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IMAGING IN FRACTURE SURGERY

R.J.O. DE MUINCK KEIZER

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Imaging in Fracture Surgery

Robert-Jan de Muinck Keizer

This thesis was prepared at the Trauma Unit, Department of Surgery, Academic Medical Center, University of Amsterdam, the Netherlands.

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CONTENTS

GENERAL INTRODUCTION AND OUTLINE OF THE THESIS

Since the discovery of x-rays in 1895 by Wilhelm Röntgen, radiographic imaging has revolutionized our understanding of fractures and has become an integral part of fracture treatment.

The implementation of radiographic imaging during fracture treatment, however does have its drawbacks. In the pre- and postoperative phases, radiographic imaging is of little value without the possibility to classify and quantify radiological findings. Moreover, to guide treatment and reliably document findings, effective scoring systems are indispensable. An important part of this thesis handles with the reliability of new and existing radiological scoring systems in fracture surgery.

The process of obtaining real time fluoroscopic images during fracture surgery is a collaboration between surgeon and technician. Miscommunication within this team may lead to unjust use of intraoperative fluoroscopy, can limit procedural satisfaction and compromise safety for both patient and operating personnel.

Finally, with the exponential growth of technology, new possibilities for imaging emerge. More complex techniques like Quantitative 3 Dimensional Computed Tomography (Q3DCT) might expand our understanding of fracture pathology, while computer assisted planning and 3D printing facilitate tailored treatment for complex cases. Nonetheless, these novel techniques need critical evaluation, as they come at additional costs and, not to be underestimated, radiation exposure.

The aim of this thesis is to explore the reliability of existing imaging techniques and radiological scoring protocols and critically evaluate the implementation of new imaging techniques in all phases of fracture treatment.

OUTLINE OF THE THESIS

Chapter 1 aims to gain insight in fracture epidemiology in the Netherlands. We perform an analysis of epidemiologic data of fractures in the Netherlands over the period of 2004-2012 and explore trends in incidence and treatment of fractures across gender and age groups. After this general introduction, this thesis deals with the role of imaging and its documentation before, during and after operative treatment of fractures.

PART ONE: PREOPERATIVE PLANNING

Conservative treatment of distal radius fractures may be complicated by malunion, resulting in pain and loss of function. A corrective osteotomy aims to restore anatomy and improve functional outcome. Conventional preoperative radiological planning frequently underestimates the complexity of these malunions. In **Chapter 2** and **3** we explore the use of computer-assisted three-dimensional (3D) planning and 3D printing technology for corrective osteotomies of the radius. In **Chapter 2**, we evaluate both radiological and functional results in a series of patients with malunion of the radius. In **Chapter 3** we perform a systematic review of the currently available literature covering this new technique.

Chapter 4 aims to provide insight in the diagnostics of ankle fractures. Up to 44% of ankle fractures have involvement of the posterior tibial margin. Treatment of these posterior fragments is guided by factors including size and morphology of the fragment, but the reliability of plain radiography in estimating these parameters is low. The addition of two dimensional computed tomography (2DCT) to the pre-operative work-up might help select patients who profit from operative treatment. The aim of **Chapter 4** is to evaluate the diagnostic accuracy of 2DCT for the assessment of articular involvement of posterior malleolar fractures of the ankle. For this purpose, we ask 50 surgeons from 23 countries to analyze pre-operative radiographs and CT scans of 31 ankle fractures with a posterior malleolar fragment. Estimations on fragment size are compared to our reference standard, Quantitative Three Dimensional Computed Tomography (Q3DCT). Additionally, we ask the 50 surgeons to classify the morphology of the posterior fragment according to Haraguchi and state whether the additional CT images changes their choice of treatment of the fragment compared to plain radiography.

PART TWO: INTRA-OPERATIVE IMAGING

A mobile C-arm with image intensifier (C-arm) is indispensable when it comes to visualizing fracture reduction and hardware positioning. In most cases, a radiographer operates the C-arm according to verbal instructions from the surgeon. Therefore, precise communication between surgeon and radiographer is vital for safe and efficient imaging.

In our Level 1 Trauma Centre, both radiographers and surgeons expressed discontent with regard to fluoroscopy during orthopaedic trauma procedures. We hypothesize that the introduction of a clear, uniform set of instructions could increase procedural satisfaction and reduce fluoroscopy time, number of images taken and accordingly reduce radiation exposure. In **Chapter 5**, we first evaluate the current terminology used between surgeon and radiographer during C-arm handling; second we develop a clear and uniform set of commands to facilitate C arm handling by the radiographer and finally we explore the potential benefit of implementing this terminology in an experimental setting.

Fractures of the calcaneus are known for their complex anatomy and are particularly difficult to visualize with intra-operative fluoroscopy. Conventional fluoroscopy might not suffice to assess fracture reduction and implant position. Several retrospective studies suggest a beneficial effect of intra-operative 3D fluoroscopy. In **Chapter 6** we perform a multicenter randomized controlled study, the EF3X-trial, in which we randomize 102 calcaneal fractures between operative treatment with and without the additional use of intra-operative 3D fluoroscopy. The primary outcome is the quality of reduction and implant positioning on a postoperative CT scan, as scored by three independent raters using a specifically designed scoring protocol. Secondary outcomes focus on patient rated- and functional outcome at 6 weeks, 12 weeks, 1 year and 2 years follow up.

PART THREE: POSTOPERATIVE EVALUATION

To uniformly document the radiographic result of operative treatment, a validated scoring protocol is indispensable. In absence of a protocol evaluating the quality of reduction and hardware positioning after calcaneal surgery, a 23-item scoring protocol was recently designed based on international consensus**. Chapter 7** is a clinical validation of this new scoring protocol. We ask three independent raters to score the quality of reduction and implant position in 102 operatively treated calcaneal fractures using the scoring protocol. Additionally, 25 fractures are scored a second time. Inter-and intrarater reliability is calculated per item and for the scoring protocol as a whole.

Moreover, reliable scoring protocols are required to evaluate treatment results and compare them with existing literature. In the evaluation of posttraumatic osteoarthritis of the subtalar joint, there is no consensus on which of the many available grading systems to use. The objective of **Chapter 8** is to identify the most appropriate grading system for posttraumatic subtalar osteoarthritis. For this purpose, we review the literature for the available grading systems. Consequently, we compare inter- and intrarater reliability of the two most frequently used systems by having four independent observers evaluate radiographs of 50 calcaneal fractures for subtalar osteoarthritis using both systems.

Finally, **Chapter 9** explores innovative measurement techniques to quantify intra-articular congruency. Traditionally, 2mm thresholds are used for acceptability of intra-articular gaps and step-offs. Despite the rise of advanced imaging techniques, these classic measurements have not been revisited. Quantitative 3 Dimensional Computed Tomography (Q3DCT) techniques facilitate precise 3 dimensional measurements that might further elucidate the role of intra-articular pathology. However, these techniques have not yet been implemented for this purpose. The aim of Chapter 9 is to introduce innovative measurement techniques to quantify operative fragment reduction of posterior malleolar fractures with use of Q3DCT. We evaluate twenty-eight ankle fractures including a posterior malleolar fragment with 2DCT and Q3DCT to postoperatively quantify fragment reduction. In addition to classic measurements of intra-articular gap and step-off, we introduce two innovative Q3DCT parameters: gap surface (mm^2) and multidirectional 3D-displacement (mm) and perform a reliability analysis.

1

EPIDEMIOLOGY OF EXTREMITY FRACTURES IN THE NETHERLANDS

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Injury 2017 April; online first

ABSTRACT

Introduction:

Insight in epidemiologic data of extremity fractures is relevant to identify people at risk. By analyzing age- and gender specific fracture incidence and treatment patterns we may adjust future policy, take preventive measures and optimize health care management. Current epidemiologic data on extremity fractures and their treatment are scarce, outdated or aiming at a small spectrum of fractures. The aim of this study was to assess trends in incidence and treatment of extremity fractures between 2004 and 2012 in.

Methods:

We used a combination of national registries of patients aged ≥ 16 years with extremity fractures. Fractures were coded by the International Classification of Diseases (ICD) 10, and allocated to an anatomic region. Absolute numbers, incidences, number of patients treated in university hospitals and surgically treated patients were reported. Logistic regression was used to calculate trends during the study period.

Results:

From 2004 to 2012 the Dutch population aged ≥16 years grew from 13,047,018 to 13,639,412 inhabitants, particularly in the higher age groups. The was an absolute increase of extremity fractures from 129,188 to 176,129 (OR 1.308 [1.299-1.318]), except for lower arm and lower leg fractures. Incidences increased significantly (3-4%) for wrist, hand/finger, hip/upper leg, ankle and foot/toe fractures. In younger age categories from 16-35 years, fractures of the extremities were more frequent in men than in women. Treatments gradually moved towards non-university hospitals for all except lower arm fractures. Both relative and absolute numbers increased for surgical treatments of clavicle/shoulder, lower arm, wrist and hand/finger fractures. Contrarily, lower extremity fractures showed an increase in non-surgical treatment, except for lower leg fractures.

Conclusion:

During the study period, we observed an increasing incidence of extremity fractures and a shift towards surgical treatment. If these trends continue, policy makers would be well advised to consider the changing demands in extremity fracture treatment and pro-actively increase capacity and resources.

INTRODUCTION

“Study the past, if you would define the future” is a famous quote by Chinese philosopher Confucius (551-479 BC). Extremity fractures comprise a major part of public health care cost in the Western world.[1,2] Insight in epidemiologic data of extremity fractures is important to identify people at risk for these fractures. By analyzing age- and gender specific fracture incidence and treatment patterns we may be able to adjust future policy, take preventive measures and optimize management in health care.

During the last decades, the ongoing development of surgical implants and a deeper understanding of fracture biology and predictors of functional outcome have changed the indications for surgical fracture treatment.[3] In addition, in Western Europe, an ageing population is creating a great challenge with a higher incidence of (severely) osteoporotic fractures. For the younger age category, fracture epidemiology has a substantial influence on societal costs in terms of loss of productivity.[4] Moreover, national registries are more reliable and therefore useful for national and global comparison.

Unfortunately, currently published epidemiologic studies about extremity fractures and their management are scarce,[5–9] outdated[10] or aiming at a small spectrum of fractures, for example osteoporotic fractures.[11,12] Therefore, in order to signal the need for possible policy adjustments in fracture care, the aim of this study was to assess trends in incidence and treatment of extremity fractures between 2004 and 2012 in relation to gender and age.

PATIENTS AND METHODS

Patients

This epidemiological study focused on extremity fractures in skeletally mature patients in the Netherlands occurring between 2004 and 2012. We assumed skeletal maturity in patients aged 16 years and older. Injury diagnoses were registered according to the International Classification of Diseases of the World Health Organization, Tenth Revision (ICD-10) and classified into fracture location by their anatomic region (online appendix). Data on fracture location, gender, age, and treatment facility (university vs non-university hospitals) were retrieved from various databases as described below. Age of patients was divided in 10-year categories from age 16 years and older. For register-based studies using anonymous data, approval of medical ethics review board is not required in the Netherlands.

Data Sources

Three databases were used for data collection. Data on the composition of the Dutch population were obtained from Statistics Netherlands (the Hague, the Netherlands).[13] Mid-year age- and gender-specific data were used to calculate incidence rates per 100,000 persons.

Fracture incidence was determined using the Dutch Injury Surveillance System (DISS).[14] This data extraction was performed by the Consumer Safety Institute (Amsterdam, the Netherlands), by recording all injuries treated at Emergency Departments (ED) of a representative sample of hospitals. During the inclusion period, thirteen hospitals, including three university hospitals and ten non-university hospitals, participated in the DISS. These thirteen hospitals served patients from both rural and urban areas across the country and were selected as a representative sample of the Dutch population in terms of age and sex. Together, the patients presenting to the ED's of the thirteen hospitals formed a sample of 12% of the total number of injured patients presenting at the ED's in the Netherlands. These data can be extrapolated to a national level, as described in previous studies.[15,16]

The DISS registers ED-visits rather than fracture treatments. In order to determine the percentage of patients receiving surgical treatment, abovementioned data were merged with data from the Dutch Hospital Data (DHD, Utrecht, the Netherlands). The DHD registers data regarding hospital admissions, surgical treatment, gender and age of admitted patients.[17] The DHD has almost complete national coverage (>95%, except in 2012, 88%) and figures were extrapolated to national coverage each year.[15,16] Patients were included in the DHD according to their main diagnosis at discharge after a hospital admission, usually the more severe injuries.

Correction of missing data

The DHD-data were corrected by weighing for incomplete coverage; the injuries were registered and categorized according to the ICD-10. To merge the extrapolated numbers of DISS and the weighted numbers of DHD datasets to determine the number of patients with a fracture, both datasets were aggregated by year, hospital type, age, gender and fracture location.

About 70-80% of the hospitals were coding surgical procedures in the DHD registry. To determine the fraction of surgically treated patients the hospitals with missing treatment data were removed and the resulting dataset was aggregated by year, hospital type, age, gender, fracture location and calculated the proportion of surgical treatment per case.

The three aggregated datasets with ED-visits-, admissions- and treatment information were merged and the resulting file was used to obtain the numbers of surgical treatment by multiplying the proportion by the number of admissions per year, hospital type, age, gender and fracture location.

Statistical analyses

Data were expressed as absolute numbers or incidence data per 100,000 inhabitants. To analyze trends in the population, incidences, number of patients treated in a university hospital, and surgically treated patients; a weighed binary logistic regression was used (SPSS version 23, IBM, Armonk, NY, USA). Results were presented as odds ratios (OR) with 95% confidence intervals (CI) with the data from the year 2004 as reference category. Changes with a p-value < 0.05 were considered significant.

RESULTS

Population

Within the nine-year study period, the Dutch adult population (aged ≥16 years) grew from 13,047,018 in 2004 to 13,639,412 in 2012. Higher age groups expanded faster than the younger age groups of which some showed a decrease in relative growth (Figure 1). In 2012 people aged 26-35 and 36-45 years represented 14.7% and 17.7% of the adult population, respectively, versus 17.8% and 19.9% in 2004.

Incidence

Figures 2 and 3 show the average incidence of fractures of the upper and lower extremities per age category. Overall, the incidence of extremity fractures is bimodal with peaks in both younger and older age categories. In younger age categories from 16-35 years, fractures of the extremities were more frequent in men than in women. Contrarily, in older age categories from 66 years and older, the incidences of fractures in women exceeded those in men.

Figures 4 and 5 show the incidence and absolute number of fractures in the study period, as well as the treatment facility (university versus non-university hospital) and type of treatment (surgical versus non-surgical).

During the study period, there was a significant increase in the absolute number of fractures in all types, except for lower arm and lower leg fractures, which showed a decrease. The Incidence in wrist, hand/finger, hip/upper leg, ankle and foot/toe fractures increased with 3-4% in 2012 compared with 2004.

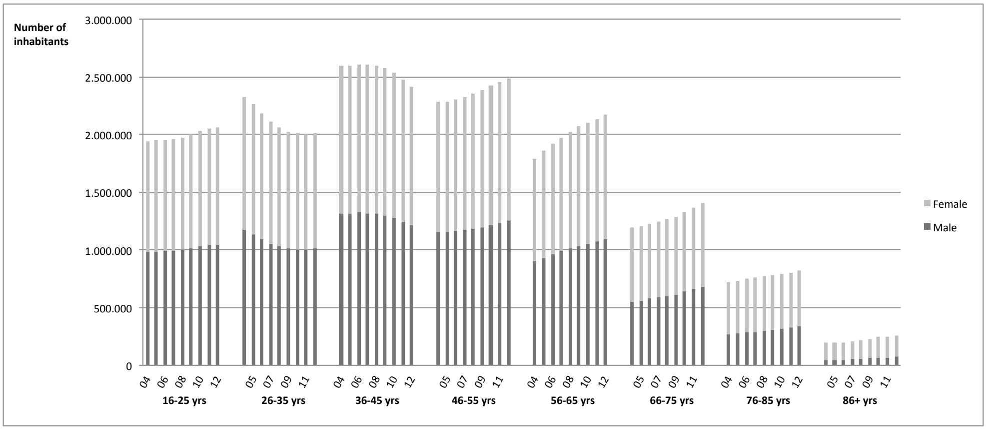

Figure 1. Mid-year population per age category in the Netherlands. The corresponding Table 1 can be found in the appendix. For every year the growth per age category was calculated with a weighed binary regression analysis, with 2014 as reference category. For the total population a multinomial logistic regression analysis was used, with 2014 as reference category. The 95% confidence intervals of 2012 compared to 2004, all with a P-value of < 0.001, were respectively 1.018 [1.016 – 1.020] for age category 16-25 years; 0.798 [0.796 – 0.799] for age category 26-35 years; 0.867 [0.866 – 0.869] for age category 36-45 years; 1.050 [1.052 – 1.050] for age category 46-55 years; 1.191 [1.188 – 1.194] for age category 56-65 years; 1.136 [1.136 – 1.142] for age category 66-75 years; 1.093 [1.090 – 1.097] for age category 76-85 years and 1.308 [1.300 – 1.315] for the age category of 86 years and older. For the total population the 95% confidence interval was 1.004 [1.004 – 1.004].
Source: Dutch Central Bureau of Statistics.

Treatment location

Lower arm fractures were treated more often in university hospitals (OR 1.430 [1.267 – 1.625] in 2012). For all other fracture types, a trend towards more treatments in non-university hospitals was seen.

Type of treatment

An increase was observed in both absolute and relative numbers of surgically treated clavicle/shoulder, lower arm, wrist and hand fractures. The increase in surgical treatment of clavicle/shoulder fractures was most prominent (OR 3.168 [2.863 – 3.505] in 2012). Contrarily, treatment of lower extremity fractures remained more or less the same (lower leg fractures; 46-55% surgical treatment) or showed more non-surgical treatments. On top of an already apparent decrease of surgical treatment of hip and upper leg fractures over the years 2006-2010 (OR 0.688 – 0.528 in 2006-2010), an additional decrease was seen in 2012 (OR 0.068 [0.064-0.072]).

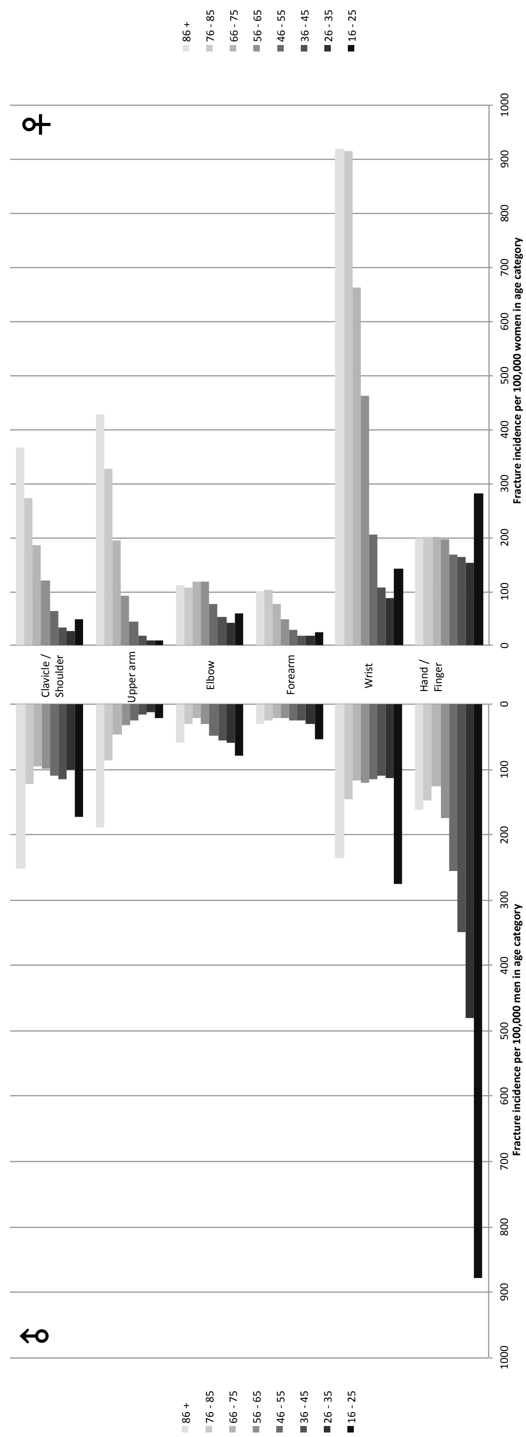

Figure 2. Average incidence of upper extremity fractures per sex and age category from the period 2004-2012. Source: Dutch Injury Surveillance System (DISS)

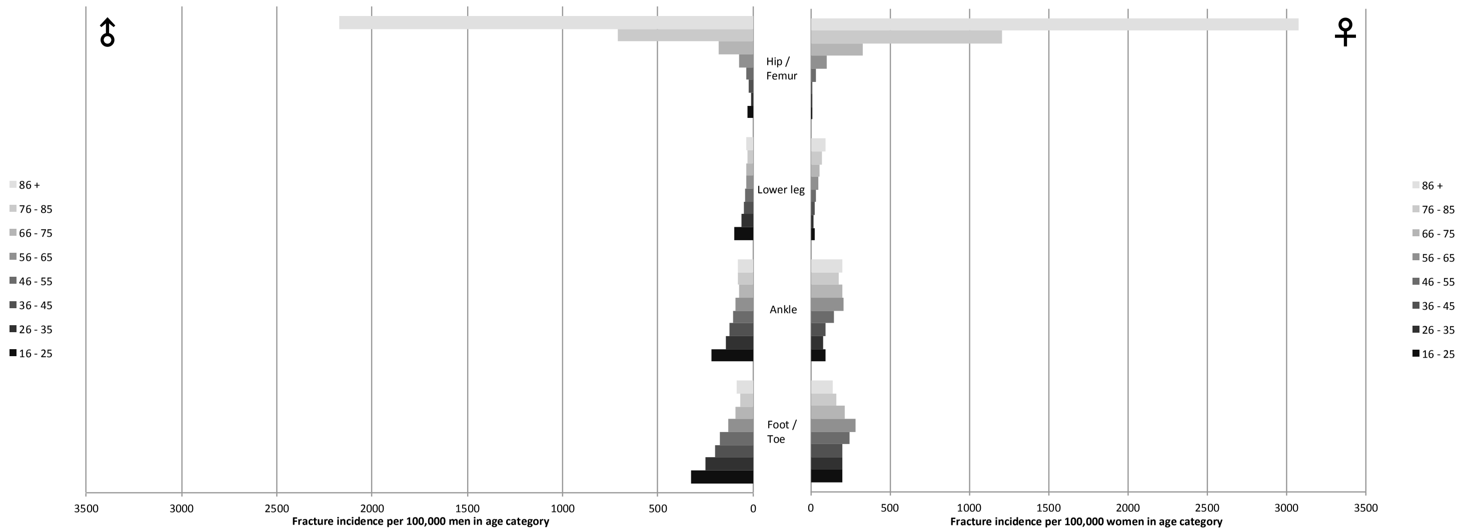

Figure 3. Average incidence of lower extremity fractures per sex and age category from the period 2004-2012. Source: Dutch Injury Surveillance System (DISS)

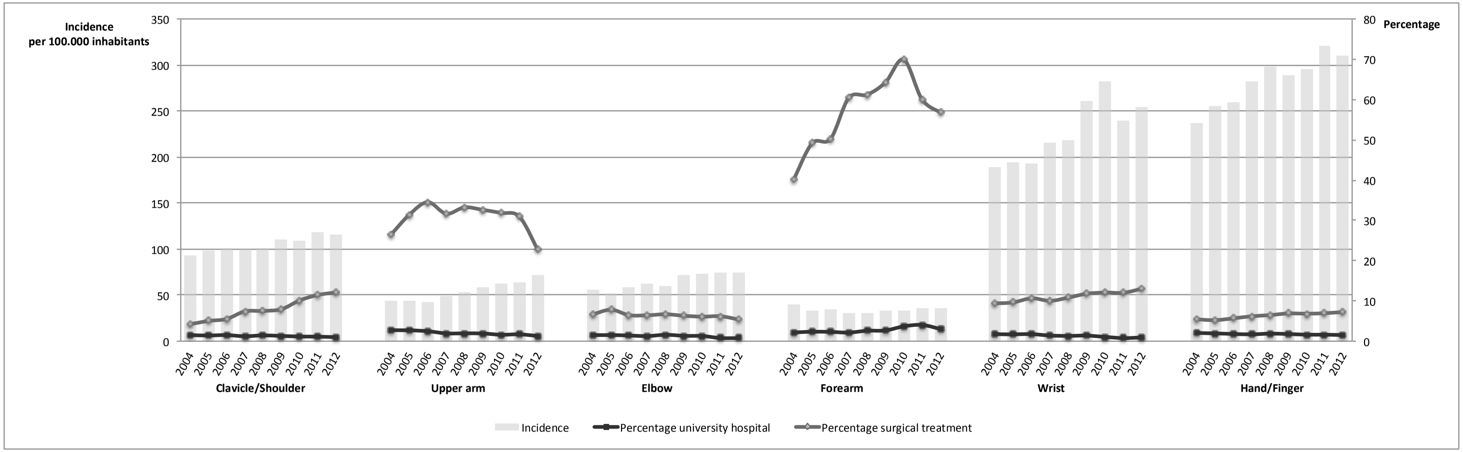

Figure 4. Incidence trends of upper extremity fractures
Figure corresponds with table 1. Incidence rates (left Y-axis), percentage patients treated in a university hospital (right Y-axis) & percentage surgically treated patients (right Y-axis) of upper extremity fractures in the period from 2004-2012 in the Netherlands.

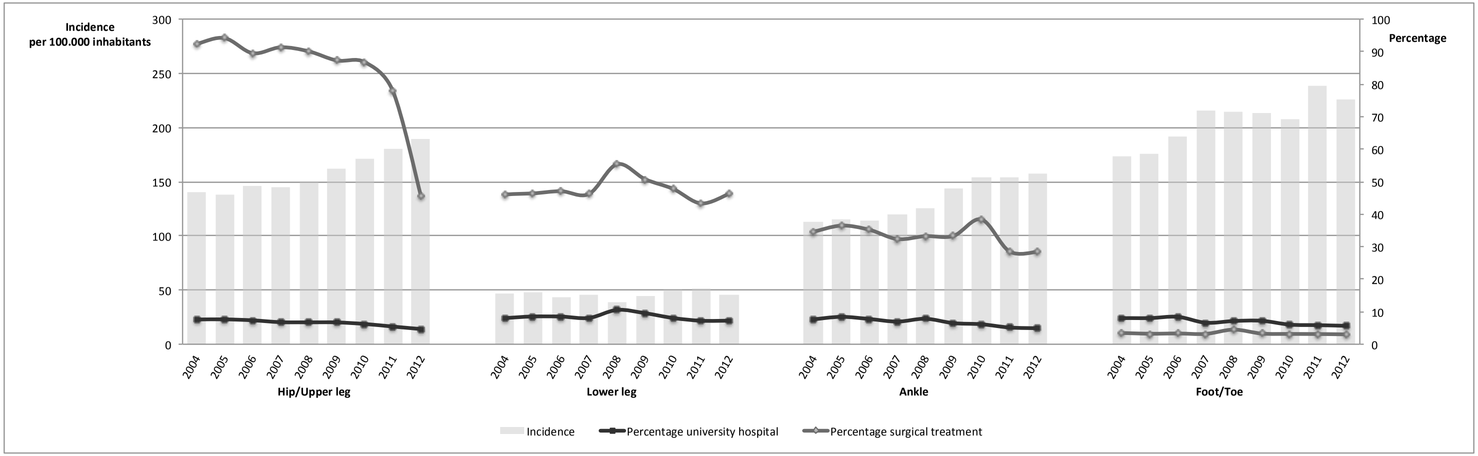

Figure 5. Incidence trends of lower extremity fractures.
Figure corresponds with table 1. Incidence rates (left Y-axis), percentage patients treated in a university hospital (right Y-axis) & percentage surgically treated patients (right Y-axis) of lower extremity fractures in the period from 2004-2012 in the Netherlands.

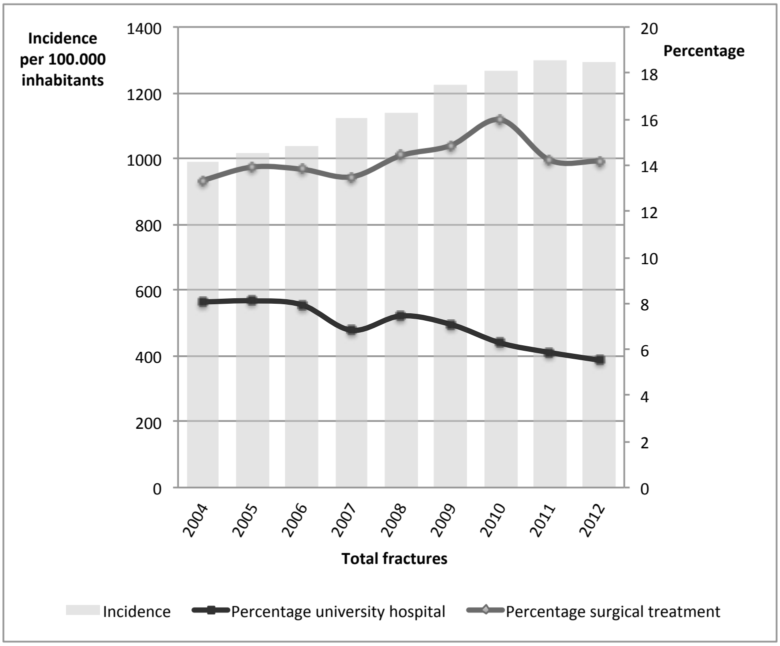

Figure 6. Incidence trend of the total of extremity fractures.
Figure corresponds with table 1. Incidence rates (left Y-axis), percentage patients treated in a university hospital (right Y-axis) & percentage surgically treated patients (right Y-axis) of extremity fractures in the period from 2004-2012 in the Netherlands.

DISCUSSION

This study shows a significant increase in both incidence and absolute numbers of wrist, hand/finger, hip/upper leg, ankle and foot/toe fractures during a recent nine-year study period. In addition, there is a trend towards more surgical treatments of shoulder/clavicle and wrist/hand fractures. For lower extremity fractures a decrease in surgical treatment was observed. A trend towards treatment in non-university hospitals was observed for all except lower arm fractures.

The increasing trends in surgical treatment reported in some extremity fractures are not unique for our country. The increase found in surgically treated upper extremity fractures is similar to a study from Finland in 2013, showing an increase of surgically treated clavicle fractures from 1.3 per 100,000 person years (n=48) in 1987 to 10.8 per 100,000 person years (n=462) in 2010.[7]

Additionally, the bimodal incidence across the different age categories are similar to those in a recent study by Court-Brown et al.[9] Incidences reported in our study are higher than in a population-based epidemiologic study of the upper extremities in the USA, reporting a total of 677 per 100,000 upper extremity fractures in 2009 compared to 824 per 100,000 in our study.[18] In contrast to the USA, in the Netherlands health insurance for all Dutch inhabitants was mandatory during the study period. Therefore the threshold to seek help for extremity fractures may have been lower compared with the USA.

The increase in absolute numbers of fractures could be explained by the growth of our population. Changes in the incidences of specific extremity fractures are probably better explained by changes in the composition of our population. Most fractures have a peak incidence in the younger and older age categories. These age categories are growing, whereas the age categories less prone to fractures are actually decreasing in number.

Strengths of this study include the fact that this study gives a unique nationwide overview of all extremity fractures over a longer, continuous time period. This distinguishes this study from the majority of similar epidemiological studies that focus on a specific fracture type [6,7,10,19–21] or describe the incidence within a single hospital.[9,22]

Recently published Dutch insurance data on the incidence of distal radius fractures reported a total of 49,615 distal radius fractures in 2012, compared to 34,666 wrist fractures in our study.[23] Despite this difference in absolute numbers, the percentage of patients treated surgically is similar (9-10%). A potential explanation for the difference in incidence could be overestimation of the insurance data due to double registration, when patients are referred to other hospitals or specialties. Nonetheless, the similarity suggests this estimate approximates reality.

Additionally, we aimed to improve accuracy and facilitate verification of observed trends by combining different databases, which separately have shown to have a high level of accuracy and validity.[15,16] Despite the high quality of the databases used, the use of their data has some limitations. For example, the DISS registers all injuries that are recorded at the ED, but fails to register changes in diagnosis after the ED visit. The DHD uses only the main (often the most severe) diagnosis at discharge. In multiple injured patients not all injuries are registered, potentially leading to an underestimation of fracture incidence. Correction for this under-registration allows extrapolation to national fracture incidences, but could still slightly deviate from the actual number of fractures, treatment location and type.

Currently in the Netherlands, there is a trend to concentrate different types of care in specialized hospitals, leading to more referrals after primary presentation at the ED. Hip/upper leg fractures, for example, are preferably referred to non-university hospitals, while multiple injured patients are presented at university level-one hospitals. It is unclear how these changes in hospital logistics affect the representability of the DISS.

An unexpected additional decline was observed in an already decreasing trend in surgical treatment of hip/upper leg and upper arm fractures in 2012. The decreasing trend in surgical treatment could potentially be granted to successful osteoporosis prevention programs, leading to more stable fractures, not requiring surgery.[12] A second explanation for this sudden drop could be the effect of an additional 7% missing data in the DHD in 2012. These additional missing data were mainly from patients aged 70 years and older. Subsequently, these missing data could have biased our results about the management of fractures with high incidences in the elderly in 2012.

CONCLUSIONS

During the study period from 2004 to 2012, we observed an increasing incidence of extremity fractures and a trend towards surgical treatment mainly performed in non-university hospitals. If, in the future, these trends continue, policy makers would be well advised to anticipate changing demands in extremity fracture treatment and pro-actively adjust capacity and resources.

