Early results and future challenges of the Danish Fracture Database

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ABSTRACT

INTRODUCTION: The Danish Fracture Database (DFDB) was established in 2011 to establish nationwide prospective quality assessment of all fracture-related surgery. In this paper, we describe the DFDB's setup, present preliminary data from the first annual report and discuss its future potential.

MATERIAL AND METHODS: The DFDB collaboration includes 13 hospitals and covers a population of 3.7 million. Data registration is performed online by the surgeon following surgery, and it includes patient-, trauma- and surgery-related data. Primary procedures, reoperations and planned secondary procedures are registered. Indication for reoperation is also recorded. The reoperation rate and the one-year mortality are the primary indicators of quality.

RESULTS: Approximately 10,000 fracture-related surgical procedures were registered in the database at the time of presentation of the first annual DFDB report (currently 15,000). 85% of all procedures were performed on adult fractures and 15% on paediatric fractures. Proximal femur (33%), distal radius (15%) and malleolar fractures (12%) were the three most common primary adult fractures. Pain and discomfort from orthopaedic hardware, infection and failure of osteosynthesis were the three most common indications for reoperation and accounted for 34%, 14% and 13%, respectively.

CONCLUSION: The DFDB is an online database for registration of fracture-related surgery that allows for basic quality assessment of surgical fracture treatment and large-scale observational research by registering primary surgery, reoperations and planned secondary procedures.

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The current annual fracture incidence in Denmark is unknown; however, studies from England suggest an annual fracture incidence of up to 3.6% [1]. Extrapolated to the Danish population, this incidence would result in approximately 200,000 fractures. Over 30% of all patients with fractures require admission to the hospital [2], which making fractures an important public health concern. In the United States, the annual economic burden associated with caring for osteoporosis-related fractures alone is estimated at $17 billion [3]. Despite this, very few data exist on fracture epidemiology and fracture-related surgery in particular.

Most of the current knowledge and recommendations on surgical treatment of fractures stem from retrospective cohort studies and prospective randomised controlled trials (RCT); and while these scientific sources of data are extremely valuable, observational research, such as registry data, should be viewed as complementary to RCTs as data from such research plays an essential role in providing the basis for evidence-based treatment in all medical fields [4, 5]. Orthopaedic surgeons worldwide do agree on a gold standard for surgical treatment for some types of fractures. Many controversies therefore remain which produces regional variations in surgical fracture treatment, and because of the lack of consensus on what is the optimal approach [6, 7], the surgeon's preference often determines which approach is chosen.

To accommodate the need for basic quality assessment of treatment and large-scale observational research, several hip fracture registries have emerged in recent years [8]. However, to our knowledge, only few national registries exist that cover other types of fracture-related surgery.

The Danish Fracture Database (DFDB) was established in 2011 to establish nationwide prospective quality assessment of all fracture-related surgery. Our goal was to create a registry allowing us to evaluate the outcome of surgical fracture treatment, to identify potential risk factors for reoperation and, finally, to provide a foundation for implant monitoring, all on a nationwide scale.

In this paper, we describe the DFDB's setup, present preliminary data from its first annual report and discuss its future potential.

MATERIAL AND METHODS

Development and regulation

The DFDB was developed in 2011 as a quality-monitoring tool for fracture-related surgery. The first pilot phase was a three-month period counting the participation of the Department of Orthopaedic Surgery, Hvidovre Hospital, Denmark, and the Department of Orthopaedic Surgery, Odense University Hospital, Denmark [9]. After having been piloted, the database was fully introduced at the two departments. Participation in the DFDB collaboration was voluntary, and several other hospitals

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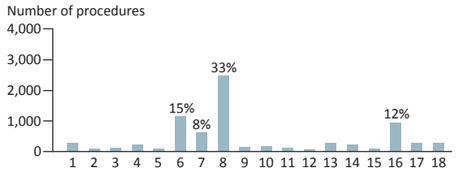
FIGURE 1

Anatomical distribution of primary fracture surgeries in adults. Percentages (procedures in area/total procedures) for the four most common surgical sites are presented. Total n = 7,578.



1 = Proximal humerus	7 = Hand	13 = Proximal tibia
2 = Humeral shaft	8 = Proximal femur	14 = Tibia shaft
3 = Distal humerus	9 = Acetabulum	15 = Distal tibia
4 = Proximal forearm	10 = Femur shaft	16 = Malleoli
5 = Forearm	11 = Distal femur	17 = Foot
6 = Distal radius	12 = Patella	18 = Shoulder belt[a]

a) Shoulder belt: includes scapular and clavicular fractures.

subsequently joined the collaboration within the following year. Currently, 24 months after the first full implementation at Hvidovre and Odense, 13 Hospitals across Denmark form part of the DFDB collaboration, covering approximately 3.7 million people.

