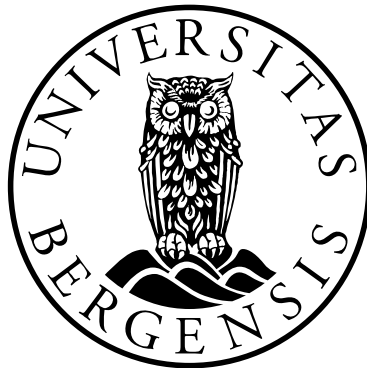


Implementation of a fracture and dislocation registry

Epidemiology and scoring validity of long-bone fractures

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Abbreviations

AO: Arbeitsgemeinschaft für Osteosynthesefragen

CI: Confidence interval

DALYs: Disability Adjusted Life Years

ED: Emergency department

Registry: The Fracture and Dislocation Registry of Stavanger University Hospital

ICD: International Classification of Diseases

K: Kappa agreement

Li-La: Licht und Lachen Für kranke Kinder

NCSP: The Nordic Medico-Statistical Committee Classification of Surgical Procedures

OR: Odds ratio

OTA: Orthopaedic Trauma Association

PA: Proportion of agreement

PCCF: AO Paediatric Comprehensive Classification of long bone Fractures

RCT: Randomized controlled trial

SUH: Stavanger University Hospital

WHO: World Health Organization

Essential glossary

Accuracy: Accuracy refers to the correctness of the dataset when compared to a reference dataset.

Agreement: How similar the datasets are, measured as the percentage of even ratings (the proportion of agreement) between each dataset.

Interrater: Interrater is a setting where the same cases are rated by different observers.

Intrater: The same observer, on separate occasions, re-classifies a fracture, given that the fracture characteristics are fixed.

Müller classification: Comprehensive Classification for Fractures of Long Bones introduced by Maurice Müller in 1979. It is adapted in the AO/ OTA classification for adult fractures.

Reliability: How similar the datasets are relative to the similarity expected to occur by chance alone. Reliability is measured by kappa statistics.

Reproducibility (precision): The similarity of two datasets measuring the same thing.

Validity: General term that involves how precise, useful and practical a classification is.

Scientific environment

This thesis has been made possible through my affiliation to the PhD programme at the Faculty of Medicine and Dentistry at the University of Bergen. I have been affiliated to the Department of Surgical Science as a PhD-candidate and through my supervisor professor Kjetil Søreide. At the time of this writing, there has historically not been any official research group going out from the Department of Orthopaedic Surgery at SUH. For optimal academic liaison during my thesis work, I have thus been connected to the ‘Surgery Research Group’ at large in our institution through my supervisor Kjetil Søreide. The Surgery Research Group has extensive connections to other national and international research groups and a vivid network of on-going projects ranging from trauma and emergency surgery to clinical cancer and translational outcomes research. As a primary investigator (among others) for trauma and emergency surgery, professor Søreide connects researchers from acute and intensive care department with those from the surgical and orthopaedic departments. It is hoped that the currently growing research activity within the Department of Orthopaedic Surgery will foster an independent and successful branch in its own and generate future collaboration with other departments and researchers within the exciting field of orthopaedic research.

Acknowledgements

I am incredibly grateful for the continuing support from my colleagues at the Department of Orthopaedic surgery at SUH. Their positive attitude during the everyday work facilitated the implementation of the Fracture and Dislocation registry. The surgeons have conscientiously reported to the registry in a busy clinical practice and, whenever I asked, I have been given the time necessary for controlling the data to maintain high quality in the registry.

Developing the idea of a registry and bringing it to fruition has been kind to a three-step rocket launch. First, the ideation and need for a registry started with senior orthopaedic surgeon Trygve Søvik who should be dedicated the most important person for initiating the registry. His dedication to the field of orthopaedic trauma has always inspired me. At first he introduced an event form, which should follow the patient during the hospitalization. All the orthopaedic surgeons should continuously report in this form the fracture classification, the complications and supplementary diagnoses in addition to the treatments and examinations that were performed during the hospital stay. I remember myself complaining about this form because I knew that the registration would not be complete, nobody was going to control the completeness, and validation in the registration, and nobody knew where and how the manually reported forms were going to be stored. Some months later (1st of January 2004) the event form was replaced by manually registering the fracture classification code (AO/OTA code) in the manually registered operation protocol. The registrations were consecutively punched into an Access database by a civil service worker, and controlled by Søvik. I was still expressing my scepticism; consequently I was challenged by Søvik to take over as the controller in June 2004.

Secondly, Astvaldur Arthursson MD, PhD needs to be honoured as he made the Access® database. His systematic skills were essential for the implementation and further development of the Registry during the first years of the Registry.

Finally, for the digitalization of the registration of the data, the orthopaedic surgeons Knut Harboe and Lars Eilertsen were instrumental. Dr. Eilertsen made the early version of the reporting module, which dr. Harboe enclosed into the electronic operation program (ORPlan) used at the hospital. Notably, the electronic data systems have been designed and developed by two clinically active orthopaedic surgeons, which truly has helped in the integration process and further development. My close friendship with Harboe, and his computer skills has made the project manageable.

It came clear that collecting data in itself was not enough. The desire and need for a formal evaluation of the data content, the scoring methods used and the quality of the coding was evident. This led to the initiation of my PhD thesis in 2008. During the process of study set up, data extraction and analyses, and scientific writing the enthusiasm and skills of my main supervisor professor Kjetil Søreide MD, PhD at the Department of Surgery has been of tremendous value. He has been available and supporting, he has gradually brought me through the difficulties. I know I have been extremely lucky, having him as my supervisor!

I want to share my gratitude to Stavanger Health Trust who engaged me in a 50% PhD scholarship in September 2009. Clearly, it would not have been possible for me to make the thesis without this scholarship. I also appreciate the 50.000 NOK that I received to the validation project (Study III and IV) from Stavanger Research Council at Stavanger Health Trust.

Also, I want to thank the patients from whom I have learned through their suffering. Hopefully, the establishment of the registry will make management better and suffering shorter for those unfortunate ones who experience a fractured bone or dislocated joint.

Last, but definitely not least, I have to acknowledge my closest family; my children and my beloved wife Randi, for enduring my frequent absence during the long hours spend on this thesis.

Abstract

Introduction: The Fracture and Dislocation Registry of Stavanger University Hospital were initiated 1st of January 2004 to accomplish the request of reliable data regarding incidence, modes of treatment and outcome of fractures. To ensure good quality in the registry the data have been consecutively controlled. To prepare the registry for further research the most important parameter, the classification code was validated.

Method: All inpatient primary and secondary treatments of fractures made at the operation theatre were classified and reported by the surgeons consecutively. The most important parameters were; the AO/OTA- and Gustilo/Anderson-classification, the method of fixation, and the reasons for the reoperations. The surgeons recoded the fractures during the intra- and inter-rater analyses. A reference code dataset was made for accuracy assessment.

Results: All involved surgeons reported to the registry. Completeness has been excellent. Approximately 28 % of the long bone fractures that was diagnosed in-hospital or at the Emergency Department were treated in the operation theatre. The overall incidence per 100,000 per year was 406 with a 95% confidence interval (95%CI) of 395–417. The male:female ratio was 2:1 among those <50 years, and 1:3 in those ≥50 years. The accuracy of (four sign of) the AO/OTA classification was for adult fractures; kappa agreement of 0.68 (95% CI: 0.65–0.71) and for children's fractures K=0.72 (95% CI: 0.64-0.79) and PA 76%. Fracture type, frequency of the fracture, and segment fractured significantly influenced accuracy, whereas the coder's experience did not.

Conclusion: The implementation of the Fracture and Dislocation Registry has been made successfully. Maintenance of the registry is assured by the controller through the features of the electronic database program. The classification according to AO/OTA classification (= Müller classification) seems to be satisfactory reliable. The

registry seems to be well prepared for contribution to quality assurance and improvements in fracture treatment.

