# OPTIMIZING PATIENT OUTCOMES IN PELVIC FRACTURES

# HEALTH-RELATED QUALITY OF LIFE & 3D PRINTING



LARS BROUWERS

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**3D PRINTING** 

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#### Colofon

Phd-thesis, entitled:' Optimizing patient outcomes in pelvic fractures; Healthrelated quality of life & 3D printing,'Radboud University Nijmegen, with a Dutch summary.

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The work presented in this thesis was carried out within the Radboud Institute for Health Sciences.

Printing of this thesis was financially supported by:

Radboud University, Elisabeth-Tweesteden ziekenhuis, vakgroep Chirurgie Midden-Brabant, Netwerk Acute Zorg Brabant, Nederlandse Vereniging voor Traumachirurgie, AO Trauma Europe, stichting Traumaplatform, Oceanz 3D printing, ABN AMRO, Chipsoft, Lay3rs 3D printing, KLS Martin, HC Den Bosch H4, Sectra, Ultimaker.

Cover design and lay-out:	Jesse Haaksman, persoonlijkproefschrift.nl
Printing:	Gildeprint Enschede, gildeprint.nl
ISBN:	978-94-6419-201-8

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# OPTIMIZING PATIENT OUTCOMES IN PELVIC FRACTURES HEALTH-RELATED QUALITY OF LIFE & 3D PRINTING

Proefschrift

ter verkrijging van de graad van doctor aan de Radboud Universiteit Nijmegen op gezag van de rector magnificus prof. dr. J.H.J.M. van Krieken, volgens besluit van het college van decanen in het openbaar te verdedigen op woensdag 8 september 2021 om 16.30 uur precies

door

Lars Brouwers

geboren op 20 mei 1988 te Son en Breugel

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Prof. dr. M.J.R. Edwards Prof. dr. M. Poeze, Maastricht UMC+

#### Copromotoren

Dr. M.A.C. de Jongh, Elisabeth-Tweesteden Ziekenhuis Dr. K.W.W. Lansink, Elisabeth-Tweesteden Ziekenhuis

#### Manuscriptcommissie

Prof. dr. B.W. Schreurs Prof. dr. T.J.J. Maal Prof. dr. M.H.J. Verhofstad, Erasmus MC Voor James

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# CHAPTER 1

**General introduction** 

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### **General introduction**

#### History of pelvic fracture management

The history of pelvic fractures goes all the way back to ancient Egypt and China, where mummified bodies with an overlapping symphysis were found.<sup>1,2</sup> It is also believed that William the Conqueror (1028-1087), king of England, died in 1087 due to complications of a pelvic injury.<sup>1</sup> He injured himself by the pommel of his saddle during an expedition.<sup>3</sup> Joseph-François Malgaigne (1806–1865), a French surgeon, published multiple textbooks on the management strategies of fractures and dislocations. He described the "Malgaigne fracture", a fracture that was associated with people jumping from buildings, currently called a jumpers' fracture. The fracture consists of a H-shaped sacral vertical shear fracture.<sup>4,5</sup> After the introduction of X-rays in 1895, invented by Wilhelm Conrad Röntgen (1845–1923), the world of pelvic surgery changed. In 1948, Sir Frank Wild Holdsworth (1904–1969), a British orthopedic surgeon and professor, reported fifty cases of pelvic ring disruptions.<sup>6</sup> By using X-rays, he discovered two types of pelvic disruptions: 1). pubic injury with sacro-iliac dislocation and 2) pubic injury with fracture near the sacro-iliac joint. In fact, Holdsworth described the "open book", lateral compression and vertical shear fractures as we currently know them. He treated patients conservatively with a pelvic sling technique (fig. 1) and used outcomes of return to work. Holdsworth potentially was the first to describe quality of life outcomes.

#### Pelvic classification system

George Pennal (1913–1976) was one of the pioneers of the pelvic classification system as we currently know it. In the 1950s, together with Sutherland, he defined a system of pelvic ring fractures based on three forces: anterior-posterior compression type, lateral compression type and vertical shear.<sup>7</sup> This classification system was modified by Marvin Tile.<sup>8,9</sup> The Tile classification consists of type A (A1, A2, and A3; stable fractures), type B (B1, B2, and B3; rotationally unstable) and type C (C1, C2, and C3; rotationally and vertically unstable).<sup>10</sup>

The Young and Burgess classification<sup>11</sup> is based on the original Pennal-Sutherland description. The AO/OTA classification<sup>12</sup> is based on the Tile classification (fig. 2).

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Figure 1 | Original photograph of a patient, treated with a pelvic sling technique

Developed by Astley Cooper (1842) and modified by Bohler (1935). Copy right: Holdsworth's 1948.



Figure 2 | Modified Tile classification according to AO/OTA for pelvic ring fractures

A-type fractures: lesion sparing (or no displacement of) posterior arch. B-type fractures: incomplete disruption of posterior arch, partially stable. C-type fractures: Complete disruption of posterior arch, unstable.

#### Acetabular classification system

From 1950-1960, Robert Judet (1909-1980), an orthopedic surgeon in Paris, investigated acetabular fracture treatment.<sup>13</sup> Judet described 10 types of acetabular fractures and divided them into two groups: elementary and associated fractures. Judet also invented an extra X-ray view, the oblique pelvis view (also known as the Judet view). This view contained an additional projection to the conventional pelvic series in case of a suspect acetabular fracture.

Student Émile Letournel (1927–1994) continued these investigations under the supervision of Judet.<sup>14</sup> Together, they invented the Judet-Letournel classification, the most commonly used classification in acetabular fracture surgery.<sup>15</sup> The Judet-Letournel classification consists of 5 simple fractures, namely, the posterior wall, posterior column, transverse, anterior column and anterior wall fractures, and 5 associated (complex) fractures, namely, the posterior column/posterior wall, transverse/posterior wall, T-shaped, anterior column/posterior hemitransverse and both column fractures (fig. 3).

Tile, Judet and Letournel are the founding fathers of pelvic, acetabular surgical and conservative treatment. Due to their pioneering work, we are able to understand fracture patterns, classify fractures and choose the appropriate surgical or conservative treatment. However, the treatment of pelvic fractures could still improve. One way could be to optimize the pre-operative work up and ensure optimal surgical conditions. Another way is to measure the quality of life after pelvic fracture injury to gain a better understanding of the burden of pelvic injury.



Figure 3 | Judet-Letournel classification

Judet-Letournel classification consists of 5 elementary fractures and 5 associated fractures.

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## THESIS PART I

#### Functional and radiological outcomes

While one hundred years ago, patients with pelvic fractures had poor survival outcomes, much has changed during the last 3 centuries. Pelvic fracturerelated innovations and the implementation of an organized trauma system enabled a significant reduction in injury-related mortality near the end of the 20<sup>th</sup> century.<sup>16</sup> The introduction of the Advanced Trauma Life Support (ATLS) guidelines in 1978 led to the professionalization of resuscitation strategies and the acute management of pelvic hemorrhage.<sup>17</sup> However, the initial management of pelvic fractures still consists of a sheet, pelvic binder or other device that reduces the pelvic volume, reduces retroperitoneal blood loss and stabilizes the pelvis. However, with the introduction of external fixators<sup>18</sup> and internal fixation techniques<sup>19</sup>, surgeons are able to choose if they would like to treat a patient in conservatively or surgically. It is now well understood that surgical fixation of unstable pelvic fractures leads to better functional outcomes and early mobilization. Currently, the incidence of all pelvic fractures in the Netherlands is 14.3 per 100,000 people. The in-hospital mortality rate for all pelvic fracture patients in the Netherlands has decreased to 5.1%.<sup>20</sup>

Due to low mortality rates at the end of the 20<sup>th</sup> century, the focus of outcome shifted to radiological and functional outcomes after pelvic trauma.<sup>21-24</sup> An important radiological scoring system was invented by Joel Matta, an orthopedic surgeon from the USA. He developed a scoring system for measuring the postoperative reduction of acetabular fractures<sup>25</sup> and used X-rays to grade the reduction as anatomical, imperfect, and poor reduction.

Although these "non-fatal" radiological and functional outcomes are of interest for medical doctors, this interest is not shared by patients. Patients may suffer greatly after trauma due to physical discomfort, mental problems and social isolation. Daily activities, such as work or leisure activities, may become difficult. Therefore, an improved understanding of the full spectrum of the societal impact and burden of injury is needed.

#### Health-related quality of life

Currently, the improved quality of medical care should be a reason for surgeons to concentrate not only on the survival rates but also on the patients' perception, social impact and discomfort. An improved understanding of these consequences of non-fatal injuries is needed to evaluate different treatment options, investigate injury prevention research and eventually ensure patient-specific customized treatment.

The individual's well-being, which changes over time after injury, can be best measured using a health-related quality of life (HRQoL) assessment. HRQoL is a multidimensional concept that includes social, physical, and psychological functioning.<sup>26</sup> Both the ability to carry out pre-defined (objective) activities and the individual's subjective feelings are measured using this concept. Many instruments, both generic and disease-specific, for measuring HRQoL have been developed over the years. Generic HRQoL measures data and is used to compare outcomes across different populations. Disease-specific outcomes are used to measure the efficacy of interventions and treatments.<sup>27</sup> A combination of a generic and disease-specific instruments is generally considered to be optimal to investigate the HRQoL.

#### Aim of this thesis, part I

In this thesis, we will perform research to optimize the outcomes of patients with pelvic fractures. Pelvic fractures might have long-term consequences in terms of decreased HRQoL in both younger patients<sup>28</sup> and elderly patients.<sup>29</sup> In 1986, Matta et al. took some cautious first steps to measure HRQoL by modifying the Merle d'Aubigné-Postel Score.<sup>30,31</sup> This questionnaire is currently the most generally used clinical grading system for evaluating outcomes after an acetabular fracture and measures pain, ambulation and mobility.

HRQoL assessments of patients with pelvic fractures can provide an improved understanding of injury outcomes, better identification of risk groups of poor outcomes and new insights into how disability following injury can be reduced. However, at this point, hospital data systems and trauma registries are commonly not sufficiently well equipped to collect long-term HRQoL outcomes.<sup>32</sup>

In recent years, a couple of prognostic factors for decreased HRQoL after pelvic trauma have been described. However, most studies that focus on these prognostic factors are single-center, retrospective, and cross-sectional in nature or consist of small samples with a follow-up starting 1 year after trauma.<sup>33-38</sup> The purpose of this thesis is to investigate the short-, mid- and long-term HRQoL following pelvic fractures in a larger prospective sample of patients. Patient-related subgroups with poor physical or mental health outcomes will be identified, and pelvic fracture treatment will be customized. The hypothesis is that, especially in short-term HRQoL, interesting recovery patterns will be identified. Furthermore, several confounders will influence the rehabilitation of patients with pelvic fractures.

# THESIS PART II

#### The history of 3D printing

In 1981, Dr. Hideo Kodama, from the Japanese Municipal Industrial Research Institute in Nagoya, developed a patent in which a laser beam resin curing system was described; this system was first 3D printing device.<sup>39</sup>

In 1984, 3 French researchers (Alain Le Méhauté, Olivier de Witte, and Jean Claude André)<sup>40</sup> and an American scientist (Charles Hull) used the same technique to create a 3D-printed system, curing photosensitive resin layer by layer.<sup>41</sup> Mr. Hull filed the patent for the Stereolithography Apparatus (SLA) in the same year and started 3D Systems, the first 3D printing company in the world, in 1986. His company commercialized the first 3D printer, the SLA-1 printer, in 1987 (fig. 4).<sup>42</sup>

In 1988, Carl Deckard, a student from the University of Texas, invented another technique, called Selective Laser Sintering (SLS).<sup>43</sup> Although it is currently the simplest 3D printing technique, "Fused Deposition Modeling" (FDM) was patented last. Scott Crump, co-founder of Stratasys (Minnesota, USA) in 1989, received a patent for this technique from the US government in 1992.<sup>44</sup> Medicine was one of the first industries to implement FDM technology. Today, approximately twenty-four 3D printing techniques exist (fig. 5), and many companies produce and market 3D printers.<sup>45</sup>

Figure 4 | the SLA-1 printer Figure 5 | Examples of FDM 3D printers



Build in 1987



Printers used in ETZ, Radboudumc and the Masanga Hospital, Sierra Leone.

#### **Explaining 3D printing techniques**

3D printers have become widely available, and in particular, the FDM technique is relatively inexpensive. There are three main categories of 3D printing techniques. 1) Extrusion: FDM uses polylactic acid (PLA), a thermoplastic filament that is

heated and extruded through an extrusion head that deposits the plastic layer by layer on a plate. FDM is the most common 3D printing technique used in desktop 3D printing. 2) Resin: a liquid resin is cured by a laser or ultraviolet light. The most common technique is called SLA. 3) Powder: a powdered material is melted together by a laser. SLS is the most common technique in this category. Laser sintering can be used to create metal, plastic, and ceramic objects.

#### 3D printing in healthcare

3D printing is an innovative technology that has been used across many medical specialties for numerous applications.<sup>46</sup> 3D printing allows a virtual 3D reconstruction to be realized as a physical object using only a printer. Medical 3D printing has applications in cardiac, neurological, maxillofacial, spinal, and orthopedic surgery.<sup>47</sup> In addition to printing anatomical models, molds, custommade implants and prostheses, in the future, it will be possible to 3D print tissue, organs and drugs.<sup>48</sup> Tissue engineering has become a promising field of research, offering hope for bridging the gap between organ shortage and transplantation needs. However, many challenges have to be overcome before 3D bioprinting of fully functional vascularized organs is possible.49 Currently, medical 3D printing is no longer exclusively available for large first-world hospitals; thirdworld hospitals have also adopted medical 3D printing to print prostheses for handicapped people, spare parts and educational models for students (fig. 6).<sup>50</sup> Although medical 3D printing has been used since the 1990s, it did not become a trending topic until 5 years ago. In 2016, Tack et al. summarized 227 papers about medical 3D printing and found that the number of medical papers has grown exponentially since 2011 (fig. 7).47 Anatomical models and molds were most frequently printed, and maxillofacial surgeons and orthopedic surgeons were the most frequent 3D printing users. The researchers concluded that the lack of evidence for the supposed advantages of reduced surgical time and improved medical outcome did not allow for conclusive statements. These authors suggest that further research is needed to determine whether the increased intervention costs can be balanced with the observable advantages of 3D printing.

#### Aim of this thesis, part II

Pelvic fractures are complex injuries and are difficult to interpret due to varied fracture lines traversing this complex three-dimensional anatomy. Due to the surrounding tissues and the three-dimensional anatomy, an extensive knowledge of the surgical approach is needed. Several (inter)national steps have been taken to improve the outcome of patients with pelvic fractures.

In addition to the Judet-Letournel classification and Tile classification to ensure a proper understanding of the anatomy, the addition of 3D CT scan has gained popularity in the identification of fracture patterns and education about pelvic fractures. 3D CT images are easier to interpret than axial CT images<sup>51</sup>, which can help to achieve a better anatomical reduction and can reduce surgical time.<sup>52,53</sup> Hu et al. found that less experienced surgeons in particular take advantage of virtual 3D planning of acetabular fractures.<sup>54</sup>

Furthermore, the Dutch Trauma Society (NVT) develops quality standards to improve trauma care. These standards serve as information platforms for patients, hospitals, health insurance companies and other stakeholders. Pelvic fractures were the first to be included to improve the outcomes of these severely injured patients.

Figure 6 | patients in Sierra Leone



Patients with 3D printed prosthesis

Sustaining a pelvic fracture can have large impacts on both the patient and society. Rehabilitation is lengthy, and patients are at risk for a low HRQoL. Surgical procedures and hospitalization are expensive,<sup>55</sup> and a significant percentage of patients do not return to work. Therefore, the surgical treatment of acetabular fractures can be seen as a surgically, economically and socially relevant topic.

3D printing is thought to offer advantages for understanding fractures, reducing surgical time, and improving in patient outcome, understanding and surgical

confidence during operations. 3D printing could be a cost-effective solution to help surgeons inform patients, treat fractures and ensure good functional outcomes. However, there are few studies available supporting these claims with hard data. Further research is needed to determine whether the increased intervention costs can be balanced with the observable advantages from 3D printing.

Our hypothesis is that 3D printing can be of added value in the surgical treatment of pelvic fractures due to the complex anatomy and difficultly of surgical treatment. In this thesis, we evaluate the value of 3D printing in the treatment of isolated acetabular fractures. The added value of 3D printing could possibly lead to improved radiological, functional and HRQoL outcomes of patients. Furthermore, patient-understanding and patient-satisfaction could improve by the use of 3D-printed models in the outpatient clinic or wards.



Figure 7 | Overview of selected papers based on publication year

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# Outline of this thesis

In this thesis, we present two techniques to improve and optimize patient outcomes of pelvic fractures: **Part I**; measuring quality of Life and **Part II**; 3D printing.

## Part I

Only a few studies have focused on HRQoL after pelvic ring injury. There are two types of HRQoL instruments: generic and disease-specific measurement instruments. Although a generic instrument measures the HRQoL of the patient, injuries of specific individuals may not be addressed, and disease-specific complaints may not be noted. Few studies have combined both types of instruments. These HRQoL studies have included only patients with surgically treated pelvic ring fractures and an Injury Severity Score (ISS) or did not include all Tile-type fractures. The main purpose of **CHAPTER 2** was to provide a cross-sectional overview of the HRQoL of all Tile-type pelvic ring fractures and to evaluate HRQoL questionnaire outcomes between different Tile groups.

Several pelvic-specific measurement instruments have been developed, but there is no gold standard available. Furthermore, no norm scores have been provided that can be used as reference values for comparison with the general population. In **CHAPTER 3**, we will investigate the differences in the Majeed Pelvic Score (MPS) between injured and uninjured patients. Furthermore, the discriminative power and applicability of the MPS in elderly populations are explored, and we will provide a norm score for the MPS in the Netherlands.

Although it is known that patients with pelvic ring fractures due to a highenergy trauma (HET) have low functional outcomes and frequent pain during follow-up, only a few studies have focused on long-term HRQoL outcomes. The study in **CHAPTER 4** was conducted to determine the long-term (5-10 years) HRQoL in patients with pelvic ring fractures due to a HET.

The Brabant Injury Outcome Surveillance (BIOS) study is a prospective longitudinal follow-up study of all the admitted adult injury patients in the region of Noord-Brabant. As part of this study, we performed follow-up of all the admitted pelvic fracture patients. In **CHAPTER 5**, we provide insight into the short-term HRQoL and identify prognostic factors of worse outcome in the first year after pelvic injury.

## Part II

3D printing of patient-specific anatomical models could contribute to a better understanding of the surgical approach and reduction and fixation of fractures, especially in complex fractures such as acetabular fractures. However, it is unclear how a 3D-printed model relates to a human bone. In **CHAPTER 6**, we conduct a validation study in which we compare human cadavers with 3D-printed models to test the accuracy of 3D printing.

Acetabular fractures are complex and difficult to classify. Although the Judet-Letournel classification is designed to increase the understanding of acetabular fractures, it remains prone to error when using conventional medical imaging. In **CHAPTER 7**, we introduce 3D printing as a new diagnostic imaging tool. Will this approach lead to increased understanding and knowledge of acetabular fractures and an optimal surgical approach?

A life-size pelvic model takes more than a day to produce, and errors can occur during this printing process. Therefore, a 3D-printed model cannot be used in emergency settings. A virtual model can overcome these errors. Virtual reality (VR) can also offer a 'real' 3D view. In **CHAPTER 8**, we conduct a study in which we investigate the value of 3D-VR in understanding acetabular fractures.

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# **CHAPTER 2**

Quality of life after pelvic ring fractures: A cross-sectional study

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Injury 2018, 49(4), 812-818

## ABSTRACT

#### Background

Pelvic ring fractures might have consequences for health-related quality of life (HrQoL). The main purpose of this study was to evaluate patients' HrQoL after a pelvic ring fracture, considering the patients' characteristics. A cross-sectional study was conducted using the EuroQoL-5D (EQ-5D) and the Majeed pelvic score (MPS).

#### Methods

One hundred ninety-five patients (86%) with pelvic ring fractures who were conservatively or surgically treated in a level 1 trauma centre between 2011 and 2015 were included in this study (mean follow up: 29 months, range 6–61). A telephone survey of all patients was conducted. Multiple logistic and linear regression analyses were used for statistical assessment with the EQ-5D and the MPS. The MPS results were split into two age groups with a cut-off point of 65 years.

#### Results

EQ-5D: The mean EQ-5D Visual Analogue Scale (VAS) for Tiles A–C was, respectively, 74 (SD 18), 74 (SD 19) and 67 (SD 21), and the mean EQ-5D index score was, respectively, 0.81 (SD 0.23), 0.77 (SD 0.30) and 0.71 (SD 0.26). Compared with Tile A, patients in Tile C experienced significantly more pain (odds ratio 6.28 (1.73–22.82 95% CI), P < 0.01). Clinically relevant differences in EQ-5D scores between Tile A and Tile C were seen in the domains of usual activities and anxiety and in the index score.

MPS: The mean MPS of Tiles A–C patients in the <65 group was, respectively, 86 (SD 15), 81 (SD 17), and 74 (SD 16), and in the ≥65 group, it was, respectively, 69 (SD 15), 68 (SD 15) and 66 (SD 9). In the <65 group, significant differences in MPS results between the Tile groups regarding pain (P < 0.01) and the total MPS score (P = 0.04) were seen. Neither significant regression coefficients nor clinically relevant differences were found in the ≥65 group.

#### Conclusions

In conclusion, our study showed that pain was increased in patients with Tile C fractures, compared with Tiles A and B. Furthermore, Tile C patients had significantly lower EQ-5D index and total MPS scores. However, these problems were not seen in the  $\geq$  65 group.

# Background

Pelvic ring injuries are relatively rare, with an incidence ranging from 3 to 23 per 100.000 persons per year<sup>1,2</sup> Pelvic fractures generally occur as a result of high impact trauma in younger patients, whereas these fractures mostly occur as a result of low impact falls and osteoporotic changes in elderly patients.<sup>3-7</sup>

Many studies have focused on radiological and functional outcomes after pelvic injury.<sup>8-11</sup> However, only a few studies have focused on health-related quality of life (HrQoL) after pelvic ring injury.<sup>12-19</sup> These HrQoL studies have included only surgically treated pelvic ring fractures or patients with an Injury Severity Score (ISS)  $\geq$ 16. Other HrQoL studies did not include all Tile-type fractures. Therefore, these studies might not be representative of the total pelvic ring fracture population.

The main purpose of this study was to provide an overview of the HrQoL of all Tile-type pelvic ring fractures and to evaluate HrQoL questionnaire outcomes between different Tile groups. A number of pelvic-specific outcome measures are available; however, none of them have been sufficiently validated.<sup>20</sup> The Majeed pelvic score (MPS) is the most commonly used pelvic specific outcome instrument.<sup>20,21</sup>

The combination of generic and disease-specific instruments provides the opportunity to focus on a specific area without missing important determinants of an individual's health state.<sup>20</sup> Few studies have combined both types of instruments.<sup>17,22,23</sup>

We conducted a cross-sectional study of patients with all types of pelvic ring fractures using generic and pelvic-specific HrQoL instruments, the EuroQoL-5D (EQ-5D) and the MPS. The primary aim in this study was to determine the HrQoL for the different Tile type fractures with the characteristics considered.

## Methods

This study was exempted from the scope of the Medical Research Involving Human Subjects Act (WMO) according to our institutional ethics committee. We used our Hospital Trauma Registry (in which all admitted trauma patients are registered) to identify patients 18 years old and older with a pelvic ring injury who were admitted (or transferred within 48 h from other hospitals) to the Elisabeth-Tweesteden Hospital, a level 1 trauma centre, between January 2011 and June 2015. The mechanisms of injury are shown in Table 1.

Patient, incident and admission characteristics were extracted from the Electronic Medical Registration. Additional injuries according to the specific regions, complications during the admission and possible operations were noted. The Abbreviated Injury Scale (AIS-90, update 98).<sup>24</sup> was used to define the anatomy

and severity of separate injuries in detail. The AIS code ranges one to six, one being a minor injury and six being maximal (currently untreatable). Minor additional injuries (scale: 1) were not included in the analysis. The Injury Severity Score (ISS) was calculated to assess overall injury severity.<sup>25</sup> The Tile/AO classification was used to classify pelvic ring fractures into type A (A1–A3; stable fractures), type B (B1–B3; rotationally unstable) and type C (C1–C3; rotationally and vertically unstable).<sup>26</sup> Classifications were performed by the principal investigator and a senior trauma surgeon experienced in the field of pelvic surgery. They reached mutual consensus on all of the cases. Diagnostic data (X-ray and CT if available) and operation reports were used to classify pelvic ring fractures.

Patients who had insufficient knowledge of the Dutch language and those who were deceased at the time of the questionnaire were not included in the study. A telephone survey of all of the included patients was conducted by a medical doctor, the principal investigator.

A total of 272 patients with pelvic ring fractures were referred to our hospital: 170 A, 73 B and 29C Tile-type fractures. In December 2015, 46 patients had died according to the municipal registration. We did not investigate the causes of death. During the telephone interviews, 10 patients were untraceable (and it was not known whether they were alive or dead), and 2 patients did not want to participate. We excluded 8 patients because of a severe state of dementia, mental illness or a vegetative state. Eleven patients with a follow-up of less than 6 months were excluded due to the possibility of a nonunited pelvic fracture, leaving us with 195 patients (mean follow-up: 29 months, range 6–61) who were available for data collection (Table 2).

	Tile A, %	Tile B, %	Tile C, %
Fall from same level	29	8	0
Fall from height	18	23	28
High-energy traffic accident	31	47	59
Weapon	1	0	3
Other (e.g. entrapment)	21	22	10
Total	100%	100%	100%

Table 1 | Mechanisms of injury

Mechanisms of injury over the different Tyle type fractures

#### EQ-5D and MPS

The EQ-5D is a questionnaire with five dimensions.<sup>27</sup> In the EQ-5D questionnaire, health is defined along the following five dimensions: mobility, self-care, usual activities, pain or discomfort, and anxiety or depression. Each dimension has the following three levels: no problem, moderate problem, or severe problem. The EQ Visual Analogue Scale (EQ VAS) records the patient's self-rated state of health on an analogue scale between 0 (worst imaginable health state) and 100 (best imaginable health state). In addition, a scoring algorithm is available by which each health status description can be expressed as a summary score. This summary score, the EQ-5D index, ranges from 1 for full health to 0 for death and can be interpreted as a judgement of the relative desirability of a health status, compared with perfect health. We compared the EQ-5D indices of patients with a pelvic ring fracture and the average EQ-5D index for the general Dutch population (0.87, SD 0.18).<sup>28</sup>

The MPS consists of the following 7 dimensions: pain (30 points), work (20 points), sitting (10 points), standing (36 points total; A: walking aids, 12 points; B: gait unaided, 12 points; C: walking distance, 12 points), and sexual intercourse (4 points). If, for any reason, sexual intercourse was not attempted, a score of four points was given. Majeed et al.<sup>21</sup> suggested cut-offs for excellent, good, fair, and poor results in patients working before their injury (>85, 70–84, 55–69, <55) and in those not working before the injury (>70, 55–69, 45–54, <45).<sup>21</sup> We updated the terms "(not) working before injury" to the following: "working patients or patients younger than 65 years old (<65 years)" and "retired patients or patients aged 65 years old and older ( $\geq$  65 years)", with maximums of 100 points and 80 points, respectively.

#### Data analysis

Descriptive statistics were used to provide an overview of the patient characteristics. The primary outcome in this study was a comparison of the HrQoL for the different Tile-type fractures with the patient characteristics considered. The variables of sex, ISS, age, additional injuries according to the AIS scale, operation and complications were added to the multiple regression model one by one. Variables were included in the final model if they changed the Beta-coefficient by >10%. The 5 EQ dimensions were dichotomized into "no problems" and "problems" (moderate and severe), and multiple logistic regression was performed. The results are presented as odds ratios (ORs) with 95% confidence intervals (CIs). The continuous variables EQ-5D VAS and Index score were analysed using a multiple linear regression model. The results are presented in Beta-coefficients (B) with 95% CIs.

The MPS analyses were split into two age groups with a cut-off point of 65 years. All of the dimensions and the total MPS scores of the different Tile types were compared and adjusted for confounding using a multiple linear regression model. The patient characteristics of sex, ISS, age, additional injuries according to the AIS scale, operation and complications were tested for confounding. The characteristics with an effect of >10% on the Betacoefficient were included in the model. The Beta-coefficients are presented with 95% CIs. All of the analyses were conducted using SPSS software, version 24.0 (Statistical Package for the Social Sciences, Chicago, IL, USA). A p-value of 0.05 was determined as significant.

## Results

#### **Patient characteristics**

One-hundred one patients with a Tile A fracture, 67 with Tile B fractures and 27 with Tile C fractures met the inclusion criteria and were interviewed, for a response rate of 86% within the survivor group. Table 2 shows the patient characteristics of the different Tile-type fractures. Seventy-seven percent of the Tile A fractures were minimally displaced fractures of the ring (A2.2 fractures). Fifty-two percent of the Tile B fractures were identified as lateral compression injuries (B2.1 fractures), and 37% of the Tile C fractures were unilateral sacral fractures that were rotationally and vertically unstable (C1.3 type) (Appendix A).
	Tile A	Tile B	Tile C
N (%)	101 (52)	67 (34)	27 (14)
Mean ISS (SD)	12 (11)	18 (11)	28 (13)
Gender, N (%)			
Male	47 (46.5)	41 (61.2)	15 (55.6)
Female	54 (54.5)	26 (38.8)	12 (44.4)
Mean age, Yr (SD)	62 (22)	54 (21)	43 (19)
Additional injuries, %			
Region 1, head	27 (26.7)	18 (26.9)	9 (33.3)
Region 2, face	9 (8.9)	6 (9.0)	2 (7.4)
Region 3, neck	2 (2.0)	0	0
Region 4, thorax	19 (18.8)	18 (26.9)	14 (51.9)
Region 5, abdomen	8 (7.9)	10 (14.9)	10 (37.0)
Region 6, spine	8 (7.9)	5 (7.5)	14 (51.9)
Region 7, upper extr.	32 (31.7)	14 (20.9)	10 (37.0)
Region 8, lower extr.	27 (26.7)	21 (31.3)	15 (55.6)
Region 9, unspecified	4 (4.0)	1 (1.5)	0
Operation, N (%)	6 (5.9)	18 (26.9)	22 (81.5)
Complications,%			
Neurological	1.0	3.0	3.7
Infection	5.0	6.0	18.5
Osteosynthesis failure	1.0	0	7.4
Mean length of follow up, in months (SD)	28 (16)	30 (16)	33 (16)

#### Table 2 | Patient characteristics

Data represents patient characteristics over the different Tile-type fractures.

#### EQ-5D

The majority of Tile A and tile B patients had no problems regarding any of the EQ-5D dimensions. In Tile C patients, pain was the only dimension with more than half of the patients suffering from moderate or severe pain (Table 3). The mean EQ-5D VAS for Tiles A–C, respectively, was 74 (SD 18), 74 (SD 19) and 67 (SD 21). The mean EQ-5D index score was for Tiles A–C, respectively, was 0.81 (SD 0.23), 0.77 (SD 0.30) and 0.71 (SD 0.26) (Table 3).

Table 4 shows the logistic regression coefficients for changes in the 5 dimensions when dichotomized into "problems" or "no problems" and the linear regression coefficients for changes in EQ5D VAS and Index score. All of the dimensions were adjusted for age, sex, pelvic operation, ISS and injury of the spine. Considering these confounders, the only significant differences were found in the dimension of pain between Tile A and Tile C (OR 6.28 (1.73– 22.82 95% CI), p = 0.005) and between Tile B and Tile C (OR 3.33 (1.04–11.08 95% CI), p = 0.049) and in the dimension of usual activities between Tile A and Tile C (OR 3.98 (1.01–15.68 95% CI), p = 0.048). Non-significant differences were found between the different Tiles in the dimensions of mobility, self-care and anxiety. In the EQ-5D index score, a significant Beta-coefficient was found between Tile A and Tile C (p = 0.037). The EQ-VAS was neither significantly different nor clinically different among the Tile groups.

## Majeed pelvic score

The mean MPS of Tiles A–C patients in the <65 group (N = 113) was, respectively, 86 (SD 15), 81 (SD 17) and 74 (SD 16) of the maximum score of 100 points. The mean MPS of Tile A–C patients in the  $\geq$  65 group (N = 82) was, respectively, 69 (SD 15), 68 (SD 15) and 66 (SD 9) of the maximum score of 80 points. Sexual intercourse was not attempted by 34 patients in the <65 group and 59 patients in the  $\geq$  65 group.

The mean scores of all dimensions are shown in Table 5. Appendix B shows the original MPS results split into Tile A–Tile C. Twenty-two percent (N = 22) of the <65 group scored a maximum of 100 points (12 Tile A, 10 Tile B, 0 Tile C), while 34% (N = 28) of the <65 group scored a maximum of 80 points (19 Tile A, 9 Tile B, 0 Tile C).

Table 6 shows the adjusted linear regression coefficients for change in MPS dimensions split into <65 and  $\geq$ 65 years. In the <65 group, a significant Beta-coefficient was found between Tile A and Tile C and between Tile A and Tile B in the dimension of pain. Patients with a Type C fracture were 6.95 (2.29–11.60) times more likely to have pain at follow-up than those with Tile A. Patients with Tile B fractures were 3.53 (0.58–6.48) times more likely to have pain at follow-up than those pain at follow-up than those with Tile A. No differences were found in the  $\geq$ 65 group.