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Appendix. Table 1. Epidemiology of extremity fractures

Fracture location		2004	2006	OR [95% CI]	2008	OR [95% CI]	2010	OR [95% CI]	2012	OR [95% CI]	P-value
Clavicle/ Shoulder	Number	12,115	13,264	1.087 [1.060 – 1.114]	13,348	1.083 [1.057 – 1.110]	14,606	1.169 [1.141 – 1.197]	15,738	1.243 [1.214 – 1.273]	**< 0.001**
	Incidence	93	101	1.086 [0.819 – 1.440]	101	1.086 [0.819 – 1.440]	108	1.161 [0.880 – 1.533]	115	1.237 [0.941 – 1.626]	0.701
	University hospital n (%)	799 (7)	880 (7)	1.006 [0.911 – 1.111]	844 (6)	0.956 [0.865 – 1.057]	744 (5)	0.760 [0.686 – 0.843]	691 (4)	0.650 [0.586 – 0.722]	**< 0.001**
	Surgical treatment n (%)	505 (4)	731 (6)	1.341 [1.194 – 1.506]	1,003 (8)	1.868 [1.673 – 2.085]	1,480 (10)	2.592 [2.336 – 2.876]	1,906 (12)	3.168 [2.863 – 3.505]	**< 0.001**
Upper arm	Number	5,770	5,678	0.977 [0.942 – 1.013]	7,098	1.210 [1.168 – 1,253]	8,497	1.427 [1.381 – 1.476]	9,849	1.633 [1.581 – 1.687]	**< 0.001**
	Incidence	44	43	0.977 [0.642 – 1.488]	53	1.205 [0.808 – 1.797]	63	1.432 [0.974 – 2.105]	72	1.637 [1.125 – 2.382]	0.057
	University hospital n (%)	682 (12)	616 (11)	0.908 [0.809 – 1.019]	604 (9)	0.694 [0.618 – 0.779]	597 (7)	0.564 [0.502 – 0.633]	563 (6)	0.452 [0.402 – 0.508]	**< 0.001**
	Surgical treatment n (%)	1,529 (26)	1,960 (35)	1.462 [1.350 – 1.584]	2,358 (33)	1.380 [1.278 – 1.490]	2,706 (32)	1.296 [1.203 – 1.396]	2,234 (23)	0.814 [0.755 – 0.877]	**< 0.001**
Elbow	Number	7,212	7,625	1.049 [1.016 – 1.084]	7,998	1.091 [1.056 – 1.126]	9,866	1.326 [1.286 – 1.367]	10,146	1.346 [1.306 – 1.387]	**< 0.001**
	Incidence	55	58	1.055 [0.729 – 1.525]	60	1.091 [0.757 – 1.573]	73	1.328 [0.935 – 1.884]	74	1.346 [0.949 – 1.908]	0.298
	University hospital n (%)	468 (6)	469 (6)	0.944 [0.827 – 1.078]	558 (7)	1.081 [0.952 – 1.227]	556 (6)	0.861 [0.758 – 0.977]	343 (3)	0.504 [0.437 – 0.582]	**< 0.001**
	Surgical treatment n (%)	473 (7)	492 (6)	0.983 [0.862 – 1.120]	535 (7)	1.021 [0.899 – 1.161]	601 (6)	0.924 [0.816 – 1.047]	543 (5)	0.806 [0.710 – 0.915]	**< 0.001**
Lower arm	Number	5,149	4,480	0.864 [0.830 – 0,899]	4,100	0.783 [0.751 – 0.816]	4,430	0.834 [0.801 – 0.868]	4,906	0.911 [0.876 – 0.948]	**< 0.001**
	Incidence	39	34	0.872 [0.550 – 1.381]	31	0.795 [0.496 – 1.274]	33	0.846 [0.532 – 1.345]	36	0.923 [0.587 – 1.452]	0.993
	University hospital n (%)	493 (10)	453 (10)	1.062 [0.929 – 1.215]	466 (11)	1.211 [1.060 – 1.385]	714 (16)	1.815 [1.605 – 2.051]	647 (13)	1.435 [1.267 – 1.625]	**< 0.001**
	Surgical treatment n (%)	2,072 (40)	2,249 (50)	1.497 [1.381 – 1.623]	2,509 (61)	2.342 [2.153– 2.547]	3,095 (70)	3.445 [3.165 – 3.751]	2,787 (57)	1.953 [1.804 – 2.114]	**< 0.001**
Wrist	Number	24,613	25,432	1.026 [1.008 – 1.044]	28,903	1.155 [1.136 – 1.410]	37,945	1.496 [1.472 – 1.520]	34,666	1.348 [1.326 – 1.370]	**< 0.001**
	Incidence	189	193	1.021 [0.835 – 1.248]	218	1.154 [0.949 – 1.402]	282	1.493 [1.242 – 1.796]	254	1.345 [1.114 – 1.624]	**< 0.001**
	University hospital n (%)	1,816 (7)	1,952 (8)	1.044 [0.977 – 1.115]	1,670 (6)	0.770 [0.719 – 0.825]	1,773 (5)	0.615 [0.575 – 0.658]	1,417 (4)	0.535 [0.498 – 0.575]	**< 0.001**
	Surgical treatment n (%)	2,297 (9)	2,709 (11)	1.158 [1.092 – 1.228]	3,131 (11)	1.180 [1.115 – 1.249]	4,585 (12)	1.335 [1.266 – 1.408]	4,516 (13)	1.455 [1.380 – 1.535]	**< 0.001**
Hand/Finger	Number	30,913	34,144	1.097 [1.080 – 1.114]	39,540	1.258 [1.240 – 1.277]	39,805	1.249 [1.230 – 1.267]	42,268	1.309 [1.290 – 1.328]	**< 0.001**
	Incidence	237	260	1.097 [0.920 – 1.309]	298	1,258 [1.061 – 1.493]	296	1.250 [1.053 – 1.483]	310	1.309 [1.105 – 1.551]	**0.006**
	University hospital n (%)	2,692 (9)	2,684 (8)	0.894 [0.846 – 0.946]	3,250 (8)	0.939 [0.890 – 0.990]	2,824 (7)	0.801 [0.758 – 0.846]	2,822 (7)	0.750 [0.710 – 0.792]	**< 0.001**
	Surgical treatment n (%)	1,671 (5)	1,935 (6)	1.051 [0.983 – 1.125]	2,560 (6)	1.211 [1.137 – 1.291]	2,722 (7)	1.285 [1.206 – 1.368]	3,063 (7)	1.367 [1.286 – 1.454]	**< 0.001**

Hip/Upper leg	Number	18,301	19,163	1.039 [1.019 – 1.061]	19,897	1.069 [1.048 – 1.091]	22,966	1.217 [1.193 – 1.240]	25,796	1.349 [1.324 – 1.375]	**< 0.001**
	Incidence	140	146	1.043 [0.827 – 1.315]	150	1.072 [0.851 – 1.349]	171	1.222 [0.977 – 1.528]	189	1.351 [1.085 – 1.681]	**0.025**
	University hospital n (%)	1,395 (8)	1,410 (7)	0.963 [0.891 – 1.040]	1,342 (7)	0.877 [0.811 – 0.947]	1,431 (6)	0.805 [0.746 – 0.869]	1,205 (5)	0.594 [0.548 – 0.643]	**< 0.001**
	Surgical treatment n (%)	16,935 (93)	17,153 (90)	0.688 [0.640 – 0.739]	17,924 (90)	0.732 [0.681 – 0.787]	19,923 (87)	0.528 [0.439 – 0.564]	11,793 (46)	0.068 [0.064 – 0.072]	**< 0.001**
Lower leg	Number	6,045	5,717	0.939 [0.905 – 0.973]	5,216	0.848 [0.818 – 0.880]	6,758	1.084 [1.047 – 1.122]	6,226	0.985 [0.951 – 1.021]	**< 0.001**
	Incidence	46	43	0.935 [0.617 – 1.417]	39	0.848 [0.553 – 1.299]	50	1.087 [0.728 – 1.622]	46	1.000 [0.664 – 1.505]	0.969
	University hospital n (%)	489 (8)	487 (9)	1.058 [0.928 – 1.206]	550 (11)	1.339 [1.179 – 1.522]	545 (8)	0.997 [0.878 – 1.132]	451 (7)	0.887 [0.777 – 1.014]	**< 0.001**
	Surgical treatment n (%)	2,793 (46)	2,691 (47)	1.035 [0.963 – 1.082]	2,888 (55)	1.444 [1.340 – 1.555]	3,229 (48)	1.065 [0.994 – 1.142]	2,882 (46)	1.003 [0.935 – 1.077]	**< 0.001**
Ankle	Number	14,803	14,961	1.003 [0.981 – 1.026]	16,711	1.110 [1.086 – 1.135]	20,744	1.359 [1.330 – 1.388]	21,487	1.389 [1.360 – 1.419]	**< 0.001**
	Incidence	113	114	1.009 [0.778 – 1.309]	126	1.115 [0.865 – 1.438]	154	1.363 [1.069 – 1.738]	158	1.399 [1.099 – 1.781]	**0.005**
	University hospital n (%)	1,135 (8)	1,162 (8)	1.014 [0.931 – 1.104]	1,309 (8)	1.023 [0.942 – 1.112]	1,276 (6)	0.789 [0.726 – 0.858]	1,060 (5)	0.625 [0.573 – 0.681]	**< 0.001**
	Surgical treatment n (%)	5,107 (35)	5,268 (35)	1.032 [0.984 – 1.082]	5,556 (33)	0.946 [0.902 – 0.991]	7,961 (38)	1.182 [1.132 – 1.236]	6,107 (28)	0.754 [0.721 – 0.789]	**< 0.001**
Foot/Toe	Number	22,568	25,218	1.109 [1.090 – 1.129]	28,379	1.237 [1.216 – 1.259]	28,022	1.204 [1.183 – 1.225]	30,844	1.308 [1.286 – 1.331]	**< 0.001**
	Incidence	173	192	1.110 [0.904 – 1.363]	214	1.238 [1.013 – 1.512]	208	1.203 [0.983 – 1.472]	226	1.307 [1.072 – 1.594]	**0.016**
	University hospital n (%)	1,832 (8)	2,128 (8)	1.043 [0.977 – 1.113]	2,028 (7)	0.871 [0.816 – 0.930]	1,690 (6)	0.726 [0.678 – 0.778]	1,748 (6)	0.680 [0.635 – 0.728]	**< 0.001**
	Surgical treatment n (%)	792 (4)	836 (3)	0.943 [0.854 – 1.041]	1,276 (4)	1.294 [1.183 – 1.417]	888 (3)	0.900 [0.816 – 0.992]	937 (3)	0.861 [0.782 – 0.948]	**< 0.001**
All Fractures	Number	129,188	136,519	1.049 [1.041 – 1.057]	151,293	1.153 [1.145 – 1.162]	170,673	1.284 [1.275 – 1.293]	176,129	1.308 [1.299 – 1.318]	**< 0.001**
	Incidence	990	1,039	1.050 [0.962 – 1.146]	1,140	1.153 [1.059 – 1.256]	1,268	1.284 [1.181 – 1.396]	1,291	1.308 [1.204 – 1.422]	**< 0.001**
	University hospital n (%)	10,406 (8)	10,831 (8)	0.984 [0.956 – 1.012]	11,280 (7)	0.920 [0.894 – 0.945]	10,719 (6)	0.765 [0.744 – 0.787]	9,741 (6)	0.668 [0.649 – 0.688]	**< 0.001**
	Surgical treatment n (%)	17,239 (13)	18,870 (14)	1.042 [1.102 – 1,065]	21,816 (14)	1.094 [1.071 – 1.118]	27,268 (16)	1.235 [1.210 – 1.261]	24,975 (14)	1.073 [1.051 – 1.096]	**< 0.001**

Sources: Number of fractures: Dutch Injury Surveillance System (DISS); Incidence: DISS combined with Statistics Netherlands; University hospital: DISS; Operative treated fractures: DISS combined with Dutch Hospital Data. P-values were calculated with a weighed binary regression analysis, with 2014 as reference category

PART I:
PREOPERATIVE
PLANNING

2

COMPUTER-ASSISTED 3D PLANNED CORRECTIVE OSTEOTOMIES IN EIGHT MALUNITED RADIUS FRACTURES

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ABSTRACT

In corrective osteotomies of the radius, detailed preoperative planning is essential to functional outcome. However, complex malunions are not completely addressed with conventional preoperative planning. Computer-assisted preoperative planning may optimize the results of corrective osteotomy of the radius. We analyzed the pre- and postoperative radiological result of computerassisted 3D planned corrective osteotomy in a series of patients with a malunited radius and assessed postoperative function. We included eight patients aged 13–64 who underwent a computer-assisted 3D planned corrective osteotomy of the radius for the treatment of a symptomatic radius malunion. We evaluated pre- and postoperative residual malpositioning on 3D reconstructions as expressed in six positioning parameters (three displacements along and three rotations about the axes of a 3D anatomical coordinate system) and assessed postoperative wrist range of motion. In this small case series, dorsopalmar tilt was significantly improved ($p = 0.05$). Ulnoradial shift, however, increased by the correction osteotomy (6 of 8 cases, 75%). Postoperative 3D evaluation revealed improved positioning parameters for patients in axial rotational alignment (63%), radial inclination (75%), proximodistal shift (83%) and volodorsal shift (88%), although the cohort was not large enough to confirm this by statistical significance. All but one patient experienced improved range of motion (88%). Computer-assisted 3D planning ameliorates alignment of radial malunions and improves functional results in patients with a symptomatic malunion of the radius. Further development is required to improve transfer of the planned position to the intra-operative bone.

INTRODUCTION

Malunion of a radial fracture may result in chronic pain and loss of function and occurs in around 5% of the cases.[1-3] A corrective osteotomy for patients with a malunited radius fracture can improve wrist function and reduce stiffness and pain.[4] Previous studies showed that accuracy of the anatomical reconstruction is essential to achieving an optimal outcome.[5-7] Therefore, conscientious preoperative planning of the procedure and accurate surgical repositioning is required.[1,5] Conventionally, planning is based on two orthogonal radiographs depicting lateral and posteroanterior views of the radius.

However, malunion of the radius commonly involves complex three-dimensional (3D) deformations in different planes, which may not be acknowledged on conventional preoperative 2D radiographs.[8-12] Two-dimensional radiographic planning does not always result in adequate restoration of alignment, as was demonstrated by a recent study performed by members of our study group.[7]

A potential solution of the challenge presented by the complex deformity of radius malunions is the use of computer-assisted 3D planning techniques. With these techniques, both physical and virtual models of the deformed radius and the mirrored contralateral radius can be created. The models are used preoperatively to conceptualize the multiple planes of deformity and to preoperatively plan the osteotomy.[4,13] Preoperative 3D planning also provides the possibility to create patient-specific cutting guides to transfer the planned osteotomy plane to the patient's bony anatomy during surgery. Patient-specific guides for cutting or drilling have been successfully introduced before.[14-16] They have proven to enable accurate positioning of surgical instruments or implants with respect to bony anatomy. However, these studies mostly focus on functional results without properly evaluating residual postoperative malpositioning using 3D imaging techniques.

Therefore, the aim of this study was to assess whether computer-assisted 3D planning and the intra-operative use of personalized cutting guides improve the accuracy of bone alignment.

MATERIALS AND METHODS

All patients who underwent a computer-assisted 3D planned corrective osteotomy of the radius for the treatment of symptomatic radius malunion between January 2009 and March 2014 were eligible for inclusion. Only patients who underwent a postoperative CT scan of both (full length) radii were included. Patients with a previous fracture of the contralateral radius were excluded.

Preoperative planning

Preoperative planning was based on computed tomography (CT) scans of both the affected and the contralateral radius. The unaffected contralateral bone served as reference for determining malalignment. All CT scans were obtained using a Brilliance 64-channel CT scanner (Phillips Healthcare, Best, The Netherlands) reconstructed to a 3D volume with a voxel spacing of 0.45 x 0.45 x 0.45 mm. Data were imported by a dedicated application program which helps quantifying pre- and postoperative malalignment.[17] In short, the program enables segmenting the affected bone using a threshold-connected region growing algorithm that collects voxels that belong to the affected bone, followed by a binary closing algorithm to close residual gaps. A Laplacian level-set segmentation growth algorithm advances the outline towards the boundary of the bone. A polygonal mesh is finally extracted, which is used for visualization of the bone deformity. It also serves to create a double-contour polygon by sampling the greylevel image 0.3 mm towards the inside (bright) and outside (dark) for each point of the polygonal bone model. This double-contour polygon with image grey levels assigned to each point enables efficient and accurate point-to-image registration.

Next, distal and proximal segments are clipped to exclude the malunited fracture region. The clipped segments are aligned with the mirrored image of the healthy contralateral bone, by point-to-image registration. This procedure provides a position matrix that brings the distal bone segment in a position that agrees with that of the mirrored contralateral bone. The matrix is used to quantify malpositioning in terms of three displacements along and three rotations about the axes of a 3D anatomical coordinate system.[7] The centroid of the clipped bone segment polygons is used as centre of rotation. Translations are determined in the ulnoradial, volodorsal and proximodistal directions. Rotations are expressed in terms of dorsopalmar tilt, radial inclination and axial rotation (pronation and supination). In case of an oblique single-cut rotation osteotomy[14], the matrix is used to determine the orientation of the osteotomy and the rotation angle for aligning the distal and proximal bone segments. The software further enables to create (1) both virtual and physical models of both radii on which the osteotomy planning was simulated (Fig. 1), and (2) patient-specific cutting guides and jigs for intra-operative guidance of the osteotomy (Fig. 2).

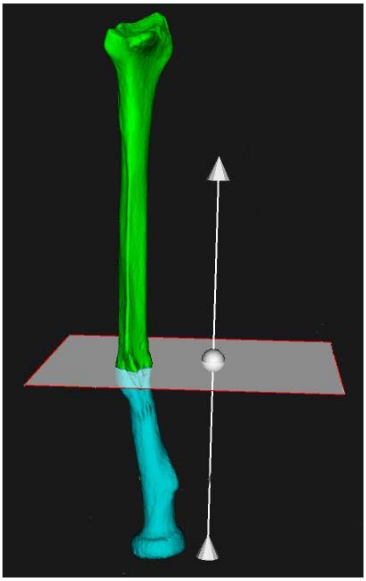

Figure 1. Positioning of cutting plane

Patient-specific bone models and cutting guides

During the preoperative planning, the surgeon was able to interactively set the position and orientation of the cutting plane in the virtual radius (Fig. 1). Synthetic acrylonitrile butadiene styrene (ABS) bone models were created using additive manufacturing technology (SST1200es 3D printer, Dimension Inc, Eden Prairie, MN, USA) with a resolution of 254 lm.

In four patients, a patient-specific cutting guide was used which snugly fitted to the bone geometry (see Fig. 2b). Polyamide cutting guides were manufactured (Materialise, Leuven, Belgium; Sirris, Charleroi, Belgium; Amitek Prototyping, De Meern, The Netherlands) and were sterilised before use in the operating room.

Surgical procedure

Depending on the complexity of the malunion, patients were treated with an open-wedge osteotomy or an oblique single-cut rotation osteotomy (OSCRO).[14] Both osteotomy types were planned by using virtual or physical synthetic models of both radii and/or assisted by intraoperative use of patient-specific cutting guides and jigs (Fig. 2). In the latter method, the sterilized surgical guide was positioned at the specific bone surface and was fixated with Kirschner wires, using the planned fixation holes. In the case of an oblique single-cut rotation osteotomy (OSCRO), the guide was removed after the osteotomy and a stainless steel jig served to set the angle between the proximal and distal bone segment.[14]

Rotational alignment was achieved by rotating the malunited distal bone segment over the planned angle. Regular plate and screw fixation was performed to maintain the position. Postoperative management varied from direct mobilization to 2 weeks of plaster of Paris immobilization.

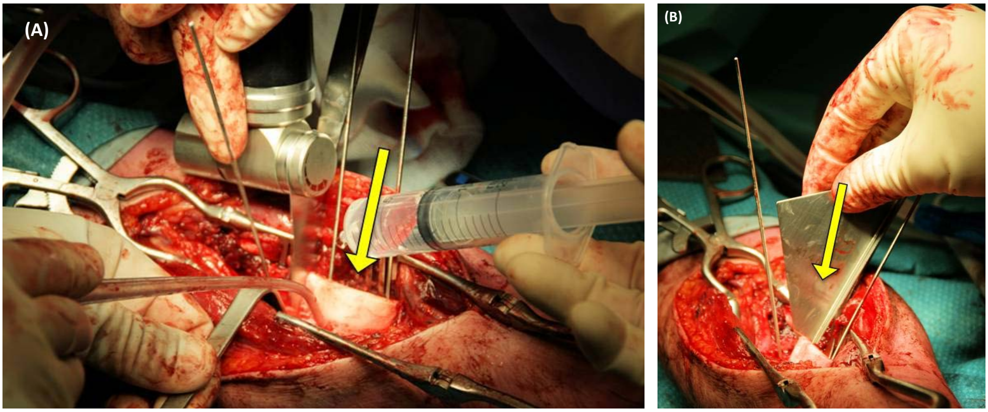

Figure 2. A) Intra-operative correction of deformation with cutting guide (yellow arrow). B) Intra-operative correction of deformation with angled jig (yellow arrow)

Data collection and outcome

Patients were evaluated postoperatively after a minimum follow-up of 6 months. The main outcome was residual 3D malpositioning based on a postoperative CT scan of both forearms. Residual malpositioning was again expressed in terms of six positioning parameters. These residual malpositioning parameters were quantified in exactly the same way as described for preoperative planning, with the one difference that the postoperative image was used for segmentation of the bone instead of the preoperative image. Secondary outcome was the postoperative range of motion of the wrist measured on both sides with a handheld goniometer.

This study was approved by the Medical Ethical Review Committee of the Academic Medical Centre of the University of Amsterdam. All subjects gave informed consent before participation in this study.

Statistical analysis

We reported medians and interquartile range (IQR) for nonparametric variables, and means and standard deviations (SD) for normally distributed variables. The absolute value of each malalignment parameter served to represent the residual error. The Kolmogorov–Smirnov test was used for the determination of the distribution form. The Wilcoxon signed rank test was used to compare the medians of each of the six malpositioning parameters before and after correction.

RESULTS

A total of 16 patients were treated for a symptomatic malunion with a computer-assisted 3D planned corrective osteotomy of the radius.

Five patients were treated recently, and their follow-up was shorter than 6 months. Two patients did not want to participate in postoperative position evaluation, and one patient had moved abroad. This resulted in a total of eight patients who were included in this series.

Of the included patients, three had originally developed a malunion after sustaining an extra-articular distal radius fracture. Five patients had sustained a forearm fracture (three antebrachial fractures and two isolated radius fractures), all of whom developed a diaphyseal malunion of the radius. The demographics of the study group are depicted in Table 1. We performed an opening-wedge osteotomy on four patients, and the other four patients received an oblique single-cut rotation osteotomy (OSCRO). All patients achieved primary osseous union. The median duration of follow-up was 26 months (IQR 12–34). No complications occurred.

The median pre- and postoperative malalignment per dimension is depicted in Table 2. Improvement in dorsopalmar tilt showed statistical significance ($p = 0.05$, Wilcoxon signed rank test). The median residual malalignment was smallest for radial length (-0.6 mm) and axial rotation (-2.6).

The individual changes in preoperative and postoperative deformations are depicted in Fig. 3. In two adolescent patients (Cases 7 and 8), the radial length (translation in proximodistal direction) was not reliable due to the patients' growing skeleton between pre- and postoperative CT scans. Volodorsal translation showed improvement (correction towards neutral) in all but one patient (88%). In six patients (75%), ulnoradial shift increased by the correction osteotomy. In two patients, this shift was corrected to nearly neutral.

Dorsopalmar tilt was improved in seven out of eight patients (88%): in one patient (Case 8), tilt was overcorrected from volar to dorsal. In one patient (Case 4), the preoperative neutral position was corrected to dorsal angulation (Fig. 4). Five patients originally had a malunion in pronation. In those five cases, rotations were corrected, although an overcorrection to supination was present in two patients (Cases 6 and 8). Radial inclination was improved in six out of eight patients (88%).

Table 1. Demographics of study population

Case	Sex	Age[a]	Location malunion	Dominant hand affected	Indication	Technique[b]	Osteotomy type	Follow-up (months)
1	F	64	Distal, extra-articular	Yes	Pain	Cutting guide	Opening	32
2	F	53	Distal, extra-articular	Yes	Pain	Simulation	Opening	56
3	F	18	Distal, extra-articular	No	Pain, DRUJ instability	Simulation	Opening	8
4	M	32	Diaphyseal	Yes	Restricted supination	Cutting guide	OSCRO	34
5	F	18	Diaphyseal	Yes	Restricted pronation	Simulation	OSCRO	12
6	F	41	Diaphyseal + ulna	No	Restricted ROM (all directions)	Simulation	OSCRO	29
7	M	18	Diaphyseal + ulna	No	Restricted pronation/ supination	Cutting guide	OSCRO	13
8	M	13	Diaphyseal + ulna	Yes	Restricted supination	Cutting guide	Opening	23

Abbreviations: F, female; M, male; ROM, Range of Motion; DRUJ, distal radioulnar joint; Opening, opening-wedge osteotomy; OSCRO, oblique single-cut rotation osteotomy
a. Age in years at time of surgery
b. Technique consisted of either pre- and intra-operative simulation of the osteotomy using virtual or physical 3D models of both radii sometimes with intra-operative use of a custom-made cutting guide and angled jig

Table 2. Residual malalignment

Malalignment parameter	Median (IQR)			P value[a]
	Pre-op	Post-op	Difference	
Ulnoradial shift in mm, ulnar (-), radial (+)	3.8 (1.4 – 9.9)	7.0 (1.1 – 11.0)	2.1 (-2.7 – 5.0)	0.327
Volodorsal shift in mm, volar (-), dorsal (+)	7.2 (-5.6 – 30.3)	4.0 (2.8 – 10.3)	-3.2 (-11.6 – 11.2)	0.069
Proximodistal shift in mm shortened (-), lengthened (+)	-5.3 (-17.0 – 13.9)	-0.6 (-3.8 – 0.2)	2.9 (-0.0 – 5.4)	0.123
Dorsopalmar tilt in deg, dorsal (-), volar (-)	-9.0 (-16.8 – 13.9)	-6.4 (-7.9 – 0.4)	5.5 (-6.9 – 10.3)	**0.050**
Radial inclination in deg, ulnar (-), radial (+)	5.6 (0.4 – 8.8)	3.2 (-1.4 – 8.8)	-1.4 (-9.3 – 5.3)	0.208
Axial rotation in deg, pronation (-), supination (+)	-7.6 (-36.4 – 2.0)	-2.6 (-13.2 – 12.3)	15.0 (1.2 – -30.6)	0.848

a.Related Samples Wilcoxon Signed Rank Test
Abbreviations: IQR, interquartile range; deg, degrees; mm, millimeter;
Bold value indicates statistical significance (p≤0.05)

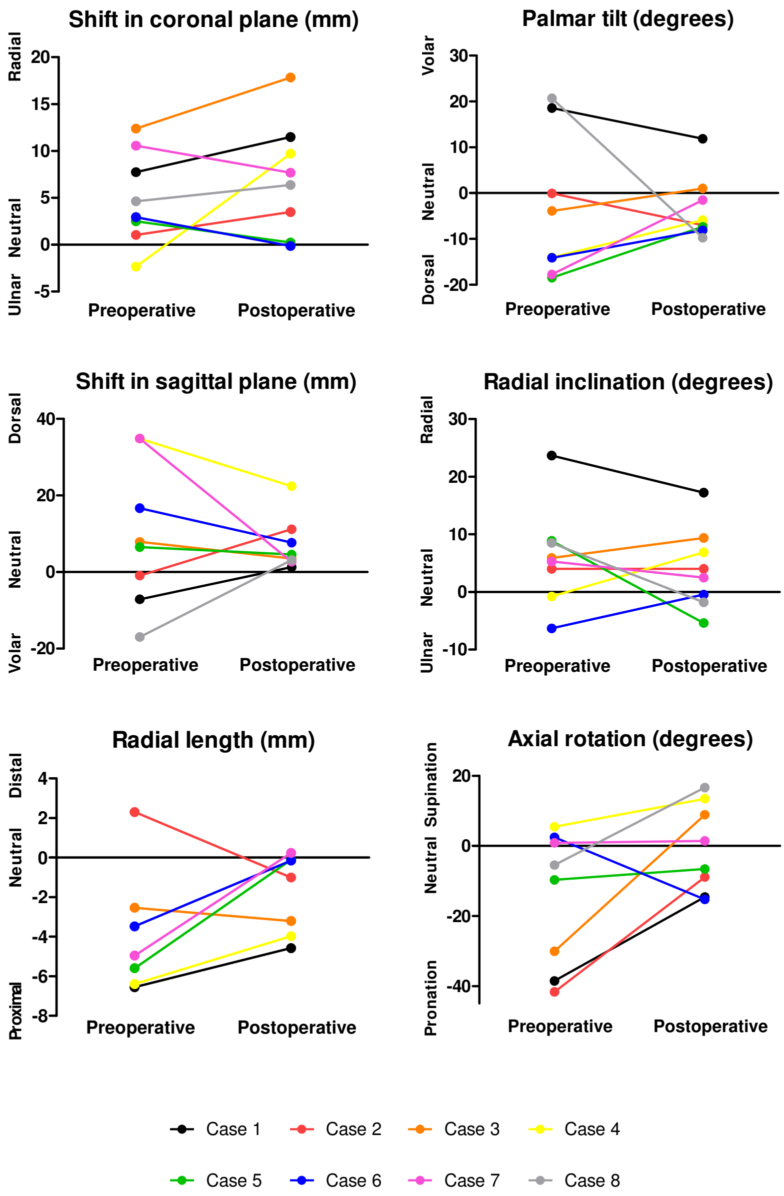

Figure 3. Pre- and postoperative positioning.

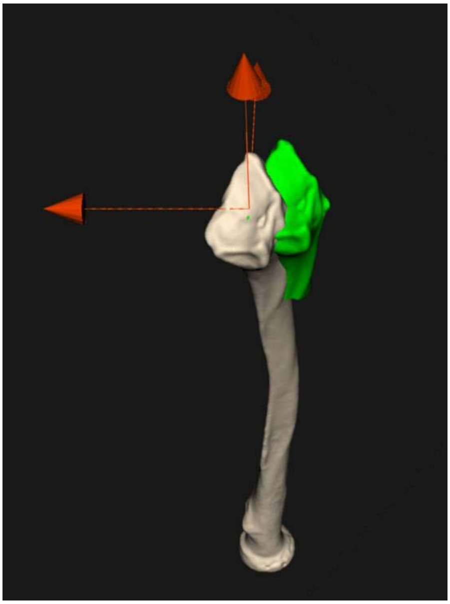

Figure 4. Postoperative alignment in virtual model. Postoperative malalignment of the distal radius segment (green) of Case 4 compared to the mirrored contralateral radius.

Six patients (88%) experienced a postoperative increased range of motion (Table 3). One patient (Case 3) slightly deteriorated. In addition to a distal radius fracture, this patient had sustained a triangular fibrocartilage complex (TFCC) tear that resulted in instability of the distal radioulnar joint (DRUJ). The performed correction osteotomy itself did not provide enough stability, and reinsertion of the TFCC was attempted 2 months after the corrective osteotomy, but was not successful. In one patient (Case 2), the indication for treatment was based on pain, instead of restricted ROM. The preoperative range of motion (ROM) was therefore not measured. There was no statistically significant difference in terms of malalignment parameters between the cases that were corrected with use of a cutting guide versus the corrections that were visualised (Table 4).

Table 3. Functional results

Case	Preoperative		Preoperative	
	Range of wrist[a]		Range of wrist[a]	
	Pronation/ supination	Flexion/ extension	Pronation/ supination	Flexion/ extension
1	150	150	165	135
2	NA	NA	180	175
3	180	155	180	150
4	115	100	145	180
5	90	NA	155	180
6	40	55	175	175
7	80	NA	135	180
8	125	180	180	180
Average	111	128	164	169

NA, not available. a. Expressed in degrees and measured with a handheld goniometer

Table 4. Differences in malalignment parameters compared to pre-op for patients treated with cutting guide versus visualization

Malalignment parameter	Difference compared to pre-op Median (IQR)		Significance[a]
	Cutting guide (n = 4)	Visualisation (n = 4)	
Ulnoradial shift in mm, ulnar (-), radial (+)	3.1 (1.9 to 10.0)	-2.6 (-3.0 to 3.5)	0.200
Volodorsal shift in mm, volar (-), dorsal (+)	10.2 (-7.3 to 18.1)	-6.7 (-26.4 to -2.6)	0.200
Proximodistal shift in mm shortened (-), lengthened (+)	2.2 (-2.0 to 15.7)	4.3 (0.3 to 5.4)	0.686
Dorsopalmar tilt in deg, dorsal (-), volar (-)	-6.8 (-24.5 to 4.4)	8.5 (5.2 to 14.9)	0.114
Radial inclination in deg, ulnar (-), radial (+)	-3.2 (-9.3 to 5.7)	0.3 (-11.4 to 5.3)	1.000
Axial rotation in deg, pronation (-), supination (+)	23.0 (11.5 to 30.6)	1.8 (-13.1 to 30.0)	0.343

Abbreviations: IQR, interquartile range; deg, degrees, mm, millimetre
a. Independent samples Mann–Whitney U test

DISCUSSION

Postoperative 3D evaluation revealed improved positioning parameters for most patients in dorsopalmar tilt, axial rotation (pronation and supination), radial inclination, proximodistal shift and volodorsal shift. Dorsopalmar tilt significantly improved. However, ulnoradial translation was worsened by the correction osteotomy. Both over- and undercorrection occurred in individual patients. All but one patient experienced improved range of motion.

Computer-assisted 3D planning techniques are expected to optimize preoperative treatment plans and therefore minimize residual malalignment.[7] In our study, alignment improved in five of the six positioning parameters, of which improvement in dorsopalmar tilt reached significance despite the small number of patients.

There are several explanations for the residual malalignment. Firstly, the transfer from the virtual plan to the actual realignment and fixation might leave room for error. Although in half of the patients, we used patientspecific cutting jigs to transfer the planned correction onto the patients' radius and used a jig to indicate the angle of the osteotomy, reduction and fixation were done in a freehand manner with K-wires. Although cutting guides generally show beneficial in reconstructive surgery[18], based on our results we cannot yet draw conclusions on its added value. For accurate bone repositioning in future corrective osteotomy treatment, we recommend using reduction guides[15] or patient-specific fixation plates.[19]

The advantage of using an oblique single-cut rotation osteotomy is the correction of angular deformities in three dimensions while maintaining optimal bone contact. However, the method does not aim to correct translational displacements. Small rotational errors after corrective osteotomy of a diaphyseal malunion may scale to relatively large translational displacements at the distal articular level. This could partly explain the residual displacements in ulnoradial and volodorsal shifts.

Secondly, the preoperative plan does not take into account the soft tissue issues many of these deformed forearms have. Earlier (surgical) trauma often causes scar formation to structures like the interosseous membrane and makes the planned repositioning difficult to realize. Additionally, full geometric restoration of bony structures may hamper full mobility if there is too much stress on the soft tissue. Therefore, in some cases, complete correction was not obtained. Despite this issue, previously published data suggest a statistically significant correlation between residual malalignment and clinical outcome.[7] When soft tissue allows, we expect that increased precision in radiological outcome will further optimize postoperative functional results.

The strength of this study is that we examined the postoperative positioning using 3D techniques. Only a few previous studies assessed postoperative results in 3D.[7,20,21] However, they focussed on intra-articular distal radius malunions and expressed their findings in terms of postoperative articular displacement. Another study by Vroemen et al.[7] evaluated the postoperative malalignment in 25 patients after a 2D planned corrective osteotomy using 3D imaging techniques. The median residual malalignments we presented in this study are comparable, but not per se superior to their results after a 2D planned corrective osteotomy. However, due to the lack of preoperative 3D malpositioning of their series and a potential selection of relatively complex cases in ours, full comparison is not possible.

The postoperative range of motion we found is better than previous studies with computer-assisted 3D planned corrective osteotomy in radial malunions.[22,23] Athwal et al. [22] included six patients with a distal radius malunion. They found an average postoperative range of motion of 89 of flexion–extension, 78% of pronation and 74% of supination after a mean follow-up of 25 months. Miyake et al. included 20 patients and reported a range of motion of 152 pronation and supination after a mean follow-up of 24 months.

Our functional results are also superior to published results of conventional 2D planned corrective osteotomies. A previous study that investigated the long-term results after 2D planned corrective osteotomy of distal malunions demonstrated a range of motion of 109 degrees of flexion– extension and 142 of pronation and supination after a mean follow-up of 13 years.[24]

This study has several limitations. Due to the retrospective nature of this study, there was no predefined protocol for selecting patients. The decision to perform a computer-assisted 3D planned corrective osteotomy was made by the surgeon. Only patients with complex malunions were selected for this type of treatment. This approach has resulted in a selection bias and potentially limits the generalizability of our results. Due to the retrospective nature of this study, we were not able to acquire preoperative grip strength or functional questionnaires (e.g. DASH, PRWE), thus limiting the evaluation of functional outcome of the procedure. Another limitation is the heterogeneity of the population. We included subjects with both diaphyseal and extra-articular distal radius malunions. Distal malunions commonly show axial malalignment in pronation[25], whereas diaphyseal malunions typically involve angular deformation.[23] Individual cases require different goals of correction. As mentioned, an oblique single-cut rotation osteotomy (OSCRO) aims to correct rotational deformities and is limited in providing ulnoradial or volodorsal shifts. This phenomenon—in combination with the low number of cases—may explain the lack of statistically significant improvement in individual directional parameters.

Some patients may benefit more from this 3D planned osteotomy than others. Future studies should focus on determining the appropriate indication for the use of 3D planning techniques in corrective osteotomy. This study suggests that virtual 3D planning of corrective osteotomies of radial malunions ameliorates alignment. Further enhancement of this technique is required to improve transfer of the preoperatively planned position to the intraoperative bone.

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3

THREE DIMENSIONAL VIRTUAL PLANNING OF CORRECTIVE OSTEOTOMIES OF DISTAL RADIUS MALUNIONS: A SYSTEMATIC REVIEW AND META-ANALYSIS

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ABSTRACT

The purpose of this study was to summarize and evaluate results of three dimensional (3D-)planned corrective osteotomies of malunited distal radius fractures. 3D-planning techniques provide the possibility to address 3D-deformity that conventional planning methods might not address. We systematically searched PubMed, EMBASE and the Cochrane library for studies that performed a 3D-planned corrective osteotomy on patients with a malunited distal radius fracture. Fifteen studies with a total of 68 patients were included in the analysis. In 96% of cases, the preoperatively present palmar tilt, radial inclination and ulnar variance showed statistically significant improvement postoperatively with restoration to within 5° or 2mm of their normal values. Mean flexion-extension, pro-supination and grip strength showed statistically significant improvement ($p<0.05$). Complications were reported in 11 out of 68 patients (16%). With the current advances in 3D printing technology, 3D-planned corrective osteotomies seem a promising technique in the treatment of complex distal radius malunions.

INTRODUCTION

Malunion of distal radius fractures is a frequently seen complication, occurring in approximately 5% of distal radius fractures.[1] Up to 83% of malunited distal radius fracture are symptomatic, causing pain, weakness or functional impairment of the joint.[1–3] These symptomatic malunited distal radius fractures often require surgical correction to restore the anatomy of the wrist and improve functional outcome.

