EUROSPINE

The international Spine Registry SPINE TANGO

Annual Report

2014

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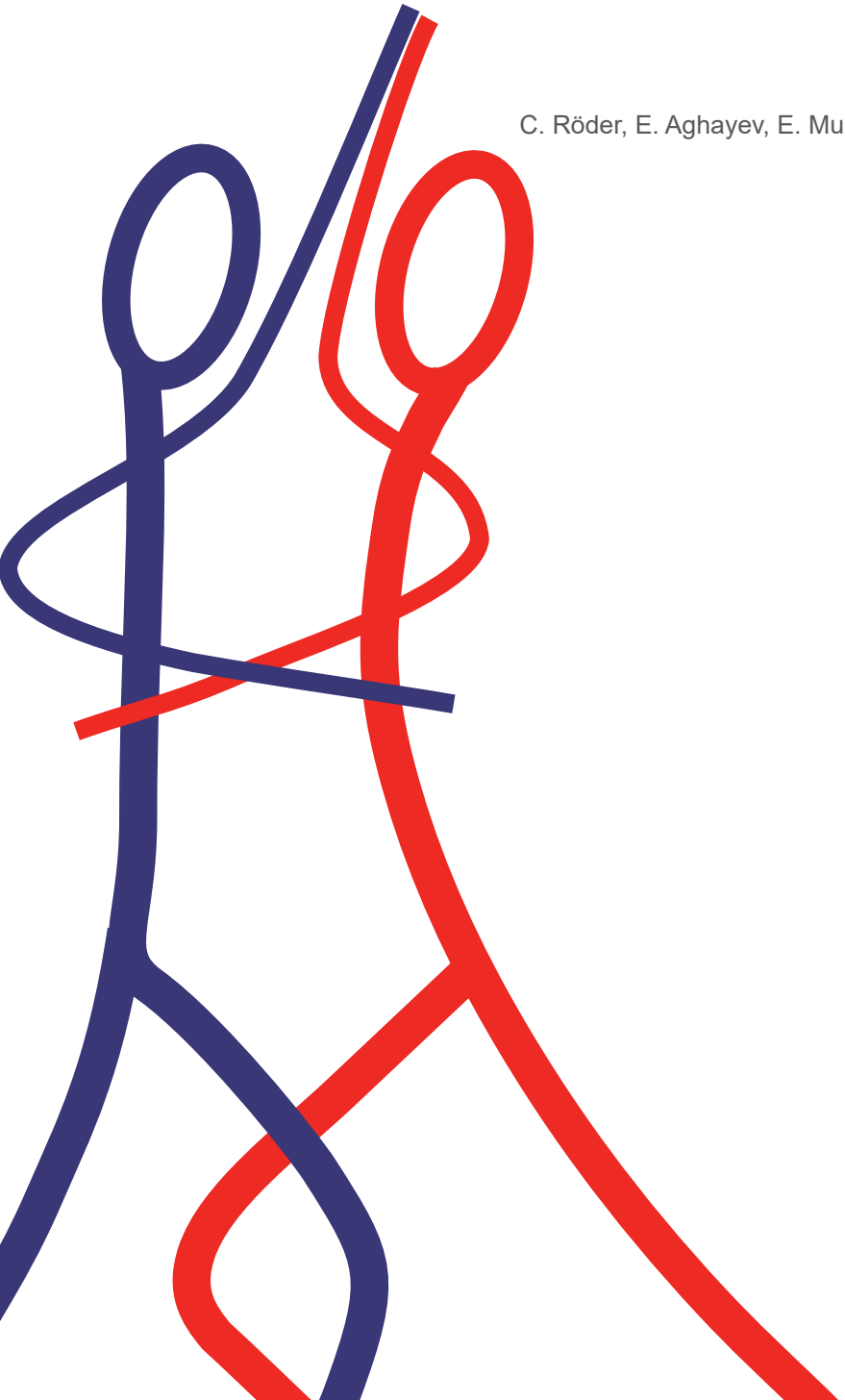

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This annual report is digitally available in the literature section of the Spine Tango web page under http://www.eurospine.org/literature.htm. The Spine Tango security details and Code of Conduct are newly available in the same section.

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Introduction

Since the year 2000 EuroSpine - The Spine Society of Europe has been developing a registry for the documentation of surgical and non-surgical treatments in response to a growing demand for outcome measurement and quality assurance. Spine Tango is the only international spinal registry and has been developed by Eurospine and the University of Bern for this purpose. Spine Tango as an idea was proposed more than a decade ago by Dieter Grob and Max Aebi, under the auspices of SSE. There has been considerable investment of clinician, academic and financial resources to develop and improve the system. Having achieved international recognition we would like to encourage national societies and individual partners to join the registry.

The German Spine Society DWG, the largest spine society in Europe, has successfully conducted a 3-year pilot of a national spine registry using the Spine Tango technology and content as its platform. It is now planning to make documentation of all spinal interventions a mandatory prerequisite for certification as a spine center of excellence in Germany. In 2013 Polish and Belgian Spine Tango modules were launched. The Spine Society of Belgium (SSBe) has chosen the Spine Tango Registry as its national registry and will conduct a pilot study in collaboration with the National Social Insurance. In Switzerland, documentation of all spinal interventions with implants will become mandatory in 2016. Spine Tango will most likely be the system of choice to be integrated into the Swiss Implant Registry SIRIS.

Those who fund health care are already limiting access to some spinal treatments due to a lack of evidence of effectiveness. The Spine Tango registry consisting of routine data from a hospital's daily practice allows clarity of activities and outcomes. Evidence from the registry has a lower internal (i.e. methodological) validity as compared to higher evidence studies like RCTs. But the external validity and therefore general application of our findings is what makes the dataset and its clinical and scientific findings so valuable for quality assurance, health service and outcome research.

The last three years have seen a significant increase in data entry and a consequent rise in the number of presentations related to this. Benchmark studies on specific issues like spinal stenosis and degenerative spondylolysthesis have been carried out and are further refined.

The Spine Tango registry has also reached new levels of technological sophistication. A first large spine center in Italy is programming a direct interface for data entry from their clinic information system into the Tango database. Further, an interface to the Surgimap measurement system for spinal deformities was developed for the German Spine Society`s deformity group and can soon also be used for Spine Tango.

Surgeon level data reporting is now a reality in the United Kingdom and is likely to spread to the rest of Europe, as can be seen in Belgium, Germany and Switzerland. Having ownership of your own data that can be benchmarked against other units in Europe offers individual surgeons considerable protection. It is in all our interests to make Spine Tango a continuing success and I would urge all spinal specialists to submit data to the registry

T. Pigott
Chair, on behalf of the Spine Tango committee

Profile

Spine Tango enables you to document the whole spectrum of spinal pathologies and the possible surgical and non-surgical treatment options. The generic approach of the Spine Tango documentation system is a must to reach the maximum number of participants using a common web based technology. This, in turn, reduces the potential for customizing the Tango in order to meet the individual expectations of specific users. There are, nevertheless, still a number of possibilities to parameterize the data collection processes according to the various hospital workflows in the user community. To give you the opportunity to document not only the surgical treatments, we have developed Spine Tango Conservative, which is increasingly being used by spinal units to document their hospitalized but non-surgically treated cases. Also, the two specialist add-on questionnaires for adolesecent scoliosis and degenerative deformities do allow a more detailed and in-depth documentation of complex deformity cases. Spine Tango is an international, non-commercial system under the auspices of EuroSpine, the Spine Society of Europe aiming at enabling national societies to organize and control their own part of the registry. For that a technology called “national module concept” has been implemented to enhance participation options and to provide the hardware structure for appropriate security measures for patient and user privacy protection. The constantly and further developed software of the MEMdoc portal does further improve these aspects. In conclusion, Spine Tango is a unique applied medical and scientific documentation and technology solution. It is to the benefit of patients, physicians and therapists whilst generating evidence based findings to improve spinal care (1, 2).

1. Aebi M, Grob D (2004).
SSE Spine Tango: a European Spine Registry promoted by the Spine Society of Europe (SSE).
Eur Spine J. 13(8): 661–662.

2. Kessler J, Melloh M, Zweig T, Aghayev E, Röder C (2011)
Development of a Documentation Instrument for the Conservative Treatment of Spinal Disorders in the International Spine Registry Spine Tango.
Eur Spine J. 20(3): 369–379.

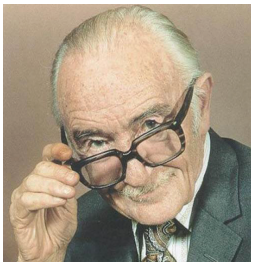
Registries versus Randomized Controlled Trials (RCT)

	RCT	Registry
Type of evidence	Efficacy	Effectiveness*, safety
Principal question	Can it work? The first step of evidence generation	Does it work? Verification in daily clinical practice
Internal validity (methodological quality)	+++	+ - ++ (expandable with e.g. monitoring, audits or comparison with secondary data, etc.)
External validity (transferability/ generalizability)	- - +	+++
Bias & Confounding	Low to very low	High to low, depending on the organisation. Well organised registries and high quality analytical methods lower bias & confounding, but can never eliminate them.
Levels of evidence	1a, 1b, 2a	2b-4, depending on methodology
Hypothesis-based approach	Yes	Usually no
Duration of observation period	Predefined	Open-ended or predefined
Focus of research/measurement	Sharp, narrow (see hypothesis)	Broad
Quality assessment	Not intended (strictly defined indications, process quality at least derivable, outcome quality depends on effectiveness, a given indication and process)	Indication, process, outcome
Early warning system	Not possible	Feasible
Long-term follow-up	Feasible	Feasible, depending on registry set-up maybe only for a representative sample
Coverage	Only among participants	From individual center/surgeon over representative clinic sample to full national / regional coverage
Benchmarking	Only benchmarking of group	Depending on the final composition of participants regional to nationally representative benchmark
Type of quality assurance	Internal, external vs. benchmark of participants	Internal, external vs. representative regional or national benchmark
Effort	Very high for a few participants	Low for many participants
Cost per case	High to very high	Low
Cost per study	High to very high	Low cost basis, costs increase depending on the stage of development and number of participants
Availability of potential patients	Low to medium	Usually high (exceptions: e.g. rare diseases)
Commitment of patients	High	Rather low
Use of generated data	Only in the framework of the scientific goal/hypothesis	Open hypothesis generation possible
Comparator	Given per definition	Ranges between none to numerous comparators, depending on registry set-up
Availability of results	At the end of the study (except interim analysis)	Ongoing in registry evaluations and reports. With longer duration 'estimates' of results are getting more precise (smaller confidence intervals with growing case numbers).

*unclear terminology, Cochrane called it "efficiency", better always specify what you mean (evidence derived from controlled experiment versus evidence derived from routine clinical practice)

Table 1: Comparison of RCT and registry characteristics

Cochrane AL, British Epidemiologist, 1909-88.
The father of Evidence Based Medicine. Effectiveness and Efficiency.
Random Reflections on Health Services.
London: Nuffield Provincial Hospitals Trust, 1972



New Developments

Improved online statistics: the selected patient sample can soon also be connected to the followup and COMI forms of the respective surgical forms for analyzing treatments and outcomes with one and and the same query. It is also planned to improve the output style for nicer looking tables and graphs generated by the Highcharts software.

Complex search tool: the current search tool allows searching patients by demographic characteristics, form type, form characteristics and certain form attributes. In the future, patients can also be searched based on outcomes of clinical parameters, i.e. all questions and answers on all forms can be used to specify a patient search. The hit list can either show the related patients or the related forms.