Patients <65 with Tile C fractures scored significantly lower on the total MPS score than those with Tile A (P = 0.045). The total MPS score in the  $\geq$ 65 group was not significantly difference among the Tile groups.

	Tile A	Tile B	Tile C
Mobility No problems, %	52	57	52
Moderate problems, %	47	42	48
Severe problems, %	1	2	0
Self-care No problems, %	71	81	85
Moderate problems, %	19	12	15
Severe problems, %	10	7	0
Usual activities			
No problems, %		73	59
Moderate problems, %	22	21	41
Severe problems, %	8	6	0
Pain			
No problems, %		55	33
Moderate problems, %	31	34	48
Severe problems, %	4	10	19
Anxiety/ depression			
No problems, %	86	78	67
Moderate problems, %	14	21	33
Severe problems, %	0	1	0
EQ-VAS, mean (SD)	74 (18)	74 (19)	67 (21)
EQ-5D Index, mean (SD)	0.81 (0.23)	0.77 (0.30)	0.71 (0.26)

# Table 3 | EQ-5D split into Tile A–C.

Data represents the different EQ-5D dimensions split into Tile A, B and C.

		Odds Ratio (95% CI)	Odds Ratio (95% CI)		P-value*
Mobility					
Tile	A–Tile B	0.88 (0.47-1.63)	1.18	(0.58–2.39)	0.637
Tile	A–Tile C	1.00 (0.43-2.35)	1.52	(0.44–5.34)	0.506
Tile	B–Tile C	1.15 (0.47–2.83)	1.29	(0.40-4.15)	0.669
Self-care					
Tile	A–Tile B	0.61 (0.29–1.29)	0.72	(0.31–1.68)	0.338
Tile	A–Tile C	0.43 (0.14–1.34)	0.77	(0.14-4.42)	0.777
Tile	B–Tile C	0.70 (0.21–2.36)	1.08	(0.22–5.80)	0.928
Usual activit	ies				
Tile	A–Tile B	0.94 (0.47–1.88)	1.18	(0.55–2.55)	0.671
Tile	A–Tile C	1.68 (0.70-4.06)	3.98	(1.01–15.68)	0.049
Tile	B–Tile C	1.80 (0.70-4.60)	3.37	(0.92–12.27)	0.066
Pain					
Tile	A–Tile B	1.59 (0.84–3.01)	1.88	(0.94–3.75)	0.073
Tile	A–Tile C	3.71 (1.51–9.13)	6.28	(1.73–22.82)	0.005
Tile	B–Tile C	2.33 (0.91–5.96)	3.33	(1.04–11.08)	0.049
Anxiety/dep	ression				
Tile	A–Tile B	1.84 (0.82–4.13)	2.27	(0.94–5.44)	0.067
Tile	A–Tile C	3.07 (1.15-8.18)	3.05	(0.71–13.02)	0.133
Tile	B–Tile C	1.67 (0.62-4.47)	1.34	(0.36–5.03)	0.651
EQ-VAS, mea	an (SD)				
Tile	A–Tile B	-1.17 (7.16 to 4.81)	-2.38 (-	-8.64 to 3.88)	0.453
Tile	A–Tile C	-7.56 (15.71 to 0.59)	-5.54 (	-16.66 to 5.57)	0.326
Tile	B–Tile C	-6.38 (14.99 to 2.21)	-3.15 (-	13.61 to 7.29)	0.552
EQ-5D Index	, mean (SD)				
Tile	A–Tile B	-0.04 (-0.12 to 0.04)	-0.07 (	-0.15 to 0.01)	0.116
Tile	A–Tile C	-0.09 (-0.21 to 0.02)	-0.16 (-	0.31 to 0.01)	0.037
Tile	B–Tile C	-0.05 (-0.17 to 0.06)	-0.09 (	-0.23 to 0.05)	0.199

Table 4 | Multiple logistic- and linear regression coefficients for change in EQ-5D score

Data represents multiple logistic- and linear regression coefficients for change in EQ-5D score dichotomized into "no problems" or "problems". Tile A, compared with Tile B and Tile C, and Tile B compared with Tile C. \*Adjusted for age, gender, pelvic operation, ISS and Injury of the spine.

Tile A	Tile B	Tile C	Tile A	Tile B	Tile C
< 65			>65		
27.92 (4)	25.00 (7)	22.72 (9)	28.55 (3)	27.27 (5)	26.00 (4)
12.87 (7)	11.47 (8)	7.82 (6)	-	-	-
8.78 (2)	8.36 (2)	8.00 (2)	9.13 (2)	9.00 (2)	8.40 (2)
3.65 (1)	3.71 (1)	3.23 (1)	3.98 (1)	4.00 (1)	4.00 (1)
11.35 (2)	11.42 (2)	11.45 (2)	9.24 (3)	9.64 (3)	10.40 (3)
10.65 (2)	10.53 (2)	10.27 (2)	8.84 (4)	8.82 (4)	8.40 (4)
10.26 (2)	10.40 (2)	9.82 (2)	8.84 (3)	8.73 (3)	8.40 (3)
85.89 (15)	81.02 (17)	73.77 (16)	68.55 (15)	67.55 (15)	65.60 (9)
	Tile A <65 27.92 (4) 12.87 (7) 8.78 (2) 3.65 (1) 11.35 (2) 10.65 (2) 10.26 (2) 85.89 (15)	Tile A     Tile B       <65	Tile A         Tile B         Tile C           <65	Tile A         Tile B         Tile C         Tile A           <65	Tile A         Tile B         Tile C         Tile A         Tile B           <65         >65           27.92 (4)         25.00 (7)         22.72 (9)         28.55 (3)         27.27 (5)           12.87 (7)         11.47 (8)         7.82 (6)         -         -           8.78 (2)         8.36 (2)         8.00 (2)         9.13 (2)         9.00 (2)           3.65 (1)         3.71 (1)         3.23 (1)         3.98 (1)         4.00 (1)           11.35 (2)         11.42 (2)         11.45 (2)         9.24 (3)         9.64 (3)           10.65 (2)         10.53 (2)         10.277 (2)         8.84 (4)         8.82 (4)           10.26 (2)         10.40 (2)         9.82 (2)         8.84 (3)         8.73 (3)           85.89 (15)         81.02 (17)         73.77 (16)         68.55 (15)         67.55 (15)

**Table 5** | MPS split into age and Tile A–Tile C.

Results expressed in mean (SD).

		< 65 N=113			≥ 65 N= 82	
	B-coefficient (95% CI)	B-coefficient (95% CI)*	P-value*	B-coefficient (95% CI)	B-coefficient (95% CI)*	<i>P</i> -value*
Pain	· ·					
Tile A – Tile B –2.	94 (-5.700.17)	-3.53 (-6.480.58)	0.019	-1.25 (-3.21 – 0.72)	-1.46 (-3.52 – 0.61)	0.164
Tile A – Tile C -5.	21 (-8.581.83)	-6.95 (-11.60 – -2.29)	0.004	-2.51 (-6.15 – 1.11)	-2.45 (-7.65 – 3.75)	0.350
Tile B – Tile C –2.2	75.69 - 1.14)	-3.42 (-7.65 – 0.82)	0.113	-1.27 (-5.12 – 2.58)	-0.99 (-6.15 – 4.16)	0.702
Work						
Tile A – Tile B –1.	80 (-4.85 – 1.26)	-1.01 (-4.25 – 2.22)	0.535			
Tile A – Tile C –5.	05 (-8.79 – -1.32)	-3.51 (-8.61 – 1.59	0.175			ı
Tile B – Tile C -3.	25 (-7.03 – 0.52)	-2.49 (-7.13 – 2.15)	0.289			
Sitting						
Tile A – Tile B –0.	51 (-1.36 – 0.35)	-0.49 (-1.39 – 0.42)	0.286	-0.19 (-1.06 – 0.70)	-0.26 (-1.18 – 0.66)	0.575
Tile A – Tile C –0.	78 (-1.83 – 0.26)	-0.46 (-1.88 – 0.97)	0.526	-0.79 (-2.41 – 0.84)	-1.89 (-4.21 – 0.42)	0.108
Tile B – Tile C -0.	28 (-1.34 – 0.78)	-0.03 (-1.27 – 1.33)	0.961	-0.60 (-2.32 – 1.12)	-1.63 (-3.93 – 0.66)	0.161
Sexual intercourse						
Tile A – Tile B 0.	05 (-0.31 – 0.40)	0.04 (-0.34 – 0.42)	0.845	0.02 (-0.04 – 0.08)	0.02 (-0.04 – 0.08)	0.596
Tile A – Tile C –0.	43 (-0.86 – 0.01)	-0.49 (-1.09 – -0.11)	0.108	0.02 (-0.09 – 0.12)	-0.02 (-0.16 - 0.14)	0.847
Tile B – Tile C –0.	47 (-0.910.03)	-0.53 (-1.080.18)	0.058	0.01 (-0.11 - 0.11)	-0.03 (-0.18 - 0.12)	0.684

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Table 6   Contin	ued.					
		< 65			≥ 65	
		N=113			N= 82	
	<b>B-coefficient</b>	<b>B-coefficient</b>	P-value*	<b>B-coefficient</b>	<b>B-coefficient</b>	P-value <sup>*</sup>
	(95% CI)	(95% CI)*		(95% CI)	(95% CI)*	
Standing A (Wa	lking aids)					
Tile A – Tile B	0.14 (-0.60 – 0.88)	0.13 (-0.63 – 0.89)	0.740	0.34 (-1.12 – 1.80)	-0.14 (-1.48 - 1.21)	0.841
Tile A – Tile C	0.11 (-0.80 – 1.02)	0.23 (-0.97 – 1.43)	0.706	1.10 (-1.60 – 3.81)	0.26 (-3.13 – 3.64)	0.880
Tile B – Tile C	-0.03 (-0.95 – 0.89)	0.10 (-0.99 – 1.20)	0.855	0.76 (-2.10 – 3.62)	0.39 (-2.96 – 3.75)	0.816
Standing B (Gai	t unaided)					
Tile A – Tile B	-0.19 (-1.12 – 0.74)	-0.19 (-1.17 – 0.79)	0.707	0.01 (-1.98 – 1.98)	-0.59 (-2.43 – 1.24)	0.520
Tile A – Tile C	-0.38 (1.52 – 0.76)	-0.18 (-0.73 - 1.36)	0.813	-0.42 ( -4.01 – 3.24)	-2.92 (-7.53 – 1.68)	0.210
Tile B – Tile C	-0.19 (-1.34 – 0.96)	0.01 (-1.40 - 1.41)	0.998	-0.42 (-4.29 – 3.46)	-2.33 (-6.90 – 2.24)	0.313
Standing C (Wa.	lking distance)					
Tile A – Tile B	0.07 (-0.92 – 1.05)	0.13 (-0.89 – 1.15)	0.799	0.10 (-1.42 – 1.62)	-0.46 (-1.83 – 0.90)	0.499
Tile A – Tile C	-0.44 (-1.64 - 0.76)	0.22 (-1.83 – 1.39)	0.788	-0.23 (-3.04 – 2.58)	-2.08 (-5.51 – 1.35)	0.230
Tile B – Tile C	-0.51 (-1.72 - 0.71)	-0.35 (-1.82 – 1.12)	0.636	-0.33 (-3.30 – 2.65)	-1.62 (-5.02 – 1.78)	0.346
Total MPS						
Tile A – Tile B	-5.43 (-12.16 – 1.30)	-5.24 (-12.04 – 1.90)	0.149	-1.07 (-7.56 – 5.44)	-3.03 (-9.21 – 3.14)	0.331
Tile A – Tile C	-12.12 (-20.34 – -3.89)	-11.54 (-22.84 – -0.27)	0.045	-3.01 (-15.03 – 9.00)	-9.96 (-25.47 – 5.56)	0.205
Tile B – Tile C	-6.69 (-15.01 – 1.62)	-6.30 (-16.56 – 3.96)	0.226	-1.95 (-14.68 - 10.79)	-6.92 (-22.31 – 8.46)	0.373
Adjusted linear reg	ression coefficients for ch	ange in MPS dimension	s and total score. T	ile A, compared with Tile B i	and Tile C, and Tile B co	mpared with

Tile C. \* Adjusted for age, gender, pelvic operation, ISS and Injury of the spine.

# Discussion

In this study, we evaluated the HrQoL of patients after a pelvic ring fracture. With a high response rate (86%) within the survivor group, the response bias was negligible. The most commonly seen trauma mechanism in our study was high-energy traffic accidents. These results were consistent with the results of other studies.<sup>16,17,22,29</sup> To our knowledge, this study was the first that compared a large cohort of patients with Tile A, Tile B and Tile C fractures and evaluated HrQoL using generic and pelvic-specific HrQoL-instruments.

# EQ-5D

Compared with Tile A and Tile B, patients with Tile C fractures showed lower scores in usual activities, pain, anxiety, EQ-VAS and the Index score. Pain and usual activities were the only dimensions with significant differences between the Tile groups after adjusting for confounding. Additionally, patients with Tile C fractures scored significantly lower on the Index score than those with Tile A. Although not statistically significant, the lower scores in mean self-care and anxiety of Tile C patients compared to Tiles A and B could be clinically relevant and might become significant in a larger study group. Our study showed that it is important to use a multivariate model to test HrQoL after pelvic ring fractures. All of the Tile-type fractures in our study showed lower Index scores than the mean score of the Dutch population (0,87). Although we cannot compare these groups statistically, it could be stated that all of the patients have not yet recovered. Compared with patients with Tile A fractures, patients with Tile C fractures could have a greater risk of prolonged recovery.

## MPS

In our study, when comparing the results of both age groups side by side, the group of  $\geq$ 65 years seemed to have a relatively better score on the MPS, perhaps because a total of 30 points (out of 80 points in the <65 group or 100 points in the  $\geq$ 65 years group) was given if the patient had slight or no pain at all. Older patients more frequently suffer from a Tile A fractures (Table 2), have less pain (Table 5) and consequently obtain more points.

Compared with Tile A, a significant increase in pain was seen in patients <65 years old with Tile B and C fractures. We did not find a significant or clinically relevant lower score in the dimension of standing when comparing Tile C with Tiles A and B. A hypothesis could be that young patients recover rapidly and will soon be on their feet again. Harvey-Kelly et al. already identified sexual dysfunction as a significant independent risk factor for decreased quality of life.<sup>22</sup> Our study did not show a significant increase in sexual complaints in the <65

group when comparing Tile A and Tile C patients and Tile B and Tile C patients. No lower scores were found for the dimension of work. The mean score of all of the Tile groups was correlated with "light work" or "change of job", which could show that pelvic ring fractures have severe socioeconomic consequences. Papasotiriou et al. found that return to work in patients with pelvic ring fractures was influenced by concomitant injuries.<sup>30</sup> In our study, we found that injuries of the spine were associated with a higher risk of decreasing HrQoL. The Total MPS significantly differed between the Tile A and Tile C patients.

When examining the ≥65 group more closely, no differences were found for the dimension of pain. A hypothesis could be that patients with Tile A fractures experience more pain due to bad physical condition. The sexual intercourse HrQoL results could be misleading. A new study is needed to investigate this domain and to observe why patients do not answer the question. Although not statistically significant, elderly people experienced low mean scores on the dimension of standing. During the telephone survey, we noted that many elderly patients already used walking aids before their accidents. However, these findings were not reported. Laxton et al. noticed that 53.4% of elderly patients were walking unaided, 39.2% were using walking aids, and 7.5% required the assistance of another person before a pelvic ring fracture. After discharge, all of the patients used at least a walking stick to aid mobility.<sup>31</sup>In our study, we were not able to measure the situation before the injury. Hence, the MPS questionnaire might not be sufficiently specific to measure the effect of a decrease in mobility due to a pelvic fracture on the HrQoL of elderly patients. It is possible that the questionnaire mostly showed us the pre-existing conditions of elderly patients. The elderly usually suffer from more than one chronic illness. As a consequence, it is possible that the total MPS score was influenced by these preexisting conditions and therefore could not differentiate between the Tile groups.

This study had several strengths. One of the strong components of this study was the number of patients, specifically patients with Tile A fractures. Other studies that have investigated HrQoL after pelvic ring fracture have included fewer patients, ranging from 54 to 172 patients.<sup>16,17,19,22,29</sup>

To improve trauma care for pelvic fractures, analysing all types of these fractures is important. In this study, all Tile-type fractures were included, independent of ISS and treatment. Our hospital, a level 1 trauma centre, aims to care for 75% of all major trauma patients from North Brabant, the second largest province in the Netherlands (population 2.497.600 in 2014), resulting in a representative group of patients with a pelvic ring fracture.

Our study also had limitations. Because of the cross-sectional design of the study, we are unable to provide more insight into the patterns of HrQoL over

time. Another limitation was the small number of Tile C fractures. This small number could be why we did not find significant differences, except for pain, when comparing the Tile C group with the other Tile groups. Additionally, the remarkably high prevalence of admitted patients with Tile A fractures might be due to the presence of many care homes for the elderly near the hospital. However, it is also possible that many patients actually suffered from posterior pelvic ring fractures as well. CT scans were only performed in a small percentage of the patients. Therefore, it is possible that several patients were misdiagnosed despite adequate treatment.

Patients were interviewed by telephone. It is possible that the patients felt rushed during the interviews, although this survey was announced in writing in advance. Furthermore, patients perhaps felt uncomfortable about the sexual intercourse question by telephone and consequently answered negatively (sexual intercourse had not been attempted) on this question.

McHorney et al. noted that floor or ceiling effects are considered to be present if >15% of respondents achieve the lowest or highest possible score.<sup>32</sup> Both agerelated groups (<65 years and ≥65 years) in our study showed a ceiling effect for the MPS. Nineteen percent of the patients in the <65 group scored a maximum score of 100 points, and 34% of the patients in the ≥65 group scored a maximum of 80 points. Lefaivre et al. demonstrated a ceiling effect in Tile B and C fractures at a mean of 56 months after pelvic trauma, with 18% of respondents reporting the highest possible score.<sup>33</sup> Similar to responsiveness, the ceiling effect can limit content validity and reliability because changes cannot be measured within the patients.<sup>34</sup>

# Conclusion

In conclusion, the HrQoL of all of the patients was lower than that of the general Dutch population. Compared with Tiles A and B, pain was especially increased in patients with Tile C fractures. Our results showed that pelvic ring fractures can have severe socioeconomic consequences. However, differences between the Tile groups were not seen in the 65 group. The question of the applicability of the MPS in patients 65 years old now arises. To our knowledge, no studies in the literature have been published regarding the effects of patient characteristics (such as age) on these instruments when used in patients with pelvic injuries.<sup>14,15,20,23,35</sup> A separate study is needed to investigate the applicability of the MPS in patients  $\geq 65$  years old.

# A cross-sectional study | 45

	Tile A, N (%)	Tile B, N (%)	Tile C, N (%)
1.1	3 (3.0)	5 (7.5)	3 (11.1)
1.2	6 (5.9)	3 (4.5)	2 (7.4)
1.3	4 (4.0)	-	10 (37.0)
2.1	7 (6.9)	35 (52.2)	1 (3.7)
2.2	78 (77.2)	6 (9.0)	3 (11.1)
2.3	2 (2.0)	9 (13.4)	2 (7.4)
3.1	0	4 (6.0)	2 (7.4)
3.2	1 (1.0)	0	0
3.3	0	5 (7.5)	4 (14.8)
	101 (100)	67 (100)	27 (100)

**Appendix A** | Extended Tile classification.

MPS	Description	MPS	Tile A,	Tile B,	Tile C,
dimension		points	%	%	%
Pain	Intense, continuous at rest	5	0	3	7.4
	Intense with activity	10	1	1.5	7.4
	Tolerable, but limits activity	15	2	9	7.4
	Moderate activity, abolished by	20	5.9	11.9	11.1
	rest				
	Mild, intermittent, normal	25	12.9	13.4	22.2
	activity				
	Slight, occasional or no pain	30	78.2	61.2	44.4
Work	Retired	0	54.5	32.8	18.5
	No regular work	4	16.8	34.3	51.9
	Light work	8	1.0	0	7.4
	Change of job	12	3.0	0	7.4
	Same job, reduced performance	16	5.0	6.0	3.7
	Same job, same performance	20	19.8	26.9	11.1
Sitting	Painful	4	3.0	4.5	11.1
	Painful if prolonged or awkward	6	17.8	25.4	25.9
	Uncomfortable	8	6.9	7.5	11.1
	Free	10	72.3	62.7	51.9
Sexual	Painful	1	1.0	4.5	11.1
intercourse	Painful if prolonged or awkward	2	4.0	0	7.4
	Uncomfortable	3	5.9	6.0	14.8
	Free	4	89.1	89.6	66.7
Standing A	Bedridden or almost	2	1.0	0	0
(Walking aids)	Wheelchair	4	2.0	1.5	0
((())))	Two Crutches	6	23.8	10.4	7.4
	Two sticks	8	0	6.0	3.7
	One stick	10	5.9	9.0	7.4
	No sticks	12	67.3	73.1	81.5
Standing B	Cannot walk or almost	2	8.9	6.0	3.7
(Gait unaided)	Shuffling small steps	4	8.9	6.0	3.7
	Gross limp	6	2.0	1.5	0
	Moderate limp	8	4.0	9.0	11.1
	Slight limp	10	22.8	25.4	48.1
	Normal	12	53.5	52.2	33.3

**Appendix B** | MPS results split into Tile A, Tile B and Tile C

MPS	Description	MPS	Tile A,	Tile B,	Tile C,
dimension		points	%	%	%
Standing C	Bedridden or few metres	2	1.0	1.5	0
(Walking	Very limited time and distance	4	7.9	3.0	0
distance)	Limited with sticks, difficult without prolonged standing possible	6	15.8	16.4	18.5
	One hour with a stick, limited without	8	18.8	9.0	22.2
	One hour without sticks, slight pain or limp	10	10.9	20.9	22.2
	Normal for age and general condition	12	45.5	49.3	37.0

**Appendix B** | MPS results split into Tile A, Tile B and Tile C

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# **CHAPTER 3**

Differences in the Majeed Pelvic Score Between Injured and Uninjured Patients

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> > Journal of Orthopaedic Trauma 2019, 33(5), 244-249

# ABSTRACT

# Background

To investigate the differences in the Majeed Pelvic Score (MPS) between injured and uninjured patients. Discriminative power and applicability of the MPS in elderly are also investigated, and a norm score for the MPS in the Netherlands is provided.

# Methods

One hundred ninety-five patients with pelvic ring disruptions; 101 61A, 67 61B, and 27 61C (OTA/AO classification; 6%, 27%, and 82% surgically treated, respectively); mean follow-up 29 months (range 6–61); 554 adults from the Longitudinal Internet Studies for the Social Sciences panel (control group). Participants were divided into 2 age groups: <65 and  $\geq$ 65 years (respectively, maximum MPS: 100 and 80 points).

# Results

Patients <65 years of age (81.6) scored lower on the MPS when compared with the control group (88.3, P < 0.001). Patients ≥65 years of age (68.1) scored lower on the MPS when compared with the control group (72.0, P = 0.006). In the <65 group, the patient group scored worse on the sexual function, work, and standing dimensions (P < 0.001). In the ≥65 group, the patient group scored worse on the dimensions sitting (P = 0.03) and standing (P < 0.001) and better on the dimension pain (P = 0.001).

## Conclusions

Compared with the general population, patients with pelvic ring disruption in both age groups perceived some health problems in almost all MPS domains. The MPS discriminates well enough to provide information about the mobility of elderly patients.

# Background

Pelvic ring disruptions are severe injuries that can be accompanied by head and chest injuries.<sup>1</sup>Severe blood loss, urinary tract problems, and sexual dysfunction are well known associated injuries to local neurovascular structures in patients with pelvic ring disruptions.<sup>2,3</sup> Certain types of pelvic ring disruptions may be difficult to treat, in particular tile B and C (AO/OTA 61-B and 61-C) with associated injuries that require a multidisciplinary approach. In treatment, it is common for the orthopaedic trauma surgeon to focus on the radiological and anatomical reduction of the fracture and function of the pelvis.<sup>4-7</sup> However, currently, it is becoming increasingly common practice to focus on the health-related quality of life (HRQoL).<sup>8-15</sup>

There are 2 types of HRQoL instruments: generic and disease-specific measurement instruments. Although a generic instrument measures the HRQoL of the patient, injuries of specific individuals may not be addressed, and disease-specific complaints may not be noted.<sup>16</sup> Several pelvic-specific measurement instruments have been developed.

Frequently used pelvic-specific questionnaires include the Iowa Pelvic Score, the Orlando Pelvic Score, and the Majeed Pelvic Score (MPS).<sup>17–19</sup> The MPS is the most commonly used.<sup>20</sup> However, none of these questionnaires has been sufficiently validated. Studies have compared pelvic-specific instruments with generic instruments to investigate the sensitivity of pelvic-specific instruments in examining pelvic-specific areas, but there is no gold standard available.<sup>16,20–22</sup> The norm scores of the measurement instruments can be used as reference values when compared with the general population.

In addition, in a previous study, the question arose of whether the MPS questionnaire was suitable for patients 65 years of age and older.<sup>23</sup> Our study group investigated the HRQoL after pelvic ring disruptions using the MPS and EuroQoL-5D (EQ-5D) and noted that patients 65 years of age and older scored worse on the MPS dimension standing (walking aids, gait unaided, and walking distance) than did patients younger than 65 years. In addition, during the telephone survey, we noticed that many old patients were already using walking aids before their accidents. Consequently, we doubted whether we only measured the complaints due to the pelvic ring disruption or complaints (eg, arthritis and vascular diseases) due to old age in general. Without a norm score for the general population, it was not possible to compare the HRQoL of patients with a pelvic ring disruption with the HRQoL of the elderly in general.

An analysis of the functional score of patients treated operatively or nonoperatively and the general population could also be important. The injury differences and associated injuries frequently found in the injuries treated operatively may have a profound effect on functional outcomes.<sup>24</sup>

The primary aim of this study was to compare the MPS scores in injured and uninjured patients in different age groups. The secondary objectives were to investigate the discriminative power and applicability of the MPS in elderly, to compare operatively and nonoperatively treated patients with the control group, and to collect norm scores for the MPS in the Netherlands.

# Methods

We compared the MPS results of patients with pelvic ring disruptions with a panel of adults representing the general Dutch population (the control group). All patients 18 years of age and older with a pelvic ring disruption who were conservatively and surgically treated in a level 1 trauma center between January 2011 and June 2015 with a follow-up of at least 6 months and who were still alive were included and interviewed by telephone about their HRQoL. Patients who had insufficient knowledge of the Dutch language were not included in the questionnaires. Patient characteristics (age, sex, operation, OTA/AO classification,<sup>25</sup> and trauma mechanism) were noted.

For the control group, we collected data from a panel of adults representing the general Dutch population. This panel consisted of 638 individuals. This Longitudinal Internet Studies for the Social Sciences (LISS) panel is based on a traditional random sample drawn from the population register by Statistics Netherlands. People without a computer or internet connection were provided with other equipment to participate. LISS panel members received an incentive of €0.75 for filling out this questionnaire.

We measured HRQoL in both groups using the MPS. If, for any reason, sexual intercourse had not been attempted, a score of 4 points was given.<sup>19</sup> We assumed that patients 65 years of age and older were no longer working; therefore, they had a maximum score of 80 points. Consequently, we developed an MPS norm score for 2 categories: patients <65 years and  $\geq$ 65 years. Operative and conservative treatment groups were compared to examine differences between the dimensions.

To examine how burdensome the questions of the survey were, the LISS survey ended with the following 2 questions: (1) Was it difficult to answer the questions? (2) Were the questions sufficiently clear?<sup>26</sup>

## Data Analysis

Descriptive statistics were performed to provide an overview of characteristics of the study population and the HRQoL after a pelvic ring disruption. An

independent-samples T test was used to analyze the difficulty and clarity of the MPS questionnaire. Age was split into 2 categories: <65 years and  $\geq$ 65 years. We compared the pelvic group with the control group in each age category. The MPS results of patients with operative or conservative treatment were also analyzed separately and compared with the control group.

Independent-sample Mann–Whitney U tests were used to compare the groups. P < 0.05 was considered statistically significant. All analyses were conducted using SPSS version 19.0 (Statistical Package for Social Sciences, Chicago, IL).

# Results

## **Patient Characteristics**

Two hundred seventy-two patients with pelvic ring disruptions were referred to our hospital for conservative or surgical treatment between January 2011 and June 2015. By December 2015, 46 patients had died according to the municipal registration. During the telephone interviews, 10 patients were untraceable, so it was not known whether they were alive or dead, and 2 patients did not want to participate. We excluded 8 patients because of a severe state of dementia, mental illness, or vegetative state. Eleven patients with a follow-up of less than 6 months were excluded, leaving us with 195 patients (mean follow-up: 29 months, range 6–61) who were available for data collection (Table 1). According to the OTA/AO classification, 101 patients had a 61A fracture, 67 patients a 61B fracture, and 27 patients a 61C fracture. Six percent of the 61A, 27% of the 61B, and 82% of the 61C patient were surgically treated.

	Pelvic fracture g	roup	Controle group
No. of patients, N (%)	195		554
<65 y	113 (58)		390 (70)
Male	103 (53)		267 (48)
Mean age, y (SD)	56 (22)		52 (17)
Range	18–96		18-87
<b>Patient Characteristics</b>			
	61A	61B	61C
N (%)	101 (52)	67 (34)	27 (14)
Mean ISS (SD)	12 (11)	18 (11)	28 (13)
Sex, N (%)	47 (46.5)	41 (61.2)	15 (55.6)
Male			
Female	54 (54.5)	26 (38.8)	12 (44.4)
Mean age, y (SD)	62 (22)	54 (21)	43 (19)
Operation, N (%)	6 (5.9)	18 (26.9)	22 (81.5)
Mean length of follow-up,	28 (16)	30 (16)	33 (16)
month (SD)			
Mechanisms of Injury			
	61A, N (%)	61B, N (%)	61C, N (%)
Fall from same level	30 (29)	5 (8)	0
Fall from height	18 (18)	15 (23)	7 (28)
High-energy traffic	31 (31)	32 (47)	16 (59)
accident			
Weapon	1 (1)	0	1 (3)
Other (eg, entrapment)	21 (21)	15 (22)	3 (10)

#### Table 1 | Patient Characteristics

\*ISS = Injury Severity Score

#### **LISS Panel Characteristics**

Our control group consisted of 638 persons. Five hundred fifty-four adults completed the MPS questionnaire (response rate 87%). The characteristics (sex and mean age) obtained with the LISS panel were in good agreement with those of patients with a pelvic ring disruption (Table 1). Participants younger than 65 years were more highly educated than the older group. This is consistent with a trend seen in the Netherlands in recent years.<sup>27,28</sup>

The mean time to complete the MPS questionnaire was 121 seconds (SD = 74); no significant difference was found between the groups <65 years of age and  $\geq$ 65 years of age (P = 0.25) (Table 2). In general, participants found the MPS questions easy to answer and sufficiently clear (Table 2). The questions were more sufficiently clear for participants  $\geq$ 65 years of age than for those <65 years of age (P = 0.02).

Controle group		P*
Time to fill in questionnaire, mean in seconds (SD)	121 (74)	0.25
<65 y	118 (81)	
≥65 y	126 (53)	
Was it difficult to answer the questions?† (SD)	1.4 (0.9)	0.23
<65 y	1.4 (0.9)	
≥65 y	1.5 (1.0)	
Were the questions sufficiently clear? † (SD)	4.3 (1.1)	0.02
<65 y	4.2 (1.1)	
≥65 y	4.4 (1.0)	

Table 2 | Difficulty and Clarity of the MPS Questionnaire

+Ranging from 1 (=definitely not) to 5 (=certainly).

\*Independent-samples t test.

#### **Majeed Pelvic Score**

Most of both the patients with a pelvic fracture and the control group scored excellent and good results, according to the suggested cutoffs of the MPS (Table 3). The mean MPS of the pelvic group in both the <65 and  $\geq$ 65 groups was lower than that of the control group (Table 4). Compared with the control group, the pelvic fracture group generally scored worse. In both the pelvic fracture and control groups, the results for patients  $\geq$ 65 years of age shifted from good to excellent more frequently than those observed for patients <65 years of age.

We also investigated all dimensions separately. In the <65 group, no difference was seen for the dimension pain (P = 0.45). Compared with the control group, the pelvic group scored worse on the dimensions sexual function, work, and standing A, B, and C (P < 0.001). In the ≥65 group, the pelvic group scored better on the dimension pain (P = 0.001) than did the control group. Compared with the control group, the pelvic group scored worse on the dimensions sitting (P = 0.03)

and standing A, B, and C (P < 0.001). No significant difference between the pelvic and control groups was seen on the dimension sexual function (P = 0.15).

A large proportion of patients was found at the highest end of the MPS scale, in both the <65 and ≥65 groups. In the former group, 19% of the pelvic fracture group scored a maximum of 100 points, whereas 39% of the control group scored the maximum. In the ≥65 group, 33% of the pelvic fracture group and 51% of the control group scored a maximum of 80 points. Comparing the maximum MPS scores in terms of the OTA/AO classification resulted in a maximum score in 31% of the 61A, 28% of the 61B, and 0% of the 61C fractures.

Table 5 shows significant differences between the operative and conservative groups in the dimensions work, sexual function, and standing A. Patients who were operatively treated experienced less problems during work, had more pain during sexual intercourse, and needed less walking aids when compared with patients who were conservatively treated.

