STUDIES OF TIBIAL FRACTURES USING THE SWEDISH FRACTURE REGISTER

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ABSTRACT

This thesis has two topics. First, the creation and application of the Swedish Fracture Register (SFR) is described. Second, a series of studies of tibial fractures based on data from the SFR follows.

Until the start of the SFR, there was no previous national fracture register with prospectively collected data on fractures of all types, treated surgically as well as non-surgically. In this thesis, the construction and implementation of the SFR is described (Study I). The validity of tibial fracture classification upon registration in the SFR is evaluated (Study II). The epidemiology and incidence of tibial fractures treated at Sahlgrenska University Hospital during a period of five years are described (Study III). In the last study, the treatment and re-operation rates for tibial fractures in the same cohort are analysed and described (Study IV).

Study I: The study demonstrates that the SFR is already a well-functioning, population-based fracture register that prospectively collects data on fractures of all types, regardless of location and treatment. The main outcomes are re-operation rates and patient-reported outcome measures (PROMs). In 2019, 42 of Sweden's 55 orthopaedic departments were affiliated to the SFR. This means that the SFR covers more than 75% of the inhabitants in Sweden. In March 2019, the SFR contained data on more than 365,000 fractures.

Study II: In this study, three experienced trauma surgeons (raters) were presented with the radiographs of 114 patients with tibial fractures randomly allocated from the SFR. The raters classified the fractures independently and were blinded to clinical patient information in two classification sessions with a time interval of four weeks. The AO/OTA classification coded by the three expert raters (the predefined gold standard) was compared with the classifications in the SFR.

The accuracy of the classification of tibial fractures in the SFR, defined as agreement (kappa value) between the SFR and the gold standard classification, was 0.75 for the AO/OTA type and 0.56 for the AO/OTA group, corresponding to substantial and moderate agreement respectively.

Study III: Study III describes epidemiological data on 1,371 tibial fractures in 1,325 persons. Approximately 50 persons per 100,000 inhabitants a year sustain a tibial fracture. Among women, the incidence of tibial fractures in all segments of the tibia increases with age, whereas men have a flat incidence curve, except for tibial shaft fractures, which displayed a peak among young males.

Study IV: The study comprised 1,371 tibial fractures – 712 proximal, 417 diaphyseal and 242 distal fractures. Sixty-six per cent of all tibial fractures were treated surgically. Almost 30% (29.8%) of all surgically treated tibial fractures underwent re-operation. The removal of internal fixation devices was by far the most commonly performed re-operation. The AO/OTA classes that had the largest numbers of re-operated fractures were 41C3 (46.0%), 42A3 (47.7%), 42B2 (45.8%), 42C1 (51.6%), 42C3 (47.1%) and 43A2 (40.0%). Re-operations due to non-union, malunion, infection and implant failure were more or less equally common.

To conclude, the SFR is a well-functioning, population-based fracture register that collects data on fractures of all types including surgeon- and patient-reported outcome. The accuracy of the classification of tibial fractures in the SFR is acceptable. Data from the SFR can be used to describe the epidemiology of fractures in detail. The re-operation rates after the surgical treatment of tibial fractures are approximately 30%. Re-operations due to non-union, malunion, infection and implant failure account for approximately half of re-operations and are more or less equally common.

SAMMANFATTNING (SUMMARY IN SWEDISH)

Denna avhandling har två teman. Först beskrivs hur Svenska frakturregistret (SFR) har byggts upp, samt hur det fungerar och används. Därefter följer en serie studier som avser underbensfrakturer baserat på data från SFR.

Svenska frakturregistret startades i Göteborg 2011. Det utökades snart och 2012 inbjöds samtliga ortopedkliniker i Sverige att delta. SFR är ett världsunikt register, som samlar in data avseende alla frakturer (benbrott) i hela kroppen, förutom skalle och revben, oavsett hur de har behandlats. SFR samlar in data som avser vem som skadat sig, vilken skademekanism som gav upphov till frakturen, vilken sorts fraktur det är, hur den har behandlats inklusive huruvida någon komplikation tillstöter och om frakturen har behövt opereras igen (reoperation). Alla patienter får dessutom i två olika enkäter (Eq5D och SMFA) först uppskatta vilken funktionsnivå och livskvalitet de hade innan skadan uppstod och senare fylla i samma enkäter ett år efter skadan. På så sätt kan patientens egen uppskattning av hur väl hon eller han har återställts efter skadan utvärderas. Första delarbetet i avhandlingen är en så kallad "database article" vilket är en artikelform som beskriver just databaser och register. Vi anser att SFR är en så stor nyhet i ortopedvärlden att vi beslutade att skriva en separat artikel om hur registret är uppbyggt, hur det har införts på de olika klinikerna, hur man registrerar, vilken sorts data som samlas in, hur arbetet för att fånga samtliga frakturer bedrivs och hur man kan använda registret för att få fram data både i det patientnära arbetet i vardagen och för forskningsändamål. Artikeln är därför en utförlig beskrivning av SFR och innehåller enbart översiktliga data för att ge exempel på vad registret innehåller. Numera är 42 av Sveriges cirka 55 ortopedkliniker anslutna till SFR vilket motsvarar cirka 75% av Sveriges befolkning. SFR innehåller i mars 2019 information om över 365 000 frakturer.

Övriga delar av avhandlingen är en serie av tre studier, som handlar om underbensfrakturer. När SFR startades fanns tydliga tankar om att man först bör genomföra studier som utvärderar tillförlitlighet och korrekthet i data i registret innan man gör studier på resultat efter frakturbehandling. Eftersom SFR är unikt, både i sitt slag, och hur man samlar in data med många olika användare som klassificerar frakturer och matar in data i registret, är det viktigt att utvärdera hur korrekta data i registret är. Viktigast är att utvärdera hur korrekt klassificeringen av frakturer i registret är. Första studien handlar därför om att utvärdera hur korrekt klassificerade underbensfrakturer i SFR är. 114 slumpmässigt framtagna underbensfrakturer från SFR klassificerades av en expertgrupp på tre traumaortopeder för att fastställa den "korrekta" klassificeringen av varje fraktur. Därefter jämfördes den ursprungliga klassificeringen i SFR med den korrekta klassificeringen. Det visade sig i denna studie att överensstämmelsen mellan klassificeringen i SFR och expertgruppen var lika god som den varit mellan två bedömare i tidigare, liknande studier. Detta trots att klassificeringen i SFR är gjord av en stor grupp läkare med varierande kunskap och erfarenhet.

Nästa studie på underbensfrakturer redovisar epidemiologiska data från en kohort av 1 371 underbensfrakturer hos 1 325 patienter behandlade vid Sahlgrenska universitetssjukhuset under fem år. Ungefär 50 personer per 100 000 invånare drabbas av en underbensfraktur årligen. Bland kvinnor ökar förekomsten av underbensfrakturer med ökande ålder, medan hos män ses jämn förekomst i olika åldrar. Underbensfrakturer orsakade av trafikolyckor är vanligare under sommarmånaderna medan de som orsakas av enkla fall är vanligare under vintermånaderna.

Den fjärde studien handlar om hur underbensfrakturer i samma kohort som den epidemiologiska studien behandlats och i vilken utsträckning de har behövt genomgå reoperation (opererats om). Reoperation är ett vanligt använt kvalitetsmått i ortopediska register. I denna studie på 1 371 underbensfrakturer behandlades en tredjedel icke-kirurgiskt med gips eller ortos (ortopediskt stödjebandage) medan två tredjedelar behandlades kirurgiskt. Cirka 30% av de opererade frakturerna behövde genomgå någon form av reoperation. Den

vanligaste reoperationen var extraktion av internt fixationsmaterial vilket var ungefär hälften av alla reoperationer. I de frakturklasser där reoperation var vanligast behövde över 50% av frakturerna genomgå reoperation. Reoperation på grund av oläkt fraktur, felläkt fraktur, infektion och implantathaveri, vilket är de allvarliga komplikationerna, var inbördes ungefär lika vanligt.

Sammanfattningsvis har avhandlingen visat att det är möjligt att skapa och införa ett frakturregister som samlar in data om frakturer, hur de behandlas och resultatet efter behandling. Klassifikationen av underbensfrakturer i SFR är tillräckligt korrekt för att data i registret kan betraktas som tillförlitliga. Data från SFR kan därför användas för att göra detaljerade epidemiologiska beskrivningar av frakturer. Patienter som opererats för underbensfrakturer behöver genomgå reoperation i ungefär 30% av fallen. Nästan hälften av dessa reoperationer görs på grund av mer allvarliga komplikationer såsom oläkt fraktur, felläkt fraktur, infektion och implantathaveri.

LIST OF PAPERS

This thesis is based on the following studies:

I Wennergren D, Ekholm C, Sandelin A, Möller M. The Swedish fracture register: 103,000 fractures registered. *BMC Musculoskeletal Disorders. 2015;16:338.*

II Wennergren D, Ekholm C, Sundfeldt M, Karlsson J, Bhandari M, Möller M. High reliability in classification of tibia fractures in the Swedish Fracture Register. *Injury. 2016;47:478-82.*

III Wennergren D, Bergdahl C, Ekelund J, Juto H, Sundfeldt M, Möller M. Epidemiology and incidence of tibia fractures in the Swedish Fracture Register. *Injury. 2018;49:2068-74.*

IV Wennergren D, Bergdahl C, Selse A, Ekelund J, Sundfeldt M, Möller M. Treatment and reoperation rates in 1,371 tibial fractures from the Swedish Fracture Register. *Submitted*

ADDITIONAL PUBLICATIONS BY THE AUTHOR

Bergdahl C, Ekholm C, Wennergren D, Nilsson F, Möller M. Epidemiology and patho-anatomical pattern of 2,011 humeral fractures: data from the Swedish Fracture Register. *BMC musculoskeletal disorders. 2016;17:159.*

Juto H, Möller M, Wennergren D, Edin K, Apelqvist I, Morberg P. Substantial accuracy of fracture classification in the Swedish Fracture Register: Evaluation of AO/OTA-classification in 152 ankle fractures. *Injury. 2016;47:2579-83.*

Wennergren D, Stjernström S, Möller M, Sundfeldt M, Ekholm C. Validity of humerus fracture classification in the Swedish fracture register. *BMC musculoskeletal disorders. 2017;18:251.*

Juto H, Gartner Nilsson M, Möller M, Wennergren D, Morberg P. Evaluating non-responders of a survey in the Swedish fracture register: no indication of different functional result. *BMC musculoskeletal disorders. 2017;18:278.*

Wennergren D, Möller M. Implementation of the Swedish Fracture Register. *Unfallchirurg. 2018;121:949-55.*

Knutsson SB, Wennergren D, Bojan A, Ekelund J, Möller M. Femoral fracture classification in the Swedish Fracture Register - a validity study. *BMC musculoskeletal disorders. 2019;20(1):197.*

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1

ABBREVIATIONS

AO	Arbeitsgemeinschaft für Osteosynthesefragen
CT	Computed Tomography
DFDB	Danish Fracture Database
EQ-5D-3L	Euroqol 5 dimensions 3 level
FDR	Fracture and Dislocation Registry
ICD-10	International Classification of Diseases Tenth Revision
MRI	Magnetic Resonance Imaging
NQR	National Quality Register
OTA	Orthopaedic Trauma Association
PROM	Patient-Reported Outcome Measure
RCT	Randomised Controlled Trial
R-RCT	Register Randomised Controlled Trial
SALAR	Swedish Association of Local Authorities and Regions [SKL, Sveriges Kommuner och Landsting]
SFR	Swedish Fracture Register
SHAR	Swedish Hip Arthroplasty Register
SMFA	Short Musculoskeletal Function Assessment
UCS	Unified Classification System

2

BRIEF DEFINITIONS

ACCURACY – How correct a measurement or assessment is, or, in other words, the degree to which the result of a measurement, calculation, or specification conforms to the correct value. In the validity study in this thesis (Study II), the accuracy of fracture classification is defined as the agreement between an assessment and a gold standard classification.

COHEN'S KAPPA – The amount of agreement between two assessors or assessments above what would be expected by pure chance

EXTERNAL FIXATION – Osteosynthesis by the application of a frame outside the limb which is attached to the bone by percutaneous screws or pins

FRACTURE GROUP – A four-digit code according to the AO/OTA classification, e.g. 42A2

FRACTURE TYPE – A three-digit code according to the AO/OTA classification, e.g. 42A

GOLD STANDARD CLASSIFICATION – The classification of a fracture that is regarded as the true or correct classification. In the validity study in this thesis (Study II), the gold standard classification of a fracture is defined as the classification on which three experienced assessors agree.

INTER-OBSERVER RELIABILITY – Agreement between two assessors

INTRA-OBSERVER RELIABILITY – Agreement between the assessments of one assessor at two different times

INTRAMEDULLARY NAIL – Osteosynthesis by a nail introduced in the medullary canal of a long bone

IMPLANT FAILURE – Failure of an implant, usually by breakage of the implant. In Study IV in the current thesis, the term “implant failure” as a reason for re-operation also includes an incorrectly positioned implant.

MALUNION – When a fracture has healed with a displacement

MOBILE BANK ID – An electronic, online personal identification solution used for digital identification

NON-UNION – A fracture that has not healed in the expected time for healing (approximately six months for tibial fractures)

PERCENTAGE AGREEMENT – The percentage of agreement between two assessors or assessments

PLATE OSTEOSYNTHESIS – Osteosynthesis by the application of a plate which is attached to the bone with screws

REGISTER RANDOMISED CONTROLLED TRIAL (R-RCT) – Randomised controlled trial conducted within a national quality register. For example, eligible patients can be detected in the register and the randomisation between the different interventions can be performed within the register platform.

SCREW FIXATION – Osteosynthesis by one or more screws only

2 BRIEF DEFINITIONS

3

INTRODUCTION

This thesis has two main topics.

The first topic is the Swedish Fracture Register (SFR). Can a successful fracture register be created and implemented? How was the SFR created and implemented? Moreover, how can register data be used to conduct epidemiological and re-operation studies?

The SFR then forms the basis of the second topic which is tibial fractures. Can an accurate classification of tibial fractures be obtained in a register setting where a large group of orthopaedic surgeons with different experience classify these fractures? How are the epidemiology and the treatment of tibial fractures in a large cohort of patients today? To what extent do patients treated for tibial fractures undergo re-operations and why?

3.1 REGISTERS IN ORTHOPAEDICS

National quality registers (NQR) have an almost 50-year-long history in the Swedish health-care system. The pioneers were the arthroplasty registers for knees and hips, which were established in the 1970s [1, 2]. The Swedish Knee Arthroplasty Register was started in 1975 and the Swedish Hip Arthroplasty Register in 1979. Since then, these two, and several other quality registers, have had a major impact on the treatment of different orthopaedic conditions [3]. Approximately 100 quality registers with national coverage have since been implemented in Sweden and 14 of them contain data on orthopaedics and orthopaedic trauma [4]. Due to the unique Swedish personal identity numbers, patients' data can be entered in registers and monitored over time. The personal identity numbers make it possible to follow patients, even when they are treated by different providers or if they move from one city or county to another.

The Swedish Hip Arthroplasty Register (SHAR) has been the role model for many quality registers both in Sweden and internationally. Through impressive work for high completeness, the SHAR has established itself as a national quality register with almost 100% completeness in Sweden [5]. Through ambitious work on annual reports, the SHAR has given many Swedish orthopaedic departments feedback and thereby the opportunity to improve. The SHAR was also early when it came to collecting PROMs, which has led to breakthroughs in the understanding of the results after hip arthroplasty surgery [6-8].

The NQRs in Sweden have all been started by individual professionals, are all based on a professional need for a register and are still run by professionals with economic support from the Swedish Association of Local Authorities and Regions (SALAR).

3.2 FRACTURE REGISTERS

There has long been a widely recognised need for population-based register data in order to determine resource allocation, promote better outcomes and develop evidence-based trauma orthopaedics. Although fracture care consumes large social and financial resources, little is known about outcomes, methods or the actual number of fractures treated each year. The previous collection of national data in Sweden, such as the Swedish Patient Register, was performed indirectly, based on diagnostic codes in the medical charts. This method of collecting data has several limitations. The diagnostic codes in the medical charts can be inaccurate for many reasons. If, for example, a person sustains a fracture in November and the diagnosis code for fracture is used at a follow-up visit in January, the Swedish Patient Register may regard this as two fractures, one each year. Since the diagnostic codes in the medical charts do not include laterality, bilateral fractures may be regarded as one fracture. Moreover, the ICD codes are a blunt grouping of fractures into segments of the affected bone and are therefore not nearly as detailed as fracture classification systems such

as the AO/OTA classification, which is described below. According to the Swedish Patient Register, an estimated 140,000 fractures are treated in Sweden each year. Further, national data based on classifications and assessments by orthopaedic surgeons are scarce.

Randomised, controlled trials (RCT) are often regarded as the highest level of evidence. In some scientific situations, however, RCTs have limitations. RCTs often focus on specific topics with strict inclusion and exclusion criteria. In contrast, register-based studies can include and observe all the patients in a specific field and in a specific geographical area and therefore describe the current treatment and results of the treatment algorithms being used in clinical practice. Although register-based studies without randomisation cannot always be used to compare different treatments or to draw conclusions about which treatment is associated with the lowest complication frequency, they assess real life and the results of everyday practice. Quality registers also enable scientific assessments in areas for which randomised, controlled trials are not always possible [9]. When the absolute risk of complications is low, quality registers are able to detect crucial differences, while randomised, controlled trials may not include enough patients to do this [10, 11]. Another crucial role for the National Quality Registers (NQR) is to be hypothesis generating for subsequent RCTs. Data from the Swedish NQR for cardiovascular diseases, Swedeheart, have showed that RCTs often report a better outcome than register-based studies, which also supports the idea that register-based studies more accurately describe the reality [12].

There have been previous attempts to create different kinds of database to collect data on fractures. The modern internet era has provided opportunities for web-based registrations of register data which probably cannot be overestimated when it comes to spreading a register in an attempt to achieve national coverage. Some national registers focusing on specific fractures, such as the Norwegian Hip Fracture Register and the Swedish equivalent, Rikshöft, have been successful and have provided valuable knowledge on the treatment and outcome of hip fractures [13, 14]. There are also two other Scandinavian examples of fracture registers, namely the Norwegian Fracture and Dislocation Register (FDR) and the Danish Fracture Database (DFDB). The Fracture and Dislocation Register (FDR) at Stavanger University Hospital is an interesting example of a regional fracture register centred around one large hospital in Norway [15]. The FDR is currently developing and, in August 2019, it will launch a national version. The new structure of this national register is largely inspired by the SFR. Another interesting example is the Danish Fracture Database (DFDB) that collects data on surgically treated fractures in Denmark. From the DFDB, valuable studies based on register data have been published [16, 17]. There are also international and Swedish examples of trauma databases, such as the American National Trauma Databank (NTDB) and the Swedish National Trauma Registry (SweTrau) [18, 19]. These databases focus on general trauma and may be feasible for performing studies of mortality and epidemiology, for example [20-22]. However, the data they collect are not as detailed in terms of fractures as those collected by a specific fracture register.

To date, despite these efforts, there has been no national register that prospectively collects data on fractures of all types, regardless of location and type of treatment, as well as patient-reported outcome measures.

The creation of the SFR was based on the hypothesis that it is possible to create a population-based fracture register that covers fractures of all types, regardless of treatment, and collects both surgeon- and patient-reported outcome measures. The hypothesis is also that a national fracture register is able to collect more detailed information in terms of the fracture type and its treatment than official health statistics can provide.

3.3 FRACTURE CLASSIFICATION

Understanding fracture morphology is essential for the decisions relating to the appropriate treatment. The classification of a fracture is a structural way of assessing and describing the fracture. Classifying fractures means clustering fracture patterns into different sets. Although the boundaries of the sets may be more or less well defined, the fractures that are classified are part of a continuum. Fractures may display features of two different fracture sets to a varying degree and, to some degree, the assessment by the person working with the system is subjective. Features of a fracture where their presence or absence would assign the fracture to one category or another, for example, a possible intra-articular fracture line, may be vague and interpreted differently by different assessors. As a result, in fracture classification, there are no absolutely correct answers but rather degrees of agreement between different assessors. In spite of this, a fracture must be analysed and described before it can be correctly treated. One of the

founders of the AO, Maurice E. Müller, argues that classification is useful only if it considers the severity of the bone lesion and serves as a basis for treatment and for evaluating the results [23]. The classification of fractures is a prerequisite for all kinds of research in the field of trauma orthopaedics. A classification system is essential to the success of a fracture register and a classification system suitable for a fracture register should ideally be comprehensive, widely recognised, extensively employed, user friendly and valid. No current classification system meets all these criteria. The AO/OTA classification (Figures 1, 2 and 3), which is described below, is, however, comprehensive and covers most body regions. The AO/OTA classification was therefore considered the best available option for the classification of most of the fractures in the SFR.