List of publications

- I Meling T, Harboe K, Arthursson AJ, Søreide K. Steppingstones to the implementation of an in-hospital fracture and dislocation registry using the AO/OTA classification: compliance, completeness and commitment. *Scand J Trauma Resusc Emerg Med.* 2010 Oct 18;18:54.
- II Meling T, Harboe K, Søreide K. Incidence of traumatic long-bone fractures requiring in-hospital management: a prospective age- and gender-specific analysis of 4890 fractures. *Injury.* 2009 Nov;40(11):1212-9.
- III Meling T, Harboe K, Enoksen CH, Aarflot M, Arthursson AJ, Søreide K. How reliable and accurate is the AO/OTA comprehensive classification for adult long-bone fractures? *J Trauma Acute Care Surg* 2012 Jul;73(1):224-31.
- IV Meling T, Harboe K, Enoksen CH, Aarflot M, Arthursson AJ, Søreide K. Is it possible to reliably classify children's fractures according to the Comprehensive classification of long bone fractures by Müller? *Acta Orthopaedica* 2013; 84 (1): x-x

1. Introduction

1. 1 History of fractures and fracture treatment

The oldest sign of a chordate is believed to be, however debated, the 505 million year old fossil of the *Pikaia Gracilens*, found by Charles Doolittle Walcott in Canada more than hundred years ago (Figure 1). ¹



Figure 1. Fossilised Pikaia Gracilens. Photo: Jean-Bernard Caron. Courtesy of Smithsonian Institution.

However, the first mineralized skeleton was found among osteichthyes (bone fish group). The oldest known signs of bone fishes are 420 million years old ². The first signs of mammals (depending on the definition) appeared about 210 million years ago ³. Anatomically modern humans (*homo sapiens sapiens*) is believed to be originated in Africa about 200,000 years ago ⁴. Bone fractures have always been one of the dreaded events that could affect a person. The treatment by immobilization with splints has been used for thousands of years. Ancient Egyptians used wooden splints (Figure 2) ⁵, and ancient Indians used bamboo splints ⁶.



Figure 2. Fracture treatment of forearm from Egyptian mummies with wooden splint about 2500 B.C. The Nubian Collection, courtesy of Royal College of Surgeons, London.

Various types of roller bandages (casts) were used among the Arabs since 800 A.D.⁷. The use of plaster of Paris (gypsum) was introduced in the fracture treatment in the second half of the nineteenth century⁶. Traction treatment of fractures was used among ancient Greeks, but the popularity of this treatment seems to have varied through time. Traction may be applied to the skin or directly to the bone. Nowadays traction is still used, but mostly as temporary treatment, ahead of definitive internal fixation. External fixation is a kind of a local traction device, actually described by Hippocrates 2400 years ago (Figure 3)⁵.

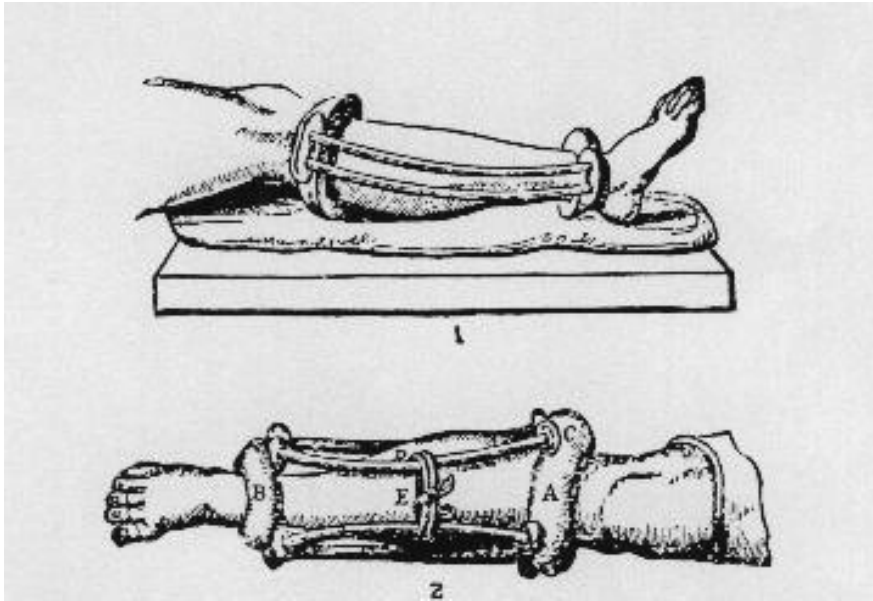


Figure 3. External fixator for tibial fracture as Hippocrates described it. Credit E.M.Bick. Source Book of Orthopaedics. (New York, Hafner).

The method gained popularity after 1938 when Raoul Hoffmann introduced a user- and soft tissue- friendly method based on closed reduction and percutaneous pin placement (Figure 4).

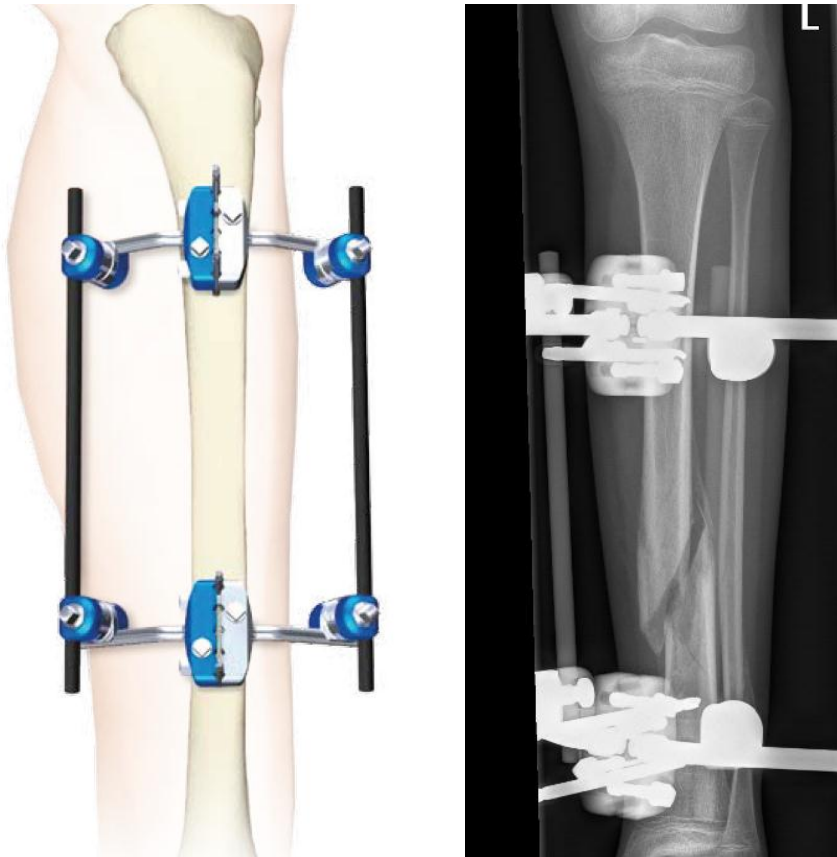


Figure 4a. External fixator Hoffmann II (courtesy of Stryker).

Figure 4b. The device applied to a patient registered in the registry.

Open fractures were a life treating condition because of the very high infection rate. If at all treated the method of choice was amputation. Mortality rate were discouraging until antiseptic method of surgery was introduced by Joseph Lister (1827-1912) in 1865. Internal fixation was probably done for the first time in 1770 with a brass wire, screw fixation around 1850 and plate fixation in 1886⁶. However, high complication rates, inadequate operation methods and fixation devices made most treatments conservative for most fractures. Improvements in the internal fixation devices and better understanding of fracture healing resulted in larger

proportion of internal fixations as treatment for unstable fractures. Intramedullary nailing took advantage of a more rapid secondary bone healing (excessive callus formation), whereas the compression screws/plates used the principle of absolute stability and primary (but slower) bone healing⁸. The introduction of locking screws/plates for the last ten years has considerably improved the possibility of stabilizing comminuted and osteoporotic fractures (Figure 5). Actually, locking plates may achieve secondary bone healing, typically through long preshaped locking plates and minimally invasive approach, leaving some of the holes in the plate at the site of the fracture empty⁹.



Figure 5a. LCP Proximal Tibia Plate 4.5/5.0. Courtesy of Synthes.

Figure 5b. The same plate applied to a patient registered in the registry.