The indication for surgical correction is predominantly based on the degree of functional impairment and correctable radiographic findings that potentially cause the patients' complaints.[3,4] The functional impact of the deformity is patient-specific, depending on the age, dominance of the affected arm and activity level of the patient.[3,5]

Acceptable limits of radiographic deformation have been established for the distal radius (Table 1).[6–8] Within these limits, symptoms of distal radius malunions are expected to be minimal.[9] Nonetheless, acceptable values vary between individuals. Often the unaffected contralateral forearm of the patient is used as a reference to evaluate patient-specific degrees of malformation.[10–12]

Several studies have shown that accurate anatomic reconstruction of the malunited radius can improve functional outcome in patients with a symptomatic malunion.[12–14] A corrective osteotomy is the treatment of choice to restore the anatomical configuration and optimize functional outcome.[5,11,12,15]

In order to optimize accuracy of the planned corrective osteotomy, extensive preoperative planning is indispensable. Radiographic evaluation of the affected limb aids in obtaining details of the deformity and determining the osteotomy plane, the fixation method, and in some cases the shaping of a bone graft.[9,16,17]

Traditionally, preoperative planning is based on 2 orthogonal radiographs depicting lateral and posteroanterior views of the radius.[12,18,19] With this method however, complex deformations are often not addressed.[19–21] Especially rotational deformities are difficult to assess on plain radiographs.[9,16,19] Computer-assisted techniques with three-dimensional (3D) images and models address 3D deformity and may further optimize functional and radiographic results of corrective osteotomies.[22–25]

3D-planned corrective osteotomies usually involve three steps.[20,26] Firstly, data is collected by obtaining a CAT-scan of the malunited and contralateral healthy forearm. Secondly, virtual models are created of both radii. By superimposing the malunited radius on a mirrored version of the healthy contralateral side, the location and degree of deformity is determined. Subsequently, a virtual cutting plane is set within the region of the malunion, which divides the bone in a proximal and distal part. The distal and proximal part of the malunited radius can be rotated and translated to match with the contralateral radius.[27] With the third and last step the preoperative plan is translated to the patient during actual surgery.[22,23]

Transferal of the planned osteotomy to the patient's bone is a delicate task for which multiple solutions have been suggested. In its simplest form, virtual or physical 3D models aid the surgeon in understanding and visualizing the planned osteotomy plane.[28] Additionally, there is the possibility to guide the reposition with optical tracking devices.[20,29] Another option is the use of synthetic templates that can be placed in the osteotomy gap, thereby restoring the original position of the distal radius.[24,30] Ultimately, 3D-planning techniques provide the possibility to create patient-specific surgical cutting guides and fixation plates.[22,23,27,28,31–35] Templates are made to match the patients' anatomy and include drilling guides and one or more osteotomy slits. Successively, the corrected position can be secured with use of preoperatively defined, patient specific plates.

Advances in computer technology and 3D printing facilities have made these techniques more accessible in daily clinical practice.[36] Therefore, the aim of this study was to assess the results of corrective osteotomies of a malunited distal radius with use of 3D planning techniques by systematically evaluating the available literature.

METHODS

This systematic review was performed in accordance with the PRISMA checklist for systematic reviews.[37]

Search strategy and inclusion criteria

In collaboration with a clinical librarian, two authors (RJODMK and KML) jointly performed a search of the medical databases MEDLINE, EMBASE and the Cochrane Central Register of Controlled trials. The search strategy was used for PubMed and adapted for each database (Table 2). All English, German and Dutch titles published between January 1st 2000 to February 1st 2016 were considered. We included systematic reviews, randomized controlled trials, cohort studies, case series and case reports. Only studies describing patients with a posttraumatic malunion of the distal radius were included. Deformities due to growth disturbances or congenital anomalies were not considered, nor were diaphyseal or bilateral malunions. Studies applying a 3D-planned corrective osteotomy solely on phantoms or cadavers were excluded, as were descriptive technical reports that did not perform a 3D-planned corrective osteotomy. The osteotomy was considered as '3D-planned' if the preoperative planning was based on computer-assisted three-dimensional images of both the malunited and uninjured distal radius.

All records from the electronic search were screened on title and abstract by two authors (RJODMK and KML). Disagreement was resolved by the consultation of a third reviewer. Of the selected articles, full texts were assessed for eligibility. Subsequently, the reference list of all included studies was screened for potentially relevant studies.

Outcome measures

The primary outcome measure was the functional outcome including range of motion (ROM) of the wrist and/or forearm and/or grip strength. Range of motion comprised flexion and extension and pro- and supination. Our secondary outcomes were radiological outcome, including palmar tilt, radial inclination, ulnar variance and rotational angle, and complications.

Quality assessment

To determine the quality of the included studies, we used the checklist suggested by the Delphi panel for case series.[38] This checklist consists of six main topics subdivided in 17 criteria (Appendix 1). The 17 criteria were scored on how well these were described: 3 points were allocated if it was clearly defined, 1 point if it was partially or inadequately defined and 0 points if it was not defined. Subsequently, subscores were calculated per main topic and labeled with a color depending on its score, respectively green (good), orange (medium) or red (not described). The points needed for a specific color are shown in Table 3. A study was considered as 'high quality' if four or more topics were scored with a green label, 'low quality' if three or more topics were scored with a red label and 'medium quality' for all other combinations.

Data collection and statistical analysis

The data of the individual articles were extracted by one author (KML) on a pre-piloted data extraction form. All data on patient characteristics, used technique, functional and radiographic results and complications were extracted. Additionally, we performed an individual patient data meta-analysis (IPDMA) in order to produce a more precise overall estimate of the average effect.[39] To optimize quality of the IPDMA, authors of included studies were contacted to provide additional data on age of patients, time between the fracture and the correction of the malunion, time until bony union and both pre- and postoperative functional and radiographic parameters. To facilitate IPD analyses, bi-directional range of motion was transposed into a single range (e.g. flexion 40 degrees, extension 25 degrees: flexion-extension range of 65 degrees). Radiographic measurements on pre- and postoperative palmar tilt, radial inclination and ulnar variance were transposed to their distance to normal values (11° palmar tilt, 23° radial inclination and neutral (0 mm) ulnar variance respectively).

Means and standard deviations were calculated for the available data. In case of normal distribution, we used a paired T-test to check for statistical significant improvement. For non-normally distributed data a Wilcoxon signed rank test was used.

Table 1. Radiographic evaluation of the distal radius; normal values and acceptable limits of deformity. [6–8]

Parameter	Normal Value	Acceptable limit of deformity
Radial inclination	21 - 25°	>15°
Radial length or height	10 – 13 mm	7 - 15 mm
Ulnar variance	Neutral, ±1 mm	<3 mm compared to contralateral side
Dorsal-volar angulation	11° volar	≤15° dorsal tilt, ≤20° volar tilt

Table 2. PubMed search

Strategy	#1 AND #2 AND #3
#1	"Colles' Fracture"[Mesh] OR colles'fracture*[tiab] OR colles fracture*[tiab] OR radius fracture[Mesh] OR distal radius fracture*[tiab] OR radius[tiab] OR distal radial[tiab]
#2	Three dimensional[tiab] OR 3d[tiab] OR 3-D[tiab] OR computer assisted[tiab] OR computer-assisted [tiab] OR computer simulation[tiab] OR patient specific instrument[tiab] OR virtual planning[tiab] OR computer aided[tiab] OR computer-aided[tiab]
#3	(("Fractures, Malunited"[Mesh] OR malunited fracture*[tiab] OR malunion[tiab] OR cross united fracture*[tiab] OR abnormal union fracture*[tiab] OR deformity[tiab])) OR ("Osteotomy"[Mesh] OR osteotomy[tiab] OR osteotomies[tiab])

RESULTS

Literature search and quality assessment

The results of the literature search are summarized in a flowchart (Fig. 1). Quality assessment of included studies is summarized in Table 4 and Appendix 1.

Included studies

Fifteen studies involving 68 participants met the inclusion criteria. Study characteristics are shown in Table 5. Twelve studies are descriptive case-series studies (therapeutic level IV evidence) with sample sizes ranging from two to eleven participants; the remaining three studies are case report studies (therapeutic level V evidence). Additional data was requested for 11 out of 15 titles, and was received from two authors.[23,30] Another author reported that the requested data was not available.

Table 3. Scoring scheme for quality assessment

Main topics (total points)	Objective (3)	Population (12)	Intervention (6)	Outcome (9)	Statistics (3)	Results (15)
Points needed for specific color	3	≥9	6	9	3	≥12
	1	6 - 8	3 - 5	4 - 8		8 - 11
	0	≤5	≤2	≤3	0	≤7

Table 4. Results of critical appraisal

Study	Objective	Population	Intervention	Outcome measure	Statistics	Results	Quality
1. Athwal et al (2003)	3	9	6	9	0	13	High
2. Croitoru et al (2001)	3	0	3	0	0	0	Low
3. Dobbe et al (2014)	3	N/A	6	4	0	12	Medium
4. Honigmann et al (2016)	3	6	3	3	N/A	7	Low
5. Kunz et al (2013)	3	4	6	6	0	12	Medium
6. Miyake et al (2011)	3	9	6	9	3	12	High
7. Murase et al (2008)	3	N/A	3	0	0	7	Low
8. Oka et al (2008)	3	N/A	3	6	0	7	Low
9. Oka et al (2010)	3	6	6	9	0	10	Medium
10. Rieger et al (2005)	3	6	6	9	3	4	High
11. Schweizer et al (2013)	3	9	6	9	3	15	High
12. Schweizer et al (2014)	3	6	3	1	0	4	Low
13. Stockmans et al (2013)	3	9	3	9	0	9	Medium
14. Walenkamp et al (2015)	3	6	3	7	3	12	Medium
15. Zimmermann et al (2003)	3	12	3	4	0	9	Medium

Participants

Of 68 included participants, 16 (23.5%) were men, 28 (41.2%) were woman; for 24 (35.3%) patients gender was not specified. Mean age of the participants was 51 (SD 17, range 15-79) years at the time of surgery. All participants suffered from a symptomatic, malunited fracture of the distal radius. For 25 participants the initial fracture type was not specified[17,24,29,31], the remaining fractures were extra-articular (n=28) or combined extra- and intra-articular (n=15) in nature. Initial treatment comprised plaster cast immobilization with or without closed reduction in 34 patients and open reduction and internal fixation in 7 patients. Four studies did not report the initial treatment (n=27).[17,23,24,29] The mean time between injury and the corrective osteotomy was specified for 38 patients and was 30 months (SD 80, range 2 - 360).

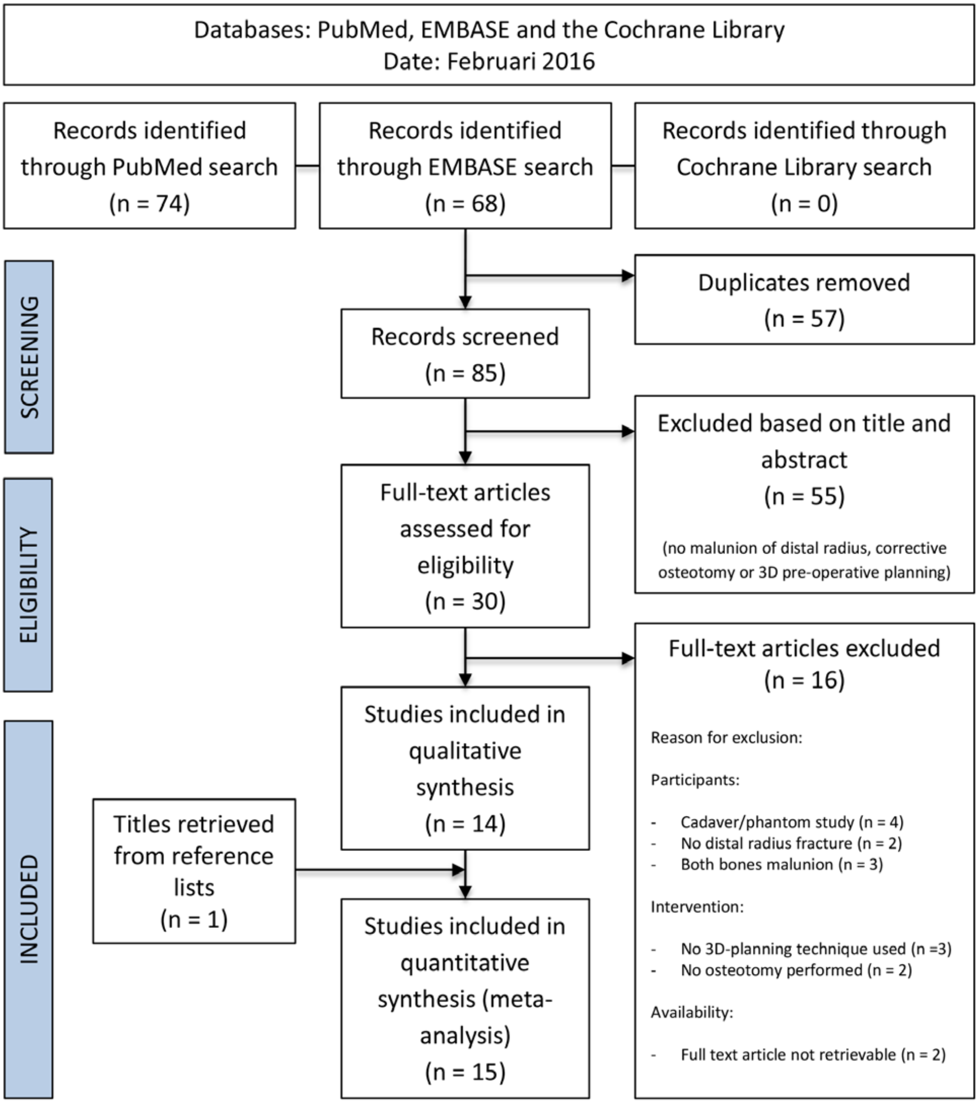

Figure 1. PRISMA flowchart of study selection.

Table 5. Characteristics of the included studies

Study	Author	Year	Patients in study (n)	Mean age in years (range)	Months between injury and osteotomy (range)	Intraoperative technique used
1	*Athwal et al*	*2003*	*6*	*50 (43 – 60)*	*9.3 (5 – 17)*	*Intraoperative guidance system*
2	*Croitoru et al*	*2001*	*6*	*N/A*	*N/A*	*Intraoperative guidance system*
3	*Dobbe et al*	*2014*	*1*	*40*	*360*	*Patient-specific surgical guide and plate*
4	*Honigmann et al*	*2016*	*1*	*54*	*13*	*Patient-specific surgical guide*
5	*Kunz et al*	*2013*	*1*	*61*	*8*	*Patient-specific surgical guide*
6	*Miyake et al*	*2011*	*10*	*56 (27 – 79)*	*48 (2 – 360)*	*Patient-specific surgical guide*
7	*Murase et al*	*2008*	*8*	*49 (19 – 72)*	*12 (5 – 23)*	*Patient-specific surgical guide*
8	*Oka et al*	*2008*	*1*	*32*	*5*	*Patient-specific surgical guide*
9	*Oka et al*	*2010*	*2*	*33 (18 – 48)*	*6 (4 – 8)*	*Patient-specific surgical guide, 3D-cut bone graft*
10	*Rieger et al*	*2005*	*11*	*N/A*	*N/A*	*Manufactured repositioning device*
11	*Schweizer et al*	*2013*	*6*	*48 (33 – 63)*	*9 (3 – 16)*	*Patient-specific surgical guide*
12	*Schweizer et al*	*2014*	*2*	*32 (15 – 62)*	*21 (4 – 48)*	*Patient-specific surgical guide*
13	*Stockmans et al*	*2013*	*4*	*54 (28 – 66)*	*9 (6 – 16)*	*Patient-specific surgical guide*
14	*Walenkamp et al*	*2015*	*3*	*46 (18 – 64)*	*31 (14 – 61)*	*Visualization, patient specific surgical guide*
15	*Zimmermann et al*	*2003*	*6*	*26 (19 – 32)*	*12 (6 – 14)*	*Patient specific surgical guide*
Available for IPD (n)			-	*46*	*39*	-
Mean (SD)			-	*51 (SD 17)*	*30 (SD 79)*	-

N/A: not applicable, IPD: individual patient data, SD: standard deviation

Preoperative work up

In all studies Computed Axial Tomography (CAT scan) was performed to plan the corrective osteotomy: all scans were bilateral except of two cases that focused solely on the correction of an intra-articular step-off. CAT-data was used to create a 3D surface mesh of the scanned bones: the affected limb was then superimposed on a mirrored version of the healthy contralateral side. All studies used dedicated software to simulate a rotational, opening or closing wedge osteotomy and to virtually realign the bones.

Transfer of preoperative plan to patient

The majority of studies (10 out of 15) relied on the use of a custom-made osteotomy template with guiding holes and an osteotomy slit.[17,22,23,26–28,30–34] Athwal et al. (2003)[20] and Croitoru et al. (2001)[29] used an optical tracking device to guide the position of drill and screws. Three studies performed the osteotomy by hand but relied on a custom-made wedge shaped repositioning device that was interposed in the osteotomy gap either temporarily[24,30] or permanently.[17]

With regard to fixation method, volar or dorsal plating with standard implants was the preferred method in the majority of studies. Five studies used a digitalized model of a standardized fixation plate to plan its exact position intra-operatively. Dobbe et al (2014)[31] created a patient-specific plate, which fitted the geometry of the patient's bone in the realigned position.

Functional results

Functional outcomes are depicted in Table 6. Mean flexion-extension, pro-supination and grip strength showed statistically significant improvement ($p<0.05$).

Radiographic results

Radiographic results can be found in Tables 7A-B. Radiographic evaluation was based on plain radiography (true anteroposterior and lateral views, n=29) or on postoperative CAT-scan of the radius (n=19). In addition to CAT evaluation, 14 patients were evaluated by comparing the same 3D planning techniques that were used for the planning of the procedure.[28,31,33,34] Improvement on palmar tilt, radial inclination and ulnar variance showed statistical significance ($p<0.05$). In all but three cases, directions were improved to within 5 degrees of their normal value. Mean intra-articular step-off improved statistically significant to 0.9 mm. Intra-articular gap was specified in 4 patients only and did not improve significantly.

Table 6. Functional results of the included studies

Study	ROM wrist		ROM forearm		Grip strength		Complications
	Flexion/extension (°)		Pro-/supination (°)				
	PREOP	POSTOP	PREOP	POSTOP	PREOP	POSTOP	
1	N/A	47/42	N/A	78%/74%*	N/A	30 kg, 79% of healthy side	1 partial laceration of EPL tendon. 1 implant removal
2	N/A	N/A	N/A	N/A	N/A	N/A	N/A
3	10/30	60/60	45/45	60/70	Intact	N/A	N/A
4	70/40	70/70	70/40	70/80	N/A	N/A	N/A
5	N/A	N/A	N/A	N/A	N/A	N/A	N/A
6	33/63	63/67	71/76	81/84	39% of healthy side	82% of healthy side	2 postop. Screw loosening**. 1 implant removal for EPL tendon problem
7	33/54	62/66	58/69	79/78	42% of healthy side	86% of healthy side	1 distal radioulnar subluxation persisted. 3 implant removal
8	5/45	70/80	N/A	N/A	42% of healthy side	86% of healthy side	N/A
9	83†	113†	120‡	150‡	N/A	N/A	1 implant removal
10	63/59	76/75	50/53	53/65	N/A	N/A	N/A
11	37/49	56/62	69/55	78/80	N/A	Improved with 10%	N/A
12	30/60	50/60	60/80	80/80	N/A	N/A	N/A
13	N/A	N/A	N/A	N/A	N/A	N/A	N/A
14	153†	153†	165‡	175‡	N/A	97% of healthy side	1 distal radioulnar subluxation persisted
15	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Available for IPD (n=)	32	39	30	37	23	32	-
Mean (SD)	91 (SD 34)	123 (SD 29)	132 (SD 36)	159 (SD 21)	47% (SD 25) of healthy side	84% (SD 14) of healthy side	-
Pre-postop difference	P<0.05		P<0.05		P<0.05		

ROM: Range of motion; N/A: not applicable; PREOP: preoperative, POSTOP: postoperative; SD: standard deviation; EPL: Extensor Pollicis Longus
* Range of motion of the forearm is measured as global percentage value
† Range of motion of the wrist was measured as the total flexion-extension angle
‡ Range of motion of the forearm was measured as the total rotational arc of the forearm
** both patients with early postoperative screw loosening had osteoporosis

Table 7A. Radiographic results of the included studies

Study	Mean time to bone union (weeks, range)	Volar tilt (°)				Radial inclination (°)		Ulnar variance (mm)	
		PREOP		POSTOP		PREOP	POSTOP	PREOP	POSTOP
		Volar	Dorsal	Volar	Dorsal				
1	10.5 (9 – 12)	21	30	9	-	12	21	7.5	1.9
2	N/A	N/A		N/A		N/A		N/A	
3	N/A	N/A		N/A		N/A		N/A	
4	6	35		9		25	25	5	-1
5	N/A	39	-	4	-	22	26	5	-2
6	16 (8 – 20)	-	27	13	-	13	24	6	1
7	9.6 (8 – 12)	-	17	8	-	14	23	3.4	0.6
8	12	N/A		N/A		N/A		N/A	
9	16 (12 – 20)	28 †	-	1 †	-	12 †	1 †	N/A	
10	N/A	26	31	10	-	20	22	5.9	0.6
11	8	N/A		N/A		N/A		N/A	
12	N/A	N/A		N/A		N/A		N/A	
13	N/A	-6‡				-1‡		0‡	
14	N/A	19 †	16 †	12 †	8 †	13 †	7 †	5.4 †	1.7 †
15	N/A	-	16	10	-	25	23	5.9	1.3
Available for IPD (n=)	28	23		27		23	27	23	27
Mean (SD)[β]	12 (SD 3.9)	30 (SD 13)		5 (SD 4)		10 (SD 7)	3 (SD 3)	4.7 (SD 2.5)	1.3 (SD 1.5)
Pre-postop difference	-	**P<0.05**				**P<0.05**		**P<0.05**	

Preop: preoperative; postop: postoperative, IPD: individual patient data, SD: standard deviation
† Volar tilt and radial inclination are provided as the difference between operated and non-operated side.
‡ Volar tilt, radial inclination and ulnar variance are provided as difference between planned and postoperative result.
[β] Distance to normal value (11° volar tilt, 23° radial inclination and neutral (0 mm) ulnar variance respectively)

Table 7B. Radiographic results of intra-articular fractures

Study	Intra-articular step-off (mm)		Intra-articular gap (mm)	
	PREOP	POSTOP	PREOP	POSTOP
1	N/A	N/A	N/A	N/A
5	N/A	N/A	N/A	N/A
8	3.0	0.0	N/A	N/A
11	2.7	0.7	N/A	0.0
12	N/A	N/A	N/A	N/A
13	1.1	0.7	2.3	1.4
Available for IPD (n=)	11	11	4	4
Mean (+/- SD)	2.5 (+/- 0.7)	0.9 (+/- 0.6)	2.6 (+/- 0.9)	2.1 (+/- 0.9)
Pre-postop difference†	P<0.05		P = 0.72	

Preop: preoperative; postop: postoperative, IPD: individual patient data, SD: standard deviation
† Wilcoxon signed rank test

3

Complications

Complications were reported in eleven patients (16%); in two patients early postoperative screw loosening occurred. These patients required revision surgery with longer plates. One patient suffered from a partial laceration of the extensor pollicis longus tendon and in two patients distal radioulnar subluxation persisted after surgery. Additionally, six patients had their hardware removed due to hardware related pain or discomfort. No other complications were observed.

DISCUSSION

We found that a 3D-planned corrective osteotomy significantly improves both radiographic and functional outcome in patients with a malunited fracture of the distal radius. All included studies reported improvement on radiographic and/or functional parameters with a considerable number of complications.

Unfortunately, our study has not identified studies comparing the results of 3D planning techniques with more conventional planning methods. Moreover, 3D-planning techniques might be reserved for the more complex cases, making it difficult to truly compare cohorts. Nonetheless, some studies show that in conventional osteotomies only 40% of the corrections reach within 5 degrees of the planned correction of the angular deformity (palmar tilt, radial inclination) and within 2 mm of the planned ulnar variance.[40] Other studies report relatively good results of conventional techniques, with significantly improved function for both intra- and extra-articular malunions.[41,42]

Moreover, it is likely that some fractures benefit more from 3D-planned procedures than other. Rotational deformities for instance are difficult to assess and address with conventional planning and are correlated with clinical outcome.[19] Additionally, intra-articular malunions can benefit specifically from a 3D-planned procedure. Articular malunions often require a multiplanar osteotomy, which can be very difficult to perform with conventional planning. 3D planning with patient specific drill- and saw guides can really facilitate this challenging procedure.

Most authors highlight the importance of 3D-planned corrective osteotomies with the fact that 3D-deformations are often not addressed with conventional 2D planning techniques. Vroemen and colleagues have shown that clinical outcome correlates with 3D rotational deficits but not with 2D evaluation parameters.[19] Subsequently, it is remarkable that the majority of studies in this review used conventional radiographs to evaluate the postoperative positioning of the radius instead of an imaging modality that facilitates 3D evaluation. Residual deformities could have been underappreciated, which may have had an influence on the results.

In this systematic review and meta-analysis with the largest cohort yet, we critically appraised available studies focusing on the results of 3D planned corrective osteotomies of distal radius and performed individual patient data analyses. However, this study is limited by the fact that all included studies had a descriptive character, which makes them highly susceptible to bias. Additionally, a great heterogeneity was seen in type of malunions treated and the technique used for the corrective procedure. Despite this heterogeneity, we chose to combine all patients in one cohort. Due to the diversity of outcome measures, we were forced to transpose data into simplified forms, often losing details in the process. For instance, due to a lack of radiographic data on contralateral extremities, we described radiographic parameters as their distance to a widely accepted normal value. Although we feel this is a valid method with the constraint of limited data availability, this method does not take into account one of the cornerstones of 3D planning techniques.

Disadvantages of the 3D-planning technique include the need for specialized software, the time and effort needed for the preoperative planning, radiation exposure and the costs for the custom-made template and CAT-scan. Unfortunately, this review could not shed light on these important aspects of this technique, as data was not provided by any of the included studies. In this systematic review, we found a considerable complication rate of 16%. Corrective osteotomies however tend to show higher percentages of complications and do not compare to less complex elective wrist surgery.[43]

To fully comprehend the added value of 3D planning corrective osteotomies, we feel a randomized controlled study is inevitable. Leong and colleagues published a protocol for such a trial in 2010, of which the first results are expected early 2018.[44]

With the current advances in 3D printing technology, most techniques reviewed in this study become commercially available. Several companies (e.g. Xilloc BV, Maastricht, The Netherlands or Materialise NV, Leuven, Belgium) provide services to develop patient specific cutting guides based on CAT-data and input by the treating surgeon. The complete process of virtual planning and production of patient specific implants take 6-8 weeks depending on the complexity of the malunion. Individualized cutting and drilling guides that fit the patients' bone geometry could make less readily available techniques such as optical tracking devices obsolete. With the importance of accuracy in mind, it is very likely that future osteotomies will go hand in hand with 3D planning techniques.

CONCLUSION

3D-planned corrective osteotomies show significant improvement to both functional and radiographic results in patients with a malunion of the distal radius. With the current advances in 3D printing technology, it seems a promising technique in the treatment of complex malunions of the distal radius. However, further research is required to draw a definite conclusion on the added value of 3D-planning techniques.

Appendix 1: Critical appraisal scored for included studies

SCORES FOR CRITICAL APPRAISAL						
Study	**Objective**	**Population**	**Intervention**	**Outcome measure**	**Statistics**	**Results and conclusions**
	Hypothesis/ aim/ objective stated clearly?	2. Participants described? 3. Cases collected in >1 center? 4. Eligibility criteria explicit and appropriate? 5. Patients recruited consecutively? 6. Entered study at similar point?	7. Intervention clearly described? 8. Additional interventions clearly reported?	9. Outcome measures clearly defined? 10. Relevant outcomes measured with objective methods? 11. Measured before and after intervention?	12. Statistical tests used to asses relevant outcomes?	13. Length of follow-up reported? 14. Provides estimates of random variability of relevant outcomes? 15. Adverse events reported? 16. Conclusions supported by results? 17. CoI/source of support reported?
Athwal et al (2003)	1. 3	2. 3 3. 0 4. 3 5. 0 6. 3	7. 3 8. 3	9. 3 10. 3 11. 3	12. 0	13. 3 14. 0 15. 3 16. 3 17. 3
Croitoru et al (2001)	1. 3	2. 0 3. 0 4. 0 5. 0 6. 0	7. 3 8. 0	9. 0 10. 0 11. 0	12. 0	13. 0 14. 0 15. 0 16. 0 17. 0
Dobbe et al (2014)	1. 3	2. 3 3. Not applicable 4. Not applicable 5. Not applicable 6. Not applicable	7. 3 8. 3	9. 0 10. 1 11. 3	12. 0	13. 3 14. Not applicable 15. 3 16. 3 17. 3
Honigmann et al (2016)	1.3	2. 3 3. 0 4. 3 5. Not applicable 6. Not applicable	7. 3 8. 0	9. 1 10. 1 11. 1	12. N/A	13. 3 14. 0 15. 3 16. 1 17. 0
Kunz et al (2013)	1. 3	2. 1 3. 0 4. 0 5. 0 6. 3	7. 3 8. 3	9. 0 10. 3 11. 3	12. 0	13. 3 14. 0 15. 3 16. 3 17. 3
Miyake et al (2011)	1. 3	2. 3 3. 0 4. 3 5. 0 6. 3	7. 3 8. 3	9. 3 10. 3 11. 3	12. 3	13. 3 14. 0 15. 3 16. 3 17. 3
Murase et al (2008)	1. 3	2. 3 3. Not applicable 4. Not applicable 5. Not applicable 6. Not applicable	7. 3 8. Not applicable	9. 0 10. 0 11. 0	12. 0	13. 3 14. Not applicable 15. 3 16. 1 17. 0

Oka et al (2008)	1. 3	2. 3 3. Not applicable 4. Not applicable 5. Not applicable 6. Not applicable	7. 3 8. Not applicable	9. 3 10. 0 11. 3	12. 0	13. 3 14. Not applicable 15. 3 16. 1 17. 0
Oka et al (2012)	1. 3	2. 3 3. 0 4. 0 5. 0 6. 3	7. 3 8. 3	9. 3 10. 3 11. 3	12. 0	13. 3 14. 0 15. 3 16. 3 17. 1
Rieger et al (2005)	1. 3	2. 0 3. 0 4. 3 5. 0 6. 3	7. 3 8. 3	9. 3 10. 3 11. 3	12. 3	13. 3 14. 0 15. 0 16. 1 17. 0
Schweizer et al (2013)	1. 3	2. 3 3. 0 4. 3 5. 0 6. 3	7. 3 8. 3	9. 3 10. 3 11. 3	12. 3	13. 3 14. 3 15. 3 16. 3 17. 3
Schweizer et al (2014)	1. 3	2. 3 3. 0 4. 0 5. 0 6. 3	7. 3 8. 0	9. 0 10. 0 11. 1	12. 0	13. 3 14. 0 15. 0 16. 1 17. 0
Stockmans et al (2013)	1. 3	2. 3 3. 0 4. 3 5. 0 6. 3	7. 3 8. 0	9. 3 10. 3 11. 3	12. 0	13. 0 14. 3 15. 0 16. 3 17. 3
Zimmermann et al (2003)	1. 3	2. 3 3. 0 4. 3 5. 3 6. 3	7. 3 8. 0	9. 0 10. 1 11. 3	12. 0	13. 3 14. 0 15. 3 16. 3 17. 0
Walenkamp et al (2015)	1.3	2. 3 3. 0 4. 3 5. 0 6. 0	7. 3 8. 0	9. 3 10. 3 11. 1	12. 3	13. 3 14. 0 15. 3 16. 3 17. 3

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4

DIAGNOSTIC ACCURACY OF 2 DIMENSIONAL COMPUTED TOMOGRAPHY FOR ARTICULAR INVOLVEMENT AND FRACTURE PATTERN OF POSTERIOR MALLEOLAR FRACTURES

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ABSTRACT

Background:

Up to 44% of ankle fractures have involvement of the posterior tibial margin. Fracture size and morphology are important factors to guide treatment of these fragments, but reliability of plain radiography in estimating size is low. The aim of the current study was to evaluate the accuracy of 2 dimensional computed tomography (2DCT) in the assessment of posterior malleolar fractures. Additionally, the diagnostic accuracy of 2DCT and its value in preoperative planning was evaluated.

Methods:

Thirty-one patients with 31 ankle fractures including a posterior malleolar fragment were selected. Preoperative CT scans were analyzed by 50 observers from 23 countries. Quantitative 3 dimensional CT (Q3DCT) reconstructions were used as a reference standard.

Results:

Articular involvement of the posterior fragment was overestimated on 2DCT by factors 1.6, 1.4, and 2.2 for Haraguchi types I, II, and III, respectively. Interobserver agreement on operative management (“to fix, or not to fix?”) was substantial ($\kappa = 0.69$) for Haraguchi type I fractures, fair ($\kappa = 0.23$) for type II fractures, and poor ($\kappa = 0.09$) for type III fractures. 2DCT images led to a change in treatment of the posterior malleolus in 23% of all fractures. Surgeons would operatively treat type I fractures in 63%, type II fractures in 67%, and type III fractures in 22%.

Conclusion:

Surgeons overestimated true articular involvement of posterior malleolar fractures on 2DCT scans. 2DCT showed some additional value in estimating the involved articular surface when compared to plain radiographs; however, this seemed not yet sufficient to accurately read the fractures. Analysis of the CT images showed a significant influence on choice of treatment in 23% with a shift toward operative treatment in 12% of cases compared to evaluating plain lateral radiographs alone.

INTRODUCTION

Approximately 7% to 44% of ankle fractures involve the posterior tibial margin.[1–3] These fractures tend to have a poorer prognosis than fractures without posterior involvement.[2,4–8] The decision whether or not to address the posterior fragment during surgery is a subject of ongoing debate, and practice varies among surgeons.[9–11] In the current literature, there seems to be a consensus that a posterior fragment that comprises more than 25% to 33% of the tibial plafond requires fixation.[3,5,9,12–14] However, reliability of these measurements has proven to be questionable.[12,15] In a previous study, we found that surgeons overestimate articular involvement of the posterior malleolar fracture on plain radiographs.[16] Apart from size, morphology of the posterior malleolar fragment might be more important.[5,10] Haraguchi and colleagues classified posterior malleolar fractures into 3 types based on their morphology: type I fractures are described as a triangular fragment of the posterolateral corner of the tibial plafond; type II fractures have extension of the fracture line into the medial malleolus; and type III fractures involve smaller shell-shaped fragments at the posterolateral lip of the tibial plafond (Figure 1).[17] Knowledge of the characteristics of posterior malleolar fragments will contribute to the general understanding of ankle fracture patterns. Hence, the relevance to address these posterior fragments operatively should be based on morphology and size instead of on sheer fragment size alone. Two dimensional computed tomography (2DCT) is expected to enhance surgeons' ability to estimate the morphology and size of the posterior malleolar fragment.[9,12,15,18,19] However, data on the accuracy and reliability of 2DCT in the assessment of posterior malleolar fracture characteristics are scarce.[20] Quantification of 3 dimensional computed tomography (Q3DCT) modeling has proven a useful technique in evaluating fracture morphology.[16,21–25]

The aim of the current study was primarily to evaluate the accuracy of 2 dimensional computed tomography (2DCT) in the assessment of posterior malleolar fractures. In addition, we assessed the value of 2DCT imaging in pre-operative planning and assessed the variability in surgeons' management of these fractures and compared the diagnostic accuracy of 2DCT to the accuracy of plain radiographs.