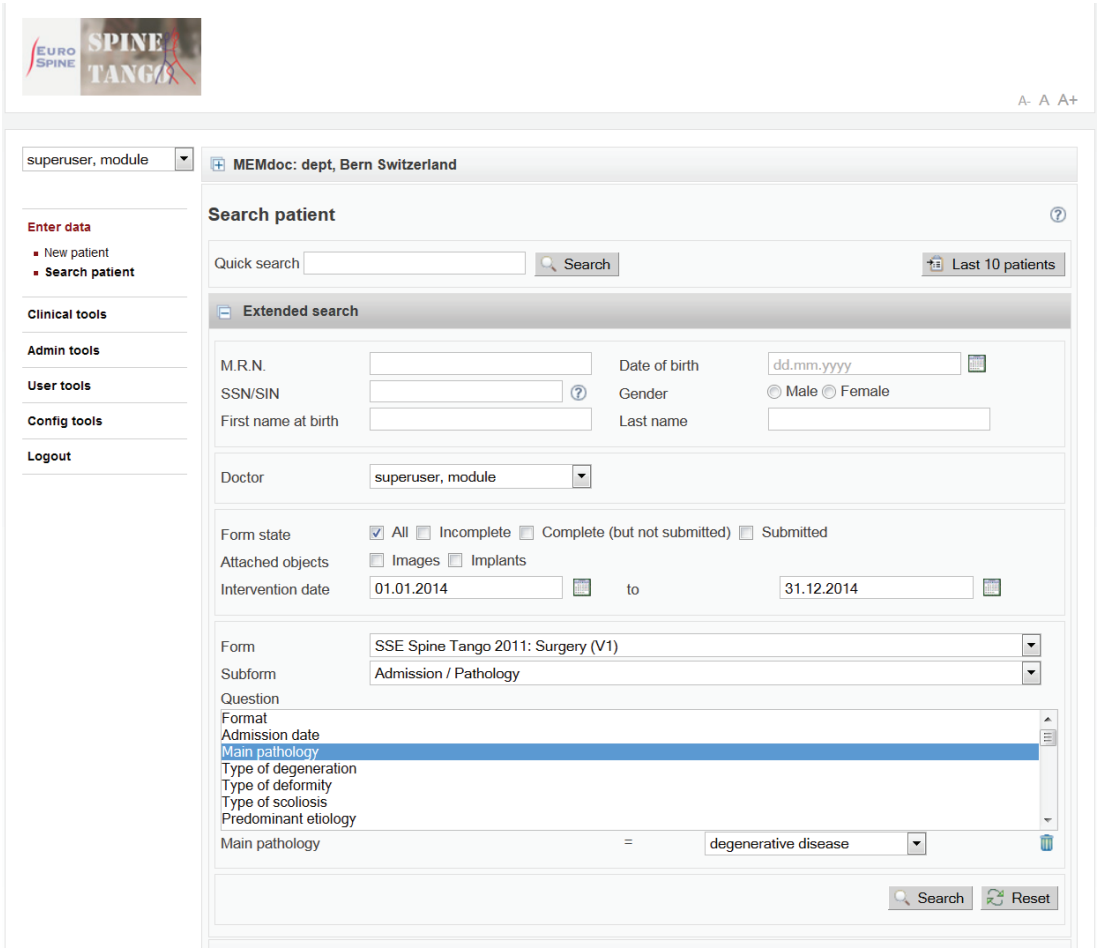


Figure 1: Newly extended search mask with possibilities to further specify the search with patient characteristics, surgical details or postoperative information

New Developments

Surgimap interface: Thanks to the deformity working group of the German Spine Society DWG an interface to the Surgimap image analysis software was created. This interface will be also implemented for the Spine Tango registry and allows importing measurement data directly into the new Spine Tango adolescent scoliosis and adult deformity add-on forms.

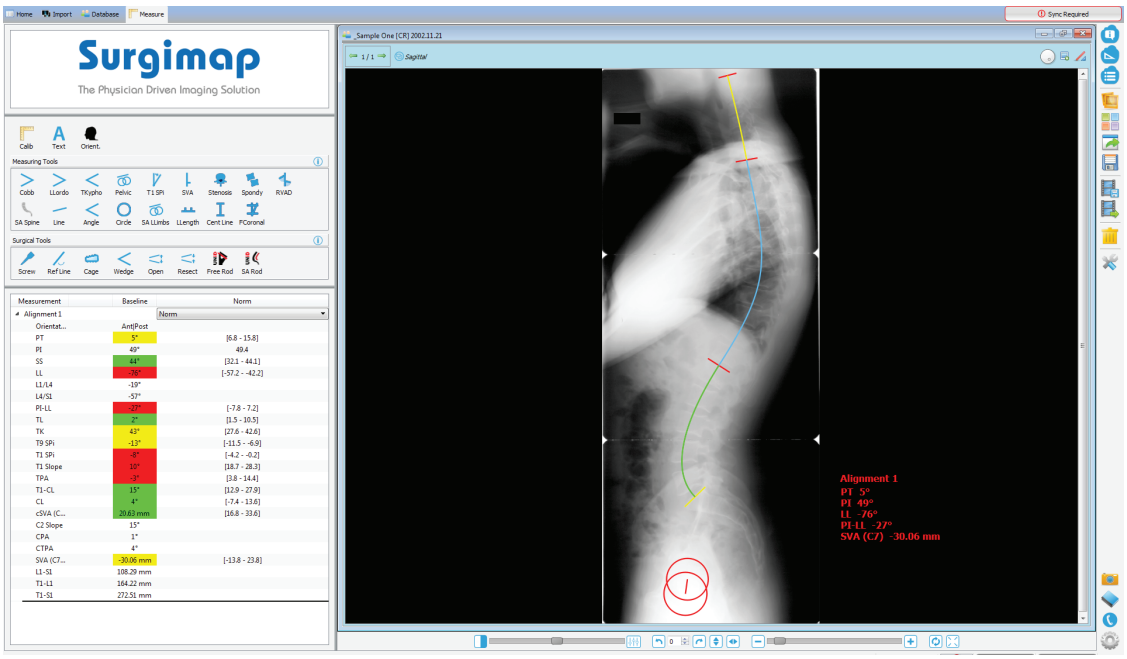


Figure 2: Surgimap measurements (green, red, yellow) for transcription into ...

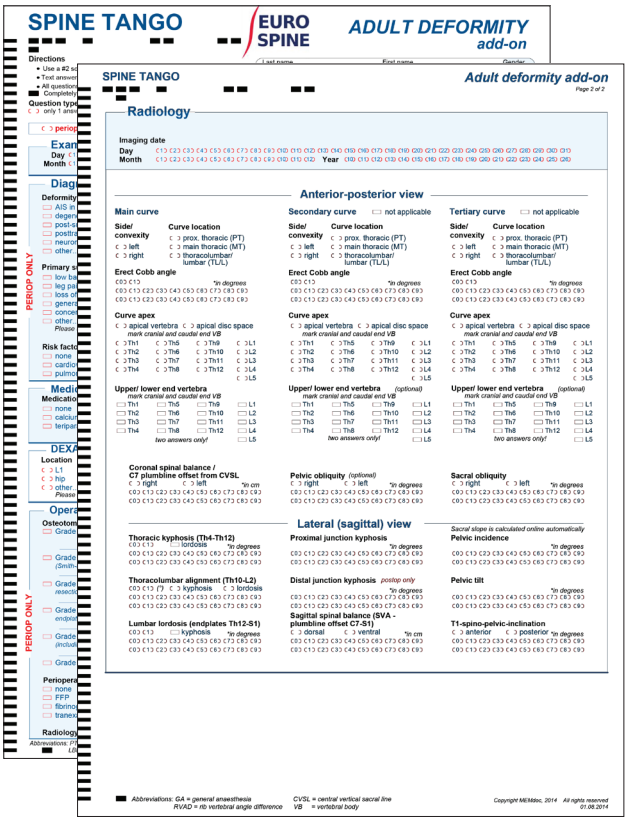


Figure 3: Adult Deformity Radiology subform

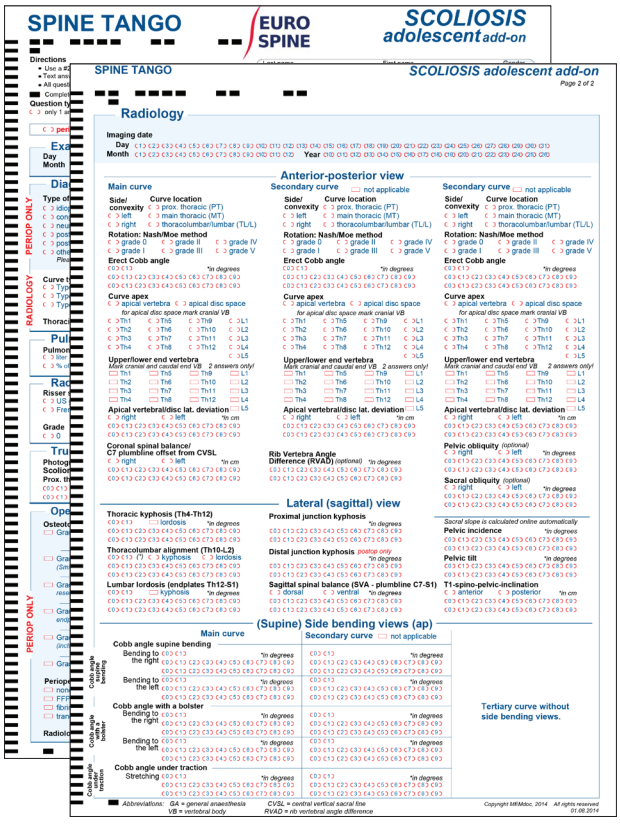


Figure 4: Adolescent Scoliosis Radiology subform

Application

Quality control, health service, comparative effectiveness and outcomes research, postmarket surveillance of implants, national and international study network.

Internal quality control: assuming that you have a complete data collection, Spine Tango enables you to monitor all types of surgery during a specific period, observing the date and duration of operation, patient characteristics and outcomes (patient- and physician-based). The comprehensive annual report that users receive in their “Documents” section can be used for performance description and comparison with previous years.

External quality control: benchmarking, the comparison of own performance with that of the national or international results in the Tango data pool is a powerful management tool because it overcomes “paradigm blindness.” Paradigm blindness can be summed up as the mode of thinking “The way we do it is the best because this is the way we’ve always done it”. Benchmarking opens organizations to new methods, ideas and tools to improve their effectiveness. It helps overcome resistance to change by presenting successful methods of problem solving that are different to the ones currently employed. Enabling benchmarking possibilities is one of the fundamental goals of the Spine Tango venture. The benchmarking report compares the user`s accumulated data with the accumulated pool data.

Code of Conduct: the underlying principles for participation in the Spine Tango registry have been written up by the ST committee and were distributed in the second half of 2014. The Code of Conduct shall serve as a common agreement between all registry stakeholders for ensuring that the collected data itself is of an acceptable quality which does no compromise the overall goals of the project.

Health services research: as a subdiscipline of health systems research, this young science is an interdisciplinary field that describes and causally explains the provision of health services to the diseased and the healthy, contributes to the development of new concepts for delivery of health services and scientifically accompanies their implementation, and evaluates the effectiveness of structures and processes of healthcare delivery under routine day-to-day conditions. The focus of health services research is the “last mile” of the health care system, where the concrete and decisive delivery of care takes place in hospitals, practices and other institutions.

Outcomes research: this aspect is actually just taking a different view for the same basic activity, i.e. the systematic and prospective collection of key data regarding interventions and outcomes for and of spinal pathologies. While quality assurance is rather used for the purposes of improving ones` own standards of care, outcomes research wants to generate new medical and scientific knowledge and make it available in the peer-reviewed literature.

Postmarket surveillance of implants: implants play a major role in modern spine surgery and just like in the domain of total joint arthroplasty their true performance can only be evaluated by systematically following the devices after implantation and documenting their outcomes in large clinical databases like the Tango. In Switzerland, all spinal implants become part of the governmentally mandated Swiss Implant Registry as of 2016.

National and international study network: the Tango is a technology backbone and currently networks about 40 active hospitals in Europe, North and South America, Australia and Asia. This provides great opportunities for national and international multicenter studies that piggyback on the ongoing routine data collection, add some hypothesis based questions and collect this extra information for the time of primary and follow-up data collection as specified in the joint study protocol. A mini study protocol template for composing the first draft of a study idea and discussing it with the Spine Tango committee or the study participants is now available for download on the Spine Tango webpage under “Forms”.

