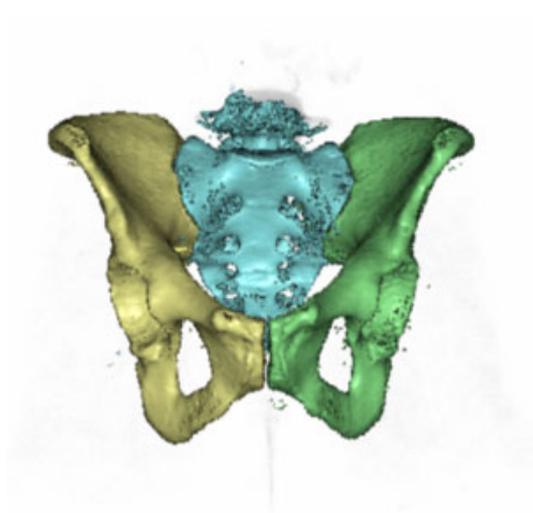


DEPARTMENT OF MOLECULAR MEDICINE AND SURGERY

Karolinska Institutet, Stockholm, Sweden

CLINICAL AND RADIOLOGICAL ASPECTS OF TRAUMATIC PELVIC RING INJURY

Peyman Bakhshayesh



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CLINICAL AND RADIOLOGICAL ASPECTS OF TRAUMATIC PELVIC RING INJURY

THESIS FOR DOCTORAL DEGREE (Ph.D.)

By

Peyman Bakhshayesh

Principal Supervisor:

Professor Anders Enocson

Karolinska Institutet

Department of Molecular Medicine and Surgery

Division of Orthopedics

Opponent:

PhD Mikael Sundfeldt

Gothenburg University

Department of Sahlgrenska Academy

Division of Orthopedics

Co-supervisor(s):

PhD Henrik Olivecrona

Karolinska Institutet

Department of Molecular Medicine and Surgery

Division of Orthopedics

Examination Board:

Professor Sune Larsson

Uppsala University

Department of Surgical Sciences

Division of Orthopedics

Associate Professor Karl-Åke Jansson

Karolinska Institutet

Department of Molecular Medicine and Surgery

Division of Orthopedics

Associate Professor Rickard Wedin

Karolinska Institutet

Department of Molecular Medicine and Surgery

Division of Orthopedics

Associate Professor Malin Jonsson Fagerlund

Karolinska Institutet

Department of Physiology and Pharmacology

Division of Anesthesiology

To the memory of Professor Lars Weidenhielm. To the memory of my father Mohammad-Ali Bakhshayesh. Thanks to my mother Mahin Bakhshayesh for being a constant source of energy. Thanks to my wife Katayoun and my children Patrick and Melina for their support. Special thanks to my main supervisor Professor Anders Enocson who made this happen.

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PREFACE

Conducting research in polytrauma is difficult. The reasons are often related to the nature of severe trauma affecting the patient's survival. Practice in this subject is often based on experience, expert opinions and retrospective data analysis. Polytrauma patients are often not in a condition to give their consent to be randomized in different trials either. Another difficulty is funding as conducting prospective randomized control trials in polytrauma is highly expensive. These are some of the main obstacles why trauma research is often retrospective by nature. Conducting retrospective analysis of prospectively collected data is cheap and with knowledge in science and statistics it gives an opportunity to analyze and to interpret data. Another possibility is to use translational research from sources like developments in engineering and to apply them into the medical field.

Establishment of major trauma centers has fortunately contributed to the possibility of creation of local and national trauma registries. Trauma registries give opportunities to enthusiastic researchers in the field of trauma to test their different hypothesis.

I started my journey with support of my supervisors, using data from the Swedish National Trauma Registry (SweTrau) to trace all pelvic fractures which were treated during a specified time period at the Karolinska Trauma Center. We found the dataset interesting and useful. My first scientific work in this thesis, while time consuming, was somehow eye-opening to me. I was in a belief that pelvic fractures were lethal injuries related to the nature of the pelvis which is surrounded by and consisted of rich blood supply and vessels.

I had ideas to focus on the lifesaving aspect of the management of pelvic trauma, which can explain the nature of my first and the second scientific work. However, we found out that polytrauma patients with pelvic fracture are not dying because of the pelvic fracture. They rather die of reasons not even directly related to the pelvis.

On the other side, we found high rate of reoperations. Some of them were found quite late. These could have been avoided in the presence of for example better pre-operative planning tools, better intra-operative imaging techniques or sensitive post-operative techniques. Further, we noticed that conventional X-ray was used for the follow-up of pelvic patients while in our department a new technique was established using low dose CT-scan, initially for hip arthroplasty patients, but could also be used for other purposes like pelvic implants.

This newly developed technique made it possible to study three dimensional aspects of a pelvic injury. Fusion of different CT volumes and merging of the surfaces of the pelvic images, contributed to the study of pelvic motion analysis following fixation.

Reverse engineering technique and fusion of the surfaces gave us an opportunity to answer the question regarding symmetry of the hemi pelvises in order to use the non-injured side as reference.

While finalizing my PhD thesis now, I am glad that with help of my senior supervisors, I could find out answers to some of my questions.

Polytrauma patients with pelvic fracture seem to die of other injuries not directly related to the pelvis. There is an unacceptably high surgical revision rate among pelvic fractures.

We need more education to give to first line medical officers dealing with trauma regarding acute management of polytrauma patients with pelvic injury. CT-scan of pelvis makes 3D analysis of pelvis possible and gives valuable information pre- and post-operatively. The contralateral hemi pelvis can be used for pre-operative templating and low dose CT-scan can be used for post-operative follow-up.

I regret to say that; I could not offer any solution for intra-operative optimization of the pelvic imaging in my thesis. However, I am going to spend the rest of my scientific career to study this issue. Current available techniques like fluoroscopy, intra-operative CT-scan, current available navigation tools etc. are either time consuming, cumbersome or inefficient and need a substitute.

ABSTRACT

Epidemiological data regarding High-Energy Traumatic Pelvic Ring Injury in Sweden was missing. Further, there was no data regarding current knowledge and level of experience of Swedish first line trauma officers about the management of traumatic pelvic ring injury. While conventional X-ray has been widely criticized as an optimal tool in assessment of pelvic ring injuries, a practical substitute has not been proposed.

We planned to study epidemiological aspects of High Energy Traumatic Pelvic Ring Injury using data from the Karolinska Trauma Center. To assess first line trauma medical officer's knowledge and level of experience regarding acute management of pelvic trauma. To investigate alternative practical options instead of conventional X-ray during the treatment of pelvic fractures.

We used data from the Swedish National Trauma Registry (SweTrau). We used the Karolinska University Hospital's Patient Notes and PACS. We used a questionnaire in order to assess Swedish trauma unit's medical officers about acute management of pelvic trauma. We further used three dimensional models for image fusion and motion analysis in order to investigate symmetry of human pelvis and to investigate a pelvic fracture model. We found that the incidence of High Energy Traumatic Pelvic Ring Injury was about 3.5/100 000 inhabitants per year in Stockholm. The 30-day mortality was 7.8% and the 1 year mortality was 9%. The main cause of mortality was traumatic brain injury. Intentional injuries had a mortality rate of 15%. The reoperation frequency was 22%. Main cause of reoperation was due to metalwork problems, and a majority of them were potentially avoidable.

We found that a majority of the Swedish first line trauma officers were aware of presence of a pelvic binder in their department and knew how to apply it, while there was more experience in the university hospitals. There was a general misconception regarding limitation of pelvic binders as 55% believed that a pelvic binder can stop an arterial bleeding. We were further able to show that human hemipelvises are symmetrical and the 3D images of the contralateral hemipelvis can be used for pre-operative templating. We were able to show that using fusion of serial 3D images of a pelvic model, translations of ± 0.2 mm and rotations of $\pm 0.2^\circ$ could be detected.

We can hereby conclude that monitoring 30-day mortality seems enough while studying high energy pelvic injuries. Intentional injuries need further future studies as per high mortality rate. Reoperation frequency following fixation of disrupted high energy pelvic fractures is high and needs addressing and early detection. Limitations of pelvic binders should be addressed during the trauma courses. Low dose CT-scan together with serial image fusion can be a future substitute for conventional X-ray. Human hemipelvises are symmetrical and the contralateral side can be used for templating.

LIST OF SCIENTIFIC PAPERS

I. Factors affecting mortality and reoperations in high energy pelvic fractures

Bakhshayesh P, Weidenhielm L, Enocson A. Factors affecting mortality and reoperations in high-energy pelvic fractures. European journal of Orthopaedic Surgery & Traumatology. 2018;28:1273-82.

II. Experience and availability of pelvic binders at Swedish trauma units; A Nationwide Survey

Bakhshayesh P, Heljesten S, Weidenhielm L, Enocson A. Experience and Availability of Pelvic Binders at Swedish Trauma Units; A Nationwide Survey. Bull Emerg Trauma. 2018;6:221-5.

III. A New CT Based Method for Post-operative Motion Analysis of Pelvic Fractures

Bakhshayesh P, Olivecrona H, Weidenhielm L, Enocson A. A New CT Based Method for Post-operative Motion Analysis of Pelvic Fractures. 3D Research. 2019;10:7.

IV. A Novel 3D Technique to Assess Symmetry of Hemi Pelvises

Bakhshayesh P, Zaghlul A, Sephton B, Enocson A. In Manuscript.

LIST OF ABBREVIATIONS

TPRI	Traumatic Pelvic Ring Injury
ATLS	Adult Trauma Life Support
PCCD	Pelvic Circumferential Compression Device
DICOM	Digital Imaging and Communication in Medicine
PACS	Picture Archive and Communication System
STL	Stereo Lithography
RSA	Radiostereometric Analysis
CTMA	CT-based Micro Motion Analysis
COM	Center of Mass
APC	Antero-Posterior Compression
VS	Vertical Shear
LC	Lateral Compression
HU	Hounsfield Units

INTRODUCTION

A general terminology in trauma science for pelvic and acetabular fractures is Traumatic Pelvic Ring Injury (TPRI)[1]. TPRI has the reported incidence of 17–37/100 000 person-years[2-6]. The complex anatomy of the pelvis, the fact that its bony and ligamentous structures are deep in the surrounding soft tissue and the proximity of important neural and vascular structures, makes the surgery of the pelvis somehow cumbersome[7,8]. Until some decades ago, these fractures were treated non-operatively[9-12]. The results of non-operative management of the traumatic pelvic fractures have historically been poor, often resulting in chronic instability, non-union, mal-union, chronic pain and leg length discrepancy etc.[10, 11].

Pelvic fractures can be a result of a low or high energy trauma[2]. The low energy type often occurs in elderly osteoporotic patients. A subgroup of the pelvic fractures, especially in young healthy adults, occur as a result of severe or high energy trauma. A substantial amount of energy is needed to break the bony pelvis which is surrounded by bulky muscles and strong ligamentous structures in a young patient[9].

Pelvic fractures are classified in different ways. The most commonly used classifications are either using the vector of energy (Young-Burgess Classification) or the pattern of instability (AO/Tile)[7, 9].

Young and Burgess defined the common patterns of pelvic fractures and found that the vectors of energy define the final deformity. The pelvis can be squeezed from the lateral side resulting in a Lateral Compression (LC) type fracture, or from the Anterior/Posterior resulting in an Antero-Posterior Compression injury (APC) or in case of a vertical direction of a force resulting in a Vertical Shearing (VS) type injury[9].