Arbeitsgemeinschaft für Osteosynthesefragen (AO-foundation)

In 1958 a group of innovative general and orthopaedic surgeons (Martin Allgöwer, Hans Willenegger and Maurice Müller) established the AO (Arbeitsgemeinschaft für Osteosynthesefragen) or the Association of the Study of Internal Fixation (ASIF) to strive to transform the contemporary treatment of fractures in Switzerland¹⁰. The AO association was revolutionary in development of instruments and implants for operative fracture treatment. The first instructional course for teaching the use of these instruments and implants occurred in Davos, Switzerland, in the newly founded Laboratory of Experimental Surgery in 1960. Through a process of internal quality control (AO documentation) the clinical success of these new techniques and implants became evident. Operative fracture treatment gained acceptance throughout Europe and finally worldwide. AO/International (AOI) was founded in 1972 to expand education and the teaching programs for surgeons and operating personnel on an international basis. In 1984, the AO/ASIF Foundation was created with an AO Board of Trustees comprising 90 leading trauma surgeons from throughout the world. Continuous research, implant and instrument development, clinical documentation, and multifaceted educational opportunities are coordinated by the AO/ASIF Foundation to maintain its position as the international authority in the treatment of trauma. The medical community recognizes today the enormous positive global effect that this respected organization has had by continually improving operative fracture treatment.

A milestone in the improvement of documentation was the introduction of the Comprehensive Classification of Fractures of Long Bones by Maurice Müller (Figure 6)¹¹. Earlier classifications did only cover some special fracture types. The Müller classification seemed ideal for study comparisons and treatment allocations. However, during the last two decades a lot of studies have questioned its reliability¹²⁻¹⁵. More recently scientists seem to realize that there always will be problems categorizing the continuously occurring complexity of the fractures. Still classification of fractures are mandatory¹⁶.

Some of the most experienced trauma orthopaedic surgeons in Norway have founded a Norwegian affiliate; AO-Alumni Norway. The same group of surgeons organize obligatory courses for residents in orthopaedic surgery at Voss and Oppdal similar to the well-known principles and advanced courses in fracture treatment by AO, which originally were localized in Davos, Switzerland.

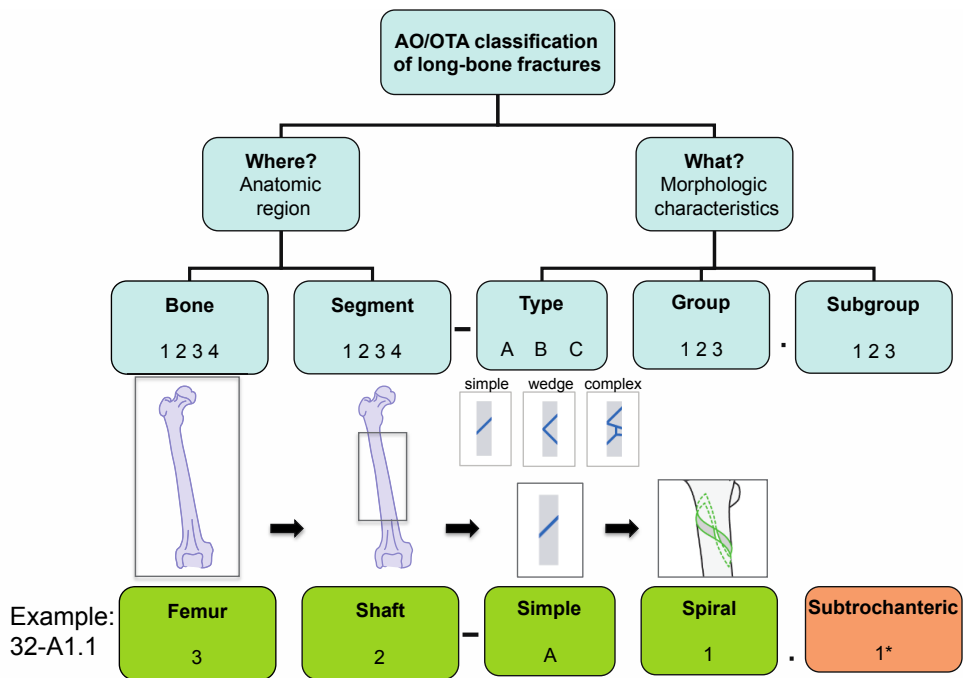


Figure 6. The Comprehensive Classification of Long Bone Fractures by Müller (Adopted by AO and OTA). Example Müller-code is given for a spiral fracture at the subtrochanteric region of the femoral shaft.

* The subgroup level is only used in subtrochanteric fractures in the registry (reproduced from Meling et al)¹⁷.

1.2 Local history – fracture treatment in Norway and Stavanger

Orthopaedic surgery developed in Norway from social aspects of orthopaedics¹⁸. Institutions for disabled and for patients with manifestations of tuberculosis in bones and joints were the first precursors of orthopaedic departments. The acute fracture treatment ('warm' orthopaedics) on the other side mostly took place at the surgical departments at the public hospitals. This differentiation into 'cold' and 'warm' orthopaedics was present until orthopaedic departments were established at the public hospitals. This long-lasting process started in Trondheim in 1959, and lasted for more than three decades (some minor hospitals still lacks separate orthopaedic departments). Even if a few fractures were surgically treated in the beginning of the 20th century, most fractures were conservatively treated in plaster cast or by long-lasting traction until 1960¹⁹. For the last 50 years great changes to treatment of almost all fractures have been made. New surgical methods have been constantly introduced (Table 1), however conservative treatment, consisting of functional bracing also increased in popularity.

	<i>Into general use around (Year)</i>
Intramedullary nailing	1955
AO-method	1965
External fixation	1965
Interlocking nailing	1980
Functional treatment	1980
Fixation of columnar fractures	1985
Angular stable screws	2005

Table 1: Major trends in fracture treatment in Norway²⁰

The methods and devices have become more customized and sophisticated. The last decade the introduction of angular stable screws and the pre-shaped plates have contributed to a tremendous increase in the numbers of different operation sets available for fracture treatment. Simultaneously, the proportion of hot orthopaedics gradually increases according to hospitalized patients and operations. The constant delays and unpredictability of cold orthopaedic operations have once again resulted in a desire to separate hot and cold orthopaedics. Simultaneously, the desire to present especially dedicated and experienced surgeons to the patients have become an important issue. Consequently subspecialisation in the orthopaedic field is inevitable.



Figure 7. Sandnes Hospital about 1950. Credit: K.Rostrup - Sandnes i bilder 1951

In the county of Rogaland, Sandnes Hospital was, from 1954, the special entity for orthopaedic surgery (Figure 7) ²¹. But, most of the fracture treatment was carried out at the surgical departments at the public hospitals. When the Rogaland Central Hospital (Figure 8) was substantially enlarged in 1982, finally both hot and cold orthopaedics was carried out at the same department. Since 2002 the department has been sectioned. Consequently, the more complex fractures are treated by specialty trained and experienced trauma orthopaedic surgeons.



Figure 8. Stavanger University Hospital (Until 2005 Rogaland Central Hospital).

Photo: Svein Lunde, SUH.

1. 3 History of orthopaedic registries

National registries of arthroplasty have been developed in many countries²²⁻²⁴. On-going registration of the surveillance ensures guidelines for the methods and implants to be chosen and, which ones to be avoided. A similar registration would be valuable for choosing the right method and fixation devices during fracture treatment. National health-economical registration like the ICD-9 and -10 and NCSP registration are readily available, but have both questionable quality, and fails to provide sufficient stratification regarding treatment options^{25, 26}. National Hip fracture registries have been established in Sweden (1988) and in Norway (2005)^{27, 28}. These registries only include hip fractures. Registries including all fractures or at least all long bone fractures are scarce. The registration of all fractures occurring in the region of Edinburgh, Scotland has been documented²⁹. Another important registry is the Victorian State Trauma Registry which collects all major trauma to the major trauma centres in the state of Victoria, Australia³⁰. Due to the definition of major trauma most of the fractures will not be registered in the latter registry.

1.4 The Fracture and Dislocation registry of Stavanger University Hospital

Funded on the desire of senior orthopaedic surgeon Trygve Søvik of sorting the fractures according to the fracture morphology and the treatment, the fracture registration started of all in-hospital managed fractures in the department of orthopaedic surgery at Stavanger University Hospital in 2004. The surgeon in charge of each fracture treatment reported consecutively the AO-classification and the Gustilo-Anderson classification of open fractures into the operation protocol. The data were consecutively digitalized into an Access database. For quality control of the treatment the reoperations and the reasons for the reoperations were registered as well. From June 2004, the quality of the data in the registry has been verified by one orthopaedic surgeon, Terje Meling. From 19th of June 2006, all registrations to the registry have been digitally reported by the surgeons, into the operation program

ORPlan. This program includes a fracture and dislocation module where all the data to the Fracture and Dislocation Registry (Registry) are registered (Figure 9).