Research with Spine Tango

Scientific articles using Spine Tango data are increasingly published and cited in the peer reviewed literature. An output from ISI Web of Knowledge about the scientific publications and impact of Spine Tango related research over the years is shown

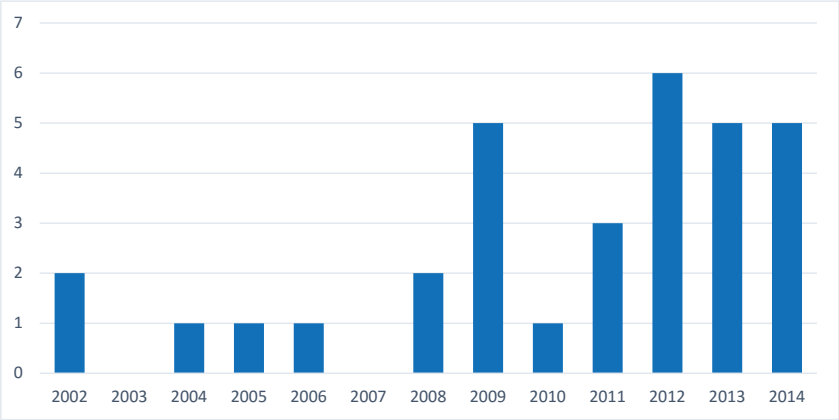


Figure 5: Published items in each year

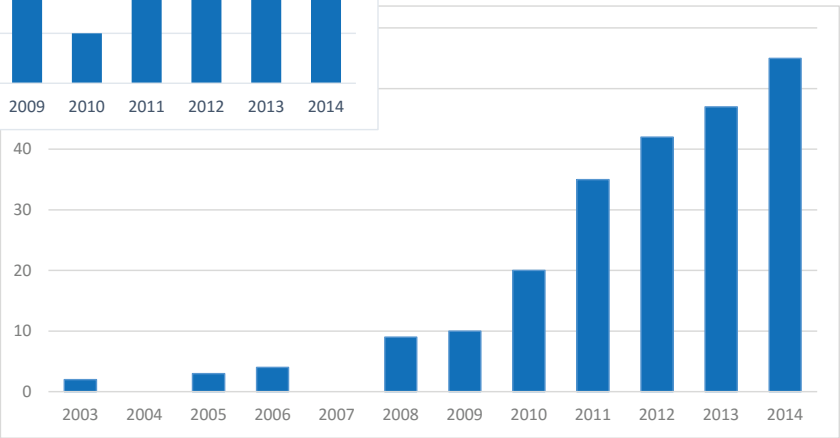


Figure 6: Citations in each year

Results found: 32

Sum of the Times Cited: 260	Citing Articles: 177
Sum of Times Cited without self-citations: 203	Citing Articles without self-citations: 154
Average Citations per Item: 8.12	h-index: 11

Reference Web of Science / Thomson Reuters

Data entry

There are 6 possible ways data can be transferred to the database (Figure 7):
1. Online data entry via the web-interface using stationary computers or wireless tablet devices (no software to be installed).
2. OMR (Optical Mark Reader) i.e. scanner-assisted entry of paper forms.
3. Using the webservice or webservice client interfaces data can be automatically imported from clinic information systems.
4. Paper based data capture with mailing to the IEFM or other partner institutions for OMR scanner-assisted entry of paper forms.
5. A handheld barcode scanner with USB (cable) or bluetooth (wireless) interface can be used to enter the exact implant information into the surgery form. Alternatively the online supplier catalogues or a section for manual entry of implant data is available.
An addition is the hybrid method of online data entry and OMR scanner-assisted entry of paper forms (not pictured). In the rectangles multiple methods of gathering patient and physician generated data are shown (by mail, inhouse, outpatient clinics, telephone and new electronic media).

The goal to generate a comprehensive database is achieved by collecting data of the patient layer and the clinic/physician layer. Having created a consistent data set the options of analyses are almost unlimited. Outcome evaluation can now be done in particular.

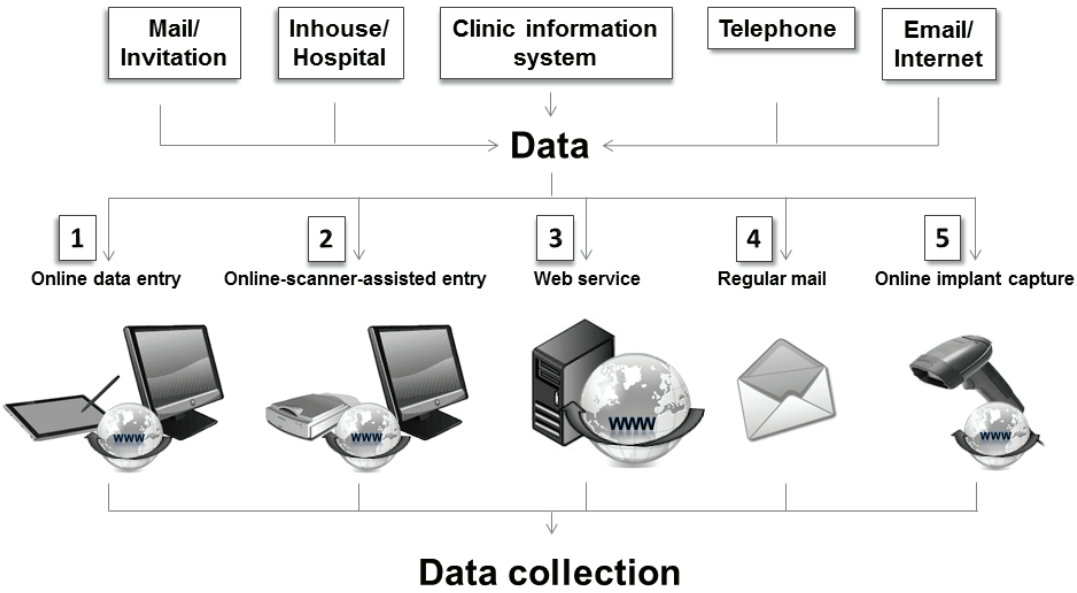


Figure 7: Spine Tango methods of data entry

A complete case

Following Ernest Codman's "end result system" the result of a surgical intervention should be recorded if the outcome can be considered as definitive (3). In most cases of spinal surgery, this can be done after a minimum of 3 months after surgery as demonstrated by Mannion et al (4). In accordance with figure 8. EuroSpine encourages one physician and patient based follow-up in the first year after surgery, ideally later than 3 months postop, and further, at least patient based follow-ups around year one and two after surgery. The registration of complications at any time during the postoperative period is self understood. Patient based outcome documentation with the COMI (Core Outcome Measure Index) questionnaires for neck and back pain has become an essential part of the Spine Tango documentation (5). Figure 9 on the next page illustrates the ideal case of a completely documented treatment (6).

3. Codman, Ernest A. (1916). A Study in Hospital Efficiency. Boston, Mass., privately printed.

4. Mannion AF, Porchet F; Kleinstück FS, Lattig F, Jeszenszky D, bartanusz V, Dvorak J, Grob D (2009). The quality of spine surgery from the patient`s perspective. Part 1: the Core Outcome Measures Index in clinical practice.
Eur Spine J. 18 Suppl 3:367-73

5. Mannion AF, Elfering A, Staerkle R, Junge A, Grob D, Semmer NK, Jacobshagen N, Dvorak J, Boos N (2005) Outcome assessment in low back pain: how low can you go?
Eur Spine J 14:1014-1026

6. Zweig T, Mannion AF, Grob D, Melloh M, Munting E, Aebi M, Tuschel A, Röder C (2009). How to Tango – a manual for implementing Spine Tango.
Eur Spine J 18 Suppl 3:312-2

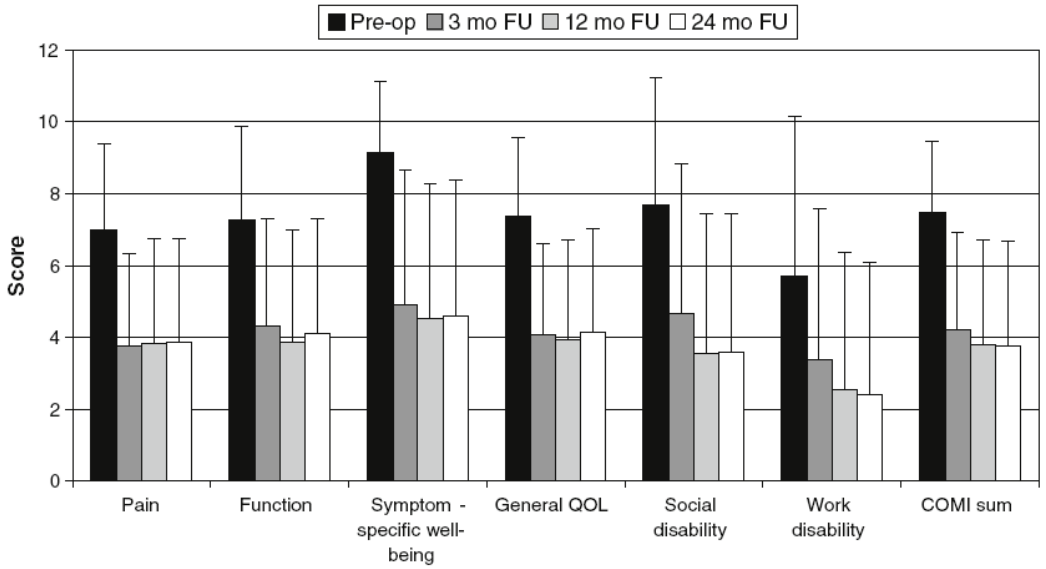


Figure 8: Patient based outcome documentation with the COMI (Core Outcome Measure Index) questionnaires, AF Mannion et al. (2009)(4)

Pre- and postoperative documentation workflow of a case

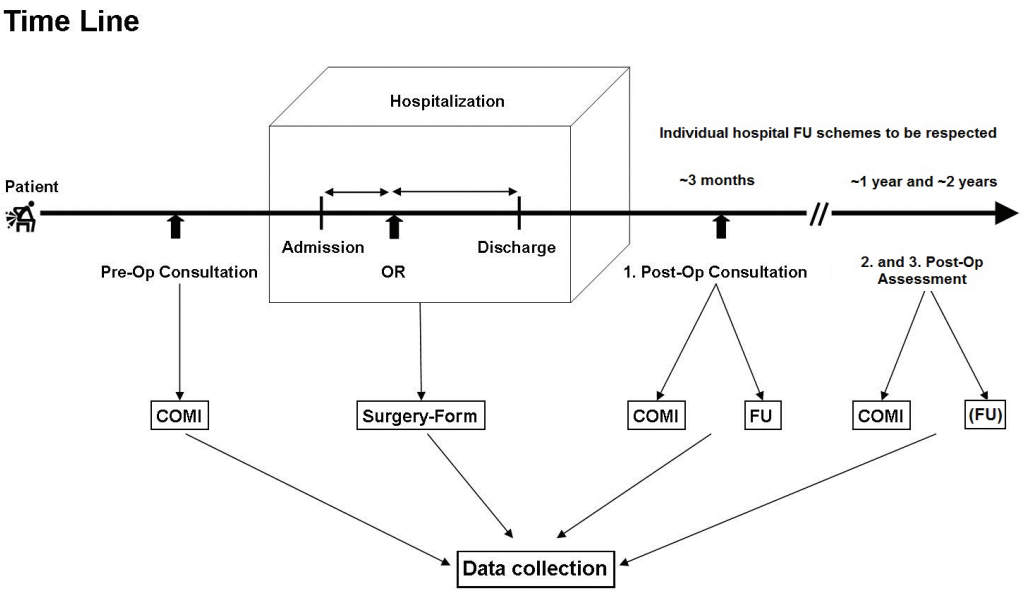


Figure 9: Timeline of data collection

Apart from the preoperative assessment of patients` quality of life and the recording of the surgical intervention, the Spine Tango Code of Conduct recommends one physician- and patient-based follow-up around the 3 months postoperative time interval. In accordance with international standards in the medical literature, an additional and at least patient-based follow-up for the follow-up intervals 1 year and 2 years is highly recommendable. If a physician-based follow-up can also be achieved, a perfect outcome documentation is in place.

