INNOVATION REPORT NO 1

Trends in the surgical treatment methods of proximal femur fractures

Šarūnas Tarasevičius

Department of Orthopaedics and Traumatology
Lithuanian University of Health Sciences

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Šarūnas Tarasevičius
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Baltic Fracture Competence Centre
Life Science Nord Management GmbH
Legienstraße 40, 24103 Kiel, Germany
+49 431 90 89 68 58
Contact: Imke Schneemann
schneemann@lifesciencenord.de
www.lifesciencenord.de

www.bfcc-project.eu

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BFCC—BALTIC FRACTURE COMPETENCE CENTRE

The Baltic Fracture Competence Centre (BFCC) is a pan-Baltic fracture cooperation network fostering innovation within fracture management. The project consortium consists of a transnational cross-sector partnership involving five hospitals, three companies from the medical technology industry, a university, three clusters and one technology transfer organization.

Due to an ageing society, the need for innovative products and clinical procedures for fracture treatment is increasing as a response to age-related fractures and co-morbidities such as osteoporosis, infections and non-unions. Innovations in fracture management must reduce the cost of care or clearly improve quality of care.

Clinicians will support the innovation process by identifying the clinical needs to ensure user-oriented product development. The collaboration between hospitals across countries will foster the innovation of clinical procedures through the exchange of best practice in fracture management influenced by different national, organizational and regulatory conditions.

However, clinicians and companies often lack insight information about total cost and effectiveness of fracture management and causes of adverse health outcomes in the hospitals. To overcome this information gap, the BFCC will develop and implement a transnational fracture registry with five hospitals from Estonia, Germany, Lithuania, Poland, and Sweden, respectively, providing evidence about fracture treatment in the clinical »real world« and reveal clinical needs as well as potentials for innovation.

The BFCC will publish two innovation reports. The Innovation Report No 1 deals with trends in the surgical treatment methods of proximal femur fractures. The Innovation Report No 2 based on results and findings from registry data analysis will identify innovation needs and potentials.

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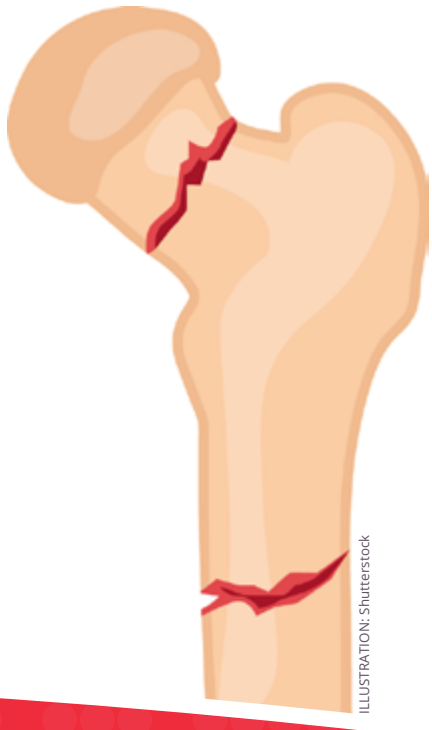
INTRODUCTION

In 2010, there were estimated 3.5 million new fragility fractures in the EU, including approximately 610,000 hip fractures, 560,000 forearm fractures, 520,000 vertebral fractures and 1,800,000 other fractures.[1] The annual number of fractures in the EU is estimated to rise by 28% from 3.5 million in 2010 to 4.5 million in 2025 and is projected to double by 2050 as the population ages.[2] In the EU, the current economic burden of incident and prior fragility fractures was estimated at € 37 billion.[1] The costs are expected to increase by 25% in 2025.[1] There are several factors contributing to an ever-increasing number of femoral neck fractures, including an increased patient lifespan, activity level, and incidence of osteoporosis.[3] The decrease in bone mass in the elderly is caused by a number of factors including reduced function of osteoblasts, increased osteoclast activity, and reduced physical activity, genetic predisposition, decreased calcium intake and hormonal influences—influences compounded by a prolonged life expectancy.[4]

The costs are expected to increase by 25% in 2025.