Significant differences between the operative treatment group and the control group were found in the dimensions sitting, sexual function, and standing A, B, and C. The control group experienced less pain problems during sitting (P < 0.01), sexual intercourse (P < 0.01), and walking (P < 0.01), needed less walking aids (P < 0.01), and walked a greater distance (P < 0.01) when compared with patients who were operatively treated.

Significant differences between the conservative treatment group and the control group were found in all dimensions except for sexual function (Table 5). The control group experienced more pain in general (P < 0.01) and less pain while sitting (P < 0.01) and during walking (P < 0.01), experienced less problems during work (P < 0.01), needed less walking aids (P < 0.01), and walked a greater distance (P < 0.01) when compared with patients who were conservatively treated.

	0		5 1	0 1
	< 65 y, %		≥65 y, %	
	Pelvic group	Control group	Pelvic group	Control group
Excellent	65	63	56	69
Good	28	25	24	17
Fair	4	8	15	9
Poor	3	4	5	5
Total	100	100	100	100

Table 3 | MPS results categorized into < 65 and ≥ 65 years and pelvic-control goup

Outcome After Pelvic Fracture, Categorized by Suggested Cutoffs According to MPS

	<65 years, mean (SD)			≥65 years, mean (SD)		
	Pelvic	Control	$P^*$	Pelvic	Control	$P^*$
(total points)	group	group		group	group	
	(N=113)	(N=390)		(N=82)	(N= 164)	
Pain (30)	25,6 (6,8)	25,2 (6,9)	0.45	28,0 (3,9)	25,0 (6,7)	0.001
Work (20)	11,3 (7,5)	14,9 (6,8)	< 0.001	0	0	-
Sitting (10)	8,5 (2,0)	9,2 (1,5)	< 0.001	9,0 (1,8)	9,5 (1,3)	0.03
Sex (4)	3,6 (0,9)	3,8 (0,5)	< 0.001	4.0 (0,1)	3,9 (0,4)	0.15
+Standing A (12)	11,4 (1,8)	11,8 (1,0)	< 0.001	9,4 (2,9)	11,6 (1,6)	< 0.001
†Standing B (12)	10,5 (2,2)	11,8 (1,0)	< 0.001	8,8 (3,9)	11,3 (2,1)	< 0.001
+Standing C (12)	10,2 (2,3)	11,5 (1,7)	< 0.001	8,6 (3,0)	10,7 (2,7)	< 0.001
Mean total	81,6 (16,4)	88,3 (13,5)	< 0.001	68,1 (12,7)	72,0 (11,7)	0.006
(100/80‡)						

**Table 4** | Results of MPS Dimensions in Pelvic and Control Group, Divided Into <65 Years and ≥ 65 Years

\*Independent-samples Mann-Whitney U test.

†A, walking aids; B, gait unaided; C, walking distance.

‡Patients 65 years of age and older are not working anymore, and therefore they had a maximum score of 80 points.

	Operation			Conservative treatment			Operation vs conservative
	Polyric	Control	D*	Polyic	Control	D*	D*
	group	group	Γ	group	group	1	1
	(N=46)	(N= 554)		(N= 149)	(N= 554)		
Pain	25.5 (7.1)	25.1 (6.8)	0.64	27.1 (5.4)	25.1 (6.8)	< 0.01	0.20
Work	7.1 (6.9)	10.5 (8.9)	0.09	6.4 (8.3)	10.5 (8.9)	< 0.01	0.03
Sitting	8.3 (2.1)	9.3 (1.5)	< 0.01	8.8 (1.9)	9.3 (1.5)	< 0.01	0.08
Sex	3.6 (0.8)	3.9 (0.5)	< 0.01	3.8 (0.6)	3.9 (0.5)	0.41	0.03
Standing A	11.4 (1.6)	11.8 (1.2)	< 0.01	10.3 (2.7)	11.8 (1.2)	< 0.01	< 0.01
Standing B	10.5 (2.2)	11.6 (1.4)	< 0.01	9.6 (3.3)	11.6 (1.4)	< 0.01	0.43
Standing C	10.1 (2.2)	11.3 (2.0)	< 0.01	9.4 (2.8)	11.3 (2.0)	< 0.01	0.20
Mean total	77.0 (14.7)	83.5 (15.0)	< 0.01	75.6 (16.9)	83.5 (15.0)	< 0.01	0.55
(SD)							

Table 5 | Results of MPS Dimensions in Pelvic and Control Group

Data represents the MPS dimensions divided Into Operation and Conservative Treatment Group. \*Independent-samples Mann–Whitney U test.

# Discussion

This study was designed to investigate the MPS scores of injured and uninjured patients in different age groups. We found that patients with pelvic ring disruption of both age groups with a mean follow-up of 29 months continued to perceive health problems on almost all MPS domains compared with the general population. Dutch norm scores for the MPS were collected for patients <65 years of age (88.3) and  $\geq$ 65 (72.0) years of age. The MPS discriminates sufficiently well to provide information about the mobility of elderly patients. Only small differences on the MPS domains between the operatively and nonoperatively treated groups were found when compared with the control group.

The scoring and interpretation of the MPS varied in different articles. Several authors applied their own grading scales to the MPS, provided only mean scores, or provided only a description of the results without providing scores.<sup>20</sup> To the best of the authors' knowledge, this is the first study in which the MPS was split and investigated in different domains. Because of this study design, we were able to investigate the discriminative power and applicability of all MPS domains in the elderly.

# All Domains

If we examine the mean total MPS scores, we might conclude that patients with pelvic ring disruption in both the <65 and ≥65 groups with a mean follow-up of 29 months perceived some health problems compared with the general population. Although the operatively and nonoperatively treated groups scored significantly lower on the total MPS score (P < 0.01) in comparison with the control group (respectively, 77.0 vs. 83.5 and 75.6 vs. 83.5), both patient groups did not differ significantly from each other (P = 0.55). These study results are supported by Papakostidis et al.<sup>29</sup> They concluded that fixation of the pelvic ring yielded better anatomical results when compared to nonoperative treatment. However, the literature was insufficient to provide evidence of operative or nonoperative treatment regarding HRQoL or functional outcome.

## **Domain Mobility**

In a previous study, our study group was unsure whether the MPS mobility outcomes were pelvic ring disruption–related or were more age-related.<sup>23</sup> In the current study, we found a significant decrease in mobility (standing A, B, and C) in the pelvic group in both age groups, indicating that the mobility outcomes were at least partly pelvic ring disruption–related and were not completely due to age.

However, the clinical relevance of the difference between the pelvic and control group outcomes in the <65 group should be questioned. All results in this age group were above 10 points, indicating that both the patients and the control group were walking in a normal way (standing A), without sticks (standing B), and normally for age and general condition (standing C).

In the  $\geq$ 65 group, most patients walked with 1 or 2 sticks (standing A) and with a moderate or slight limp (standing B) and were able to walk for 1 hour with a stick without limitation (standing C), whereas the control group walked normally, without sticks, and normally for age and general condition. We are not able to investigate whether this significant decrease in mobility in patients  $\geq$ 65 years of age was caused by the pelvic ring disruption alone or by a combination with any comorbidity.

Both treatment groups (operative and conservative) scored significantly lower on the domain mobility when compared with the control group (P < 0.01). Only standing A in the conservative treatment group was significantly lower when comparing both treatment groups with each other. However, this difference is small and could be clinically irrelevant.

### **Domain Sexual Function**

Sexual function is another interesting dimension. Harvey-Kelly et al investigated the sexual function of a cohort of patients (mean age 46 years, assessed at a median of 36 months after injury) with operatively treated pelvic fractures. They found that all questionnaire items about female and male sexual function were significantly decreased and concluded that sexual dysfunction was an independent risk factor for a decreased quality of life after injury. Furthermore, the researchers found increased age to be a predictive factor for sexual dysfunction.<sup>3</sup> Other studies showed that younger patients have higher sexual function scores than older patients do<sup>30</sup> or that there is a greater risk for older patients to develop impotence after a pelvic fracture.<sup>31</sup>

In our study, no significant difference between the pelvic and control groups in the  $\geq$ 65 group was seen for the dimension sexual function, indicating that sexual function was not an independent risk factor for a decreased quality of life. The difference between the outcomes of our study and those of the studies listed above may be due to the existence of only 1 question about sexual function. It could be the case that our dimension questions about sexual function were insufficiently discriminative.

Sexual function was significantly lower in patients who were operatively treated when compared with the control group. This was in contrast to patients who were conservatively treated. A reason could be that patients who needed to undergo an operation were more heavily injured with more associated injuries around the pelvis.

### **Domain Pain**

It is notable that mean scores in both age groups were, for the most part, determined by the dimension pain because of a large weighting factor. Other studies only provided total scores,<sup>20</sup> so the question remained about which domain was the most affected. In our opinion, the best way to investigate the MPS questionnaire is to split the questionnaire into different domains and analyze the domains separately instead of only reporting total MPS scores. When comparing both treatment groups with each other, no significant difference was found. However, patients with a conservative treatment had less pain than the control group.

## **MPS** Questionnaire Design

We asked the LISS panel to evaluate the clarity of the MPS questions. In general, participants found MPS questions to be sufficiently clear, and a small significant difference was seen at the expense of the <65 group. No significant difference between age groups was found for the mean completion time of the questionnaire. In a previous study conducted by Lefaivre et al,<sup>16</sup> the mean time to complete the English version of the MPS was also investigated: Patients with surgically treated pelvic fractures completed the questionnaire in an average of 156 seconds (95% confidence interval, 134– 178). Both age groups in our LISS panel completed the questionnaire quicker than did patients in the study of Lefaivre et al. Our results show that the MPS questions were easy to interpret and that the questionnaire design was applicable for the elderly.

## **Ceiling Effect**

A ceiling effect can occur if more than 15% of the patients achieve the highest possible score.<sup>32</sup> Lefaivre et al<sup>16</sup> demonstrated a ceiling effect in patients with a pelvic ring disruption (61B and C) 56 months after trauma. In our study, a large proportion of the pelvic patients with 61A and 61B fractures was found at the highest end of the MPS scale at a mean follow-up of 29 months after injury. This result might indicate that patients with 61A or 61B fractures had truly recovered, whereas patients with 61C fractures were still recovering. However, when comparing both age groups, elderly patients still had scores lower than the norm, possibly indicating that some segment had not completely recovered from the injury. In our opinion, no new MPS items are needed because we are

not interested in whether the patients are able to function better than normal for age and general condition.

Compared with the younger group, a larger part of the elderly group had the maximum MPS score (19% vs. 33% for patients and 39% vs. 51% for the control group, respectively). It could be possible that the elderly regain their pre-fracture level of functioning more quickly than younger patients do because of a lower pre-fracture level. Furthermore, the elderly usually sustain 61A fractures that lead to a faster recovery time than that observed for 61B and 61C fractures.

The major limitation of the analysis could be the small group of operatively treated patients (24%) and the large group of 61A patients (52%). It could be possible that the conclusions drawn in this study are influenced by lower energy fracture patterns and therefore do not apply to all pelvic ring disruptions. We also did not include an evaluation of radiographic outcomes or anatomical reduction with the MPS score.

Another limitation of this study could be the difference in collecting data between the patient group and the control group. Patients were interviewed by telephone, whereas the control group received the questionnaire by email or by mail. It could be possible that patients felt rushed during the interview, although this survey was announced in advance. Furthermore, patients may have felt uncomfortable about answering the sexual intercourse question over the telephone and consequently answered in the negative (sexual intercourse had not been attempted) on this question. This could have caused different outcomes compared with the control group. Finally, we do not know how many members of the control group had a history of pelvic ring injury because this question was not included in the questionnaire.

# Conclusions

Overall, the MPS seems to be an adequate questionnaire for testing the HRQoL of patients with pelvic fractures. The MPS is a short questionnaire, and the questions are well designed for all age groups. The need remains to thoroughly and prospectively validate this questionnaire.

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# **CHAPTER 4**

Quality of life after pelvic ring fractures: Long-term outcomes. A multicentre study

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Injury 2019, 50(6), 1216-1222

# ABSTRACT

# Background

This study was conducted to determine long-term (5-10 years) health-related quality of life (HRQOL) and ceiling effects in patients with a pelvic ring fracture.

# Methods

We identified all patients with pelvic ring fractures after high-energy trauma admitted at two level 1 trauma centres in the Netherlands from 2006 to 2011. Patients were asked to complete the Majeed Pelvic Score (MPS), EuroQol-5D (EQ-5D) and Short Musculoskeletal Function Assessment (SMFA) questionnaires. HRQOL analysis used a multiple linear regression model.

## Results

In total, 136 patients returned the questionnaires. The median follow-up period was 8.7 years. The mean MPS and EQ-5D-VAS scores were 85.1 and 74, respectively. The mean EQ-5D index scores were 0.87, 0.81 and 0.82 in Tile B, A and C patients, respectively. The mean SMFA index was 24. A ceiling effect was observed for 1/3 of the patients. After multiple linear regression analysis, no differences were identified among the various fracture types for each questionnaire, with the exception of 2 subscales of the MPS.

## Conclusions

Patients who suffer pelvic ring fractures generally have good HRQOL outcomes after 5-10 years. No significant differences were found among different fracture types. Long-term follow-up of patients with Tile C fractures is warranted.
# Background

Pelvic fractures with disruption of the pelvic ring usually occur due to highenergy trauma (HET).<sup>1</sup> Patients with pelvic ring fractures often sustain multiple additional injuries.<sup>2</sup> Mortality and morbidity are significant, and the mortality rate can reach approximately 10-16%.<sup>34</sup>

Numerous studies have been performed regarding the early management of pelvic fractures to improve functional outcomes.<sup>2,5</sup> The results of the conservative management of unstable fractures are poor, with complications such as mal- or non-union and chronic pain.<sup>6</sup> Surgical therapy for unstable fractures is therefore currently an accepted treatment.<sup>7</sup>

Few studies have focused on long-term health-related quality of life (HRQOL) evaluation and functional outcomes at 5-10 years after trauma. Oliver et al.<sup>8</sup> examined long-term HRQOL in patients with unstable pelvic fractures and found a 14% physical impairment and a 5.5% mental impairment compared to the American population, regardless of the type of management. Suzuki et al.<sup>9</sup> concluded that neurological impairment of the lower extremities was the main predictor of worsened quality of life and poor functional outcomes. Factors that contribute to poor outcomes identified in other studies include age, presence of a complex fracture type, surgery and chronic pain.<sup>10,11</sup> Additionally, several authors have identified sexual and urological dysfunction as risk factors for decreased quality of life.<sup>12</sup> However, these studies include relatively small patient groups, with a follow-up period of only 2 years.<sup>13/14</sup>

As a result, patient outcomes 5-10 years after trauma are not well understood. Furthermore, it is not clear how long the HRQOL of patients continues to improve. Several authors<sup>15</sup> have reported an improvement in HRQOL up to the fifth year after injury; however, other authors<sup>16</sup> have reported a significant decrease in HRQOL over time. The degree of increase or decrease in HRQOL can be measured using the maximum HRQOL score. Several studies have shown a large ceiling effect (>15% of patients with the highest score<sup>17</sup>) in follow-up analyses of patients with pelvic ring fractures. Brouwers et al. <sup>18</sup> and Lefaivre et al.<sup>19</sup> demonstrated ceiling effects at 29 and 56 months after injury, respectively. The present study was conducted to determine long-term (5-10 years) HRQOL and ceiling effects in pelvic ring fracture patients.

# Methods

The study was reviewed by the medical ethics committee of the Radboudumc and was determined to fall outside the scope of the Medical Research Involving Human Subjects Act. We identified all patients with a pelvic ring fracture who were admitted to two level 1 trauma centres in the Netherlands from 2006 to 2011 from our trauma registry. These trauma centres are both larger hospitals in the Netherlands, which treat >350 patients with an ISS>16 per year. Patients were included if they were 18-80 years old, and their accident involved a HET, which was defined as an accident involving a moped travelling >30 km/h, a car accident at a high velocity, being thrown out of a vehicle/motorcycle, a collision with a pedestrian at >30 km/h, a fall from a high altitude (>5 metres) or severe entrapment with long extrication.

Patients with osteoporotic fractures or a low-energy trauma (LET) were excluded. We also excluded patients who died and patients who did not demonstrate good command of the Dutch language.

Data concerning patient and trauma characteristics, fracture type (according to Tile category), Injury Severity Score (ISS),<sup>20</sup> concomitant injuries, acute and definitive treatment, complications and mortality were acquired from the relevant hospital databases.

All patients were asked to complete the Majeed Pelvis Score (MPS),<sup>21</sup> EuroQol-5D (EQ-5D)<sup>22</sup> and Short Musculoskeletal Function Assessment (SMFA)<sup>23</sup> questionnaires.

The MPS is widely used in research concerning quality of life of patients with pelvic injuries and is divided into 5 "subscales": pain (30 points), work (20 points), sitting (10 points), standing (36 points total: walking aids, 12 points; gait unaided, 12 points; walking distance, 12 points), and sexual intercourse (4 points). If sexual intercourse was not attempted, for any reason, a score of four points was given.<sup>15</sup> The EQ-5D is a questionnaire with five dimensions: mobility, self-care, usual activities, pain or discomfort, and anxiety or depression. Each dimension has three levels: no problem, moderate problem, or severe problem. The EQ Visual Analogue Scale (EQ-5D-VAS) records the patient's self-rated state of health on an analogue scale between 0 (worst imaginable health state) and 100 (best imaginable health state). In addition, a scoring algorithm is available by which each health status (HS) description can be expressed as a summary score. This summary score, the EQ-5D index, ranges from 1 for full health to 0 for death and can be interpreted as a judgement on the relative desirability of an HS compared to perfect health. A normal score on the EQ-5D index for the Dutch population is 0.87 (SD: 0.18).24

The SMFA is designed to assess the HS and HRQOL of patients with a broad range of musculoskeletal injuries and disorders. The Function index contains 39 items, and the Bother index contains 14 items. Both indices use a five-point Likert scale with scores ranging from 1 (not at all/never/none) to 5 (unable to

do/always/extremely). The indices range from 0 to 100. Higher scores indicate a lower HS and lower HRQOL. The adapted Dutch version of the SMFA has been validated in patients with fractures of the upper or lower extremities<sup>23</sup>. In this study, only questions regarding the lower extremities were used.

# Data analysis

Patient characteristics were analysed with descriptive statistics. A multiple linear regression model was used for the HRQOL analysis. The following demographic and clinical characteristics and relevant adjustment factors for the present analysis were considered: the EQ-5D dimensions were dichotomized into "no problems" and "problems", and multiple logistic regression was performed. The results are presented as odds ratios (ORs) with 95% confidence intervals (CIs). Continuous variables including the EQ-5D-VAS, EQ-5D index score and MPS were analysed using a multiple linear regression model with correction for the following confounders that were thought to have a significant impact on outcome: age, sex, ISS, fracture type (stable versus unstable), neurologic injury, urogenital injury, open fracture, injuries to the lower extremities and surgical treatment. The results are presented as  $\beta$ -coefficients (B) with 95% CIs. All statistical analyses were performed using SPSS, version 22 (SPSS Inc, Chicago, IL, USA), with consultation from biostatisticians. A p-value of ≤0.05 was considered statistically significant.

# Results

In total, 336 patients with a pelvic ring injury were identified. Of these 336 patients, 42 had died, 46 patients did not speak Dutch, and the contact addresses of 17 patients were not found. Therefore, 231 patients were ultimately eligible for this study. These patients were contacted and asked to complete the MPS, SMFA and EQ-5D questionnaires. One hundred thirty-six patients completed the questionnaires (59%). No significant differences were observed in age, gender, Tile classification and ISS between the included patients and patients who were not contacted.

The mean age of the included patients was 39 (SD 17) years, and the mean ISS was 22.8 (SD 14). Thirty-one patients (22.7%) were haemodynamically unstable upon presentation in the ER (shock class 3 or higher). Eighty-one patients were male (58.8%). Of the 136 patients returning the questionnaire, 23 had a Tile A fracture (16.9%), 65 had a Tile B fracture (47.7%), and 48 had a Tile C fracture (35.3%). Patient characteristics for the various Tile groups are listed in Table 1. Patients with a complex fracture type had a significantly higher ISS and shock class and were more often treated surgically.

	Total	Tile A	Tile B	Tile C	p-value
	(N=136)	(N=23)	(N=65)	(N=48)	
Age (yrs)	39	38	36	43	NS
Male (%)	81	12 (52)	42 (65)	27 (56)	NS
ISS	29.9	16	28	33	p<0.01
Shock ≥grade3 (%)	31 (23)	5 (22)	7 (11)	19 (40)	p=0.02
Open fracture (%)	10 (7)	2 (8)	4 (6)	4 (8)	NS
Surgical treatment (%)	75 (55)	0	34 (52)	41 (85)	p<0.01
Concomitant injuries (%)	119 (88)	19 (83)	57 (88)	43 (90)	NS
Lower extremity (%)	44 (32)	10 (43)	18 (28)	16 (33)	NS
Neurological injury (%)	47 (35)	7 (30)	23 (35)	17 (35)	NS
Urogenital injury (%)	5 (4)	1 (4)	1 (2)	3 (6)	NS

#### Table 1 | Patient Characteristics

\*NS=not significant

Open fractures were observed in 10 patients (7.3%), of which seven were grade two or higher based on the scale reported by Gustilo & Anderson.<sup>25</sup> Seventy-five patients were treated operatively for the pelvic fracture (55.1%). Concomitant injuries were identified in 87% of patients. The majority of patients had concomitant injuries to the chest or extremities. Concomitant injuries to the lower extremities were observed in 44 patients (32.4%).

Neurological injury was observed in 47 patients (34.5%); of whom, 28 suffered severe head trauma (20.6%). Focal neurological deficits were observed in 9 patients (6.6%). Two patients exhibited complete paralysis due to spinal cord injury (1.5%).

Urogenital injuries were observed in five patients (4%); three patients had an urethral rupture, and two had a bladder rupture. The median follow-up period was 8.7 years (range: 5-10 years).

#### **Outcome scores**

### MPS

All 136 patients completed the MPS. The mean MPS score was 85.1 (SD 16.6). MPS scores are listed in Table 2. Almost 25% of patients reported significant sexual problems (fewer than 3 points on the MPS). No significant differences were found among the different fracture types. Return to work was reported in 57% of patients with a Tile A fractures, 63% with a Tile B fractures and 52% with a Tile C fractures. Regarding our follow-up period, 34% of patients had a maximal score of 100 points on the MPS, including 32% of Tile A, 36% of Tile B and 33% Tile C fracture patients.

MPS	Description	MPS	Tile A, %	Tile B, %	Tile C, %
dimension		points	N=23	N=65	N=48
Pain	Intense, continuous at rest	5	0	0	2
	Intense with activity	10	4	2	2
	Tolerable, but limits activity	15	13	9	19
	Moderate activity, abolished by	20	9	8	10
	rest				
	Mild, intermittent, normal	25	17	15	6
	activity				
	Slight, occasional or no pain	30	57	66	60
Work	No regular work	4	39	29	38
	Light work	8	4	3	0
	Change of job	12	0	5	8
	Same job, reduced performance	16	4	12	8
	Same job, same performance	20	53	51	44
Sitting	Painful	4	0	0	0
	Painful if prolonged or	6	26	23	25
	awkward				
	Uncomfortable	8	13	3	6
	Free	10	61	74	69
Sexual	Painful	1	4	2	0
intercourse	Painful if prolonged or	2	9	8	10
	awkward				
	Uncomfortable	3	0	3	8
	Free	4	87	87	82

#### Table 2 | MPS results

MPS	Description	MPS	Tile A, %	Tile B, %	Tile C, %
dimension		points	N=23	N=65	N=48
Standing A	Bedridden or almost bedridden	2	0	0	0
(walking	Wheelchair	4	0	0	2
aids)	Two crutches	6	13	3	10
	Two sticks	8	0	0	0
	One stick	10	4	0	6
	No sticks	12	83	97	82
Standing B	Cannot walk or can barely walk	2	4	2	4
(gait	Shuffling small steps	4	0	0	4
unaided)	Gross limp	6	0	2	0
	Moderate limp	8	0	6	10
	Slight limp	10	17	8	25
	Normal	12	78	82	57
Standing C	Bedridden or few metres	2	0	0	0
(walking	Very limited time and distance	4	9	0	21
distance)	Limited with sticks, difficult	6	0	6	6
	without prolonged standing possible				
	One hour with a stick, limited	8	4	2	0
	without				
	One hour without sticks, slight	10	13	12	8
	pain or limp				
	Normal for age and general	12	74	80	65
	condition				

#### Table 2 Continued.

\* Linear-by-linear association chi-squared test

## EQ-5D

The results of the EQ-5D are shown in Table 3. This questionnaire was completed by all included patients. The EQ-5D-VAS score was 74-76 of 100 and did not differ significantly among the Tile groups. The EQ-5D index score also did not differ significantly among the fracture types. A mean index score of 0.87 was observed in Tile B patients, while for Tile A and C patients, the mean index scores were 0.81 and 0.82, respectively. The average EQ-5D index score of the general Dutch population is 0.87<sup>24</sup>.

	Tile A	Tile B	Tile C
N (%)	23 (16.9)	65 (47.8)	48 (35.3)
Mean age, yrs (SD)	38 (19)	36 (16)	43 (17)
EQ-5D			
Mobility, %	61	77	48
Self-care, %	91	92	90
Usual activities, %	57	72	56
Pain, %	44	55	56
Anxiety/depression, %	78	88	81
EQ-5D-VAS score (SD)	74 (18)	76 (15)	76 (15)
Average EQ-5D index (SD)	0.81 (0.19)	0.87 (0.19)	0.82 (0.22)

#### Table 3 | EQ-5D

#### *SMFA* (lower extremities)

The results of the SMFA are listed in Table 4. The Function questionnaire was completed by 126 patients (92.6%), and the Bother questionnaire was completed by 123 patients (90.4%). The mean score of the SMFA Function index was 24 (SD 19), and the mean score of the Bother index was 24 (SD 23).

#### Table 4 | SMFA

	Tile A	Tile B	Tile C	p-value
SMFA_Bother, mean (SD)	21 (17)	24 (18)	25 (21)	0.695
SMFA_Function, mean (SD)	20 (22)	22 (21)	27 (25)	0.384

## Multiple linear analysis

Table 5 shows adjusted linear regression coefficients, after adjusting for age, sex, ISS, fracture type (stable versus unstable), neurologic injury, urogenital injury, open fracture, injuries to the lower extremities and surgical treatment.

Regarding the MPS, a significant difference was found in the dimension of standing (walking aids), with an OR of 0.26 (95% CI: 0.11-0.66), p=0.02. Patients with a Tile B fracture scored significantly higher than patients with a Tile C injury. The mean MPS scores did not differ significantly among the fracture types.

For the EQ-5D, a significant difference was found in the domain of mobility. Similar to the MPS, patients with type B fractures scored significantly higher than patients with type C fractures (&-coefficient: 0.73 (95% CI: 0.04-1.42) p=0.048). No differences were found among the fracture types for the EQ-5D-VAS and index scores. For both the SMFA Bother and Function indices, no differences were found among the fracture types.

EQ-5D	Odds ratio	95% CI	Significance
Mobility			p=0.02
Tile B-Tile A	0.50	0.17-1.46	
Tile C-Tile A	1.90	0.61-5.92	
Tile B-Tile C	0.26	0.11-0.66	
Self-care			p=0.88
Tile B-Tile A	0.63	0.10-4.12	
Tile C-Tile A	0.79	0.12-5.42	
Tile B-Tile C	0.79	0.17-3.58	
Usual activities			p=0.14
Tile B-Tile A	0.46	0.16-1.28	
Tile C-Tile A	0.98	0.33-2.90	
Tile B-Tile C	0.47	0.99-1.04	
Pain			p=0.43
Tile B-Tile A	0.54	0.20-1.49	
Tile C-Tile A	0.52	0.17-1.53	
Tile B-Tile C	1.05	0.47-2.43	
Anxiety/Depression			p=0.33
Tile B-Tile A	0.39	0.11-1.43	
Tile C-Tile A	0.69	0.18-2.58	
Tile B-Tile C	0.56	0.18-1.77	
	ß-coefficient	95% CI	Significance
EQ-5D-VAS			p=0.73
Tile B-Tile A	3.00	(-5.33-11.34)	
Tile C-Tile A	3.39	(-5.47-12.26)	
Tile C-Tile B	-0.39	(-6.93-6.15)	
EQ-5D index			p=0.24
Tile B-Tile A	0.07	(-0.03-0.17)	
Tile C-Tile A	0.02	(-0.09-0.13)	
Tile B-Tile C	0.05	(-0.03-0.14)	

 Table 5 | Multiple logistic regression model

Majood	R-coofficient	05% CI	Significanco
n'i jeeu	b-coefficient	95 /0 CI	
Pain	0.45		p=0.22
Tile B-Tile A	2.15	(-0.95-5.24)	
Tile C-Tile A	0.24	(-3.07-3.54)	
Tile B-Tile C	1.91	(-0.62-4.44)	
Work			p=0.73
Tile B-Tile A	1.17	(-2.40-4.73)	
Tile C-Tile A	0.17	(-3.66-4.01)	
Tile C-Tile B	0.99	(-1.98-3.98)	
Sitting			p=0.63
Tile B-Tile A	0.39	(-0.45-1.24)	I
Tile C-Tile A	0.21	(-0.71-1.11)	
Tile C-Tile B	0.19	(-0.51-0.89)	
	0117	( 0.01 0.07)	
Sexual Intercourse	0.00		p=0.83
THE B-THE A	0.09	(-0.25-0.43)	
Tile C-Tile A	0.03	(-0.34-0.39)	
Tile C-Tile B	0.07	(-0.22-0.35)	
Standing A (walking aids)			p=0.048
Tile B-Tile A	0.84	(-0.03-1.72)	
Tile C-Tile A	0.11	(-0.82-1.05)	
Tile C-Tile B	0.73	(0.04-1.42)	
Standing B (gait unaided)			p=0.11
Tile B-Tile A	0.34	(-0.79-1.46)	1
Tile C-Tile A	-0.62	(-1.83-0.58)	
Tile C-Tile B	0.96	(0.07-1.85)	
Standing C (walking dista	nce)		p=0.06
Tile B-Tile A	0.42	(-0.94 - 1.78)	P cloc
Tile C-Tile A	-0.87	(-2.33-0.59)	
Tile C-Tile B	1.29	(0.22-2.37)	
		(0)	m=0.15
Tile B Tile A	2 /1	(6121004)	p=0.15
Tile C Tile A	4.92	(-0.13 - 10.94)	
Tile C Tile R	-4.23	(-13.40-4.95)	
The C-The B	0.03	(-0.08-13.34)	
SMFA Function	B-coefficient	95% CI	Significance
			p=0.47
Tile B-Tile A	1.56	(-9.90-13.02)	
Tile C-Tile A	6.62	(-5.81-19.05)	
Tile C-Tile B	-5.06	(-14.40-4.28)	
SMFA Bother	ß-coefficient	95% CI	Significance
			p=0.73
Tile B-Tile A	1.51	(-8.72-11.72)	
Tile C-Tile A	4.04	(-6.94-15.02)	
Tile C-Tile B	-2.54	(-10.70-5.63)	

## Table 5 Continued.

# Discussion

In this study, we evaluated the long-term HRQOL of pelvic ring fracture patients with a minimum follow-up period of 5 years. To our knowledge, our study is the first to describe a follow-up period of more than 5 years in a large patient group with pelvic ring fractures.

Recently, Brouwers et al.<sup>18</sup> reported the short and mid-term HRQOL of patients with pelvic ring fractures. They found that pain was increased in patients with a Tile C injury and observed significantly lower EQ-5D and MPS scores in patients with a Tile C injury than in patients with Tile A and B fractures.

In our study, no significant differences in pain and no large significant differences in functional outcomes and HRQOL were observed among the different Tile types. Significant differences were found in only 2 dimensions: mobility on the EQ-5D and standing on the MPS. In both dimensions, patients with Tile B fractures scored significantly better than those with Tile C fractures, while no significant difference between patients with Tile A and C fractures was found. The reason for this finding could be the relatively high percentage of Tile B2 fractures. Tile B2 fractures are lateral compression injuries with intact ligaments. Patients are normally allowed to mobilize within their pain limits and often do not require operative treatment. Patients with a Tile A fracture often suffer an isolated iliac wing fracture. The characteristics, ISS and concomitant injuries of patients with iliac wing fractures resemble those of patients with type C fractures<sup>26</sup>. This finding could explain why the scores for Tile B fracture patients are higher for certain dimensions than for those with other fractures.

Most studies report lower HRQOL values in patients with a pelvic ring fracture than in the normal population.<sup>9102728</sup> Ayvaz et al.<sup>29</sup> reported SF-36 scores of patients treated with closed reduction and internal fixation that were comparable with the normal population. The results of the EQ-5D index score in our group were also comparable with those of the validated Dutch population. However, an analysis comparing the composition of our study population and that of Stolk et al.<sup>24</sup> was not performed. Therefore, we do not know whether both groups have comparable patient characteristics.