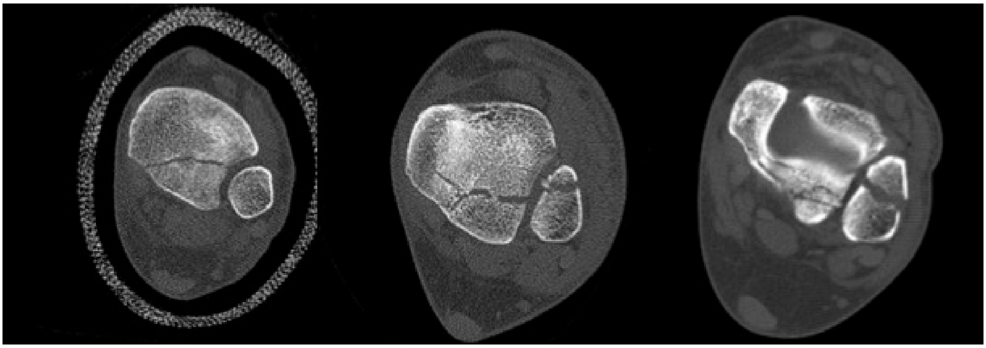


Figure 1. On the left, a Haraguchi type I fracture of the posterior malleolus, with a triangular fragment, comprising only the posterolateral corner. In the middle, a Haraguchi type II fracture, with extension of the fracture into the posteromedial corner. Sometimes, there is an extension into the medial malleolar fracture. Mostly type II fractures consist of 2 fragments: posterolateral and posteromedial (posterior colliculus of medial malleolus). On the right, a Haraguchi type III fracture is seen, with small shell-shaped fragments at the posterior rim.

METHODS

This study was approved by our institutional review board.

Subjects

Thirty-one patients with 31 ankle fractures involving a posterior malleolar fragment (OTA type 44) were selected, based on an equal distribution of Haraguchi types I to III. All patients were treated in a level III trauma center (Sint Lucas Andreas Hospital, Amsterdam, the Netherlands) between March 2005 and December 2012 and had both preoperative plain radiographs and CT scans of the injured joint.

Computed Tomography

All preoperative CT scans were acquired with 1 of 2 different systems (Toshiba Aquilion 4 Slice, Toshiba Medical Systems Cooperation, Tokyo, Japan, or GE Discovery ct750 HD, GE Healthcare, Fairfield, CT, United States) with a maximal slice thickness of 1 mm. Reconstructions in 3 (sagittal, coronal, and axial) planes were available for review. There were no 3D reconstructions available for review.

Quantitative 3 Dimensional Computed Tomographic Modeling

We used Q3DCT modeling techniques as a reference standard to quantify fragment size and morphology.[21,23–26] Reliability of this technique has been assessed in a separate study.[16] To create reconstructions, sagittal images of CT scans (DICOM files; Digital Imaging and Communications in Medicine) were analyzed with an algorithm that identified the outer margin of highest density (cortical or subchondral) bone using Matlab (version 8.0; Mathworks, Natick, MA). These outlines were then stacked using Rhinoceros (version 4.0; McNeel North America, Seattle, WA), creating a wire mesh representing the outer margin of the bone. This wire mesh model was then transformed into a polygon mesh, a hollow 3D model of the outer surface of the bone. Fracture fragments with articular surface attached were then identified and isolated for analysis. Articular surface area of the posterior fragments was reported as a percentage of articular surface of the complete tibial plafond. In case of multiple posterior fragments, the surface areas of the separate fragments were combined. Fracture patterns were analyzed at the level of the tibial plafond and categorized according to the Haraguchi classification.[17]

Observers

This study was performed as part of the Ankleplatform Study Collaborative—Science of Variation Group.[27,28] One hundred one independent orthopaedic surgeons were invited to take part in this study. Observers were assigned to review 31 2DCT scans of ankle fractures involving the posterior malleolus using an online DICOM viewer. The following 5 questions were asked of each case:

(1) What is the involved articular surface of the posterior malleolar fracture as a percentage of the complete tibial plafond articular surface? (in %, open question); (2) According to the Haraguchi classification, which type of posterior malleolar fragment is seen in this patient? (type I, type II or type III); (3) Are the CT images a valuable contribution to preoperative planning? (yes/no); (4) Based on the CT images, would you operatively address the posterior malleolar fragment? (yes/no); and (5) If yes, what would your operative approach be? (multiple choice: A, anterior; B, posterolateral; C, posteromedial; or D, posterolateral and posteromedial approach)

Statistical Analysis

Statistical analysis was performed with SPSS 20.0 for Windows (IBM Corp, Armonk, NY). Data were normally distributed and measurements are presented as means with standard deviations (SDs). For diagnostic accuracy assessment, the average value of the 50 observers was used to describe the difference between the observations (on 2DCT) and the reference standard (Q3DCT). Paired t tests were performed to test the differences for the entire group, and the 3 types of fractures separately. A P value less than .05 was considered to be statistically significant.

Assessment of precision of measurements was performed by calculation of the interclass correlation coefficient ($ICC_{agreement}$), interobserver agreement regarding the Haraguchi classification, and the decision to operate was determined by calculating the kappa value. Both ICC and kappa value were interpreted according to the categorical rating of Landis and Koch: slight agreement, 0.00-0.20; fair agreement, 0.21-0.40; moderate agreement, 0.41-0.60; substantial agreement, 0.61-0,80; and almost perfect agreement, greater than 0.81, with 1.00 being the highest obtainable value.[29]

The standard error of measurement (SEM) was used to calculate the smallest detectable difference (SDD) between the observers.

Comparison with Plain Radiographs

In a previous study, we used the same group of observers and the same cohort of ankle fractures to assess the accuracy of plain radiographs in estimating articular involvement of posterior malleolar fractures.[16] Also, we evaluated management decisions based on plain radiographs. Apart from operative approach and assessment of Haraguchi type, which were not assessed, all questions were identical to the current study. Hence, we were able to compare diagnostic performance characteristics (sensitivity, specificity, and accuracy) and effect on treatment decisions of plain radiographs and 2DCT imaging. To compare these results, we matched identical observers of both study groups.

RESULTS

Of the 101 surgeons invited, 50 surgeons from 23 countries responded and evaluated all images. For characteristics of the participating observers, see Table 1. All participating observers evaluated the complete series of 31 fractures and answered all 5 questions if applicable.

Table 1: Demographics of Participating Observers

Fractures Surgically Addressed (%)		
Sex		n (%)
	Men	48 (96)
	Women	2 (4)
Location of practice		
	Argentina	1 (2)
	Belgium	2 (4)
	Brazil	4 (8)
	Colombia	1 (2)
	Croatia	2 (4)
	Egypt	1 (2)
	Estonia	1 (2)
	Greece	1 (2)
	Hungary	1 (2)
	Italy	4 (8)
	Japan	1 (2)
	Malaysia	1 (2)
	Netherlands	6 (12)
	Norway	1 (2)
	Poland	1 (2)
	Portugal	6 (12)
	South Africa	1 (2)
	Spain	2 (4)
	Sweden	2 (4)
	Turkey	1 (2)
	Ukraine	1 (2)
	United Kingdom	6 (12)
	United States	3 (6)
Years in practice		
	0-5	21
	6-10	12
	11-20	11
	>20	5
Posterior malleolar fractures per year		
	0-10	26
	11-25	19
	26-50	4
Specialization		
	General orthopedics	43
	Orthopedic traumatology	2
	Foot and ankle	1
	Other	4

Involved Articular Surface on 2DCT Versus Reference Standard Q3DCT

According to the reference standard Q3DCT, the mean posterior malleolar fragment involved 14% (SD = 10.8) of the tibial plafond articular surface. The mean articular involvement of the posterior malleolar fracture as measured by 50 observers on the 2DCT images was found to be 22% (SD = 10.39). This difference of 9% (95% CI = 6.4, 10.8) was statistically significant (P < .001).

Haraguchi type 1 fractures involved 16% (SD = 13.0) of the articular surface according to the reference standard Q3DCT, compared to 27% (SD = 13.1) estimated by the observers on the 2DCT images. This difference of 11% (95% CI = 8.1, 12.9) was significant (P < .001). Haraguchi type 2 fractures involved 18% (SD = 10.1) on Q3DCT, compared to 26% (SD = 6.49) on the 2DCT images. This difference of 8% (95% CI = 1.3, 14.7) was significant (P = .024). Haraguchi type 3 fractures involved 7% (SD = 4.7) of articular surface, compared to 14% (SD = 4.6) according to observers evaluating 2DCT images. This difference of 8% (95% CI = 4.8, 9.97) was significant (P < .001). These overestimations compare to a factor 1.6, 1.4, and 2.2 for Haraguchi types I, II, and III, respectively.

Diagnostic Performance Characteristics of 2DCT

2DCT showed an accuracy of 0.74 with a sensitivity of 0.77 and a specificity of 0.77 for Haraguchi type I fractures. For type II fractures, accuracy was 0.79 with a sensitivity of 0.65 and a specificity of 0.86. For type III fractures, accuracy was 0.68 with a sensitivity of 0.44 and a specificity of 0.80. See Table 2 for 95% confidence intervals.

The diagnostic accuracy of 2DCT for posterior malleolar fragment size depended on cut-off values chosen. Within limits ranging 5% below and above the reference standard value, accuracy was 30%.

Table 2: Sensitivity, specificity and accuracy of 2DCT

	Sensitivity	95% CI	Specificity	95% CI	Accuracy	95% CI
Haraguchi type I	0.77	0.71, 0.83	0.72	0.86, 0.75	0.74	0.71, 0.76
Haraguchi type II	0.65	0.58, 0.71	0.86	0.83, 0.88	0.79	0.76, 0.83
Haraguchi type III	0.44	0.37, 0.50	0.80	0.76, 0.84	0.68	0.64, 0.71

Reliability of Measurements

Within the group of 50 observers, the intraclass correlation coefficient (ICC) of the fragment size measurement for all fractures was 0.57 (95% CI = 0.45, 0.70). For Haraguchi type I fractures the ICC was 0.69 (95% CI = 0.50, 0.88), for Haraguchi type II fractures the ICC was 0.26 (95% CI = 0.13, 0.55) and for type III fractures the ICC 0.27 (95% CI = 0.15, 0.54).

The standard error of measurement (SEM) for all fracture types was 9% with a smallest detectable difference (SDD) of 25%. The SEM for Haraguchi type I fractures was 9% with an SDD of 24%. The SEM for Haraguchi type II fractures was 11% with an SDD of 30% and Haraguchi type III fractures had a SEM of 7% with an SDD of 21%. Kappa value for the Haraguchi classification was 0.27 (95% CI = 0.0, 0.54) with an absolute agreement between the observers of 53%.

Operative Management of Posterior Malleolar Fractures

None of the observers would operatively address all fractures; neither would an observer treat all fractures conservatively. From all the fractures presented, the majority of observers (consensus agreement) would operatively address 50%. The observer most leaning toward operative treatment would fix 87% of posterior fragments, the most conservative observer would fix 19%. The fracture least operated on (1 observer) was one of the 3 fractures that comprised 0% of the articular surface, a Haraguchi type III avulsion. There were 2 fractures that 100% of the observers would fix, involving 11% and 34% of the articular surface, respectively (according to the reference standard Q3DCT; Figure 2). The fractures most observers would fix were not the largest. Overall, 88% of surgeons would operatively address fractures involving >25% of the articular surface. Fractures involving >15% would be addressed by 85%, fractures involving >10% by 74%, and 14% of the observers would operate fractures of <5% of the articular surface (as measured on Q3DCT).
See Table 3 for the management of fractures per Haraguchi subtype.

Out of the 50 observers, 85% found the 2DCT scan to be of added value in the preoperative planning of Haraguchi type II fractures. For Haraguchi type I and III fractures, the 2DCT scan was considered valuable by 62% and 54% of the observers, respectively.

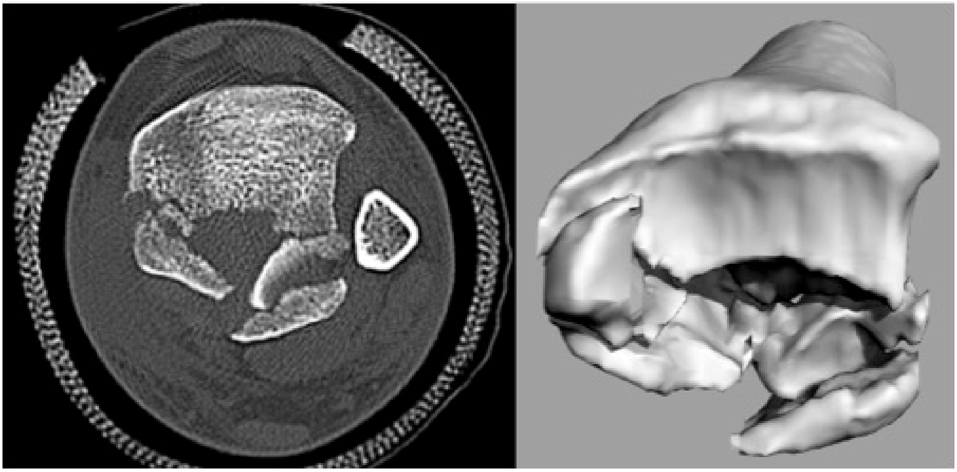
When the surgeon aimed to address the posterior malleolus, 68% and 65% of observers preferred the posterolateral approach for Haraguchi types I and III fracture, respectively. For Haraguchi type II fractures, there was less consensus about the approach; 37% of observers preferred the posterolateral approach, 26% the posteromedial approach, 21% the posterolateral and posteromedial approaches, and 16% the anterior approach.

Comparison With Plain Radiographs

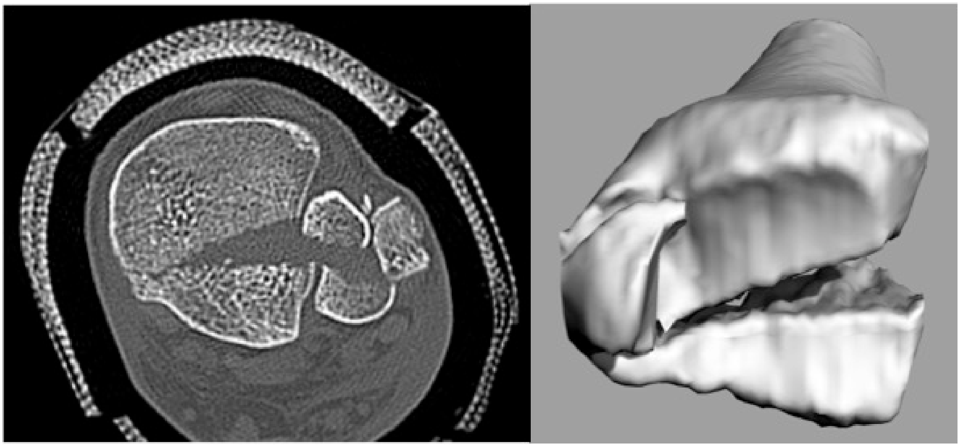
The answers of the current selection of 50 observers were extracted from the original plain radiography database and compared to the current results. All 50 observers had answered all questions in the evaluation of plain radiography.

The mean articular surface measured on plain radiography was 2.3% higher than on 2DCT (95% CI = −0.1, 4.8, P = .06). The differences in surface area of fracture fragment between plain radiography with 2DCT per Haraguchi type were 2.2% (95% CI = −1.9, 6.4, P = .26), 0.6% (95% CI = −4.0, 5.2, P = .79), and 4.1% (95% CI = −1.1, 9.2, P =.11) for Haraguchi types I, II, and III, respectively.

In 23% of cases, treatment of the posterior fragment was changed after reviewing the 2DCT images (interobserver agreement; kappa = 0.54). For shifts in treatment, see Table 4.



A.



B.

Figure 2. (A) Posterior malleolar facture with 11% articular involvement that 100% of observers would fix. (B) Posterior malleolar facture with 34% articular involvement that 100% of observers would fix.

Table 3: Management of posterior fragments per Haraguchi type.

	Fractures Surgically Addressed (%)	Kappa	95% CI	Absolute Agreement (%)
Haraguchi type I	63	0.69	0.43, 0.96	85.7
Haraguchi type II	67	0.23	−0.24, 0.60	65.6
Haraguchi type III	22	0.09	−0.40, 0.58	69.6
All types	50	0.47	0.16, 0.78	73.5

Table 4: Direction of Treatment Shift after Evaluation of 2DCT Images.

	Shift in treatment (%)	Kappa	Non-operative → operative (%)	Operative → Non-operative (%)
Haraguchi type 1	11	0.77	8	4
Haraguchi type 2	33	0.29	20	13
Haraguchi type 3	25	0.32	10	15
All types	23	0.54	12	11

DISCUSSION

Our study suggests that surgeons systematically overestimate true articular involvement of posterior malleolar fractures on 2DCT scans. Involved articular surface was overestimated in all Haraguchi subtypes with factor 1.6 (type I), factor 1.4 (type II), and factor 2.2 (type III), respectively. Although 2DCT seemed insufficient to accurately read the fractures, this technique would lead toward a more appropriate treatment when compared to plain radiography alone.

There was higher agreement in estimating the fracture surface of type I fractures (substantial agreement) than type II and III fractures (fair agreement). The fair agreement and high overestimation of type III suggests it is difficult to estimate the involved surface correctly in these shell-shaped fragments of the posterior lip. This is exacerbated by the fact that in general, the smaller the proportion of involved articular surface, the larger the relative over- or underestimation is. Thus, the clinical importance of involved articular surface in type III fractures is likely to be limited, keeping in mind that these fragments are thought to be avulsion fractures that indicate associated posterior syndesmotic injury.

CT evaluation was found to be valuable in 62%, 85%, and 54% for Haraguchi types I, II, and III, respectively. Analysis of the CT images showed a significant influence on choice of treatment in 23%; a shift towards operative treatment was seen in 12% of cases compared to evaluating plain lateral radiographs alone. This suggests CT evaluation would not merely economize on operative treatment; it would enable us to do a better job at selecting the right patients. In line with Büchler and colleagues, we recommend preoperative CT evaluation in all patients with trimalleolar fractures.[12]

Fragments most observers would operatively address were not the largest. This confirms there are more factors that guide treatment than mere fracture size, as mentioned by Buchler and Gardner et al.[10,12] There were 2 fractures that 100% of the observers would fix, involving 11% and 34% of the articular surface, respectively (Figure 2). The first case involving 11% of articular surface was a type II fracture that involved multiple severely displaced fragments creating a large intra-articular gap. The case involving 34% of articular surface was a typical displaced type I fracture that left a large gap in the tibiofibular joint.

If surgeons decided to address the posterior fragment operatively, the posterolateral approach was preferred when confronted with a Haraguchi type I (68%) and type III fracture (65%). In recent literature, interest in this posterolateral approach of posterior fragments has seemingly been growing among orthopaedic surgeons, because of its easy visualization and excellent outcomes with a low complication rate.[30–34] Additionally, this approach offers more direct access to the posterolateral corner of the tibial plafond, which is specifically affected in Haraguchi type I fractures.[30]

For Haraguchi type II fractures, there was less agreement about the approach, but the medial involvement guided the surgeon toward a (partial) medial approach in almost half the cases (47%). However, 37% of observers preferred the posterolateral approach and 16% the anterior approach, through which posteromedial fragments cannot be accurately reduced and fixated. A significant amount of the Haraguchi type II fractures are indeed recognized with 2DCT, but would be inadequately treated.

Strengths of our study include the fact that we used 50 observers from 23 countries to assess posterior malleolar fractures. This group of observers provided us with the best possible representation of the current treatment standards worldwide. Furthermore, to our knowledge, we are the first to examine the accuracy of 2DCT in the evaluation of posterior malleolar fractures by comparing it to Q3DCT as a reference standard.26 The overestimation of involved articular surface is clinically important and adds to our understanding of posterior malleolar fractures.

Limitations of this study include that we have included the articular surface of the medial malleolus in the calculation of articular surface on Q3DCT. Although this technique is indispensable in Haraguchi type II fractures as the medial malleolus itself is part of the posterior fracture, this might partially explain the overestimation in type I and III fractures. Nonetheless, even in type II fractures, there was an overestimation with factor 1.4 which cannot be accounted for by our choice of technique.

Additionally, we acknowledge the possible discrepancy between what CT images found as articular surface and what was true articular surface. As CT images do not show cartilage, the articular surface measured by 2DCT or Q3DCT reconstructions might differ from the actual articular surface. Using proportions to describe the involved surface might have minimized the impact of this effect. Nonetheless, additional studies using magnetic resonance imaging (MRI) or cadaveric bone could point out the degree of over- or underestimation.[16,35,36]

Finally, as mentioned by Gardner and colleagues, there are other factors such as comminution and impaction of fragments that are important in guiding operative management.[10] To optimize the feasibility of this study and limit the workload for our observers, we focused on the estimation of fracture size and pattern and did not address these other factors. This makes it difficult to assess treatment consensus based on Haraguchi type alone. Future studies should take all fracture characteristics into account.

This study showed that observers inaccurately interpret 2DCT data. Studies have shown that extracting 3 dimensional data from 2 dimensional images is a difficult task for the human brain.[37] Although quantification of 3DCT data is yet too laborious for use in clinical practice, 3DCT images might assist in further improving the accuracy of human estimation of the degree of articular involvement.

As the attention for operative fixation of posterior fragments grows, we would recommend a prospective follow-up study to further elucidate the clinical relevance of 3D patho-anatomy of posterior malleolar fractures. With more focus on fracture morphology, we may eventually focus less on fracture size. Further understanding of clinical behavior of these fracture types might eventually have a positive effect on the consensus for treatment of posterior malleolar fragments.[20]

CONCLUSION

Surgeons overestimated true articular involvement of posterior malleolar fractures on 2DCT scans. There was a wide variety in treatment decisions to manage posterior malleolar fractures, and interobserver agreement on management varied greatly per fracture type. Although 2DCT seemed insufficient to accurately assess posterior malleolar fractures, this technique would possibly lead to more appropriate treatment when compared to plain radiography alone. Analysis of the CT images showed a significant influence on choice of treatment in 23% with a shift toward operative treatment in 12% of cases compared to evaluating plain lateral radiographs alone.

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PART II:
INTRAOPERATIVE
IMAGING

5

"TURN LATERALLY TO THE LEFT!". THE NEED FOR UNIFORM C-ARM COMMUNICATION TERMINOLOGY DURING ORTHOPAEDIC TRAUMA SURGERY

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ABSTRACT

Background:
To avoid disturbed teamwork, unnecessary radiation exposure, and procedural delays, we designed and tested a uniform communication language for use in fluoroscopy-assisted surgical procedures.

Methods:
Input of surgeons and radiographers was used to create a set of commands. The potential benefit of this terminology was explored in an experimental setting.

Results:
There was a tremendous diversity in the currently used terminology. Use of the newly designed terminology showed a reduction of procedural time and amount of images needed.

Conclusion:
Our first standardized Dutch language terminology can reduce total fluoroscopy time, number of images acquired, and potentially radiation exposure. For Dutch speaking colleagues, the developed terminology is freely available for use in their OR.

INTRODUCTION

The mobile C-arm with image intensifier (C-arm) has an important use in orthopaedic trauma surgery, most notably in the visualisation of fractures, fracture reduction, and the position of internal or external fixation material.[1–4] With increasing applications for minimally invasive orthopaedic surgery, reliance on image intensification (or fluoroscopy) is increasing.[4]

In most cases, an radiographer operates the C-arm according to instructions from the operating surgeon.[1,2] Accordingly, adequate communication between surgeon and radiographer during C-arm fluoroscopy is vital for efficient imaging. Efficient and safe use of C-arm imaging could protect theatre staff from unnecessary exposure to radiation and can benefit the course of the procedure.[2,5–9] In contrast, miscommunication in the operating theatre has been shown to lead to increased risk of errors, disturbed teamwork, potential conflict, and procedural delays.[2,5–9]

Despite its importance, in practice, communication between surgeons and radiographers is often incoherent and ambivalent.[10] Previous studies have shown that standard, coherent instructions for C-arm movements are lacking.[1,2,5,6] Due to the large number of different specialists involved in surgical procedures and the pressure to perform well in these situations, conflicts could easily arise.[7–9] To solve this problem, standardized sets of commands have been developed, with significant reduction of fluoroscopy time and radiation dose as a result.[2,5,6]

In our Level 1 Trauma Centre, both radiographers and surgeons expressed discontent with regard to fluoroscopy during orthopaedic trauma procedures. We hypothesised that the introduction of a clear, uniform set of instructions could increase procedural satisfaction and reduce fluoroscopy time, number of images taken and accordingly reduce radiation dose. Therefore, the objectives of the current study were: 1. To assess the attitude and experience of orthopaedic trauma surgeons and radiographers with regard to intra-operative C-arm fluoroscopy; 2. To evaluate the current terminology used in C-arm communication; 3. To develop a clear and uniform set of Dutch language commands to control the C-arm; and 4. To explore the potential benefit of implementing this terminology.

MATERIALS AND METHODS

This study was performed in a level 1 trauma center: in 2014, the orthopaedic, trauma, vascular and general surgeons performed 1255 fluoroscopy assisted procedures.

Assessment of experience during C-arm communication

In February 2014, questionnaires were sent to all trauma and orthopaedic surgeons/ residents and radiographers in our hospital. Questionnaires consisted of multiple choice questions to evaluate their experience with intra-operative C-arm fluoroscopy.

Evaluating the currently used terminology

In addition to the multiple choice questions, we provided pictorial representations of C-arm movements in all 6 degrees of freedom (i.e. 12 movements) and asked for the appropriate command to describe the specific movement (open questions). These given commands were compared within groups and between surgeons and radiographers.

Development of uniform terminology

From these questionnaires, four optional verbal instructions per movement were derived. During an expert meeting in June 2014, 22 trauma- and orthopaedic surgeons voted for the most appropriate instructions. The authors composed a uniform communication language based on these answers.

Exploring the potential benefit of uniform terminology

Inspired by earlier work by Yeo and colleagues, we designed and conducted a fluoroscopy experiment in the operating theatre to explore the potential benefit of the new terminology. For this experiment, we randomly assigned two clinicians (a trauma surgeon and a surgery resident) to an experienced radiographer, forming an experimental team.
The experimental teams were instructed to take fluoroscopic images of two metal washers taped to either pole of a spherical, radiolucent object (a soccer ball) in such a way that the washers would overlap (figure 1 A-C).[2] This simulated "limb" was positioned on a carbon operating table and covered with a sheet. Two sets of ten orientations were marked on the object: in each case, the participants were blinded to the orientation of the washers.

Prior to instructing any communication strategy, the total of 10 predefined orientations of the washers were executed per team. The time taken by the surgeon to verbally instruct the radiographer on how to position the C-arm in order to let the washers overlap was recorded, as well as the radiation dose and number of images needed. The surgeon was not allowed to physically adjust the C-arm. After 10 orientations, the surgeons' and radiographers' opinion was evaluated with regard to procedural satisfaction and collaboration.

Subsequently, the newly developed communication terminology was introduced by written and pictorial representations of the commands. The experiment was repeated with another 10 orientations, using the newly introduced C-arm communication terminology. The new instructions were readily available throughout this task.

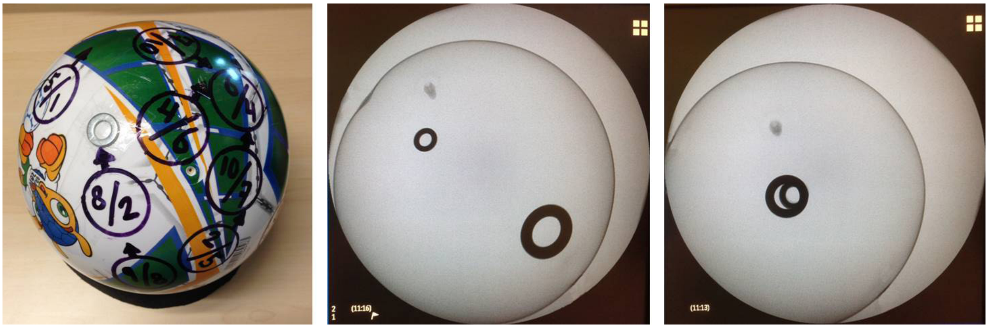

Figure 1 A-C. Macroscopic and fluoroscopic images of the soccer ball with A. two random series of predefined positions and B. washers not aligned and C. washers aligned

Data analysis

To reduce the effect of a possible learning curve during the execution of the experiment, only the last 7 observations of each task were compared. Due to the relatively low number of observations, we assumed the obtained data to be unevenly distributed and accordingly used the Wilcoxon signed rank test to compare data. Variables are denoted as median [inter quartile range].

RESULTS

The questionnaire was sent to 24 trauma or orthopaedic surgeons/residents and 76 radiographers. Seventeen (71%) trauma and orthopaedic surgeons/residents and sixteen (21%) radiographers responded to the questionnaire. Surgeons had an average of 9 years of experience; radiographers averaged 17 years of experience.

Assessment of experience during C-arm communication

During fluoroscopy, 82% of surgeons were assisted by a radiographer during 95-100% of procedures. However, 60% of radiographers came to the OR less than twice a week.

The majority of surgeons estimated that in 25-50% of movements, the C-arm would move in the opposite direction than they intended. 65% of surgeons and 70% of radiographers were of the opinion that incorrect movements of the C-arm were caused by miscommunication. 65% of radiographers thought instructions given by surgeons were confusing or unclear. 94% of surgeons were of the opinion that inadequate positioning of the C-arm led to annoyance in the OR, while 88% of surgeons thought it caused a significant delay in the procedure.

Evaluating the currently used terminology

With regard to the pictorial representations of the C-arm movements, a tremendous variety of commands was provided by both surgeons and radiographers. Certain movements had high inter-surgeon agreement but low surgeon – radiographer agreement. Others had low inter-surgeon, inter-radiographer and surgeon – radiographer agreement. Examples of commands suggested by the participants are provided in figure 2 A-B for two movements: to enable interpretation and overcome the language barrier, Dutch commands were converted into letters. Best possible translations are given for movement B in table 1.

Development of a uniform terminology

The authors composed a uniform communication terminology based on the votes of 22 trauma- and orthopaedic surgeons. Consensus was reached for all but two single movements, for which the antonym of the opposite direction was chosen.

Exploring the potential benefit

After the introduction of the new terminology, Team 1 showed a reduction in time, images and overall radiation dose needed to achieve overlapping washers. Reduction in both the number of images and the radiation dose reached significance (Table 2). Team 2 showed a reduction in both time and images needed, but an increase in radiation dose after the introduction of the new terminology.

All team members unanimously rated the new terminology as clear and instinctive. The terminology was thought to be helpful, especially when working with many different colleagues. Additionally, 3 out of 4 team members remarked it would take additional time to familiarize with the terminology in order to fully utilize its potential.

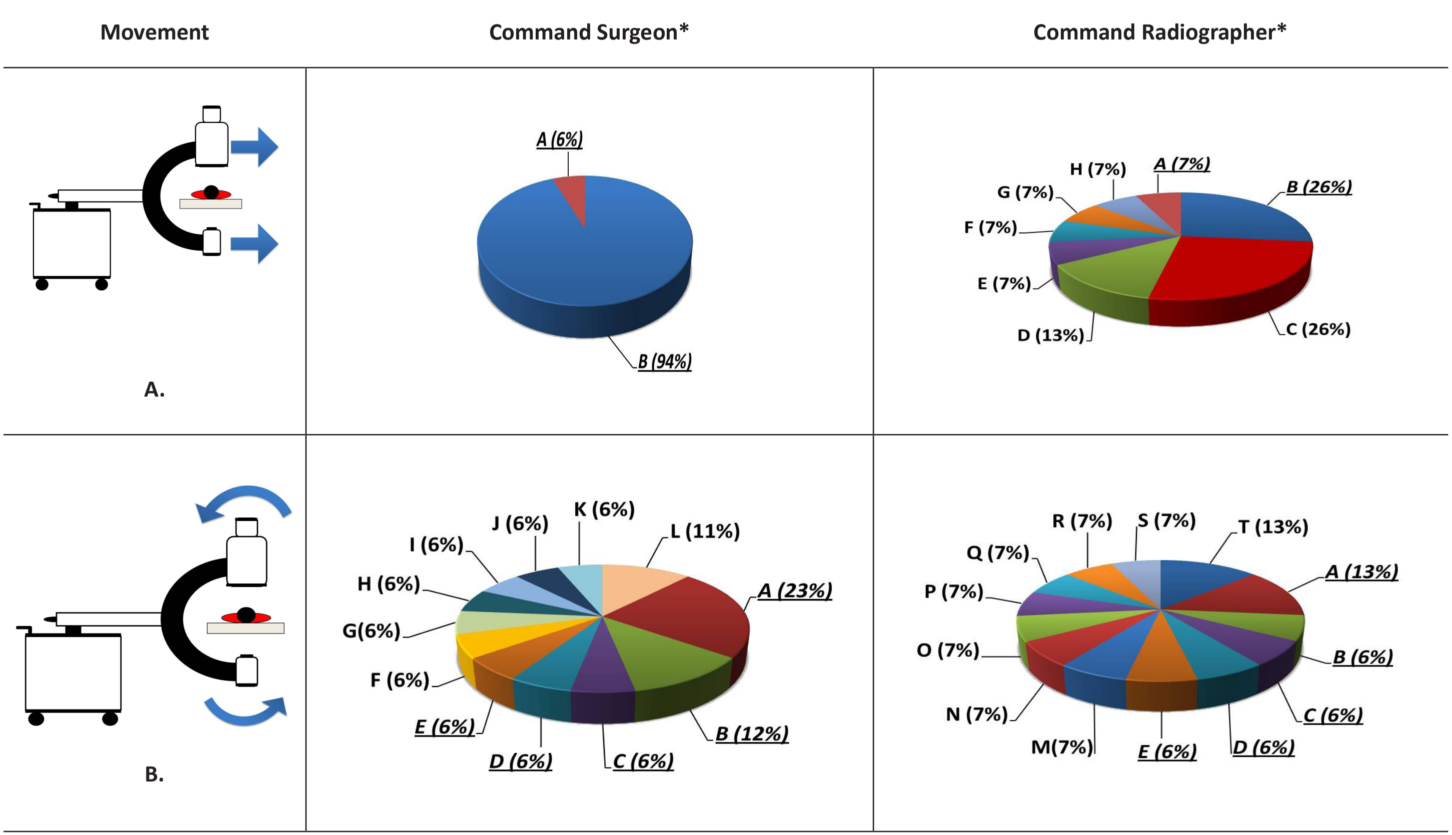

Figure I A-B. Example of two C-arm movements and the suggested commands. Coinciding commands (Table I) given by both surgeons and radiographers are underlined and in *italics*

Table 1. Best possible English translations of commands as suggested by surgeons and radiographers for movement B. Coinciding commands given by both surgeons and radiographers are underlined and in *italic.*

	Dutch command	English translation
A	*Boog/buis achterover kantelen/tilten*	*Tilt C-arm/tube backwards*
B	*Buis onder de patiënt door kantelen*	*Tilt tube underneath patient*
C	*Buis terugkantelen*	*Tilt C-arm/tube backwards*
D	*Lateraal doorlichten*	*X-ray laterally*
E	*Buis naar links draaien/kantelen*	*Tilt/turn tube to the left*
F	"Handgebaar"	"Hand gesture"
G	Naar je toe kantelen	Tilt towards you
H	C-boog kantelen van operateur af	Tilt C-arm away from surgeon
I	In-roteren	Rotate inwards
J	Exo-roteren	Exorotate
K	Oblique mediaal	Oblique and medially
L	Onderuit (draaien)	(Turn) downwards
M	Inschieten van mij af (vanuit de chirurg)	Shoot away from me (from standpoint of surgeon)
N	Latero-mediaal of medio-lateraal	Lateromedial or mediolateral
O	LAO	LAO (Left Anterior Oblique)
P	Axiaal/lateraal	Axially/Laterally
Q	Naar links lateraal draaien	Turn laterally to the left
R	Naar jou zwiepen	Swivel towards you
S	Boog naar lateraal anguleren, onderlangs	Angulate the C-arm laterally and underneath
T	Inschieten naar/vanaf links	Shoot to/from the left

Table 2. Results of experiment before and after introducing uniform terminology for C-arm movements

Variable*		PRE	POST	p-value**
Time needed in seconds	**Team 1**	50 [27-65]	32 [27-90]	0.416
	Team 2	126 [45-141]	69 [54-94]	0.128
Number of images needed	**Team 1**	5.00 [4.00-5.00]	4.00 [3.00-4.00]	**0.025**
	Team 2	6.00 [3.00-7.00]	4.00 [3.00-4.00]	0.057
Radiation dose in mGy	**Team 1**	0.009 [0.007-0.013]	0.002 [0.001-0.004]	**0.018**
	Team 2	0.011 [0.0047-0.0154]	0.019 [0.008-0.047]	0.063

*Variables are denoted as median [inter quartile range]. **Differences were tested with the Wilcoxon signed rank test.

DISCUSSION

We found a tremendous diversity of commands for C-arm positioning with a lack of agreement between surgeons and radiographers. The majority of surgeons acknowledged that inadequate positioning of the C-arm lead to annoyance in the OR and caused a significant delay in the procedure. The introduction of uniform terminology resulted in a significant reduction of images and time needed to perform fluoroscopy tasks. Currently, our study presents the first Dutch language terminology for the use of assisted fluoroscopy during orthopaedic trauma procedures.