Hip fractures are the most common fractures in the elderly and have consequences extending into the domains of medicine, rehabilitation, psychiatry, social work, and medical economics. Hip fracture patients are related with high morbidity, decrease in quality of life, and high mortality ranging from 14 to 58%[5–10]; thus, clinical guidelines, based on scientific research are a tool that may aid in reducing this variability. Although it is a frequent health problem, there is a wide variability in the approaches taken regarding treatment methods and health care management. Despite recent advances in surgical techniques, implant technology, combined with improvements in patient care, hip fractures continue to pose a substantial economic burden on medical systems in the developed and the developing world.

Innovations as well as best practice transfer are needed in the near future for healthcare systems to accommodate the increasing burden of fractures, predominantly regarding the elderly populations in all societies. Improvements in patient care management for today's treatment routines are necessary for hospitals and other caregivers to ensure a progressive and beneficial change. To achieve these goals, current knowledge, networking resources and technology can be used. BFCC successfully established a shared information network aimed at providing and compiling useful data to ensure improvement in fracture management for the future.



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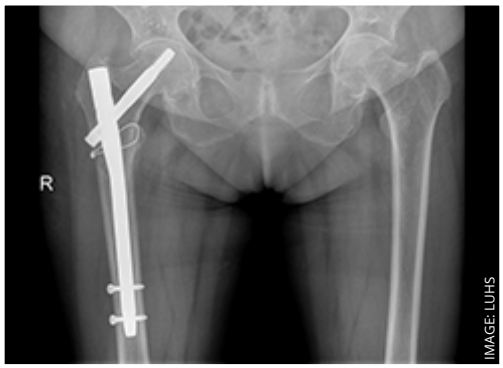
THE PROBLEM AT HAND

Surgical treatment has been established as the gold standard for hip fractures; the primary aim being early mobilization to prevent morbidity associated with recumbence. However, there is no definitive consensus amongst the medical community regarding the surgical options providing best possible outcome. In a systemic review by Nyholm AM *et al.,* it was noted that the clinical evidence behind the current implants used for proximal femoral fractures is weak. It was concluded that a systematic post-market surveillance of implants used for fracture treatment, preferably as a national registry, is necessary. Such a national or transnational database could be a particularly useful tool for assessing, and analysing the surgical treatment outcome for hip fracture patients.

There is an extensive variation in fixation devices used for operative treatment of proximal femoral fractures, i. e. intramedullary fixation, extramedullary/ plate-screw fixation and endoprosthetic reconstruction. Treatment methods used in different institutions are not always based on current scientific evidence and may be influenced by previous country traditions, which may also play a role in both diagnostic and treatment strategies.



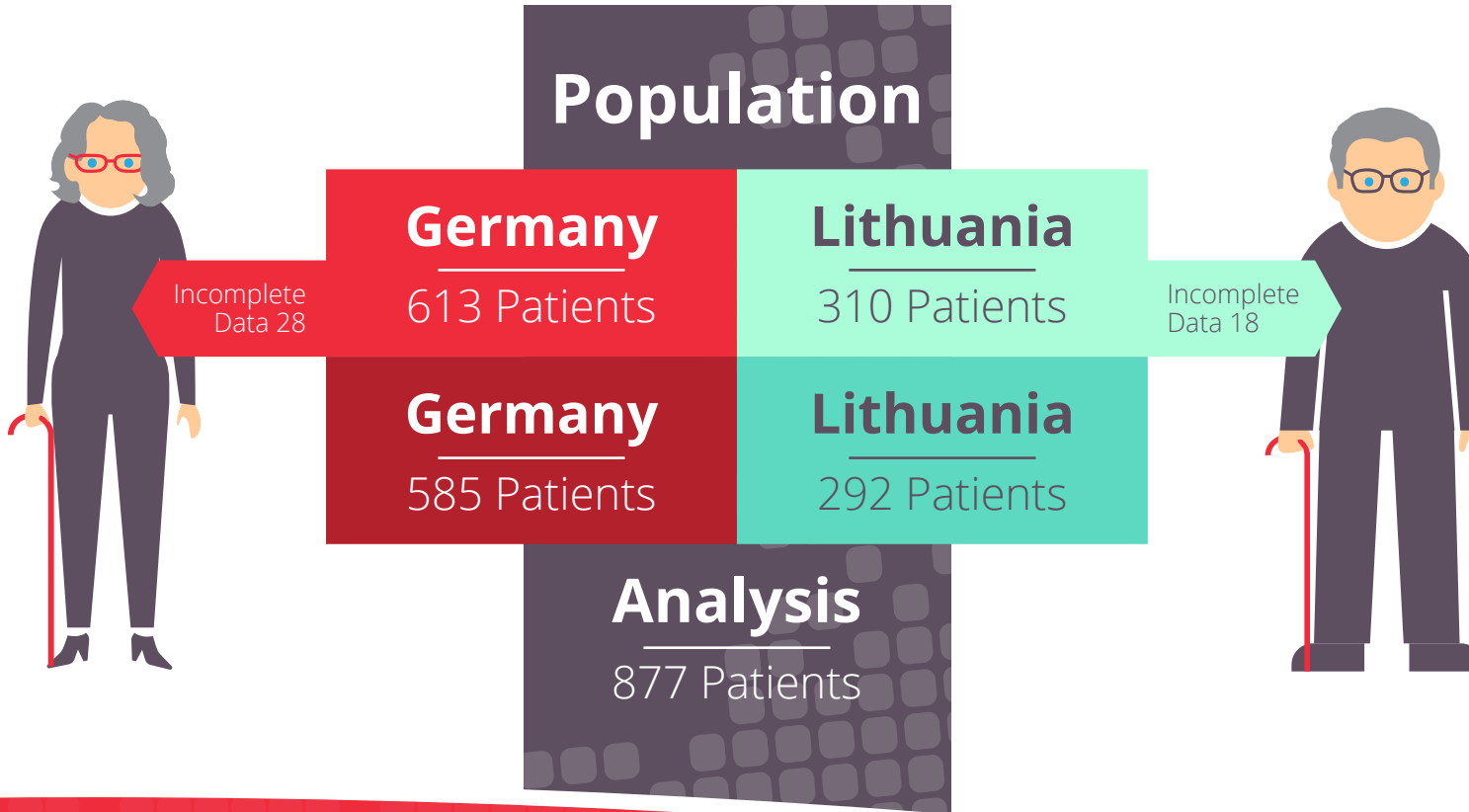
Trochanteric fracture before and after the fixation using femoral nail.