The mean MPS in our study was high compared to the studies of Suzuki<sup>9</sup> and van den Bosch<sup>30</sup> (85.1 versus 79.7 and 78.6, respectively). The EQ-5D index score in our group was 0.84, which was also higher than the results of Harvey-Kelly<sup>12</sup> (0.59) and Holstein<sup>10</sup> (0.78). The EQ-5D-VAS was 75.6 in our study, compared to 64.1 reported by Harvey Kelly<sup>12</sup> and 70.5 reported by Kerschbaum.<sup>28</sup>

The ISS score in our group is higher than that found in previous studies.<sup>9,12</sup> Only in the study by van den Bosch<sup>30</sup> was the mean ISS higher (30.4). The follow-up periods in the above studies were all shorter than that in our study. Therefore,

a possible explanation for these differences could be a change in the ability of patients to manage their present situation. Another hypothesis could be that more patients had fully recovered during the longer follow-up period of our study. We observed a maximal MPS score in 34% of patients, with a median follow-up of 8.7 years. Brouwers et al.<sup>18</sup> reported a maximal MPS score in 31% of Tile A, 28% of Tile B and 0% of Tile C fracture patients, with a median follow-up period of 2.5 years. Lefaivre et al.<sup>19</sup> reported a maximum MPS score in 18.4% of patients, with a median follow-up period of 4.5 years. However, that study only included Tile B and C fractures.

Furthermore, no large differences were observed in our study among the Tile groups. Approximately one-third of the pelvic patients with Tile A (32%), Tile B (36%) and Tile C (33%) fractures were reportedly at the highest end of the MPS scale. Comparing these results with those of Brouwers et al.<sup>18</sup>, it could be concluded that between 2.5 and 8.7 years of follow-up, no substantial increase in HRQOL was observed in patients with Tile A or B Fractures. However, the HRQOL of patients with Tile C fractures increased from 0 to 33%. This finding could illustrate that the recovery of patients with Tile C fractures may be longer than previously assumed<sup>2</sup> and that long-term follow-up is warranted in these patients.

Previous studies have shown that age, injury severity, fracture type, neurological injury, urological injuries, sexual dysfunction and method of treatment could influence the functional and HRQOL outcomes.<sup>9,10,12, 14,31</sup> These factors, including open fractures, were identified as confounders in our linear regression model.

Chronic pain due to persistent neurological injury is a well-recognized factor that influences outcomes and is very difficult to treat.<sup>6</sup> The prevalence of focal neurologic deficits was low in our group (6.6%). Additionally, the prevalence of urogenital disorders was low (4%). However, almost 25% of all patients reported sexual problems on the MPS. One possible explanation could be that sexual complaints are underreported by patients during follow-up because of the sensitive nature of these complaints. This hypothesis is supported by the findings of Harvey-Kelly et al<sup>12</sup>, who reported a high rate (28%) of patients who declined to complete the sexual questionnaires. Another explanation could be that, although there are no obvious injury to the urogenital systems, the lumbosacral plexus is damaged and causes severe problems. Pro-active evaluation by the treating physician should be mandatory in the follow-up of patients with a pelvic ring injury.

There are certain limitations to this study. The first is the cross-sectional nature of this study, which did not allow us to obtain baseline values of these patients for a comparison of our results. Hernefalk<sup>32</sup> reported that the pre-traumatic QOL

in patients with surgically treated pelvic fractures is generally high and that pre-existing discomfort from the pelvic region is uncommon. Currently, we are performing a longitudinal designed study, which includes pre-injury assessment, short term outcomes.<sup>33</sup>

Second, the possibility of selection bias exists. Of the 336 total patients with pelvic fractures identified in the study period, only 136 patients (40%) were ultimately included. This may have influenced the overall outcomes. However, of the 231 eligible patients who were contacted, no differences were found between the responders and non-responders in terms of age, gender, Tile classification and ISS.

# Conclusions

Patients who have suffered a pelvic ring fracture generally have good HRQOL outcomes after 5-10 years. With the exception of 2 subscales of the evaluated questionnaires, no significant differences were found among the different fracture types in these patients. Long-term follow-up of patients with Tile C fractures is warranted.

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# **CHAPTER 5**

Prognostic factors and quality of life after pelvic fractures; the Brabant Injury Outcome Surveillance (BIOS) study

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> PLoS ONE 2020, 15(6): e0233690

# ABSTRACT

## Background

Pelvic fractures can have long-term consequences for health-related quality of life (HRQoL). The main purpose of this study is to provide insight into short-term HRQoL in the first year after pelvic injury and to identify short-term prognostic factors of decreased outcome.

## Methods

This is a prospective, observational, multicenter, follow-up cohort study in which HRQoL and functional outcomes were assessed during 12-month follow-up of injured adult patients admitted to 1 of 10 hospitals in the county of Noord-Brabant, the Netherlands. The data were collected by self-reported questionnaires at 1 week (including preinjury assessment) and 1, 3, 6 and 12 months after injury. The EuroQoL-5D (EQ-5D), visual analog scale (VAS), Merle d'Aubigne Hip Score (MAHS) and Majeed Pelvic Score (MPS) were used. Multivariable mixed models were used to examine the course of the HRQoL and the prognostic factors for decreased HRQoL and functional outcomes over time.

## Results

A total of 184 patients with pelvic fractures were identified between September 2015 - September 2016; the fractures included 71 Tile A, 44 Tile B and 10 Tile C fractures and 59 acetabular fractures. At the pre-injury, 1 week, and 1, 3, 6 and 12 months after injury time points, the mean EQ-5D Index values were 0.90, 0.26, 0.45, 0.66, 0.77 and 0.80, respectively, and the mean EQ-VAS values were 83, 45, 57, 69, 75 and 75, respectively. At 6 and 12 months after injury, 22 and 25% of the MPS < 65 year group, 38 and 47% of the MPS  $\geq$  65 year group and 34 and 51% of the MAHS group, respectively, reached the maximum score. Pre-injury score, female gender and high Injury Severity Score (ISS) were important prognostic factors for a decreased HRQoL, and the EQ-5D VAS  $\beta$ = 0.43 (95% CI: 0.31 – 0.57), -6.66 (95% CI: -10.90 – -0.43) and -7.09 (95% CI: -6.11 – -5.67), respectively.

# Conclusions

Patients with pelvic fractures experience a reduction in their HRQoL. Most patients do not achieve the HRQoL of their pre-injury state within 1 year after trauma. Prognostic factors for decreased HRQoL are a low pre-injury score, high ISS and female gender. We do not recommend using the MAHS and MPS in midor long-term follow-up of pelvic fractures because of ceiling effects.

# Background

Pelvic fracture is a collective name for pelvic ring fractures and acetabular fractures and can occur as a result of both high- and low-energy trauma. In young patients, these injuries normally occur due to a high-energy trauma,<sup>1</sup> whereas in elderly patients, these fractures occur more often due to low-energy trauma.<sup>2,3</sup> In the Netherlands, the current annual incidence of pelvic fractures in the elderly population ( $\geq$  65 years) is nine-fold higher (57.9 per 100.000 inhabitants) than that the younger population.<sup>4</sup> Pelvic fractures have long-term consequences for health-related quality of life (HRQoL) in both younger<sup>5</sup> and elderly patients.<sup>6</sup> Several studies have reported the health status of trauma patients in a general trauma population and found little improvement beyond 9 to 12 months after minor injury,<sup>78</sup> while patients with major injury showed continuous improvement in HRQoL for up to 2 years after injury.<sup>9,10</sup>

In 2010 and 2012, Borg et al. demonstrated a substantially lower HRQoL 2 years after the surgical treatment of pelvic fractures compared with a reference population.<sup>5,11</sup> In 2015, Gabbe et al. showed that 2 years after injury, 77% of patients with severe pelvic ring fractures were living independently, and 59% had returned to work.<sup>12</sup> These authors advised a large-scale multicenter study to fully understand the burden of severe pelvic ring fractures.

However, to the best of our knowledge, no prospectively designed multicenter study has been performed in which HRQoL is investigated during the first year after pelvic injury. A better understanding of the HRQoL and the burden of pelvic injury is crucial to improve the quality of healthcare provided to pelvic trauma patients.<sup>13</sup> To identify prognostic factors for HRQoL after pelvic injury, a longitudinal study with both a generic questionnaire and disease-specific instruments are needed.<sup>13</sup> The main purpose of this study was to gain insight into short-term HRQoL in the first year after pelvic injury. Our other aim was to identify short-term prognostic factors of outcome after pelvic trauma.

# Methods

# The Brabant Trauma Registry

The Dutch Noord-Brabant region has 2.5 million inhabitants. Approximately 12,000 injured trauma patients are admitted and included in the Brabant Trauma Registry (BTR) annually.<sup>14</sup> The BTR includes 12 emergency departments (ED) of Network Emergency Care Brabant, including 1 level 1 trauma center, and compiles prehospital and hospital data of all trauma patients admitted after presentation to the ED.

## **BIOS study**

This study was approved by the Medical Ethics Committee of Brabant (project number NL50258.028.14). This pelvic fracture study, in which the HRQoL is assessed during 12 months of follow-up after patient admittance to one of the hospitals, is part of the Brabant Injury Outcome Surveillance (BIOS) study.<sup>15</sup> The BIOS is a prospective longitudinal follow-up study among all admitted adult injury patients ( $\geq$  18 years) in the Noord-Brabant region, regardless of the severity or classification of the injury, to evaluate the total non-fatal burden of injury from the patient and societal perspectives. Patients who had sufficient knowledge of the Dutch language and completed the questionnaires after 1 week, 1 month or 3 months were included in the study. The exclusion criteria were patients with a pathological fracture caused by a malignancy or metastasis or patients older than 80 years. If patients were incapable of completing the self-reported measures themselves because of mental retardation, dementia or other neurological conditions, the questionnaires were completed by a proxy informant. For a detailed description of the study, we refer to the previously published study protocol.<sup>15</sup> The inclusion period in this study was 1 year, from September 1<sup>st</sup>, 2015, until September 30<sup>th</sup>, 2016.

## Data collection

Patient characteristics, injury characteristics, additional injuries, complications during admission and possible surgical procedures were extracted from the BTR. We used the Abbreviated Injury Scale (AIS-90, update 2008)<sup>16</sup> to define the anatomical location and severity of the additional injuries. We calculated the Injury Severity Score (ISS) to assess the overall injury severity.<sup>17</sup> The AO/ OTA classification was used by the principal investigator to classify pelvic ring fractures into stable fractures (61A1–A3), rotationally unstable fractures (61B1–B3), or rotationally and vertically unstable fractures (61C1–C3) and acetabular fractures into partial articular, isolated column and/or wall fractures (62A), partial articular, transverse type fractures (62B) or complete articular, associated both column fractures (62C).<sup>18</sup>

## **Outcome measures**

## Generic HRQoL

The EQ-5D questionnaire,<sup>19</sup> defined along five dimensions, including mobility, self-care, usual activities, pain or discomfort, and anxiety or depression, with 3 levels each (no, moderate or severe problems) was used to measure the generic HRQoL. The EQ Visual Analogue Scale (EQ VAS) records the patient's self-rated

state of health on an analogue scale between 0 (worst imaginable health state) and 100 (best imaginable health state).

A Dutch scoring algorithm (EQ-5D index score) is available by which each health status description can be expressed into a summary index score.<sup>20,21</sup> This index score ranges from -0.329 to 1, in which 0 represents death, 1 represents full health and < 0 represents a health state considered worse than death. The EQ-5D index and VAS score of patients with a pelvic fracture and the average EQ-5D index summary score and VAS score for the general Dutch population were compared.<sup>20,21</sup>

# Disease-specific HRQoL

Several specific questionnaires have been designed to investigate the HRQoL after pelvic injury. The Majeed Pelvic Score (MPS) is a frequently used pelvic ring-specific HRQoL instrument.<sup>22,23</sup> Recently, the Dutch norm scores for the MPS were collected for the < 65 years (88.3) and  $\geq$ 65 years (72.0) age groups.<sup>24</sup> The Merle d'Aubigné Hip Score (MAHS) is a commonly used questionnaire to evaluate functional results after acetabular fractures.<sup>25-27</sup> We used the MPS to measure HRQoL in patients with pelvic ring fractures and the MAHS to measure HRQoL in patients with isolated acetabular fractures.

# MPS

The MPS questionnaire<sup>22</sup> is defined along seven dimensions, including pain, work, sitting, sexual intercourse and standing, (walking aids, unaided gait, walking distance), with scores of 5/30, 0/20, 4/10, 1/4 and 6/36, respectively (2/12, 2/12, 2/12) (minimum/maximum points). The MPS ranges between 16 (worst health state) and 100 (best health state). The patients were divided into <65 years (working) and ≥65 years (retired) age groups, with maxima of 100- and 80 points, respectively.<sup>28</sup>

# MAHS

The MAHS is a clinical hip score that evaluates pain, ambulation and mobility. The pain and ambulation domains are divided into 6 grades, where 1 indicates the worst and 6 indicates the best state of the patient.<sup>25</sup> The domain mobility/ range of motion (ROM) is determined by comparison of the total score for the injured side with that for the uninjured side (flexion, abduction, adduction and rotation). This domain is divided into 5 grades (0-39, 40-59, 60-79, 80-94, and 95-100% ROM), with points given as 1, 3, 4, 5 and 6, respectively. The total minimum score is 3, and the maximum is 18; Excellent is indicated by 18, Good by 15–17, Fair by 12–14, and Poor by 3–11.

## Follow-up

Patients received the information letter, informed consent form, pre-injury questionnaire and first questionnaire within the first week of hospital stay or at their home address. Patients could choose between returning the questionnaires online or with paper and pencil. The EQ-5D data were collected at 1 week and 1, 3, 6 and 12 months after trauma. The MPS data were collected 1, 3, 6 and 12 months after trauma. The MAHS data were collected at 6 weeks and 3, 6 and 12 months after trauma. Patients were considered lost to follow-up if the questionnaires were not completed from any follow-up time point permanently. The level of education was included in the questionnaire according to the Dutch standards of Statistics Netherlands (Centraal Bureau voor Statistiek): low education level (highest degree basisonderwijs of vmbo, mbo 1, havo onderbouw), intermediate education level (havo, vwo, mbo 2, 3, 4) or a high education level (hbo, wo bachelor, wo master, doctor).

## **Data Analysis**

Descriptive statistics were calculated to provide an overview of the characteristics of the study population. The maximum scores of the MPS and MAHS were assessed. Ceiling effects were considered to be present if >15% of respondents achieved the highest possible score.<sup>23,29</sup> Multivariable mixed models were used to examine the course of HRQoL and prognostic factors for decreased HRQoL and functional outcomes over time. Patient characteristics, self-reported pre-injury HRQoL and injury-related characteristics, ISS, pelvic operation (yes or no) and low-energy trauma (LET) or high-energy trauma (HET), were tested as prognostic factors of decreased HRQoL. The ISS was categorized into the 1-8, 9-15 and >15 groups . Age was categorized into the <65 (N= 97) and  $\geq$  65 years (N= 87) groups. Statistical test results were considered significant at a level of p<0.05. All analyses were conducted using SPSS V.24.0 (Statistical Package for Social Sciences, Chicago, Illinois, USA).

# Results

# Inclusion and exclusion

A total of 204 patients with pelvic fractures were admitted (fig. 1). Ninety percent of the patients (N= 184) were included in the study. Twelve patients did not want to participate. Eight patients were excluded; 1 patient was lost to follow-up soon after discharge from the hospital, and 7 patients were excluded because of a preinjury poor mental state without the availability of a proxy informant. Almost all the included patients completed their follow-up. However, during follow-up, 4 patients died as a result of cardiovascular of cardiorespiratory diseases and their advanced age, and 1 died due to suicide. Eight patients showed no interest in participating anymore during follow-up. All data received for patients who did not complete their follow-up were used during our analysis.

Figure 1 | Flow of participants through the study



## **Patient characteristics**

Mean age of females in our study was 62 (SD 16) years and mean age for male patients was 56 (SD 17) years (P = 0.03). Mean pre-injury EQ5D index score of female patients was 0.85 (SD 0.20) while the score of male patients was 0.93 (SD 0.16), a significant difference (P = 0.01). The patient characteristics are shown in table 1. The pelvic fractures were divided over the two AO/OTA groups (61 and 62 respectively). Eighty-seven percent (N=62) of the 61A fractures were minimally displaced fractures of the ring (62A2). Eighty percent (N=35) of the 61B fractures were identified as lateral compression injuries (61B2), and 70% (N=7) of the 61C fractures were unilateral, rotationally and vertically unstable (61C1). Eleven acetabular fractures were classified as posterior wall types, 2 as anterior wall, 6 as anterior column, 6 as transverse, 14 as T-type, 2 as posterior wall/posterior column, 6 as anterior column/posterior hemitransverse and 12 as

both column. This resulted in 21 62A, 26 62B and 12 62C type fractures according to the AO/OTA classification.

Eighty-two patients (45%) had a low education level, 62 (34%) an intermediate education level and 37 (20%) a high education level. In the general Dutch working population, 29% have a low education level, 40% have an intermediate education level and 30% have a high education level.<sup>30</sup>

# Mean questionnaire scores

Fig. 2 shows a global graphic of the mean EQ-5D VAS, index and MPS at each time point post-injury. Pre-injury EQ-5D index and VAS scores were 0.90 and 83, respectively. The average EQ-5D index summary and VAS scores for the general Dutch population were, respectively, 0.87, SD 0.18 and 77.72, SD 15.19.(30,31) At 1 week post-injury, patients scored means of 0.26 and 45, respectively. Patients scored means of 0.45, 57, 49 and 47 points on the Index, VAS and < 65 and  $\geq$  65 MPS, respectively, at one month after injury. At 3, 6 and 12 months after injury, patients scored 0.66/69/70/66, 0.77/75/81/72 and 0.80/75/83/70 points, respectively. Fig. 3 shows the mean values. At 6 weeks and 3, 6 and 12 months after injury, patients with an acetabular fracture scored means of 11.38, 14.02, 15.75 and 16.79 points on the MAHS, respectively.

Table 1 | patient characteristics

	61A	61B	61C	Acetabulum
N (%)	71 (39)	44 (24)	10 (5)	59 (32)
Pelvic AO/OTA subtypes N (%)	71 (07)	11(21)	10 (0)	05 (02)
1	0 (0)	1 (2)	7 (70)	
2	62 (87)	35 (80)	2(20)	
3	9 (13)	8 (18)	$\frac{1}{1}(10)$	
Acetabulum AO/OTA subtypes N (%)	) (10)	0 (10)	1 (10)	
62A				21 (36)
62B				26 (44)
62C				12 (20)
Gender				()
% male	41	57	60	81
Age				
Mean Years (SD)	63 (16)	53 (19)	44 (19)	59 (14)
Mechanism in %	(-)			
Fall from same level	63	27	0	32
Fall from height	17	25	50	24
Traffic accident	18	43	40	41
Entrapment	2	5	10	3
Trauma mechanism in %				
Low Energy Trauma	62	23	0	32
High Energy Trauma	38	77	100	68
Associated injuries (AIS severity>1) %				
AIS region Head	14	23	0	19
AIS region Face	11	9	10	3
AIS region Neck	0	0	0	0
AIS region Thorax	11	25	40	17
AIS region Abdomen	4	16	40	7
AIS region Spine	13	18	70	5
AIS region Upper extremity	25	27	20	29
AIS region Lower extremity	100	100	100	100
AIS region Unspecified	7	7	30	29
Shock type %*				
Туре 1	96	61	10	80
Type 2	4	32	60	18
Туре 3	0	7	20	2
Type 4	0	0	10	0
Mean ISS (SD)	7 (6)	13 (12)	26 (12)	8 (6)
Pelvic operation %	1	39	100	42
Median hospitalization in days (IQR)	5 (6)	9 (9)	25 (28)	10 (10)
Neurological complication %	1	16	30	7
Total hip arthroplasty < 1 year %	0	0	0	12
1-year mortality, N (%)	2 (3)	0	1 (10)	2 (3)

\*Types of hemorrhagic shock according to ATLS guidelines.

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\*To combine all questionnaires in one figure, the results of the EQ-5D index are multiplied by a hundred ("x 100").





# Maximum MPS and MAHS

In general, very few maximum scores of the MPS were seen at 1 month after injury in both age groups (table 2). Three months after injury, 9% of the patients < 65 years scored a maximum score of 100 points, while 23% of the patients  $\geq$ 65 years scored the maximum score of 80 points. At 12 months after injury, almost 50% of the patients  $\geq$ 65 years had a maximum score on the MPS. At 6 and 12 months after trauma 34% and 50% of patients with an acetabular fracture had a maximum MAHS, respectively (table 3).

Time point	Mean (SD)	Mean (SD)	Maximum score	maximum score
	< 65 years	≥65 years	(%) < 65 years	(%) ≥ 65 years
1 month	49 (16)	47 (13)	0 (0)	1 (2)
3 months	70 (19)	66 (13)	5 (9)	10 (23)
6 months	81 (17)	72 (10)	12 (22)	15 (38)
12 months	83 (17)	70 (13)	13 (25)	21 (47)

 Table 2 | Mean MPS (standard deviation) scores and frequency of patients with maximum scores

Table 3  $\mid$  Mean MAHS (standard deviation) scores and frequency of patients with maximum scores

Time point	Mean (SD)	maximum score (%)
6 weeks	11 .4 (2.9)	0 (0)
3 months	14.0 (2.5)	5 (9)
6 months	15.8 (2.6)	20 (34)
12 months	16.8 (1.8)	30 (51)

## HRQoL outcomes over time and prognostic factors of decreased HRQoL

Tables 4, 5 and 6 show regression coefficients (95% CI) from the multivariable mixed models investigating the predictors of reporting problems on the EQ-5D index, VAS, MPS and MAHS, respectively. The outcomes of the EQ-5D index and VAS questionnaires 1, 3, 6 and 12 months after trauma were compared to the outcome 1 week after trauma.

The pre-injury score was an important prognostic factor for a decreased HRQoL in the EQ-5D VAS and index score. Female gender was associated with a lower score on the EQ-5D VAS ( $\beta$ = -6.67 (95% CI: -10.90 – -0.43)) compared with male gender. Patients with a higher ISS were associated with a lower score on the

EQ-5D VAS and Index score (respectively  $\beta$ = -7.1009 (95% CI: -12.41 – -1.78-6.11 – -5.67) and  $\beta$ = -0.11 (95% CI: -0.19 – -0.03)) compared with those with a lower ISS. Females  $\geq$  65 years with pelvic ring fractures were associated with a lower MPS ( $\beta$ = -7.79 (95% CI: -14.44 – -1.14)) compared with males. Patients  $\geq$  65 years with a pelvic ring fracture and a higher ISS were associated with lower scores on the MPS ( $\beta$ = -13.76 (95% CI: -24.27 – -3.24)) compared with those with a lower ISS. Pelvic type, acetabulum type, pelvic operation, high- or low-energy trauma and education level were not significantly associated with lower or higher HRQoL after pelvic injury.

**Table 4** | The HRQoL outcome over time and prognostic factors in the first year. Regression coefficients (95% CI) for EQ-5D and VAS for the first year after trauma assessed with multivariable mixed models.

	EQ-5D index score#		E	EQ-5D VAS score#		
	Beta	95% CI	p-value	Beta	95% CI	p-value
1 week	0*	-	-	0*	-	-
1 month	0.21	0.16 - 0.25	< 0.001	14.23	10.95 – 17.51	< 0.001
3 months	0.43	0.38 - 0.48	< 0.001	26.67	23.38 - 29.95	< 0.001
6 months	0.53	0.49 - 0.58	< 0.001	32.21	28.86 - 35.56	< 0.001
12 months	0.56	0.52 - 0.61	< 0.001	32.80	29.44 - 36.17	< 0.001
Female	-0.06	-0.13 - 0.00	0.05	-6.67	-10.902.43	< 0.001
HET	-0.03	-0.10 - 0.05	0.52	-1.81	-6.86 - 3.23	0.48
Pelvic operation	-0.02	-0.09 - 0.05	0.53	-2.22	-6.93 - 2.49	0.35
Age≥65 years	0.017	-0.05 - 0.08	0.61	2.83	-1.52 – 7.19	0.20
ISS 1-8	0*	-	-	0*	-	-
ISS 9-15	-0.03	-0.12 0.06	0.46	-0.22	-6.12 - 5.67	0.94
<b>ISS</b> ≥ 16	-0.11	-0.190.03	< 0.001	-7.10	-12.41 – -1.78	< 0.001
Low education	0*	-	-	0*	-	-
level						
Intermediate	0.05	-0.02 - 0.11	0.19	0.80	-3.69 - 5.29	0.73
education level						
High education	0.03	-0.05 - 0.11	0.43	-1.39	-6.60 - 3.82	0.60
level						
Pre-injury scorea	0.61	0.43 - 0.79	< 0.001	0.44	0.31 - 0.57	< 0.001

\*Reference group. \*Pre-injury EQ-5D index score and pre-injury EQ-5D VAS score for respectively EQ-5D index score and EQ-5D VAS score. \*Adjusted for all other variables in the table. Beta = regression coefficient, ISS = Injury Severity Score, CI = Confidence Interval, HET = High Energy Trauma

		MPS < 65 year	sa		MPS ≥ 65 yearsa			
	Beta	95% CI	p-value	Beta	95% CI	p-value		
61A	0*	-	-	0*	-	-		
61B	-1.92	-12.19 – 8.35	0.71	-0.65	-7.89 - 6.59	0.86		
61C	-12.23	-31.63 - 7.18	0.21	9.91	-8.47 - 28.28	0.28		
1 month	0*	-	-	0*	-	-		
3 months	19.49	15.06 - 23.91	< 0.001	18.64	14.91 – 22.37	< 0.001		
6 months	31.52	27.13 - 35.92	< 0.001	23.50	19.71 – 27.28	< 0.001		
12 months	33.77	29.32 - 38.22	< 0.001	23.45	19.77 – 27.14	< 0.001		
Female	-7.44	-16.47 – 1.59	0.10	-7.79	-14.44 – -1.14	0.02		
HET	2.09	-9.60 - 13.78	0.72	3.47	-4.50 - 11.44	0.38		
Pelvic operation	4.79	-6.69 - 16.27	0.41	-6.63	-18.96 - 5.70	0.28		
ISS 1-8	0*	-	-	0*	-	-		
ISS 9-15	5.98	-6.10 - 18.06	0.33	-3.53	-12.21 – 5.14	0.42		
ISS ≥ 16	-5.99	-16.78 - 4.80	0.27	-13.76	-24.273.24	0.01		
Low education	0*	-	-	0*	-	-		
level								
Intermediate	5.12	-4.00 - 14.24	0.27	2.69	-3.85 - 9.22	0.41		
education level								
High education	7.89	-3.04 - 18.82	0.15	2.84	-4.94 - 10.62	0.47		
level								

**Table 5** | The HRQoL outcome over time and prognostic factors in the first year, separate for patients younger than 65 years and 65 years or older, with multivariable mixed models.

\*Reference group. aAdjusted for all other variables in the table. Beta = regression coefficient, ISS = Injury Severity Score, CI = Confidence Interval, HET = High Energy Trauma

	Merle d'Aubigne hip score		
	Beta	95% CI	p-value
Elementary fracture	0*	-	-
Associated fracture	-1.16	-2.36 - 0.03	0.06
6 weeks	0*	-	-
3 months	2.66	2.03 - 3.28	< 0.001
6 months	4.40	3.78 - 5.02	< 0.001
12 months	5.24	4.59 - 5.89	< 0.001
Female	0.14	-1.37 – 1.64	0.86
HET	1.24	-0.20 - 2.67	0.09
Pelvic operation	-0.28	-1.62 - 1.07	0.68
Age≥65 years	-0.04	-1.33 - 1.26	0.96
ISS 1-8	0*	-	-
ISS 9-15	-0.12	-2.28 - 2.04	0.91
ISS ≥ 16	-0.41	-2.14 - 1.32	0.63
Low education level	0*	-	-
Intermediate education level	-0.01	-1.53 - 1.52	0.99
High education level	0.78	-0.98 - 2.54	0.38

**Table 6** | The HRQoL outcome over time and prognostic factors in the first year with multivariable mixed models.

\*reference group. Beta = regression coefficient, ISS = Injury Severity Score, CI = Confidence Interval, HET = High Energy Trauma

# Discussion

This study was performed to gain more insight into short- and mid-term HRQoL after pelvic injury. Furthermore, prognostic factors of decreased outcome in the first year after pelvic injury were identified. Patients with pelvic fractures experience a severe reduction in their HRQoL and functional outcomes, especially within the first 3 months after injury. Although patients recover up to 12 months after trauma, most patients do not reach their pre-injury status. Prognostic factors for a decreased quality of life after pelvic trauma are high ISS, low pre-injury HRQoL status and female gender.

## Short- and mid-term HRQoL

The EQ5D-index and VAS outcomes of pelvic fracture patients in our study showed steep decreases in the first week and steep increases in the first 3 months after trauma when compared with their pre-injury status. Although the HRQoL recovery continues to improve up to 12 months after trauma, most patients do not achieve their pre-injury state of HRQoL. One year of follow-up could be insufficient to reach a pre-injury status. This hypothesis could be confirmed by the index score of the general Dutch population, which is 0.87<sup>20</sup>, while our mean index score was 0.80 at 12 the month time point after trauma.

Borg et al. observed a substantially lower HRQoL in patients with surgically treated 61B and C fractures two years after injury compared with a reference population.<sup>5</sup> Giannoudis et al. observed a mean EQ-5D index score of 0.73 (population norm score 0.85) and a mean VAS score of 71.5 in patients with operatively treated isolated acetabular fractures with a mean follow-up of 36 months.<sup>31</sup> Although these studies were not completely comparable to our study (only 29% surgically treated patients), they showed a decreased HRQoL of at least one year after trauma and possibly up to even 2 years after trauma.

For the MPS and MAHS, three months after trauma seems to be an turning point. The recovery curves of the MPS  $\geq$  65 years and MAHS plateau after this time point, while the recovery curves of the MPS < 65 years patients only plateau 6 months after trauma. This observation could mean that younger patients need more time to recover, probably due to more severe trauma. The older group seems to "stagnate" at 3 months after trauma in terms of recovery, although this stagnation could mean that this group is almost fully recovered at that time due to their less severe injury. This hypothesis of the relationship between age and trauma severity could be confirmed by the patient characteristics: older patients are more frequently seen in the 61A group (low-energy trauma) compared with the 61B and C group (high-energy trauma).

### Prognostic factors that could influence HRQoL after pelvic trauma

Prognostic factors that are known to influence the quality of life after pelvic trauma include neurological impairment of the lower extremities, aging, complex fracture type, surgery, chronic pain and sexual and urological dysfunction.<sup>32-25</sup> Patients with isolated acetabular fractures are at risk for a decreased HRQoL especially due to osteoarthritis, heterotopic ossification and avascular necrosis of the femoral head.<sup>36</sup> However, most studies that focus on prognostic factors after a pelvic trauma are single-center, retrospective, and cross-sectional in nature or feature small sample sizes with a follow-up starting 1 year after trauma.<sup>23,28,29,34,35,37,38</sup>

Our study shows several prognostic factors that lead to decreased HRQoL after pelvic trauma. A low pre-injury HRQoL status seems to be an important prognostic factor for both acetabular- and pelvic ring fractures. However, the timing of the pre-injury score has been debated in earlier studies. Williamson et al.<sup>39</sup> concluded that it was allowed to implement a pre-injury score up to 6 months after trauma. Hernefalk et al. concluded that completing the preinjury HRQoL questionnaire 1-2 months after trauma was more accurate and that pre-injury assessments were possibly susceptible to distortion.<sup>40</sup> The preinjury VAS scores of patients with surgically treated acetabular and pelvic ring fractures were calculated by these authors to be 79, 85 and 86 at 1 week, 1 and 2 months after injury, respectively. In our study, we found a mean pre-injury VAS score of 83, which is comparable with the results of Hernefalk 1-2 months after injury. Williamson et al. demonstrated that patients with increasing age (> 65 years) reported a higher pre-injury status at 12 months post-injury when compared with the pre-injury status reported earlier in the year after trauma. Thus, although the studies of Hernefalk et al., Williamson et al. and our study showed that the timing of the pre-injury questionnaires is arbitrary, our study demonstrated that the pre-injury assessment is important to measure and that a low pre-injury status is a risk factor for a decreased HRQoL for young and old patients.

Gender is an also important prognostic factor. A significant difference was found in the EQ5D VAS score, and specific for the older pelvic ring fracture patients (MPS  $\geq$  65). No significant difference was found in the subset of acetabular patients (MAHS). This could imply that women of  $\geq$  65 years with a pelvic ring fracture are more prone for a worse HRQoL. In contrast to the study of Holstein et al.,<sup>34</sup> we found the female gender to be a prognostic factor for a reduced quality of life after sustaining a pelvic fracture. Polinder et al. and Holbrook et al.<sup>8,41</sup> found female gender to be a prognostic factor for a poor HRQoL after trauma in general. Holbrook concluded that a better understanding of the impact of major trauma in men and women will be an important component of efforts to improve trauma care and long-term outcome in mature trauma systems. It could be that females in general have a lower pre-injury score when compared with male.

To gain a better understanding of the HRQoL and burden of pelvic injury, it is important to investigate the overall impact of the injury and to determine the ISS. In our study, we measured ISS, including the AIS of the pelvic fracture, meaning that the ISS could be slightly influenced by the gradation of the pelvic fracture. However, it is known that patients with pelvic fractures suffer from many associated injuries.<sup>42</sup> We found ISS to be a prognostic factor for a decreased HRQoL.