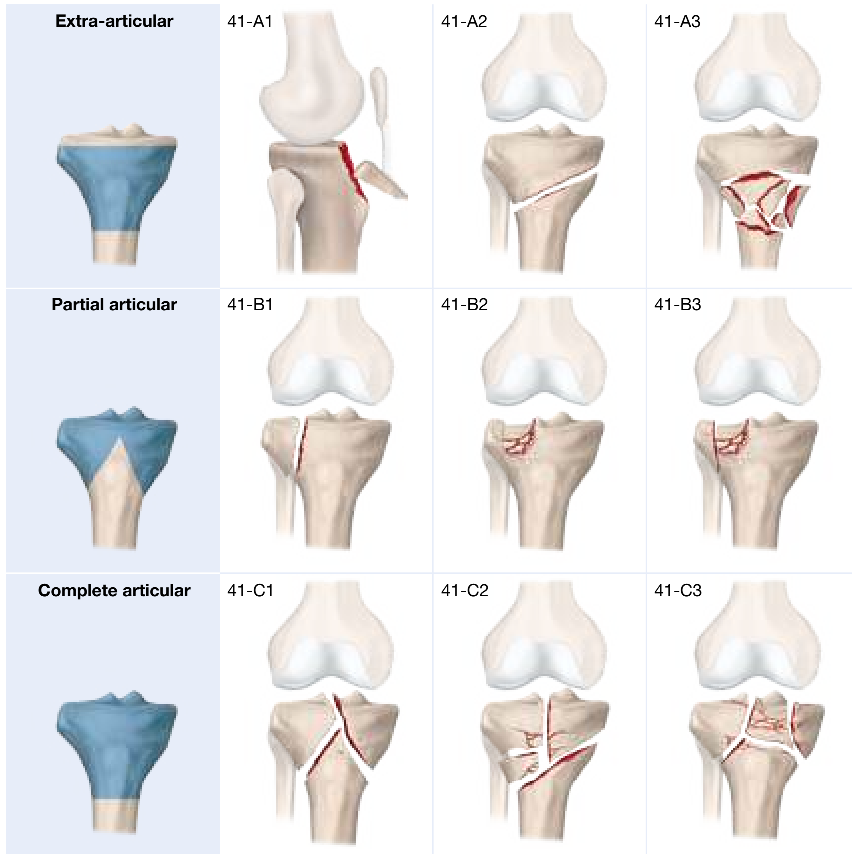

FIGURE 1 The AO/OTA classification of proximal tibial fractures

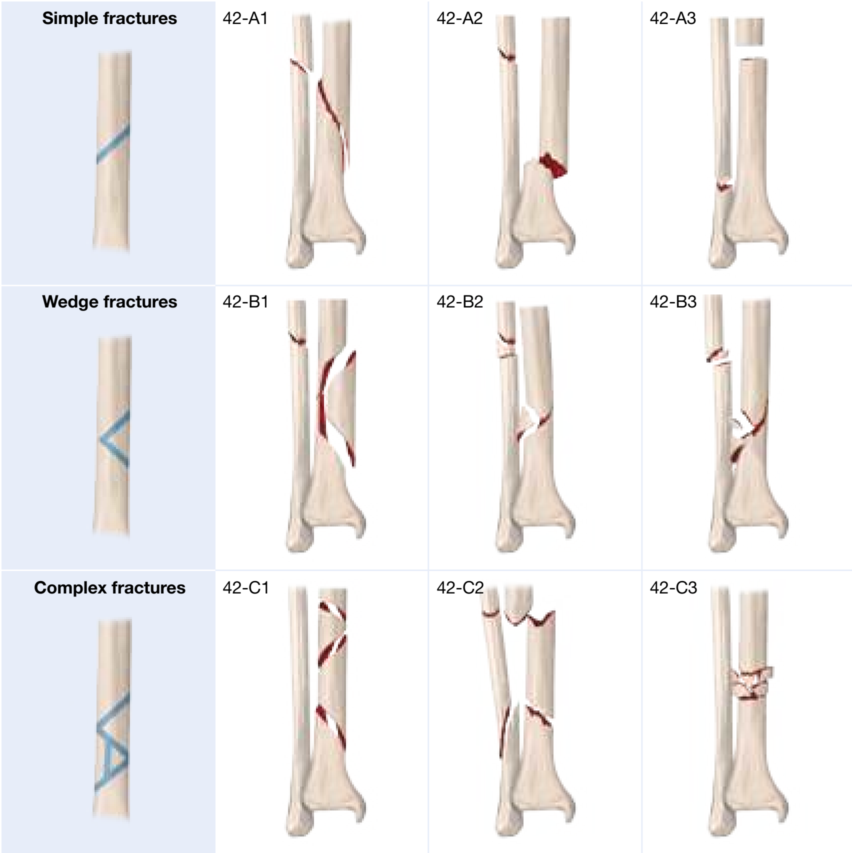

FIGURE 2 The AO/OTA classification of tibial shaft fractures

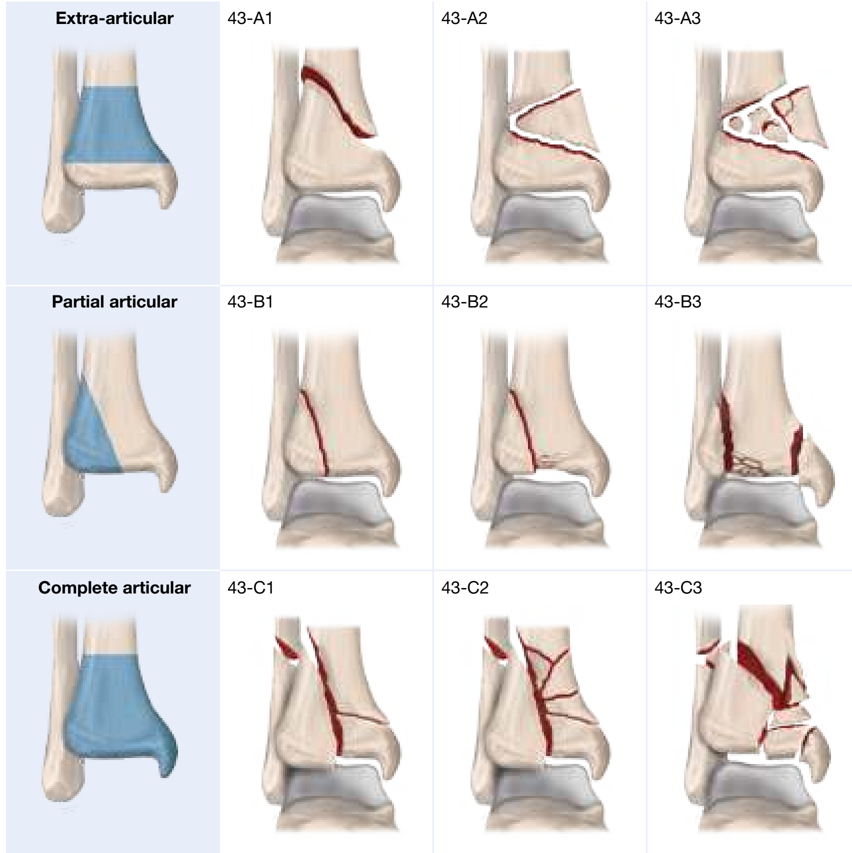

FIGURE 3 The AO/OTA classification of distal tibial fractures

For the proximal tibia, the Schatzker classification (Figure 4) is perhaps even more widespread than the AO/OTA classification [24, 25]. The AO/OTA classes of proximal tibial fractures resemble the Schatzker classification to large extent and the fracture classes in the Schatzker system can also be found in the AO/OTA classification. The Schatzker classification does not, however, include the extra-articular fractures of the proximal tibia, which the AO/OTA classification does. The fact that the AO/OTA is more comprehensive and has a common structure for all long bones has made the AO/OTA classification more feasible for the SFR in proximal tibial fractures, as well as the rest of the body.

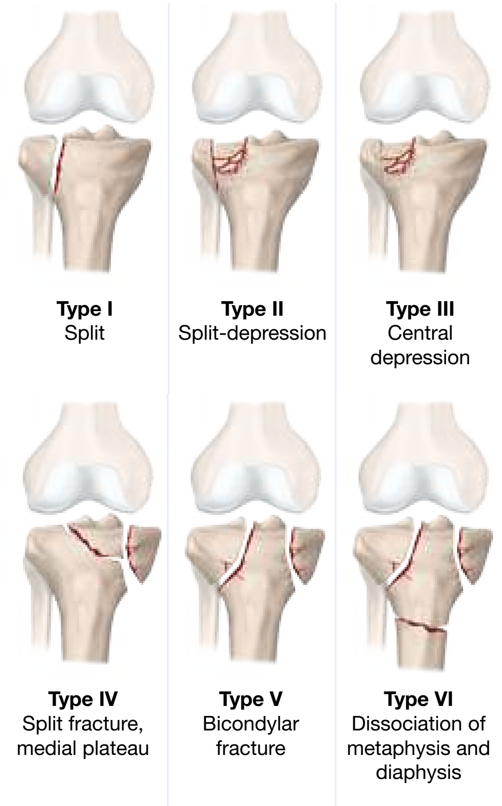

FIGURE 4 The Schatzker classification of tibial plateau fractures

During the preparations for Study II in the current thesis, the AO/OTA classification of tibial fractures was further analysed. The fracture groups in the AO/OTA classification can be defined by Boolean questions (yes/no) – for example, "Intra-articular fracture? Depression? Split? Multifragmentary?". To understand the grounds for classification disagreement, the possible relationship between fracture groups was analysed. Fracture groups or subgroups separated by only one of these questions can be regarded as "related". Fracture groups that are separated by two or more questions can be regarded as being unrelated. "Related" fractures differ by only one question and one could be mistaken for the other if the defining fracture feature is vague (e.g. whether or not there is an intra-articular fracture line in a proximal or distal tibial fracture). In Figure 5, 6, 7 and 8 the relationship between fracture groups is shown by arrows, which correspond to the Boolean question separating the two fracture groups.

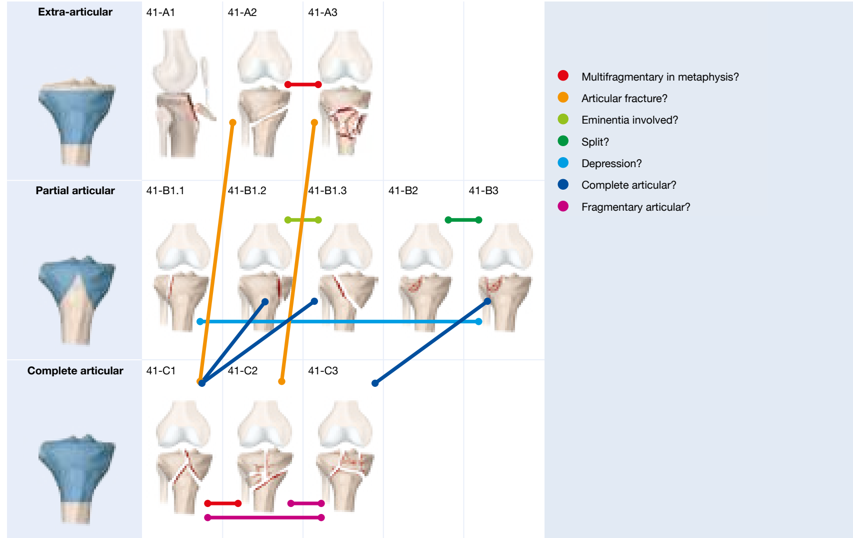

FIGURE 5 The relationship between fracture classes among proximal tibial fractures according to the AO/OTA classification. "Related" fracture classes differ only by the answer to one question, as indicated by the coloured arrows. For example, the only factor distinguishing 41A2 from 41C1 is whether there is an intra-articular fracture line (orange arrow).

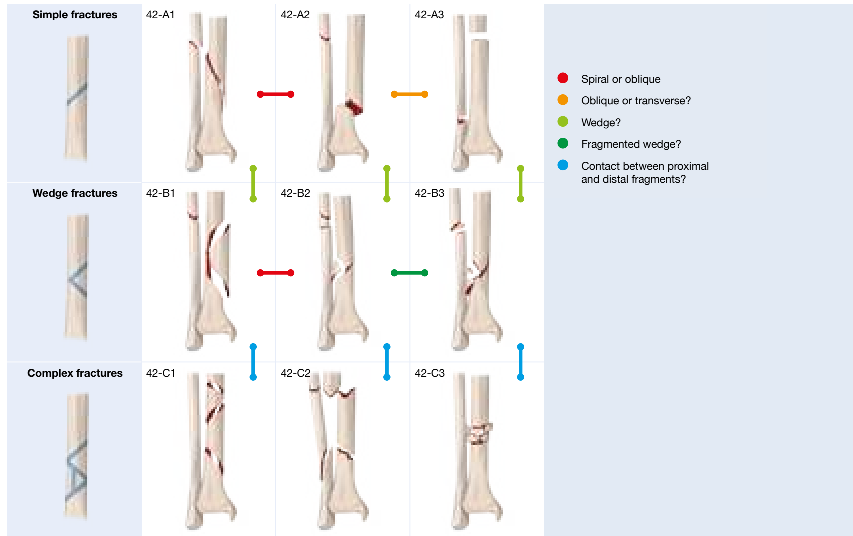

FIGURE 6 The relationship between fracture classes among tibial shaft fractures according to the AO/OTA classification. "Related" fracture classes differ only by the answer to one question, as indicated by the coloured arrows. For example, the only factor distinguishing 42A1 from 42B1 is whether there is a wedge fragment (light green arrow).

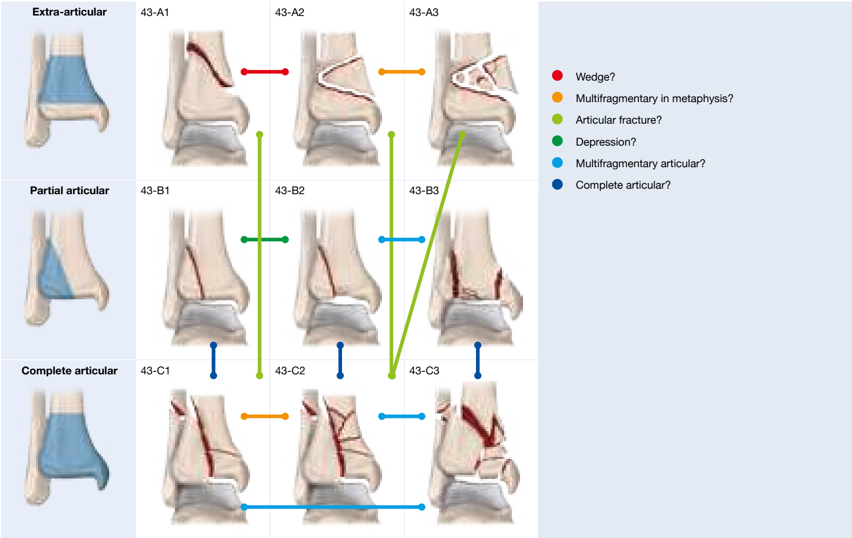

FIGURE 7 The relationship between fracture classes among distal tibial fractures according to the AO/OTA classification. “Related” fracture classes differ only by the answer to one question, as indicated by the coloured arrows. For example, the only factor distinguishing 43A2 from 43A3 is whether the fracture is multifragmentary in the metaphysis (orange arrow).

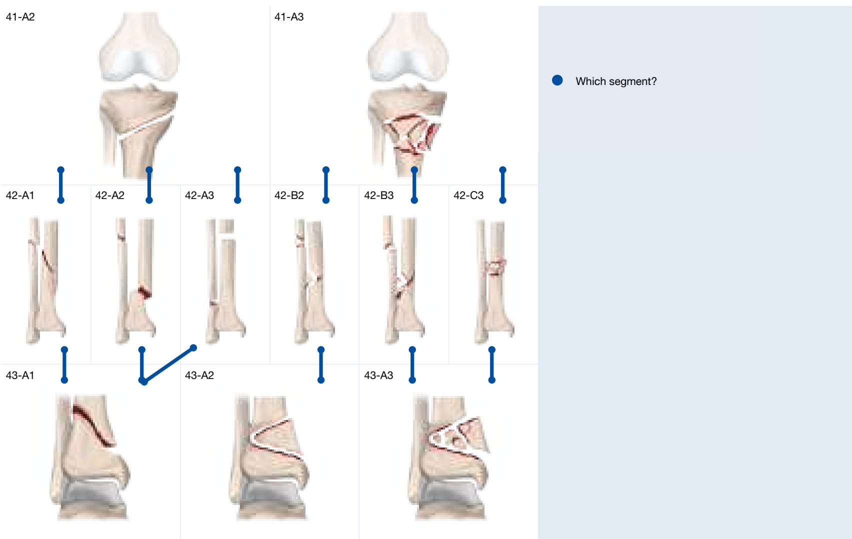

FIGURE 8 The relationship between fracture classes in the different segments of the tibia. Depending on the segment in which a fracture is considered to be located, the fracture classes connected with the blue arrows can be mixed up with one another.

3.4 AO/OTA CLASSIFICATION

The Arbeitsgemeinschaft für Osteosynthesefragen (AO) was founded in 1958 by 13 surgeons specialising in the treatment of fractures. The AO foundation is an international non-profit organisation for research and education in the field of fracture treatment. During work on research on the treatment of fractures, the AO developed a system for classifying fractures. The first complete version of the AO classification was presented by Müller et al. and was published in French in 1987 and in English in 1990 [26]. It was expanded and developed in collaboration with the Orthopaedic Trauma Association (OTA) in 1996 [27]. It was revised in 2007 and 2018 [28, 29]. The AO/OTA classification is designed to have a similar structure for all the bones in the body. The classification code is based on a four-digit code, where the first digit stands for the body part (for the tibia 4) and the second digit stands for the segment of the affected bone (1=proximal, 2=diaphyseal and 3=distal). The third position is a letter, A, B or C, which has similar meanings in all parts of the body. For the end segments, A indicates an extra-articular fracture, B a partly articular fracture and C a completely articular fracture. For diaphyseal fractures, there are also common features for the A, B and C fractures, where A are simple fractures, B fractures have intermediate fragments and C are fractures with intermediate fragments and no contact between the main fragments. The last digit is 1, 2 or 3 and describes features specific to the bone and segment in question. The distinction between the segments of the long bones is defined as the “Müller square”, meaning that the end segment is defined as the segment within a square where the sides are as long as the width of the bone at the broadest part in that particular segment (Figure 9). There are further subgroups, with which one needs to be acquainted, since some specific fractures, such as avulsions of the proximal tibia, are found here, but it is otherwise difficult to know how to classify if you are not acquainted with the subgroups. These are, however, not described in detail in this thesis but can be found online on the AO foundation website [30]. Upon classification of a fracture in the SFR, tooltips are shown when pointing with the marker at each specific fracture class. The process of fracture classification in the SFR is described in detail in the Methods section of this thesis.

The latest revision of the AO/OTA classification introduces some changes in terms of tibial fractures [29]. In the latest revision, adjacent fibular fractures are classified with a separate code which has not previously been the case. Another change that might actually affect studies of tibial fractures in the future is that an isolated medial malleolar fracture, which, in the earlier versions of the AO/OTA classification, was classified as a malleolar fracture (44A2), is classified as a distal tibial fracture (43B1) in the new version. This last revision has, however, not been implemented in the SFR.

FIGURE 9 The proximal and distal segments of the tibia, according to the AO/OTA classification, are defined as the part within a square whose sides are as long as the broadest part of the bone in that segment. The shaft segment is defined as the part between the proximal and distal segments.

3.5 THE TIBIA

The tibia is the second largest bone in the human body (Figure 10). It is the weight-bearing and most important bone in the lower leg, whereas the fibula is important for ankle joint stability and the origins of muscles, but it does not bear any weight at all. Proximally, the tibia is a part of the knee joint and, distally, it is part of the ankle joint. The proximal articular surface of the tibia is composed of the medial and lateral tibial plateau, with the eminentia intercondylaris and the attachments of the cruciate ligaments in between. Anteriorly, at the tibial tuberosity, the patellar ligament attaches to the tibia. At the proximal tibia, the medial collateral ligament, iliotibial tract and parts of the hamstring muscles attach. Along the course of the lateral and posterior aspects of the tibia, the muscles of the lower leg have their origins. The transection of the tibial shaft has a triangular shape. Distally, the articular surface of the tibia is in continuity with the medial malleolus. The lateral malleolus of the fibula is strongly attached to the lateral aspect of the distal tibia by the tibiofibular syndesmosis. Together, the distal tibia and the lateral malleolus form the ankle mortise. Large parts of the tibia are covered by only subcutaneous fat and skin. In the proximal tibia, muscles cover only the posterior parts, while the medial, anterior and lateral parts of the proximal tibia are covered by only subcutaneous fat and skin. The tibial shaft is covered by muscles laterally and posteriorly, while the anterior border and the medial surface of the tibial shaft are only covered by subcutaneous fat and skin. The medial malleolus of the distal tibia is only covered by more or less skin, while, anteriorly and posteriorly, the distal tibia is covered by tendons and skin. So, in contrast to the femur, the tibia has fewer muscles and soft tissues surrounding it and, anteriorly and medially, it is only covered by subcutaneous fat and skin. This makes the tibia less protected and, when fractured, more exposed to adjacent soft-tissue injuries and thereby open fractures. Along the course of the tibia, vessels and nerves run in close relation to the posterior aspect of the tibia. In some parts of the lower leg, such as the popliteal fossa and along the proximal tibia, the vessels and nerves run closely underneath or between the origins of muscles, such as the tendinous arch of the soleus muscle, which do not allow much movement. This makes the vessels and nerves even more vulnerable when the tibia is fractured. This implies that tibial fractures can occur alongside severe soft-tissue injuries, such as open fractures or vessel injuries, large haematomas and compartment syndrome.