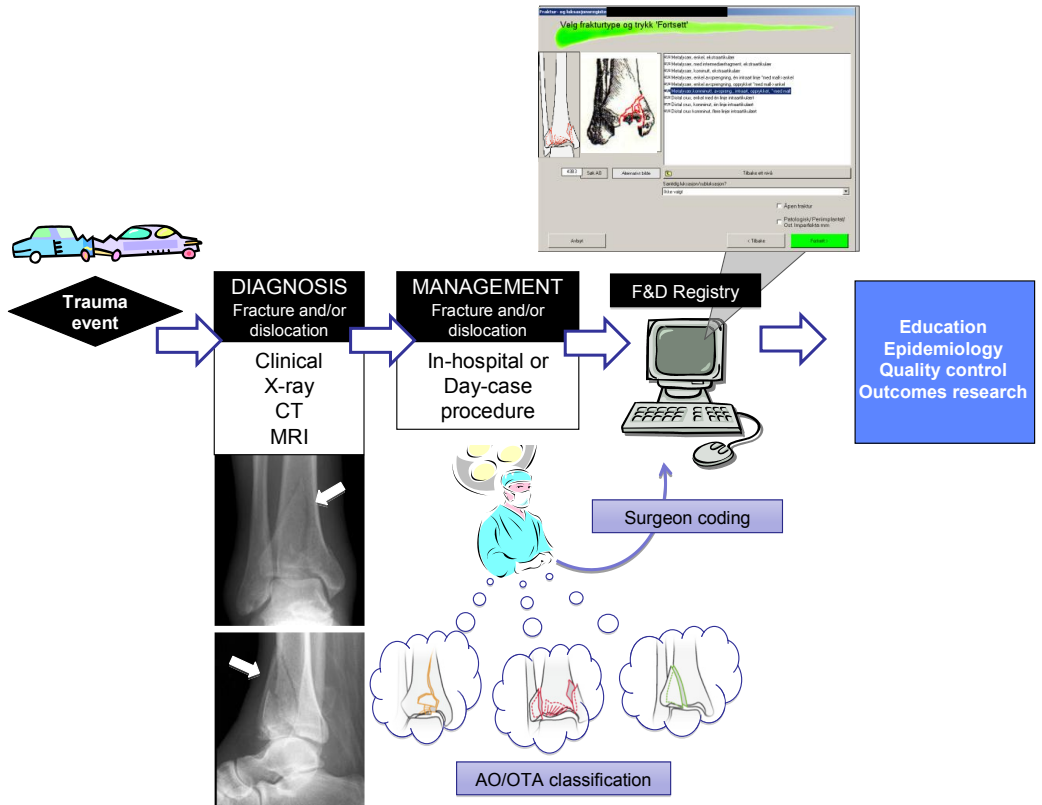


Figure 9. Flow chart of Registry use. Flow chart of the use of the Fracture and Dislocation Registry in the orthopaedic department (reproduced from Meling et al)³¹.

2. Objectives

2.1 Main goals

Establish a prospective and valid population-based fracture registry to allow for quality assurance and improvements in fracture management in a defined catchment area.

2.2. Secondary objectives

- 1: To describe the establishment, implementation and maintenance of the registry.
- 2: To describe the epidemiology for age and gender distributions of in-hospitally managed long bone fractures.
- 3: Investigate the reproducibility and accuracy of the Müller classification of long bone fractures in adult fractures in a fracture registry setting.
- 4: Investigate the reproducibility and accuracy of the Müller classification of long bone fractures in childhood fractures in a fracture registry setting.

3. Patients and methods

3.1 Study population

The study population has been the same for all of the studies as well as for the registry; the population in the catchments area of Stavanger University Hospital (SUH). SUH serves as the only primary trauma and emergency care facility for a mixed population of about 317,000 inhabitants (index year 2008; Norway Statistics) in the South-Western part of Norway (Figure 10), which allows for population-based assessment and analysis of trauma and emergency conditions³²⁻³⁵. The SUH orthopaedic department, in principle, covers all aspects of general orthopaedic trauma and non-trauma orthopaedic surgery for all age groups, with some exceptions (e.g. complex fractures of the pelvic ring and the acetabulum, fractures and dislocations of the face, head, neck, complex fractures of the hand and some of the fractures of the thoracic and lumbar spine). The primary catchment area has an urban: rural ratio of about 5:1³². While having a growing population, the SUH serves as the only primary health care facility for the population under investigation and, thus, providing for reliable incidence and epidemiological investigations of disease in this region over time. Consequently, the study population should be well representative of other Western, non-metropolitan, mixed urban/rural regions.

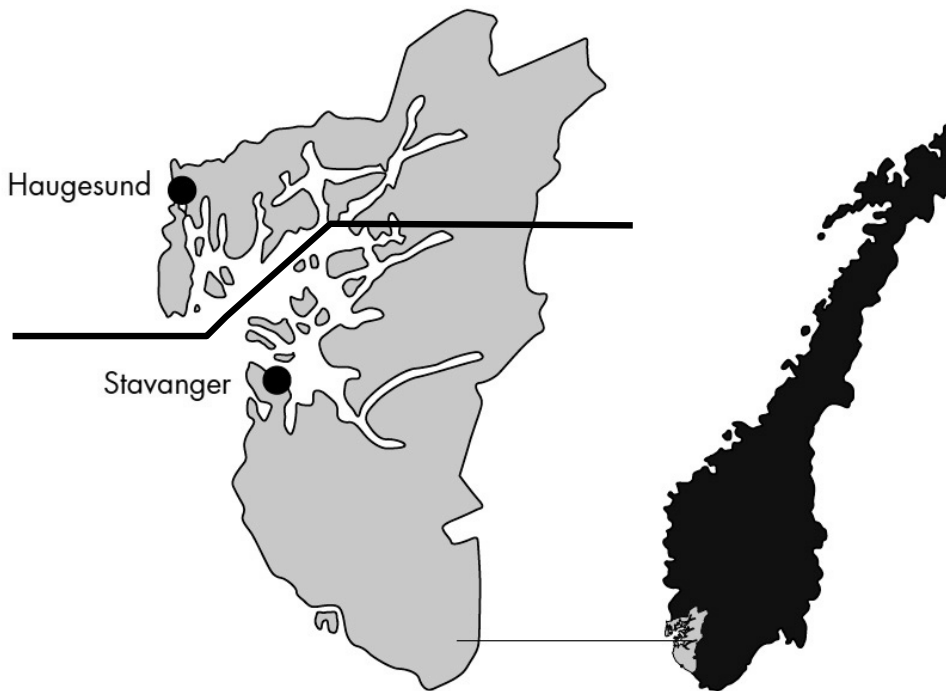


Figure 10. The southern part of the county Rogaland. The catchment's area of Stavanger University Hospital. Reproduced with permission from: Emerg Med J - BMJ Publishing Group Ltd and the College of Emergency Medicine ³⁶.

3.2 Inclusion and exclusion criteria

Starting 1st of January 2004 all inpatient procedures to fractures and dislocations by orthopaedic surgeons were included in the Fracture and Dislocation Registry at SUH. Patients of all ages were included. Patients living outside the region, but treated at SUH were not excluded to the registry. Day case procedures were also included, starting 19th of June 2006. All kind of secondary procedures to fractures and dislocation were also included. Procedures made at the emergency department (ED), like casting with or without reduction, were not included. Closed reduction and plaster casting of children's fractures are most often done under general anaesthesia,

thus included to the Registry. For this PhD-thesis, we restricted the focus to include only long-bone fractures to allow for a more focused search and analyses.

Study I included all registrations to the Registry during the time period of 19th of June 2006 until March 10th 2010. Study II was limited to the primary treatments of long bone fractures treated in the time period of 1st of January 2004, until 31st of December 2007. Included in the study III and IV were the primary treatments of the long bone fractures in 2008. Adult and paediatric fractures differ considerably; the paediatric skeleton is softer and more Study III were restricted to patients 16 years of age or more, while Study IV were restricted to those less than 16 years of age. The reasons for the splitting of the data were related to the differences in fracture appearances, treatment and prognosis and the fact that separate classification systems are available for paediatric fractures.