AIMS

One aim is to characterize the technical preferences, as well as to identify areas of consensus regarding specific clinical presentations and their treatment strategies. This would be accomplished through an online registry platform with membership and administration regulated by the Baltic Fracture Competence Centre (BFCC). Based on the analysis of current transnational fracture registry information, the BFCC aims at comparing quality and efficiency of clinical procedures and health outcome of fracture management, in this issue focusing on hip fractures, transnationally, in the participating hospitals. Additionally, the BFCC aims at identifying innovation needs and potentials for clinical and industrial stakeholders based on the comparison of best practices in the participating hospitals of the Baltic countries.

TREATMENT METHODS ANALYSIS

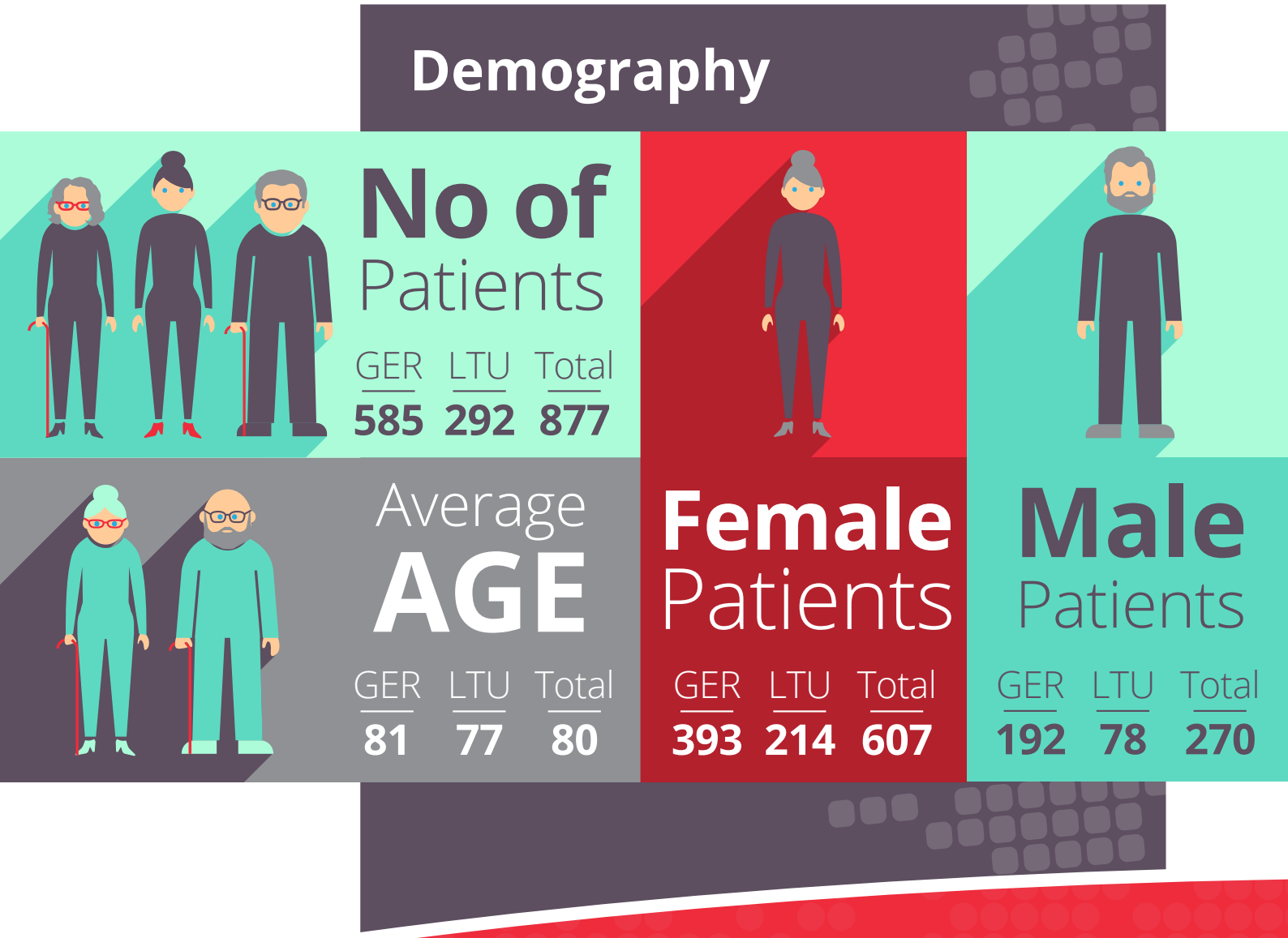
- Retrospective analysis of hip fracture patients' data
- Patients of Lithuanian University of Health Sciences Kauno Klinikos and University Medical Center Schleswig-Holstein, Lübeck were included
- Follow-up started on the day of treatment and ended on the day of revision, death or one year after operation
- Included all proximal femur fractures
- Inclusion period from 2014-06-01 till 2016-06-30
- Investigated variables:
  - Patients demographic data
  - Fracture types
  - Differences in time periods from admission to surgery
  - Type of implants used
  - Reoperations before one-year follow-up
  - Complications
  - Mortality rates



Lithuanian patients appeared slightly younger. The gender distribution amongst both countries was similar.

Several studies have analysed the effects of delayed surgery after admission as a factor affecting patient mortality and functional outcome. In a retrospective study, Bottle *et al.* in 2006 investigated 129,522 admissions in 151 hospitals and found that delaying surgical intervention by even one day was associated with increased patient mortality.[12] Sebestyen *et al.* analysed in 2008 3,783 hip fractures and found that delaying surgical treatment for more than 12 hours was also associated with increased mortality.[13] Comparisons investigating the intervals between the time of admission to surgical intervention in Lithuania and Germany showed significant differences between the two countries. The mean time of a patient's admission to hospital and followed surgical treatment was 36 hours in Germany, while 48 hours in Lithuania. Despite the relatively small difference in time to surgery periods in countries, this factor may affect mortality rates in hip fracture patients and should certainly encourage for patient care pathway improvements.

In addition, a difference in fracture type distribution between countries was observed. In Lithuania, displaced femoral neck fractures were the dominant type of proximal fracture, while in Germany the majority of fractures included in the study were categorized as trochanteric two fragment fractures.