FIGURE 10 The tibia

3.6 HISTORY OF TIBIAL FRACTURES

Before the era of sterile surgical techniques and antibiotics, a tibial fracture, especially an open fracture, could be a life-threatening injury in itself, which could lead to the amputation of the limb or even death. Since surgery in this era was often associated with a risk of life-threatening complications, the

vast majority of fractures were treated non-surgically. When sterile surgical techniques and antibiotic prophylaxis were introduced, the surgical treatment of tibial fractures had the opportunity to evolve. The intramedullary nailing of long-bone fractures was introduced after the Second World War. Ernest William Hey Groves and Gerhard Küntscher are often regarded as the early pioneers of intramedullary nailing. It was, however, J. Otto Lottes who introduced the first intramedullary nail for tibial fractures [31, 32]. At an early stage, the AO identified the principles of obtaining an exact open reduction and osteosynthesis with absolute stability via internal fixation [33]. The purpose of these principles was to enable patients to mobilise at an early stage to preserve joint range of motion and prevent the complications associated with immobilisation. To realise these principles, plates and screws were introduced. At the beginning, the importance of the gentle handling of soft tissues was not always well understood. Large-scale surgical exposure of the bones without the appropriate handling of the soft tissues could lead to complications such as deep infections, skin necrosis, malunion, non-union and implant failure, which in turn prevented fracture healing and could sometimes threaten the limb. Our understanding of soft-tissue injuries and the importance of limiting the surgical exposure and trauma to the soft tissues has evolved. Gentle handling of the soft tissues and the introduction of staged procedures and less invasive surgical techniques, such as percutaneously inserted intramedullary nails and minimally invasive plate osteosynthesis (MIPO), have improved the results. The surgical techniques and implant designs have further evolved. Most previous studies of epidemiology, treatment and re-operation rates were conducted or published before the introduction of anatomic locking plates and modern locking intramedullary nails [34-41].

3.7 EPIDEMIOLOGY OF TIBIAL FRACTURES

Tibial fractures can affect all people, from the young toddler after a simple fall, the middle-aged individual twisting his or her leg during skiing, injuring the lower leg in a car crash or falling from a ladder, to the elderly osteoporotic person taking a miscalculated forceful step off the pavement or being struck by a car on a pedestrian crossing. The spectrum of injuries ranges from non-displaced fractures that can be treated with a plaster cast or a brace to complex fractures with severe soft-tissue injuries that require osteosynthesis in combination with plastic surgery or even amputation.

The different types of fracture can be caused by different trauma mechanisms. The proximal tibial fractures include the less complex fractures caused by low-energy valgus or varus trauma to the knee, resulting in tibial plateau fractures with depression of the joint surface. A proximal tibial fracture can also occur as a high-energy trauma, resulting in a complex intra-articular fracture as a result of a traffic accident or other high-energy trauma.

Tibial shaft fractures can be caused by low-energy rotational forces, resulting in a two-part spiral fracture. They can also be caused by high-energy direct blows to the lower leg, such as motorcycle or other traffic accidents.

In distal tibial fractures, the typical pilon fracture is caused by an axial load on the foot and leg, causing the talus to blow as a pilon into the distal articular surface of the tibia. These fractures are typically seen after falls from heights or traffic accidents. Distal tibial fractures also include extra-articular fractures caused by a trauma mechanism that more closely resembles the trauma mechanism of the other segments of the tibia, such as simple falls and traffic accidents.

A group of researchers in Edinburgh, Scotland, under the leadership of Charles Michael Court-Brown, performed several epidemiological studies of fractures during the 1990s and 2000s. Many of these studies are regarded as the basis of epidemiological studies of fractures and are often referred to in the literature [36, 42-64]. When conducting epidemiological studies in the field of trauma orthopaedics, there is often a conflict between being either detailed and focusing on one specific segment of one bone or one specific fracture type or, on the other hand, having a wider perspective and describing fractures in one part of the body or even the whole body. As will be described later in the section on the classification of fractures, there is sometimes a problem in terms of the segment of a bone to which a fracture should be assigned. There are therefore advantages to performing epidemiological studies of whole bones and not just one segment. The data collection in previous epidemiological studies has often been based on retrospective reviews of medical charts, radiographs or operating theatre logs. Some studies include only surgically treated or inpatient-treated fractures. These methods prompt questions on how high the level of completeness in these studies actually is. The retrospective design does not make it possible to evaluate completeness and few studies present their methods for achieving high levels of completeness.

The study Court-Brown et al. published on tibial fractures was a study of the epidemiology of tibial shaft fractures [36]. The epidemiology of tibial shaft fractures in Sweden during the 1950s and 1980s has been described by Bengnér et al. and, during the 1990s and 2000s, by Weiss et al. [34, 35]. Elsoe et al. have described the epidemiology of tibial plateau fractures based on data from one hospital in Denmark [65]. There is, however, no current study that describes the epidemiology of fractures of the whole tibia.

The western world has an ageing and increasingly urban population. The epidemiology of tibial fractures can therefore be expected to change over time. Most previous studies of the epidemiology of tibial fractures were conducted during or before the 1990s and they often focused on one segment of the tibia. However, no previous epidemiological study of fractures in all the segments of the tibia, classified by orthopaedic surgeons according to the AO/OTA classification, has been published [26, 28]. It is therefore important to evaluate the epidemiology of fractures in the whole of the tibia today.

3.8 COMPLICATIONS

In register studies of orthopaedics, re-operation is a widespread and commonly used indicator of a complication. The most important complications following the treatment of tibial fractures include non-union, malunion, superficial or deep infection, implant failure and compartment syndrome.

The living bone in the human body continuously remodels and strengthens when bearing weight and being subjected to stress and loads. An implant, on the other hand, is a material with more or less limited strength. When subjected to repeated loading, no implant will hold forever. When a fracture heals, the bone resumes weight-bearing and the implant is no longer loaded. Most implants are designed to hold for as long as normal fracture healing takes. If the fracture does not heal, the implant will eventually break. Implant failure is therefore a sign of non-union. Metaphyseal fractures, for example, proximal and distal tibial fractures, have a better blood supply and thereby better healing conditions. Re-operations due to non-union and implant failure could therefore be expected to be less common in proximal and distal tibial fractures.

The inability correctly to reduce and/or adequately stabilise a fracture might lead to malunion. Malunion can lead to malalignments, resulting in affected gait, pain and reduced range of motion. Malunion in terms of a displaced intra-articular fracture can lead to post-traumatic osteoarthritis.

The trauma resulting in a tibial fracture also results in some degree of soft-tissue injuries, which increases the risk of postoperative infections. Postoperative infections can also lead to wound-healing problems and skin necrosis. Deep infections also affect bone healing. Sometimes, it is difficult to cure an infection without removing the implants. The removal of implants, on the other hand, leads to an unstable situation in the fracture which in turn prevents fracture healing. An infected fracture can therefore be a problematic, sometimes Catch 22, situation.

In the acute setting, one feared complication is compartment syndrome, which has to be addressed immediately with fasciotomy. This is, however, often performed at the slightest suspicion and often in combination with other surgical procedures such as temporary external fixation. The fasciotomy might therefore not be regarded as the main procedure and its registration might be forgotten. Compartment syndrome and the fasciotomies that are performed are therefore difficult to identify in a fracture register.

The removal of internal fixation devices can be performed for many different reasons. Patients might experience discomfort or pain due to internal fixation devices such as protruding heads of screws leading to pain when touched or pressed on. The removal of internal fixation devices may also be necessary in the event of a deep infection or if the internal devices are incorrectly positioned or the fracture is not adequately reduced. It is therefore important in a register setting to record not only the kind of re-operation that has been performed but also the reason behind the re-operation.

3.9 RATIONALE OF THIS THESIS

Surprisingly little is published on outcomes, methods or the actual number of fractures treated each year. As a result, there has been a widely recognised need for population-based register data in order to determine resource allocation, promote better outcomes and develop evidence-based trauma orthopaedics. No previous national register has prospectively collected data on fractures of all types, regardless of location and type of treatment, as well as re-operation rates and patient-reported outcome measures.

The data in a newly developed register have to be validated before they can be used for scientific purposes. The accuracy of the classification of fractures is central to the validity of the data in a fracture register. Most previous studies show moderate to substantial inter-observer agreement in fracture classification. In most of these studies, the classification has been made by a small group of equally experienced orthopaedic surgeons. In the SFR, on the other hand, the classification of fractures is made by a large group of orthopaedic surgeons with different experience and knowledge. It was therefore considered important to evaluate the accuracy of fracture classification in the SFR.

Due to the ageing and increasingly urban population of the western world, the epidemiology of tibial fractures can be expected to change over time. Since no previous epidemiological study of fractures in all the segments of the tibia classified by orthopaedic surgeons has been published, it is important to evaluate the epidemiology of fractures in the whole of the tibia.

During the past twenty years, the treatment of tibial fractures has evolved. There is, however, a lack of large cohort studies that describe the treatment and re-operation rates of tibial fractures in everyday practice. To the best of our knowledge, there is no previous register-based study that describes the treatment and re-operation rates for fractures in all the segments of the tibia.

4

AIMS

STUDY I

To present the development, implementation and current use of the SFR

STUDY II

To evaluate the accuracy of the classification of tibial fractures in the SFR. We secondarily aimed to determine the inter- and intra-observer agreement on the classification of tibial fractures according to the AO/OTA classification.

STUDY III

To describe the epidemiology and incidence of tibial fractures in all the segments of the tibia for a cohort of consecutive tibial fractures over a period of five years

STUDY IV

To describe and analyse the treatment and re-operation rates of tibial fractures in all the segments of the tibia for a cohort of consecutive tibial fractures at one large hospital over a period of five years

5

METHODS

Since the Swedish Fracture Register (SFR) is the first topic in this thesis and forms the basis of the way Studies II-IV were conducted, methodological aspects of the SFR are described first (Study I). Various methodological aspects specific to Studies II-IV are then described.

5.1 THE CREATION OF THE SWEDISH FRACTURE REGISTER

The SFR was created by orthopaedic surgeons and is run by a national board with members representing different parts of the country, orthopaedic departments, specialities and academic disciplines. The board is supervised by a director who is responsible for maintaining and developing the register. The Swedish Orthopaedic Trauma Society, a section of the Swedish Orthopaedic Association, is the professional organisation that provides support. The main funding comes from the Western Healthcare Region and the Swedish Association of Local Authorities and Regions. Economic support has also been provided by various academic departments and Landstingens Ömsesidiga Försäkringsbolag (LÖF), which is a nationwide Swedish insurance company, whose main task is to insure publicly financed healthcare providers. In recent years, the affiliated departments have covered the costs of administering the patient-reported outcome questionnaires.

The process of defining the variables to be included began in 2007 and was initiated by two senior consultants at the Department of Orthopaedics at Sahlgrenska University Hospital (Michael Möller and Carl Ekholm). Two years later, the structure of the register was finalised. In 2009, the new competence centre for national quality registers, the Centre of Registers Västra Götaland, offered its support to the founders. After a year of close collaboration between system developers, project managers and orthopaedic surgeons, a beta version was launched on 1 January 2011 by the Department of Orthopaedics and Trauma at Sahlgrenska University Hospital. Fractures of the tibia and humerus were entered during the trial period. Fractures of the other long bones, shoulder, pelvis and foot were included in April 2012, followed by the hand in October 2012, the spine in February 2015 and paediatric fractures in May 2015.

All orthopaedic departments in Sweden have been invited to participate. Participation is, however, voluntary.

The number of variables in any register that aims to include all fractures needs to be limited. Otherwise, the workload of entering data in the register might be too high and affect the completeness. This is particularly important for the SFR because the data are entered by the physician. As in most other national quality registers studying surgical interventions, the main outcome measure was chosen to be the rate of re-operations. The registration of re-operations divided by reasons for the re-operation will cover most complications, such as non-union, malunion, deep infection or implant failure. The other main outcome variable in the SFR is patient-reported outcome measures (PROM) [66-69].

5.2 INCLUSION AND EXCLUSION CRITERIA

As previously described, the SFR started in 2011 and subsequently expanded gradually during the first few years. Since 2015, however, the SFR has collected data on all "orthopaedic fractures", i.e. upper and lower extremity fractures, pelvic and spinal fractures (in other words, all fractures except the skull and the ribs) that occur in Sweden in Swedish citizens of all ages and have been diagnosed or treated at affiliated departments. Data entry requires the patient to have a permanent Swedish personal identity number and have a fracture diagnosed on the basis of radiographs, computed tomography (CT scan) or magnetic resonance imaging (MRI). Fractures that have occurred abroad are not included.

5.3 TECHNICAL DESCRIPTION

The SFR is fully web based and built on the Stratum platform, designed specifically for national health quality registers. Since February 2019, a digital web-based version of the PROM questionnaires has been used and the whole data entry process is therefore paperless.

The system provides users with input choices based on previously entered data, thereby speeding up the process and minimising the risk of error. The system permits the consecutive entry of new injuries, treatment and follow-up, including PROMs for every patient.

Data are stored under the responsibility of the county council and on computer servers run by the University of Gothenburg.

5.4 COLLECTION OF DATA

The data entry is made by the attending physician, normally a specialist or resident in orthopaedics and trauma, or by others who are on call at accident and emergency departments. They log in to the SFR webpage with a personal service identification card and a personal identification number (PIN) code or using Mobile Bank ID. The Swedish Personal Data Act mandates the two-step process. The patient's personal identity number, an eight-digit date of birth and a unique four-digit control code, is then entered. The number is verified online with the Swedish Population Register and a new file is created if the number is correct. This entire process takes less than one minute to complete.

The data entry process consists of four different colour-coded steps and is described in Figures 11-15. The first three steps are performed by the physician, while the fourth step includes PROMs.

Registration of injury occasion

The diagnosing physician enters the date, cause, location and activity at injury and type of injury (high-energy or low-energy) in the first panel (Figure 11). The mechanism, location and activity in which the patient was engaged when the injury occurred are chosen by means of drop-down menus that contain submenus for each specific variable, thus creating a V or W code in accordance with ICD-10. Pathological, stress and spontaneous fractures are distinguished from traumatic fractures. The amount of energy that caused the fracture/s is estimated on the basis of generally accepted criteria. If the patient has subsequent accidents and sustains new fractures later in life, new injury occasions can be added, such that data relating to a particular fracture will always be associated with the relevant injury and date.

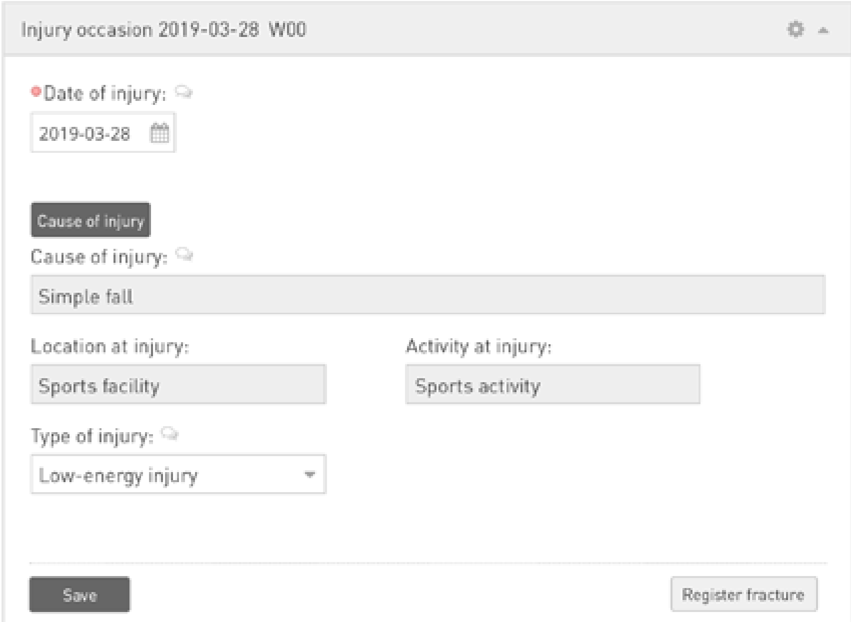

FIGURE 11 Registration of injury occasion

Registration of the fracture

The second panel contains data relating to the fracture (Figure 12). Data in terms of the fracture pattern are included, generally in accordance with the AO/OTA classification. The physician chooses a location and side of the body on the skeleton (Figure 13), after which the classification pictogram appears and a fracture class is chosen (Figure 14). This is followed by a series of alternatives and answers to a few mandatory questions such as open or closed fracture. The diagnosis is assigned an ICD-10 code, side of the body, information about whether the injury is open or closed and an AO/OTA class or other category. Boxes can be checked to indicate whether the fracture is related to an implant. Fractures close to joint replacements are classified according to the Unified Classification System (UCS) [70]. In the case of multiple fractures, a new panel is generated for each additional fracture.

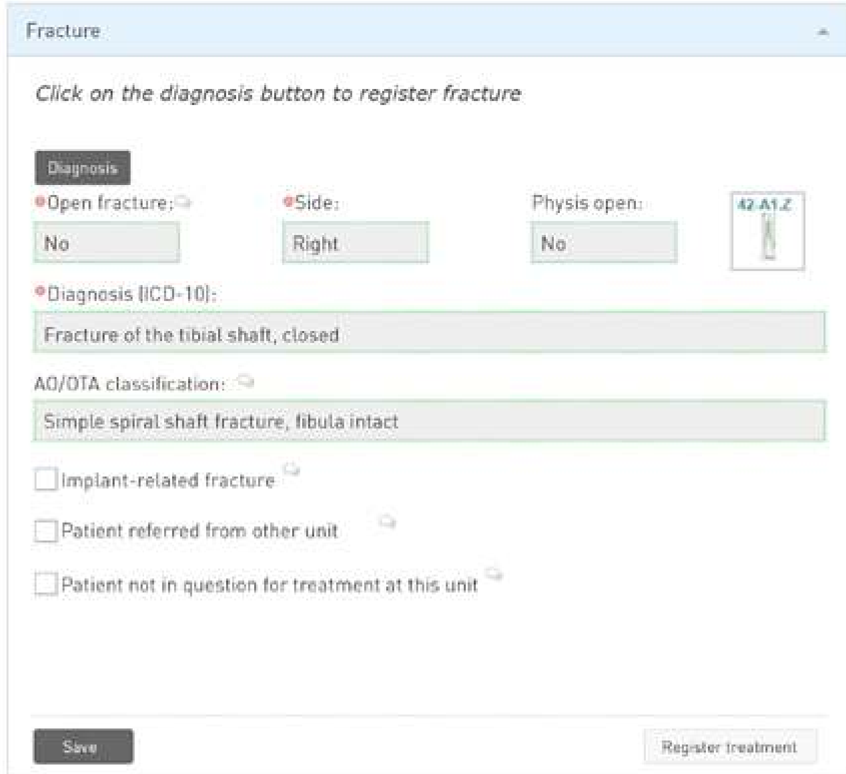

FIGURE 12 Registration of the fracture

FIGURE 13 Selecting location, side of the body and segment of the affected bone

Classification of fracture

After selecting the location, side of the body and segment of the bone on the skeleton (Figure 13), the classification window for the segment in question appears (Figure 14). Moving the cursor to a particular fracture category brings up a written description to supplement the drawing. Examples of radiographs for each specific fracture class are also available. The classification of the fracture is based on the available radiological information. Optionally, final classification can be made after surgery.