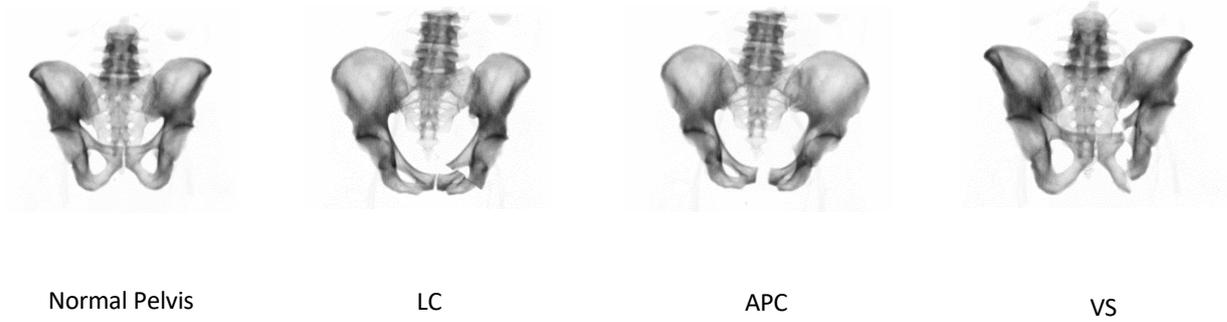


Figure 1. The Young-Burgess Classification

The AO/Tile classification divides the pelvic fractures in stable (rotationally and vertically) Type A fractures, rotationally unstable Type B fractures or rotationally and vertically unstable Type C fractures[7].

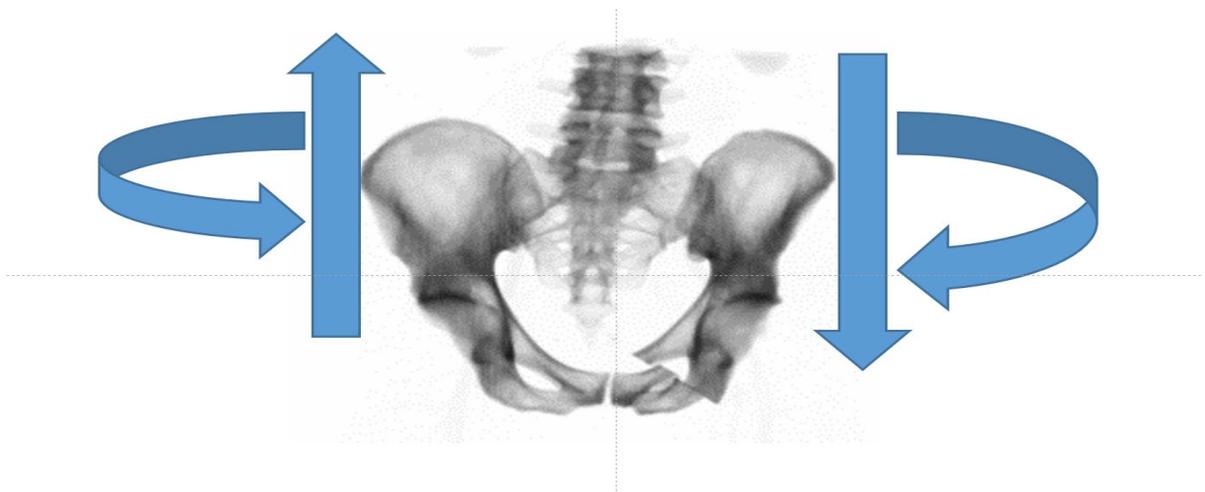


Figure 2. The rotational and shearing forces in the Tile/AO classification

Pelvic fractures have historically been considered as serious injuries with a high mortality rate[13-18]. The main focus, while studying mortality following pelvic trauma has been on bleeding[19-22]. This bleeding has mostly been reported during the initial phase of the management of these injuries. After this initial phase, pelvic fractures together with other accessory injuries have often been related to serious complications such as multiple organ failure, sepsis and eventually death[8, 23].

The majority of patients with pelvic fracture reportedly die during the early and intermediate phase and often during the first admission. The fatality occurs mainly during the first 30 days following major trauma. This is the reason why reports on 30-day mortality following major trauma are common in the literature[24].

The late phase in the management of pelvic trauma often addresses issues following discharge and during follow-up. Internal fixation applied during the surgical fixation of pelvic fractures should endure the healing phase. Wounds should heal uneventfully. The goal of the late phase is restoration of pre-injury function. Late infections mainly due to low virulent bacteria might occur, implants might fail, fractures might go to non-union and pain might be a serious issue[10, 25-29].

Treatment of pelvic fractures often require a multi-disciplinary management during these three phases (early, intermediate and late). Because of aforementioned reasons, treatment of TPRI is often centralized to dedicated trauma centers with all necessary medical and surgical disciplines available[30-34].

The Karolinska University Hospital is a dedicated trauma center in Stockholm's county dealing with TPRI. The author of this thesis has conducted a majority of these research works at the Trauma Centre Karolinska (TCK)[35].

Early phase

During the early phase, all trauma patients undergo investigation and treatment according to Advanced Trauma Life Support (ATLS). This is a concept which is well formulated, well studied, taught and owned by the American College of Surgeons (ACS)[36].

According to ATLS, all injuries should primarily be diagnosed and cared for according to an algorithmic and alphabetical approach. Airway (A) should be checked and secured. Further Breathing (B) should be controlled and appropriate care should be given. Later Circulation (C) should be checked. If there is any problem with pulse (often tachycardia in trauma patients) or blood pressure (often hypotension in trauma patients), then initial resuscitative infusion of blood or fluids should be undertaken. Pelvic fractures with ongoing bleeding often cause disturbances in Circulation (C). Further Disability (D) or obvious neurological impairments should be checked. Neurological deficiencies are not uncommon in certain patterns of pelvic fractures, for example when vertical shearing forces have been applied or a sudden disruption of the pelvic ring has occurred. These types of injuries might put pressure on single or multiple nerve roots like the L5 or the S1 roots, the lumbo-sacral plexus or peripheral femoral/sciatic nerves etc.[36].

Glasgow Coma Score (GCS) is used internationally and in Stockholm's county to report the patient's general neurological function[37]. Finally, Extremities/Environment (E) should be addressed. Major extremity deformities should gently be reduced and the patient kept warm during transport to a trauma center or during inhouse transfer.

Pelvic fractures with visible instability and physiological impairment (low blood pressure or high pulse) are often stabilized with different tools such as pelvic sheet wrapping or pelvic binder[19]. It is important that paramedics taking care of the trauma patients and medical officers in the Acute and Emergency Services (A&E) are familiar with these devices and are aware of the benefits and limitations of them. Non-invasive external compression devices to stabilize the pelvic ring are commonly named as Pelvic Circumferential Compression Devices (PCCDs)[19].

Pelvic Circumferential Compression Devices

Vermeulen et al introduced a device which was easy to apply in the field and that could quickly stabilize an unstable fractured pelvic ring[19]. The idea that pelvic examination on the field has a low sensitivity (59%) has contributed to introduction of pelvic binders in polytrauma patients with suspected but not necessarily verified pelvic ring injury in the field[19]. In a previously systematic review of the literature we found evidence that PCCDs could mechanically close a disrupted pelvic ring injury. Further, we found evidence that PCCDs should be applied over the level of greater trochanters to achieve maximum stability. We did not find enough evidence to support superiority of any of the current available PCCDs in the market. In couple of case series, application of PCCDs contributed to an increase in Mean Arterial Pressure, which was assumed to be in favor of physiological parameters. However, in the era of hypotensive resuscitation the question has been raised how this reaction should be interpreted[19]. Elastic configuration of PCCDs and application of them in trauma might cause a misunderstanding that these devices work as a tourniquet.

However, a cadaveric study conducted by Grimm et al showed that mechanical stabilization of the pelvic ring could contribute to intra-pelvic pressure raises up to 30 mm Hg, and thus it can only be useful in bleedings from the bony fracture surfaces and low-pressure venous structures, but the pressure is not enough to stop arterial bleedings[19].

After arrival to the hospital and initial report from the Emergency Medical Crew (EMC), the trauma patient is examined again according to A, B, C, D and E[36]. Massive Blood Transfusion and injection of Tranexamic Acid (Cyklokapron) are adjuncts during this primary survey[36]. Non-invasive stabilization of TPRI with physiological impairment, for those who have not received it from the paramedics, is part of this initial assessment. Initial X-ray of neck, chest and pelvis might be needed during this initial assessment of trauma patients. Pelvic X-ray might address pelvic fractures missed during the transport[36].

Pelvic circumferential compression devices are meant to be checked to sit over the level of the greater trochanters and close an open and disrupted pelvic ring[19].

The trauma patient is either stabilized to undergo a whole-body scan using CT-scan or not. If the trauma patient is not physiologically stabilized enough, mainly because of bleeding, decision should be made to take the patient to theater for urgent laparotomy or/ and thoracotomy to address the source of bleeding in order to get control over it. If the bleeding source is from the pelvis, then pelvic packing can be considered and the pelvis will be further stabilized exteriorly with external fixator/ pelvic binder/ sheet wrapping etc. This scenario is however less common and a majority of patients with TPRI undergo CT-scan[38].

Adding angiography to the CT-scan gives valuable information regarding bleeding and its potential sources[39-43]. Most of the modern hospitals have angiography labs using endovascular embolization of bleeding vessels.

This technique is less invasive compared to laparotomy and gives an opportunity to targeted hemostatic approach[39-43].

Upon introduction of major trauma centers, certain hospitals have been dedicated as such[32, 34, 44]. Centralization of the knowledge regarding traumatic pelvic ring injury together with facilities such as the possibility of 24/7 CT angiogram, might have caused negative impact on the overall education of smaller trauma units regarding management of traumatic pelvic ring injury[32]. The available initial resources at smaller trauma units are often restricted to pelvic binders/pelvic sheets and random availability of CT angiogram. This fact might give a false security to the first line trauma officers at different trauma units wishing that a pelvic binder could help to stop all type of pelvic related bleedings[32].

Intermediate Phase

During this stage, all injuries should be addressed and sequentially be cared for. A secondary survey should be conducted as soon as possible. Pelvic fractures demanding surgical treatment should be pre-operatively cautiously planned. Soft tissues around the pelvis should be carefully examined prior to surgical incisions. Neurological assessment prior to surgery is recommended but might be difficult because of the poly-traumatized patient's general condition. Potential urogenital or colorectal injuries should be addressed and cared for[8]. Timing of surgery is still a matter of debate between authorities in the field of trauma[45, 46]. Damage Control principles have been widely practiced with its "Two hits theory"[45]. The idea behind this is that the primary inflammation following major trauma should settle before the critically ill trauma patient is exposed to

major surgeries, which cause secondary inflammatory response unless these are important for physiological stability. New research on polytrauma patients have shown promising results regarding earlier surgery, as soon as the patient's physiology is stabilized. Combination of earlier surgical care together with damage control surgery has contributed to "Early Appropriate Care"[47]. Implementation of dedicated trauma centers with available different specialties and subspecialties has made it possible for doctors from different disciplines to communicate and conduct procedures needed in an appropriate manner[47].