Statistics in Spine Tango

Various statistical analyses are performed in Spine Tango based research. The used methods include descriptive analyses for data exploration, parametric and non-parametric tests, uni- and multivariate linear and logistic regression analyses (7, 8, 9, 10) and inverse probability of treatment weighting using the propensity score (11). Comparative effectiveness research studies across different spine registries were also published (12, 13). A first matching study was just performed and received an outstanding paper award from "The Spine Journal" of NASS in 2015 (14). Additionally to clinical studies, a multitude of reliability and validation studies of the COMI form in different languages were performed and published in the last decade. Furthermore, the preliminary experience with the assessment of predictors of surgical outcome using Spine Tango data has led to a large project aiming to develop clinical prediction models of patient outcomes in a leading Spine Tango hospital in Switzerland. Finally, the Spine Tango Research Group continuous its work on the epidemiological description of patient, treatment and outcome characteristics of different diagnostic groups (the so-called Benchmarking Project). A new challenge is the minimization of Spine Tango documentation for implant registry purposes. The mandatory Swiss minimal data set for the SIRIS spine registry will be purely based on index and reoperation/revision surgeries. With just one form, i.e. the Spine Tango surgery form, a quality assurance system for hospitals and implants will have to be developed. For putting such a system into place we intend to use the concept of revisions per 100 observed component years (r100ocy) from international joint implant registries and convert it to revisions per 100 observed surgery years (r100osy).

7. Sobottke et al. (2012). Predictors of surgical, general and follow-up complications in lumbar spinal stenosis relative to patient age as emerged from the Spine Tango Registry.
Eur Spine J. (3):411-7.

8. Kleinstueck et al. (2011). The outcome of decompression surgery for lumbar herniated disc is influenced by the level of concomitant preoperative low back pain.
Eur Spine J. (7):1166-73.

9. Lattig et al. (2009). Ratings of global outcome at the first post-operative assessment after spinal surgery: how often do the surgeon and patient agree?
Eur Spine J. Suppl 3:386-94.

10. Kleinstück et al. (2009). The influence of preoperative back pain on the outcome of lumbar decompression surgery.
Spine 34(11):1198-203.

11. Munting et al. (2014). Patient outcomes after laminotomy, hemilaminectomy, laminectomy and laminectomy with instrumented fusion for spinal canal stenosis: a propensity score-based study from the Spine Tango registry.
Eur Spine J. (2):358-68

12. Burkhardt et al. (2013). A comparative effectiveness study of patient-rated and radiographic outcome after 2 types of decompression with fusion for spondylotic myelopathy: anterior cervical discectomy versus corpectomy.
Neurosurg Focus. 35(1):E4.

13. Aghayev et al. (2012). Comparative effectiveness research across two spine registries.
Eur Spine J. (8):1640-7.

14. Staub et al. (2014). A matching study of anterior cervical interbody fusion versus total disc arthroplasty from an international spine registry: does it reflect clinical reality?
The Spine Journal, accepted for publication.

Spine Tango growth curve

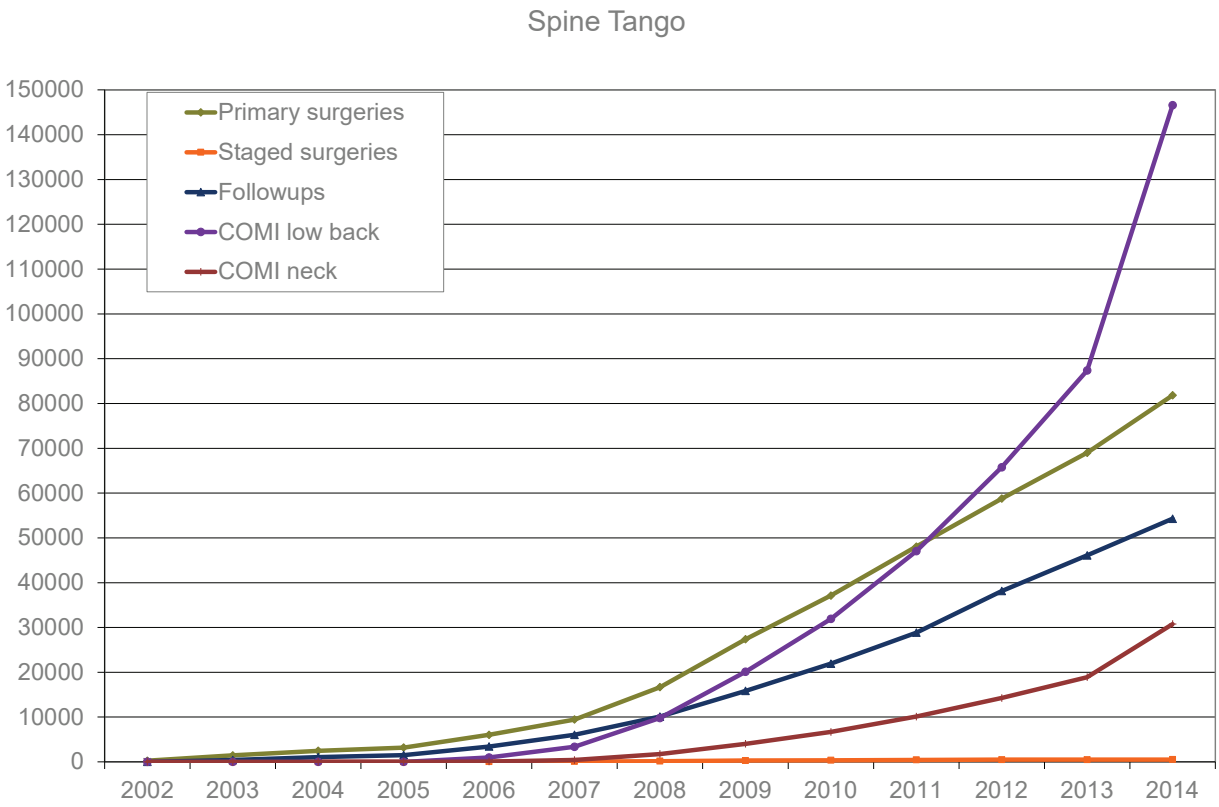
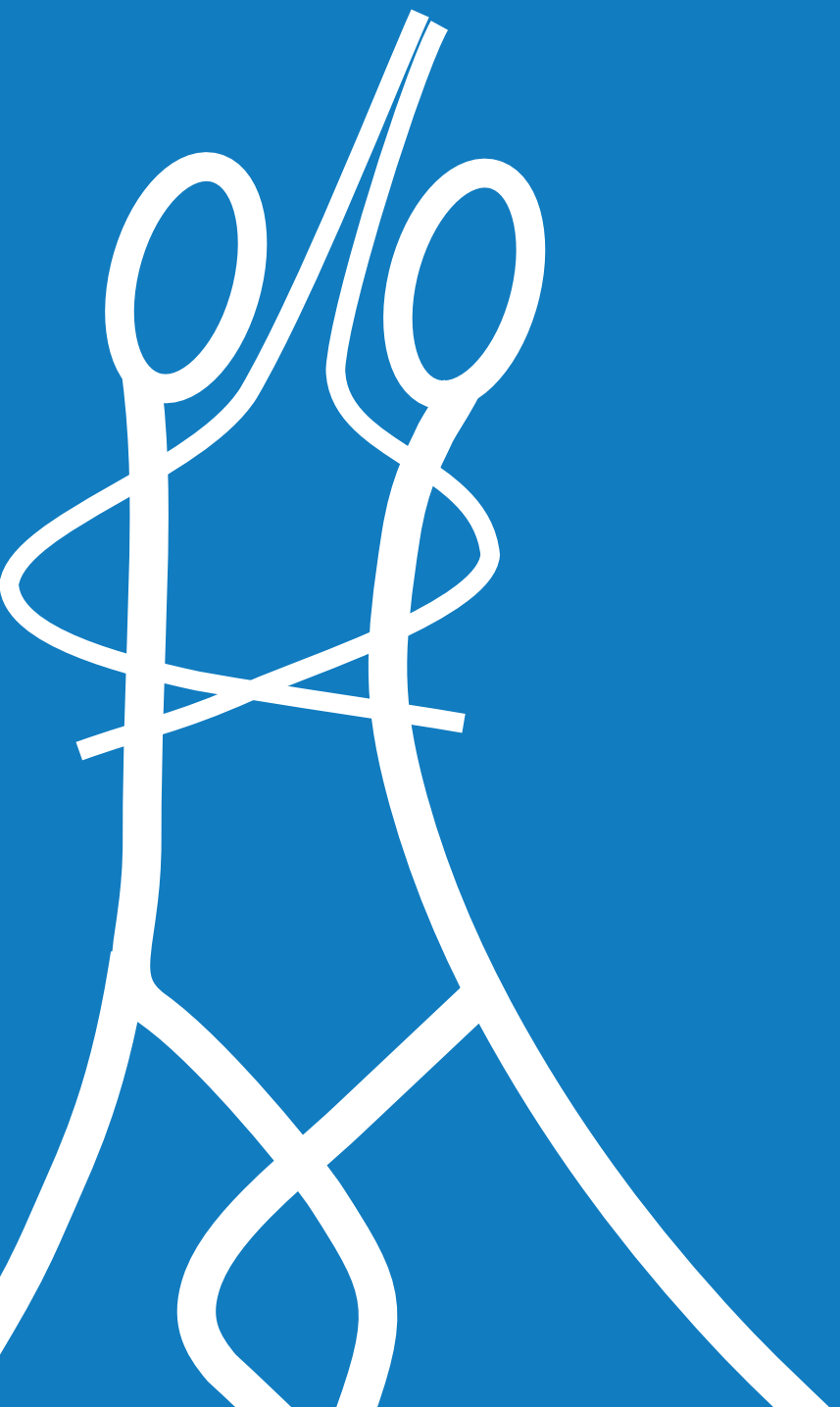


Figure 10: Growth curves of implemented forms (primary and staged surgery and follow-up) as well as COMI low back and neck over the years.

The Spine Tango database`s number of COMI forms has made a visible leap in the year 2014. Thanks to a joint effort of the Spine Tango documentation team at Schulthess hospital in Zurich and the IT group of IEFM at the University of Bern, over 35`000 COMI back and 7‘000 COMI neck forms could be imported from the Schulthess clinic information system into the respective surgeons` Spine Tango accounts.

SPINE TANGO Statistics

Surgery Form



Part I: Descriptive analysis form version 2011 Surgery Form

Sample description

Since January 2012 the newly developed Spine Tango form version 2011 was exclusively used for data collection. Consequently, the information gained during the years 2012 - 2014 is based on these new forms while the previous annual reports covered the complete data pool based on the SSE form versions 2005 and 2006. For this annual report 2014 we will exclusively show information retrieval with the form version 2011. In total the form version sample 2005 and 2006 counts 48`140 surgeries. Until the end of 2014 33'745 new surgeries could be registered with the form version 2011.

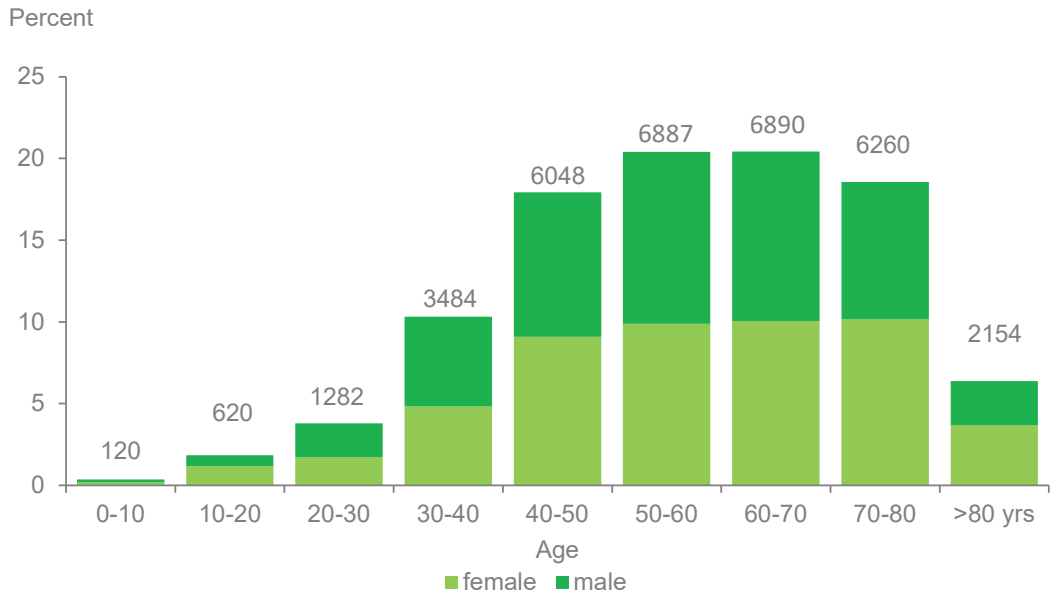


Figure 11: Distribution of age by gender (at surgery), all cases based on surgery form version 2011 (N=33'745)

Admission Subform

Length of stay (LOS)

The hospitalization times (length of stay [LOS]) were compared between the 4 biggest Spine Tango modules (Switzerland, Great Britain, Germany, Belgium). Differences between countries, respectively health care systems become visible in that the NHS in the UK seems to promote short-term hospitalisations up to two days, followed by Belgium where about half of the patients stay no longer than five days. Overall, the majority of patients is hospitalized between zero to eight days. No adjustment of LOS was made for case mix.