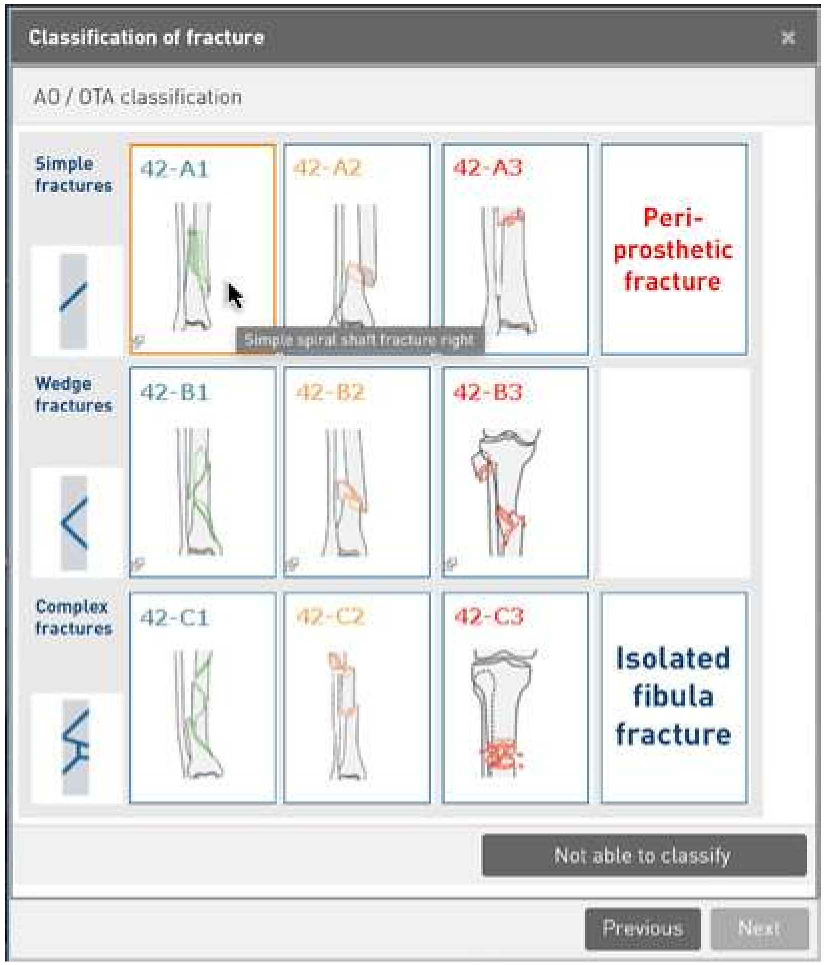

FIGURE 14 Classification of fracture

Registration of treatment

Data related to treatment are entered by the treating physician once the treatment has been performed (Figure 15). If the fracture is treated non-surgically, the physician on call enters this information. If the fracture is treated surgically, the surgeon enters the data postoperatively. The date and type of treatment are chosen from drop-down menus. Only treatments possible for the particular fracture are shown. The registration of treatment includes information about the specific type of implant used. Finally, the surgeon's experience level is entered and boxes are checked to indicate whether additional surgery will be performed at another hospital. All treatments and procedures performed are registered. If a new procedure is performed, a second treatment panel is opened. If surgery is performed secondary to non-surgical treatment that has failed, the entire sequence of events is recorded. Scheduled secondary procedures are distinguished from re-operations, which are entered, along with the indications for which they were performed.

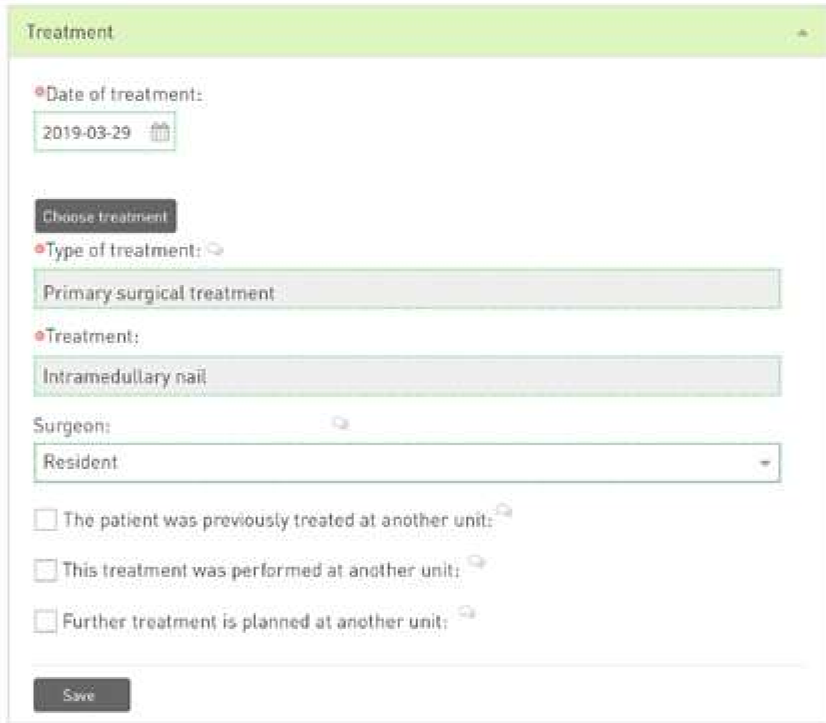

FIGURE 15 Registration of treatment

5.5 CLASSIFICATION OF FRACTURES

The AO/OTA classification is comprehensive and has a common structure for classifying fractures in all parts of the body, thereby meeting the demands of the SFR [26, 28]. It was therefore considered the best available option for the classification of fractures in the SFR and was chosen whenever feasible and meaningful. In some parts of the body, it was adapted to the demands of the register. The online features are particularly useful for pelvic, acetabular and forearm fractures. For example, pelvic fractures can be assigned an ICD code based on the individual fracture components indicated on a pelvic overview in the first step, with the AO/OTA code (instability pattern) generated in the next step. Similarly, proximal radial and ulnar fractures are classified for each bone separately and the SFR automatically links the choices that have been made together and creates the ultimate classification.

In some specific types of fracture, classifications other than the AO/OTA are used. Acetabular fractures are classified in accordance with both the AO/OTA and Letournel classifications [71]. Hip fractures are classified in accordance with the AO/OTA classification, but the descriptions shown in the classification process refer to the Garden classification of cervical hip fractures [72]. In the same way, proximal humeral fractures are assigned an AO/OTA class, but the descriptions of the classification parallel Neer's terminology [73]. Clavicular fractures are classified in accordance with Robinson and scapular fractures are classified in accordance with Euler and Rüedi or Ideberg, depending on the type of scapular fracture [74-76]. For foot fractures, minor modifications and simplifications of the OTA code have been made. Periprosthetic fractures and fractures close to implants are registered and classified according to the Unified Classification System (UCS) [70].

5.6 COMPLETENESS

The completeness of any NQR is essential. The larger the percentage of all fractures that are entered, the higher the level of completeness and the more valuable the data. Comparisons of registrations in an NQR with the official health databases in Sweden are most frequently made on the basis of the ICD codes for diagnosis. This method has limitations, but it is the only way for an NQR to estimate its completeness. The SFR has created an algorithm in collaboration with the Swedish National Board of Health and Welfare, which

runs the analyses of completeness between NQR data and data from the National Patient Register. The completeness data per hospital were published for the first time in the annual report for 2017 [77].

The SFR has a search function to identify incomplete data relating to the injury, fracture, treatment or PROMs. In addition to this function, each department is free to incorporate methods of its own in order to ensure the most complete data possible. At Sahlgrenska University Hospital, structured searches are made in the digital medical records. Each week, the medical records are scanned for ICD codes related to fractures. These search results are matched to entries in the SFR and the fractures that have not been registered in the SFR are registered secondarily. In this way, all patients who have a fracture diagnosis code in the medical chart are registered in the SFR.

To make sure all re-operations were included in Study IV in the current thesis, the operation planning system was checked for all patients included in the study. If a treatment not registered in the SFR was detected, the medical chart was reviewed and missed treatments were registered in the SFR. Subsequently, a new data extraction was made from the SFR on which the calculations and analysis for Study IV were based.

5.7 COVERAGE

The goal for an NQR such as the SFR is naturally that all inhabitants are covered. This will be achieved when all the orthopaedic departments treating fractures in Sweden are affiliated to the SFR. Participation in the SFR is, however, voluntary for the departments. All departments have been invited to participate and information related to the SFR is continuously distributed at national meetings and professional conventions.

5.8 MORTALITY

The SFR uses a real-time link to the Swedish Tax Agency population register for all citizens (Folkbokföringsregistret). When entering the personal identity number, key data on the individual, such as name, address and so on, are returned and the registration can take place. When a Swedish citizen dies, this information automatically appears in the SFR within a few days, enabling straightforward studies of mortality rates in the register, without the need for other data sources.

5.9 RETRIEVAL OF DATA FROM THE SWEDISH FRACTURE REGISTER

When a user is logged into the SFR website, he or she can easily access real-time data. As previously mentioned, the available data can be divided into aggregated data and data specific to one department with the opportunity to identify individual patients. The aggregated data are predefined in different modules. In each module, the users can filter the data that are retrieved from the SFR, using most of the available variables (e.g. date, age, AO/OTA class and treatment) to create customised graphs and figures. For example, the number of fractures per month, year and so on can be displayed compared with other departments in the country and filtered for age groups, gender, fracture types and so on. The percentage of a fracture type that is treated surgically is another example of the available data. The percentage of hip and femoral fractures operated on within 24 or 36 hours from the time of the initial radiographs is presented. Re-operation rates, PROM results and PROM response rates can also be displayed.

Probably the most useful tool in clinical practice when accessing a department's own data is the search for possible osteoporotic fractures. The database will return the personal identity numbers of patients with fractures of the proximal humerus, wrist, hip, pelvis or spine for the period of time chosen. The hospital can then offer the patients the opportunity of an investigation with dual-energy X-ray absorptiometry (DEXA) and, if needed, a proposal for pharmacological and other treatment protocols for osteoporosis in order to prevent subsequent fractures.

5.10 PATIENTS

The studies of tibial fractures in the thesis (Studies II-IV) are based on the same cohort. The studies are, however, based on three separate data extractions from the SFR made at three different time points. The first was a randomised extraction to identify 114 randomly allocated fractures to study the validity of fracture classification (Study II). The second extraction comprised all tibial fractures treated at Sahlgrenska University Hospital from 1 January 2011 to 31 December 2015 (Study III). Prior to the third data extraction, all the patients from Study III were reviewed in the operation planning programme at Sahlgrenska University Hospital to identify missing treatments. The missing treatments were registered in the SFR retrospectively and a third data extraction of all tibial fractures treated at Sahlgrenska University Hospital from 1 January 2011 to 31 December 2015 was subsequently performed, on which Study IV was based.

5.11 VALIDITY OF FRACTURE CLASSIFICATION

In Study II, the gold standard classification was defined as three experienced trauma surgeons agreeing on one classification of a given fracture. As the use of the SFR began with the registration of tibial fractures at Sahlgrenska University Hospital on 1 January 2011, this study focused on tibial fractures registered between 1 January 2011 and 31 December 2012.

The total number of tibial fractures (i.e. ICD S82.10, S82.11, S82.20, S82.21, S82.30 and S82.31) registered in the SFR at Sahlgrenska University Hospital in 2011 and 2012 was 598 (Figure 16). During this time period, 114 patients with tibial fractures were randomly allocated from the SFR. Information in terms of birth date, personal identity number, date of injury, ICD-10 code, AO/OTA code and affected side was extracted from the SFR for each of the 114 patients. The medical charts and radiographs for each patient were reviewed by one of the authors (DW). With dates and patients' ID removed, the same radiological images, of all the modalities that were available at the time of registration, were extracted and used for the assessments in the study. The plain radiographs were all standardised series including anteroposterior, lateral and oblique views.
In clinical practice, the quality of the radiographs was approved by both the radiologist on call and the orthopaedic surgeon at the emergency department. CT imaging was used when the attending physician who diagnosed the fracture decided that a CT scan was necessary to analyse and classify the fracture (54 cases). In Study II, for all patients, the same imaging modalities used when the fracture was originally classified and registered in the SFR were presented to the assessors in the study. As a result, in order to replicate the conditions at registration, if CT imaging was used when the attending physician classified the fracture, the CT images were available to the assessors in the study as well.

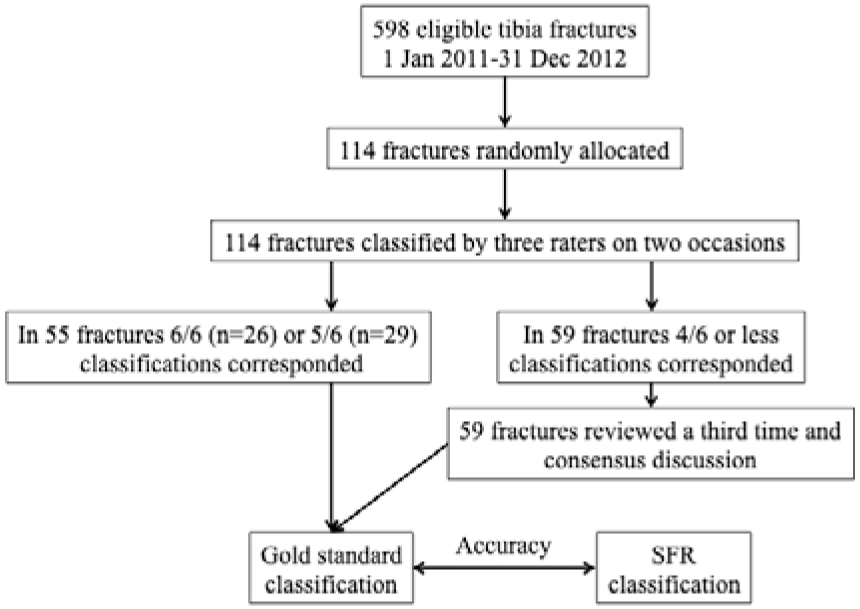

FIGURE 16 Flow chart showing how Study II was conducted

The radiographs of the 114 patients were presented to a group of three experienced trauma surgeons (CE, MS and MM) in two classification sessions with a time interval of one month. The three assessors in the study are senior consultants in trauma orthopaedics and are very familiar with the AO/OTA classification from their everyday clinical practice. Prior to the classification sessions, they had no specific training in fracture classification. However, during the classification sessions, the same pictures and descriptions of the fracture classes that are used during registration in the SFR were available. During the classification sessions, the three assessors classified the fractures independently and blinded to clinical patient information. They were not allowed to discuss or comment on the fracture cases, nor were they allowed to study each other's classifications. At the second seminar, the cases were presented in a different order. When the three assessors had classified the fractures at these two seminars, each case had been classified two times each by three assessors, which means that each fracture was classified six times. When classifications were identical in five or six out of six, this was accepted as the gold standard classification. In cases where four or fewer classifications corresponded, the

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cases were presented once more at a third seminar. The assessors were again shown the cases blinded and they classified the cases a third time independently. They were then presented with their previous classifications and a discussion was held between the assessors to reach consensus. In this way, gold standard classification was defined for each of the 114 fractures.

5.12 MECHANISM OF INJURY

When presenting the mechanism of injury in Study III, the same six categories as defined by Bergdahl et al. in a previous study of the epidemiology of humeral fractures from the SFR were used [78]. The six categories are simple fall, fall from a height, unspecified fall, traffic-related trauma, miscellaneous injuries (including sports-related injuries, falling objects and mechanical forces) and non-traumatic fractures including pathological fractures, spontaneous fractures and stress fractures.

5.13 CALCULATION OF INCIDENCE

In Study III, the incidence of tibial fractures was calculated. Sahlgrenska University Hospital is the sole provider of fracture care in Gothenburg and the surrounding areas. The SFR is thought to include all patients with tibial fractures within the catchment area for the hospital at the time of the study. Data related to the population of the catchment area for the hospital were obtained from Statistics Sweden [79].

5.14 TREATMENT

All treatments given to a specific patient and fracture are registered in the SFR. Primary treatments (surgical as well as non-surgical) are distinguished from planned secondary treatments and re-operations. If a patient is primarily assigned to non-surgical treatment but converts to surgical treatment at an early stage after the non-surgical treatment was considered inappropriate (e.g. due to increasing dislocation at an early radiographic check), this sequence is recorded as well, i.e. "Surgical treatment after failed non-surgical treatment".
Since the chain of treatment for tibial fractures is sometimes complex, an algorithm for determining the main treatment was created. For example, a patient might be treated with a temporary external fixation as the primary

surgical treatment and subsequently with an intramedullary nail as a planned secondary treatment. In such a case, the intramedullary nailing is regarded as the main treatment, even though it is performed as a planned secondary treatment.

5.15 RE-OPERATION RATES

In the SFR, as in many other orthopaedic quality registers, re-operation is the main surgeon-reported outcome registered. Re-operations and late operations after failed non-surgical treatment, e.g. malunion, are regarded as failures because they were not part of the original treatment plan. Re-operations are sub-grouped according to the reason for the re-operation:

– Re-operation due to non-union
– Re-operation due to malunion
– Re-operation due to infection
– Re-operation due to implant failure or incorrectly positioned implant
– Re-operation due to patient discomfort
– Re-operation due to other reason

During the first years of the SFR, the registration options for reason for re-operations were fewer. It was then realised that "re-operation due to other reason", which at that time included re-operations due to patient discomfort, was the most commonly registered reason for re-operation. It was suspected that most of these re-operations were due to patient discomfort. So, in February 2016, "re-operation due to patient discomfort" was added as a separate choice. After that date, "re-operations due to other reason" decreased dramatically. As a result, the majority of re-operations registered as "due to other reason" can be assumed to have been performed due to patient discomfort.

5.16 STATISTICS

In Study II, the accuracy of fracture classification, intra- and interobserver agreement were analysed with percentage of agreement and Cohen's kappa. Cohen's kappa was calculated with the "proc freq" procedure using the SAS statistical software. Studies III and IV only contain descriptive statistics. No statistical comparisons between groups were therefore made. All statistical

analyses for the studies in the thesis were calculated with IBM SPSS v. 25 and SAS v. 9.4.

5.17 ETHICS

The Swedish Fracture Register is approved by the Swedish Data Inspection Board and operates in accordance with Swedish legislation, i.e. the Swedish Personal Data Act, the Swedish Patient Data Act and, since May 2018, the General Data Protection Regulation (GDPR). All patients are informed that registration will take place and that they have the right to decline. According to Swedish legislation, NQRs do not require signed consent from the individual registered patient. The benefit of this so-called opt-out system for NQRs in Sweden cannot be overestimated.

The studies in this thesis were approved by the Central Ethical Review Board, Gothenburg (Dnr: 401-13 (Study II) and Dnr: 594-16 (Studies III and IV)).

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RESULTS/ SUMMARY OF PAPERS

STUDY I

The Swedish Fracture Register: 103,000 fractures registered

The aim of Study I was to describe the development, implementation and current use of the SFR. Since Study I was published in 2015, the tables and figures presented here in the thesis correspond to the tables and figures in Study I, but with updated numbers.

Results

As of 31 May 2019, 42 orthopaedic departments are affiliated with the SFR. These hospitals cover approximately 80% of the Swedish population. As of 31 May 2019, more than 370,000 fractures have been registered in the SFR. Figures 17 and 18 show cumulative growth in number of fractures and age distribution of patients included in the SFR respectively. Table 1 shows gender distribution of patients in the SFR and Table 2 shows distribution of high- and low-energy injuries.

Conclusions

The SFR is already a well-functioning, population-based fracture register that covers fractures of all types, regardless of treatment, and collects both surgeon- and patient-reported outcome measures. It is used as a clinical routine at the majority of the orthopaedic departments in Sweden. The success of the initial implementation makes it clear that satisfactory compliance with the aims of the register is possible and that surgeons can find the time to perform the required data entry. As demonstrated in Studies II-IV, the SFR has been able to present results of fracture treatment and valuable epidemiological data as well.

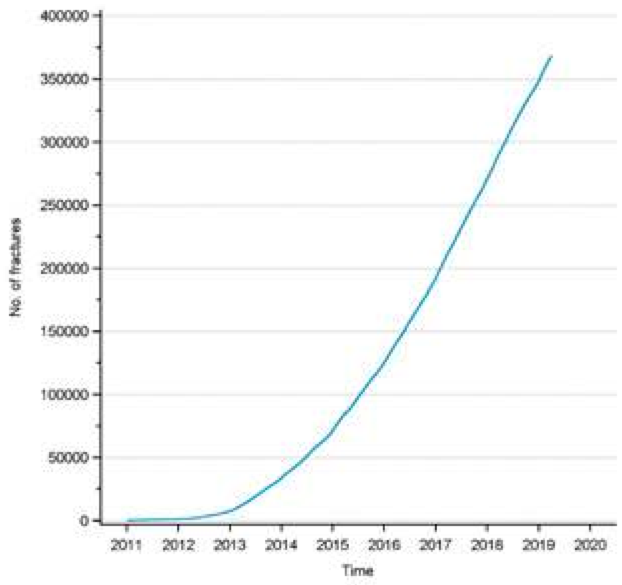

FIGURE 17 Cumulative growth in number of fractures included in the SFR on 1 January 2011-31 March 2019. Figure 17 replaces Table 1 in the published version of Study I.