There are new imaging modalities available in 3D visualizing patient's injuries based on the initial CT-scan[48, 49]. Dynamic fracture reduction tools are offered making precision of surgical planning feasible. Navigation systems are valuable tools for surgery of complex fractures with respect to fracture type and proximity to important structures (nerves, vessels etc.) [50-59].

Orthopedic surgeons have traditionally used conventional X-ray to classify and understand the pattern of pelvic and acetabular fractures[60, 61].

The standard X-ray views in practice for pelvic fractures are:

- 1) Antero-Posterior (AP) Pelvis; 2) Pelvic Inlet; 3) Pelvic Outlet. Then further special views like : 4) Lateral 5) Down-the-wing 6) Teepee View 7) Obturator Oblique etc. are possible (Fig 3).

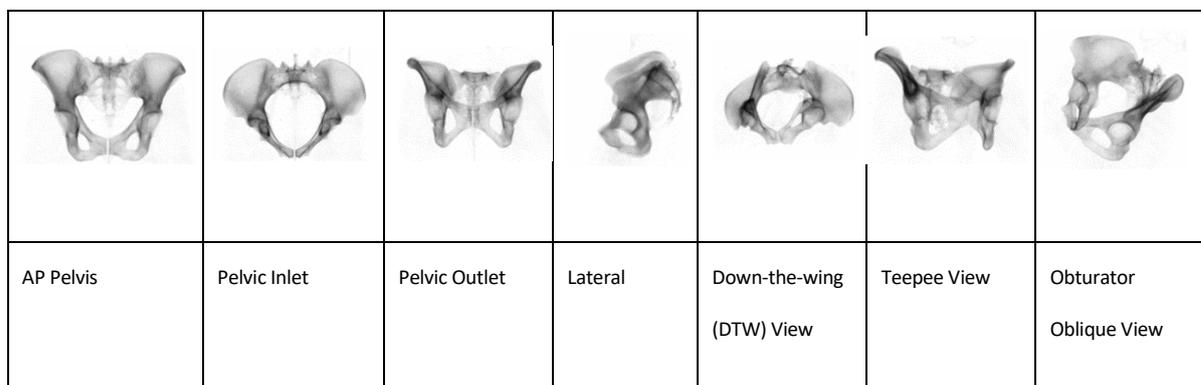


Figure 3. Illustrates standard views on the left (AP Pelvis, Pelvic Inlet and Pelvic Outlet) and further special views

The standard acetabular views are:

- 1) AP Pelvis
- 2) Obturator Oblique
- 3) Iliac Oblique (Fig.4)

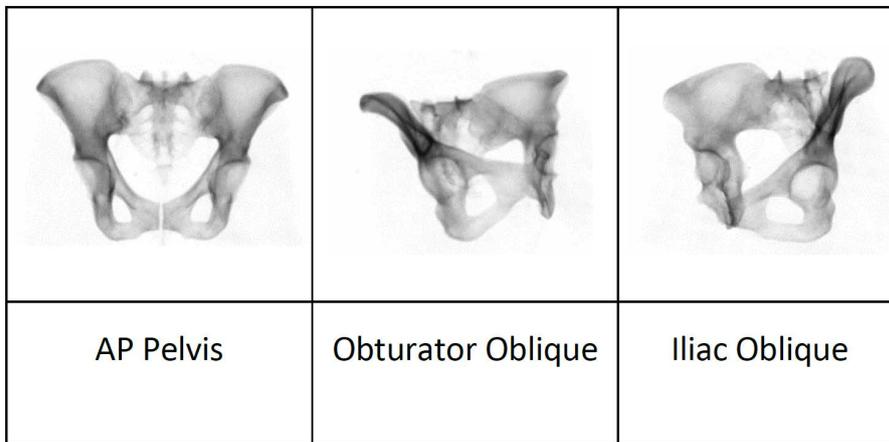


Figure 4. Illustrates standard acetabular views

The introduction of CT-scanning has contributed to a better understanding of fracture patterns, underlying biomechanics and surgical planning[62, 63]. Trauma centers are conducting total/sub total body CT-scan which is common practice in trauma management. Using available software tools, it is possible to three-dimensionally investigate fractures, to apply fracture reduction and to virtually test implants. This should ideally be part of the pre-operative planning. Virtual reconstruction of the pelvis and acetabulum and, when possible, using the contralateral side might work as a frame work to set a goal prior to the surgery[48, 49]. Further, using the contralateral less damaged or healthy side might work as a template to plan the desired implant and make it somehow custom-made. However, using these new technologies might be considered as time consuming and cumbersome at the moment, without adding any actual new information to a well-trained pelvic surgeon[54].

Attempts have been made to predict risk of implant failure following pelvic fracture surgery using either finite element technique or dynamic software tools[54, 64]. Some of these techniques need further validation. Reported rates of early and late implant failure, malposition of implants and mechanical complications following surgical fixation of pelvic fractures are unnecessary high and many of these complications are potentially avoidable[8, 65-67].

Late Phase

When all injuries in a polytrauma patient have been addressed and treated, whether surgically or non-surgically, then the rehabilitation phase starts[33]. The aim of orthopedic surgical fixation of fractures is to offer stable constructs to permit early mobilization, early weight bearing and early range of motion training. However, this goal is sometimes difficult to achieve. The bone quality or implant quality might contribute to a semi stable construct demanding a period of non or partial weight bearing and careful mobilization.

There are several studies on duration of fracture healing using different tools, but most of them are for research purposes. Using conventional X-ray to report post-operative outcome and healing during follow-up is still common practice[68].

Conventional X-ray has a measurement error of $\pm 5\text{mm}$ [68-70]. This means that, detecting early implant failure or early diagnosis of fracture non-union might be delayed. Apart from this, the assessment of quality of post-operative images based on conventional X-ray are highly debatable[60, 61]. The most common technique following pelvic fracture surgery is based on conventional X-ray[61].

In this technique, the quality of reduction of fractures and anatomical reduction of SI-joints and/or symphysis pubis is graded to excellent when the displacement either in the SI-joints or the symphysis is under 4 mm, good for 4-10 mm, fair when this displacement is 10-20 mm and poor for displacements more than 20 mm. Correlation of this radiological reporting and clinical outcome has been reported[71, 72].

This technique together with other measurement techniques using conventional X-ray have been widely criticized. Manual calculation, lack of reproducibility of reference points, precision issues with conventional X-ray etc. have been factors mentioned in the literature[61].

High resolution CT-scan has been proposed for complex fracture cases to see the micro pattern of the fracture healing or the bone-implant interface. However, this is not a common practice at the moment[68].

Cost, radiation dosage, access to CT-scans and time have been factors mentioned in the literature making CT-scan a salvage diagnostic procedure for special circumstances (non-union, delayed union, suspected infections etc.)[68].

Radio Stereometry (RSA) is a technique commonly used in orthopedic implant research using implantation of small metal (tantalum) beads inside the patient's bone or/and around the implant to monitor and report undesirable and excessive implant movements[73-75].

Olivecrona et al have published several articles using volume registration of CT-scans to report excessive movements of orthopedic implants (Joint Replacement)[73, 75-85]. This technique has been further adapted and been commercialized by Sectra[86]. Introduction of low-dose CT-scan together with a new software, CT-based Micro Motion Analysis (CTMA) by Sectra has made it feasible and non-invasive to register each

volume of previous CT-scans and report deformity and excessive movement of unstable parts of the pelvis over time. This technique has been compared to Radio Stereometric Analysis (RSA) in investigations of artificial joints, with comparable precision and accuracy[75].

Quality of life studies and patient reported outcome measurements (PROMs) have been proposed as reasonable measures to report quality of care following pelvic fracture surgery[87]. However, as long as a unified post-operative radiologic reporting system is missing, the relationship between surgical outcome (which normally is evaluated radiologically) and patient's satisfaction remains somehow unclear[61].

The aim of this PhD thesis was to focus on the acute phase of the pelvic trauma management initially. This contributed to my early works including the first and the second studies[19, 88-91]. With the results of the first and the second studies in hand, familiarizing with the non-fatal nature of pelvic fracture per se, I turned my focus towards the radiological outcome measurements using a novel technique[48, 92].

In general, I would say that when finalizing my thesis, we are going:

- 1) To report and analyze factors affecting mortality and risk for reoperation following pelvic fractures at TCK (Register study).

- 2) To report experience and availability of external pelvic compression devices in Sweden.

- 3) To assess precision and repeatability of CTMA (CT-based Micro Motion Analysis) in a fractured pelvic model.

- 4) To assess symmetry of the hemi pelvises using image fusing of the mirrored contralateral hemi pelvis.

MATERIAL & METHODS

Study 1

Formal ethical approval from the Regional Ethics Committee was retrieved. Karolinska University Hospital has been a dedicated trauma unit for all high energy trauma victims in the Greater Stockholm and its surrounding area since several years[35]. The catchment population of the Karolinska Trauma Centre was about 2.3 million at the time of study[93]. All trauma alerts to the Karolinska University Hospital during 2011-2015 were included. Trauma alerts were identified via the SweTrau registry[35]. SweTrau is The Swedish National Trauma Registry with a coverage of almost 70% of all poly trauma patients in the country[35]. Criteria for registration in the SweTrau registry are trauma victims accepted to the trauma units when a trauma alert has been triggered[35]. A TPRI was defined as a bony or ligamentous injury to the pelvic ring (sacrum, coccyx, ischium, pubic bone or innominate bones including acetabulum). Patient records were searched until December 31, 2016 or death, giving a minimum follow-up time of 1 year[89].

During 2011-2015, a total number of 8453 trauma records were identified. Each trauma admission in SweTrau, had up to 10 diagnoses classified based on the International Classification of Disease 10 (ICD 10) in their records[37]. Diagnoses with main code of S32 and/or S33 were selected and included. A total number of 750 patients were found. Spinal fractures with ICD code S32.00 but with no TPRI were excluded. This left us with 586 patients whose records were reviewed with respect to the following inclusion criteria:

- 1) Injury mechanism indicating high energy, for example road and traffic-related injuries, industrial and agricultural injuries, high falls etc.[2]
- 2) CT-scan reporting injury to the pelvic ring.

3) Presence of vital signs upon arrival.

4) Presence of a Swedish Personal ID-Number.

5) Adult on admission (age ≥ 18 years).

Non-survivors were categorized as study group and were compared with survivors (control group). We divided surgically treated patients into those who underwent a reoperation (study group) and those who did not (control group). An unexpected event following primary surgery demanding new surgery during the study period was defined as a reoperation. Extensive co-morbidities were defined as patients with one or more systematic disease. Cause of death was analysed based on review of the patient records and the death report if present. High age was defined as age >70 years. Fracture patterns were analysed and classified using the initial trauma CT-scan and using the Young-Burgess classification system[9]. Acetabular fractures were classified according to Letournel[94].

We used the Shapiro-Wilk test to check normality of our variables[95]. This tests whether a random sample comes from a normal distribution or not. The null-hypothesis of the Shapiro-Wilk test is that the study population is normally distributed. With other word, if the p value is less than 0.05, then there is evidence that the data tested are not normally distributed. If the p value is >0.05 , then the null hypothesis that the data came from a normally distributed population cannot be rejected[95]. The Mann-Whitney U test was then used for scale variables which were not normally distributed. This test can be used to investigate whether two independent samples were selected from populations having the same distribution. A similar nonparametric test used on dependent samples is the Wilcoxon signed-rank test[95]. Nominal variables were tested by the Chi-square test or the Fisher's exact test.