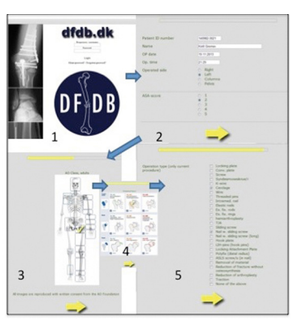
The DFDB Steering Group consists of an administration and representatives from all participating departments.

An annual meeting is held for adjustment and development purposes.

The database

The database is an online registration tool running on a secure webpage using specially developed software (Procordo Aps, Denmark). Data are entered by the operating surgeon after the surgical procedure has been completed. The surgeon uses a specific ID and password. All patients are identified by a unique ten-digit social security number used for all contacts with the health-care system in Denmark. The time required to complete a registration is approximately two minutes per procedure. The database and registration of data was approved by the Danish Data Protection Agency.

Patient-, trauma- and surgery-related data are recorded. Patient-related data include: social security number (i.e. CPR number), sex, age and American Society of Anesthesiologists (ASA) score. Trauma-related data include: operated side, date and time of the radiological examination that provided indication for surgery, trauma, Gustilo type for open fractures, neuro-vascular status and, finally, presence of a pathologic fracture. Surgery-related data include: date and time of surgery, type of procedure (primary, planned secondary or reoperation), type of fracture (adult, child or periprosthetic), fracture diagnosis according to the AO Müller classification in all applicable regions (the Vancouver and Rorabeck classifications are used for periprosthetic hip and knee fractures, respectively), method of osteosynthesis, supplemental surgical procedures, antibiotic prophylaxis, use of tourniquet, method of reduction, surgical technique and, finally, educational level of the surgeon and the supervisor, if such data are available. Planned secondary procedures are defined as surgical procedures that are a part of a primary treatment plan following primary surgery. Reoperations are defined as surgical procedures that are not a part of an initial treatment plan following primary surgery. Planned secondary procedures and reoperations are linked to primary procedures by the social security number, date, operated side and anatomical region. Indication for reoperation is also recorded. Reoperation rate and one-year mortality are the primary indicators of quality.



Selected screenshots of surgical procedure registration in the DFDB.
1: online log in 2: patient and surgery data
3 & 4: anatomical region and fracture classification
5: method of osteosynthesis.

Implant scanning

The DFDB allows for peroperative barcode scanning of used implants, which makes it possible to link the implant to the patient and the specific procedure performed by the surgeon upon data entry [10]. This feature is, however, currently only implemented at the Department of Orthopaedic Surgery, Hvidovre Hospital, Denmark.

Completeness and data validity

We have performed and published a validation and completeness analysis of the data [9] shortly after the implementation of the database, and we found a 83% completeness for all types of data entry, with 88% completeness for primary fracture surgery and 77% for reoperation, respectively. Patient- and trauma-related data were 82-100% valid, while surgery-related data were valid in 89-99% of the cases.

Trial registration: not relevant.

RESULTS

General demographics

Approximately 10,000 fracture-related surgical procedures were registered in the database at the time of presentation of the first annual DFDB report.

A total of 85% of all procedures were performed on adult fractures and 15% on paediatric fractures. The reoperation burden (percentage of reoperations from all registered procedures) was higher for adult fractures (10%) than for paediatric fractures (5%). Removal of orthopaedic hardware due to pain or discomfort accounted for 3% of all registered procedures.

The anatomical distribution of primary surgery on adult fractures is presented in **Figure 1**. Proximal femur (33%), distal radius (15%) and malleolar fractures (12%) were the three most common primary fractures and accounted for over half of all adult primary surgeries. The forearm (58%), the humerus (23%) and the lower leg (8%) were the three most common paediatric fracture sites.

Reoperations

The four most common anatomical locations for reoperations were the proximal femur (30%), the distal radius (6%), the tibial shaft (6%) and the malleoli (19%). The recorded indications for reoperation of the proximal femur, the tibial shaft and the malleoli fractures are summarised in **Figure 2**. Pain and discomfort from orthopaedic hardware, infection and failure of osteosynthesis were the three most common indications for reoperation and accounted for 34%, 14% and 13%, respectively.