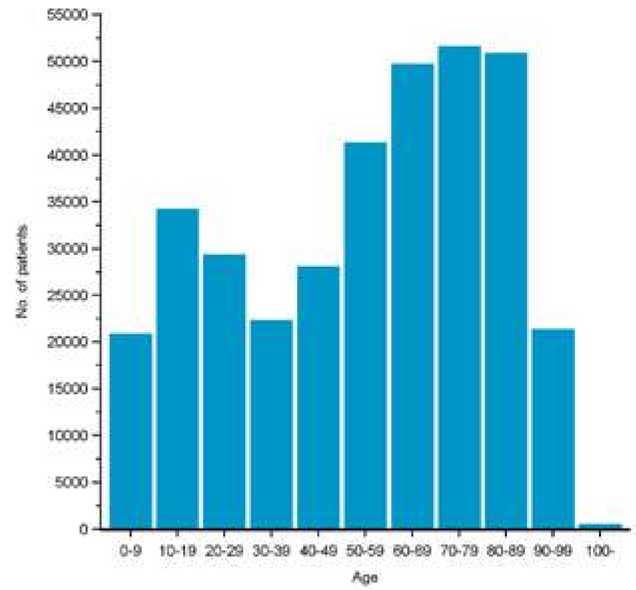

FIGURE 18 Age distribution of patients in the SFR (1 January 2011-31 March 2019). Figure 18 replaces Table 3 in the published version of Study I.

6 RESULTS/SUMMARY OF PAPERS

TABLE 1 Gender distribution of patients in the SFR (1 January 2011-31 March 2019)

Women	Men	Total
200254	150362	350616
57 %	43 %	

TABLE 2 Number of injuries in the SFR distributed according to high- or low-energy injury (1 January 2011-31 March 2019)

Cause of injury	Number of injuries	Percent
High energy	24990	7
Low energy	285606	81
Unknown/missing	36007	10
Not applicable	4013	1
Total	350616	

STUDY II

High reliability in classification of tibia fractures in the Swedish Fracture Register

The accuracy of the classification of fractures is important for the reliability of the data in the SFR. This study aimed to evaluate how accurate the classification of tibial fractures in the register is.

Results

One hundred and fourteen tibial fractures were randomly allocated from the SFR. Gold standard classification was determined for each fracture. The gold standard classification was defined as three experienced orthopaedic surgeons agreeing on one classification. The accuracy of the SFR, defined as agreement between the SFR and the gold standard classification, was kappa = 0.75 for the AO/OTA type and 0.56 for the AO/OTA group (Table 3). These values correspond to substantial and moderate agreement respectively. Mean inter-observer agreement across the three assessors in the study was kappa = 0.74 for the AO/OTA type and 0.53 for the AO/OTA group (Table 4). Intra-observer agreement was kappa = 0.74-0.79 for the AO/OTA type and 0.62-0.64 for the AO/OTA group (Table 5).

Conclusion

This study shows that the accuracy of the classification of tibial fractures in the SFR was substantial for the AO/OTA type (kappa=0.75) and moderate for the AO/OTA group (kappa=0.56), as defined by Landis and Koch. This degree of accuracy is similar to that in previous studies. Our interpretation is that the accuracy of the classification of tibial fractures in the SFR was as high as could be expected. It can also be concluded that this level of accuracy enables data relating to tibial fractures in the SFR to be used for further scientific analysis.

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TABLE 3 Accuracy, defined as classification in the SFR compared with gold standard classification

	Accuracy	
	SFR vs GS	
	PA	Kappa (95% CI)
AO/OTA group (4 signs)	59%	0.56 (0.46-0.65)
AO/OTA type (3 signs)	80%	0.75 (0.66-0.84)

PA Percentage of agreement, GS Gold standard classification

TABLE 4 Inter-observer agreement comparing the three raters at the two classification seminars.

	Inter-observer agreement					
	Rater 1 vs Rater 2		Rater 1 vs Rater 3		Rater 2 vs Rater 3	
	Seminar 1 Kappa (95% CI)	Seminar 2 Kappa (95% CI)	Seminar 1 Kappa (95% CI)	Seminar 2 Kappa (95% CI)	Seminar 1 Kappa (95% CI)	Seminar 2 Kappa (95% CI)
AO/OTA group (4 signs)	0.52 (0.42-0.62)	0.52 (0.42-0.62)	0.50 (0.41-0.60)	0.52 (0.43-0.62)	0.55 (0.46-0.65)	0.58 (0.48-0.67)
AO/OTA type (3 signs)	0.70 (0.60-0.79)	0.78 (0.69-0.86)	0.73 (0.64-0.82)	0.73 0.64-0.82)	0.68 (0.58-0.77)	0.80 (0.72-0.89)

TABLE 5 Intra-observer agreement comparing the classification of each rater at the two different classification seminars.

	Intra-observer agreement					
	Rater 1		Rater 2		Rater 3	
	PA	Kappa (95%CI)	PA	Kappa (95%CI)	PA	Kappa (95%CI)
AO/OTA group (4 signs)	68%	0.64 (0.54-0.73)	67%	0.63 (0.54-0.72)	65%	0.62 (0.53-0.71)
AO/OTA type (3 signs)	83%	0.79 (0.71-0.87)	82%	0.78 (0.69-0.87)	79%	0.74 (0.65-0.83)

PA Percentage of agreement, CI Confidence interval

STUDY III
Epidemiology and incidence of tibia fractures in the Swedish Fracture Register

Most previous studies of the epidemiology of tibial fractures were conducted during or before the 1990s and often focused on only one segment of the tibia. No previous epidemiological study of fractures in all the segments of the tibia classified by orthopaedic surgeons according to the AO/OTA classification has been published.

The aim of this study was to describe the epidemiology and incidence of fractures in all segments of the tibia in a cohort of consecutive tibial fractures over a period of five years at Sahlgrenska University Hospital, Gothenburg, Sweden.

Results
During the five-year period of this study, 1,325 patients sustained 1,371 tibial fractures on 1,343 injury occasions. Twenty-seven (2%) patients had more than one tibial fracture on the same injury occasion. Of these 27 patients, 17 had bilateral tibial fractures and one had three tibial fractures on the same injury occasion (proximal and distal fracture of the right tibia and a shaft fracture of the left tibia). There were 712 proximal tibial fractures, 417 tibial shaft fractures and 242 distal tibial fractures.

For all tibial fractures, there was an equal gender distribution (male:female 49:51) (Table 6). Among the proximal tibial fractures, there was a predominance of women (male:female 42:58), while, among the tibial shaft fractures and the distal tibial fractures, there was a predominance of men (male:female 59:41 and 54:46 respectively).

The men with tibial fractures had a mean age of 43.8 (range 16-95) years and the women 58.4 (16-101) years (Table 6). The mean age of patients with proximal tibial fractures was 54.3 (16-101) years, for tibial shaft fractures 47.0 (16-95) years and for distal tibial fractures 48.7 (16-95) years. Of the tibial shaft fractures, 74/417 (17.7%) were open, whereas 17/712 (2.4%) and 28/242 (11.5%) of the proximal and distal fractures were open.

Among proximal tibial fractures, the partial intra-articular B fracture was the most common fracture type and constituted 64% of proximal tibial fractures and 32% of

all tibial fractures (Table 7). Among the tibial shaft fractures, the A fractures were the most common (56% of tibial shaft fractures). The distal tibial fractures were the least common and constituted 18% of all tibial fractures. With regard to the distal tibial fractures, there was a more or less equal distribution between A, B and C fractures – 7%, 6% and 5% respectively of all tibial fractures.

Simple falls were the most common mechanism of injury for all tibial fractures (44%) and in each segment separately (48%, 41% and 39% for proximal, diaphyseal and distal tibial fractures respectively). Traffic-related trauma was the second most common mechanism of injury for proximal tibial fractures (23%) and tibial shaft fractures (24%), whereas a fall from height was the second most common mechanism of injury for distal tibial fractures (22%).

The overall, total incidence of tibial fractures was 51.7 per 100,000 per year (Table 8). The incidence of proximal, diaphyseal and distal tibial fractures was 26.9, 15.7 and 9.1 respectively per 100,000 and year. For all segments of the tibia, women had an increasing incidence with increasing age (Figure 20). Men, however, had a fairly flat incidence curve for proximal and distal tibial fractures and a peak at young age for tibial shaft fractures.

Conclusions
This study describes the epidemiology and incidence of fractures for all segments of the tibia classified by orthopaedic surgeons according to the AO/OTA classification. The study shows an overall, total incidence of tibial fractures of 51.7 per 100,000 per year. Women had an increasing incidence with higher age for fractures of all segments of the tibia, whereas men had a more or less flat incidence curve, apart from tibial shaft fractures, which showed a peak among young men.

TABLE 6 Demograhics for patients with tibia fractures divided into segments of the tibia 1 January 2011 to 31 December 2015 at Sahlgrenska University Hospital, Gothenburg. Non-traumatic fractures include pathological fractures, spontaneous fractures and stress fractures.

		Proximal N=712 (52%)	Shaft N=417 (30%)	Distal N=242 (18%)	Total N=1,371 (100%)
Gender	Male, N (%)	300 (42)	245 (59)	131 (54)	676 (49)
	Female, N (%)	412 (58)	172 (41)	111 (46)	695 (51)
Age, yrs	< 50, N (%)	285 (40)	229 (55)	126 (52)	640 (47)
	≥ 50, N (%)	427 (60)	188 (45)	116 (48)	731 (53)
Side	Left, N (%)	382 (54)	209 (50)	116 (48)	707 (52)
	Right, N (%)	330 (46)	208 (50)	126 (52)	664 (48)
Fracture	Open, N (%)	17 (2.4)	74 (17.7)	28 (11.5)	119 (8.7)
	Non-traumatic, N (%)	4 (0.6)	10 (2.4)	9 (3.7)	23 (1.7)
Mean age	Male, yrs (range)	46.0 (16-95)	41.5 (16-88)	42.3 (16-93)	43.8 (16-95)
	Female, yrs (range)	60.4 (17-101)	54.9 (16-95)	56.1 (16-96)	58.4 (16-101)
	Total, yrs (range)	54.3 (16-101)	47.0 (16-95)	48.7 (16-96)	51.1 (16-101)

TABLE 8 Incidence of tibia fractures per 100,000 and year for each segment of the tibia and all tibia fractures. The mean number of inhabitants, aged 16 years and above, in the catchment area of Sahlgrenska University Hospital during the study period was 530,000.

	Incidence of tibia fractures			
	Proximal	Diaphyseal	Distal	All
Men	23.0	18.8	10.0	51.7
Women	30.7	12.8	8.3	51.7
All	26.9	15.7	9.1	51.7

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TABLE 7 Distribution of tibia fractures according to the segment of the tibia and AO/OTA group 1 January 2011 to 31 December 2015 at Sahlgrenska University Hospital, Gothenburg. Fourteen fractures were registered as "not able to classify" and two fractures were classified as paediatric fractures and so the total number of fractures in Table 7 is 1,355.

	Proximal N=704 (52%)					Shaft N=413 (30%)					Distal N=238 (18%)				
Fracture group	Number of patients	Percentage of all tibia fractures	Percentage of proximal tibia fractures	Mean age	Women %	Number of patients	Percentage of all tibia fractures	Percentage of tibial shaft fractures	Mean age	Women %	Number of patients	Percentage of all tibia fractures	Percentage of distal tibia fractures	Mean age	Women %
A1	59	4	8	42	42	113	8	27	51	50	55	4	23	58	67
A2	54	4	8	69	56	51	4	12	47	49	7	1	3	52	57
A3	12	1	2	70	58	67	5	16	37	31	30	2	13	61	50
Total A	125	9	18	56	50	231	17	56	46	44	92	7	39	59	61
B1	182	13	26	53	56	41	3	10	48	49	53	4	22	39	49
B2	141	10	20	57	70	50	4	12	44	32	13	1	5	50	31
B3	127	9	18	54	62	24	2	6	50	29	13	1	5	42	54
Total B	450	32	64	54	62	115	9	28	47	37	79	6	33	42	47
C1	46	3	7	56	61	31	2	8	52	52	9	1	4	42	33
C2	19	1	3	57	58	17	1	4	52	41	11	1	5	52	46
C3	64	5	9	49	47	19	1	5	49	21	47	3	20	42	19
Total C	129	9	18	53	53	67	4	16	51	40	67	5	28	44	25

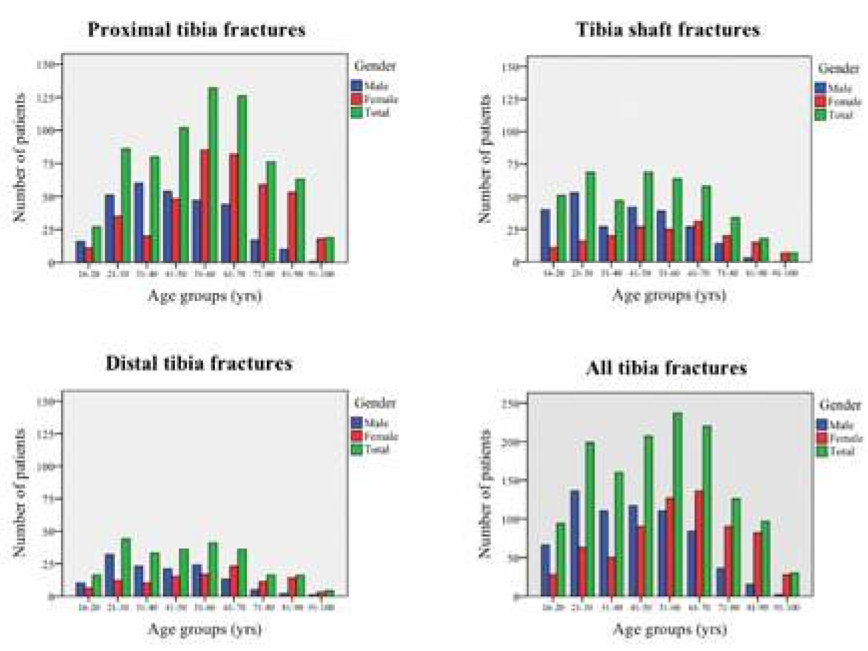

FIGURE 19 Age and gender distribution of tibial fractures for each segment and all tibial fractures. In the study cohort, there was one patient above 100 years of age (i.e. one patient at the age of 101 years with a proximal tibial fracture). However, the bar representing this single patient was omitted in this figure for simplicity.

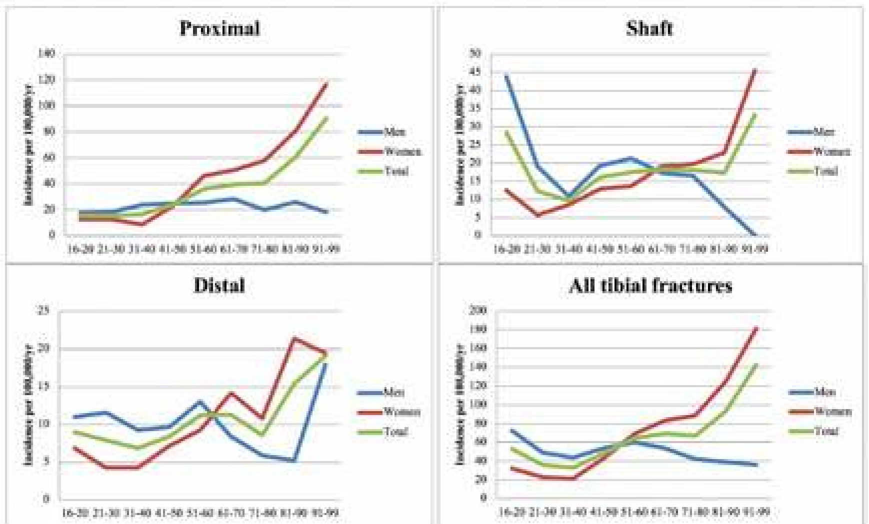

FIGURE 20 Age- and gender-specific incidence for all tibial fractures and each segment

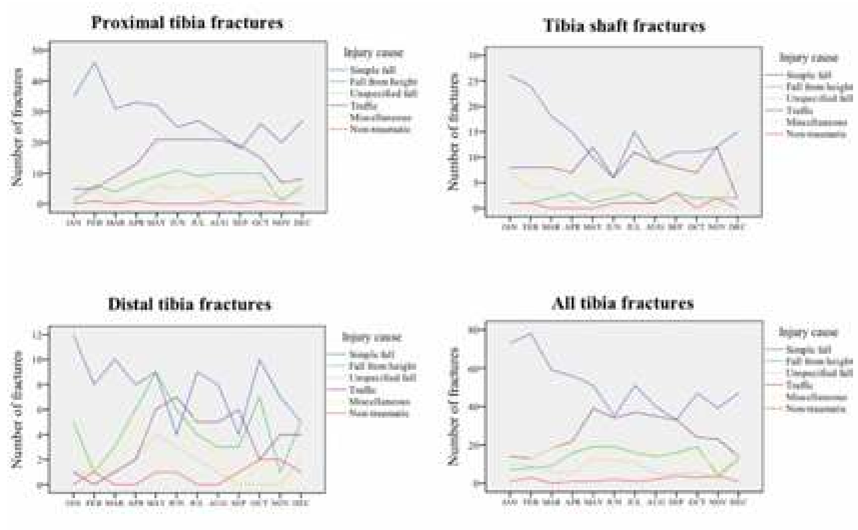

FIGURE 21 Seasonal variation in tibial fractures according to injury cause presented for each segment and all tibial fractures respectively

STUDY IV

Treatment and re-operation rates in 1,371 tibial fractures from the Swedish Fracture Register

A few recent studies of different aspects of specific types of tibial fracture have reported re-operation rates after the treatment of tibial fractures [37-41]. To the best of our knowledge, there is, however, no previous register-based study that describes the treatment and re-operation rates of fractures in all segments of the tibia.

The aim of this study was to describe the treatment and re-operation rates of tibial fractures in all segments of the tibia for a cohort of consecutive tibial fractures at Sahlgrenska University Hospital over a period of five years.

Results

The study showed 99% completeness for the registration of primary treatment, 88.7% for planned secondary surgery and 63% for re-operations on tibial fractures (Table 9). The primarily missed treatments were registered secondarily before the calculations for the study were performed and all treatments are thereby included in the study.

The majority (66%) of tibial fractures were treated surgically, while 34% were treated non-surgically (Figure 22). Non-surgical treatment was chosen in 341/699 (49%) of proximal tibial fractures, 48/411 (12%) of tibial shaft fractures and 68/237 (29%) of distal tibial fractures (Table 10). Among the proximal and distal tibial fractures, plate fixation was the most commonly used surgical method, whereas, among tibial shaft fractures, intramedullary nailing was most commonly used.

Among all tibial shaft fractures, 292/411 (71%) were treated with intramedullary nailing (Table 10). The A and B1 fractures were treated non-surgically in 10-29%, whereas the other fracture classes were almost exclusively treated surgically.

In terms of the distal tibia, among A1 and B1 fractures, approximately half the fractures were treated non-surgically (30/56 (54%) and 29/51 (57%) respectively) (Table 10). For all other distal tibial fractures, the majority were

treated surgically, most commonly with plate fixation, apart from some A fractures that were treated with intramedullary nailing.

Almost 30% (29.8%) of all surgically treated tibial fractures underwent re-operation (Table 11). Among proximal tibial fractures, 24.3% underwent re-operation, tibial shaft fractures 37.0% and distal tibial fractures 26.3%. The removal of internal fixation devices was by far the most common re-operation (258/438 re-operations).

Among the proximal tibial fractures, three underwent re-operation due to non-union and 20 due to malunion (Table 12). Among the tibial shaft fractures, it was the other way around – 22 fractures underwent re-operation due to non-union, whereas nine were due to malunion. Among the distal tibial fractures, re-operations due to non-union and malunion were equally common – six fractures underwent re-operation due to non-union and eight due to malunion. Re-operations due to infection occurred in A, B and C fractures in all segments.

Of the surgically treated tibial fractures, 28/892 (3.1%) underwent re-operation due to non-union, 32/892 (3.6%) due to malunion, 38/892 (4.3%) due to infection and 22/892 (2.5%) due to implant failure. Re-operations due to infection appear to have a peak in patients 51-80 years of age (Figure 23). For re-operations due to non-union, malunion and implant failure, however, there were no obvious differences in re-operation rates in the different age groups. Re-operations due to patient discomfort and other reasons appear to be more commonly performed in younger patients (age ≤ 60).

Of the 118 re-operations performed due to patient discomfort, 102 involved the removal of internal fixation devices. Of the 126 re-operations performed due to “other reasons”, 73 involved the removal of internal fixation devices.

Conclusions

Of all surgically treated tibial fractures, 30% underwent re-operation. The removal of internal fixation devices was the most commonly performed re-operation. Re-operations due to non-union, malunion, infection and implant failure were more or less equally common. Among the surgically treated fractures, re-operations due to infection were more or less equally common in the different segments of the tibia. In proximal tibial fractures, re-operations due to malunion were more common than those due to non-union. In tibial shaft fractures, re-operation due to non-union was more common than malunion. Moreover, in distal tibial fractures, re-operations due to non-union and malunion were almost equally common.

