on a CT scan, was an indication for recommending surgery. Some patients with gaps and/or stepoffs exceeding 2 mm might not have had surgery due to shared decision-making. The exclusion criteria were age younger than 18 years at the time of injury, pathologic fractures, isolated tibial eminence avulsions (such as cruciate ligament injuries), and patients who were deceased at the time of follow-up. Between 2003 and 2018, 530 patients were treated nonoperatively for a tibial plateau fracture, of which 45 had died at follow-up, 30 were younger than 18 years at the time of injury, and 10 had isolated tibial eminence avulsions, leaving 445 patients for follow-up analysis. All eligible patients were approached by posted mail and asked to provide informed consent and complete validated patient-reported outcome measures. A total of 46% (203 of 445) of the patients participated. The mean age at the time of injury was 53 ± 16 years, 70% (142 of 203) of patients were women, and the mean follow-up duration after injury was 6 ± 3 years (Table 1).

Table 1: Patient characteristics (n=203)

Parameter	Value
Age (years)	53 ± 16
Woman	70% (142)
Smoking	13% (26)
BMI in kg/m2	27 ± 4.6
Schatzker classification	
Type I	18% (37)
Type II	27% (54)
Type III	39% (80)
Type IV	12% (25)
Type V	2% (4)
Type VI	1% (3)
Three Column classification	
One Column	58% (118)
Two Columns	35% (71)
Three Columns	7% (14)
Gap (mm)	2.1 ± 1.3
Stepoff (mm)	2.1 ± 1.2
Conversion to total knee prosthesis	3% (7)
Follow-up (years)	6 ± 3

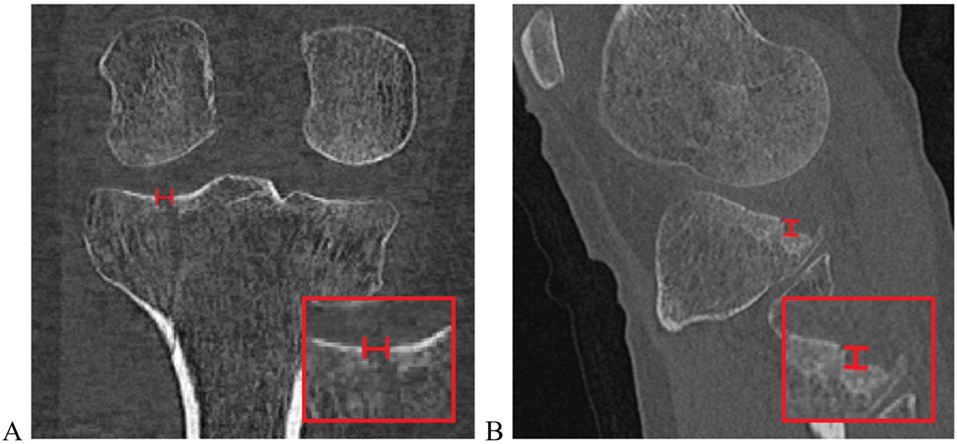

Figure 1: A-B The measurements of the fracture displacement are displayed in the (A) coronal (gap 3.7 mm) and (B) sagittal (stepoff 3.8 mm) views.

CT-based Gap and Stepoff Measurements

All knee radiographs and CT images, which were taken within 2 weeks after the patient's injury, were reassessed through consensus by two observers (NA, FFAIJ) with experience in tibial plateau fracture management. All tibial plateau fractures were classified according to the Schatzker classification [14] and three-column classification [20]. Gap and stepoff measurements were taken using CT images. Gap was defined as separation of fracture fragments along the articular surface. Stepoff was characterized as separation of fracture fragments perpendicular to the articular surface [1]. For each patient, the maximum value of the gap or stepoff on any of the axial, coronal, or sagittal CT slices was measured (Fig. 1). Measurements were performed with a digital measurement tool in the Mimics Medical software package (Version 21.0, Materialise). The relationship between the measured initial fracture displacement (gaps and stepoffs) and functional outcome was assessed.

Patient-reported Outcomes

All eligible patients were approached by posted mail and asked to complete the standardized Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaire [2]. Additionally, patients were asked whether they received a total knee prosthesis. The KOOS is a validated questionnaire consisting of five subscales: symptoms, pain, activities of daily living (ADL), function in sports and recreation, and knee-related quality of life (QOL). A normalized score (100 indicating no symptoms and 0 indicating extreme symptoms) was calculated for each subscale. Scores of the subscales are calculated by adding the individual items (questions) and transforming scores to a range from 0 to 100, with higher scores indicating better function. The minimum clinically important differences (MCID) for five subscales of the KOOS are: symptoms = 11, pain = 17, ADL = 18, sport = 13, and QOL = 16.

Data Sources

Baseline characteristics of the participants were retrieved from the patients' electronic records. The scores of the KOOS questionnaire were calculated from the patient survey of the responding patients.

Primary and Secondary Study Outcomes

Our primary study goal was to assess whether an increased gap and/or stepoff is associated with poorer functional outcome after nonoperative management of tibial plateau fractures. To achieve this, we reassessed CT scans for initial fracture displacement (gaps and/or stepoffs) and related these measurements to a validated patient-reported outcome (KOOS questionnaire) at follow-up.

Our secondary study goal was to assess the survivorship of the knee free from conversion to total knee prosthesis after nonoperative management of tibial plateau fractures. To achieve this, we asked all patients whether they had conversion to total knee prosthesis at follow-up and determined the survivorship of the native knee among patients with tibial plateau fractures who were treated without surgery. Two authors (NA, FFAIJ) reassessed radiographs taken at the time of injury and at follow-up for the presence of osteoarthritis according to the Kellgren-Lawrence classification [6]. Conversion to a total knee prosthesis was considered a worse outcome (or endpoint), and therefore, KOOS scores obtained after placement of the prosthesis could not be included in the analysis.

Ethical Approval

The institutional review boards of all participating centers approved the study procedures, and the study was performed in accordance with the relevant guidelines and regulations.

Statistical Analysis

We used IBM SPSS software, version 23.0 for Windows (IBM Corp), for statistical analyses. Continuous variables are presented as the mean and SD for normally distributed data and median and IQR for nonnormally distributed data. Descriptive statistics were used to describe the study population. The study population was divided into groups based on the size of the gap or stepoff (< 2 mm, 2 to 4 mm, and > 4 mm), and ANOVA was used to assess differences between the groups in terms of functional outcome. Post hoc sample size calculation showed that at least 16 patients would be needed in each group to detect an MCID of 10 points in KOOS score by using 80% statistical power, $\alpha = 0.05$, and an SD of 10. We used linear regression to analyze the relationship between the gap or stepoff and KOOS score. The model was adjusted for potential confounders, including gender, age at the time of injury, BMI, and the number of columns involved (Supplementary Digital Content 1; https://links.lww.com/CORR/A828). We estimated the survivorship of the knee free from conversion to total knee prosthesis at a mean follow-up of 5 years using a Kaplan-Meier survivorship estimator. The significance level was set at $p < 0.05$.

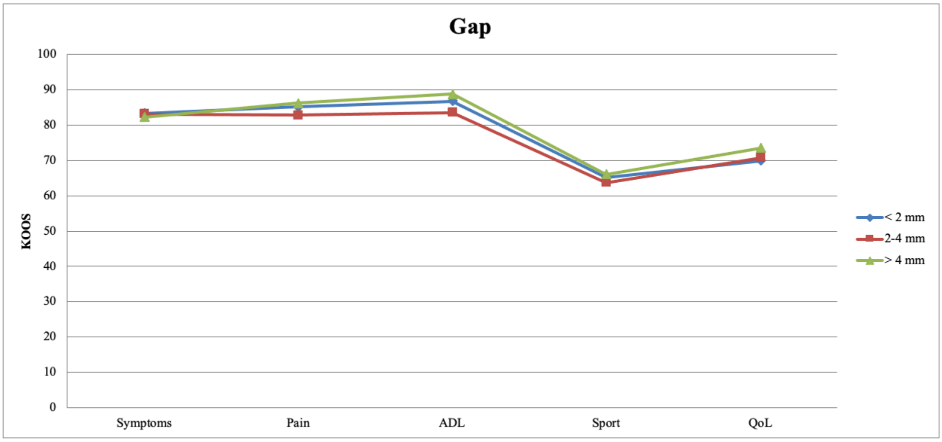

Figure 2: The KOOS subscales, representing functional outcome, are displayed for 196 nonoperatively treated patients divided into three subgroups based on the size of the articular gap. No differences in mean KOOS scores were found between subgroups, meaning that gaps up to 4 mm are well tolerated. Due to the small number of patients in the group with a gap greater than 4 mm, the results of this group need to be interpreted with caution.

Analysis of Nonparticipants

For the nonresponse analysis, we used an independent-samples t-test for continuous variables and a chi-square test for noncontinuous variables. The nonresponse analysis showed no differences in age between responders and nonresponders (53 ± 16 years versus 54 ± 20 years; $p = 0.89$). Women responded more often (70% (142 of 203) versus 59% (142 of 242); $p = 0.01$). There was no difference in the mean stepoff between responders and nonresponders (2.1 ± 2.2 mm versus 1.9 ± 1.7 mm; $p = 0.13$). The mean gap was slightly smaller in the nonresponders group (2.1 ± 1.3 mm versus 1.7 ± 1.6 mm; $p = 0.02$). There was not much difference in fracture classification between responders and nonresponders (Schatzker I 18% (37 of 203) versus 11% (26 of 242); Schatzker II 27% (54 of 203) versus 25% (61 of 242); Schatzker III 39% (80 of 203) versus 35% (85 of 242); Schatzker IV 12% (25 of 203) versus 16% (39 of 242); Schatzker V 2% (4 of 203) versus 6% (15 of 242); Schatzker VI 1% (3 of 203) versus 7% (16 of 242)). Also, there were few differences between responders and nonresponders in fracture classification according on the three-column concept (involvement of one column 58% (118 of 203) versus 52% (127 of 242); two columns 35% (71 of 203) versus 36% (86 of 242); three columns 7% (14 of 203) versus 12% (29 of 242)).

RESULTS

Relationship Between Fracture Displacement and Functional Outcome

Nonoperative treatment of minimally displaced tibial plateau fractures resulted in a good functional outcome regardless of the gap (Fig. 2) or stepoff (Fig. 3). KOOS scores

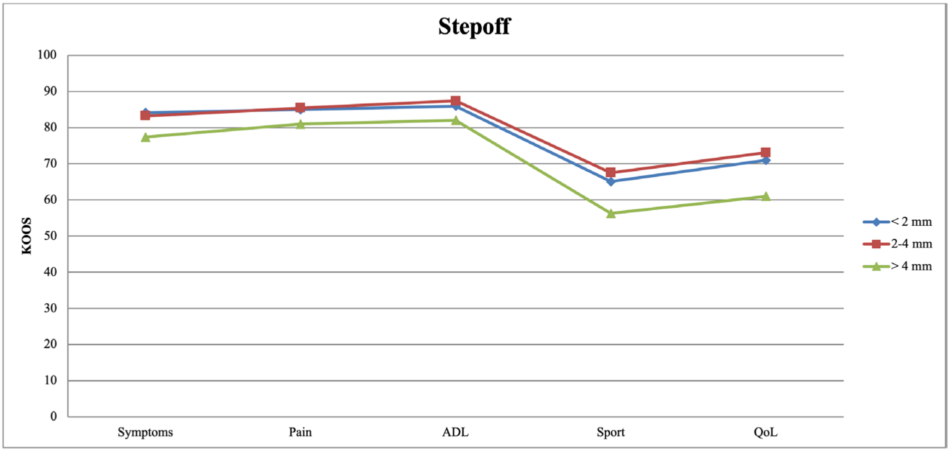

Figure 3: The KOOS subscales, representing functional outcome, are displayed for 196 nonoperatively managed patients divided into three subgroups based on the size of the articular stepoff. No differences in mean KOOS scores were found between subgroups, meaning that stepoffs up to 4 mm are well tolerated. Due to the small number of patients in the group with a stepoff greater than 4 mm, the results of this group need to be interpreted with caution.

in patients with a less than 2 mm, 2 to 4 mm, or more than 4 mm gap did not differ in symptoms (83 ± 17 versus 83 ± 21 versus 82 ± 20; p = 0.98), pain (85 ± 19 versus 83 ± 22 versus 86 ± 17; p = 0.69), ADL (87 ± 18 versus 84 ± 21 versus 89 ± 15; p = 0.44), sports (65 ± 33 versus 64 ± 34 versus 66 ± 33; p = 0.95), and QOL (70 ± 26 versus 71 ± 28 versus 74 ± 28; p = 0.85) (Table 2). KOOS scores in patients with a less than 2 mm, 2 to 4 mm, or more than 4 mm stepoff did not differ in symptoms (84 ± 17 versus 83 ± 21 versus 77 ± 20; p = 0.32), pain (85 ± 20 versus 85 ± 18 versus 81 ± 21; p = 0.66), ADL (86 ± 19 versus 87 ± 18 versus 82 ± 21; p = 0.54), sport (65 ± 33 versus 68 ± 30 versus 56 ± 40; p = 0.43), and QOL (71 ± 26 versus 73 ± 24 versus 61 ± 33; p = 0.19) (Table 3).

After correction for potential confounders including age, gender, BMI, and the number of columns involved, the linear regression analysis showed there was no relationship between gaps or stepoffs up to 4 mm and the KOOS score (Supplementary Digital Content 1; https://links.lww.com/CORR/A828). This applied to each of the five subscales of the KOOS. Stepoffs more than 4 mm were associated with lower scores for symptoms (β: -9.0 (95% CI -17.5 to -0.5); p = 0.04) and QOL (β: -14.0 (95% CI -25.9 to -2.0); p = 0.02).

Conversion to a Total Knee Prosthesis

Survivorship of the knee free from conversion to total knee prosthesis was 97% (95% CI 94% to 99%) at 5 years. Three percent (7 of 203) of patients had a conversion to a total knee prosthesis. The mean age of these patients was 63 ± 3 years. The mean gap was 1.7 ± 1.4 mm and the mean stepoff was 2.3 ± 0.9 mm. Four of 7 patients already had

Table 2: Size of the articular gap and KOOS scores

Size of articular gap	< 2 mm (n = 114)	2-4 mm (n=63)	>4 mm (n=19)	P value[a]
KOOS symptoms	83 ± 17	83 ± 21	82 ± 20	0.98
KOOS pain	85 ± 19	83 ± 22	86 ± 17	0.69
KOOS ADL	87 ± 18	84 ± 21	89 ± 15	0.44
KOOS sports	65 ± 33	64 ± 34	66 ± 33	0.95
KOOS QoL	70 ± 26	71 ± 28	74 ± 28	0.85

Data presented as mean ± SD.
[a]Comparison of KOOS scores (mean ± SD) between groups with increasing gap sizes (< 2 mm, 2 to 4 mm, and > 4 mm).

Table 3: Size of the articular steppff and KOOS scores

Size of articular Stepoff	< 2 mm (n = 119)	2-4 mm (n=65)	>4 mm (n=21)	P value[a]
KOOS symptoms	84 ± 17	83 ± 21	77 ± 20	0.32
KOOS pain	85 ± 20	85 ± 18	81 ± 21	0.66
KOOS ADL	86 ± 19	87 ± 18	82 ± 21	0.54
KOOS sports	65 ± 33	68 ± 30	56 ± 40	0.43
KOOS QoL	71 ± 26	73 ± 24	61 ± 33	0.19

Data presented as mean ± SD.
[a]Comparison of KOOS scores (mean ± SD) between groups with increasing stepoff sizes (< 2 mm, 2 to 4 mm, and > 4 mm).

moderate (Kellgren-Lawrence Grade 3) and 3 of 7 had mild (Kellgren-Lawrence Grade 2) preexisting osteoarthritis seen on a radiograph taken at the time of injury. Indications for conversion to total knee prosthesis were progressive posttraumatic osteoarthritis (Kellgren-Lawrence Grade 4).

DISCUSSION

Nonoperative management is considered a good treatment option for minimally displaced tibial plateau fractures [5, 10, 11]. However, there is no consensus about the maximum gap or stepoff that should lead to a recommendation for nonoperative treatment. We evaluated a large cohort of patients with tibial plateau fractures who were treated nonoperatively and correlated CT-determined fracture displacement with functional outcomes after a mean follow-up of 6 ± 3 years. Patients after nonoperative treatment of minimally displaced tibial plateau fractures are generally doing fine. We found that increasing fracture displacement with gaps and/or stepoffs up to 4 mm did not result in poorer functional outcome. The survivorship of the knee, free from conversion to a total knee prosthesis, was high. Based on these findings, we believe that minimally displaced tibial plateau fractures with a gap and/or stepoff up to 4 mm could be treated nonoperatively.

Limitations

We acknowledge that nonresponse bias is inherent to a cross-sectional study design caused by loss to follow-up and nonparticipation [3]. We attempted to reduce the risk of selection bias by approaching all eligible patients. The response proportion was quite high (46%) considering the relatively long follow-up time because patients in the northern part of the Netherlands do not migrate much. Nonresponse analysis showed only minor differences in terms of gender and fracture gap between responders and nonresponders, which does not affect our results. In our study population, results regarding gaps and stepoffs more than 4 mm should be interpreted cautiously because the number of patients in these subgroups was limited. Another limitation was the high variation in the length of follow-up, which ranged from 1 to 15 years (mean 6 ± 3 years), which was also inherent in the cross-sectional study design but does not affect our results. The consequences of gaps and stepoffs after 20 years or 30 years of follow-up are still unknown. Therefore, our findings are applicable for midterm follow-up but not for long-term follow-up. Furthermore, this study did not evaluate prospective longitudinal data about short-term patient outcomes, such as time to return to work or sports. This information could be important for active, high-demand patients during clinical decision-making about treatment options. Finally, this study did not include the region of the tibial plateau (which is possible using fracture maps) where the gaps or stepoffs were located. We tried to do so but found that this was not possible because regions are hard to define properly, and fracture lines often involve multiple regions. We believe that exact localization of fracture displacement warrants 3D fracture assessment. We do not think this limitation disqualifies our findings regarding the relationship between gaps and/or stepoffs and functional outcome because fracture displacement assessment is performed according to clinical practice.

Relationship Between Fracture Displacement and Functional Outcome

Because fracture displacement is so important for determining the indication for surgery and prognosis, we assessed the relationship between the initial fracture displacement (gap and stepoff) and patient-reported outcome (KOOS). Our study revealed that fracture gaps and stepoffs up to 4 mm, as measured on CT images, might result in good functional outcome in patients who consider nonoperative treatment for a minimally displaced tibial plateau fracture. No differences in functional outcomes were found between subgroups with increasing gaps and stepoffs up to 4 mm, meaning that the arbitrary 2-mm gap or stepoff limit could be revisited. There is much controversy about what degree of fracture displacement could be accepted to justify nonoperative treatment of minimally displaced tibial plateau fractures. To our knowledge, the frequently reported 2-mm limit for gaps and stepoffs is arbitrary and seems to be based on radiographs instead of CT and is not supported by clinical evidence from recent studies. A study about fracture displacement in the treatment of tibial plateau fractures focused on the impact of residual gaps and stepoffs after operative treatment [16]. However, results regarding residual fracture displacement cannot be automatically translated to clinical recommendations regarding initial fracture displacement. Studies on initial fracture displacement and functional outcome after nonoperative treatment of tibial plateau fractures are limited. According to recent guidelines, patients with fracture displacements less than 2 mm should opt for nonoperative treatment [12, 13]. However, these guidelines do not specify whether the 2-mm limit applies to gaps and stepoffs, nor do they state which imaging modality should be used to assess gaps and stepoffs. Giannoudis et al. [4] reviewed current evidence on the correlation between articular fracture displacement and the risk of posttraumatic osteoarthritis. For tibial plateau fractures, they concluded that the acceptable range of intraarticular stepoff should be somewhere between 2 and 10 mm [4]. However, most of the articles they referred to were from the 1990s, when measurements of fracture displacement were still performed on plain radiographs, whereas over time, clinical decision-making has become increasingly based on CT images.

Conversion to a Total Knee Prosthesis

Based on our results, patients who consider nonoperative treatment for a minimally displaced tibial plateau fracture could be informed that the survivorship of the native knee, free from conversion to total knee prosthesis, is high. Progressive posttraumatic arthritis with conversion to a total knee prosthesis is considered a worse outcome after tibial plateau fracture treatment [1, 5, 10, 11]. Depending on the fracture type and treatment, the proportion of patients who undergo total knee replacement after tibial plateau fractures has ranged from 4% to 22% [17, 18, 19, 21]. Wasserstein et al. [21] recently performed a large population-based, retrospective, comparative study and reported that after operative treatment, 7.3% of patients underwent conversion to a total knee prosthesis at 10 years of follow-up, which corresponded to a hazard ratio of 5.3 relative to peers from the general population. However, these numbers represent patient outcomes after surgical management of tibial plateau fractures and do not apply to patients treated without surgery. To our knowledge, there are no studies on conversion to a total knee prosthesis after nonoperative treatment.

Conclusion

Patients with minimally displaced tibial fractures who opt for nonoperative fracture treatment should be told that fracture gaps or stepoffs up to 4 mm, as measured on CT images, could result in good functional outcome. Therefore, the arbitrary 2-mm limit of gaps and stepoffs for tibial plateau fractures could be revisited. The survivorship of the knee free from conversion to a total knee prosthesis at a mean follow-up of 5 years is high. Conversion to a total knee prothesis mostly occurred in patients older than 60 years who often had preexisting osteoarthritis. These findings can be used as a guide for personalized treatment and shared decision-making in the management of minimally displaced tibial plateau fractures. Large, prospective, cohort studies with high response rates are needed to learn more about the relationship between the degree of fracture displacement and functional recovery after tibial plateau fractures.

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CHAPTER 3

What Is the Patient-reported Outcome and Complication Incidence After Operative Versus Nonoperative Treatment of Minimally Displaced Tibial Plateau Fractures?

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Abstract

Background: Much controversy remains about whether minimally displaced tibial plateau fractures should be treated operatively or nonoperatively. It is generally accepted that gaps and stepoffs up to 2 mm can be tolerated, but this assumption is based on dated studies using radiographs instead of CT-scans to assess the degree of initial fracture displacement. Knowledge regarding the relationship between the degree of fracture displacement and expected functional outcome is crucial for patient counseling and shared decision-making, whether to perform surgery or not.

Questions/purposes: (1) Does operative treatment lead to improved patient-reported outcomes compared with nonoperative treatment in minimally displaced tibial plateau fractures? (2) What is the complication incidence after operative versus nonoperative treatment in minimally displaced tibial plateau fractures?

Methods: A multicenter, cross-sectional study was performed in patients treated for tibial plateau fractures between 2003 and 2019 within six hospitals. Between Januari 2003 and December 2019, a total of 2241 patients were treated for tibial plateau fractures at six different trauma centers. During that time, the general indications for open reduction internal fixation (ORIF) was an intra-articular displacement of > 2 mm. Patients treated with ORIF as well as those treated non-operatively were potentially eligible; a total of 0.2% (4) were excluded since they required amputation due to severe soft tissue damages, whereas 4.0% (89) were excluded due to coexisting conditions complicating outcome measurement including Parkinson, CVA, or paralysis (i.e. conditions causing an inability to walk). A further 2.7% (60) and 1.4% (31), respectively, we excluded since their address was unknown or spoke a foreign language. Based on that, 1322 were potentially eligible for analysis in the operative group and 729 were potentially eligible in the nonoperative group. At least one year after injury, all patients were approached and asked to complete the Knee injury and Osteoarthritis Outcome Scale (KOOS) questionnaire. A total of 810 operatively and 345 nonoperatively treated patients responded to the questionnaire (response rate 56%). Patient characteristics including age, gender, BMI, smoking, and diabetes were retrieved from electronic patient records, and imaging data was shared with the initiating center. Displacement (gap and step-off) was measured for all participating patients and all patients with minimally displaced fractures (gap or stepoff ≤4 mm) were included, leaving 195 and 300 in the operative and nonoperative group, respectively, for analysis here. Multivariate linear regression was performed to assess the association of treatment choice (nonoperative or operative) with patient-reported outcome in minimally displaced fractures. In the multivariate analysis, we accounted for a total of nine potential confounders (age, gender, BMI, smoking, diabetes, gap, stepoff, AO/OTA classification, number of involved segments). In addition, differences in complications after operative and nonoperative treatment were assessed.

Results: Multiple linear regression models showed that operative treatment was not associated with an improvement in patient-reported outcomes. Operative treatment resulted in poorer KOOS score in term of pain (-4.7 points, p=0.03), sport (-7.6 points, p=0.04) and quality of life (-7.8 points, p=0.01) as compared to nonoperative treatment. Though, this difference did not reach the point that was considered clinically important. Patients treated operatively had more complications (p=0.01) as well as reoperations (p<0.001) as compared to patients treated nonoperatively. Complications after operative treatment occurred in 4% (7 of 195) patients (four fracture-related infections, three peroneal nerve neurapraxias). No complications were reported after nonoperative treatment. A total of 81 additional surgical procedures were performed in 39% (76 of 195) of the patients treated operatively (three meniscal or ligamentous repairs, one corrective osteotomy, 70 elective removals of osteosynthesis material, and seven conversions to a Total Knee Arthroplasty(TKA)). Additional surgical procedures were performed in 6% (18 of 300) patients who underwent nonoperative treatment (10 meniscal or ligamentous repairs, one corrective osteotomy, and seven conversions to TKA).

Conclusion: Regardless of the treatment type, no differences in patient-reported outcomes should be expected at mid-term follow-up. Therefore, nonoperative treatment could be considered as the preferred treatment option in minimally displaced fractures. Patients who opt for nonoperative treatment should be told that complications are rare, and only 6% of patients might require surgery at a later stage. Patients who opt for surgery of a minimally displaced tibial plateau fracture should be told that complications may occur in up to 4% of patients, and 39% of patients may undergo a secondary intervention (of which 36% elective implant removal). The increased risks of operative treatment should be outweighed against potential benefits such as early mobilization.

INTRODUCTION

Tibial plateau fractures with relatively small gaps and/or stepoffs up to 4 mm could be considered minimally displaced [22]. For these injuries, both operative and nonoperative management might be suitable. Gap and stepoff measurements, both representing fracture displacement, are often used for clinical decision-making when deciding between operative and nonoperative treatment [12, 17, 18]. Whether to choose for operative or nonoperative treatment, however, remains especially in these minimally displaced fractures a topic of debate. Evidence regarding the accepted residual incongruency varies from 2 to 10 mm [5, 15, 16, 20]. For every fracture, one should ask themselves whether the surgical advantages outweigh the potential complications that requires shared decision-making. However, there is hardly any evidence to support patient counselling in minimally displaced fractures.

The generally accepted indication for proceeding to surgical treatment of tibial plateau fractures includes an intraarticular fracture gap or stepoff of more than 2 mm [7, 17, 18]. In our experience, especially in minimally displaced tibial plateau fractures that slightly exceed the 2 mm threshold, there remains considerable variation in treatment type. Treatment choice highly depends on in which hospital and by whom a patient is treated. This 2-mm cutoff was suggested by research dating more than 30 years ago [4, 21]. Yet, based on the evidence available in the literature, there is little rationale for the assumption that accurate articular reduction of tibial plateau fractures to tolerances of <2 mm is critical to the attainment of a good clinical outcome [9]. Despite the substantial personal and societal impact of these injuries, evidence on this topic is scarce and comparative studies between nonoperative and operative treatment of minimally displaced tibial plateau fractures are lacking. In addition, current studies are limited to residual displacement after the surgery which does not allow for recommendations regarding how to treat fractures based on the initial displacement. A recent study demonstrated that initial fracture gaps or stepoffs even up to 4 mm, as measured on CT-scans, could result in good functional outcome after nonoperative treatment [22]. The question is whether the old recommendation with a threshold of 2 mm based on radiographs could be justified or if this should be revisited based on evolving insights from CT images. To our best knowledge, this is the first CT-based comparative study on minimally displaced tibial plateau fractures.

We hypothesized that operative treatment does not lead to improved functional outcome as compared to nonoperative treatment for management of minimally displaced tibial plateau fractures. This study aims to answer the following research questions: (1) Does operative treatment lead to improved patient-reported outcome compared with nonoperative treatment in minimally displaced tibial plateau fractures? (2) What is the complication incidence after operative versus nonoperative treatment in minimally displaced tibial plateau fractures?

PATIENTS AND METHODS

Study Design and Setting

A multicenter, cross-sectional study was performed in patients treated for a tibial plateau fracture between January 2003 and December 2019 within the orthopedic and trauma surgery department of six hospitals (four Level 1 and two Level 2 trauma centers). Hospitals consisted of two academic centers and four nonacademic centers located in medium-sized cities within the Netherlands and Belgium.

Participants

Between Januari 2003 and December 2019, a total of 2241 patients were identified who were treated for their tibial plateau fractures, had an available diagnostic CT-scan, and were still alive according to the national population registry at follow-up. Patients treated with ORIF as well as those treated non-operatively were potentially eligible; a total of 0.2% (4) were excluded since they required amputation due to severe soft tissue damages, whereas 4.0% (89) were excluded due to coexisting conditions complicating outcome measurement including Parkinson, CVA, or paralysis (i.e. conditions causing an inability to walk). A further 2.7% (60) and 1.4% (31), respectively, were excluded since their address was unknown or spoke a foreign language. Based on that, 1322 were potentially eligible for analysis in the operative group and 729 were potentially eligible in the nonoperative group. At least one year after injury, all patients were approached and asked to complete the Knee injury and Osteoarthritis Outcome Scale (KOOS)

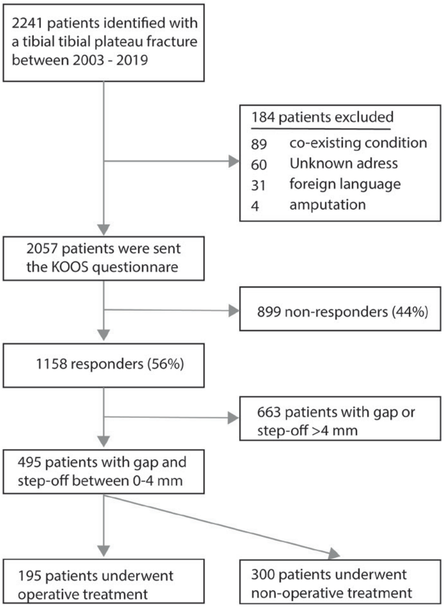

Figure 1: The patient inclusion process for this study is depicted in this flowchart.

questionnaire. A total of 810 operatively and 345 nonoperatively treated patients responded to the questionnaire (response rate 56%). Patient characteristics including age, gender, BMI, smoking, and diabetes were retrieved from electronic patient records, and imaging data was shared with the initiating center. Displacement (gap and step-off) was measured for all participating patients and all patients with minimally displaced fractures (gap or stepoff ≤4 mm) were included, leaving 195 and 300 in the operative and nonoperative group, respectively, for analysis here (Fig. 1).

Analysis of Nonresponders

For the nonresponse analysis, we used an independent samples t-test for continuous variables and a chi-square test for noncontinuous variables. The nonresponse analysis showed that nonresponders were slightly younger (53 ± 16 versus 51 ± 18; p = 0.001), less often women (69% versus 58%; p = 0.001) and received more often nonoperative treatment (43% versus 30%). Knee radiographs and CT images of nonresponders were only approved for analysis in the initiating and its affiliated center (n=550). Analysis showed that nonresponders in these centers had significant lower gap (4.2 ± 5.2 versus 6.4 ± 6.3 mm; p<0.001) and step-off (4.5 ± 4.7 versus 6.3 ± 5.7 mm; p<0.001). AO/OTA fracture classification did not differ between nonresponders and responders (B1: 11 vs 15 %, B2: 16 vs. 19%, B3: 45 vs 39%, C2: 6 vs. 8%, C3: 22 vs. 17%; p=0.26).

Descriptive Data

Patients who received operative treatment for their minimally displaced tibial plateau fracture did not differ to nonoperatively managed patients in terms of age (51 ± 15 vs. 54 ± 16, p=0.09), gender (64% vs. 72% women, p=0.07), BMI (26 ± 4 vs. 26 ± 5, p=0.22), smoking (21% vs 17%, p=0.38), and diabetes (7% vs 8%, p=0.58) (Table 1). Operatively treated fractures consisted slightly more often of split-depression fractures (AO/OTA B3), whereas nonoperatively treated fractures consisted more often of pure split (AO/OTA B1) and pure depression (AO/OTA B2) fractures (P<0.001). Also, operatively treated fractures had slightly more articular segments involved (4 ± 2 vs. 3 ± 1, p<0.001) (Table 1).

Image Review and Gap and Stepoff Measurements

All knee radiographs and CT images, which were taken at the time of injury, were reassessed through consensus by an attending orthopaedic trauma surgeon (> 10 years of experience) and technical physician (> 5 years of experience) (FFAIJ, NA). Fracture classification was determined according to the AO/OTA and the 10-segment classification system [8, 13]. Based on fracture characteristic, the AO/OTA classification classifies intra-articular tibial plateau fractures into different types of fractures: partial articular fractures (B1:pure split, B2: pure depression, B3: split-depression) or complete articular fractures (C1: simple articular and metaphyseal, C2: articular simple and metaphyseal multifragmentary, C3: articular multifragmentary) [13].Ten-segments classification divides the plateau into 10 segments, therefore more segments involved

Table 1: Patient characteristics of patients with a minimally displaced tibial plateau fracture (gap and step-off ≤ 4 mm)

Parameter	Operative (n = 195)	Nonoperative (n = 300)	p value
Age in years	51 ± 15	54 ± 16	0.09
Women	64% (125)	72% (216)	0.07
BMI in kg/m2	26 ± 4	26 ± 5	0.22
Smoking	21% (40)	17% (50)	0.38
Diabetes	7% (13)	8% (23)	0.58
AO/OTA classification			< 0.001
41-B1	15% (30)	25% (75)	
41-B2	32% (62)	44% (133)	
41-B3	44% (85)	26% (77)	
41-C1	5% (9)	4% (12)	
41-C2	2% (4)	0% (1)	
41-C3	2% (5)	1% (2)	
Number of involved segments (10-segment classification)	4 ± 2	3 ± 1	< 0.001
Follow-up in years	7 ± 4	6 ± 3	0.06

Data presented as mean ± SD or % (n).

indicate a more extensive fracture [8]. Preoperative CT-scans were reassessed in the axial, sagittal, and coronal planes; in addition, gap and stepoff measurements were performed within the CT-slice where displacement was found to be highest. Gap was defined as separation of fracture fragments along the articular surface, and stepoff was characterized as separation of fracture fragments perpendicular to the articular surface [3, 22]. For each patient, the maximum value of the gap and stepoff on any of the axial, coronal, or sagittal CT slices was reported. In order to assess the impact of gap and stepoff separately, a subanalysis was performed for which patients were divided into four groups based on the size of their maximum gap and stepoff: patients with a gap and stepoff less than 2 mm, patients with a gap between 2 to 4 mm and stepoff less than 2 mm, patients with a stepoff between 2 to 4 mm and gap less than 2 mm, and patients with a gap and stepoff between 2 to 4 mm (Fig. 2).

Patient-reported Outcomes

All eligible patients were approached by posted mail and asked to provide informed consent and complete the validated and standardized Knee injury and Osteoarthritis Outcome Scale (KOOS) questionnaire in Dutch [6]. The KOOS is a questionnaire designed to assess short- and long-term patient-relevant outcomes after knee injuries. It contains 42 items in five separately scored subscales: pain, symptoms, activities of daily living (ADL), function in sport and recreation (sport), and quality of life (QoL). We calculated the subscales scores by adding the individual items (questions) and transforming scores to a range from 0 to 100, with higher scores indicating better function. The minimum clinically important differences (MCID) for five subscales of the KOOS are: symptoms = 11, pain = 17, ADL = 18, sport = 13, and QOL = 16 [11].

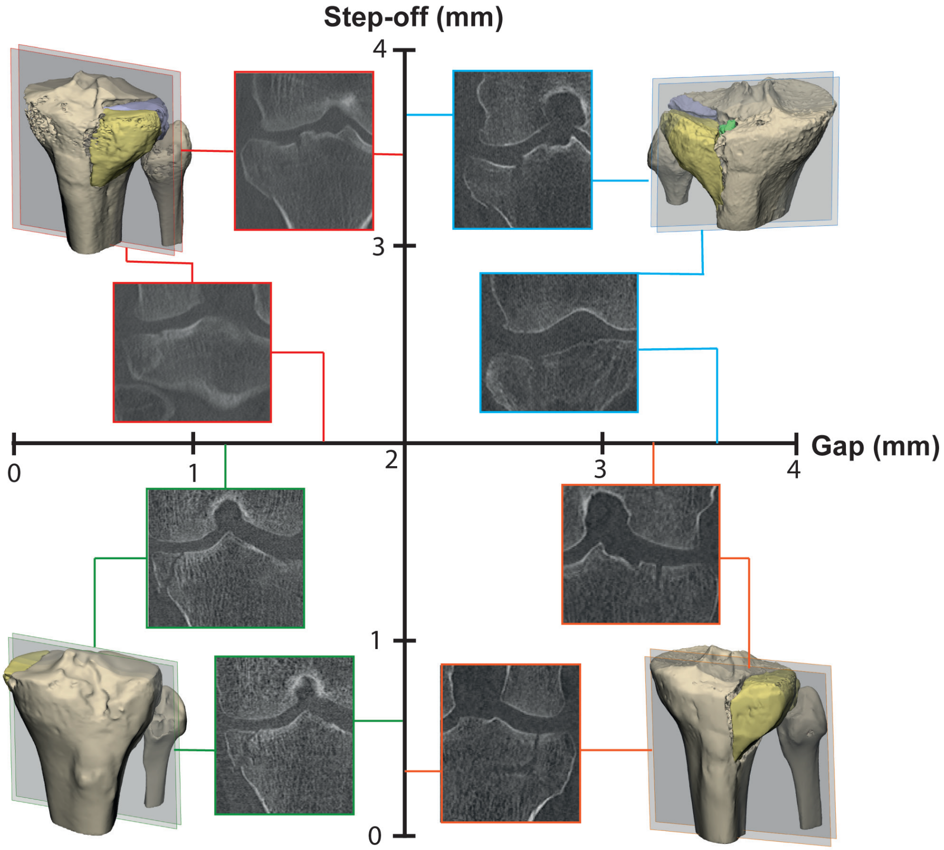

Figure 2: Based on their gap and stepoff patients were divided into four groups: stepoff between 2-4 and gap less than 2 mm (upper left), gap and stepoff between 2-4 mm (upper right), gap and stepoff less than 2 mm (lower left), gap between 2-4 and stepoff less than 2 mm (lower right). This illustrates the different combinations of sizes of gaps and step-offs which are consider minimally displaced fractures.

Data Sources

Baseline characteristics of the participants were retrieved from the patients' electronic records. KOOS scores were calculated from the returned patient questionnaires. Gap and stepoff measurements were performed on the diagnostic CT-scans.

Primary and Secondary Study Goals

The primary study goal was to assess patient-reported outcome after nonoperative compared with operative treatment of minimally displaced tibial plateau fractures. In order to assess the impact of gap and stepoff separately, a subanalysis was performed for which patients were divided into four groups with varying sizes of gap and stepoff. In addition, we performed multivariate regression to assess the association of treatment choice with patient-reported outcome when accounted for patient characteristics and facture characteristics (size, classification, location). Our secondary goal was to report the incidence of complications after nonoperative versus operative treatment of minimally displaced tibial plateau fractures.

Ethical Approval

The institutional review board of all centers approved the study procedures, and the research was performed in accordance with the relevant guidelines and regulations. All participants signed an informed consent, and their imaging data was transferred to the initiating center.

Statistical Analysis

Statistical analysis was performed using SPSS (version 28, IBM). Differences in characteristics between operative and nonoperative treated patients were assessed using a Student t-test for continuous variables and a chi-square test for noncontinuous variables. We performed an ANOVA test to assess the difference in patient-reported outcomes between the patients in the nonoperative versus operative groups. We performed multivariate linear regression to assess the association of treatment choice (nonoperative or operative) with patient-reported outcomes in minimally displaced fractures. The analysis accounted for nine potential confounders (age, gender, BMI, smoking, diabetes, gap, stepoff, AO/OTA classification, number involved segments, according to the definition of Krause et al. [8]). Post-hoc power size analysis showed a power of 99%. Effect size was retrieved based on the found R-squared of the multivariate regression with 10 predictors and an α of 0.05. Chi-square test was performed to assess difference between incidence of complications and additional surgeries after operative and nonoperative treatment. A p value of less than 0.05 was considered statistically significant.

RESULTS

Patient-Reported Outcomes After Operative Versus Nonoperative Treatment

After controlling for potential confounding variables including age, gender, BMI, smoking, diabetes, gap, stepoff, AO/OTA classification, and number of involved segments, we found no clinically important difference between operative and nonoperative treatment in terms of all subscales of the KOOS questionnaire (Table 2, full regression model accessible in Appendix 1). Operative treatment resulted in poorer KOOS score in term of pain (-4.7 points, p=0.03), sport (-7.6 points, p=0.045) and quality of life (-7.8 points, p=0.01) as compared to nonoperative treatment. Though, this difference did not reach the point that was considered clinically important. Univariate sub-analysis of different combination of gap and step-off size is available in the supplementary data (Appendix 2).

Table 2: Multivariate regression analysis of the association between choice for operative treatment and patient-reported outcome in minimally displaced tibial plateau fractures.

Operative treatment[a]		
	B (95% CI)	p value
KOOS-Symptoms	-3.7 (-7.8 to 0.4)	0.08
KOOS-Pain	-4.7 (-9.0 to -0.3)	0.03
KOOS-ADL	-3.5 (-7.7 to 0.7)	0.10
KOOS-Sport	-7.6 (-15.0 to -0.2)	0.045
KOOS-QoL	-7.8 (-13.5 to -2.1)	0.01

The B values indicate the average increase in KOOS value associated with the choice for operative instead of nonoperative treatment. This means that choice for operative treatment reduces the functional outcome in terms of KOOS-symptoms for example with 3.7 points as compared to nonoperative treatment when accounted for confounders.
[a]Included confounders: age, gender, BMI, smoking, diabetes, gap, stepoff, AO/OTA classification, involved segments.

Complications and Additional Surgical Procedures

Patients treated operatively had more complications (p=0.01) as well as reoperations (p<0.001) as compared to patients treated nonoperatively. After surgical treatment, 7 patients (4%) had complications (four infections and three neurapraxias) whereas nonoperative treatment did not result in any complications. Furthermore, 81 additional surgical procedures subsequent to the initial surgery were reported in 76 (39%) of patients who were treated operatively. Most of these reoperations were performed as elective procedures for removing osteosynthesis plates and/or screws material . After nonoperative treatment, 6% (18 of 300) of the patients underwent an additional surgery (Table 3).

Table 3: Complications and additional surgery

	Operative (n = 195)	**Nonoperative (n=300)**	**P value**
Complications	4% (7)	0% (0)	0.01
Fracture-related infection	2% (4)	0% (0)	
Peroneal nerve neurapraxia	2% (3)	0% (0)	
Additional surgery	39% (76*)	6% (18)	<0.001
Revision for meniscal or ligamentous damage	2% (3)	3% (10)	
Corrective osteotomy after malunion	0.5% (1)	0.3% (1)	
Elective removal of osteosynthesis material	36% (70)	0% (0)	
Conversion to TKA	4% (7)	2% (7)	

Data are presented as % (n)
* 81 additional surgeries were performed in 76 patients

DISCUSSION

Whether minimally displaced tibial plateau fractures should be treated operatively or nonoperatively remains controversial. There is no consensus regarding whether the generally used indication for operative treatment based on fracture displacement greater than 2 mm is crucial for attaining a good clinical outcome [9, 22]. We evaluated a large cohort of patients with tibial plateau fractures with minimal displacement to assess whether this recommendation based on radiographs could be justified, or if this should be revisited based on evolving insights from CT images. We found that, regardless of the treatment type, no differences in patient-reported outcomes should be expected at mid-term follow-up. From the patients who underwent operative treatment, 4% had a complication. Moreover, 39% of the operatively treated patients underwent one or more additional surgical procedures, often in the form of elective implant removal (36%). The increased risks of operative treatment should be outweighed against potential benefits such as early mobilization. Based on these findings, we believe that nonoperative treatment should be considered as the preferred treatment option in patients with a minimally displaced tibial plateau fracture with gaps and stepoffs up to 4 mm.

Limitations

We acknowledge that this study has some degree of response bias, which is inherent to the cross-sectional study design caused by loss to follow-up and nonresponse. By approaching all patients multiple times, we reduced the risk of nonresponse bias as much as possible. In fact, our response of 56% is in line with what could be expected from a postal survey according to the existing evidence [10]. Nonresponse analysis showed only minor differences in terms of gender and age between responders and nonresponders, which is not expected to affect our results. Yet, nonresponders were found to be treated more often nonoperatively and had less displacement in terms of gap and stepoff. This could indicate that nonresponders had less severe fractures, and did not respond, due to experiencing minimal to no complains. Potential inclusion of nonresponders to our results would probably strengthen our findings that nonoperative treatment in minimally displaced fractures leads to similar patient-reported outcomes as operative treatment. Another limitation caused by the cross-sectional study design was the variation in the length of follow-up, which ranged from 1 to 17 years (mean 6 years). The consequences of gaps and stepoffs at long-term follow-up (20+ years) are still unknown. Therefore, our findings are applicable for midterm follow-up, but should be interpreted with caution for long-term follow-up. Lastly, this study focused on fracture displacement in terms of gaps and stepoffs. Yet, the location and extent of the fracture might also affect the choice for operative or nonoperative treatment. By quantifying the extent of the fracture through an evaluation of the number involved segments, as defined by Krause et al. [8], we corrected for this confounding factor in our analysis.

Therefore, we do not think this limitation disqualifies our findings. Gap and stepoff measurements are and will remain the gold standard for some time in the clinical practice.

Patient-Reported Outcomes After Operative Versus Nonoperative Treatment

Regardless of the treatment type, no differences in patient-reported outcomes at mid-term follow-up were found in this study. Current guidelines on treatment of tibial plateau fractures includes an intraarticular fracture gap or stepoff of greater than 2 mm as indication for surgical treatment [7, 17, 18]. Yet, with no expected difference in functional outcome between operative and nonoperative treatment, nonoperative treatment might be preferred in patients with minimally displaced fractures with initial gaps and stepoffs up to 4 mm. In literature, much controversy remains regarding the level of articular incongruity that would be considered acceptable to justify nonoperative treatment [5]. One review of the current evidence on the correlation between residual articular fracture displacement and the risk of posttraumatic osteoarthritis and concluded that the acceptable range of intraarticular stepoff should be somewhere between 2 and 10 mm [5]. Whereas Singleton et al. [20] reported that patients with less than 2.5 mm of residual articular depression had improved outcomes. However, both studies report on residual instead of initial fracture displacement like in our study and therefore these results cannot automatically be translated to clinical recommendations regarding initial fracture displacement. A recent study showed that nonoperative treatment of minimally displaced fractures with initial gaps and stepoffs up to 4 mm result in good patient-reported outcomes [22]. However, this study did not make a direct comparison with operatively treated patients. One could argue that some patients with displacement exceeding the 2-mm threshold might have received nonoperative treatment because of other patient-related factors such as age or comorbidities. However, this was probably not the case because patients who were treated operatively and nonoperatively in this study did not differ in terms of patient characteristics such as age, gender, BMI, smoking and diabetes. In terms of fracture characteristics, fractures that were treated operatively seemed to involve a slightly larger area of the tibial plateau compared with nonoperatively treated fractures (4 ± 2 versus 3 ± 1 segments as defined by Krause et al. [8]). We conducted multivariable analysis to account for these confounding factors, and it reconfirmed our findings that nonoperative treatment was noninferior to operative treatment in minimally displaced fractures with gaps and stepoffs up to 4 mm. Future studies to gain more evidence on this topic should include multicenter, prospective registry studies with preferably availability of pre- and postoperative CT-scans and three-dimensional fracture analysis of initial and residual fracture displacement [1, 2].

Complications and Additional Surgical Procedures

This study shows that operative management of minimally displaced fractures is associated with a higher chance on complications and likelihood of return to clinic for additional surgeries. Although relatively rare in minimally displaced fractures, complications such as infections and neuropraxia can significantly impact patients' well-being [14]. Additionally, subjecting the patient to further surgeries introduces this risk once again. This suggest that one should be thoughtful before recommending surgery and treatment choice in tibial plateau fracture should involve an evaluation about whether the surgical advantages outweigh the potential complications. This is especially true for the minimally displaced fractures in which surgical advantages (such as minimal fracture reduction to reduce the risk on posttraumatic osteoarthritis) might be limited. After all, surgery is not without risks. A recent systematic review including 2214 procedures reported surgical site infections in 9.9% of patients after surgical treatment of tibial plateau fractures [19]. The minimally displaced fractures evaluated in this study had a lower infection incidence of 2%. Moreover, injury of the peroneal nerve was observed in 2% of patients. Also, 70 patients (36%) underwent a removal of their osteosynthesis material at follow-up, exposing patients to additional risks associated with surgical treatment. None of these complications were reported in the nonoperative treatment group. Although patients in the nonoperative treatment had a number of revisions for meniscal or ligamentous damage, these numbers were lower than in the patients who had operative treatment. Reducing the risk of posttraumatic arthritis at follow-up might still be reason to opt for operative treatment, but at the mid-term follow-up, we found no advantage to surgery, since there was no difference between patients treated nonoperatively compared with the operatively treated group in terms of the proportion converted to TKA (2% versus 4%). Future prospective studies might provide a more comprehensive overview of complications and reinterventions.

Conclusion

Regardless of the treatment type, no differences in patient-reported outcomes should be expected at mid-term follow-up. Therefore, nonoperative treatment could be considered as the preferred treatment option in minimally displaced fractures. Patients who opt for nonoperative treatment should be told that complications are rare and only 6% of patients might require surgery at a later stage. Patients who opt for surgery should be told that complications may occur in up to 4% of patients, and 39% of patients may undergo a secondary intervention (of which 36% elective implant removal). The increased risks of operative treatment should be outweighed against potential benefits such as early mobilization.

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Appendix 1. Full regression model for treatment type in relation to KOOS functional outcome.

	KOOS-Symptoms (R2=0.09, adj R2=0.07)		KOOS-Pain (R2=0.09, adj R2=0.07)		KOOS-ADL (R2=0.10, adj R2=0.08)		KOOS-Sport (R2=0.09, adj R2=0.07)		KOOS-QoL (R2=0.10, adj R2=0.08)	
	B (95% CI)	P Value	B (95% CI)	P Value	B (95% CI)	P Value	B (95% CI)	P Value	B (95% CI)	P Value
Operative Treatment	-3.7 (-7.7 to 0.4)	0.08	-4.7 (-9.0 to -0.4)	0.03	-3.5 (-7.7 to 0.7)	0.10	-7.6 (-15.0 to -0.2)	0.045	-7.8 (-13.5 to -2.1)	0.01
Age	0.2 (0.1 to 0.4)	<0.001	0.2 (0.0 to 0.3)	0.01	-0.1 (-0.1 to 0.1)	0.46	0.1 (-0.1 to 0.3)	0.25	0.3 (0.1 to 0.4)	<0.001
Male	6.7 (2.8 to 10.5)	<0.001	5.6 (1.6 to 9.7)	0.01	5.1 (1.1 to 8.9)	0.01	13.4 (6.5 to 20.3)	<0.001	7.0 (1.7 to 12.3)	0.01
BMI	-0.8 (-1.1 to -0.4)	<0.001	-1.0 (-1.4 to -0.6)	<0.001	-1.2 (-1.6 to -0.8)	<0.001	-1.8 (-2.5 to -1.1)	<0.001	-1.4 (-1.9 to -0.9)	<0.001
Smoking	-4.8 (-9.3 to -0.2)	0.04	-6.4 (-11.2 to -1.6)	0.01	-8.0 (-12.6 to -3.2)	<0.001	-12.5 (-20.6 to -4.2)	0.01	-5.8 (-12.1 to 0.5)	0.07
Diabetes	0.2 (-6.4 to 6.7)	0.96	1.7 (-5.2 to 8.7)	0.63	3.3 (-3.4 to 10.1)	0.33	5.0 (-7.2 to 17.1)	0.42	1.2 (-7.9 to 10.3)	0.79
Gap	1.2 (-0.8 to 3.2)	0.24	0.3 (-1.8 to 2.3)	0.80	0.6 (-1.4 to 2.7)	0.53	0.7 (-2.9 to 4.3)	0.69	-0.4 (-3.2 to 2.3)	0.76
Stepoff	0.5 (-1.4 to 2.4)	0.63	0.8 (-1.2 to 2.8)	0.43	0.7 (-1.3 to 2.6)	0.51	0.6 (-2.9 to 4.1)	0.73	0.9 (-1.8 to 3.5)	0.53
AO/OTA	-0.03 (-2.0 to 1.9)	0.98	0.8 (-1.2 to 2.9)	0.43	1.3 (-0.7 to 3.3)	0.22	0.4 (-3.1 to 3.9)	0.83	1.7 (-1.1 to 4.4)	0.23
Involved Segments	-0.5 (-1.6 to 0.6)	0.38	0.5 (-1.1 to 1.2)	0.94	-0.5 (-1.7 to 0.6)	0.36	-0.3 (-2.3 to 1.8)	0.80	-0.4 (-1.9 to 1.2)	0.64

Appendix 2. Patient-reported outcomes after operative versus nonoperative treatment of minimally displaced tibial plateau fractures stratified according to increasing fracture displacement. When stratifying groups based on the size of the gap and step-off, operative treatment resulted in slightly lower patient-reported outcome as compared to nonoperative treatment in terms of KOOS symptoms, pain, sport and quality of life. Clinically important difference was only found in terms of sports within patients with a gap between 2-4 mm and step-off <2 mm.

	Gap and stepoff < 2 mm		**Gap 2-4 mm (and stepoff < 2 mm)**		**Stepoff 2-4 mm (and gap < 2 mm)**		**Gap and stepoff 2-4 mm**		
	Operative (n = 28)	Nonoperative (n = 169)	Operative (n = 36)	Nonoperative (n = 45)	Operative (n = 53)	Nonoperative (n = 56)	Operative (n = 78)	Nonoperative (n = 30)	p value
KOOS – Symptoms	79 ± 16	80 ± 20	76 ± 21	86 ± 13	83 ± 18	83 ± 19	78 ± 23	85 ± 16	0.03[a]
KOOS – Pain	78 ± 20	81 ± 21	78 ± 22	87 ± 17	85 ± 18	84 ± 19	77 ± 23	86 ± 18	0.03[a]
KOOS - ADL	82 ± 20	83 ± 21	82 ± 20	89 ± 17	87 ± 16	85 ± 19	81 ± 23	87 ± 18	0.19
KOOS - Sport	54 ± 36	56 ± 35	50 ± 32	69 ± 32	56 ± 36	59 ± 32	52 ± 37	59 ± 35	0.03
KOOS - QoL	61 ± 26	68 ± 27	61 ± 27	72 ± 22	67 ± 26	71 ± 25	61 ± 32	74 ± 27	0.01[a]

Data presented as mean ± SD. Minimum Clinically Important Differences: KOOS-symptoms = 11, KOOS-pain = 17, KOOS-ADL = 18, KOOS-sport = 13, and KOOS-QOL = 16

[a] Difference unlikely to be clinically important

CHAPTER 4

Radiographic Predictors of Conversion to Total Knee Arthroplasty After Tibial Plateau Fracture Surgery: results in a large multicenter cohort.

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Abstract

Background: Radiographic measurements of initial displacement of tibial plateau fractures and of postoperative reduction are used to determine treatment strategy and prognosis. We assessed the association between radiographic measurements and the risk of conversion to total knee arthroplasty (TKA) at the time of follow-up.

Methods: A total of 862 patients surgically treated for tibial plateau fractures between 2003 and 2018 were eligible for this multicenter cross-sectional study. Patients were approached for follow-up, and 477 (55%) responded. The initial gap and step-off were measured on the preoperative computed tomography (CT) scans of the responders. Condylar widening, residual incongruity, and coronal and sagittal alignment were measured on postoperative radiographs. Critical cutoff values for gap and step-off were determined using receiver operating characteristic curves. Postoperative reduction measurements were categorized as adequate or inadequate on the basis of cutoff values in international guidelines. Multivariable analysis was performed to assess the association between each radiographic measurement and conversion to TKA.

Results: Sixty-seven (14%) of the patients had conversion to TKA after a mean follow-up of 6.5 ± 4.1 years. Assessment of the preoperative CT scans revealed that a gap of >8.5 mm (hazard ratio [HR] = 2.6, $p < 0.001$) and step-off of >6.0 mm (HR = 3.0, $p < 0.001$) were independently associated with conversion to TKA. Assessment of the postoperative radiographs demonstrated that residual incongruity of 2 to 4 mm was not associated with increased risk of TKA compared with adequate fracture reduction of <2 mm (HR = 0.6, $p = 0.176$). Articular incongruity of >4 mm resulted in increased risk of TKA. Coronal (HR = 1.6, $p = 0.05$) and sagittal malalignment (HR = 3.7 $p < 0.001$) of the tibia were strongly associated with conversion to TKA

Conclusions: Substantial preoperative fracture displacement was a strong predictor of conversion to TKA. Postoperative gaps or step-offs of >4 mm as well as inadequate alignment of the tibia were strongly associated with an increased risk of TKA.

INTRODUCTION

The main goals of surgery for a tibial plateau fracture are to reestablish joint stability, achieve normal limb alignment, and restore the articular surface [1,2]. Achieving these surgical goals reduces the risk of posttraumatic osteoarthritis and the subsequent need for total knee arthroplasty (TKA) [3]. However, adequate reduction is not always possible because of comminution and severe fracture displacement. A suboptimal operative result has been reported in up to 30% of surgically treated tibial plateau fractures [4]. Also, the initial irreversible damage to the articular surface may induce posttraumatic osteoarthritis despite a good operative result [5,6]. Therefore, pre- and postoperative radiographic assessments of fracture displacement and tibial alignment are important to estimate risks of conversion to TKA at follow-up.

Adequate preoperative assessment of fractures is essential to determine the treatment strategy and counsel patients regarding the prognosis. Initial fracture displacement, which can be assessed by measuring the intra-articular gap and step-off on preoperative computed tomography (CT) scans, is among the decisive factors in the choice between nonoperative and operative management. The results of surgical treatment are usually assessed on postoperative radiographs by measuring the quality of the reduction and tibial alignment. Since these radiographic measurements are important for both treatment decisions and patient counselling about prognosis, it is important to understand their relationship with the clinical outcome. Even though existing research suggests that initial fracture displacement, quality of reduction, and postoperative tibial alignment contribute to the development of posttraumatic osteoarthritis and the need for TKA, the actual impact of these parameters has not yet been clarified [3,6,7].

We hypothesized that initial fracture displacement, quality of reduction, and postoperative tibial alignment are predictors of conversion to TKA. The aim of this study was to answer the following research questions: (1) What is the association between the preoperative fracture displacement, in terms of gap and step-off as measured on CT scans, and the risk of conversion to TKA at the time of follow-up? (2) What is the association between the postoperative fracture reduction and knee alignment, as measured on radiographs, and the risk of conversion to TKA at the time of follow-up?

MATERIALS AND METHODS

Study Design

All patients who underwent tibial plateau fracture surgery between 2003 and 2018 in four trauma centers (two level 1, two level 2) were eligible for this retrospective multicenter cross-sectional study if they had a preoperative CT scan, postoperative anteroposterior and lateral radiographs, and follow-up of >1 year. Patients who required amputation, were <18 years old, were deceased, or had an unknown address were excluded. The baseline characteristics of the included patients were retrieved from the electronic patient file. Patients were approached by mail and asked whether they still had their own, native knee (without conversion to TKA) and whether they had undergone any reoperations. If no response was received, a reminder was sent after 3 weeks. Written informed consent was obtained from all patients. The institutional review board of each center approved the study procedures (registry: 201800411), and the research was performed in accordance with the relevant guidelines and regulations. This study is reported in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guideline [8].

Image Review

All images were reassessed by 2 authors (N.A., F.F.A.IJ.) to determine the fracture classification according to the AO/OTA system [9]. Follow-up radiographs were assessed to verify whether or not patients had undergone conversion to TKA. Measurements were performed in a medical image viewer (Sectra UniView). Radiographs and CT scans were made using standard settings for the x-ray tube or CT scanner. All measurements represented a consensus by the 2 observers (i.e., the observers performed the measurements together).

Preoperative Fracture Assessment

Preoperative CT scans were assessed in axial, sagittal, and coronal planes. The largest gap and step-off within any of these 3 planes was determined and reported (Fig. 1).

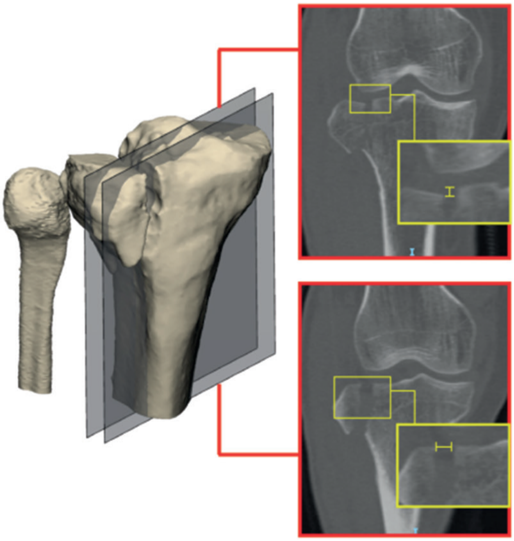

Figure 1: Gap and step-off measurements performed on separate coronal slices. Upper right: step-off measurement, defined as the separation of fracture fragments perpendicular to the articular surface. Lower right: gap measurement, defined as the separation of fracture fragments along the articular surface.

Postoperative Fracture Assessment

The quality of the fracture reduction and tibial alignment was evaluated on radiographs made ≤2 weeks postoperatively, using 4 radiographic parameters: articular fracture reduction, coronal alignment, sagittal alignment, and condylar widening. Fracture reduction was assessed by measuring the residual intra-articular incongruity (maximum gap and step-off). Coronal alignment was assessed by measuring the medial proximal tibial angle (MPTA) on the anteroposterior radiograph, and sagittal alignment was assessed by measuring the posterior proximal tibial angle (PPTA) on the lateral radiograph (Fig. 2). Condylar widening was assessed as described by Johannsen et al. (Fig. 3) [10]. Measurements were considered adequate if they were within the normal range. The articular reduction was considered adequate when both the gap and step-off were <2 mm; coronal alignment, when the MPTA was 87° ± 5°; sagittal alignment, when the PPTA was 9° ± 5°; and condylar widening, when it was between 0 and 5 mm [11–13].

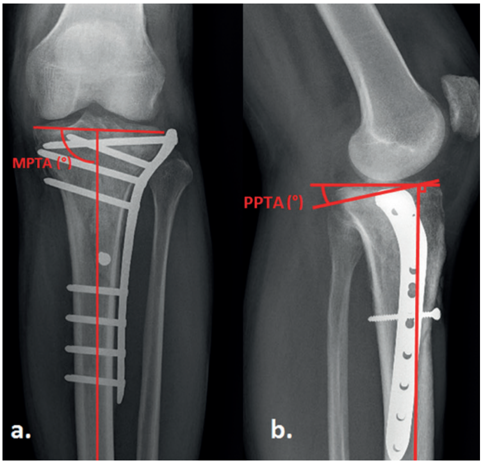

Figure 2: Proximal tibial alignment measurements. a) Coronal alignment, or medial proximal tibial angle (MPTA; normal range, 82° to 92°). b) Sagittal alignment, or posterior proximal tibial angle (PPTA; normal range, 4° to 14°).

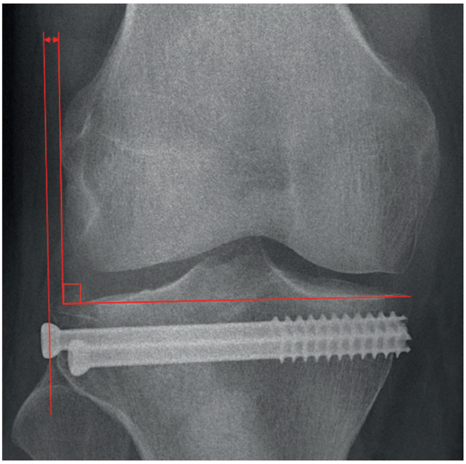

Figure 3: Condylar widening measurement. Lateral condylar widening (normal range, 0 to 5 mm) is measured by drawing 2 lines perpendicular to the medial tibial articular surface, one along the most lateral aspect of the distal femoral condyle and the other along the most lateral aspect of the proximal tibia. The measured distance between these lines is considered condylar widening.

Statistical Analysis

Mann-Whitney U and chi-square tests were performed to assess differences in baseline characteristics between responders and nonresponders. Critical cutoffs for the preoperative gap and step-off were determined by identifying the point that maximized sensitivity and specificity after plotting a receiver operating characteristic (ROC) curve. For each of the 6 measurements of interest, patients were stratified into groups on the basis of the identified cutoff value or normal range, and Kaplan-Meier curves were plotted for the groups. Log-rank tests were performed to assess differences between these groups. The proportionality assumption was assessed by inspecting log-minus-log plots and by adding an interaction term with time. Cox regression was performed to identify the adjusted hazard ratio (HR, representing the relative risk of a complication based on comparison of the event rates) for conversion to TKA that was associated with each measurement after correction for potential confounders (age, sex, smoking, body mass index [BMI], and AO/OTA classification) [14–16]. The intraobserver variability of each measurement was determined by repeating the measurements for 20 cases (with a >1-month interval) and calculating the intraclass correlation coefficient (ICC). We used a 2-way mixed, single-measurement model with absolute agreement. Statistical analysis was performed using SPSS (version 23; IBM). A p value of <0.05 was considered significant.

Source of Funding

There was no external funding source for this study.