Surgical delay

We defined surgical delay as the time from radiological diagnosis to the initiation of surgery. Surgical delay for adult and paediatric fractures is presented in **Figure 3**. Close to 50% of adult fractures and 70% of paediatric fractures were operated within 24 hours. When investigating the most common fracture types separately, we found that 70% of the proximal femoral fractures are operated within 24 hours, and 94% within 48 hours. Similarly, 75% of the malleolar fractures and 57% of the distal radius fractures were operated within 48 hours.

Time of surgery

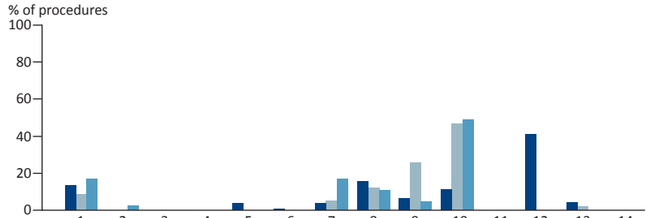
We found that most of the surgical procedures (71%) were performed during the day-time (08-16), whereas only 7% were performed during the night (22-08). Children were operated as often as adults during the night.

Educational level of the surgeon and supervision

Attending trauma surgeons performed 24% of primary surgeries and 32% of reoperations in adults. The rest of the procedures were performed by residents and attending non-trauma surgeons. The same trend was seen for paediatric fractures as attending trauma surgeons

FIGURE 2

Distribution of indications for reoperation for the three most commonly reoperated surgical sites: proximal femur, tibial shaft and malleoli – presented as percentages of all reoperations at the specific surgical site.



1 = Infections	7 = Suboptimal osteosynthesis	11 = Other
2 = Muscle- and soft tissue revision	8 = Neurovascular complication	12 = Arthroplasty dislocation
3 = Neurovascular complication	9 = Secondary displacement of a surgically treated fracture	13 = Osteonecrosis
4 = Secondary displacement of a conservatively treated fracture	10 = Pain or discomfort from orthopaedic hardware	14 = Haematoma
5 = New fracture		
6 = Peroperative fracture, missed		

Proximal femur (n = 271) Tibial shaft (n = 58) Malleoli (n = 168)

FIGURE 3

Surgical delay for adult fractures (**A**) and paediatric fractures (**B**), presented as number of procedures performed within 24, 48, 72 etc. hours after radiological diagnosis.

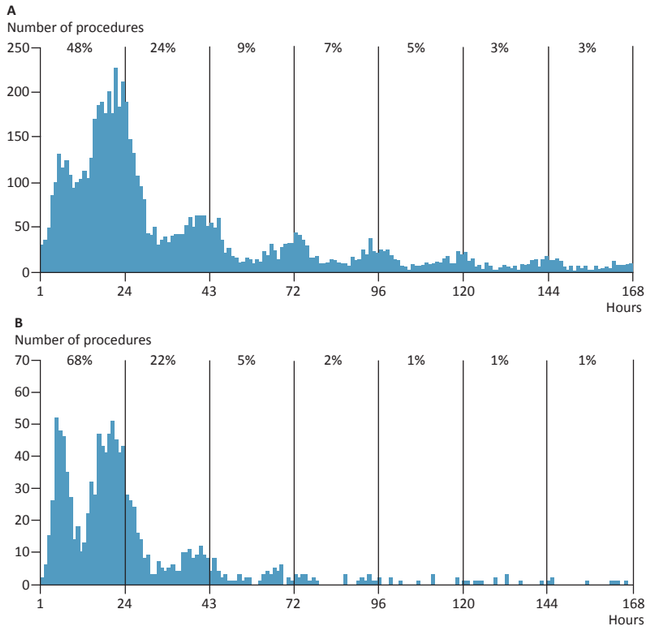
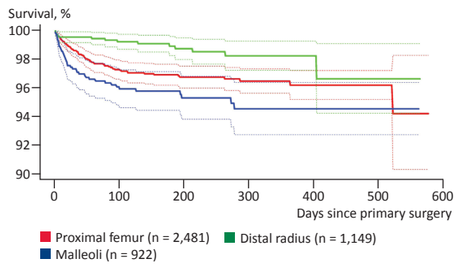


FIGURE 4

Kaplan-Meier survival plot for proximal femur, distal radius and malleoli fractures, with the first reoperation as end-point. Solid lines present mean survival with dotted lines as 95% confidence intervals.



performed 20% of the primary procedures and 37% of the reoperations. When investigating the level of supervision, we found that 23% of the surgeries performed by residents were unsupervised.