Literature has shown that aging could be a prognostic factor for a reduced quality of life after pelvic trauma<sup>34</sup> and trauma in general.<sup>13</sup> However, except for females in the MPS  $\geq$  65 group, we did not find a relationship between aging and a decreased HRQoL when using the EQ5D Vas, Index score or MAHS. An important reason for this lack of association in the combined pelvic ring/ acetabular fracture group could be the inclusion of a pre-injury HRQoL questionnaire in our longitudinal analysis, which was not included in the questionnaires of other studies. Our hypothesis is that elderly patients with multiple comorbidities will score lower on the pre-injury questionnaire compared with the healthy young population. Therefore, the pre-injury score is a stronger prognostic factor for a reduced HRQoL than age.

Pelvic fracture type, acetabular fracture type, HET or LET, education level and pelvic operation were not prognostic factors. It is possible that the sample size of patients was insufficient to draw conclusions about these prognostic factors. It could also be possible that prognostic factors such as pelvic or acetabular type and operation are of importance to the follow-up during the first months after trauma. Prognostic factors were assessed over the first year after injury; prognostic factors for short-term recovery could be leveled out if they were not also prognostic factors for long-term recovery. Therefore, a new study is needed with larger sample sizes to draw conclusions using these prognostic factors.

## Strengths and limitations

The strengths of our study include the multicenter prospective longitudinal design, high response rate and low prevalence of missing data. To the best of our knowledge, this is the largest longitudinal study of the follow-up of patients with pelvic fractures. A longitudinal design has several benefits<sup>43</sup>: 1). following the change in individual patients over time, 2). recording the sequence of an event, 3). avoiding recall bias by its prospective nature and 4). relating exposures to event. A disadvantage of this study design might be an incomplete or loss

to follow-up of individuals. However, in our study, both the inclusion rate and follow-up rate were high. We are aware of the fact we earlier concluded that Tile C patients <65 years had significantly lower EQ-5D index and total MPS scores. (28) We now feel that a longitudinal analysis is much more comprehensive in investigating HRQoL patterns when compared with just one follow-up moment without a pre-injury score.

Our study also has important limitations. Few patients with 61C fractures were included. Therefore, we were not able to perform a sub-analysis of the AO/OTA-61 and 62 groups. Furthermore, other possible prognostic factors were not collected (i.e., quality of surgical fracture reduction). Other studies have debated the importance of the relationship between surgical fracture reduction and HRQoL outcomes.<sup>44-46</sup> Prognostic factors were assessed over the first year after injury; prognostic factors for short-term recovery could be leveled out if they were not also prognostic factors for long-term recovery. Therefore, a new study is needed with larger sample sizes to draw conclusions using these prognostic factors.

Serious remarks can be made about the disease-specific HRQoL instruments, MPS and MAHS. Although both questionnaires are often used in pelvic or acetabular-related research, they have not been validated by a formal validation process, nor have they been officially translated into Dutch.<sup>47-48</sup> While the pre-injury scores of the EQ5D-VAS and index showed non-completed recovery 12 months after trauma, ceiling effects of the MPS and MAHS were already present at 3 and 6 months after trauma, meaning that neither questionnaire is specific enough to differentiate between specific recovery levels during the follow-up of pelvic fractures and that long-term outcomes are biased. Lefaivre et al. compared with the MPS with another major generic HRQoL instrument, the Short Form-36; these authors also found ceiling effects and questioned the reliability and responsiveness of this approach over time.<sup>47</sup>

Therefore, we do not recommend the use of the MAHS and MPS in the midand long-term follow-up of pelvic fractures. More research is needed to develop disease-specific HRQoL questionnaires that are suitable for long-term follow-up.

# Conclusion

Patients with pelvic fractures experience a reduction of their HRQoL, especially in the first 3 months. The HRQoL recovery continues to improve up to 12 months after trauma, and most patients do not achieve their pre-injury state of HRQoL. Prognostic factors for decreased HRQoL after pelvic trauma are a low pre-injury score, high ISS and female gender. A longer follow-up is needed to examine the HRQoL of pelvic fracture patients. We do not recommend the use of MAHS and MPS in the mid- and long-term follow-up of pelvic fractures.

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# **CHAPTER 6**

Validation Study of 3D printed anatomical models using 2 PLA printers for preoperative planning in trauma surgery, a human cadaver study

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European Journal of Trauma and Emergency Surgery 2019, 45(6), 1013-1020

# ABSTRACT

#### Background

3D printing contributes to a better understanding of the surgical approach, reduction and fixation of complex fractures. It is unclear how a 3D printed model relates to a human bone. The accuracy of 3D printed models is important to prebend plates and fit of surgical guides. We conduct a validation study in which we compare human cadavers with 3D printed models to test the accuracy of 3D printing.

#### Methods

Nine specimens were scanned, volume rendered into 3D reconstructions and saved as STL data. All models were in a ratio of 1:1 printed on the Ultimaker 3 and Makerbot Replicator Z18.

Two independent observers measured all distanced between the K-wires on the human cadavers, 2D CT, 3D reconstruction, Meshlab and both printers. A paired Samples T-test was used to compare the measurements between the different modalities.

#### Results

The least decrease in average distance in millimetres was seen in "the 3D printed pelvis 1", -0.3% and -0.8% on respectively the Ultimaker and Makerbot when compared with cadaver Pelvis 1. The 3D model of "Hand 2" showed the most decrease, -2.5% and -3.2% on the Ultimaker and Makerbot when compared with cadaver hand 2. Most significant differences in measurements were found in the conversion from 3D file into a 3D print and between the cadaver and 3D printed model from the Makerbot.

#### Conclusions

Our 3D printing process results in accurate models suitable for preoperative workup. The Ultimaker 3 is slightly more accurate than the Makerbot Replicator Z18. We advise that medical professionals should perform a study that tests the accuracy of their 3D printing process before using the 3D printed models in medical practice.

# Background

Complex fractures are difficult to characterise and analyse preoperatively, even with computed tomography (CT).<sup>2,3</sup> Surgeons generally need years of practice to transform a two-dimensional (2D) image into a three-dimensional (3D) image in their mind in order to get a proper understanding of the fracture patterns. CT software however easily enables volume rendering of 2D CT into a 3D reconstruction.<sup>4</sup>

3D printing has become increasingly utilized in the preoperative planning of clinical orthopaedics, trauma orthopaedics and other disciplines over the past decade.<sup>1</sup> 3D printed models are readily accessible due to the wide availability of 3D printing techniques and 3D printers.<sup>1</sup> 3D printing contributes to a better understanding of the surgical approach, reduction and fixation of fractures, especially in complex fractures such as acetabular fractures.<sup>3,5-7</sup> Zeng et al.<sup>8</sup> describe the combination of a 3D printed model and a computer-assisted virtual surgical program for preoperative planning. This combination resulted in improved patient-specific preoperative planning. Furthermore, more accurate reduction and shorter operation times can be achieved.<sup>9,10</sup>

Mallepree et al.<sup>11</sup> concluded that the accuracy of a medical print was mostly influenced by scan parameters and not by the process of converting CT data into 3D prints. The process from scanning the patient to the final 3D printed model will result in loss of data. However, it is unclear how a 3D printed model relates to a human bone. To our knowledge, there is no literature that validates the accuracy of 3D printed models in a preoperative planning strategy when applied to real human bones. The accuracy of 3D printed models is important to pre-bend plates and fit of surgical guides. We have conducted a validation study in which we compare human cadavers with 3D printed models to test the accuracy of 3D printing.

# Methods

#### **Study preparations**

Three fresh frozen human cadavers were obtained from the department of anatomy. The pelvis, hands and feet were dissected and freed from all soft tissue exposing the bony structures. The ligamentous structures on the bone were left intact. Nine anatomic specimens - 3 pelvis, 3 hands and 3 feet - were used (Figure 1). Titanium Kirschner (K-) wires were inserted to mark anatomical landmarks (figure 2).

Pelvic landmarks were defined as the left and right: (1) tubercle on the pubic bone, (2) anterior superior iliac spine (ASIS), (3) posterior superior iliac spine (PSIS), (4) sacroiliac (SI) joint and (5) distance between the SI-joint and pubic bone on the right side of the pelvic bone.

Hand landmarks were defined as: (1) the radial styloid process and distal radioulnar articulation, (2) base and head of the second metacarpal bone and (3) base and head of the fifth metacarpal bone. Figure 3 shows a hand of a cadaver with these marker points.

Foot landmarks were defined as: (1) the distal medial malleolus, (2) between base and head of the first metatarsal bone and (3) base and head of the fifth metatarsal bone. Figure 4 shows a foot with the marker points. The distances between all landmarks were subsequently measured by two independent observers using a Vernier caliper. The point of intersection was defined as the intersection between bone and K wire.

#### Process of creating 3D prints from CT data

In order to create a 3D print, a Standard Tessellation Language (STL) file is needed. This is a specific file format used by 3D software to generate 3D prints. Converting CT scans in Digital Imaging and Communication (DICOM) file format to STL occurs in three stages<sup>4</sup>: image acquisition,<sup>12</sup> image post-processing<sup>13</sup> and 3D printing.

#### **Image acquisition**

The nine specimens were scanned using a Siemens Somatom Definition AS 64slice CT (Siemens Healthcare, Forchheim, Germany). Slice thickness of 0.6 mm and soft reconstruction filters were used for our protocol in order to generate high resolution images and minimalize soft tissue image noise.

DICOM data of all cadavers was saved in Picture Archiving and Communication System (PACS). The two independent reviewers used the hospital's integrated *Philips Intellispace Portal*® software to measure the distance between the markers in 2-dimensional views.

**Figure 1** | Figure 1 shows dissected the pelvis cadaver number 3 with all five marker points.



**Figure 2** | This is a close up of the dissected pelvis with one of the created marker point by titanium K-wires.



**Figure 3** | A cadaver of the hand with the marker points.



**Figure 4** | A cadaver of the foot with the marker points.



#### Image post-processing

The image post processing was divided into 3 phases:

#### Phase 1: Creating a volume rendered model of the object.

We used *Philips Intellispace Portal* software to volume render the DICOM data into 3D reconstructions and to ascertain measurements of the 3D CT landmarks by the two independent observers. Figure 5 shows a 3D CT of the pelvis and a hand with respectively the 5 and 3 anatomical landmarks.

# *Phase 2: Cleaning of the model and creating an STL file from the volume rendered model.*

The 3D reconstruction was digitally cleaned from all surrounding artifacts and remnants of the soft tissue in the Philips Intellispace Portal and then saved as a STL file. The landmarks in the STL file were measured by the two independent reviewers using Meshlab, an open-source program.

#### *Phase 3: Importing the STL file in 3D print software and generating the print code* Our hospital uses both the *Makerbot Replicator Z18* (Makerbot Industries, USA) - a high end consumer extrusion 3D printer with a large build volume and the *Ultimaker 3* (Ultimaker B.V., the Netherlands) a desktop 3D printer with a dual extruder. These printers use Polylactic Acid (PLA), a thermoplastic polyester, to extrude the plastic on a build platform where it solidifies.

The print code (G-code) for the Makerbot was generated using *Simplify 3D* and the print code for the Ultimaker was generated using *Cura*. The following process settings were standardized: extruder temperature 215°C, chamber temperature 24°C, primary layer height 0.2 mm, infill 2% (the outer side of bone exists of cortical bone, therefore the model supports itself and less infill can be used), support infill 20%, maximum overhang without support 60%.

#### 3D printing

The 3D models of the cadavers were printed in a ratio of 1:1. A 3D printed model of a hand and the cadaver hand can be seen in Figure 7. The amount of material used, PLA and support, printing time and filament costs were also noted. The two independent observers measured all distances on all 3D printed models.



Figure 5 | A 3D model of a pelvis and a hand

In this figure a 3D model of a pelvis and a hand after CT-scanning are seen with all measurements between the five marker points performed on the Philips Intellispace Portal.

Figure 6 | A view of the 3D model of a Figure 7 | The cadaver hand with titanium pelvis in the open software source Meshlab.

K-wires maker points next to a 3D printed model of the hand. The printed k-wires are clearly seen on the 3D printed model.



#### **Two Observers**

All of the measurements described above were undertaken by two independent observers. In summary, they measured the distances between the anatomical landmarks on the human cadavers (cadaver), 2D CT (Port 2D), 3D reconstructions (Port\_3D), Meshlab (Mesh\_3D) and 3D printed models on the Ultimaker and Makerbot (Print UM, Print MB).

After one month, both observers were asked to measure all distances again to measure the inter-observer and intra-observer agreement. The distances between the k-wires on the fresh human cadavers were only measured once, because the cadavers had to be disposed of after two days.

#### Data analysis

Descriptive statistics were calculated to provide an overview of the print process settings. Observer data was analyzed and expressed in terms of intra- and interobserver agreement. We used Pearson correlation to calculate the correlation coefficient r and to analyse the relationship between the measurements of both observers.

The measurements between both 3D printers and cadavers was also expressed as a percentage of cadavers. A Paired Samples T test was used to compare the measurements between cadavers, 2DCT, 3DCT, Meshlab and both 3D printers. A p-value of 0.05 was determined as significant. IBM SPSS Statistics 24 was used for the database (Statistical Package for the Social Sciences, Chicago, IL, USA).

# Results

Table 1 shows an overview of the print process settings of both 3D printers. The mean raw material costs for printing a pelvis, foot and hand were respectively 25, 6 and 4 euro for the Makerbot and 34, 13 and 6 euro for the Ultimaker.

Table 2 shows the correlation of the measurements between the observers - the inter-observer agreement. The Pearson correlation coefficient of 1 for each measurement shows that both observers had exact agreement in measuring the distances in all objects.

The intra-observer agreements of both observers are shown in table 3. All Pearson correlations here too are 1, indicating absolute agreements for each observer.

	Makerbo	t			Ultimake	er		
	Building	Weight	Support,	Mean	Building	Weight	Support,	Mean
	time in	in	%	filaments	time in	in	%	filament
	hours	grams		costs in	hours	grams		costs in
				euro				euro
Pelvis 1	92.00	613	32		97.00	710	45	
Pelvis 2	56.00	392	53	25	76.00	588	59	34
Pelvis 3	72.00	631	35		106.00	720	55	
Foot 1	23.50	140	24	6	30.26	270	50	
Foot 2	24.00	116	38		22.30	227	51	13
Foot 3	25.00	177	46		26.50	276	56	
Hand 1	11.20	70	29		13.50	111	58	
Hand 2	16.00	70	23	4	14.50	118	49	6
Hand 3	10.30	65	31		14.40	131	49	

Table 1 | Printing characteristics

Printing characteristics for the Makerbot and the Ultimaker 3D printer.

	Pearson correlation <b>inter-observer</b>	P-value
Cadaver	1,000	0,000
Port_2D	1,000	0,000
Port_3D	1,000	0,000
Mesh_3D	1,000	0,000
Print_UM	1,000	0,000
Print_MB	0,999	0,000
Port_2D_1	1,000	0,000
Port_3D_1	1,000	0,000
Mesh_3D_1	1,000	0,000
Print_UM_1	1,000	0,000
Print_MB_1	1,000	0,000

Table 2 | Interobserver agreements

This data shows the correlation of the measurements between the observers - the inter-observer agreement.

	Pearson correlation	P-Value	Pearson correlation	P-value
	intra-observer_1		intra-observer_2	
Cadaver	-			-
Port_2D	1,000	0,000	1,000	0,000
Port_3D	1,000	0,000	1,000	0,000
Mesh_3D	1,000	0,000	1,000	0,000
Print_UM	1,000	0,000	1,000	0,000
Print_MB	1,000	0,000	1,000	0,000

Table 3 | Intra-observer agreements

This data shows the intra-observer agreements of both observers.

Table 4 shows the mean distances of the objects measured on all modalities. The average distance in millimetres was calculated of each of the 5 marker points on the pelvis and 3 marker points on each foot and hand. For example; the mean distance measured on the cadaver of pelvis 1 was 129,90 mm, 2D CT: 130.17mm, 3D CT: 130,40mm, Meshlab: 130.07mm, Ultimaker: 129.50mm and Makerbot :128.80mm. Furthermore, in table 4 the measurements of both 3D printers and the cadavers are compared and the difference in percentage between both modalities in calculated. In general, a decrease in measured distances can be seen in all

specimens. The least decrease can be seen in "the 3D printed pelvis 1", -0.3% and -0.8% on respectively the Ultimaker and Makerbot when compared with cadaver Pelvis 1. The 3D model of "Hand 2" shows the most decrease, -2.5% and -3.2% on the Ultimaker and Makerbot when compared with cadaver hand 2.

Table 5 shows the P-values of the differences in measurements between cadavers, 2DCT, 3DCT, Meshlab and both 3D printers. Most significant differences in measurements were found in the conversion from 3D file into a 3D print and between the cadaver and 3D printed model from the Makerbot.

						1
	Cadaver	2D	3D	Mesh	UM (%)*	MB (%)*
Pelvis 1	129.90	130.17	130.40	130.07	129.55 (99.7)	128.80 (99.2)
Pelvis 2	136.60	137.07	136.78	137.03	135.25 (99.0)	135.10 (98.9)
Pelvis 3	129.40	129.58	129.42	129.39	128.00 (98.9)	127.25 (98.3)
Foot 1	61.17	62.35	60.97	62.06	61.00 (99.7)	60.42 (98.8)
Foot 2	68.83	69.00	68.56	68.98	67.42 (98.0)	67.67 (98.3)
Foot 3	54.50	54.27	53.97	54.53	53.25 (97.7)	52.92 (97.1)
Hand 1	45.17	45.22	45.32	44.93	44.67 (98.9)	44.25 (98.0)
Hand 2	44.00	43.91	43.67	44.48	42.92 (97.5)	42.58 (96.8)
Hand 3	38.83	39.33	39.62	38.74	38.42 (98.9)	38.33 (98.7)

**Table 4**Mean measured distances in millimetres. 2D: 2-dimensional CT, 3D:3-dimensional CT, Mesh: Meshlab, UM: Ultimaker 3, MB: Makerbot Replicator Z18.

\* The percentages given in the UM and MB column are the mean distances with reference to the measurements of the cadavers.

**Table 5** | A Paired Samples *t* test was used to compare the measurements between cadavers, 2DCT, 3DCT, Meshlab and both 3D printers.

	Cadaver-	2DCT-	3DCT-	Meshlab-	Meshlab-	Cadaver-	Cadaver-
	2DCT	3DCT	Meshlab	UM	MB	UM	MB
Pelvis 1	0.658	0.317	0.591	0.020	0.007	0.720	0.330
Pelvis 2	0.382	0.222	0.646	0.005	0.015	0.055	0.031
Pelvis 3	0.551	0.597	0.961	0.009	0.006	0.130	0.015
Foot 1	0.092	0.081	0.207	0.190	0.065	0.423	0.035
Foot 2	0.486	0.298	0.263	0.025	0.003	0.003	0.034
Foot 3	0.395	0.391	0.161	0.091	0.016	0.130	0.003
Hand 1	0.701	0.096	0.299	0.568	0.558	0.423	0.368
Hand 2	0.774	0.332	0.121	0.049	0.014	0.096	0.161
Hand 3	0.293	0.212	0.073	0.539	0.632	0.497	0.597

A p-value of 0.05 was determined as significant.

#### Discussion

3D printed anatomical models have to be accurate, especially for pre-bending plates in complex fracture surgery.<sup>716</sup> This validation study investigated the accuracy of our 3D printing process. To the best of our knowledge, the accuracy of 3D printed anatomical models has not been investigated.<sup>6,7,14,15</sup> In this study we validated the 3D printing process for our clinical setting.

The literature we reviewed on the clinical use of 3D printing in daily practice did not clarify the validation of their 3D printing process. Mallepree et al.<sup>11</sup> reported in their study that accuracy of medical 3D models was mainly affected by scan parameters and not the printing process itself. However, our study highlighted different results. Table 4 highlights that step 1 (cadaver – 2DCT) showed smaller differences in measured distances when compared with differences measured in step 4 (i.e. Meshlab – 3D printers). In step 1, only "foot 1" showed a difference of > 1 mm between the measurements on the cadaver and 2D CT. In step 4, a difference of > 1 mm between the measurements using Meshlab and both printers was found in: pelvis 1, pelvis 2, pelvis 3, foot 1, foot 2 and hand 2 (table 4). This observation is confirmed by the results in table 5, which show a significant decrease in measured millimetres when both 3D printers are compared with Meshlab. No significant differences were found between the cadavers and CT and CT and Meshlab. Additionally, this table also shows that there are more significant differences between the cadaver and Makerbot, than between the cadaver and Ultimaker. Therefore, it seems that the Ultimaker is more accurate than the Makerbot.

We measured a decrease in distance between the landmarks when comparing the actual 3D prints with the digital files. However, on closer inspection of the 3D printed models, we noticed that the 3D printed K-wires were more flattened than the actual K-wires (Figure 8). This resulted in a shorter distance when measuring on 3D printed models. A reason for this difference in shape could be that scanning titanium wires cause artifacts on the digital files which lead to small measurement errors on the 3D printed objects.

Even though the differences between the cadavers and 3D printed models are statistically significant (table 5), we find the clinical importance less significant. We believe that these small differences will neither affect the position of the pre-bended plate nor the anatomy of the bone irrespective of the location or type of fracture.

Our study has some limitations. A small sample size (n=9) was used. Nevertheless, a clear trend can be seen between the different modalities. In analysing 3D models, a volumetric analysis would be more accurate and is in fact the gold standard. We did not perform a volumetric analysis of the cadavers

and the printed models, for this we would need a fluid displacement method.<sup>22,23</sup> This in theory is an easy method but not feasible in our study. Utilising a fluid displacement model makes removal of all the soft tissue of the cadaver models essential. This however was not possible in our study design. Also, the PLA filament in use is permeable and hydrophilic. Therefore, a fluid displacement measurement comparison with a 3D printed model would be unreliable as the model would absorb water. Another limitation of this study is that we used specific software to convert and modify the files and the results cannot be extrapolated to other software. Our results are only applicable for Philips software (Royal Philips N.V., the Netherlands) and the open source software we used. We only validated our 3D printing process and cannot say anything about 3D printing with other types of software and 3D printers.

#### Conclusion

We can conclude that our 3D printing process results in accurate models suitable for preoperative workup. The Ultimaker 3 is slightly more accurate than the Makerbot Replicator Z18. Medical professionals must be aware that titanium can give artifacts on 3D printed models. We advise that medical professionals should perform a study that tests the accuracy of their 3D printing process before using the 3D printed models in medical practice.



**Figure 8** | Difference between the titanium K-wires and 3D printed pins.

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# CHAPTER 7

# The value of 3D printed models in understanding acetabular fractures

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> 3D Printing & Additive Manufacturing 2018, 5(1), 37-46

# ABSTRACT

#### Background

Acetabular fractures are complex and difficult to classify. Although the Judet-Letournel classification is designed to increase the understanding of acetabular fractures, it remains prone to error when using conventional medical imaging. We hypothesize that three dimensional (3D printing), as a new diagnostic imaging tool, will lead to an increased understanding and knowledge of acetabular fractures and an optimal surgical approach.

#### Methods

Digital data (DICOM) of 20 acetabular fractures were converted into 3D files [standard tessellation language (STL data)]. These STL files were used to prepare 3D prints of life-size hemi-pelvic models with acetabular fractures.

Seven senior trauma surgeons specializing in pelvic and acetabular surgery, 5 young fellowship-trained trauma surgeons, 5 senior surgical residents, 5 junior surgical residents and 5 interns classified 20 acetabular cases using X-ray/two dimensional (2D) CT, 3D reconstructions and 3D printed models according to the Judet-Letournel classification.

Furthermore, all junior and senior surgeons were instructed to evaluate their surgical approach and the positioning of the patient during operation. Time to classify each case was recorded. Calculations were done using Fleiss' kappa statistics.

#### Results

Only slight and fair interobserver agreements for senior surgeons ( $\kappa$ =0.33) and interns ( $\kappa$ =0.16) were found when using X-ray/2D CT. However, 3D printed models showed moderate and substantial interobserver agreements for senior surgeons ( $\kappa$ =0.59), junior surgeons ( $\kappa$ =0.56), senior surgical residents ( $\kappa$ =0.66), junior surgical residents ( $\kappa$ =0.51) and interns ( $\kappa$ =0.61).

Compared with X-ray/2D CT, the interobserver agreement regarding the surgical approach for junior surgeons using 3D printed models increased by  $\kappa$ =0.04 and  $\kappa$ =0.23, respectively. Except for the interns, a significant time difference for classification was found between X-ray/2D CT and 3D CT and 3D printed models for junior and senior surgical residents and junior and senior surgeons (p<0.001).

#### Conclusion

3D printing is of added value in the understanding, classification, and surgical evaluation of acetabular fractures. We recommend the implementation of 3D printed models in trauma surgery training.

### Background

Acetabular fractures are complex injuries and are difficult to classify due to varied fracture lines in a complex three-dimensional (3D) anatomy.<sup>1</sup> In addition to the complex 3D anatomy, the complex surrounding tissue of nerves and blood vessels makes an optimal preoperative plan essential. The anatomy of surrounding tissues can be learned from textbooks and cadaver studies; however, the options for learning fracture patterns are limited and thereby preoperative planning is a bottleneck to treatment.

The fracture patterns and classification of acetabular fractures have been described by Judet et al.<sup>2</sup> and Letournel.<sup>3</sup> High inter- and intraobserver reliability has been reported when this classification is used by surgeons treating acetabular fractures on a regular basis. However, this classification remains prone to error for inexperienced observers using conventional diagnostic imaging;<sup>4,5</sup> recent studies could not reproduce the high inter- and intraobserver reliability for plain radiographs alone or for plain radiographs combined with axial view computed tomography (CT) scans.<sup>67</sup> Despite this limitation, the Judet-Letournel classification still remains the most commonly used classification system for understanding acetabular fracture characteristics.<sup>8-9</sup>

Currently, it is generally acknowledged that the addition of CT images is essential for the treatment of acetabular fractures. The addition of 3D reconstructions (3D CT) has gained popularity in the identification of fracture patterns and education regarding acetabular fractures. Garrett et al. found 3D CT images easier to interpret than axial CT images.<sup>5</sup> The use of 3D CT resulted in achieving near anatomical reduction and reduced surgical time.<sup>10,11</sup> Hu et al. found that less experienced surgeons in particular take advantage of virtual 3D planning for acetabular fractures.<sup>12</sup> However, these volume-rendered models are still viewed on a two-dimensional (2D) computer monitor screen.

3D printers have become widely available and inexpensive. There are three main categories of 3D printing techniques: (1) Extrusion: fused deposition modeling (FDM) uses polylactic acid (PLA), a thermoplastic filament that is heated and extruded through an extrusion head that deposits the plastic layer by layer on a plate. FDM is the most common 3D printing technique used in desktop 3D printing. (2) Resin: a liquid resin is cured by a laser or ultraviolet light. The most common technique is called stereolithography (SLA). (3) Powder: a powdered material is melted together by a laser. Selective laser sintering (SLS) is the most common technique in this category. 3D printing is an innovative technology that is been used across many medical specialties for numerous applications.<sup>13</sup> The clinical use of 3D printing (rapid prototyping) in understanding and classifying acetabular fractures has been inadequately studied. In 2012, Hansen

et al.<sup>14</sup> concluded that 3D pelvic models improved the ability of residents to classify acetabular fracture patterns. However, these models were standard pelvic models on which fracture patterns were created by using an oscillating saw. Last year, Manganaro et al.<sup>15</sup> concluded that patient-specific 3D printed models were promising educational tools for teaching and improving learner confidence in using the Judet-Letournel classification system. Furthermore, a couple of case series is available in which it was concluded that 3D printing can be of added value in pre-contouring plates for acetabular fractures.<sup>16,17</sup> These case series found that 3D printed models are an important advancement for better understanding fracture patterns. However, all these statements are not supported by hard metrics.

Although researchers have reported the same advantages in preoperative planning as with 3D CT,<sup>18,19</sup> Preece et al. found that the use of physical models is advantageous in enhancing the visuospatial and 3D understanding of complex anatomical architecture when compared with 3D CT models.<sup>20</sup> Recently, one small study measured the intra- and interobserver agreement between X-rays and 3D printed models without combining radiographs, 2D CT and 3D CT images as commonly performed in clinical practice.<sup>19</sup>

Our hypothesis is that 3D printing will increase the understanding of acetabular fractures evaluated by the Judet-Letournel classification. Furthermore, we expect that extra practice in classification will lead to a better understanding of acetabular fracture patterns, complex 3D anatomy and its surgical treatment. To our knowledge, this is the first study to investigate whether 3D printed models can be a reliable and valid way for senior residents to classify acetabular fractures. We will differentiate between several levels of training in surgery to investigate the value of implementation of 3D printed models.

In addition, until now, surgeons have-based their preoperative plan of action on conventional diagnostic imaging. Will their plan of action change when classifying acetabular fractures with 3D printed models?

#### Methods

#### **Study preparations**

This study was exempted from the scope of the Medical Research Involving Human Subjects Act (WMO) according to our institutional ethics committee. We used the Dutch Trauma Registry to identify all acetabular fractures from the Elisabeth-TweeSteden Hospital and Isala Hospital (both are level 1 trauma centers). Two trauma surgeons from both hospitals selected 20 cases with acetabular fractures that represented fracture types as described by Judet and Letournel. Each case was evaluated using X-ray, 2D CT, 3D CT and intra-operative findings if treated surgically. Classifying acetabular fractures according to Judet-Letournel only shows a substantial reliability when used by very experienced pelvic surgeons.<sup>4</sup> Because of this, we did not choose a gold standard for classification. The fractures were distributed according to the meta-analysis methodology by Giannoudis et al.<sup>9</sup> According to the opinion of both trauma surgeons, 4 both columns, 1 posterior wall, 3 transverse posterior walls, 2 anterior column posterior hemi transverse, 3 T-shaped, 3 anterior columns, 1 transverse, 2 posterior columns and 1 anterior wall type acetabular fractures were identified.

All X-rays, 2D CT, 3D CT and 3D prints of a hemi-pelvis with an acetabular fracture were collected. The images were organized in *Sectra IDS7* without patient identifiers for presentation. This radiology workstation is designed to optimize the workflow and ensure quick and easy access to images integrated in our research laptop. Using a free online randomization program, all images of all cases were arranged in a random order (for example: (1) Print 10, (2) X-ray/2D CT 12, (3) Print 20, (4) 3D 11, (5) X-ray/2D CT 17 to present to the observers. Observers were allowed to view the 2D CT slices in axial, coronal and sagittal planes. 3D reconstructions could be turned around in two directions: horizontally and vertically. Observers were allowed to hold the 3D printed models in their hands to rotate in all directions.

#### Process of creating 3D prints from DICOM data

The process of converting Digital Imaging and Communications in Medicine (DICOM)-format data into standard tessellation language (STL) format and 3D print is divided into several parts: (1) image acquisition, (2) image post-processing and (3) 3D printing.<sup>13</sup>

#### Image acquisition

The Elisabeth-TweeSteden Hospital and Isala clinics used acetabular CTs for data acquisition, namely, a *Siemens Somatom Definition AS 64-slice CT* and a *Philips iCT 256 slice*, respectively. A slice thickness of 1 millimeter (mm) or less was used. Soft reconstruction filters were applied to minimalize image noise of soft tissue. Raw data of acetabular images were saved in a DICOM format.

#### Image post-processing

In both hospitals, DICOM data of acetabular fractures were saved in a picture archiving and communication system (PACS). *Philips Intellispace Portal* software

was used for converting and volume rendering DICOM data into 3D CT (figure 1). Using the thresholding technique, bone was differentiated from surrounding soft tissue. The femur was digitally removed to enhance intra-articular fracture visualization, and the healthy side of the pelvis was removed to reduce printing time. The 3D reconstruction of a hemi-pelvis was saved as an STL file. *Philips Intellispace Portal* was integrated into the PACS of the Elisabeth-TweeSteden Hospital.

We used open-source programs to manipulate the STL file. In *Meshlab*, errors such as holes were fixed, and global smoothing was applied. In *Simplify 3D*, the design of an added support and a raft was performed to hold the parts of the printed acetabular model in place.



Figure 1 | 3D CT of pelvis.

#### 3D printing

FDM print technology is considered simple-to-use and environmentally friendly. These printers offer an attractive price-performance combination. Although SLA printers produce higher resolution objects, it is more expensive, is slower in creating large models and remains a laborious process. Since the thickness of the DICOM data was 0.6-1 mm, print layers of 0.2 mm were sufficient. The FDM technique is capable of printing this layer thickness.

The Elisabeth-TweeSteden Hospital has unlimited access to a Makerbot Replicator Z18, a high-end consumer FDM 3D printer with a large build volume, which is especially important for printing pelvic models.

In *Simplify 3D*, the following process settings were utilized: extruder temperature, 215°C; chamber temperature, 24°C; primary layer height, 0.2 mm; infill, 2% (the outer side of the bone consists of cortical bone; therefore, the model supports itself, and less infill can be used); support infill, 20%; and maximum overhang without support, 60%. Finally, a digital preview of the print was made, and the building time and material costs were calculated. The STL file was converted into G-code to prepare the file for the 3D printer. The hemi-pelvic models with acetabular fractures were printed on a scale of 1:1. After printing, the models required post-processing to remove the support and raft (figures 2, 3 and 4).

#### Intra- and interobserver agreement

Seven senior trauma surgeons from several level 1 trauma centers in the Netherlands, experienced in the field of pelvic- and acetabular surgery, were instructed to complete three tasks:

- 1. Classify acetabular fractures on X-ray/2D CT, 3D CT and 3D printed models according to the Judet-Letournel classification.
- 2. Evaluate their surgical approach for every acetabular fracture on X-ray/2D CT/3D CT and reassess for a potential change to their surgical approach when classifying with 3D printed models.