RESULTS

Patient Characteristics

Between 2003 and 2018, 1,035 patients were treated surgically for a tibial plateau fracture. Of these, 5 had an amputation, 45 were <18 years old, 97 were deceased at the time of follow-up, and 18 had an unknown address. Eight additional patients were excluded because of insufficient quality of the postoperative radiographs, leaving 862 patients eligible for follow-up. All of these patients were approached, and 477 responded (55% response rate). Table 1 displays patient demographics. Sixty-seven (14%) of the patients had conversion to TKA and none had conversion to unicompartmental knee arthroplasty. Comparison of the responders with the nonresponders demonstrated small differences in age (mean and standard deviation, 53 ± 14 versus 50 ± 16 years, respectively, p = 0.011) and in the proportion of women (68% versus 61%, p = 0.038).

Preoperative Fracture Assessment

Patients who underwent conversion to TKA had a significantly wider preoperative gap (10.1 ± 6.5 versus 6.6 ± 5.9 mm, p < 0.001) and greater step-off (10.6 ± 7.3 versus 7.5 ± 6.1 mm, p < 0.001) compared with those without conversion to TKA. The intraobserver comparison showed an ICC of 0.79 for the gap and 0.78 for step-off. The area under the ROC curve was 0.68 for the preoperative gap and 0.67 for step-off (Fig. 4). The critical cutoff values derived from the ROC analysis were 8.5 mm for the preoperative gap and 6 mm for the step-off.

Postoperative Fracture Assessment

The group with conversion to TKA had significantly higher percentages of patients with inadequate condylar widening (25% versus 13%, p = 0.008), inadequate articular congruity (64% versus 44%, p = 0.002), coronal malalignment (46% versus 22%, p < 0.001), and sagittal malalignment (64% versus 21%, p < 0.001) compared with patients who did not undergo conversion to TKA and still had their own, native knee (Table 2). The intraobserver comparison showed an ICC of 0.8 for condylar widening, 0.8 for articular incongruity, 0.7 for MPTA, and 0.8 for PPTA.

Table 1: Patient characteristics

Demographics	N=477
Age (years)	53 (±14)
Female	326 (68%)
BMI	26.1 (±5)
Smoking	113 (24%)
AO/OTA classification	
41-B1	27 (6%)
41-B2	75 (16%)
41-B3	260 (54%)
41-C1	24 (5%)
41-C2	9 (2%)
41-C3	82 (17%)
Operative treatment	
Plate osteosynthesis	393 (82%)
Screw osteosynthesis	84 (18%)
Conversion to knee arthroplasty	67 (14%)
Unicompartmental Knee Arthroplasty	0 (0%)
Total Knee Arthroplasty	67 (14%)
Follow-up (years)	6.5 (±4.1)
Reinterventions during follow-up	
Elective removal of osteosynthesis material	186 (39%)
Reoperation for Fracture-related infection	15 (0.3%)
Revision surgery for residual displacement	8 (0.2%)
Reoperation for meniscal or ligamental repair	7 (0.2%)

Native Knee Survival

Kaplan-Meier survival curves showed an overall survival rate of 84% for the native knee (free of conversion to TKA) at 10-year follow-up. When stratified on the basis of the critical cutoff value for the preoperative gap, the 10-year knee survival was 91% in the group with a preoperative gap of ≤8.5 mm versus 67% in the group with a gap of >8.5 mm (Figure 5). When stratified on the basis of a preoperative step-off of ≤6 versus >6 mm, the survival rates were 93% and 75%, respectively. When stratified on the basis of tibial alignment, 10-year survival was 88% in patients with adequate coronal alignment versus 72% in patients with malalignment. When stratified on the basis of adequate versus inadequate sagittal alignment, 10-year survival was 92% versus 63%, respectively. The log-rank test showed that the difference between the survival curves was significant for each measurement (p ≤ 0.011).

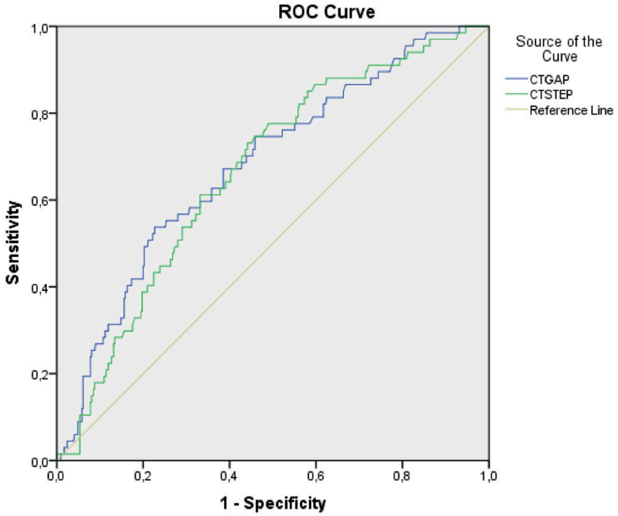

Figure 4: Receiver operating characteristic (ROC) curve demonstrating the association of preoperative fracture gap (CTGAP, blue) and step-off (CTSTEP, green) with conversion to total knee arthroplasty.

Table 2: Pre- and postoperative measurements for patients with vs without conversion to a TKA.

Measure	Conversion to TKA (n=67)	No conversion to TKA (n=410)	P value*
PREOPERATIVE			
Gap > 8.5 mm	36 (54%)	99 (24%)	<0.001
Step-off > 6.0 mm	49 (73%)	185 (45%)	<0.001
POSTOPERATIVE			
Condylar widening > 5 mm	17 (25%)	53 (13%)	0.008
Articular incongruence > 2 mm	43 (64%)	179 (44%)	0.002
MPTA < 82° or > 92°	31 (46%)	90 (22%)	<0.001
PPTA < 4° or > 14°	43 (64%)	87 (21%)	<0.001

*All p values were significant

Independent Risk Factors for Conversion to TKA

An HR of 3.3 (95% confidence interval [CI] = 2.0 to 5.4, $p < 0.001$) was found for patients with a preoperative gap of >8.5 mm, meaning that the instantaneous rate of receiving a TKA at any time during follow-up was 3.3 times higher among patients with a gap of >8.5 mm compared with those with a gap of ≤8.5 mm. Patients with a step-off of >6.0 mm showed an HR of 3.6 (95% CI = 2.0 to 6.3, $p < 0.001$). Similar results were found after adjusting for confounders (Table 3).

Condylar widening was not associated with conversion to TKA after adjusting for confounders. However, certain other postoperative measurements were associated with

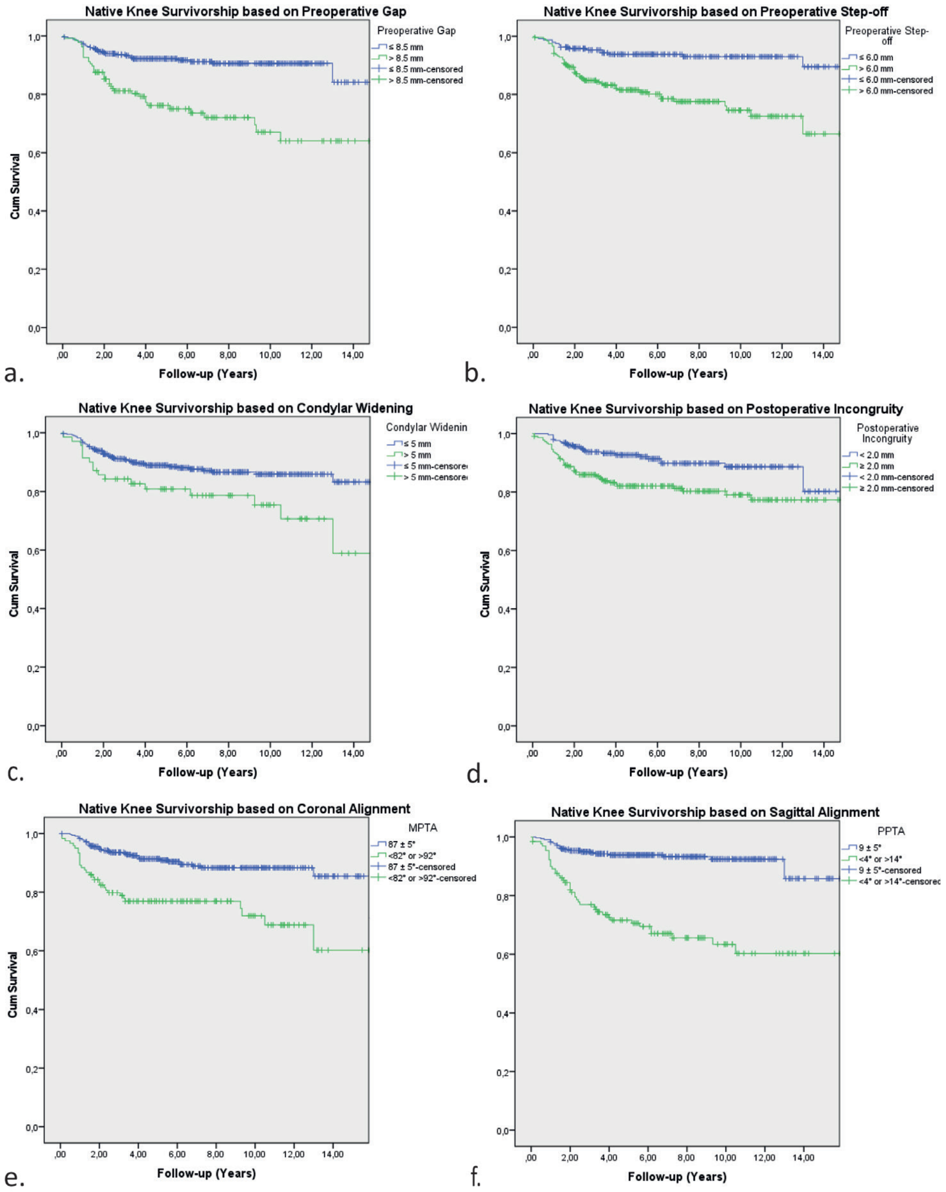

Figure 5: Kaplan-Meier survival curves comparing groups stratified on the basis of preoperative gap (log-rank p < 0.001) (A) and step-off (log-rank p < 0.001) (B), condylar widening (log-rank p = 0.011) (C), postoperative articular incongruity (log-rank p = 0.002) (D), coronal alignment (log-rank p < 0.001) (E), and sagittal alignment (log-rank p < 0.001) (F).

Table 3: Multivariate Analysis of the Association of Radiographic Characteristics with Conversion to TKA

Measure	Unadjusted Hazard Ratio (95% CI)	P-Value	Adjusted Hazard Ratio* (95% CI)	P-Value
PREOPERATIVE				
Gap > 8.5 mm	3.3 (2.0 - 5.4)	<0.001†	2.6 (1.5 – 4.5)	<0.001†
Step-off > 6.0	3.6 (2.0 - 6.3)	<0.001†	3.0 (1.6 – 5.6)	<0.001†
POSTOPERATIVE				
Condylar widening > 5 mm	2.0 (1.1 – 3.5)	0.013†	1.2 (0.7 – 2.1)	0.59
MPTA < 82° or > 92°	2.9 (1.8-4.7)	<0.001†	1.6 (1.0 – 2.8)	0.05†
PPTA < 4° or > 14°	5.2 (3.2 – 8.7)	<0.001†	3.7 (2.1 – 6.3)	<0.001†
Articular incongruence				
<2.0 mm (reference)	-	-	-	-
2.0-4.0 mm	0.9 (0.5 – 1.9)	0.919	0.6 (0.3 – 1.2)	0.176
4.0-6.0 mm	5.0 (2.8 - 9.2)	0.006†	2.7 (1.4 – 5.0)	0.002†
> 6.0 mm	5.2 (2.4-11.3)	<0.001†	5.0 (2.4 – 11.2)	<0.001†

* Adjusted for age, gender, smoking, BMI and AO/OTA classification.
† Significant

conversion. The risk of conversion to TKA was higher among those with an abnormal MPTA (HR = 1.6, 95% CI = 1.0 to 2.8, p = 0.05) and PPTA (HR = 3.7, 95% CI = 2.1 to 6.3, p = 0.001). With regard to articular incongruity, displacement of 2 to 4 mm did not significantly affect the risk compared with the reference group (<2.0 mm). Although the adjusted HR of 0.6 corresponded to an estimated 40% decrease in the (instantaneous) risk of conversion to TKA, the estimated HR was also consistent with an increase of up to 20% according to the CI (HR = 0.6, 95% CI = 0.3 to 1.2, p = 0.176). As the gap or step-off increased beyond 4 mm, the risk of conversion to TKA increased as well. The conversion rate among those with a gap or step-off between 4.0 and 6.0 mm was 2.7 (95% CI = 1.4 to 5.0, p = 0.002) times higher than among the reference group. A gap or step-off of >6.0 mm further increased the risk of conversion to TKA (HR = 5.0, 95% CI = 2.4 to 11.2, p <0.001).

DISCUSSION

Achieving anatomical restoration of the articular surface, adequate tibial alignment, and joint stability are the main goals in surgical treatment of tibial plateau fractures. However, comminuted fractures do not always allow for anatomical reduction. Controversy remains regarding the impact of articular incongruity and tibial alignment on clinical outcome. Our study presents a cohort of surgically treated tibial plateau fractures in which radiographic parameters measuring pre- and postoperative fracture displacement were found to be associated with clinical outcome in terms of conversion to TKA at the time of follow-up. Assessment of preoperative CT scans indicated that substantial initial fracture displacement was independently associated with the need for conversion to TKA. Assessment of postoperative radiographs demonstrated that sagittal and coronal malalignment were strongly associated with conversion to TKA. In contrast to common belief, postoperative gaps or step-offs of <4 mm were not associated with an increased risk of TKA. However, more severe postoperative articular incongruity of >4 mm was associated with an increased risk of conversion to TKA.

Osteoarthritis may still develop after adequate fracture reduction because of extensive irreversible damage to the articular surface caused by the initial trauma. Several studies have indicated that the severity of the fracture is predictive of early-onset osteoarthritis [6,17]. Additionally, Parkkinen et al. showed that a preoperative step-off of >3.4 mm in medial tibial plateau fractures was predictive of the development of moderate to severe osteoarthritis [7]. Nevertheless, literature on the association between initial fracture displacement and the risk of conversion to TKA after surgical treatment of tibial plateau fractures is still limited. In line with previous studies [6,7,17], we found that substantial initial fracture displacement was a strong predictor of the development of progressive osteoarthritis eventually requiring conversion to TKA. In addition, our results indicated that not only the step-off but also the gap was predictive of the clinical outcome [7]. Knowledge about the association between substantial initial fracture displacement and an increased risk of conversion to TKA at the time of follow-up may aid in expectation management and patient counseling about the prognosis.

Postoperative assessments of residual incongruity and tibial alignment are essential for decision-making about revision surgery and patient counseling about the prognosis. Much controversy exists regarding the degree of residual displacement that can be accepted. Residual displacement of <2 mm as measured by the gap or step-off is generally considered an adequate reduction [11,12]. Recent studies have reconfirmed that a residual step-off of >2 mm, as measured on a postoperative radiograph, is associated with worse functional outcomes3,7. However, a review by Giannoudis et al. showed that controversy remains regarding the degree of articular incongruity that can be tolerated in tibial plateau fracture management [18]. Our recent study demonstrated that a fracture gap or step-off of ≤4 mm, as measured on CT scans, could result in good functional outcomes in patients who opt for nonoperative fracture management [19]. In addition to these studies, our current results seem to indicate that initial displacement of up to 4 mm does not affect the risk of conversion to TKA. Therefore, the arbitrary 2-mm limit for gaps and step-offs in tibial plateau fractures might be revisited. However, our study did show that greater postoperative incongruity, with displacement exceeding 4 mm, was associated with an increased risk of TKA. Although much literature has focused on residual articular incongruity, hardly any studies have reported on the relationship between the achieved tibial alignment and functional outcome. Recently, Van den Berg et al. reported that sagittal malalignment was associated with worse outcomes and emphasized the importance of restoring the sagittal alignment when treating posterior tibial plateau fractures [13]. Additionally, Parkkinen et al. showed that coronal malalignment was associated with the development of osteoarthritis and worse pain [3,7]. However, those studies were limited by small sample sizes and a focus on specific fracture types, and they did not provide HRs. Our study adds to the literature by including >450 patients with all tibial plateau fracture types. Our results indicated that both the postoperative coronal and sagittal malalignment of the tibia were strong predictors of conversion to TKA. Therefore, surgeons should be aware of the importance of restoring tibial alignment when performing surgical management of complex tibial plateau fractures.

This study has several limitations. First, selection bias caused by loss to follow-up and nonresponse is inherent to a cross-sectional study design. Second, meniscal and/or ligamentous injuries might be considered an important confounder, but it was challenging to identify whether the patients in this retrospective study had any meniscal injuries because magnetic resonance imaging or arthroscopy is not regularly performed within our clinics. Nevertheless, we gathered as much information as possible about the impact of concomitant soft-tissue injuries. All patients were contacted and asked whether they had undergone any reintervention, and patient files were verified. Only 7 (0.15%) of 477 patients underwent a reoperation for meniscal or ligamentous repair. Future studies should incorporate concomitant soft-tissue injury and assess its impact on patient outcome. Third, not all radiographs were made by the same radiology technician, and some radiographs may not have been aligned perfectly in the anteroposterior and lateral views or may have had slight differences in magnification since the radiographs were not calibrated. However, this is inherent to clinical practice. Furthermore, there are concerns regarding the interobserver reliability of radiographic measurements even though these measurements are still the gold standard in clinical practice [5,20]. Gap and step-off measurements in particular are prone to interobserver variability[21,22], although measurements of tibial alignment have shown good reliability [23,24]. Nevertheless, intraobserver measurements within this study showed good reliability for all measurements. Fourth, the number of patients who underwent conversion to TKA was limited since conversion to TKA is relatively uncommon. Finally, our findings may be parochial to the clinical environment from which the substrate was developed and therefore cannot be assumed to be generalizable to other clinical environments. Performance in other clinical contexts should be tested to ensure validity. Given these limitations, this work can only be considered hypothesis-generating and not prescriptive.

Worldwide, fracture displacement and tibial alignment are generally still determined on radiographs and 2-dimensional CT slices. However, more advanced 3-dimensional (3D) imaging techniques are increasingly used in treatment of tibial plateau fractures25. For example, we recently introduced a novel 3D technique to measure intra-articular incongruity in tibial plateau fractures [21]. Measurements of sagittal alignment of the tibia might also be improved by using 3D technology [26]. We envision that novel 3D measurements will be increasingly used in addition to current classification systems in order to evaluate the true fracture extent and estimate the prognosis. Furthermore, we chose conversion to TKA as the sole end point in this study since it is a commonly used and unambiguous end point, but the results of surgical treatment could also be evaluated using outcome measures. Future research should therefore focus on the association between radiographic measurements and the risk of poor results as measured by patient-reported outcomes.

In summary, this large multicenter study of medium-term clinical outcomes after tibial plateau fracture surgery demonstrated that substantial initial fracture displacement is a strong independent predictor of conversion to TKA. Moreover, this study showed that postoperative incongruity of >4 mm and sagittal and coronal malalignment were strong independent predictors of conversion to TKA at the time of follow-up. These findings can be used as a guideline for counseling patients with complex tibial plateau fractures and could help to estimate the prognosis.

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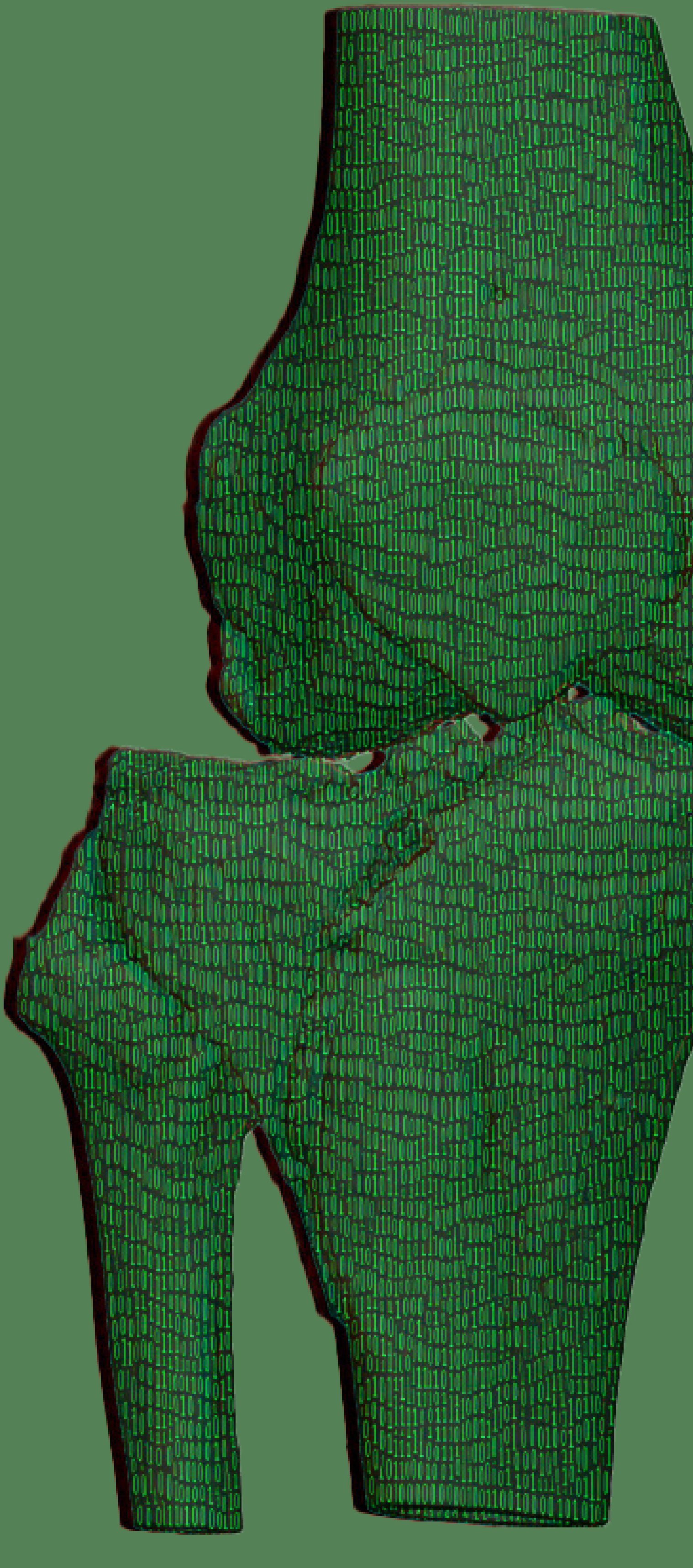

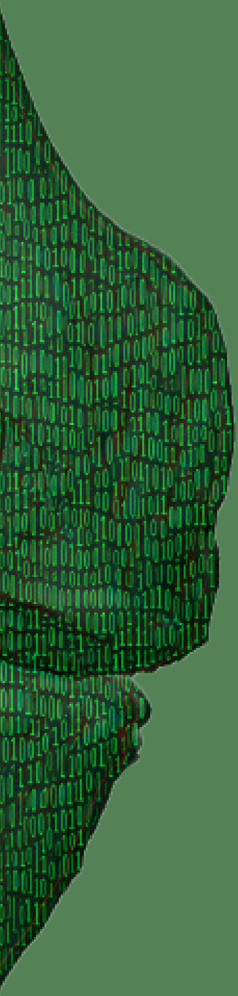

OUTCOME PREDICTION

PART TWO

CHAPTER 5

Development of a clinical prediction model in orthopaedic trauma surgery: Can machine learning based algorithms predict the risk of total knee arthroplasty after tibial plateau fracture treatment?

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This chapter is under submission

Abstract

Background: Prediction models for clinical outcome in orthopaedic trauma surgery are lacking. This study introduces a concept of predicting clinical outcome following injuries that have significant personal and societal impact. Prediction of worse outcome, such as progressive osteoarthritis resulting in total knee arthroplasty (TKA), following tibial plateau fractures remains challenging due to numerous patient and fracture characteristics involved. We developed and internally validated a clinical prediction model using machine learning algorithms for 2 and 5-year risk on TKA following tibia plateau fractures.

Methods: A multicentre, cross-sectional study was performed in six hospitals in patients treated for a tibial plateau fracture between 2003-2019. Three machine learning based algorithms were developed and internally validated: Logistic Regression, Random Forest, and XGBoost. Performance was assessed by the Area Under the Receiver Operating Characteristic Curve (AUC), F1, precision, and recall.

Results: In total 1160 patients were included of which 6.8% (n=79) and 9.1% (n=106) underwent conversion to a TKA at 2 and 5-year follow-up, respectively. The features of the models included: age, BMI, AO/OTA fracture classification, fracture displacement (gap, step-off), and tibial alignment (MPTA, PPTA). The logistic regression model showed best performance for both 2 and 5-year prediction models in terms of AUC (2-year:0.83; 5-year:0.83), macro F1 (0.61;0.65), precision (0.60;0.63), recall (0.71,0.71). The models are accessible in an online tool: https://3dtrauma.shinyapps.io/knee_prosthesis_prediction/

Conclusion: This study presented an innovative proof-of-concept for developing clinical prediction models in orthopaedic trauma. Our machine learning algorithms achieved good accuracy and performance in predicting risk on TKA conversion following tibial plateau fractures.

INTRODUCTION

Lower leg injuries have major impact on the patient's mobility, social activities, and ability to work. Especially injuries of the loadbearing part of the knee, including tibial plateau fractures, may result in significant impairment of movement [1]. The incidence of tibial plateau fractures is 10-25 per 100.000 [2,3], which accounts for up to two-million injured individuals worldwide annually. Especially in metropoles, where millions of people ride motorbikes, these injuries are common. The World Health Organization recommends to take 10.000 steps a day to stay healthy. Therefore, good functioning joints in the lower extremity are essential and operative treatment might be required to achieve restoration of joint function. Despite achieving anatomical reduction, damage to the tibial plateau might progress into posttraumatic osteoarthritis and instability resulting in complaints as pain and stiffness, ultimately leading to the conversion to a total knee arthroplasty (TKA) [4,5]. As compared to the general population, tibial plateau fractures are associated with a 3.5-5 times increased risk of TKA [6,7]. Though, due to many factors involved, surgeons can hardly predict which patients will do well and which will struggle, do worse and eventually needs conversion to TKA.

Injured patients often face critical decisions regarding their treatment options, making shared-decision making a crucial aspect of their care. At time of injury, their primary concerns are uncertainty about injury severity, necessity of surgery, and prognosis. Providing effective patient counselling necessitates the ability to estimate prognosis accurately. However, this task is challenging due to the multifactorial nature of prognosis determination, which relies on factors such as patient characteristics (e.g. age, BMI, comorbidity), fracture classification, and the alignment of the fracture on pre- and post-operative radiographs [7–9]. With numerous variables to consider, accurate prediction of clinical outcome remains challenging. Moreover, estimation of prognosis often remains subjective, heavily reliant on the surgeon's prior experiences rather than data-driven insights. Machine learning based algorithms have the potential to combine different features into one model and show great potential in terms of fracture detection, grading osteoarthritis, and predicting outcomes like mortality [10,11]. These algorithms could be valuable as well in predicting clinical outcome after injuries. Such a model could benefit patient counselling and shared-decision making, as it would allow for more personalized and informed treatment plans. Though, currently there is a lack of good clinical prediction models in orthopaedic-trauma surgery. One of the reasons is the difficulty in obtaining large high-quality datasets including patient, fracture, and follow-up data. We present an innovative proof-of-concept for developing clinical prediction models in orthopaedic-trauma, aiming to establish a baseline work for outcome prediction after injuries. For this purpose, we collected clinical outcomes from a large multicentre cohort of patients with tibial plateau fractures.

The goal of this study was to develop and internally validate a machine-learning based prediction model utilizing patient characteristics for a patient-specific risk assessment of two- and five-year conversion to a TKA. We aimed to answer the following research question: can we use machine learning based algorithms to predict the risk of conversion to TKA in patients with a tibial plateau fracture at 2- and 5-year follow-up?

MATERIALS AND METHODS

This study is reported following the Transparent Reporting of Multivariable Prediction Models for Individual Prognosis or Diagnosis Guideline (TRIPOD-Statement) and the JMIR Guidelines for Developing and Reporting Machine Learning Predictive Models in Biomedical Research [12,13].

Study design and population

A multicentre, cross-sectional study was performed in patients treated between 2003-2019 for a tibial plateau fracture in six hospitals within the Netherlands and Belgium. A total of 2241 patients were identified who were treated in that period for a tibial plateau fracture, had an available diagnostic CT-scan, and were still alive according to the national population registry. From the identified patients, 0.2% (4) were excluded since they required amputation, whereas 4.0% (89) were excluded due to coexisting conditions complicating outcome measurement including Parkinson, CVA, or paralysis. A further 2.7% (60) and 1.4% (31), respectively, were excluded since their address was unknown or spoke a foreign language. Subsequently, 2051 patients were eligible for inclusion and were sent informed consent and questionnaire asking whether if they had undergone conversion to TKA. A total of 1160 patients responded at 6.3 ± 3.8 years after injury (response rate 57%). Patient characteristics including age, gender, BMI, smoking, and diabetes were retrieved from electronic patient records, and imaging data was shared with the initiating centre from which fracture characteristics were determined. Images from all patients were reassessed to determine the fracture classification according to the AO/OTA, fracture severity, and operative fracture reduction. Severity of the fracture was assessed on the preoperative CT-scan by measuring gap and step-off (appendix 1). The quality of the operative fracture reduction and tibial alignment was evaluated on postoperative radiographs by measuring: articular fracture reduction, medial proximal tibial angle(MPTA, Appendix 2a), posterior proximal tibial angle(PPTA, appendix 2b), and condylar widening [8].

Enrolled patients had a mean age of 53±15 years at the moment of injury. A total of 70.1% (814/1160) was treated with open reduction and internal fixation, whereas 29.8% of the patients was treated non-surgically with a cast. In total 6.8% (79/1160) of patients had conversion to a TKA at 2-year follow-up, whereas at 5-year follow-up this number increased to 9.1% (106/1160). All patients and fracture characteristics are reported in table 1.

Table 1: Patient characteristics (n=1160)

Characteristics (n=1160)	Value
Patient characteristics	
Age	53 ± 15
Gender (Male)	32.1 % (372)
BMI	26 ± 4.7
Smoking	20.2% (234)
Comorbidities	
Diabetes	7.9% (92)
Cardiovascular disease	10.8% (125)
Rheumatoid Arthritis	5% (59)
Fracture characteristics	
High energy trauma	11.7% (136)
Side (right)	40% (452)
AO/OTA classification	
41-B1	11.9% (138)
41-B2	23.6% (274)
41-B3	44.7% (518)
41-C1	3.6% (41)
41-C2	1.7% (19)
41-C3	14.7% (170)
Coincident fibular head fracture (yes/no)	19.7% (228)
Initial gap (mm)*	5.3 ± 5.5
Initial step-off (mm)*	6.2 ± 6.1
Treatment	
Operative	70.2% (815)
Conservative	29.8% (345)
Radiographic outcome*	
Adequate Condylar widening (0-5 mm)	79.9% (888)
Adequate Medial Proximal Tibial Angle (87 ± 5°)	83.7% (971)
Adequate Posterior Proximal Tibial Angle (9 ± 5°)	80.9% (938)
Adequate Incongruence < 2 mm	60.8% (705)
Conversion to Total Knee Arthroplasty	10.8% (125)

* See appendix 1 & 2 for example of radiographic measurements.

Primary outcome

Primary outcome of the model was conversion to TKA at two- and five-year follow-up. Information about whether and when a patient underwent conversion to a TKA was collected by approaching all patients.

Data cleaning and feature selection

The obtained features, derived from follow-up questionnaires, electronic patient records, and radiographic assessments as presented in Table 1, were eligible for development of the prediction model. First step for data cleaning included simple type formatting (e.g. converting "yes"/"no" columns into Booleans). In addition, main actions for dataset cleaning included standardization of the numerical columns, and outlier removal. Outliers were defined as any data point beyond 1.5 times the Inter-Quartile Range (IQR), and were replaced with the closest bound. Subsequent feature selection consisted of literature review according to the methodological framework principles as proposed by Levac et al. [14] and expert opinion. This was followed by bivariate analysis of the identified features. Following the rule of thumb for building prediction models with a binary outcome, feature selection was limited to ensure that at least 10 events(conversions to TKA) for each feature were included within the model [15]. Feature selection resulted in the following included features: age, BMI, AO/OTA classification, initial gap, initial step-off, Medial Proximal Tibial Angle(MPTA) and Posterior Proximal Tibial Angle(PPTA).

Missing data

Missing values among the chosen features included 4.4% for BMI (52/1160). The other features contained no missing values. The missing values were imputed through K-Nearest Neighbours (KNN) imputation. KNN was chosen to increase the biological feasibility of the imputations.

Development and internal validation of the model

The cleaned and processed dataset was used to train a total of three models: Logistic Regression, Random Forest, and XGBoost [16,17]. These models were chosen due to their simplicity, which might boost performance given the size of the obtained dataset. The models were tested using 5-fold cross validation in which data is divided into five equal datasets, after which the model undergoes five iterations of training and validation. To ensure optimal classification, every cross-validation fold uses a subset of the training set to determine the classification threshold.

Assessment of model performance

5-fold cross validation was used to compare the models. Accuracy was deemed an inappropriate measure for performance, since the highly imbalanced nature of the dataset allows an accuracy of 91% just from predicting the false label. Instead, Area Under the Receiver Operating Characteristic Curve (AUC) was chosen as the main performance metric. The AUC is widely used to measure the accuracy of diagnostic tests and provides an aggregate measure of performance across all possible classification thresholds. The AUC score ranges from 0-1 with a score of 0.5 indicating random guessing, and 1 indicating perfect performance. Additionally, F1, precision, and recall were evaluated, along with macro versions of these scores. Macro-scores are particularly significant due to the data imbalance.

Statistical analysis

Descriptive statistics were used to describe the study population. For normally distributed data, continuous variables are presented as mean with standard deviation (SD), and for nonnormally distributed data as median with IQR. Data pre-processing and analysis was performed using Python Scripting (Version 3.10.6., Python Software Foundation, Wilmington, US), importing the scikit-learn [18] and Pandas libraries [19].

Ethical approval

The institutional review board of each center approved the study procedures (registry: 201800411), and the research was performed in accordance with the relevant guidelines and regulations.

Web application

The algorithms that showed highest performance metrics were integrated into an online, freely accessible prediction tool.

RESULTS

Model performance

With regards to predicting two-year conversion to TKA, the five folds of the random forest, logistic regression, and XGBoost algorithm show AUCs between 0.73-0.86, 0.75-0.89, and 0.63-0.82, respectively(Fig. 1). In predicting five-year conversion to TKA, the five folds of the random forest, logistic regression, and XGBoost algorithm show AUCs between 0.66-0.87, 0.74-0.92, and 0.60-0.85, respectively. When also taking into account the other outcome measures, the Logistic regression algorithm showed the highest values with respect to AUC, (macro) F1, (macro) Precision and (macro) Recall (Table 2).

Table 2: Performance of machine-learning algorithms predicting two-year conversion to TKA following a tibial plateau fracture after five-fold cross validation.

	Random forest		**Logistic regression**		**XGBoost**	
	2 years	**5 years**	**2 years**	**5 years**	**2 years**	**5 years**
AUC	0.79 ± 0.06	0.80 ± 0.09	0.83 ± 0.05	0.83 ± 0.08	0.71 ± 0.07	0.75 ± 0.11
F1	0.29	0.35	0.32	0.39	0.23	0.31
Macro F1	0.60	0.63	0.61	0.65	0.58	0.62
Precision	0.24	0.32	0.23	0.32	0.20	0.31
Macro Precision	0.60	0.63	0.60	0.63	0.57	0.62
Recall	0.43	0.49	0.57	0.55	0.27	0.30
Macro Recall	0.66	0.69	0.71	0.71	0.59	0.62

Clinical showcases

Figure 2 illustrates the potential clinical usage of the developed model. It includes a total of three different cases which were imputed into the model:

The first case consisted off a 72-year-old woman with a BMI of 28. After falling from the stairs, she suffered an AO/OTA B2 fracture with a gap and step-off or 2 and 5 mm, respectively. After treatment MPTA remained inadequate, whereas PPTA was restored. The model estimated the of conversion to a TKA at 7.3% in 2 years and 16.5% in 5 year.

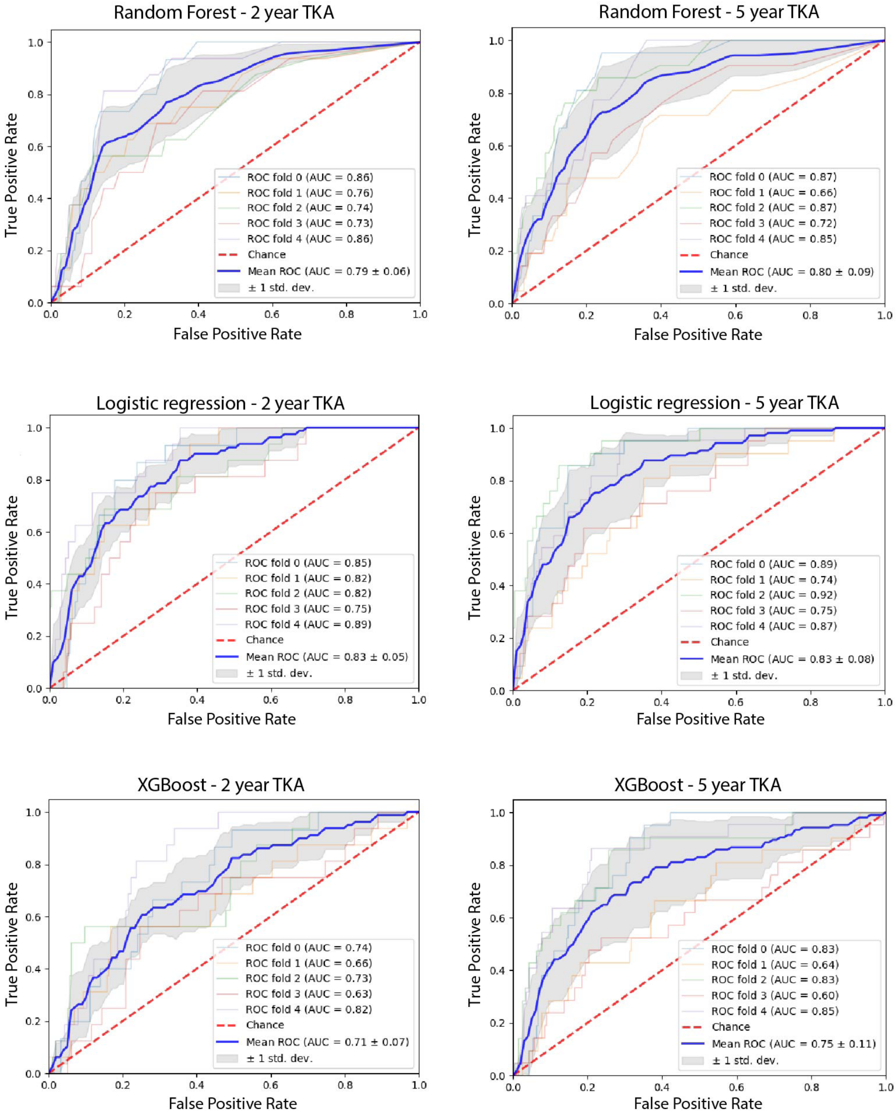


Figure 1: Receiver Operating Characteristic (ROC) curve demonstrating the performances of the five folds of the random forest, logistic regression, and XGBoost algorithms for prediction of two and five year Total Knee Arthroplasty (TKA).

The second case is a 30-year-old male with a BMI of 22. The patient had a traffic accident with his car, resulting in an AO/OTA B3 tibial plateau fracture with a gap of 4 mm, and a step-off of 8 mm. Surgical treatment resulted in adequate MPTA and PPTA, meaning the risk of this patient receiving a TKA is only 1.2% and 1.9% at 2- and 5-years follow-up, respectively.

The last case entailed a 59-year-old woman who fell from her bicycle. The woman, with a BMI of 27, sustained a C3 tibial plateau fracture with a gap and step-off of 10 and 8 mm, respectively. After surgical treatment, MPTA was restored but the PPTA retained inadequate. This would give the woman a risk of 19.3% of conversion to a TKA in 2-years, and 47.2% in 5-years according to the model.

Feature importance

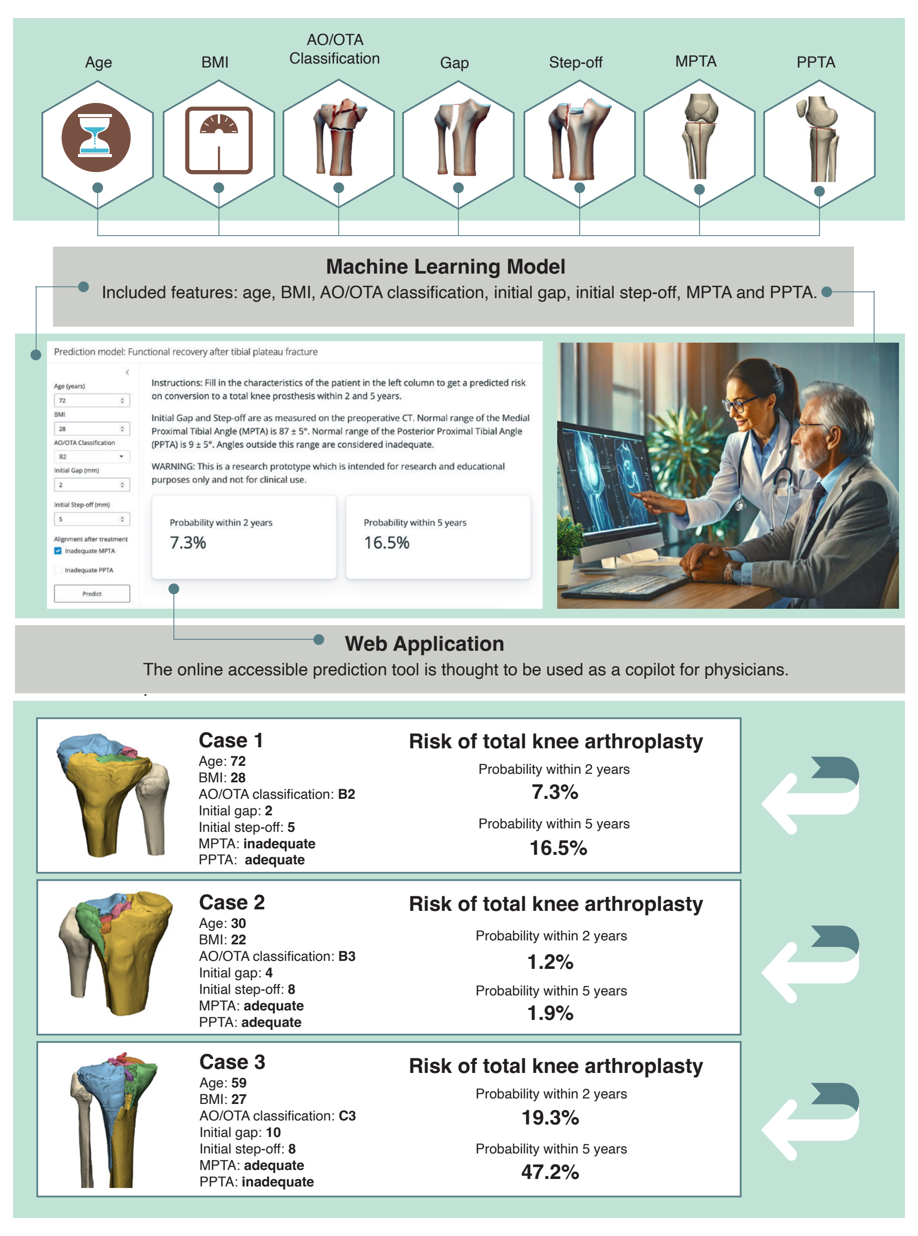
The proposed logistic regression model predicts outcome probabilities using a multi-dimensional curve based on input features. The curve is a weighted sum of features, with coefficients determining each feature's impact on the probability. Training begins with a random curve, then iteratively calculates errors and adjusts coefficients via gradient descent, improving the curve's accuracy with each example. Coefficients reveal how significantly each feature influences the predicted probability. The raw and normalized coefficients for the 2-year and 5-year logistic regression models can be found in table 3. These coefficients represent the best-performing model, aiming for accuracy without considering biological relevance or feature minimization.

Table 3: Weights of the different features for both the 2 and 5 year prediction models. Features are multiplied with the coefficient to adjust for the weight. Normalized coefficients are adjusted to represent the weights of the features on a common scale for direct comparability.

Feature	Coefficients for 2-Year model	Normalized Coefficients for 2-Year model	Coefficients for 2-Year model	Normalized Coefficients for 5-Year model
Age	0.93	0.38	0.88	0.31
BMI	0.24	0.10	0.37	0.13
AO/OTA	0.21	0.09	0.28	0.10
Gap	0.18	0.07	0.24	0.09
Step-off	0.55	0.22	0.63	0.22
MPTA	0.01	0.003	-0.01	-0.003
PPTA	0.33	0.14	0.43	0.15

Web application

The web application providing the prediction tool could be accessed through: https://3dtrauma.shinyapps.io/knee_prosthesis_prediction/



Machine Learning Model

Included features: age, BMI, AO/OTA classification, initial gap, initial step-off, MPTA and PPTA.

Prediction model: Functional recovery after tibial plateau fracture

Age (years): 72
BMI: 28
AO/OTA Classification: B2
Initial Gap (mm): 2
Initial Step-off (mm): 5
Alignment after treatment
☑ Inadequate MPTA
☐ Inadequate PPTA

Instructions: Fill in the characteristics of the patient in the left column to get a predicted risk on conversion to a total knee prosthesis within 2 and 5 years.

Initial Gap and Step-off are as measured on the preoperative CT. Normal range of the Medial Proximal Tibial Angle (MPTA) is 87 ± 5°. Normal range of the Posterior Proximal Tibial Angle (PPTA) is 9 ± 5°. Angles outside this range are considered inadequate.

WARNING: This is a research prototype which is intended for research and educational purposes only and not for clinical use.

Probability within 2 years
7.3%

Probability within 5 years
16.5%

Web Application

The online accessible prediction tool is thought to be used as a copilot for physicians.

Case 1
Age: **72**
BMI: **28**
AO/OTA classification: **B2**
Initial gap: **2**
Initial step-off: **5**
MPTA: **inadequate**
PPTA: **adequate**

Risk of total knee arthroplasty
Probability within 2 years
7.3%
Probability within 5 years
16.5%

Case 2
Age: **30**
BMI: **22**
AO/OTA classification: **B3**
Initial gap: **4**
Initial step-off: **8**
MPTA: **adequate**
PPTA: **adequate**

Risk of total knee arthroplasty
Probability within 2 years
1.2%
Probability within 5 years
1.9%

Case 3
Age: **59**
BMI: **27**
AO/OTA classification: **C3**
Initial gap: **10**
Initial step-off: **8**
MPTA: **adequate**
PPTA: **inadequate**

Risk of total knee arthroplasty
Probability within 2 years
19.3%
Probability within 5 years
47.2%

Figure 2: Graphical illustration of the potential clinical usage of the machine learning based prediction model. The included features (age, BMI, AO/OTA classification, gap, step-off, MPTA, and PPTA) can be imputed for each patient into the model to compute a personalized risk on total knee arthroplasty at 2 and 5 year follow-up. A total of three clinical showcases are presented here to illustrate different risks for these individual patients.

DISCUSSION

In this study, we developed one of the first internally validated machine learning models for predicting clinical outcome in orthopaedic-trauma surgery. It should be considered a proof-of-concept for developing future prediction tools for clinical outcome in patients who sustained different injuries. Our model accurately predicts risk on conversion to TKA following a tibial plateau fracture. These findings suggest that machine learning algorithms have potential to create valuable tools for patient counselling and shared decision-making in the field of orthopaedic-trauma surgery. Our model is unique in its ability to provide a 'personalized outcome prediction for each patient' based on specific patient- and fracture characteristics, which adds to previous studies that only assessed associations between single features and the risk on a TKA [8,20].

In the past few years, use of machine learning models in orthopaedic-trauma have increasingly been investigated. Most models focus on fracture detection, grading osteoarthritis, and predicting complications [10,11]. Most existing outcome prediction models are limited to mortality or length of hospital stay. One recent study which developed a model predicting mortality, length of hospital stay > 3 days, and 30-day readmission following surgical treatment of ankle fractures showed AUC values up to 0.76 [21]. Oosterhoff et al. developed and internally validated a prediction model for 90-day and 2-year mortality in patients with femoral neck fractures which showed AUC of 0.74 and 0.7, respectively [22]. Our model is unique as it predicts clinical outcome instead of complications. With an AUC of 0.83 of our best performing logistic regression model, our algorithm does not underperform compared to previous mentioned models. Interestingly, our study results showed that a relatively simple model like logistic regression performed better than more complex models such as XGboost. Simpler models are usually more robust to issues like relatively small sample size. On the contrary complex models are prone to overfitting on small datasets. This illustrates that dataset size is limiting performance of advanced models, since the more advanced model is failing to tune all of its parameters to the dataset. Therefore, logistic regression shows to be the best algorithm for our dataset with 1160 patients. While this sample size may be considered limited from a data science perspective, it represents the largest high-quality dataset with tibial plateau fractures and follow-up data from a clinical view. With precision and recall scores varying around 0.6-0.7 the models perform moderate in making a distinction between a binary choice of conversion and no conversion to TKA. However, it is worth noting that the model's actual output is a risk on TKA rather than a straightforward yes or no prediction. Therefore, by chance, there will always be some extent of false positives and negatives. It should be noted that in the two- and five-year models, respectively 21% and 6% of the false-positive patients actually did receive a TKA but at a later timeframe. This personalized risk should be interpreted by the physician and taken into account alongside his/her professional experience and patient's wishes and social environment. In a clinical setting such a model could be used for shared-decision making. By using such a model, the patient will be better informed and with that expectations regarding the expected outcome could be managed. Additionally, this prediction model might also guide discussions between professionals regarding the surgical treatment plan. In selective cases, primary TKA might be a suitable option for elderly patients with tibial plateau fractures who are at high risk of a TKA in the short term [23]. Alternatively, one could also try to minimize surgical exposure in high-risk patients as scar tissue, retained metalwork, bony deficiency, and instability can lead to poorer outcomes and higher complication rates [24].

While our model seems promising, it is important to recognize that the use of AI in predicting outcomes for patients with fractures is still in its early stages. Also, our developed model was compromised by several limitations which arise from the study set-up. First, the dataset from which the model was developed was relatively small within the field of data science. One of the main challenges in orthopaedic-trauma remains the lack of large, high-quality datasets that are necessary for developing prediction models. Though, when comparing our dataset to different prediction models in orthopaedic-trauma research, our model is based on slightly more patients than the median sample size of 875 within these studies [25]. Also, there was a significant data imbalance within the dataset, where only 9.1% (106/1160) of the samples are in the positive class (conversion to TKA). Imbalanced datasets may exhibit bias towards the majority class. Therefore, we had to force the model to artificially be biased towards the minority class to prevent underperformance in this class. Furthermore, the retrospective character of the dataset was a limitation since you have to deal with incomplete records, varying follow-up time, unknown physical activity levels before injury and unknown health and psychosocial status. A prospective study should be set-up incorporating a wider spectrum of potential features which might influence the need for a conversion to a TKA. Despite these challenges, we believe that AI has the potential to greatly improve the accuracy of predictions and ultimately manage patient expectations, and our model is a step in that direction.

The potential clinical implications of AI-based predictive models like ours are significant. By providing physicians with additional information about the risk of TKA for their patients, these models can help to properly inform treatment decisions and improve patient expectations. One might consider expending these models with a prediction of the expected patient-reported outcome to evaluate the impact of a treatment choice. Recent studies showed that recognition and classification of fractures using AI is already feasible 26. In future models, automatic CT-based fracture assessment might even be possible, reducing the need for input variables of the surgeon. Furthermore, automatic assessment of MRI images to assess the soft tissue conditions could further enhance these models. In other industries, AI is already being used to augment human decision-making and improve efficiency, and we believe that medicine can benefit from this technology as well. However, the adoption of AI in medicine has been slower due to the unique challenges and risks involved, such as data privacy concerns and the potential for bias in AI models. We envision a future where AI systems serve as "copilots" for physicians, providing them with data-driven insights that can inform their discussions with patients and guide treatment decisions. By combining the expertise of physicians with the analytical power of AI, we can move towards a more personalized and effective approach to healthcare.

Conclusion

In this study, we aimed to develop and validate a machine-learning based prediction model for identifying patients at risk of conversion to a TKA within 2 and 5 years following a tibial plateau fracture. We utilized patient and fracture characteristics to create a personalized risk assessment tool that can aid in clinical decision-making and patient counselling. Our results indicate that machine learning algorithms, particularly random forest and logistic regression, can achieve reasonable accuracy and performance in predicting TKA conversion. However, further refinement and external validation of these models are necessary to improve their accuracy and reliability. Ultimately, we believe that the integration of machine learning into clinical practice has the potential to manage patient expectations and utilize personalized treatment plans for patients with tibial plateau fractures.

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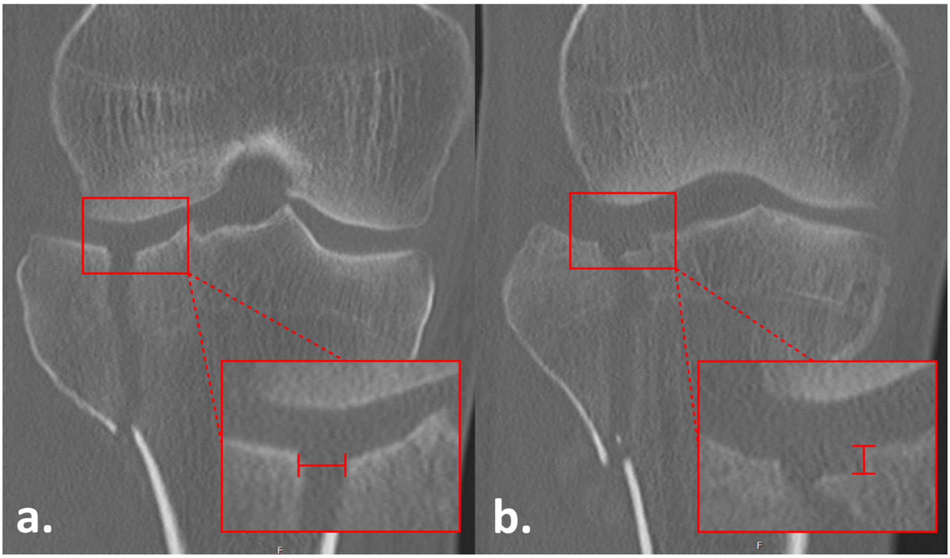
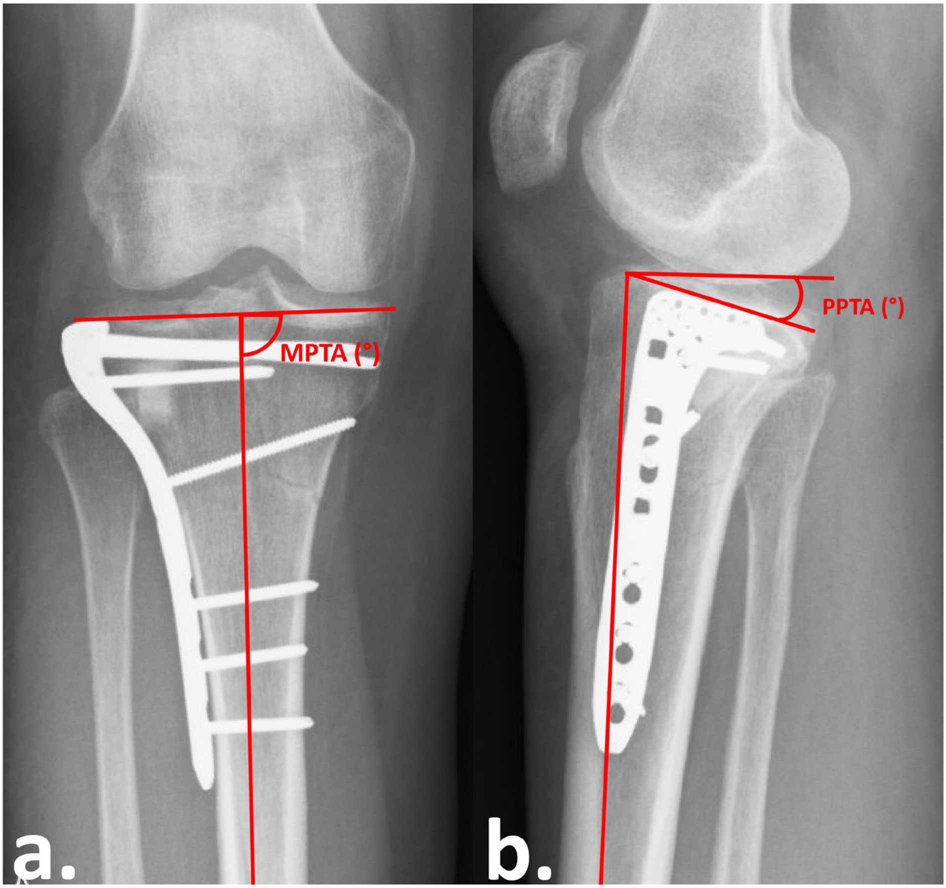
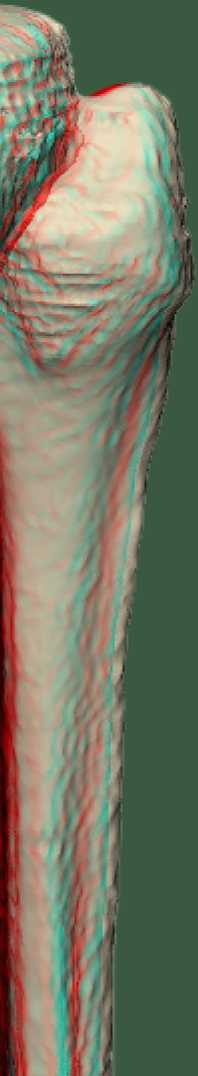
Appendix 1: Gap and step-off measurements performed on separate coronal slices of the preoperative CT-scan. a) Gap measurement, defined as the separation of fracture fragments along the articular surface; b) Step-off measurement, defined as the separation of fracture fragments perpendicular to the articular surface.



Appendix 2: Proximal tibial alignment measurements as measured on postoperative radiographs. a) Coronal alignment, or medial proximal tibial angle (MPTA; normal range, 82° to 92°); b) Sagittal alignment, or posterior proximal tibial angle (PPTA; normal range, 4° to 14°).





THREE-DIMENSIONAL FRACTURE ASSESSMENT

PART THREE

CHAPTER 6

Quantitative 3D measurements of tibial plateau fractures

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Abstract

Introduction: Fracture gap and step-off measurements on 2DCT-slices probably underestimate the complex multi-directional features of tibial plateau fractures. Our aim was to develop a quantitative 3D-CT (Q3DCT) fracture analysis of these injuries.

Methods: CT-based 3D models were created for 10 patients with a tibial plateau fracture. Several 3D measures (gap area, articular surface involvement, 3D displacement) were developed and tested. Gaps and step-offs were measured in 2D and 3D. All measurements were repeated by six observers and the reproducibility was determined by intra-class correlation coefficients.

Results: Q3DCT measurements demonstrated a median gap of 5.3 mm, step-off of 5.2 mm, gap area of 235 mm², articular surface involvement of 33% and 3D displacement of 6.1 mm. The inter-rater reliability was higher in the Q3DCT than in the 2DCT measurements for both the gap (0.96 vs. 0.81) and step-off (0.63 vs. 0.32). Q3DCT measurements showed excellent reliability (ICC of 0.94 for gap area, 1 for articular surface involvement and 0.99 for 3D displacement).

Conclusion: Q3DCT fracture analysis of tibial plateau fractures is feasible and shows excellent reliability. 3D measurements could be used together with the current classification systems to quantify the true extent of these complex multi-directional fractures in a standardized way.

INTRODUCTION

Tibial plateau fractures represent 1–2% of all fractures in adults and are reported as one of the most challenging injuries of the knee [1]. Since the tibial plateau is among the most loadbearing areas in the body, any fractures affect knee alignment, stability and motion. Adequate treatment is crucial to minimize patient disability and other consequences (e.g. posttraumatic arthritis) [2]. Adequate classification and fracture assessment of tibial plateau injuries is essential in the choice of the right treatment strategy [3]. Currently, the Schatzker and AO/OTA are the most widely used and accepted classification systems [4,5,6]. Although these classifications represent the gross fracture patterns, they do not include detailed information about the severity of the dislocation, gap, and step-off [7,8]. Furthermore, it has been reported that these classification systems have their limitations, because of their moderate inter-rater reliability [3,9,10].

The goal of any surgical treatment of the fractured tibial plateau is to restore the articular surface and provide a stable fixation, which allows immediate postoperative exercising [11]. A CT-scan provides information about the fracture anatomy, which helps in the physician's choice between conservative or operative treatment. In clinical practice, the surgeon scrolls through the CT slices and tries to get a general impression of the fracture. Furthermore, the gaps and step-offs on the various slices can be measured. The physician's assessment of the CT-scan, however, depends heavily on the way these are performed and which CT slice is selected for the measurements. Therefore, two-dimensional (2D) measurements of the CT scan can vary significantly between physicians. Moreover, it is difficult to quantify the true extent of the injuries from a few 2D CT slices, since articular incongruity frequently involves three-dimensional (3D) displacement (e.g, gaps and step-offs) in multiple planes [12].

The importance of the three-dimensional aspect of tibial plateau fractures was recently acknowledged with the attempt to convert the most commonly used Schatzker classification to a new 3D classification system by the original author who posed this classification four decades ago [13]. In other complex fractures types has been demonstrated that the implementation of 3D technology for visualization, classification and surgical planning provides clinical benefits. The application of 3D technology in acetabular fracture surgery for instance improved education, classification, surgical planning and recently resulted in the development of patient-specific implants at our department [14,15,16]. Also, in the field of oral and maxillofacial surgery the use of 3D virtual planning and guided surgery is of substantial clinical value in order to perform complex jaw reconstructions within millimeters [17]. Recently, 3D statistical shape models of the tibia were introduced in this journal [18]. These models seem to be a promising tool for assessing anatomical variations and will be helpful in gaining a more patient-specific approach regarding fracture reduction techniques and implant fitting. In line with these developments, we present a quantitative 3D CT (Q3DCT) measurement tool for tibial plateau fractures. To our best knowledge, 3D measurement tools for these types of fractures are still lacking.

Quantitative 3DCT measurements have the potential advantage of representing the multidirectional (3D) aspect of fractures and they provide a uniform way of measuring the gap and step-off in these injuries [12, 19-23]. The clinical applicability of these 3DCT measurements would be usage in addition to the current classification systems to assess initial and/or residual displacement, and they might eventually be related to patients reported outcome measures. The goal of this study was to develop a standardized 3D measurement tool to determine quantitatively the extent of the tibial plateau fractures.

METHODS

Patients

Ten patients with a tibial plateau fracture were included in this study. All of them underwent surgery at the University Medical Center of Groningen (UMCG). They were included upon the availability of a pre-operative CT-scan of the injured knee with a slice thickness of 0.6 mm (pixel spacing: 0.44 × 0.44 mm). The CT data were used to develop a quantitative 3D measurement technique for tibial plateau fractures. All the fractures were graded according to the Schatzker and AO/OTA classification systems by using both preoperative plain radiographs and CT-scans. The institutional review board of the University Medical Center Groningen approved the study procedures and the research was performed in accordance with the relevant guidelines and regulations. Informed consent was obtained from all subjects.

3D Fracture models

Mimics Medical software package (Version 19.0, Materialise, Leuven, Belgium) was used to create 3D models of all the injured knees. First, the CT data (DICOM files, Digital Imaging and Communications in Medicine) were imported. Secondly, a segmentation process was performed by using a preset bone threshold (Hounsfield Units ≥226) combined with region growing in order to separate the independent fragments. Subsequently the fragments were checked and if needed manually separated from adjacent fragments. Smoothing was applied (factor 0.4) and each fragment was assigned a different color. Subsequently, virtual anatomical reduction of the fragments was performed. The fragment was moved to its anatomical position and exactly fitted on a template of a healthy tibia. The accuracy of the reduction was checked and approved by two surgeons. Figure 1 represents the 3D models of nine of the ten included patients (the 3D model of patient 7 is presented in Figs 2–4).