Survival until first reoperation

We performed Kaplan-Meier survival analysis for primary surgeries with the first reoperation as end-point. Survival was 96% after 500 days, which increased to 97% if reoperations due to hardware discomfort were excluded. Malleolar fractures had the poorest one-year survival of 94.5%; the one-year survival was 98.3% for distal radius fractures and 96.5% for proximal femoral fractures (**Figure 4**).

DISCUSSION

In this paper, we present the setup and preliminary data from the DFDB. Currently, 13 hospitals participate in the DFDB collaboration, covering a population of 3.7 million, which constitutes nearly 65% of the entire Danish population.

Not surprisingly, we found proximal femoral and distal radial fractures to be the largest groups of primary surgeries as well as reoperations in adults, whereas forearm fractures were the most commonly registered paediatric fractures, which is in agreement with previous findings [1, 11].

Pain and discomfort due to hardware was generally the most common indication for reoperation, followed by infection and failure of osteosynthesis. When investigating surgical delay, we found that 72% of all adult fractures were operated within 48 hours of radiological diagnosis. Examining the data according to fracture groups, we found that 94% of adult proximal femoral fractures were operated within 48 hours. We believe that this could be an important factor, particularly for the outcome following specific types of fractures [12, 13].

Finally, we present Kaplan-Meier survival plots for the most common adult primary fracture surgeries showing survival until first reoperation. We recorded 94.5%, 96.5% and 98.3% one-year survival rates for malleolar, proximal femur and distal radius fractures, respectively.

It is important to stress that these findings are preliminary, and definite conclusions should therefore not be made. The main shortcoming of the presented data that the completeness of data registration of primary surgeries and reoperations has so far not been ascertained for the entire database. We performed and published a validation study showing 88% completeness for primary surgeries and 77% completeness for reoperations [9] for the two first-runner departments, and continuous monitoring of the completeness of the data for the entire database is therefore warranted. Such monitoring will be implemented in the future based on surgical codes from the Danish National Patient Registry (DNPR). Currently, the short follow-up for the registered procedures also makes it virtually impossible to evaluate potential risk factors for reoperations.

As we have not performed calculations of the "true" number of reoperations using data from the DNPR, the Kaplan-Meier survival plots overestimate survival as reoperations are most likely underreported. The reason why we have chosen to present them, well aware of this error, is that we want to demonstrate the potential for analysis and presentation of the data in the DFDB.

We believe that the DFDB has two major strengths. First, the online method of data collection allows customisation of output, which makes it possible to investigate very specific events and populations, for example when examining the level of supervision depending on the time of surgery [14]. Second, the DFDB allows for collection of data on a large scare, which allows evaluation of very rare events such as pathological or open fractures – something that is difficult to do in prospective randomised trials [15].

Studies based on registry data play a crucial role in providing guidance for evidential medical therapy, supplementing the knowledge we gather from RCTs and other high-level evidence trials. Arthroplasty registries are often used as examples of observational research that have greatly contributed to advances in orthopaedic surgery; their importance has been underlined by the existence of substantially lower arthroplasty revision rates in countries with such registries compared with countries without these registries [16]. The same trend in registry-based research is seen in other medical fields around the world [17]. Unfortunately, at present observational, registry-based data are lacking in the field of fracture-related surgery.

To our knowledge, The DFDB is one of the few registries that cover all types of fracture-related surgery. We believe that it will provide us with valuable epidemiological knowledge on fracture-related surgery and also help us identify potential risk factors for reoperations.

In recent years, there has been considerable focus on the need for increased regulation when introducing new medical implants as well as for implant monitoring – in particular following the recall of the ASR prosthesis [18] as well as the Poly Implant Prothèse (PIP) [19].This year, changes were made in EU regulatory provisions. These changes introduced stricter rules on implant approval; however, continued monitoring of orthopaedic implants is currently not possible.

We believe that the DFDB could provide a solution meeting the requirements for such monitoring as it allows for peroperative scanning of orthopaedic implants used for fracture-related surgery and linking of these to the patient and the specific procedure.

CONCLUSION

In this paper, we presented the setup for systematic registration of fracture-related surgery through the DFDB. We presented preliminary one-year data, including patient demographics, anatomical distribution of primary procedures as well as reoperations and surgical delay for various types of procedures. Finally, we demonstrated the potential for survival analysis for various types of fracture-related surgical procedures with first reoperation as end-point.

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