TABLE 9 Number of initially missed registrations of procedures and completeness according to type of procedure for tibia fractures at Sahlgrenska University Hospital 2011-2015

	Missed registrations	Total number of procedures	Completeness
Primary procedure	12	1,396	99.1%
Planned secondary surgery	34	302	88.7%
Reoperation	171	462	63.0%
Total	217	2,160	90.0%

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TABLE 10 Treatment of tibial fractures according to AO/OTA class at Sahlgrenska University Hospital in 2011-2015. The percentage figures refer to the percentage within each row, i.e. the percentage per AO/OTA class. 10 fractures had missing information regarding main treatment and two fractures were classified as paediatric fractures and are not included in this table. As a result, the total number of fractures in the table is 1,359.

	Treatment, number of fractures (%)						
AO/OTA class	Non-surgical	IM nail	Plate fixation	External fixation	Other surgical treatment*	Amputation	Total
41-A1	38 (64)	0 (0)	1 (2)	0 (0)	20 (34)	0 (0)	59
41-A2	27 (49)	1 (2)	26 (47)	1 (2)	0 (0)	0 (0)	55
41-A3	1 (8)	1 (8)	10 (83)	0 (0)	0 (0)	0 (0)	12
41-B1	119 (66)	1 (1)	45 (25)	0 (0)	15 (8)	0 (0)	180
41-B2	107 (77)	0 (0)	24 (17)	0 (0)	8 (6)	0 (0)	139
41-B3	37 (29)	0 (0)	81 (64)	0 (0)	8 (6)	0 (0)	126
41-C1	9 (20)	0 (0)	33 (73)	0 (0)	3 (7)	0 (0)	45
41-C2	1 (5)	0 (0)	14 (74)	2 (11)	2 (11)	0 (0)	19
41-C3	2 (3)	0 (0)	52 (81)	7 (11)	1 (2)	2 (3)	64
Total 41	**341 (49)**	**3 (0.4)**	**286 (41)**	**10 (1)**	**57 (8)**	**2 (0.3)**	**699**
42-A1	15 (13)	82 (73)	12 (11)	4 (4)	0 (0)	0 (0)	113
42-A2	6 (12)	38 (75)	3 (6)	1 (2)	2 (4)	1 (2)	51
42-A3	19 (29)	41 (62)	2 (3)	2 (3)	2 (3)	0 (0)	66
42-B1	4 (10)	31 (76)	5 (12)	1 (2)	0 (0)	0 (0)	41
42-B2	2 (4)	38 (76)	9 (18)	1 (2)	0 (0)	0 (0)	50
42-B3	1 (4)	14 (58)	6 (25)	2 (8)	0 (0)	1 (4)	24
42-C1	0 (0)	26 (84)	5 (16)	0 (0)	0 (0)	0 (0)	31
42-C2	0 (0)	14 (82)	2 (12)	1 (6)	0 (0)	0 (0)	17
42-C3	1 (6)	8 (44)	6 (33)	3 (17)	0 (0)	0 (0)	18
Total 42	**48 (12)**	**292 (71)**	**50 (12)**	**15 (4)**	**4 (1)**	**2 (0.5)**	**411**
43-A1	30 (54)	11 (20)	15 (27)	0 (0)	0 (0)	0 (0)	56
43-A2	2 (29)	1 (14)	4 (57)	0 (0)	0 (0)	0 (0)	7
43-A3	3 (10)	11 (37)	13 (43)	3 (10)	0 (0)	0 (0)	30
43-B1	29 (57)	0 (0)	8 (16)	1 (2)	13 (25)	0 (0)	51
43-B2	1 (8)	0 (0)	9 (69)	0 (0)	3 (23)	0 (0)	13
43-B3	1 (8)	0 (0)	9 (69)	0 (0)	3 (23)	0 (0)	13
43-C1	2 (22)	0 (0)	7 (78)	0 (0)	0 (0)	0 (0)	9
43-C2	0 (0)	2 (18)	8 (73)	1 (9)	0 (0)	0 (0)	11
43-C3	0 (0)	0 (0)	44 (94)	1 (2)	2 (4)	0 (0)	47
Total 43	**68 (29)**	**25 (11)**	**117 (49)**	**6 (3)**	**21 (9)**	**0 (0)**	**237**
Not able to classify	6 (50)	0 (0)	1 (8)	0 (0)	2 (17)	3 (25)	12
Total	**463 (34)**	**320 (24)**	**454 (33)**	**31 (2)**	**84 (6)**	**7 (0.5)**	**1359**

* “Other surgical treatment” includes screw fixation, pin fixation, fixation with cerclage etc.

TABLE 11 Number of reoperation procedures according to AO/OTA class and type of procedure based on all surgically treated fractures. Two fractures were classified as paediatric fractures and are not included in this table, so the total number of surgically treated fractures is 890. Please note that, in some cases, more than one procedure has been performed on one fracture and sometimes on one occasion. The total number of procedures is therefore higher than the total number of reoperated fractures. Table 11 presents all the procedures, regardless of whether they were performed in different reoperations or simultaneously in one reoperation. The number of procedures in Table 11 is therefore higher than the number of reoperations in Table 12. For example, if a patient undergoes surgical debridement and the removal of internal fixation devices in one reoperation, both these procedures are presented in Table 11, whereas, in Table 12, this is presented as one reoperation due to infection.

	Number of procedures															
AO/OTA	IM nail	Plate fixation	External fixation	Other fracture fixation*	Arthro-plasty	Arthro-desis	Amput-ation	Arthro-scopy	Correction osteotomy	Other soft-tissue surgery**	Removal of internal devices	Extrac-tion of external fixation	Total number of pro-cedures	Total number of reoperated fractures	Percentage reoperated fractures	Total number of surgically treated fractures
41-A1	0	0	0	0	0	0	0	2	0	2	0	0	4	4	19.0	21
41-A2	0	0	0	0	0	0	0	0	0	2	2	0	4	2	7.1	28
41-A3	0	0	0	0	0	0	0	0	0	1	1	0	2	2	18.2	11
41-B1	0	0	0	0	0	0	0	1	0	3	7	0	11	8	13.3	60
41-B2	0	0	0	0	2	0	0	0	1	0	8	0	11	9	28.1	32
41-B3	0	2	0	0	5	0	0	2	1	1	13	0	24	17	19.1	89
41-C1	0	1	1	1	0	0	0	4	1	3	8	0	19	10	27.8	36
41-C2	0	1	2	1	0	0	0	0	0	1	5	0	10	6	33.3	18
41-C3	0	1	1	1	7	1	2	4	2	15	26	1	61	29	46.0	63
Total 41	**0**	**5**	**4**	**3**	**14**	**1**	**2**	**13**	**5**	**28**	**70**	**1**	**146**	**87**	**24.3**	**358**
42-A1	4	2	0	4	0	0	0	0	0	0	31	0	41	29	29.6	98
42-A2	0	0	0	0	0	0	1	0	0	0	12	1	14	10	22.2	45
42-A3	2	0	0	2	0	0	0	0	0	0	27	0	31	21	47.7	44
42-B1	2	0	0	0	0	0	0	0	1	2	13	0	18	13	35.1	37
42-B2	3	1	4	1	0	0	0	0	1	4	22	2	38	22	45.8	48
42-B3	1	0	2	0	0	0	2	0	1	3	8	0	17	8	36.4	22
42-C1	3	1	0	1	0	0	0	0	0	2	19	0	26	16	51.6	31
42-C2	0	0	1	1	0	0	0	0	0	1	6	1	10	6	35.3	17
42-C3	1	2	0	2	0	0	0	0	1	2	7	0	15	8	47.1	17
Total 42	**16**	**6**	**7**	**11**	**0**	**0**	**3**	**0**	**4**	**14**	**145**	**4**	**210**	**133**	**37.0**	**359**
43-A1	0	1	2	0	0	0	0	0	0	1	5	0	9	6	25.0	24
43-A2	0	0	0	0	0	0	0	0	0	0	2	0	2	2	40.0	5
43-A3	2	0	3	2	0	0	0	0	0	0	8	0	15	9	33.3	27
43-B1	0	0	0	1	0	1	0	0	0	1	5	0	8	3	13.6	22
43-B2	0	0	0	1	0	0	0	0	0	0	3	0	4	3	25.0	12
43-B3	0	1	0	0	0	0	0	0	3	0	2	0	6	3	25.0	12
43-C1	0	0	0	0	0	0	0	0	0	0	1	0	1	1	14.3	7
43-C2	0	2	0	0	0	0	0	0	0	0	3	0	5	3	27.3	11
43-C3	0	2	2	2	0	3	0	0	0	6	14	1	30	14	29.8	47
Total 43	**2**	**6**	**7**	**6**	**0**	**4**	**0**	**0**	**3**	**8**	**43**	**1**	**80**	**44**	**26.3**	**167**
Not able to classify	0	0	0	1	0	0	0	0	0	1	0	0	2	1	16.7	6
Total	**18**	**17**	**18**	**21**	**14**	**5**	**5**	**13**	**12**	**51**	**258**	**6**	**438**	**265**	**29.8**	**890**

* "Other fracture fixation" includes screw fixation, pin fixation, fixation with cerclage and a combination of fixation methods.
** "Other soft-tissue surgery" includes fasciotomy, surgical debridement and surgery due to superficial and deep infections etc.

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TABLE 12 Number of reoperations according to AO/OTA class and reason for reoperations based on all surgically treated fractures. Two fractures were classified as paediatric fractures and are not included in this table, so the total number of surgically treated fractures is 890. Please note that some fractures have been reoperated more than once. The total number of reoperations is therefore higher than the total number of reoperated fractures. Table 12 presents all reoperations according to the reason for reoperation. As a result, if more than one procedure was performed in one reoperation, this is still presented as one reoperation. The number of reoperations in Table 12 is therefore lower than the number of procedures in Table 11. For example, if a patient undergoes surgical debridement and the removal of internal fixation devices in one reoperations, both these procedures are presented in table 11, whereas, in table 12 they are presented as one reoperation due to infection.

	Number of reoperations									
AO/OTA	Non-union	Mal-union	Infection	Implant failure	Patient discomfort	Other reason	Total number of reoperations	Total number of reoperated fractures	Percentage reoperated fractures	Total number of surgically treated fractures
41-A1	0	0	0	0	3	1	4	4	19.0	21
41-A2	0	0	3	0	0	1	4	2	7.1	28
41-A3	0	0	1	0	1	0	2	2	18.2	11
41-B1	0	0	1	0	6	2	9	8	13.3	60
41-B2	0	2	0	0	4	5	11	9	28.1	32
41-B3	0	7	1	2	5	7	22	17	19.1	89
41-C1	0	3	1	0	5	4	13	10	27.8	36
41-C2	2	2	1	0	2	3	10	6	33.3	18
41-C3	1	6	21	1	11	13	53	29	46.0	63
Total 41	**3**	**20**	**29**	**3**	**37**	**36**	**128**	**87**	**24.3**	**358**
42-A1	2	2	2	3	12	15	36	29	29.6	98
42-A2	0	0	0	0	8	5	13	10	22.2	45
42-A3	5	2	0	1	11	10	29	21	47.7	44
42-B1	0	2	3	1	5	4	15	13	35.1	37
42-B2	6	0	3	4	10	8	31	22	45.8	48
42-B3	0	3	2	1	4	4	14	8	36.4	22
42-C1	3	0	4	2	7	6	22	16	51.6	31
42-C2	3	0	0	0	3	3	9	6	35.3	17
42-C3	3	0	5	2	1	3	14	8	47.1	17
Total 42	**22**	**9**	**19**	**14**	**61**	**58**	**183**	**133**	**37.0**	**359**
43-A1	1	2	0	0	3	2	8	6	25.0	24
43-A2	0	0	0	0	0	2	2	2	40.0	5
43-A3	4	0	1	3	1	4	13	9	33.3	27
43-B1	0	0	3	1	2	0	6	3	13.6	22
43-B2	0	0	2	0	2	0	4	3	25.0	12
43-B3	0	1	0	0	1	3	5	3	25.0	12
43-C1	0	0	0	0	0	1	1	1	14.3	7
43-C2	0	0	0	2	1	0	3	3	27.3	11
43-C3	1	5	7	1	2	7	23	14	29.8	47
Total 43	**6**	**8**	**13**	**7**	**12**	**19**	**65**	**44**	**26.3**	**167**
Not able to classify	0	0	1	0	0	1	2	1	16.7	6
Total	**31**	**37**	**62**	**24**	**110**	**114**	**378**	**265**	**29.8**	**890**

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TABLE 13A Number of reoperations according to main treatment and reason for reoperation for proximal tibial fractures. Six proximal tibial fractures had missing information regarding main treatment, so the total number of fractures in the table is 706.

Main treatment		Reason for reoperation: Non-union	Malunion	Infection	Implant failure	Patient discomfort	Other reason	Total number of reoperations	Total number of reoperated fractures	Percentage reoperated fractures	Total number of fractures
Main treatment	Non-surgical	0	3	1	0	2	0	6	6	2	344
	IM nail	1	0	0	0	0	0	1	1	33	3
	Plate fixation	3	16	20	3	31	24	97	65	23	286
	External fixation	0	3	3	0	0	2	8	5	50	10
	Other surgical treatment*	0	1	0	0	6	8	15	14	23	60
	Amputation	0	0	1	0	0	2	3	2	67	3
Total		4	23	25	3	39	36	130	93	13	706

* "Other surgical treatment" includes screw fixation, pin fixation, fixation with cerclage etc.

TABLE 13B Number of reoperations according to main treatment and reason for reoperation for tibial shaft fractures. Three tibial shaft fractures had missing information regarding main treatment, so the total number of fractures in the table is 414.

Main treatment		Reason for reoperation: Non-union	Malunion	Infection	Implant failure	Patient discomfort	Other reason	Total number of reoperations	Total number of reoperated fractures	Percentage reoperated fractures	Total number of fractures
Main treatment	Non-surgical	0	0	0	0	0	0	0	0	0	48
	IM nail	19	10	11	10	62	45	157	114	39	292
	Plate fixation	7	0	7	5	0	10	29	20	39	51
	External fixation	0	0	0	0	0	2	2	1	7	15
	Other surgical treatment*	0	0	0	0	0	0	0	0	0	4
	Amputation	0	0	2	0	0	3	5	3	75	4
Total		26	10	20	15	62	60	193	138	33	414

* "Other surgical treatment" includes screw fixation, pin fixation, fixation with cerclage etc.

TABLE 13C Number of reoperations according to main treatment and reason for reoperation for distal tibial fractures. One distal tibial fracture had missing information regarding main treatment, so the total number of fractures in the table is 241.

Main treatment	Reason for reoperation						Total number of reoperations	Total number of reoperated fractures	Percentage reoperated fractures	Total number of fractures
	Non-union	Malunion	Infection	Implant failure	Patient discomfort	Other reason				
Non-surgical	1	0	0	0	0	0	1	1	1	71
IM nail	6	1	0	2	2	5	16	9	36	25
Plate fixation	2	8	11	5	8	12	46	33	28	117
External fixation	1	0	0	0	0	1	2	1	17	6
Other surgical treatment*	1	0	2	1	3	2	9	4	18	22
Amputation	0	0	0	0	0	0	0	0	0	0
Total	11	9	13	8	13	20	74	48	20	241

* "Other surgical treatment" includes screw fixation, pin fixation, fixation with cerclage etc.

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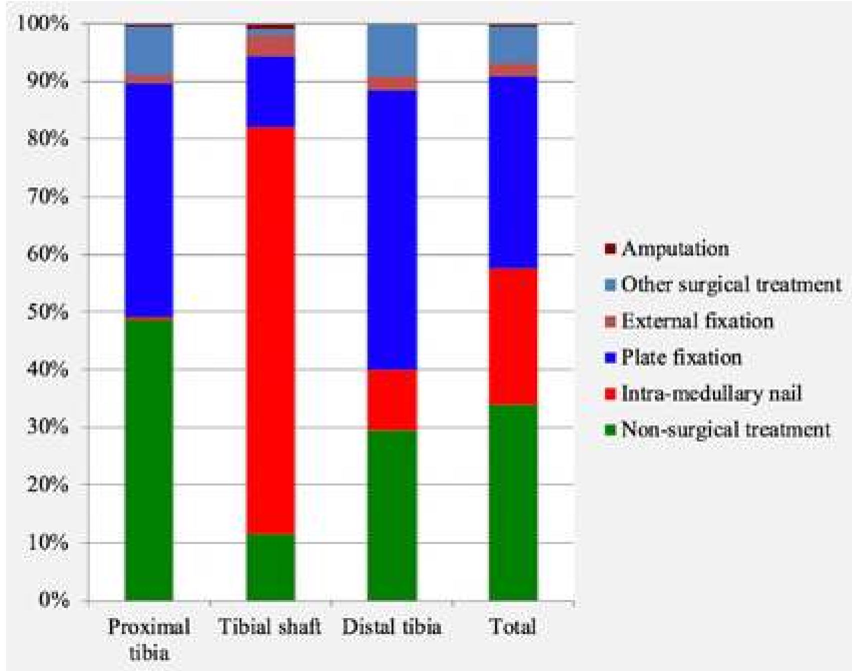

FIGURE 22 Distribution of treatment of tibial fractures according to the segment of the tibia

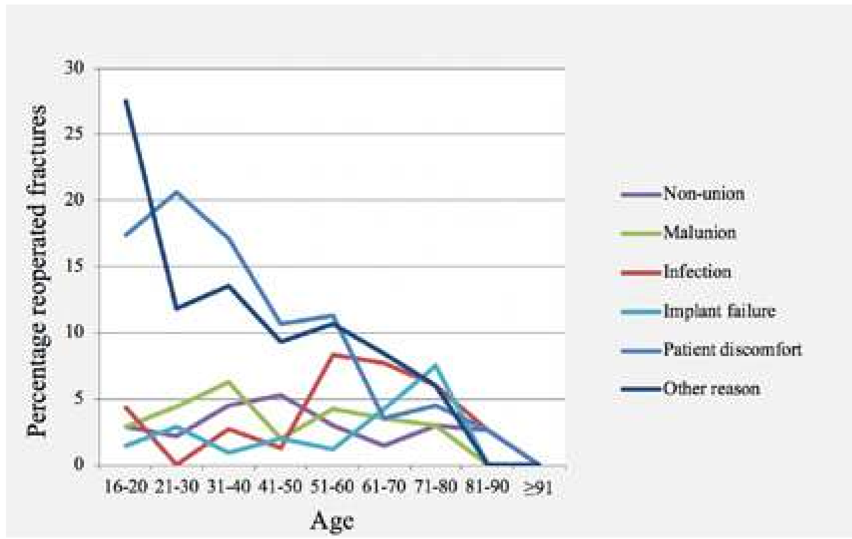

FIGURE 23 Percentage of re-operated fractures according to the reason for re-operation and age

7

DISCUSSION

7.1 DEVELOPMENT OF THE SWEDISH FRACTURE REGISTER

During the eight and a half years that the SFR has been active, more than 380,000 fractures at 42 different orthopaedic departments have been included. Taken together, these 42 orthopaedic departments cover approximately 80% of the Swedish population. Nevertheless, many issues remain to be resolved. As will be discussed later, the greatest possible completeness (entry of a satisfactory percentage of the fractures treated at each department) is the most important goal. The SFR can already be considered to have high coverage (participation rate among the departments that treat fractures in Sweden), but nationwide coverage is still the ultimate goal. Attaining this goal is a daunting challenge, given that enrolment in the SFR is not compulsory. The success of the well-known Swedish registers for hip and knee arthroplasties is due at least in part to the fact that the registers are run by the orthopaedic profession and that participation is not mandatory. For these registers, the implementation process to achieve full coverage among the orthopaedic departments in Sweden took approximately 10 years. The burden of fracture registration is probably heavier than registration in the hip or knee arthroplasty registers. It might therefore take a long time for the SFR to achieve full coverage.

The successful creation and implementation of the SFR was made possible for many reasons. The system of personal identity numbers makes things easier for all the NQRs in Sweden. The long history of NQRs in general in Sweden and, in particular, the many examples of successful orthopaedic registers played an important role. The support of the Centre of Registers was probably a prerequisite for the tireless work of the creators of the SFR to bear fruit. The benefit of the opt-out system in Swedish legislation, that an NQR does not require signed consent from the individual patient, cannot be overestimated. Moreover, from the very start, the support of the orthopaedic profession has been, and still is, essential for the SFR to be a success and obtain nationwide acceptance. Hopefully, now that the coverage is approximately 80%, participation in the SFR will be the new standard in the country. This already high coverage shows that the SFR has changed from being a small pilot study to become a true national quality register. This might make it easier for the remaining departments in Sweden to join the SFR.