Determine the positioning of the patient during operation: supine, prone, lateral, supine/prone, or lateral/prone.

These tasks were also completed by 5 young fellowship-trained trauma surgeons. Five senior surgical residents (postgraduate years 5-6, specialization in trauma surgery), 5 junior surgical residents (postgraduate years 1-2) and 5 surgical interns were only asked to complete the first task. The time needed to complete the tasks was noted. Participants were informed that each of Judet-Letournel's fracture pattern could be represented once, more than once, or not at all. Surgical approaches were defined according to the principles of the AO foundation ((modified) Stoppa, ilioinguinal, Kocher-Langenbeck, (extended) iliofemoral, Trochanter flip, and/or pararectal).<sup>21</sup> The opinions of all observers on the different classification modalities were collected.

After 2 months, all observers were asked to classify the acetabular fractures on all modalities presented in a random order. This score was used to compare with the first "classification round" and calculate a potential learning curve for classifying acetabular fractures.

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**Figure 2** | Hemipelvic model before postprocessing.

Figure 3 | Hemipelvic model after postprocessing; lateral view.



Figure 3 | Hemipelvic model after postprocessing; AP view.



#### Data analysis

Descriptive statistics were calculated to provide an overview of the print process settings. A paired samples *t* test was used to compare the calculated printing time and real print time. One-way ANOVA with a post hoc Bonferroni test was used to calculate the time all observers needed to classify 20 cases. A paired samples *t* test was used to calculate the difference in time between the first and second rounds of measurement. A level of significance of  $\alpha = 0.05$  was used. Observer data were analyzed and expressed in terms of intra- and interobserver agreement. Calculation was done using Fleiss' kappa statistics ( $\kappa$ ). Fleiss' kappa calculates the agreement between a fixed number of observers when assigning categorical ratings to a number of items or classifying items.<sup>22</sup> We interpreted the multi-ratio field in the process of  $\alpha = 0.20$  in direct plice to the provide and the process of  $\alpha = 0.20$  in direct plice to the provide and the provide the p

the multi-rater kappa statistics as follows: values of 0.01 - 0.20 indicate slight agreement; 0.21 - 0.40, fair agreement; 0.41 - 0.60, moderate agreement; 0.61 - 0.80, substantial agreement; and more than 0.80, good agreement.<sup>23</sup>

IBM SPSS Statistics 24 was used for statistical analysis. The Fleiss' kappa calculator was taken from an open-access Microsoft Excel spreadsheet.<sup>24</sup> Calculations were performed using 95% confidence intervals (CIs).

#### Results

Twenty 3D printed hemi-pelvic models with acetabular fractures were manufactured using a *Makerbot Replicator Z18 Printer*. The mean weight of the models was 129,5 grams (SD 26,5). The mean weight of the support and raft was 111,8 grams (SD 54,5), 46% of the total weight. The mean printing time was 32,6 hours (SD 11,5). The mean material (PLA) cost per hemi-pelvic model was  $\in$  11,5 (SD 2,4) or \$12,9 (SD 2,7).

#### Classification

The interobserver agreement for interns improved from slight, to fair to substantial when acetabular fractures were classified by X-ray/2D CT, 3D CT and 3D printed models, respectively. The  $\kappa$  values of X-ray/2D CT, 3D CT and 3D printed models for junior surgical residents were 0.19, 0.37 and 0.51, respectively. Senior surgical residents obtained  $\kappa$  values of 0.17, 0.43 and 0.66 when viewed by X-ray/2D CT, 3D CT and 3D printed models, respectively. The  $\kappa$  values of junior-and senior surgeons were 0.18 and 0.33 when viewed by X-ray and 2D CT, 0.43 and 0.42 when viewed by 3D CT and 0.56 and 0.59 when viewed by 3D printed models, respectively. In general, the 3D printed model  $\kappa$  values of all groups approached each other when compared with X-ray/2D CT and 3D CT (table 1). The overall  $\kappa$  values for interobserver agreement for the classification of 20 acetabular fracture cases were 0.19 (95% CI 0.18-0.19) when only X-ray and 2D

CT were viewed, 0.34 (95% CI: 0.33-0.35) when only 3D CT was viewed and 0.47 (95% CI: 0.46-0.47) when only 3D printed models were viewed (table 1).

Classification	2D, к (95% CI)	3D, к (95% CI)	Print, κ (95% CI)
Overall	0.19 (0.18-0.19)	0.34 (0.33-0.35)	0.47 (0.46-0.47)
Senior surgeon	0.33 (0.30-0.35)	0.42 (0.39-0.44)	0.59 (0.57-0.62)
Junior Surgeon	0.18 (0.15-0.21)	0.43 (0.40-0.47)	0.56 (0.52-0.60)
Senior surgical resident	0.17 (0.14-0.21)	0.43 (0.40-0.46)	0.66 (0.62-0.69)
Junior surgical resident	0.19 (0.16-0.23)	0.37 (0.34-0.40)	0.51 (0.47-0.54)
Intern	0.16 (0.12-0.19)	0.38 (0.35-0.41)	0.61 (0.57-0.64)
Learning curve	2D, к	3D, к	Print, κ
Overall	0.04	0.01	0.01
Senior surgeon	0.03	0.08	0.06
Junior surgeon	0.16	0.05	0.04
Senior surgical resident	0.05	-0.09	-0.17
Junior surgical resident	-0.01	-0.01	0.16
Intern	0.05	0.08	-0.02

Table 1 | Classification of Interobserver Agreements

Difference in  $\kappa$  between first round and second round of observations. 2D, two-dimensional; 3D, three-dimensional; CI, confidence interval.

The time to classify 20 cases of each modality was recorded (table 2). Except for the interns, a significant time difference between X-ray/ 2D CT and 3D CT and 3D printed models was found for junior and senior surgical residents and junior and senior surgeons (p< 0.001). However, there was no significant time difference between 3D CT and 3D printed models (p= 1.00).

The same significant time difference was found when all observer groups were combined. No significant time difference was found between the groups of observers per modality: X-ray/2D CT (p=0.58), 3D CT (p=0.31), and 3D printed models (p=0.61).

Time	2D	3D	Print	Р
Overall, min (SD)†	27.59 (18.74)	10.77 (4.97)	9.25 (3.22)	0.000
Senior surgeon*	21.42 (7.61)	8.32 (3.49)	9.19 (2.5)	0.000
Junior surgeon*	30.14 (10.21)	10.64 (3.50)	10.20 (3.12)	0.000
Senior surgical resident*	28.30 (6.81)	14.47 (4.42)	10.07 (5.30)	0.000
Junior surgical resident*	21.43 (2.62)	9.19 (3.88)	9.63 (3.17)	0.000
Intern	38.41 (40.41)	11.55 (7.55)	7.18 (1.55)	0.096
Р	0.578	0.311	0.607	

Table 2 | Time to Classify 20 Acetabular Fracture Cases Per Modality

Note: One-way analysis of variance (ANOVA). Post hoc multiple comparisons Bonferroni.

+ Difference between 2D CT and 3D CT/print: p < 0.000. Difference between 3D and print: p = 1.000.

\*Difference between 2D CT and 3D CT/print: p < 0.01. CT, computed tomography; SD, standard deviation.

The potential learning curve for acetabular fractures is given in table 1; it shows the difference in  $\kappa$  values between the first and second rounds (after 2 months) of measurement.

Junior surgeons obtained the best learning curve when only X-ray and 2D CT were viewed ( $\kappa$ = 0.36), whereas senior surgeons and interns both scored 0.08 higher when only 3D CT data were viewed. Junior surgical residents obtained the best learning curve when only 3D printed models were viewed ( $\kappa$ = 0.67). Overall, slightly higher  $\kappa$  values for X-ray/2D CT, 3D CT and 3D printed models compared with the first classification round were found, at 0.23, 0.35 and 0.48, respectively.

The difference in time between the first and second rounds of observation to complete the sets of acetabular cases was recorded. Overall, observers needed less time to complete the second round of acetabular cases when compared with the first round (table 3). Significant differences were found for all modalities: X-ray/2D CT (p= 0.01), 3D CT (p= 0.00) and 3D printed models (p= 0.00).

Difference	2D	Р	3D	Р	Print	Р
Overall, min (SD)	-8.73 (-16.36)	0.013	-3.55 (-4.17)	0.000	-3.45 (-3.28)	0.000
Senior surgeon	-8.38 (-6.33)	0.013	-2.52 (-2.81)	0.056	-4.70 (-2.68)	0.004
Junior surgeon	-12.91 (-10.53)	0.091	-3.11) (-2.70)	0.105	-3.41 (-4.00)	0.129
Senior surgical resident	0.85 (-15.74)	0.910	-3.22 (-5.58)	0.267	-4.14 (-3.01)	0.037
Junior surgical resident	-3.23 (-5.48)	0.324	-4.13 (-2.63)	0.113	-3.38 (-2.34)	0.032
Intern	-19.84 (-29.60)	0.208	-5.36 (-6.44)	0.136	-1.10 (-4.28)	0.595

 Table 3 | Difference in Time Between First Round and Second Round of Observations.

Paired-samples t test.

#### Surgical approach

Table 4 shows that junior surgeons obtained  $\kappa$  values of 0.04, 0.16 and 0.23 when viewing X-ray/2D CT, 3D CT and 3D printed models, respectively. The  $\kappa$  values of senior surgeons were 0.26, 0.24 and 0.31 when viewing X-ray/2D CT, 3D CT and 3D printed models, respectively.

The overall  $\kappa$  values for interobserver agreement for the surgical approach were only slight and fair for all modalities. The reassessment of agreement regarding the surgical approach is also shown in table 4; it shows the difference in  $\kappa$  values between the first and second rounds of measurement. Senior surgeons slightly agreed more on 3D CT ( $\kappa$ = 0.26), whereas the junior surgeons slightly agreed more on 3D printing ( $\kappa$ = 0.25).

Surgical approach	2D, к (95% CI)	3D, к (95% CI)	Print, κ (95% CI)
Overall	0.16 (0.13-0.19)	0.23 (0.20-0.26)	0.30 (0.26-0.33)
Senior surgeon	0.26 (0.20-0.32)	0.24 (0.18-0.30)	0.31 (0.24-0.37)
Junior surgeon	0.04 (-0.02-0.11)	0.16 (0.09-0.23)	0.23 (-)
Learning curve	2D, κ	3D, к	Print, κ
Overall	-0.01	-0.04	-0.03
Senior surgeon	-0.06	0.02	-0.06
Junior surgeon	-0.03	-0.11	0.02

 Table 4 | Interobserver Agreements for the Surgical Approach

Difference in  $\kappa$  between first round and second round of observations.

#### Positioning of the patient

Table 5 shows that both senior and junior surgeons agreed the most on the positioning of the patient with help of a 3D printed model, at  $\kappa$ = 0.31 and  $\kappa$ = 0.28, respectively. The overall  $\kappa$  values for interobserver agreement for positioning of the patient were fair on all modalities. The second round of observations did not show large improvements in the agreement.

Prone or lateral positioning could be the preference of the treating surgeon. To rule this out, both positions of the patient were taken together to calculate new interobserver agreement, as shown in table 6. This table shows higher interobserver agreement compared with those in table 5, which shows the initial analysis.

Positioning	2D, к (95% CI)	3D, к (95% CI)	Print, κ (95% CI)
Overall	0.23 (0.19-0.27)	0.28 (0.24-0.31)	0.31 (0.27-0.34)
Senior surgeon	0.30 (0.23-0.36)	0.31 (0.24-0.37)	0.31 (0.25-0.37)
Junior surgeon	0.16 (0.06-0.25)	0.21 (0.11-0.30)	0.28 (0.18-0.38)
Learning curve	2D, к	3D, к	Print, κ
Overall	0.09	0.01	0.07
Senior surgeon	0.05	0.06	0.07
Junior surgeon	0.04	-0.05	0.01

Table 5 | Interobserver agreements for the positioning of the Patient

Difference in  $\kappa$  between first round and second round of observations. 2D, two-dimensional; 3D, three-dimensional; CI, confidence interval.

Positioning without	2D, к (95% CI)	3D, к (95% CI)	Print, κ (95%
preference			CI)
Overall	0.33 (0.28-0.38)	0.44 (0.39-0.48)	0.44 (0.40-0.49)
Senior surgeon	0.40 (0.32-0.48)	0.47 (0.39-0.55)	0.43 (0.35-0.51)
Junior surgeon	0.27 (0.15-0.40)	0.40 (0.28-0.52)	0.47 (0.35-0.59)

Table 6 | Positioning of the Patient: Preference of Lateral or Prone Combined

#### Overall impressions of the observers

The opinions of all observers regarding the different classification modalities were structured and are given in table 7. Observers found X-ray/2D CT to be most detailed. 3D CT was able to give a quick overview; however, this modality was not "real 3D". 3D printed models gave a "natural" 3D view; however, small details were melted together.

Table 7   Summarized Comments of All Observers on the Different Modalit	ties
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X-ray / 2D CT	Most detailed, fissure fractures visible as well. However, the
	relevance of this finding is questioned.
3D CT	Quick overview. The model can only be turned one way at the
	time. No actual 3D view, because the model is shown on a 2D
	screen.
3D printing	"Natural" 3D view. The model can be rotated in all directions.
	Small details are melted together.

# Discussion

In contrast to previous studies about the role of 2D CT, 3D CT and 3D printed models in classifying acetabular fractures, we also investigated the interobserver agreement regarding the surgical approach and the time needed to classify the acetabular fractures. This study shows the added value of 3D printed models in classifying acetabular fractures and evaluating the surgical approach. The highest kappa values were obtained when acetabular fractures were classified with the usage of 3D printed models. Interns, residents, and junior surgeons showed greater improvement in agreement from X-ray/2D CT / 3D reconstructions to 3D printing than the senior surgeons, with the greatest benefit from 3D printing found in interns. Moreover, a reduction in time to classify the acetabular fractures was seen when viewed by 3D printed models.

#### **Classifying acetabular fractures**

Several studies only investigated the role of 2D CT and 3D CT among different groups with varying levels of experience in classifying acetabular fractures.<sup>5</sup> The outcomes differed from those of our study due to a rapid change in the quality of CT data and improvement in high-resolution 3D images,<sup>25</sup> other medical specialists (radiologists) or less instructed observers, creating a greater chance of agreement.<sup>6</sup>

A comparison between 3D printed models and 3D CT was not found in the literature. All groups of observers benefited from 3D printed models when compared with 3D CT. A reason could be that 3D reconstructions are normally seen on a 2D screen, which gives no actual 3D view. On the one hand, it could be possible that the limitation in rotating the 3D reconstruction led to less understanding of the fracture patterns. On the other hand, even the most experienced surgeons obtained much higher kappa values in 3D printing ( $\kappa$ = 0.59) than 3D reconstructions ( $\kappa$ = 0.42). In our opinion, this finding confirms that 3D printing is superior than 3D reconstructions.

Only one study compared conventional diagnostics with 3D printing to classify acetabular fractures. We found lower  $\kappa$  values for senior and junior surgeons in our study compared to the single former study.<sup>19</sup> It could be that we included more observers per subgroup, creating a greater chance of disagreement.

#### Preparation time and costs of a 3D print

In our opinion, 3D printed models should be ready quickly, ensuring enough time for decent surgical preparation. Our models were prepared in less than one-and-a-half days. Although acetabular fractures should be surgically treated as soon as possible to diminish fracture pain and stabilize the hip joint, as a result of concomitant injuries, patients are usually surgically treated within one week, ensuring enough time to prepare a 3D printed hemi-pelvis and decent surgical preparation. Taking into account the higher agreement for classification when compared with 2D CT and 3D reconstructions, the benefits outweigh the disadvantages of the extra time needed to prepare a 3D print.

To make the 3D print process cost efficient, development and operating costs should be as low as possible. Our *Makerbot Replicator Z18 Printer* cost us €7900 (\$8860). This investment refunded itself in less than 18 life-size hemipelvic models when we compare our 3D printing process with the outsourced production of 3D printed models.<sup>19</sup> We developed a robust and low-cost workflow that allows the creation and design of complex anatomic models using free open-source and in-hospital software, without the need for technical support. Other benefits of a basic in-hospital 3D printing laboratory are that DICOM files of patients do not have to be sent away by mail and that 3D printing will be accessible 24/7 instead of during office hours when managed by other parties.

#### Surgical approach and time needed to classify acetabular fractures

Although an improvement in agreement on surgical approach was seen with 3D printing, only slight and fair agreements were found on all modalities. The reason could be the preference of the surgeon. In our study, too many surgical approaches were available to obtain high  $\kappa$  values. Nevertheless, junior surgeons had the greatest benefit from 3D printed models for the type of surgical approach when compared with the senior surgeons.

The same trend in agreement was seen for the positioning of the patient. Although 3D printed models appeared to have the highest agreement, only slight and fair agreements were found. Junior surgeons had the greatest benefit from 3D printed models for the positioning of the patient when compared with senior surgeons. We hypothesized that prone or lateral positioning would be particularly likely to cause disagreement because of the personal preference of the surgeon. The reanalysis results yielded higher  $\kappa$  values, but these values still not higher than moderate agreement. This finding indicates that acetabular surgery is still a more experienced-based surgery instead of evidence-based surgery.

Significant time reduction was seen when comparing X-ray/2D CT with the other modalities. However, no significant time difference was seen between 3D CT and 3D printed models. There is no need to scroll through images in both modalities. Taking into account the benefit of higher interobserver values for 3D printing, we prefer 3D printed models.
#### Definition of experienced observers

Beaulé et al.<sup>4</sup> divided surgeons into three groups with varying levels of experience and concluded that 2D CT was not essential for the classification of acetabular fractures. The definition of an "experienced surgeon" is not known and differs by country.<sup>5-7,25</sup> The Dutch Trauma Society (NVT) has set a minimum of 20 surgical treated acetabular and/or pelvic ring fractures per hospital annually to improve the trauma care and outcome of these severely injured patients.<sup>26</sup> In 2016, 42 patients presented themselves with an acetabular fracture (without associated pelvic ring fracture) in our level 1 trauma center. Twenty-two patients were surgically treated, distributed over 2 senior trauma surgeons, and both surgeons had more than 10 years of experience in treating acetabular fractures. It is interesting to note that our "experienced surgeons" seem to belong to "less experienced" according to the study of Beaulé et al. This means that "experienced" is not a universal term and should be specified in each study.

#### Limitations

This study has some limitations. We did not set a "gold standard" for the classification of acetabular fractures. Currently, it is common to determine the gold standard by the intraoperative findings. However, this can be challenging in acetabular surgery, especially for fracture approaches without access to fracture lines on the other column. To the best of our knowledge, there has not been a study that reached good agreement ( $\kappa$ > 0.80) in the classification of acetabular fractures.<sup>4-7</sup> Therefore, the accuracy of the original diagnosis could be questioned. Another limitation was the different quality of the CT scans. Because of the study's retrospective design, there was no consistent acetabular CT protocol. Although, we think the quality of the included CT scans was good enough, small differences in slice thickness or reconstruction filters were seen. All observers took the CT sets in the same format, equalizing the results. Furthermore, it could be possible that there are inaccuracies between the printed models and 2D/3D CT.<sup>13</sup> Although an earlier study showed that the accuracy of 3D printed models is mostly influenced by the scan parameters and not by the process of converting CT data into 3D prints,<sup>27</sup> observers noted melted details on the 3D printed models. These melted details make it difficult to identify fracture patterns sometimes and may cause lower κ values in the classification of acetabular fractures. However, we are not sure whether these melted fissure fractures are clinically relevant for surgical and conservative treatment. We do not think the agreement regarding the surgical approach and positioning of the patient was affected by these melted details. A new study is needed to investigate the accuracy of a 3D printed model compared with CT, 3D reconstructions and the human bone.

Two recent literature reviews analyzed all articles about 3D printing.<sup>28,29</sup>

There is a need for a randomized controlled trial to test several aspects of 3D printing in acetabular fractures, such as the cost effectiveness, reduced operation time and blood loss by pre-bending plates, decreased length of hospital stay, patient satisfaction and health-related quality of life.

## Conclusion

In conclusion, this study shows that 3D printing is of added value in understanding acetabular fractures. The implementation of 3D printed models in the trauma surgery training is recommended. Furthermore, 3D printed models can be used for teaching medical students.

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## CHAPTER 8

What is the value of 3D Virtual Reality in understanding acetabular fractures?

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> European Journal of Orthopaedic Surgery & Traumatology 2020, 30(1), 109-116

## ABSTRACT

#### Background

Acetabular fractures are difficult to classify owing to the complex threedimensional (3D) anatomy of the pelvis. 3D printing helps to understand and reliably classify acetabular fracture types. 3D-Virtual Reality (VR) may have comparable benefits. Our hypothesis is that 3D-VR is equivalent to 3D printing in understanding recognize acetabular fracture patterns.

## Methods

A total of 27 observers of various experience levels from several hospitals were requested to classify twenty 3D printed and VR-models according to the Judet-Letournel classification. Additionally, surgeons were asked to state their preferred surgical approach and patient positioning. Time to classify each fracture type was recorded. The cases were randomized to rule out a learning curve. Inter-observer agreement was analyzed using Fleiss' kappa statistics ( $\kappa$ ).

#### Results

Inter-observer agreements varied by observer group and type of model used to classify the fracture. Medical students: 3D print( $\kappa$ = 0.61), VR( $\kappa$ = 0.41). Junior surgical residents: 3D print(0.51) VR(0.54). Senior surgical residents: 3D print(0.66) VR(0.52). Junior surgeons: 3D print(0.56), VR(0.43). Senior surgeons: 3D print( $\kappa$ = 0.59), VR( $\kappa$ = 0.42).

Using 3D printed models, there was more agreement on the surgical approach (junior surgeons  $\kappa$ = 0.23, senior surgeons  $\kappa$ = 0.31) when compared with VR (junior surgeons  $\kappa$ =0.17, senior surgeons 0.25). No difference was found in time used to classify these fractures between 3D printing and VR for all groups (P= 1.000).

#### Conclusion

The Judet-Letournel acetabular classification stays difficult to interpret, only moderate Kappa agreements were found. We found 3D-VR inferior to 3D printing in classifying acetabular fractures. Furthermore, the current 3D-VR technology is still not practical for intra-operative use.

Project was supported by the Royal Dutch Medical Association stimulus fund (KNMG)

## Background

Acetabular fractures are difficult to classify due to the three-dimensional (3D) shape of the pelvis and acetabulum.<sup>1</sup> Physicians initially learn how to classify these fractures from books and didactic teaching. Since there are more pelvic and acetabular surgeons and decreased high-energy trauma in first world countries, there is both a dilution and decrease in physician exposure to these injuries. These fractures, unlike some other orthopedic injuries, are very difficult to reduce and fix due to the complexity of understanding fracture lines, anatomic exposure, difficult reduction techniques, proper wound closure, and propensity for complications.<sup>2</sup>

The first step in treating acetabular fractures is identifying the correct fracture pattern on an anteroposterior (AP) pelvic radiograph. Letournel felt that the vast majority of acetabular fracture patterns can be identified from the AP pelvis x-ray.<sup>3</sup> It is important for the surgeon and student to understand basic radiography, pelvic landmarks and lines, and extrapolate a 3D structure from a two-dimensional (2D) image. This learning is lifelong since each of these fracture patterns can be so different. However, recognition of certain patterns can facilitate proper classification of acetabular fractures. Improving this process of pattern recognition is reliant on volume. Since surgical approach is dependent on the correct fracture classification, this first step is critical to treatment of these injuries.

Currently, plane films (AP pelvis and Judet views) and computed tomography (CT) are the modalities utilized to diagnose the correct acetabular fracture pattern. Two-dimensional and 3D CT reconstructions are helpful in extrapolating the 2D image to 3-dimensions in the surgeon's brain.<sup>4-6</sup> However, every effort should be made to classify the fracture pattern based on the AP pelvis and Judet views. The 3D CT reconstruction should be used for confirmation. This exercise forces the surgeon to critically analyze the radiographs and create his/her own 3D image in his/her own brain. This process, if done for each fracture, is far more valuable to the surgeon intra-operatively than relying on the reconstruction. Drawing the fracture lines on either a 2D drawing of the pelvis or a 3D model is also extremely helpful to this process.

In a previous study from our group, we demonstrated the benefits of 3D printed models in classifying acetabular fractures and evaluation of its surgical approach when compared with X-ray, 2D CT and 3D reconstructions seen on a 2D computer screen.<sup>7</sup> Three dimensional printed acetabular models ( $\kappa$ = 0.59) showed higher inter-observer rates for senior surgeons when compared with X-ray/ 2D CT ( $\kappa$ = 0.33) and 3D CT ( $\kappa$ = 0.42).<sup>7</sup> However, in this previous study a life-size hemi-pelvic model was made in 33 hours, and errors can occur during

this print process. Therefore a 3D printed model cannot be used in emergency settings. Orthopedic trauma procedures will normally not be performed within the first 24 hours after injury; however, a virtual model could speed up the pre-operative workup.

Virtual Reality (VR) could offer a 'real' 3D view as well. The first health care applications for VR were invented in the early 90's.<sup>8</sup> However, in the first years VR was limited by complex development of virtual environments and a technical engineer was needed. Furthermore, a VR experience using a desktop computer based system was restricted by wires and the need of a controller and glasses. VR was mainly used as an interactive tool for surgical planning and training.<sup>9</sup> VR training led to an improvement of technical skills in orthopedic surgery.<sup>10</sup> However, all those VR experiences and trauma simulators<sup>11-12</sup> are still projected on a computer screen and hence, the physicians are still learning surgical procedures and anatomy in 2D and not 3D.

The introduction of mobile VR-headsets has changed the situation due to the stereoscopic head-mounted display. Three-dimensional VR has become less expensive and the equipment is reduced to a headset. These headsets give the user the feeling that they are in another environment. Open-source software can be used to build high-quality 3D games and deploy them across a smartphone. Creating an application can still be challenging for doctors, however, non-profit 3D specialists have become widely available in academic hospitals.

A VR-headset compromises stereo-sound and head motion tracking sensors. Two types of VR-headsets have been developed; (1) VR-headsets that need to be connected or tethered to a desktop computer with a competent Graphics Processing Unit (such as The Oculus Rift and HTC Vice, released in 2016) and (2) Mobile VRheadsets (smartphones).

To the authors' knowledge, there are no reports that investigate the benefit of VR-headsets in classifying acetabular fractures. In this study we sought to determine the efficacy of 3D-VR models versus 3D printed models in facilitating fracture classification. Our hypothesis is that 3D-VR is equivalent to 3D printing in understanding acetabular fractures. We differentiate between several levels of training in surgery to investigate the value of implementation of 3D-VR.

## Methods

This study was exempted from the scope of the Medical Research Involving Human Subjects Act (WMO) according to our institutional ethics committee. The Dutch Trauma Registry was used to identify all acetabular fractures from 2 hospitals; the Elisabeth-Tweesteden Hospital and Isala Hospital. Twenty acetabular fractures were selected and chosen in consensus by two trauma surgeons (experienced in the field of acetabular surgery). Both surgeons classified all acetabular fractures according the Judet-Letournel classification<sup>3,13</sup> and distributed the cases according to the acetabular incidence findings of Giannoudis et al.<sup>14</sup> To their best knowledge, the surgeons identified 4 both columns, 1 posterior wall, 3 transverse posterior walls, 2 anterior column posterior hemi transverse, 3 T-shaped, 3 anterior columns, 1 transverse, 2 posterior columns and 1 anterior wall type acetabular fracture. However, due to low expected inter-observer agreements in acetabular fracture classification using conventional methods (X-ray, 2D- and 3D CT), we did not set a gold standard in classification of acetabular fractures for our study.<sup>4,5</sup> The distribution of acetabular fractures in real practice.

#### **3D** printing

Digital Imaging and Communications in Medicine (DICOM) data of 20 acetabular CT-scans with 1 millimeter slices or less were taken. *Philips Intellispace Portal* software, integrated in the hospital, was used to remove the femur and contralateral healthy hemi-pelvis to enhance intra-articular fracture visualization. Three dimensional reconstructions were saved as Surface Tessellation Language (STL)-data. Open-source software (*Meshlab and Simplify 3D*) was used to prepare the STL data for the 3D printer. All hemi-pelvic models were printed in a scale of 1:1 using our in-hospital 3D printer; the *Makerbot Replicator Z18* (figure 1).

#### Virtual-Reality headset

A mobile VR-headset (Samsung Gear VR and Samsung Galaxy S7 Edge) was selected due to its accelerometer and a gyrometer for tracking head movements. All STL-data of 20 hemi-pelvic models with acetabular fractures were sent anonymously to the 3D laboratory in the Radboud University Medical Center. *Unity*, a game development platform, was used to design a mobile software application with a virtual environment for each hemi-pelvic model. Head movements were used to rotate the model horizontally or to zoom in and out. Finally 20 apps (one for each model) from *Unity* (commercially available) were installed on the Samsung Galaxy S7 Edge (figure 2).

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Figure 1 | Two life-size examples of 3D printed hemi-pelvic models.

Figure 2 | Head-movements to rotate the hemi-pelvic model using the Samsung Gear VR.



#### **Inter-observer agreements**

Observers from several level 1 and level 2 traumacenters were divided into 5 groups; (1) five medical students (surgical interns), (2) five junior surgical residents (postgraduate year 1-2), (3) five senior surgical residents (postgraduate year 5-6, specialization in trauma surgery), (4) five junior trauma surgeons and (5) seven senior trauma surgeons, experienced in the field of acetabular surgery. Three tasks were designed:

- 1. Classify 20 acetabular fractures using 3D printed models and 3D-VR according to the Judet-Letournel classification.
- 2. Evaluate the surgical approach of acetabular fractures using 3D printed models and reassess for a potential change when classifying using 3D-VR. Surgical approaches were defined according to principles of the AO foundation.

Determine the positioning of the patient during operation; supine, prone, lateral, supine/prone, or lateral/prone, using 3D printing and 3D-VR.

Group 1-3 was instructed to complete task 1, group 4 and 5 were instructed to complete all 3 tasks. All cases were mixed to ensure outcomes were not correlated and to rule out a potential learning curve. All observers were informed that each fracture pattern was represented once, more than once, or not at all. Before start of the study, all observers were teached about the Judet-Letournel classification by showing pictures of the all Judet-Letournel fracture types. Time needed to complete all tasks was noted. Comments of the observers to classify acetabular fractures using both modalities were summarized and listed.

Our hypothesis was that a 3D printed model or 3D-VR could be used to improve surgical confidence. Surgical confidence was defined as the believe or trust that is needed to perform an operation. Comments of senior- and junior surgeons about their modality of choice for *surgical confidence* during the surgical procedure was listed as well.

All cases were presented in a random order again after two months. The firstand second round scores were used to investigate a potential learning curve.

#### Data analysis

One-Way ANOVA was used to calculate the difference in time between 3D printing and 3D-VR needed to complete the sets of 20 cases. Paired Samples T tests were used to calculate the difference in time between the first and second round of observations. A p-value of 0.05 was determined as significant. IBM SPSS Statistics 24 was used for statistical analysis. Calculations were performed using 95 % confidence intervals (CI).

Observer data was analyzed and expressed in terms of inter-observer agreements. Calculation was done using Fleiss' kappa statistics ( $\kappa$ ). Fleiss' kappa calculates the agreement between a fixed number of observers when assigning categorical ratings to a number of items or classifying items.<sup>15</sup> We interpreted multirater kappa statistics as follows; values of 0.01 – 0.20 indicate slight agreement, 0.21 – 0.40 fair agreement, 0.41 – 0.60 moderate agreement, 0.61 – 0.80 substantial agreement, and more than 0.80 almost perfect agreement. The Fleiss' kappa calculator was available from an open-access Microsoft Excel spreadsheet.<sup>16</sup>

## Results

#### Inter-observer agreements to classify acetabular fractures

Inter-observer agreements for interns decreased from substantial to moderate, when acetabular fractures were classified by respectively, 3D printed models and 3D-VR (table 1). Junior surgical residents were found to have moderate agreements in both modalities. The  $\kappa$  values of 3D printed models and 3D-VR for senior surgical residents were respectively, 0.66 and 0.52. Junior surgeons obtained  $\kappa$  values of 0.56 and 0.43 when viewed by 3D printing and 3D-VR respectively. Inter-observer agreements of senior decreased from  $\kappa$ = 0.59 to  $\kappa$ = 0.42. The overall  $\kappa$  values were 0.47 (95% CI 0.46-0.47) when viewed by 3D printing and 0.38 (95% CI 0.37-0.38) when viewed by 3D-VR.

#### Potential learning curve

The potential learning curve for acetabular fractures is shown in table 1; it shows the difference in  $\kappa$  values between the first and second round of measurements. Compared with 3D printing, the inter-observer agreements of interns, senior surgical residents and junior surgeons increased more when viewed by 3D-VR.