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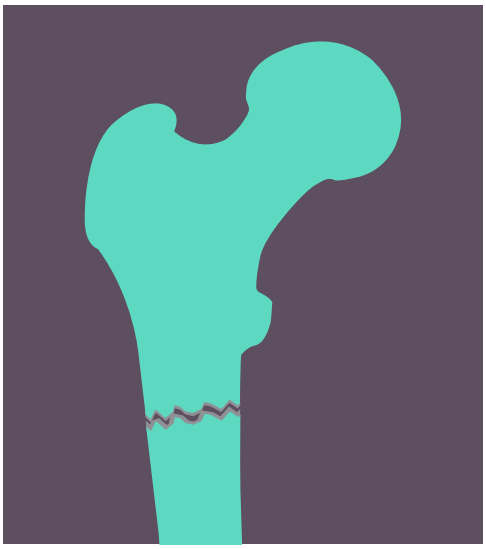
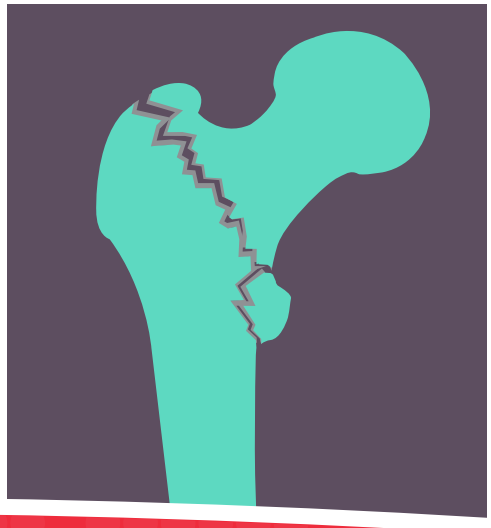


Displaced femoral neck fracture (left)

Subtrochanteric fracture (right)



Trochanteric fracture (left)

Undisplaced femoral neck fracture (right)

Types of fractures investigated

FRACTURE TYPE	GERMANY (%)	LITHUANIA (%)	TOTAL
Displaced femoral neck fracture	116 (20)	179 (61)	295
Subtrochanteric fracture	62 (11)	20 (7)	82
Trochanteric two fragments fracture	240 (41)	42 (15)	282
Trochanteric fracture multi fragments	0 (0)	12 (4)	12
Undisplaced femoral neck fracture	167 (28)	39 (13)	206
TOTAL	585	292	877

While comparing operative treatment methods used for displaced femoral neck fractures, a similar surgical approach was observed in which total hip arthroplasty was dominating in both countries.

Displaced femoral neck fractures

TREATMENT	GERMANY		LITHUANIA	
	N	%	N	%
Arthroplasty	103	88.79%	172	96.09%
Screw osteosynthesis	1	0.86%	4	2.23%
DHS	7	6.03%	3	1.68%
Gamma nail	5	4.31%	0	0.00%
TOTAL	116		179	

Devices for arthroplasty (left) and osteosynthesis screw (right)

Statistically significant differences were observed when comparing surgical approaches related to trochanteric and subtrochanteric fractures. Gamma nail treatment was the preferred operative choice in Germany for both, trochanteric and subtrochanteric fracture fixation, while in Lithuania dynamic hip screws (DHS) were most commonly used to treat both fracture types.

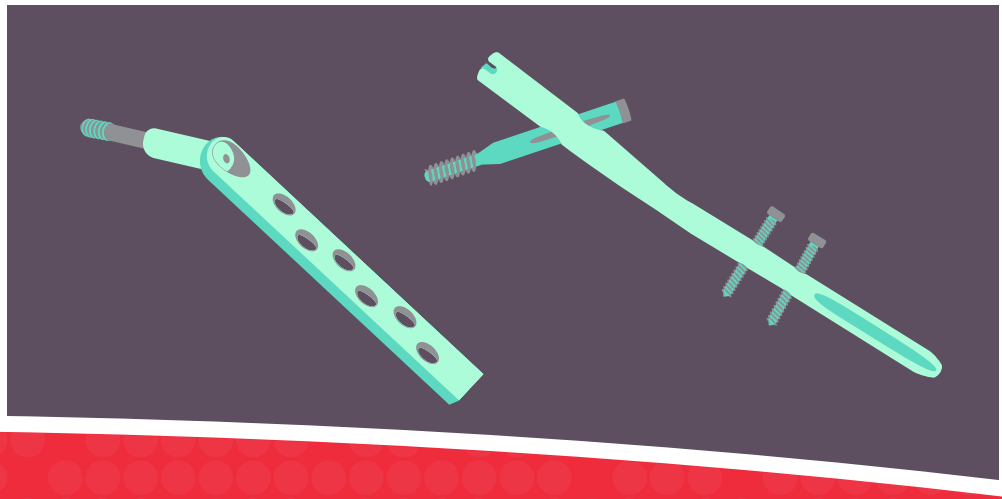
Trochanteric fractures

TREATMENT	GERMANY		LITHUANIA	
	N	%	N	%
Arthroplasty	11	4.58%	3	5.56%
Screw osteosynthesis	1	0.42%	0	0.00%
DHS	21	8.75%	46	85.18%
Gamma nail	207	86.25%	5	9.26%
TOTAL	240		54	