3.3 Study design

The first and second studies represent prospective, observational cohort studies based on patients recruited from a defined catchment area. These studies focus on implementation, completeness and epidemiological data obtained from the registry.

Study III and IV represent studies evaluating the use of scores for traumatic long-bone fractures. Specifically, the inter- and intrarater agreements are assessed for adult and paediatric fractures, respectively. Their accuracy in a routine clinical practice is evaluated as well.

3.4 Data collection

Age and gender of the patient, fracture type and location, the kind of treatment and the reasons for the secondary operations were reported in addition to well-known fracture classifications (AO/OTA and Gustilo-Anderson). The surgeon involved made the reporting consecutively in the electronic, hospital system-integrated operation planning program (ORPlan).

Quality of each parameter was ensured by extensive use of tool tips and by reporting all the parameters in digital scroll-down menus. Stepwise coding of the fracture classification was done of the same reason; first the fractured bone was chosen (e.g. the humerus), secondly the bone segment involved was chosen (e.g. the shaft). Finally the AO/OTA-type and AO/OTA-group was selected by choosing the most appropriate definition for each AO/OTA-group. At the same time, illustrations of each chosen AO/OTA-group was presented by the program (Figure 11). Once the computer knew the AO/OTA-code and the fixation method that was used, the program suggested the diagnose (ICD-10) and the procedure code (NCSP).

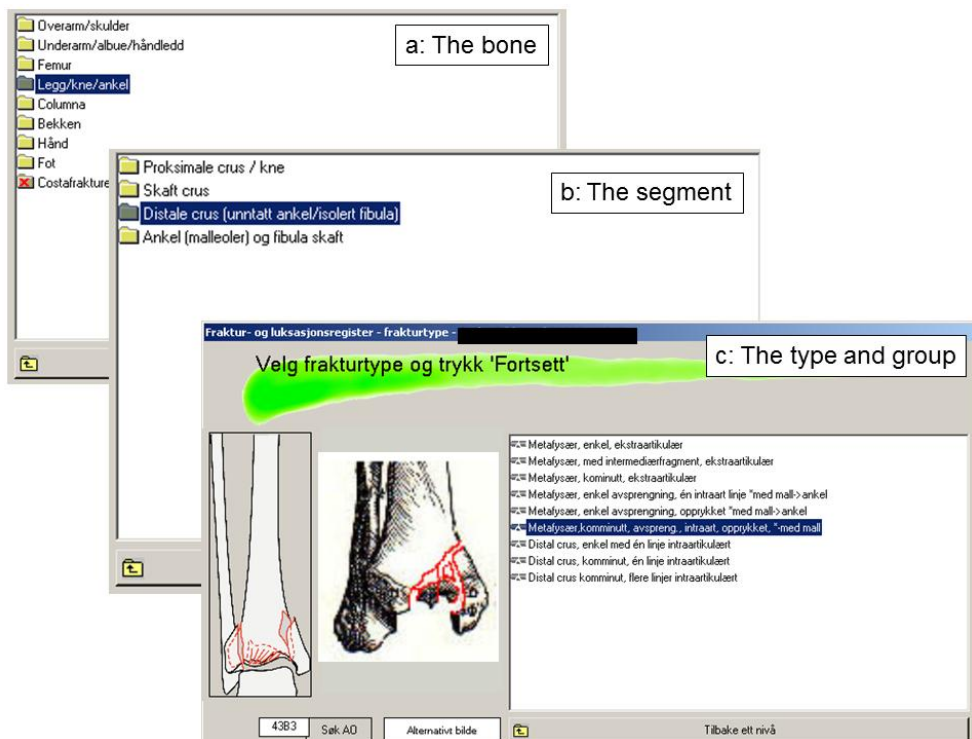


Figure 11: The classification setting process. First the classifiers choose the fractured bone (a), then the segment (b) and finally the type and group (c).

Study I: The data were obtained from the Fracture and Dislocation Registry.

Study II: The data were extracted directly from the Fracture and Dislocation Registry. Population statistics were collected from Norway Statistics ³².

Study III and IV: The initial classification code was obtained from the Fracture and Dislocation Registry. The intra- and interrater codes were collected in a separate module in the ORPlan program. The involved surgeon and the controller re-classified the fractures in the same way as initially (Figure 12). Albeit during the first classification setting the surgeons had very good intraoperative knowledge of the fracture. Consequently the surgeons were allowed to watch both pre- and

postoperative x-rays and read the operation notes during the second classification setting.

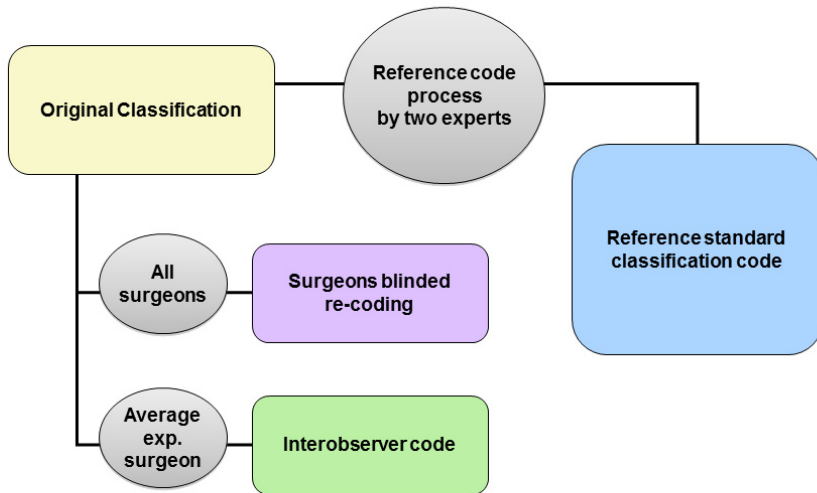


Figure 12. Overview of the classification datasets in study III and IV. (Reproduced from Meling et al)³⁷.

3.5 Ethics

The registry has been reported to the Norwegian Social Science Data Service (NSD). (Project nr 15090). The regional Ethic Committee has decided that the studies did not need any special approval; it is considered as quality assurance and general description of the procedures made by the department.

3.6 Data analysis and statistics

The statistical analysis was performed using the Statistical Package for Social Sciences (version 15.0, SPSS Inc., Chicago, IL, USA). Comparison between categorical variables was performed with binomial or chi-square (2x2) test. All statistical tests were two-tailed, and the significance level was set at $p < 0.05$. The data were reported with 95% confidence interval (95%CI) where applicable.

Study I and II mostly presented descriptive data, and did not involve statistical analysis.

Study III and IV presented the intra- and interrater reliability using Cohen's Kappa (kappa agreement) and percentage of agreement (PA) for adult and paediatric long bone fractures, respectively. Interpretation of the Kappa was performed according to the guidelines of Landis and Koch (Table 2). Uni- and multivariate analysis was performed with logistic regression, and were given as odds ratios (OR) with 95% CI. The variables with the smallest contribution were stepwise excluded until all remaining variables contributed significantly to the agreement.

<i>Value of κ</i>	<i>Strength of agreement</i>
0.81 – 1.00	Excellent
0.61 – 0.80	Substantial
0.41 – 0.60	Moderate
0.21 – 0.40	Fair
0.01 – 0.20	Slight
< 0	Poor

Abbreviations denote: κ , kappa coefficient

Table 2. The guidelines for the interpretation of the kappa coefficient according to Landis and Koch

4. Summary of results

4.1 Study I

This study was initiated to serve as a guide for other departments to make their own fracture registry. It described the initiation, introduction, maintenance and the feedback/ control of the registry. The content of the registry according to number of registrations and the involved parameters are roughly presented. During the study period (June 2006 until March 2010) practically all 39 orthopaedic surgeons in the department recorded 4,986 long bone fractures, 467 non long bone fractures, 123 dislocations and 2612 secondary treatments. A total of 532 fractures or dislocations were treated at least once for one or more serious complications. Approximately 28% of the fractures that were diagnosed either at the ED or in hospitalized patients were treated at operation rooms under anaesthetic assistance thus registered in the Registry.