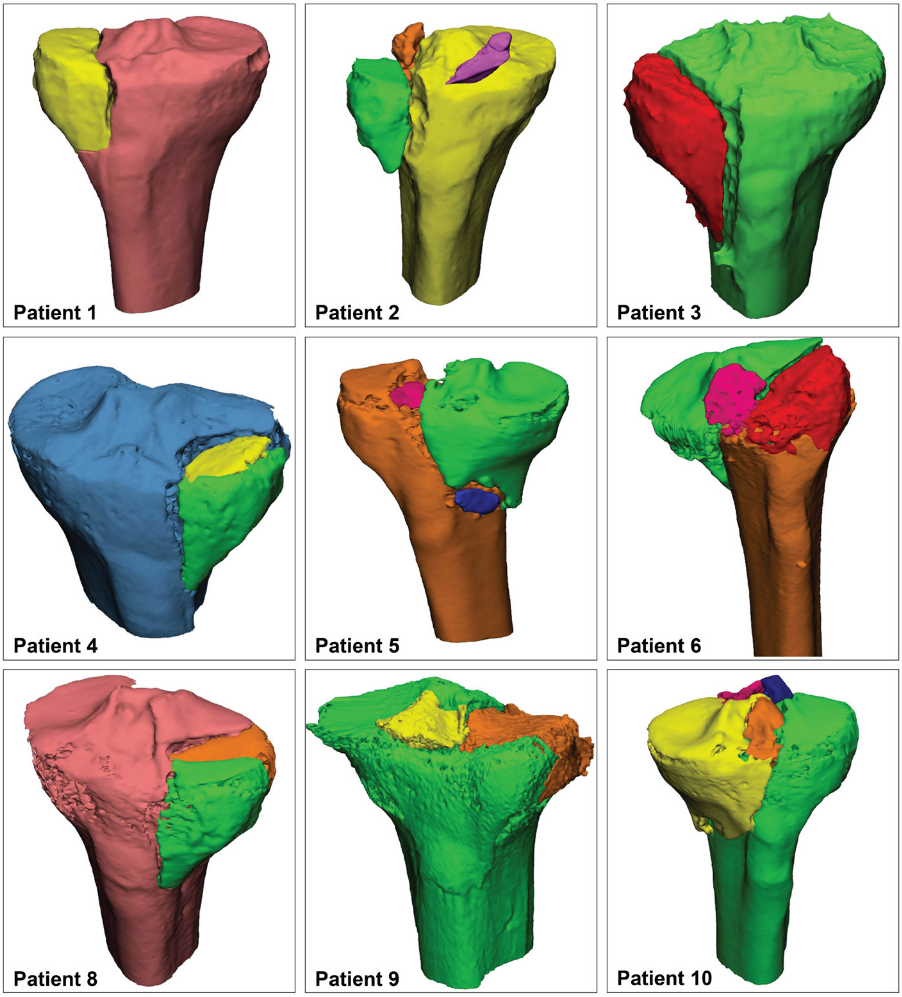

Figure 1: 3D reconstructions of all the patients except for patient 7. This patient is used to illustrate the Q3DCT measurements in Figs 2–4.

Quantitative 3D measurements

The 3D measurements were conducted by using both the 3-matic Medical (Version 11.0, Materialise, Leuven, Belgium) and Matlab (R2014B, Mathworks, Natick, Massachussetts, US) software. First of all, the edges of all the fracture fragments at the level of the articular surface were determined by using the 3-matic (Fig. 2). The "classic" gaps and step-offs were measured in Q3DCT. Furthermore, three additional 3D parameters were introduced, namely the gap area, articular surface involvement and 3D-displacement. The details of these measurements are clarified below.

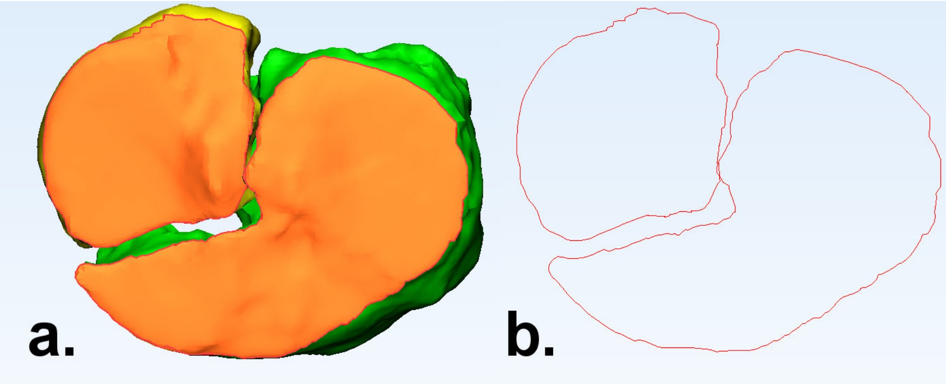

Figure 2: (a) The articular surface, in terms of the top axial view of the tibial plateau, is marked orange; (b) The contour of the articular surface, demonstrating the fracture pattern.

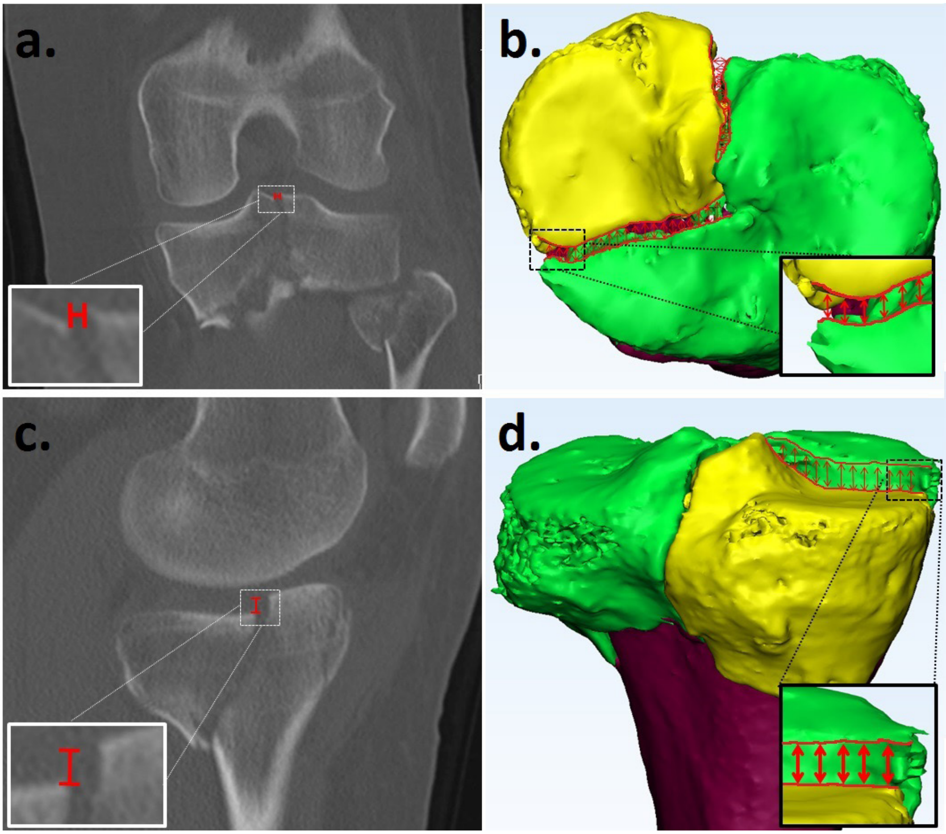

Figure 3: Gap measurement from a 2DCT slice (a) and a Q3DCT model (b). Step-off measurement on 2D (c) and Q3DCT. (d) The 2DCT slices had to be scrolled to find the maximum gap and step-off. The Q3DCT has the advantage that the gap and step-off could be measured between all points along the fracture lines within the same plane providing a maximum and a mean 3D value of both parameters.

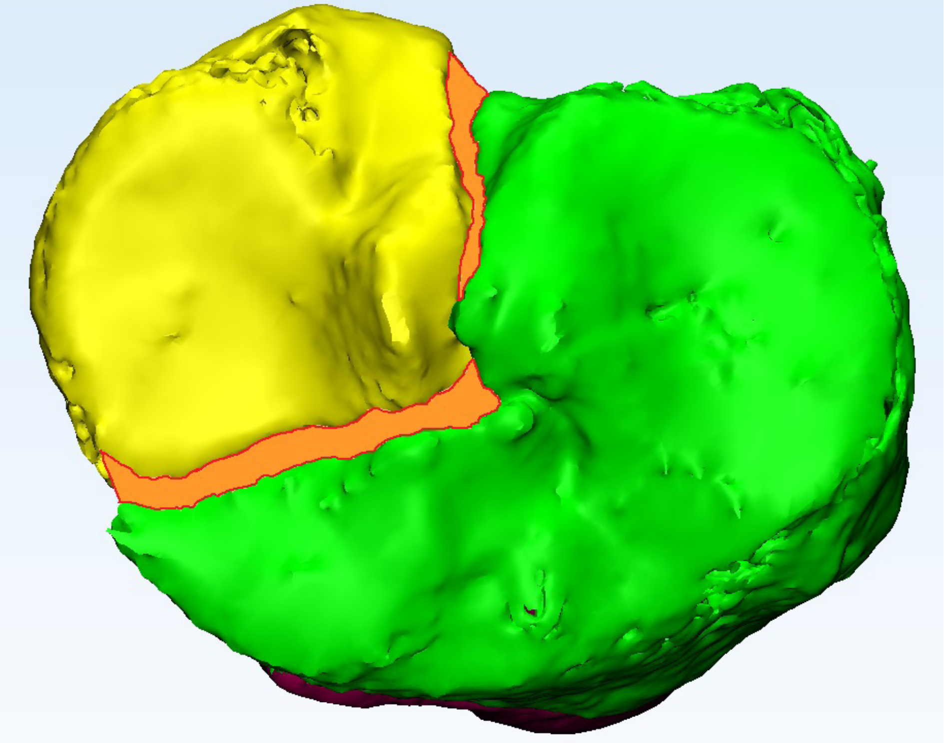

Figure 4: Measurement of the gap area (mm²), which is marked as the orange surface area between the fracture lines.

Gap and step-off

The 3D articular gaps and step-offs were determined by calculating the differences in distance and height between the fracture lines of adjacent fracture fragments at the articular level (Fig. 3). In order to calculate the gap and step-off, the fracture lines were identified and exported from the 3-matic to the Matlab software. A gap was defined as a separation of fracture fragments along the articular surface. A step-off was characterized as a separation of fracture fragments perpendicular to the articular surface. Besides the maximum gap and step-off, the mean of the gaps and step-offs were determined between all the points along adjacent fracture lines in the 3D model. Furthermore, the maximum gap and step-off in the coronal, sagittal and axial plane of the 2DCT slices were measured according to current practice in order to compare them with the 3DCT measurements. The gaps and step-offs were measured in the CT slices and the largest gap and step-off was used for the analysis (Fig. 3a,c).

Gap area

The gap area is defined as the total surface area of the gap between all fracture fragments. It was measured by calculating the surface area (mm²) between all the fragment fracture lines, which were projected in one plane at the articular level (Fig. 4).

Articular Surface involvement

Articular surface involvement represents to what extent the articular surface is damaged due to the fracture. It was determined by dividing the sum of all the articular surface areas of the displaced fracture fragments by the total joint surface of the tibial plateau according to formula 1.

$$Articular\ surface\ involvement = \frac{\sum Fragment_i}{Total\ surface} \times 100\% \qquad (1)$$

3D displacement

The extent of dislocation of each fragment was determined by calculating its 3D displacement along the axis in three directions (x, y and z). In order to calculate the 3D displacement, the fracture has to be reduced in the 3D model. The 3D model of the fragment represents numerous surface points (vertices). The 3D displacement (in mm) was determined by the sum of the distances between every point before and after reduction according to formula 2. A 3D displacement is therefore determined for each fragment based on tens of thousands of single points. Furthermore the displacement of each part of the fragment can be presented as a distance map as shown in Figure 5.

$$3D\ Displacement = \sum \sqrt{\Delta x_i^2 + \Delta y_i^2 + \Delta z_i^2} \qquad (2)$$

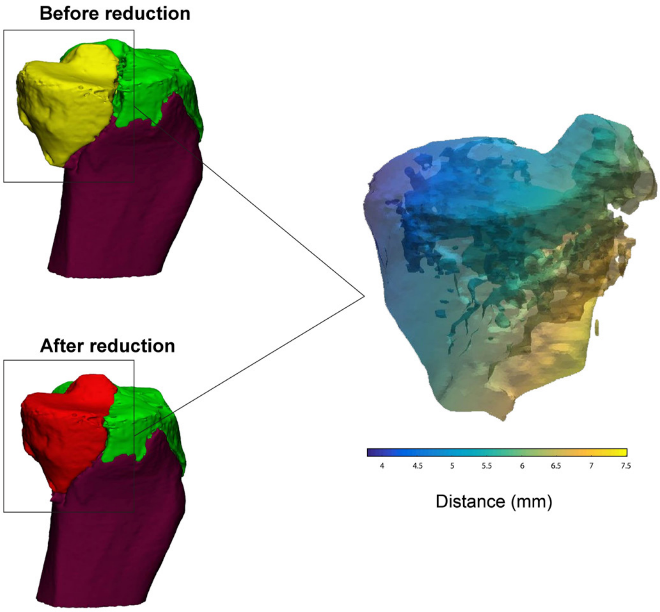

Figure 5: Measurement of the 3D displacement (mm). Left: fragment of the tibial plateau fracture before (yellow) and after (red) reduction. Right: distance map representing the difference in the fragment's position before and after the reduction (3D displacement). The colour corresponds with the severity of the displacement, whereby yellow represents a relatively big displacement and blue represents a relatively small displacement.

Statistical analysis

Statistical analysis was performed with SPSS (version 23, IBM, Chicago, IL, US). The Wilcoxon signed-rank test was used to evaluate differences between 2DCT and 3DCT measurements of the gaps and step-offs. A P-value of less than 0.05 was considered statistically significant. Furthermore, a Spearman's rank-order correlation coefficient was used to assess whether there was a correlation between the maximum gap (measured in 2D and Q3DCT) and the gap area.

Reliability

To assess the reliability of the 3D measurements, six observers independently performed the Q3DCT measurement on all the cases. Furthermore, six observers measured the gap and step-off on 2DCT slices from all the cases. The Cohen's Kappa was calculated to determine the agreement between the observers regarding slice selection and the maximum gap and step-off measurement from the 2DCT images.

The inter-rater reliability (IRR) was calculated by using intraclass correlation coefficients (ICC). We used 2-way mixed, single measurements and absolute agreement. Interpretation of the ICC values was performed according to the guidelines proposed by Cicchetti [24] whereby IRR is considered to be poor when the ICC values are less than 0.40, fair when the values are between 0.40 and 0.59, good when the values are between 0.60 and 0.74 and excellent when the values are higher than 0.74.

In order to determine the reproducibility of the 3D-displacement, this measurement was repeated by one observer after a period of 4 weeks. The IRR was determined from the 3D-displacement calculated on the two separate occasions.

Ethical approval

This study has been approved by the local medical ethical committee.

RESULTS

Ten patients (6 females, 4 males, mean age 43 (range 18–81)) with a tibial plateau fracture were included and 3D computer models of their fractures were created (Fig. 1). Five of them were treated with open reduction and plate fixation and five with percutaneous screw fixation only. The following fracture types were included; one patient with a Schatzker 1, five with a Schatzker 2, three with a Schatzker 4 and one with a Schatzker 5 fracture. According to the AO/OTA classification system, these injuries were classified as one 41-B1, eight 41-B3 and one 41-C1 fracture. The results of the 2D and Q3DCT measurements of the different types of fractures are presented in Table 1.

Table 1: Q3DCT and 2DCT measurements of the fracture characteristics in 10 patients who had suffered various types of tibial plateau fractures.

Patient	Classification		Q3DCT measurements			
No.	Schatzker	AO/ OTA	Gap		Step-off	
			Maximum (mm)	Mean (mm)	Maximum (mm)	Mean (mm)
1.	1	41-B1	2.9	1.2	3.3	1.6
2.	2	41-B3	14.9	10.3	6.6	3.7
3.	2	41-B3	8.5	5.6	3.7	1.7
4.	2	41-B3	3.9	1.8	6.1	4.8
5.	4	41-B3	18.3	14.2	3.7	1.8
6.	4	41-B3	6.6	3.7	6.4	2.3
7.	5	41-C1	4.4	2.2	5.0	2.6
8.	2	41-B3	2.8	2.0	5.9	1.7
9.	2	41-B3	2.7	1.0	6.6	3.2
10.	4	41-B3	5.3	2.7	4.3	1.9
Median (IQR)	N/A	N/A	5.3 (4.3)	2.5(3.3)	5.2 (2.3)	2.1(1.3)

Quantitative measurements

The maximum gaps and step-offs, as measured on the Q3DCTs, are presented in columns 4 and 6 of Table 1, respectively. Within the 10 patients, the measured maximum gaps showed a median value of 5.3 mm (IQR: 4.4), whereas the maximum step-offs had a median value of 5.2 mm (IQR: 2.3). The maximum gap and step-off measurements from the 2D CT slices resulted in higher median values of 8.6 mm (IQR: 7.8) and 5.3 mm (IQR: 1.7), respectively. No significant differences were found between both the maximum gap (P-value: 0.29) and step-off (P-value: 0.29) measured on the Q3DCTs and 2DCTs. The mean gaps and step-offs between all the points along the fracture lines were calculated for each case (Table 1; Columns 5 and 7) and showed values between 1–14 mm and 1.6–4.8 mm, respectively.

The gap area (column 8 of Table 1) was measured for each patient and demonstrated a median gap area of 235 mm² (IQR: 233). The Spearman's correlation coefficient between the maximum gap measured in 2D and the gap area was 0.94 ($P < 0.001$). The Spearman's correlation coefficient between the maximum gap measured in Q3DCT and the gap area was 0.88 ($P < 0.001$). However, the maximum gap in some of the patients (cases 6, 7 and 10) was relatively small but the gap area was quite large due to a multitude of fracture lines with moderate gapping.

The articular surface involvement (column 9 of Table 1) could be determined for each patient and demonstrated a median value of 33% (IQR: 50). The three cases classified as

Gap area (mm2)	Articular surface involvement (%)	3D- displacement			2DCT measurements	
		Fragments (N)	Displaced fragments (N)	Displacement (mm)	Maximum Gap (mm)	Maximum Step-off (mm)
57	18.9	2	1	2.2	2.4	3.3
314	28.8	4	3	6.4; 47.2; 15.0;	11.2	7.8
254	12.7	2	1	5.0	7.4	3.1
28	10.5	3	2	4.3; 2.0;	3.3	5.1
510	78.0	4	3	11.3; 9.0; 8.1;	12.4	6
215	100.0	3	3	17.6; 10.8; 15.4;	7.3	0
298	37.3	2	1	5.7;	3.9	4.6
18	15.3	3	2	2.7; 2.6;	2.8	2.9
77	39.7	3	2	3.6; 2.3	2.9	3.8
286	75.1	5	4	3.2; 6.7; 6.8; 5.6;	5.2	5.2
235 (233)	33 (50)	N/A	N/A	6.1 (7.1)	8.6 (7.8)	5.3 (1.7)

Schatzker 4 (cases 5, 6 and 10) had the largest articular surface involvement with values of over 75%.

The 3D displacement (columns 10, 11 and 12 of Table 1) of each fracture fragment could also be determined for all the cases. The number of fragments in each injury and the degree of their displacement was established in the 3D models. These measurements showed the feasibility of determining the 3D displacement of individual fracture fragments. The mean 3D displacement of all the fragments in the various injuries was 6.1 mm (IQR: 7.1).

Reliability

The inter-rater reliability (IRR) of the measured maximum gaps was found to be excellent with an ICC of 0.81 from 2DCTs. The reliability of the maximum gap measurements increased to 0.96 with Q3DCT (Table 2). The IRR of the step-offs was found to be poor from 2DCTs, with an ICC of 0.32 and good from Q3DCTs, with an ICC of 0.63. On measuring the mean gaps and step-offs in the 3D fracture model, the IRR improved considerably to 0.97 and 0.80, respectively. When measuring the maximum gaps and step-offs from the CT scans, the observers had selected different 2D slices. This led to a mean Cohen’s kappa of 0.12 and 0.09 for the slice selection agreements between the 2DCT gap and step-off measurements, respectively.

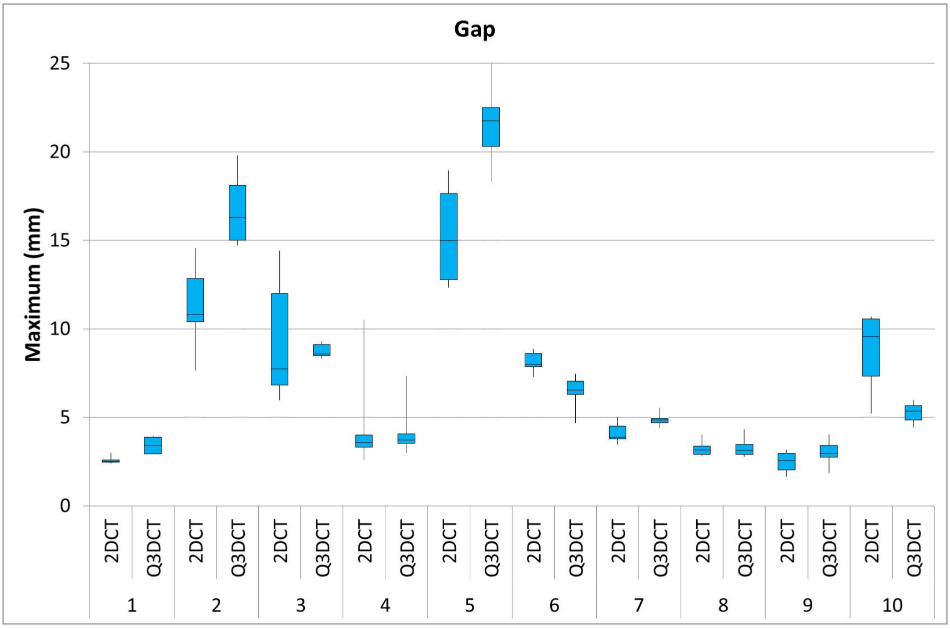

Figure 6: A boxplot showing the dispersion of the maximum gap measurements from 2DCT slices in comparison to our 3DCT measurements, performed by six different observers for all the patients.

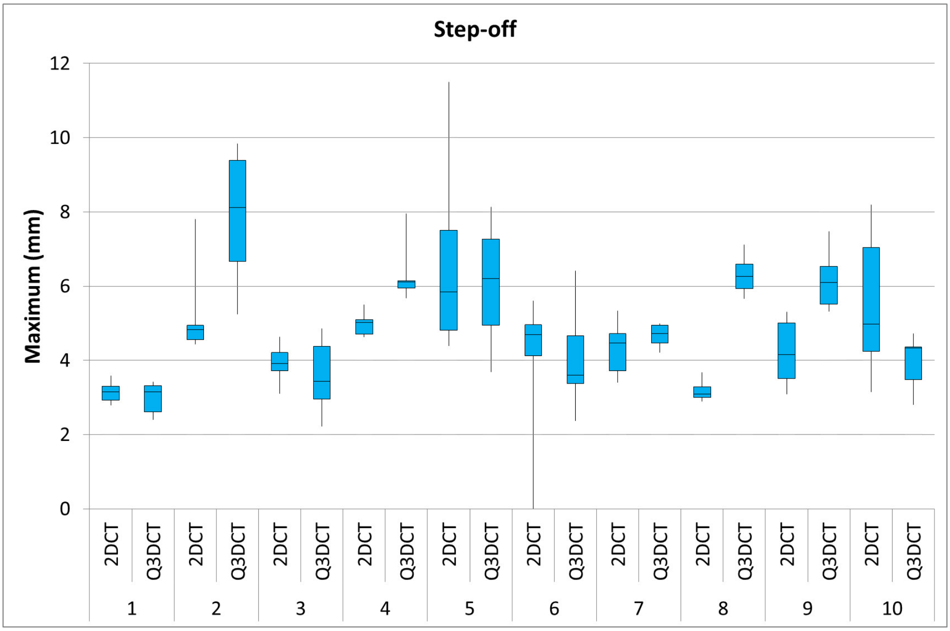

Figure 7: A boxplot showing the dispersion of the maximum step-off measurements from 2DCT slices compared to our Q3DCT method, performed by six different observers for all patients.

Table 2. Intra correlation coefficients (ICC) with their 95% conficence interval (CI) were determined for all the 2DCT and 3DCT gap and step-off measurements of all cases made by six observers.

Parameters	2DCT measurements	Q3DCT
Maximum Gap	0.81 (95% CI: 0.62 – 0.94)	0.96 (95% CI: 0.91 – 0.99)
Mean Gap	-	0.97 (95% CI:0.93 – 0.99)
Maximum Step-off	0.32 (95% CI: 0.1 – 0.67)	0.63 (95% CI: 0.35 – 0.87)
Mean Step-off	-	0.80 (95% CI:0.60 – 0.94)

Figures 6 and 7 depict the degree of dispersion between observers when performing the 2DCT and Q3DCT measurements of the maximum gap and step-off for each patient. There was more dispersion in the 2DCT measurements of the gap in 6 out of the 10 patients compared to the Q3DCT measurements. Regarding, the measurements of the step-off, the dispersion between 2DCT and Q3DCT was equally distributed.

There was excellent reliability between the different observers for the additionally introduced Q3DCT measurements. The gap area showed an ICC of 0.94 (95% CI: 0.85–0.98), the articular surface involvement had an ICC of 1 (95% CI: 0.99–1), and the 3D-displacement demonstrated an ICC of 0.99 (95% CI: 0.96–1).

DISCUSSION

This study presents a quantitative 3DCT measurement technique to determine the 3D fracture characteristics of tibial plateau fractures. This study demonstrates that accurate intra-articular gap and step-off measurements in 3D are feasible for tibial plateau fractures. Furthermore, three additional 3D measurement tools are presented, namely the gap area, articular surface involvement and 3D-displacement of individual fracture fragments, to gain a better three dimensional insight of the fracture.

Recently, Millar et al. extensively reviewed current classifications for tibial plateau fractures and they identified no less than 38 classification systems [3]. Moreover, most of these classification systems had moderate intra- and inter-observer reliability and did not provide quantitative information about the fracture patterns and morphology. They suggested the use of more sophisticated imaging modalities such as 3D CT to improve reliability estimates.

Q3DCT measurements have some potential advantages in comparison to 2DCT measurements. First of all, the inter-rater reliability of 3D measurements is higher than 2DCT measurements in the current analysis. The results of the 2DCT measurements depend heavily on the slice selection and the way gaps and step-offs are interpreted from different angles (axial, coronal or sagittal). The poor inter-observer agreement regarding the selected slice for the 2D measurement was illustrative for the complexity of performing uniform measurements in 2D. Especially patients, who sustained comminuted fractures (≥3 fragments), demonstrated a high dispersion of maximum gap and step-off measurements (Figs 6 and 7; patients 2, 5 and 10). Observers not only measured the gap and step-off at different 2DCT-slices, but also between different fragments. Q3DCT showed a lower dispersion in these patients in comparison with 2DCT. Except for patient 2, who had a small, severely displaced fragment (Fig. 1; purple fragment) that was disregarded by the observers in the 2D, but not in the 3D measurements. In contrast to 2D measurements, 3D analysis enables a complete and wider assessment of the fracture. Also, Q3DCT has the potential to provide improved quantitative information about the extent of the fracture.

The first parameter, the gap area (Fig. 4), is a reliable tool to quantify the total gap area of the fracture. In daily practice, the maximum fracture gap (mm) is mostly determined from a single CT slice in the coronal, sagittal, or axial direction. This 2DCT measurement is neither standardized, nor suitable for measuring multiple gaps, and therefore does not represent the entire injury. A discrepancy in the 3D gap area and 2DCT maximum gap due to multiple gaps in different directions is, for instance, demonstrated in patients 7 and 10 (Table 1, Fig. 3). The potential advantages of gap measurements from 3D are that they represent the gap of the entire fracture and can be used as a standardized quantitative measure of the extent of the fracture.

The second parameter, the articular surface involvement, was found to be a reliable parameter to assess how much of the articular surface was affected by the fracture. It is no surprise that as the Schatzker classification increased, the percentage of articular surface involvement gradually increased as well. However, substantial differences in articular surface involvement could be observed between patients who had similar fracture types. For instance, the articular surface involvement in all the cases with a Schatzker 2 injury varied from 12.7 to 39.7%. Therefore, this parameter could be a valuable addition to the currently used classification systems and might be of interest in fracture analysis within different subsets of fracture patterns.

The third parameter, 3D displacement, quantifies the displacement of each fracture fragment in all directions. The rationale behind exploring this parameter was that gaps and step-offs might arise from the displacement of these fragments. In this study, we demonstrated that it is possible to visualize the movement, tilting and rotation of each fracture fragment in three-dimensional space. For instance, this parameter might be of interest for research purposes regarding 3D analysis of specific parts of the fracture. The value of the total 3D displacement of all fracture fragments together, as a quantitative measure of the severity of the fracture, needs further exploration.

The Q3DCT method also has certain limitations. One of these is that the edges of the articular surface and the fracture lines still need to be determined manually in the current software program. An automatic edge detection tool for identifying the different fracture lines would be helpful to make these 3D measurements more consistent. A software package with automatic detection tools, snap to fit reduction tools and incorporated 3D measurements is probably the next step to avoid inter-observer variability in 3D fracture analysis. Of note is that the current workflow only utilizes a CT-scan of the affected knee. However, if a 3D model of the non-affected knee had been available as well, this could have been used as a reference when analyzing the injured side. Finally, the current process of creating the 3D model and performing the measurements takes at least half an hour, depending on the complexity of the fracture. However, further automation is being conducted for universal clinical applicability.

Q3DCT measurements of the fractured tibial plateau could be considered an additional tool for the surgeon to assess and quantify preoperatively the extent of the fracture. The aim of this study was to present a standardized 3D measurement technique for tibial plateau fractures, which could be beneficial for further applications. These 3D measurements might also be helpful in comparing pre- and postoperative CT scans (if specifically requested) in order to assess the quality of the postoperative reduction. Finally, we included a case example where we applied our 3D measurements to pre- and postoperative CTs of a patient who was operated on a tibial plateau fracture in order to demonstrate that these can be used as a standardized quantitative measure for assessing the quality of the postoperative reduction (Fig. 8). Furthermore, the connection between quantitative 3D measurements and patient reported outcomes might be of interest to surgeons to reassess fracture parameters and then decide whether to proceed to an operative treatment regimen.

Conclusion

We present a feasible and reliable method for Q3DCT fracture analysis of tibial plateau fractures. These 3D measurements can, potentially, be used to assess complex multi-directional injuries and to quantify the extent of the fracture.

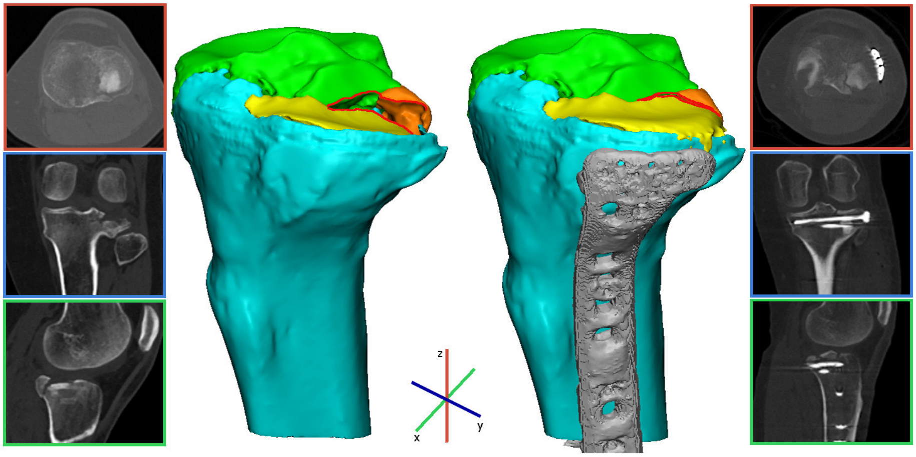

Figure 8: These images represent a clinical case in which we demonstrate the application of the quantitative 3D fracture measurements. Pre- and postoperative 3D assessment of a patient who was operated on a Schatzker 3 tibial plateau fracture. A 3D model of the pre-operative CT scan displayed a mean 3D gap of 0.5 mm, a step-off of 3.3 mm, a gap area of 27 mm² with an articular surface involvement of 32.5% consisting of 3 fracture fragments. An open reduction and plate osteosynthesis was performed. A 3D model of the postoperative CT scan demonstrated an anatomical reduction of the fracture with a 20% decrease in the mean 3D gap (0.5 mm pre vs 0.4 mm postoperative), an 85% decrease in the mean 3D step-off (3.3 mm pre vs 0.5 mm postoperative), and a 10% decrease in the gap area (27 mm² pre vs 24 mm² postoperative).

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CHAPTER 7

3D assessment of initial fracture displacement of tibial plateau fractures is predictive for risk on conversion to total knee arthroplasty at long-term follow-up

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Abstract

Purpose: Currently used classification systems and measurement methods are insufficient to assess fracture displacement. In this study, a novel 3D measure for fracture displacement is introduced and associated with risk on conversion to total knee arthroplasty (TKA).

Methods: A multicenter cross-sectional study was performed including 997 patients treated for a tibial plateau fracture between 2003 and 2018. All patients were contacted for follow-up and 534 (54%) responded. For all patients, the 3D gap area was determined in order to quantify the degree of initial fracture displacement. A cut-off value was determined using ROC curves. Multivariate analysis was performed to assess the association of 3D gap area with conversion to TKA. Subgroups with increasing levels of 3D gap area were identified, and Kaplan–Meier survival curves were plotted to assess survivorship of the knee free from conversion to TKA.

Results: A total of 58 (11%) patients underwent conversation to TKA. An initial 3D gap area ≥ 550 mm2 was independently associated with conversion to TKA (HR 8.4; p = 0.001). Four prognostic groups with different ranges of the 3D gap area were identified: excellent (0–150 mm²), good (151–550 mm²), moderate (551–1000 mm²), and poor (> 1000 mm²). Native knee survival at 10-years follow-up was 96%, 95%, 76%, and 59%, respectively, in the excellent, good, moderate, and poor group.

Conclusion: A novel 3D measurement method was developed to quantify initial fracture displacement of tibial plateau fractures. 3D fracture assessment adds to current classification methods, identifies patients at risk for conversion to TKA at follow-up, and could be used for patient counselling about prognosis.

INTRODUCTION

Tibial plateau fractures are usually composed of complex fracture patterns consisting of multiple bone fragments with displacement in different directions. Achieving normal limb alignment and articular surface restoration is the main goal for surgical treatment. Achieving these goals is crucial to minimize the risk on posttraumatic osteoarthritis (OA) and the subsequent need for a total knee arthroplasty (TKA) [1]. However, adequate anatomical reduction cannot always be achieved due to comminution and severe initial fracture displacement. Meulenkamp et al. [2] recently reported that unsatisfactory reduction in fracture fragments occurs in up to 30% of the surgically treated tibial plateau fractures. Moreover, nearly anatomical reconstruction of severely displaced fractures may still result in early onset osteoarthritis [3, 4]. Altogether, irreversible initial damage to the articular surface (e.g., fracture displacement and comminution) affects to some extent the patient's outcome.

Initial fracture displacement is decisive for the treatment strategy. Moreover, the initial damage to the joint mainly determines the prognosis [5]. The currently used classification systems and measurement methods are insufficient to assess fracture displacement [6]. The most frequently used classification systems (i.e., Schatzker, AO/OTA, Three-column [7,8,9]) describe fracture patterns instead of intra-articular incongruity. The degree of intra-articular fracture displacement is usually assessed by measuring the maximal gap and step-off on a single coronal, sagittal, or axial CT-slice. This method is known for its high inter- and intra-observer variability, tends to underestimate fracture displacement, and does not provide a full representation of the articular incongruity [10, 11]. Therefore, controversy remains within the literature regarding the association between the degree of initial intra-articular incongruity and the development of posttraumatic OA and functional recovery [12]. Consequently, patients with a tibial plateau fracture cannot properly be informed about their prognosis based on their fracture characteristics.

Recently, Assink et al. introduced a quantitative 3D CT (Q3DCT) method to quantify the intra-articular displacement in tibial plateau fractures [10]. This method showed superior reliability compared to 2DCT measurements and could be used as an addition to the current fracture classification systems [10]. This method involves the "3D gap area", which quantifies the total surface area between all fracture fragments at the articular level. It includes all gaps and step-offs between all fracture fragments and represents a full quantification of the intra-articular incongruity. This current study aims to assess the association between the initial fracture displacement as measured in 3D and the risk of conversion to TKA at long-term follow-up.

METHODS

Study design

A multicenter cross-sectional study was performed including all patients who have been treated for a tibial plateau fracture in three hospitals (one Level 1 and two Level 2 trauma centers) between 2003 and 2018. Patients were eligible for inclusion based upon the availability of a preoperative (diagnostic) CT scan of the injured knee with a slice thickness of ≤ 1 mm and a follow-up of at least 1 year. Patients with an isolated tibial eminence avulsion, a complicated fracture requiring amputation of the injured leg, age < 18 years, and those who had deceased or with an unknown address at the time of follow-up were excluded. Demographics were retrieved from the patients' electronic records. For all patients, it was verified whether they were still alive according to the population registry. Patients were contacted by posted mail and asked whether they had conversion to a total knee prosthesis or not. Written informed consent was obtained from all participants. All available fracture types were included to avoid potential selection bias. The institutional review board of all centers approved the study procedures, and the research was performed in accordance with the relevant guidelines and regulations (research number: 201800411). This study is reported following Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline [13].

2D imaging review

All CT scans at the time of the injury were reassessed by two independent observers in the axial, sagittal, and coronal planes to determine the fracture classification according to the Schatzker and the three-column classification systems [7, 9].

3D Fracture models

The data of the CT scan of the initial fracture of each patient was used to create a 3D fracture model. Mimics Medical software package (Version 21.0, Materialise, Leuven, Belgium) was used for this process. CT data (DICOM files, Digital Imaging and Communications in Medicine) were imported into the software after which a segmentation process was performed. A preset bone threshold (Hounsfield Unit ≥ 226) was used combined with the 'region growing' function in order to separate independent fragments. The segmentation was checked and if needed fragments were manually separated from adjacent fragments. Each fragment was assigned a different color and a smoothing filter was applied (factor 0.4).

Introduction of the "3D gap area"

The 3D gap area was measured on the 3D fracture models (Fig. 1a) by using 3-matic Medical software (Version 13.0, Materialise, Leuven, Belgium). The 3D gap area is defined as the three-dimensional surface area between all fracture fragments and represents the total fracture displacement. It includes all gaps and step-offs between all fracture fragments and represents a full quantification of the intra-articular incongruity.

In order to determine the 3D gap area, first, the articular surface was delineated on each fragment using the wave "brush mark" function (Fig. 1b). Secondly, the contours from the marked surface were extracted and trimmed with the "trim curve" function so that only the fracture lines at the articular surface level remained. After the fracture lines were separated, the ends of the fracture lines were connected resulting in an enclosed area (Fig. 1c). A 3D surface was constructed connecting all fracture lines by using the "surface construction" function in the 3-matic software (Fig. 1d). The surface, named 3D gap area, was measured in square millimeters (mm²). This area incorporates distances between fracture lines in all planes and is therefore considered a quantitative measure of the initial fracture displacement (Fig. 2).

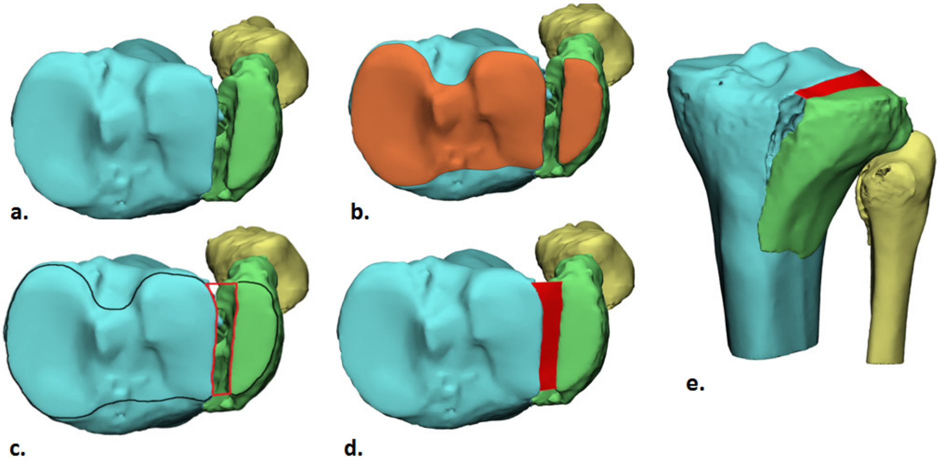


Figure 1: Method of measuring the 3D Gap area: a.) Cranial view of a lateral tibial plateau fracture (green); b.) Marking of the articular surface (orange); c.) Extracted contour of the articular surface (black line) from which the fracture lines are separated. The ends of the fracture lines are connected, resulting in an enclosed area (red lines); d.) The surface area between all fracture lines is measured resulting in a gap area (red surface) of 141 mm² indicating an excellent prognosis; e.) Anterolateral view of the fracture with the measured gap area. (see Appendix to experience the ***3D anaglyph*** of the case represented in this figure)

Study outcomes

This study intended to introduce and evaluate an innovative 3D measurement method–named 3D gap area–to assess initial fracture displacement of tibial plateau fractures. We hypothesize that a single 3DCT measurement for tibial plateau fractures will provide an observer independent CT-based analysis of the "initial damage to the joint" and could be a main factor that indicates whether a patient is at risk for a TKA during follow-up. The study did not aim to evaluate results (e.g., residual fracture displacement) after surgery, which is mostly based on radiographs and does not allow for advanced 3D measurements.

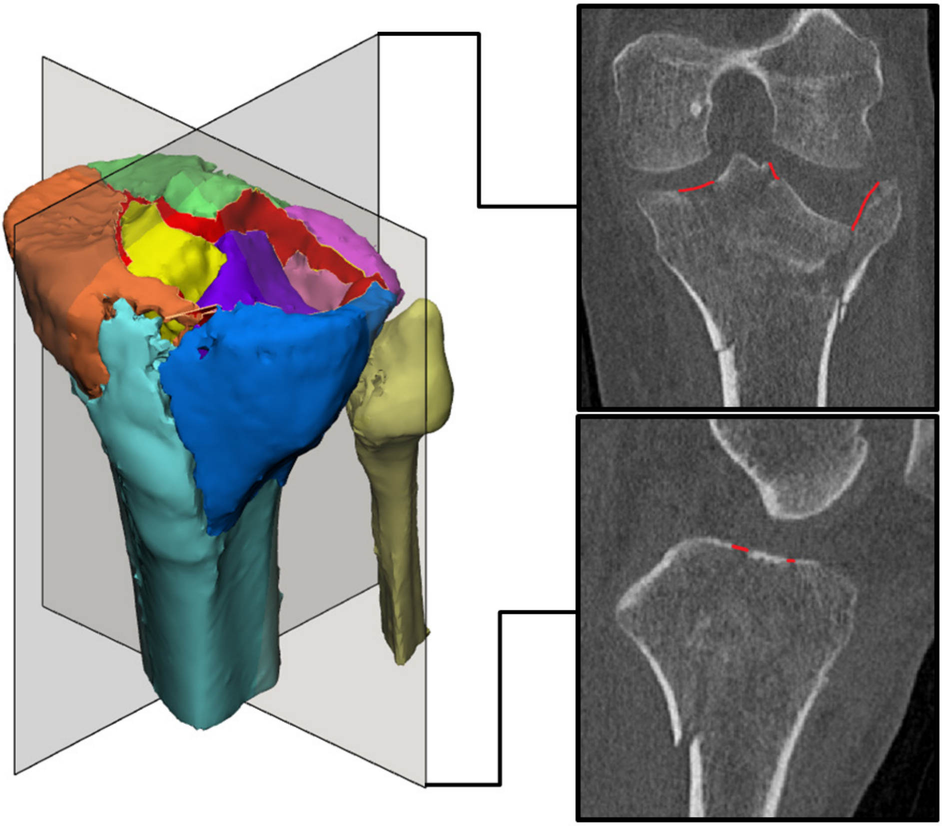


Figure 2: 3D gap area (red surface) measurement on a 3D fracture model representing total fracture displacement between all fracture fragments at the articular level and the corresponding coronal and sagittal 2DCT slices.

Our aim was to assess whether a detailed 3D measurement of initial fracture displacement is predictive for developing severe posttraumatic osteoarthritis with the subsequent need for a TKA. If the preoperative 3D gap area can be used to predict the risk of conversion to TKA during follow-up, this could have major implications for patient counselling about treatment options and expectations regarding the course of rehabilitation. To achieve our goal, we created 3D virtual fracture models based on the CT data of each patient and measured the "3D gap area" (three-dimensional surface area between all fracture fragments) on these 3D fracture models. Secondly, we contacted all patients asked whether they had conversion to total knee prosthesis (primary endpoint) at follow-up. To answer our research question, we assess the relationship between the 3D gap area (initial fracture displacement on the diagnostic CT-scan) and conversion to a total knee arthroplasty at long-term follow-up.

Statistical analysis

Statistical analysis was performed using SPSS (version 23, IBM, Chicago, IL, US). Continuous variables were presented as mean and standard deviation (SD) for normally distributed data and median and interquartile range (IQR) if not normally distributed. A p value of less than 0.05 was considered statistically significant. Descriptive statistics were used to describe the study population. Mann–Whitney U test was performed to assess differences in baseline characteristics between responders and non-responders.

A receiver operating curve (ROC) was plotted to assess the association between initial fracture displacement as measured by the 3D gap area and conversion to a total knee arthroplasty at long-term follow-up. The area under the curve (AUC) was then determined to assess the diagnostic ability of the measurement. Critical cut-off for an increased risk on TKA was determined by using Youden's J Statistics. Critical cut-off was defined as the value for which the combined sensitivity and specificity are the highest.

Kaplan–Meier curves of native knee survivorship were constructed for different subgroups with increasing 3D gap areas. The groups (excellent, good, moderate, and poor) were established based on a log relative hazard plot. Native knee survivorship curves were plotted and log-rank tests were performed to assess differences between groups with an excellent, good, moderate, or poor prognostic 3D gap area, respectively.

Cox regression analysis was performed to correct for other factors (age, sex, smoking, BMI, and inadequate articular reduction) which are potential confounders for the risk on osteoarthritis and conversion to a TKA [14,15,16]. Articular reduction (e.g., residual fracture displacement) was assessed on the first follow-up radiograph of each patient and considered adequate when both the maximum gap and step-off were ≤ 2 mm [17, 18].

Funding statement

This research received no specific grant from any funding agency in the public, commercial or non-for-profit sectors.

RESULTS

Patient demographics

Between 2003 and 2018, a total of 1220 patients were treated for a tibial plateau fracture in three hospitals of which 39 had and isolated tibial eminence avulsions (e.g., cruciate ligament injuries), four had an amputation, 50 were aged < 18 years, 112 had died at follow-up, and 18 had an unknown address, leaving 997 patients eligible for follow-up analysis. All patients were contacted by posted mail, from which 534 responded

Table 1: Patient characteristics

Demographics	N=534
Age (years)	53.1 (± 14.4)
Male	155 (29.0%)
BMI	26.3 (STD: 4.6)
Smoking	105 (19.6%)
Schatzker classification	
Type I	50 (9.4%)
Type II	200 (37.5%)
Type III	106 (19.9%)
Type IV	57 (10.6%)
Type V	39 (7.3%)
Type VI	82 (15.3%)
Three Column classification	
One Column	174 (32.6%)
Two Columns	231 (43.3%)
Three Columns	129 (24.1%)
Operatively treated	372 (69.6%)
Conversion to TKA	58 (10.8%)
Follow-up (years)	6.7 (± 3.6)

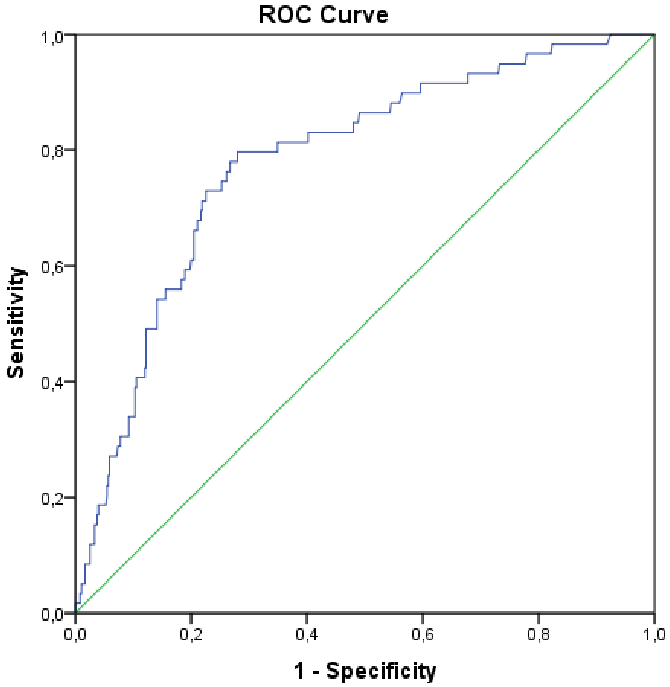


Figure 3: Receiver Operating Characteristic (ROC) curve demonstrating the 3D gap area associated with the conversion to total knee arthroplasty

(response rate 54%) at a mean follow-up of 6.7 ± 3.6 years. Patient demographics are presented in Table 1. Non-response analysis demonstrated no differences between responders and non-responders in age ($p = 0.067$), gender ($p = 0.478$), and type of treatment ($p = 0.96$).

Initial fracture displacement related to TKA

Patients with conversion to a TKA compared to those who still had their native knee had significant more initial fracture displacement as measured by the 3D gap area (954.5 vs. 419.3 mm², $p < 0.001$). The ROC curve showed an area under the curve of 0.78 for the 3D gap area associated with conversion to TKA (Fig. 3). The critical cut-off value, indicating the point that maximized sensitivity and specificity, was 550 mm² (Table 2).

Table 2: 3D gap area cut-off values with their associated sensitivity, specificity, and Youden's J derived from the ROC Curve analysis

3D gap area cut-off values (mm2)	Sensitivity (%)	Specificity (%)	Youden's J
150	91.5	41.4	0.33
350	81.4	61.7	0.43
550[a]	76.3	73.9	0.50
750	59.3	81.2	0.41
950	49.2	86.3	0.36

[a] Critical cut-off point

Native knee survival

From the plotted log relative hazard, two additional cut-off values for the 3D gap area (150 mm² and 1000 mm²) were determined. Using these cut-off values for the 3D gap area, four prognostic groups were established: excellent (3D gap area 0–150 mm²), good (151–550 mm²), moderate (551–1000 mm²), and poor (>1000 mm²). Kaplan-Meier survival curves (Fig. 4) show that at 2-years follow-up in the excellent prognostic group, 98.4% still have their native knee compared to 97.8% in the good group, 91.4% in the moderate group, and 80.3% in the poor group. At 10-years follow-up, the percentage of patients who still have their native knee was 96.4%, 95%, 75.5%, and 58.5%, respectively in the excellent, good, moderate, and poor group. Log-rank test showed a significant difference between the native knee survival distributions of the established prognostic four groups ($p < 0.001$). Cumulative risks for the conversion to a TKA for each of the prognostic subgroups are presented in Figure 5.

Cox regression indicates that an increase in 3D gap area is independently associated with an increased risk on conversion to a TKA (HR 7.6, $p < 0.001$) (Table 3). Subgroup analysis showed that the hazard ratios increased alongside with the size of the 3D gap area. Compared to the excellent group (reference), the hazard ratios for conversion to TKA were respectively 1.7 ($p = 0.34$), 6.8 ($p < 0.001$), and 15.0 ($p < 0.001$) for the good, moderate, and poor prognostic group.

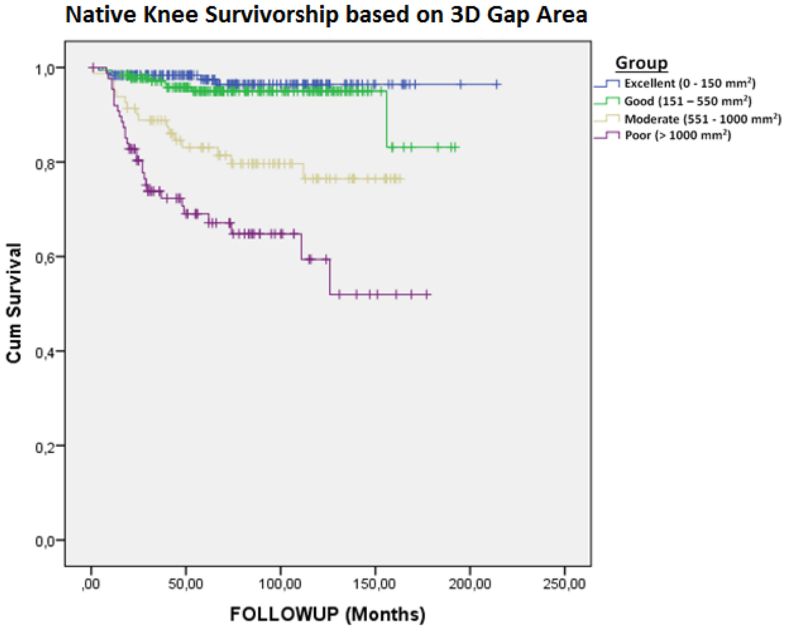
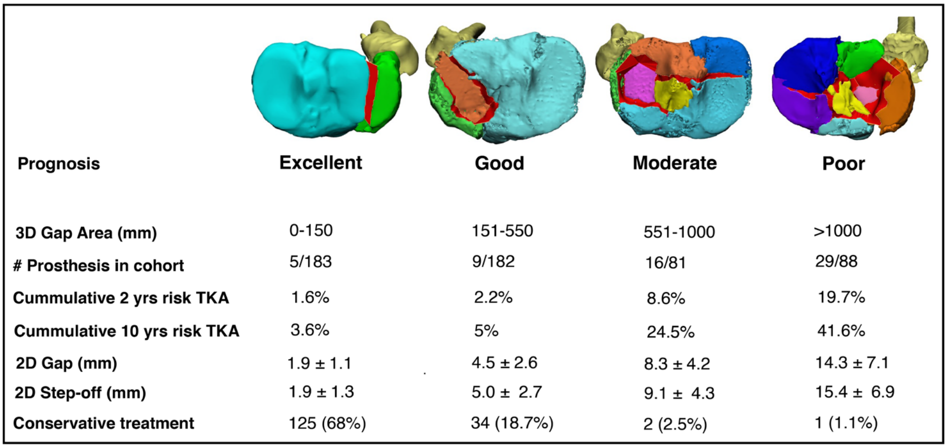


Figure 4: Kaplan–Meier curves of the native knee survival for fractures with respectively an excellent, good, moderate, or poor prognostic 3D gap area (log rank, $p < 0.001$)



Prognosis	Excellent	Good	Moderate	Poor
3D Gap Area (mm)	0-150	151-550	551-1000	>1000
# Prosthesis in cohort	5/183	9/182	16/81	29/88
Cummulative 2 yrs risk TKA	1.6%	2.2%	8.6%	19.7%
Cummulative 10 yrs risk TKA	3.6%	5%	24.5%	41.6%
2D Gap (mm)	1.9 ± 1.1	4.5 ± 2.6	8.3 ± 4.2	14.3 ± 7.1
2D Step-off (mm)	1.9 ± 1.3	5.0 ± 2.7	9.1 ± 4.3	15.4 ± 6.9
Conservative treatment	125 (68%)	34 (18.7%)	2 (2.5%)	1 (1.1%)

Figure 5: Four subgroups with increasing 3D gap area's and their corresponding 2- and 10-year cumulative risk on conversion to TKA

Table 3: Multivariate analysis, presenting unadjusted and adjusted hazard ratios for 3D gap area associated with conversion to TKA

Measure	Unadjusted hazard ratio (95% CI)	p value	Adjusted hazard ratio[a] (95% CI)	p value
3D Gap Area ≥ 550 mm²	7.4 (4.1–13.5)	< 0.001	7.6 (4.1–14.4)	< 0.001
3D Gap Area subgroups				
Excellent (0–150 mm²; reference)	–	–	–	–
Good (151–550 mm²)	1.7 (0.6–5.1)	0.32	1.7 (0.6–5.1)	0.34
Moderate (551–1000 mm²)	6.8 (2.5–18.6)	< 0.001	6.8 (2.4–19.1)	< 0.001
Poor (> 1000 mm²)	14.3 (5.5–36.8)	< 0.001	15.0 (5.6–40.2)	< 0.001

[a] Adjusted for age, gender, smoking, BMI and inadequate reduction

DISCUSSION

The rationale for relating initial fracture displacement of tibial plateau fractures to risks on TKA at long-term follow-up is to inform the patients about their prognosis and guide treatment decisions shortly after the injury. Currently, objective measures for determining initial fracture displacement are lacking. This is the first study that introduced a quantitative 3D measure for initial fracture displacement and assessed the relationship between the degree of displacement in 3D and the risk of developing severe posttraumatic osteoarthritis and the subsequent need for a TKA. The 3D gap area is defined as a three-dimensional surface area between all fracture fragments and should be considered the next level of tibial plateau fracture assessment. Our findings demonstrate that the degree of initial fracture displacement is a strong predictor for conversion to a TKA. By defining clear cut-off values for the 3D gap area, a clear distinction could be made between groups with increasing risks on conversion to TKA at follow-up.

A limitation of this study is that our 3D analysis solely focused on preoperative fracture displacement. Ideally, the postoperative 3D gap area should be taken into account as well in order to assess and correct for the quality of the reduction. Unfortunately, this was not possible since postoperative CTs were not routinely performed in the participating centers. This is consistent with the current practice in many centers worldwide. Therefore, relationship between the 3D fracture reduction (i.e., residual fracture displacement) and clinical outcome could not be assessed. Regardless of the operation itself, clinical decision making based on initial fracture displacement is helpful for patient counselling regarding treatment options and prognosis in the early phase after the injury. As shown in this paper, there is an association between the severity of the injury and the risk of a TKA. Another limitation was the high variation in follow-up duration (12–214 months), which is inherent to a cross-sectional study design. Furthermore, since patients were contacted by posted mail some response bias can be expected within this study. Yet, no significant differences in age, gender and type of treatment were found between the responders and non-responders.

While the majority of studies, assessing the risk on posttraumatic osteoarthritis, focus on the quality of the surgical reduction, Marsh et al. [3] suggest that the most important factor in determining outcome should be considered damage to the articular surface caused by the injury. The initial damage may lead to some joint degeneration despite an accurate fracture reduction after surgery. In addition, Parkkinen et al. [5] concluded that the initial displacement of the fracture seems to have a role in the occurrence of posttraumatic OA. The results of our study are in line with previous findings and reconfirms that the degree of initial incongruity is indeed strongly associated with the risk of development of OA and eventually the need for conversion to TKA. However, this study adds to the results of previous studies that the degree of initial fracture displacement could be accurately quantified and stratified based on clinical follow-up data. Moreover, our study included the whole spectrum of initial fracture displacement ranging from minimally displaced nonoperatively treated fractures to severely displaced operatively treated fractures (Appendix 1 provides an overview of these varying cases). This study completely focusses on the relationship between initial fracture displacement and outcome regardless of type of treatment. Compared to the general population, patients with a tibial plateau fracture have a 5.3 times increased likelihood to undergo conversion to a TKA at ten-year follow-up regardless of the fracture severity [19]. This study, however, shows that this likelihood increases as the fracture severity increases. Patients in the good prognostic group are 1.8 times as likely to undergo conversion to a TKA compared to the excellent prognostic group. This likelihood increases up to 15.3 times for patients with major initial fracture displacement indicated as the poor prognostic group.

Our proposed 3D measurement method could be used as an addition to the current fracture classification methods in order to identify patients who are at risk for developing severe osteoarthritis resulting in conversion to TKA at follow-up. 3D fracture assessment could be used post-injury to fully inform the patient on the future risk on developing severe OA and the subsequent need for a TKA. Also, it could be used as a guideline for shared decision-making regarding treatment options taken into account these risks. This is especially true in the patients with a high risk on a TKA, since conversion to a TKA secondary to a tibial plateau fracture is associated with a higher rate of complications than TKA for primary osteoarthritis due to previous scars, bone loss and poor knee alignment [20,21,22]. Primary or early treatment with a TKA was found to be a suitable alternative in elderly patients with a complex fracture [20], and could be considered in these high-risk patients. Furthermore, it could be considered to minimize the surgical approach in poor prognostic patients to reduce complication rates (e.g., unnecessary fracture-related infections associated with multiple approaches in severely contused soft tissues) in the work-up to an early TKA. Besides the additional value of preoperative 3D fracture assessment, this measurement technique could also be applied on postoperative CT scans if needed in order to assess the quality of reduction.

Despite the potential benefits, the major limitation of performing the 3D fracture assessments is that it is labor-intensive. Depending on the fracture comminution, the segmentation and measurement process could take up to one hour. In the beginning, 3D fracture assessment of the initial displacement could therefore be reserved for selected cases in which there is a combination of substantial initial displacement and other known prognostic factors for conversion to TKA (i.e., increased age, smoking, BMI). Due to improvements in the segmentation software, the segmentation process is already semi-automatized. Yet, before widespread implementation in clinical practice, further automatization of the 3D measurements would be helpful.

In conclusion, we present an innovative 3D measurement method to quantify the degree of fracture displacement of tibial plateau fractures and correlated this to clinical outcome. Preoperative 3D fracture assessment could be used as an addition to the current fracture classification methods to identify patients who have a higher risk on developing progressive osteoarthritis and receiving a TKA at follow-up.

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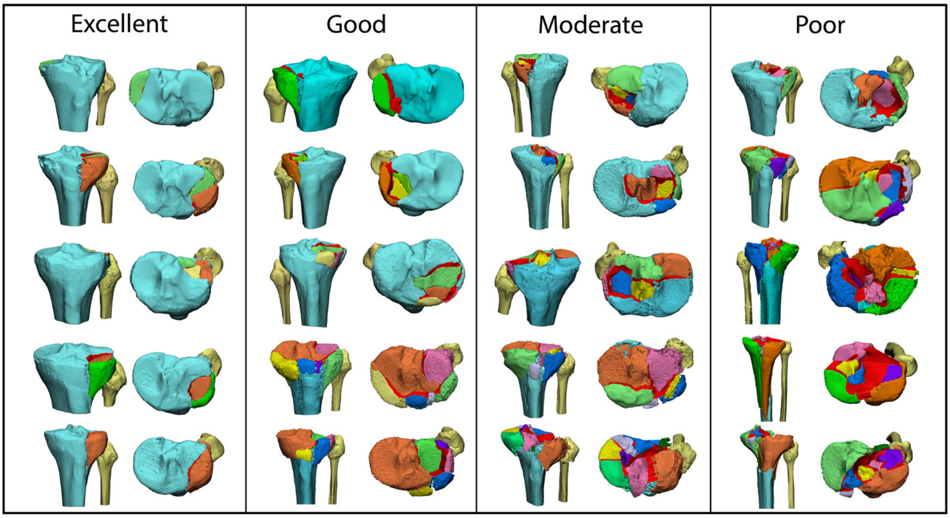
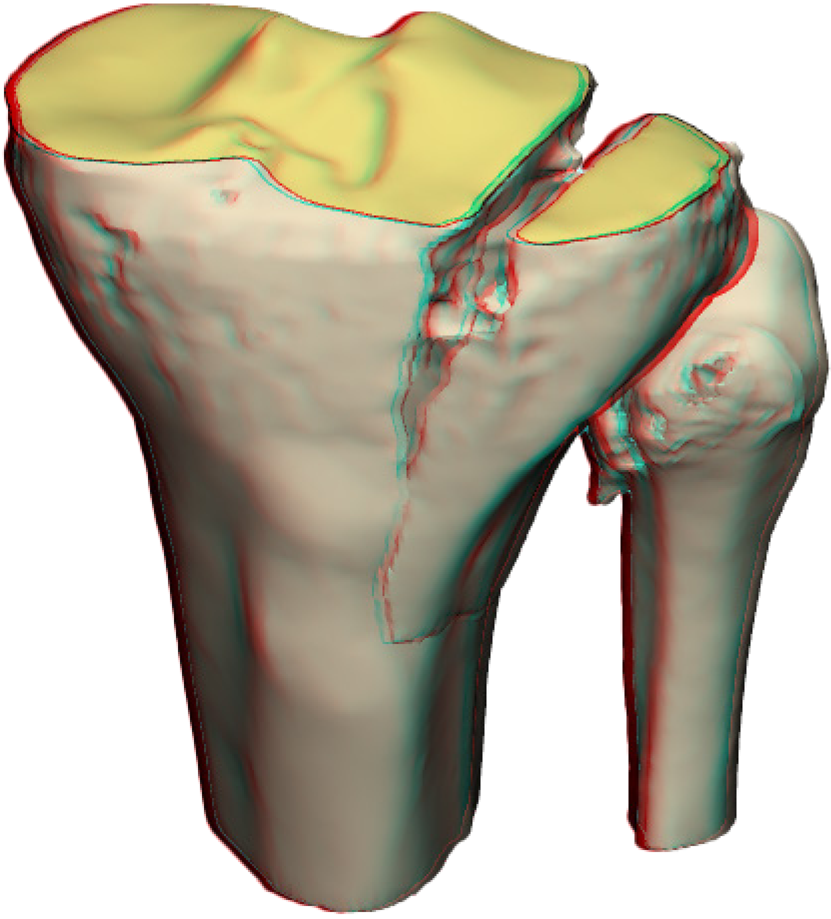
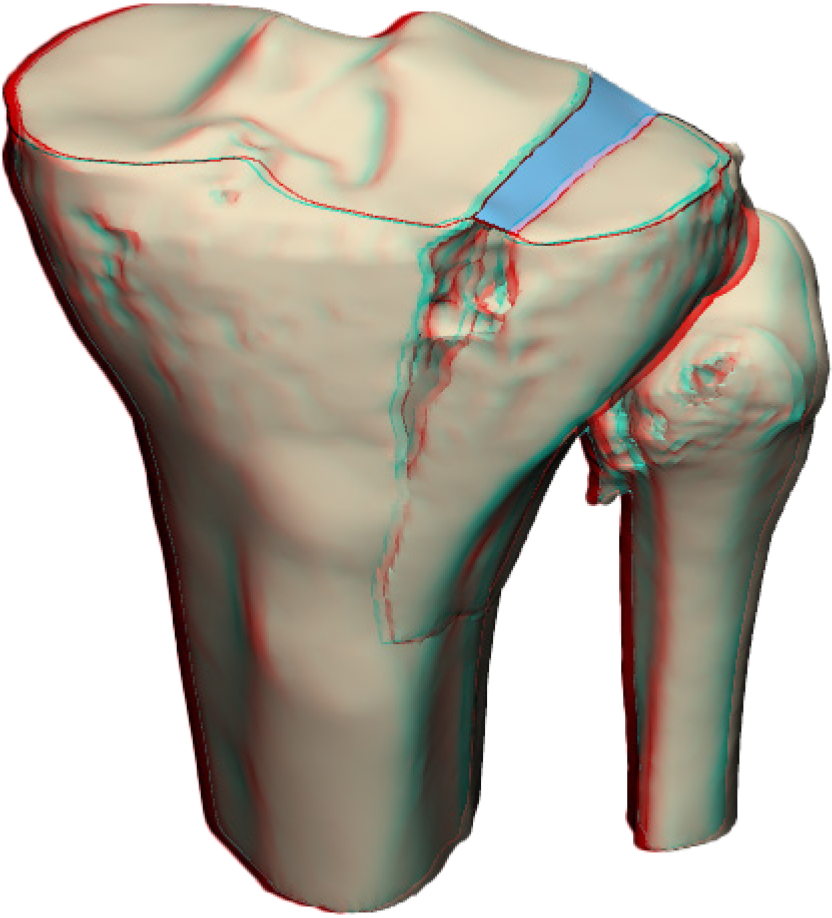
APPENDIX

Appendix 1: Overview of varying fractures which fall within the four identified subgroups



Appendix 2: 3D anaglyph of the 3D Gap Area measurement. After marking of articular surface (Left, yellow surface), the subsequently subtracted contour of the articular surface is used to fill the 3D gap area (Right, blue surface).