We know of three studies that have reported similar experiments. Firstly, Williams et al. (2009) introduced a similar, standardized terminology and showed a significant reduction in time and exposure during a series of 56 targeting maneuvers.[6] Although they used a large series of observations, they were done by one single team of surgeon and radiographer.[6] Secondly, Yeo et al. (2014) designed a standard language and tested it with a similar experiment as the one described in the present study.[2] Time needed for a successful image and the mean number of images decreased significantly after introduction of their terminology. In contrast to Williams et al., they used 15 pairs of surgeon/radiographer instead of one, yet they only performed 3 sets of ball positions per pair. This design underestimates the effect of the expected learning curve within this task, thus potentially confounding outcome measurements. Finally, Pally and Kreder (2013) developed standard instructions after consulting radiographers and trauma surgeons for the most commonly used commands.[5] Like the present study, they found tremendous inconsistency in the commands used. They subsequently developed terminology based on the input of 261 surgeons and 225 radiographers, but did not explore the effect of the terminology in an experimental setting.

Overall, despite their shared common goal of minimizing confusion in the operating theatre, the three suggested sets of terminology are in no way identical. For example, an identical orbital rotational movement of the C-arm is respectively called “roll over/under” (Williams), “swing up/down” (Yeo) and “rotate over/back” (Pally). Additionally, the term “swing” as used by Yeo et al for an *orbital* movement is reserved for *horizontal* movements by Williams and Pally. Also, the term “roll” is used by Williams and Yeo for contradictory movements, while it is not used in the terminology of Yeo et al.

In the present study, we found that 60% of radiographers came to the OR less than twice a week. In concordance, Pally and Kreder found that only 4.4% of radiographers spent more than half of their time at work using fluoroscopy in the operating theatre. In addition to a uniform terminology, dedicated OR radiographers could potentially benefit the process of fluoroscopy during surgery.

Strengths of our study include the fact that we used a step-up approach to involve both surgeons and radiographers in the development of a new terminology, and tested this terminology in a realistic experimental setting. Additionally, to our knowledge we are the first to present a Dutch language communication strategy for the use of intra-operative fluoroscopy. Although its use is limited when compared to English variants, the Dutch language caters for approximately 28 million citizens in countries like the Netherlands, Belgium, Surinam and the islands formally known as the Dutch Antilles.

Our study is limited by the number of experimental teams that participated to explore the potential of our new terminology. This was partly due to logistical challenges: the limited availability of C-arms and radiation protected rooms (e.g. operating room) forced us to conduct the experiment outside of office hours, during which the availability of radiographers was limited. The main focus of this study however was the development of new terminology: the experimental part of our study illustrated what to expect when implementing this terminology in day-to-day practice.

Additionally, Team 1 proved to be more successful in completing the tasks compared to the second team. This could be explained by the relative inexperience of the surgery resident in the second team in interpreting fluoroscopic images. Unlike Yeo et al, we did not record the time taken for surgeons and radiographers to become familiar with the terminology.[2] In retrospect, 3 out of 4 team members suggested that more time was needed to familiarize the terminology. Also, despite using only the last 7 measurements of each session, a learning effect is still plausible. Additional repetitions could minimize this potential effect even further, but would add significant time to the experiment.

Previous studies have shown the importance of efficient and safe use of C-arm imaging: it protects theatre staff from unnecessary radiation and can benefit the course of the procedure.[2,5–9] In the near future, we plan to implement our terminology throughout our Level 1 Trauma Center and evaluate surgeons' and radiographers' satisfaction. Also, we will further improve the terminology by adding commands for movements when the C-arm is not positioned perpendicular to the OR-table.

CONCLUSION

There is a need for uniform terminology during fluoroscopy assisted orthopaedic trauma surgery. Based on input from both surgeons and radiographers, we developed and experimented with the first standardized Dutch language terminology to be used during intra-operative fluoroscopy. Its implementation could reduce the total fluoroscopy time, the number of images required and potentially reduce the overall radiation exposure, while simultaneously improving collaboration and progress of the procedure in the operating theatre.

Acknowledgment

This study would not have been feasible without the support of all participating surgeons and radiographers. We want to thank R.S Edelman, A. de Vries, C.M. Tol and J.J. Atema specifically for their willingness to partake in our experiment.

For Dutch speaking colleagues, the developed terminology is freely available for use in their OR. Please contact the corresponding author (rjodemuinckkeizer@amc.nl).

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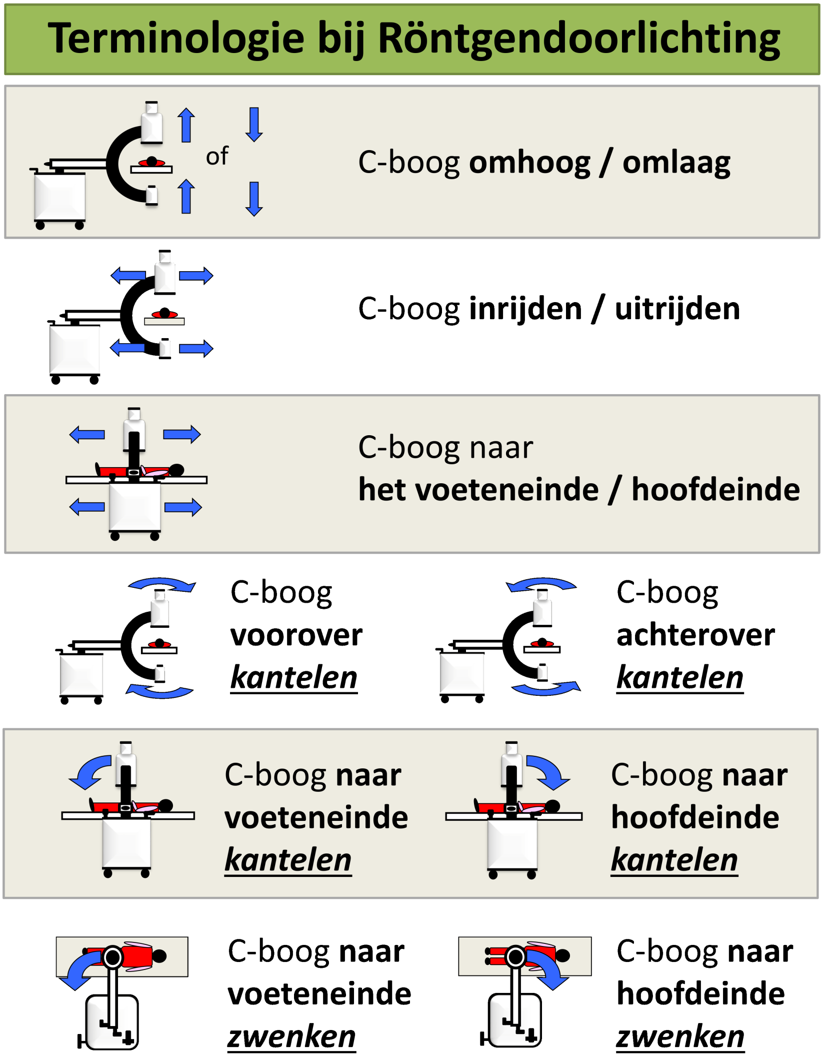
Appendix 1. Instructions for the Dutch terminology



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THE EFFECTIVENESS OF INTRAOPERATIVE 3D-RX IN THE TREATMENT OF FRACTURES OF THE CALCANEUS: A RANDOMIZED CONTROLLED TRIAL

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Submitted

ABSTRACT

Background:

Three-dimensional (3D) fluoroscopy is thought to be beneficial in the operative reduction and fixation of calcaneal fractures. The goal of this multicenter RCT was to investigate the effectiveness of the additional use of intraoperative 3D fluoroscopy compared to conventional 2D fluoroscopy in patients requiring operative treatment for intra-articular fractures of the calcaneus.

Methods:

Patients were prospectively enrolled in 3 hospitals and randomized between 3D or conventional fluoroscopy during operative treatment of their calcaneal fracture. Primary outcome was the quality of fracture reduction and implant position on postoperative computed tomography (CT). Secondary endpoints included intraoperative corrections, complications, and revision surgery. Function and patient reported outcome was evaluated at 6 weeks, 12 weeks and one and two years postoperatively and included range of motion, Foot and Ankle Outcome Score (FAOS), American Orthopedic Foot and Ankle Score (AOFAS), Short-Form 36 (SF-36) questionnaires and post-traumatic osteoarthritis.

Results:

A total of 102 calcaneal fractures were included in the study. There was a statistically significant difference in length of surgery between the groups (3D: 147 min, range 76-507; 2D: 125 min, range 69-219). After 3D fluoroscopy a total of 57 intraoperative corrections were performed in 28 subjects (56.0%). Of these corrections, 91.2% aimed to improve implant position. The postoperative CT-scan showed an indication for additional revision of reduction or implant position in 69.4% of the 3D group versus 59.6% in the 2D group. At two years, there was no difference in revision surgery, complications, FAOS, AOFAS, SF-36 or post-traumatic osteoarthritis.

Conclusion:

The use of intraoperative 3D fluoroscopy prolongs the operative procedure without improving the quality of reduction and fixation in the management of calcaneal fractures. There was no benefit of intraoperative 3D fluoroscopy with regard to postoperative complications, quality of life, functional outcome or post-traumatic osteoarthritis.

INTRODUCTION

Displaced intra-articular calcaneal fractures are commonly treated by open reduction and internal fixation (ORIF)[1,2]. The goal of operative treatment is to restore functional anatomy, as intra-articular incongruency leads to poor clinical outcomes due to posttraumatic osteoarthritis of the subtalar joint[3–6]. Despite the efforts to restore anatomy, up to 20% of operatively treated patients show a persisting step-off in the subtalar joint of >2mm[7–9].

As part of the standard of care in the operative treatment of fractures, fluoroscopy is used to evaluate the quality of reduction and implant position during the operative procedure. Due to the complex anatomy of the calcaneus and the subtalar joint however, in calcaneal fractures conventional fluoroscopy might not always provide sufficient insight[3,10].

Three-dimensional (3D) fluoroscopy comprises a mobile C-arm unit, modified to provide a motorized rotational movement combined with a workstation. This system provides multiplanar 3D reconstructions of bony structures next to 2-dimensional (2D) fluoroscopic images. The diagnostic accuracy of 3D fluoroscopy appears to be higher than 2D fluoroscopy and X-ray and similar to computed tomography (CT) for the evaluation of both reduction and implant position[11–14].

3D fluoroscopy has proven to be a valuable addition to conventional intraoperative imaging techniques[15]. Previous studies that used 3D fluoroscopy in calcaneal fracture surgery have shown an intraoperative correction rate of up to 47% for indications that were not noticed on conventional fluoroscopy[3,10,16,17]. However, the effect of these extra corrections on the quality of the patient relevant outcomes has been scarcely investigated[16,18].

In order to elucidate the clinical effectiveness of 3D fluoroscopy in calcaneal fracture surgery, we need to evaluate its effect on postoperative quality of reduction and implant position, patient reported outcome and functional outcome parameters. Hence, the objective of this study was to investigate the clinical effectiveness of additional intraoperative 3D fluoroscopy as compared to conventional 2D fluoroscopy in patients with intra-articular fractures of the calcaneus.

METHODS

This multicenter randomized clinical trial was conducted in two academic level 1 trauma centers and one regional teaching hospital from December 2010 until July 2015. Patients were eligible to participate if they sustained an intra-articular fracture of the calcaneus that required operative reduction and internal fixation. The coordinating or local investigator counseled patients that presented to the Emergency Department (ED) or outpatient clinic.

Patients were included if they were older than 17 years and signed informed consent was obtained. Patients with bilateral fractures were allowed to participate with both extremities evaluated. Patients were excluded in case of pregnancy, a history of rheumatoid arthritis, or inability to comprehend the trial's features.

Reduction and internal fixation was performed via an extended lateral or sinus tarsi approach, according to the surgeons' preference. Choice of implants was at the surgeon's discretion.

Intraoperatively, only 2D fluoroscopy was used for imaging until the surgeon was satisfied with the reduction and implant position. Before ending the procedure a 3D scan was performed in all patients, and subjects were randomized for the intraoperative availability of its results.

A dedicated and secured online randomization module performed randomization. We used block randomization and stratified for participating center. Patients were blinded for the availability of the 3D scan. Surgeons were blinded for the results of the 3D scan by turning away the screens of the workstation.

In case the results of the 3D scan were not available, the surgeon ended the procedure. If the results were made available to the surgeon, the surgeon was asked to evaluate the images according to a scoring protocol for anatomical reduction and implant position, which was published previously[19]. If the surgeon saw indications for additional operative corrections, they were performed (if feasible) and registered accordingly, after which a conclusive 3D scan was made and evaluated. A postoperative CT-scan was obtained within 7 days post-surgery. Follow-up visits were planned at 6 and 12 weeks and 1 and 2 years postoperatively.

In all participating centers, a BV Pulsera 3D-RX was used. The BV Pulsera 3D-RX (Philips Healthcare, Best, the Netherlands) is a mobile C-arm unit equipped with a motorized rotational movement for volumetric acquisition and a Philips 3D-RA workstation for visualization of the 3D data set. A series of 225 projection images is acquired over a period of 30 seconds during a 200° rotation of the C-arm. The projection images are used to reconstruct a 3D data set. Both volume rendering and multiplanar reformations (MPR) in axial, coronal and sagittal planes are available for evaluation. The image visualization can be enhanced by coloring the implant (Titanview©).

Intraoperative 3D scans and postoperative CT scans were collected, anonymized and systematically evaluated by three independent raters (an experienced foot- and ankle surgeon [TS], a radiologist with specialty in musculoskeletal trauma [LFB], and a surgical trainee in orthopaedic surgery/PhD candidate with 4 years of research experience in calcaneal fractures [RJDMK]). The previously mentioned protocol was used, which consists of 23 items addressing reduction and hardware position of the most important anatomical landmarks of the calcaneus[19]. Each of these 23 multiple-choice items was answered as:

'optimal', 'suboptimal (but acceptable)', 'not-acceptable (correction required)' or 'not judgeable'. In case of intra-articular gaps and steps a threshold of 2 mm was used for acceptability[19]. Answers of the three raters on these 23 items were combined into a single radiological 'profile' of the fracture, where the majority of raters had to agree on the items' judgment.

For the primary outcome, after scoring 23 items separately, each rater answered a concluding dichotomous question whether the subject showed an indication for revision surgery (i.e. Yes or No). Per patient, these conclusive dichotomous questions of the three raters were summarized into a definitive verdict whether the subject required revision surgery.

Secondary outcomes were the number and type of corrections made after a 3D scan, complications, revision operations within one year, Foot and Ankle Outcome Score (FAOS), American Orthopedic Foot and Ankle Score (AOFAS) hindfoot score[20] and Short Form 36 (SF-36) questionnaire. Posttraumatic osteoarthritis was classified according to the Kellgren & Lawrence Classification at two years postoperatively by three independent reviewers[21]. Total fluoroscopy time is given in seconds, total radiation dose is given as a dose area product (DAP) in mGy*cm^2. Previously published calculations have shown a sample size of 250 subjects (125 subjects in both arms) was needed[22].

Analyses were performed in accordance with the intention to treat principle using software (SPSS 20.0 for Windows; Chicago, IL). The primary dichotomous outcome, indication for revision yes/no, as well as the number of intraoperative corrections is described as a percentage in both groups. Differences between groups were given as a risk ratio (RR) and risk difference (RD). Scores of functional outcomes are expressed as means and standard deviations (SD) in case of normal distribution; non-normally distributed data was expressed as medians with ranges. Continuous parameters were analyzed using the Student's T-test (parametric data) or the Mann-Whitney U-test (non-parametric data).

Based on a previous study by Agren and colleagues[2], an additional subgroup analysis was performed. We selected the superior 50% AOFAS scores at 2 years postoperatively of 102 subjects and performed a logistic regression analysis on age, fracture type (Sanders classification), open fractures, infections and the availability of 3D fluoroscopy. We repeated this analysis for arthrodesis at 2 years postoperatively.

This study was reported according to the principles of the Consolidated Standards of Reporting Trials (CONSORT) statement guidance. Approval was obtained from the medical ethics committee and all patients provided written informed consent. The study was registered under Dutch Trial Register NTR 1902.

RESULTS

Between December 2010 and July 2015, a total of 102 fractures (i.e. subjects) in 100 patients were included in the study (Figure 1). The study ended prior to reaching the expected 250 inclusions due to a lower accrual rate and budgetary restrictions. No patient withdrew consent. Six patients were lost to follow up at 12 months postoperatively.

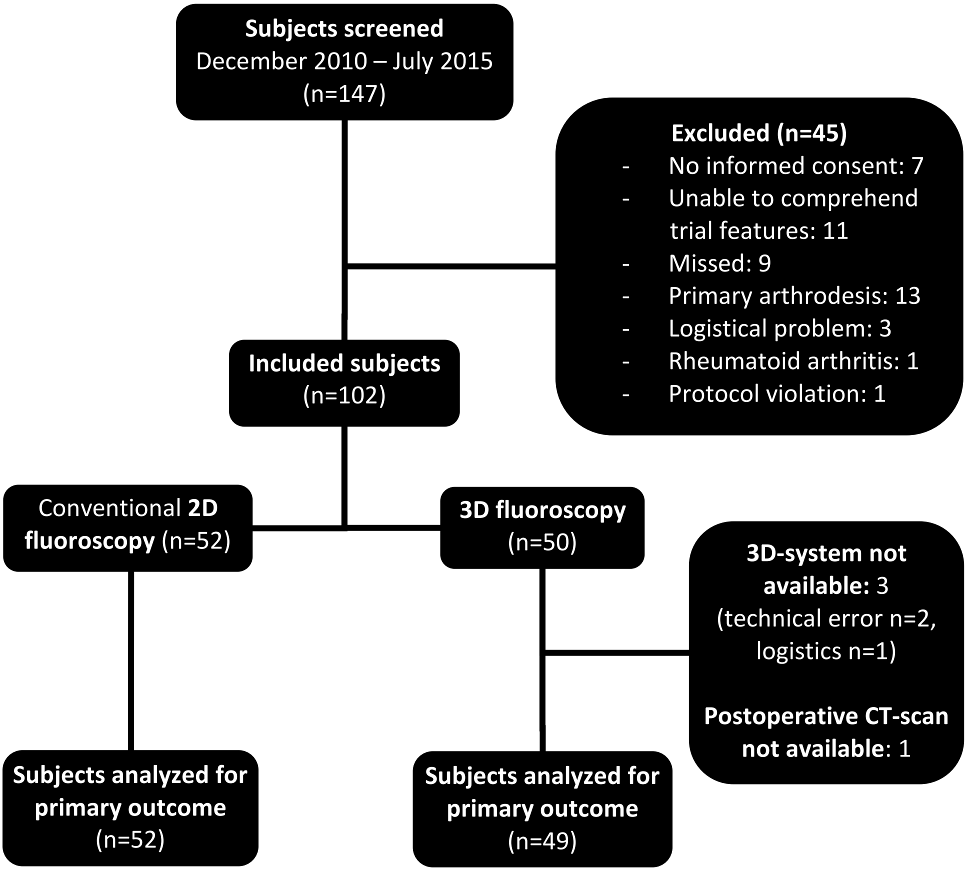


Figure 1. Consort flowchart of patient inclusion

Of the total study population 79.4% were male, mean age was 46.5 (range 18 to 75) years at the day of surgery. Baseline characteristics are displayed in Table 1. In 81 (79.4%) subjects an extended lateral approach (ELA) was used; in 20 (19.6%) subjects the sinus tarsi approach (STA) was used and one subject (1.0%) received closed reduction and percutaneous fixation. A postoperative drain was used in 60 (58.8%) subjects. All subjects received intraoperative prophylactic antibiotics.

Table 1. Patient, trauma and fracture characteristics

Characteristic	2D group N (%)	3D group N (%)	Mean Difference [95% CI]	Risk Ratio [95% CI]	Risk Difference [95% CI]
Number of subjects	52 (51.0)	50 (49.0)			
Including hospital				0.96 [0.70-1.32]	-1.31 [-11.87-9.25]
I	45 (86.5)	44 (88)		1.02 [0.88-1.18]	1.46 [-11.47-14.39]
II	5 (9.6)	3 (6.0)		0.62 [0.15-2.47]	-3.61 [-13.98-6.75]
III	2 (3.8)	3 (6.0)		0.69 [0.12-3.98]	-1.76 [-10.12-6.58]
Gender male	39 (75)	42 (84)		1.12 [0.91-1.37]	9 [-6.5-24.55]
Age, mean (SD)	47.3 (13.4)	45.6 (12.4)	1.7 [-3.4-6.8]		
Diabetes Mellitus	2 (3.8)	2 (4.0)		1.04 [0.15-7.10]	0.15 [-7.38-7.69]
CVD	2 (3.8)	5 (10.0)		2.6 [0.53-12.79]	6.15 [-3.67-15.98]
Smoking	25 (58.1)	18 (41.9)		0.75 [0.47-1.19]	-12.8 [-31.09-6.93]
Trauma mechanism					
Low Energy fall	12 (23.1)	10 (20.0)		0.87 [0.41-1.82]	-3.08 [-19.02-12.86]
Fall from height	38 (73.1)	37 (74.0)		1.01 [0.80-1.28]	0.92 [-16.2-18.04]
Motor vehicle accident	2 (3.8)	1 (2.0)		0.52 [0.05-5.56]	-1.85 [-8.36-4.66]
Other	0 (0.0)	2 (2.0)		-	3.48 [-1.38-9.07]
Concomitant fractures	10 (19.2)	17 (34.0)		1.77 [0.90-3.48]	14.77 [-2.18-31.71]
Ipsilat. lower extremity	3 (5.8)	2 (4.0)		0.69 [0.12-3.98]	-1.76 [-10.12-6.58]
Contralat. lower extremity	5 (9.6)	6 (12.0)		1.25 [0.41-3.83]	2.39 [-9.67-14.44]
Left-sided fracture	26 (50.0)	25 (50.0)		1.00 [0.68-1.47]	0.00 [-19.41-19.41]
Open fracture	1 (2.0)	2 (4.1)		2.08 [0.20-22.23]	2.12 [-4.60-8.84]
Sanders fracture type				1.08 [0.79-1.48]	2.21 [-3.25-7.66]
I	1 (1.9)	2 (4.0)		2.08 [0.19-22.22]	2.08 [-4.51-8.67]
II	18 (34.6)	18 (36.0)		1.04 [0.61-1.76]	1.39 [-17.17-19.94]
III	24 (46.2)	23 (46.0)		1.00 [0.65-1.52]	-0.15 [-19.50-19.20]
IV	9 (17.3)	7 (6.9)		1.34 [0.54-3.32]	4.54 [-9.58-18.66]

SD: standard deviation; CVD: cardiovascular disease; CI: confidence interval

Of the 102 subjects, 50 were randomized to availability of the 3D scan; 52 subjects were operated with conventional 2D fluoroscopy alone. In 3 subjects allocated in the 3D group, the 3D system was not available due to a technical error. In the remaining 47 subjects, a total of 57 additional corrections were performed in 28 subjects (56.0% of subjects in 3D group). Of these corrections, the majority (91.2%) aimed to enhance implant position: 48 screws were considered too long (84.2% of all corrections), one (1.8%) too short, and three (5.3%) were reinserted under a different angle. Further fracture reduction was performed in five (8.8%) subjects. Details are depicted in Table 2. In the 3D group, in seven subjects indications for corrections were identified but not performed: reasons are specified in Table 2.

Table 2. Operation characteristics, intra-operative imaging, corrections and postoperative radiologic outcome

	Characteristic	2D group N (%)	3D Group N (%)	Risk Ratio [95% CI]	Risk Difference [95% CI]	P
	Days to surgery, median (range)	18 (2-60)	18 (4-72)			0.43
	Duration of surgery (min), median (range)	125 (69-219)	147 (76-507)			**0.00**
	Radiation dose, median (range)					
	mGy-cm^2	570 (286-1290)	726 (304-2110)			**0.04**
	Time (s)	100 (28-260)	105 (50-274)			0.28
INTRAOPERATIVE	Number of 3D scans					
	1	-	20 (40.8)			
	2	-	24 (49.0)			
	3	-	4 (8.2)			
	No. of corrections after 3D	-				
	0	-	21 (42.9)			
	1	-	14 (28.6)			
	2	-	5 (10.2)			
	3	-	4 (8.2)			
	4	-	4 (8.2)			
	5	-	1 (2.0)			
	Total		**57**			
	Type of corrections after 3D					
	Gap		2 (3.5)			
	Bone fragment	-	2 (5.3)			
	Other	-	1 (1.8)			
	Total Reduction		**5 (8.8)**			
	Screw too long	-	48 (84.2)			
	Screw too short	-	1 (1.8)			
	Screw direction/position	-	3 (5.3)			
	Total implant position		**52 (91.2)**			
	Not performed, due to					
	Inadequate bone quality		1			
	Screw length not in stock		1			
	Reason unspecified		5			
	Total not performed		**7 (15.2)**			
POSTOPERATIVE	Radiological outcome **(*3D*)**					
	Inadequate reduction	3 (6.4)	3 (6.5)	1.02 [0.22-4.80]	0.14 [-9.85-10.13]	
	Inadequate implant position	6 (12.8)	13 (27.7)	2.17 [0.90-5.22]	14.89 [-1.06-30.85]	
	Total inadequate ORIF	**8 (17.0)**	**15 (31.9)**	**1.88 [0.88-4.00]**	**14.89 [-2.22-32.01]**	
	Radiological outcome ***(CT)***					
	Inadequate reduction	8 (15.7)	11 (22.9)	1.46 [0.64-3.32]	7.23 [-8.29-22.75]	
	Inadequate implant position	14 (26.9)	12 (24.5)	0.91 [0.47-1.77]	-2.43 [-19.47-14.60]	
	Total inadequate ORIF	16 (32.0)	19 (40.4)	1.26 [0.74-2.15]	8.43 [-10.65-37.04]	
	Revision required	**31 (59.6)**	**34 (69.4)**	**1.16 [0.87-1.56]**	**9.77 [-8.78-28.33]**	

There was a statistically significant difference in duration of surgery between the groups with a median of 147 minutes (3D group) versus 125 minutes (2D group). There was one outlier in the 3D group with 507 minutes due to operative treatment of concomitant fractures in other extremities.

After *postoperative* evaluation of the 3D scans, the three independent raters agreed on persisting indications for revision of reduction and/or implant position in 31.9% of subjects in the 3D group versus 17.0% in the 2D group. Figure 2 shows two examples of intraoperative 3D- and corresponding postoperative CT images.

After evaluation of the postoperative CT scans, raters agreed on individual indications for revision of reduction and/or implant position in 40.4% (3D group) versus 32.0% (2D group).

The primary outcome, the cumulative verdict whether the subject required revision surgery based on the postoperative CT scan, scored 69.4% (3D group) versus 59.6% (2D group). The corresponding risk ratio of 1.16 (95% CI 0.87-1.56) did not reach statistical significance.

Patient outcomes are shown in Table 3. There were no significant differences between groups in terms of revision surgery, complications, wound infections, posttraumatic osteoarthritis or short-term rate of arthrodesis. Additionally, patient reported outcome measures including AOFAS, FAOS and SF-36 showed no significant differences between the groups.

Additional subgroup regression analysis showed no association for superior 50% AOFAS score at 2 years postoperatively and age, fracture type, open fractures, infections, availability of 3D fluoroscopy or duration of operation (Table 4a). Also, we found no association for these factors with arthrodesis at 2 years postoperatively (Table 4b).

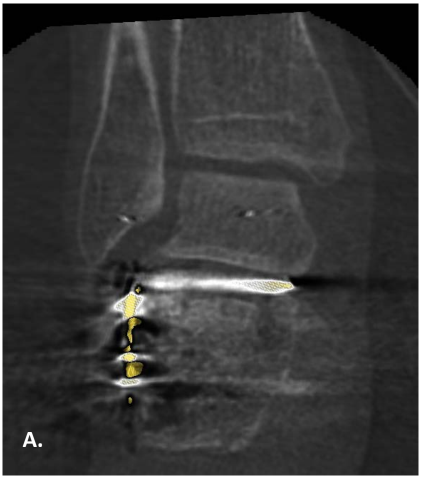
Table 3. Patient outcomes

Characteristic		2D group N (%)	3D group N (%)	Risk Ratio [95% CI]	Risk Difference [95% CI]	P
Revision surgery (within 1 year)						
	Infection	6 (11.5)	3 (6.0)	0.52 [0.14-1.97]	-5.54 [-16.43-5.36]	
	Reduction	1 (1.9)	1 (2.0)	1.04 [0.07-16.18]	0.08 [-5.31-5.46]	
	Implant removal (planned)	0 (0.0)	1 (2.0)	X	2 [-1.88-5.88]	
	Implant removal (infection)	4 (7.7)	2 (4.0)	0.52 [0.10-2.71]	-3.69 [-12.74-5.36]	
	Implant removal (complaints)	8 (15.4)	6 (12.0)	0.78 [0.29-2.09]	-3.39 [-16.70-9.93]	
	Arthrodesis	1 (1.9)	2 (4.0)	2.08 [0.19-22.22]	2.08 [-4.51-8.67]	
Infection (within 1 year)						
	Superficial without antibiotics	0 (0.0)	2 (4.0)	X	4 [-1.43-9.43]	
	Superficial with antibiotics	4 (7.7)	1 (2.0)	0.26 [0.03-2.25]	-5.69 [-13.91-2.52]	
	Deep with debridement	7 (13.5)	4 (8.0)	0.59 [0.19-1.91]	-5.46 [-17.40-6.48]	
	Deep with hardware removal	3 (5.8)	4 (8.0)	1.39 [0.33-5.89]	2.23 [-7.60-12.06]	
	Total infections	**14 (26.9)**	**11 (22.0)**	**0.82 [0.41-1.63]**	**-4.92 [-21.57-11.72]**	
OTHER COMPLICATIONS	*Wound dehiscence*					
	6 wks FU	11 (21.2)	4 (8.0)	0.76 [0.33-1.72]	-5.15 [-20.20-9.89]	
	12 wks FU	7 (13.5)	5 (10.0)	0.74 [0.25-2.19]	-3.46 [-15.92-9.00]	
	1 yr FU	7 (13.5)	5 (10.0)	0.74 [0.25-2.19]	-3.46 [-15.92-9.00]	
	Neurologic					
	6 wks FU	3 (5.8)	2 (4.00)	0.69 [0.12-3.98]	-1.77 [-10.12-6.58]	
	12 wks FU	3 (5.8)	3 (6.0)	1.04 [0.22-4.91]	0.23 [-8.91-9.37]	
	1 yr FU	1 (1.9)	2 (4.0)	2.08 [0.19-22.22]	2.08 [-4.51-8.67]	
	Thrombo-embolic	None reported				
	CRPS	None reported				
	Compartment syndrome	None reported				
	Bleeding	0 (0.0)	1 (2.0)	X	2 [-1.88-5.88]	
Osteoarthritis (at 2 years, KLGS)						
	0	2 (3.8)	1 (2.0)	0.53 [0.05-5.57]	-2.49 [-11.39-6.42]	
	1	7 (13.5)	10 (20.0)	1.51 [0.64-3.53]	9.36 [-9.77-28.49]	
	2	12 (23.1)	8 (16.0)	0.70 [0.33-1.52]	-9.36 [-29.43-0.71]	
	3	12 (23.1)	10 (20.0)	0.88 [0.43-1.78]	-3.80 [-24.6-16.99]	
	4	5 (9.6)	7 (14.0)	1.48 [0.52-4.24]	6.29 [-10.52-23.1]	
Arthrodesis (within 2 years)		1 (2.0)	5 (10.2)	5 [0.61-41.2]	8.16 [-1.19-17.5]	
Because of	Pain	1	3			
	Persisting infection	0	1			
	Malunion	0	1			
ROM, median (range)						
	Dorsi/plantar flexion					
	12 wk FU	47.5 (20-90)	45.0 (20-80)			0.12
	1 yr FU	50.0 (30-80)	55.0 (20-80)			0.44
	2 yr FU	50.0 (30-90)	55.0 (20-80			0.43
	In/Eversion					
	12 wk FU	25.0 (5-80)	30.0 (0-65)			0.82
	1 yr FU	15.0 (0-50)	20.0 (0-60)			0.80
	2 yr FU	7.5 (0-60)	10.0 (0-40)			0.48

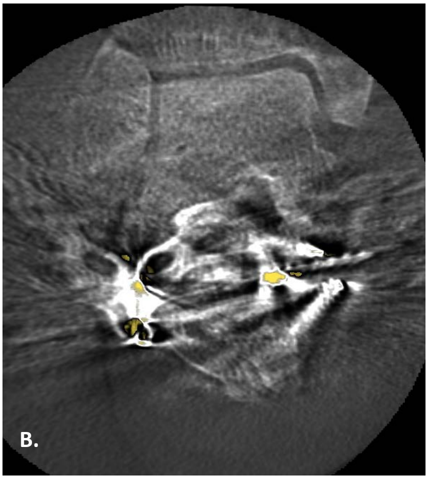
AOFAS, median (range)				
	12 wk FU	76.0 (53-96)	71.0 (53-97)	0.15
	1yr FU	80.5 (54-97)	78.0 (38-97)	0.19
	2 yr FU	82.0 (46-100)	80.0 (26-100)	0.51
FAOS, median (range)				
Symp	12 wk FU	53.6 (21-86)	53.6 (32-96)	0.83
	1yr FU	57.1 (18-82)	55.4 (29-82)	0.75
	2 yr FU	57.1 (29-86)	53.6 (29-79)	0.51
Pain	12 wk FU	63.9 (28-100	63.9 (25-100)	0.41
	1yr FU	65.3 (3-100)	69.4 (39-100)	0.37
	2 yr FU	75.0 (6-100)	75.0 (28-100)	0.82
ADL	12 wk FU	68.4 (22-97)	67.6 (15-94)	0.69
	1yr FU	82.4 (19-100)	79.4 (32-100)	0.94
	2 yr FU	92.7 (15-100)	86.8 (32-100)	0.50
Sport/ Rec	12 wk FU	20.0 (0-100)	15.0 (0-100)	0.85
	1yr FU	40.0 (0-100)	45.0 (0-100)	0.90
	2 yr FU	65.0 (0-100)	70.0 (0-100)	0.50
QoL	12 wk FU	31.3 (0-10	25.0 (0-75)	0.29
	1yr FU	56.3 (6-100)	43.8 (0-94)	0.34
	2 yr FU	56.3 (0-94)	86.8 (32-100)	0.88
SF-36, median (range)				
PCS	12 wk FU	36.2 (22-53)	32.6 (20-57)	0.17
	1yr FU	43.1 (23-59)	41.9 (27-59)	0.96
	2 yr FU	48.6 (29-61)	45.2 (27-61)	0.43
MCS	12 wk FU	47.3 (23-59)	52.3 (27-68)	0.29
	1yr FU	56.5 (28-65)	41.9 (27-59)	0.17
	2 yr FU	50.9 (20-60)	52.6 (26-61)	0.71

KLGS: Kellgren & Lawrence Grading Scale; CRPS: Complex Regional Pain Syndrome; ROM: Range of Motion; PCS: Physical Component Scale; MCS: Mental Component Scale.

Figure 2. Two examples of intraoperative 3D- and corresponding postoperative CT images.



Intraoperative 3D fluoroscopy



Intraoperative 3D fluoroscopy

Postoperative CT scan

Postoperative CT scan

2a. This subject was randomized in the c**onventional 2D fluoroscopy** group. The postoperative CT scan clearly showed an unacceptable reduction of the posterior talocalcaneal (PTC) joint and an intra-articular screw position; both findings were also recognized on the postoperative evaluation of the 3D fluoroscopy. Patient underwent revision surgery within 24h and suffered from a superficial wound infection.

2b. This subject was randomized to the **3D fluoroscopy group**. The 3D images however show substantial scattering, impeding proper evaluation of the images. The postoperative CT scan showed a medially protruding screw that missed the sustentaculum.