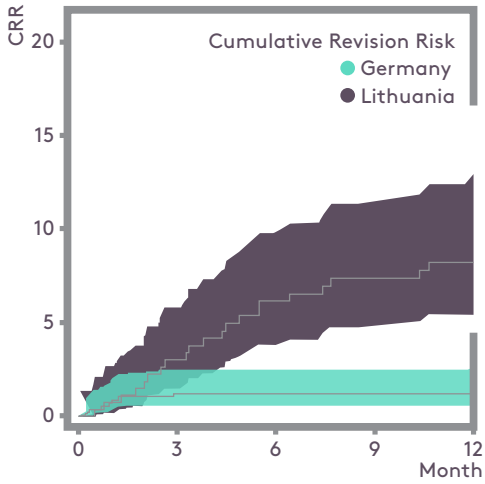
Subtrochanteric fractures

TREATMENT	GERMANY		LITHUANIA	
	N	%	N	%
Arthroplasty	5	8.06%	0	0.00%
DHS	7	11.29%	18	90.00%
Gamma nail	50	80.65%	2	10.00%
TOTAL	62		20	

There is no definitive consensus currently present in literature regarding the »best« fixation device for trochanteric fractures, leaving this fracture treatment still up for debate. However, there is also no unanimous agreement for when to support the use of dynamic hip screw or gamma nail. Such a shortage of good quality scientific data suggests that more detailed studies are required to assess the various risks, costs and benefits regarding optimal treatment methods for this fracture type in future studies.



DHS (left) and gamma nail (right)

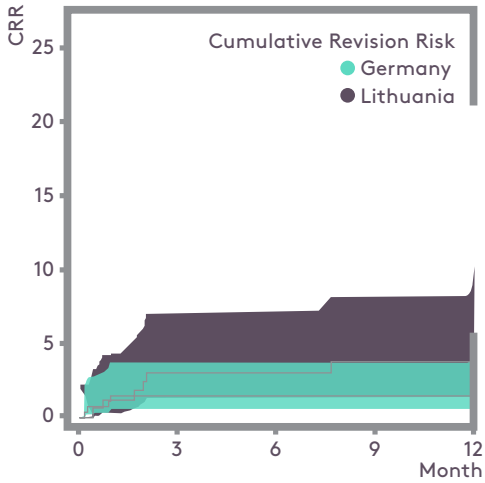


A comparison of implant revision rates between Lithuania and Germany using any reoperation as an endpoint was performed. It concluded that the overall cumulative revision rate (CRR) was observed to be statistically higher in Lithuania than in Germany (p=0.00005):

Germany:
1.21% (95% CI 0.59—7.67%)

Lithuania:
8.20% (95% CI 5.42—21.17%)

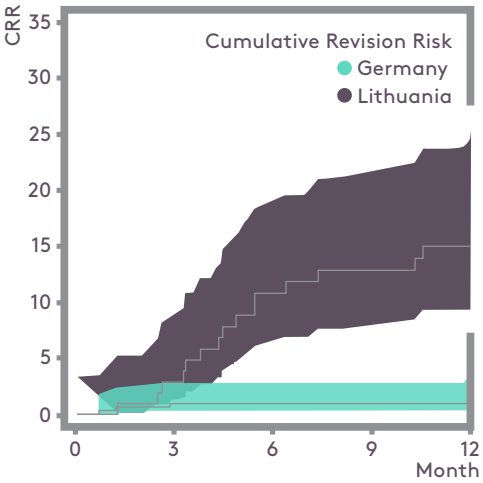
CRR arthroplasty



Germany:
1.49% (95% CI 0.58—26.94%)

Lithuania:
3.73% (95% CI 1.72—25.32%)
p=0.1510

CRR osteosynthesis



Germany:
0.97% (95% CI 0.33—8.40%)

Lithuania:
15.05% (95% CI 9.32—34.21%)
p=0.00005

Higher failure rate was observed in Lithuania after osteosynthesis.