CHAPTER 8

Initial and Residual 3D Fracture Displacement Is Predictive for Patient-Reported Functional Outcome at Mid-Term Follow-Up in Surgically Treated Tibial Plateau Fractures at long-term follow-up

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Abstract

Background: Conventional measures of fracture displacement have low interobserver reliability. This study introduced a novel 3D method to measure tibial plateau fracture displacement and its impact on functional outcome.

Methods: A multicentre study was conducted on patients who had tibial plateau fracture surgery between 2003 and 2018. Eligible patients had a preoperative CT scan (slice thickness ≤ 1 mm) and received a Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaire. A total of 362 patients responded (57%), and assessment of initial and residual fracture displacement was performed via measurement using the 3D gap area (mm2). Patients were divided into four groups based on the 3D gap area size. Differences in functional outcome between these groups were assessed using analysis of variance (ANOVA). Multiple linear regression was used to determine the association between fracture displacement and patient-reported outcome.

Results: Functional outcome appeared significantly worse when initial or residual fracture displacement increased. Multivariate linear regression showed that initial 3D gap area (per 100 mm2) was significantly negatively associated with all KOOS subscales: symptoms (−0.9, $p < 0.001$), pain (−0.0, $p < 0.001$), ADL (−0.8, $p = 0.002$), sport (−1.4, $p < 0.001$), and QoL (−1.1, $p < 0.001$). In addition, residual gap area was significantly negatively associated with the subscales symptoms (−2.2, $p = 0.011$), ADL (−2.2, $p = 0.014$), sport (−2.6, $p = 0.033$), and QoL (−2.4, $p = 0.023$).

Conclusion: A novel 3D measurement method was applied to quantify initial and residual displacement. This is the first study which can reliably classify the degree of displacement and indicates that increasing displacement results in poorer patient-reported functional outcomes.

INTRODUCTION

Accurate anatomical fracture reduction of tibial plateau fractures is often challenging since these fractures usually consist of multiple fragments which are displaced in different directions [1,2]. Surgical treatment consists of screw or plate osteosynthesis and aims to restore articular surface, achieve normal limb alignment, and re-establish joint stability [3,4]. Achieving these goals is believed to reduce the risk of post-traumatic osteoarthritis [5,6]. Most studies reporting on functional recovery after surgical treatment of tibial plateau fractures focus on achieved surgical reduction and their relationship with functional outcome. Yet initial displacement is often neglected. The exact impact of both initial fracture displacement and the quality of operative fracture reduction on patient-reported outcome remains a matter of debate [7].

Both the severity of the fracture as well as the postoperative quality of reduction are assessed by evaluating fracture displacement. Displacement is measured in terms of the maximal gap and step-off on a single coronal, sagittal, or axial CT slice. This method is, however, known for its high inter- and intraobserver variability [8,9]. Moreover, it tends to underestimate fracture displacement and does not provide a full representation of the articular incongruity [8,10]. Assessment of fracture displacement unfortunately relies on which CT slice is selected for measurement and by whom it is measured. This complicates any study which addresses the association between fracture displacement and the functional outcome at follow-up [9].

Recently, we introduced a Quantitative 3D CT (Q3DCT) method to quantify the fracture displacement in tibial plateau fractures. This method introduces the 3D gap area, which represents a full quantification of the intra-articular incongruity and shows less user dependency compared to conventional 2D measurements of fracture displacement [8]. In addition, a recent study showed that this measurement is predictive for risk for conversion to a total knee arthroplasty at follow-up [11]. The aim of this study is to assess the association between fracture displacement and mid-term functional recovery. Our research questions were: (1) What is the association between the initial fracture displacement, as measured in 3D on the preoperative CT scan, and the patient-reported functional outcome at follow-up? (2) What is the association between the residual fracture displacement, as measured in 3D on the postoperative CT scan, and the patient-reported functional outcome at follow-up? Our hypothesis is that both initial and residual fracture displacement is associated with patient-reported functional outcome.

MATERIALS AND METHODS

Study Design

A multicentre cross-sectional study was performed within three hospitals (one level 1 and two level 2 trauma centres). All patients who had been treated surgically for a tibial plateau fracture between 2003 and 2018 were identified. Patients were eligible for inclusion based upon the availability of a preoperative CT scan of the injured knee with a slice thickness of ≤1 mm. Patients' demographics were retrieved from their electronic records, and we verified whether they were still alive using the population registry. Fracture classification was performed according to the AO/OTA system [12]. Patients with an isolated tibial eminence avulsion, a complicated fracture requiring amputation of the injured leg, age <18 years, and those deceased or with an unknown address at the time of follow-up were excluded.

Participants

A total of 766 patients were treated surgically for a tibial plateau fracture, of which 4 had an amputation, 33 were <18 years, 74 had died at follow-up, and 12 had an unknown address. An additional 6 patients had to be excluded due to insufficient quality of the postoperative images, leaving 637 eligible patients for follow-up analysis. All patients were approached by posted mail, of which 362 responded at a mean follow-up of 7.0 ± 3.7 years (57% response rate). Patient demographics are described in Table 1.

Table 1: Patient characteristics (n = 362).

Parameter	Value
Age in years	52 (±14)
Women	250 (69%)
BMI in kg/m2	26.2 (±4.7)
Smoking	83 (23%)
AO/OTA classification	
41-B1	19 (5%)
41-B2	58 (16%)
41-B3	195 (54%)
41-C1	22 (6%)
41-C2	9 (3%)
41-C3	59 (16%)
Surgical treatment	
Plate osteosynthesis	294 (81%)
Screw osteosynthesis	68 (19%)
Complication	
Infection	21 (6%)
Malunion	11 (3%)
Meniscal or ligamental reconstruction	6 (2%)
Nerve damage	2 (1%)
Compartment syndrome	1 (0%)
Follow-up (years)	7.0 (±3.7)
Conversion to total knee arthroplasty	51 (14%)

Patient-Reported Outcome

All eligible patients were approached by posted mail and asked to provide informed consent and complete the validated and standardized Knee Injury and Osteoarthritis Outcome Scale (KOOS) questionnaire using the Dutch language [13]. KOOS is a questionnaire designed to assess short- and long-term patient-relevant outcomes following knee injuries. It contains 42 items in 5 separately scored subscales: pain, symptoms, activities of daily living (ADL), function in sport and recreation (sport), and quality of life (QoL). Scores for the subscales were calculated by adding the individual items (questions) and transforming scores to a range from 0 to 100, with higher scores indicating better function. Patients who underwent conversion to total knee arthroplasty (TKA) were assigned an average KOOS score as it would have been just before conversion to TKA was performed. The assigned score was retrieved from a previous cohort [14]. The assumed KOOS subscores were 52 for symptoms, 45 for pain, 55 for ADL, 16 for sport, and 27 for QoL. The rationale for doing this was that the KOOS should represent the situation as it was just before conversion to TKA, since this corresponds to the complaints that arose from the initial and residual displacement.

Three-Dimensional Assessment of Initial (Preoperative) and Residual (Postoperative) Fracture Displacement

Initial Fracture Displacement

The data from the preoperative CT scan of each patient were used to create a 3D fracture model. CT data (DICOM files, Digital Imaging and Communications in Medicine) were imported into Mimics software (Version 23.0, Materialise, Leuven, Belgium), in which a segmentation process was performed, in which all fragments were segmented. A 3D assessment of the initial fracture displacement was performed for each patient by measuring the 3D gap area according to our previously published method: (1) delineating the articular surface; (2) extracting the fracture lines from the contours of the articular surface; and (3) measuring a 3D surface between all these fracture lines [11]. The 3D gap area represents the distances between all fracture lines in all planes, and the created surface (mm2) is considered a quantitative measure of the initial fracture displacement between all fracture fragments (Fig. 1).

Residual Fracture Displacement

A postoperative CT scan was only available in some cases. It was not part of the standard of care, and the decision to perform a CT scan was based on the clinical judgement of the treating surgeon. The main reason for performing a postoperative CT scan was dissatisfaction with the fracture reduction on the postoperative radiograph. In order to assess the residual fracture displacement, the postoperative CT data (DICOM) were imported into the Mimics software (Version 23.0, Materialise, Leuven, Belgium), in which a segmentation process was performed. A preset bone threshold range (Hounsfield Unit 226-2500) was used, combined with the 'region growing' function, to separate

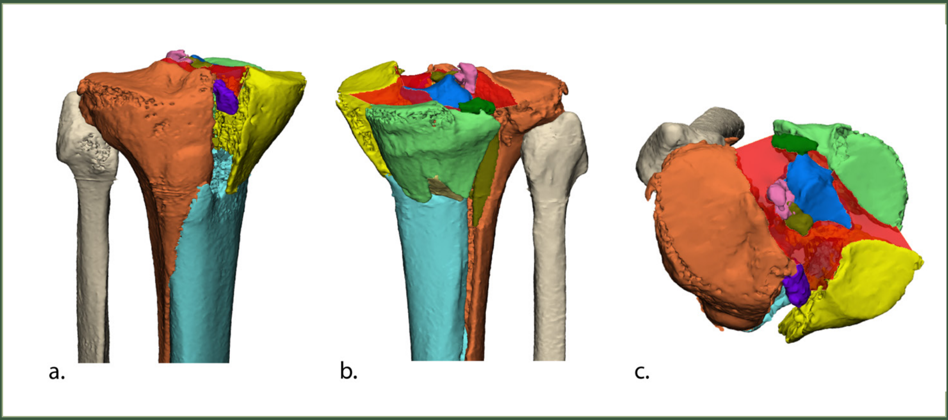


Figure 1: The 3D gap area (red surface) measurement on a 3D fracture model representing total fracture displacement between all fracture fragments at the articular level. All different fracture fragments were assigned a different colour. The 3D gap area is depicted from the anterior (a), posterior (b), and cranial (c) view.

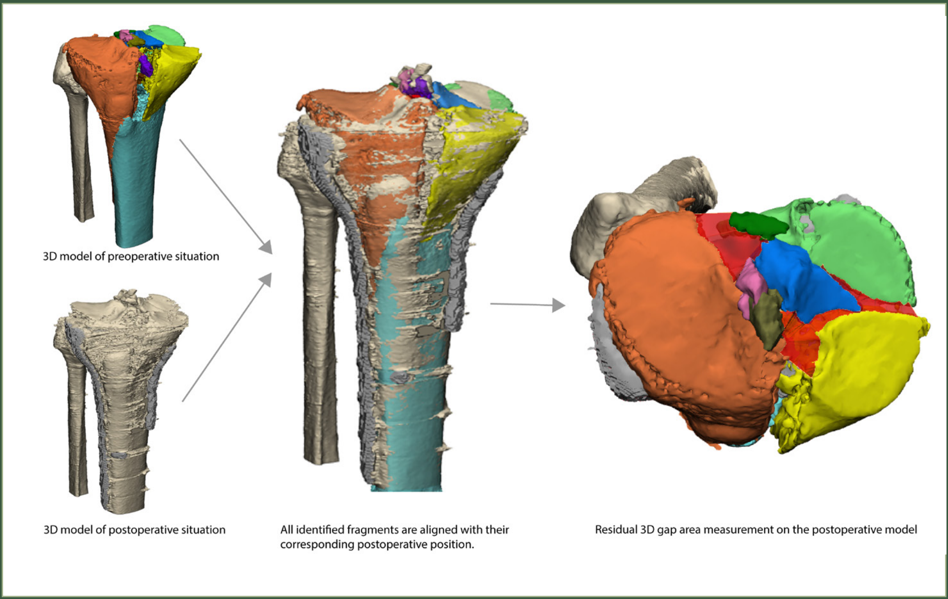


Figure 2: Residual 3D gap area (red area) is measured after all identified fragments (all assigned a different colour) are positioned according to the postoperative situation. (see Appendix to experience the ***3D anaglyph*** of the measurement represented in this figure)

the tibia from the implant(s), screws, and femur. The segmentation was checked and manually brushed to correct for the artefacts resulting from the implants and screws. After segmentation, both the pre- and postoperative 3D models were imported into 3-matic medical software (Version 15.0, Materialise, Leuven, Belgium). To subsequently measure the residual 3D gap area, the preoperative fracture fragments were matched with the postoperative 3D model using surface-based matching to avoid the possible influence of metal artefacts (Fig. 2). The 3D gap area was measured on the (preoperative) fragments positioned on their positions after surgery. For this measurement, the same method as applied preoperatively was used.

Postoperative Evaluation

Poor articular reduction and tibial alignment are associated with worse functional outcome [15,16,17]. In order to correct for the quality of the reduction in patients without a postoperative CT scan, the quality of the fracture reduction and the tibial alignment were evaluated on the postoperative radiographs using three radiographic parameters: articular fracture reduction, coronal alignment, and sagittal alignment. Articular fracture reduction was assessed by measuring the maximum residual intra-articular incongruence (gap and step-off). Coronal alignment was assessed by measuring the medial proximal tibial angle (MPTA) on the anteroposterior radiograph, whereas sagittal alignment was assessed by measuring the posterior proximal tibial angle (PPTA) on the lateral radiograph. The fracture reduction was considered as "anatomical" when both the gap and step-off were ≤ 2 mm, when the MPTA was 87 ± 5°, and the PPTA was 9 ± 5 [18,19].

Primary and Secondary Study Goals

The primary study goal was to assess the association between initial fracture displacement and the patient-reported outcome at follow-up. To achieve this, we measured the initial displacement in terms of 3D gap area on the 3D reconstruction of the initial CT scan and related this to a validated patient-reported outcome at follow-up. To correct for the quality of reduction, the articular reduction and the tibial alignment were evaluated on the postoperative radiographs using three radiographic parameters: articular fracture reduction, coronal alignment, and sagittal alignment.

The secondary study goal was to assess the association between residual fracture displacement and the patient-reported outcome at follow-up. To achieve this, we performed a subanalysis in patients with available postoperative CT scans. The residual displacement in terms of 3D gap area was measured in these patients on the 3D reconstruction of the postoperative CT scan and was related to validated patient-reported outcome at follow-up.

Statistical Analysis

Statistical analysis was performed using SPSS (version 28, IBM, Chicago, IL, USA). Continuous variables are presented as the mean with standard deviation for normally distributed data and median with interquartile range for non-normally distributed data. Descriptive statistics are used to describe the study population. The study population was divided into groups based on the size of the initial and residual 3D gap area. These prognostic groups were identified in our previous research and were excellent (gap area: 0–150 mm²), good (151–550 mm²), moderate (551–1000 mm²), and poor (>1000 mm²) [11]. Analysis of variance (ANOVA) was used to assess differences between these groups in terms of functional outcome. Multiple linear regression was performed to assess the association between initial and residual fracture displacement and the patient-reported outcome. The five subscales of the KOOS questionnaire were the outcomes of interest (dependent variable). Two potential predictors (initial and residual 3D gap area) were assessed within two separate regression models. A total of eight potential confounders (age, gender, BMI, smoking, AO/OTA classification, complication, inadequate reduction on postoperative radiograph, and follow-up time) were included in both models. A p-value of less than 0.05 was considered statistically significant.

Analysis of Nonresponders

Nonresponse analysis demonstrated no differences in age (52.7 ± 14.0 vs. 48.9 ± 16.9; p = 0.207) between responders and nonresponders. Responders were more often women compared to nonresponders (69.6% vs. 59.7%; p = 0.031).

RESULTS

Association between Initial 3D Displacement and Functional Outcome

In a total of 55 patients, the initial gap area was <150 mm²; a total of 148 patients had a gap area between 151 and 550 mm²; a total of 72 patients had a gap area between 551 and 1000 mm²; and 87 patients had a gap of >1000 mm². Functional outcome became worse when initial 3D gap area increased in all subscales of the KOOS questionnaire (Fig 3). In terms of symptoms, the KOOS value dropped from 86.1 ± 18.2 in the 0–150 group to 68.9 ± 24.6 in the >1000 mm² group ($p < 0.001$). Similar results were seen in the pain (86.9 ± 16.8 to 72.6 ± 23.3, p = 0.002), ADL (89.4 ± 14.7 to 75.5 ± 23.0, p = 0.002), sport (59.8 ± 33.2 to 38.2 ± 32.1, $p < 0.001$), and QoL (68.5 ± 24.5 to 48.9 ± 26.3, $p < 0.001$) subscales.

Multivariate linear regression shows that the initial 3D gap area is a negative predictor for all subscales of the KOOS with correlation coefficients varying from −0.8 to −1.4 after correction for potential confounders (Table 2).

Association between Residual 3D Displacement and Functional Outcome

In 72 patients, a postoperative CT scan was available. A total of 11 patients had a gap area < 150 mm², 31 between 151 and 550 mm², 25 between 551 and 1000 mm² and 5 > 1000 mm². Patient-reported outcome as measured in all KOOS subscales became worse when the postoperative 3D gap area increased (Fig. 4). In terms of symptoms, the

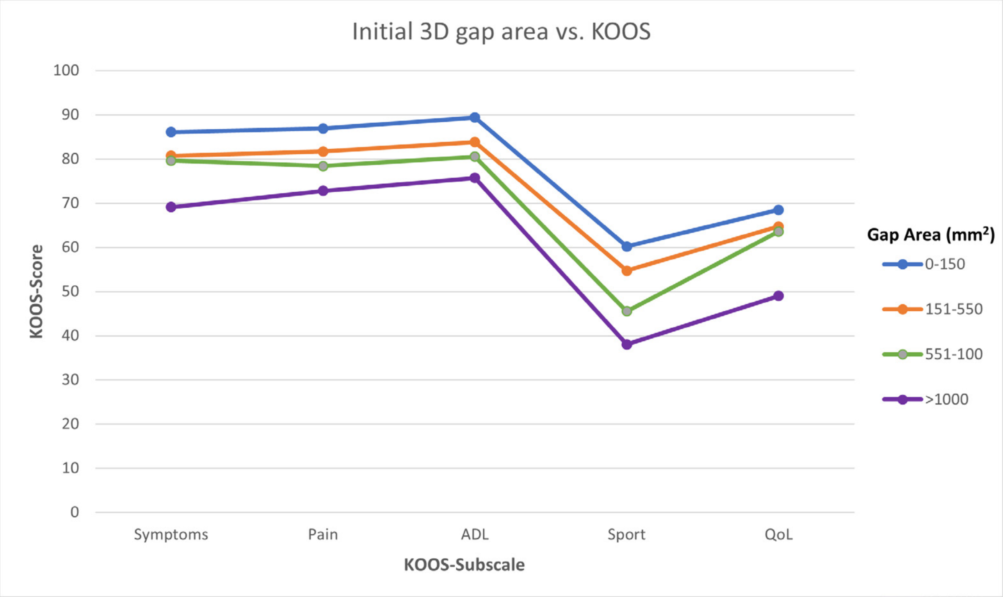


Figure 3: Assessment of the association between initial (preoperative) fracture displacement and functional outcome. The average scores of the KOOS subscales for the four groups, which were divided based on an increasing preoperative 3D gap area.

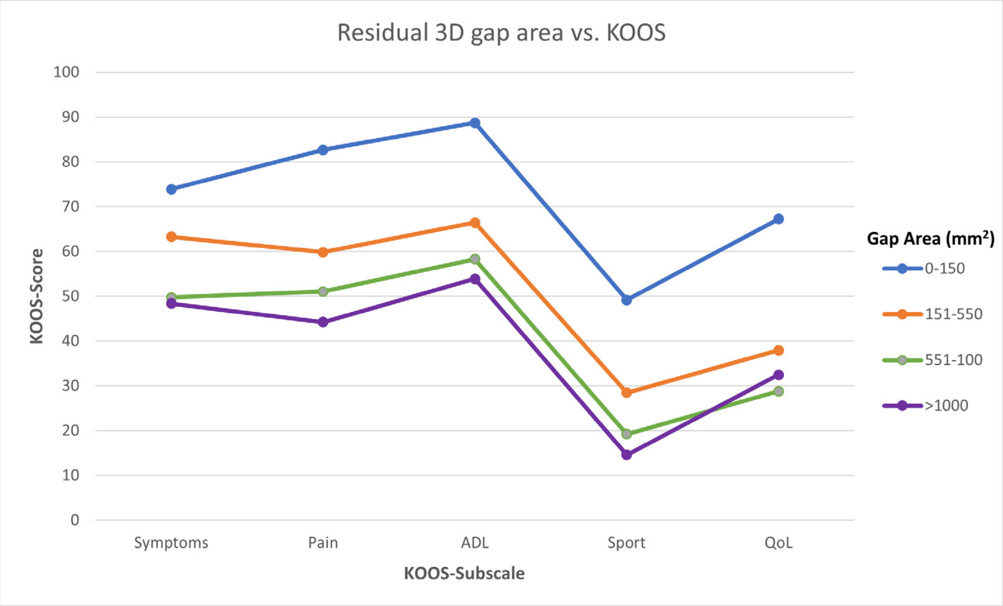


Figure 4: Assessment of the association between residual (postoperative) fracture displacement and functional outcome. The average scores of the KOOS subscales for the four groups, which were divided based on an increasing postoperative 3D gap area.

Table 2: Multiple linear regression models for initial and residual 3D gap area associated with the different KOOS subscales.

	Initial 3D gap area (x100) (n=362)*		**Residual 3D gap area (x100) (n=72)****	
	B (95% CI)	**P Value**	**B (95% CI)**	**P Value**
KOOS-Symptoms	-0.9 (-1.3 to -0.5)	<0.001	-2.2 (-3.9 to -0.5)	0.011
KOOS-Pain	-0.9 (-1.4 to -0.5)	<0.001	-2.4 (-4.4 to 0.2)	0.17
KOOS-ADL	-0.8 (-1.2 to -0.4)	0.002	-2.2 (-3.9 to -0.0)	0.014
KOOS-Sport	-1.4 (-2.1 to -0.7)	<0.001	-2.6 (-5.0 to -0.2)	0.033
KOOS-QoL	-1.1 (-1.7 to -0.5)	<0.001	-2.4 (-4.5 to -0.3)	0.023

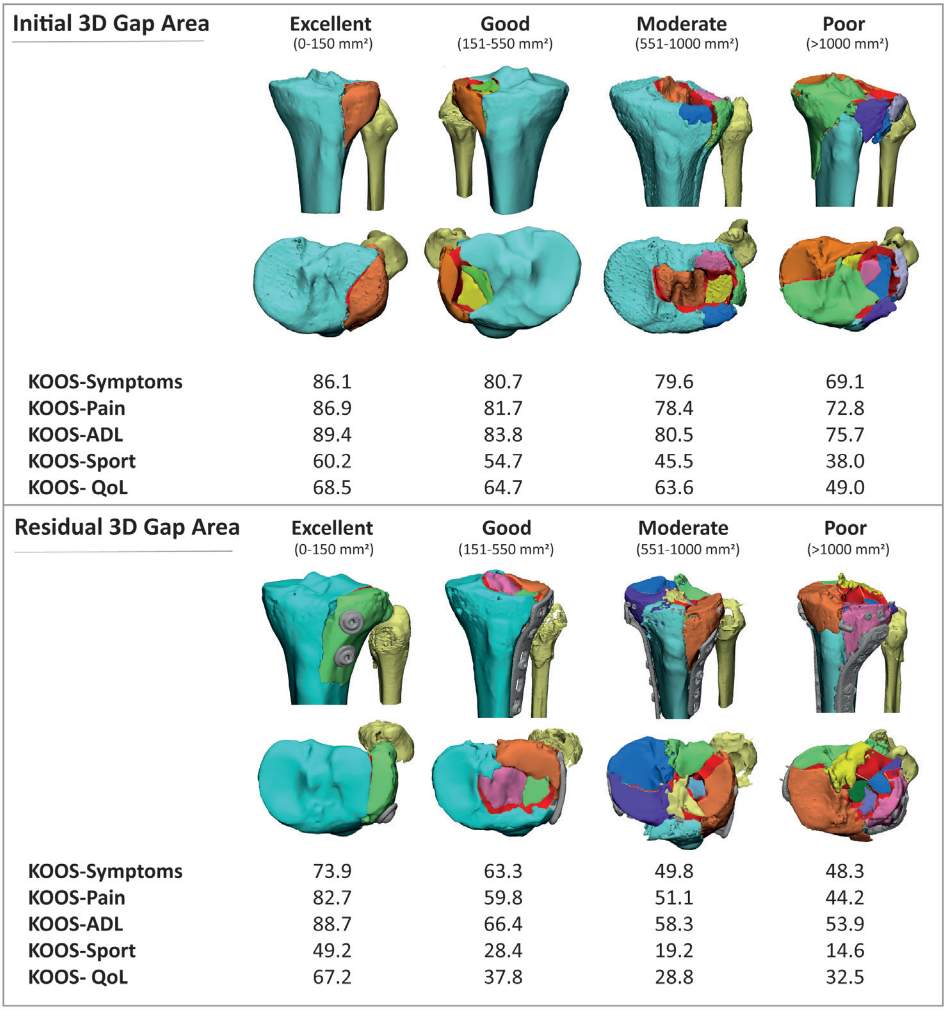
*Included confounders: age, gender, BMI, smoking, AO/OTA classification, complication, inadequate reduction on postoperative radiograph, and follow-up time.
**Included confounders: age, gender, BMI, smoking, AO/OTA classification, complication, and follow-up time.

KOOS value dropped from 73.9 ± 21.1 in the 0–150 group to 48.3 ± 16.4 in the >1000 mm2 group ($p < 0.001$). Similar results were seen in the pain (82.7 ± 18.2 to 44.3 ± 15.0, $p = 0.001$), ADL (88.7 ± 13.6 to 53.9 ± 17.2, $p = 0.001$), sport (49.2 ± 30.1 to 14.6 ± 8.1, $p < 0.001$), and QoL (67.2 ± 23.4 to 32.5 ± 11.9, $p < 0.001$) subscales. Multiple linear regression models showed that the residual 3D gap area had a negative association with the symptoms, ADL, sport, and quality of life subscale of KOOS with correlation coefficients varying from −2.2 to −2.6 (Table 2). The full regression models for both initial and residual 3D displacement can be found in the Appendix A and Appendix B.

DISCUSSION

This study shows that both increasing initial and residual displacement, as measured using a validated 3D measurement technique, are negatively associated with the patient-reported functional outcome. These results indicate that part of the functional outcome might already be determined by the irreversible damage to the articular surface caused by the initial trauma. Yet, patients benefit from the quality of the reduction, which is positively associated with a patient's outcome. Assigning patients based on their 3D gap area into four different prognostic groups (excellent, good, moderate, and poor), shows that the higher the 3D gap area, the lower average KOOS values (Fig 5). This provides a tool which could potentially be used for patient counselling regarding their expected functional outcome.

Irreversible damage to the articular surface and the ligamentous structures of the knee joint caused by the initial trauma contributes to worse functional outcome despite adequate articular fracture reduction [9,20]. However, only a limited number of studies have reported on the relationship between severity of the trauma and functional



Initial 3D Gap Area	Excellent (0-150 mm^2)	Good (151-550 mm^2)	Moderate (551-1000 mm^2)	Poor (>1000 mm^2)
KOOS-Symptoms	86.1	80.7	79.6	69.1
KOOS-Pain	86.9	81.7	78.4	72.8
KOOS-ADL	89.4	83.8	80.5	75.7
KOOS-Sport	60.2	54.7	45.5	38.0
KOOS- QoL	68.5	64.7	63.6	49.0

Residual 3D Gap Area	Excellent (0-150 mm^2)	Good (151-550 mm^2)	Moderate (551-1000 mm^2)	Poor (>1000 mm^2)
KOOS-Symptoms	73.9	63.3	49.8	48.3
KOOS-Pain	82.7	59.8	51.1	44.2
KOOS-ADL	88.7	66.4	58.3	53.9
KOOS-Sport	49.2	28.4	19.2	14.6
KOOS- QoL	67.2	37.8	28.8	32.5

Figure 5: Overview of the different prognostic groups, represented by 3D fracture models (gap area indicated in red, all fragments assigned a different colour) and their associated average KOOS value.

recovery of the patient. Recently, Parkkinnen et al. showed that initial articular depression measured from preoperative CT scans was a significant predictor of the development of osteoarthritis [21]. In addition, our research group recently showed that initial displacement, as measured in 3D, is independently associated with the development of severe osteoarthritis with the need for TKA [11]. No studies, however, have reported on the actual relationship of the initial displacement and the patient-reported outcome. The current study is the first study that addresses this association and shows that the initial 3D fracture displacement is independently associated with functional recovery in terms of the subscales symptoms, all day activities, sport, and quality of life. Our results indicates that with every 100 mm² increase in the preoperative gap area, the KOOS value decreases up to 1.4 points. With gap area sizes observed up to 3000 mm², this can lead to a clinically significant change in outcome [22]. This shows that despite good anatomical reduction, the initial fracture displacement is already a predictor of outcome for the patient. This is of importance for a full understanding of these fractures and patient counselling.

This study shows that not only initial but also residual 3D fracture displacement affects the functional outcome. Our results indicate that with every 100 mm² increase in the residual gap area, the KOOS value decreases up to 2.6 points. This shows that the residual displacement has a strong impact on the functional outcome and emphasizes the need for accurate reduction of the articular surface. Various authors have already demonstrated the importance of articular reduction on functional outcome by showing that a postoperative gap and step-off of more than 2 mm is associated with worse functional outcome or the development of osteoarthritis [5,19,21]. However, all these measurements were performed on plain postoperative radiographs, which are often an underestimation of the truth gap or step-off [23,24]. Singleton et al. recently assessed postoperative reduction on a CT scan and showed that a step-off of less than 2.5 mm was associated with a better functional outcome [15]. These observations, together with our findings, underscore the need for accurate articular reduction. Measuring the displacement in 3D solves the problems with observer reliability. In addition to previous research, this provides a reliable quantification of the impact of displacement and the association with functional recovery. For clinical use, patients could, for instance, be placed in the four proposed prognostic groups (excellent, good, moderate, and poor) with their corresponding expected functional outcome. With that, it could guide the physician in providing the patient with a personalized estimation of prognosis. Yet, performance in other clinical contexts should be performed to ensure validity.

This study has several limitations: (1) Selection bias is inherent to our cross-sectional cohort study, caused by loss to follow-up and nonresponse to the sent questionnaire. Nonresponse analysis indicated that responders were more often women. Yet, no significant differences in age were found between responders and nonresponders. (2) There was a high variation in follow-up duration (7.0 ± 3.7 months), which is inherent to a cross-sectional study design. To correct for this, we included follow-up time as a potential confounder in the analysis. (3) The number of patients with a postoperative CT scan was limited because it was not part of the standard of care. These patients had a postoperative CT due to a clinical suspicion of inadequate fracture reduction, which introduces selection bias for the assessment of residual displacement. However, despite potential bias, the results indicate a clear association between increasing postoperative fracture displacement and worse functional outcome. Given the limited number of available postop CT scans, our findings regarding the association between 3D residual fracture displacement and patient-reported outcome can only be considered hypothesis-generating and not prescriptive. (4) Another important practical limitation is that performing the 3D fracture assessments is labour-intensive. Depending on the fracture comminution, the segmentation and measurement process can take up to one hour. The 3D fracture assessment of the initial displacement should therefore be reserved for selected cases. Before widespread implementation in clinical practice, further automatization of the 3D measurements is recommended.

CONCLUSIONS

In this study, a novel 3D measurement method, which is not subject to problems with interobserver reliability, was applied to quantify the initial and residual displacement. This is the first study that could reliably classify the degree of displacement and shows that increasing displacement results is poorer patient-reported functional outcomes. Potentially, these measurements could guide the physician in providing the patient with personalized estimation of the prognosis. Large, prospective, cohort studies with the availability of pre- and postoperative CT scans are needed to assess the truth relationship between the degree of 3D fracture displacement and functional recovery after surgical treatment of tibial plateau fractures.

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APPENDIX

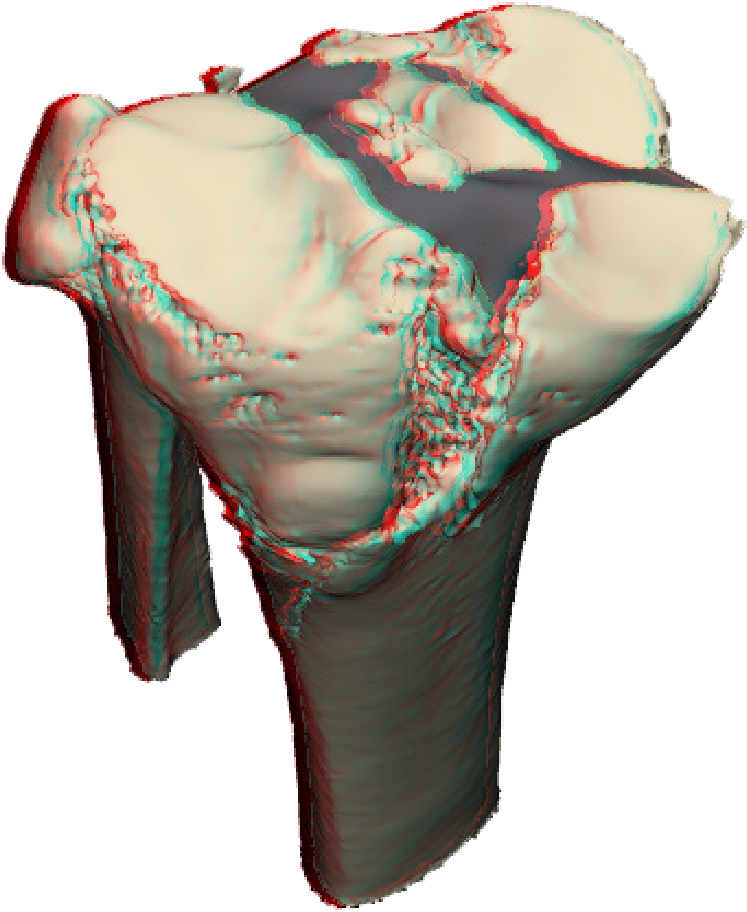
Appendix 1: Full regression model for initial 3D displacement in relation to KOOS functional outcome.

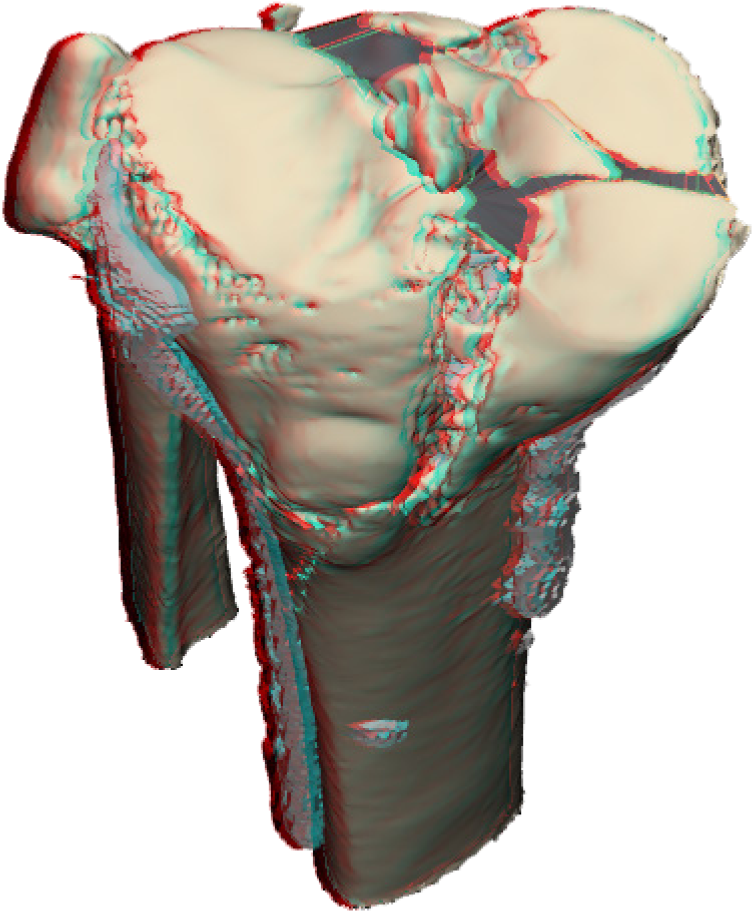
	KOOS-Symptoms (R2=0.22, adj R2=0.20)		KOOS-Pain (R2=0.21, adj R2=0.19)		KOOS-ADL (R2=0.22, adj R2=0.20)		KOOS-Sport (R2=0.18, adj R2=0.16)		KOOS-QoL (R2=0.18, adj R2=0.16)	
	B (95% CI)	P Value	B (95% CI)	P Value	B (95% CI)	P Value	B (95% CI)	P Value	B (95% CI)	P Value
Preoperative 3D gap area (x 100)	-0.9 (-1.3 to -0.5)	<0.001	-0.9 (-1.4 to -0.5)	<0.001	-0.8 (-1.2 to -0.4)	0.002	-1.4 (-2.1 to -0.7)	<0.001	-1.1 (-1.7 to -0.5)	<0.001
Age	0.2 (0.0 to 0.4)	0.016	0.1 (-0.1 to 0.2)	0.452	-0.1 (-0.2 to 0.1)	0.429	0.1 (-0.2 to 0.3)	0.482	0.1 (-0.1 to 0.3)	0.221
Male	5.2 (0.7 to 9.7)	0.027	6.3 (1.5 to 11.1)	0.010	6.3 (2.0 to 10.7)	0.004	12.1 (4.9 to 19.3)	0.001	4.6 (-1.3 to 10.6)	0.127
BMI	-0.7 (-1.1 to -0.3)	0.002	-0.9 (-1.4 to -0.5)	<0.001	-1.0 (-1.4 to -0.5	<0.001	-1.4 (-2.1 to -0.7)	<0.001	-0.9 (-1.4 to -0.3)	0.004
Smoking	-4.0 (-8.8 to 0.8)	0.104	-6.5 (-11.7 to -1.3)	0.014	-7.1 (-11.8 to -2.4)	0.003	-6.3 (-14.1 to 1.5)	0.115	-5.6 (-12.0 to 0.9)	0.090
AO/OTA	-0.8 (-2.4 to 0.9)	0.374	-0.3 (-2.1 to 1.5)	0.714	-0.7 (-2.3 to 0.9)	0.410	-1.6 (-4.2 to 1.1)	0.256	-0.8 (-3.0 to 1.4)	0.494
Postoperative complication	-9.9 (-16.3 to -3.4)	0.003	-9.8 (-16.8 to -2.9)	0.006	-8.9 (-15.2 to -2.6)	0.006	-9.1 (-19.4 to 1.3)	0.086	-11.2 (-19.9 to -2.6)	0.011
Non-Anatomical reduction	-5.7 (-10.3 to -1.0)	0.016	-5.0 (-10.0 to -0.5)	0.048	-2.8 (-7.3 to 1.7)	0.223	-4.6 (-12.2 to 2.9)	0.229	-7.4 (-13.6 to -1.2)	0.018
Follow-up time (years)	0.7 (0.1 to 1.2)	0.018	0.5 (-0.1 to 1.1)	0.089	0.5 (-0.1 to 1.0)	0.081	0.3 (-0.6 to 1.2)	0.548	0.8 (0.0 to 1.5)	0.045

Appendix 2. Full regression model for residual 3D displacement in relation to KOOS functional outcome.

	KOOS-Symptoms (R2=0.28, adj R2=0.19)		KOOS-Pain (R2=0.27, adj R2=0.17)		KOOS-ADL (R2=0.31, adj R2=0.21)		KOOS-Sport (R2=0.20, adj R2=0.09)		KOOS-QoL (R2=0.27, adj R2=0.17)	
	B (95% CI)	P Value	B (95% CI)	P Value	B (95% CI)	P Value	B (95% CI)	P Value	B (95% CI)	P Value
Preoperative 3D gap area (x 100)	-2.2 (-3.9 to -0.5)	0.011	-2.4 (-4.4 to -0.5)	0.17	-2.2 (-3.9 to -0.0)	0.014	-2.6 (-5.0 to -0.2)	0.033	-2.4 (-4.5 to -0.3)	0.023
Age	-0.2 (-0.5 to 0.2)	0.360	-0.4 (-0.8 to -0.0)	0.046	-0.4 (-0.7 to -0.0)	0.044	-0.2 (-0.7 to 0.3)	0.418	-0.2 (-0.6 to 0.0)	0.361
Male Gender	6.1 (-4.0 to 16.2)	0.232	2.6 (-9.3 to 14.6)	0.659	2.1 (-8.3 to 12.5)	0.687	2.5 (-11.7 to 16.8)	0.723	-4.8 (-17.3 to 7.8)	0.449
BMI	-0.4 (-1.2 to 0.5)	0.367	-0.3 (-1.3 to 0.6)	0.487	-0.4 (-1.2 to 0.5)	0.383	0.0 (-1.1 to 1.2)	0.938	0.3 (-0.7 to 1.4)	0.505
Smoking	-6.3 (-16.6 to 3.8)	0.216	-2.5 (-14.6 to 9.5)	0.675	-1.9 (-12.4 to 8.6)	0.723	-0.8 (-15.2 to 13.6)	0.912	-3.5 (-16.1 to 9.2)	0.588
AO/OTA	-1.1 (-4.3 to 2.0)	0.479	-1.2 (-4.9 to 2.6)	0.532	-1.3 (-4.6 to 1.9)	0.424	-2.1 (-6.6 to 2.2)	0.339	-2.9 (-6.9 to 1.0)	0.143
Postoperative complication	-4.7 (-14.8 to 5.7)	0.361	-2.3 (-14.3 to 9.6)	0.698	-3.4 (-13.8 to 7.0)	0.513	5.6 (-8.7 to 20.0)	0.433	-1.8 (-14.4 to 10.8)	0.773
Follow-up time (years)	0.3 (-1.0 to 1.6)	0.641	-0.6 (-2.1 to 0.9)	0.448	0.4 (-0.9 to 1.7)	0.557	0.2 (-1.6 to 2.0)	0.829	0.2 (-1.4 to 1.8)	0.798

Appendix 2: 3D anaglyph of the initial (Left) and residual (Right) 3D gap area of the case represented in figure 1 & 2 of this chapter. The 3D gap area is the dark grey surface representing the displacement between all fracture fragments.





CHAPTER 9

Tibial plateau fracture morphology based on injury force mechanism is predictive for patient-reported outcome and conversion to total knee arthroplasty: Results of a large multicenter cohort

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Abstract

Purposes: The aim of this study was to assess the relationship between injury mechanism–based fracture patterns and patient-reported outcome as well as conversion rate to total knee arthroplasty (TKA) at follow-up.

Methods: A multicenter cross-sectional study was performed including 1039 patients treated for a tibial plateau fracture between 2003 and 2019. At a mean follow-up of 5.8 ± 3.7 years, patients completed the Knee injury and Osteoarthritis Outcome Score (KOOS) questionnaire. For all patients, the injury force mechanism was defined based on CT images. Analysis of variance (ANOVA) was used to assess the relationship between different injury mechanisms and functional recovery. Cox regression was performed to assess the association with an increased risk on conversion to TKA.

Results: A total of 378 (36%) patients suffered valgus-flexion, 305 (29%) valgus-extension, 122 (12%) valgus-hyperextension, 110 (11%) varus-flexion, 58 (6%) varus-hyperextension, and 66 (6%) varus-extension injuries. ANOVA showed significant different KOOS values between injury fracture patterns in all subscales ($P < 0.01$). Varus-flexion injuries had the lowest average KOOS scores (symptoms 65; pain 67; ADL 72; sport 35; QoL 48). Varus-flexion mechanism was associated with an increased risk on a TKA (HR 1.8; $P = 0.03$) whereas valgus-extension mechanism was associated with a reduced risk on a TKA (HR 0.5; $P = 0.012$) as compared to all other mechanisms.

Conclusion: Tibial plateau fracture patterns based on injury force mechanisms are associated with clinical outcome. Varus-flexion injuries have a worse prognosis in terms of patient-reported outcome and conversion rate to TKA at follow-up. Valgus-extension injuries have least risk on conversion to TKA.

INTRODUCTION

Tibial plateau fractures are one of the most challenging intra-articular fractures to treat due to complex fracture morphology [1, 2]. These fractures result from a varus or valgus load along with or without an axial load on the tibial plateau [3, 4]. Depending on the exact injury mechanism and the position of the knee, the resulting fracture patterns vary from simple split fractures to complex multi-fragmentary fractures of lateral, medial, or bicondylar types [1, 5, 6].

Both the revisited Schatzker and the three-column classification emphasized the importance of the injury mechanisms causing a tibial plateau fracture [7, 8]. Both classifications included the assessment of these mechanisms in four dimensions (varus, valgus, flexion, and extension) in order to guide surgical fixation. In addition, the hyperextension injury mechanism has been reported as a unique fracture mechanism [4, 9], which resulted in a total of six different unique tibial plateau injury mechanisms: valgus-flexion, valgus-extension, valgus-hyperextension, varus-flexion, varus-extension, and varus-hyperextension. Xie et al. recently introduced a method to assess the relationship between these different injury force mechanisms and fracture patterns [4]. This study demonstrated that those injury force mechanisms – represented by those unique fracture patterns – predict associated soft tissue injuries. Besides the descriptive nature of these mechanisms, these specific injury patterns may have predictive value on the patient's recovery over time. Even though Xie et al. identified distinct mechanism-associated 3-dimensional pattern characteristics, these well-established mechanisms – which are incorporated in the current classification mechanisms – have never been associated with functional recovery [4].

In this study, we aim to assess the relationship between the different unique tibial plateau injury mechanisms and the functional recovery at follow-up. We posed the following research questions: (1) Is the type of injury force mechanism which causes a tibial plateau fracture predictive for patient-reported functional outcome at follow-up? (2) What is the association between the type of injury force mechanism and the risk on conversion to total knee arthroplasty (TKA) at follow-up?

METHODS

A multicenter cross-sectional study was performed including all patients who have been treated for a tibial plateau fracture in five trauma centers (University Medical Center Groningen, Martini Hospital, Isala Hospital, Gelre Hospital, and KU Leuven University Hospitals) between January 2003 and December 2019. Patients were eligible for inclusion based upon the availability of a preoperative (diagnostic) CT scan of the injured knee. Patients with a follow-up of less than 1 year, age < 18 years, pathological fractures, isolated tibial eminence fractures, or those with a complicated fracture requiring amputation of the affected leg were excluded. Patients' demographics were retrieved from the electronic records. All patients were verified whether they were still alive according to the national population registry. All eligible patients were approached by posted mail, asked for informed consent, and asked to complete validated patient-reported outcome measures. Written informed consent was obtained from all participants.

Fracture injury mechanism assessment

Fracture injury mechanism was assessed in consensus of two independent observers. Any disagreements were solved during a consensus meeting with a third observer. Assessments were performed on the 2D CT slices using the Mimics Medical software package (Version 23.0, Materialise, Leuven, Belgium) according to the method described by Xie et al. [4]. Additionally, the injury mechanism was verified on a 3D reconstruction of the fracture. This reconstruction was obtained following a segmentation process in which a preset bone threshold (Hounsfield unit ≥ 226) was used combined with the "region growing" function in order to remove the femur bone. Figure 1 illustrates the fracture injury mechanism assessment.

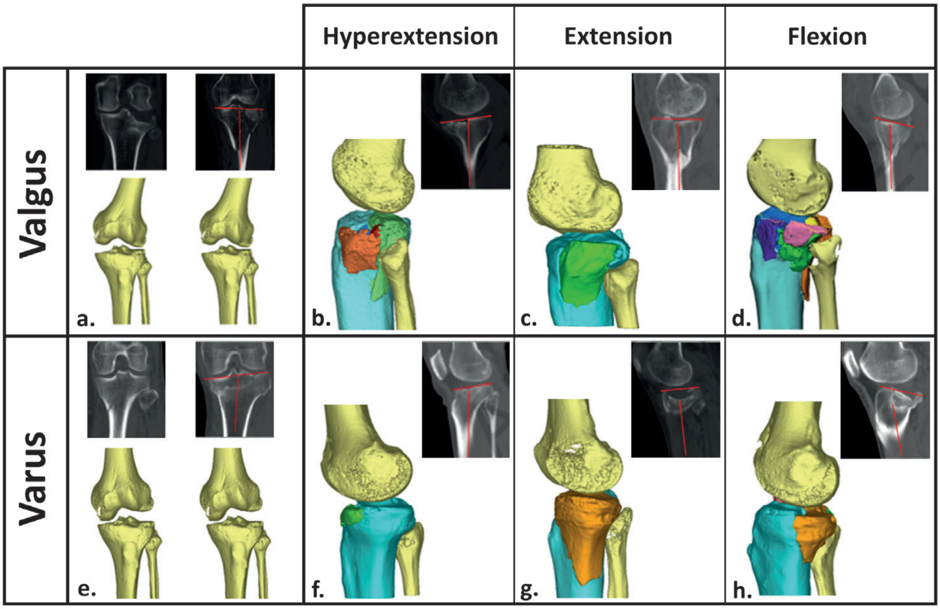

Figure 1: Fracture injury mechanism assessment. Fractures limiting to the lateral side or with an increased medial proximal tibial angle (MPTA) are considered caused by valgus impact (a) and fractures limited to the medial side or with decreased MPTA as varus impact (e). Fractures with a decreased tibial slope are considered as hyperextension (b, f), normal tibial slope as extension (c, g), and increased tibial slope as flexion (d, h)

Patient-reported outcomes

All eligible patients were approached by posted mail and asked to complete the standardized Knee injury and Osteoarthritis Outcome Score (KOOS) questionnaire [10]. Additionally, patients were asked whether they received a total knee prothesis. The KOOS is a validated questionnaire consisting of five subscales: pain, symptoms, activities of daily living (ADL), function in sport and recreation (sport), and knee related quality of life (QoL). A normalized score was calculated for each subscale. Scores of the subscales are calculated by summing up the individual items (e.g., questions) and transforming scores on a range from 0 to 100, with higher scores indicating better function. In addition, the patients were also asked whether they underwent conversion to TKA.

Statistical analysis

IBM SPSS software, version 23.0 for Windows (IBM Corporation, Chicago, IL, USA), was used for statistical analysis. Continuous variables ware presented as mean and standard deviation (SD) for normally distributed data and median and interquartile range (IQR) if not normally distributed. Descriptive statistics were used to describe the study population. The study population was divided into groups based on the injury mechanism, after which analysis of variance (ANOVA) was used to assess differences between the groups in terms of functional outcome. Cox regression was performed to assess the risk on conversion to a TKA. In this analysis, we corrected for other factors (age, sex, smoking, and BMI) which are potential confounders for the risk of conversion to a TKA. A P-value of less than 0.05 was considered statistically significant.

Ethical approval

The institutional review board of all centers approved the study procedures, and the research was performed in accordance with the relevant guidelines and regulations. This study is reported following the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline [11].

Source of funding

There was no external funding source for this study.

RESULTS

A total of 2331 patients were treated for a tibial plateau fracture between 2003 and 2019, of which 61 had and isolated tibial eminence avulsions (e.g., cruciate ligament injuries), 115 were aged < 18 years, 191 had died at follow-up, 82 had co-existing conditions complicating outcome measurement (e.g., Parkinson, paralysis), 4 had an amputation, 13 had no knowledge of the Dutch language, and 53 had an unknown address or were lost at follow-up, leaving 1750 patients eligible for follow-up analysis.

All patients were approached by posted mail, from which 1039 responded (response rate 59%) at a mean follow-up of 5.8 ± 3.7 years. The mean age was 53 ± 15 years and 32% (329) of patients were male. A total of 728 (70%) patients were treated operatively by using plate and/or screw osteosynthesis. Eventually, 111 (11%) patients underwent conversion to TKA during follow-up. Non-response analysis demonstrated that non-responders were slightly younger (51 ± 18 vs. 53 ± 15, P = 0.001), less often female (59% vs. 68%, P = 0.001), and less often treated surgically (56% vs. 70%, P = 0.001) in comparison with responders.

Valgus mechanisms (805/1039, 77%) occurred more frequently than varus (234/1039, 23%) mechanisms. A total of 378 (36%) patients were classified as valgus-flexion, 305 (29%) as valgus-extension, 122 (12%) as valgus-hyperextension, 110 (11%) as varus-flexion, 58 (6%) as varus-hyperextension, and 66 (6%) as varus-extension. Table 1 describes patients demographics for each trauma mechanism.

Table 1: Patient characteristics

	Valgus-Flexion	Valgus-Extension	Valgus-Hyperextension	Varus-Flexion	Varus-Extension	Varus-Hyperextension
Number of patients	378 (36%)	305 (29%)	122 (12%)	110 (11%)	58 (6%)	66 (6%)
Age (yrs)	54 ± 14	54 ± 15	51 ± 15	53 ± 17	55 ± 16	46 ± 14
Male	98 (65%)	100 (33%)	46 (38%)	33 (32%)	22 (38%)	30 (45%)
BMI (kg/m2)	26.2 ± 4.8	26.3 ± 4.7	25.4 ± 4.0	26.5 ± 4.5	26.6 ± 4.2	27.4 ± 5.5
Smoking	73 (19%)	68 (22%)	26 (21%)	22 (20%)	8 (14%)	13 (20%)
Diabetes	28 (7%)	28 (9%)	12 (10%)	6 (6%)	7 (12%)	3 (5%)
AO/OTA classification						
B1	20 (5%)	48 (16%)	5 (4%)	10 (9%)	17 (30%)	26 (39%)
B2	109 (29%)	94 (31%)	22 (18%)	8 (7%)	9 (16%)	5 (8%)
B3	167 (44%)	148 (48%)	80 (66%)	38 (34%)	19 (32%)	15 (22%)
C1	12 (3%)	1 (0%)	6 (5%)	4 (4%)	6 (10%)	7 (11%)
C2	2 (1%)	3 (1%)	3 (2%)	2 (2%)	0 (0%)	6 (9%)
C3	68 (18%)	11 (4%)	6 (5%)	48 (44%)	7 (12%)	7 (11%)
Treatment						
Non-operative	117 (31%)	94 (31%)	14 (11%)	25 (22%)	32 (55%)	29 (44%)
Screw osteosynthesis	38 (10%)	65 (21%)	13 (11%)	2 (2%)	3 (5%)	8 (12%)
Plate osteosynthesis	223 (59%)	146 (48%)	95 (78%)	83 (76%)	23 (40%)	29 (44%)
Conversion to TKA	46 (12%)	22 (7%)	11 (9%)	20 (18%)	8 (14%)	4 (6%)
Follow-up (yrs)	5.6 ± 3.6	6.1 ± 3.9	5.6 ± 3.6	5.3 ± 3.3	5.9 ± 3.9	6.6 ± 4.2

Patient-reported outcomes

The average KOOS score per KOOS subscale for each trauma mechanism is depicted in Figure 2. ANOVA analysis showed significant different KOOS values between injury mechanism groups in terms of all KOOS subscales (P < 0.001, Appendix). Tukey's post hoc analysis showed that patients with a fracture caused by a varus-flexion injury had significantly worse KOOS subscales regarding symptoms (P ≤ 0.002), pain (P ≤ 0.007),

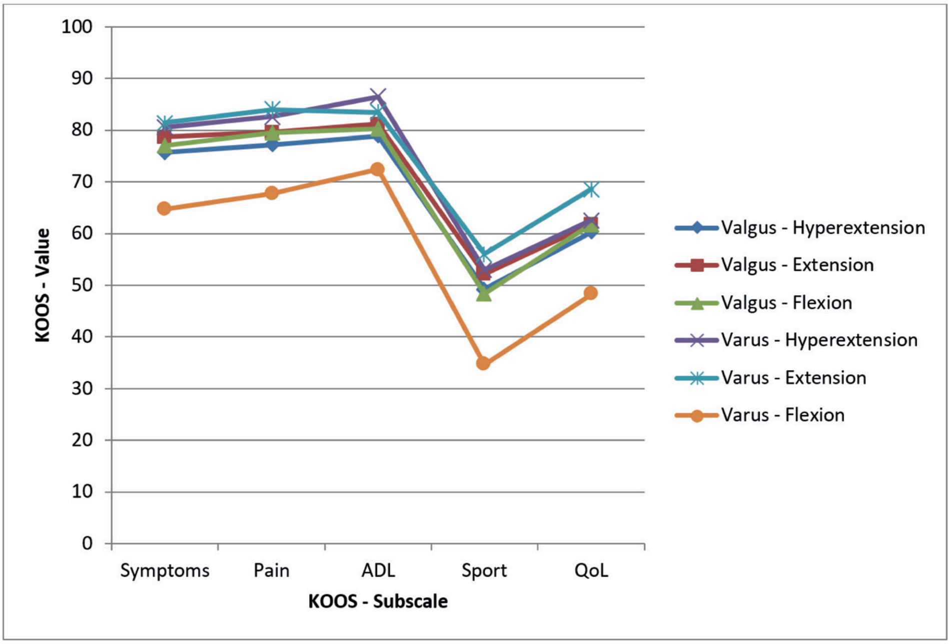

Figure 2: The average KOOS values for each of the KOOS subscales, representing functional outcome, are displayed for 944 patients with a tibial plateau fracture divided into six subgroups based on the injury fracture mechanism

sport ($p \leq 0.01$), and QoL ($P \leq 0.026$) as compared to all other mechanisms. In terms of ADL, varus-flexion was significantly worse as compared to all other subscales with exemption of valgus-hyperextension ($P = 0.012$).

Conversion to TKA

Kaplan–Meier survival analysis shows knee survival free of conversion to TKA in non-surgical treated patients of 97% at 2 years and 94% at 10 years. In surgically treated patients, 2- and 10-year knee survival was 93% and 82%, respectively. When stratifying groups based on the injury force mechanism, the 2-year knee survival (no conversion to TKA) was 92% for valgus-flexion, 96% for valgus-extension, and 96% for valgus-hyperextension. For varus-flexion, extension, and hyperextension injuries, the 2-year knee survival was 92%, 90%, and 95%, respectively. The 10-year knee survival was 84% for valgus-flexion, 91% for valgus-extension, 88% for valgus-hyperextension, 71% for varus-flexion, 86% for varus-extension, and 92% for varus-hyperextension (Figs. 3 and 4).

Univariate analysis shows that the valgus-extension mechanism was associated with a reduced risk on a TKA (HR 0.6; $P = 0.028$), whereas the varus-flexion mechanism was associated with an increased risk on a TKA (HR 2.0; $P = 0.003$) as compared to the other

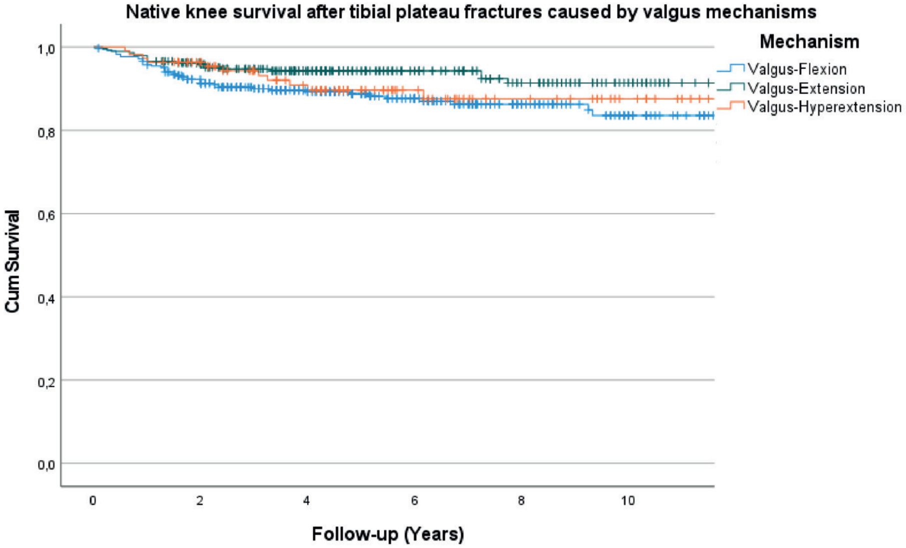

Figure 3: Native knee survival free from conversion to total knee arthroplasty stratified by valgus injury mechanisms (log rank, P = 0.010)

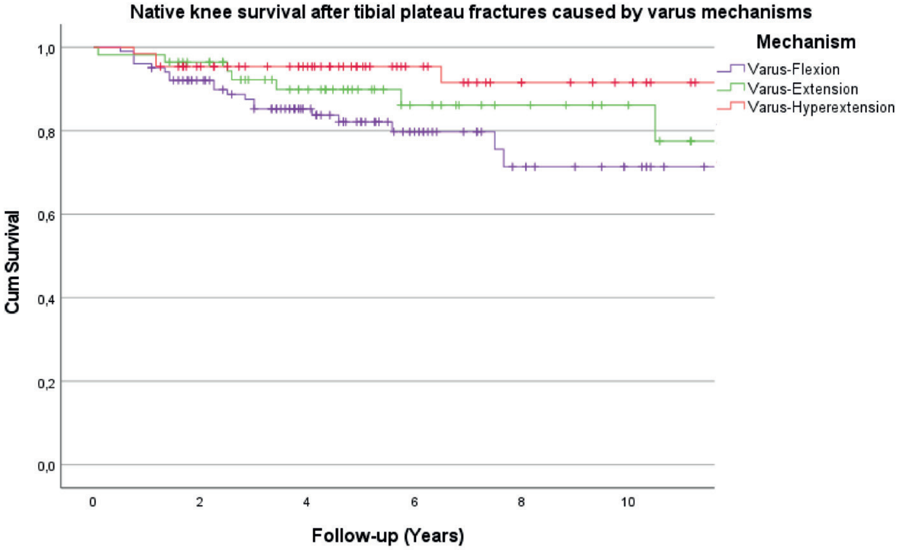

Figure 4: Native knee survival free from conversion to total knee arthroplasty stratified by varus injury mechanisms (log rank, P = 0.075)

mechanisms. After correction for age, sex, smoking, diabetes, and BMI, multivariate analysis showed similar results with valgus-extension mechanism associated with a reduced risk (adj HR 0.5; P = 0.012) and varus-flexion with increased risk on a TKA (adj HR 1.8; P = 0.030) (Table 2).

Table 2: Multivariate analysis of the association of injury force mechanisms with the conversion to TKA.

Injury Mechanism[a]	**Unadjusted Hazard**		**Adjusted Hazard**	
	Ratio (95% CI)	P-Value	Ratio † (95% CI)	P-Value
Valgus-flexion	1.2 (0.8 – 1.8)	0.333	1.4 (0.9 – 2.1)	0.105
Valgus-extension	0.6 (0.3 – 0.9)	0.028*	0.5 (0.3 - 0.9)	0.012*
Valgus-hyperextension	0.8 (0.4 – 1.5)	0.777	0.9 (0.5 – 1.7)	0.750
Varus-flexion	2.0 (1.3 – 3.3)	0.003*	1.8 (1.1- 3.1)	0.030*
Varus-extension	1.3 (0.7 – 2.8)	0.428	0.8 (0.3 – 2.0)	0.672
Varus-hyperextension	0.6 (0.2 – 1.5)	0.246	0.9 (0.3 – 2.5)	0.847

[a] The patients who had a different injury force mechanism as the injury mechanism of interest served as the reference group.
† Adjusted for age, sex, smoking, diabetes and BMI.
* Significant

Why injury force mechanisms affect clinical outcome

A subanalysis was performed to assess the role of revision surgeries as potential explanation for the identified variations in clinical outcomes among different injury mechanisms. Varus-flexion injuries are associated with substantial rates of revision surgery as a result of fracture-related infections (13%), residual displacement (8%), or meniscal/ligamentous repairs (7%) as compared to the other injury mechanisms. Table 3 presents rates of revision surgery pertaining to different injury mechanisms in tibial plateau fracture surgery.

Table 3: Revision surgery associated with different injury force mechanisms in tibial plateau fracture surgery.

	Valgus-Flexion	**Valgus-Extension**	**Valgus-Hyperextension**	**Varus-Flexion**	**Varus-Extension**	**Varus-Hyper-extension**
Number of patients	378 (36%)	305 (29%)	122 (12%)	110 (11%)	58 (6%)	66 (6%)
Operative treatment	261 (67%)	211 (69%)	108 (89%)	85 (77%)	26 (45%)	37 (56%)
Revision surgery						
Reoperation for fracture-related infection*	15 (6%)	4 (2%)	1 (1%)	11 (13%)	0 (0%)	0 (0%)
Revision surgery for residual displacement	7 (2%)	2 (1%)	3 (3%)	9 (8%)	0 (0%)	0 (0%)
Reoperation for meniscal or ligamentous repair	8 (2%)	4 (1%)	1 (1%)	8 (7%)	1 (2%)	4 (6%)

* As percentage of patients treated operatively

DISCUSSION

Tibial plateau fracture morphologies based on six different injury force mechanisms, each with its own associated distinct fracture characteristics and soft tissue involvement, have been introduced [4]. To our knowledge, this is the first large multicenter study which relates these specific injury mechanisms to patients' functional recovery in terms of patient-reported outcome and conversion to TKA. Our results show that especially fractures caused by a varus-flexion force have worse prognosis as compared to the other mechanisms regarding both patient-reported outcome and risk on conversion to TKA. On the contrary, fractures caused by a valgus-extension mechanism are associated with reduced risk on a TKA as compared to the other injury mechanisms.