4.2 Study II

This study was conducted to present the incidence of inhospitally managed long bone fractures in the well-defined catchment's area of SUH according to age and gender. A total of 4890 long bone fractures were recorded in the study period (2004-2007). The incidence per 100,000 per year was 406, the corresponding 95% confidence intervals (95%) were 395-417. A bimodal distribution of fracture incidence according to age was found. The first peak appeared in children. An increased fracture incidence occurred among both sexes until about 11 years of age. Then the girl's fracture incidence dropped to a steady state at 16 years of age. The incidence of fractures among boys increased until the age of 15, before dropping to a steady state at 20 years of age. The second peak consisted of a logarithmic increase in fracture incidence after the age of about 60 in females and about ten years later in males. More or less fractures of all long bone segments in females contributed to the peak, whereas only hip fractures contributed among male citizens. The distribution between

the fractures in each gender differed significantly from male:female ratio of 2:1 before the age of 50 to 1:3 for those older than 50 years. Only 3% of the fractures were considered open. We found a significant increase in the application of angular stable plates during the study period. The children's fractures were most often treated with closed reduction and plaster cast application. Only 8% of the children were given internal fixation, compared to as much as 56% of the adult cases.

4.3 Study III

The third and fourth studies were done to evaluate the reliability and accuracy of the Müller classification among the surgeons in the registry. A total of 26 surgeons classified 949 long bone fractures during the study period. Intrarater analysis showed an overall agreement of $K=0.67$ (95%CI: 0.64-0.70) and a PA of 69%. For the corresponding interrater analysis; $K=0.67$ (95% CI: 0.62-0.72) and PA of 69%. Accuracy of surgeons' blinded re-coding was $K=0.68$ (95%CI: 0.65-0.71) and PA 68%. Coder's experience did not seem to significantly influence accuracy. Fracture type, frequency of the fracture, and the segment involved did influence the accuracy of coding.

4.4 Study IV

During the study period 232 fractures were reported in the study. Overall agreement in the intrarater assessment were $K=0.75$ (95% CI: 0.68-0.81) and PA 79%. Interrater analysis revealed $K=0.71$ (95% CI: 0.61-0.80) and PA 77%. The results of the accuracy estimation were $K=0.72$ (95% CI: 0.64-0.79) and PA 76%. The variables that significantly influenced the accuracy were the frequency of fractures occurring in each fracture group, complexity of the fracture, and segment involved in the fracture. The coder's experience did not significantly influence the accuracy.

5. Discussion

5.1 General discussion

Injuries are worldwide concern in public health (Figure 13). There has been a reduction in the rates of injury in the high-income countries, but rates from the low- and middle-income countries have increased in part due to increased use of motorized transport³⁸. Road traffic accidents were the ninth most important factor of both mortality and burden of disease (2004 statistics)³⁹. Road traffic injuries are believed to be the fifth leading cause of death in 2030⁴⁰.

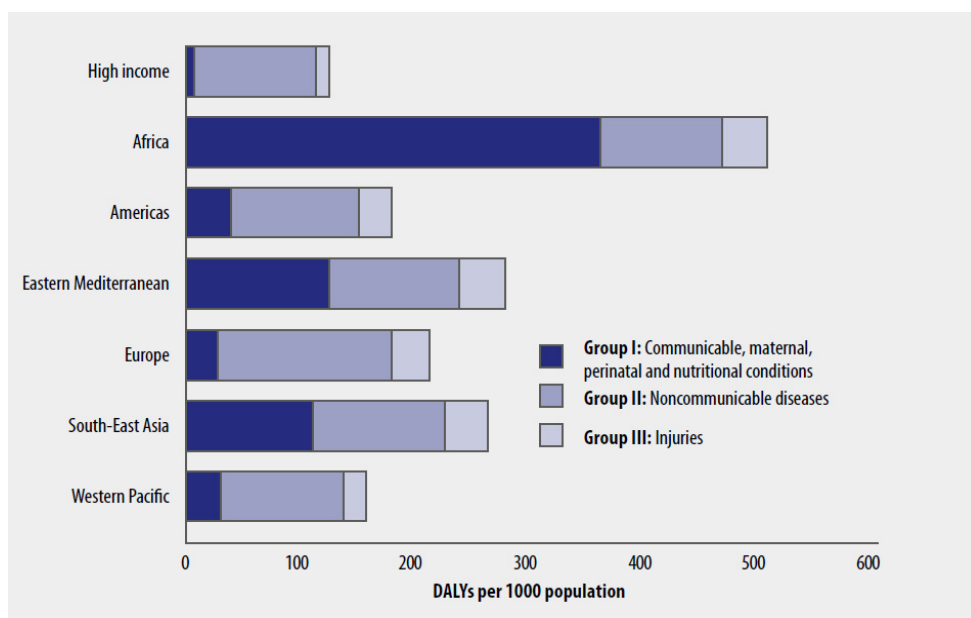


Figure 13. The burden of disease by broad cause group and region. The figure shows that injuries constitute a considerable health concern globally, especially in middle income countries. DALYs: Disability Adjusted Life Years. Reused with permission. The global burden of disease: 2004 update World Health Organization (WHO), 2004³⁹.

5.2 Trauma epidemiology

Injuries occur in all categories of severity. Very often the impact of trauma to the society is underestimated because the models are often based only on data from one of the following sources; general practitioners, emergency departments, hospital admissions or mortality data (Figure 14) ⁴¹.

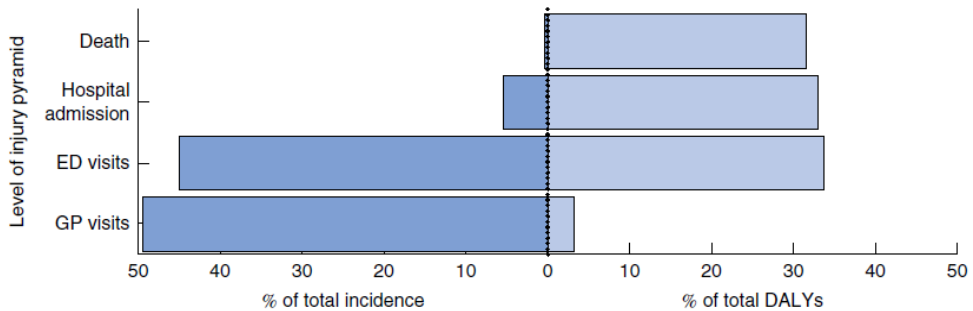


Figure 14. Levels of severity according to the different sources of unintentional injury. Percentage of total incidence and disability-adjusted life-years (DALYs) for unintentional injury by level of the injury pyramid. ED; emergency department, GP; general practitioner. Reused with permission – Polinder, S. Epidemiological burden of minor, major and fatal trauma in a national injury pyramid/ Br J Surg/ John Wiley & Sons Ltd ⁴¹.

5.3 Fracture epidemiology

Defining a fracture is believed to be easy; consequently finding the fracture incidence in a population should be relatively straightforward. Surprisingly the task is more difficult than expected ⁴².

Some fractures will not be detected because they are not referred to radiological examination: Fractures of the ribs are mostly clinically diagnosed, consequently not registered in x-ray files. Degenerative compression fractures of the vertebrae are extremely often present in the eldest part of the population although the patient and the doctor may not be aware of the fractures ^{43,44}. It is more or less part of the

degenerative process. Fractures of the fingers and toes are sometimes diagnosed by x-rays at the dentists' offices, and other times not visualised at all.

Fractures may run through several bones in the hand or foot or through several ribs or vertebrae; thus are the source of a counting dilemma; should each of these fractures be counted? ⁴⁵ E.g. very often all metatarsal bones are broken simultaneously.

Relatively frequently these fractures are combined with fracture-avulsions of the cuneiforms or the phalangeal fractures etc.

Diagnosing dislocated fractures may be easy, but non-displaced fractures can be hard to separate from fissures or bone marrow oedema in magnetic resonance imaging ⁴⁶. Counting bony avulsions of different sizes may also be of limited value.

Some fractures do not need any treatment, others can be extremely disabling. Depending on the focus rather different epidemiological data could be of interest; for general practitioners and emergency department workers every fracture might be of interest. Orthopaedic surgeons pay more attention to those needing operative treatment. During the last decade increasing focus has been put into osteoporotic fractures, consequently such studies only deal with fractures in the elderly population. The children's fractures are very often omitted.

The method of collecting the data differs considerably ⁴¹. The studies that present the highest incidence of fractures are studies where the researcher ask their participants how many fractures they have experienced ⁴², some studies are based on the diagnose reported by general practitioners (Figure 14) ⁴⁷. Others studies do retrospectively search through the radiological archives or the patient journals for diagnosed fractures ⁴⁸. Others have prospectively collected the fractures occurring in emergency departments ⁴⁹. The most readily available data derives from health economically motivated registration ^{50, 51}.