The outcome of our study was either death (=1) or survival (=0) in our mortality analysis (30 days and one year). For reoperation analysis, we used reoperation (=1) and no reoperation (=0) as possible outcomes.

Binary logistic regression analysis was performed and the results were calculated as odds ratio (OR) with confidence interval (CI)[95].

We used IBM SPSS Statistics version 24 for Windows, for our statistical analysis.

Study 2

Ethical approval was retrieved from the Regional Ethics Committee. A list of all hospitals with trauma units in Sweden was prepared. Hospitals were categorized as: "University hospitals", "General hospitals" or "District General hospitals"[96]. This was done based on information from the Swedish Health Authorities[96]. The study was conducted daytime, Monday to Friday. The study was conducted during September 2016. Each hospital's local switchboard was contacted[97]. The present on-call doctor in charge of trauma was contacted. We gave all the doctors a short explanation of the study and verbal consent was retrieved. Following that a structured telephone interview was conducted. We asked initially about their level of experience. The level of experience was defined as: "Intern" (once medical school was finished and provisional registration was warranted, working towards permanent registration), "Resident" (doctors under specialty training) or "Specialist" (doctors on specialist registry). Thereafter, four questions about availability, experience and knowledge of PCCDs were asked: Question no 1 "Do you have a PCCD in your emergency room?" represents resource availability, Question no 2 "How many times have you applied a PCCD?" represents experience, Question no 3

“Which is the best level of application for a PCCD?” represents knowledge, and we considered the level of the greater trochanters as the correct level, Question no 4 “Can a PCCD stop an arterial bleeding?” represents knowledge, and we considered “No” as the correct answer. All responses were handled anonymously after the collection.

We had nominal variables in our study and therefore used the Chi-square test. All tests were two-sided. We set the α value at 0.05 meaning that a p value <0.05 was considered statistically significant. Statistical analysis was performed using IBM SPSS Statistics version 23 for Windows for this study.

Study 3

We used a human pelvic model at the department of trauma and orthopedics, Karolinska University Hospital. We raised the ethical aspect of using this human cadaveric model to the Stockholm’s local ethical committee. Their answer was that as this specimen was not traceable to an existing physical body, there were no ethical concerns. The model had previously been used for educational purposes in our department.

We immobilized the right SI-joint with a 3.5 mm cortical screw (Synthes, Napoli). We used an anterior symphyseal plate (Synthes, Napoli), over the symphysis using three cortical screws on each side. We backed the screws on the left side of the symphysis, with two revolutions in order to allow some mobility. We marked the model with 0.8 mm diameter tantalum beads, two on each side of the symphysis pubis. In the same manner we used further tantalum beads, four anteriorly on the superior and inferior margin of the left SI-joint. We further marked the right and left side, with tantalum beads in each acetabulum and three distributed over the superior margin of each iliac wing.



Figure 5. The pelvic fracture model used in study 3

A clinical CT-scanner (Toshiba Aquilion ONE, Toshiba Medical Systems, Tochigi-ken, Japan) was used in this study. A software called SEMAR (single-energy metal artefact reduction) was used to reduce artefact effect. We used a protocol for low-dose CT-scanning with 137kv. Slice thicknesses were 0.5mm[48].

To assure that an actual change in distance was occurring, before each CT examination, the distance between two tantalum beads over the superior portion of the anterior symphysis pubis and two tantalum beads over the superior portion of the left SI-joint were measured. A commercial caliper(Cocraft, ClasOhlson, article number 40-8745) was used to monitor direction of distance changes. We always examined the pelvic model in two different positions on the CT bed (position a & b). The pelvic model was lifted from the CT bed and reoriented to simulate different patient positioning on repeated examinations. We displaced the hemi pelvises in relation to each other by using one, two, and three plastic spacers respectively. These spacers were placed over the symphysis initially and then over the left SI-joint, again using one, two, and three plastic spacers.

We created seven pairs of CT volumes (denominated 1a to 7b). The a- and b-scan represented the same pelvic anatomy but acquired in different position in the scanner. We then used the Sectra CTMA program for analyzing the CT data. An assumption was made that the right side of the pelvis was the stable part of the system. This was confirmed using manual testing. We then used the right side as reference during the study and analysis. We performed three experiments, comprising volume registration and measurements.

In each experiment we performed:

- 1) Right side of the pelvis was considered as the stationary object.
- 2) Left hemi pelvis was registered as the moving object.
- 3) Using Multi Planar Reconstruction (MPR) the most appropriate inlet and outlet views were created. We used pelvic inlet view in this study.
- 4) The software permits creating and dedicating certain points in the volumes to be followed over the series. We designated one point on the left side of the symphysis and one point on the iliac side of the left SI-joint. All calculations of movement of left side of pelvis relative to the right across the volumes were automatic.
- 5) Using CTMA software, translation of the moving object at any specified point as well as rotation in 3D were calculated.
- 6) To report repeatability; points 1-4 were repeated after one week.

Experiment 1 was based on the bone data and experiment 2 used data from the tantalum beads.

Definition of precision was “The closeness of agreement between independent test results obtained under same conditions”[98]. In order to calculate precision, the dual CT-examinations at each displacement (when the object were lifted and then gently placed back in a different position) level were compared. We did this as per definition no movement should be reported. In other word the closer the test results to zero are, with multiple imputation the technique has higher precision.

Accuracy was defined as “The closeness of agreement between a test result and the accepted reference (the “true”) value”[98]. In our study we used CT-scan with tantalum registration as Gold Standard as this has been shown as accurate as RSA previously[73].

Figure 6 illustrates definitions of Precision and Accuracy.

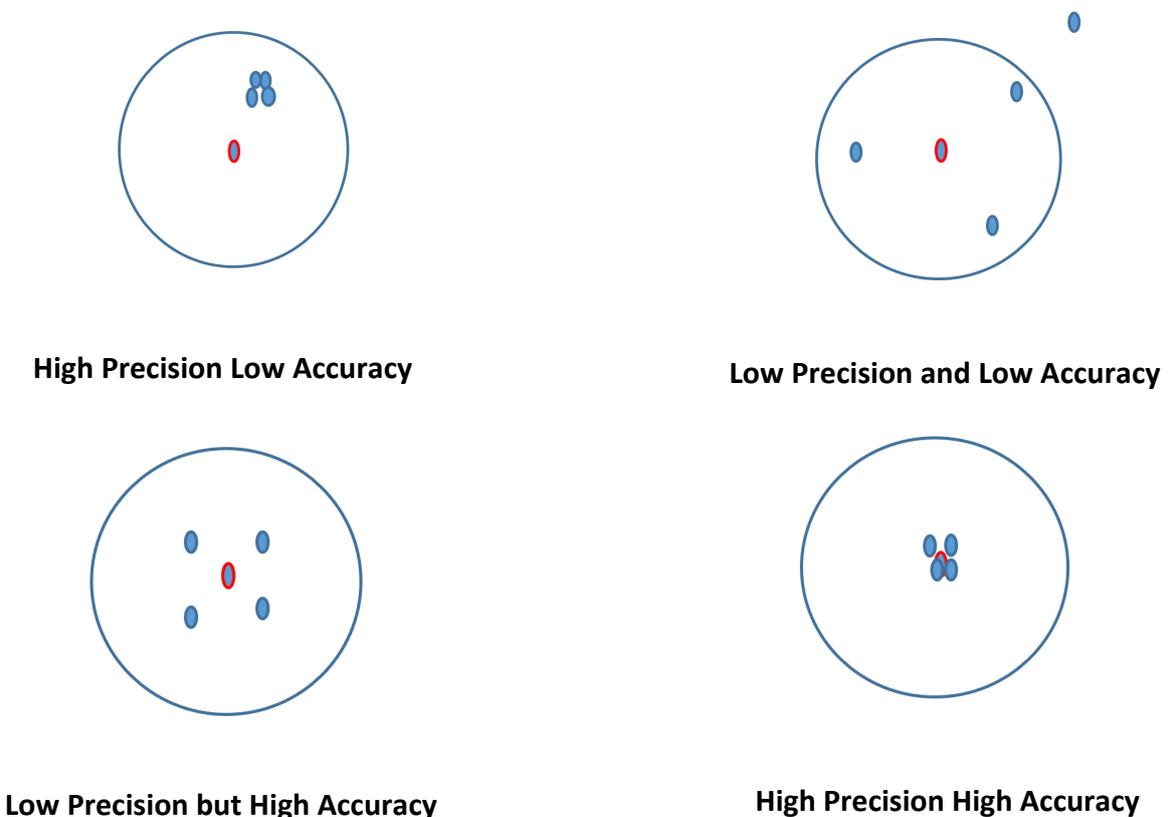


Figure 6. Schematic view of Precision and Accuracy

One-way ANOVA-test was used with Calipers measurements as input and tantalum- and bone-registrations as outcome variables. ANOVA or Analysis of Variances uses variances between one sample respect to a second sample.

Paired Student T-test was used for comparison analysis of scale variables with normal distribution. A paired student T-test is analyzing the mean difference of each paired measurement. For example, in our study we matched measurements based on tantalum beads and using bony surfaces. Normality of data sets in our study were tested based on plotting of the data. Assumption for both ANOVA and Student T-test is homogeneity of the variables which were checked with the Leven's test.

Precision and accuracy were measured according to RSME and was reported as mean ± 2 SEM (standard error of mean). Repeatability means calculating the precision while the scenario is repeatable[99].

Interclass Correlation was used to test repeatability. Statistical analysis was performed using IBM SPSS Statistics version 25 for Windows for this study.

Study 4

This study was approved by the Imperial College Healthcare, London, United Kingdom following formal application – institutional approval. The study was conducted according to local guidelines and regulations at Imperial College Healthcare and was approved by the medical directorate (Mr. Bhattacharya). To obtain images, we used institutional Picture Archiving and Communication System (PACS). Analysis was undertaken of all CT-scans performed for major trauma patients between January and December 2018, identifying a series of 10 patients without evidence of pelvic injury.

The CT machine used for this series was a 256-slice Philips Brilliance contrast-enhanced CT-scan (Koninklijke Philips N.V., Amsterdam, Netherlands). The Gantry was Air Glide, Aperture 700 mm, Focus-isocenter distance was 570 mm and Focus-detector distance was set at 1040 mm. The rotation time was 0.27 s and Collimation was 2x128 x 0.625 mm. A Field of View (FOV) of 200-500 mm and matrix of 512 was used. The filter used was the iDose4 Premium Package. The tube current was set to 89-134 mAs and a dose of 520-920 mGy*cm. The average tube voltage used was 100Kv.

All images were downloaded as Digital Imaging and Communications in Medicine (DICOM) files. All files were anonymized, coded and transferred to a research server afforded by Sectra. Stereo Lithographic (STL) files were created in 3D using a 3D Trauma package (Sectra, Linköping, Sweden). This mechanism can be compared by creating 3D images by putting thin horizontal images of the object on the top of each other.

Right and left side of the pelvises were then segmented[54]. Segmentation means coloring and highlighting and defining each bone segment. The left hemi pelvis was mirrored using available applications in the 3D Trauma package. Mirroring is achieved by a point to point manner, which means creating a mirrored point of the same object in the space[92].