In the recently updated versions of the Schatzker and three-column classification methods, more focus is directed on mechanisms of injury which result in different fracture patterns [7, 8]. In these classifications, identifying the position of the knee (flexion/extension) and the deforming force (varus/valgus) guides the surgeon in the preoperative planning and surgical stabilization of the fracture [7, 8]. The results of our study add knowledge regarding the consequences of these mechanisms on patients' prognosis. Therefore, increasing knowledge about the injury mechanism and the corresponding fracture morphology could aid in providing the patient information regarding his or her expected functional recovery.

The results of this study indicate that especially the varus-flexion mechanism results in worse patient-reported outcomes as compared to other mechanisms of injury. These fractures are caused by a varus force, with the knee in a flexion position. Therefore, these fractures usually involve the medial and posterior part of the tibial plateau. Recently, van den Berg et al. showed that especially fractures with posterior involvement as well as sagittal malalignment were associated with poor outcomes [12, 13]. It is believed that fractures of the medial plateau usually require more force and are therefore often not only limited to the medial compartment. This is confirmed by Xie et al. who describe that varus-flexion fractures are associated with posterolateral articular comminution and anterior cruciate ligament avulsion [4]. The combination of a medial fracture with posterolateral comminution and associated ligamental damage in fractures caused by a varus-flexion trauma might explain the worse clinical outcome. This is supported by our subanalysis which showed that patients who had a fracture caused by a varus-flexion injury required more often reoperations for meniscal or ligamentous repair, residual displacement, and fracture-related infections as compared to other mechanisms of injury. Therefore, fractures caused by a varus-flexion trauma might especially benefit from an extensive 3D surgical planning which could potentially improve surgical outcomes [14]. Moreover, valgus traumas are associated with medial collateral ligament (MCL) sprains which are relatively forgiving, whereas varus traumas are associated with (postero)lateral ligamental injuries which are often underestimated and could affect outcome negatively [15].

Tibial plateau fractures could result in severe post-traumatic osteoarthritis or ligamentous instability needing eventually conversion to total knee arthroplasty. This study shows that patients with a fracture caused by a flexion injury mechanism are more likely to receive a TKA as compared to the other injury mechanisms. Varus-flexion mechanisms appear to be almost two times more likely to undergo conversion to a TKA compared to the other injury mechanisms (adj HR 1.8, 95% CI, 1.1–3.1). Also, the valgus-flexion mechanism showed a trend towards an increased risk of conversion to TKA (adj HR 1.4, 95% CI, 0.9–2.1). This increased risk in fractures caused by a flexion force could be explained by the involvement of the posterior part of the tibial plateau as well as the relatively high incidence of C3 fractures. Our findings are in line with recent research, indicating that inadequate alignment of the sagittal tibial axis is strongly associated with conversion to TKA [16]. On the contrary, the valgus-extension mechanism was associated with a reduced risk on conversion to a TKA compared to other groups (adj HR 0.5, 95% CI, 0.3–0.9). This reduced risk could be explained by the fact that these fractures are mainly limited to the lateral compartment of the tibial plateau and usually consist of solely a central depression and/or pure split fragment [4].

This study has a few limitations which need to be addressed. First, we acknowledge that selection bias is inherent to a cross-sectional study design caused by loss to follow-up and non-response. Non-response analysis demonstrates that non-responders were on average 2 years younger and more often female. Yet, the small difference in age and gender is not expected to affect the generalizability of our results. Interestingly, when comparing our patient group with the patients described by Xie et al., our population has a higher proportion of females and less fractures caused by a varus force. This may be due to demographic and cultural differences between western Europe and China. Second, our research solely focusses on the relationship between the injury force mechanism and patient-reported outcome as well as conversion to TKA. For future research, a more detailed comparison between injury force mechanisms regarding both the fractures' location and initial displacement of tibial plateau fractures and of postoperative reduction based on two-dimensional CT slices and even more advanced three-dimensional imaging techniques would be helpful to further elucidate factors that affect prognosis. [17, 18]. Third, our subanalysis demonstrated some differences in reoperations due to soft tissue injuries between injury mechanisms. Although, the true level of concomitant ligamental and meniscal damage presented at the time of injury is still matter of debate. A recent review indicated that at least one ligamental or meniscal lesion is present in 93% of patients with tibial plateau fractures [19]. This again emphasizes the importance of a full assessment of concomitant soft tissue injuries in especially tibial plateau fractures with posterolateral involvement caused by varus-flexion mechanisms [20]. A preoperative MRI could therefore be useful in selected cases and contribute to decision-making regarding treatment strategies. In addition, a preoperative MRI could help to quantify the condition of the cartilage and the extent of preexisting osteoarthritis. We envision for the future to tibial plateau fracture management a three-dimensional diagnostic workup in which fracture characteristics and a full soft tissue assessment will be combined [17].

In conclusion, this large multicenter study demonstrated that tibial plateau fracture morphology based on injury force mechanism is predictive for patient-reported outcome and conversion to total knee arthroplasty. This study showed that in particular fractures caused by a varus-flexion force have a worse prognosis, whereas fractures caused by a valgus-extension force have less risk on conversion to a TKA. These findings can help in patient counselling, identifying patients who might benefit from advanced preoperative workup (i.e., MRI/3D surgical planning), and estimating prognosis in the management of complex tibial plateau fractures.

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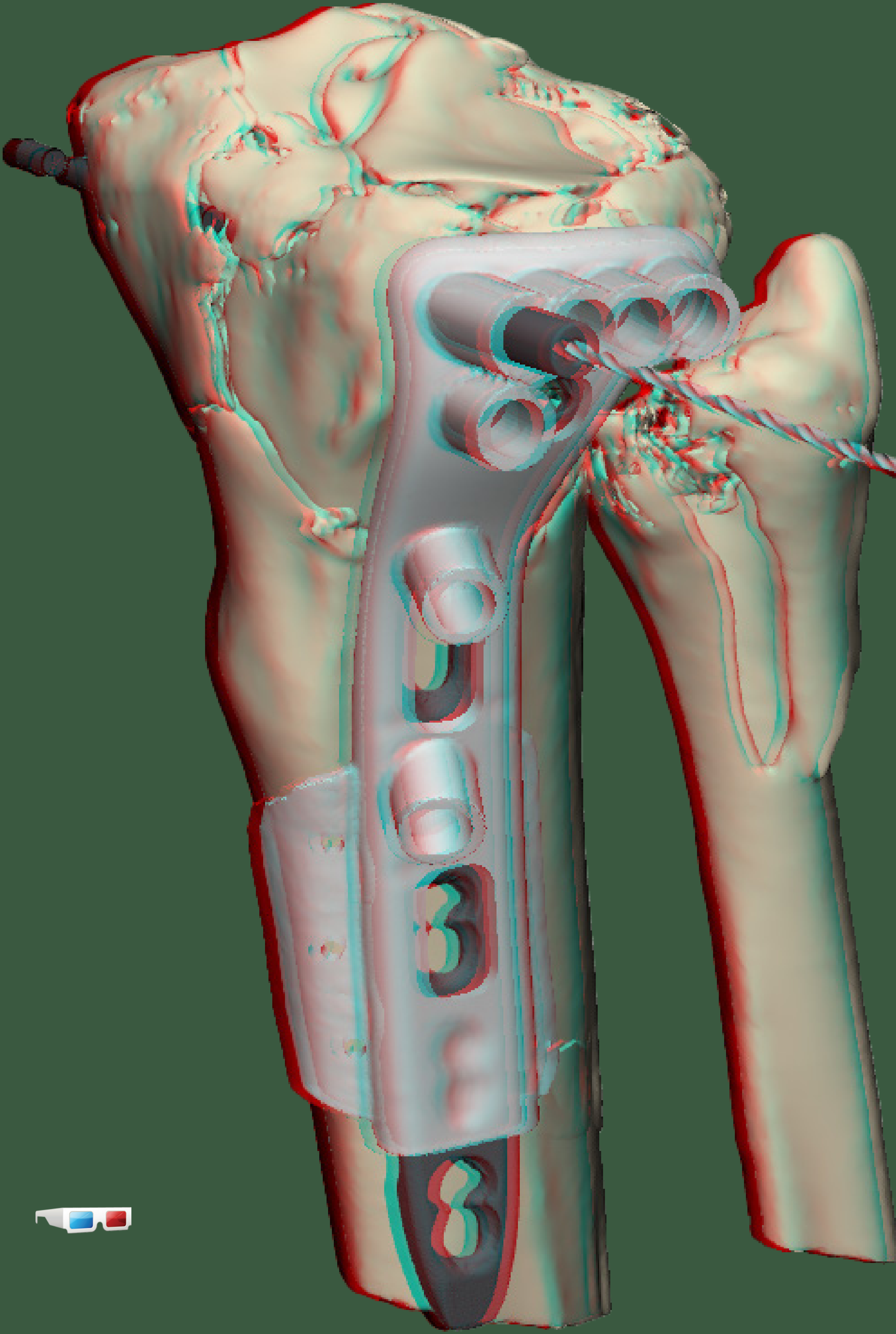
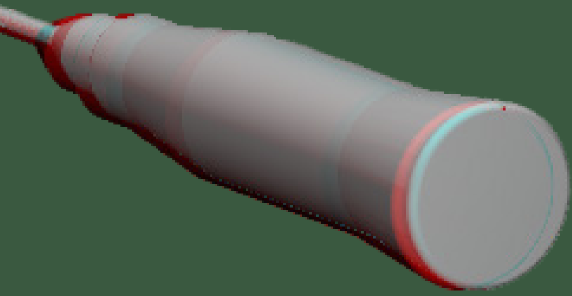
Appendix 1: Injury mechanisms correlated with patient-reported outcome

	Valgus-Flexion	Valgus-Extension	Valgus-Hyperextension	Varus-Flexion	Varus-Extension	Varus-Hyperextension	P-Value
No. of fractures	378	305	122	110	58	66	
KOOS Symptoms	76.8 ± 21.5	78.2 ± 20.7	75.7 ± 22.5	65.0 ± 21.9	80.9 ± 22.1	80.8 ± 18.0	<0.001
KOOS Pain	78.9 ± 21.9	79.1 ± 21.8	77.1 ± 22.5	67.0 ± 22.5	83.8 ± 19.4	82.9 ± 19.7	<0.001
KOOS ADL	80.0 ± 21.9	80.8 ± 21.2	79.1 ± 22.2	71.7 ± 22.5	83.0 ± 22.8	86.7 ± 16.8	<0.001
KOOS Sport	48.4 ± 35.4	51.4 ± 34.	50.7 ± 36.5	34.6 ± 29.1	54.5 ± 38.3	53.7 ± 32.8	<0.001
KOOS Quality of life	61.2 ± 28.9	60.9 ± 28.8	60.3 ± 29.5	47.8 ± 24.7	68.2 ± 28.1	63.2 ± 26.1	<0.001





THREE-DIMENSIONAL SURGICAL PLANNING

PART FOUR

CHAPTER 10

Does 3D-assisted surgery of tibial plateau fractures improve surgical and patient outcome? A systematic review of 1074 patients

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Abstract

Purpose: The aim of this systematic review was to provide an overview of current applications of 3D technologies in surgical management of tibial plateau fractures and to assess whether 3D-assisted surgery results in improved clinical outcome as compared to surgery based on conventional imaging modalities.

Methods: A literature search was performed in Pubmed and Embase for articles reporting on the use of 3D techniques in operative management of tibial plateau fractures. This systematic review was performed in concordance with the PRISMA-guidelines. Methodological quality and risk of bias was assessed according to the guidelines of the McMaster Critical Appraisal. Differences in terms of operation time, blood loss, fluoroscopy frequency, intra-operative revision rates and patient-reported outcomes between 3D-assisted and conventional surgery were assessed. Data were pooled using the inverse variance weighting method in RevMan.

Results: Twenty articles evaluating 948 patients treated with 3D-assisted surgery and 126 patients with conventional surgery were included. Five different concepts of 3D-assisted surgery were identified: ’3D virtual visualization’, ’3D printed hand-held fracture models’, ‘Pre-contouring of osteosynthesis plates’, ’3D printed surgical guides’, and ‘Intra-operative 3D imaging’. 3D-assisted surgery resulted in reduced operation time (104.7 vs. 126.4 min; $P < 0.01$), less blood loss (241 ml vs. 306 ml; $P < 0.01$), decreased frequency of fluoroscopy (5.8 vs. 9.1 times; $P < 0.01$). No differences in functional outcome was found (Hospital for Special Surgery Knee-Rating Scale: 88.6 vs. 82.8; $P = 0.23$).

Conclusions: Five concepts of 3D-assisted surgical management of tibial plateau fractures emerged over the last decade. These include 3D virtual fracture visualization, 3D-printed hand-held fracture models for surgical planning, 3D-printed models for pre-contouring of osteosynthesis plates, 3D-printed surgical guides, and intra-operative 3D imaging. 3D-assisted surgery may have a positive effect on operation time, blood loss, and fluoroscopy frequency.

INTRODUCTION

Intra-articular fractures of the tibial plateau are usually composed of complex fracture patterns including multiple fracture fragments, which are displaced and rotated in multiple directions. Achieving normal knee alignment and an optimal reconstruction of the articular surface decreases the risk of progressive osteoarthritis [1]. However, due to the complexity of these fractures, the goals of surgery cannot always be achieved. Recently, it has been shown that up to 30% of the surgically treated tibial plateau fractures resulted in a suboptimal reduction [2]. Assessment of the fracture is essential to fully understand the fracture pattern and to choose the optimal treatment strategy. Clinical decision-making and preoperative planning is mostly based on conventional imaging modalities, including plain radiographs, two-dimensional (2D) fluoroscopy and 2D CT images [3]. With these modalities, it is difficult to fully comprehend the true extent of these injuries, since the fracture fragments are often displaced and rotated in multiple directions. 3D visualization and printing modalities have the potential to provide the physician with a better understanding of the fracture pattern and could improve treatment strategy and patient outcome [4, 5].

The growing popularity and expansion across industries providing 3D printing resources has substantially decreased costs, increased access, and led to multiple applications in orthopaedic trauma surgery [6, 7]. Early results on the clinical application of 3D printing improved levels of understanding into complex fractures for both surgeons and patients and strengthened the informed consent process [8]. Also, 3D technologies may be valuable for teaching students about fracture morphology or explaining residents about the surgical plan [9]. 3D-assisted surgery encompasses the use of 3D technology to pre-plan the operation and guide the surgeon to the planned outcome during surgery. This includes a spectrum of modalities such as 3D visualization, 3D printing and patient-specific surgical guides or implants. However, the potential advantages of 3D-assisted surgery in tibial plateau fracture management are still subject of debate.

Despite the rapid advances in technology and an increasing number of publications on the applications of 3D technologies, a comprehensive overview of the current evidence for the application of 3D-assisted surgery of tibial plateau fractures is still lacking. Therefore, the purpose of this systematic review is to provide a complete and comprehensive overview of the currently used concepts of 3D-assisted surgery in patients receiving surgical treatment for their tibial plateau fracture by including both observational and intervention studies. The aim is to answer the following clinical research questions: (1) Does the clinical application of 3D-assisted surgery for tibial plateau fractures improve intra-operative results in terms of operation time, blood loss, fluoroscopy time and intra-operative surgical revisions compared to conventional surgery? (2) Does the application of 3D-assisted surgery improve postoperative results in terms of patient functional outcome compared to conventional surgery?

MATERIALS AND METHODS

This systematic review was performed according to the Preferred Reporting Items for Systematic Reviews (PRISMA) [10]. The protocol of this systematic review is registered in the international PROSPERO-database (CRD42021235524). Ethical approval was not required for this study.

Search strategy

The Pubmed and Embase libraries were searched on the 1st of February 2021 for articles published on state-of-the-art 3D technology between January 2010 until January 2021. The search string was developed in collaboration with a medical librarian. The exact search string for the different libraries is shown in the online supplementary (Appendix 1 in Supplementary file 1).

Study selection

Eligible studies for inclusion were randomized controlled trials, prospective and retrospective observational studies, descriptive studies, and case reports reporting on the use of 3D techniques in the management of tibial plateau fractures in orthopaedic trauma patients. Studies were excluded in case of: (1) paediatric fractures; (2) fracture classification studies; (3) animal or cadaveric studies; (4) review articles, letters to the editor or conference abstracts; and (5) studies in another language than English, German, French, Spanish or Dutch.

All articles were imported into Rayyan QCRI, a web-based sorting tool for systematic literature reviews [11]. The study selection was then performed in two phases: first two reviewers (NA, FIJ) independently screened the articles for eligibility based on the titles and abstracts using the Rayyan QCRI tool. Second, all articles which were considered eligible, were subsequently screened in full text by the same reviewers. Disagreement was resolved by discussion according to the Cochrane Handbook for Systematic Reviews of Interventions [12].

Quality check and data extraction

Methodological quality and risk of bias of the included studies were independently assessed by NA and FIJ according to the guidelines of the McMaster University Occupational Therapy Evidence-Based Practice Research Group [13]. Any continued disagreements were solved during a consensus meeting with NA, FIJ and IR. The McMaster critical appraisal consists of eight categories including: (1) study purpose; (2) literature review; (3) study design; (4) study sample; (5) study outcome; (6) study intervention; (7) study results; and (8) conclusions and implications. Scores were giving with ‘yes = 1 point’, ‘no = 0 points’, ‘not addressed (NS)’, and ‘not applicable (NA)’. The total score reflects the methodological quality with a maximum score of 16 for RCTs and 14 for other designs. The definitive score is expressed as a percentage that may vary from 0 to 100%, with a higher score indicating a higher methodological quality.

Scores between 90 and 100% were considered as excellent quality, studies between 75 and 89% as good quality studies and studies < 75% as moderate quality studies. The data extraction was independently conducted (NA, FIJ) using a precompiled extraction file (Microsoft Excel version 14.0; Microsoft Inc., Redmond, WA, USA). Information on study characteristics, fracture classification, 3D technologies and outcome measures were extracted. In case data regarding the reported outcomes was missing, authors were contacted to retrieve raw data or means with their standard deviations.

Outcome measures

All parameters describing the operation were determined to assess the effect of 3D-assisted surgery on intra-operative results. These parameters include operation time, blood loss, fluoroscopy time, and the number of intra-operative revisions of the fracture reduction or implant position as a result of intra-operative 3D imaging. Second, Patient-Reported Outcome Measures (PROMs) were recorded to evaluate the effect of 3D-assisted surgery on postoperative functional outcome.

Statistical analysis

Analysis of the extracted data was performed using RevMan (version 5.4.1). Continuous variables were presented as means with standard deviation (SD) and dichotomous variables as frequencies and percentages. Continuous outcomes were pooled using the inverse variance weighting method and were presented as weighted mean difference (WMD) with the corresponding 95% confidence interval (95%CI). Heterogeneity between studies was assessed for all reported outcomes by the I2 statistic for heterogeneity. The I2 statistic was interpreted according to the benchmarks of the Cochrane Handbook for Systematic Reviews of Interventions, which considered < 40% as irrelevant, 30–60% as moderate heterogeneity, 50–90% as substantial heterogeneity, and > 75% as considerable heterogeneity [12]. A P value of < 0.05 was considered to indicate statistical significance.

RESULTS

Search

The search resulted in 953 studies, and after removal of duplicates, 741 eligible studies were screened on title and abstract. Eventually, 22 articles were included for full-text screening of which two articles were excluded [14, 15]. Twenty studies met the inclusion criteria of this systematic review [8, 16-34]. The review process is summarized in Figure 1. There were seven prospective cohort studies [20, 21, 24, 27, 28, 32, 34], four retrospective cohort studies [16, 19, 26, 29], five case series [22, 23, 30, 31, 33], two case reports [17, 18], one descriptive study [8], and one observational study [25]. No Randomized controlled trials were found. The included studies enrolled a total of 1074 patients with a tibial plateau fracture (mean sample size 53.7; 1–559). Of all included patients, 948 received 3D-assisted tibial plateau fracture surgery and 126 had conventional surgery.

There were no differences in fracture classifications between the 3D-assisted and the conventional group. The study characteristics are presented in Table 1.

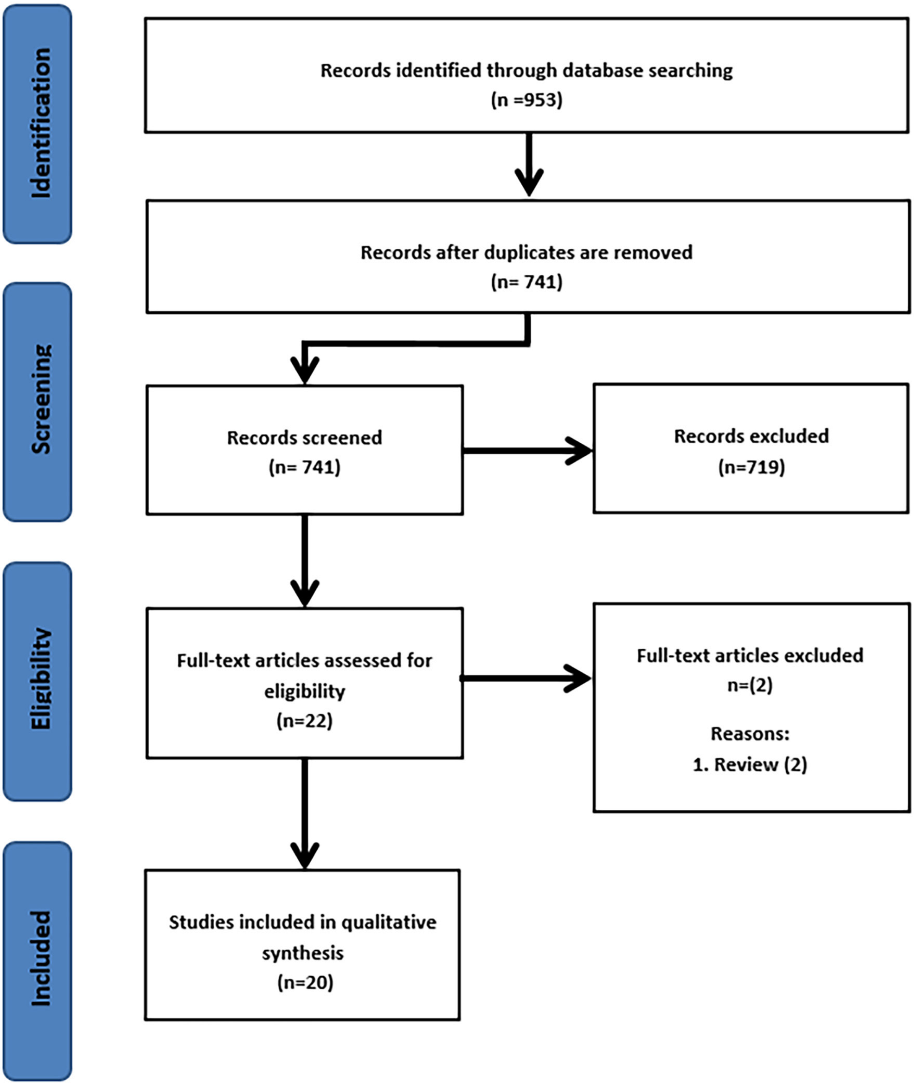


Figure 1: Flow diagram according to PRISMA strategy

Table 1: Study Characteristics

Study	Year	Country	Design	N	Period	3D Technology assessed	Fracture classification	Outcomes of interest
Beisemann et al. [13]	2019	Germany	Retrospective cohort study	559	2001 – 2017	Intra-operative 3D imaging	AO/OTA: 41 B1-3 and C1-3	Intra-operative revisions
Bizzotto et al.[14]	2016	Italy	Descriptive study	102 (O/W 19 TPFs)	2014 – 2015	3D printed fracture model	AO/OTA: 41 B1-3 and C1-3	User-experience
Citak et al. [15]	2010	Germany; USA	Case report	1	NS	Intra-operative 3D imaging	Schatzker III	User-experience; Operation time
Delcogliano et al. [16]	2020	Switzerland; Italy	Case-report	1	NS	Pre-contouring of osteosynthesis plate	NS	User-experience
Franke et al. [17]	2016	Germany	Retrospective cohort study	279 (O/W 109 TPFs)	2001 – 2011	Intra-operative 3D imaging	AO/OTA: 41 C1-3	Intra-operative revisions
Giannetti et al. [18]	2016	Italy	Prospective cohort study	40	NS	3D printed fracture model vs. Conventional	Schatzker I - VI	Length of hospital stay; Operation time; Tourniquet time; Blood loss; Rasmussen functional score
Guo et al. [19]	2019	China	Prospective cohort study	28	2016 – 2018	3D printed fracture model vs. Conventional	Schatzker II, IV-VI	Operation time; Blood loss; Fluoroscopy time; Costs; HSS Score
Horas et al. [20]	2020	Germany	Case series	4 (O/W 1TPF)	NA	3D printed fracture model	Moore type II	User-experience
Huang et al. [21]	2018	China	Case series	6	2013 – 2014	3D Printed surgical guide	Schatzker V-VI	Screw length; Screw entry point; Screw direction
Lou et al. [22]	2016	China	Prospective cohort study	72	2014 – 2015	3D printed fracture model vs. Conventional	Schatzker III-VI	Operation time; Blood loss; No. fluoroscopy; HSS Score
Mishra et al. [23]	2019	India	Observational study	91 (O/W 10 TPFs)	2017 – 2019	Pre-contouring of osteosynthesis plate	NS	Surgeons experience
Nie et al. [24]	2019	China	Retrospective cohort study	13	2015 – 2016	3D Printed surgical guide	Schatzker V-VI	Length of screws; Operation time; Blood loss; HSS Score
Ozturk et al. [25]	2020	Turkey	Prospective cohort study	20	2017 – 2018	3D printed fracture model vs. Conventional	Schatzker I, II & VI	Operation time; Blood loss; Tourniquet time; No. fluoroscopy; Rasmussen score
Ruan et al. [26]	2011	China	Prospective cohort study	30	2009 – 2010	Intra-operative 3D imaging vs. Conventional	Schatzker II, IV-VI	Intra-operative revisions
Shen et al. [27]	2020	China	Retrospective cohort study	42	2014 – 2018	3D printed fracture model vs. Conventional	Schatzker IV-VI	Operation time; Blood loss; No. Fluoroscopy; No. plate reshaping; Rasmussen score; HSS score
Suero et al. [28]	2010	USA; Germany	Case series	5	NS	3D virtual visualization	AO/OTA: 41 B3, C1 and C3	Planning time 3D reconstruction
Wang et al. [29]	2017	China; United Kingdom	Case series	6	NS	3D Printed surgical guide	Schatzker I, III & IV	Liker scale; Radiographic reduction; Oxford Knee Score
Wu et al. [30]	2019	China	Prospective cohort study	69	2014 – 2016	3D printed fracture model	Schatzker V-VI	Radiographic reduction; Rasmussen Clinical Funtional Score; Infections
Yang et al. [31]	2016	China	Case series	7	2012 – 2014	3D printed fracture model	Schatzker I - III	Operation time; Blood loss; Rasmussen Anatomy score; Rasmussen knee functional score
Zhang et al. [32]	2015	China	Prospective cohort study	36	2011 –2013	3D virtual visualization vs. conventional	Schatzker III	Operation time; Incision length; Blood loss

Identified 3D applications in tibial plateau fracture surgery

Within this search, five different concepts of 3D-assisted surgery in the management of tibial plateau fractures were identified over the past decade: '3D virtual fracture visualization', '3D printed hand-held models', 'Pre-contouring of osteosynthesis plates', '3D printed surgical guides' and 'Intra-operative 3D imaging'. Figure 2 depicts a representation of these concepts.

3D virtual fracture visualization

Two studies reported about the use of 3D virtual visualization of the fracture before surgery [30, 34]. Suero et al. used the VoXim software (IVS Solutions AG, Chemnitz, Germany) to create a 3D reconstruction of the fracture from which the surgeon determined the surgical plan [30], whereas Zhang et al. used the Mimics software (Materialise, Leuven, Belgium) to determine a preoperative plan in which the reduction procedure was simulated [34]. Using the 3D software, the required elevation of the depressed articular surface was measured and the surgical procedure was virtually planned.

3D-printed hand-held models

The majority of the studies reported on the use of 3D-printed models of tibial plateau fractures [8, 20,21,22, 24, 27, 29, 32, 33]. In these studies, a 3D-printed model of the fractured tibial plateau was used to determine the surgical plan and to guide the surgeon during surgery (Fig. 3). Furthermore, the 3D-printed models were found to be useful for educating residents and students, and to inform patients about their injury [8].

Pre-contouring of osteosynthesis plates

Two studies reported on the use of pre-contoured osteosynthesis plates [18, 25] using either a 3D-printed contralateral mirrored tibia or a virtually reduced fracture model. Using the printed models, implants were (pre-)operatively bended for optimized fitting along the contour of the proximal tibia.

3D printed surgical guides

Three studies described the use of 3D-printed surgical guides [23, 26, 31]. In two studies, the directions of the screws were virtually predetermined. A surgical guide was designed to translate the predetermined screw trajectories to the actual surgical procedure [23, 26]. Another application of a surgical guide was found in the operative correction of a malunited tibial plateau fracture by Wang et al. [31]. First the osteotomy was performed using a guide, which helped the surgeon to perform the (virtually) predetermined osteotomy. Secondly, a reduction guide was applied to help the surgeon to reduce the fragment to its original anatomical position.

Intra-operative 3D imaging

Four studies reported on the use of intra-operative 3D images [16, 17, 19, 28]. These

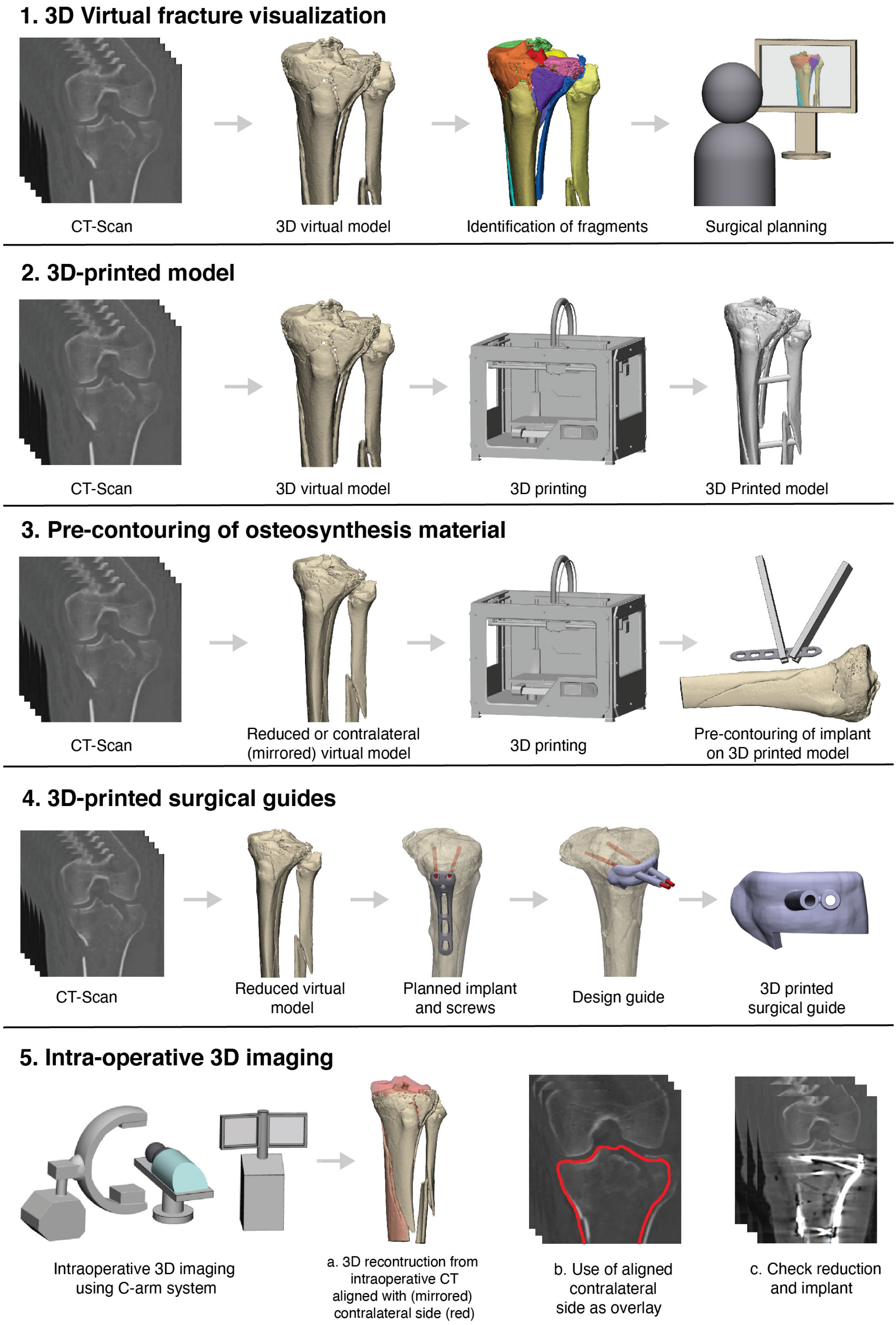


Figure 2: Schematic overview of the different concepts of 3D-assisted surgery in tibial plateau fractures

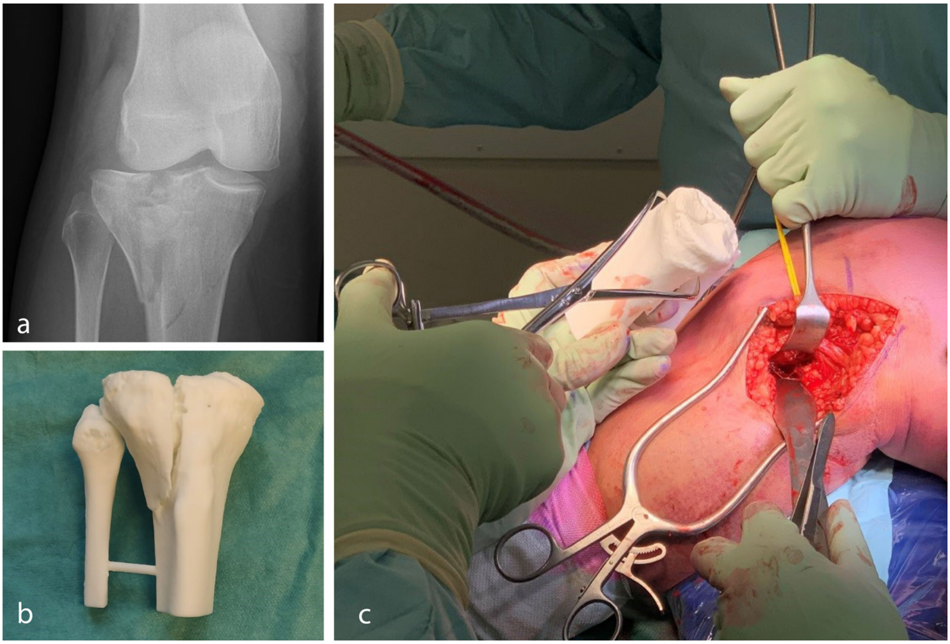


Figure 3: a) Fluoroscopy of an intra-articular fracture of the tibial plateau. b) 3D-printed handheld model of the tibial plateau fracture. c) Intra-operative fracture assessment using the 3D-printed handheld model

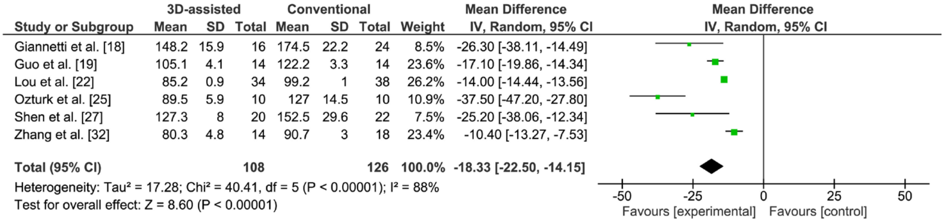
studies investigated the use of an intra-operative 3D imaging system, which was used to verify whether the achieved surgical reduction was satisfactory. Using this technology, the surgeon was able to make prompt perioperative decisions based on 3D instead of 2D fluoroscopy images. In case of dissatisfaction with the articular reduction or the position of the screws or implant, the surgeon could decide instantly during the operation to perform a revision.

Effect of 3D-assisted surgery on clinical outcome

To answer the first research question, the effect of 3D-assisted surgery on intra-operative results in terms of operation time, blood loss, fluoroscopy time and intra-operative revisions was assessed. The second research question concerns the effect of 3D-assisted surgery on post-operative results in terms of functional outcome.

Operation time

Six studies reported on operation time [20, 21, 24, 27, 29, 34], including one excellent quality, one good quality and four moderate quality studies (Appendix 2 in Supplementary file 2). Five studies reported that surgery assisted by a 3D-printed hand-held model of the fracture led to a significantly shorter operation time in comparison with conventional surgery [20, 21, 24, 27, 29]. Zhang et al. reported that the use of a preoperative 3D virtual model resulted in a significantly reduced operation time compared to conventional surgery [34]. The operation time was significantly shorter for the 3D-assisted group in comparison with the conventional group weighted mean difference (WMD) 18.3 min, 95% CI −22.5 to −14.5) (Fig. 4). The heterogeneity was considerable within these studies (I2 = 88%).



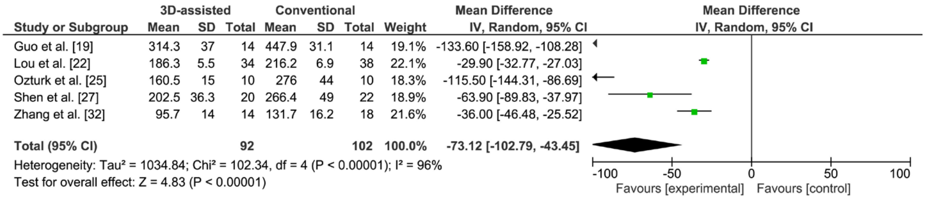
Study or Subgroup	3D-assisted Mean	SD	Total	Conventional Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Giannetti et al. [18]	148.2	15.9	16	174.5	22.2	24	8.5%	-26.30 [-38.11, -14.49]
Guo et al. [19]	105.1	4.1	14	122.2	3.3	14	23.6%	-17.10 [-19.86, -14.34]
Lou et al. [22]	85.2	0.9	34	99.2	1	38	26.2%	-14.00 [-14.44, -13.56]
Ozturk et al. [25]	89.5	5.9	10	127	14.5	10	10.9%	-37.50 [-47.20, -27.80]
Shen et al. [27]	127.3	8	20	152.5	29.6	22	7.5%	-25.20 [-38.06, -12.34]
Zhang et al. [32]	80.3	4.8	14	90.7	3	18	23.4%	-10.40 [-13.27, -7.53]
Total (95% CI)			**108**			**126**	**100.0%**	**-18.33 [-22.50, -14.15]**

Heterogeneity: Tau² = 17.28; Chi² = 40.41, df = 5 (P < 0.00001); I² = 88%
Test for overall effect: Z = 8.60 (P < 0.00001)

Figure 4: Forest plot for the operation time (min)

Blood loss

Six studies reported on blood loss [20, 21, 24, 27, 29, 34]. However, Giannetti et al. did not report the standard deviation and was, therefore, excluded from further analysis [20], leaving five studies, including one excellent quality study and four moderate quality studies. Four studies reported that 3D-printed model-assisted fracture surgery led to significantly less blood loss in comparison with conventional surgery [21, 24, 27, 29]. Zhang et al. reported that the use of a preoperative 3D virtual model resulted in significantly less blood loss compared to conventional surgery [34]. The blood loss was significantly less in the 3D-assisted group in comparison with the conventional group (WMD 73.1 ml, 95% CI −102.8 to −43.5) (Fig. 5). The heterogeneity was considerable within these studies (I2 = 96%).



Study or Subgroup	3D-assisted Mean	SD	Total	Conventional Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Guo et al. [19]	314.3	37	14	447.9	31.1	14	19.1%	-133.60 [-158.92, -108.28]
Lou et al. [22]	186.3	5.5	34	216.2	6.9	38	22.1%	-29.90 [-32.77, -27.03]
Ozturk et al. [25]	160.5	15	10	276	44	10	18.3%	-115.50 [-144.31, -86.69]
Shen et al. [27]	202.5	36.3	20	266.4	49	22	18.9%	-63.90 [-89.83, -37.97]
Zhang et al. [32]	95.7	14	14	131.7	16.2	18	21.6%	-36.00 [-46.48, -25.52]
Total (95% CI)			**92**			**102**	**100.0%**	**-73.12 [-102.79, -43.45]**

Heterogeneity: Tau² = 1034.84; Chi² = 102.34, df = 4 (P < 0.00001); I² = 96%
Test for overall effect: Z = 4.83 (P < 0.00001)

Figure 5: Forest plot for the blood loss (ml)

Fluoroscopy frequency

Four studies reported on the frequency of use of fluoroscopy [21, 24, 27, 29], including one study of excellent quality and three of moderate quality. The use of fluoroscopy was significantly reduced in the 3D-assisted group in comparison with the conventional group (WMD 3.5 times used, 95% CI −4.7 to −2.4) (Fig. 6). The heterogeneity was considerable within these studies (I2 = 96%).

Table 2: Study outcomes

Measure	Study	3D technology	Groups		Outcome		
			3D (N)	Conventional (N)	3D	Conventional	P-value
Operation results							
Operation time (min) Mean ± SD	Giannetti et al. [18]	3D printed fracture models	16	24	148.2 ± 15.9	174.5 ± 22.2	0.041*
	Guo et al.[19]		14	14	105.1 ± 4.1	122.2 ± 3.3	<0.05*
	Lou et al.[22]		34	38	85.2 ± 0.9	99.2 ± 1.0	<0.001*
	Ozturk et al. [25]		10	10	89.5 ± 5.9	127 ± 14.5	<0.05*
	Shen et al.[27]		20	22	127.3 ± 8.0	152.5 ± 29.6	0.001*
	Zhang et al.[32]	3D Virtual visualization	14	18	80.3 ± 4.8	90.7 ± 3	<0.001*
Blood loss (mL) Mean ± SD	Guo et al.[19]	3D printed fracture models	14	14	314.3 ± 37.0	447.9 ± 31.1	<0.05*
	Lou et al.[22]		34	38	186.3 ± 5.5	216.2 ± 6.9	0.013*
	Ozturk et al. [25]		10	10	160.5 ± 15	276 ±44	<0.05*
	Shen et al.[27]		20	22	202.5 ±36.3	266.4 ± 49.0	0.001*
	Zhang et al.[32]	3D Virtual visualization	14	18	95.7 ± 14.0	131.7 ± 16.2	<0.001*
Fluoroscopy frequency (Number of times)	Guo et al.[19]	3D printed fracture models	14	14	2.7 ± 0.4	4.7 ± 0.6	<0.05*
	Lou et al.[22]		34	38	5.3 ± 0.2	7.1 ± 0.2	<0.001*
	Ozturk et al. [25]		10	10	10.7 ± 2	18.5 ± 2.2	<0.05*
	Shen et al.[27]		20	22	6.5 ± 1.1	11 ± 1.8	0.001*
Intra-operative 3D imaging	Beisemann et al.[13]	Intraoperative revision rates resulting from 3D imaging (%)	-559		148 (26.5%)	-	-
	Franke et al.[17]		109	-	29 (27%)	-	-
	Ruan et al.[26]		30	-	6 (20%)	-	-
PROMs							
Hospital for Special Knee Surgery (HSS) score	Lou et al.[22]	3D printed fracture models	34	38	90.0 ± 0.3	85.0 ±0.4	<0.001*
	Shen et al.[27]		20	22	86.1 ± 7.7	79.1 ± 6.8	0.003*
Hospital for Special Knee Surgery (HSS): Excellent and good rate (%)	Guo et al.[19]	3D printed fracture models	14	14	92.9	85.7	0.54

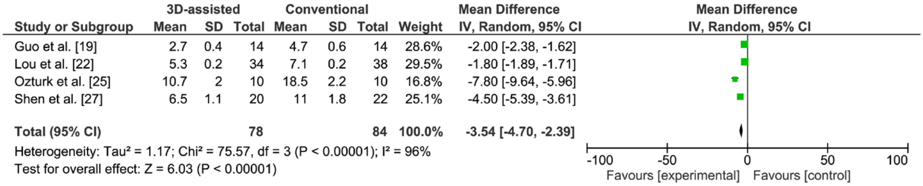


Figure 6: Forest plot for the fluoroscopy frequency (number of shots)

Intra-operative revision rates

Three studies reported on immediate intra-operative revision rates resulting from intra-operative 3D imaging [16, 19, 28], including two good quality and one moderate study. These articles reported on a total of 698 patients of which 183 (26.2%) patients had an instant intra-operative revision of the fracture reduction or implant position as a result of intra-operative 3D imaging (Table 2).

Patient-reported functional outcome

Three studies reported on functional outcome [21, 24, 29], of which one was of excellent quality. All studies used the Hospital for Special Surgery (HSS) scoring system. The HSS scoring system is based on a total of 100 points. A HSS score of ≥ 85 points is considered excellent, 70–84 points is good, 60–69 points is fair, and ≤ 59 points is poor [35]. Two studies reported the actual HSS score [24, 29], whereas another study provided the rating of the score [21]. The weighted HSS score was 88.6 (86.1–90) in the 3D-assisted group and 82.8 (79.1–85) in the conventional group. Guo et al. reported no relevant differences in HSS score between 3D printing assisted and conventional surgery [21].

DISCUSSION

The rationale for applying 3D technology in tibial plateau fracture surgery is that it may optimize preoperative planning, potentially improves fracture reduction and eventually benefits the patients' recovery. This systematic review aimed to provide an overview of the current concepts of 3D-assisted tibial plateau fracture surgery and their relation to clinical outcome. The search was not limited to study design, which provides a complete overview of all 3D applications for tibial plateau fracture surgery published over the last decade. Five different concepts of 3D-assisted surgery were identified including '3D virtual visualization', '3D printed hand-held models', 'Pre-contouring of osteosynthesis plates', '3D printed surgical guides', and 'Intra-operative 3D imaging'. Pooled analysis of studies, concerning mainly the use of 3D-printed models, showed to have a positive effect on operation time, blood loss, and fluoroscopy frequency.

This review revealed that the majority of the studies (nine) used 3D-printed hand-held fracture models in clinical practice. Converting a CT-scan into a hand-held 3D-printed model could provide valuable insights for the pre-operative planning of the fracture reduction and fixation. Care should be taken regarding the soft tissue injuries which cannot be taken into account in the 3D model. These models could be sterilized and used in theatre to guide the surgeon during the operation. From an educational perspective, these models allow surgical trainees to accurately plan the surgery ahead of time, and subsequently discuss their plan with a senior. Moreover, a 3D-printed model may help in providing patient information during clinical consultation [8]. One could argue that most of these benefits could also be achieved with only 3D virtual visualization of the fracture [36]. Besides that it saves the cost of printing (€ 50 -100,- for a proximal tibia), it is instantly available and has no environmental impact. Yet, in this review only two articles were identified that described the use of a 3D virtual model for surgical planning [30, 34]. It should be noted that 3D visualization and printing itself has a learning curve, and it takes time to become familiar with the software. Virtual preoperative planning and discussing a new case may easily take up to two hours, of which a significant part is spent on the process of segmenting the CT-scan into a 3D model, virtually reducing the fracture fragments, and predetermining the implant positions.

Several of the identified 3D concepts go beyond 3D visualization and focus on translating a predetermined plan to the operative procedure itself. Pre-contouring the osteosynthesis plate on a 3D-printed model of either the mirrored contralateral side or the reduced fracture site might improve implant fitting. Implant pre-contouring showed beneficial results in acetabular fracture surgery regarding decrease in operation time and improved fracture reduction [37]. Moreover, good implant fitting in tibial plateau fracture surgery could reduce the need for elective implant removals due to optimal fitting of bulky plates. This technology was described in two of the included articles which also showed potential improvement in operation time, fracture reduction and patient outcome [18, 25]. These studies, however, were pilot studies and, therefore, limited to small case series. The full potential of this technique should therefore be further explored.

The use of 3D-printed surgical guides should be considered another 3D technique, which aims at translating a pre-operative plan to the patient [23, 26, 31]. Three case series introduced this concept for tibial plateau fractures and showed that 3D-printed guides may help the surgeon to accurately adhere to the pre-determined surgical plan. 3D-printed surgical guides are widely used in clinical practice and have been successfully applied in neurosurgery, dental surgery, spinal surgery and maxillofacial surgery [38]. In spinal surgery for instance, the use of 3D-printed drill guides led to accurate vertebral screw insertion with a mean deviation of 1.4 mm and 6.7° from the planned entry point and screw trajectory, respectively [39].

Several studies assessed the use of intra-operative 3D imaging to verify fracture reduction, implant position, and screw trajectories and lengths. These studies showed instant intra-operative revision rates up to 27% as a consequence of the 3D imaging [16, 19, 28]. However, these studies evaluated only the intra-operative acts resulting from the 3D imaging and not the clinical outcome. Downsides of this technique are the radiation exposure and increased operation time, where in more than 70% of the patients the intra-operative 3D imaging did not lead to any adjustments in the achieved surgical reduction. It should therefore be evaluated which fractures might benefit from this technique, and which not.

The main research questions concerned the effects of 3D-assisted surgery of tibial plateau fractures on intra- and postoperative outcomes. Surgery assisted by 3D visualization or prints resulted in improved intra-operative results in terms of operation time, blood loss and frequency of fluoroscopy. This is in line with previous findings regarding the use of 3D printing techniques in orthopaedic trauma fracture care [5, 38]. 3D technology provides the surgeon the ability to extensively prepare the surgery. This benefits the workflow in the operating room leading to a reduction in operation time and the frequency of fluoroscopy. A possible explanation for the decrease in blood loss could be the efficiency during the operation and a smaller incision size due to improved preoperative planning. Zhang et al. showed that the 3D-assisted group had a significant smaller incision length [34]. Studies included in this review indicate that 3D-assisted surgery might improve functional outcome. It could be hypothesized that 3D-assisted surgery leads to improved preoperative planning and eventually better reduction of the fracture. This assumption is still a matter of debate since no post-operative CTs were available in any of the studies. The effect of the 3D technique on the fracture reduction should, therefore, be further assessed.

This review has some strengths and some limitations. First, this review provides a clinically question-driven overview about the ongoing debate whether these advanced 3D technologies contribute to operation results and patient-recovery. To present a complete overview of the stare-of-the-art 3D technologies applied for tibial plateau fracture surgery we were forced to not restrict our search to solely RCTs. Inevitably, the included studies therefore encompass a wide range of study designs including case series, observational studies and retro- and prospective cohort studies. Due to the wide range of the methodological quality and heterogeneity between these studies, the pooled analysis of operation time (I2 = 88%), blood loss (I2 = 96%) and fluoroscopy frequency (I2 = 96%) should be interpret with caution. Moreover, some studies suffered from a limited sample size. Lastly, different concepts of 3D technologies were aggregated under the term “3D-assisted surgery”. However, the studies used for the pooled analysis mainly concerned the use of 3D-printed models and 3D virtual visualization. This hampers the generalizability of the results and therefore these should be interpreted with caution. High-quality randomized controlled trials for each of the 3D application are, therefore, recommended to fully explore the potential benefits of these rapid developing advanced technologies.

CONCLUSION

Over the last decade, five different concepts of 3D-assisted surgical management of tibial plateau fractures emerged: '3D virtual visualization', '3D printed hand-held models', 'Pre-contouring of osteosynthesis plates', '3D printed surgical guides', and 'Intra-operative 3D imaging'. Several studies indicate that 3D-assisted surgery had a positive effect on operation time, blood loss, frequency of fluoroscopy, and functional outcome. However, 3D technologies also come with a price in preparation time and production costs (i.e. software, materials, printing devices). The potential benefits should be further investigated in high-quality studies before widespread clinical use.

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APPENDIX

Appendix 1: Search Strategy

Database	Search string
Pubmed (n=401)	(3D[tiab] OR three dimension*[tiab] OR 3 dimension*[tiab] OR "Printing, Three-Dimensional"[Mesh] OR "Imaging, Three-Dimensional"[Mesh]) AND ("Tibia"[Mesh] OR "Tibial Fractures"[Mesh] OR tibial[tiab] OR tibia[tiab]) AND (fractur*[tiab] OR "Fractures, Bone"[Mesh]) AND "2010/01/01"[PDat] : "3000/12/31"[PDat]
Embase (n=521)	('three dimensional imaging'/exp OR 'three dimensional printing'/exp OR '3d':ti,ab OR '3 dimension*':ti,ab OR 'three dimension*':ti,ab) AND ('tibia'/exp OR 'tibial plateau fracture'/exp OR tibia:ti,ab OR tibial:ti,ab) AND ('fracture'/exp OR fractur*:ti,ab) AND [embase]/lim AND [2010-2021]/py

Appendix 2: Quality assessment

Categories	**Shen, 2020**	**Zhang, 2015**	**Giannetti, 2016**	**Beisemann, 2019**	**Franke, 2016**	**Huang, 2015**	**Nie, 2019**	**Lou, 2016**
1. Study purpose								
Was the study question clearly stated?	1	1	1	1	1	1	1	1
2. Literature review								
Was relevant background literature reviewed?	1	0	1	1	1	1	0	0
3. Study design	RCS	PCS	PCS	RCS	RCS	CS	RCS	PCS
4. Sample								
Was the sample described in detail?	1	1	1	1	1	1	1	1
Was the sample justified?	1	1	0	1	1	0	1	1
Were the groups randomized?	0	1	0	0	0	0	0	1
Was randomizing appropriate done?	NA	0	NA	NA	NA	NA	NA	0
5. Outcomes								
Were the outcome measures reliable?	1	1	1	1	1	1	1	1
Were the outcome measures valid?	1	1	1	1	1	1	1	1
6. Intervention								
Intervention was described in detail?	1	0	1	1	1	1	1	1
Contamination was avoided?	NA	1	1	NA	NA	NA	NA	1
Cointervention was avoided?	NA	NS	NS	NA	NA	NA	NA	NS
7. Results								
Results were reported in terms of statistical significance?	1	1	1	0	0	1	1	1
Were the analysis method/s appropriate?	1	1	1	1	1	1	0	1
Clinical importance was reported?	1	1	1	1	1	1	1	1
Drop-outs were reported?	1	0	0	0	0	0	1	0
8. Conclusion								
Conclusions were appropriate given study methods and results?	1	1	1	1	1	1	1	0
Total	12/13	12/15	11/14	10/13	10/13	10/13	10/13	11/15
%	92	80	79	77	77	77	77	73

Yes = 1 point, no = 0 points, not addressed = NS, not applicable = NA, RSC = retrospective cohort, PSC = prospective cohort, DS = descriptive study, OS = observational study, CS = case series, CR = case report

Guo, 2019	Ozturk, 2020	Wu, 2019	Yang, 2016	Ruan, 2011	Bizotto, 2016	Horas, 2020	Suero, 2010	Citak, 2010	Delcogliano 2020	Mishra, 2019	Wang, 2017
1	0	1	0	1	1	1	1	1	1	0	0
0	1	1	0	1	1	1	1	1	1	0	1
PCS	PCS	PCS	CS	PCS	DS	CS	CS	CR	CR	OS	CS
1	1	1	1	1	1	1	1	1	0	1	1
1	0	1	1	1	1	0	0	0	0	1	0
1	1	0	0	0	0	0	0	0	0	0	0
0	NS	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
1	1	0	1	0	0	0	1	0	0	0	0
1	1	1	1	0	0	0	0	0	0	0	0
1	1	1	1	1	1	1	0	1	1	1	1
1	1	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
NS	NS	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
1	1	1	1	1	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
1	1	1	1	1	1	1	1	1	1	1	1
0	0	0	0	0	0	0	0	0	0	0	0
0	1	0	1	0	0	1	1	0	0	0	0
10/15	10/15	8/13	8/13	7/13	6/13	6/13	6/13	5/13	4/13	4/13	4/13
67	67	62	62	54	46	46	46	38	31	31	31

CHAPTER 11

3D surgical planning including patient-specific drilling guides for tibial plateau fractures

A prospective feasibility study

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Abstract

Aims: Proper preoperative planning benefits fracture reduction, fixation, and stability in tibial plateau fracture surgery. We developed and clinically implemented a novel workflow for 3D surgical planning including patient-specific drilling guides in tibial plateau fracture surgery.

Methods: A prospective feasibility study was performed in which consecutive tibial plateau fracture patients were treated with 3D surgical planning, including patient-specific drilling guides applied to standard off-the-shelf plates. A postoperative CT scan was obtained to assess whether the screw directions, screw lengths, and plate position were performed according the preoperative planning. Quality of the fracture reduction was assessed by measuring residual intra-articular incongruence (maximum gap and step-off) and compared to a historical matched control group.

Results: A total of 15 patients were treated with 3D surgical planning in which 83 screws were placed by using drilling guides. The median deviation of the achieved screw trajectory from the planned trajectory was 3.4° (interquartile range (IQR) 2.5 to 5.4) and the difference in entry points (i.e. plate position) was 3.0 mm (IQR 2.0 to 5.5) compared to the 3D preoperative planning. The length of 72 screws (86.7%) were according to the planning. Compared to the historical cohort, 3D-guided surgery showed an improved surgical reduction in terms of median gap (3.1 vs 4.7 mm; $p = 0.126$) and step-off (2.9 vs 4.0 mm; $p = 0.026$).

Conclusion: The use of 3D surgical planning including drilling guides was feasible, and facilitated accurate screw directions, screw lengths, and plate positioning. Moreover, the personalized approach improved fracture reduction as compared to a historical cohort.

Take home message
(1) This study is among the first clinical studies to evaluate the application of 3D-printed surgical drilling guides in combination with conventional plates in tibial plateau fracture surgery.
(2) The use of 3D surgical planning including drilling guides during the operation was feasible, and facilitated accurate screw directions, screw lengths, and plate positioning according to the preoperative 3D surgical planning.

INTRODUCTION

Tibial plateau fractures are among the most challenging fractures to treat. Surgical treatment of these fractures usually consists of open reduction and internal fixation using plates and screws [1,2]. Ideal plate positioning and screw trajectories benefit fracture fixation and stability of the construct [3]. The introduction of anatomical shaped variable angle-locking compression plates (VA-LCPs) enables variable angle screw trajectories (diverging up to 30°) to ensure adequate fracture fixation and articular support [4]. With this concept, screw trajectories can be adjusted until these fit patient-specific fracture morphology [5]. Based on 2D perioperative fluoroscopy, however, it can be hard to determine and verify the optimal screw positions relative to the fracture fragments.

Over the last few years, innovative 3D technologies have been increasingly used for the surgical treatment of tibial plateau fractures [6]. Virtual or 3D-printed models of a fracture could aid in understanding complex fracture patterns and plan surgical treatment [7,8]. In addition, surgeries could be virtually preplanned, and surgical guides can be designed to translate a virtual surgical plan to the actual surgical procedure [9]. Recently, we developed an innovative workflow for the clinical application of 3D-printed drilling guides which envelop conventional 'off-the-shelf' implants to aim the screws in the predetermined directions [9]. This personalized surgical approach enabled execution of the preoperative plan and helped to attain predetermined osteosynthesis plate and screw positions. In this study, our concept of surgical guides will be applied in combination with VA-LCP proximal tibia plates, potentially ensuring optimal screw placement.

We hypothesized that 3D virtual surgical planning in combination with 3D-printed surgical guides facilitates optimal screw directions and improved fracture reduction as compared to conventional surgery. The aim of this study is to assess whether 3D-guided surgery can be used to facilitate optimal screw trajectories in tibial plateau fracture surgery. We assessed the feasibility and accuracy of this innovative procedure through a prospective clinical cohort study and compared results with a historical cohort.

METHODS

Study design

A prospective feasibility study was performed in which consecutive patients treated surgically for a tibial plateau fracture with an anterolateral VA-LCP plate between January 2021 and April 2023 were included. Patients aged > 18 years with the availability of a CT scan with a slice thickness of < 1 mm were eligible for 3D-assisted treatment. Excluded were patients who had open fractures, pathological fractures, or were treated nonoperatively. The intervention consisted of 3D surgical planning including the design, production, and clinical application of patient-specific drilling guides. A matched historical control group (conventional group) consisted of consecutive patients who were operated with standard VA-LCP plates (i.e. without 3D planning and surgical guides) within the two years before the introduction of 3D-assisted surgery (2019 to 2020). Written informed consent was obtained from all patients. The University Medical Center Groningen institutional review board approved the study procedures, and the research was performed in accordance with the relevant guidelines and regulations (NL72543.042.20./201900879). Patients did not receive any reimbursement for participation. This study is reported following the STROBE guidelines [10].

Preoperative fracture characteristics

All preoperative CT scans at the time of the injury were assessed by two blinded observers (FFAIJ, NA). The observers consisted of an attending orthopaedic trauma surgeon (> ten years of experience) and technical physician (> five years of experience). CT scans were assessed in the axial, sagittal, and coronal planes to measure the initial displacement in terms of gap and step-off according to previously described methods [11,12], and to determine the fracture classification according to the AO/OTA classification system [13]. Patient characteristics were retrieved from the electronical patient file.

3D surgical planning and guide design (intervention group)

Mimics Medical software (version 23.0; Materialise, Belgium) was used to create a 3D model of the tibial plateau fracture based on the CT data. A segmentation process was performed using a preset bone threshold (Hounsfield Units ≥ 226). All fracture fragments were identified and separated to individual masks, by combining both region growing and split mask functions. Subsequently, the fragments were checked and, if needed, manually separated from adjacent fragments. Virtual fracture reduction was performed, in which all fracture fragments were moved back to their anatomical position. This process was supported with the (mirrored) contralateral side or template of a healthy tibia. Together with the treating surgeon, the virtual fracture reduction was verified, and optimal position of the plate and screw trajectories were predetermined. Plate and screw trajectories were digitally positioned within the 3D software.

The drilling guides were designed to perfectly envelop the VA-LCP lateral plates (DePuy Synthes, USA). The drilling guides consisted of multiple cylindric tubes in which a stainless-steel drill sleeve (316 L, 25 mm in length, with an inner diameter of 2.9 mm for a 2.8 mm drill) could be inserted to guide the drill bit. After the designing process (3-Matic 15.0; Materialise), the guides were 3D-printed by selective laser sintering using polyamide 12 (PA12) and sterilized for usage during the operation. The 3D surgical planning and guide design process is depicted in Figure 1.

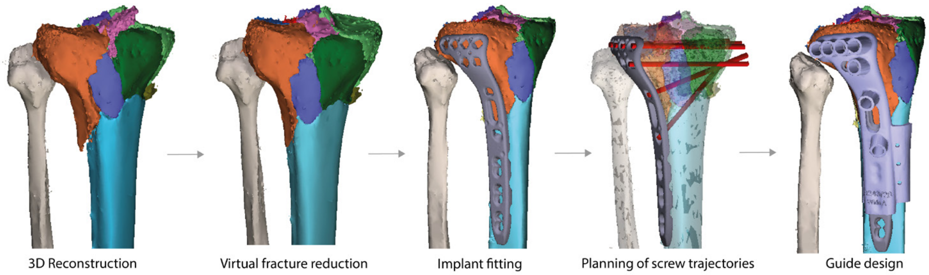

Figure 1: Process of 3D surgical planning including patient-specific drilling guide design. First, a 3D reconstruction is created from the initial CT scan in which all fragments are identified and assigned a different colour. Then, virtual fracture reduction is performed, after which a plate is digitally fitted and screw trajectories (red bars) are predetermined. Finally, the drilling guide is designed to envelop the variable angle-locking compression plate (VA-LCP) to guide the drill bit and screw in the planned trajectories. To position the plate at the intended location, bone-supporting extensions were added to the design of the guide. The guide is subsequently 3D-printed and used during the operation to convert the virtual plan to the patient.

3D-assisted surgery

All surgeries were performed by attending orthopaedic trauma surgeons with several years of experience. 3D-assisted surgery included a virtual surgical planning (Fig. 2), including a 3D-printed patient-specific drilling guide. Depending on the fracture characteristics, either an anterolateral approach or a combined two-incision anterolateral and medial approach was performed. In case of bicondylar fractures, the double plating technique was used, in which first the medial plateau was reconstructed and fixated. Then, lateral fragments were reduced and the VA-LCP plate was positioned and screws were placed with our patient-specific drilling guide (Fig. 3). In case of a lateral fracture only, fracture reduction was performed through an anterolateral approach and positioning of the plate, and screws were again executed with the aid of the patient-specific drilling guide. Screw lengths were chosen according to the preoperative planning.

Postoperative assessment of 3D-guided surgery

All patients underwent a postoperative CT scan within two weeks after surgery. The CT data were used to generate a postoperative 3D model of the reconstructed tibial plateau with the implants and screws in situ. In order to assess the accuracy of the screw placements, the postoperative 3D model of the implant with screws was aligned with the preoperative planning of the position of the implant. The difference between the achieved and obtained screw direction were assessed by measuring the angle between those screw trajectories (Fig. 4). The difference between the planned and obtained entry point was determined by measuring the Euclidean distance between these entry points. Quality of the fracture reduction was assessed by measuring the residual intra-articular incongruence (maximum gap and step-off) on the postoperative CT scan in both the 3D-guided group (intervention) and the conventional group (control).