The validity of data is of the utmost importance if data are to be used for scientific and quality improvement purposes. The SFR and its users share responsibility for ensuring that data are entered in an appropriate manner. Study II in this thesis, as well as the other validity studies that have been conducted, was required for the data in the SFR to be regarded as reliable and useful [80-84]. As will be discussed in the context of the validity of the classification of tibial fractures later in this thesis, the accuracy of fracture classification is not perfect in any way. However, to be honest, when preparing for these studies, our fears were greater. Given the circumstances of the collection of data in the SFR, it is surprisingly impressive that the validity studies conducted so far have shown the same high reliability as in previous studies in the field, in spite of the fact that many of the previous studies were conducted in a more typical study setting with only experienced surgeons classifying fractures and not in everyday clinical practice as in the SFR.

7.2 COMPLETENESS

The objective for participating departments is to report all the fractures that are treated. This goal is ambitious and even the most efficient register is unable to reflect fracture incidence to 100%. The ways of attaining a high level of completeness are described in the methods section of this thesis. Every week, a great effort is made to achieve a high level of completeness in registrations in the SFR at the affiliated departments. As described in the methods section, each department is free to incorporate methods of its own in order to ensure the most complete data possible. The annual report describes the completeness numbers, based on the algorithm created in collaboration with the Swedish National Board of Health and Welfare [77]. The completeness numbers vary

from department to department, from fracture type to fracture type and over time as well. This was the main reason for performing the epidemiological, treatment and re-operation studies (Studies III and IV) based only on data from Sahlgrenska University Hospital. We are well acquainted with the methods of achieving high completeness at our own department, which is even more important when it comes to re-operation rates.

The achievement of a high completeness level in the registration of re-operations faces several challenges. The surgeons have to remember to enter the re-operation in the register. The validation of the completeness of re-operations in an NQR can be achieved by making comparisons with official health databases, in a similar way to that used regularly by the arthroplasty registers. This is, however, far more challenging in the case of fractures, due to the large number of possible treatment codes to check against. When performing studies of re-operation rates for specific fractures, such as in Study IV, it is still recommended to validate the re-operation rates as was done in that study. In Study IV, there was a clear difference in completeness for primary procedures (99%), planned secondary procedures (89%) and re-operations (63%). There could be many reasons for the different levels of completeness. There is an automatic search in the SFR for fractures without treatments. Thanks to this function, every fracture is assigned a primary treatment. This is the most obvious reason for the high completeness level for primary procedures. Unfortunately, for obvious reasons, there is no possible equivalent system for identifying unregistered planned secondary procedures or re-operations. The register database simply cannot know that a re-operation should have been registered. It is also easier to remember to register primary treatments, as they occur closer in time to the fracture. It is more obvious that the primary treatment is related to the fracture. The longer the time between the injury and the performed procedure, the harder it is to remember to register the procedure. In some cases, it is less obvious that a re-operation is performed due to a fracture. If a patient undergoes arthroscopy for knee pain two years after a proximal/intra-articular tibial fracture, it is not as obvious that this is a re-operation due to sequelae after the fracture as if the same patient underwent a re-operation due to a postoperative infection two weeks after primary surgical treatment of the fracture. Nor is it as obvious that a total knee replacement some years after a proximal tibial fracture is a re-operation due to sequelae after the fracture. As long as no automatic system for identifying re-operations is found, it is important to perform the kind of validation and retrospective registration of re-operations, as was done in Study IV, before re-operation studies based on data from the SFR are conducted.

If data from an NQR such as the SFR are presented without this kind of validation, it is important to be aware of pitfalls of all kinds and to try to make allowances for them. If, for example, the performance of different departments in a register is compared based on re-operation rates, it is important to take care before any conclusions are drawn. It might turn out that the department with the poorest numbers is in fact the department with the highest completeness of registrations of re-operations and not necessarily the department with the poorest outcome.

7.3 FRACTURE CLASSIFICATION

It is possible to discuss whether an accuracy of kappa 0.56, as in Study II, is good enough to regard data on tibial fracture classification in the SFR as reliable. According to the most commonly used interpretations of kappa values, this does not represent excellent but only moderate agreement [85]. In spite of this, this level of agreement appears to be as good as it gets in terms of fracture classification [86-90]. It is possible to ask why studies of the validity of fracture classification seldom report greater agreement. In a study of the validity of humeral fracture classification, not included in this thesis, we elaborated on interpreting the kappa values by taking account of the relationship between fracture classes [81]. In order to calculate weighted kappa, it is necessary to define both the classes that are next to one another and the extent to which the classes are related to one another. This is convenient when dealing with categories on an interval or ratio scale. Fracture classes are, however, a nominal scale and weighted kappa is therefore not applicable. Instead, we discussed creating new fracture classes by combining the classes we regarded as the most closely related. We analysed the classification system and structured Boolean questions that defined the classes (yes/no). Fracture classes separated by the answer to only one Boolean question were defined as related. The same kind of analysis of relationships between classes of tibial fractures is presented in Figure 5-7 on pages 33-34. This was not included in Study II, but it is presented in the introduction to this thesis. The analysis reveals that the relationship between the fracture classes in the AO/OTA classification is not restricted to the fracture classes positioned next to one another in the classification system. Instead, one fracture class can be closely related to a fracture class at the opposite end of the classification scheme. For example, the only factor distinguishing a 41A2 fracture from a 41C1 fracture is whether or not there is an intra-articular fracture line (Figure 5, page 33). On the other hand, the 41A2 and 41A1 fractures, which are positioned next to one another in the classification system, share hardly any common features and are not particularly closely related. This example demonstrates that, in terms of classification, the 41A2 fracture is more closely related to the 41C1 fracture than to the 41A1, which is the closest neighbour in the classification system. Despite this, the most common way of simplifying the classification system in validity studies is to omit the last digit of the four-digit AO/OTA code (AO/OTA group) thereby converting it to a three-digit code (AO/OTA type) (e.g. 41A2 becomes 41A). For example, this merges the 41A1 and 41A2 fractures from the example above into the same fracture type, i.e. 41A. As discussed above, it is not, however, necessarily the case that the fracture classes within one type are closely related. So, simplifying the classification system from four-digit groups to three-digit types means clustering some fracture classes with little or no relationship into one type. This does not necessarily increase the degree of agreement, as the crucial decisions have not necessarily been made between the classes within the type. Taking the kind of relationships shown in Figures 5-7 into account, it is easier to accept that greater agreement than that seen in most studies of the validity of fracture classification is probably not possible. When calculating kappa values for agreement using the new fracture classes in the study of the validity of humeral fracture classification, the kappa values increased to kappa = 0.91-0.97 [81]. This is because the new fracture classes convert disagreement between two related fracture classes into agreement within one new fracture class. This can be compared with the fact that the kappa values for inter-observer agreement increased from 0.50-0.58 to 0.70-0.80, when simplifying from AO/OTA group (4 digit) to AO/OTA type (3 digit) in Study II. If, instead, simplification based on relationships between fracture classes was performed, as was done in the study of humeral fracture classification, there would probably be greater agreement [81]. It is therefore suggested that the disagreement that gives the relatively low kappa values, such as 0.56 in Study II, is probably disagreement related to small features separating related fracture classes.

Compared with previous studies, Study II shows accuracy, inter- and intra-observer agreement for the AO/OTA classification of tibial fractures on similar levels [86-90]. No other study has been conducted in exactly the same manner. The methods in the study by Meling et al., however, resemble the methods used in Study II [90]. Meling et al. evaluated 69 fractures in all three segments of the tibia that were originally classified by 26 different orthopaedic surgeons when registered in the Fracture and Dislocation Registry (FDR) at Stavanger University Hospital. They, too, defined a gold standard classification (named "Reference standard classification" in their study), albeit in a slightly different manner, and compared this gold standard classification with the original classification in the FDR [90]. Meling et al. reported kappa values of 0.47-0.60 for the accuracy of the AO/OTA group for the three different segments of the tibia, which is similar to the kappa values in Study II.

The results of Study II are on the same level as or higher than the results of the studies by Swiontkowski et al., Martin et al. and Walton et al., which were all related to one segment of the tibia [86, 87, 89]. Swiontkowski et al. presented kappa values of 0.49-0.58 for inter-observer agreement in a study of 84 distal tibial fractures, Martin et al. reported average inter-observer kappa values of 0.38 in a study of 43 distal tibial fractures and Walton et al. presented a mean kappa coefficient for inter-observer agreement of 0.45 in a study of 30 tibial plateau fractures (all AO/OTA group) [86, 87, 89]. One previous study, namely the study by Yacoubian et al., presented higher kappa values [88]. In that study, 52 tibial plateau fractures were classified by three experienced orthopaedic trauma surgeons based on both plain radiographs and plain radiographs combined with a CT scan and MRI [88]. Tibial plateau fractures represent the AO/OTA 41B and 41C fractures, i.e. six fracture classes, while distal tibial fractures represent nine classes (43A, B and C), which can be compared with 27 classes in Study II, which includes fractures of all segments of the tibia. In the study by Yacoubian et al., the classification based on plain radiographs combined with a CT scan (kappa 0.73) is best compared with the classification in Study II. In Study II, CT scans were made when the attending physician decided that a CT scan was necessary to decide on the treatment plan and a CT scan was thus available for most of the tibial plateau fractures. In Study II, in 14 cases, the assessors disagreed on the segment of the tibia to which the fracture was to be assigned and, in 19 cases, there was disagreement on whether or not a fracture was intra-articular. These types of disagreement do not occur in a selected material

of tibial plateau fractures, since the tibial plateau fractures are all within one segment. This probably explains the greater degree of agreement in the study by Yacoubian et al. [88]. Another explanation of the differences in the level of agreement is the large group of assessors with different levels of experience that classified the fractures upon registration in the SFR, in Study II. In terms of the results reported by Meling et al., the FDR includes surgically treated fractures and the fractures are classified by the surgeon in charge of the operation [90]. In the SFR, all fractures regardless of treatment are included and the fractures are classified by the attending physician at the emergency department, i.e. a large group of physicians with different levels of experience. In spite of this, the accuracy of the classification of tibial fractures in the FDR and the SFR showed kappa values on similar levels.

The conclusion is that the classification made upon the registration of fractures in the SFR is performed under more difficult circumstances and by less experienced surgeons than in previous studies in the field. Despite this, the accuracy of the classification of tibial fractures in the SFR is on a level similar to that in previous studies.

7.4 EPIDEMIOLOGY OF TIBIAL FRACTURES

The SFR offers a unique opportunity to present and analyse the epidemiology of fractures [78, 91, 92]. In Study III, prospectively collected data on the epidemiology of tibial fractures treated at Sahlgrenska University Hospital in 2011-2015 were described and analysed. To the best of our knowledge, this is the largest and most detailed study of the epidemiology of fractures of the whole tibia. The cohort is unique since it comprises both surgically treated and non-surgically treated fractures. The fractures were classified by orthopaedic surgeons and the methods of attaining a high level of completeness, i.e. identifying all fractures, is defined and described. Study III was conducted using methods and design similar to those in the study of fractures in all segments of the humerus by Bergdahl et al. [78]. The fact that epidemiology studies from the SFR have a similar design is regarded as a strength. This makes the results easier to interpret and compare with one another.

The main findings in Study III were that, among women, tibial fractures showed an increasing incidence with age in all segments, whereas men have a fairly flat incidence curve, except for tibial shaft fractures, which exhibit a peak among young males. The incidence curves for tibial shaft fractures show a peak both in young adults (16-30 years) and among the elderly (>80 years), whereas proximal and distal tibial fractures show an increasing incidence with increasing age. The bimodal pattern for the age-specific incidence of tibial shaft fractures appears to comprise a peak for young men and a peak for elderly women. The same pattern was seen in the studies by Weiss et al., Connelly et al. and Larsen et al., although Larsen et al. did not report such a distinct peak among the elderly [35, 93, 94]. Bengnér et al. did not report an increase in incidence among the elderly either [34]. Singer et al., on the other hand, did not report a clear peak among young adults [95]. Study III showed an increasing incidence of fractures in all segments of the tibia among women. The increasing incidence of tibial fractures with older age among women in all segments of the tibia suggests that tibial fractures among elderly women can be regarded as fragility fractures. This is also supported by the fact that women have a higher mean age for fractures in all segments of the tibia. In men, however, the incidence curves for proximal and distal tibial fractures are fairly flat, while the incidence curve for tibial shaft fractures among men peaks in young adults, indicating that osteoporosis does not have an equally high impact on tibial fractures in men.

Most previous studies of the epidemiology of fractures have focused on either fractures of all the bones in the whole body or on one segment of one bone, such as tibial shaft fractures or tibial plateau fractures [34-36, 96, 97, 42, 95, 93, 94, 65]. Studies of the epidemiology of fractures in the whole body do not provide detailed information on every part of the body and all fracture types. On the other hand, the studies of fractures in one segment do not offer an opportunity to analyse the data in the context of the other segments of the bone in question. As described in Study II, it is sometimes difficult to determine the segment in which the fractures should be classified. This makes it important to include fractures of the whole tibia in an epidemiological study. However, most previous studies of the epidemiology of tibial fractures have focused on either tibial shaft fractures or tibial plateau fractures [34-36, 42, 93, 94, 65]. The epidemiology of tibial shaft fractures in Sweden during the 1950s and 1980s has been described by Bengnér et al. and, during the 1990s and 2000s, by Weiss et al. [34, 35].

The distribution of tibial fractures according to the AO/OTA classification in Study III was similar to that in Study II, which was conducted on a smaller sample of patients from the same cohort. When comparing the distribution of tibial fractures according to the AO/OTA classification, the distribution for proximal tibial fractures was roughly the same as in the study by Elsoe et al. [65]. When comparing the distribution between the tibial shaft fractures according to the AO/OTA classification with previous studies, the distribution of AO/OTA type (A, B and C fractures) in the studies by Court-Brown et al., Connelly et al. and Larsen et al. was similar, although there were some small differences in the exact distribution of AO/OTA groups (A1, A2, A3 etc) [36, 93, 94]. This supports the conclusion that the study populations in these different studies are similar and comparable.

In Study III, there was a higher percentage of men within the more complicated fractures, usually associated with higher energy trauma, e.g. the C3 fractures in all segments of the tibia, the A3, B2, B3, C2 and C3 fractures in the shaft of the tibia and the B2, C1, C2 and C3 fractures in the distal tibia. The mean age also appeared to be lower in most of these groups. This supports the idea that predominantly young males tend to sustain the more severe tibial fractures. This idea is also supported by the fact that there was a predominance of women among the patients with fractures caused by simple falls and unspecified falls, whereas there was a predominance of men among the fractures caused by falls from height, traffic and miscellaneous injuries (as defined by Bergdahl et al., including sports-related injuries, falling objects and mechanical forces) [78].

Not surprisingly, there was a peak in fractures caused by simple falls during the winter months of December, January and February, when the weather is usually colder, with snow and ice on the streets. This was seen for all segments, as well as for all tibial fractures. In contrast, fractures caused by traffic accidents peaked during the summer months of May to September. This pattern was most obvious for proximal and distal tibial fractures, as well as for all tibial fractures.

7.5 INCIDENCE OF TIBIAL FRACTURES

Study III is the first to report the incidence of fractures in the whole of the tibia based on classifications made by orthopaedic surgeons. Bengnér et al., Weiss et al. and Study III have all reported on the incidence of tibial shaft fractures in different decades in Sweden [34, 35]. When combined, the three studies report the incidence of tibial shaft fractures during the 1950s, 1980s, 1990s, 2000s and 2010s. There is also a recent study by Larsen et al., which reports the incidence of tibial shaft fractures in Denmark, based on 198 fractures [94]. The incidence in Study III was similar to that in the studies by Weiss et al. and Larsen et al., which suggests that the numbers are close to the true incidence. The incidence in these studies was lower than that reported by Bengnér et al. for the 1950s and the 1980s. However, it is difficult to evaluate whether there was a true decrease in the incidence of tibial shaft fractures during this time period or whether this is due to differences in the methods and design of the studies. Weiss et al. reported a decreasing incidence during their study period, from 18.7 tibial shaft fractures per 100,000 and year in 1998 to 16.1 in 2004, while Larsen et al. reported an incidence of 16.9 per 100,000 and year. The incidence of tibial shaft fractures in Study III was 15.7 per 100,000 and year. During the study period, 2011-2015, there was no indication of decreased incidence. When comparing the incidence in the study by Weiss et al. and Study III, it is important to consider the different study designs. In the study by Weiss et al., the number of fractures was based on data from the Swedish National Hospital Discharge Register, which includes patients that had been admitted for in-patient treatment only, whereas Study III includes all fractures. As is mentioned in the study by Weiss et al., it is unclear whether the results represent a true reduction in the incidence of tibial shaft fractures or whether they reflect a shift in treatment protocols to a higher proportion of out-patient treatment. So, due to the two different study designs, the incidence numbers from Weiss et al. and Study III are not immediately comparable [35]. When taking account of the inclusion of only in-patients in the study by Weiss et al., the conclusion is that the design of Study III, based on data from the SFR, is the best way to study fracture incidence [35].

All methods for determining fracture incidence pose different challenges. The key points are of course to determine the true number of fractures that have occurred and the true number of people in the studied population. Both these points have their difficulties. In terms of national data on the number of patients suffering from specific conditions, such as a fracture, the Swedish National Patient Register is often regarded as the gold standard or best source of data in Sweden. An unpublished study of the completeness of the registration of fractures in the SFR points out weaknesses in using data such as the National Patient Register (NPR) as reference data for the number of fractures (personal

communication Filip Nilsson). The data in the NPR are based on ICD codes from medical charts. The unpublished study by Nilsson et al. pointed out that there is a risk that the NPR overestimates the number of fractures as it may include other fractures or injuries that have been assigned an incorrect ICD code. Thanks to the thorough work to attain a high level of completeness in the SFR, data on the number of fractures from the SFR are probably more reliable than data from the NPR. On the other hand, since the SFR does not yet have 100% coverage in Sweden, defining the catchment area in an epidemiological study, such as Study III, is a greater challenge than defining the number of fractures. Sahlgrenska University Hospital is the only provider of fracture care in Gothenburg and almost no fractures are treated at private hospitals or healthcare centres. Some patients in the borderline areas may, however, seek care at the hospitals in the adjacent catchment areas and vice versa. It is difficult to define the exact patterns of the way the patients seek care and thereby the exact borders of the catchment area of the hospital.

Due to the differences in methods in previous studies and Study III, it is difficult to draw conclusions about whether the incidence of tibial fractures is changing over time. In a recently published study, Court-Brown et al. compared the incidence of different fractures in the body among older adults based on data from one centre during two different years ten years apart, i.e. in 2000 compared with 2010/2011 [57]. This study design is well suited to detecting changes in epidemiology. In that study, no definite changes in the incidence of tibial fractures were seen. In the future, it will be possible to conduct similar studies using data from the SFR. The SFR will soon have collected data on fractures in Sweden during a period of ten years. The suggestion, if the aim is to investigate changes in fracture incidence, is to use data from the SFR during longer periods of time. It will also be possible to compare fracture incidence in different geographical parts of the country or rural parts with urban parts of the country.

7.6 TREATMENT OF TIBIAL FRACTURES

Study IV describes the treatment and re-operation rates in a cohort of 1,371 tibial fractures treated at Sahlgrenska University Hospital during a period of five years. The study reveals that the majority of all tibial fractures were treated surgically (66%). Approximately half the proximal tibial fractures (51%)

were treated surgically and the majority of tibial shaft fractures and distal tibial fractures were treated surgically (88% and 71% respectively). The most commonly used surgical method was plate fixation for proximal and distal tibial fractures and intramedullary nailing for tibial shaft fractures.

In terms of the way tibial fractures were treated in Study IV, it is possible to detect clear patterns for the way treatment was chosen according to the AO/OTA classification. For example, 49% of proximal tibial fractures were treated non-surgically and 41% using plate osteosynthesis, while 71% of tibial shaft fractures were treated with an intramedullary nail. When reviewing the specific fracture classes, in 10 of 27 fracture classes, more than 75% of the fractures were treated with one specific treatment method (e.g. non-surgical treatment, an intramedullary nail or plate fixation) and, in 20 of 27 fracture classes, more than 60% are treated with one specific treatment method. The choice of treatment for the majority of tibial fractures appears not to be controversial at the investigated department.

Another interesting finding was that, in all segments, the "1" and "2" fractures (e.g. 41A1 and A2, 41B1 and B2, 43A1 and 43B1) appear to be more commonly treated non-surgically, whereas the more complex "3" fractures appear to be treated surgically to a larger extent. This supports the idea that the AO/OTA classification system is predictive of treatment choice [26, 28].

Amputation is a devastating but fortunately uncommon result of tibial fractures. In Study IV, seven tibial fractures resulted in amputation. These patients were all men aged between 19 and 76 years. They all had sustained open fractures due to high-energy traumas. The fractures were classified as 41C3 (n=2), 42A2 (n=1) and 42B3 (n=1). There were three fractures that could not be classified. Two of the patients underwent amputation as primary treatment and five underwent amputation later as a re-operation. These seven patients who underwent amputation due to a tibial fracture represent 0.5% of the patients.