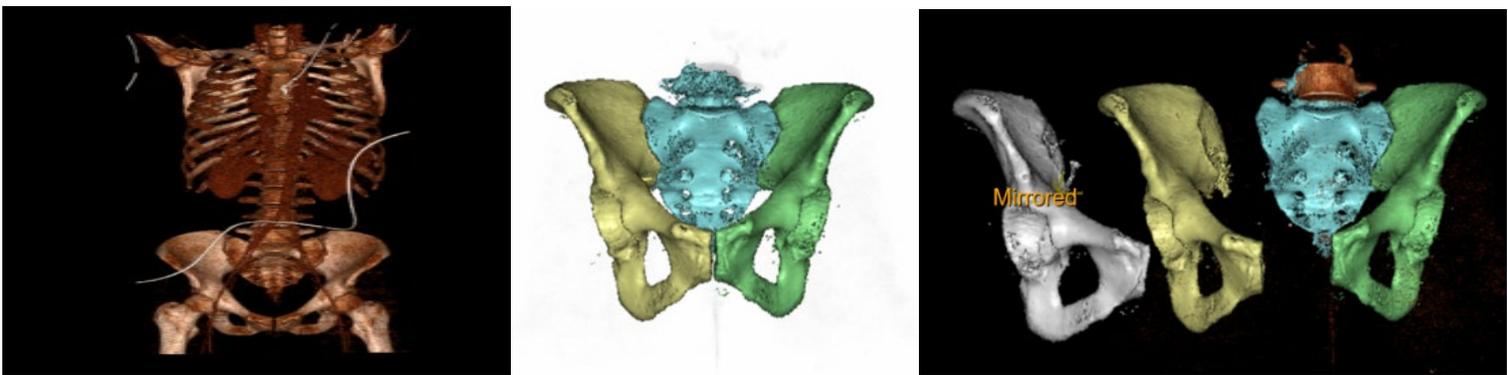


Figure 7. 3D CT Module showing the steps in the reconstruction

Images of the right hemi pelvis and mirrored images of left hemi pelvis were saved.

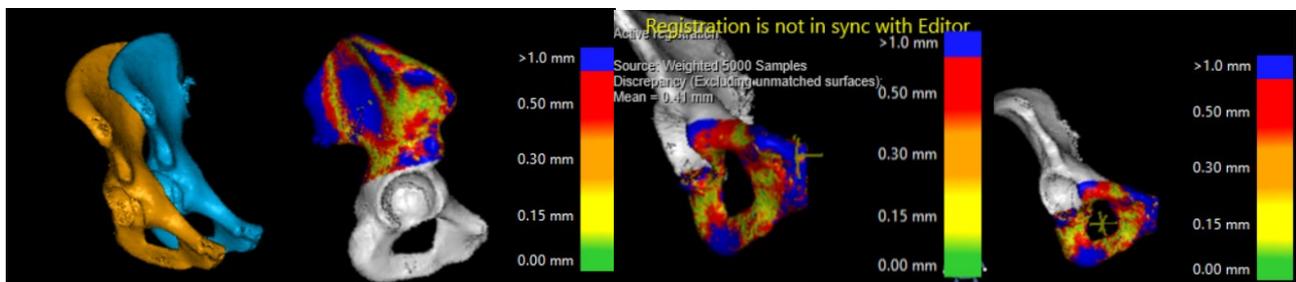


Figure 8. CTMA Module shows steps in the volume merging. The picture to the right shows marking of a point in the anterior superior aspect of the symphysis to measure the translational differences

The 3D Trauma software offered by the Sectra package uses two parameters to find the optimal segmentation. The user first differentiates the femur from the pelvis. This is done by clicking on their respective surfaces in the software. The first commando in combination with the Hounsfield Unit values (HU-values) was used to find where one bone ends and the other starts (i.e. optimal segmentation), as the second parameter.

Motion analyses of images were conducted using CT-based Micro Motion Analysis (CTMA). This software can precisely find the relative movement of an object between two different 3D created surfaces. Up to 500 000 points on the surface of the object of interest are spread randomly, in both CT-stacks. These random points create geometrical patterns.

Afterwards the software rotates and translates the object in the second CT-stack to get the best possible match in the first CT-stack as closely as possible. The operator can manually help the software by placing the objects as close to each other as possible to minimize fusion time. However, entirely automated function is possible as well, which might need several attempts in order to get optimal matching of the surfaces. This procedure is done by minimizing the distance between the two groups of points. As the used surfaces are much larger than any artifact areas, impact of the artifacts is limited on the matching process. This process is done initially for a reference object which is defined as stationary, with which the frame of reference is created. Thereafter, the movement of the object of interest is measured in the same way and the second part is defined as the moving object. The process has been previously described in greater detail[48, 49].

Based on our previous experience from using this software, 10 000 points with a mean distance difference between meshes of 0.5 mm or less was chosen. The posterior part of each of the hemi pelvises, excluding acetabular vault and including the posterior superior iliac spine, posterior inferior iliac spine and parts of the pelvic wing were chosen. The created 3D STL volumes were merged with the mirrored contralateral side (Figure 8). These merged images were saved as static, or non-moving parts, and were used as reference volumes. Furthermore, the anterior part of the hemi pelvises, excluding acetabulum but including superior/inferior rami were merged.

Translational and rotational changes in 3 different Euler axes (X, Y and Z) were calculated in the CTMA package. As per DICOM standard these axes and the rotations were defined; axis X from the patient's left to the right, axis Y from the patient's front to the back and axis Z from the patient's feet to head. A clockwise rotation was defined as positive alongside an axis. Translational changes were reported for the entire volume of an object based on Centre of Mass (COM) or any user defined point. This COM was similar but not identical to the mathematical center of the geometric volume on which the 10 000 points were spread out. As user defined points in our study we used one point in the Anterior Superior Symphysis (ASS) and another point in the Anterior Inferior Symphysis (AIS). Rotation was reported for the entire geometrical volume.

Accuracy was analyzed as per Root Mean Square Error (RMSE) with mean, median and 95% confidence interval (CI) of the mean. Shapiro-Wilk and Kolmogorov-Smirnov tests were used to test the distribution of normality. Statistical analysis was performed using IBM SPSS Statistics version 25 for Windows. A p-value <0.05 was considered statistically significant.

RESULTS

Study 1

We found 385 patients (145 females), mean age (\pm SD) 47.5 ± 20.6 years which fulfilled all the inclusion criteria. Follow-up time in median was 40 (IQR 26-56) months. The majority of these patients (n=251, 65%) were treated non-operatively. Surgically treated patients had a median time to primary surgery of 3 (IQR 2-5) days.

There were 317 cases of pelvic fractures, 48 acetabular fractures and 20 combined pelvic and acetabular fractures. For pelvic fractures the mean age (\pm SD) was $48.0 (\pm 21.1)$ years for patients with acetabular fractures $46.1 (\pm 18.2)$ years and $44.5 (\pm 16.7)$ years for patients with combined fractures. There was a greater proportion of females among patients with pelvic fractures (131/317, 41%) compared to patients with acetabular fractures (9/48, 19%) ($p=0.002$). In terms of proportion of surgically treated patients, 38 out of 48 (79%) acetabular fractures were treated surgically in comparison with 78 out of 317 (25%) pelvic fractures ($p<0.001$).

The overall 30-day mortality in our study was 7.8% (30/385). The 1-year mortality was 9.4% (36/385). Jump/fall from high altitude was the injury mechanism in 19 out of 30 cases of 30-day mortality. In 24 out of 36 cases of 1-year mortality high fall/jump was the mechanism of injury. Mortality in the first 30 days was related to: traumatic brain injury (n=13), high age (>70 years) with extensive comorbidities (n=6), traumatic chest injury (n=4), pelvic bleeding (n=4), abdominal bleeding (n=2) or chest bleeding (n=1).

Fatalities because of bleeding happened either on arrival or during the first 24 hours in 100% of the cases. The remaining cause of death for those 6 patients who died between 30 days and one year were: sepsis with multi organ failure in three cases, high age (>70

years) with extensive comorbidities in two cases, or sequelae from a traumatic brain injury in one case. Mortality in 30 days in surgically treated patients was lower (2/134, 1.5%) compared to non-surgically treated patients (28/251, 11%) ($p < 0.001$). So was the case for 1-year mortality among surgically treated (4/134, 3.0%) compared to non-surgically treated patients (32/251, 13%) ($p = 0.001$).

There was an increased 30-day mortality among patients with intentional (14/92, 15%) compared to non-intentional (16/293, 5.5%) cause of injury ($p = 0.006$). There was also an increased 1-year mortality among patients with intentional (14/92, 15%) compared to non-intentional (22/293, 7.5%) cause of injury ($p = 0.04$). However, no further fatalities happened in the intentional group between 30 days and one year.

Intentionally injured patients had higher ISS (median, IQR) (34, 22-43) compared to non-intentional patients (20, 12-33) ($p < 0.001$), and they had a greater proportion of fall from high altitude (76/92, 83%) compared to non-intentional patients (78/293, 27%) ($p < 0.001$).

Regression analysis including factors affecting mortality was conducted. Based on 36 cases of fatalities up to one year, three factors were selected to predict a mortality model. These three factors were calculated based on Peduzzi et al (1996), $N = 10k / p$ or $k = p \times N / 10 [100]$.

As N was pre-defined in our study (385) and p was ca 0.8 as per 30-day mortality, we could choose 3 factors to build a model.

We found that Mechanism of injury and Injury reason were confounding each other. A model based on Intentional versus Non-intentional (OR 4, CI 1.5-11.5), Glasgow Coma Scale (GCS) ≤ 8 (OR 11, CI 4-30), Age ≥ 70 (OR 21, CI 7-61) showed an appropriate Goodness of fit using Hosmer-Lemeshow test ($p = 1.0$). Nagelkerke R square was 0.4 which basically describes that 40% of the fatalities could be explained by our model. Another model using Mechanism of

injury showed that Fall from high altitude (Fall) compared to Motor Vehicle Accident (MVA) (OR 3.5, CI 1.4-9), GCS \leq 8 (OR 14, CI 5-37) and Age \geq 70 (OR 13, CI 5-33) had reliable Goodness of fit with Hosmer-Lemeshow test ($p=0.9$) and comparable Nagelkerke R square, 0.4. A combination of Injury reason and Mechanism of injury in a regression model was thus more appropriate.

In this final model Intentional Fall compared to Non-intentional MVA had OR 6 (CI 2-17), GCS \leq 8 OR 12 (CI 5-33) and Age \geq 70 OR 17 (CI 6-51). Hosmer-Lemeshow Goodness of fit test had a p -value=0.9 and Nagelkerke R square was 0.4. ISS as a scale variable ($p=0.3$) or ISS >16 ($p=0.9$) or ISS >25 ($p=0.5$) did not remain significant in a multivariate analysis.

Thirty out of 134 (22%) surgically treated patients were reoperated. The reoperation analysis showed, there were hardware related complications in 18 patients and non-hardware related in 12 patients. Complications related to hardware were: aberrant screw placement ($n=7$), mal-placed plate ($n=1$), catastrophic implant failure ($n=6$) or mechanical irritation from the implant ($n=4$). Reasons for reoperation, which were not related to hardware, were: infection ($n=10$), skin necrosis ($n=1$) or total hip replacement (THR) due to post traumatic osteoarthritis ($n=1$).