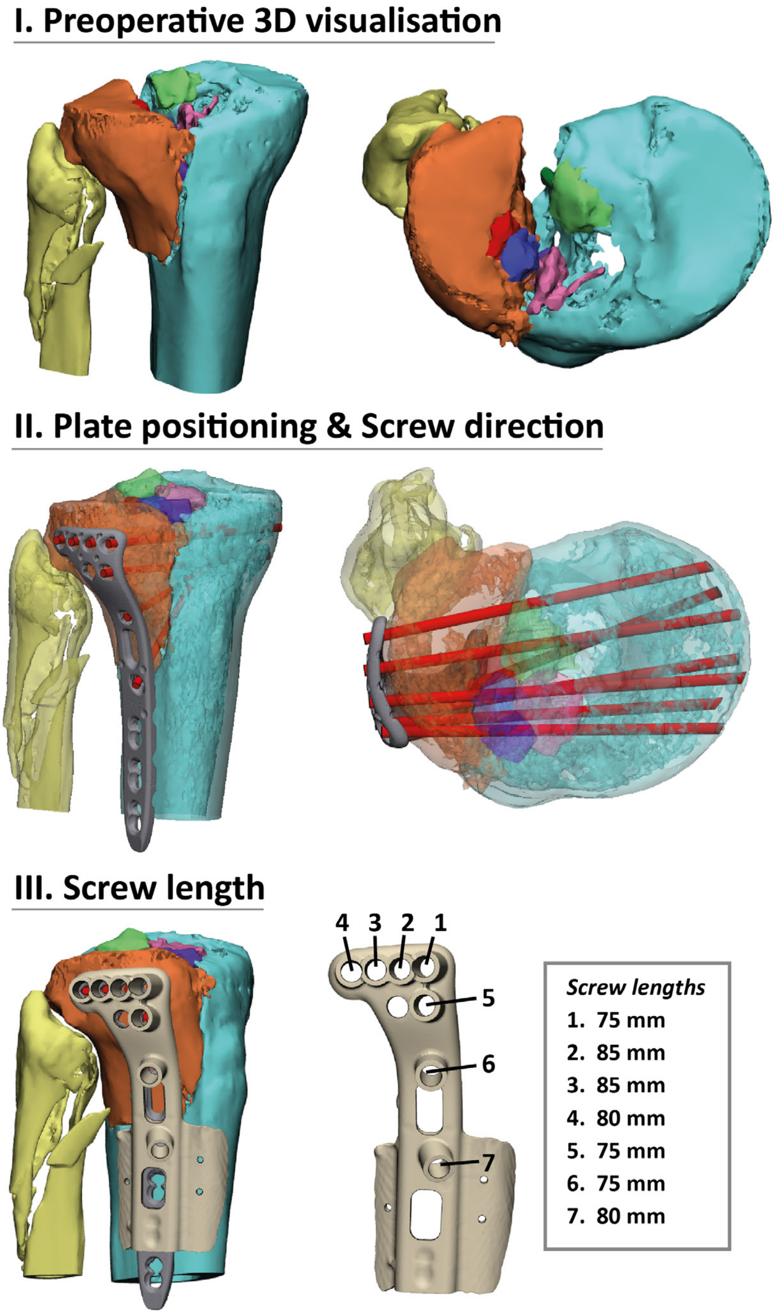

Figure 2: 3D virtual surgical planning including visualization of the fracture (I), visualization of the planned position of the plate and directions of screws (II), and the lengths of the screws (III). A 3D-printed guide that fits on top of the plate (III) is used to translate the preoperative plan (e.g. guiding plate position, screw directions, screw lengths) to the actual operative procedure. (see Appendix to experience the ***3D anaglyph*** of the case represented in this figure)

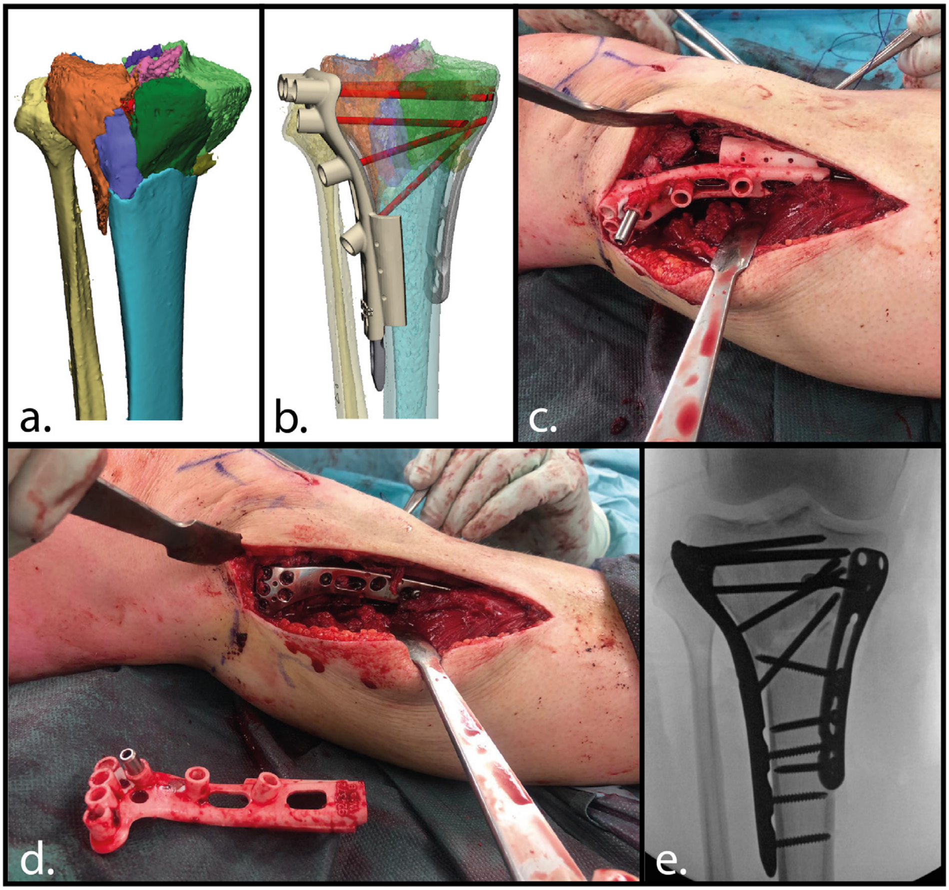

Figure 3: 3D-assisted surgery in case 3. a) Preoperative 3D visualization of the fracture. b) Virtual surgical planning. c) Intraoperative use of the 3D-printed surgical drilling guides. Screw trajectories are drilled through the stainless-steel drill sleeve. d) Osteosynthesis plate after screw placement. e) Fluoroscopic image of the achieved surgical result.

Conventional treatment (control group)

The control group was treated surgically with standard VA-LCP plates without 3D visualization and 3D-printed guides during surgery. Treatment in these patients was according to the standard of care.

Patient demographic data

Between January 2021 and April 2023, a total of 15 patients were treated for their tibial plateau fracture by using our 3D planned method including surgical guides. In addition, results of a control group, consisting of patients treated for similar fractures in the years before introduction of 3D-guided tibial plateau fracture surgery, were evaluated. Table I depicts the patient characteristics of both groups. Both groups were quite similar in terms of age, sex, American Society of Anesthesiologists (ASA) grade [14], and fracture classification.

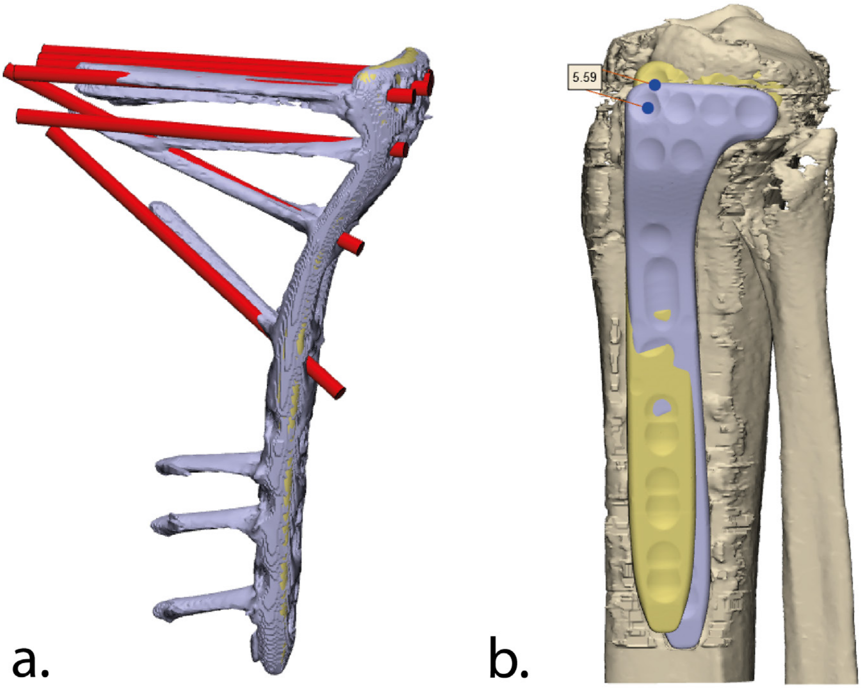

Figure 4: Postoperative assessment of the accuracy of the screw placement. a) The difference between the achieved (purple) and obtained (red) screw directions were assessed by measuring the angle between those screw trajectories. b) The planned (yellow) and obtained (purple) position of the implant. The difference between the planned and the obtained screw entry points were determined for all screws by measuring the Euclidean distance between these entry points.

Table 1: Patient characteristics

Characteristics	Intervention (n=15)	Control (n=15)	P-value
Age, yrs (IQR)	55 (44 to 59)	61 (59 to 65)	0.01*
Female, n(%)	10 (66.7)	11 (73.3)	0.69†
ASA Classification, n(%)			0.549†
ASA I	3 (20)	3 (20)	
ASA II	11 (73.3)	9 (60)	
ASA III	1 (6.7)	3 (20)	
AO/OTA classification, n(%)			0.587†
AO/OTA B3	7 (46.7)	7 (46.7)	
AO/OTA C1	1 (6.6)	0 ()	
AO/OTA C3	7 (46.7)	8 (53.5)	
Median days until surgery (IQR)	10 (8 to 13)	8 (7 to 11)	0.101*

* Mann-Whitney U test; † Chi-squared test; ASA, American Society of Anesthesiologists; IQR, interquartile range.

Quality of fracture reduction

Patients in both the intervention and control group underwent a postoperative CT scan in order to assess quality of the surgical intervention. Fracture reduction was assessed in terms of maximum residual gap and step-off. Assessment was performed independently by two blinded observers, and the average of both measurements for each patient was used for the analysis.

Statistical analysis

Statistical analysis was performed using SPSS (version 23; IBM, USA). Continuous variables were presented as mean and standard deviation (SD) for normally distributed data, and median and interquartile range (IQR) if not normally distributed. A p-value of less than 0.05 was considered statistically significant. Descriptive statistics were used to describe the study population. Mann-Whitney U and chi-squared test were performed to assess differences in baseline characteristics and quality of the reduction between intervention and control group.

RESULTS

Accuracy of guided screw insertion

A total of 83 screws were placed through the guided method. The median deviation of the achieved screw trajectory from the planned trajectory was 3.4° (2.5° to 5.4°), whereas the median difference between planned and achieved position of the entry point was 3.0 mm (IQR 2.0 to 5.5). In total, for 11 out of 83 screws (13.3%) the actual screw length used was slightly shorter than the originally planned screw length. This occurred because the inserted screws were blocked by the screws placed freehand from the medial plate on the opposite side (Table II; see Supplementary Material 1 for example). Placement of a slightly shorter screw did not result in any clinical consequences.

Table 2: Accuracy of the screw placement.

Parameter	Value
Screws placed, n	83
Screw angulation, ° (IQR)	3.4 (2.5 to 5.4)
Screw entry point, mm (IQR)	3.0 (2.0 to 5.5)
Correct screw length, n (%)	72 (86.7)

IQR, interquartile range.

Fracture reduction

Initial fracture displacement did not show a significant difference between the patients who underwent 3D planned surgery (intervention) and the control group (Table III). 3D planned tibial plateau fracture surgery showed an improved surgical reduction in terms of median gap (3.1 vs 4.7 mm; p = 0.13) and step-off (2.9 vs 4.0 mm; p = 0.03) compared to the control group.

Table 3: Initial fracture displacement and quality of the articular reduction in terms of median gap and step-off in the intervention as compared to the control group. Data are presented as medians and interquartile ranges.

Fracture displacement as measured on CT-scans	Intervention n=15	Control n=15	P-Value*
Preoperative Gap, mm	9.7 (4.9 to 13.2)	7.9 (6.9 to 11.8)	0.713
Preoperative Step-off, mm	9.9 (5.6 to 11.9)	6.7 (5.3 to 14.8)	0.744
Postoperative Gap, mm	3.1 (1.8 to 4.7)	4.7 (3.0 to 5.4)	0.126
Postoperative Step-off, mm	2.9 (1.8 to 3.7)	4.0 (3.3 to 5.0)	0.026

* Mann-Whitney U test.

DISCUSSION

Operative treatment of tibial plateau fractures is usually complex due to fracture comminution, displacement in multiple directions, limited exposure, and soft-tissue injuries. Moreover, achieving optimal plate and screw positions might be challenging, and the achieved position is hard to verify with fluoroscopy. Preoperative planning is crucial to achieve optimal results in tibial plateau fracture surgery: 'plan your operation, and operate your plan' is one of the adages in surgery. In this study, we developed and presented the next level of surgical planning in tibial plateau fracture surgery. This is one of the first clinical studies in which we literally plan our operation in 3D, and operate our plan by using 3D-printed drilling guides in combination with regular tibial plates. In summary, this personalized approach facilitates accurate screw directions, screw lengths, and plate positioning according to the preoperative 3D surgical planning. Moreover, it improved fracture reduction as compared to a historical cohort.

Over the past years, several innovative 3D technologies have been introduced for the surgical treatment of tibial plateau fractures as described in an extensive review about this topic [6]. These include two preliminary attempts of 3D-printed screw guides to facilitate guided screw placement [15,16]. First, Huang et al [15] used 3D-printed templates in six patients to insert several Kirschner (K)-wires, which mark the preferred screw directions. After placing K-wires, this template was removed and a locking plate was placed along the K-wires, which were subsequently exchanged for screws. Although they use the concept of guided surgery, their basic K-wire templates differ substantially from our patient-specific drilling guides. Their preliminary results show a deviation between planned and achieved screw trajectories of 6.34° (SD 3.42°) and 4.68° (SD 3.94°) in the coronal (x–y) and transverse (x–z) plane, respectively. Second, Nie et al [16] used 3D-printed templates to facilitate screw osteosynthesis. These templates were designed to fit the shape of the bone and to guide K-wire placement. After K-wires were removed, screws were inserted and plates were placed alongside the screws. Additionally, this technique differed substantially since they only facilitate 'out-of-plate' screw placement. Their method was applied in only four patients, and the achieved accuracy was not assessed. Our method adds to these previous reports, because our surgical guides were designed to envelop the plate as well as guide the position of the implant due to press-fit extensions on the guide. In addition, stainless-steel drill sleeves could be inserted to directly guide the drill bit in contrary to the previous reported methods of drilling K-wires which indirectly guide screw placement. Our technique leads to accurate screw placement with a median deviation of the screw trajectories of only 3.4° (IQR 2.5° to 5.4°) and median deviation of the screw entry point (i.e. plate position) of only 3.0 mm (IQR 2.0 to 5.5). This degree of accuracy is sufficient, since this could be accounted for in the 3D preoperative planning, and the screws did not penetrate the joint. Moreover, this study included both an intervention and historic control group of 15 patients. As compared to this historic cohort, our 3D-guided workflow showed an improved fracture reduction.

Surgeons may wonder how 3D-guided surgery benefits the operative results, and what it takes to implement it in their own hospital. The improved surgical results in the 3D-guided patients could be explained by the detailed preoperative 3D planning in combination with the accurate intraoperative translation of the plan by using a patient-specific drill guide. The positive effects of 3D planning and surgical guides on patients' outcome in orthopaedic trauma care have been previously described [7,17]. The 3D workflow as described in the current study requires some efforts including segmentation of the bone fragments, virtual fracture reduction, planning of the implants and screws, and finally the design of the surgical guides. Therefore, it requires several multidisciplinary moments in which the (3D) surgical plan is discussed before surgery, potentially leading to an improved understanding of the fracture morphology and treatment strategy. In order to facilitate this 3D workflow, specialized 3D software, technical physicians skilled in the software, and dedicated surgeons are needed. This workflow starts with a 3D segmentation of the fracture, after which the fracture is reduced and a proposal for implant position and screw direction is made (which usually takes 1 to 2 hours). The proposed plan is discussed and altered based on the preferences of the surgeons, after which the surgical guide is designed (a process which takes 30 to 60 minutes). After the design of the surgical guide is approved in another multidisciplinary meeting, the approved design will be fabricated (costs €50 to €200). In our study, this was done by an external printing facility which complies with EU safety regulations, and takes three to four days including returning the printed guides by mail. Lastly, after receiving the

3D-printed guides, they were sterilized within our own hospital sterilization unit, which takes another day, leading to a total of five to six days' process time for the whole 3D workflow. Due to swelling of the knee after the injury, surgery is generally extended for about seven days following the injury. Considering a timeframe of five to six days for the whole 3D workflow, this process was deemed feasible.

One of the limitations of this study is that it is a case-control study instead of a randomized controlled trial. Ideally, patients should be randomized into either the intervention or the control group. However, the goal of this pilot study was to show the feasibility of an innovative 3D workflow. Another limitation of our proposed method is that in the 3D surgical planning, anatomical reduction of the fracture is assumed. Prior to the use of our 3D guides, the fracture needs to be reduced. However, the complexity of the fracture does not always allow for perfect anatomical reduction in practice. Therefore, accurate positioning of the implant with the enveloped surgical drilling guide appeared to be to most challenging part of our 3D workflow. Yet, despite these challenges, achieved surgical reduction was sufficient in all cases for executing the 3D surgical planning. Lastly, widespread clinical implementation of this workflow depends of the presence of the required resources. Personnel skilled in 3D software are required, as is a printing facility that complies with regional safety regulations. In this study, 3D printing costs varied between €50 and €200. In addition, the designing, printing, and sterilization usually takes around five to six days. Yet, in most cases this timeframe was feasible, as the delay in surgery due to surrounding soft-tissue swelling associated with tibial plateau fractures provides an opportunity for the completion of the 3D surgical work-up.

In summary, this is among the first clinical studies to evaluate the application of 3D-printed surgical drilling guides in combination with conventional plates in tibial plateau fracture surgery. The use of 3D surgical planning including drilling guides during the operation was feasible, and facilitated accurate screw directions, screw lengths, and plate positioning according to the preoperative 3D surgical planning. Moreover, 3D surgical planning improved fracture reduction as compared to a historical cohort.

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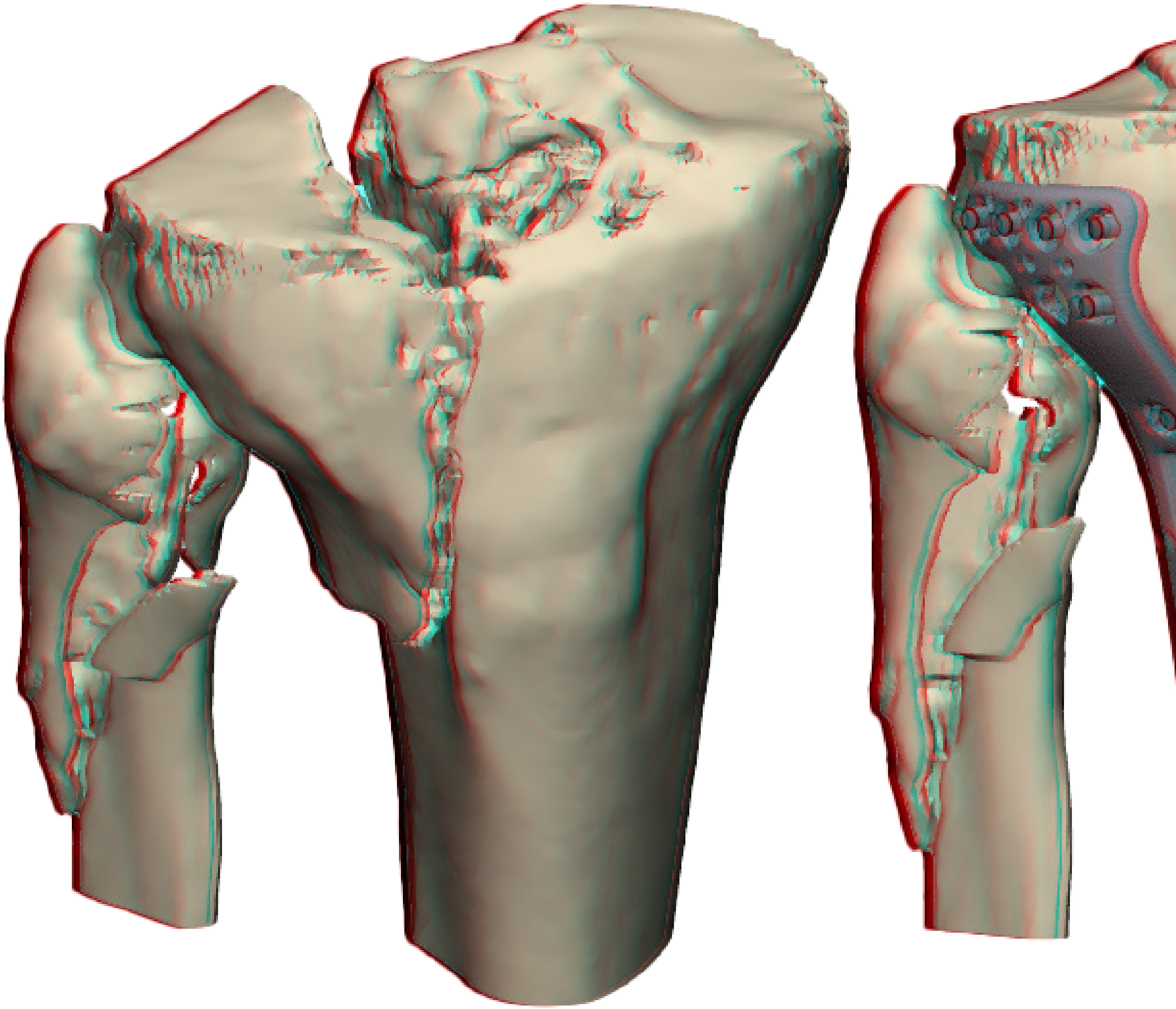
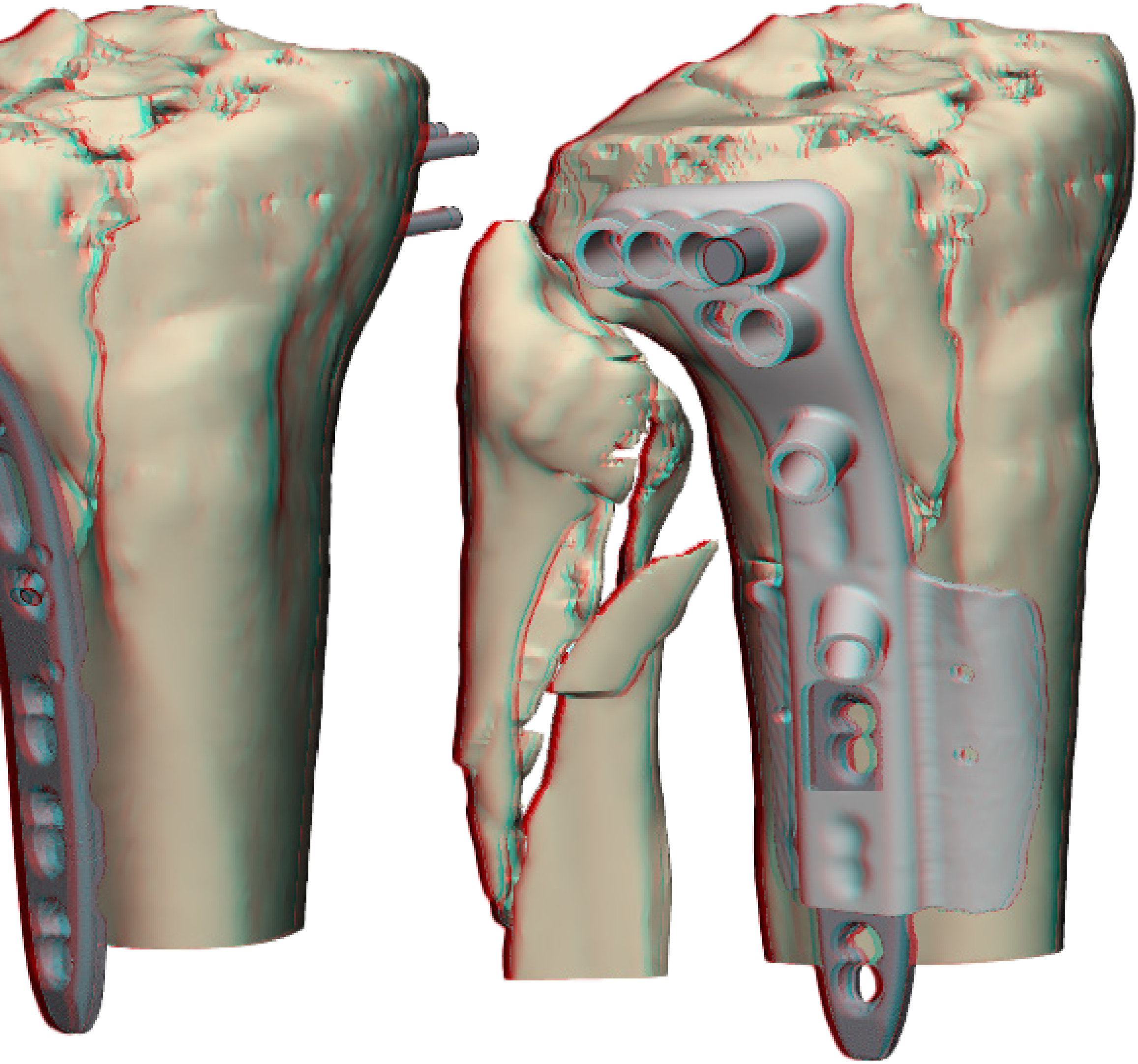
APPENDIX

Appendix 1: 3D anaglyph of the virtual surgical planning including patient-specific drilling guide as featured in figure 2 of this chapter.





CHAPTER 12

Development of patient-specific osteosynthesis including 3D-printed drilling guides for medial tibial plateau fracture surgery

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Abstract

Purpose: A substantial proportion of conventional tibial plateau plates have a poor fit, which may result in suboptimal fracture reduction due to applied -uncontrolled- compression on the bone. This study aimed to assess whether patient-specific osteosyntheses could facilitate proper fracture reduction in medial tibial plateau fractures.

Methods: In three Thiel embalmed human cadavers, a total of six tibial plateau fractures (three Schatzker 4, and three Schatzker 6) were created and CT scans were made. A 3D surgical plan was created and a patient-specific implant was designed and fabricated for each fracture. Drilling guides that fitted on top of the customized plates were designed and 3D printed in order to assist the surgeon in positioning the plate and steering the screws in the preplanned direction. After surgery, a postoperative CT scan was obtained and outcome was compared with the preoperative planning in terms of articular reduction, plate positioning, and screw direction.

Results: A total of six patient-specific implants including 41 screws were used to operate six tibial plateau fractures. Three fractures were treated with single plating, and three fractures with dual plating. The median intra-articular gap was reduced from 6.0 (IQR 4.5–9.5) to 0.9 mm (IQR 0.2–1.4), whereas the median step-off was reduced from 4.8 (IQR 4.1–5.3) to 1.3 mm (IQR 0.9–1.5). The median Euclidean distance between the centre of gravity of the planned and actual implant was 3.0 mm (IQR: 2.8–3.7). The lengths of the screws were according to the predetermined plan. None of the screws led to screw penetration. The median difference between the planned and actual screw direction was 3.3° (IQR: 2.5–5.1).

Conclusion: This feasibility study described the development and implementation of a patient-specific workflow for medial tibial plateau fracture surgery that facilitates proper fracture reduction, tibial alignment and accurately placed screws by using custom-made osteosynthesis plates with drilling guides.

INTRODUCTION

Fractures of the tibial plateau are usually composed of complex fracture patterns including multiple bone fragments. During surgical treatment of these fractures, the main goals are to re-establish joint stability, achieve normal limb alignment and restore the articular surface [1, 2]. Surgical treatment of intra-articular tibial plateau fractures consists of closed or open reduction and internal fixation using screw or plate fixation. Adequate fit of the plates is of great importance for both the biomechanical stability and to minimize soft-tissue irritation [3,4,5]. In addition, plates who match the anatomical shape of the bone can serve as a template which facilitates indirect fracture reduction. In the last decades, plate osteosynthesis has continuously evolved into the present generation of off-the-shelf locking plates which match the average shape of the tibia [6]. However, both clinical experience and literature suggest that in a substantial proportion of the population these plates still have an improper fit [5]. The recent studies regarding statistical shape models of the tibia confirm this assumption by showing large anatomical bone variations, especially around the tibial plateau and across ethnic groups [4, 7].

A plate with a poor fit may result in suboptimal fracture reduction and therefore inadequate tibial alignment due to applied -uncontrolled- compression on the bone during surgery, which may result in residual displacement of fracture fragments. One of our recent clinical cases clearly illustrates the potential negative effect of a poor fitting medial tibial plateau plate. This patient was treated for a Schatzker 6 tibial plateau fracture with dual plate fixation. Compression on the bone with a poor-fitting posteromedial plate led to inadequate sagittal alignment of the tibia (Fig. 1). Medial tibial plateau plates in particular often do not fit properly in our experience, which could be explained by the variation in size and slope and this is slightly more prominent at the medial plateau when compared with the lateral plateau [4]. This case illustrates that despite the progress in osteosynthesis plates and surgical techniques, even experienced surgeons do not always achieve adequate articular reduction and tibial alignment. Similar clinical experiences were confirmed by Meulenkamp et al., who reported that in 30% of the surgically treated tibial plateau fractures, an unsatisfactory reduction of fracture fragments was achieved [8]. Achieving adequate fracture reconstruction is essential since it is associated with improved functional outcome and reduced risk of progressive osteoarthrosis and decreased risk on conversion to a total knee arthroplasty (TKA) [9, 10].

Recently, we developed an innovative surgical procedure for fracture treatment using 3D virtual surgical planning and custom-made patient-specific osteosynthesis plates with drilling guides [11, 12]. Two previous studies showed that a personalized approach with perfect implant fitting facilitates proper fracture reduction and yielded good clinical outcomes. We hypothesized that this new patient-specific approach would benefit tibial plateau fracture treatment and may result in optimal osteosynthesis plate fitting, templating for adequate fracture reductions, and accurate screw placements. The clinical relevance of our study is the currently available medial tibial plateau plates often do not fit properly and hamper fracture reduction. A personalized approach might overcome this issue. The aim of this study is to assess whether our innovative workflow can be used to fabricate patient-specific implants for medial tibial plateau fracture surgery. We assessed the feasibility, accuracy, and efficiency of this innovative procedure through six cadaveric knees.

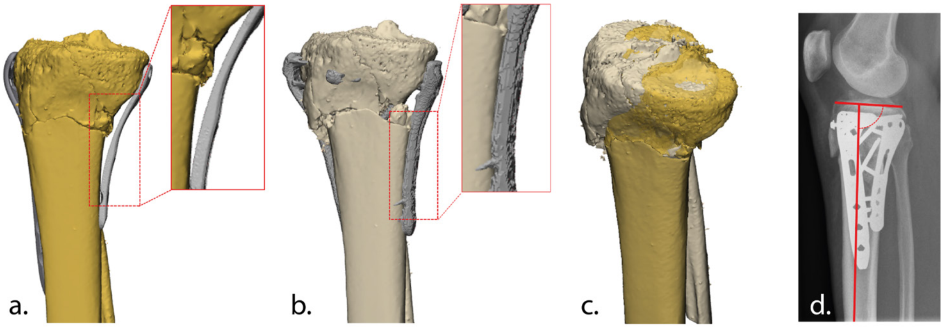

Figure 1: Clinical case of a female patient in her 40 s, who was treated for a Schatzker 6 tibial plateau fracture. a) Surgical plan involving dual-plating including a posteromedial plate which had substantial space in between plate and bone due to suboptimal fitting. b) Postoperative result: Due to uncontrolled compression on the bone with the poor-fitting posteromedial plate, the tibial shaft and the fragments are not properly aligned. c) Planning (yellow) vs. postoperative result (grey). d) Postoperative result on a lateral radiograph shows reduced sagittal alignment (2°)

MATERIALS AND METHODS

Specimens and fracture fabrication

Three full body Thiel embalmed human cadavers were obtained from the anatomy department [13]. Three pure medial articular fractures (Schatzker 4, one fragment) and three multifragmentary complete articular fractures (Schatzker 6, three fragments) were created by a consultant trauma surgeon. The fractures were made in each knee using an oscillating saw and an osteotome through a parapatellar approach. The fabricated fractures and the degree of initial displacement were comparable with fractures seen in clinical practice [14]. A CT scan of the lower extremities was made of each cadaver according to our standard imaging procol used in clinical practice (0.6 mm slice thickness, voxel size 0.4 mm), which is the starting point for our 3D surgical planning.

3D surgical planning

3D models of all cadaveric knees were created using the Mimics Medical software package (Version 22.0, Materialise, Leuven, Belgium). The CT data (DICOM files, Digital Imaging and Communications in Medicine) was imported after which a segmentation process was performed by using a preset bone threshold (Hounsfield Units ≥ 226). All bones in the knees were separated to individual masks, by combining both region growing and split mask functions. This process was repeated in order to separate the independent fragments. Subsequently the fragments were checked and if needed manually separated from adjacent fragments. Based on a template of a healthy tibia, the fracture was virtually reduced by repositioning the fragments to their anatomical location, after which the 3D models were imported into the 3-matic software (Version 15.0, Materialise, Leuven, Belgium). The optimal screw trajectories and lengths were determined taken into account the fracture pattern. Based on these screw positions, a patient-specific plate was designed in a multidisciplinary meeting with surgeons, technical physicians, and engineers.

The patient-specific titanium plates for the tibia were designed according to our well-established workflow for the manufacturing of patient-specific plates [11, 12]. The shape of the plate was designed to perfectly deliver the preferred screw locations and directions. The customized titanium osteosynthesis plates were created using 3-Matic software version 15.0 (Materialise), Solidworks Professional software version 2020 (Dassault Systèmes Solidworks), and the Geomagic package for Solidworks (3D Systems). The plates were made of a medical grade titanium alloy by CNC milling using a 5-axis milling machine. Fabrication was done by a regional ISO 13485 certified medical company (Witec Medical B.V., Stadskanaal, The Netherlands).

The drilling guides, which were designed to fit on top of the customized plates, assisted the surgeon to position the plate and steer the screws in the preplanned direction. The drilling guides consisted of multiple cylinderic holes in which a stainless-steel drill sleeve (316 L, 25 mm in length, with an inner diameter of 2.9 mm for a 2.8 mm drill) could be inserted to guide the drill. In addition, bone supporting extensions were added to the design, which directed the plate to its intended position. After the designing process, the guides were 3D-printed by selective laser sintering using polyamide 12 (PA12), which can be sterilized for usage during the operation. The entire 3D surgical planning workflow from CT scan to surgery is depicted in Fig. 2.

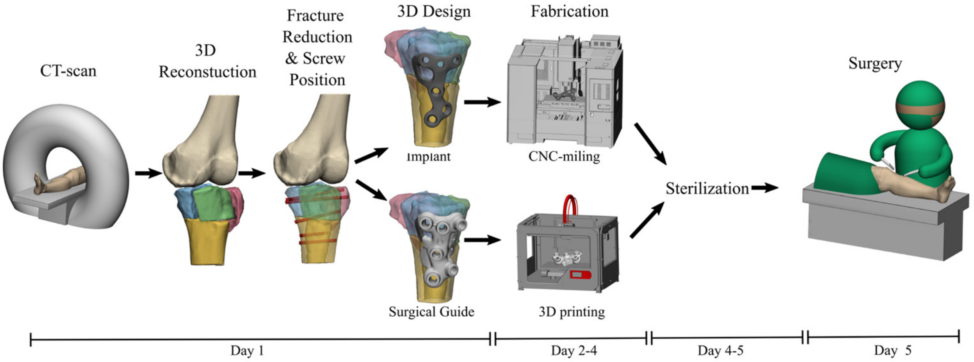

Figure 2: Workflow of manufacturing the patient-specific implant and the accompanied surgical guides for management of medial tibial plateau fractures. The whole workflow of designing, producing, sterilizing and (clinical) application is feasible within days in our clinic.

Patient-specific osteosynthesis plate design

The patient-specific osteosynthesis plates were designed with 3-Matic software (version 17.0 Materialise), Solidworks Professional software (version 2020, Dassault Systèmes Solidworks), and the Geomagic package for Solidworks (3D Systems). The implant was designed to fit the specific anatomy such that the plate could serve as a template which facilitates the fracture reduction. Minimal clearance (± 0.2 mm) between the bone and implant was used to ensure a proper fit. For optimal fitting on the bone, the patient-specific implants were designed in such a way that the distal part of the implant followed an S-shape which covers the margo medialis of the proximal tibia (Fig. 3, bottom right). In addition, the proximal part of the implant was designed to follow the curvature of the medial tibial condyle of the proximal tibia just below the articular surface (Fig. 3, upper right). The unique features of the implant force the fracture fragments in correct alignment with the tibial shaft when applying compression. In addition, the fitting of the implant provides direct feedback to the surgeon regarding the fracture reduction, since poor fitting suggests that the fracture reduction in suboptimal.

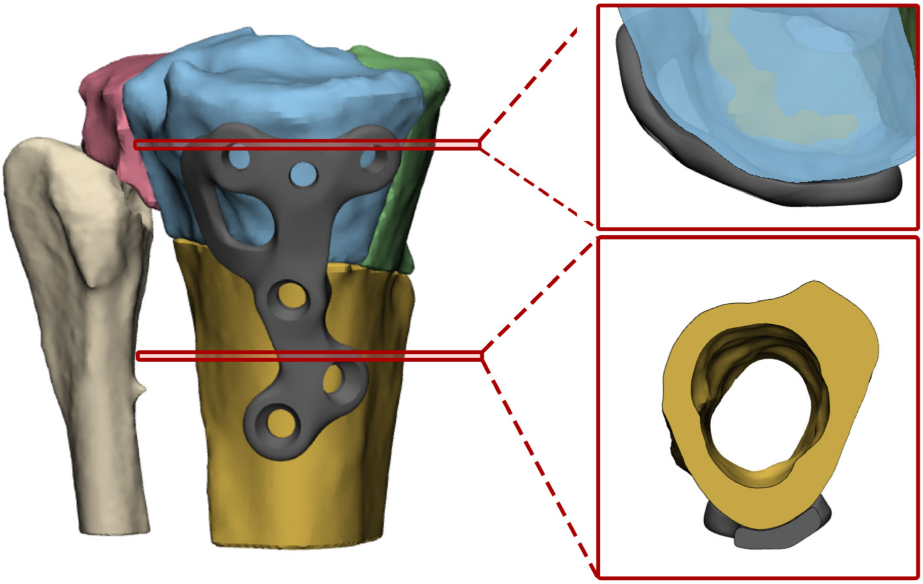

Figure 3: Unique features of the patient-specific implant (case 2, left): The distal part of the implant followed an S-shape which covers the margo medialis of the proximal tibia, whereas the proximal part of the implant was designed to follow the curvature of the medial condyl of the proximal tibia (right). This unique combination forces the tibial shaft and the fragments in the desired sagittal alignment.

In this series, the proximal screws holes were designed to fit 3.5 mm locking screws, whereas the distal screw holes along the shaft of the tibia fit 3.5 mm cortical screw heads. For future application, choice for locking or cortical screws could be personalized based on the surgeons' preference. The patient-specific plate is accompanied with a surgical guide, which fitted on top of the plate and facilitated the surgeon in positioning the plate and achieving the preplanned screw trajectories by drilling through the drill sleeve (Fig. 4).

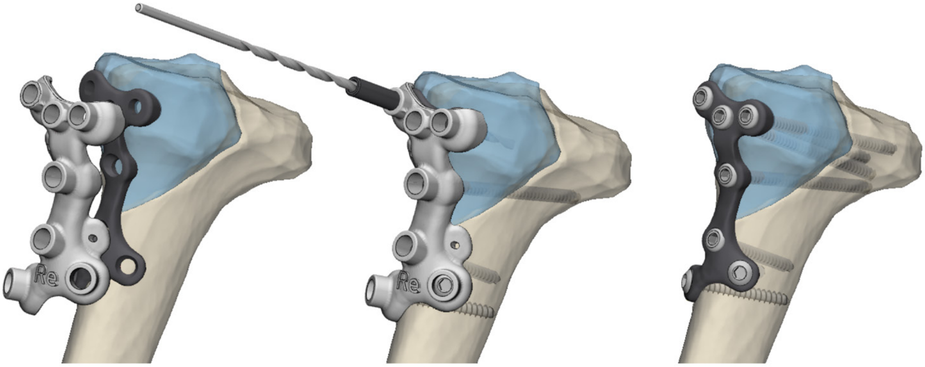

Figure 4: 3D virtual surgical planning (case 3, right knee): Left) The implant and surgical guide, which were designed to fit a pure medial fracture of the proximal tibia. Middle) In the surgical guide, which fits on top of the designed implant, drill sleeves can be placed which direct the drill bit to the predetermined screw trajectories. The cylindrical holes within the surgical guides were designed to fit the drill sleeves. In addition the screwheads of the subsequently placed screws also fit through these cylinders so that it allows the screws to be placed without removal of the guide. Right) Final position of the patient-specific implant and screws

Surgical procedure

The operations were performed by a consultant trauma surgeon. In three cadaver knees with an isolated medial fracture, a posteromedial surgical approach was performed with the patient in supine position. The posteromedial approach consisted of a longitudinal incision overlying the posteromedial border of the proximal tibia. The plane between the pes anserinus (anteriorly) and the medial head of the gastrocnemius (posteriorly) was developed by which the posteromedial border of the tibia was exposed. In three cadaver knees with a complete articular fracture, bilateral approaches (anterolateral and posteromedial) were performed. After reduction of the fractures, the patient-specific implants combined with the surgical guides were positioned according to the 3D surgical plan and verified using intraoperative fluoroscopy. A drill sleeve was inserted into the cylinder holes of the guide, and through this sleeve the screw trajectory was drilled. After drilling, the sleeve was removed and the screw was inserted while leaving the guide in place. After placing all screws, the guide was removed. In the specimens treated with a bilateral approach, a conventional lateral locking plate was then placed in addition to the patient-specific posteromedial implant. The implant and screw positions were verified by fluoroscopy before wound closure. Figure 5 and 6 depict the surgical procedure for both single and dual plating.

Figure 5: Surgical procedure of a pure medial split fracture (Schatzker 4). 1) After fabrication, the patient-specific implant and surgical guide can be sterilized and brought to the operating room (upper left). 2) Through a bilateral approach, the fracture was reduced and plate and guide were positioned after which the preplanned screw trajectories could be drilled (upper right). 3) The surgical guide was removed after placement of the screws (lower left). 4) The implant and screw positions were verified by fluoroscopy before wound closure (lower right)

Postoperative measurements

For each cadaver, a postoperative CT scan (0.6 mm slice thickness; iterative metal artefact reduction) was made to evaluate the articular reduction, tibial alignment, plate positioning and screw directions. The postoperative CT data was used to generate a 3D model of the reconstructed tibial plateau with plate and screws in situ.

Articular reduction and tibial alignment

Articular reduction was assessed by measuring the maximum residual gap and step-off on the CT slices. A gap was defined as a separation of fracture fragments along the articular surface. A step-off was characterized as a separation of fracture fragments perpendicular to the articular surface [15]. From the postoperative CT scan, pure

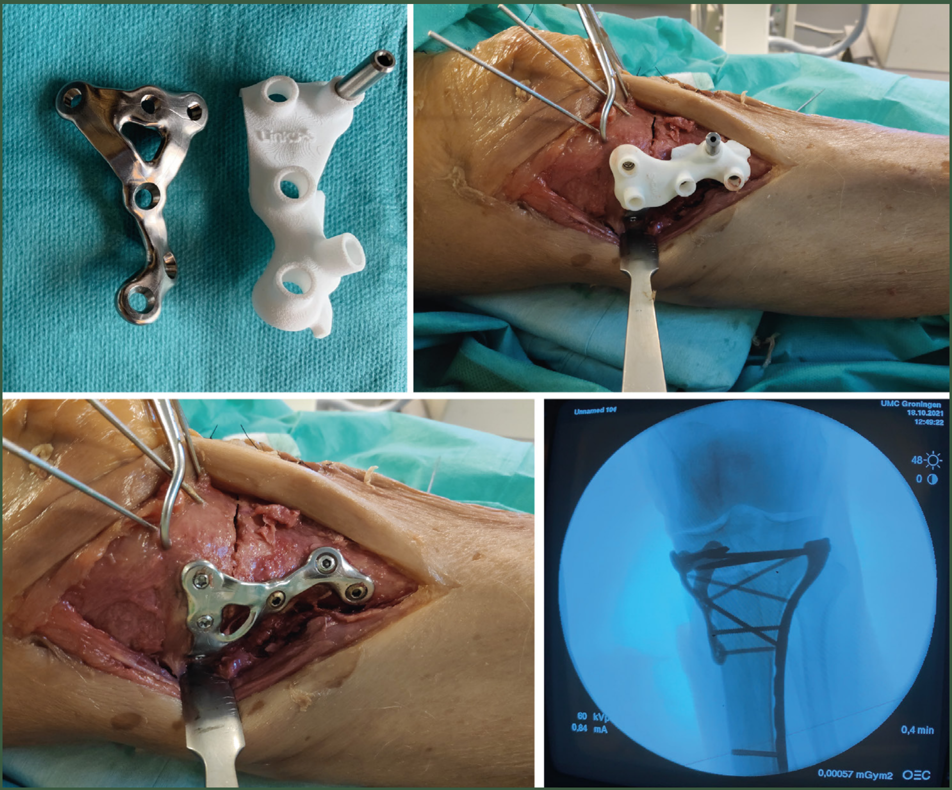

Figure 6: Surgical procedure of a full articular fracture (Schatzker 6). 1) After fabrication, the patient-specific implant and surgical guide can be sterilized and used during the operation (upper left). 2) Through a bilateral approach, the fracture was reduced and plate and guide were positioned after which the preplanned screw trajectories could be drilled (upper right). 3) The surgical guide was removed after insertion of the screws (lower left). 4) The implant and screw positions were recorded by fluoroscopy before wound closure (lower right)

anteroposterior and lateral radiographs were obtained using the Mimics software. Coronal alignment was then assessed by measuring the Medial Proximal Tibial Angle (MPTA) on the postoperative anteroposterior radiograph, whereas sagittal alignment was assessed by measuring the Posterior Proximal Tibial Angle (PPTA) on the postoperative lateral radiograph. The articular reduction was defined as adequate when both the residual gap and step-off were ≤ 2 mm, coronal alignment when the MPTA was 87 ± 5°, and sagittal alignment when the PPTA was 9 ± 5° [10, 16].

Plate positioning

We designed a plate that facilitates placement in a medial position (Fig. 5) and another plate that can be positioned further towards the posteromedial direction (Fig. 6). In order to compare the definitive positioning of the plate with the planned position, the 3D model of the postoperative tibial plateau was aligned with the 3D model of the surgical planning using the global registration function in 3-Matic version 15.0 (Materialise). The accuracy of positioning of the plate was obtained by measuring the Euclidean distance in millimeters between the center of gravity of the plate in the planned position and the plate in the postoperative position (Fig. 7a).

Screw directions and length

The lengths of the screws were determined in the preoperative surgical plan. Occurrence of screw penetration was considered when screws protrude the second cortex with more than 2 mm. The differences in screw direction were assessed by comparing the planned and postoperative screw trajectories, through matching of the postoperative plate (e.g., retrieved from the postoperative CT scan) with the planned plate (Fig. 7b). The 3D deviation in screw direction was measured between the inertia axes of the planned and postoperative screw trajectories in degrees.

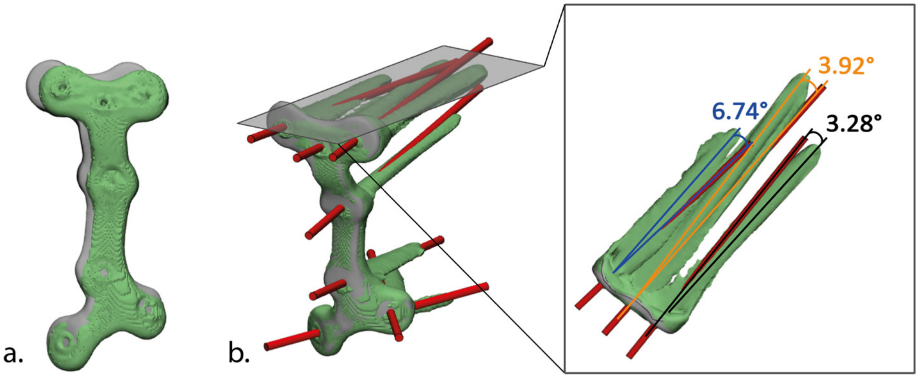

Figure 7: Postoperative evaluation: a The planned (gray) and achieved (green) position of the plate. Plate positioning was assessed by measuring the Euclidean distance between their center of gravities. b Measurement of the deviation between the achieved (green) and planned (red) screw directions.

RESULTS

A total of six tibial plateau fractures were operated using a patient-specific plate. Three fractures (right knees) consisted of an isolated medial fracture for which a medial patient-specific plate was designed and implanted. The other three fractures (left knees) consisted of multifragmentary complete articular fractures and were treated with dual plating: A conventional lateral locking plate (VA-LCP, DePuy Synthes) in combination with a patient-specific posteromedial plate. All articular reductions were considered adequate (gaps and step-offs < 2 mm), except in one case where the step-off was slightly higher with 2.8 mm (case 2, right knee). In terms of tibial alignment, all cases showed an adequate postoperative coronal (87 ± 5°) and sagittal (9 ± 5°) alignment. Table 1 describes the initial and postoperative articular incongruencies as well as the postoperative alignment for each case.

The six placed patient-specific plates had a median deviation of 3.0 mm (IQR: 2.8–3.7 mm) from their positions in the 3D surgical planning. A total of 41 screws were placed using the drilling guides. The placed screws showed a median deviation of 3.3° (IQR: 2.5–5.1°) when compared with the planned direction of the screws (Table 2). No screw penetration was observed.

Table 1: Articular reduction in terms of gap (mm) and step-off (mm), and postoperative tibial alignment(°).

Case	Fracture classification	Gap (mm)		Step-off (mm)		Alignment (°)	
		Preoperative	Postoperative	Preoperative	Postoperative	MPTA	PPTA
Case 1 – Left knee	Schatzker 6	11.5	1	5.5	1.2	88.5	10.0
Case 1 – Right knee	Schatzker 4	7.4	1.9	2.8	0.8	88.0	11.5
Case 2 – Left knee	Schatzker 6	4.6	1.5	4.8	1.5	87.5	6.5
Case 2 – Right knee	Schatzker 4	10.2	0	5.5	2.8	85.5	8.0
Case 3 – Left knee	Schatzker 6	4.2	0.8	4	1.4	86.0	8.5
Case 3 – Right knee	Schatzker 4	4.5	0	4.7	0	86.0	10.0
Median (IQR)		6.0 (4.5-9.5)	0.9 (0.2-1.4)	4.8 (4.1-5.3)	1.3 (0.9-1.5)	86.8 (86.0-87.9)	9.3 (8.1-10.0)

Table 2: Difference in position of the plate (mm) and the deviation in screw directions (°) between the planned and the achieved position of plate and screws.

Case	Fracture classification	Position plate Δ Distance (mm)	Direction screws	
			N	Δ Direction (°)
Case 1 – Left knee	Schatzker 6	2.9	5	3.1 (1.7)
Case 1 – Right knee	Schatzker 4	3.9	8	3.3 (1.3)
Case 2 – Left knee	Schatzker 6	4.5	6	2.7 (0.6)
Case 2 – Right knee	Schatzker 4	2.8	7	6.1 (3.7)
Case 3 – Left knee	Schatzker 6	3.1	8	3.9 (2.2)
Case 3 – Right knee	Schatzker 4	2.8	7	4.1 (3.5)
Median (IQR)		3.0 (2.8-3.7)	7 (6.3-7.8)	3.3 (2.5-5.1)

DISCUSSION

This case series demonstrates that 3D virtual surgical planning including patient-specific osteosynthesis combined with drilling guides is feasible in the surgical treatment of tibial plateau fractures with involvement of the medial plateau. The application of patient-specific osteosynthesis plates with drilling guides not only facilitates accurate plate and screw positions according to the preoperative plan, but also allows for adequate surgical reduction.

In the last years, 3D-assisted surgery emerged in the treatment of tibial plateau fractures. This includes a spectrum of modalities, such as 3D printing models, pre-contouring of osteosynthesis material and surgical guides [17]. Patient-specific implants have also found their way into clinical practice in the field of acetabular fracture surgery [11, 12]. To our knowledge, no patient-specific plate has been used in the clinical treatment of tibial plateau fractures, though some concept implants have been introduced. Teo et al. recently showed the feasibility of 3D-printed patient-specific locking plates for lateral tibial plateau fractures [18, 19]. However, they focused more on the feasibility and time management of the production and the biomechanical strength of the construct, rather than the surgical advantages. Also, for treatment of Schatzker 2 fractures conventional implants may suffice. Our proposed technique is assumed to be of additional value for complex fractures or tibial bones that differ from the mean tibial shape and could therefore benefit from the personalized shape of the implant. Schmutz et al. state that conventional implants were designed with the view to fit the 50th percentile of the population [20]. Therefore, especially tibial anatomy that differ from the mean shape (e.g., pre-existent bone deformities, the previous fractures, or comminuted acute fractures) are assumed to benefit from personalized techniques.

The surgical treatment with the use of a patient-specific implant, led to a satisfactory tibial alignment in all treated fractures and in five (out of six) to adequate surgical reduction. One case showed a postoperative step-off of 2.8 mm, which was slightly higher than the generally accepted 2 mm cut-off. In addition, the use of the custom-made patient-specific implants was considered easy to handle (e.g., positioning and fitting according to virtual planning) by the operating surgeon. The rationale behind a custom-made patient-specific implant is that it can serve as a template which facilitates the fracture reduction and restoring tibial alignment. This study shows promising results regarding the latter. In this study, we used a posteromedial approach with the body placed in a supine position. We presented a plate that can be placed in a medial position (Fig. 5) and another plate that can be placed posteromedial (Fig. 6).In clinical practice, the preferred plate positioning will obviously depend on fracture morphology. However, it should be acknowledged that positioning of the patient and exposure of the medial tibial condyle may differ between surgeons, which might limit the use of a plate or guide as a fracture reduction device. A future study should validate these results in a clinical setting. Applying these tibial implants in clinical practice should be feasible, because patient-specific plates have already been designed, produced, and clinically applied in different body regions in our clinic [11, 12].

The placement of the screws through the surgical guides went without any difficulties. Only one screw could not be placed through the guide due to blocking by the soft tissue, but could be placed after removal of the surgical guide. Huang et al. recently used patient-specific surgical guides in combination with conventional implants in tibial plateau fracture surgery, which resulted in an average difference between planned and achieved screw trajectory of 6.3 ± 3.4° [21]. In addition, our research group recently assessed the use of surgical guides in the treatment of acetabular fractures. In this cadaver study, median difference between planned and achieved screw trajectory was 5.9° (IQR: 4–8°) [22]. Both these studies, however, used these surgical guides in combination with conventional implants. This current study showed superior results with a median difference between planned and achieved screw trajectories of 3.3° (IQR: 2.6°), which may be facilitated by the use of a patient-specific implant.

One of the limitations of this study is that it is an experimental design with a limited number of human cadavers. The fractures were created with the use of an oscillating saw in combination with an osteotome, which were similar but not identical to fractures seen in clinical practice. The use of the osteotome introduced some plastic deformation and removal of bone, especially along the corners of the fragments. This complicated the anatomical reduction of the fragments. Moreover, no control group was used to compare fracture fixation with a patient-specific plate to a conventional plate. The reason for this is that it is already clear from clinical practice that currently available medial tibial plateau plates often do not fit properly. This study only aimed to assess the feasibility of patient-specific plates for medial tibial plateau fractures. Future challenges are related to manufacturing time and applicability of the workflow. Previous clinical studies and clinical experience, however, show that these implants can be designed and manufactured within four days, fitting within the clinical timeline for treatment of tibial plateau fractures [11]. However, we realize that this innovative workflow requires substantial resources, including a dedicated team, validated software packages and an osteosynthesis plate production facility. The associated costs for these resources were not part of this feasibility study. Also, only two different types of fracture patterns were included in this study and treated by one experienced surgeon. A next step would be to perform a clinical study to assess surgical parameters, patient-reported outcomes, and cost-effectiveness in order to determine which medial tibial plateau fracture patterns would benefit most from fixation with a patient-specific plate.

In conclusion, this feasibility study described the development and implementation of 3D virtual surgical planning including patient-specific osteosynthesis for medial tibial plateau fracture surgery. This study showed that the use of custom-made osteosynthesis plates facilitates proper fracture reduction and tibial alignment. Moreover, all screws could be placed according to accurately using the accompanied drilling guides.

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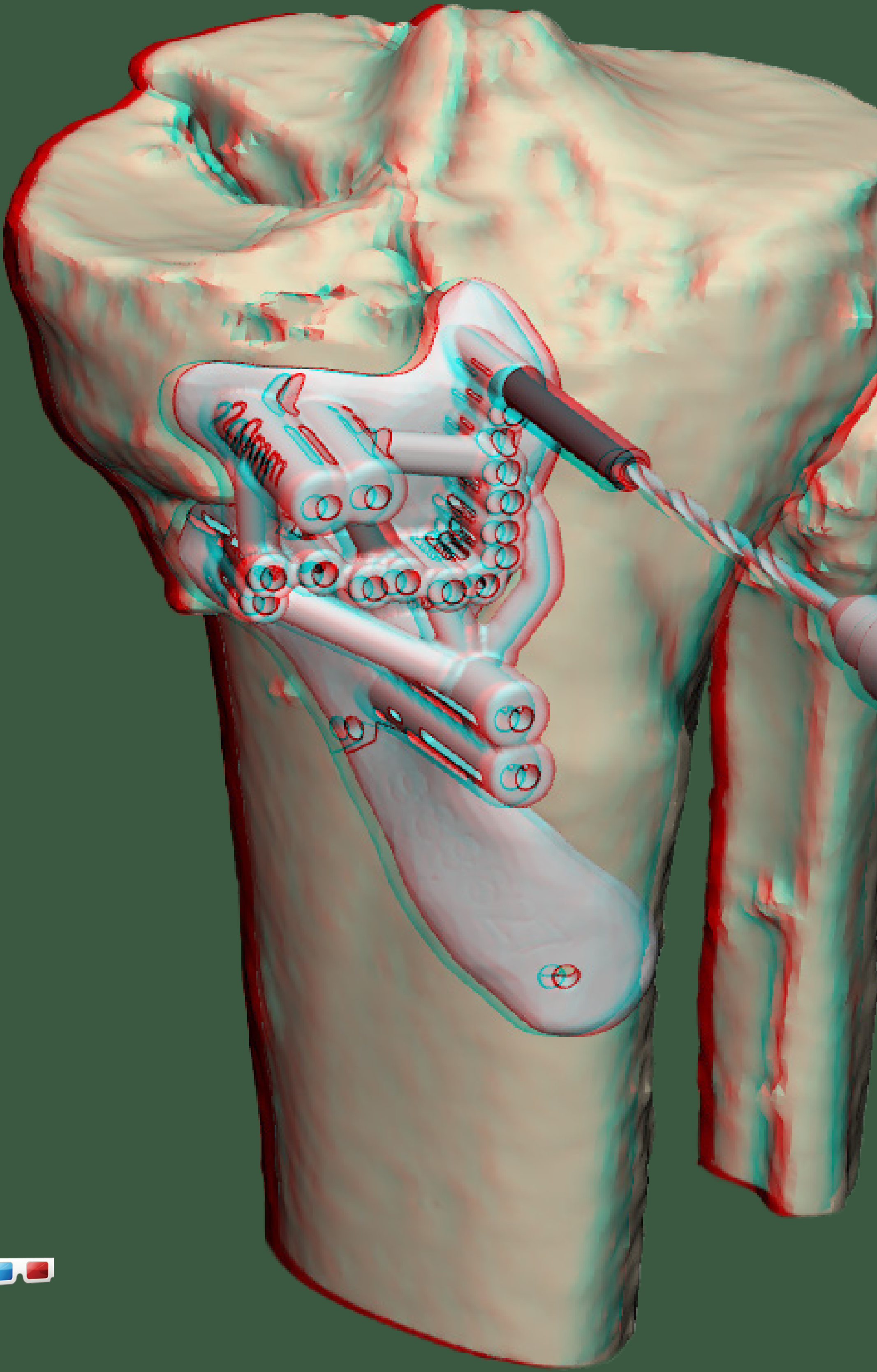

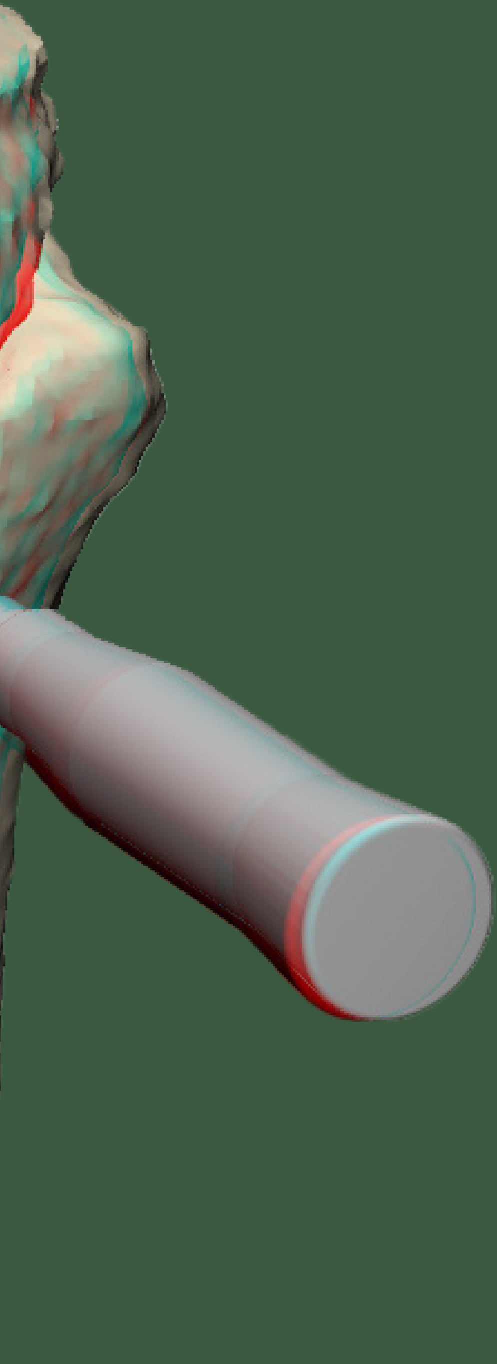

THREE-DIMENSIONAL PLANNED CORRECTIVE SURGERY

PART V

CHAPTER 13

A Two-Step Approach for 3D-Guided Patient-Specific Corrective Limb Osteotomies

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Abstract

Background: Corrective osteotomy surgery for long bone anomalies can be very challenging since deformation of the bone is often present in three dimensions. We developed a two-step approach for 3D-planned corrective osteotomies which consists of a cutting and reposition guide in combination with a conventional osteosynthesis plate. This study aimed to assess accuracy of the achieved corrections using this two-step technique.

Methods: All patients (≥12 years) treated for post-traumatic malunion with a two-step 3D-planned corrective osteotomy within our center in 2021 were prospectively included. Three-dimensional virtual models of the planned outcome and the clinically achieved outcome were obtained and aligned. Postoperative evaluation of the accuracy of performed corrections was assessed by measuring the preoperative and postoperative alignment error in terms of angulation, rotation and translation.

Results: A total of 10 patients were included. All corrective osteotomies were performed according to the predetermined surgical plan without any complications. The preoperative deformities ranged from 7.1 to 27.5° in terms of angulation and 5.3 to 26.1° in terms of rotation. The achieved alignment deviated on average 2.1 ± 1.0 and 3.4 ± 1.6 degrees from the planning for the angulation and rotation, respectively.

Conclusions: A two-step approach for 3D-guided patient-specific corrective limb osteotomies is reliable, feasible and accurate.

INTRODUCTION

Corrective osteotomy surgery for long bone anomalies can be very challenging since the deformation of the bone is often present in three dimensions. Conventional planning methods use two-dimensional (2D) imaging to plan the osteotomy and subsequent surgery is performed freehand, which leads to unpredictable results. With rapid advances in three-dimensional (3D) printing technologies, surgeons have started to apply 3D printing for a wide range of applications in orthopedic trauma surgery [1]. Particularly in corrective osteotomy surgery, the use of 3D-printed surgical guides is well-described and shows promising results in terms of functional outcome and reduced operating time [1-4]. The use of 3D virtual surgical planning allows the surgeon to visualize the anatomy in 3D, and virtually plan the osteotomy based on the CT scan. Additionally, patient-specific instruments can be designed and 3D printed to guide the cutting and reduction process during surgery. This process takes into account the specific anatomy of the patient and the desired surgical approach, which might lead to a more accurate result [5].