Table 4a. Odds ratios for superior 50% AOFAS score at 2 years postoperatively

		Univariable OR [95% CI]	P	Multivariable OR [95% CI]	P
Age		0.98 [0.93-1.02]	0.33	0.98 [0.93-1.04]	0.56
Sanders			0.98		0.84
	I	No subjects in group		No subjects in group	
	II	1.13 [0.18-7.24]		2.50 [0.25-24.55]	
	III	0.87 [0.15-5.06]		1.58 [0.18-14.16]	
	IV	Equal in groups		Equal in groups	
Open fracture yes/no		No patients in group	1.00	-	-
Infection			0.14		0.14
	Superficial	1.43 [0.12-17.23]		0.46 [0.02-9.51]	
	Deep	0.24 [0.06-1.03]		0.20 [0.04-0.99]	
3D-availability		0.54 [0.18-1.62]	0.27	0.58 [0.14-2.43]	0.46
OR-time (min)		1.00 [0.98-1.01]	0.29	1.00 [0.98-1.01]	0.41

OR: Odds Ratio; Sanders: fracture type according to Sanders classification

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Table 4b. Odds ratios for arthrodesis at 2 years postoperatively

		Univariable OR [95% CI]	P	Multivariable OR [95% CI]	P
Age		1.01 [0.95-1.07]	0.82	1.03 [0.94-1.14]	0.51
Sanders			0.24		0.27
	II	0,13 [0.01-1.34]		0.07 [0.02-1.80]	
	III	0.20 [0.03-1.34]		0.06 [0.00-1.14]	
Open fracture yes/no		8.90 [0.69-115.58]	0.10	0.83 [0.00-449.06]	0.95
Infection			0.11		0.25
	Superficial	5.75 [0.45-73.00]		6.67 [0.18-250.15]	
	Deep	6.90 [1.06-44.96]		8.91 [0.60-132.44]	
3D-availability		6.07 [0.68-54.01]	0.11	11.39 [0.76-171.44]	0.08
OR-time (min)		1.00 [0.97-1.02]	0.75	0.99 [0.96-1.03]	0.56

OR: Odds Ratio; Sanders: fracture type according to Sanders classification

DISCUSSION

Despite 57 intraoperative corrections in 28 subjects (56% of the 3D group), the current study did not find a beneficial effect of intraoperative 3D fluoroscopy in terms of radiological, patient reported or functional outcome as compared to conventional 2D fluoroscopy. Moreover, there was a statistically significant increase in length of the operative procedure in the 3D group.

To our knowledge, this is the first randomized controlled trial reporting the functional results of patients in which additional 3D fluoroscopy was compared to conventional fluoroscopy in the treatment of calcaneal fractures. In 2015, Gwak et al. published a retrospective cohort study of 60 calcaneal fractures, half of which were treated with additional 3D fluoroscopy. In accordance with our results, they found no statistically significant differences between groups in terms of Böhlers angle, Gissanes angle, AOFAS or VAS pain score after 2 years postoperatively[18].

Most other available studies reporting on 3D fluoroscopy lack a control group or put emphasis on the number of intraoperative 3D related corrections rather than reporting functional or radiological outcomes[3,10,17,23]. In 2015, Eckhardt et al. published on a series of 62 calcaneal fractures operated on using intraoperative 3D imaging[23]. They used an O-arm with high quality imaging, leading to 40% corrections and good radiological results on the final intraoperative 3D scan. No postoperative CT scan was made as a gold standard, they did not have a control group with conventional fluoroscopy, nor did they report functional outcome.

In 2014, Franke et al. published a large retrospective cohort of operatively treated calcaneal fractures using 3D fluoroscopy and showed an intraoperative correction rate of 40.3%[3]. Of the evaluated group, 45% still had residual step-off of ≥2mm on the postoperative evaluation of the 3D scan. No control group was mentioned in terms of 2D fluoroscopy.

Our results show considerable percentages of indications for revision based on the postoperative CT-scan. Multiple factors potentially contribute to these high revision rates. First, we evaluated 23 items of reduction and fixation per subject. When scoring to such an extensive degree instead of solely focusing on e.g. the joint surface, it is more likely to find indications for improvement. Second, despite the Titanview® software, it was often difficult to interpret the images due to the amount of scattering caused by the implants. Third and most important, the evaluation of our CT images was done outside of the operation theater. Consequently, raters were not hampered by the reality of operative challenges, creating a lower threshold for seeing indications for improvement.

In addition to high revision rates, Table 2 shows a discrepancy between individual indications for revision *per item* (3D: 40.4% vs. 2D: 32.0%) and the primary outcome: the definitive verdict on indication for revision *per subject* (3D: 69.4% vs. 2D: 59.6%). This is likely caused by the fact that the latter is a cumulative score: the 30 additional subjects (15 from both groups) that did not show non-acceptable items but were in need for revision had an average of 6 items scored as *suboptimal*, hence the raters' conclusive judgment to suggest revision.

Despite the high percentage of indicated revisions, functional results of our cohort are comparable to the literature. In 2009, Kienast et al. used 3D fluoroscopy in a series of 136 operatively treated calcaneal fractures[17]. At an average follow up of 8.6 months the average AOFAS scored between 81 and 84. The previously mentioned study by Gwak et al. reported average AOFAS scores between 78.3 and 82.3 after two year follow up[18]. The minimal clinically important difference (or MCID) of the AOFAS following calcaneal fracture surgery is not known, but for hallux valgus surgery it is 7.9 points which we did not meet[24]. SF-36 scores are comparable to other large RCT's[8,9]. Infection rates vary in the literature. In our study, 24.5% of subjects had an infection, which is considerable but also seen in other studies[8,9,23].

Strength of this study is that we were able to evaluate clinical effectiveness of this technique by comparison of an intervention (3D) and a control group (2D). We did not only obtain validated functional outcome parameters, but also systemically evaluated reduction and hardware position on CT using a detailed protocol. Instead of exact measurements that are mostly performed in research settings, we have used subjective evaluations (e.g. good, moderate or poor). This approach mimics intraoperative evaluation. During surgery no measurements (e.g. Böhlers angle measurement) can be performed: the surgeon can only eyeball the quality of reduction and fixation, based on his experience with the acceptable measurements. Moreover, subjective (categorical) and objective (numerical values) evaluations have previously proven to have a good correlation[25].

Limitations of this study include that as the project progressed, surgeons got more accustomed to the use of 3D fluoroscopy techniques. Inspired by the benefits of multiple angle views, surgeons sporadically used continuous fluoroscopy whilst turning the foot manually. While this provided additional information, we did not prohibit this, potentially leading to more radiation exposure and more corrections in the 2D group.

This study was designed with analysis of the diagnostic accuracy of 3D fluoroscopy in mind. For this purpose, both randomization groups were subject to 3D fluoroscopy. As the radiation dose of a single 3D scan is different for each individual subject, we were not able to correct for the received 3D scan in the 2D group. Hence, the additional radiation dose in the 3D group as mentioned in Table 2 is a consequence of fluoroscopy (2D or 3D) used *after* the initial 3D scan. The radiation exposure was given as dose area product (DAP) in mGy*cm^2: we chose to refrain from estimating effective dose (mSv) because of its doubtful reliability[26,27]. Rausch et al. reported a mean DAP of 392 ± 145 mGy/cm^2 for 3D fluoroscopy in a series of operatively treated wrist fractures[28]. Our 3D group received a median of 726 mGy/cm^2. The bigger mass of the lower extremity is accountable for a large part of this difference in radiation dose.

With high percentages of intraoperative corrections, it is likely that 3D fluoroscopy has some form of advantage. Future studies should further elucidate and specify these advantages, potentially by narrowing down the indications for use of this technique. Calcaneal fractures that are particularly at risk for medial or intra-articular screw protrusion might profit more from 3D fluoroscopy than fractures that need less complex fixation.

CONCLUSION

The use of intraoperative 3D fluoroscopy prolongs the procedure without improving the quality of reduction and fixation in the management of calcaneal fractures. We did not find a benefit of intraoperative 3D fluoroscopy with regard to postoperative complications, quality of life, functional outcome or post-traumatic osteoarthritis at 2-year follow-up.

Competing interests:
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PART III: POSTOPERATIVE EVALUATION

7

SYSTEMATIC CT EVALUATION OF REDUCTION AND HARDWARE POSITIONING OF SURGICALLY TREATED CALCANEAL FRACTURES: A RELIABILITY ANALYSIS

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ABSTRACT

Introduction:

Up to date, there is a lack of reliable protocols that systematically evaluate the quality of reduction and hardware positioning of surgically treated calcaneal fractures. Based on international consensus, we previously introduced a 23-item scoring protocol evaluating the reduction and hardware positioning in these fractures based on postoperative computed tomography. The current study is a reliability analysis of the described scoring protocol.

Methods:

Three raters independently and systematically evaluated anonymized postoperative CT scans of 102 surgically treated calcaneal fractures. A selection of 25 patients was scored twice by all individual raters to calculate intra-rater reliability. The scoring protocol consisted of 23 items addressing quality of reduction and hardware positioning. Each of these four-option questions was answered as: 'optimal', 'suboptimal (but not needing revision)', 'not-acceptable (needing revision)' or 'not judgeable'. We used intraclass correlation coefficients (ICC's) to calculate inter-and intra-rater reliability.

Results:

Inter-rater reliability of the overall 23-item protocol was good (ICC 0.66, 95% CI 0.64-0.69). Individual items that scored an inter-rater ICC ≥ 0.60 included evaluation of the calcaneocuboid (CC) joint, the posterior talocalcaneal (PTC) joint, the anterior talocalcaneal (ATC) joint, the position of the plate and sustentaculum screws and screws protruding the tuber and medial wall. The intra-rater reliability for the overall protocol was good for all 3 individual raters with ICC's between 0.60 and 0.70.

Conclusion:

Our scoring protocol for the radiological evaluation of operatively treated calcaneal fractures is reliable in terms of inter- and intra-rater reliability.

INTRODUCTION

The main goal of surgical treatment of calcaneal fractures is to restore the anatomy, as intra-articular incongruences are associated with posttraumatic osteoarthritis of the subtalar joint and poor clinical outcomes.[1–3] To adequately restore the anatomy, different surgical techniques have been proposed.[4] In order to compare the radiological results of these techniques, a blinded, independent radiological assessment with a fixed set of reliable criteria should be standard.

Unfortunately, there is lack of a validated scoring protocol on the qualitative assessment of calcaneal fracture reduction and hardware positioning.[5–10] As evaluation of plain radiography seems insufficient[11], different computed tomography (CT) based measurements have been proposed.[12,13] Individual studies use different thresholds to specify acceptability of angles or intra-articular congruity.[8,11,13–16] Additionally, reliability of these measurements is only seldom reported.

A recently published international Delphi consensus on how to evaluate postoperative results of surgically treated calcaneal fractures showed that in addition to the quality of reduction, the quality of hardware positioning also requires evaluation.[17] Additionally, it showed that measurements were performed scarcely in clinical practice; evaluation of both reduction and hardware positioning is mostly performed by expert opinion.

Based on this international consensus, a fixed set of criteria for the assessment of the quality of fracture reduction and hardware positioning of the calcaneus has been composed. The aim of the current study was to determine the inter- and intra-rater reliability of this radiological scoring protocol.

METHODS

To determine the inter- and intra-rater reliability of the scoring protocol, we used postoperative CT scans of 100 patients with 102 surgically treated calcaneal fractures. These patients had been enrolled in the EF3X-trial, a multicenter randomized clinical trial exploring the clinical value of additional 3D fluoroscopic imaging in the treatment of calcaneal fractures.[18]

Postoperative CT-scans were anonymized and systematically evaluated with use of the scoring protocol by three independent raters (an experienced foot- and ankle surgeon [TS], a radiologist with specialty in musculoskeletal trauma [LFB], and a surgical trainee in orthopaedic surgery and PhD candidate with 4 years of research experience in calcaneal fractures [RJDMK]). No three-dimensional CT reconstructions were available.

The scoring protocol used was developed after Delphi consensus between 18 international experts in the field (both surgeons and radiologists) and previously published in this journal.[17] The protocol consists of 23 items addressing postoperative reduction and hardware positioning of the most important anatomical landmarks of the calcaneus (Appendix 1). Each of these multiple-choice questions was answered as: 'optimal', 'suboptimal (but acceptable)', 'not-acceptable (revision required)' or 'not judgeable'. In case of gaps and steps a threshold of 2 mm was held for acceptability.[19] After scoring 23 items separately, a concluding dichotomous question was answered about whether any of the findings required correction (i.e. Yes or No). Statistical analyses were performed with SPSS (IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY).

Inter-rater Reliability

We used a two-way random, average measures, absolute agreement intraclass correlation coefficient (ICC) to determine the degree of agreement amongst raters, including its 95% confidence interval (CI). As we used a fully crossed design (all subjects were rated by all raters) we chose a two-way model.[20] As we intended to generalize the results to a larger population of clinicians, we chose a random effects model.[21] A good inter-rater reliability (IRR) was characterized by absolute agreement and not by consistency in the ratings. Concerning interpretation, we expect the protocol to be used in a clinical research environment were postoperative results are scored by more than one rater. Consequently, we primarily calculated the average-measures ICC. We used cut-offs as provided by Cicchetti et al., with reliability being 'poor' for ICC values less than 0.40, 'fair' for values between 0.40 and 0.59, 'good' for values between 0.60 and 0.74, and 'excellent' for values between 0.75 and 1.0.[22] An ICC ≥ 0.60 was set as minimally acceptable level of agreement.[22]

Intra-rater reliability

After a minimum of 30 days of scoring, raters were asked to again evaluate a selected subset of 25 CT scans that they had seen before but had been given a new study ID. These cases were selected to represent the full range of postoperative results. Scoring results of both sessions were combined in a database per rater to analyze the degree of agreement within the observations (i.e. intra-rater reliability). In contrast to the inter-rater reliability, we used a two-way *mixed*, absolute agreement, *single measures* ICC as we wanted to determine the degree of agreement with the raters own ratings and do not intend to extrapolate this to a different rater [21]. As for the inter-rater reliability, a good reliability was characterized by absolute agreement and not by consistency in the ratings. Again, cut-offs were used as provided by Cicchetti et al.[22]

RESULTS

The inter-rater reliability of the overall 23-item protocol was good: ICC of 0.66 (95% CI 0.64-0.69) (Table 1). Individual items that scored an inter-rater ICC ≥0.60 included the calcaneocuboid (CC) joint (symmetry/width, intra-articular steps, gaps and screws), the posterior talocalcaneal (PTC) joint (symmetry/width, intra-articular steps, gaps and screws), the anterior talocalcaneal (ATC) joint (intra-articular screws), the position of the plate and the sustentaculum screws and screws protruding the tuber and medial wall. Items that did not score acceptable inter-rater agreement (ICC <0.60) included Böhler's and Gissane's angles, length of the calcaneus and varus/valgus position of the tuber, intra-articular fragments in CC, PTC or ATC joints, intra-articular gaps and step offs in the ATC and the positioning of anterior process screws. When only the items that scored an acceptable ICC (≥0.60) were combined, the protocol scored 14 items (Table 1, marked grey) and had an excellent overall inter-rater reliability with an ICC of 0.77.

The intra-rater reliability for the overall protocol was good for all 3 individual raters with ICC's between 0.60 and 0.70. Individual raters scored acceptable ICC's for an average of 11 items. Items that scored an ICC ≥ 0.60 for all three raters included steps and gaps in the PTC joint and presence of intra-articular screws in the ATC joint. Items that did not score acceptable ICC's with any of the raters included length of the calcaneus, intra-articular fragments and screws in the CC joint, fragments in the PTC joint and gaps in the ATC joint.

Table 1. Inter- and intra-rater reliability per item

		INTER-rater ICC (95% CI)	INTRA-rater ICC (95% CI) Rater 1	ICC (95% CI) Rater 2	ICC (95% CI) Rater 3
Böhlers angle		0.49 (0.19-0.67)	**0.62** (0.31-0.81)	0.47 (0.09-0.73)	**0.72** (0.47-0.87)
Gissanes angle		0.36 (0.13-0.55)	0.53 (0.19-0.76)	0.52 (0.16-0.76)	**0.62** (0.29-0.81)
Length of the calcaneus		0.11 (-0.11-0.32)	0.00 (-0.39-0.389)	0.57 (0.22-0.78)	0.30 (-0.10-0.61)
Varus/varus of the tuber		0.21 (-0.09-0.44)	0.00 (-0.33-0.36)	**0.73** (0.48-0.87)	0.17 (-0.23-0.52)
CC joint	**Symmetry/width**	**0.75** (0.65-0.82)	0.37 (-0.01-0.66)	**0.73** (0.48-0.87)	**0.73** (0.48-0.87)
	Intra-articular steps	**0.75** (0.65-0.83)	0.49 (0.12-0.74)	0.56 (0.24-0.78)	**0.72** (0.46-0.87)
	Intra-articular gaps	**0.63** (0.48-0.74)	**0.65** (0.35-0.83)	0.45 (0.07-0.71)	**0.71** (0.45-0.86)
	Intra-articular fragments	0.25 (-0.31-0.34)	0.00 (-0.39-0.34)	0.47 (0.09-0.73)	Zero variance
	Intra-articular screws	**0.80** (0.73-0.86)	Zero variance	0.04 (-0.35-0.42)	0.00 (-0.39-0.39)
PTC joint	**Symmetry/width**	**0.73** (0.62-0.81)	**0.82** (0.64-0.92)	0.30 (-0.12-0.62)	0.51 (0.13-0.75)
	Intra-articular steps	**0.76** (0.67-0.83)	**0.86** (0.70-0.94)	**0.75** (0.52-0.88)	**0.61** (0.30-0.81)
	Intra-articular gaps	**0.74** (0.63-0.82)	**0.97** (0.93-0.99)	**0.66** (0.37-0.84)	**0.75** (0.52-0.88)
	Intra-articular fragments	0.46 (0.25-0.62)	0.01 (-0.40-0.40)	-0.04 (-0.44-0.36)	-0.02 (-0.41-0.37)
	Intra-articular screws	**0.80** (0.72-0.86)	0.43 (0.05-0.71)	**0.65** (0.35-0.83)	1.000
ATC joint	**Intra-articular steps**	0.38 (0.15-0.56)	**0.77** (0.54-0.89)	**0.65** (0.34-0.83)	0.51 (0.16-0.75)
	Intra-articular gaps	0.33 (0.09-0.52)	0.48 (0.10-0.73)	0.28 (-0.13-0.61)	0.18 (-0.23-0.54)
	Intra-articular fragments	0.41 (0.19-0.59)	1.00	**0.65** (0.35-0.83)	0.22 (-0.16-0.55)
	Intra-articular screws	**0.76** (0.66-0.84)	**0.60** (0.29-0.80)	**0.83** (0.65-0.92)	**0.81** (0.61-0.91)
Positioning of	**Plate**	**0.74** (0.63-0.81)	0.48 (0.13-0.73)	**0.92** (0.82-0.96)	**0.64** (0.33-0.82)
	Sustentaculum screws	**0.64** (0.50-0.75)	0.51 (0.16-0.75)	0.49 (0.14-0.74)	0.47 (0.11-0.73)
	Anterior Process screws	0.26 (-0.02-0.47)	0.30 (-0.11-0.62)	0.42 (0.05-0.70)	**0.64** (0.32-0.82)
Screws protruding	**Medial wall**	**0.70** (0.58-0.79)	0.34 (-0.06-0.64)	0.42 (0.03-0.70)	**0.93** (0.84-0.97)
	Tuberosity	**0.68** (0.55-0.77)	0.18 (-0.24-0.54)	**0.68** (0.40-0.85)	**0.89** (0.76-0.95)
REVISION INDICATED		**0.62** (0.46-0.73)	**0.61** (0.29-0.80)	0.58 (0.25-0.79)	**0.71** (0.46-0.86)
OVERALL		**0.66** (0.64-0.69)	**0.60** (0.55-.0.65)	**0.62** (0.56-0.66)	**0.70** (0.66-.74)
OVERALL (grey items with ICC ≥0.60 combined)		**0.77** (0.74-0.79)	-	-	-

DISCUSSION

Our scoring protocol assessed quality of both reduction and hardware positioning and showed a good inter-rater reliability based on 300+ observations, suggesting sufficient reliability for use in clinical and research settings. It can aid future studies in the structural comparison of treatment results in the field of operatively treated calcaneal fractures, where there is currently no practicable alternative.

Calcaneal fractures are often complex and classification systems typically show poor to moderate inter-rater reliability.[23] Scoring protocols on the postoperative evaluation of these fractures are numerous, but often do not mention data on reliability or only focus on (parts of) fracture reduction.

In 2003, Gupta et al. used pre- and postoperative CT scans to measure 7 displacement parameters in 32 calcaneal fractures. Measurements were done by a single rater without providing intra-rater reliability.[12] Sahota et al. focused on the postoperative alignment of the posterior facet.[24] They reported excellent inter-rater reliability between 3 independent raters by comparing 10 postoperative CT scans. Kurozumi et al. evaluated parameters of calcaneal deformity by comparing postoperative CT images of both the injured and healthy contralateral side.[13] They found better reduction of the posterior facet and better reduction of the calcaneocuboid joint to be prognostic factors of functional outcome, but did not provide data on reliability of their measurements. In 2010, Magnan et al. performed postoperative CT analysis of 54 patients with calcaneal fractures using the Score Analysis of Verona (SAVE).[4,25] The SAVE scoring system was specifically designed for CT evaluation of calcaneal fractures and describes five displacement parameters.[4,25] After a mean follow up of 49 months, parts of the score showed statistical correlation with the clinical outcome as judged by the Maryland Foot Score: better clinical outcomes showed a significant association with vertical/longitudinal realignment and restoration of the calcaneal height.[25] Despite its correlation with clinical outcome, data on the reliability of the SAVE scoring system is currently unavailable. Lastly, in 2014, Sanders et al. described a long term follow up of 108 surgically treated patients with his well-known Sanders classification.[26] In addition to his traditional fracture classification[27], he added measurements of posterior facet congruity, dividing the extent of anatomic reduction in 4 categories. They confirmed that after 10-20 years of follow up, the classification was still prognostic for outcome, as worsening outcome occurred with higher Sanders fracture types. However, included patients only had one of two types (Sanders II vs Sanders III). No data on reliability were published.

Although all abovementioned scoring systems were specifically designed for post-operative evaluation, none of them assessed hardware positioning such as presence of intra-articular or medially protruding screws.

We have chosen to base this scoring protocol on CT imaging as it is currently the golden standard with respect to visualization of intra-articular gaps, step-offs and hardware positioning.[13] Nonetheless, despite its qualities, some measurements might be poorly visible on CT imaging. Böhler's and Gissane's angle measurements were originally designed for lateral radiographs. We hypothesized that estimation of these angles could be done by scrolling through the sagittal reconstructions of the CT scan. Also, as mentioned by Kurozumi et al., Böhler's angle comprises multiple factors: anterior lateral wall, PTC, and tuber displacement: all of which are evaluated separately with CT imaging.[13] Still, in line with the existing literature, we did not produce high reliability of Böhler's and Gissane's angle measurements on CT.[23,28]

The posterior talocalcaneal (PTC) is widely regarded as having the largest impact on post-operative complaints.[29–32] In contrast to measurements of Böhler's angle, measurements of the PTC joint scored good agreement on 4 out of 5 items. The presence or absence of intra-articular bone fragments scored only fair agreement, possibly due to disagreement with regard to the posterior limits of the PTC joint.

On a statistical note, reliability analyses are frequently reported by the percentage that raters agree in their ratings, often referred to as percentage agreement. However, this measure systematically overestimates the level of agreement by not correcting for agreement that would be expected by chance alone.[20] The intraclass correlation or ICC is a measure that is suitable for ordinal, interval and ratio variables. It incorporates the magnitude of disagreement as does a weighted kappa, but has the advantage that it can handle more than two raters.[33]

To accurately calculate inter-rater reliability, sufficient variance in the observed cohort is indispensable. For instance, very low prevalence of intra-articular screws in the CC joint can cause a low ICC. The low variance for this item is expressed by a broad range of the 95% confidence interval, suggesting a low representability of the ICC.

Some items have a high inter-rater (>0.6) but a low (<0.6) intra-rater reliability within individual raters. Raters can agree with each other at a certain moment, but not with themselves the next. This variability is inherent to classification systems, and in our case, does not hamper the good overall reliability of the scoring protocol.

Instead of exact measurements that are mostly performed in research settings, we have used subjective evaluations (e.g. good, moderate of poor). Subjective evaluation dismisses the need for tedious measurements, thereby allowing for a broader, more extensive evaluation without extending the burden of the task. Also, subjective (categorical) and objective (numerical values) evaluations have previously proven to have a good correlation.[34] Moreover, during surgery no measurements can be performed and all the surgeon can do is estimate the quality of reduction and fixation, based on his experience with the acceptable angle measurements and distances.

This is also where a potential underestimation of the inter-rater reliability comes in: we used raters with sufficient expertise, but a different background. A radiologists' perspective is likely to be different to that of a foot and ankle surgeon, especially when asked for a subjective opinion; e.g. the term “acceptable” could have different meanings for the two based on (a lack of) surgical experience. Undoubtedly, inter-rater reliability suffers from this phenomenon and is expected to be higher when rating is performed solely by experienced foot and ankle surgeons.

In the original study published in this journal we concluded that more items required evaluation than traditionally used in scoring protocols.[17] However, the current study shows that many of the 23 items scored do not show sufficient inter-rater reliability. If we would design a protocol by using only the items that scored an inter-rater reliability of 0.6 or higher, this protocol would evaluate 14 items and have an excellent reliability with an ICC of 0.77. This would, however, discard the previously mentioned consensus and potentially ignore items with high predictive value of functional outcome. Future studies should focus on identifying which items indeed correlate with functional outcome to help optimize the reliability and usability of the current protocol.

CONCLUSION

In conclusion, the results of the present study show that our previously developed scoring protocol for the radiological evaluation of operatively treated calcaneal fractures is reliable in regard to inter- and intra-rater reliability. The scoring protocol can be used in future clinical research settings that focus on the radiological comparison of operatively treated fractures of the calcaneus.

Appendix 1. The scoring protocol as based on international Delphi consensus

Reduction	1. Böhler's angle	Anatomical	Not anatomical, but acceptable	Not anatomical, not acceptable	Not judgeable
	2. Gissane's angle				
	3. Length of the calcaneus	Anatomical	Shortened, but acceptable	Shortened, not acceptable	Not judgeable
	4. Varus/valgus position of the tuber	Anatomical	Not anatomical, but acceptable	Not anatomical, not acceptable	Not judgeable
CC	5. Symmetry/width of the CC-joint				
	6. Presence of steps in CC-joint	No	≤ 2 mm (acceptable)	> 2 mm (not acceptable)	Not judgeable
	7. Presence of gaps in CC-joint				
	8. Presence of bone fragments in CC-joint				
	9. Intra-articular protrusion of screws/K-wires in the CC joint	No	Subchondral (acceptable)	Yes, not acceptable	Not judgeable
PTC	10. Symmetry/width pf PTC-joint space	Anatomical	Not anatomical, but acceptable	Not anatomical, not acceptable	Not judgeable
	11. Presence of steps in PTC-joint space	No	≤ 2 mm (acceptable)	> 2 mm (not acceptable)	Not judgeable
	12. Presence of gaps in PTC-joint space				
	13. Presence of bone fragments in PTC-joint space				
	14. Intra-articular protrusion of screws/K-wires in the PTC joint	No	Subchondral (acceptable)	Yes, not acceptable	Not judgeable
ATC	15. Presence of steps in ATC-joint space	No	≤ 2 mm (acceptable)	> 2 mm (not acceptable)	Not judgeable
	16. Presence of gaps in ATC-joint space				
	17. Presence of bone fragments in ATC-joint space				
	18. Intra-articular protrusion of screws/K-wires in the ATC joint	No	Subchondral (acceptable)	Yes, not acceptable	Not judgeable
Hardware	19. Position of fixation plate(s)	Good	Moderate	Poor	Not judgeable
	20. Grip of screws/K-wires in sustentaculum	Exactly right	Quite near	Not at all	Not judgeable
	21. Grip of screws in anterior process				
	22. Protrusion of screws/K-wires in the medial wall	No	Yes, but acceptable	Yes, not acceptable	Not judgeable
	23. Medial protrusion of screws / K-wires in the tuberosity				
	24. Based on the radiologic evaluation alone, do you think a revision in reduction or fixation is indicated	No		Yes	

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8

POST-TRAUMATIC SUBTALAR OSTEOARTHRITIS: WHICH GRADING SYSTEM SHOULD WE USE?

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ABSTRACT

Purpose:

To assess and compare post-traumatic osteoarthritis following intra-articular calcaneal fractures, one must have a reliable grading system that consistently grades the post-traumatic changes of the joint. A reliable grading system aids in the communication between treating physicians and improves the interpretation of research. To date, there is no consensus on what grading system to use in the evaluation of post-traumatic subtalar osteoarthritis. The objective of this study was to determine and compare the inter- and intra-rater reliability of two grading systems for post-traumatic subtalar osteoarthritis.

Methods:

Four observers evaluated 50 calcaneal fractures at least one year after trauma on conventional oblique lateral, internally and externally rotated views, and graded post-traumatic subtalar osteoarthritis using the Kellgren and Lawrence Grading Scale (KLGS) and the Paley Grading System (PGS). Inter- and intra-rater reliability were calculated and compared.

Results:

The inter-rater reliability showed an intra-class correlation (ICC) of 0.54 (95 % CI 0.40-0.67) for the KLGS and an ICC of 0.41 (95 % CI 0.26 – 0.57) for the PGS. This difference was not statistically significant. The intra-rater reliability showed a mean weighted kappa of 0.62 for both the KLGS and the PGS.

Conclusion:

There is no statistically significant difference in reliability between the Kellgren and Lawrence Grading System (KLGS) and the Paley Grading System (PGS). The PGS allows for an easy two-step approach making it easy for everyday clinical purposes. For research purposes however, the more detailed and widely used KLGS seems preferable.

INTRODUCTION

Displaced intra-articular calcaneal fractures are complex injuries which can lead to longstanding disability. These fractures are notorious for the development of symptomatic osteoarthritis (OA) of the subtalar joint due to post-traumatic intra-articular incongruency.[1–3] Although the calcaneus involves multiple joints, it is mostly the subtalar joint in which OA causes problems.[3]

The treatment of intra-articular calcaneal fractures remains subject to discussion.[4–8] In order to adequately assess and compare the different treatment options, one must have a reliable radiological grading system that consistently grades the post-traumatic changes of the joint. Up till now, it is unclear which radiological grading system is best for evaluating post-traumatic subtalar OA. To our knowledge, there is only one systematic review that evaluates the methods of grading foot OA.[9] This study showed that 70% of studies describing OA in all foot and hindfoot joints use the Kellgren and Lawrence Grading System (KLGS).

The KLGS was originally introduced in 1957 for the evaluation of OA of the hand, wrist, spine, hip, and knee joint.[10] It is a grading scale that reaches from 0 (no radiographic findings of osteoarthritis) to 4 (definite osteophytes with severe joint space narrowing and subchondral sclerosis) (Table 1).[10] A recent study evaluated the inter- and intra-rater reliability of the system for the subtalar joint in patients following total ankle replacement and found a moderate inter- and intra- rater agreement at best (K = 0.37 and K = 0.43 respectively).[11] Despite its widespread use, the KLGS has never been validated for use in the evaluation of post-traumatic OA of the subtalar joint.

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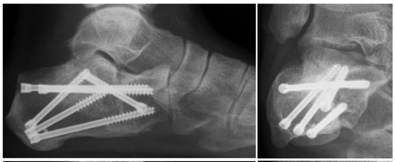
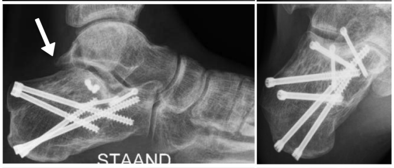
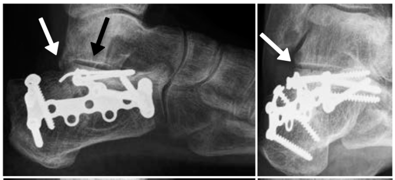
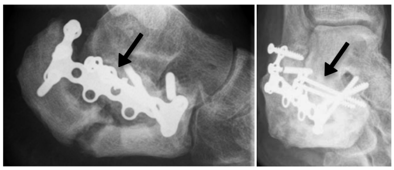
Other systems that assess arthritic changes of the subtalar joint include systems that were developed for cadaveric studies (Drayer-Verhagen)[12], rheumatoid arthritis (Larsen)[13], or use CT imaging to visualize post-traumatic changes (Ogut).[14] One of the classifications that was specifically introduced to grade subtalar OA after calcaneal fractures, is the grading system by Paley and colleagues in 1993.[3] This scale reaches from 0 (normal joint space) to 3 (complete destruction of joint space) (Table 1).

A reliable grading tool should not only benefit the assessment of OA in epidemiological and clinical studies, it should also improve the communication between involved clinicians. In order to reach this goal, a grading system needs to show a high inter- and intra-rater reliability. The purpose of this study was therefore to assess the inter- and intra-rater reliability of the most widely used grading system for post-traumatic osteoarthritis of the subtalar joint (Kellgren and Lawrence Grading System) and to compare it with a lesser-known sys-tem and less complex system (Paley Grading System).

Table 1. Kellgren and Lawrence (KL) grading system and Paley (P) grading system

KL-0. No radiographic findings of osteoarthritis		**P-0.** A normal joint space, with no evidence of degenerative cysts or subchondral sclerosis
KL-1. Minute osteophytes of doubtful clinical significance (white arrow)		-
KL-2. Definite osteophytes (white arrow) with unimpaired joint space		**P-1.** Subchondral sclerosis (black arrow), osteophytes (white arrow) and cyst formation, without narrowing of the joint space
KL-3. Definite osteophytes (white arrow) with moderate joint space narrowing (black arrow)		**P-2.** Narrowing of the joint space (black arrow), with sclerosis and cyst formation
KL-4. Definite osteophytes with severe joint space narrowing (black arrow) and subchondral sclerosis		**P-3.** Complete loss of the joint space (black arrow)

MATERIALS AND METHODS

Between November 2010 and June 2014 102 patients (aged 18 to 75) with 104 displaced intra-articular calcaneal fractures (Sanders type II-IV) were managed with open reduction and internal fixation through either an extended lateral or sinus tarsi approach. As part of their participation in a large prospective trial (EF3X-trial)[15], these patients underwent radiographic evaluation of post-traumatic osteoarthritis (OA). Approval to use anonymized radiographs was given by the medical ethical board for the EF3X-trial and its successive studies.

A selection of 50 patients representing the full spectrum of OA severity were evaluated by means of one lateral, one internally (Brodén), and one externally rotated view of the subtalar joint. Radiographs were blinded for patient identifiers and numbered randomly.

To minimize influence of the statistical challenge often referred to as the “kappa paradox”, 50 cases were selected by an independent observer to represent the full spectrum of OA severity.[16]

The presence and severity of post-traumatic OA was assessed by four observers: one experienced foot and ankle trauma surgeon and three MD, PhD fellows with calcaneal fractures as the main focus of their research. To reflect clinical practice, radiographs were reviewed on a standard PC monitor. Prior to classifying the OA, the two grading systems were explained to the observers. A reference sheet detailing the grading system was available throughout the task. A standardized data entry sheet was used to record the grading.

The initial read used the KLGS to grade the presence and severity of OA of the subtalar joint. After a minimum of five days, a second set of 25 cases was scored again to evaluate intra-rater variability. This process was repeated with the Paley Grading System. All observers were blinded to the ratings of the other observers.

Inter-rater reliability (IRR) was calculated using intra-class correlations (ICC). Higher ICC values indicate greater IRR, with an ICC estimate of 1 indicating perfect agreement and 0 indicating only random agreement. We used a two-way mixed, single-measures, consistency ICC, which is identical to a weighted kappa strategy but can be used for three or more raters.[17] Cut-offs were used as provided by Cicchetti et al., with IRR being poor for ICC values less than 0.40, fair for values between 0.40 and 0.59, good for values between 0.60 and 0.74, and excellent for values between 0.75 and 1.0.[18] Inter-rater reliability was computed using IBM SPSS Statistics for Windows, version 22.0 (IBM Corp, Armonk, NY).

To compute intra-rater reliability, we used Lights’ kappa strategy.[19] With this technique, we computed a (square) weighted kappa for both observers’ sessions separately, yielding four different intra-rater weighted kappa’s per grading system. We then used the arithmetic mean of these estimates to provide an overall index of agreement for each grading system. As this mean is in fact a weighted kappa, interpretation was based on the guidelines proposed by Landis and Koch: a kappa less than 0.00 indicates poor agreement, 0.00–0.20 slight, 0.21–0.40 fair, 0.41–0.60 moderate, 0.61–0.80 substantial, and 0.81–1.00 almost perfect agreement.[20] Weighted kappa was computed using R Statistical Software (R-Project for Statistical Computing, Version 3.1.2, Package IRR, Vienna, Austria) followed by manually computing the arithmetic mean.

RESULTS

Each of the four observers graded all the available radiographs. For both grading systems, it took approximately 30– 45 minutes to grade the series of 50 sets.