Of eight patients with aberrant screw positioning, there were 3 patients with mal-positioned SI-screws, of which 1 SI-screw penetrated to the ipsilateral S1 root, 1 SI-screw penetrated the contralateral sacral wall inducing L5-root symptom and the third case was bilateral SI-screws causing anterior displacement of the sacral body with L5-S1 symptoms.

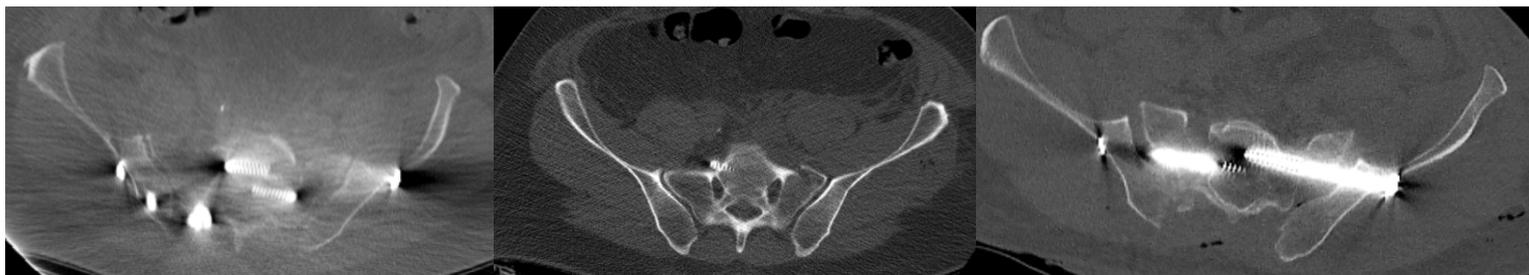


Figure 9. SI-screw penetrating the left SI-joint

There were 3 cases of screw penetration to the hip joint following anterior column fixation of acetabular fractures. Two of these were found early on the postoperative CT-scan. One was found during THR surgery 2.5 years after the initial surgery. Another case in the aberrant screw group was 1 case with 2 SI-screws who needed screw tightening. There was a mal-placed implant where an anterior SI-joint plate was placed too medial and was causing local L5-root symptom.

We found 6 cases of catastrophic failure. In 3 cases, posterior wall acetabular fractures showed loss of reduction. There were 2 anterior symphyseal plates with loss of reduction. Finally, there was one iliac wing fracture which was fixed using plate and screws that showed loss of reduction. The median (IQR) hospital length of stay was 23 (10-44) days for patients who underwent a reoperation during their primary hospital stay, compared to 18 (10-25) for surgically treated patients who were not re-operated ($p=0.2$).

Study 2

We found a total of 52 hospitals with an active trauma unit in Sweden (9 University hospitals, 22 General hospitals and 21 District General hospitals). We were able to reach all 52 primary on-call doctors. All agreed to participate in our study. They were all able to answer all of the questions.

The level of experience of the on-call doctor on the day of interview was: 20 Specialists, 15 Residents and 17 Interns. A larger proportion of Specialists were serving at the University hospitals (67%) compared to the other hospitals (33%) but this was not statistically significant ($p=0.071$).

A PCCD was reported to be available in 44/52 (85 %) of all trauma units in the country (further research by contacting the A&E staff, showed 100% availability). Based on the hospital category, 7/9 of the University hospitals knew that a PCCD was available. The figure further was, 20/22 for the General hospitals and 17/21 in the District General hospitals ($p=0.5$).

Regarding previous experience and exposure, 29/52 (56 %) of the doctors had used a PCCD at least once. In university hospitals this figure was higher (8/9), compared to General hospitals (13/22) and District General hospitals (8/21) ($p=0.03$).

The greater trochanters level was defined as the correct level of application for a PCCD in a total number of 43/52 (83 %). Based on the hospital type the numbers were 8/9 in the University hospitals, 20/22 in the General hospitals and 15/21 in the District General hospitals ($p=0.2$).

Regarding the potential ability of a pelvic binder to stop an arterial bleeding, 22 of 52 (42 %) doctors answered that a PCCD cannot stop an arterial bleeding. This figure in University hospitals was 5/9, in the General hospitals the number was 9/22 and in the District General hospitals it was 8/21 ($p=0.7$).

Study 3

We examined all data sets using plotting to show normal distribution. Using ANOVA test we found significant correlation between calipers measurements and distance changes measured in the SI-Joint using CT-scan with tantalum registration ($p=0.01$) and with bone registration ($p=0.01$). Significant correlation was found between calipers measurements and distance changes measured in the symphysis using CT-scan tantalum registration ($p<0.001$) and bone registration ($p<0.001$) based on ANOVA test.

Precision

Precision based on bone registration, measuring distance changes over the symphysis, was $0.15\pm 0.06\text{mm}$ compared to tantalum registration 0.23 ± 0.08 ($p=0.2$). Bone registration showed a precision of $0.10^\circ\pm 0.04^\circ$ compared to tantalum registration $0.23^\circ\pm 0.04^\circ$ in reporting total angular deformity of left side of the pelvis with respect to the right side of the pelvis ($p=0.008$). Bone registration showed a precision of $0.17\pm 0.04\text{mm}$ compared to tantalum registration $0.23\pm 0.08\text{mm}$, in reporting distance changes over the SI-joint ($p=0.2$).

Accuracy

Registration based on bone showed to be as accurate as tantalum registration in measuring distance changes over the SI-joint (CI ± 0.1 mm, $p=0.7$). Bone registration was as accurate as tantalum registration to measure total angular deformity of the left side of the pelvis with respect to the right side of the pelvis (CI ± 0.1 degree, $p=0.14$). Bone registration was as accurate as tantalum registration to report distance changes over the symphysis pubis (CI $\pm 0.1\text{mm}$, $p=0.4$).

Repeatability

An interclass correlation of 0.99 ($p<0.001$) was observed during repeated measurements with tantalum registration regarding measurement of distance changes over the symphysis pubis, distance changes over the SI-joint and total angular deformity.

Similar results of 0.99 (<0.001) in interclass correlation was observed for repeated measurements using bone registration. These were the measurements of distance changes over the symphysis pubis, distance changes over the SI-joint and total angular deformity.

Study 4

Mean age of our study population was 54 ± 20 years. There were six males and four females. Eight cases were of white British origin, one from the middle east and one Black African. Rotational differences and translational differences in X, Y and Z-axes of Center of Mass (COM) are presented in Table 1.

Table 1. Differences in rotation (degrees) and translation (mm) for each subject in X, Y and Z-axes

Subject no	COMX (mm)	COMY (mm)	COMZ (mm)	TADX (Deg)	TADY (Deg)	TADZ (Deg)	ASSX (mm)	ASSY (mm)	ASSZ (mm)	AISX (mm)	AISY (mm)	AISZ (mm)
1	-.761	-.435	.438	-1.903	.187	.703	-.127	-.688	2.233	-.589	-1.184	1.119
2	-1.273	-.523	.405	-2.120	.353	.463	-.835	-.629	2.520	-1.070	-1.083	1.790
3	-.364	1.500	1.396	1.375	1.036	.889	.359	2.700	-1.078	-.214	3.133	-.692
4	-1.820	.644	-.004	1.820	1.589	.282	-2.111	1.638	-3.395	-2.758	2.269	-2.814
5	-1.427	-1.717	-.532	-1.722	1.052	.369	-1.443	-2.024	.310	-1.837	-2.378	-.548
6	-2.443	-4.453	.883	-1.765	-2.269	-1.209	-4.096	-4.972	4.344	-2.767	-5.784	3.956
7	2.624	.635	.629	.589	-2.670	-.196	3.187	.604	2.618	4.039	.775	2.853
8	-1.638	.785	1.856	1.148	1.760	1.523	-.863	2.758	-.967	-2.332	3.151	-.295
9	-1.546	.992	-.761	-.758	1.952	1.395	-.280	2.020	-1.547	-1.361	1.857	-1.891
10	-1.014	-3.315	.037	-3.673	-1.292	3.045	2.083	-1.063	4.630	.893	-2.221	2.752

Deg: degrees, COM: Centre of Mass, TAD: Total Angular Difference, ASS: Anterior Superior Symphysis, AIS: Anterior Inferior Symphysis

In table 2: Mean, Median, and 95% CI of the mean are presented, according to RMSE (Root Mean Square Error). Variables were normally distributed.

Table 2. Median, mean and 95% CI of mean differences in rotation (degrees) and translation (mm) in X, Y and Z-axis for all subjects

	Median	Mean	95% CI of Mean
COMX (mm)	-1.386	-0.966	-1.958 – 0.256
COMY (mm)	0.100	-.588	-2.008 – 0.830
COMZ (mm)	0.421	0.434	-0.144– 1.013
TADX (Deg)	-1.240	-0.701	-2.011– 0.609
TADY (Deg)	-0.694	-0.169	-1.032– 1.372
TADZ (Deg)	0.583	0.726	-0.081 – 1.534
ASSX (mm)	-.557	-.412	-1.878– 1.052
ASSY (mm)	-0.012	0.034	-1.698– 1.767
ASSZ (mm)	1.271	0.966	-0.959– 2.893
AISX (mm)	-1.215	-0.799	-2.273– 0.673
AISY (mm)	-0.154	-0.146	-2.216– 1.923
AISZ (mm)	0.412	0.623	-0.964 – 2.210

CI: Confidence Interval, Deg: degrees, COM: Centre of Mass, TAD: Total Angular Difference, ASS: Anterior Superior Symphysis, AIS: Anterior Inferior Symphysis

Figure 10 and 11 illustrates the normal distribution of differences alongside the coordinates showing 95% CI of the mean differences and Interquartile Range (IQR) of the differences covering 0.

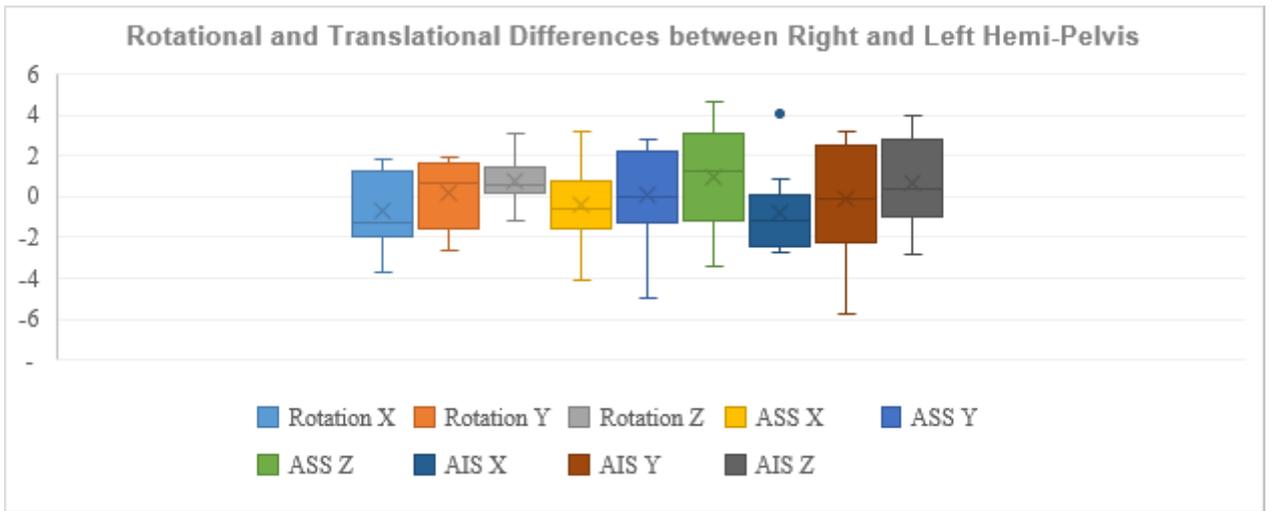


Figure 10. Interquartile Range (IQR) of translational and rotational differences between right and left hemi pelvis) in X, Y and Z-axis for all subjects (ASS: Anterior Superior Symphysis, AIS: Anterior Inferior Symphysis)