In recent years, different respective methods and techniques for corrective osteotomies of various mechanisms of deformities (i.e., post-traumatic deformities, growth disturbances, congenital anomalies) have been described. The majority of these methods consist of a surgical guide with a cutting slot for the planned osteotomy plane and drilling holes for preplanned screws [6-12]. Since the screw holes are predrilled, this technique requires an adequate fit of the preplanned plate in order to achieve the planned correction. However, due to the deformity of the bone, conventional plates usually do not fit, which potentially compromises accuracy and can lead to impaired functional outcome. For some cases, precontouring the plate provides a solution [11]. However, bending of a plate does not always result in a good fit; therefore, another solution for adequate use of this 3D technology may be provided by using a patient-specific plate [12]. Yet, currently, patient-specific plates are not widely available; they may be costly and pose logistical and legal challenges. An alternative reported approach is the use of a surgical cutting guide in combination with a reduction guide. The correction is then controlled by placing Kirschner wires (K-wires) with the cutting guide and subsequently realigning of the K-wires towards a parallel position with the use of a reduction guide. However, the combined use of both a reduction guide and a plate is often limited by the small surgical working space. This technique is only described for a few applications [13-16].

We present this alternative strategy, which consists of our two-step approach for 3D-planned corrective osteotomy, which has been successfully clinically applied. Our method adds to previous reports because a reduction guide, which envelops the planned osteosynthesis plate, is introduced, and therefore the technique is less limited by the surgical working space. This method can be applied disregarding the deformation or location, and is based on our experience in 3D-planned corrective osteotomy surgery over the past few years. This study aimed to assess the accuracy of the achieved corrections using this technique.

MATERIALS AND METHODS

Patients

All patients (≥12 years) treated for post-traumatic malunion with a single- or double-cut 3D-planned corrective osteotomy within our center between January and December 2021 were prospectively included upon availability of a pre- and postoperative CT scan with a slice thickness of less than 1 mm. The institutional review board of our center approved the study procedures, and the research was performed in accordance with the relevant guidelines and regulations (registry: 202100639). Written consent was obtained from all patients.

3D Virtual Surgical Planning of the Corrective Osteotomy

For all patients, a CT scan of the malunited as well as the corresponding contralateral uninjured bone was available. The DICOM (Digital Imaging and Communications in Medicine) image data were imported into the Mimics Medical software package (Version 21.0, Materialise, Leuven, Belgium) in order to create a 3D reconstruction of the affected bone and its counterpart. A segmentation process was performed using a preset bone threshold (Hounsfield unit ≥ 226) combined with the 'region growing' and 'split mask' function in order to separate the bone from adjacent bones. After the segmentation process, the 3D models of both the malunited and the contralateral bone were imported into the 3-matic software (Version 15.0, Materialise, Leuven, Belgium). The contralateral bone was then mirrored and aligned on an unaffected part of the malunited bone in order to measure the deviation. Based on the deviation, the osteotomy and correction were planned, and a virtual model of the osteosynthesis plate chosen by the surgeon was imported and positioned on the corrected bone. K-wires, at least two on each side of the osteotomy plane, were then placed parallel on the bone after virtual correction, duplicated and reversed engineered towards their original position on the 'uncorrected' malunited bone. A cutting guide was then designed, which included the planned osteotomy and the position of the K-wires before correction. In addition, a reposition guide was designed to be placed on top of the planned plate, fitting the K-wires as positioned after the planned correction (Fig. 1). During this workflow, multiple interdisciplinary meetings between technical physicians and (orthopedic) trauma surgeons were held to determine surgical approach, level of osteotomy and desired plate positioning in order to ultimately meet our patient's clinical needs.

Surgical Procedure

After designing the guides, the patient-specific cutting and reposition guides were 3D-printed by selective laser sintering using polyamide 12 (PA12). Additionally, real-

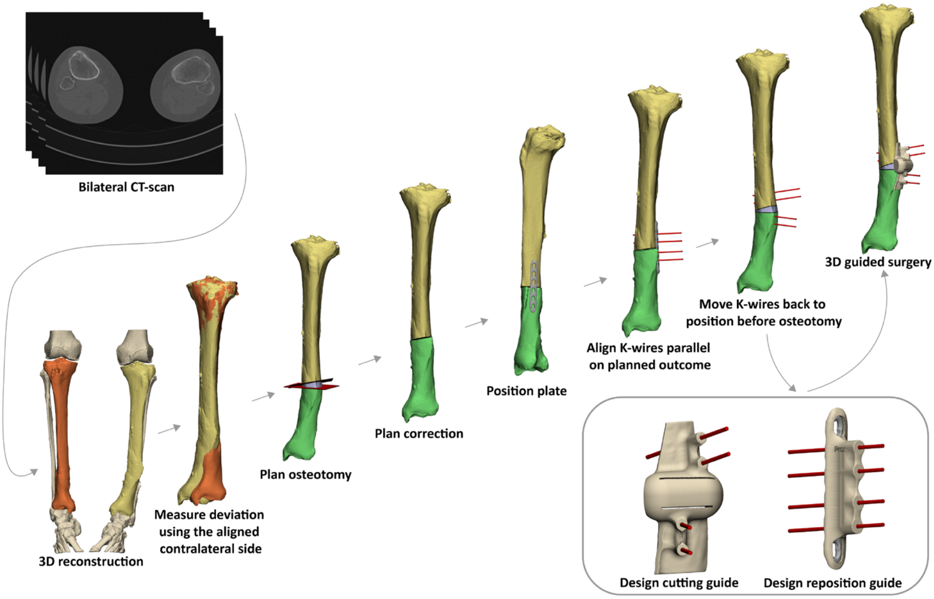

Figure 1: Workflow of a 3D-guided patient-specific corrective osteotomy using a two-step approach. (1) First, a 3D reconstruction is made from a bilateral CT scan. (2) By mirroring and aligning the contralateral (healthy) side on the malunited bone (orange), the deviation is measured. (3) Based on the deviation, the osteotomy and the correction are planned. (4) An osteosynthesis plate is chosen and positioned on the bone after correction. (5) K-wires are positioned parallel on the planned correction. (6) K-wires are placed parallel on the corrected bone, duplicated and moved to the corresponding position on the malunited bone before the correction is performed. (7) Patient-specific cutting and reposition guides are designed. (8) 3D-guided osteotomy is performed using the patient-specific cutting guide. Subsequently, the cutting guide is removed and the reposition guide (including the plate) is slid over the K-wires to achieve the intended correction.

size models of the malunion and planned correction were printed 1:1. These prints were sterilized and used during surgery. Exposure of the affected bone was obtained during surgery using a surgical approach as discussed with the surgeon during the stepwise 3D planning process. The cutting guide was then fitted on the bone using bony landmarks, and the K-wires were then placed through the guide (Fig. 2c and Fig. 3c). The unique footprint directs the guide to the intended location. Positioning of the guide was confirmed by verifying the position of the K-wires with respect to the bony landmarks using fluoroscopy. In the case of incorrect positioning, the guide was repositioned until the surgeon was confident about the correct positioning after repeated visual inspection and radiographic confirmation. The osteotomy was performed through the cutting slot of the cutting guide using an oscillating saw. Subsequently, the planned correction was performed by aligning the K-wires to a parallel position. This process was controlled by sliding the reposition guide, which enveloped the plate, over the K-wires (Fig. 2d and Fig. 3d). In opening-wedge high tibial osteotomy cases, the planned wedge was incorporated into the guide design for additional strength of the construct

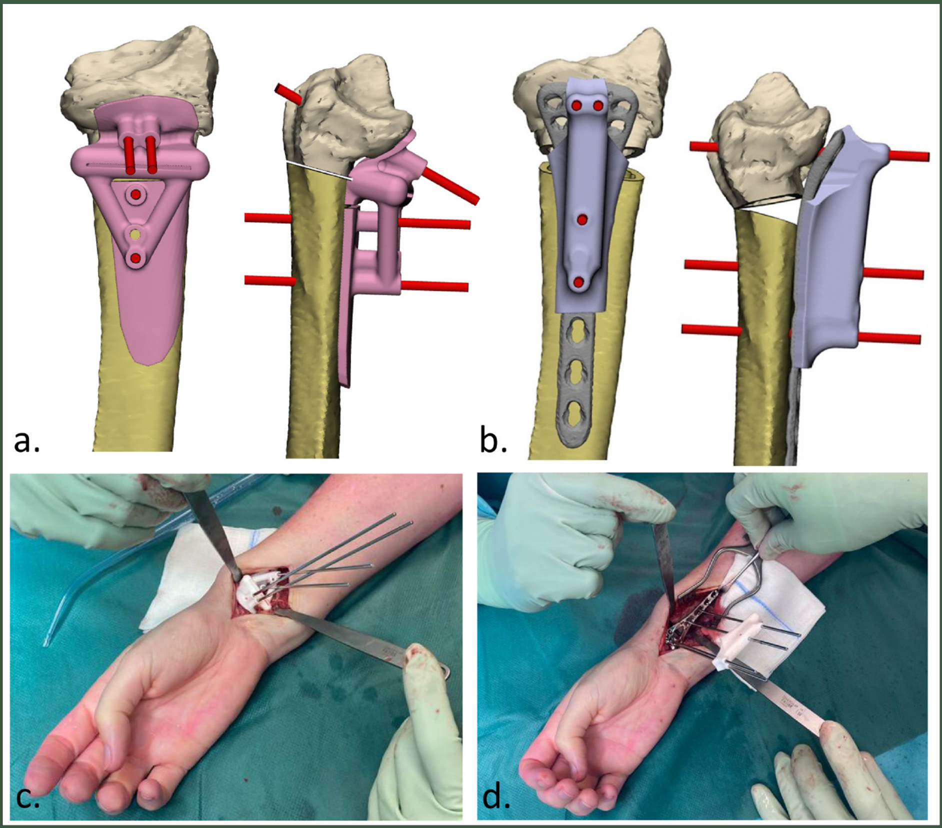

Figure 2: 3D-guided patient-specific corrective osteotomy of a malunited distal radius that was initially treated conservatively in a cast (Case 6). (a) Frontal and lateral view of the designed cutting guide (pink) with the -wires (red); (b) frontal and lateral view of the designed reposition guide (purple) with the parallel K-wires (red); (c) operative usage of the cutting guide; (d) operative usage of the reposition guide. The specific design of the reposition guide allowed for at least two screws to be drilled and placed both distal and proximal to the osteotomy level. Note the convergent K-wires in the cutting guide (c), and the parallel K-wires as reduction aids in the reposition guide (d).

and to prevent K-wires from bending during the opening of the wedge (Fig. 3). After correction, the design of the reposition guide allowed for at least two screws to be drilled and placed both distal and proximal to the osteotomy level. After placement of these screws, the reposition guide was removed, and the remaining screws were placed. The reposition guide was designed in such a way that the construct of the guide with the fixed K-wires did not block the drilling and placement of the screws.

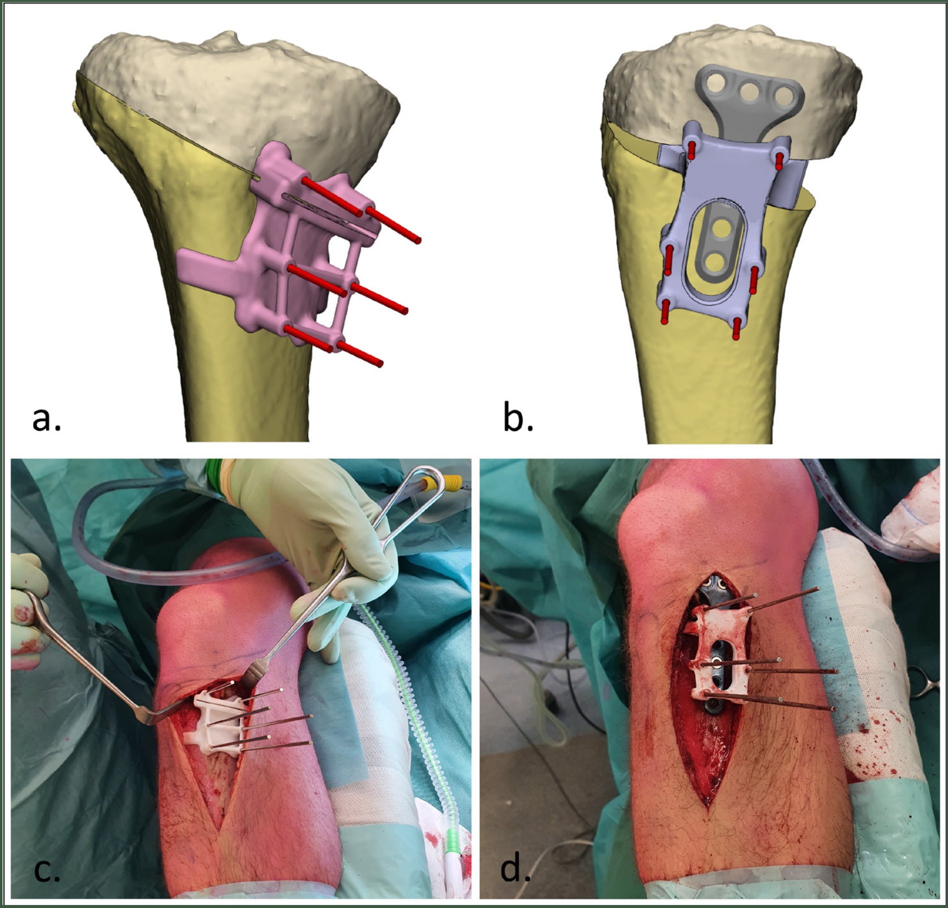

Figure 3: 3D-guided patient-specific corrective osteotomy of a proximal tibia (Case 8). (a) Frontal view of the designed cutting guide (pink) with the K-wires; (b) lateral view of the designed reposition guide (purple) with the parallel K-wires and insertion of the planned wedge; (c) operative usage of the cutting guide; (d) operative usage of the reposition guide. (see Appendix to experience the ***3D anaglyph*** of the case represented in this figure)

Postoperative Evaluation

Postoperative evaluation of the accuracy of the performed correction was performed by superimposition of the plan and the postoperative outcome. Subsequently, the preoperative and postoperative alignment error were measured in terms of angulation, rotation and translation. A 3D model of the bone before correction was retrieved from the initial planning. This model was duplicated and aligned with the planned outcome and the postoperative 3D model, such that there were three identical parts with different alignments (preoperative, planned and postoperative parts). In order to measure the angulation and rotation, the inertia axes were automatically drawn using the 'create analytical primitive' function in the 3-matic software (Figure 4a). The angulation was then

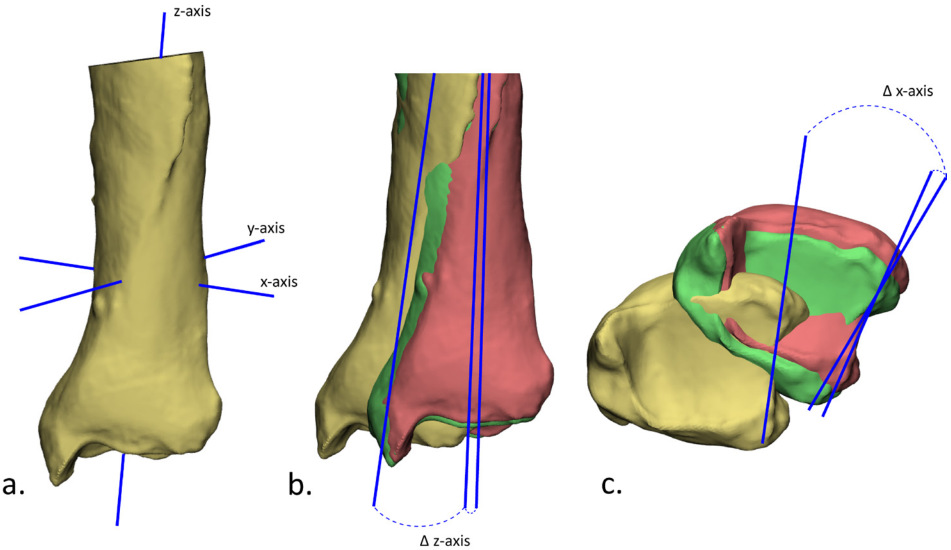

Figure 4: Evaluation of the achieved correction in terms of angulation and rotation. (a) First, the inertia axes were determined; (b) the angulation was then determined by measuring the angle between the z-axis of the preoperative (yellow) and planned (green) position of the bone, and between the planned and the postoperative (red) position; (c) the rotation was determined by measuring the angle between the x-axis of the preoperative and planned position, and the planned and postoperative position.

measured as the difference in angle in the z-axis (Figure 4b) and the rotation as the difference in angle in the x-axis (Figure 4c). The translation was obtained by measuring the Euclidean distance in millimeters between the center of gravity of these three parts (preoperative, planned and postoperative). In addition, the clinical outcome was assessed by evaluating the range of motion before surgery and six months after surgery. A Mann–Whitney U test was performed to assess the difference between planned and obtained angulation, rotation and translation. A p-value of <0.05 was considered statistically significant.

RESULTS

Patients

A total of 10 patients, treated for their post-traumatic malunion with a 3D-planned corrective osteotomy, were prospectively included in this study. The age of the patients varied from 12 to 64 years old, and seven of the patients were males (Table 1). The patients were treated for a malunion in various bones including the clavicle, humerus, radius, femur and tibia. Indication for corrective osteotomy was loss of function by decreased range of motion post-trauma due to acquired pathoanatomy in all patients with an upper limb deformity (n = 6). In the patients with a deformity of the lower limb (n = 4), the correction was performed due to complaints of pain and instability of the knee or ankle.

Table 1: Patient characteristics.

	Case	Sex	Age at time of surgery (years)	Area of deformity	Deformity	Planned correction
Upper limb	1	V	16	Clavicula	Angulation; Shortening	Closed wedge
	2	V	23	Proximal humerus	Varus; Rotation	Closed wedge
	3	M	12	Midshaft radius	Angulation	Closed wedge
	4	M	16	Distal radius	Rotation	Rotation
	5	M	17	Distal radius	Volar angulation	Open wedge
	6	V	59	Distal radius	Volar angulation	Open wedge
Lower limb	7	M	28	Femur	Rotation	Rotation
	8	M	17	Proximal tibia	Varus; Increased tibial slope	Open wedge
	9	M	24	Proximal tibia	Increased tibial slope	Closed wedge
	10	M	64	Distal tibia	Varus; Rotation	Closed wedge

Table 2: Postoperative evaluation of the performed corrective osteotomies. Accuracy was assessed in terms of angulation (degrees), rotation (degrees) and translation (millimeters).

Case	Angulation (°)			Rotation (°)			Translation (mm)	
	Preoperative vs. plan	Postoperative vs. plan	Over/under correction	Preoperative vs. plan	Postoperative vs. plan	Over/under correction	Preoperative vs. plan	Postoperative vs. plan
1	20.5	3.7	Under	-	-	-	8.1	0.3
2	14.7	2.7	Under	22.8	1.3	Over	6.2	3.2
3	14.7	1.3	Over	-	-	-	7.2	0.8
4	-	-	-	26.1	4.3	Over	4.4	0.5
5	12.5	2.7	Over	-	-	-	7.5	1.6
6	27.5	1.8	Over	5.3	1.6	Over	7.1	1.0
7	-	-	-	26.0	5.1	Under	1.1	0.8
8	13.5	2.6	Under	-	-	Over	37.8	6.2
9	7.1	0.2	Under	-	-	-	3.5	0.4
10	13.6	1.6	Over	24.7	4.8	Under	17.2	2.9
Average	15.5 ± 5.7	2.1 ± 1.0		21.0 ± 7.9	3.4 ± 1.6		10.0 ± 10.1	1.8 ± 1.8

Table 3: Range of motion in the upper extremities before and 6 months after correction.

	Case	Restricted joint	Preoperative range of restricted motion	Postoperative range of motion (6 months)
Upper limb	1	Clavicula	F/E 110-0-40; Ab/Ad 140-0-30	F/E 160-0-40; Ab/Ad 160-0-30
	2	Proximal humerus	F/E 150-0-40; Ab/Ad: 140-0-30; Exo/Endo: 90-0-L5	F/E 170-0-40; Ab/Ad: 160-0-30; Exo/Endo: 80-0-T12
	3	Midschaft radius	P/S: 10-0-60	P/S: 45/0/70
	4	Distal radius	P/S: 70-0-55	P/S: 70-0-80
	5	Distal radius	P/S: 70-0-30	P/S: 70-0-80
	6	Distal radius	F/E: 50/0/20 P/S: 20/0/80	F/E: 40/0/50 P/S: 60/0/80

F/E: flexion/extension, Ab/Ad: abduction/adduction, ER/IR: external rotation/internal rotation, P/S: pronation/supination, L5: 5th lumbar vertebra, T12: 12th thoracic vertebra.

Accuracy

All corrective osteotomies were performed according to the predetermined plan without any complications. The preoperative deformities ranged from 7.1 to 27.5° in terms of angulation and 5.3 to 26.1° in terms of rotation. The achieved alignment deviated on average 2.1 ± 1.0 and 3.4 ± 1.6 degrees from the planning for the angulation and rotation, respectively (Table 2). In four cases, the achieved angulation was more than what was needed in the planned direction (overcorrection), and in another four cases, the angulation was less than what was needed (undercorrection). In terms of rotation, in four patients, the applied correction was more than intended, whereas in two patients, the correction was less. The achieved positioning of the bone deviated on average 1.8 mm from the intended position. Differences between planned and obtained angulation ($p < 0.001$), rotation ($p = 0.009$) and translation ($p < 0.001$) were found to be statistically significant.

Clinical Outcome

In all six patients who underwent a corrective osteotomy for a malunion of the upper limb, the range of motion was significantly improved after six months (Table 3). After correction of the malunions of the lower limb, all patients reported a significant reduction in pain and instability.

DISCUSSION

Bone deformities in both the upper and lower extremities frequently lead to functional impairment, pain, instability and/or aesthetic concerns. Additionally, in the long term, this could lead to early-onset osteoarthritis of adjacent joints. Corrective osteotomy surgery of these post-traumatic acquired deformities can be very challenging since the deformation of the bone is often present in three dimensions. With the use of 3D-printing technologies, corrective osteotomy surgery has become more predictable. In this study, we presented our clinically applied two-step approach (cutting guide followed by reposition guide) of patient-specific 3D-planned corrective limb osteotomies. The results of this study show that our clinically applied method is reliable, feasible, user-friendly and accurate.

Several studies describe 3D-planned corrective limb osteotomies and show their technique to be feasible, leading to good functional outcomes [6-14]. Yet, even though the surgery is planned using state-of-the-art 3D software, postoperative evaluation is usually still performed in 2D on plain radiographs since postoperative CTs are not routinely made. Therefore, the majority of these studies evaluated their achieved accuracy based on postoperative radiographs, thereby only providing the accuracy in two dimensions: the anteroposterior and lateral direction [6-9,11]. Since the performed correction was planned in three dimensions, it is essential to assess the postoperative result in three dimensions as well to provide the accuracy of the performed correction and to gain insight into the cause of deviation in relation to suboptimal clinical outcomes. Omori et al. performed corrective osteotomies in 17 patients with a deformity of the humerus and compared postoperative 3D bone models with the preoperative planning using a surface registration technique [13]. In terms of translation, they showed a mean error of 1.7 mm in anterior–posterior translation, 1.3 mm in lateral–medial translation and 7.1 mm in proximal–distal translation, whereas they showed mean errors of 0.6°, 0.8° and 2.9° for varus–valgus, flexion–extension and internal–external rotation, respectively. Additionally, Dobbe et al. successfully performed a 3D-guided corrective osteotomy using a patient-specific plate in seven patients with post-traumatic distal radius deformities and showed a median residual translation and rotation error of 3.0 mm and 8.5°, respectively [12]. In addition to these scarce studies, this current study is one of the few studies which assessed the postoperative result in 3D. Where the previous studies were limited to one specific malunited bone, in this study, we performed 3D-planned corrective limb osteotomies in different body regions of ten patients, indicating the wide applicability of our technique. The results of this study show similar accuracy compared to previous reports with an average angulation of 2.1 ± 1.0°, rotation of 3.4 ± 1.6° and translation of 1.8 ± 1.8 mm.

The rationale behind using patient-specific 3D-printed guides is that it helps the surgeon perform the osteotomy and predrill the screws more reliably and according to the plan, leading to a more accurate correction. However, one of the possible pitfalls is translation of bone fragments over the osteotomy planes due to applied uncontrolled compression on the plate [10]. This is especially true in cases with extensive deformation of the bone where there is no good fit between the plate and bone. A suboptimal correction in these patients may result in residual functional impairment, pain and joint instability. Our two-step approach provides a solution for these patients by not predrilling the screws but using K-wires to secure the cutting guide, and subsequentially a reposition guide with these positioned K-wires, which forces bone fragments into the correct 3D-planned alignment while serving as a temporary fixation as well. The plate can generally be placed under the reposition guide for easy application. The specific design of the reposition guide allows for at least two screws to be drilled and placed both distal and proximal to the osteotomy level, which then hold the reposition while the guide is removed. Definitive fixation can then be performed by placing the remaining screws within the plate.

One of the limitations of this pilot study is the relatively small patient group. Since the goal of this study was to critically evaluate the accuracy of our two-step approach, we included all patients who were treated with this technique irrespective of anatomical site or nature of the post-traumatic deformity. Even though this study showed that our technique is clinically feasible and accurate in both upper and lower extremity deformities, the inclusion of different osteotomy locations led to a highly heterogeneous study population. Yet, one could also argue this a study strength, as it improves the external validity of our results regardless of the anatomical site. Additionally, since the primary aim of this research was to assess the accuracy of this technique, the clinical outcome in this study was limited to the range of motion, which was only of importance in the cases with upper limb deformities. Further studies should also incorporate patient-reported outcomes to also fully assess the impact of this method on functional recovery. This is especially true in patients with lower limb deformities, since these patients were not affected by a restricted range of motion.

Even though high accuracy of the planned correction was achieved in all patients, some minimal residual angulation, rotation and translation error were still present, although we argue this is clinically not relevant to patients' functional outcome. At this stage, it is impossible to assess at what part of the surgery the error happened (e.g., positioning of the guides, securing the screws). In order to further improve the current method, it would be recommended to investigate each specific step within the procedure. In particular, the positioning of the cutting guide along the longitudinal axis is usually quite challenging in the case anatomical landmarks for verifying the correct position of the guides are limited (e.g., shaft fractures). Where the proximal or distal end of the bone generally has quite distinguishable features, the fit of the guide on the midshaft bone is usually less rigid. Further investigation on what impact guide positioning has on the accuracy is therefore recommended. In addition, this study included patients with relatively severe deformities with an average angulation of 15.5 ± 5.7° and rotation of 21.0 ± 7.9°. Patients with more subtile deformities might also benefit from 3D-guided corrective osteotomy surgery. To our knowledge, no clear cut-off for the point at which a deformity is too small to correct accurately has been established. Therefore, it further investigation of what deformities can accurately be corrected in order to utilize this technique to its full potential is also recommended.

CONCLUSIONS

This study showed that a two-step approach for 3D-guided patient-specific corrective limb osteotomies is reliable, feasible, user-friendly and accurate for corrective osteotomies of deformities of all long bones.

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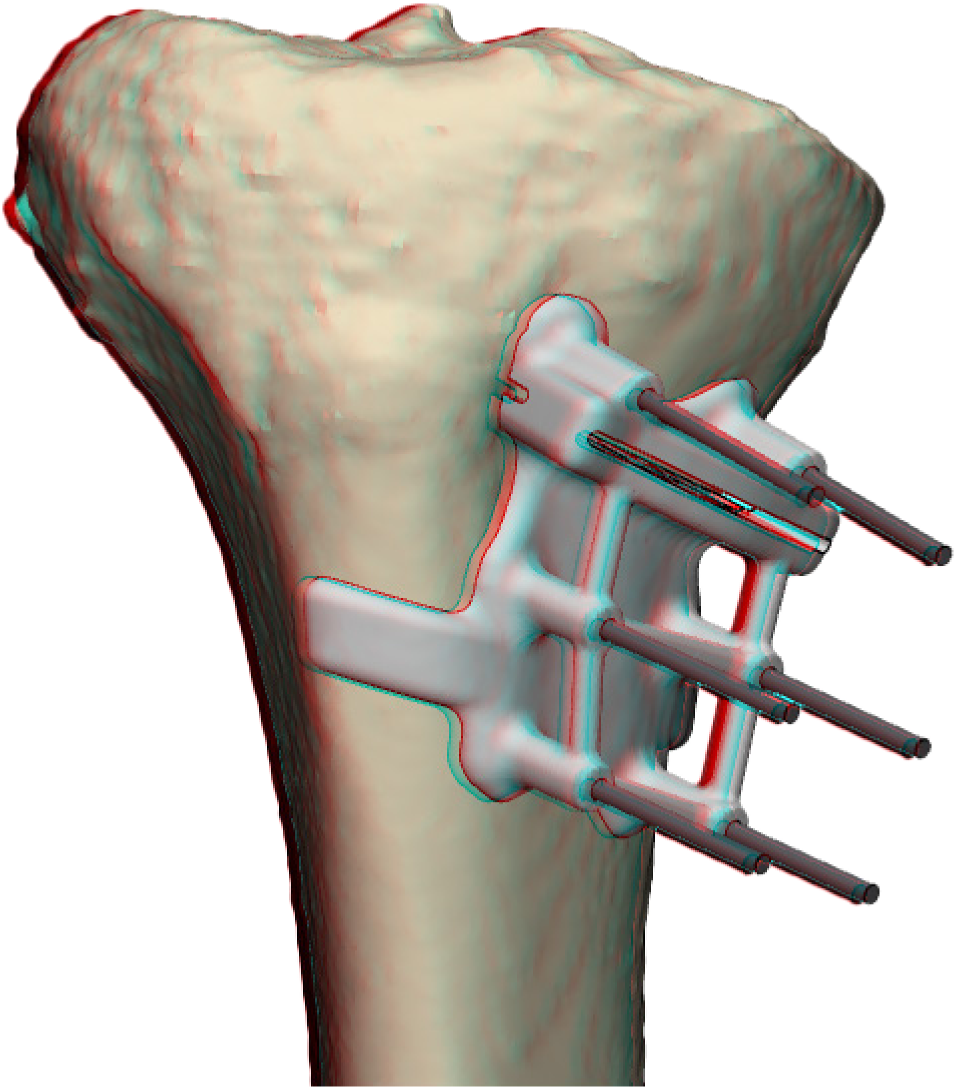
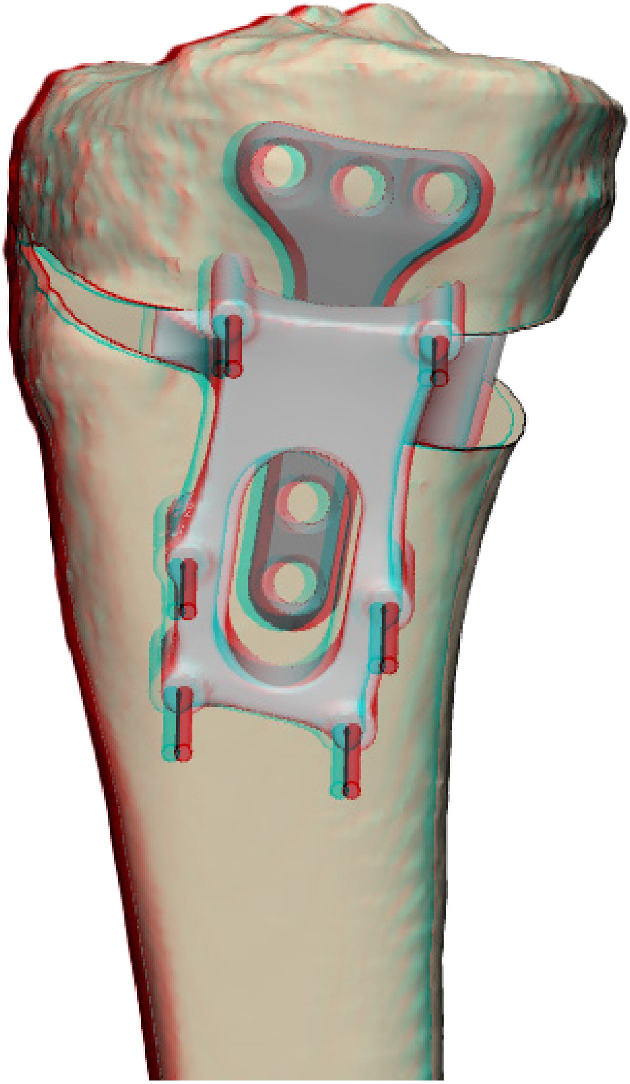
APPENDIX

Appendix 1: 3D anaglyph of the 3D-guided patient-specific corrective osteotomy of a proximal tibia as represented in figure 3 of this chapter.





CHAPTER 14

The Panflute Technique: Novel Three-Dimensional Printed Patient Specific Instrumentation to Guide Curved Intra-Articular Osteotomies for Tibial Plateau Malunions

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Job N. Doornberg, Frank F.A. IJpma
& Peter A.J. Pijpker

This chapter is under submission

Abstract

Background: 3D patient-specific corrective osteotomies are optimized for use with oscillating saws, thereby rendering it incapable of executing curved osteotomies. In this technical note, we introduce the Panflute technique which facilitates curved osteotomies with precise depth control for intra-articular corrective osteotomies in posttraumatic tibial plateau malunions.

Methods: A 33-year-old male patient with an intra-articular malunion was treated one year after index surgery of a lateral split-depression tibial plateau fracture with the Panflute technique. The guide design allowed for multiple drill trajectories in a curved path recreating the original fracture lines. Cylindrical drill tubes in the guide were tailored to match bone trajectory length. This resulted in a patient-specific Panflute-like design enabling precise depth control safeguarding posterior neurovascular structures. Secondly, the recreated fragment was reduced with a reduction guide, applied to the plate in situ, to facilitate reposition using the plate as tool and reference.

Results: The procedure went without technical drawbacks, nor surgical complications. Postoperative assessment showed that repositioning of the osteotomized articular fragment was performed accurately: pre- to postoperative translational corrections were 5.4 to 0.5 mm posterior displacement for AP deformity(x-axis); 2.9 to 1.0 mm lateral to medial reduction(y-axis); and 5.9 to 0.6 mm cranial-caudal correction(z-axis). Clinically, at 3 months, the fracture united, patient regained full flexion and valgus defect-laxity resolved.

Conclusion: The presented Panflute-osteotomy guide allows for pre-planned curved osteotomy. Additionally, for every drill trajectory the depth could be controlled. The proposed method may expand our surgical armamentarium of patient-specific 3D techniques and solutions for complex intra-articular osteotomies.

INTRODUCTION

Tibial plateau fractures may be complex fractures which usually consist of several intra-articular fragments and occur in specific patterns that guide treatment [1–3]. Surgical treatment of these fractures is often considered challenging due to associated fracture comminution, or patterns that require specific posterior fixation [4,5]. In more than 30% of the surgically treated tibial plateau fractures, a suboptimal operative result has been reported [6]. Malunions of tibial plateau fractures present significant challenges for the orthopedic trauma surgeon. Corrective osteotomy surgery provides a good option for these cases when carefully planned [7–9]. One recent study reported that revision surgery for residual displacement was required in 2% of the surgically treated tibial plateau fracture patients [10]. However, the maximum step-off and gap we may accept is subject of debate to date [11].

In the past years, an increasing number of methods for 3D-assisted corrective osteotomies have been introduced to correct for post-traumatic malunions [12–15]. Yet, these 3D-assisted methods mostly aim to correct extra-articular malunions. Corrective osteotomies for intra-articular malunions remain more challenging, and literature on 3D-assistance in these osteotomies is limited [16,17]. Current existing 3D technology for patient-specific corrective osteotomies is mostly optimized for use with oscillating saws, thereby rendering it incapable of executing curved osteotomies or facilitating precise depth control.

In this technical note, we present our novel technique for 3D-assisted intra-articular corrective osteotomies for post-traumatic malunions after a tibial plateau fracture, coined the Panflute technique. The technique is named because of the 'Panflute-like’ design of the 3D printed osteotomy guide that is introduced in this technical note. The concept facilitates the execution of curved osteotomies and precise depth control. This report describes the stepwise approach, encompassing 3D virtual planning, osteotomy- and reduction guide design, 3D-assisted surgery, and postoperative assessment.

MATERIALS AND METHODS

A 33-year-old male patient, working as a personal trainer, was referred to our outpatient clinic with an intra-articular malunion one year after index surgical treatment of a lateral split-depression tibial plateau fracture (AO 41-B3) (Fig. 1A&B). Patient presented knee instability, subjectively reported when weightbearing in flexion (squats, stairs, hiking) and resulting pain. Patient reported no instability in full extension while standing, and showed very good quadriceps recovery after index procedure.

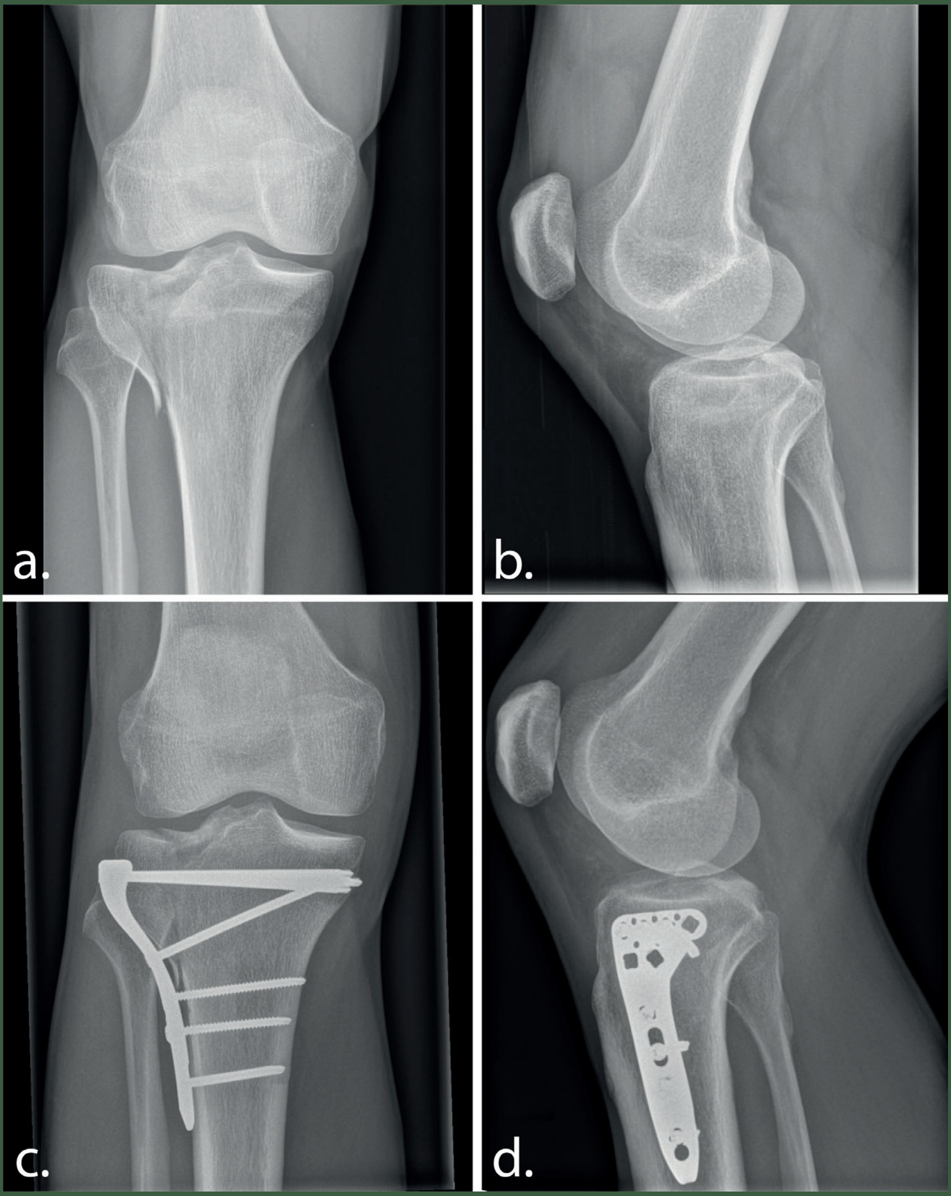

Figure 1: Anteroposterior and lateral radiograph of the initial tibial plateau fracture (a &b) and of the situation 1-year postoperative (c&d).

Physical examination showed lateral defect laxity beyond 30 degrees of knee flexion, with the medial collateral ligament complex intact. Patient identified resulting pain upon examination, which recognized as the pain during his example of squatting. Plain radiographs of the affected knee suggested slight widening and distal translation of the split fragment, and of a defect at the site of traumatic depression of the lateral tibial plateau (Fig. 1 C&D). It was felt that the malunited split fragment with widening and distal translation, allowed for the lateral femoral condyle to sink in the bony defect and was explanatory for patient's complaints: it was theorized that the femur fell into the defect beyond 30 degrees of flexion.

Quantification and segmentation of the Intra-Articular Malunion

A CT-scan of both the affected as well as the contralateral intact tibia was performed. CT-data were then imported into the Mimics Medical software package (Version 25.0, Materialise, Leuven, Belgium). 3D reconstructions were made by performing a segmentation process using a bone threshold (Hounsfield unit ≥ 226) combined with the 'region growing' and 'split mask' function in order to separate the tibial bone from the fibula and femur reconstruction (Fig. 2a). The created 3D models of the tibia were subsequently imported into the 3-matic software (Version 17.0, Materialise, Leuven, Belgium). The contralateral tibia was then mirrored and aligned on the shaft of the affected proximal tibia to quantify the malunion in terms of a translational and rotational error. The mirrored contralateral side was subsequently used as a template to plan reconstruction (Fig. 2B).

Quantitative 3D assessment of the CT scan (Q3DCT) revealed the following translational errors with respect to the contralateral side in three planes: 1) 5.4 mm in anterior-posterior plane (x-axis); 2) 2.9 mm medial to lateral widening (y-axis); 3) and 5.9 mm cranial-caudal displacement. In addition, 3D rotational malalignment showed an error of 10.2° in the sagittal plane (ζ), 23° in the coronal view (θ), and 0.8° in the axial view (φ).

Virtual Surgical Planning (VSP)

Multiple drill trajectories were planned along the old fracture line resulting in a curved osteotomy cut that replicates the original split fracture (Fig. 2C). Then, the lateral split fragment, which needed to be osteotomized and reduced, was virtually planned to its anatomical position by aligning it with the mirrored template (Fig. 2D&E). Surgical guides were then designed to translate the virtual plan to surgery. Guide design was also performed in the 3-Matic software. A total of three guides were designed: 1) the cutting; 2) intermediate; and 3) reposition guide. The cutting guide included our novel "Panflute" design which facilitated the creation of a curved plane and precise depth control (Fig. 3). The cutting guide, which included multiple drill trajectories to form the osteotomy plane, had two extensions to facilitate accurate positioning: an extension which covers the anterior tibial shaft (distal to the tibial tuberosity) and one which fits the in-situ tibial plate.

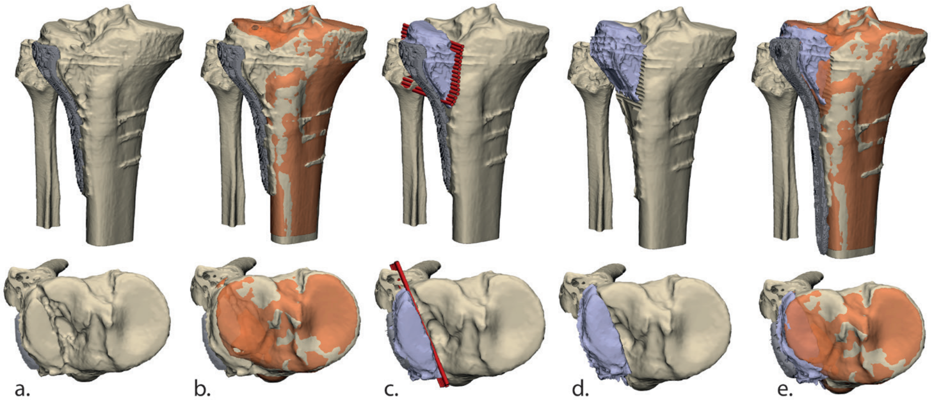

Figure 2: Process of 3D virtual surgical planning. a.) 3D reconstruction of the affected bone is created from the CT-scan. b.) The contralateral unaffected side (orange) is mirrored and aligned to serve as a template for reduction. c.) The osteotomy cut(red) consisted of several drill trajectories and is planned to cut the malpositioned fragment. d.) the malpositioned fragment is virtually reduced to its anatomical position. e.) The new position is verified with the matching of the mirrored contralateral side.

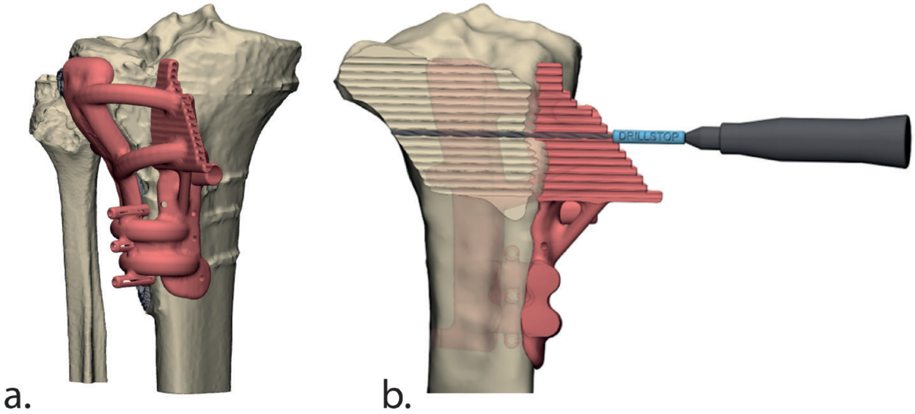

Figure 3: The 'Panflute guide' in anterior (a) and cross-sectional view (b). Tailoring the cylindrical drill tube to match the bone trajectory length for each hole creates a panflute-like design that enables precise depth control and safeguards posterior vascular structures.

Through this guide, three additional K-wires could be placed to facilitate the exact subsequent placement of the other two guides. The intermediate guide was designed to facilitate the process of predrilling the distal holes for the planned proximal tibia plate. To complete the process, we created a reposition guide to envelop the new proximal tibial plate to ensure correct positioning (Fig. 4).

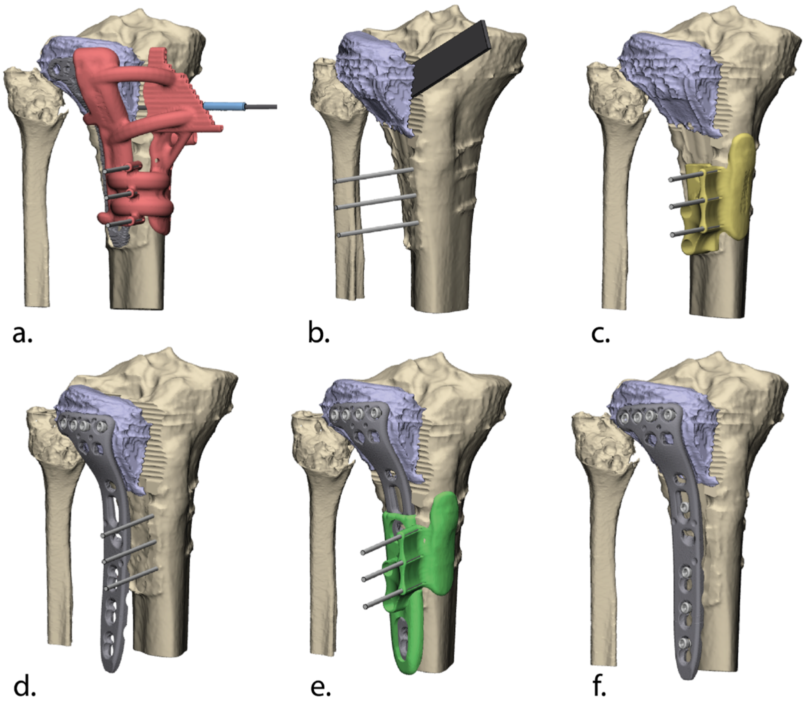

Figure 4: 3D-assisted surgery: The panflute osteotomy guide (red) was positioned on top of the in-situ plate and kept in position with K-wires which later serves as reference for the intermediate (yellow) and reposition (green) guide at a later stage of the procedure. After satisfactory positioning a 1.8 mm drill was used through the different holes in the panflute guide to create the osteotomy plane (a); After all trajectories were drilled, the guide and implant were removed and the bone fragment – that needs to be reduced - was separated from the rest of the proximal tibia with a osteotome (b); The osteotomy was followed by predrilling the distal holes for the screws of the new plate using the intermediate guide (c); Then the new plate was fixated on the osteotomized fragment using the old proximal screw holes (d); The reposition guide, which fitted on top of the new implant, was then used to steer the fragment to the planned position relative to the bone after which the plate was fixated on the shaft (e.); After fixation of the plate, the reposition guide was removed and the wound was closed. (f). (This figure is also represented as a ***3D anaglyph*** in the appendix)

3D-assisted surgery

The patient was positioned in supine position. An anterolateral approach to the proximal tibia was used. Exposure included the lateral tibial plateau and plate, including a transverse capsulotomy and elevation of the lateral meniscus to allow for visualization of the articular surface. The osteotomy guide was positioned, and K-wires were placed to keep the guide in position and to serve as reference for subsequent guides used at a later stage of the procedure. The position of the guide was verified on fluoroscopy, and after satisfactory positioning a 1.8 mm drill was used through the respective holes in the panflute drill guide to create the curved osteotomy plane (Fig. 4a). An additional sleeve (Fig. 4a, blue sleeve) was used to ensure the drill stopped at the planned depth. After all trajectories were drilled, the guide and implant were removed, and the planned bone fragment was separated from the rest of the bone with an osteotome (Fig. 4b).

Subsequently, the small impacted depressed healed central fragment was identified, after opening "the book" by pushing the lateral split fragment open with a laminar spreader. The remainder of the small depressed fragment was elevated, and preliminary fixated with inside-out K-wires. The osteotomy was followed by predrilling the distal holes for the screws of the new plate using the intermediate guide, which was positioned with the in-situ K-wires (Fig. 4c). A new implant was then placed on the osteotomized fragment and attached with unicortical locking screws through the existing proximal screw holes from the old plate (Fig. 4D). The reposition guide, which fitted on top of the new implant, was used to steer the fragment to the planned position relative to the bone (Fig. 4e). After fixation of the plate, the reposition guide was removed and the wound was closed (Fig. 4f). Figure 5 illustrates the per-operative use of the surgical guides guide. A supplementary animation illustratig the performed correction using the Panflute technical is provided (Supplementary video 1).

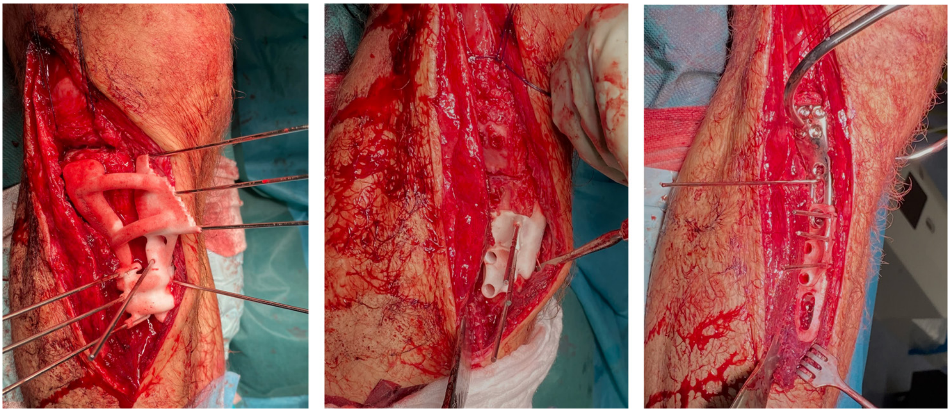

Figure 5: Per-operative usage of the different surgical guides: panflute guide (left), intermediate guide (middle), and reposition guide (left).

Postoperative assessment

A postoperative CT-scan was made as part of the follow-up. Segmentation of the postoperative situation was performed in the same manner as the preoperative segmentation process. The virtually planned fragment reduction was then aligned with the postoperative model.

The preoperative, planned and postoperative bone models were exported from the 3-matic software and imported within the Matlab (R2014B, Mathworks, Natick, Massachussetts, US) software. Translational error with respect to the planned positions was measured in terms of the anterior-posterior, left-right, and cranial-caudal distance (mm). The 3D rotational error (in degrees) was measured in coronal, sagittal and axial direction.

RESULTS

The procedure went without any technical drawbacks, nor intra-operative surgical complications. Clinically, the patient was satisfied and without pain at 3 months follow-up, regaining full knee flexion. Defect laxity, presented as a subjective feeling of instability resolved for squatting, climbing stairs or hiking such as experienced pre-operatively. Post-operative radiograph showed quantified improvement of the height of the corrected lateral plateau resulting in improved tibial alignment (Fig. 6).

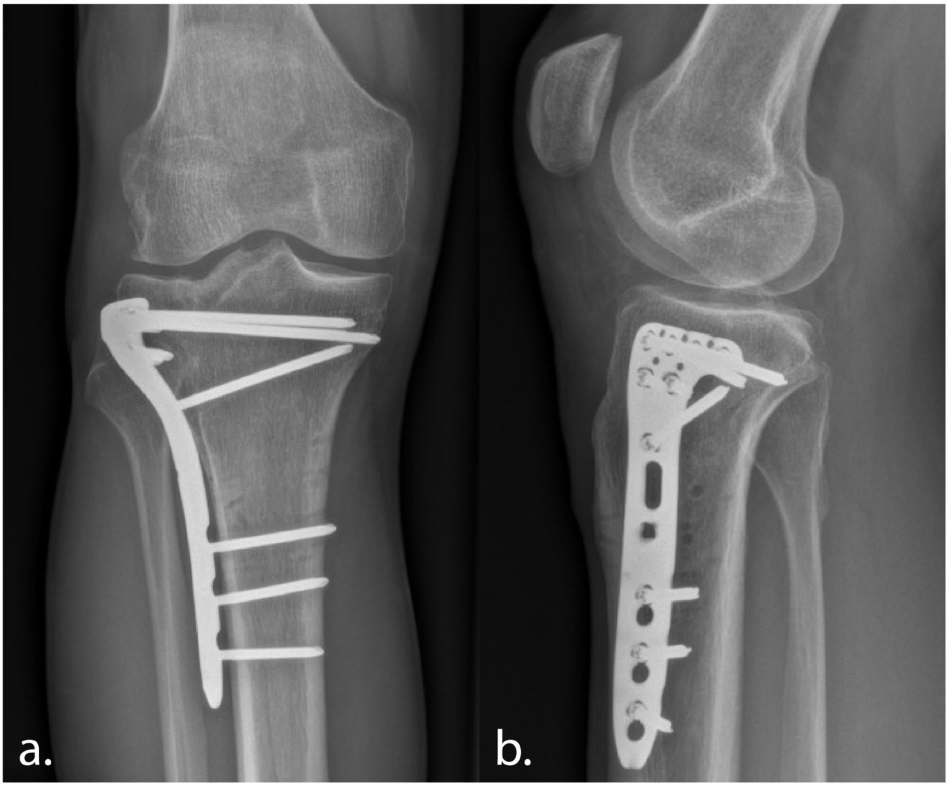

Figure 6: Postoperative anteroposterior and lateral radiographs at 3 months follow-up demonstrating improved alignment and progressive consolitation.

Quantitative 3D assessment of the postoperative CT scan was performed (Fig. 7). The translational error with respect to the planned positions was subdivided into anterior-posterior, left-right, and cranial-caudal displacement parameters. An 0.5 mm posterior displacement (x-axes, initial 5.4 mm), 1.0 mm lateral displacement (y axis, initial 2.9 mm) and 0.6 mm cranial displacement (z-axes, initial 5.9 mm) was observed. The 3D rotational error analysis in this case showed 3.8° in the sagittal view (ζ, initial 10.2°), 1.3° in the coronal view (θ, initial 23°), and 0.1° in the axial view (φ, initial 0.8°).

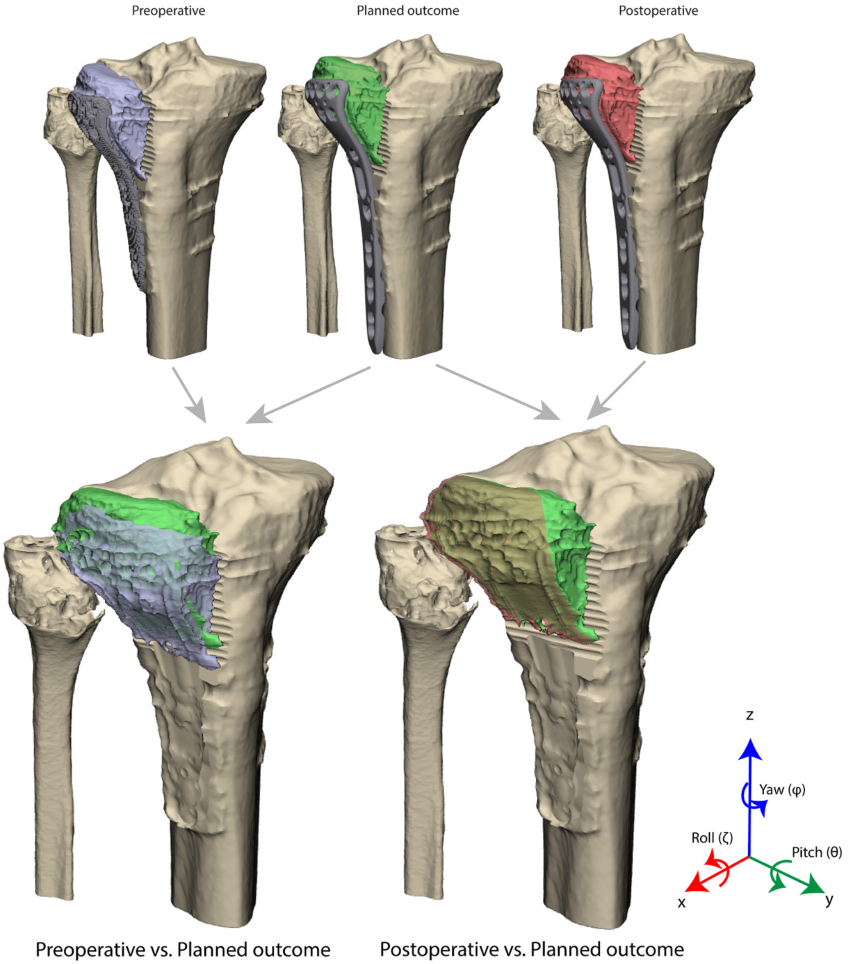

Figure 7: Preoperative (purple), planned (yellow) and postoperative (green) position of the reduced fragment. 3D assessment is performed to assess the fragment position before and after surgery as compared to the planned outcome. Difference is assessed in terms of translation (Δx, Δy, Δz) and rotation (Δζ, Δθ, Δφ) in three axes.

DISCUSSION

Intra-articular corrective osteotomies of malunited tibial plateau fractures are technically demanding and require extensive preoperative planning [8,9]. 3D technology allows for preoperative planning and provides a tool for translating a virtual plan into the patient [15]. This technical note presents a novel 3D method using the Panflute concept in which the curved osteotomy cut is composed of several drill trajectories and therefore is not limited to a single plane. In addition, it allows for depth control of the osteotomy. This study shows that this method is feasible and allows for accurate reconstruction of the malunited bone.

Typically, osteotomies are performed with the use of a sawblade and osteotome to separate the malunited bone into the required bone fragments for reduction. For extra-articular osteotomies usually, a plain cut is sufficient since secondary bone growth will not impair function. When one is treating an intra-articular malunion, plain cuts are often not sufficient. Particularly, since you are dealing with cartilage which should be cut and aligned anatomically to allow for improved functional outcome. Due to these difficulties, intra-articular corrective osteotomies remain challenging and only a few studies report a limited number of patients who underwent conventional intra-articular corrective osteotomy [8,9,18]. Yet, without 3D guidance accurate reduction of malunions may lead to unpredictable results [15].

3D guided extra-articular corrective osteotomies are well described in literature, however only few studies describe 3D guided intra-articular corrective osteotomy. Recently a few case studies described corrections of malunited tibial plateau fractures with 3D-assistance. Pagkalos et al. used a 3D printed surgical guide through which the saw blade was steered to perform an osteotomy through the eminentia [19]. Two other recent studies reported the use of a surgical guide to place k-wires along which subsequently the saw blade was guided [16,20]. Our specific Panflute design differs from the beforementioned methods, enabling the creation of multiple drill trajectories that together form the curved osteotomy cut while controlling the depth for each hole. In addition, our method also incorporates a reposition guide to allow for accurate repositioning of the affected bone fragment.

The key aspect of this in-house workflow was the close collaboration between surgeons (JD, FIJ, HV) and technical physicians (NA, PP, WB) to ensure the best patient matched solution. However, throughout the planning and execution of the 3D-assisted correction according to our method a few difficulties were observed. Firstly, the VA-LCP proximal tibia plate which was already in-situ resulted in significant scattering of the CT-scan. Consequently, the design of the guides was complicated since the bone surface is affected by the scattering which made the segmentation of the bone less reliable. Ideally, for accurate 3D planning no hardware should be in-situ. Yet, our case demonstrated a good solution by using the plate as a reference for the positioning of the osteotomy guide. Another complicating factor was the patellar tendon which blocked the positioning of the osteotomy guide, which is not accounted for on CT imaging. In our case the guide was slightly too bulky and part of the guide which interfered with the tendon had to be cut. As this was anticipated, the guide was planned with other landmarks for positioning and it did not affect our intra-operative planning, soft tissues should be taken into account during the planning.

Despite the beforementioned difficulties, this technique showed to be accurate and resulted in anatomical reduction of the malunited fragment as compared to the contralateral templated side. The use of the Panflute concept for intra-articular osteotoy guides provides the possibility of curved cuts. In addition, from every drill trajectory the depth could be controlled. The proposed method allows a technical solution for complex intra-articular osteotomies.

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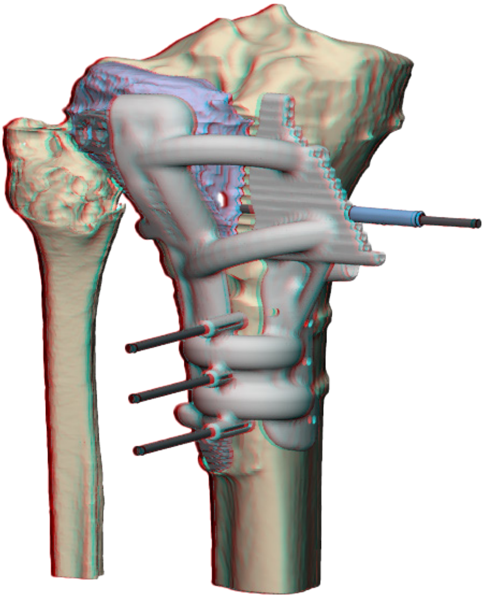
APPENDIX

Appendix 1: 3D anaglyph of the intra-articular 3D-assisted corrective osteotomy using the panflute technique as represented in figure 4 of this chapter.