The interrater reliability showed an ICC of 0.54 (95 % CI 0.40-0.67) for the KLGS and an ICC of 0.41 (95 % CI 0.26 – 0.57) for the Paley Grading System (Table 2). This difference was not statistically significant.

The intra-rater reliability showed a mean weighted kappa of 0.62 for both the KLGS and the Paley Grading System (Table 3).

Table 2. Inter-rater reliability

	Kellgren and Lawrence Grading System ICC (95% CI)	Paley Grading System ICC (95% CI)	P-value
Single measures	0.54 (0.40-0.67)	0.41 (0.26 – 0.57)	NS
Average measures	0.82 (0.73 – 0.89)	0.74 (0.58 – 0.84)	NS

ICC: intraclass correlation. CI: confidence interval. NS: not significant

Table 3. Intra-rater reliability

	Kellgren and Lawrence Grading System Weighted kappa	**Paley Grading System** Weighted kappa
Rater 1	0.480	0.579
Rater 2	0.516	0.434
Rater 3	0.671	0.863
Rater 4	0.813	0.605
Lights' kappa	0.620	0.621

DISCUSSION

We found a fair inter-rater reliability for both the Kellgren and Lawrence (ICC 0.54) and the Paley Grading System (ICC 0.41). Intra-rater reliability was substantial for both systems (kappa 0.62 and 0.62 respectively). There was no statistically significant difference in reliability between the two systems. Although the average measures ICC is substantially higher than the single measures ICC (Table 2), this interpretation is reserved for clinical studies that use multiple observers, which is often not the case.

The lack of comparable studies makes it difficult to interpret our results in the light of existing literature. To our knowledge, this is the first study to assess reliability and compare these grading systems for posttraumatic subtalar joint OA. We did not find comparable studies that evaluate the Paley Grading System.

With regard to the Kellgren and Lawrence Grading System, we found higher reliability than Mayich and collegues, who assessed subtalar osteoarthritis after total ankle replacement and found weighted kappa's of 0.37 ± 0.06 (interrater) and 0.43 ± 0.07 (intrarater).[11] This is surprising, as in contrast to secondary causes for subtalar osteoarthritis, the fractured subtalar joint is often incongruent and its view more often hampered by implants, potentially lowering reliability. To describe reliability they used both weighted kappa and Fleiss' kappa, which are limited in accommodating more than two observers and handling categorical data respectively. A more appropriate statistical analysis would perhaps have given different and more comparable results. Holzer and colleagues found higher reliability of the KLGS in post-traumatic ankle joints (inter-rater ICC 0.61 and intra-rater ICC 0.75).[21] Moreover, Moon and colleagues evaluated post-traumatic OA of the ankle using the KLGS and found weighted kappa's of 0.58–0.80 (inter-rater) and 0.51-0.81 (intra-rater).[22] The complex anatomy of the subtalar joint when compared to the ankle joint might account for the slighty lower ICC for the KLGS we found in our study.

There are many ways to determine the degree of agreement amongst or within raters. Frequently agreement is reported by the percentage that raters agree in their ratings, often referred to as percentage agreement. However, this measure systematically overestimates the level of agreement by not correcting for agreement that would be expected by chance alone.[17] A more sophisticated analysis that corrects for this overestimation is the kappa-statistic.[23] Cohen's kappa is thought to be a robust measure for inter-rater agreement; however, it is not applicable to ordinal data and does not take into account the distance between two ratings. Cohen's weighted kappa can be used for data with an ordinal structure; it has the advantage that the further two raters are apart, the lower the IRR estimate will be.[24] It is limited however by the fact that it can only accommodate two raters. Fleiss' kappa is suitable for three or more raters, but is only available for nominal data and not suitable for fully crossed designs (were all subjects are rated by all raters).[25] A final solution for larger numbers of raters is using Lights strategy, where kappa's are computed for all coder pairs and then uses the arithmetic mean of these estimates to provide an overall index of agreement.[19] A measure that is suitable for ordinal, interval, and ratio variables is the intraclass correlation (ICC). It is identical to a weighted kappa but has the advantage that it can handle more than two raters.[26]

Strengths of this study include that we are the first to report on reliability of grading systems that evaluate post-traumatic OA of the subtalar joint specifically. Additionally, we have not only assessed inter-rater reliability but also evaluated reliability within raters. We used observers with different levels of experience in the assessment of calcaneal fractures in both clinical and research context. Earlier studies have shown that the level of experience of the observers, and the complexity of the classification system, do not usually affect inter-observer reliability.[27] Our study will help guide future researchers in their choice of grading system when reporting on post-traumatic subtalar osteoarthritis, and assist in the comparison of different treatment modalities for calcaneal fractures.

This study is limited in the number of grading systems it compares. However, many available systems are similar or poorly documented. Many systems resemble each other, grading osteophytes, subchondral sclerosis, and narrowing and dis-appearance of the joint space in various degrees. We chose to compare the most widely used (KLGS) and a lesser-known but more joint-specific and less complex system (PGS). We excluded systems that were not specifically used for the subtalar joint or were developed for cadaveric studies (Drayer-Verhagen)[12], rheumatoid arthritis (Larsen)[13], or were CT-based (Ogut)[14]. An additional limitation is the fact that we did not have a gold standard available to determine the accuracy of both grading systems. To minimize the potential effect of the kappa paradox, we selected fractures with a wide spectrum of OA severity. In published cohorts however, the severity of osteoarthritis leans toward more severe osteoarthritis.[28]

Our results suggest that there is no statistically significant difference in reliability between the Kellgren and Lawrence and the Paley Grading Systems. This leaves room for a comparison on different grounds. The Paley grading system describes subchondral sclerosis from grade 1 and higher, while the KLGS only describes this feature in the most severe grade 4. The KLGS leans heavily toward the presence of osteophytes and adds an extra grade to the system by classifying “osteophytes of doubtful clinical significance”. While this might improve accuracy of the description of the state of the joint, it is indeed doubtful what its clinical relevance is and whether this justifies a more complex grading system. The Paley Grading System simply acknowledges the presence of 1) secondary characteristics (osteophytes, subchondral sclerosis, and cyst formation) and 2) joint space narrowing, allowing for a two-step approach when grading OA. Since the Paley Grading System is non-inferior to the Kellgren and Lawrence Grading system and less complex to comprehend, this could be a reason to use the Paley system in future clinical settings. However, when it comes to comparing different treatment modalities in research, a more detailed and widely used system (i.e., KLGS) would be more convenient.

CONCLUSION

Both the Kellgren and Lawrence Grading System (KLGS) and the Paley Grading System (PGS) have a fair inter-rater reliability. Intra-rater reliability is substantial for both systems. There is no statistically significant difference in reliability between the KLGS and the PGS.

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9

ARTICULAR GAP AND STEP-OFF REVISITED: 3D QUANTIFICATION OF OPERATIVE REDUCTION FOR POSTERIOR MALLEOLAR FRAGMENTS

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ABSTRACT

Objectives:

Despite advanced imaging techniques, classic measurements of fracture reduction have not been revisited to date. The purpose of this study was to evaluate the reliability of innovative measurement techniques to quantify operative fragment reduction of posterior malleolar fractures by quantification of three-dimensional computed tomography (Q3DCT).

Methods:

Twenty-eight ankle fractures including a posterior malleolar fragment (AO/OTA type 44) were evaluated using 2DCT and Q3DCT to postoperatively quantify fragment reduction. “Classic” maximum gap and step-off of the posterior fragment were measured on 2DCT and Q3DCT. In addition, 2 innovative Q3DCT parameters were introduced and their reliability was tested using intraclass correlations (ICCs): gap surface (mm^2) and multidirectional 3D-displacement (mm).

Results:

“Classic” measurements showed a median maximum step-off of 1.1 mm [interquartile range (IQR) 0.0–1.8 mm] on 2DCT versus a median step-off of 0.6 mm (IQR 0.0–1.1) on Q3DCT. Median maximum gap was 1.2 mm (IQR 0.0–3.8) on 2DCT, and its equivalent on Q3DCT showed no median displacement. Q3DCT measurements revealed a median gap surface of 14.5 mm^2 (IQR 4.7– 30.0) and a median multidirectional 3D-displacement of 0.7 mm (IQR 0.0–1.1). Interrater reliability of these new Q3DCT parameters of displacement was excellent (ICC 0.92, 95% CI 0.79–0.98) for gap surface and good (ICC 0.64, 95% CI 0.28–0.88) for 3D-displacement.

Conclusions:

Q3DCT is a reliable and promising technique for postoperative evaluation of fracture fragment reduction. In addition to “classic” gap and step-off measurements, we propose to explore total gap surface and 3D-displacement as innovative radiographic measurements in future clinical studies.

INTRODUCTION

Approximately 7%–44% of ankle fractures have involvement of a posterior tibial fragment.[1–3] Patients with fractures that include a posterior tibial fragment tend to have a poorer prognosis than fractures without posterior involvement.[1,4–9] Outcome of these fractures is related to the overall pattern of fracture fragment size, displacement, and congruity of the articular surface.[4,9–14] However, "classic" unidirectional measurements of size and displacement may have oversimplified our understanding of complex multidirectional fragment displacement.[12,15] Despite advanced imaging techniques, classic measurements of postoperative fracture reduction (ie, Knirk & Jupiter's "classic" 2-millimeter displacement)[16] have not been revisited to date. To fully elucidate the role of posterior malleolar fragment morphology and displacement, innovative and reliable postoperative measurements of reduction and fixation may be a promising adjunct. In general, 2-millimeter intra-articular step-off remains the most cited radiographic parameter for postoperative judgment of fracture reduction, although it is also often inaccurately referenced as a preoperative radiographic parameter to indicate operative treatment.[17]

Plain radiographs have limited value for evaluating posterior fragment characteristics.[18–21] Two-dimensional computed tomography (2DCT) allows for improved characterization of fracture types but nonetheless overestimates true articular involvement.[22] In addition, articular incongruity often involves 3-dimensional displacement in multiple planes that may not be appreciated on conventional 2DCT. In this journal, we recently reported on quantification of 3-dimensional computed tomography (Q3DCT)-modeling to quantify fragment size and true articular involvement of posterior malleolar fragments.[15,22]

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The goal of this study was to evaluate the reliability of this new measurement technique to quantify postoperative fracture fragment reduction. We evaluate "classic" measurements of posterior fragment reduction—step-off (mm) and maximum gap (mm)—on both 2DCT and Q3DCT. In addition, this article introduces 2 innovative radiographic parameters: gap surface (mm^2) and the multidirectional 3D-displacement of posterior fragments by virtually re-reducing the fragment to an anatomic reduction. We hypothesize that Q3DCT is a reliable technique to quantify postoperative fracture fragment reduction in intra-articular fractures.

METHODS

This retrospective imaging study was approved by our institutional review board for the use of anonymized CT images from our prospective EF3X-trial database of intra-articular fractures of wrist, ankle, and calcaneus.[23]

Subjects

We used a convenience sample of 28 operatively treated ankle fractures with a posterior malleolar fragment (OTA type 44) who were included in the EF3X-trial.[23] Of the posterior fragments, 11 were indirectly reduced, 17 direct with 3 of these anterior–posterior and the remainder 14 posterior–anterior. All patients were treated in a level I Trauma Center between January 2010 and December 2013 (Academic Medical Center, Amsterdam). All patients had a CT scan of the distal third of the injured lower leg within 7 days postoperatively with a maximal slice thickness of 1 mm.

Evaluation of 2DCT

Two authors not involved in patient care classified posterior malleolar fractures according to Haraguchi on 2DCT.[12] In case of disagreement, individual cases were analyzed and solved by consensus. There were 17 type 1 fractures, 8 type 2 fractures, and 3 type 3 fractures on 2DCT. Q3DCT revealed a median posterior fragment size that involved 11.8% of the complete articular surface of the tibial plafond [interquartile range (IQR) 5.9%–23.8%]. Postoperative maximum step-off and gap were measured on the coronal (mortise) or sagittal (perpendicular to coronal) reconstructions and given in millimeters (Figs. 1A, 2A).

Quantitative Q3DCT Modeling

We used Q3DCT modeling techniques to quantify characteristics of the posterior fragments as previously described in this journal.[15,24–28] In short, to create Q3DCT reconstructions, sagittal images of CT scans (DICOM files; Digital Imaging and Communications in Medicine) were analyzed with an algorithm that identifies the outer margin of the highest density (cortical or subchondral) bone using MATLAB (version 8.0; Mathworks, Nattick, MA). These outlines were then stacked using Rhinoceros (version 4.0; McNeel North America, Seattle, WA), creating a wire mesh representing the outer margin of the bone. This wire mesh model was then transformed into a polygon mesh: a hollow 3D model of the outer surface of the bone. This model was systematically placed in a 3D environment by superimposing it on a template of a full, unfractured tibia. This tibia was positioned in such a way that the tibial shaft was parallel to the y-axis: the x-axis represented the anteroposterior (or sagittal) plane and the z-axis represented the mediolateral (or coronal) plane. After fitting the individual models to the template, fracture fragments with articular surface attached were then identified and isolated for analysis. A video to depict our Q3DCT modeling technique for posterior malleolar fractures is available at www.traumaplatform.org/science.

Evaluation of Q3DCT

To determine the postoperative step-off and gap on Q3DCT, the posterior fragment was virtually reduced to its anatomical position. Postoperative step-off was determined as fragment displacement on the y-axis (ΔY) and reported in millimeters (Fig. 1B). Postoperative gap was measured as posterior (ΔX) or lateral displacement (ΔZ) of the fragment and given in millimeters. In addition to "classic" measurements of intra-articular gaps, we calculated the gap surface measurement by filling out the articular surface of any visible recess between the tibial plafond and the posterior fragments with a calculable grid (Fig. 1D). Surface of this grid was then given in square millimeters. In case of multiple gaps, the accumulated surface area was calculated. As a second innovative measurement, 3D-displacement is given as a vector of the combined displacements on the x-, y-, and z-axis (Fig. 2) and calculated as follows[29]:

3D – displacement (mm) = $(\sqrt{(\Delta x^2+\Delta y^2+\Delta z^2})$.

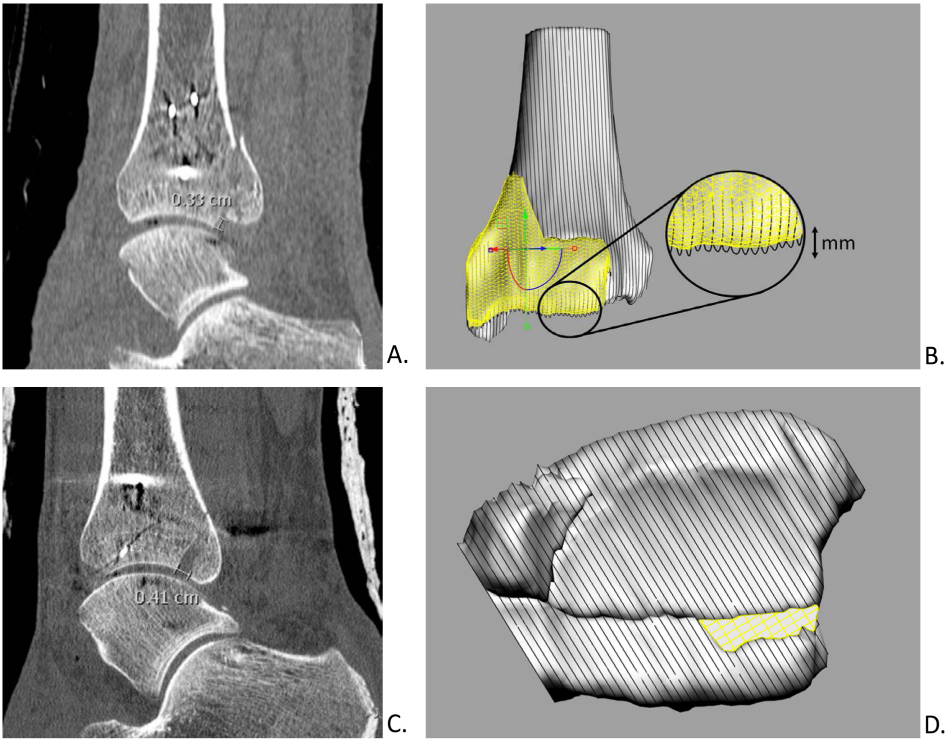

Figure 1. Example of step-off measurement on 2DCT (A) and Q3DCT (B) and gap measurement on 2DCT (mm) (C) and Q3DCT (yellow grid, mm²) (D).

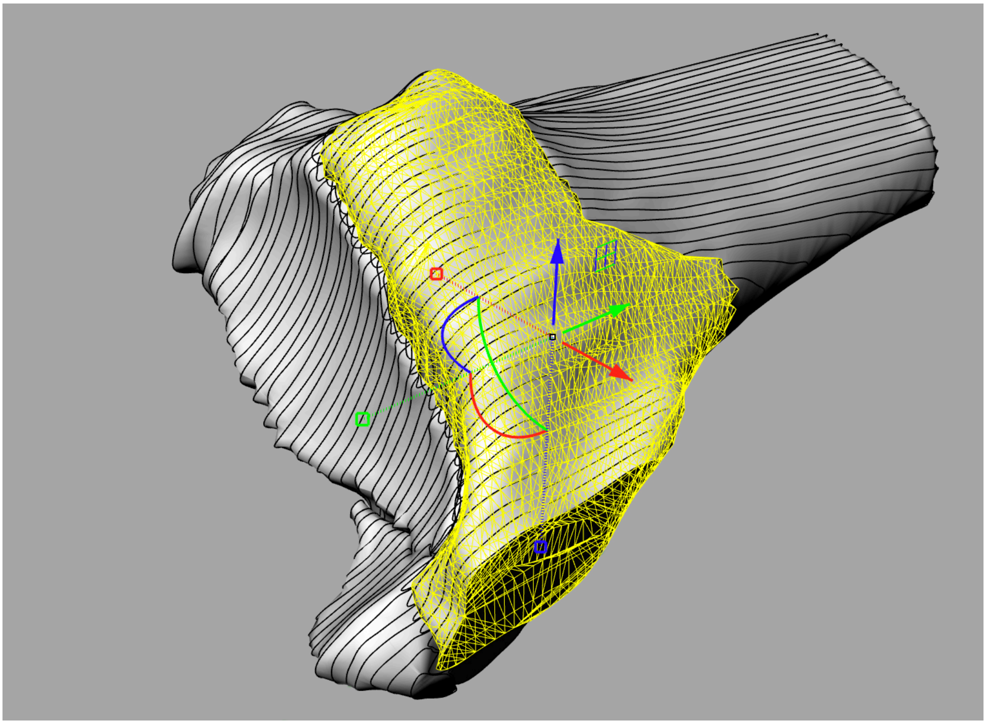

Figure 2. 3D-displacement is calculated as a vector of displacement in X (blue), Y (green), and Z (red) axis. 3D-displacement represents the multidirectional displacement of the posterior fragment (yellow) as a whole, compared with describing only the maximum step-off on articular level.

Statistical Analysis

Statistical analysis was performed with software (SPSS 20.0 for Windows; Chicago, IL). Data were non-normally distributed and measurements are presented as medians and IQRs. The Wilcoxon signed-rank test was performed to test the differences between 2DCT and Q3DCT measurements. A P-value less than 0.05 was considered to indicate statistical significance. We used the Spearman rank correlation coefficient (Spearman r) to determine the correlation between 2DCT and Q3DCT measurements. Correlations alone were not sufficient to indicate similarity, as they do not account for systematic variance. We created Bland–Altman plots to assess any systematic differences by plotting the mean of the 2DCT and Q3DCT on the x-axis and the difference between the 2 on the y-axis. If there is perfect similarity, measurements will be plotted at zero on the y-axis.[30]

Reliability

To assess reliability of the 3D-displacement and gap surface measurements, a random sample of 10 cases were quantified twice on separate occasions by 3 different observers not involved in patient care. All steps as described above (superimposing fracture models on template, gap surface measurement, and virtual reduction) were performed by all observers (R. de M.K., D.M., B. van der G.) independently. All observers were blinded to the ratings of the other observers.

Interrater reliability (IRR) was calculated using intraclass correlations (ICCs). Higher ICC values indicate greater IRR, with an ICC estimate of 1 indicating perfect agreement and 0 indicating only random agreement. We used a 2-way mixed, single measures, consistency ICC, which is identical to a weighted kappa strategy but can be used for 3 or more raters.[31,32] Cutoffs were used as provided by Cicchetti, with IRR being poor for ICC values less than 0.40, fair for values between 0.40 and 0.59, good for values between 0.60 and 0.74, and excellent for values between 0.75 and 1.0.[33] IRR was computed using IBM SPSS Statistics for Windows, version 22.0 (IBM Corp, Armonk, NY).

To compute intrarater reliability, we used Lights' kappa strategy.[34] With this technique, we computed a (square) weighted kappa for both observers' sessions separately, yielding 3 different intrarater weighted kappa's for both 3D-displacement and gap surface. We then used the arithmetic mean of these estimates to provide an overall index of agreement for both measures. As this mean is in fact a weighted kappa, interpretation was based on the guidelines proposed by Landis and Koch: a kappa less than 0.00 indicates poor agreement, 0.00– 0.20 slight, 0.21–0.40 fair, 0.41–0.60 moderate, 0.61–0.80 substantial, and 0.81–1.00 almost perfect agreement.[35] Weighted kappa was computed using R Statistical Software (R-Project for Statistical Computing, Version 3.1.2; Package IRR, Vienna, Austria) followed by manually computing the arithmetic mean.

RESULTS

"Classic" Postoperative Measurements of Reduction I: Intra-articular Gap

The maximum postoperative gap showed a median of 1.2 mm (IQR 0.0–3.8) on 2DCT. Median Q3DCT gap measurements showed no displacement in posterior or lateral direction. Subsequently, a one sample T test of the difference between gap measurements showed a P-value <0.05 indicating a systematic difference, thus ruling out correlation (Table 1).

Table 1. Correlation Between 2DCT and Q3DCT Measurements: A Bland–Altman Test With a P-Value of <0.05 Indicates a Systematic Difference and Rules Out Correlation

		Spearmans Rank		Bland-Altman#
2DCT	**Q3DCT**	**Correlation**	**P-value**	**P-value**
Step-off, mm	Step-off, mm	0.570	**< 0.05**	0.249
Gap, mm	Gap, posterior, mm	0.163	0.408	**<0.05**
	Gap, lateral, mm	-0.067	0.734	**<0.05**
	Gap surface, mm^2	0.462	**< 0.05**	**<0.05**
Step-off, mm	3D-displacement, mm	0.533	**< 0.05**	0.399
Gap, mm	3D-displacement, mm	0.177	0.367	**<0.05**

#One sample T test of difference between measurements
Bold values indicate statistical significance

"Classic" Postoperative Measurements of Reduction II: Intra-articular Step-off

Median maximum step-off was 1.1 mm (IQR 0.0–1.7 mm) on 2DCT. Median step-off on Q3DCT was 0.6 mm (IQR 0.0– 1.1). There was no statistical significant difference between step-off measurements on 2DCT and Q3DCT. Both measurements showed a significant correlation according to Spearman r, a Bland–Altman plot and a one sample T test (Table 1; Fig. 3). The funnel shape of the Bland–Altman plot indicates that when mean step-off increases, correlation between 2DCT and Q3DCT decreases.

Postoperative 3D Quantification of Reduction: Gap Surface and 3D-Displacement

Q3DCT showed a median gap surface of 14.5 mm^2 (IQR 4.7–30.0). IRR of gap surface measurements was excellent according to Cicchetti et al with an ICC of 0.92 (95% CI: 0.79–0.98). Intrarater reliability showed a moderate mean weighted kappa of 0.49. Although a Spearman rank test suggested correlation between gap measurements on 2DCT and gap surface measurements, a one sample T test indicated a systematic difference thus ruling out correlation.

Median 3D-displacement was 0.7 mm (IQR 0.0–1.1). IRR of 3D-displacement was good with an ICC of 0.64 (95% CI: 0.28–0.88). Intrarater reliability showed a substantial mean weighted kappa of 0.71 (Table 2). Step-off on 2DCT showed a significant correlation with 3D-displacement (Table 1; Fig. 3).

Table 2. Intrarater Reliability: For Each Rater the Weighted Kappa Was Calculated for Both Innovative Measurement Parameters (Gap Surface and 3D-Displacement)

	Gap surface	3D-displacement
	Weighted kappa	Weighted kappa
Rater 1	0.461	0.579
Rater 2	0.505	0.803
Rater 3	0.499	0.740
Lights' kappa	0.489	0.708

Lights' kappa was calculated by the arithmetic mean of these estimates.

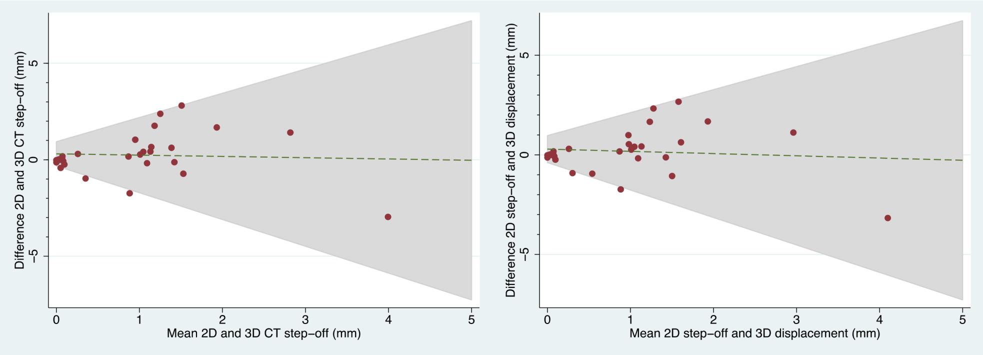

Figure 3. Bland–Altman plots for step-off (2DCT and Q3DCT) and 3D-displacement (Q3DCT) measures. Green dotted line indicates the mean difference between measures.

DISCUSSION

This study introduces new methods to quantify posterior malleolar fracture reduction in ankle fractures involving the posterior malleolar fragment. In addition to "classic" unidirectional measurements of step-off and gap, we found good to excellent IRR of innovative radiographic measures of gap surface in mm^2 and 3D-displacement.

Residual articular incongruity of posterior fragments remains a "hot topic" in recent publications.[3,9,13] A recent systematic review showed that the incidence of posttraumatic arthrosis was not associated with the size of the posterior malleolar fragment but with congruity of the joint surface.[9] Xu et al. linked the importance of articular congruity to fragment size: the larger the posterior fragment, the more influence an uneven articular surface would have.[3] Drijfhout van Hooff et al. recently confirmed that a postoperative step-off of 1 mm or more was associated with a higher incidence of radiographic arthrosis, but clinical relevance of radiographic signs of posttraumatic arthrosis remain unclear.[13] In addition, step-off was measured on postoperative plain lateral radiographs instead of more advanced imaging methods. As previous work showed, plain radiography is limited in evaluating posterior fragment characteristics.[18–20] In addition, the development of posttraumatic arthrosis is most likely to be multifactorial, including age, ligament damage, and cartilage injury.[36]

Strengths of this study include the fact that we have explored imaging techniques in both a traditional and innovative way. The use of Q3DCT allows for virtual reduction of fragments that opens up new possibilities in the evaluation of postoperative fracture reduction, as well as tools for preoperative planning beyond the scope of this study. We introduced reliable innovative measures based on plain unilateral CT images. In a separate prospective clinical trial, we correlate Q3DCT reconstructions to both patient- and surgeon-based outcome measurements, as well as early signs of posttraumatic arthrosis.[37] Although a promising technique, Q3DCT modeling has some known limitations.

To start, 3D model creation is a laborious process, which increases with fracture complexity. Recently, software that uses a CT model from the intact opposite side to facilitate automatic reduction of fracture fragments is now available and might reduce the time per model, but this would require a CT scan of the opposite unfractured ankle.[38] Further development of this technique might further reduce interobserver variability, and automate methodology, allowing Q3DCT to become a more widely used technique for fracture assessment.

In addition, there is a possible discrepancy between what CT images show as articular surface and what is true articular surface. As CT images do not show cartilage, articular surface measured by 2DCT or Q3DCT reconstructions might differ from true articular surface, especially as articular impaction injuries may explain some of the gaps seen on CT. Additional studies using magnetic resonance imaging or cadaveric bone could point out the degree of overestimation or underestimation.[15,39,40] Thirdly and more specific, the techniques we introduce describe only 3 of 6 degrees of freedom. Displacement of a fragment involves multidirectional translations in 3 directions x, y, and z—but also rotations about these axes.[41]

Not many new methods to quantify articular congruity have been introduced recently. In 2014, Yao et al. studied morphologic features of posterior malleolar fragments using 3D CT scanning, but focused on the description of fracture lines and fragment size and did not assess articular congruity.[42] In this journal, our group quantified preoperative 3D CT scans of posterior malleolar fracture patterns and found in essence 2 types of posterior malleolar fractures: a spectrum of posterolateral oblique fractures in a wide range in terms of articular involvement (Haraguchi I and III), and the better defined combined posteromedial and posterolateral fractures (Haraguchi II). To the best of our knowledge, Kern and Anderson were the first to describe a 3D step-off measurement that evaluates the articular surface but their technique requires a CT scan of the contralateral (healthy) tibia as comparison. The same authors have shown that contact stress evaluation can be used as a predictor of posttraumatic arthrosis.[43] It seems that contact stress evaluation is of preclinical interest at this point, as it comprises time-consuming and expensive techniques.

With current advances in medical imaging and computing power, innovative measurements using quantification of 3D imaging are likely to become an adjunct to classic measurements of postoperative articular congruity. Q3DCT evaluation of "classic" intra-articular gaps (mm) by evaluating posterior or lateral displacement of posterior fragments seems undesirable. Often, a gap is not caused by displacement of the whole posterior malleolar fragment, but more so by local impaction of the articular surface (Fig. 1 C–D). To solve this, we propose new Q3DCT surface area measurements for intra-articular gaps (mm^2). By correlating clinical outcome to total surface of these gaps (as opposed to mere one-directional measures), we can gain further understanding of its role in predicting clinical outcome, since some literature suggest this role may have been overestimated.44 Future study could assess how to further improve reliability. Computer-assisted virtual reduction could potentially increase reliability and save time.[38]

We have introduced a valid innovative 3D measuring technique that captures surface measurements and multidirectional displacement without discarding "classic" measurements of articular incongruity (step-off and gap). The clinical relevance of these techniques is the subject of ongoing future studies.

CONCLUSION

Q3DCT is a feasible technique in the postoperative evaluation of posterior fragments. We propose gap surface in square millimeters and 3D-displacement as innovative measurements and found good to excellent IRR.

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SUMMARY AND FUTURE PERSPECTIVES

SUMMARY AND FUTURE PERSPECTIVES

THESIS SUMMARY

With the exponential growth of technology, new possibilities for imaging arise. This thesis aims to explore the reliability of existing imaging techniques and radiological scoring protocols and critically evaluate the implementation of new imaging techniques in all phases of fracture treatment.

In **Chapter 1** we painted a general picture of fracture epidemiology in the Netherlands. Over the study period of 2004-2012, we observed an increasing incidence of extremity fractures and a shift towards more operative treatment mainly performed in non-academic hospitals. If this trend continues, policy makers will have to relocate capacity and resources to cope with these findings. With higher demand for scarce resources, critical selection of patients is ever so important. Imaging techniques are of indispensable value in this process by providing further insight in fracture morphology and to predict and enhance patient outcome.

PART ONE: PRE-OPERATIVE PLANNING

In corrective osteotomies of distal radius malunions, radiographic imaging is used for complex pre-operative planning. With restoration of the anatomy in mind, mirrored images of the contralateral non-injured extremity of the patient can be used as a template. Transfer of the preoperative plan can be achieved with help of 3D printed patient specific cutting guides. In **Chapter 2,** we describe a case series of eight patients who were treated with a computer-assisted 3D planned corrective osteotomy of the radius. We analyzed the postoperative residual malpositioning on 3D reconstructions that is expressed in six positioning parameters (three translations along three orthogonal axes and three rotations about these axes). In this case series, postoperative 3D evaluation showed a statistically significant improvement of dorsopalmar tilt ($p=0.05$). However, ulnoradial shift was worsened by the correction osteotomy (in 6 of 8 cases). Additional positioning parameters showed improvement in axial rotational alignment, radial inclination, proximodistal shift and volodorsal shift, although the group was not large enough to reach statistical significance. All but one patient experienced improved range of motion. We conclude that computer assisted 3D planning can ameliorate alignment of complex radius malunions.

To evaluate this procedure on a broader scale, we performed a meta-analysis of studies describing 3D-planned correction osteotomies of distal radius malunions in **Chapter 3**.

After systematically screening PubMed, EMBASE and the Cochrane library, we found fifteen studies with a total of 68 patients. In 96% of cases, preoperative volar tilt, radial inclination and ulnar variance showed statistical significant improvement to within 5 degrees or 2mm of their normal value. Mean flexion-extension, pro-supination and grip strength showed statistically significant improvement ($p<0.05$). Complications were reported in 11 out of 68 patients (16%). With the current advances in 3D printing technology, 3D-planned corrective osteotomies seem a promising technique in the treatment of complex distal radius malunions.

Pre-operative radiological work-up can also be used to identify indications for open reduction and fixation of ankle fractures. Up to 44% of ankle fractures have involvement of the posterior tibial margin. The treatment of these fragments is guided by different factors including size and morphology of the fragment, however the reliability of plain radiography in estimating these parameters is low. **Chapter 4** evaluated the diagnostic accuracy of computed tomography (CT) for the assessment of articular involvement of posterior malleolar fractures of the ankle. We asked 50 observers from 23 countries to analyze pre-operative CT scans of 31 ankle fractures including a posterior malleolar fragment. Quantitative 3-dimensional CT (Q3DCT) reconstructions were used as reference standard. We found that surgeons overestimated true articular involvement of posterior malleolar fractures on CT scans by factors 1.6, 1.4, and 2.2 for Haraguchi types I, II, and III respectively, potentially causing overtreatment of fragments that don't necessarily need fixation. Availability of the CT images proved to have a significant influence on choice of treatment in 23% with a shift toward operative treatment in 12% of cases compared to evaluating plain lateral radiographs alone.

PART TWO: INTRA-OPERATIVE IMAGING

After the preoperative planning, intra-operative imaging provides the surgeon with visual feedback to help guide the procedure. The process of obtaining intra-operative fluoroscopic images is evaluated in **Chapter 5.** In most cases, a radiographer operates the C-arm according to instructions from the operating surgeon. Accordingly, adequate communication between surgeon and radiographer is mandatory. Nonetheless, we found a wide variety of commands used in daily clinical practice. Based on input from both surgeons and radiographers, we developed and experimented with the first standardized Dutch language terminology to be used during intra-operative fluoroscopy. The introduction of uniform terminology resulted in a significant reduction of images and time needed to perform fluoroscopy tasks in an experimental setting. Its implementation in clinical practice could potentially reduce the overall radiation exposure, while simultaneously improving collaboration and progress of the procedure in the operating theatre.

Calcaneal fractures are known for their complex anatomy and are particularly demanding when it comes to obtaining visual feedback on fracture reduction and implant position. Based on literature describing high percentages of intra-operative revisions, use of intra-operative 3D fluoroscopy is thought to be beneficial in these procedures. **Chapter 6** describes the results of a multicenter randomized controlled study, the EF3X-trial, in which we randomized 100 patients with 102 operatively treated calcaneal fractures between additional intraoperative 3D fluoroscopy versus conventional 2D fluoroscopy. After two year follow up, we concluded that the use of intra-operative 3D fluoroscopy prolongs the surgical procedure without improving the quality of reduction and fixation in the management of calcaneal fractures. There was no benefit of intra-operative 3D fluoroscopy with regard to postoperative complications, quality of life, functional outcome or post-traumatic osteoarthritis.

PART THREE: POSTOPERATIVE EVALUATION

The final part of this thesis focusses on the postoperative radiological evaluation of fracture surgery. In absence of a reliable protocol to systematically evaluate the quality of reduction and hardware positioning of surgically treated calcaneal fractures, we previously introduced a 23-item scoring protocol based on international consensus[1]. **Chapter 7** describes the validation of this scoring protocol. We asked three independent raters to score the quality of reduction and implant position in 102 operatively treated calcaneal fractures using the scoring protocol. Additionally, 25 fractures were scored a second time by all raters. Inter-rater reliability of the overall 23-item protocol was good (ICC 0.66, 95% CI 0.64-0.69). Intra-rater reliability for the overall protocol was good for all 3 individual raters with ICC's between 0.60 and 0.70.