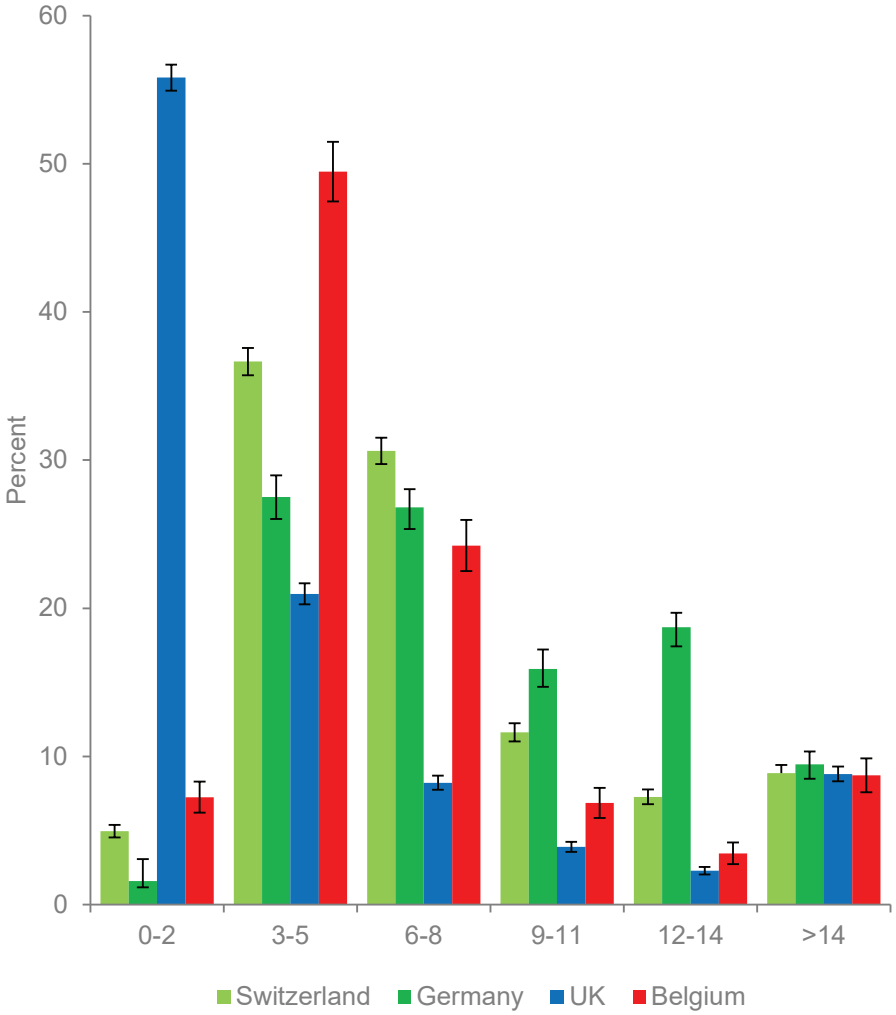


Figure 12: Length of stay for the surgery form version 2011 (N 32'657)

Admission Subform

Body Mass Index (BMI)

A comparison of BMI distribution also reveals slight differences. Switzerland has the highest percentage of patients with normal BMI, whereas Germany has the highest percentage of overweight and obsese patients. Patients at the extreme ends of the spectrum (very low or very high BMI) are rare in all four countries.

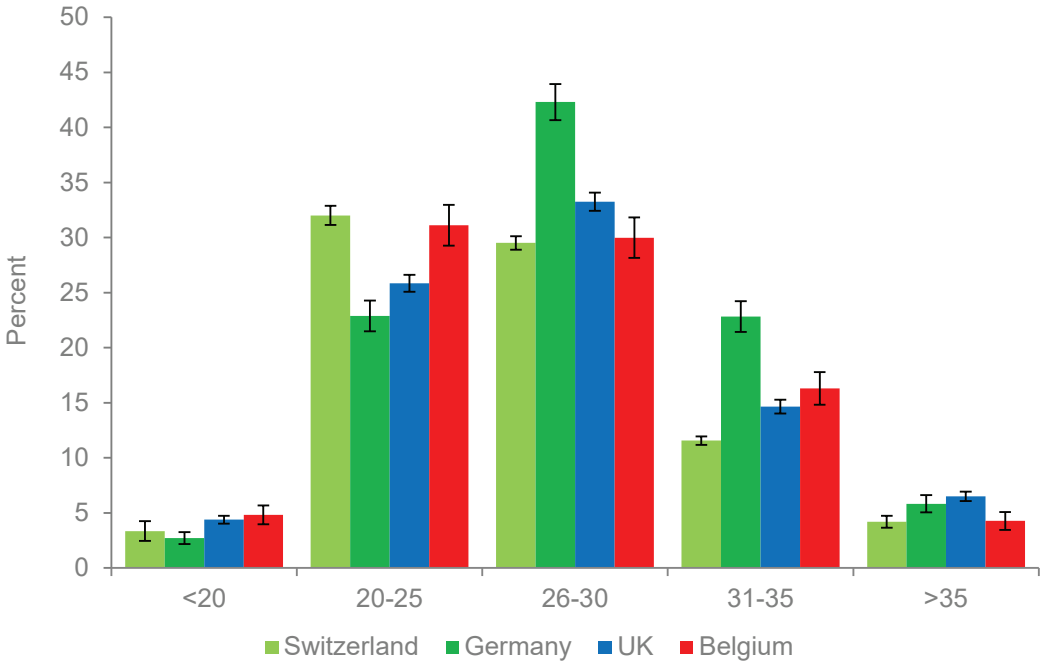


Figure 13: Distribution of body mass index (BMI), surgery form version 2011 (N= 32'721)

Admission Subform

Smoking Status

Belgium seems to have the greatest percentage of non-smoking patients, whereas the percentage of smoking patients is rather equal in Switzerland, Germany and the UK.

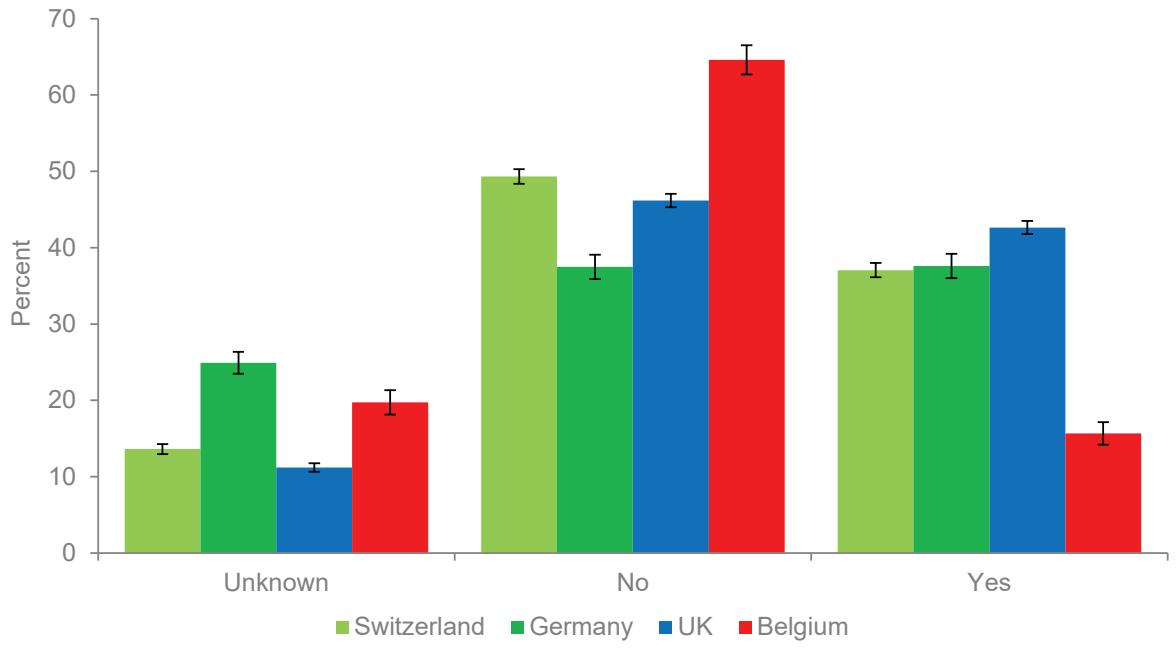


Figure 14: Distribution of current smoking status, surgery form version 2011 (N= 32'721)

Admission Subform

Risk factors - flags

The flags are a parameter for risk adjustment. It is a classification/assessment for the treatment of low back pain (LBP) patients considering psychosocial risk factors. The psychosocial flag system can help e.g. occupational health practitioners to create suitable rehabilitation plans for employees. A brief legend of the meanings of the different colors is given in table 2.

Flag	Short description
Red:	Biomedical Factors; serious spinal pathology
Yellow:	Psychosocial or behavioral factors
Orange:	Abnormal psychological processes indicating psychatric disorders
Blue:	Socioeconomic/ work factors
Black:	Occupational and societal factors

Table 2: Description of flag types

Risk factors - flags

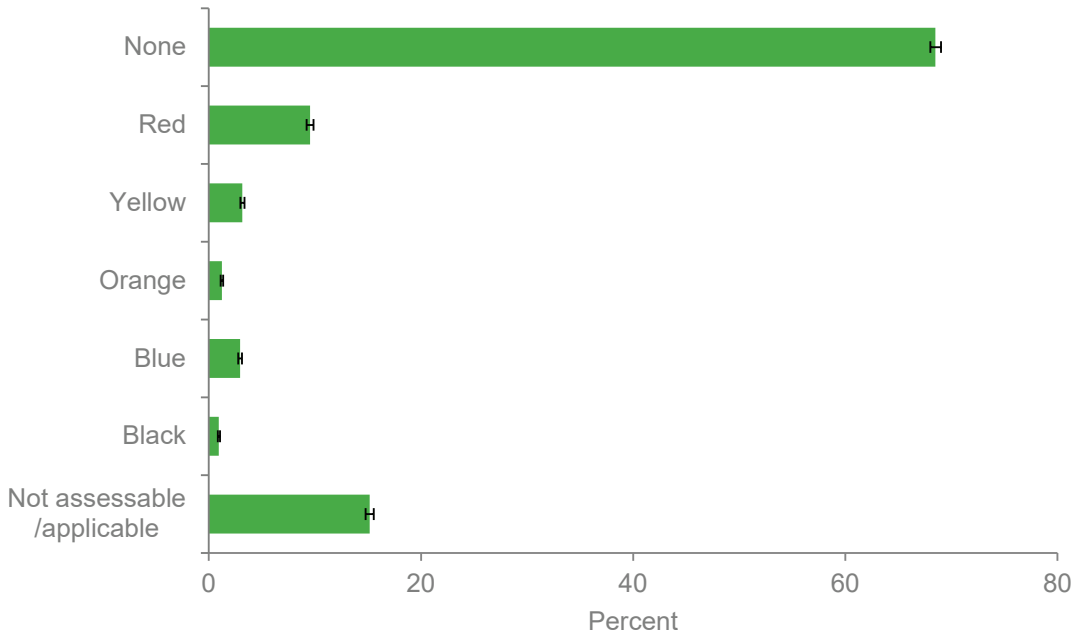


Figure 15: Distribution of risk factors - flags, all patients with surgery form version 2011 (N= 33'219)

Admission Subform

Distribution of main pathology

As compared to last year`s report the degenerative diseases have increased from 76.5% to almost 80%. The second most frequent “pathology”, though not a true one, remains the failed and repeat surgery staying stable around 6%. This combined question offers answers about true treatment failures like non-union or neurocompression but also about reasons for elective repeat surgeries like hardware removal.