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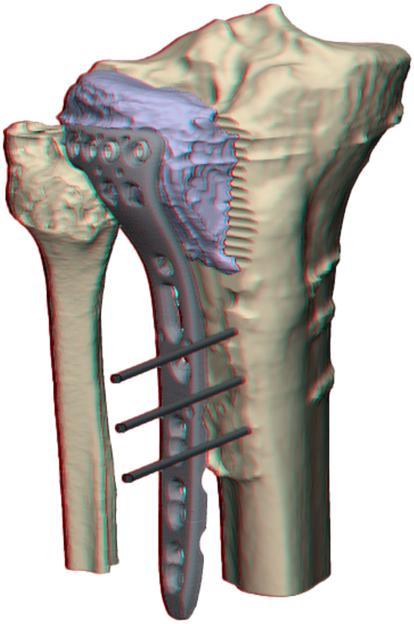

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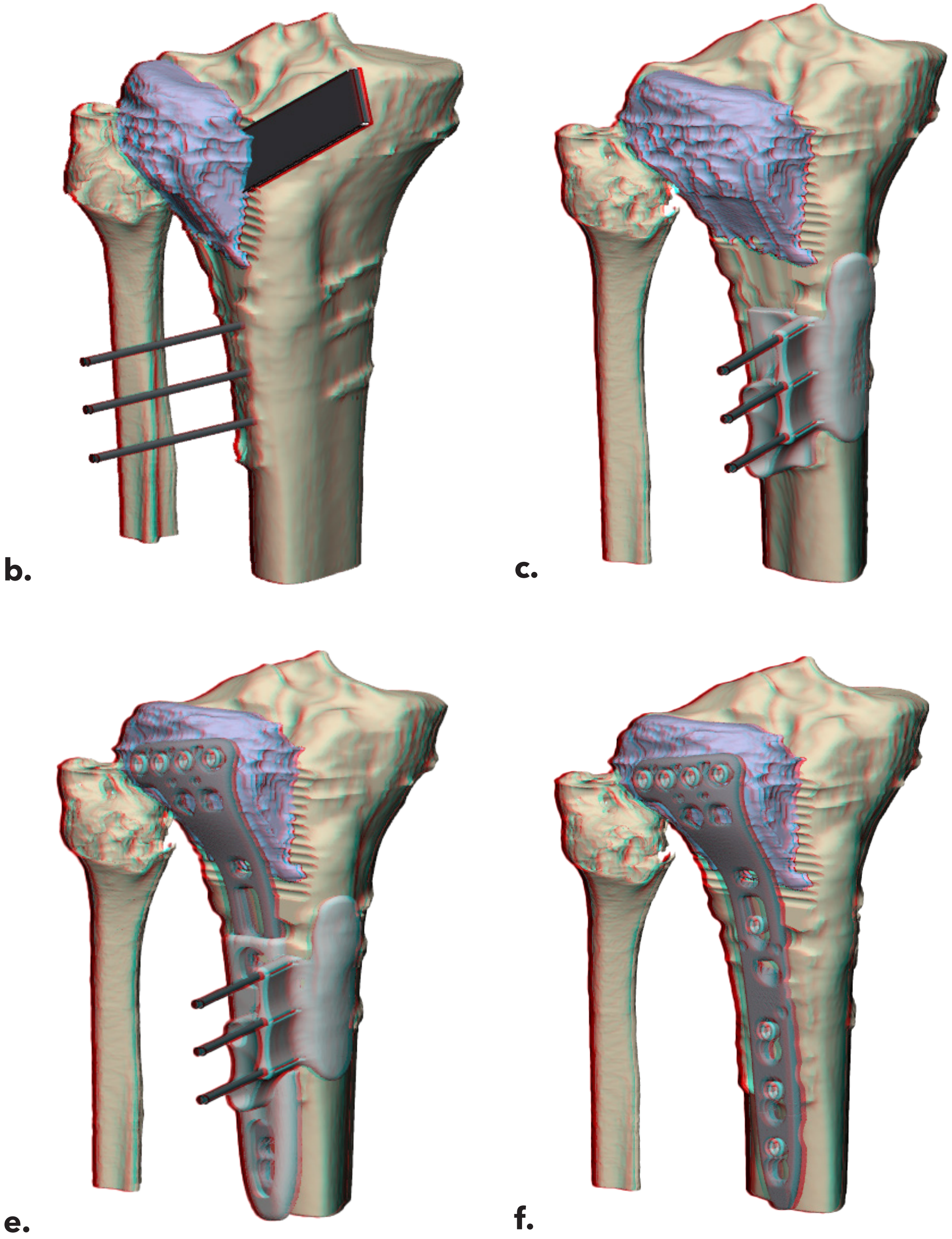
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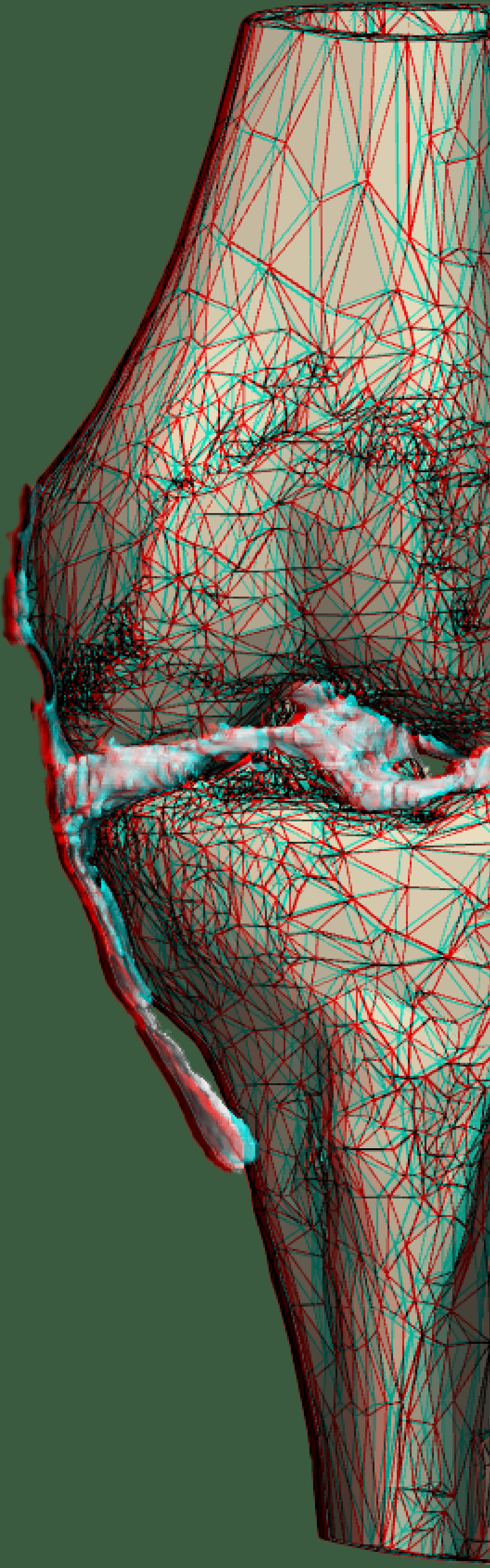
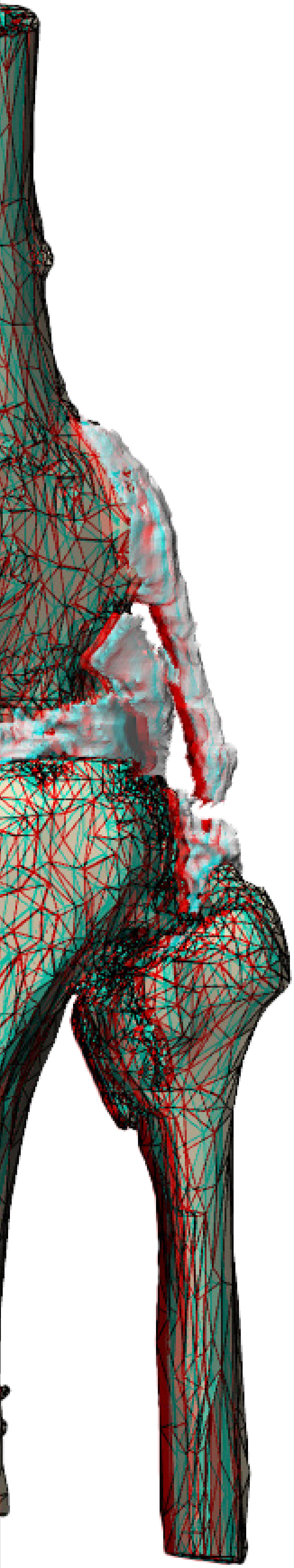
CHAPTER 15





DISCUSSION

Over the past few years, an increasing number of different 3D technologies have found their way into clinical practise. In healthcare, 3D technology has proven to be a disruptive technology, changing the way how treatment is performed. The aim of this thesis was to introduce novel 3D techniques in the field of orthopaedic trauma surgery. Different techniques were developed, clinically applied and evaluated with the ultimate goal to customize treatment for patients with tibial plateau fractures. This chapter provides a discussion on the findings of the research presented in this PhD thesis and offers scenarios for future developments and research.

FRACTURE ASSESSMENT

The principle "Primum non nocere" meaning "First, do no harm" is a longstanding adage in medicine dating back to the ancient Greeks. It emphasizes the need to carefully weigh the potential negative effects against the positive effects of any medical intervention, and suggests that in some cases, choosing not to intervene may be the preferable option. In order to follow this principle and to assess which patient does, and which patient does not benefit from surgical intervention, a proper assessment of a tibial plateau fracture is crucial. Early indications for proceeding to surgical treatment in tibial plateau fractures were based on radiographs, and include an intra-articular fracture gap or step-off of more than 2 mm [1–3]. Though, ever since its introduction more than 30 years ago, the 2 mm cut-off has been self-propagated, despite numerous research with contradicting findings [4]. In this thesis was assessed whether the justification of surgical indications, such as the 2 mm cut-off for surgery, still holds based on evolving insights from CT-imaging. In chapter 2, the assessment therefore focused on whether nonoperatively treated patients with fracture displacement just above and below this 2 mm threshold, as measured on CT, differed in terms of functional outcome. Interestingly, our analysis revealed no significant differences between these groups, indicating that nonoperative management may be applicable for larger fracture displacements than traditionally thought. While numerous studies examined outcomes of surgical intervention, our study is unique as it addresses the less frequently explored territory of nonoperative treatment across a substantial cohort of over 200 patients. Though, a direct comparison with the operatively treated patients was not made. Therefore, in chapter 3 a comparative study between operative and nonoperative patients with minimally displaced fractures (gap/step-off ≤ 4 mm) was initiated. Results of this study reconfirm our findings of chapter 2 and indicate that regardless of the treatment type, no differences in patient-reported outcomes should be expected at mid-term follow-up in minimally displaced fractures. Furthermore, 4% of the patients experienced complications after operative treatment, and 39% required a secondary intervention, mostly for implant removal, which exposes the patient to further harm. Nonoperative treatment should therefore be considered as the preferred treatment option in fractures with minimally displaced fractures. These results align with a growing awareness in recent years that non-surgical treatment might serve as a good treatment option for some fractures, associated with fewer adverse events and lower costs [5]. This perspective was also shared in the book "Surgery, the ultimate placebo", which sheds light on a broader reconsideration of operative treatments, suggesting that for many conditions, the perceived benefits of surgery may not always outweigh the risks [6]. This viewpoint encourages both patients and physicians to critically evaluate the necessity and potential outcomes of surgical procedures. As the demand for healthcare continues to rise in the near future, challenges regarding capacity are anticipated, potentially placing society for difficult choices where limited healthcare resources must be allocated. Opting for nonsurgical treatment in patients with minimally displaced tibial plateau fractures might save valuable resources without compromising functional outcomes as chapter 2 & 3 indicate. Also, this knowledge is of importance in the shared decision-making process, in which surgeon and patients should weigh the increased risks of operative treatment against potential benefits such as early mobilization. Should surgery be the chosen path, the surgeon strives to achieve anatomical restoration, providing the patient with the strongest foundation for recovery. However, the complexity of the fracture, soft tissue damage, and limited sight with intraoperative fluoroscopy can sometimes make this goal unattainable, and even if anatomical restoration is achieved, the damage caused by the initial trauma may still negatively affect outcomes. Though, the exact impact of both the initial trauma and the achieved reduction on patient outcomes remains subject that requires further research. To aim for improved patient counselling regarding prognosis, chapter 4 assessed the relationship between initial fracture displacement, quality of reduction, and postoperative tibial alignment with the need for conversion to a total knee arthroplasty (TKA). This study is unique as it simultaneously evaluates initial and postoperative radiographic predictors in a large cohort of 477 patients who underwent operative treatment. Our findings reveal that substantial initial displacement indeed strongly indicates a higher risk of TKA, even if anatomical reduction is achieved. This association is likely due to irreversible damage to the soft tissues and cartilage resulting from the initial trauma. Notably, tibial alignment emerged as a crucial predictor, while a residual displacement of up to 4 mm appeared to be well tolerated. These insights underscore the importance of prioritizing tibial alignment in surgical planning to minimize the risk of adverse long-term outcomes.

Current radiographic measurements of articular displacement and tibial alignment are and will remain important in clinical practice due to their simplicity and practicality. Yet, some concerns have been raised regarding the accuracy and reliability of measuring articular displacement [7]. Measuring the displacement on a plain projection or single CT-slice might not represent the true three-dimensional fracture displacement, and selecting a single CT-slice for measurement induces observer variability [8–10]. Quantitative 3D measurement is a promising technique for reliable assessment of true fracture displacement [11]. In chapter 6, a novel 3D measurement of articular displacement in tibial plateau fractures, named 3D gap area, was introduced. Evaluation showed that this measurement has superior reliability as compared to conventional gap and step-off measurements. Yet, only improved reliability does not justify the usage of this novel measurements if precision is suboptimal. In other words, being able to reliably reproduce a measurement which does not measure anything meaningful does not add anything to clinical practice. Therefore, Chapter 7 & 8 further investigated the association of the 3D gap area measurement with functional outcome in terms of risk on TKA and patient-reported outcome. This research showed that increasing 3D gap area is associated with both increased risk on TKA as well as worse patient-reported outcome, and therefore these findings provided justification and value to the use of 3D fracture assessment. This 3D measurement could be used as an addition to the current fracture classification methods in order to identify patients who are at risk for conversion to TKA and providing the patient with estimation of the prognosis. Though, an important practical limitation is that performing the 3D fracture assessments is still labour intensive and should therefore be reserved for selected cases. Future software packages might include automated analysis tools to streamline these assessments, potentially making them more accessible and less time-consuming for clinical use.

Besides severe damage to the osseous part of the knee, tibial plateau fractures are frequently accompanied by soft tissue injuries, with studies reporting incidences of associated soft tissue injury ranging from 93% to 99%[12,13]. Tibial plateau fractures are characterized by unique 3D patterns linked to specific injury mechanisms, which in turn are correlated with particular types of soft tissue damage [14]. In Chapter 9, our analysis has further established that these injury mechanisms are closely tied to clinical outcomes. Especially fractures resulting from varus-flexion forces often lead to poorer functional outcomes, attributed to their complexity and associated soft tissue injuries including damage to the (postero)lateral ligaments. By identification of the injury mechanism, one could identify patients who would most benefit from advanced surgical planning and treatment strategies, thereby enhancing the likelihood of improved surgical results and patient recovery. By integrating these 3D pattern characteristics into preoperative planning, clinicians can better tailor their surgical approach to address both the osseous and soft tissue components of the injury, potentially mitigating the risk of postoperative complications and optimizing long-term functional outcomes.

OUTCOME PREDICTION

As highlighted in the first part of this thesis, fracture characteristics have a significant impact on the outcome after a tibial plateau fracture. Logically, more severe fractures tend to have poorer outcomes than less severe fracture. However, there is growing evidence that objective measures of injury severity do not consistently align with the intensity of symptoms experienced by patients [15]. A variety of other aspects including patients' demographics, social background and mental health also play a role in what outcome can be expected [15]. Combining all these different features to provide a solid prediction may lead to complex models in which interrelationships between these different features are hard to understand. Artificial intelligence show high potential for combining huge sets of datapoints into one cohesive prediction model. Though, in the field of orthopaedic trauma surgery there is a lack of good clinical prediction models, partly due to the difficulty in obtaining large high-quality datasets including patient information, fracture details, and follow-up data. The dataset compiled for this thesis is unique in both its size and comprehensiveness, enabling us, in Chapter 5, to develop a tool for predicting the personalized risk of conversion to TKA using a machine-learning based algorithm (access through: https://3dtrauma.shinyapps.io/knee_prosthesis_prediction/). This model includes both patient and fracture characteristics and has demonstrated considerable robustness with an area under the curve (AUC) of 0.83. Though, as the dataset is relatively small by AI standards and was collected retrospectively, it should be considered a proof-of-concept for developing future prediction tools for clinical outcome. Also, there was deliberately chosen to include 2D radiographic measurements of the fractures as features since these are widely known and applicable throughout the medical field. Yet, future models should investigate whether the use of 3D imaging data and measurements will further improve accuracy of the predictions. The prediction model built here represents a first concept towards a decision-making process based on big data and patient-specific features in the treatment of tibial plateau fractures. Although our model seems promising, it is important to recognize that the use of AI in predicting outcomes for patients with tibial plateau fractures is still in its early stages. In the future, AI systems could serve as "copilots" for physicians by providing data-driven insights. These insights could help them inform discussions with patients and guide treatment decisions, ultimately facilitating more personalized and informed decisions at the individual level. By combining the expertise of (technical) physicians with the analytical power of AI, the move towards a more personalized and effective approach to healthcare is possible. Furthermore, future models are anticipated to incorporate feedback mechanisms, thereby enhancing their accuracy and utility through ongoing application (Fig. 1).

3D SURGICAL PLANNING

Acute fracture treatment

3D visualization technologies have been integrated within orthopaedic trauma care within the past few years. Chapter 9 provides a full overview of what existing 3D technologies are employed in the treatment of tibial plateau fractures. Additionally, the meta-analysis shows that the use of 3D technologies reduces operation time, blood loss and perioperative use of radiography. The 3D technique used in most studies, however, was limited to 3D printed tangible fracture models used for visualisation of the fracture. Within this thesis, our aim was to explore and develop more advanced 3D methods to translate a virtual surgical plan into practical applications within the operating room.

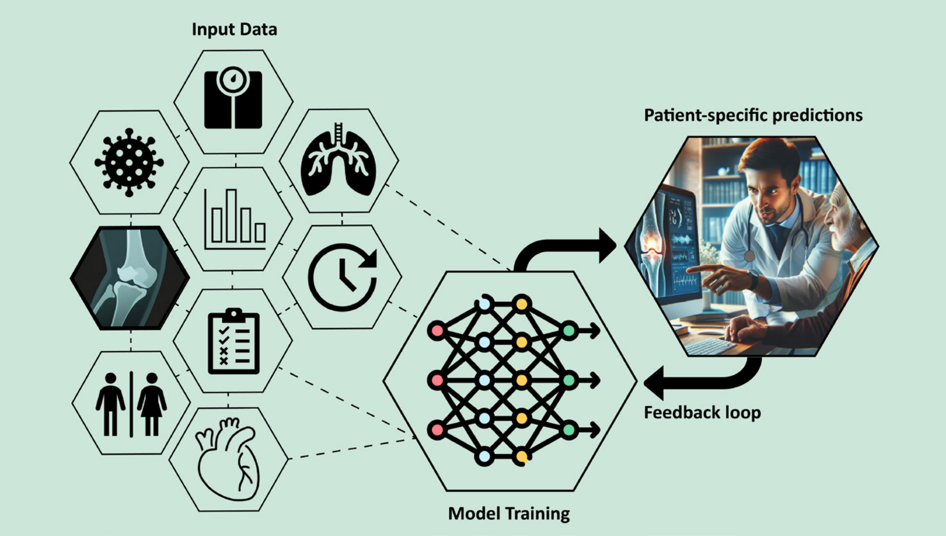


Figure 1: Patient-specific prediction modeling can enhance data-driven shared decision-making, allowing physicians and patients to weigh the potential benefits against the risks of treatment options. This approach utilizes the model's output, combined with the physician's expertise and the patient's personal preferences, to make informed choices about treatment.

One way to translate a virtual surgical plan into real-world surgical actions is by using 3D printed cutting and drilling guides which are tailored to a patient's unique anatomy. In Chapter 10, 3D printed surgical drilling guides, designed to envelope the standard variable angle locking plate, were developed and applied. This method facilitated accurate translation of planned screw directions and entry point within a margin of 3.4° and 3.0 mm of the planning, respectively. These results illustrate that a virtual planning of a tibial plateau fracture could be accurately translated into the actual surgical procedure. When dealing with communitive fractures, however, the achieved reduction still dependents on both the overall reconstructability and the surgeon's expertise, which cannot be fully directed with 3D technology. Despite this less predictable factor, our study demonstrated an improved surgical reduction as compared to a historical cohort. The improvement in the quality of the reduction is likely attributable to the integration of the 3D workflow which included thorough preoperative planning. This process allows for a detailed understanding and visualization of the fracture, enabling surgeons to strategize more effectively before and during the procedure. A variety of studies have already acknowledged the benefits of preparing surgeries by using 3D technology in this manner [15,16]. The surgical guides, such as developed in chapter 10, could provide a valuable tool to further enhance the execution of the planning and are considered a first step to fully guide the surgeon during surgery.

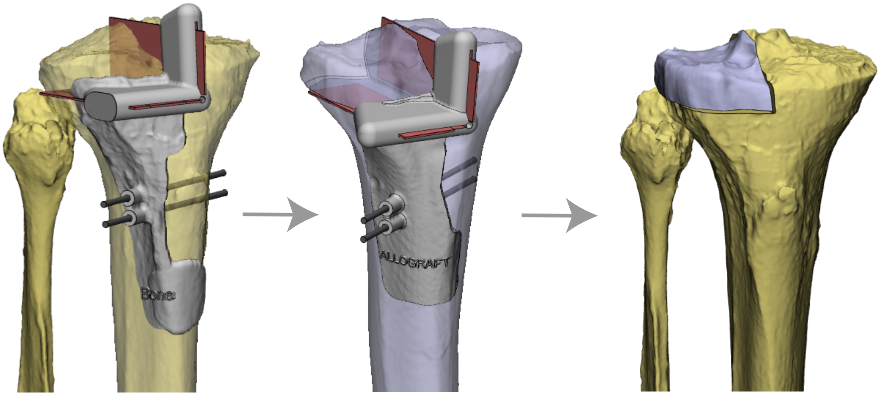
The potential of 3D surgical planning in tibial plateau fracture treatment could be further elevated through the application of patient-specific implants. These customized implants could serve as a template to facilitate anatomical reduction. In case the fit of the implant is suboptimal, it signals to the surgeon that there is a deviation from the planned reduction, serving as a direct feedback mechanism during surgery. This is particularly beneficial in the management of complex fractures, where the fracture fragments are completely separated from the shaft. In chapter 11, therefore a patient-specific implant for tibial plateau fracture treatment was developed. This study encompassed a cadaveric study in which our designed implants were tested on a self-inflicted fracture. Results showed that using custom-made osteosynthesis plates with drilling guides facilitate proper fracture reduction, tibial alignment and accurate screw placement. Also, the whole workflow including 3D surgical planning, design and fabrication of implants, and sterilization was feasible within 5 days. Implementation of these customized plates into clinical care would equip surgeons with a more sophisticated and effective strategy for addressing even the most challenging fractures, potentially improving surgical outcomes and patient recovery. Next step before implementation encompasses a finite element analysis after which a prospective pilot study should be performed to further assess the additional value of these patient-specific implants in tibial plateau fracture care.

Deformity correction

The outcomes of operatively treated tibial plateau fractures, particularly those that are highly comminuted, do not always meet expectations due to the complexity and severity of these injuries [16]. The retrospective data gathered for this thesis showed that in 2.2% of the patients, revision surgery was required to correct for the poor reduction. Such revisions might be necessary shortly after initial procedure or at a later stage, when bone healing has occurred, with corrective osteotomy surgery often as the chosen method. 3D technology emerged as promising, and by now proven, technique to enhance predictability of the surgical procedure of these corrective osteotomies [17].

The most frequently used technique involves utilizing a 3D-printed guide to accurately drill the screw trajectories and to guide the osteotomy cut with precision. The use of an osteosynthesis plate, in conjunction with the pre-drilled screws, subsequently guides the repositioned bone segments into their pre-planned alignment. However, this method assumes good fitting of the osteosynthesis plate, which is not always the case, especially when dealing with deformed bones. In chapter 12, the use of an alternative method using the 'two-step osteotomy method' was therefore explored. This technique involves initially placing K-wires through a 3D-printed guide, followed by performing the osteotomy using the same guide. Subsequently, the planned correction is achieved by forcing the bone into planned position using a reduction guide that slides over the K-wires. This method resulted in an accurate correction of bone deformities with alignment deviations of 2.1 ± 1.0 for angulation and 3.4 ± 1.6 degrees for rotation from the preoperative planning. Therefore, this method should be the preferred treatment option in scenarios where the fitting of osteosynthesis plates is not ideal.

Where most 3D assisted corrections are dealing with extra-articular fractures, intra-articular malunions are more challenging. In chapter 13, an innovative 3D guided method which is called the ‘panflute’ method was developed. Where ‘normal’ osteotomies are usually restricted to plain cuts, this concept provides the possibility of curved cuts. In addition, from every drill trajectory the depth could be controlled which safeguards posterior vascular structures. This method was found accurate and feasible, and provides another solution to our arsenal, namely to also treat intra-articular malunions. Though this method requires that there is still relatively good cartilage for the knee to function properly. In situations where the damage to the articular surface precludes the effectiveness of an intra-articular osteotomy, and a patient is reluctant or too young to undergo uni-compartmental or total knee arthroplasty, an alternative treatment option is the reconstruction of the articular surface using an allograft [18]. Figure 2 illustrates a clinical case of this complex correction in which the 3D printed surgical guides are first used to resect a severely damaged lateral plateau, then to cut the lateral plateau from an allograft, allowing it to fit perfectly in the defect as planned. This technique complements the range of different 3D assisted corrective osteotomies available today.



Resection lateral plateau patient

Resection lateral plateau allograft

Placement allograft in knee patient

Figure 2: 3D planned articular reconstruction using an allograft. The affected lateral plateau is resected using a patient-specific 3D printed guide. A similar guide is used for the allograft such that the resected allograft fits perfectly if the patients’ knee.

FUTURE PERSPECTIVES

MRI based surgical planning

Soft tissue injuries accompanying a tibial plateau fracture are more the rule than exception with reported incidences between 93% to 99% [11,12]. Despite this high prevalence, a preoperative MRI for surgical planning is barely performed in current clinical practice. In high-energy injuries, MRI could help in the preoperative surgical planning as it helps to assess cartilage damage and soft tissue injuries [19]. For surgical planning, fusion of MRI and CT has demonstrated its value in oncological cases, offering a more complete view of the structures involved [20]. This approach could also be beneficial in managing complex tibial plateau fractures, as the insight offered by combining these imaging modalities could lead to a more nuanced understanding of the injury, facilitating a tailored surgical approach that addresses both bony structures and soft tissue. Ultimately, CT might not even be needed as recent reports show the creation of synthetic CT from MRI, or bone segmentation from black bone MRI [21,22]. This does not only reduce the patient's exposure to radiation but also simplifies the diagnostic process by relying on a single imaging modality.

Optimalisation by Digital Twins

Digital twins are digital representations of an actual physical asset. Concrete applications can be found mainly in the industrial context. Healthcare represents another relevant area where digital twins can have a disruptive impact[23]. By creating a digital twin of a patient, several patient-specific aspects can be taken into account including medical history, bone density/quality, fracture pattern, and real-time biomechanical data (e.g. ligamental attachment and muscle forces). This allows the healthcare practitioner to simulate different treatment scenarios, personalize treatment plans, and predict potential health outcomes. Within orthopaedic trauma care, and specifically in treatment of tibial plateau fractures, a digital twin of a patients' knee could further enhance personalized care. By incorporating CT, MRI, and kinematic data into a digital representation of the knee (Fig. 3), different scenarios could be assessed to facilitate personalized clinical decision-making. Combining these data in a model could allow for a patient-specific finite element model in which biomechanical behaviors associated with different stabilization methods of tibial plateau fractures can be assessed [24]. Such advanced modeling could guide decisions regarding whether to use a conventional or customized implants, and ultimately which shape and thickness a customized implant should get. Additionally, by simulating the biomechanical forces acting on the knee during movement, the model could provide valuable insights into the feasibility of early weight-bearing post-surgery [25]. This capability would have significant implications for patient recovery, as early weight-bearing potentially enables faster rehabilitation, a quicker return to daily activities and sports, and reduced hospital stays [26]. Whereas in the long-term, early weight-bearing may ultimately lead to improved patient-reported outcomes [27]. This approach could fundamentally alter how clinicians plan and execute treatments, making it possible to anticipate challenges and optimize outcomes in a way that was previously unimaginable.

Hybrid Operating Room

The Hybrid Operating Room is a facility that combines the capabilities of a traditional operating room with advanced medical imaging technology for real-time intraoperative guidance. This integration has the potential to facilitate the translation of patient-

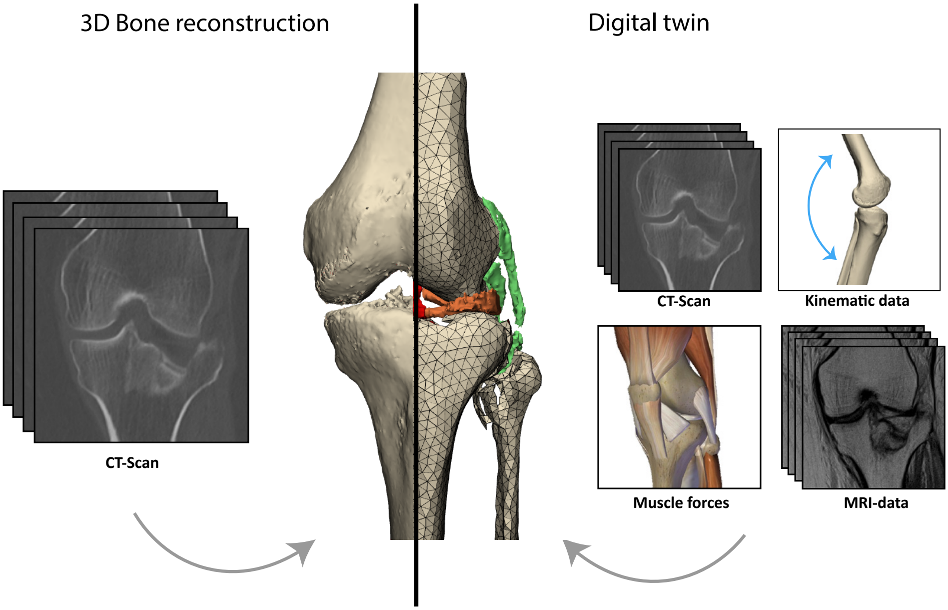


Figure 3: Visualization of the process of creating a digital twin. Where current 3D surgical planning is based on solely the CT-scan (left), future digital twin models (right) include the CT-scan, MRI-scan, kinematic data, muscle attachments and forces to create a patient-specific digital representation.

specific 3D virtual surgical plan into precise surgical interventions. In orthopaedic trauma surgery, bringing intraoperative 3D imaging into the hybrid operating room allows for several intra-operative applications [28]. One application involves the intra-operative assessment of the achieved fracture reduction. A recent study showed that in tibial plateau fractures intraoperative 3D imaging leads to substantial intra-operative revision rate of 26% [29]. Decisions whether to revise or not were based on surgeon's expertise and interpretation of the intraoperative imaging. The development of an automated fracture assessment tool that correlates achieved surgical reduction with expected functional outcomes could revolutionize surgical decision-making. A "traffic light" model could provide a solution, giving the surgeon three possible outcomes: acceptable result (green), requiring reassessment (orange), and definitive revision (red). Such a model would aid the surgeons in making informed decisions during surgery.

Additionally, the integration of a preoperative surgical plan with intra-operative navigation techniques could help in translating the plan into the patient, improving accuracy and predictability. Augmented reality could significantly contribute to this integration by overlaying virtual surgical plans—like screw trajectories or osteotomy lines—directly onto the surgeon's view. This eliminates the need for the surgeon to rely on viewing these plans on a (2D) screen, thus freeing them from associated restrictions and seamlessly incorporating these plans into the surgical field of view. Taking it one step further, one could think about robot assisted screw placement in which a robotic arm precisely positions a drilling sleeve for the surgeon. In the specific context of tibial plateau fracture surgery, these technologies could enable minimally invasive approaches. For instance, in the treatment of a depression fracture, a punch could be guided to elevate the depressed bone segment, followed by the guided placement of screws to stabilize the corrected fragments.

Workflow

The complete workflow from detailed preoperative planning until image guided surgery relies on expertise and understanding of anatomy, pathology, complex imaging techniques and data processing. This workflow greatly benefits from a close collaboration between surgeon and technical experts. In response to the technological transformation of healthcare, a new type of professional was created: the technical physician. The technical physician is trained in both medical and technical competencies to enhance individual patient care through the utilization of technology. Their integration into the healthcare sector in the Netherlands might benefit effectiveness, efficiency, and safety of patient care [30]. The dynamic collaboration between surgeons and technical physicians, each with their unique insights and skills, could further enhance the workflow outlined in this thesis. By merging the clinical insights of surgeons with the technological knowhow of technical physicians, cutting-edge technology could be utilized to its fullest potential. Through combined efforts, the full potential of technology could be exploited to move the field of surgical intervention into a new era of customized treatment for patients with a variety of fractures.

CONCLUSION

Technology has impacted society greatly in the past decades, and has enabled a high degree of personalization across various aspects of our lives. Also in healthcare, personalization holds immense potential to enable customized patients' treatment plans and personalized outcome prediction. This PhD thesis showed aspects of personalization in each phase of the patient's treatment including preoperative assessment, intraoperative guidance, postoperative corrections of malunions, and outcome prediction. Through this thesis existing guidelines were challenged, patient-specific prediction tools developed, measurement enhanced by quantitative 3D imaging, and 3D virtual surgical planning implemented. As 3D technology keeps developing, it is my strong belief that this thesis is only a first step of an ongoing journey towards customized treatment of injured patients. Through continued research, innovation, and collaboration between surgeons and technical physicians, the full potential of personalization in healthcare could be unlocked, ultimately leading to an era where every patient receives treatment tailored to their circumstances and unique needs.

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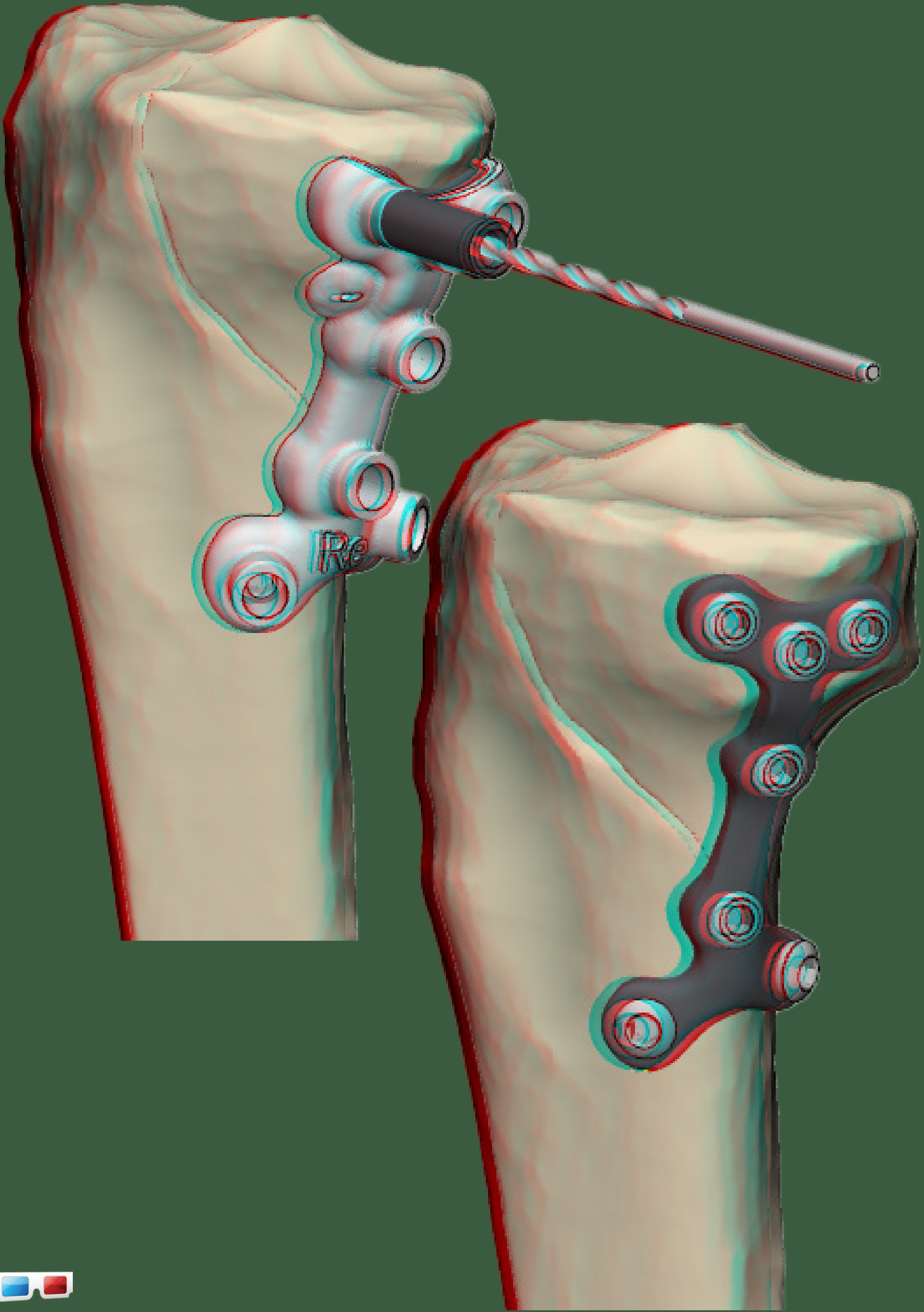
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APPENDICES

SUMMARY

Fractures of the tibial plateau involve the articular surface of the tibia within the knee joint. Since the knee is one of the body's most load-bearing structures, such fractures significantly impair patients' mobility, severely restricting their ability to engage in social activities and work. Effective treatment of these fractures requires a detailed understanding of its nature. Visualization, characterization, and quantification of the displacement are essential in order to determine the appropriate treatment of the fracture. Recent advances in high-resolution CT scanners enable detailed 3D reconstructions, while increased computing power facilitates the processing and analysis of large datasets, paving the way for innovations that could greatly enhance both diagnostics and treatment. This PhD research has focused on using novel (3D) techniques to improve measurements, customize patient treatment, and provide patient-specific outcome predictions. The aim of this thesis was to contribute to a more patient-tailored approach in treating tibial plateau fractures.

For every fracture, it is essential to weigh the surgical benefits against potential complications, which requires shared decision-making for each patient. However, there is limited evidence to support patient counselling, especially for minimally displaced fractures. ***Part I*** of this thesis, therefore, focuses on conventional fracture assessment and its relationship to clinical outcomes. The research focused on whether the old recommendation for surgical treatment with a 2 mm threshold based on radiographs could be justified or if this should be revisited based on evolving insights from CT images. **Chapter 2** assessed if conservatively treated patients with gaps or step-offs over 2 mm have worse functional outcomes than those with displacement below 2 mm. This study found no significant differences in functional outcomes between subgroups with gaps and step-offs up to 4 mm, suggesting that current guidelines may be overly conservative. However, only conservatively treated patients were included, lacking a direct comparison with operative treatment. **Chapter 3** therefore included a direct comparison between 195 operatively and 300 conservatively treated patients with minimally displaced fractures (<4 mm). The study revealed that, regardless of treatment type, there were no significant differences in patient-reported outcomes at mid-term follow-up. Additionally, operative treatment had a 4% complication rate, while no complications were reported in the nonoperative group. Furthermore, 39% of operatively treated patients required secondary interventions, mostly for elective implant removals, compared to 6% in the nonoperative group. These findings suggest nonoperative treatment may be preferable for minimally displaced fractures when considering mid-term outcomes. The increased risks associated with operative treatment should be outweighed against potential benefits, such as early mobilization. The findings suggest that the arbitrary 2-mm threshold for surgical intervention, traditionally based on radiographs, may no longer be appropriate in light of more precise assessments using

CT imaging.
In case surgical treatment is pursued, main goals of surgery for a tibial plateau fracture are to restore joint stability, limb alignment, and articular surface. Since radiographic measurements guide both treatment decisions and prognosis, understanding their association with clinical outcomes is crucial. While fracture displacement, reduction quality, and tibial alignment are thought to influence the risk of posttraumatic osteoarthritis and Total Knee Arthroplasty (TKA), their exact impact remains unclear. **Chapter 4** assessed this relationship, finding that significant preoperative displacement (gap >8.5 mm, step-off >6.0 mm) was strongly associated with conversion to TKA. Postoperative sagittal and coronal malalignment were also associated with increased TKA risk, while, in contrast to common belief, postoperative gaps or step-offs of up to 4 mm were not. These findings can be used as a guide for shared decision-making in tibial plateau fracture treatment, and may aid in expectation management and patient counselling about the prognosis.

Providing effective patient counselling necessitates the ability to estimate prognosis accurately. The associations found in the previous chapters give some indications regarding expected outcome. However, personalized predictions remain challenging due to the multifactorial nature of prognosis determination, which relies on factors including both patient as fracture characteristics. ***Part II*** of this thesis covered patient-centred outcome prediction tools. **Chapter 5** describes the development and internal validation of a clinical prediction model using machine learning algorithms for 2 and 5-year risk on TKA following tibia plateau fractures. Patient and fracture characteristics were utilized to create a personalized risk assessment tool that could aid in clinical decision-making and patient counselling. The results indicate that machine learning algorithms, particularly random forest and logistic regression, can achieve reasonable accuracy and performance in predicting TKA conversion. These findings suggest that machine learning algorithms have potential to create valuable tools for patient counselling and shared decision-making in the field of orthopaedic-trauma surgery. The final model which facilitates 'personalized outcome prediction for each patient' was made available through an online tool: https://3dtrauma.shinyapps.io/knee_prosthesis_prediction/.

As fractures frequently involves 3D displacement across multiple planes, it is difficult to accurately quantify the true extent of the fracture on conventional (2D) imaging modalities. Moreover, concerns remain regarding interobserver reliability of these radiographic measurements, particularly on CT-slices in which the measurement heavily depends on which CT slice is selected. Therefore, in ***Part III*** of this thesis novel quantitative 3D-CT (Q3DCT) measurements to determine fracture displacement have been developed. In **Chapter 6** several new metrics to quantify initial displacement were introduced: the 3D gap area, articular surface involvement, and 3D displacement. The results showed that Q3DCT measurements were superior in reliability, with intraclass correlation coefficients (ICCs) of more than 0.96, compared to 0.81 and 0.32 for the gap and step-off measurements on 2D CT slices, respectively. The 3D gap area, the surface area (mm^2) between all fracture fragments, represents the total displacement at the articular level. This measure particularly showed potential for clinical use. Therefore, in **Chapter 7**, its association with the risk of conversion to TKA was assessed. The results demonstrated that the degree of initial fracture displacement as measured by the 3D gap area was a strong predictor for conversion to TKA. Four prognostic groups were established based on 3D gap area cut-off values, with increasing risks of conversion to TKA at follow-up: excellent (0–150 mm2), good (151–550 mm2), moderate (551–1000 mm2), and poor (> 1000 mm2). At 10-years follow-up, the percentage of patients still having their own knee (i.e. no conversion to TKA) was 96.4% in the excellent group, 95% in the good group, 75.5% in the moderate group, and 58.5% in the poor group. These findings suggest that the 3D gap area measurement could be a valuable tool for assessing initial fracture displacement and predicting long-term outcomes in tibial plateau fractures. **Chapter 8** further expanded the application of the 3D gap area measurement method by also facilitating postoperative assessments. The study examined the association between the 3D gap area and patient-reported outcome, as measured by the KOOS (Knee Injury and Osteoarthritis Outcome Score) questionnaire. The findings demonstrated that patient-reported outcomes worsened significantly as initial or residual fracture displacement increased. Specifically, for every 100 mm^2 increase in initial 3D gap area, the KOOS subscale scores (0-100) decreased by 0.8 to 1.4 points, while each 100 mm^2 increase in residual 3D gap area led to a decrease of 2.2 to 2.6 points. These findings suggest that both the initial trauma, which may cause irreversible damage, and accurate fracture reduction play a role in the patient's recovery. Reliable 3D measurements of initial and residual displacement could help physicians provide more accurate prognoses for tibial plateau fracture patients.

The patterns of tibial plateau fractures vary widely based on the injury mechanism and knee position at trauma. These range from simple split fractures to complex multi-fragmentary fractures involving the lateral, medial, or bicondylar. Different injury forces, such as varus or valgus stresses combined with knee flexion or extension, are linked to specific fracture patterns and associated soft tissue injuries, both of which can significantly impact patient outcomes. **Chapter 9** explored the relationship between these injury mechanisms, assessed in 3D, and patient outcomes. The results of this study show that especially fractures caused by a varus-flexion force have worse prognosis as compared to the other mechanisms regarding both patient-reported outcome and risk on conversion to TKA. In addition, these injuries required more reoperations, and fracture-related infections as compared to other mechanisms of injury. On the contrary, fractures caused by a valgus-extension mechanism showed reduced risk on a TKA as compared to other mechanisms. Therefore, especially fractures caused by a varus-flexion trauma might benefit from more extensive preoperative workup, including 3D surgical planning and potentially MRI for soft tissue assessment. This research highlights the need to understand injury mechanisms for better patient counselling, planning, and prognosis.

Part IV of this thesis focused on the use of different tools such as surgical guides and custom-made implants to translate a virtual patient-specific surgical plan into the operating room. **Chapter 10** provides an overview of the current 3D technology concepts and their impact on patient outcomes. A total of five different concepts of 3D assisted surgical management of tibial plateau fractures were identified: '3D virtual visualization', '3D printed hand-held models', 'Pre-contouring of osteosynthesis plates', '3D printed surgical guides', and 'Intra-operative 3D imaging'. The reviewed studies suggest that 3D assisted surgery improves operation time, reduces blood loss and fluoroscopy frequency, and enhances functional outcome. Though potential benefits should be further investigated whereas most identified studies focussed on visualization by 3D printed fracture models rather than translation of a virtual plan into the operating room using 3D techniques. In **Chapter 11** a prospective feasibility study was therefore set up in which the application of 3D printed surgical drilling guides in combination with conventional plates in tibial plateau fracture surgery was evaluated. A total of 15 patients underwent 3D-guided surgery, in which the whole surgery was virtually planned and 3D printed surgical guides were used intraoperatively to translate the virtual positioning of the plate and screw trajectories into the surgery. In these patients a total of 83 screws were placed, which had a median deviation of 3.4° from the planned trajectory, whereas the screw entry point differed by 3.0 mm. Additionally, improved fracture reduction was achieved as compared to a historical control group. This study showed that the use of 3D surgical planning including drilling guides during the operation was feasible and facilitates accurate screw directions, screw lengths and plate positioning according to the preoperative plan. Though, as poor fitting of conventional plates could lead to suboptimal fracture reduction and tibial misalignment, the 3D surgical planning could be further optimized by using customized implants. In **Chapter 12** a feasibility study was therefore performed on the use of patient-specific osteosynthesis plates in combination with 3D-printed drilling guides for medial tibial plateau fracture surgery. In a total of six cadaver knees, fractures were created and a patient-specific implant including drilling guides were designed. This patient-specific workflow was found to be feasible and facilitated proper fracture reduction, tibial alignment and accurately placed screws by using custom-made osteosynthesis plates with drilling guides.

Outcomes after treatment of tibial plateau fractures, particularly those that are highly comminuted, do not always meet expectations due to the complexity and severity of these injuries. The last part of this thesis (***Part V***) covered the use of 3D planned corrective surgery in malunited fractures. In **Chapter 13** the two-step approach for performing 3D-guided patient-specific corrective limb osteotomies was presented. The commonly used pre-drilling method for 3D-guided corrective osteotomies assumes a good fit of the osteosynthesis plate, which is not always achievable, especially with deformed bones. The two-step technique uses a cutting guide to perform the osteotomy and a reposition guide to achieve the planned correction, and is therefore not dependent on perfect fit of the implant. A total of 10 patients were treated using this method with various post-traumatic bone deformities. Results showed good accuracy, with average deviations of 2.1° in angulation, 3.4° in rotation, and 1.8 mm in translation from the planned corrections. The two-step approach is reliable, feasible, user-friendly and accurate for corrective osteotomies of deformities in all long bones, and provides a good alternative when conventional implants have suboptimal fitting without requiring patient-specific plates. Yet, this method focusses on extra-articular malunions and is mostly optimized for use with oscillating saws, thereby rendering it incapable of executing curved osteotomies or facilitating precise depth control. In **Chapter 14** therefore a novel technique for 3D-assisted intra-articular corrective osteotomies for post-traumatic malunions after a tibial plateau fracture was developed. The concept facilitates the execution of curved osteotomies and precise depth control. In this study the feasibility was of this method was illustrated through a clinical case and showed accurate reconstruction of the malunited bone. The proposed method allows for a technical solution for complex intra-articular osteotomies.

Novel technological innovations allow for a high level of personalization, including in healthcare. Personalization in medicine offers great potential for customized treatment plans and outcome prediction. This dissertation explored personalization throughout the patient's treatment journey, from preoperative assessment to intraoperative guidance, postoperative corrections, and outcome prediction. It challenged existing guidelines, developed patient-specific tools, improved measurements with 3D imaging, and implemented 3D virtual surgical planning. As 3D technology advances, it is my believe that this work is just the beginning of a shift toward personalized care. Ongoing research and collaboration between surgeons and technical experts could unlock the full potential of personalized treatment, tailoring care to each patient's unique needs.

NEDERLANDSE SAMENVATTING

Fracturen van het tibiaplateau zijn breuken doorlopend in het gewrichtsoppervlak van het scheenbeen in het kniegewricht, een van de meest gewichts-dragende structuren van het lichaam. Deze fracturen hebben een grote impact op de mobiliteit, waardoor patiënten minder in staat zijn om te werken en deel te nemen aan sociale activiteiten. Effectieve behandeling vereist een goed begrip van de aard van de fractuur, waarbij nauwkeurige visualisatie, karakterisering en kwantificatie van de fractuurdislocatie essentieel zijn voor het bepalen van de juiste behandeling. Ontwikkelingen in hoge resolutie CT-scanners en verhoogde computer rekenkracht maken gedetailleerde 3D reconstructies en analyses mogelijk, wat innovatie in zowel diagnostiek als behandeling kan stimuleren. Dit promotieonderzoek richt zich op het gebruik van nieuwe (3D) technieken om meetmethoden te verbeteren, de behandeling te personaliseren en patiënt-specifieke uitkomstvoorspellingen te bieden. Het doel van dit onderzoek is om bij te dragen aan een gepersonaliseerde patiënt-specifieke behandeling van tibiaplateau fracturen.

Voor elke fractuur is het essentieel om de chirurgische voordelen af te wegen tegen mogelijke complicaties, wat gepersonaliseerde gezamenlijke besluitvorming voor elke patiënt vereist. Er is echter beperkt bewijs om het adviseren van patiënten te ondersteunen, vooral bij minimaal verplaatste fracturen. ***Deel I*** van dit proefschrift richt zich daarom op conventionele radiografische metingen aan de fractuur en de relatie daarvan met klinische uitkomsten. Het onderzoek richtte zich op de vraag of de oude aanbeveling voor chirurgische behandeling met een drempelwaarde van 2 mm dislocatie, gebaseerd op röntgenfoto's, gerechtvaardigd kon worden, of dat dit herzien zou moeten worden op basis van nieuwe inzichten van CT-beelden. **Hoofdstuk 2** beoordeelde of conservatief behandelde patiënten met gaps of step-offs groter dan 2 mm slechtere functionele uitkomsten hebben dan degenen met een verplaatsing onder de 2 mm. Deze studie vond geen significante verschillen in functionele uitkomsten tussen subgroepen met gaps en step-offs tot 4 mm, wat suggereert dat de huidige richtlijnen mogelijk te conservatief zijn. Er werden echter alleen conservatief behandelde patiënten geïncludeerd, waardoor een directe vergelijking met operatief behandelde patiënten ontbrak. **Hoofdstuk 3** omvatte daarom een directe vergelijking tussen 195 operatief en 300 conservatief behandelde patiënten met minimaal verplaatste fracturen (<4 mm dislocatie). De studie toonde aan dat, ongeacht het type behandeling, er geen significante verschillen waren in door de patiënt gerapporteerde uitkomsten op middellange termijn. Bovendien had de operatieve behandeling een complicatiepercentage van 4%, terwijl er geen complicaties werden gerapporteerd in de niet-operatieve groep. Daarnaast had 39% van de operatief behandelde patiënten secundaire ingrepen nodig, meestal voor implantaatverwijdering, vergeleken met 6% in de niet-operatieve groep. Deze bevindingen impliceren dat niet-operatieve behandeling de voorkeur heeft voor minimaal verplaatste fracturen, wanneer je kijkt naar uitkomsten op middellange termijn. De verhoogde risico's die gepaard gaan met operatieve behandeling moeten worden afgewogen tegen potentiële voordelen, zoals vroege mobilisatie. De bevindingen suggereren dat de willekeurige 2-mm-drempel voor chirurgische interventie, traditioneel gebaseerd op röntgenfoto's, mogelijk niet langer geschikt is in het licht van nauwkeurigere beoordelingen met CT-beelden.

Indien er voor chirurgische behandeling wordt gekozen, zijn de belangrijkste doelen van een operatie het herstellen van de gewrichtsstabiliteit, de stand van het been en het gewrichtsoppervlak. Aangezien röntgenmetingen zowel de behandel beslissingen als de prognose sturen, is het essentieel om hun verband met klinische uitkomsten te begrijpen. Hoewel men denkt dat fractuur dislocatie, kwaliteit van de reductie en uitlijning van het bot invloed hebben op het risico op posttraumatische artrose en een knieprothese, blijft de exacte impact onduidelijk. **Hoofdstuk 4** onderzocht deze relatie en vond dat significante preoperatieve verplaatsing (gap >8,5 mm, step-off >6,0 mm) sterk geassocieerd was met een knieprothese. Inadequate sagittale en coronale uitlijning van het scheenbeen waren ook geassocieerd met een verhoogd risico op een knieprothese, terwijl, in tegenstelling tot de gangbare opvatting, postoperatieve dislocatie tot 4 mm dat niet was. Deze bevindingen kunnen dienen als leidraad voor gedeelde besluitvorming bij de behandeling van tibiaplateau fracturen en kunnen helpen bij verwachtingsmanagement en het adviseren van patiënten over de prognose.

Effectieve patiëntconsultatie vereist de mogelijkheid om de prognose nauwkeurig te schatten. De associaties die in de vorige hoofdstukken zijn gevonden, geven enige aanwijzingen over de verwachte uitkomst. Persoonlijke voorspellingen blijven echter uitdagend vanwege de multifactoriële aard van prognosebepaling, die afhangt van zowel patiënt- als fractuurkenmerken. ***Deel II*** van dit proefschrift behandeld gepersonaliseerde predictiemodellen. **Hoofdstuk 5** beschrijft de ontwikkeling en interne validatie van een klinisch voorspellingsmodel met behulp van machine learning algoritmen voor het risico op een knieprothese op 2 en 5 jaar na een tibiaplateau fractuur. Patiënt- en fractuurkenmerken werden gebruikt om een gepersonaliseerd risicobeoordelingsinstrument te creëren dat kan helpen bij klinische besluitvorming en patiëntconsultatie. De resultaten geven aan dat machine learning-algoritmen, met name Random forest en Logistieke regressie, redelijke nauwkeurigheid en prestaties kunnen behalen bij het voorspellen van een knieprothese. Deze bevindingen suggereren dat machine learning algoritmen potentieel hebben om waardevolle tools te creëren voor patiëntconsultatie en gedeelde besluitvorming op het gebied van orthopedische-trauma chirurgie. Het uiteindelijke ontwikkelde model, dat 'gepersonaliseerde uitkomstvoorspelling voor elke patiënt' mogelijk maakt, is beschikbaar gemaakt via een online tool: https://3dtrauma.shinyapps.io/knee_prosthesis_prediction/.

Aangezien breuken vaak een 3D verplaatsing over meerdere vlakken met zich meebrengen, is het moeilijk om de werkelijke uitgebreidheid van de fractuur nauwkeurig te kwantificeren met conventionele (2D) beeldvormingsmodaliteiten. Bovendien blijven er zorgen bestaan over de betrouwbaarheid van deze radiografische metingen, vooral bij CT-slices waarbij de meting sterk afhangt van welke CT-slice wordt geselecteerd. Daarom zijn in ***Deel III*** van dit proefschrift nieuwe kwantitatieve 3D-CT (Q3DCT) metingen ontwikkeld om de breukverplaatsing te bepalen. In **Hoofdstuk 6** werden verschillende nieuwe metingen geïntroduceerd om de initiële fractuurdislocatie te kwantificeren: '3D gap area', 'articular surface involvement', en '3D displacement'. De resultaten toonden aan dat Q3DCT-metingen superieur waren in betrouwbaarheid, met intraclass correlatiecoëfficiënten (ICC's) van meer dan 0.96, vergeleken met 0.81 en 0.32 voor de gap- en step-off metingen op 2D CT-slices. De 3D Gap Area, ofwel het oppervlak (mm²) tussen alle breukfragmenten, vertegenwoordigt de totale verplaatsing op het gewrichtsniveau. Met name deze meting toonde potentieel voor klinisch gebruik. Daarom werd in **Hoofdstuk 7** de associatie met het risico op een knieprothese beoordeeld. De resultaten toonden aan dat de mate van initiële fractuurdislocatie, gemeten door de 3D gap area, een sterke voorspeller was voor een knieprothese. Vier prognostische groepen werden vastgesteld op basis van 3D gap area afkapwaarden, met toenemende risico's op een knieprothese tijdens follow-up: uitstekend (0–150 mm²), goed (151–550 mm²), matig (551–1000 mm²) en slecht (> 1000 mm²). Bij 10-jaars follow-up was het percentage patiënten dat nog hun eigen knie had (dus geen knieprothese) 96.4% in de uitstekende groep, 95% in de goede groep, 75.5% in de matige groep en 58.5% in de slechte groep. Deze bevindingen suggereren dat de 3D gap area meting een waardevol hulpmiddel kan zijn voor het beoordelen van initiële breukverplaatsing en het voorspellen van langetermijnuitkomsten bij tibiaplateau fracturen. **Hoofdstuk 8** breidde verder de toepassing van de 3D gap area meting uit door ook postoperatieve beoordelingen mogelijk te maken. De studie onderzocht de associatie tussen de 3D gap area en door de patiënt gerapporteerde uitkomsten, zoals gemeten met de KOOS (Knee Injury and Osteoarthritis Outcome Score) vragenlijst. De bevindingen toonden aan dat door de patiënt gerapporteerde uitkomsten significant verslechterden naarmate de initiële of postoperatieve fractuurdislocatie toenam. Specifiek, voor elke 100 mm² toename van het initiële 3D gap area, daalden de KOOS-subschalen (0-100) met 0.8 tot 1.4 punten, terwijl elke 100 mm² toename van de postoperatieve 3D gap area leidde tot een afname van 2.2 tot 2.6 punten. Deze bevindingen suggereren dat zowel het initiële trauma, dat onherstelbare schade kan veroorzaken, als een nauwkeurige fractuurreductie een rol spelen bij het herstel van de patiënt. Betrouwbare 3D metingen van initiële en postoperatieve dislocatie kunnen artsen helpen om nauwkeurigere prognoses te geven voor patiënten met tibiaplateau fracturen.

De patronen van tibiaplateau fracturen variëren sterk op basis van het mechanisme en de positie van de knie tijdens het trauma. Deze variëren van eenvoudige split fracturen tot complexe multi-fragmentaire fracturen die de laterale, mediale of beide condylen kunnen omvatten. Verschillende krachten, zoals een varus- of valguskracht in combinatie met kniebuiging of -strekking, worden geassocieerd met specifieke fractuurpatronen en bijbehorende letsels aan kniebanden en pezen. Beide factoren kunnen een aanzienlijke impact hebben op de uitkomsten voor de patiënt. **Hoofdstuk 9** onderzocht de relatie tussen deze traumamechanismen, geëvalueerd in 3D, en de uitkomsten voor de patiënt. De resultaten van deze studie tonen aan dat vooral fracturen veroorzaakt door een varus-flexiekracht een slechtere prognose hebben in vergelijking met andere mechanismen, zowel wat betreft door de patiënt gerapporteerde uitkomsten als het risico op een knieprothese. Bovendien vereisten deze verwondingen meer heroperaties en kregen vaker een infectie in vergelijking met andere traumamechanismen. Daarentegen toonden fracturen veroorzaakt door een valgus-extensie mechanisme een verminderd risico op een knieprothese in vergelijking met andere mechanismen. Daarom zouden vooral fracturen veroorzaakt door een varus-flexietrauma profiteren van een uitgebreider preoperatief onderzoek, inclusief 3D chirurgische planning en mogelijk MRI voor beoordeling van kniebanden en pezen. Dit onderzoek benadrukt de noodzaak om traumamechanismen te begrijpen voor betere patiëntconsultatie, planning en prognose.

Deel IV van dit proefschrift richtte zich op het gebruik van verschillende (3D geprinte) hulpmiddelen, zoals chirurgische mallen en patiënt-specifieke implantaten, om een virtueel chirurgisch plan te vertalen naar de operatie. **Hoofdstuk 10** geeft een overzicht van de huidige 3D technologie concepten en hun impact op de patiëntuitkomsten. In totaal werden vijf verschillende concepten van 3D geassisteerde chirurgie van tibiaplateau fracturen geïdentificeerd: '3D virtuele visualisatie', '3D-geprinte modellen', 'Vooraf contouren van osteosynthesemateriaal', '3D geprinte chirurgische mallen' en 'Intra-operatieve 3D beeldvorming'. De gevonden studies suggereren dat 3D geassisteerde chirurgie de operatietijd verkort, bloedverlies en fluoroscopie frequentie vermindert en de functionele uitkomst verbetert. Hoewel de potentiële voordelen verder onderzocht moeten worden, richtten de meeste geïdentificeerde studies zich vooral op visualisatie door 3D geprinte fractuurmodellen in plaats van op de vertaling van een virtueel plan naar de operatiekamer met behulp van 3D technieken. In **hoofdstuk 11** werd daarom een prospectieve haalbaarheidsstudie opgezet waarin de toepassing van 3D geprinte chirurgische boormallen in combinatie met conventionele platen bij tibiaplateau fractuur operaties werd geëvalueerd. In totaal ondergingen 15 patiënten 3D geassisteerde chirurgie, waarbij de gehele operatie virtueel werd gepland en 3D-geprinte chirurgische mallen intra-operatief werden gebruikt om de virtuele positie van de plaat en schroeftrajecten tijdens de operatie te behalen. Bij deze patiënten werden in totaal 83 schroeven geplaatst, met een mediane afwijking van 3.4° van het geplande traject, terwijl de entree van de schroeven met 3.0 mm verschilde. Bovendien werd een verbeterde fractuurreductie bereikt in vergelijking met een historische controlegroep. Deze studie toonde aan dat het gebruik van 3D chirurgische planning, inclusief boormallen tijdens de operatie, haalbaar was en nauwkeurige schroefrichtingen, schroeflengtes en plaatpositionering volgens het preoperatieve plan mogelijk maakte. Aangezien een slechte fit van conventionele platen op het bot kan leiden tot suboptimale fractuurreductie en uitlijning, zou de 3D chirurgische planning verder geoptimaliseerd kunnen worden door op maat gemaakte implantaten te gebruiken. In **Hoofdstuk 12** werd daarom een haalbaarheidsstudie uitgevoerd naar het gebruik van patiënt-specifieke osteosynthesemateriaal in combinatie met 3D geprinte boormallen voor mediale tibiaplateau fractuur operaties. Bij zes kadaverknieën werden fracturen gecreëerd en een patiënt-specifiek implantaat, inclusief boormallen, ontworpen. Deze patiënt-specifieke workflow bleek haalbaar en faciliteerde een goede fractuurreductie, uitlijning en nauwkeurig geplaatste schroeven door het gebruik van op maat gemaakte osteosynthesemateriaal met boorgidsen.

Uitkomsten na de behandeling van complexe multifragmentaire tibiaplateau fracturen voldoen niet altijd aan de verwachtingen door de complexiteit en ernst van deze verwondingen. Het laatste deel van dit proefschrift (***Deel V***) behandelde het gebruik van 3D geplande correctie osteotomieën malunions. In **Hoofdstuk 13** werd de twee-staps benadering voor het uitvoeren van 3D geassisteerde patiënt-specifieke correctie osteotomieën gepresenteerd. De meest gebruikte methode van 3D geassisteerde correctie osteotomieën is de ‘voorboormethode’ en gaat uit van een goede fit van het osteosynthesemateriaal, wat niet altijd haalbaar is bij vervormde botten. De twee-staps techniek maakt gebruik van een zaagmal om de osteotomie uit te voeren en een repositiemal om de geplande correctie te bereiken, en is daardoor niet afhankelijk van een perfecte fit van het implantaat. In totaal werden 10 patiënten behandeld met deze methode voor verschillende posttraumatische botdeformaties. De resultaten toonden goede nauwkeurigheid, met gemiddelde afwijkingen van 2.1° in angulatie, 3.4° in rotatie en 1.8 mm in translatie van de geplande correcties. De twee-staps benadering is betrouwbaar, haalbaar, gebruiksvriendelijk en nauwkeurig voor correctie osteotomieën van deformiteiten in alle lange beenderen en biedt een goed alternatief wanneer conventionele implantaten een suboptimale fit hebben zonder dat patiënt-specifieke platen vereist zijn. Deze methode richt zich echter op extra-articulaire malunions en is voornamelijk geoptimaliseerd voor gebruik met oscillerende zagen, waardoor deze niet in staat is om gebogen osteotomieën uit te voeren of een precieze dieptecontrole te faciliteren. In **Hoofdstuk 14** werd daarom een nieuwe techniek voor 3D geassisteerde intra-articulaire correctie osteotomieën voor posttraumatische malunions na een tibiaplateau fractuur ontwikkeld. Het concept faciliteert de uitvoering van gebogen osteotomieën en precieze dieptecontrole. In deze studie werd de haalbaarheid van deze methode geïllustreerd aan de hand van een klinische casus en werd een nauwkeurige reconstructie van het bot aangetoond. De voorgestelde methode biedt een technische oplossing voor complexe intra-articulaire osteotomieën.

Nieuwe technologische innovaties maken een verregaande mate van personalisatie mogelijk, ook in de gezondheidszorg. Personalisatie in de geneeskunde biedt kansen voor op maat gemaakte behandelmethoden en het voorspellen van prognoses. Dit proefschrift beschrijft de personalisatie gedurende het gehele behandeltraject van de patiënt, van preoperatieve beoordeling tot intra-operatieve begeleiding, en van postoperatieve correcties tot uitkomstvoorspellingen. Het stelde de bestaande richtlijnen ter discussie, ontwikkelde patiënt-specifieke hulpmiddelen, verbeterde metingen met 3D beeldvorming en implementeerde 3D virtuele chirurgische planning. Nu 3D technologie zich voortdurend blijft ontwikkelen, ben ik ervan overtuigd dat dit slechts het begin is van een verschuiving naar meer gepersonaliseerde zorg. Voortdurende innovatie en samenwerking tussen chirurgen en technische experts bieden mogelijkheden om het volledige potentieel van gepersonaliseerde behandelingen te benutten, en zo de zorg nauwkeurig af te stemmen op de unieke behoeften van elke patiënt.

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ABOUT THE AUTHOR

Nick Assink was born on February 9, 1992, in Hengelo. During his final year of primary school, he moved to the northern part of Groningen. After completing high school in Appingedam, he returned to Twente to pursue a degree in Technical Medicine at the University of Twente. After earning his bachelor's degree, he began two master's programs in Health Sciences and Technical Medicine. For his Health Sciences master's, he completed a graduation project at Philips Healthcare. Following that, Nick completed two years of clinical internships at the University Medical Center Groningen (UMCG), Isala Hospital in Zwolle, and Guy’s Hospital in London. After finishing his graduation internship at the 3D Lab and the trauma surgery department of the UMCG, he continued on the same topic of 3D analysis and 3D assisted surgery in tibial plateau fractures with a PhD project.

During his PhD, Nick became a 3D specialist at the UMCG 3D Lab, contributing to several clinical cases involving 3D applications in orthopedic trauma surgery. Upon completing his PhD, he continued his work as a technical physician and 3D specialist at UMCG, with a primary focus on orthopedic trauma.

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