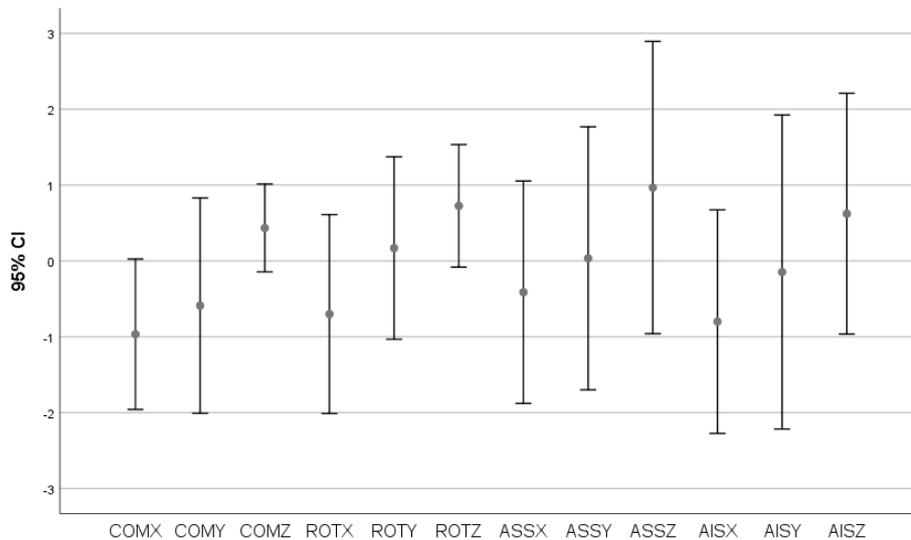


Figure 11. 95% Confidence Interval (CI) of mean between right and left hemi pelvis in X, Y and Z-axis for all subjects (COM: Centre of Mass, ROT: Rotation, ASS: Anterior Superior Symphysis, AIS: Anterior Inferior Symphysis)

In terms of rotational differences, the 95% CI for all mean angular differences between right hemi pelvis and mirrored left hemi pelvis were -2.011 – 1.534.

In terms of translational differences, the 95% CI for all mean translational differences between these two objects were -2.273 – 2.893. Between the right hemi pelvis and the mirrored images of the left hemi pelvis, for any patient, differences greater than 3 mm or 2 degrees could be excluded with a 95% confidence.

DISCUSSION

Study 1

The main finding of our first study was that the overall mortality following traumatic pelvic ring injury was relatively low in comparison with the literature. A subgroup of patients, with an intentional trauma mechanism and/or intentional fall from high altitude had a severely elevated mortality rate. Following regression analysis, intentional injuries (particularly Intentional Falls), GCS <8 and High age (>70) were predictors of mortality in our study population. A traumatic brain injury was the main cause of mortality in our study. The reoperation rate following open reduction and internal fixation of the pelvises was considerable. Several of these reoperations could possibly have been avoided.

The incidence of pelvic fractures in our study (3.6/100 000 person years) was lower than the previously reported incidence of high energy pelvic trauma of 10/100 000 person years in international populations[2]. This may be due to a lower incidence of motor vehicle accidents in our Swedish study population. Pelvic fractures were more common than acetabular fractures in our material, and this agrees with other reports[8, 101]. Pelvic fractures were proportionally more common among women. This finding has been reported by others[4, 102]. We had more fall-injuries (40%) compared to previous published data (5-36%)[2, 8, 16, 101]. Our results were comparable to epidemiological findings by Lüthje et al in a study from another Scandinavian country (Finland) with a reported incidence of 51% for fall injuries[4]. This can be explained by the fact that road traffic accidents were less common in our material.

Our 30-day mortality rate of 8% is in the lower span of other reports (7-47%)[13-15, 17, 18, 102]. The mortality rate increased with one percent between 30 days and one year.

This information is unique as it has not been reported previously. With other words: victims of traumatic pelvic ring injury are either dying early or if they survive in 30 days, then they will most likely survive the year. The most common cause of death in our study was not bleeding, as is commonly believed[20, 103-105]. A traumatic brain injury was the main cause of fatality in our study. Our results might be because of the fact that we had a substantial number of intentionally injured patients (24%) and the other fact, that a fall from high altitude was a common trauma mechanism (40%). Sweden is a safe country with respect to traffic injuries. The fact that Head injuries or GCS <8, Age >70 and Intentional falls were predictors of mortality in our study might only give information about our population of study. Our results should primarily be compared with data from similar trauma populations.

We found an increased rate of 30-day mortality among a category of patients with intentional injury mechanism. Increased mortality related to traumatic brain injury among the category of intentional injuries in our material could be related to more cases landing on their heads compared to an intentional injury group studied by Gabbe et al[106]. On the other side, Gabbe et al had higher mortality rate (48%), which could be explained by higher ISS as they included only cases with ISS >16[32]. ISS was a predictor of mortality in a univariate regression analysis. However, the effect of ISS was excluded as a predictor of mortality in a multivariate regression analysis in our study. When including GCS, High Age and Injury Intention were confounding with the effect of ISS. This might reflect the fact that ISS is not a reliable predictor of mortality while studying a trauma population with predominantly head injury.

Our operation frequency was 35% (135/385). Of these were 22% (30/135) reoperated. Reasons for reoperation were mainly because of either hardware related complications or infections[1].

We found only a few reports regarding the overall reoperation frequency of this patient category[65, 66]. While considering our overall reoperation rate as high, it was in level with other reports[65, 66]. The category of mal-placed implants (n=8) or implant failures (n=6) could have been avoidable in the presence of better pre-operative planning and better intra-operative imaging[107]. In our cohort, 24 cases with either a “posterior wall” or a “transverse and posterior wall” acetabular fracture type were operated. We had three cases of implant failure in this category. All of these suffered from multi fragmentation of the posterior wall. This fact has previously been highlighted by Saterbak et al[67]. In a retrospective study of 42 cases with posterior wall acetabular fractures the authors reported 26% implant failure with loss of reduction. In their series multi fragmentation of the posterior wall and fractures into the subchondral arc were studied and were reported as predictors for reoperation.

Two of 22 cases with anterior symphyseal plate in our study had reoperation as a result of implant failure. In a retrospective study of 148 cases with anterior symphyseal plates, Morris et al reported 42% implant failure. However, the majority of these failures were asymptomatic and removal of osteosynthes material could potentially have been avoided[108].

Some words about the strength and limitations of this study. Because of linkage between the Swedish Population Registry and the hospital's patient record system, our study had no lost to follow-up in terms of mortality. This linkage even made it possible to report 1-year mortality. The unique Swedish personal identification number enabled us to follow all the cases in different data systems such as patient records, PACS etc.

The retrospective design of our study and lack of pre-designed control groups were some of our limitations. The heterogeneity of our cohort and relatively low number were some other limitations of our study.

Study 2

The main finding of our second study was that the reported availability of PCCDs and the knowledge regarding the level of application of it were acceptable and similar between the three hospital categories. As attending ATLS courses is very common in Sweden, this might reflect the fact that a majority of doctors in our survey probably had attended the course. As only less than half of the questioned doctors had the knowledge regarding PCCDs limitations in stopping arterial bleeding, we had to assume that this issue has not been addressed or debated enough during the ATLS courses.

The literature regarding the availability, experience and knowledge about use of PCCDs is sparse. Reported PCCD availability rate was 85 % in the Swedish trauma units. This was higher than the 75-78 % that was reported by Jain et al in 2013 in the UK[109]. Given the fact that ATLS is so well adopted in Sweden, as well as in the UK, it is surprising that the reported availability was not 100%. Following further research in our study we found that, in reality all the trauma units had PCCDs available, but this fact was not known to the participants. As data is showing that pelvic fractures might be missed in pre-hospital setting, knowledge of the first on-call trauma doctors regarding availability of PCCD in the ER is valuable[104]. A majority (56 %) of the doctors in our study, had used PCCD at least on one occasion. The fact that 3/22 doctors in the General hospitals and 3/21 doctors in the District General hospitals had used a PCCD more than 5 times illustrates that some of the high energy pelvic trauma cases still are initially referred to these centers. An explanation could be that Sweden is a country with some sparsely populated areas with long distances to university hospitals. The initial assessment of high energy patients is sometimes started at these smaller units. The transport to the definitive care level then happens following initial physiological stabilization of these patients.

The general recommendation is to apply a PCCD at the level of greater trochanters[110]. In our study, 83 % of the doctors defined the greater trochanters as the preferred level of application. This rate was slightly higher compared to a previous study[109]. A substantial proportion in our study were specialists (40 %), in contrary to Jain et al who only had registrars in their study. Surprisingly, we found that only 42 % of the doctors were aware that a PCCD cannot stop an arterial bleeding. This is somewhat startling as a physiologically unstable patient with a PCCD might still suffer from an arterial pelvic bleeding. If the first line medical officer believes that the PCCD can stop an arterial pelvic bleeding this might result in a delay to appropriate treatment. In a cadaveric study, Grimm et al reported a maximum of 30mHg increase in intra-pelvic pressure upon reduction of a disrupted pelvic ring[111]. This pressure might be beneficial to tamponade the bleeding from fracture sites and sacral venous plexus but not from arterial bleedings which are common sources in fractured pelvis[112]. There are 2 case series reporting physiological improvements following application of PCCD while both of which were conducted in major trauma centres with available resources to stop arterial bleedings if needed[103, 105].

Angio-embolization, pelvic packing and arterial ligation have been reported useful in pelvic fractures with on-going arterial bleeding[38, 40-43, 113, 114].

One strength of this study was the 100 % response rate and full coverage of all trauma units in the country. Telephone interview also gives a special opportunity to capture information in real time without the opportunity to answer by asking around which increases the risk of bias. One limitation of this study was its cross sectional, snap shot nature. The answers we collected could easily represent the opinion of the individuals we interviewed rather than the actual practice in the trauma units.

Study 3

The main finding of our third study was that fusion of the 3D surfaces, using either bone registration or tantalum registration had a precision substantially better than 1 mm for translational deformity and better than 1 degree of rotational deformity[48]. These values were much better than conventional X-ray with a reported precision of ± 5 mm. CT-scan with registration of volumes using bone registration was as accurate as registration with tantalum (± 0.1 mm for translation and ± 0.1 degree for rotation). Both of these techniques were repeatable. Implantation of tantalum beads did not add any information and can thus be avoided[48].

Orthopedic surgeons use X-ray during clinical follow-up of their patients for post-operative control and to monitor healing over time[61, 70, 115-117]. A number of different measurement techniques such as RSA, vibration analysis, CT-scan and ultrasound etc. have been used and proposed as alternatives to report fracture healing and to detect excessive movements[68]. However, the main fracture follow-up technique still remains conventional X-ray, which has a reported measurement error of ± 5 mm[70]. This technique also suffers from lack of reproducibility because of manual measurement and interpretation[118].