As described in the Methods section, the chain of events when treating tibial fractures is sometimes complex, with multiple treatments and staged procedures. All the different combinations of multiple treatments and staged procedures cannot be reported. There would be too many options and no opportunity to obtain an overview of the study cohort. To be able to describe

the treatment and the outcome of treatment in the study, it is necessary to define the main treatment of each fracture. An algorithm for determining the main treatment for each fracture was therefore created. If, for example, a patient underwent multiple treatments including intramedullary nailing, the intramedullary nailing was regarded as the main treatment. The same goes for plate fixation. Taken together, there was no room for further presentations of the treatments other than the main treatment. For this reason, treatment with temporary external fixation is not presented in Study IV. Nowadays, final treatment with external fixation is uncommon and only used in selected cases. In Study IV, ten proximal, fifteen diaphyseal and six distal tibial fractures were treated with external fixation as the final treatment. This represents 2% of all tibial fractures and was most common among the tibial shaft fractures of which 4% were treated with external fixation as the final treatment. External fixation is, however, more commonly used as temporary fixation in complex fractures before the final osteosynthesis can be performed. In Study IV, temporary external fixation was used in 159 (12%) fractures (47 proximal, 49 diaphyseal and 63 distal). Not surprisingly, the use of external fixation appeared to be more common in the more complex fracture classes. For some fracture classes, more than 30% of the fractures were treated with external fixation (41C2, 41C3, 42C3, 43A3, 43B3, 43C1, 43C2 and 43C3) and, among the 43C fractures, 58% of the fractures were treated with temporary external fixation.

7.7 RE-OPERATION RATES IN TIBIAL FRACTURES

The most important finding in terms of re-operations is an overall re-operation rate (percentage of re-operated fractures among the surgically treated fractures) of approximately 30% (29.8%) for fractures in all segments of the tibia. Tibial shaft fractures had a higher re-operation rate (37.0%) than proximal and distal tibial fractures (24.3% and 26.3% respectively). The removal of internal fixation devices was the most commonly performed re-operation (258 of a total of 438 re-operations). Re-operations due to non-union, malunion, infection and implant failure were more or less equally common (3.1, 3.6, 4.3 and 2.5% re-operated fractures respectively). Among the surgically treated fractures, re-operations due to infection appear to be more or less equally common in the different segments of the tibia (24 re-operations in 362 surgically treated proximal tibial fractures, 20 re-operations in 366 surgically treated tibial shaft fractures and 13 re-operations in 170 surgically treated distal tibial fractures

(Table 13a-c)). Re-operations due to patient discomfort and “other reasons” accounted for approximately half the re-operations (224/378) (Table 12).

During the calculations in Study IV, we discussed presenting either the crude number of re-operations or the percentage of re-operated fractures. It would naturally be ideal to present both. As mentioned in other parts of the discussion, the presented data are, however, already comprehensive and complex. We therefore chose to limit the data and parameters presented. In most tables, we considered it was relevant to present the percentage of re-operated fractures for the total and this was therefore done. For each separate cell in the tables, however, only the number of re-operations are presented. When interpreting the data in Tables 11 and 12 in Study IV, it is also important to be aware that Table 11 presents all the procedures, regardless of whether they were performed in different re-operations or simultaneously in one re-operation, whereas Table 12 presents the re-operations based on the reason for re-operation. As a result, if more than one procedure was performed during one re-operation, this is presented as one re-operation in Table 12, whereas, in Table 11, all the procedures are presented. For example, if a patient undergoes surgical debridement and the removal of internal fixation devices during one re-operation, due to infection, both these procedures are presented in Table 11, whereas, in Table 12 they are presented as one re-operation due to infection. The number of re-operations in Table 12 is therefore lower than the number of procedures in Table 11. It is also important to bear in mind that, in some patients, more than one re-operation was performed on one fracture. As a result, the total number of re-operations is higher than the total number of re-operated fractures.

It is important to be aware of these differences in the way data are presented in the different tables to ensure that satisfactory conclusions are drawn from the data in each table. As discussed above, Table 12 in Study IV does not present the percentage of re-operated fractures for each specific reason for re-operation. The suggestion is that, despite this, some conclusions in terms of the reason for re-operation in the different segments of the tibia can be drawn. In proximal tibial fractures, three re-operations due to non-union were performed, while 20 re-operations were performed due to malunion. It is reasonable to conclude that, in proximal tibial fractures, malunion appears to be more common than non-union. The metaphyseal bone of the proximal tibia often has a good blood

supply and non-union is seldom a problem. In distal tibial fractures, however, re-operations due to non-union and malunion appear to be almost equally common – six re-operations were performed due to non-union and eight re-operations due to malunion. Since the distal tibia is also metaphyseal bone, non-union could be expected to be less common than malunion. One possible explanation of why non-union is equally common might be diminished blood supply to the distal tibia compared with the proximal tibia, especially in the elderly, and possibly more severe soft-tissue injuries in distal tibial fractures. As presented in Study III, there was a higher proportion of open fractures among distal tibial fractures compared with proximal tibial fractures (11.5% versus 2.4%), which supports this theory. In tibial shaft fractures, on the other hand, more re-operations due to non-union than due to malunion were performed (22 re-operations versus nine). This was expected, as the cortical bone of the tibial shaft has a more limited blood supply and heals more slowly. At the same time, the introduction of an intramedullary nail, which was the most common treatment, often offers good reduction in a tibial shaft fracture and thereby prevents malunion.

Probably the largest published study of re-operation rates after tibial fractures is the study by Henry et al. that presents re-operation rates and mortality after the surgical treatment of tibial plateau fractures in more than eight thousand patients [41]. Although no specific classification of fractures is reported in that study, it is stated that tibial plateau fractures correspond to 41A-C fractures in the AO/OTA classification. Henry et al. showed that 15.3% of the patients with tibial plateau fractures underwent re-operation. In Study IV, the corresponding number for AO/OTA 41A-C fractures was 24.3% (7.1-46.0%). The higher numbers in Study IV could be due to a longer follow-up period. It is also possible that the meticulous work that has been done to achieve a high level of completeness in the report on re-operations in Study IV has contributed to the higher re-operation rate in Study IV. In a prospective study of 275 consecutive surgically treated proximal tibial fractures, Kugelman et al. reported a higher risk of complications in AO/OTA C fractures [39]. These findings are in agreement with the findings in Study IV, where there was a high frequency of re-operated fractures among the 41C fractures (27.8-46.0%).

In a systematic review, Henkelmann et al. report an infection rate of 9.8% (range 2.6-45.0%) in proximal tibial fractures [98]. It is, however, difficult to compare the infection rate reported in the systematic review with the results in Study IV, as Study IV is based on re-operations and the re-operation rates were not reported in the review. In Study IV, 4.3% of all tibial fractures underwent re-operation due to infection. It is interesting to note that there is no obvious difference in re-operation rates due to infection in the different segments of the tibia in Study IV. In Study IV, there was, however, a peak of re-operations due to infection in the 51- to 80-year age group (6-8.3% re-operated fractures). It is difficult clearly to identify the reason. One possible explanation might be higher comorbidity, such as cardiovascular diseases and diabetes mellitus, at these ages, with a diminished blood supply to the lower extremities. It is also possible that the soft-tissue injuries in this age group are underestimated.

Re-operations due to non-union appear to be equally common among tibial shaft and distal tibial fractures (26 re-operations among 414 tibial shaft fractures and 11 re-operations among 241 distal tibial fractures), but they are uncommon among proximal tibial fractures (four re-operations among 706 fractures) (Tables 13a-c, Study IV). The fact that non-union occurs in tibial shaft fractures is not surprising. The cortical bone of the tibial shaft often heals more slowly than metaphyseal bone. The non-union rate might, however, be expected to be lower in distal tibial fractures, since the distal tibia, like the proximal tibia, is metaphyseal bone, which does not normally present healing problems. As mentioned in the discussion of re-operations due to infection, comorbidity with a diminished blood supply might affect the distal part of the lower leg more than the proximal part and thereby affect the prerequisites for healing in the distal tibia. Re-operations due to malunion and infection appear to be equally common in all segments (two to five re-operations per 100 fractures) (Tables 13a-c, Study IV).

In Study IV, the vast majority of tibial shaft fractures were treated with an intramedullary nail (71%), while a small number were treated non-surgically or with plate fixation (12% each). Interestingly, re-operations among tibial shaft fractures treated with an intramedullary nail and plate fixation in Study IV were equally common (39% each). However, it appears that fractures treated with an intramedullary nail underwent re-operation to a greater extent due to patient discomfort or "other reasons" which, in most cases, were related to the removal of hardware, while the tibial shaft fractures treated with plate fixation underwent re-operation to a greater extent due to non-union, infection and

implant failure, which are re-operations related to more severe complications. Interestingly, no re-operation due to malunion was performed in tibial shaft fractures treated with plate fixation, whereas ten re-operations due to malunion were performed in tibial shaft fractures treated with an intramedullary nail (Table 13b, Study IV). The data in the SFR and the AO/OTA classification do not distinguish fractures in the different parts of the tibial shaft. It is therefore not possible to evaluate where in the tibial shaft the fractures re-operated due to malunion were located. It is possible to speculate that the tibial shaft fractures treated with an intramedullary nail that underwent re-operation due to malunion might have been distal or proximal tibial shaft fractures. In the distal and proximal third of the tibial shaft, an intramedullary nail might provide less stability and allow displacement, which osteosynthesis with a plate does not.

To the best of our knowledge, there is no other register-based study of re-operation rates after the treatment of tibial fractures with the same design. This makes it somewhat difficult to compare the results. There are, however, previous studies of re-operation rates after the treatment of tibial shaft fractures that can be compared to some extent with the results of Study IV. In the study by Fong et al., 13.5% of tibial shaft fractures underwent re-operation (not including hardware removal), which is similar to the re-operation rate in Study IV when excluding the removal of internal fixation devices [37]. According to the study by Costa et al., osteosynthesis with an intramedullary nail and plate fixation in distal extra-articular tibial fractures showed no differences in terms of functional results [38]. However, more secondary operations and infections were observed in the fractures treated with plate osteosynthesis compared with intramedullary nailing. The distal extra-articular fractures in the study by Costa et al. were defined as "a fracture within two Müller squares of the ankle joint", which means a mixture of tibial shaft and distal tibial fractures according to the AO/OTA classification. This makes it even more difficult to compare the results with those in Study IV. Minhas et al. reported no differences in re-operation rates between fractures treated with an intramedullary nail and plate fixation in a retrospective study with a 30-day follow-up of 771 patients with distal tibial shaft fractures [40]. In Study IV, the tibial shaft fractures treated with an intramedullary nail and plate osteosynthesis have the same overall re-operation rate (39% re-operated fractures each). The studies by Fong et al., Minhas et al. and Study IV are all non-randomised, where the surgeon has decided on the treatment [37, 40]. Fong et al. do not report any differences in re-operation rates, while Minhas et al. and Study IV report equal re-operation rates in tibial shaft fractures treated with an intramedullary nail and plate osteosynthesis. This suggests that, in current practice, orthopaedic surgeons appear to be good at selecting the fractures that are best treated with an intramedullary nail and plate osteosynthesis respectively. As will be discussed later, the results of non-randomised studies, such as the register-based Study IV, cannot be used to draw conclusions about which treatment is superior to another. It is nonetheless interesting to note that, when the orthopaedic surgeons decide on the treatment of tibial shaft fractures, the outcome in terms of re-operation rates are equal for intramedullary nailing and plate osteosynthesis.

The higher re-operation rate among tibial shaft fractures compared with the other segments in Study IV appears to be made up of more re-operations due to patient discomfort and "other reasons", which generally involve the removal of internal fixation devices. The re-operations performed due to non-union, malunion, infection and implant failure should be regarded as re-operations due to more severe complications. The re-operations performed due to patient discomfort are not severe complications in the same manner. These re-operations are still, however, surgical procedures that consume the resources of both the healthcare provider and the patient. During the first years of the SFR, there were fewer registration options for reasons for re-operations. It was then realised that "re-operation due to other reasons" which, at that time, included re-operations due to patient discomfort, was the most commonly registered reason for a re-operation. It was suspected that most of these re-operations were due to patient discomfort. In February 2016, "re-operation due to patient discomfort" was added as a separate choice. After that date, "re-operations due to other reasons" decreased dramatically. It can therefore be assumed that the majority of re-operations registered as "due to other reasons" were performed due to patient discomfort. In the tables and figures in Study IV, re-operations "due to other reasons" and "due to patient discomfort" have a similar distribution, which also supports this assumption.

Study IV also reveals that 2.4% (14/573) of intra-articular proximal tibial fractures led to re-operation with arthroplasty. These re-operations with arthroplasty were performed 0.5-3.5 years after the injury. Since the follow-up period is two to eight years, more patients might develop post-traumatic osteoarthritis later on, but this number still provides an indication of how

common post-traumatic osteoarthritis after intra-articular proximal tibial fracture might be.

A systematic review of outcomes following tibial shaft fractures in adults was recently published [99]. The aim of the study was to determine how clinical and patient-reported outcome measures are used to report results following tibial shaft fractures. The authors conclude that "the best way to monitor the results, outcome, recovery and impact of the treatment in these patients remains elusive". They also state that "simple determinants of outcome, such as need for additional surgery, should be stratified". The detailed description of re-operation rates and the reasons for re-operations after tibial fractures in Study IV provide new data in this field.

The results in terms of re-operation rates from Study IV can be regarded as a kind of baseline data relating to the results that can be expected following the treatment of tibial fractures. RCTs are able to answer questions on which treatment is superior in specific fractures in specific groups of patients. The results of RCTs can, however, only be generalised to apply to patients who fulfil the same inclusion and exclusion criteria as those studied. On the other hand, the results of register-based studies, such as this thesis, can be used to compare the outcome of clinical practice in different hospitals. If a department has inferior results compared with the results in Study IV, there are good reasons to wonder why. Quality control of this kind could be the starting point for further analyses and improvements of clinical practice, which was one of the main aims of the SFR.

7.8 STRENGTHS AND LIMITATIONS

Perhaps the most important strength of the studies in this thesis is that they describe in detail the validity of classification, epidemiology, incidence, treatment and re-operation rates in a cohort covering five years of consecutive tibial fractures including all patients, all types of fracture and all treatments in the whole of the tibia. Since the studies do not exclude any type of patients, fractures or treatments, the thesis describes the epidemiology, incidence, treatment and re-operation rates in a real-world setting.

One strength of Study II is that it was conducted according to the quality criteria for validity studies defined by Audigé et al. [100]. One important strength in Studies III and IV is that the completeness of the registration of fractures and the validity of the classification of fractures are described and evaluated. The achievement of a high level of completeness is described in Study I, the classification of fractures for a sample of the cohort was validated in Study II and a great effort was made to achieve a high level of completeness of re-operations in Study IV. Moreover, the follow-up period of two to eight years in Study IV is comparatively long.

The fact that the studies were based on patients treated at a single hospital can be regarded as both a strength and a limitation. In Gothenburg, all tibial fractures are treated at Sahlgrenska University Hospital, as it is the sole provider of fracture care. This enabled the assurance of a high level of completeness in registrations of fractures, primary treatments and re-operations. This could also be regarded as a limitation, as the patient cohort and the treatment traditions at a university hospital might not represent the whole population of a country. However, not all patients in the catchment area of Sahlgrenska University Hospital live in the urban areas of Gothenburg.

Another limitation is that register-based data do not reveal every clinical aspect of the patients' status and performance, such as pain, mobility, range of motion and radiographic healing.

The studies in this thesis are based on register data and reveal the validity of classification, the epidemiology of tibial fractures and the way tibial fractures are treated in current clinical practice at one large hospital in Sweden (approximately 530,000 inhabitants aged 16 and above in the primary catchment area and 1,700,000 inhabitants (all ages) in the secondary catchment area). This thesis describes the re-operation frequencies of different fracture types and different treatments in the whole tibia. This kind of data cannot be used to compare different treatments or to draw conclusions about which treatment is associated with the lowest re-operation frequency. Nevertheless, it describes the reality in a systematic and detailed way that has not been done before.

8

CONCLUSION

STUDY I

Eight years after the start of the SFR, 42 orthopaedic and trauma departments, which cover approximately 80% of the Swedish population, register fractures. The success of initial implementation makes it clear that satisfactory compliance with the aims of the register is possible and that surgeons can find the time to perform the required data entry. In the future, the SFR will be able to present both the results of fracture treatment and valuable epidemiological data.

STUDY II

This study shows that the accuracy of the classification of tibial fractures in the SFR was substantial for the AO/OTA type (kappa=0.75) and moderate for the AO/OTA group (kappa=0.56), as defined by Landis and Koch. The degree of accuracy of the classification of tibial fractures in the SFR is on a level similar to that in previous studies, despite the fact that the classification made upon registration in the SFR is performed under more difficult circumstances and by less experienced surgeons than in previous studies in the field. Our interpretation is that this level of accuracy enables data relating to tibial fractures in the SFR to be used for further scientific analysis.

STUDY III

This study describes the epidemiology and incidence of fractures for all segments of the tibia classified by orthopaedic surgeons according to the AO/OTA classification. The study shows an overall, total incidence of tibial fractures of 51.7 per 100,000 per year. Women had an increasing incidence with higher age for fractures in all segments of the tibia, whereas men had a more or less flat incidence curve, apart from tibial shaft fractures, which showed a peak among young men.

STUDY IV

Among surgically treated fractures in all segments of the tibia, 30% underwent re-operation. Tibial shaft fractures had a higher re-operation rate (37.0%) than proximal and distal tibial fractures (24.3% and 26.3% respectively). The removal of internal fixation devices was the most commonly performed re-operation (258 of a total of 438 re-operations). Re-operations due to non-union, malunion, infection and implant failure were more or less equally common (3.1, 3.6, 4.3 and 2.5% re-operated fractures respectively). Among the surgically treated fractures, re-operations due to infection were more or less equally common in the different segments of the tibia. In proximal tibial fractures, re-operations due to malunion were more common than those due to non-union. In tibial shaft fractures, re-operation due to non-union was more common than malunion. Finally, in distal tibial fractures, re-operations due to non-union and malunion were almost equally common.

8 CONCLUSION

9

FUTURE PERSPECTIVES

The SFR is unique, as it is population based, covers fractures of all types, regardless of treatment, and collects both surgeon- and patient-reported outcome measures. Its vision for the future is to supply researchers and healthcare providers with population-based data that add to the body of knowledge on the treatment of fractures. Many orthopaedic surgeons and organisations are involved in a valiant effort to collect these data day by day. When combined with appropriate scientific analysis, the SFR will be able to serve as a springboard for improving health care and raising the standards that patients demand and expect. The SFR is already able to present both the results of fracture treatment and valuable epidemiological data.

Perhaps one day, thanks to artificial intelligence, computers will be able to classify fractures with the same or even better accuracy than orthopaedic surgeons [101]. Even so, as is pointed out in this thesis, the classification of a fracture is a structural way of analysing, describing and thereby understanding a fracture. In the authors' opinion, in order to be able to treat a fracture satisfactorily, the orthopaedic surgeon will therefore always have to classify the fracture.

It is to be hoped that, one day, the SFR will have 100% coverage in Sweden. On that day, the SFR will be able to report the number of all fractures in all inhabitants and not samples as used in the epidemiology study of tibial fractures in this thesis. If it is combined with a continued high level of completeness, the SFR will be able to report the true incidence of fractures with great confidence.

There are many ongoing projects in the SFR involving the evaluation of the results of fracture treatment, including re-operation rates and PROMs, as well as comparisons of different treatments. In the near future, it will also be possible to conduct randomised controlled trials within the SFR, so-called Register Randomised Controlled Trials (R-RCT). The creation of a platform, on which it is possible to run R-RCTs within the SFR, will utilise the full potential of the register. A way of providing the surgeon with feedback on treatment options based on patient characteristics and fracture class is also under development. In the future, it will hopefully also be possible to add registrations of implants to the SFR, using barcode detectors in the operating theatre. The exchange of data between registers in Sweden enables studies of many variables primarily not included in the SFR, e.g. comorbidity. If the profession agrees, it will be possible to register individual surgeons. It will also be possible to publish analysed data with comparisons between departments for the public and not only for the profession.

In a way, the nature of the validity study, the descriptive epidemiology and the treatment and re-operation studies in this thesis constitute groundwork science. It was our firm belief that this was the correct way to start the scientific work in the SFR. The unique database that the SFR is today was possible thanks to the effort made by the participating orthopaedic surgeons and staff who have collected the data together. In the authors' opinion, alongside the continuous work on achieving a high level of completeness and coverage, the most important task for the future of the SFR is to make the most of this unique database. This will be done by using the data in the SFR to develop the quality, science and knowledge of fracture treatment. This is the greatest challenge for the future of the SFR. The groundwork has been laid. Hopefully, this will lead to a new era in the research and development of fracture treatment.

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