In this PhD thesis only the fractures that were treated at the operation theatre are included. Study II revealed that around 28% of the fractures that were diagnosed in the emergency or orthopaedic department were treated at the operation theatre, consequently included in the Registry. The amount is comparable to what was reported from Trondheim⁴⁹. One important confounder using this selection is that the indications for treatment differ considerably between different countries, departments and even between orthopaedic surgeons in a department. Consequently, different incidences may be related to different indications for surgery rather than difference in occurrence of fractures. Regardless this problem, there has to be a selection to identify the fractures that are of interest for orthopaedic surgeons.

Long bone fractures are nearly always the task of all orthopaedic departments. Non-long bone fractures like fractures of the hand, ribs, neck etc. may be treated by non-orthopaedic surgeons. Therefore, we did not focus on the non-long bone fractures in the thesis albeit they are included in the Registry. Actually the occurrence rate of long bone fractures in an area appears to be one of the most sensitive methods of measuring, as a proxy, the clinical injury incidence of the area⁵².

The bimodal distribution of fracture incidence according to age found in study II⁵³ was already presented 50 years ago⁵⁴. The reason for the first peak is probably due to the high activity level behaviour of children and especially among male adolescent. The appearances and incidences of fractures in children also depend upon the maturity of the ligaments, physal plate and skeleton. The bone, which is more elastic, are more easily plastically deformed rather than broken apart. Along with the thicker periosteum it gives rise to the appearances of bowing, torus or greenstick fractures. Moreover the physal plate is during adolescence more easily torn than the mineralized bone⁵⁵. Therefore fractures like those found in the ankle are almost non-existing until completion of bone maturation (Study II, figure 3D)⁵³. More or less fractures of all long bone segments in elderly females contributed to the second peak, whereas only hip fractures contributed among male citizens (Study II, figure 4)⁵³. Osteoporosis likely explained the increased incidence. But it is still unknown why

there were reported about ten times higher incidence of distal radial fractures in elderly women compared to elderly men ⁵³.

5.4 Prospective registry

Although Randomized controlled studies (RCT) are the best way of investigating different treatments, the RCTs certainly have disadvantages: Consent of the traumatized patients might be difficult and sometimes unethical to provide ⁵⁶. Blinding both of the patient and the surgeon is very often not possible due to the visible operation wounds/scars or implants. RCTs are only suitable for limited patient series (too expensive) over a limited period of time. Side effects very often occur relatively infrequently; therefore they are often not discovered in RCT studies ⁵⁷. Further interpretation of the results may be difficult to perform if the fractures and patients are not similar in the RCT and in the population of interest. To fulfil the need of a certain number of similar fractures, the fracture type that is of interest has to occur relatively frequently, which is most often not the case. Consequently, the best feasible way of monitoring the quality of the treatment is by an on-going registry ⁵⁶. However, collecting data in a registry is only valuable if the data is continuously critically analysed and made available.

5.5 The selection of the registry parameters

The prospective registration has to be manageable and of good quality, therefore limited amount of parameters are included. The reporter has to be well informed and motivated at the timing of the registration. Immediately after the operation, the surgeon in charge of each operation sits down to make his operation note for the patient journal. This is the time chosen for the registration to the Registry, a time when the surgeon really knows the fracture and the treatment (Figure 9). The surgeons are often not aware of or don't remember the injury mechanism at that time consequently the injury mechanism is not reported to the Registry even if it is the

basic parameter for understanding why fractures occur and how the fractures can be prevented. The registration, however, should preferably be reported at a time when the person registering is aware of the trauma mechanism, and the patient is available for questioning, preferably at the emergency department. Moreover the Registry is more focused on the inhospital treatment rather than the prevention of the accident.

5.6 Quality measurement of the fracture treatment

Monitoring the quality of the fracture treatment require at least one parameter that describes the outcome of the patient. Examining, or at least telephone interviewing all patients and scoring them after specifically designed quality of life forms are desirable. However, because of limited resources the registration of the numbers and reasons for the reoperations are used as quality measurement of the treatments registered. Patients having their reoperations in other clinics are not reported to the local registry. However, the catchments area of SUH is well defined and the dropout of patients is believed to be rather small for this kind of treatment. A national fracture registry would have been interesting, collecting more fractures and complications. However, the uncertainty of the quality and completeness of the registration will be cause for concern.

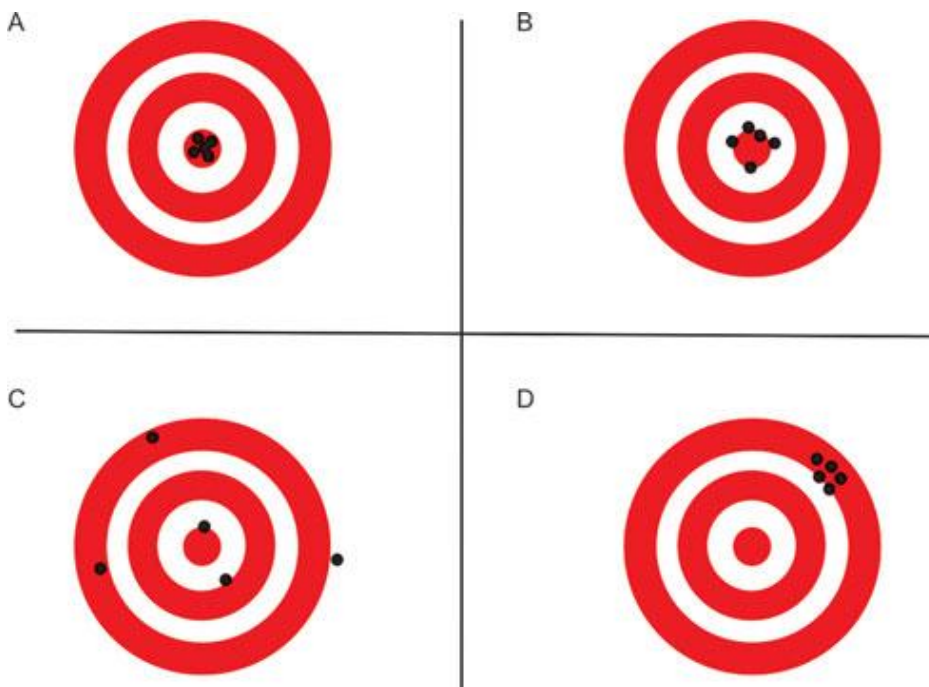
5.7 Fracture classification systems

Epidemiological data of fractures are reported according to different classifications^{29, 42, 47, 49, 54, 58}. For orthopaedic surgeons, categorizing the data according to a comprehensive but still sufficiently detailed, well-known and well-defined classification is beneficial. ICD-10 classification is comprehensive albeit the definitions are weak, leaving grey zones of fractures between each category. Moreover it does not give enough stratification for treatment allocation²⁶. Several more detailed classifications are available for segments of the skeleton, like Neer classification for proximal humeral fractures, Garden classification for fractures of

the femoral neck, Schatzker classification for proximal tibia fractures, Gartland classification for distal humeral fractures in children and Salter Harris classification for fractures through the growth plate^{55, 59-63}. However, the classification in a registry has to be comprehensive; cover all the fractures, and also deal with definitions that define each segment from each other. The AO/OTA classification appears to be the only suitable comprehensive classification, giving enough stratification for treatment allocation (Figure 6). Gustilo-Anderson classification for open fractures is comprehensive, quite well defined and well known, and indicates the prognosis of the fractures, but has to be coupled with an anatomical classification to be useful^{64, 65}. In the registry both the AO/OTA classification and the Gustilo-Anderson classification were registered.

5.8 Validation of the classification

To compare treatment methods and outcomes, a valid fracture classification system is required⁶⁶. Compared to former studies⁶⁷⁻⁶⁹, the intra- and interrater reproducibility of the Müller classification, as used in the registry, is good, as presented in study III and IV^{17, 37}. However, as demonstrated in figure 15 good precision does not implicate good accuracy⁷⁰. Therefore we made a reference dataset that were compared to the other datasets to measure the accuracy of the classification. This measurement demonstrated the same, high level^{17, 37}.