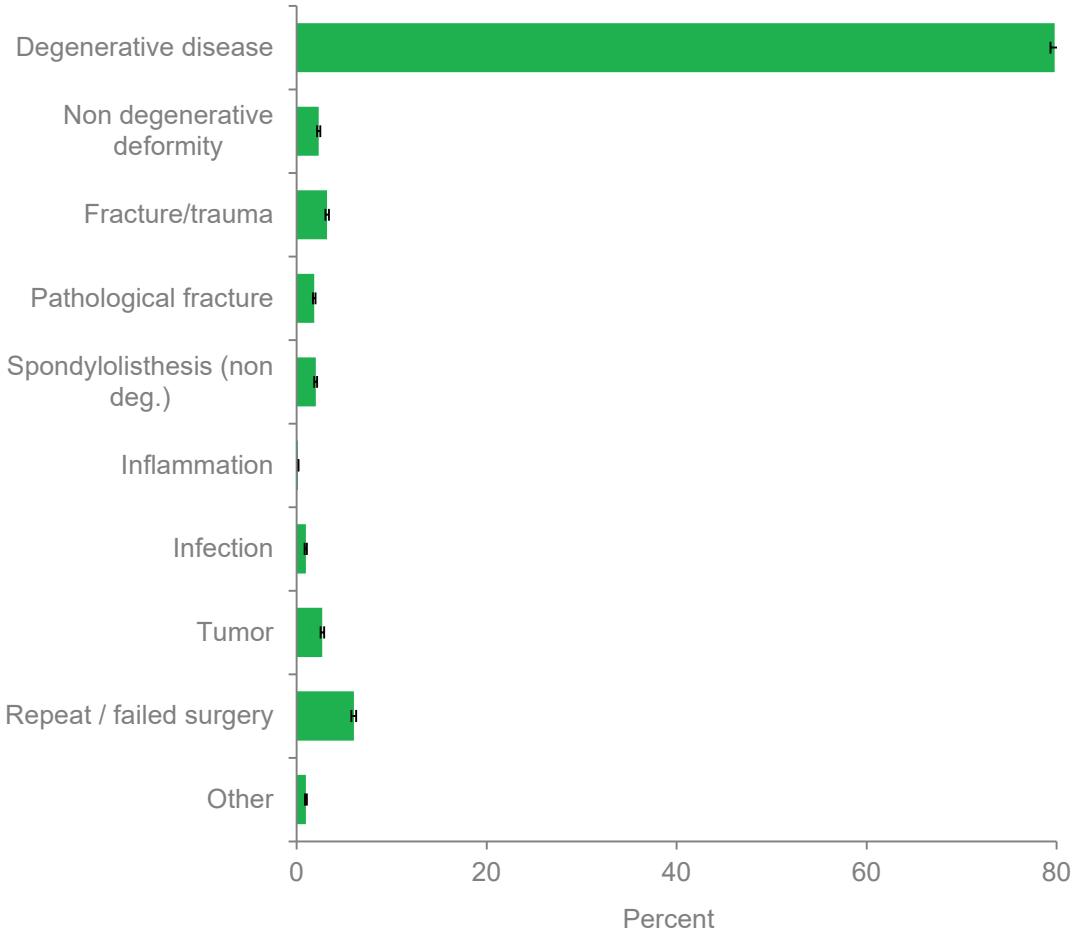


Figure 16: Distribution of main pathology for the surgery form version 2011 (N= 33’745)

Admission Subform

Specification of degenerative diseases

Figure 17 shows the distribution of the answer categories of the question about degenerative diseases. Disc herniation is the most frequent type of degeneration, but if the different types of spinal stenosis are added up, they are even more frequent.

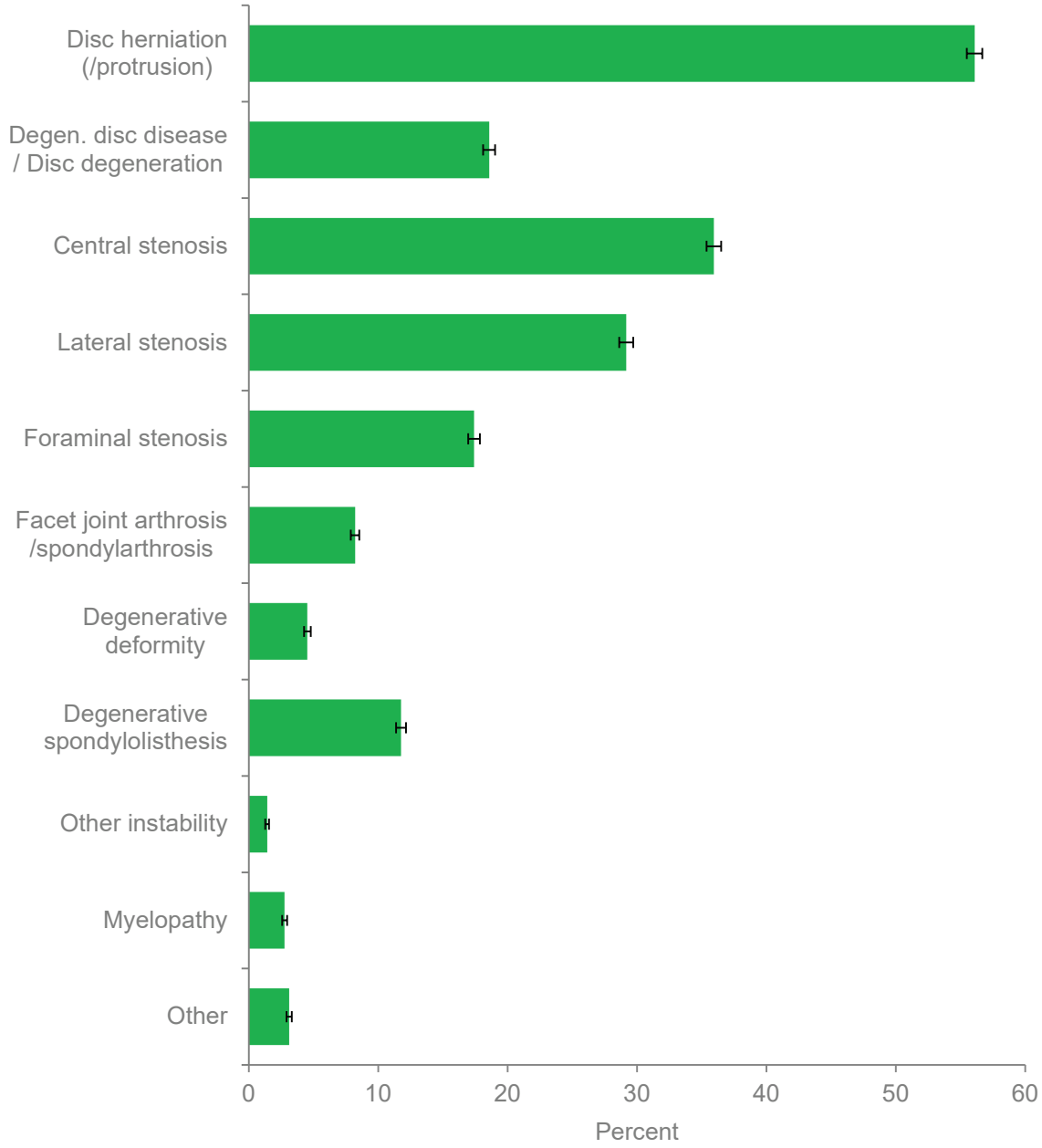


Figure 17: Specification of degenerative disease for the surgery form version 2011 (N= 26'922)

Admission Subform

Specification of spondylolisthesis

Four out of five patients with spondylolisthesis suffer from a degenerative type. The isthmic type makes up about 15%, the congenital type about 3%.

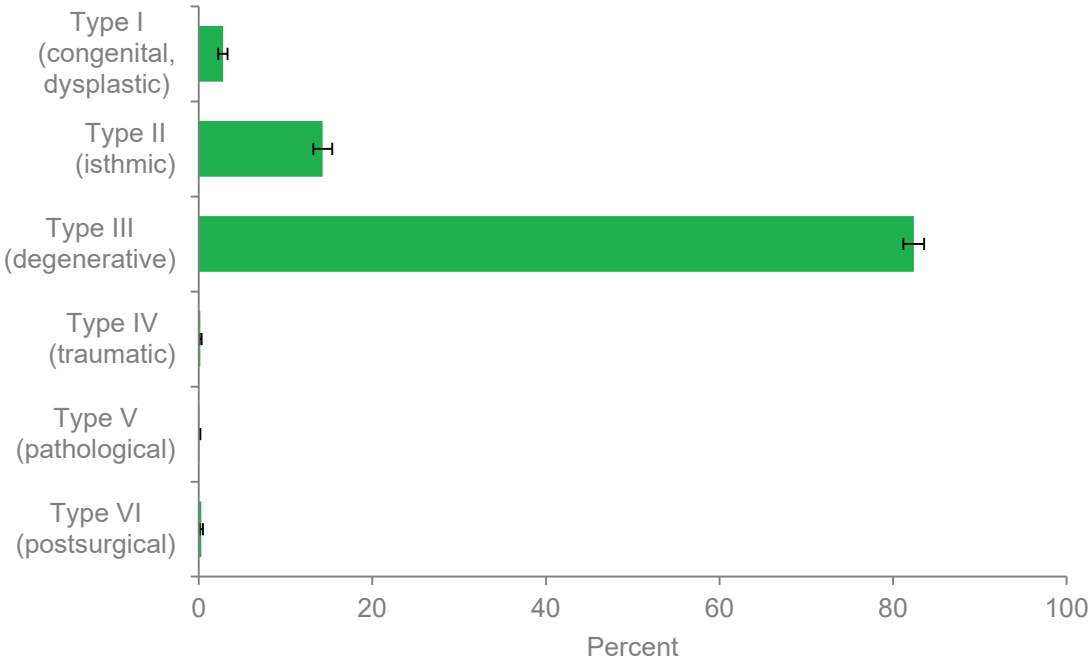


Figure 18: Distribution of type of spondylolisthesis for the surgery form version 2011 (N= 3'844)

Age distribution by gender

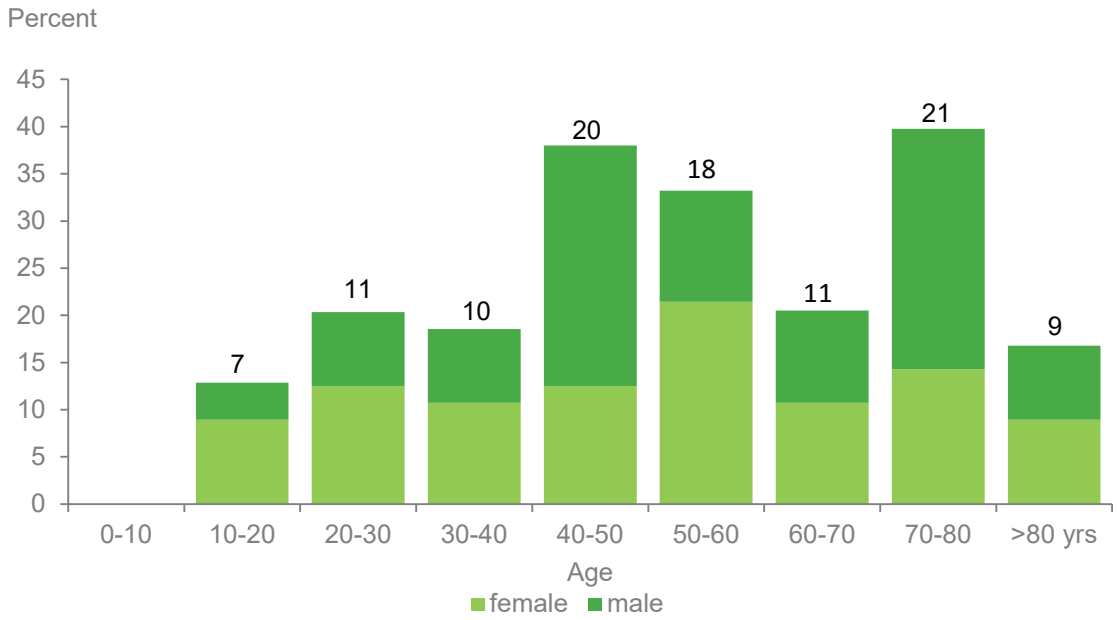


Figure 19: Distribution of age by gender (at surgery), patients with type I spondylolisthesis (congenital, dysplastic)