Classification	Print, κ (95% CI)	3D-VR, к (95% CI)
Overall	0.47 (0.46-0.47)	0.38 (0.37-0.38)
Senior surgeon	0.59 (0.57-0.62)	0.42 (0.39-0.44)
Junior Surgeon	0.56 (0.52-0.60)	0.43 (0.40-0.47)
Senior surgical resident	0.66 (0.62-0.69)	0.52 (0.48-0.55)
Junior surgical resident	0.51 (0.47-0.54)	0.54 (0.50-0.57)
Intern	0.61 (0.57-0.64)	0.41 (0.37-0.44)
Learning curve	Print, ĸ	3D-VR, κ
Overall	0.01	0.07
Senior surgeon	0.06	0.06
Junior surgeon	0.04	0.16
Senior surgical resident	-0.17	0.11
Junior surgical resident	0.16	0.04
Intern	-0.02	0.16

Table 1 | Classification: inter-observer agreements

Learning curve: Difference in kappa between first round and second round of observations

#### Time to classify acetabular fractures

Table 2 shows the time needed to classify 20 acetabular fracture cases. No significant time difference between 3D printing and 3D-VR was found for all observer groups (P= 1.000). No significant difference was found between all observer groups when using 3D printing (P= 0.607) or VR (P= 0.768).

Time	Print	3D-VR	P*
Overall, min (SD)	9.25 (3.22)	10.71 (3.33)	1.000
Senior surgeon	9.19 (2.5)	10.29 (2.18)	1.000
Junior surgeon	10.20 (3.12)	12.31 (3.79)	1.000
Senior surgical resident	10.07 (5.30)	11.08 (2.14)	1.000
Junior surgical resident	9.63 (3.17)	10.50 (3.24)	1.000
Intern	7.18 (1.55)	9.52 (3.43)	1.000
Р	0.607	0.768	

 Table 2 | Time to classify 20 acetabular fracture cases per modality

\*One-way ANOVA. Post hoc multiple comparisons Bonferroni

#### Differences between the first- and second round of observations

Table 3 shows the difference in time between the first round and second round of observations. Overall, in both the 3D printing- and 3D-VR group, observers needed less time to complete the second round of acetabular cases when compared with the first round.

Difference	Print	Р	3D-VR	<b>P</b> *
Overall, min (SD)	-3.45 (-3.28)	0.000	-3.58 (-2.31)	0.000
Senior surgeon	-4.70 (-2.68)	0.004	-4.48 (-1.87)	0.001
Junior surgeon	-3.41 (-4.00)	0.129	-3.90 (-3.20)	0.053
Senior surgical resident	-4.14 (-3.01)	0.037	-2.44 (-2.25)	0.073
Junior surgical resident	-3.38 (-2.34)	0.032	-3.81 (-1.73)	0.008
Intern	-1.10 (-4.28)	0.595	-2.90 (-2.68)	0.072

 Table 3 | Difference in time between first round and second round of observations

\*Paired samples T test

#### Surgical approach

Agreements on the different surgical approaches are shown in table 4. Overall  $\kappa$  values of 3D printed models and 3D-VR were respectively, 0.30 and 0.24,

representing fair agreements. Compared with 3D-VR, both junior- and senior surgeons reached higher  $\kappa$  values on evaluating the surgical approach when using 3D printed models.

Table 4 also shows the difference between the first- and second round of observations. Junior surgeons slightly agreed more on 3D-VR ( $\kappa$ = 0.06), when compared with 3D printing ( $\kappa$ = 0.02).

Surgical approach	Print, κ (95% CI)	3D-VR, κ (95% CI)
Overall	0.30 (0.26-0.33)	0.24 (0.21-0.27)
Senior surgeon	0.31 (0.24-0.37)	0.25 (0.19-0.31)
Junior surgeon	0.23 (-)	0.17 (0.10-0.24)
Learning curve	Print, κ	3D-VR, к
Overall	-0.03	-0.01
Senior surgeon	-0.06	-0.04
Junior surgeon	0.02	0.06

Table 4 | Surgical approach

Learning curve: Difference in kappa between first round and second round of observations

#### Positioning of the patient

Both junior- and senior surgeons reached fair agreements on positioning of the patients using 3D printed models and 3D-VR. The second round of observations did not show large improvements on the agreements (table 5).

Surgeons may have a preference for prone or lateral position while this is not evidenced based. Therefore, we calculated new inter-observer agreements with both positions taken together, seen in table 6. Compared with table 5, interobserver agreements increased from fair to moderate.

Positioning	Print, κ (95% CI)	3D-VR, κ (95% CI)
Overall	0.31 (0.27-0.34)	0.28 (0.24-0.31)
Senior surgeon	0.31 (0.25-0.37)	0.27 (0.21-0.33)
Junior surgeon	0.28 (0.18-0.38)	0.27 (0.17-0.37)
Positioning	Print ĸ	3D-VR K
Overall	0.07	0.08
Senior surgeon	0.07	0.10
Junior surgeon	0.01	0.05

 Table 5 | Positioning of the patient

Difference in kappa between first round and second round of observations

Positioning without preference	Print, κ (95% CI)	3D-VR, к (95% CI)
Overall	0.44 (0.40-0.49)	0.44 (0.40-0.49)
Senior surgeon	0.43 (0.35-0.51)	0.44 (0.36-0.52)
Junior surgeon	0.47 (0.35-0.59)	0.45 (0.33-0.57)

Table 6 | Positioning of the patient. Preference of lateral or prone combined

#### Overall impression of the observers

Comments of all observers are shown in table 7. Observers indicated that small fractures were melted together when using 3D printing models and one observer became nauseous when using the VR headset.

The modality of choice to use during the operation regarding *surgical confidence* was also noted. Five out of 6 senior surgeons and all junior surgeons found the 3D printed models most easy to use during the operation.

Table 7 | Summarized comments of all observers on the different modalities

Classification:	3D	"Natural" 3D view. The model can be rotated in all
	printing	directions. Small details are melted together.
	3D-Virtual	Good 3D view, direct insight in fracture patterns.
	Reality	Limited possibilities to turn around model, no vertical
		rotation, nausea.
Surgical	3D	Practical, most easy to use, useful for education,
procedure:	printing	tangible.
	3D-Virtual	Less details melted together, better view. Due to the
	Reality	integrated head-movements for rotation, everything
		stays sterile. Isolated from patient.

Summarized comments on modality of choice for surgical procedure

## Discussion

This study primarily shows that 3D-VR is inferior to 3D printing in classifying acetabular fractures. In general, observers found 3D printed models more practical to use and a higher inter-observer agreement was found when acetabular fractures were classified using 3D printed models.

However, group-specific outcomes show different patterns in outcomes of classifying acetabular fractures. The highest Kappa values for 3D-VR were obtained by the younger generation surgeons, surgical residents and medical students. When compared with 3D printing, young surgeons and residents showed a clear learning curve in classifying acetabular fractures using 3D-VR. No difference in time to complete all sets of acetabular cases was noted.

Surgical VR applications can be divided into three subtypes: (1) Surgical training, (2) Pre-operative workup and (3) Augmented Reality during the surgical procedure.<sup>17</sup> Many studies have investigated the role of VR in surgical training and pre-operative workup using trauma simulators and concluded that VR could be of added value.<sup>11,18,19</sup> However, all studies provided VR on a 2D computer screen. To the authors' knowledge this is the first study in which 3D-VR is investigated. Hence, no comparison with other studies could be performed.

With regard to the pre-operative workup, only fair agreements were found for senior- and junior surgeons when determining the surgical approach and positioning of the patient using both modalities. Furthermore, a clear learning curve was not found. These results imply that preference of surgical approach and positioning of the patient are rather experienced based than evidence based. This hypothesis is confirmed by the results of table 6; even when the results of positioning of the patient are limited to three options, only moderate agreements for junior- and senior surgeons using 3D printed models or 3D-VR are found.

There are many surgical approaches for acetabular surgery. Different surgical approaches for the same type of acetabular fracture can lead to the same surgical outcomes. However, different surgical approaches mean that there is an extra confounding variable in the treatment of acetabular fractures. This could adversely affect acetabular outcome studies. Therefore, it is desirable to standardize the surgical approach for acetabular fractures.

To the authors' knowledge, this is also the first study which investigates the value of a VR-headset in several levels in surgical training. From this given fact, 3D-VR could also be used for anatomical education in the future. Although, a small added value in understanding acetabular fractures was found, junior- and senior trauma surgeons still preferred a 3D printed model before and during the surgical procedure. This implies that surgeons found the 3D-VR technique too complex and impractical for routine clinical use. However, using 3D-VR,

observer agreements especially among younger observers increased. On the one hand, this could imply that medical students can classify an acetabular fracture as well as a very experienced senior trauma surgeon when using 3D-VR. The learning curve to identify fracture patterns is shortened by many years of experience and students can step in at a higher level than they did 20 years ago. On the other hand, the increased inter-observer agreement does not mean that all young observers classified the right subtype. It could be possible that they all agreed on the wrong subtype, indicating a good agreement.

The major study limitation was the absence of a "gold standard" for classifying acetabular fractures. We were not able to measure the intra-observer agreements and calculate a learning curve individually. The difference between both rounds of observations was calculated to care for this problem and provide a learning curve in groups. Furthermore, due to the absence of a gold standard we were not able to investigate if experienced surgeons were better in classifying associated (complex) acetabular fractures, when compared with interns and residents. Small fractures were melted together when using 3D printed models of 3D-VR. Although these small fracture patterns could not be of importance in a clinical setting, it is possible that observers did not choose the appropriate fracture subtype.

One observer developed VR motion sickness. This problem could be solved by including a horizon in the virtual environment. A disadvantage of 3D-VR in general is the fact that these virtual models cannot be touched. We believe that feeling a construct could add valuable information. Another disadvantage of 3D-VR is the lack of interaction with the natural environment. Consumers are isolated from the surroundings, which is not an ideal situation in the operation room. Although a proper classification is normally performed before entering the operation room, surgeons often will change their plan of action during the operation. We believe the next step to full 3D-VR is interaction with the environment and not just look around in a virtual world. This is called; Augmented Reality, a technique that will develop in the upcoming years.

## Conclusions

In conclusions, acetabular fracture classification can be difficult for young and old surgeons alike. Any process that facilitates classification of these complex injuries can be beneficial to patient care since surgical approach frequently follows correct fracture classification. In this study, we found 3D-VR inferior to 3D printed acetabular fracture models. Furthermore, the current 3D-VR technology is still not practical for intra-operative use. Future improvements in technology may facilitate a beneficial translation of VR technology in treatment of acetabular fractures.

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# CHAPTER 9

General summary and future perspectives

## **General summary**

Pelvic fractures are complex injuries,<sup>1</sup> and an extensive knowledge of the anatomy, surrounding tissues and surgical approaches is needed. Several (inter) national steps have been taken in the past to improve the long-term outcomes in both younger patients and elderly patients with pelvic fractures.<sup>2,3</sup>

Pelvic fracture-related innovations and the implementation of an organized trauma system enabled a significant reduction in injury-related mortality near the end of the 20th century.<sup>4</sup> The incidence of all pelvic fractures in the Netherlands is 14.3 per 100,000 people. The in-hospital mortality rate in the Netherlands has decreased to 5.1%.<sup>5</sup> In the last centuries, the focus of outcome shifted to radiological and functional outcomes after pelvic trauma.<sup>6-9</sup> However, patients may greatly suffer after trauma due to physical discomfort, mental problems and social isolation.

In this thesis, we focused on two different ways of optimizing patient outcomes of pelvic fractures. In **Part I**, we focused on the health-related quality of life (HRQoL) after sustaining a pelvic fracture. Although there is substantial scientific knowledge about the radiological and functional outcomes of patients with pelvic fractures, little is known about the social, physical and psychological functioning of patients after pelvic injury.

In **Part II**, we focused on the value of 3D-printed models in understanding acetabular fractures. Several pelvic-classification systems have been invented to ensure a proper understanding of the anatomy. X-ray, and later 2D CT, have long been considered the standards for pelvic injury care. The addition of 3D CT scan for the identification of fracture patterns and education of pelvic fractures has grown in popularity. However, all these modalities still use a 2D screen on which to project the pelvis. 3D printing of patient-specific anatomical models is thought to have advantages in understanding fractures, reducing surgical time, and improving patient outcome, understanding and surgical confidence during operations.

## Part I

In **Chapter 2**, we conducted a cross-sectional study of patients with all types of pelvic ring fractures using both generic and pelvic-specific HRQoL instruments, namely, the EuroQoL-5D (EQ-5D) and the Majeed Pelvic Score (MPS), respectively. The primary aim in this study was to determine the HRQoL for the different Tile-type fractures considering the patient characteristics. One hundred one patients with Tile A fractures, 67 with Tile B fractures and 27 with Tile C fractures met the inclusion criteria and were interviewed (response rate of 86%). After a mean follow-up of 29 months post-injury, the EQ-5D of all the

patients was still lower compared with that of the general Dutch population. However, performing a comparable analysis of the MPS was not possible due to the lack of an existing MPS norm score.

Differences in MPS between the Tile groups were not seen in the group of patients aged 65 years and older. However, in the group of patients younger than 65 years, patients with Tile C fractures had significantly more pain when compared with patients with Tile A or B fractures. We could not exclude the impact of comorbidities (such as arthrosis) or age on the pain of elderly patients after an injury. Therefore, we questioned the applicability of the MPS in patients aged 65 years and older and investigated this question in Chapter 3. In this chapter, we compared the MPS outcomes of injured patients with a reference cohort of uninjured patients in different age groups. The discriminative power and applicability of the MPS in the elderly population were investigated, and norm scores for the MPS in the Netherlands were collected. The same patient group as stated in Chapter 2 was included. For the control group, we collected data from a panel of adults representing the general Dutch population. Five hundred fifty-four adults completed the MPS questionnaire (response rate 87%). In contrast to our hypothesis about the poor applicability of MPS in patients aged 65 years and older in Chapter 2, this chapter showed that the MPS discriminated sufficiently well to provide information about elderly patients. We found significant decreases in mobility (standing A, B, and C) in the pelvic group in both age groups, indicating that the mobility outcomes were at least partly related to pelvic ring disruption and were not completely due to age. The Dutch norm scores for the MPS (88.3 for < 65 years and 72.0 for  $\ge$  65 years) showed that both age groups described in Chapter 2 had not recovered yet (81.6 for < 65 years and 68.1 for  $\geq$  65 years) at the follow-up.

Chapter 2 and Chapter 3 showed that patients were still not recovered during a 2-year follow-up. However, ceiling effects of the MPS were also noted. In **Chapter 4**, we investigated the HRQoL outcomes 5-10 years after high-energy pelvic injury. The study was conducted in two level 1 trauma centers (Radboud University Medical Center and Elisabeth-Tweesteden Hospital), and the MPS, EQ-5D and Short Musculoskeletal Function Assessment (SMFA) questionnaires were included. The mean follow-up period was 8.7 years, and 136 patients completed the questionnaires. Differences between the Tile scores for all the questionnaires were not significantly different. Thirty-two percent of Tile A, 36% of Tile B and 33% of Tile C patients had a maximal score on the MPS. We concluded that patients who survived a pelvic fracture had generally good HRQoL outcomes 5-10 years after injury. Comparing the results of Chapter 2 and Chapter 4, we concluded that after 2.5 and 8.7 years of follow-up, no substantial

increase in the HRQoL was observed in patients with Tile A or B fractures. However, an increase in the HROoL was seen in patients with Tile C fractures, meaning that long-term follow-up of patients with Tile C fractures is warranted. The prognostic factors that are known to influence the quality of life after pelvic ring trauma are studied in single-center studies that are retrospective in nature or begin follow-up 1 year after trauma.<sup>14-20</sup> Therefore, the main purpose of **Chapter 5** was to identify prognostic factors of decreased outcome after pelvic trauma and to provide insight into short-term HRQoL in the first year after pelvic injury. This study was part of the Brabant Injury Outcome Surveillance (BIOS) study, a prospective longitudinal follow-up study of all admitted adult injury patients in the Noord-Brabant region.<sup>21</sup> We included 184 patients (90% inclusion rate) with pelvic fractures and concluded that patients experience a reduction in their HRQoL after a pelvic fracture, especially in the first 3 months. Although the HRQoL recovery continues to 12 months after trauma, most patients do not achieve their pre-injury HRQoL within the first year after injury. Prognostic factors for decreased HRQoL after pelvic trauma are a low pre-injury HRQoL score, high Injury Severity Score and female gender. A limitation of this study is that 22% and 38% of the patients < 65 years and  $\geq$  65 years, respectively, had already reached the maximum MPS score 6 months after injury. Although these maximum scores could show full recovery of patients, it is more likely that ceiling effects of the questionnaire limit content validity and reliability; changes cannot be measured within the patients. All the MPS results and maximum MPS scores in this part of the thesis have influenced our decision not to recommend the use of the MPS in the mid- and long-term follow-up of pelvic fractures.

## Part II

The accuracy of 3D-printed models is important for pre-bending plates and fitting surgical guides.<sup>22,23</sup> In **Chapter 6**, we conducted a validation study in which we compared human cadavers with 3D-printed models to test the accuracy of 3D printing. Nine specimens were scanned, volume-rendered into 3D reconstructions and saved as standard tessellation language (STL) data. All the models were in a ratio of 1:1 printed on two 3D printers; the Ultimaker 3 and Makerbot Replicator Z18. Most significant differences in measurements were found in the conversion from 3D file into a 3D print and between the cadaver and 3D-printed model from the Makerbot. Even though the differences between the cadavers and 3D-printed models were statistically significant, we found the clinical importance to be less significant. We concluded that our 3D printing process results in accurate models that are suitable for preoperative workup. We believe that these small differences will affect neither the position of a pre-

bended plate nor the anatomy of the bone, regardless of the location or type of fracture.

3D-printed anatomical models can be used during the preoperative workup for a better understanding of the pelvic anatomy. In Chapter 7, we investigated the value of 3D-printed anatomical models in understanding isolated acetabular fractures using the Judet-Letournel classification. We differentiated between several levels of surgical training to investigate the value of implementation of 3D-printed models. Furthermore, we instructed junior and senior surgeons to determine their surgical approach using conventional diagnostics or 3D-printed models. In general, 3D-printed models were superior when compared with X-ray, 2D CT and 3D CT. Interns, residents, and junior surgeons showed greater improvement in agreement from X-ray, 2D CT, 3D CT reconstructions to 3D printing compared with that of the senior surgeons. Although an improvement in agreement on surgical approach was seen with 3D printing, only slight and fair agreements were found for all the modalities. This finding could indicate that acetabular surgery is still a more experienced-based surgery than an evidence-based surgery. All observers needed significantly less time to complete the datasets of 3D-printed models than datasets of X-ray, 2D CT or 3D reconstructions.

Although orthopedic trauma procedures will normally not be performed within the first 24 hours after injury, creating a life-size pelvic 3D-printed model requires time. However, a virtual 3D model could accelerate the preoperative workup. Virtual reality (VR) could also offer a 'real' 3D view. In **Chapter 8**, we investigated the benefit of VR headsets in classifying acetabular fractures. We compared 3D-VR pelvic models with 3D-printed pelvic models and differentiated between several levels of surgical training to investigate the value of 3D-VR implementation. In general, we found 3D-VR inferior to 3D-printed models in classifying acetabular fractures using the Judet-Letournel classification. 3D-printed models were found to be more practical to use. However, when compared with 3D printing, young surgeons and residents showed a clear learning curve in classifying acetabular fractures using 3D-VR. We concluded that current 3D-VR technology is still not practical for intra-operative use.

## **Future perspectives**

Pelvic fracture-related innovations will hopefully lead to optimized outcomes of patients with pelvic fractures. However, measuring HRQoL after a pelvic injury or using 3D-printed models are just the beginning of a new era in personalized medical care. This hypothesis is supported by the vision document of the *Federatie Medisch Specialisten*, the Dutch association of medical specialists.<sup>24</sup> In

this document, the Medical Specialist Committee 2025 of the Dutch Association of Medical Specialists describes the developments that are needed in specialized medical care in the Netherlands to offer the best specialized medical care in the world. Keywords that are included in this vision-document include "optimizing patient's quality of life", "big data analysis", "Patient Reported Outcome Measures (PROMs)", "3D printing" and "implementing a Chief Medical Information Officer (CMIO) that will serve as a link between the medical specialist, patient and technology supplier."

## Part I

As investigated in Part I, patients with pelvic fractures are at risk for short- and long-term reductions in HRQoL. Generic and disease-specific questionnaires were used; however, our research revealed that the MPS is probably not suitable to examine the mid- and long-term follow-up of pelvic fractures. Many different questionnaires are used to examine the HRQoL of trauma patients.<sup>25-27</sup> However, several questionnaires have not been properly validated, and the concepts are not well defined or have a ceiling effect that limits content validity and reliability. A solution is the use of the Patient Reported Outcome Measurement Information System (PROMIS). This dataset consists of generic self-reported measures for functions, symptoms, behaviors and feelings. The three domains evaluate physical, mental and social health. The PROMIS scores are expressed as T-scores and range from 0 to 100. A mean of 50 represents the average score of the general population with a standard deviation of 10. Due to this large dataset, it is possible to select relevant questions for specific patient groups. All the questions of the different PROMIS domains have been developed and validated based on existing Patient Reported Outcomes Measures (PROM) questions.<sup>28</sup> The Dutch-Flemish PROMIS group translated the PROMIS domains into Dutch.<sup>29</sup> PROMIS has already been used in other trauma research.<sup>30,31</sup>

A relatively new way for patients to complete PROMIS datasets is using Computer-Adaptive Testing (CAT), which is based on Item Response Theory (IRT).<sup>32</sup> An algorithm selects the next questions after the patient completes the first question.<sup>28</sup> Less time is needed to complete questionnaires, and fewer questions are required because the algorithm only selects the relevant questions.<sup>33</sup>

#### The future of questionnaire testing

In our studies, we provided data about the development of HRQoL over time in patients with pelvic trauma. These follow-up data and prognostic factors for decreased HRQoL can be used at the outpatient clinic to compare the outcomes of the individual patient with the mean outcomes of our BIOS study group. In the future, PROMIS CAT could be used as a continuous monitoring system at the outpatient clinic. By using big data, it will be possible to check the rehabilitation status of the pelvic patient at specific time points after injury and to compare these results with the BIOS study group, adjusted for age, gender, comorbidities and other confounders. In this way, personalized care can be given to each patient, and the influence of different (surgical) treatments and rehabilitation plans can be investigated. An improved understanding of the impact of non-fatal injury on personal and population health and the support of continuous quality improvement of care are the main goals of this research. A time- and cost-saving suggestion for clinical implementation could be instructing patients to arrive a few minutes before the appointment in the outpatient clinic. The nurse will provide a tablet with the questionnaire, and the results will be immediately sent to the patient's hospital file. In this way, the doctor is informed of the patient's current health status, is able to compare this with his database and can provide patient-specific instructions for the follow-up.

## Part II

In Part II of this thesis, the supposed benefits of 3D printing and virtual reality in understanding pelvic fractures were investigated. In 2007, Apple released the first iPhone, using 2G. Only, twelve years later, the iPhone XR with 4G was launched, and 5G will soon be released. This incredibly rapid development of iPhone technology could be compared with 3D printing: "Both relatively young techniques that are widespread, however, it can be better, the technique can act faster". From 2016, when the 3D printing lab was founded in Elisabeth-Tweesteden Hospital, to this day, many software and hardware updates have fine-tuned the 3D printing technique. A 3D printer that was printing "air" all night is history with the invention of a flow-sensor, which pauses the print and notifies the user when the 3D printer is out of material. Breaking down polylactic acid (PLA) support structures in 3D-printed models took a long time, and users were left with finger and eye PLA splinters. However, using water-soluble polyvinyl alcohol (PVA) as building support for 3D-printed models resolved these issues. All updates (which were not groundbreaking) were part of our continuously improving workflow and enthusiasm. 3D printing has the potential to revolutionize the future of medicine, and the possibilities are endless. Only the value of 3D-printed models was discussed in this thesis. However, it is also already possible to 3D print plates for acetabular fracture surgery.<sup>34</sup> Using 3D printing, patient-specific care can be delivered in all forms. However, one has to be critical as well. Although it could be possible that 3D printing could reduce costs by reducing intraoperative fluoroscopy, blood loss volume and surgical time, the time needed for the pre-operative work-up must also be considered. Recently, Chen et al. investigated the role of 3D-printed models in the treatment of fractures and performed a randomized clinical trial.<sup>36</sup> The study group included 48 AO-C distal radius fractures and randomized the pre-operative workup into using a 3D model or routine surgical treatment. The surgeons were allowed to pre-bend plates and measure screws using 3D-printed models. Significant reductions in intraoperative X-rays, blood loss (41 vs. 54 ml) and surgical time (66 vs. 75 min) were noted. Postoperative function was similar, and "Patients wanted the doctor who used the 3D model to describe the condition". However, surgeons needed 1 hour of pre-processing, 3-4 hours of 3D printing and 2.5 hours for simulating the surgical procedure. It is still uncertain whether 3D printing is cost-effective technique or not, when taking all the pre-, per- and post-operative aspects into account. Finally, 3D printing could also have great benefits for patients. The statement from the study of Chen et al. is one that is heard many times while explaining to patients using 3D-printed models at the outpatient clinic. However, to the best of our knowledge, no data exist in trauma surgery about educating patients using 3D-printed models. The first studies have been performed in lung and kidney surgery to investigate the value of 3D printing in improving the patient's understanding of their medical condition and treatment satisfaction.<sup>37,38</sup> Both studies showed improved patient comprehension in informed consent and pre-surgical knowledge. This improved comprehension could be of importance for understanding medical decisions during follow-up, weight-bearing instructions or improved patient satisfaction. Currently, our study group is investigating the value of 3D-printed models in patient education of mono-trauma patients at the Elisabeth-Tweesteden Hospital.

However, 3D printing is not the only modality that is upcoming. There are several technical innovations and new health professionals that will be part of daily pelvic fracture care in the future. 3D CT could lead to a new pelvic classification system, artificial intelligence (AI) can help to classify the fracture, holographic-guided surgery could be the holy grail of surgery, and the implementation of a Chief Medical Information Officer is needed to improve "digital" care.

#### 3D CT: a new way to measure pelvic fracture reduction?

Acetabular fractures are prone to long-term complications, such as osteoarthritis, when the displacement is not correctly repositioned during surgery. Post-operative joint congruity determines the risk of hip osteoarthritis and functional outcome, especially when the weight-bearing dome is involved in the fracture.<sup>39-41</sup> Matta's criteria (anatomical:  $\leq 1 \text{ mm of displacement}$ , imperfect: 2 to 3 mm of displacement, or poor: > 3 mm displacement) are used to determine the post-

operative reduction.<sup>42</sup> Although the classification is originally based on plain radiographs, CT scans are commonly used currently because they show detailed information on articular steps and gaps at the joint surface. Verbeek et al. concluded that residual gap and step displacement as measured on CT scans are both related to long-term hip-survivorship.43 However, all information is provided in 2D slices of the acetabulum, while the acetabulum is a 3-dimensional structure. It could be possible that by using 3D reconstructions, a more reliable method of post-operative acetabular fracture reduction and joint congruity assessment exists. The contralateral side could be used as a mirrored template for the anatomical configuration of the affected joint. In a pilot study, our study group already demonstrated the similarity of 3D-reconstructed models of the healthy left and right acetabulum and concluded that 3D reconstructions could be potentially used as mirrored duplicates.<sup>44</sup> The next step of our study group from Radboud University Medical Center will be to match pre- and postoperative acetabular fractures of patients with unilateral acetabular fractures and to assess the fracture reduction. Furthermore, the clinical relevance of potential acetabular surface (a)symmetry should be investigated. It could be possible that certain percentages and locations of asymmetry are potential predictors for clinical outcome. 3D CT is a promising invention that could lead to new classifications and criteria in post-operative reduction.

#### The application of AI in detecting pelvic fractures

Our study, which investigated the added value of 3D-printed models in understanding acetabular fractures, showed the difficulty of the Judet-Letournel classification. Although the classification system is important for the making decisions about (surgical) treatment and surgical approach, it is prone to different interpretations. Aiding image interpretation using computers could be the future in radiology. Computers can learn by experience; deep learning is a subset of this machine learning. In deep learning, artificial neural networks learn from large amounts of data. Using a deep learning algorithm, Chung et al. showed promising diagnostic performance in distinguishing normal shoulders from proximal humerus fractures (96% accuracy) and classifying different types of proximal humerus fractures (65-86% accuracy).<sup>45</sup> Langerhuizen et al. reviewed the applications and limitations of AI for fracture detection and classification in orthopedic trauma imaging. Although promising levels of performance were found when using AI, more research is needed regarding a reference standard assignment, more exposure to challenging scenarios is required, and more information about the implementation in daily care and legal regulation should be acquired.46

#### Is holographic-guided surgery the holy grail?

It is believed that two technologies, 3D printing and virtual reality (VR), will become mainstream, but need to be further developed in the near future. However, a disadvantage of VR is the lack of interaction with the natural environment. Surgeons are isolated from their surroundings, which is far from an ideal situation in the operating room. The next step of VR is interaction with the environment, not just looking around. Augmented reality (AR) solves these problems and is a technique that will continue to be developed in the upcoming years. In 2016, the Microsoft HoloLens was introduced (Microsoft Corporation, Redmond, WA, USA), which is a head-mounted display that can be used to visualize virtual content (holograms) within the surgeon's view (fig. 1). Thus far, the HoloLens has been mainly used for education purposes and training.<sup>47,48</sup> However, AR could also play an important role during surgical procedures. In addition to the possibility of projecting a hologram in the operating room to obtain a better understanding of the disease or fracture, the technique could be used in more advanced applications in combination with image guided surgery (IGS) systems.

IGS systems guide the surgeon during the procedure by displaying the position of a tracked surgical instrument, in relation to a virtual patient planning, on a 2D screen. IGS is used in neurosurgery for treatment of brain tumors<sup>49</sup> and for positioning of the implant in orbital reconstruction<sup>50</sup> in oral and maxillofacial surgery. In pelvic surgery, IGS is currently used for percutaneous iliosacral (IS) screw positioning to stabilize the posterior pelvic ring.<sup>51</sup> However, using this setup, surgeons have to simultaneously look at the patient and at the 2D or 3D navigation system, also known as the *switching focus problem*.<sup>52</sup>

AR in combination with IGS could overcome this problem. Using these techniques, it will be possible to visualize a hologram as an overlay of the patient within the surgeon's view. This approach enables minimally invasive surgery because the surgeon is able to see the anatomy and pathology without opening the body.

Radboud University Medical Center and Elisabeth-Tweesteden Hospital have access to multiple state-of-the-art hybrid operating rooms that are equipped with 3D C-arms. The systems are used for intraoperative 3D imaging. The data that are generated by these systems could be connected with the HoloLens to provide up-to-date information about the patient's condition during the operation.

The role of holographic-guided navigation is being extensively studied at the 3D lab of Radboud University Medical Center. For the first time internationally, Meulstee et al. performed an accuracy study in which the combination of the HoloLens and IGS systems was investigated.<sup>53</sup> These results showed that

the accuracy was affected by an average of 1.6 mm when AR was added to an IGS system. The presented system provided a solution for the switching focus problem and created a more intuitive guidance system. The 3D labs of Radboud University Medical Center and Elisabeth-Tweesteden Hospital and their Technical Medicine students cooperate to further fine-tune the accuracy, test AR solutions for various surgical procedures and improve IGS systems without the use of markers.



Figure 1 | Microsoft Hololens visualizing a pelvis with a left sighted acetabular fracture.

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# 3D printing, 3D CT, AI and holographic-guided surgery: the future of pelvic surgery?

3D will revolutionize the (surgical) treatment of pelvic fracture. Once the patient enters the trauma room, a CT scan is performed of the pelvis, the pelvic fracture is automatically assessed and classified using AI, and doctors are be able to print a life-size pelvis. This 3D-printed model can be used for pre-operative work up, to measure the most suitable plate and screws, and build molds for an accurate reduction of the fracture. The 3D prints can be used for explanation of the operation and follow-up to the patient. Moreover, the same CT scan is used to prepare a hologram of the patient's pelvis, which will be used during the operation. By using holographic-guided surgery, minimally invasive surgery is possible. By using AI technology, recognition of both the pelvis and the surgeon's tools will automatically lead to the best possible positioning of the SI screws. All these innovations enable patients to recover faster and with high quality of life standards.

#### The implementation of a new academic professional

The implementation of these complex technologies could not be possible without the expansion of a (new) academic professional. The Dutch association of medical specialists already defined this professional in their vision document 2025 as a *"Chief Medical Information Officer (CMIO) that will serve as a link between the medical specialist, patient and technology supplier"*.

Although the authors provide a vague description of an CMIO, this individual could be a *Technical Physician*. It is believed these students fill the gap between classical medicine and complex technology. In 2003, the University of Twente, and in 2014, the Technical University of Delft, initiated a novel field of study, namely, Technical Medicine. The healthcare system is becoming more complex, and the use of complex technology is expanding. It is hardly impossible for surgeons to stay up-to-date about anatomy, pathology, osteosynthesis, medical instruments, biological implants and software or engineering. Technical Medicine studies combine the medical and technical domains. Technical Physicians have a technical-medical perspective and the ability to develop innovative diagnostic and treatment solutions for patients. More recently, Technical Physicians were given full BIG registration (Individual Healthcare Professionals Act). The competencies of Technical Physicians have been recognized by the Dutch Government, and Technical Physicians are now qualified to treat patients independently.

The expectations about the role of Technical Physicians is that they will cooperate with surgeons in the near future. Operations are being prepared with combined clinical and technical knowledge. Patients are being seen at the outpatient clinic by both the surgeon and the Technical Physician. Using 3D-printed models and augmented reality, patients will be well informed about their disease or injury, treatment and follow-up. In fact, this is already the case at the Oral & Maxillofacial Surgery department of Radboud University Medical Center, where Technical Physicians and surgeons are working and meeting in the same rooms.