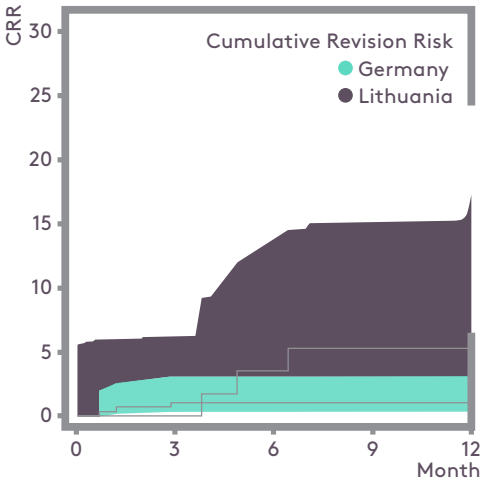
A more detailed analysis comparing revision rates in Lithuania with those in Germany, primarily focusing on the treatment method used (osteosynthesis vs. arthroplasty) showed no significant differences in revision rates for the arthroplasty group. When comparing osteosynthesis revision rates in Germany, they were significantly lower compared to Lithuanian cohort. These findings suggest that fracture patients undergoing treatment in Lithuania using osteosynthesis, as opposed to those receiving arthroplasty treatment modalities, should be the primary concern. The differences in the revision rates should be investigated more thoroughly in the future to prevent negative outcomes.

A separate analysis was performed for patients receiving treatment for trochanteric fractures only. This was done to compare revision rates between Lithuania and Germany with a statistically higher failure rate being observed in Lithuania (p=0.0313):

Germany:
1.06% (95% CI 0.36—9.41%)

Lithuania:
5.33% (95% CI 1.83—30.73%)

Observed differences suggest that the variation of devices used for fracture fixations in both countries may play a role by increasing the cumulative revision risk.



FIELDS FOR IMPROVEMENT

Based on data analysis, it was observed that treatment methods, together with postoperative care, vary between the two countries, and this variation between various measured parameters may have influenced the outcomes. An important finding performing this international analysis was that Lithuanian patients operated with osteosynthesis for proximal femur fractures had a 15% cumulative revision rate one-year after follow-up. This can be contrasted to the 1% revision rate in a one-year follow-up in Germany. These differences in outcome may be due to the nation's preferential use of specific devices for fracture fixation. This is demonstrated by Lithuania's preference for the use of sliding hip screw implants, while in Germany for proximal femoral fractures gamma nails are used as a dominant implant. Currently, there is no conclusive evidence in the literature to support one treatment method against another. In a Cochrane database review, Parker MJ and Handoll HH[14] showed that sliding hip screws had lower complication rates in comparison with intramedullary nails. However, in the meta-analysis of Ma KL *et al.*[15] it was stated that proximal femoral gamma nail should be a priority choice for treatment of intertrochanteric fractures due to the minimal rate of fixation failure, less blood loss during the procedure, and shorter length of hospital stay. Based on the transnational data results, it was observed that proximal femoral fracture treatment using gamma nails had a superior outcome compared to the use of sliding hip screws. This finding is an important message and provides a field for improvement for the fracture community, clinicians, health care professionals, professional associations, research and companies contributing to fracture management, especially implant manufactures.

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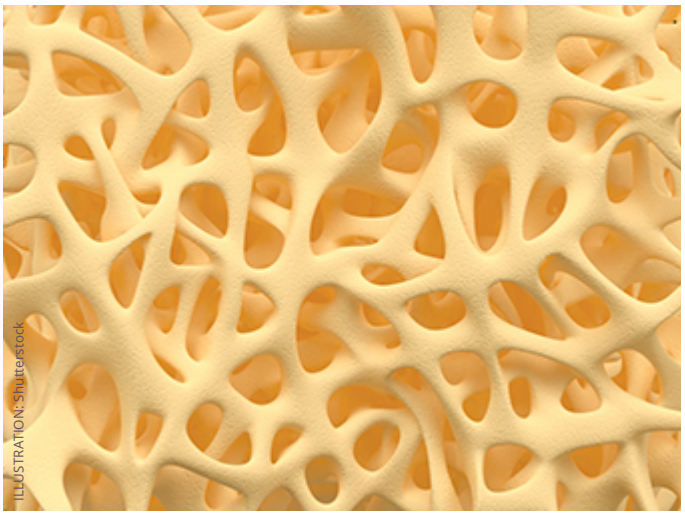
However, a more detailed analysis of fractures in the fracture registry would be of great importance for providing more supportive study data in order to find the evidence for treatment methods providing best possible outcome with the lowest revision rates and mortality in this highly sensitive demographic group.