Admission Subform

Age distribution by gender

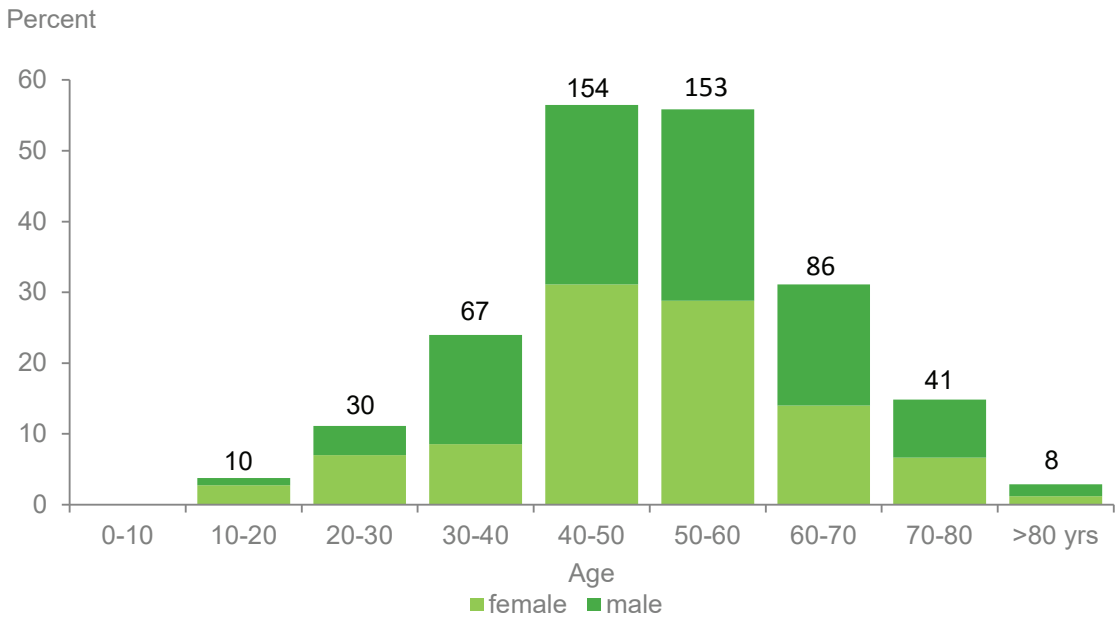


Figure 20: Distribution of age by gender (at surgery), patients with type II spondylolisthesis (isthmic)

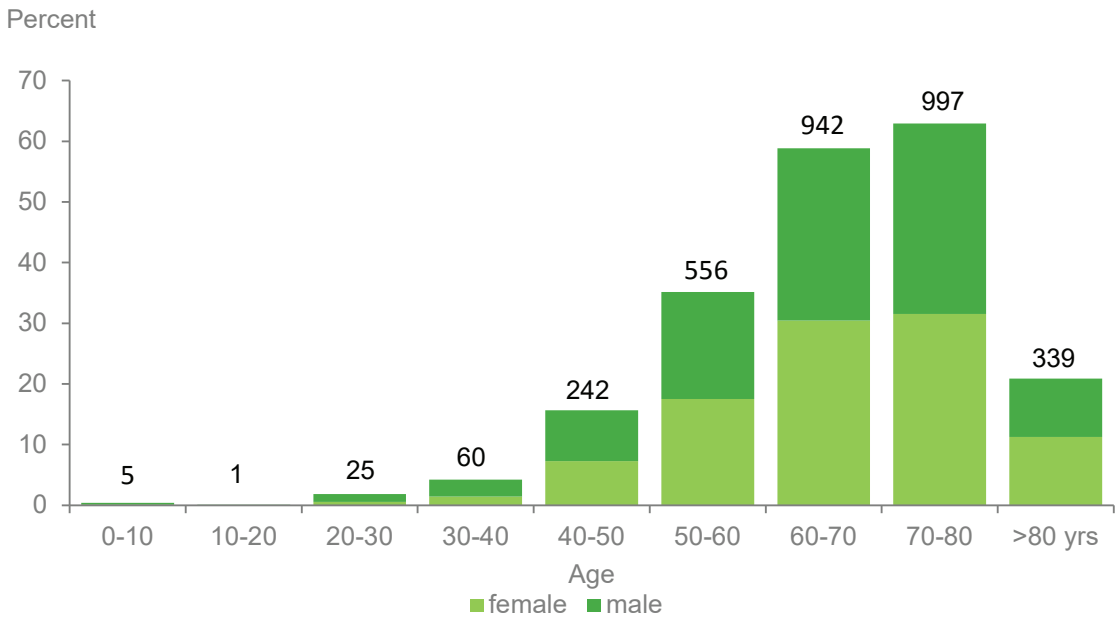


Figure 21: Distribution of age by gender (at surgery), patients with type III spondylolisthesis (degenerative)

The age and gender distribution of the three most frequent types of spondylolisthesis is rather mixed for the congenital/dysplastic patients, whereas the isthmic type shows an almost perfect Gaussian curve, and the degenerativ type has a clear shift towards older patients with a still rather equal gender distribution.

Admission Subform

Aetiology of deformity

With the ageing society many more degenerative compared with idiopathic, congenital or neuromuscular deformities are surgically treated. For these types of interventions, two specialist add-on forms are available in Spine Tango. The age distributions make it obvious why there is an „adolescent scoliosis“ and an „adult degenerative deformity“ form.

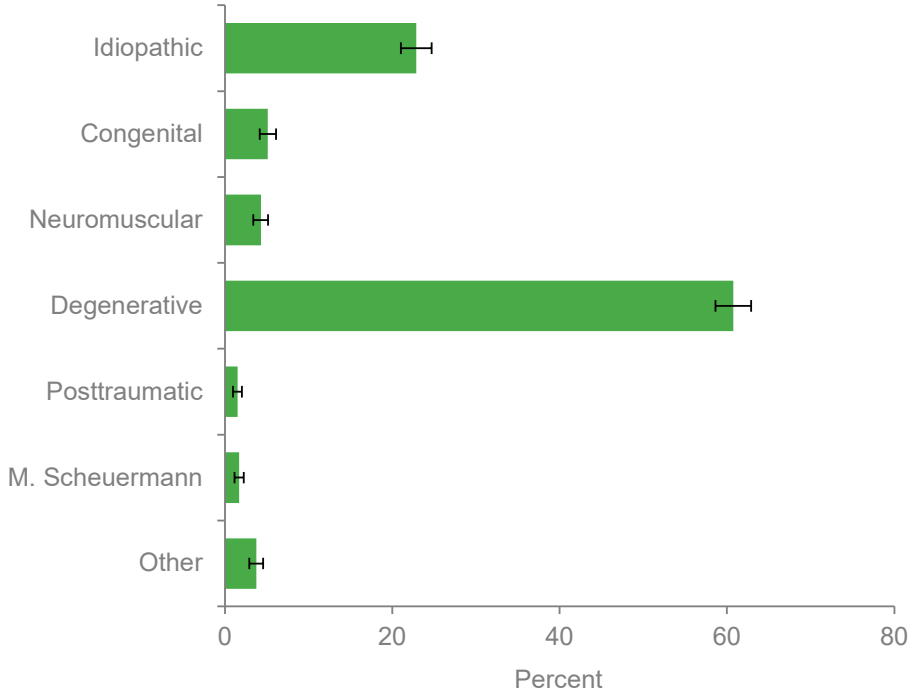


Figure 22: Distribution of predominant aetiology of deformity for the surgery forms version 2011 (N= 2'006)