Despite the availability of multiple grading scales, there is no consensus on what grading system to use in the evaluation of posttraumatic osteoarthritis of the subtalar joint. The objective of **Chapter 8** is to identify the most suitable grading system for posttraumatic subtalar osteoarthritis.

After screening the literature for available grading systems, four observers evaluated 50 calcaneal fractures at least one year after trauma on conventional oblique lateral, internally and externally rotated views and graded posttraumatic subtalar osteoarthritis using the Kellgren and Lawrence Grading Scale (KLGS) and the Paley Grading System (PGS). We found no statistically significant difference in reliability between the two grading systems. We concluded that for research purposes, the more detailed and widely used KLGS seems preferable.

Finally, in **Chapter 9** we discuss a novel method of evaluating the size and characteristics of posterior malleolar fractures of the ankle. Despite the rise of advanced imaging techniques, classic measurements of fracture reduction have not been revisited to date. The purpose of this study was to introduce innovative measurement techniques to quantify operative fragment reduction of posterior malleolar fractures with use of quantification of three-dimensional computed tomography (Q3DCT). We evaluated twenty-eight ankle fractures including a posterior malleolar fragment with 2DCT and Q3DCT to postoperatively quantify fragment reduction. In addition to classic measurements of intra-articular gap and step-off, we introduced two innovative Q3DCT parameters: gap surface (mm^2) and multidirectional 3D-displacement (mm). Interrater reliability of these new Q3DCT parameters of displacement was excellent (ICC 0.92, 95% CI 0.79-0.98) for gap surface and good (ICC 0.64, 95% CI 0.28-0.88) for 3D-displacement. An upcoming study will further explore the role of these innovative radiological measurements in predicting clinical outcome.

GENERAL DISCUSSION AND FUTURE PERSPECTIVES

The aim of this thesis was to explore the reliability of existing imaging techniques and radiological scoring protocols and critically evaluate the implementation of new imaging techniques in fracture treatment. It has shown us that 3D-planned computer assisted corrective osteotomies of distal radius fractures are safe, feasible and have good clinical results. In the evaluation of intra-articular ankle fractures, new 3D measurements are reliable. Intraoperative 3D fluoroscopy, although generally thought to be beneficial, might disappoint in terms of clinical outcome. Lastly, we have evaluated reliability of new and existing scoring protocols for postoperative evaluation of osteoarthritis and fracture reduction and implant position.

Since the 1980's, with the emergence of computerized tomography (CT), orthopedic trauma surgeons have been able to obtain cross-sectional axial images to gain insight in complex fractures[2]. With the availability of multiplanar reformations (MPR) conventional axial slices were reconstructed into coronal and sagittal projections, for the first time truly providing information in three dimensions. Moreover, additional volume rendering techniques provided the opportunity to navigate around a 3-dimensional object, often referred to as 3DCT. Besides creating impressive images to show the patient, these projections have proven to assist the orthopaedic trauma surgeon to gain insight in fracture pathology[3–5]. With these developments, multiple studies have shown that plain radiography or 2D fluoroscopy alone often does not provide sufficient detail to detect clinically important intra-articular pathology[6–10].

The concept of generating a 3D dataset by multi-angle imaging found its way to the operating room with the development of motorized isocentric C-arms in early 21st century[11]. Since its introduction, 3D fluoroscopy has gained popularity in fracture surgery, mainly because it led to high percentages of intra-operative revisions[12–15]. Studies on this subject however often miss a control group or lack clinical outcome parameters[13,14,16,17]. To our knowledge, we are the first to perform a randomized controlled trial with a long-term clinical follow up. Our results suggest that intra-operative revisions do not necessarily predict a better functional outcome.

Vascular and cardiothoracic surgery have led the way to further incorporating complex imaging devices into the operating room. Hybrid operation rooms with a robotic c-arm form the current state of art and bring about great advantages[18,19]. Robotic c-arms are operated by the surgeon through a sterile control panel or are voice activated, eliminating dependability on additional colleagues[18,19]. These systems are fully integrated with a navigation interface for 3D guidance of screw placement. With a wide field of view, simultaneous contralateral imaging can be obtained to facilitate intra-operative comparison with the patient's own anatomy.

3D imaging often creates images that are visually appealing and are instinctively beneficial. In daily clinical practice however, there are more factors to take into account. When used in pre-operative planning for instance, feasibility might be limited by the approach or soft tissue restrictions. Intra-operative imaging might show indications for revision that are not possible to realize due to insufficient stability or bone stock. Moreover, clinical relevance of postoperative radiological parameters remains to be further elucidated. We need to steer away from operating for a perfect postoperative image and towards operating for indications that are actually beneficial for the patient. Novel techniques can assist in further appreciating the relevance of anatomical imperfections. Quantification of 3 dimensional computed tomography or Q3DCT allows for calibrated calculations in dynamic three-dimensional models. By comparing these measurements with clinical outcome parameters we can re-evaluate indications for surgical treatment. Although current Q3DCT techniques often imply a laboursome process, computer-assisted virtual reduction could potentially increase reliability and save time[20].

Finally, progress in technology is exponential, not linear. Price-performance of computing (or calculations per second per dollar) is following an smooth, exponential pattern[21] and new technologies are becoming more widely available. With this exponential growth and availability, the medical community needs to adopt its position in this rapidly changing field. Without losing sight of our patients, we should embrace and familiarize with new technologies to push further development and expose indications for improvement.

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NEDERLANDSE SAMENVATTING EN TOEKOMSTPERSPECTIEF

NEDERLANDSE SAMENVATTING EN TOEKOMSTPERSPECTIEF

Beeldvormende technieken vormen een essentieel onderdeel van de diagnostiek en operatieve behandeling van botbreuken (fractuurchirurgie). Mede dankzij de exponentiële groei in technologische ontwikkelingen, ontstaan er steeds meer mogelijkheden op het gebied van medische beeldvorming. Het doel van dit proefschrift was om de betrouwbaarheid van bestaande beeldvormende technieken en radiologische scoringsprotocollen in de fractuurchirurgie te toetsen en de implementatie van nieuwe technieken kritisch te evalueren.

In **Hoofdstuk 1** schetsten we een algemeen beeld van het vóórkomen van botbreuken in Nederland. Gedurende de onderzoeksperiode van 2004 tot 2012, waren er twee opvallende bevindingen. Allereerst zagen we een toename in incidentie van botbreuken van de ledematen. Ten tweede was er een verschuiving van conservatieve naar meer operatieve behandelingen, voornamelijk uitgevoerd in niet-academische ziekenhuizen. Als deze trend zo doorzet, zullen beleidsmakers de beschikbare middelen in de toekomst anders moeten inzetten. Daarnaast blijft een kritische selectie van patiënten en indicaties voor operatief ingrijpen belangrijk. Voor deze selectie zijn beeldvormende technieken van onmisbare waarde: ze geven inzicht in fractuurkarakteristieken en helpen het behandelresultaat van patiënten te voorspellen en te verbeteren.

DEEL I: PREOPERATIEVE PLANNING

Een malunion is een mogelijk gevolg van inadequate behandeling van een radius fractuur, hetgeen kan resulteren in pijn en functieverlies. Bij de preoperatieve planning van een correctie van een dergelijke malunion kan computertomografie (CT) uitkomst bieden. Met het oog op herstel van de functionele anatomie kan een gespiegeld 3D model van de niet-aangedane arm van de patiënt als voorbeeld dienen. Gepersonaliseerde, 3D geprinte zaagmallen maken het vervolgens mogelijk om het digitale preoperatieve plan naar de patiënt te vertalen. In **Hoofdstuk 2** beschreven we een serie van acht patiënten die werden behandeld met een computer-geassisteerde 3D geplande correctie-osteotomie.

We analyseerden de postoperatieve resterende malpositionering op 3D reconstructies en drukten deze uit in zes positionerings-parameters (drie translaties langs drie orthogonale assen en drie rotaties om deze assen). We constateerden in het merendeel van de patiënten een verbetering van de volaire kanteling, radiale inclinatie, radiale lengte en sagittale shift (volair – dorsaal), echter, deze bevindingen waren niet statistisch significant. De dorsopalmaire tilt afwijking was wel significant verbeterd na de ingreep ($p=0.05$). In 6 van de 8 patiënten was de ulnoradiale shift juist verslechterd door de correctie-osteotomie.

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Op één patiënt na hadden alle patiënten een verbeterde bewegingsuitslag van de pols en onderarm. We concludeerden dat computer-geassisteerde 3D planning de postoperatieve stand bij radius malunions kan verbeteren, in het bijzonder bij rotatieafwijkingen.

Om de resultaten van deze procedure op grotere schaal te evalueren, voerden we in **Hoofdstuk 3** een meta-analyse uit van studies die een 3D geplande correctie osteotomie van distale radius malunions beschrijven. Na een systematische zoekactie in de databases van PubMed, EMBASE en Cochrane vonden we vijftien studies met in totaal 68 patiënten. In 96% van de gevallen werd er een statistisch significante verbetering gezien van de preoperatieve volaire kanteling, radiale inclinatie en ulnaire variantie tot op 5 graden of 2mm van de normaalwaarden. Ook de gemiddelde flexie-extensie, pro-supinatie en knijpkracht vertoonden statistisch significante verbetering ($p < 0.05$). Bij elf van de 68 patiënten (16%) werden complicaties gezien. Met de huidige vooruitgang in 3D printtechnologie lijkt de 3D geplande correctie-osteotomie een veelbelovende techniek voor de behandeling van complexe distale radius malunions.

Naast de 3 dimensionale planning van correcties, speelt preoperatieve beeldvorming ook een rol bij het stellen van indicaties voor operatieve behandeling van specifieke fractuurfragmenten. Tot 44% van de enkelfracturen omvatten het achterste gedeelte van de tibia of de posterieure malleolus. De behandeling van deze posterieure fragmenten wordt bepaald door verschillende factoren zoals de grootte en de morfologie van het fragment, maar de betrouwbaarheid van normale röntgenfoto's bij het inschatten van deze factoren is laag. **Hoofdstuk 4** evalueerde de diagnostische nauwkeurigheid van computertomografie (CT) voor de beoordeling van betrokkenheid van het gewrichtsoppervlak bij deze posterieure fragmenten van enkelfracturen. We vroegen 50 chirurgen uit 23 landen om preoperatieve CT-scans van 31 enkelfracturen met posterieure fragmenten te beoordelen. Als referentiestandaard gebruikten we gekwantificeerde 3 dimensionale CT (Q3DCT) reconstructies.

Chirurgen bleken de betrokkenheid van het gewrichtsoppervlak van posterieure fragmenten op CT scans te overschatten met een factor 1.6, 1.4 en 2.2 voor respectievelijk Haraguchi type I, II en III fragmenten. Mogelijk leidt dit tot overbehandeling van fragmenten die niet noodzakelijkerwijs gefixeerd hoeven te worden. Het zien van de CT beelden bleek van invloed op de keuze van behandeling: ten opzichte van de normale röntgenfoto's werd in 23% van de gevallen overgegaan op een operatieve behandeling, terwijl in 12% daar juist van werd afgezien.

DEEL II: PEROPERATIEVE BEELDVORMING

Na de preoperatieve voorbereidingen, is beeldvorming tijdens de operatie van essentieel belang om de chirurg van visuele feedback te voorzien. In de meeste gevallen wordt het mobiele Röntgenapparaat (of C-boog) bediend door een gespecialiseerde röntgenlaborant. Omdat in deze situatie de chirurg aan de laborant kenbaar moet maken wat in beeld gebracht moet worden, is goede communicatie tussen beide partijen onontbeerlijk. In **Hoofdstuk 5** evalueerden we hoe de communicatie ten tijde van het verkrijgen van deze peroperatieve doorlichtingsbeelden verloopt. Eerst brachten we de gebruikte terminologie in kaart: deze bleek zeer divers en sprak elkaar bovendien regelmatig tegen. Op basis van suggesties van orthopedisch- en traumachirurgen, laboranten en een expertpanel werd vervolgens nieuwe, gestandaardiseerde terminologie voorgesteld. In een experimentele setting leidde het gebruik van deze terminologie tot een verkorting van de procedure en verminderde het aantal doorlichtingsbeelden dat gemaakt werd. Het gebruik komt de samenwerking tussen laborant en chirurg ten goede en zou in de dagelijkse praktijk de blootstelling aan röntgenstraling kunnen verminderen.

Botbreuken van het hielbeen of de calcaneus staan bekend om hun complexe anatomie en zijn bijzonder veeleisend als het gaat om het verkrijgen van accurate doorlichtingsbeelden. In de beschikbare literatuur wordt het gebruik van 3D doorlichting bij deze operaties gunstig geacht, met name omdat het hoge percentages correcties van fractuurrepositie en positie van het implantaat tot gevolg heeft. **Hoofdstuk 6** beschrijft de resultaten van een multicenter gerandomiseerde gecontroleerde studie, de EF3X-trial, waarin we 100 patiënten met 102 operatief behandelde calcaneusfracturen hebben gerandomiseerd tussen aanvullende peroperatieve 3D doorlichting of conventionele 2D doorlichting. Wij concludeerden dat het gebruik van peroperatieve 3D doorlichting de chirurgische procedure verlengt zonder dat dit een positief effect heeft op de kwaliteit van fractuurrepositie en positie van het implantaat op de postoperatieve CT scan. Na twee jaar follow-up was er geen statistisch significant verschil tussen de groepen op het gebied van complicaties, kwaliteit van leven, functionele uitkomst of posttraumatische artrose.

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DEEL III: POSTOPERATIEVE EVALUATIE

Het laatste deel van dit proefschrift richtte zich op de postoperatieve radiologische beoordeling van fracturen. Bij het zorgvuldig en systematisch beoordelen van de kwaliteit van fractuurrepositie en positie van implantaten is een goed scoringsprotocol onmisbaar. Omdat deze voor operatief behandelde calcaneusfracturen niet beschikbaar was introduceerden we eerder een scoringsprotocol met 23 items op basis van internationale consensus[1]. **Hoofdstuk 7** beschrijft de validatie van dit scoringsprotocol. We vroegen drie onafhankelijke beoordelaars om de kwaliteit van fractuurrepositie en positie van implantaten in 102 operatief behandelde calcaneusfracturen te beoordelen met behulp van het scoringsprotocol. Bovendien werden 25 fracturen een tweede keer door alle beoordelaars gescoord. De betrouwbaarheid van het totale scoringsprotocol was tussen de verschillende beoordelaars goed (ICC 0.66, 95% CI 0.64-0.69). Bij herhaling van de beoordelingen was ook de betrouwbaarheid binnen de afzonderlijke beoordelaars goed met ICC's tussen de 0.60 en 0.70.

Botbreuken van het hielbeen gaan op de lange termijn vaak gepaard met artrose van het onderste spronggewricht (subtalaire artrose). Ondanks dat er meerdere classificatiesystemen beschikbaar zijn om deze artrose te beoordelen is het niet duidelijk welk systeem we het beste kunnen gebruiken. Het doel van **Hoofdstuk 8** was om het meest geschikte classificatiesysteem voor posttraumatische subtalaire artrose vast te stellen. Nadat we uit de beschikbare literatuur de twee meest gebruikte classificatiesystemen hadden geïdentificeerd, vroegen we vier beoordelaars om Röntgenfoto's van 50 calcaneusfracturen van minstens één jaar na het trauma op posttraumatische subtalaire artrose te scoren met behulp van de Kellgren en Lawrence Grading Scale (KLGS) en het Paley Grading System (PGS). Er werd geen statistisch significant verschil in betrouwbaarheid tussen beide systemen gevonden. We concludeerden dat voor onderzoeksdoeleinden de KLGS het meest gebruikte en meest gedetailleerde classificatiesysteem is en daarom de voorkeur boven het PGS heeft.

Ondanks de opkomst van geavanceerde beeldvormende technieken, zijn de traditionele methoden om fractuurrepositie te kwantificeren nooit herzien. Het doel van **Hoofdstuk 9** was om innovatieve meettechnieken te introduceren voor de postoperatieve evaluatie van de repositie van posterieure fragmenten van enkelfracturen. Dit deden we met behulp van gekwantificeerde driedimensionale computertomografie (Q3DCT) technieken. We evalueerden achtentwintig enkelfracturen met een posterieur fragment met 2DCT en Q3DCT om de postoperatieve fractuurrepositie te kwantificeren. Naast de klassieke metingen van intra-articulaire 'gap' en 'step-off', introduceerden we twee innovatieve Q3DCT metingen: gap oppervlak (in mm^2) en 3D-verplaatsing (in mm). De betrouwbaarheid tussen de beoordelaars van deze nieuwe Q3DCT parameters was uitstekend (ICC 0,92, 95% CI 0,79-0,98) voor gap oppervlak en goed (ICC 0,64, 95% CI 0,28-0,88) voor 3D-verplaatsing. Een volgende studie zal verder onderzoeken wat de rol van deze nieuwe meetmethoden is in het voorspellen van klinische uitkomst.

ALGEMENE DISCUSSIE EN TOEKOMSTPERSPECTIEF

Het doel van dit proefschrift was om de betrouwbaarheid van bestaande beeldvormende technieken en radiologische scoringsprotocollen in de fractuurchirurgie te toetsen en de implementatie van nieuwe technieken kritisch te evalueren. We concludeerden dat:

1. 3D geplande computer geassisteerde correctie-osteotomieën van distale radius malunions haalbaar en veilig zijn, en bovendien goede klinische resultaten laten zien;
2. 2DCT van enkelfracturen de grootte van het posterieure fragment overschat, en dat nieuwe 3D metingen van de fractuurrepositie haalbaar en betrouwbaar zijn;
3. De communicatie bij Röntgendoorlichting op OK verbeterd kan worden door implementatie van nieuwe terminologie;
4. de toegevoegde waarde van peroperatieve 3D doorlichting bij calcaneusfracturen met betrekking tot klinische uitkomst beperkt is;
5. de betrouwbaarheid van een nieuwe scoringsprotocol voor postoperatieve evaluatie van fractuurrepositie en positie van het implantaat bij calcaneuschirurgie goed is;
6. voor de beoordeling van posttraumatische subtalaire artrose we het beste de Kellgren en Lawrence Score kunnen gebruiken.

Sinds de komst van computertomografie (CT) in de jaren ’80 zijn orthopedisch- en traumachirurgen in staat om met cross-sectionele axiale coupes meer inzicht te krijgen in complexe fracturen[2]. Later ontstonden de ‘multiplanar reconstructions’ (MPR) van de axiale coupes: doordat er nu ook coronale en sagittale projecties beschikbaar waren konden fracturen voor het eerst in 3 dimensies beoordeeld worden. Volume rendering biedt vervolgens de mogelijkheid om rondom 3D modellen van gescande extremiteiten heen te draaien, een techniek die vaak 3DCT als wordt aangeduid. Behalve dat 3DCT indrukwekkende beelden voor de patiënt biedt, ondersteunen deze beelden de orthopedisch- en traumachirurgen in het vergroten van inzicht in fractuur pathologie[3–5]. Met de opkomst van deze nieuwe technieken werd ook aangetoond dat er op conventionele röntgenfoto’s of 2D doorlichting vaak onvoldoende details zichtbaar zijn om klinisch relevante intra-articulaire pathologie in kaart te brengen[6–10].

Het concept om een voorwerp vanuit meerdere hoeken te belichten en daarmee een 3D dataset te genereren heeft daarna ook zijn weg naar de operatiekamer gevonden[11]. Sinds de introductie van 3D doorlichting begin 2000, heeft deze techniek in de fractuurchirurgie aan populariteit gewonnen, vooral omdat het hoge percentages peroperatieve correcties tot gevolg heeft[12–15]. Studies die deze techniek belichten missen echter vaak een controle groep of evalueren geen klinische uitkomsten, waardoor de echte toegevoegde waarde moeilijk te onderzoeken is[13,14,16,17]. Wij voerden voor het eerst een gerandomiseerde gecontroleerde

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studie uit met een lange-termijn klinische follow up. Onze resultaten suggereren dat het gebruik van 3D doorlichting bij calcaneuschirurgie niet direct een betere functionele uitkomst tot gevolg heeft.

In de afgelopen jaren hebben de vasculaire en cardiothoracale chirurgie de integratie van complexe beeldvormende apparatuur op de operatiekamer verder voortgestuwd. De meest moderne hybride operatiekamers hebben een robot-gestuurde C-boog of Cone Beam CT en bieden ook voor de fractuurchirurgie grote voordelen[18,19]. Doordat de chirurg de robot-gestuurde C-boog via een steriel bedieningspaneel of zelfs via spraakactivering kan besturen wordt deze minder afhankelijk van ondersteunend personeel[18,19]. Deze systemen zijn meestal volledig geïntegreerd met een 3D navigatie-interface voor complexe fractuurchirurgie. Doordat ze een breed scanvlak hebben kan er peroperatief eenvoudig beeldvorming van de collaterale zijde van de patiënt verkregen worden, wat peroperatieve vergelijking met de eigen anatomie van de patiënt mogelijk maakt.

Driedimensionale beelden zijn op het eerste gezicht visueel aantrekkelijk en lijken voor veel problemen de uitkomst te bieden. In de dagelijkse klinische praktijk spelen er echter veel factoren mee die de ogenschijnlijke mogelijkheden beperken. Preoperatieve plannen kunnen op een computerscherm nog zo nauwkeurig zijn, maar in de praktijk wordt de haalbaarheid vaak beperkt door bijvoorbeeld weke delen die niet in de beeldvorming zijn meegenomen. Bovendien moet verder onderzocht worden wat de klinische relevantie is van verschillende afwijkingen. We moeten niet zozeer streven naar een perfecte postoperatieve röntgenfoto of CT scan maar ons richten op indicaties die daadwerkelijk een gunstig effect hebben op de uitkomst voor de patiënt. Nieuwe technieken kunnen ons helpen om verder inzicht te krijgen in het klinische belang van anatomische afwijkingen. Met gekwantificeerde driedimensionale computertomografie (Q3DCT) hebben we beschikking tot gekalibreerde interactieve driedimensionale modellen van de patiënt. Hoewel de huidige Q3DCT technieken nog omslachtig kunnen zijn, kan in de toekomst computergestuurde virtuele repositionering het proces versnellen en mogelijk de betrouwbaarheid vergroten[20].

Tot slot: technologische vooruitgang verloopt exponentieel, niet lineair. De verhouding tussen de rekensnelheid van computersystemen en de kosten voor ontwikkeling (uitgedrukt in berekeningen per seconde per dollar) volgt al decennia een vloeiende, exponentiele groei en nieuwe technologieën worden steeds sneller en op grotere schaal beschikbaar[21]. Als medici moeten wij ons bewust zijn van dit snel veranderende landschap en actief betrokken blijven bij nieuwe ontwikkelingen. Met onze patiënten als uitgangspunt moeten we nieuwe technologieën blijven verkennen en aan de dagelijkse praktijk toetsen. Alleen dan kunnen we gebreken blootleggen en verdere technologische ontwikkeling stimuleren.

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PHD PORTFOLIO

PHD PORTFOLIO

Name PhD student: R.J.O. de Muinck Keizer
PhD period: June 2012 – June 2017
Name PhD supervisor: Prof. dr. J.C. Goslings, Prof. Dr. D. Eygendaal

	Year	Workload (ECTS)
General courses		
- *Scientific Writing in English*	2014	1.5
- *Clinical Data Management*	2013	0.3
- *Practical Biostatistics*	2013	1.1
- *Basiscursus Regelgeving en Organisatie voor Klinisch*	2012	0.9
Onderzoekers (BROK)	2012	0.1
- *Evidence-Based Searching*		
Specific courses		
- Stralingshygiëne deskundigheidsniveau 4A	2014	1.7
Seminars, workshops and master classes		
- Regionaal refereren regio II	2012-2015	0.3
- Masterclass Prof. J. Powell: How to publish a paper?	2012	0.2
- Weekly surgical department seminars	2012-2015	2.5
Oral presentations		
- Chirurgendagen, Veldhoven, the Netherlands	2016	0.5
- 3D kwantificatie van posterieure malleolaire fractuur fragmenten correleert met klinische uitkomst (presented by D.T. Meijer)	2016	0.5
- 17th European Congress of Trauma & Emergency Surgery, Vienna, Austria		
- 3D Quantification of Posterior Malleolar Fragment-Reduction Predicts Clinical Outcome in a Prospective Trial	2016	0.5
- 17th European Congress of Trauma & Emergency Surgery, Vienna, Austria	2016	0.5
- Three Dimensional Virtual Planning of Corrective Osteotomies of Distal Radius Malunions: A Systematic Review		
- 17th European Congress of Trauma & Emergency Surgery, Vienna, Austria	2015	0.5
- Articular Gap and Step-off Revisited: 3D Quantification of Posterior Malleolar Fragment Reduction	2014	0.5
- AAOS Annual Meeting, Orlando, Florida, USA		
- 3D Quantification of Posterior Malleolar Fragment-Reduction Predicts Clinical Outcome in a Prospective Trial (presented by D.T. Meijer)	2013	0.5

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- Symposium Complicaties in de Traumachirurgie, AMC - Communicatie tijdens peroperatieve Röntgendoorlichting: op weg naar eenduidige terminologie	2013	0.5
- Symposium Verstoord Bewegen, AMC Amsterdam, NL - Radiuskopfracturen en de RAMBO-trial		
- NVvH Chirurgendagen, Veldhoven, NL - De eerste episode van een anterieure schouderluxatie in adolescenten: behandeling anno 2013		

Poster presentations

- NVT Traumadagen, Amsterdam, NL		
- Q3DCT measurements of Posterior Malleolar Fragments	2015	0.5
- NVT Traumadagen, Amsterdam, NL		
- Communicatie bij peroperatieve Röntgendoorlichting: op weg naar een uniforme terminologie.	2014	0.5

(Inter)national conferences

- NVT Traumadagen, Amsterdam, NL	2015	0.25
- NVT Traumadagen, Amsterdam, NL	2014	0.25
- NVT Traumadagen, Amsterdam, NL	2012	0.25
- 17th European Congress of Trauma & Emergency Surgery,	2016	0.25
Vienna, Austria	2015	0.25
- 16th European Congress of Trauma & Emergency Surgery,	2015	0.25
Amsterdam, NL	2013	0.25
- NVvH Chirurgendagen, Veldhoven, NL		
- NVvH Chirurgendagen, Veldhoven, NL		

Teaching

Tutoring, Mentoring

- Kiira Lechner, 5th year medical student: 3D planned corrective osteotomies of distal radius malunions	2014	1.0
- Dorine Klei, 3rd year medical sciences student: Communication during intra-operative fluoroscopy	2014	1.0
- Skillslab, Musculoskeletal system	2014	0.5
- Lara Vos, 5th year medical student: Minimal Clinically Important Difference of the PRWE Questionnaire	2013	1.0
- Siert Peters, 4th year medical student: Minimal Clinically Important Difference of the PRWE Questionnaire	2012	1.0

Supervising

- Gor Khatchikyan, development digital goniometer	2012-2013	1.0

Organisation

- 4th Symposium Impaired Mobility, AMC, Amsterdam, NL	2013	2.0

Parameters of Esteem

Grants

- AO Start-up grant	2013	

CURRICULUM VITAE

CURRICULUM VITAE

Robert-Jan (Oene) de Muinck Keizer werd geboren op 16 augustus 1984 in Den Haag, alwaar hij op het Maerlant Lyceum zijn VWO doorliep. Vanaf 2003 studeerde hij Geneeskunde aan de Vrije Universiteit van Amsterdam, waarna hij zijn artsexamen behaalde in juli 2010. Hij werkte vervolgens als arts-assistent op de afdeling Heelkunde van het toenmalige Sint Lucas Andreas Ziekenhuis in Amsterdam en later in het Rode Kruis Ziekenhuis in Beverwijk. In 2012 startte hij, onder begeleiding van prof. dr. J.C. Goslings en prof. dr. D. Eygendaal met het onderzoek dat heeft geleid tot dit proefschrift. In januari 2016 is hij begonnen met de vooropleiding tot orthopedisch chirurg in het Onze Lieve Vrouwe Gasthuis (opleiders Dr. B.C. Vrouenraets en Dr. M.F. Gerhards). Hij heeft samen met Nicolien de Clercq twee zoons, Ole en Ties.

LIST OF PUBLICATIONS

LIST OF PUBLICATIONS

This PhD thesis

Epidemiology of extremity fractures in the Netherlands
M.S.H. Beerekamp, R.J.O. de Muinck Keizer, N.W.L. Schep, D.T. Ubbink, M. Panneman, J.C. Goslings
Submitted

Computer-assisted 3D planned corrective osteotomies in eight malunited radius fractures
R.J.O. de Muinck Keizer, M.W. Walenkamp*, J.G.G. Dobbe, G.J. Streekstra, J.C. Goslings, P.Kloen, S.D. Strackee, N.W.L. Schep. *Equally contributing authors*
Strategies Trauma Limb Reconstr. 2015 Aug;10(2):109-16

Three Dimensional Virtual Planning of Corrective Osteotomies of Distal Radius Malunions: A Systematic Review and Meta-Analysis
R.J.O. de Muinck Keizer, K.M. Lechner, M.A.M. Mulders, N.W.L. Schep, D. Eygendaal, J.C. Goslings
Accepted, Strategies Trauma Limb Reconstr. 2017

Diagnostic Accuracy of 2 Dimensional Computed Tomography for Articular Involvement and Fracture Pattern of Posterior Malleolar Fractures
R.J.O. de Muinck Keizer, D.T. Meijer*, J.N. Doornberg, I.N. Sierevelt, S.A.S. Stufkens, G.M.M.J. Kerkhoffs, C.N. van Dijk and the Ankle Platform Study Collaborative – Science of Variation Group *Equally contributing authors*
Foot Ankle Int. 2016 Jan;37(1):75-82

“Turn laterally to the left!”. The need for uniform C-arm communication terminology during orthopaedic trauma surgery
R.J.O. de Muinck Keizer, D. Klei, P. van Koperen, C.N. van Dijk, J.C. Goslings
Acta Orthopaedica Belgica, published Q1 2017

The clinical effectiveness of intraoperative 3D-RX in the treatment of fractures of the calcaneus: a randomized controlled trial
R.J.O. de Muinck Keizer, M.S.H. Beerekamp, T. Schepers, L.F.M. Beenen, J.S.K. Luitse, M. Maas, J.C. Goslings,on behalf of the EF3X-studygroup
Submitted

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Systematic CT Evaluation of Reduction and Hardware Positioning of Surgically Treated Calcaneal Fractures: a Reliability Analysis
R.J.O. de Muinck Keizer, M.S. Beerekamp, D.T. Ubbink, L. Beenen, T. Schepers, J.C. Goslings
Submitted

Post-traumatic Subtalar Arthrosis: which grading system should we use?
R.J.O. de Muinck Keizer, M. Backes, S. Dingemans, J.C. Goslings, T. Schepers
Int Orthop. 2016 Sep;40(9):1981-5.

Articular Gap and Step-Off Revisited: 3D Quantification of Operative Reduction for Posterior Malleolar Fragments
R.J.O. de Muinck Keizer, D.T. Meijer, B.AT.D. van der Gronde, T. Teunis, S.A.S. Stufkens, G.M.M.J. Kerkhoffs, J.C. Goslings, J.N. Doornberg
J Orthop Trauma. 2016 Dec;30(12):670-675.

Other publications

A randomized controlled trial of nonoperative treatment versus open reduction and internal fixation for stable, displaced, partial articular fractures of the radial head: the RAMBO trial.
W. Bruinsma, I.F. Kodde, R.J.O. de Muinck Keizer, N.W.L. Schep, D. Eygendaal, RAMBO-Studygroup
BMC Musculoskelet Disord. 2014 May 6;15:147

Mason type 1 fractures of the Radial Head: A systematic review of the literature
R.J.O. de Muinck Keizer, M.M.J. Walenkamp, J.C. Goslings, N.W.L. Schep
Orthopedics. 2015 Dec;38(12):e1147-54.

The Minimal Clinically Important Difference Of The Patient-Rated Wrist Evaluation Score For Patients With Distal Radius Fractures. A Prospective Cohort Study.
M.M.J. Walenkamp, L.M. Vos, R.J.O. de Muinck Keizer, J.C. Goslings, N.W.L. Schep
Clin Orthop Relat Res. 2015 Oct;473(10):3235-41

Prospective Computed-Tomography analysis of osteochondral defects of the ankle joint associated with ankle fractures
T.L. Nosewicz, M.S.H. Beerekamp, R.J.O. de Muinck Keizer, T. Schepers, M. Maas, C.N. van Dijk, J.C. Goslings
Foot Ankle Int. 2016 Aug;37(8):829-34.

A clinical audit: determination of pathogens in postoperative wound infection in surgically reduced calcaneal fractures and implications for prophylaxis and treatment.
M. Backes, I.J.B. Spijkerman, R.J.O. de Muinck Keizer, J.C. Goslings, V.M. de Jong, J.S.K. Luitse, T. Schepers
Submitted

Letter to the Editor: Intraoperative Syndesmotic Reduction: Three-Dimensional Versus Standard Fluoroscopic Imaging.
R.J.O. de Muinck Keizer, J.C. Goslings, on behalf of the EF3X-group
Unfallchirurg. 2014 Mar;117(3):262.

Lateraal onderlangs anguleren! Uniforme terminologie tijdens Röntgendoorlichting op de operatiekamer.
R.J.O. de Muinck Keizer, D.S. Klei, P.J. van Koperen, C.N. van Dijk, J.C. Goslings
Nederlands Tijdschrift voor Traumachirurgie, 2015 nov

State of the Art: correctie van malunions van de radius met behulp van 3D modellen.
M.M. Walenkamp, R.J.O. de Muinck Keizer, J.C.G. Dobbe, S.D. Strackee, N.W.L. Schep
Nederlands Tijdschrift voor Traumachirurgie, 2015 okt

Guesstimation of posterior malleolar fractures on lateral radiographs.
DT Meijer, JN Doornberg, IN Sierevelt, WH Mallee, CN van Dijk, GMMJ Kerkhoffs, SA Stufkens, Ankle Platform Study Collaborative – Science of Variation Group
Injury. 2015 Oct;46(10):2024-9

Cast immobilization with and without immobilization of the thumb for nondisplaced and minimally displaced scaphoid waist fractures: a multicenter, randomized, controlled trial.
GA Buijze, JC Goslings, SJ Rhemrev, AA Weening, B van Dijkman, JN Doornberg, D Ring, CAST Trial Collaboration
J Hand Surg Am. 2014 Apr;39(4):621-7.

Functional outcomes after distal radius fractures with and without a concomitant ulnar styloid process fracture; a meta-analysis
M.A.M. Mulders, L.J. Fuhri Snethlage, R.J.O. de Muinck Keizer, J.C. Goslings, N.W.L. Schep
Submitted

3D Quantification of Posterior Malleolar Fragment-Reduction Predicts Clinical Outcome in a Prospective Trial
D.T. Meijer, R.J.O. de Muinck Keizer, B.van der Gronde, T. Teunis, S.A.S. Stufkens, J.N. Doornberg, T. Schepers, G.M. Kerkhoffs, J.C. Goslings
With authors.

Posterior Malleolar Fracture Morphology Determines Outcome in Rotational Type Ankle Fractures: A Prospective Clinical Trial
R.P. Blom, D.T. Meijer, R.J.O. de Muinck Keizer, S.A. Stufkens, I. Sierevelt, T. Schepers, G.M. Kerkhoffs, J.C. Goslings, J.N. Doornberg, on behalf of the EF3X-trial Study Group
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Odor recognition memory is not independently impaired in Parkinson's disease.
S. Boesveldt, R.J.O. de Muinck Keizer, ECh. Wolters, H.W. Berendse
J Neural Transm (Vienna). 2009 May;116(5):575-8

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S. Boesveldt, R.J.O. de Muinck Keizer, D.L. Knol, ECh. Wolters, H.W. Berendse
Mov Disord. 2009 Jan 15;24(1):85-90

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DANKWOORD

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Terugkijkend op 5 jaar onderzoek, hebben veel mensen direct en indirect bijgedragen aan het feit dat dit proefschrift bij de drukker terecht is gekomen.
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Liefde. In 2008 danste jij mijn leven in, en sindsdien krijgt alles vorm. Ik ben de gelukkigste man op aarde dat ik elke ochtend weer met jou aan een nieuwe dag mag beginnen. Mijn dank is zoveel groter dan dit boekje.
De lucht is terug. Zullen we…? Bichamtete ♥

CONFLICTS OF INTEREST STATEMENT

CONFLICTS OF INTEREST STATEMENT

During 2012-2015 Robert-Jan de Muinck Keizer was employed by the AMC Research BV, which received an unrestricted grant from Philips Healthcare, Best, the Netherlands and the AO Foundation, Davos, the Netherlands.