*Figure 15. The bulls eye analogy of accuracy and precision (= reproducibility). Accuracy is pictured by how well the bullets hit the bulls eye, precision is given by how close the bullets are assembled together. The figure demonstrates in (A) perfect accuracy and precision; (B) fair accuracy, but reduced precision; (C) poor accuracy and low precision, and (D) poor accuracy, but high precision. Reproduced with permission from: *Ann Surg – Wolters Kluwer Health*⁷⁰.*

The grey zone with uncertainty between each category in the classifications will always be present¹⁶, as will the uncertainty of how each fracture best could be treated. Clear and synonymous definitions are crucial for reliability because it reduces the grey zones, which are most often the case of the Müller classification. Sufficient stratification in the classification for treatment allocation is on the other hand important for the utility. The Müller classification does not generally consider the level of displacement of the fractures, which promotes the reliability but compromises the utility¹¹. In the same way the child specific fracture patterns are not included for children's fractures. The latter is the reason why child specific

classifications are presented by the AO and Li-La foundations^{71,72}. However, introducing a separate classification in the Registry for the relatively infrequent paediatric fractures may result in significantly reduced scoring reliability. Despite the substantial to excellent kappa agreement considering the Müller classification in the paediatric fractures the classification may be less useful because the classification does not stratify the fractures enough to guide the surgeon in the choice of treatment. E.g. torus fractures (fractures without discontinuity) are more stable than greenstick fractures (discontinuity of the cortex on the distraction side of the bone), consequently requiring less stable fixation⁷³.

The reliability and accuracy measurements presented in study III and IV have to be interpreted with caution. Kappa statistics is sensitive to the number of possible categories, the distribution of fractures in those categories (the prevalence index)⁷⁴ and the symmetry of the contingency table (bias index)⁷⁴. Another problem with Kappa statistic is that it does not take into account the degree of disagreement, as weighted Kappa does. The weighted kappa cannot be applied because the overall classification is not ordinary arranged⁷⁵. The kappa that is appropriate for a classification also depends on the purpose of using the classification.

The most frequently fractured segment among children was the distal forearm. Second most commonly affected was the antebrachial shaft. Many fractures in children have their centre on the border between these two segments, resulting in reduced reliability.

The rule of the square defines if the fracture is located to the shaft or to the end segments. The rule of the square of Müller considers both bones and is defined according to the most distal part of the radius. Unfortunately, this part of the bone is not calcified in the children. Consequently it is difficult to use the definitions. The metaphysis of children's bones seems to be relatively wider (and the shaft seems to be shorter) than in adult bone. The definition in the AO-Paediatric classification did find greatly improved reliability when defining the physeal plate as the distal portion

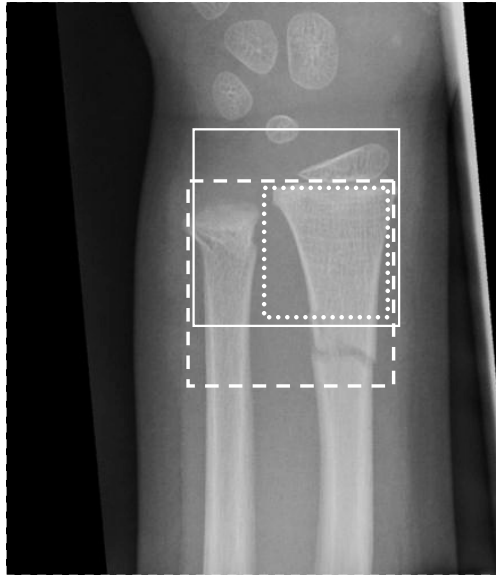
for the square, resulting in a wider metaphyseal portion of the bone, thus a greater portion of fractures were defined as distal forearm fractures⁷⁶. The rule of the square of Li-La, which has been used in the Registry, defines the distal portion according to the width of the radius only, and using the distal radial physal plate as the distal reference point. The different rules of the square are illustrated in Figure 16.

5.9 External validity

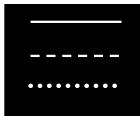
SUH serves as the only facility for primary and secondary treatment of long-bone fractures in the well-defined population in the South-Western part of Norway (Figure 10). The urban: rural ratio in the region is about 5:1. Thus the region and the epidemiological data of the registry might be compared to and largely represent other western, non-metropolitan populations. However, local traditions and different opinions among the involved surgeons about which fractures that need treatment at the operation theatre will likely affect the numbers reported.

The reliability and accuracy of the AO/OTA classification will depend on how the classification process is performed. Probably essential for the reliability are the use of scroll down menus, and the simultaneous presentation of the corresponding illustrations of the selected fractures, as presented in Figure 11.

Forearm shaft?



Distal forearm?



The rule of Müller (adult)

The rule of the AO-classification for children

The rule of Li-La classification and for this study

Classification system	Reference line	Defined by one/two bones
Müller	The most distal (or proximal) part of bone	Both bones
Li-La	The epiphyseal plate	One bone
AO-pediatric	The epiphyseal plate	Both bones

Figure 16. The rule of the square: 'The proximal and distal segments of long bones are defined by a square whose width are the same length as the widest part of the epiphysis' (Müller et al. 1990)¹¹. The x-ray illustrates the application of the different rules of the square in a relatively common fracture type in children. The table highlights the difference in definition between the classifications. (Reproduced from Meling et al)³⁷.

6. Conclusion

All the 39 involved surgeons at the Department of Orthopaedic Surgery at SUH were reporting to the registry during the study period in study I. Compliance and completeness were made possible by the electronic system and the data controller. A total of 28% of the patients that visited the ED or were hospitalized for fractures or dislocations were treated at the inpatient or day-case operation rooms, thus registered in the Registry.

Slightly more than 1200 long bone fractures were registered yearly during the study period of Study II. This corresponds to an incidence of 406 long bone fractures per 100,000 person years. The male/female ratio was approximately 2:1 for patients younger than 50 years of age and 1:3 for those older than 50 years of age because of the exponentially increased incidence of fractures with age in the female population. The dominating fracture treated in the elderly patients was the proximal femur fracture, whereas in children the distal and the shaft segment of the forearm dominated.

According to other studies and to the most widely used guideline the reliability and accuracy of the Müller classification were substantial to excellent as used in study III and IV. However, the usefulness of the stratification in the Müller classification when applied to children's fractures is disputable.

The fracture and dislocation registry has been welcomed by the orthopaedic surgeons at SUH. Compliance and completeness in the registry have been excellent, the accuracy of the classification is good, and the registry and the long bone fracture incidence are presented in recognized journals. A solid basis for quality assurance and improvement in fracture management is certainly made through the registry.

7. Areas of future research

The important mission doing this PhD thesis has been to prepare the Fracture and Dislocation Registry for future research. A large number of prospectively collected data are ready for evaluation. First of all the registered complications and their clinical cause should be disseminated according to the fractured segment, type and group, the kind of treatment, the age and gender of the patient, the level of experience of the surgeons, the time of the day and the time-to treatment.

Second, the Registry is and should be used by other researchers to identify groups of patients that are further evaluated in initiated retrospective follow-up studies.

Third, the Registry is a strong tool for calculating the number of patients which may be needed to provide appropriate statistical power in any future prospective studies.

Fourth, the scope of the Registry is to monitor epidemiological time trends in fracture treatment and changes in the incidences of different fracture types.

Fifth, yearly data reports of the main parameters in the registry should be available for the department, and also for the population in the area.

Sixth, there is a desire to extend the registration to the whole region, or maybe even to the whole country. Essential for this mission is the operation program, which would need to be fully prepared for other departments. In that case software backup staffing has to be organized. The involved departments need to change their operation program. Involved surgeons need some teaching. Most importantly, dedicated persons are needed to motivate and correct the involved surgeons in every department.

Seventh, cooperation and connection of the Registry to some of the national registries, may lead to further analysis: Data from the Cause of Death Registry may be considered during the analysis of the quality of the fracture treatment. Data from the Norwegian Hip Fracture Registry and the Norwegian Arthroplasty Registry may elaborate data from Hip fractures in the Fracture and Dislocation Registry. Data from the National Population Register can be interesting regarding reports considering for example the apparently high occurrence rate of fractures among foreign workers. Cooperation with the local trauma registry at SUH may be beneficial considering multitraumatized patients. Finally, data from the local emergency department registry may be helpful to analyse the outcome of conservative vs. operative treatment.

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