QUESTIONS TO THE FUTURE FRACTURE REGISTRY

The differences observed in metal devices used for hip fracture fixation and related postoperative care between Germany and Lithuania leads to further questions regarding these statistically significant differences some of which contradict current literature reports. One possible explanation is that bone quality might differ between the two nations for patients suffering from hip fractures. One may suspect that higher osteoporosis level, but not the device used for fracture fixation, may have an influence on Lithuania's inferior results compared to Germany's. Such a hypothesis influenced the development of a research plan with focus on hip fracture patient's osteoporosis level in cooperation with the Bindex® company Bone Index Finland. The base of the new research plan was not only to assess the fracture type, but also to evaluate bone quality, which could have some influence on the treatment outcome of hip fracture patients. The same parameter may also be an influential variable in bone healing and hardware migration. Frequently, bone quality assessment requires some time and cost consuming testing. However, Bone Index Finland has an efficient and accurate device in osteoporosis diagnostics which provides a fast and reliable result for both patients and the medical staff. Thus, a research plan was created to test osteoporosis level in hip fracture patients in three BFCC partner hospitals (Germany, Lithuania and Estonia) and correlate that with postoperative outcome. Doing so, the BFCC could provide an important message and room for improvement in evidence-based treatment decisions, taking into account a patient's osteoporosis level.



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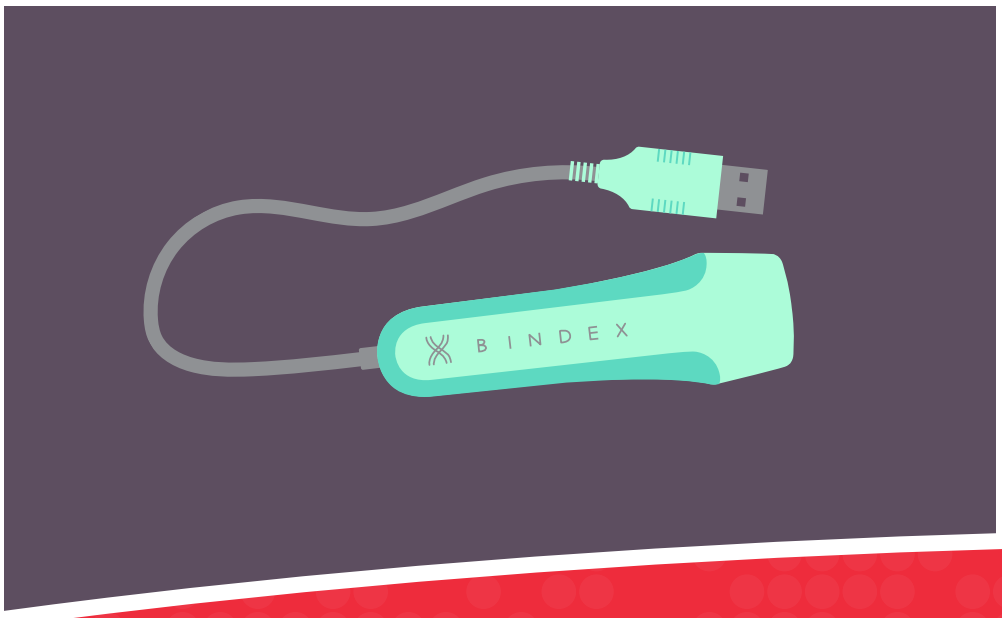
Furthermore, with the development of the transnational fracture registry more clinically important variables could be added and assessed to provide knowledge about evidence-based correlations, thereby offering opportunities to develop ideas and starting points for innovative solutions in fracture management.



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- Fund: European Regional Development Fund
- Flagship project of the EU Baltic Sea Region strategy

PROJECT PARTNERS

- Life Science Nord Management GmbH (Germany; Lead Partner)
- Stryker Trauma GmbH (Germany)
- University Medical Center Schleswig-Holstein (Germany)
- University Medicine Greifswald (Germany)
- Sahlgrenska University Hospital (Sweden)
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