#### **Embrace the future**

Success Is Going from Failure to Failure Without Losing Your Enthusiasm -Winston Churchill-

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# ADDENDUM

Nederlandse Samenvatting

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Dankwoord

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# Nederlandse samenvatting

### Samenvatting

Bekkenbreuken zijn complexe breuken en lastig te doorgronden vanwege verschillende breuklijnen die de anatomie doorkruisen. Door de omringende weefsels en deze driedimensionale anatomie is een uitgebreide kennis van de chirurgische benadering vereist. Bekkenbreuken hebben op lange termijn gevolgen voor patiënten in alle leeftijdscategorieën. In het verleden zijn verschillende (inter)nationale maatregelen genomen om de uitkomst van patiënten met bekkenbreuken te verbeteren. Het doel van dit onderzoek was om de resultaten van patiënten met bekkenbreuken te optimaliseren.

Innovaties op bekken-chirurgisch gebied, implementatie van een goed georganiseerd trauma systeem en een goede methodiek voor trauma opvang (Advanced Trauma Life Support) hebben voor een significante vermindering van bekkenletsel-gerelateerde mortaliteit gezorgd rondom het einde van de 20<sup>ste</sup> eeuw. De incidentie van bekkenbreuken in Nederland is heden 14.3 per 100.000 inwoners. Van alle patiënten die met een bekkenbreuk worden opgenomen in het ziekenhuis sterft heden nog maar 5.1%. Omdat het merendeel van de patiënten blijft leven, verschoof de focus de afgelopen decennia naar radiologische- en functionele uitkomsten na een bekken trauma.

Hoewel dit focus van belang is voor artsen, kunnen patiënten andere resultaten belangrijker vinden. Patiënten kunnen na trauma veel last ervaren als gevolg van fysiek ongemak, mentale problemen en sociaal isolement. In **Deel I** hebben we ons gericht op de gezondheid gerelateerde kwaliteit van leven (KvL) na het oplopen van een bekkenbreuk. Hoewel veel bekend is over de radiologische en functionele uitkomsten van patiënten met bekkenbreuken, is er weinig bekend over het sociaal-, fysiek- en psychologisch functioneren van patiënten na een bekkenletsel.

Verschillende bekkenclassificatiesystemen zijn ontwikkeld om een goed begrip van de anatomie te verkrijgen. Lange tijd was het gebruik van röntgenfoto's en later 2D CT standaard zorg om bekkenletsel adequaat in kaart te brengen. Met de toevoeging van 3D CT-scans konden breuklijnen al beter begrepen worden en beter educatie gegeven worden over bekkenbreuken. Echter, al deze aanvullende onderzoeken hebben nog steeds een tweedimensionaal scherm nodig om het te visualiseren. Er wordt verondersteld dat het 3D-printen van patiënt-specifieke anatomische modellen voordelen kan hebben bij het begrijpen van breuken, leidt tot kortere operatietijd, verbeterd resultaat, meer inzicht bij de patiënt en meer chirurgisch vertrouwen tijdens operaties. In **Deel II** hebben we ons gericht op de toegevoegde waarde van 3D-geprinte modellen bij het begrijpen van heupkombreuken. De heupkom, als onderdeel van het bekken, is een complex geheel. Wanneer de heupkom breekt en het herstelt niet goed kan men nooit meer goed lopen, zitten, geslachtsgemeenschap hebben, en heeft men veel pijn. Artrose en pijn kunnen uiteindelijk leiden tot destructie van de heupkom en een totale heupprothese is dan nodig. Een breuk laat zich zeer lastig op röntgenfoto's en 2D CT visualiseren en begrijpen. Gespecialiseerde chirurgische zorg is nodig om heupkombreuken te behandelen.

### Deel I

In hoofdstuk 2 hebben we met behulp van generieke- en bekken-specifieke KvL vragenlijsten bij patiënten met alle typen bekkenbreuken patiënt-gerapporteerde uitkomsten gemeten. Hierbij is gebruik gemaakt van de EuroQol-5D (EQ-5D) en de Majeed Pelvic Score (MPS). Het primaire doel in deze studie was om de KvL te bepalen voor de verschillende Tile-type breuken rekening houdend met de patiëntkenmerken. Honderd-en-een patiënten met een Tile A, 67 met Tile B en 27 met Tile C type breuken voldeden aan de inclusiecriteria en werden geïnterviewd (respons percentage van 86%). Na een gemiddelde follow-up van 29 maanden na oplopen van het letsel was de EQ-5D van alle patiënten nog steeds lager in vergelijking met de algemene Nederlandse bevolking. Verschillen in MPS tussen de Tile groepen werden niet gezien in de patiënten van 65 jaar en ouder. Daarentegen hadden patiënten jonger dan 65 jaar met een Tile C breuk meer pijn in vergelijking met Tile A en B patiënten. De toepasbaarheid van de MPS bij patiënten van 65 jaar en ouder jaar werd daarom in twijfel getrokken. Een andere bevinding was dat 19% van de patiënten in de groep van jonger dan 65 jaar en 34% van de patiënten in de groep van 65 jaar en ouder een maximale MPS scoorden. Een belangrijke bevinding, omdat dit gevonden plafondeffect (indien >15% van de patiënten de maximale score op de vragenlijst behaald, spreekt met van een plafondeffect) de geldigheid en betrouwbaarheid van de vragenlijst kan verminderen. Met andere woorden, een maximum score kan betekenen dat de patiënt daadwerkelijk is genezen, maar het kan ook betekenen dat kleine veranderingen niet binnen de patiëntengroep worden gemeten omdat de vragenlijst niet specifiek genoeg is.

In **hoofdstuk 3** hebben we de MPS uitkomsten vergeleken bij patiënten en gezonde personen in verschillende leeftijdsgroepen. Het onderscheidend vermogen en toepasbaarheid van de MPS bij ouderen werd onderzocht en normscores voor de MPS in Nederland werden verzameld. Dezelfde patiëntengroep als vermeld in hoofdstuk 2 werd geïncludeerd. Voor de controlegroep verzamelden we gegevens van een panel volwassenen die de algemene Nederlandse bevolking vertegenwoordigen (LISS panel). Vijfhonderdvierenvijftig volwassenen vulden de MPS-vragenlijst in (responspercentage 87%). De MPS discrimineerde goed genoeg om informatie te verschaffen over oudere patiënten. We vonden een significante afname in mobiliteit in de bekkengroep in beide leeftijdsgroepen, wat aangeeft dat de mobiliteitsresultaten ten minste gedeeltelijk gerelateerd waren aan de bekkenbreuk en niet volledig te wijten waren aan de leeftijd. Nederlandse normscores voor de MPS (88,3 voor <65 jaar en 72,0 voor  $\geq$  65 jaar) toonden aan dat beide leeftijdsgroepen van hoofdstuk 2 nog niet hersteld waren (81,6 voor <65 jaar en 68,1 voor  $\geq$  65 jaar).

De meeste studies die de KvL onderzoeken van patiënten met bekkenbreuken bevatten relatief kleine patiëntengroepen, met een follow-up periode van slechts 2 jaar. Hoofdstuk 2 en 3 toonden aan dat patiënten nog steeds niet hersteld waren na een bekkenbreuk gedurende een follow-up van 2 jaar. Er werden echter ook plafondeffecten van de MPS opgemerkt. Daarom onderzochten we in hoofdstuk 4 de KvL-resultaten 5-10 jaar na hoog-energetisch opgelopen bekkenbreuk en beoordeelden we plafondeffecten van verschillende KvL-vragenlijsten. De studie werd uitgevoerd in twee grote level 1 traumacentra (Radboud Universitair Medisch Centrum en Elisabeth-Tweesteden ziekenhuis). De MPS, EQ-5D en Short Musculoskeletal Function Assessment (SMFA) werden afgenomen in het onderzoek. De gemiddelde follow-up periode was 8,7 jaar en 136 patiënten vulden de vragenlijsten in. Bij geen enkele vragenlijst werden significante verschillen gevonden voor de verschillende Tile-scores. Tweeëndertig procent van de patiënten met Tile A, 36% patiënten met Tile B en 33% patiënten met Tile C hadden een maximale score op de MPS. Geconcludeerd kon worden dat patiënten die een bekkenbreuk overleefden over het algemeen een goede KvL hadden 5-10 jaar na het letsel. Uit een vergelijking van de resultaten tussen hoofdstuk 2 en hoofdstuk 4 vonden we dat na 2,5 en 8,7 jaar follow-up geen substantiële verbetering van KvL werd waargenomen bij patiënten met een Tile A- of B-breuk. Er werd echter tijdens de follow-up nog steeds een toename van de KvL waargenomen bij patiënten met een Tile C bekkenbreuk, wat betekent dat langdurige follow-up van patiënten met Tile C-breuken gerechtvaardigd is. Van verschillende prognostische factoren is bekend dat ze de kwaliteit van leven na bekkentrauma beïnvloeden; neurologische stoornissen van de benen, veroudering, complexe breuk-types, een operatie, chronische pijn en seksuele en urologische disfunctie. De meeste onderzoeken die zich op deze prognostische factoren richten, zijn echter verricht in één ziekenhuis, retrospectief, of bestaan uit populaties met een follow-up vanaf 1 jaar na trauma. Het hoofddoel van hoofdstuk 5 was om prognostische factoren voor verminderde uitkomst na bekkentrauma te identificeren en inzicht te geven in korte-termijn KvL in het eerste jaar na bekken letsel. Deze studie was onderdeel van de Brabant Injury Outcome Surveillance (BIOS)-studie, een prospectieve longitudinale followup studie onder alle opgenomen volwassen trauma patiënten in de regio

Noord-Brabant. Honderdvierentachtig patiënten (90% inclusiepercentage) met bekkenring breuken of geïsoleerde heupkom breuken werden in opgenomen tijdens de studie. We concludeerden dat patiënten met een bekkenbreuk een vermindering van hun KvL ervaren, vooral in de eerste 3 maanden na trauma. Het KvL-herstel vindt met name in de eerste 12 maanden na het trauma. Desondanks bereiken de meeste patiënten het niveau van KvL van vóór het letsel niet binnen het eerste jaar na het letsel. Prognostische factoren voor verminderde KvL na bekkentrauma zijn een lagere KvL voorafgaand aan het letsel, hogere totaal letsel ernst en het vrouwelijk geslacht. Zes maanden na het letsel werden plafondeffecten gevonden van de Merle d'Aubigne Hip Score (MAHS) en MPS. Respectievelijk 22% en 38% van de patiënten <65 jaar en ≥65 jaar bereikten de maximale MPS-score. De MPS-resultaten in Deel I van het proefschrift hebben geleid tot de aanbeveling om de MPS niet te gebruiken voor de middellange en lange termijn follow-up van bekkenbreuken. Een generieke vragenlijst zoals de EQ-5D kan daarentegen wel gebruikt worden. Echter, in de nabije toekomst zullen de methodiek van afname en interpretatie van vragenlijsten volledig op de schop gaan. In de paragraaf *toekomst* zal ik daar verder op ingaan.

### Deel II

De nauwkeurigheid van 3D-geprinte modellen is belangrijk voor het voorbuigen van osteosynthese-platen en de pasvorm van chirurgische mallen. In hoofdstuk 6 hebben we een validatiestudie uitgevoerd waarin we menselijke kadavers vergeleken met 3D-geprinte modellen om de nauwkeurigheid van 3D-printen te testen. Negen stoffelijk overschotten werden gescand, omgezet in 3D-reconstructies en opgeslagen als standard tessellation language (STL) gegevens. Alle modellen werden in een verhouding van 1: 1 geprint met behulp van twee 3D-printers; de Ultimaker 3 en Makerbot Replicator Z18. De belangrijkste verschillen in metingen werden gevonden bij de omzetting van 3D-reconstructie naar een 3D-print en tussen het stoffelijk overschot en het 3D-geprinte model van de Makerbot. Hoewel de verschillen tussen de stoffelijk overschotten en 3D-geprinte modellen statistisch significant waren, vonden we het klinische belang minder significant. We geloven dat deze kleine verschillen noch de positie van de voorgebogen plaat, noch de anatomie van het bot beïnvloeden, ongeacht de locatie of het type breuk. We concludeerden dat ons 3D-printproces resulteert in nauwkeurige modellen die geschikt zijn voor pre- en peroperatief gebruik.

3D-geprinte anatomische modellen kunnen tijdens de preoperatieve work-up gebruikt worden voor een beter begrip en kennis van de bekken anatomie. In **hoofdstuk 7** onderzochten we de waarde van 3D-geprinte anatomische

modellen voor het begrijpen van heupkom breuken met behulp van de Judet-Letournel-classificatie. We maakten onderscheid tussen verschillende fases in opleiding en chirurgische carrière om de waarde van de implementatie van 3D-geprinte modellen te onderzoeken. Daarnaast instrueerden we junior en senior chirurgen om hun chirurgische aanpak te bepalen aan de hand van conventionele diagnostiek of 3D-geprinte modellen. Over het algemeen waren 3D-geprinte modellen superieur in vergelijking met röntgenfoto's, 2D CT en 3D CT. Coassistenten, arts-assistenten en jonge chirurgen (fellow's) lieten een meer opwaartse lijn zien wat betreft de mate van overstemming over het type classificatie met röntgen/ 2D CT, 3D-reconstructies en 3D geprinte modellen dan de senior chirurgen. Hoewel een relatieve verbetering van de overeenstemming over chirurgische aanpak werd gezien met 3D-printen, waren de absolute getallen wat betreft overeenstemmingen laag voor alle modaliteiten. Deze laatste bevinding geeft aan dat heupkom chirurgie nog steeds een meer op ervaring gebaseerde chirurgie (experienced based) is in plaats van op onderzoek gebaseerde chirurgie (evidenced based). Alle deelnemers van de studie hadden aanzienlijk minder tijd nodig om de datasets van 3D-geprinte modellen te voltooien dan datasets van röntgen/ 2D CT of 3D-reconstructies.

Hoewel orthopedische trauma georiënteerde operaties normaal gesproken niet binnen de eerste 24 uur na het letsel worden uitgevoerd, kan het maken van een levensgroot bekken 3D-geprint model tijd kosten. Een virtueel 3D-model kan echter de preoperatieve work-up versnellen. Virtual Reality (VR) kan ook een 'echte' 3D-weergave bieden. In hoofdstuk 8 onderzochten we de waarde van een VR hoofdset bij het classificeren van heupkom breuken. We vergeleken 3D-VRbekkenmodellen met 3D-geprinte bekkenmodellen en maakten onderscheid tussen verschillende niveaus in chirurgische opleiding om de waarde van de implementatie van 3D-VR te onderzoeken. Over het algemeen vonden we 3D-VR inferieur aan 3D-geprinte modellen bij het classificeren van heupkom breuken met behulp van de Judet-Letournel-classificatie. Bovendien bleken 3D-geprinte modellen praktischer in gebruik. In vergelijking met 3D-printen vertoonden jonge chirurgen en arts-assistenten echter een duidelijkere leercurve bij het classificeren van heupkom breuken met behulp van 3D-VR. We concludeerden dat de huidige 3D-VR-technologie nog steeds niet praktisch genoeg is voor intraoperatief gebruik.

### Toekomst

De afgelopen honderd jaar heeft een verschuiving opgetreden van traumasterfte als belangrijkste uitkomstmaat naar radiologische- en functionele uitkomsten na een bekken letsel. Voor de patiënt is echter de kwaliteit van leven een belangrijke uitkomstmaat. Er zijn veel vragenlijsten te vinden die allemaal proberen de kwaliteit van leven in kaart te brengen. Het meest praktisch is om dit te reduceren tot één vragenlijst die alle type trauma patiënten in kaart kan brengen. In de toekomst kan het gebruik van Patient-Reported Outcomes Measurement Information System (PROMIS) door middel van Computer Adaptive Testing (CAT) hierbij helpen. Deze innovatieve technieken kunnen helpen patiënten niet te overvragen, maar toch de juiste vragen te stellen. Daarnaast zal door grote databases (zoals de BIOS studie) meer kennis komen over onder andere het type botbreuk, verschillende patiëntfactoren en ook resultaten van de behandeling. Deze informatie kan zowel de chirurg als patiënt een realistische prognose geven voor uitkomsten op korte- en lange-termijn.

Operaties worden tot op heden door de chirurg voorbereid met behulp van röntgen en CT. Een aantal technologieën gaan hier verandering in brengen. 3D printen, Artificial Intelligence, Virtual Reality, Augmented Reality gecombineerd met computer-genavigeerde chirurgie gaan de chirurg helpen de juiste beslissing te maken, zowel preoperatief als peroperatief. Met behulp van deze technologieën kunnen patiënten beter ingelicht worden wat leidt tot een betere follow-up en meer patiënt tevredenheid. Arts-assistenten kunnen hopelijk een snellere leercurve doormaken waardoor operaties op hoger niveau verricht kunnen worden. Echter, alles valt en staat bij gedegen onderzoek. Zonder wetenschappelijk bewijs zullen deze technologieën alleen "gimmicks" blijven. Het behandelend chirurgisch team wordt in de komende jaren uitgebreid met nieuwe academici die dé schakel zijn tussen arts en techniek.

# **Research Data Management**

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The study protocols of studies involving patient data were submitted to local Medical Ethics Committees. For Chapter 2, 3, 5, 7 and 8 this was Tilburg, for Chapter 4 this was Nijmegen. The study protocol of Chapter 6 was not reviewed by a local Medical Ethics Committee since this was a cadaver study.

Chapter 2, 3, 4, 7 and 8 were declared exempt from the scope of the Medical Research Involving Human Subjects Act (WMO) according to the institutional ethics committee. For each of these chapters a positive judgement on the study protocol was received form the local Medical Ethics Committee. All studies were performed in accordance with the ethical standards of the Helsinki declaration of 1964 and local ethical standards. Informed consent was received from the participants before inclusion in the studies.

Chapter 5 was approved by the Medical Ethics Committee of Brabant (project number NL50258.028.14). The study protocol is also registered at the clinical trial registry of clinicaltrials.gov (NCT02508675).

Original and processed data, and accompanying files (descriptive files, SPSS files, etc.) from this thesis project are stored in a folder on the department server of the Elisabeth-Tweesteden Hospital and the Radboud University Medical Center. Only the main researchers and team members of this project have access to this folder. When applicable, data from participants were encrypted using individual subject codes to ensure privacy of the participants. This code is stored separately from the study data on the department server.

After completion of this thesis project, the data will be saved for 15 years at the department server of the Elisabeth-Tweesteden Hospital and the Radboud University Medical Center, with restricted access. Using the data for future research is only possible after permission is provided. The datasets analyzed during this thesis are available from the corresponding author on request.

# PhD Portfolio

#### 198 | Addendum

Name PhD student:	L. Brouwers	PhD period:	2015 - 2020		
Department:	surgery	Promotor(s):	Prof. dr. M.J.R. Edwards Prof. dr. M. Poeze		
Graduate school:	Radboud Institute for Molecular Life Sciences	Co-promotor(s):	dr. K.W.W. Lansi dr. M.A.C. de Jor	r. K.W.W. Lansink r. M.A.C. de Jongh	
TRAINING ACT	<b>FIVITIES</b>		Year(s)	ECTS	
a) Courses & Wo					
Good Clinical Practice			2016	0.80	
Practical Biostatistics, AMC			2016	1.25	
Practical Biostatistics, part II, AMC			2017	1.25	
Advanced 7	2017	2.25			
OTC II: Op	2018	0.40			
Gastrointes	os 2018	2.80			
Basiscursus Operatieve technieken II (BOT-II)			2018	0.40	
AO Basiscursus Operatieve Fractuurbehandeling			2018	1.20	
Mini defin Course	itive Surgical and Anaes	thetic Trauma Ca	are 2018	0.40	
CASH cursus, blok 1, NVVH			2019	7.00	
CASH curs	us, blok 2, NVVH		2020	5.00	
b) Seminars & Lo	ectures				
Cursorisch regionaal chirurgie Onderwijs (regio VII)			2018 - 2020	4.00	
Regional lecture nights at Radboudumc			2015 - 2020	0.30	
Acute zorgregio Oost (AZO) trauma lecture nights			2016 - 2017	0.20	
c) (Inter)national Symposia & Congresses					
ESTES, Vier	nna, Austria *		2016	1.25	
SEOHS Utr	echt *		2016	0.50	
NVT assistenten symposium, Soestduinen *			2016	0.50	
Traumadagen, Amsterdam #			2016	0.75	
Healthcare Conference. Amsterdam *			2016	0.50	
NVT assistenten symposium, Soestduinen *			2017	0.50	
ESTES, Buc	harest, Romania *		2017	1.25	
Chirurgenc	lagen, Veldhoven **		2017	1.00	
European	Society for Surgical	Research (ESS	R), 2017	0.50	
Amsterdam	1 *				
Orthopaed	ic Trauma Association	(OTA) Vancouv	er, 2017	1.25	
Canada *			2015	0.50	
SEOHS Niji	megen *		2017	0.50	
Traumadag	en, Amsterdam *#		2017	1.00	
Chirurgenc	lagen, Veldhoven *		2018	0.75	
Orthopaed	c Irauma Association (O	IA) Orlando, USA	* 2018	1.25	

Traumadagen, Amsterdam **	2018	0.75		
Chirurgendagen, Veldhoven *	2019	0.75		
ESTES , Oslo, Norway *	2020	1.25		
d) Other				
Reviewer European Journal of Trauma and Emergency	2015 - 2020	0.40		
surgery				
Reviewer British Medical Journal case reports	2015 - 2020	0.20		
TEACHING ACTIVITIES	Year(s)	ECTS		
e) Lecturing				
Teaching interns weekly, Elisabeth-Tweesteden Hospital	2015 - 2017	8.00		
Organisatie symposium chirurgendagen.	2017	2.00		
Co-founder podcast: met het mes aan tafel	2019 - 2021	1.00		
Other				
Blog about PhD activities: Twitter account /	2015 - 2020	30.00		
physiciansweekly				
Students coaching (Technical Medicine UTwente / TU	2016 - 2021	8.00		
Delft)				
Chef symposium & supervisor Traumaplatform	2018 - 2020	1.00		
Supervising and jury topclass Innovatie Radboudumc	2019	0.20		
NVT PR commissie	2019 - 2021	1.00		
Invited speaker				
Vereniging Orthopaedisch Chirurgische Assistenten,	2017	0.50		
Amsterdam				
"game changer sessie". Traumadagen.	2018	0.50		
Willy Wortel sessie AO gevorderden symposium,	2019	0.75		
Kotterdam Traumanlatform vliegbasis Leeuwarden	2019	0.50		
Limhurgs Trauma genootschap	2019	0.50		
Cash 11 da taakamet yan da shirurgia da Baaharet Eda	2019	0.50		
Enderstie Medicek Createlister Distance Incorrection	2019	0.75		
Utrecht	2019	0.50		
Innovatie avond Technische Geneeskunde, TU Delft	2020	0.50		
Additive days, Balkan 3D printing conference, Sofia,	2020	1.00		
Bulgaria				
TOTAL				

Oral and poster presentations are indicated with a \* and # after the name of the activity, respectively.

### **Grants and Awards**

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### **Grants and Awards**

- 2021 Prof. dr. G.P. Vooijs Award, meest klinisch relevante afstudeeronderzoek. Technische Geneeskunde TU Delft & Universiteit Twente. 3D printing in Sierra Leone. Student: van der Stelt M. Begeleiders: Maal TJJ, Brouwers L.
- 2020 Best poster, Rehabilitation Medicine Congress the Netherlands. Pioneering low-cost 3D printed transtibial prosthetics in Sierra Leone. Van der Stelt M, Grobusch MP, Koroma AR, Papenburg M, Kebbie I, Slump CH, Maal TJJ, **Brouwers L**.
- 2019 Nederlandse Albert Schweitzer fonds: benoeming gezondheidspionier.
  Ondersteuning van crowdfunding actie. €12.418,- Van der Stelt M,
  Brouwers L.
- 2019 Voorgedragen door alle sub-verenigingen van de Nederlandse Vereniging voor Heelkunde voor de Wetenschaps- en Innovatieprijs van de Federatie Medische Specialisten. Brouwers L, de Jongh MAC, Lansink KWW, Bemelman M.
- 2019 Innovatiefonds, COC Radboudumc. Ontwikkeling van low-budget nonprofit 3D software in samenwerking met 3D lab. €10.000,- **Brouwers L**, prof. Maal T, Peters J, van Wageningen B, Poyck P, prof. Edwards M.
- 2018 Computable Awards. Beste ICT-project in de zorg van Nederland. 3D printing in de traumachirurgie. **Brouwers L**, Heyligers J, Bemelman M.
- 2018 Collegicum Chirurgicum Neerlandicum (CCN) congres ondersteuning; Orthopaedic Trauma Association (OTA), Orlando, USA. **Brouwers L**.
- 2018 Aanmoedigingsprijs Albert Schweitzer, Nederlandse Albert Schweitzer Fonds. 3D printing in 3<sup>de</sup> wereld landen. **Brouwers L**, Nolet WWE.
- 2017 Best poster International Trauma Care Forum, Orthopaedic Trauma Association (OTA), Vancouver, Canada. The value of 3D printed models and Virtual reality in understanding acetabular fractures. **Brouwers L**, Pull ter Gunne AF, de Jongh MAC, Bemelman M, Lansink KWW.

- 2017 B. Braun Technical Innovation Award; European Society for Surgical Research. The value of 3D printed models and Virtual reality in understanding acetabular fractures. **Brouwers L**, Pull ter Gunne AF, de Jongh MAC, Bemelman M, Lansink KWW.
- 2017 AOTrauma Support Grant ter ondersteuning voor deelname OTA Vancouver. The value of 3D printed models and Virtual Reality in understanding acetabular fractures. **Brouwers L**.
- 2017 KNMG Midden-Brabant stimuleringsfonds. De toegevoegde waarde van Virtual Reality bril bij het begrijpen van acetabulumfracturen. **Brouwers L**, Pull ter Gunne AF, de Jongh MAC, Maal T, Bemelman M, Lansink KWW.
- 2016 AOTrauma Europe Research Grant. The value of 3D printed models in understanding acetabular fractures. CHF7000,- **Brouwers L**, Pull ter Gunne AF, de Jongh MAC, Lansink KWW.

# Publications

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### **Publications**

- 2021 van der Stelt M, Grobusch MP, Koroma AR, Papenburg M, Kebbie I, Slump CH, Maal TJJ, Brouwers L. Pioneering Low-Cost 3D-Printed Transtibial Prosthetics to Serve a Rural Population in Sierra Leone. EClinicalMedicine, published by The Lancet.
- 2021 van der Stelt M, Verhulst AC, Slump CH, Papenburg M, Grobusch MP, Brouwers L, Maal TJJ. Design and Production of Low-Cost 3D-Printed Transtibial Prosthetic Sockets in Rural Areas. Journal of Prosthetics and Orthotics.
- 2021 Abbadya HEMA, Klinkenberg ETMK, de Moela L, Nicolaia N, van der Stelt M, Harlaar J, Maal TJJ, **Brouwers L**. 3D-printed prostheses compared with conventional prostheses in developing countries: a systematic review. Prosthetics and Orthotics International.
- 2021 Van Gaalen M, van der Stelt M, Vas Nunes JH, **Brouwers L**. People with Amputations in Rural Sierra Leone: The Impact of 3D-Printed Prostheses. British Medical Journal Case Rep.
- 2020 **Brouwers L**, de Jongh MAC, de Munter L, Edwards M, Lansink KWW. Prognostic factors and quality of life after pelvic fractures. The Brabant Injury Outcome Surveillance (BIOS) study. PLOS ONE.
- 2019 van der Stelt M, Verhulst AC, Vas Nunes J, Koroma AR, Nolet WWE, Slump CH, Grobusch MP, Maal TJJ, Brouwers L. Improving lives in three dimensions: Feasibility of 3D printing in creating personalized medical aids in a rural area of Sierra Leone. The American Journal of Tropical Medicine & Hygiene.
- 2019 **Brouwers L**, Pull ter Gunne AF, de Jongh MAC, Maal TJJ, Vreeken R, van der Heijden FHWM, Leenen LPH, Spanjersberg WR, van Helden SH, Verbeek DO, Bemelman M, Lansink KWW. What is the value of 3D virtual reality in understanding acetabular fractures? European journal of orthopaedic surgery & traumatology.

- 2019 Hermans E, **Brouwers L**, van Gent T, Biert J, de Jongh MAC, Lansink KWW, Edwards MJR. Long-term quality of life in patients with pelvic fractures; a multicenter study. Injury.
- 2019 **Brouwers L**, Lansink KWW, van Delft-Schreurs CC, de Jongh MAC. Differences in the Majeed Pelvic Score between injured and uninjured patients. Journal of Orthopaedic Trauma.
- 2018 **Brouwers L**, Teutelink A, van Tilborg GFAJB, de Jongh MAC, Lansink KWW, Bemelman M. Validation Study of 3D printed anatomical models using Makerbot and Ultimaker for preoperative planning in trauma surgery, a human cadaver study. European Journal of Trauma and Emergency Surgery.
- 2018 **Brouwers L**, Lansink KWW, de Jongh MAC. Quality of life after pelvic ring fractures; A cross-sectional study. Injury.
- 2018 Brouwers L, Pull ter Gunne AF, de Jongh MAC, van der Heijden FHWM, Leenen LPH, Spanjersberg R, van Helden SH, Verbeek DO, Bemelman M, Lansink KWW. The value of 3D printed models in understanding acetabular fractures. 3D Printing and Additive Manufacturing.
- 2018 Arts E, Nijsink H, Verhamme L, Biert J, Bemelman M, **Brouwers L**, van Wageningen B. The value of 3D reconstructions in determining postoperative reduction of acetabular fractures; a pilot study. European Journal of Trauma and Emergency Surgery.
- 2018 Inge SY, **Brouwers L**, van der Heijden FHWM, Bemelman M. 3D printing for correction osteotomy, a low cost work-flow. British Medical Journal Case Rep.
- 2018 Klijn AJ, **Brouwers L**, Dik P, Van Haersma, Buma-Lap CCMM, Kramer WLM. Urologische, genitale en perineale letsels. Handboek Kindertraumachirurgie. Kramer WLM, Bessems JHJM, Besselaar AT, Edwards MJR, e.a.
- 2017 van Sambeek C, van Stigt S, **Brouwers L**, Bemelman M. Necrotizing fasciitis; a ticking time bomb? British Medical Journal Case Rep.

- 2016 de Jongh MAC, Kruithof N, Gosens T, van de Ree CL, de Munter L, Brouwers L, Polinder S, Lansink KWW BIOS-group. Prevalence, recovery patterns and predictors of quality of life and costs after non-fatal injury: the Brabant Injury Outcome Surveillance (BIOS) study. Injury Prevention.
- 2016 Brouwers L, Bemelman M, Kramer WLM, van der Heijden FHWM. Behandeling van stomp nierletsel bij kinderen. Stand van zaken, Nederlands Tijdschrift voor Geneeskunde.
- 2015 Dekkers K, **Brouwers L**, Rutten AMF. Diagnose in beeld: zwevend sternum, Nederlands Tijdschrift voor Geneeskunde.
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## Curriculum Vitae

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Lars Brouwers was born on 20 May 1988 in Son en Breugel, the Netherlands. He graduated from the Eckartcollege in Eindhoven in 2006. During medical school at Maastricht University, he performed his first research and clinical work in the field of traumasurgery at Maastricht University Medical Centre (MUMC+) under supervision of dr. PFW Hannemann, drs. PH Breedveld and prof. dr. PRG Brink. He completed extracurricular clinical rotations in trauma surgery and emergency medicine; twice in the Alps Trauma Center, Grenoble, France, under supervision of prof. dr. D Saragaglia and once in the Kalafong hospital, Pretoria, South Africa. After graduating in 2012, he started working as a surgical senior house officer (ANIOS) at the Amphia hospital under supervision of prof. dr. L van de Laan. He continued as an ANIOS at the Elisabeth-Tweesteden hospital (ETZ) in 2014 under supervision of dr. PWHE Vriens and dr. MS Ibelings. In 2015, he was accepted as a PhD student at Netwerk Emergency Care Brabant (NAZB), under



supervision of dr. MAC de Jongh and dr. KWW Lansink, focusing on quality of life after pelvic trauma and 3D printing to improve pelvic-related surgical care. The research team later joined the PhD team of prof. dr. MJR Edwards at the Radboudumc. The 3D printing-related research performed during his PhD was honored with several grants and awards. In 2018, he entered surgical training (AIOS) at the Radboudumc under supervision of dr. BH Verhoeven and dr. OR Buyne and continued in 2019 at the ETZ where he has been working since.

In 2016, together with drs. M Bemelman and dr. JMM Heyligers, the ETZ medical 3D lab was set up. This team supervises students from the Technical University of Twente (prof. dr. ir. CH Slump) and Technical University of Delft (prof. dr. ir. J Harlaar). In 2018, the ETZ 3D team was honored with the national ICT award for best ICT project in healthcare. Lars is reviewer for European Trauma journals, a member of the national research and innovation commission of the Dutch society for Surgery (NVvH) and he assists other medical 3D labs. In 2018, he started a 3D lab at the Masanga hospital in Sierra Leone. He cooperates with the 3D lab of the Radboudumc (prof. dr. TJJ Maal) to develop patient specific prostheses. From 2020 onwards, he is co-supervisor of the research group first PhD student. Lars Brouwers lives together with his fiancé Irene Fleur Kramer, and their newborn son James in Vught, the Netherlands.