The most cited radiographic technique to evaluate pelvic fracture surgery and during the follow-ups is the technique presented by Matta and Tornetta. This technique is using X-ray with pelvic frontal, inlet and outlet views. Tornetta and Matta recommended the distance in the SI-joints or anterior symphysis in any plane to be measured. The maximum distance in any plane is then reported. This distance is then scaled to excellent if the distance is under 4 mm. The result is good if the distance in the SI-joint in any view is under 10 mm.

If the distance is between 10-20 mm then it is fair and if any measurement over 20 mm, then it is considered as a poor result[71, 72, 119].

As our study was in 3D, we used a modified Matta and Tornetta's technique. We used distance changes over the symphysis pubis and over the SI-joint by comparing a point with its previous position in the space. Matta and Tornetta's original technique has been criticized because of lack of methodology and reproducibility[118]. We were able to show that using appropriate imaging modality together with an automated interpretation technique minimizes the level of uncertainty. This combination might contribute to better precision and accuracy and can show the path towards a unified reporting system. Automatic reporting of the distance changes for each point is with respect to its previous position in a 3D manner against a fast reference object, which can be the contralateral site. Matta and Tornetta presented their simple technique in absence of any sophisticated technique. It would be more interesting for a pelvic surgeon, following a patient with fractured pelvic ring, to report deformity of fracture components with respect to a previous position[48].

RSA-technique has been used in fracture research. Solomon et al studied tibia plateau fractures using RSA technique and used implantation of 6 tantalum beads in each fragment section[99]. The authors showed promising results to report deformity over time with a reported precision of ± 0.05 mm for translation and ± 0.2 degree of rotation[99]. The authors concluded that RSA technique, because of its precision and accuracy justifies implantation of tantalum beads in fracture surgery research[99]. The technique is however invasive and cumbersome and demands implantation of tantalum beads around the fracture. This could be quite demanding to conduct in daily practice[68].

Olivecrona et al have extensively studied CT-scan with volume registration using tantalum beads, and were able to show that the technique was not inferior to RSA technique regarding accuracy, precision and radiation dosage[73, 75, 77-79, 81, 84]. Implementation of low-dose CT-scan using volume fusion technique has been promising with use of radiation dosage as low as 0.7 mSv, which is comparable to conventional X-ray[120].

The major strength of our study was its novelty to introduce a new technique making it feasible for clinicians to use an automated function to report their outcome over time. We were able to show that implanting tantalum beads was not necessary to detect motion of a repaired disrupted pelvic ring.

We had several limitations in our study. One limitation was its model character. The human pelvic model we used was without soft tissue, spinal column and femurs. Our model had limited artefact during analysis. We used only 6 metal markers on the right side and 8 on the left side, as proposed by Solomon et al[99]. The question remains whether implantation of more tantalum beads could improve precision of volume registration with tantalum and widen the measurement gap with bone registration. However, this would be unlikely as precision of bone registration in our study was very close to reported RSA measurements and probably more tantalum would only make the confidence intervals narrower[48].

Study 4

The main finding of our last study in this thesis was that mirrored images of the left hemi pelvis were highly symmetrical with the right hemi pelvis. Osterhoff et al recently published an article using mirror images of contralateral pelvis and 3D templates of peri-acetabular plates in order to test symmetry of left versus right acetabulum[121]. The authors found no statistically significant differences between right and left acetabulum when measuring the distances between a mirrored pre-contoured acetabular plate to the acetabular bone. While the authors offered a new technique to define symmetry of contralateral acetabulum based on distances, no direct measurement technique has been introduced to measure the rotational differences between the two volumes[121].

Badii et al, utilising CT-scans alongside manual measurement found a range of asymmetry; -11 to 7 mm difference between right and left hemi pelvis. The authors described a manual technique using the distance between the iliac crest to the acetabulum bilaterally[122]. However, manual calculations are highly subject to bias because of intra- and inter-observer reliability issues[60, 61]. Finding reference points and reproduction of the different measurement techniques is difficult[61]. Measuring rotational differences between two hemi pelvises has been a recurrent problematic issue in previous studies[61, 116].

We were able to introduce a new technique with fusion of the volumes using two software packages (3D trauma and CTMA). Application of CTMA in a pelvic fracture model in a previous study showed a precision of ± 0.2 mm for translation and ± 0.2 ° for rotation[48].

In this study, we used translation of two points in the symphysis pubis with respect to the merged images in the posterior aspect of the pelvises. Osterhoff et al used the mid portion of the pelvises where the acetabulum is located[121].

If we had merged the images posteriorly and included areas very close to the acetabulum, we would have been able to report a narrower confidence interval of the mean differences similar to that presented by the Osterhoff et al (± 0.2 mm). However, we decided to use the pubic symphysis in our study as it was aimed to investigate the entire pelvis rather than acetabulum only[121].

In the era of three-dimensional planning and 3D printing of pre-contoured implants, knowledge regarding symmetry of the hemipelvises using a highly precise technique is useful. Additionally, the technique can be used for the reconstructed pelvis to check the quality of the post-operative reconstruction[123-127].

CONCLUSIONS

Non-survivors in our clinical epidemiological study died mainly because of factors not directly related to their pelvic injury, but instead factors like traumatic brain injury or high age with extensive co-morbidities were of significance. Most of the mortalities occurred early why reporting 30-day mortality seems reasonable. Intentional injuries and especially intentional falls had high mortality rate in our study. Intentional injury needs further focus in future studies as a separate category because of their high mortality. Reoperation frequency was high but in the level with previous reports. Implementation of optimal imaging techniques for pre-operative planning and intra-operative application needs further focus. A majority of the hardware related complications could potentially have been avoided in the presence of these techniques.

We found that the majority of the hospitals had PCCDs available and the majority of the primary on-call doctors knew at which level to apply a PCCD. The experience in using PCCDs was greatest in the University hospitals. Less than half of the asked knew that a PCCD cannot stop an arterial bleeding, a matter which highlights a need for educational improvement in for example ATLS courses.

For measurement of translational and angular deformities of a repaired pelvic fracture model, CT-scan with volume registration based on bone registration was as accurate, precise and repeatable as volume registration based on tantalum beads and both results were superior to conventional X-ray. Adding metal markers did not give more information in our study as bone registration could replace registration using tantalum. Future clinical studies using bone registration are encouraged to further study practical application of CTMA. This technique can be a potential substitute instead of conventional X-ray during post-operative follow-up of pelvic fractures.

Hemi pelvises of healthy adults appear to show enough symmetry to be used for pre-contouring of implants and planning of pelvic fracture surgery.

IMPLICATIONS FOR FUTURE RESEARCH

Orthopaedic surgeons dealing with traumatic pelvic ring injuries are facing challenges as this bony ring is embedded in a large amount of soft tissues surrounded by vessels, nerves and muscles in proximity to the abdomen. National registries are important tools to create a platform for research and study on polytrauma.

Unfortunately, pure pelvic registers are not currently available in many countries. Becken-AG in Germany is registering the pelvic injuries with data from the national trauma registry and hopefully other countries start registering the pelvic fractures as well.

Artificial intelligence is gaining popularity and created tools can help clinicians in decision making prior to surgery to minimize risk of complications or at least be able to somehow predict them. This type of study demands big national data which hopefully becomes more available pending on national pelvic registries.

We need intra-operative navigation tools which are easy to apply and with high precision and accuracy. In the presence of such tools the successful surgery of the traumatic pelvic ring injuries can be applied to a wider population, such as elderly patients. Further, this technique could be an asset for minimally invasive surgery. The current techniques are not user friendly and are cumbersome.

In summary the future research should focus on:

- 1) Creation of national pelvic registries.
- 2) Creation of tools for decision making using artificial intelligence to predict post-operative outcomes in order to avoid the unfavourable ones.
- 3) A new post-operative classification of quality of reconstruction using pre-operative 3D virtual reconstruction as a template.
- 4) Prospective case series with low-dose CT scan for the follow-up of reconstructed pelvic rings to report healing and correlation of healing to patient reported outcome.
- 5) Creation of new intra-operative mapping devices to merge with the 3D pre-operative images to use as navigation. This could be a supportive asset for surgeons.

ABSTRACT IN SWEDISH

Sedan tidigare, fanns det ingen information gällande omfattningen av högenergi relaterade bäckenskador i Sverige. Vidare fanns det ingen information gällande kunskap och erfarenhetsnivå hos doktorer som initialt tar hand om traumapatienterna i Sverige avseende bäckengördlar. Slätröntgen används fortfarande för att kontrollera opererade bäckenfrakturer. Trots att tekniken har kritiserats en del. För närvarande har bättre alternativ inte introducerats i praktiken .

Vi planerade att studera epidemiologiska aspekter av högenergi bäckenskador genom att använda data från det Svenska Trauma Registret (SweTrau) för samtliga patienter som var behandlade på Karolinska Universitetssjukhuset. Vidare planerade vi att studera primärjourernas kunskap, utbildningsnivå samt erfarenhet gällande akut handläggning av bäckenskador med bäckengördel. Vi planerade även att studera alternativa praktiska undersökningar istället för slätröntgen.

Vi använde data från SweTrau. Vi använde Karolinska Universitetssjukhusets elektroniska journalsystem och det elektroniska röntgenarkivet PACS. Vi använde ett formulär för att ställa frågor till samtliga tjänstgörande primärjourer på akuter i Sverige vid ett tillfälle. Vi använde mjukvarorna 3D Trauma samt CTMA för att studera rörelser på en bäckenmodell efter operation samt för att analysera symmetri av bäckenhalvor.

Vi fann att incidensen av högenergi bäckenskador i Stockholm var ca 3,5/100 000 invånare. Ett-års mortaliteten var 9% och 30-dagarsmortaliteten 7.8% hos bäckenfrakturpatienter. Huvudorsaken till mortalitet var traumatiska hjärnskador. Självförvållade skador hade en högre mortalitet (15%).

Reoperationsfrekvensen för alla opererade bäcken- och acetabulumfrakturer var 22%. Huvudorsaken till reoperation var implantatrelaterade problem vilka i de flesta fall var undvikbara. Vi kunde visa att 30-dagarsmortalitet är adekvat i rapportering av mortalitet efter traumatiska bäckenskador. Självförvållade skador har hög mortalitet och behöver därmed studeras vidare. Reoperationsfrekvensen efter operationen av traumatiska bäckenskador är hög och kräver mer studier.

Vi fann att majoriteten av primärjourer var medvetna om att de hade en bäckengördel på akuten och visste hur dessa skulle appliceras. Erfarenheten av att använda bäckengördel var dock större på universitetssjukhusen. Det fanns en generell missuppfattning hos 55% att en bäckengördel kunde stoppa arteriella blödningar.

Vi kunde bevisa att lågdos datortomografi kan användas för uppföljningen av opererade bäckenskador. Avstånd i form av $\pm 0,2$ mm i sidorörelse eller $\pm 0,2$ grader rotation kunde upptäckas. Lågdos datortomografi tillsammans med användning av seriebildfusionering kan ersätta konventionell röntgen för uppföljningen av bäckenskador.

Vi kunde visa att bäckenhalvorna hos människor är symmetriska och att den motsatta sidan därför kan användas vid planering av kirurgi om det skulle behövas.

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