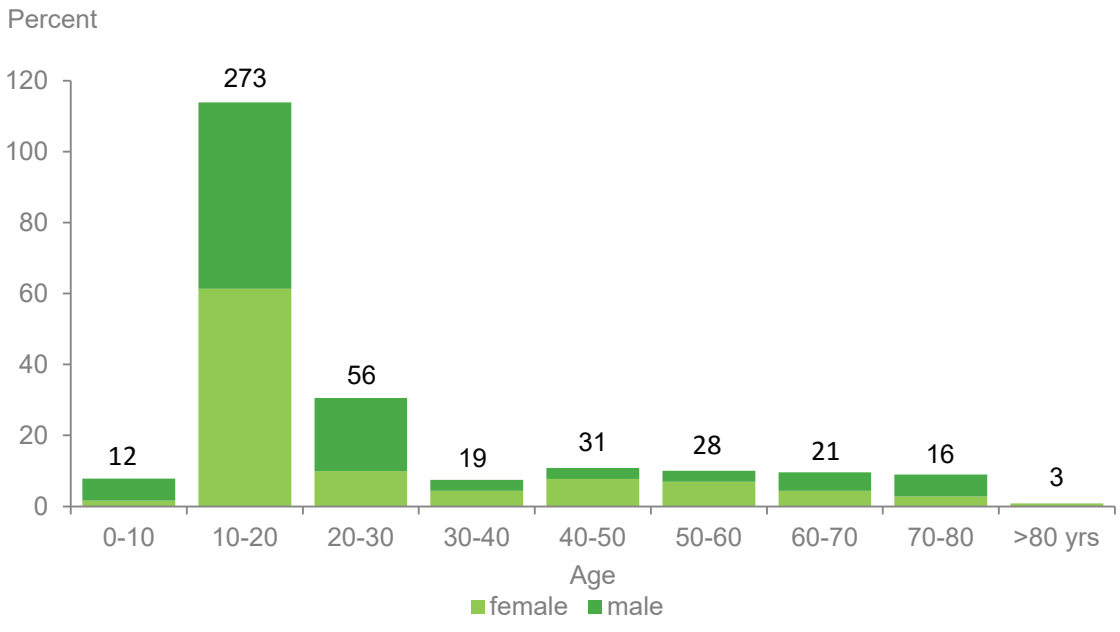


Figure 23: Distribution of age by gender, patients with idiopathic scoliosis

Admission Subform

Age distribution by gender

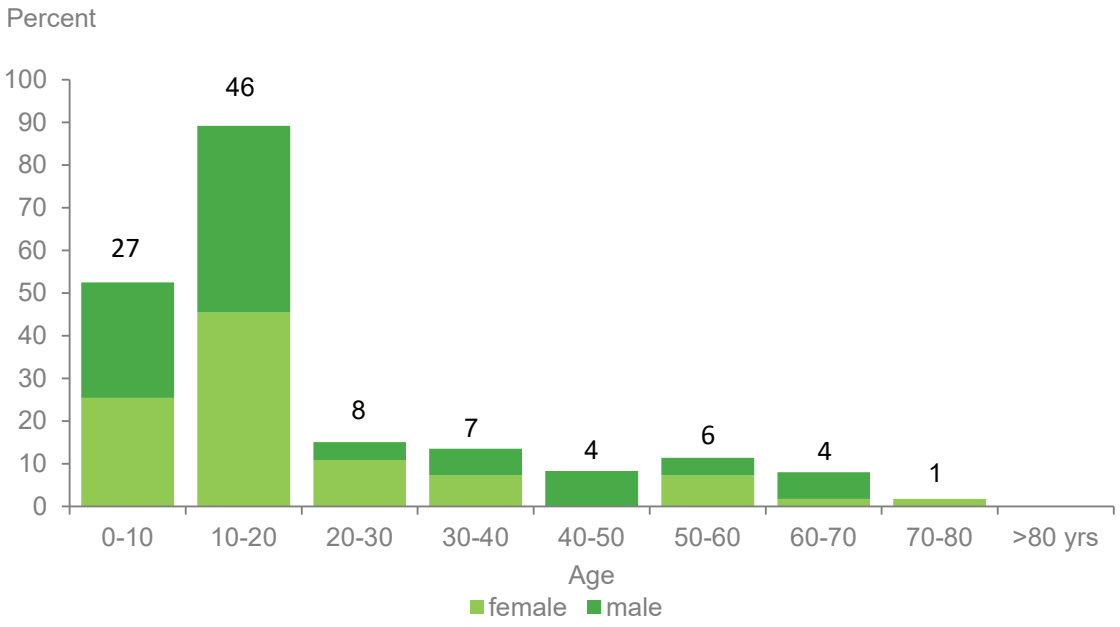


Figure 24:Distribution of age by gender, patients with congenital deformity

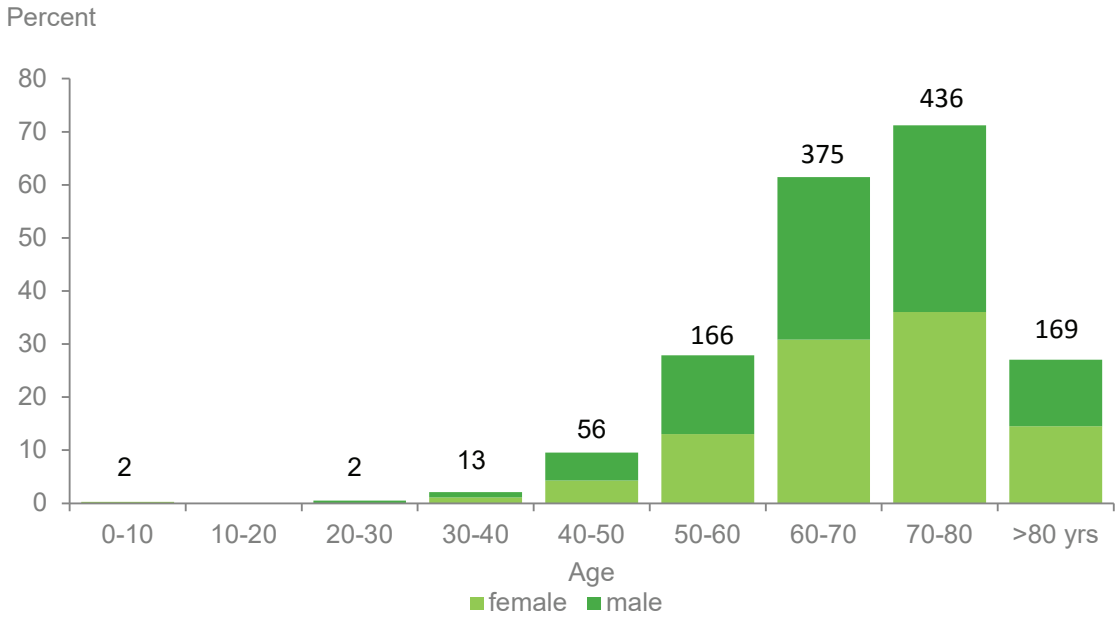


Figure 25: Distribution of age by gender, patients with degenerative deformity

Admission Subform

Type of repeated / failed surgery

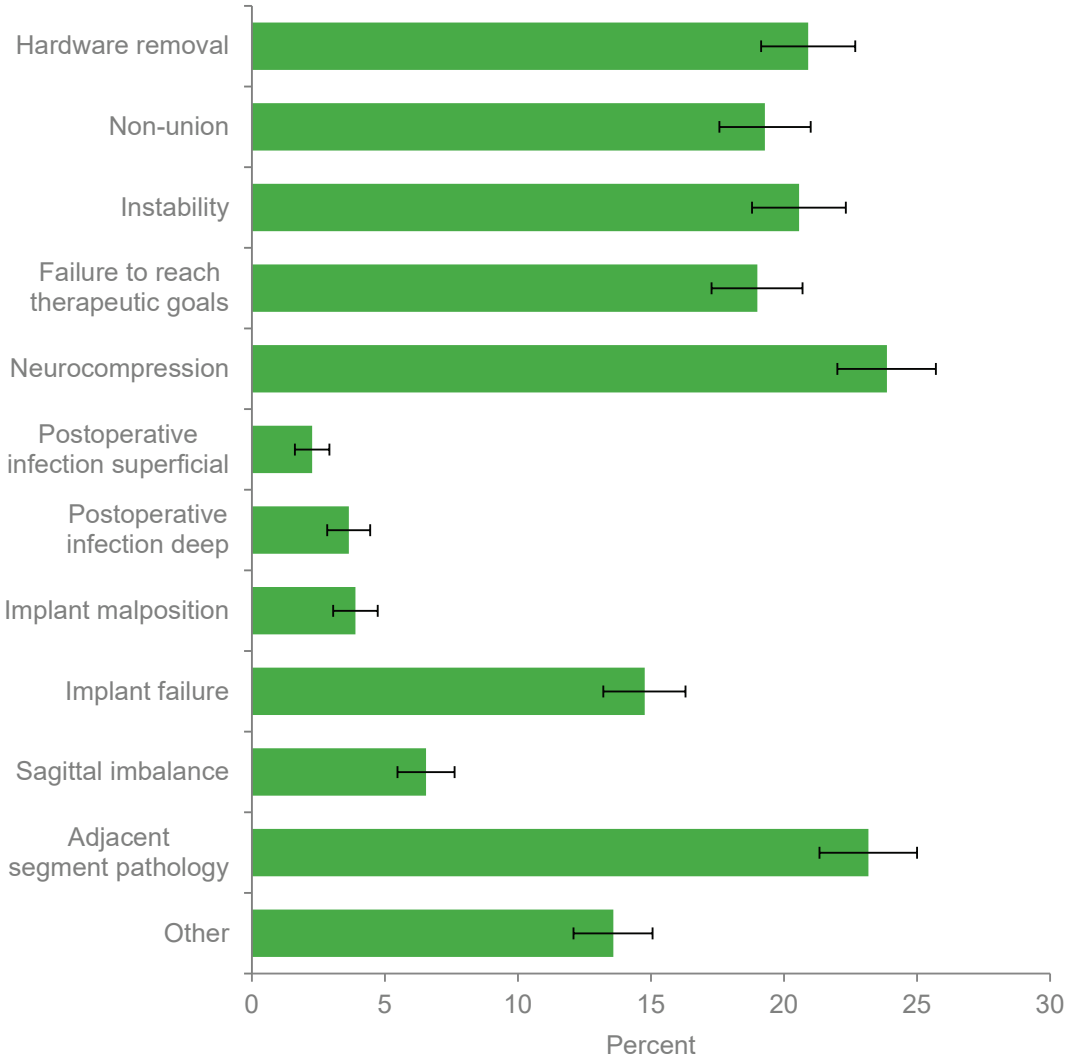


Figure 26: Type of failed/ repeated surgery for the surgery form version 2011 (N= 2'033)

About 6% of cases (N=2'033) recorded in 2012 - 2014 were repeat surgeries. Neurocompression is the most frequent reason for a reintervention (23.9%), followed by adjacent segment pathology (23.2%) and instability (20.6%). Hardware removal was performed in 20.9% of cases. This surgical measure does not necessarily imply a failed index surgery, which explains the new variable name "repeat surgery". Failure to reach the initial therapeutic goals was given as a reason for repeat surgery in 19% of cases.

Surgery Subform

Therapeutic goals / goals of surgery

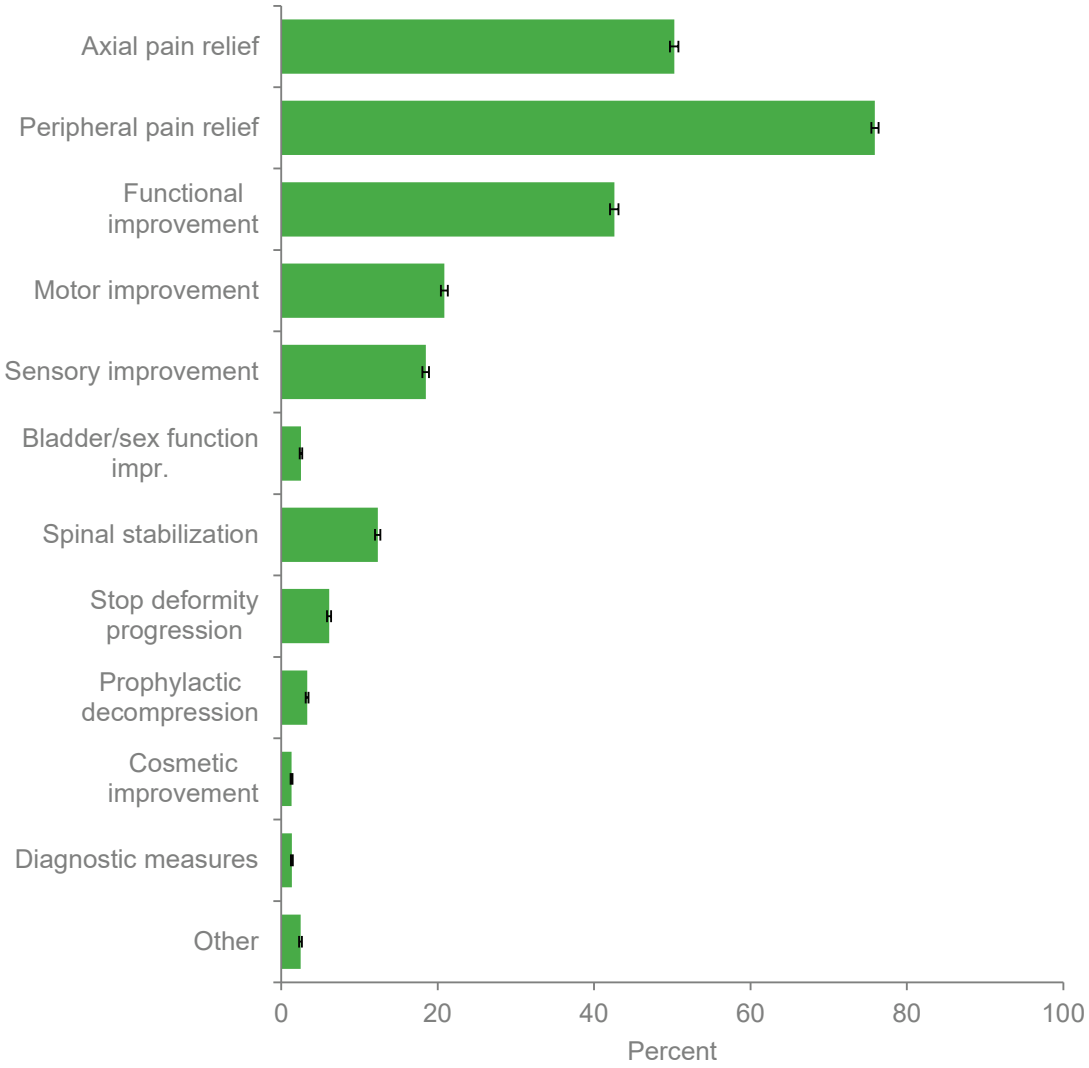


Figure 27: Distribution of therapeutic goals/ goals of surgery for the surgery form version 2011 (N= 33'745)

The therapeutic goals can be more precisely defined in the form version 2011. Pain relief was split into axial and peripheral pain relief to consider back/ neck and leg/ arm pain. The neurological improvement can now be specified as sensory, motor and bladder/sex function improvement. Further new answer options are spinal stabilization, stop deformity progression and prophylactic decompression.

Surgical Measures Subform

Specification of surgical measures for the degenerative diseases

A comparison of the surgical measures for the degenerative cervical and lumbar spinal diseases shows an inversely mirrored proportion of solely decompressive interventions which dominate in the lumbar spine and decompressions with rigid stabilization and intention to fuse in the cervical spine. All other surgical measures and their combinations are rather rare.

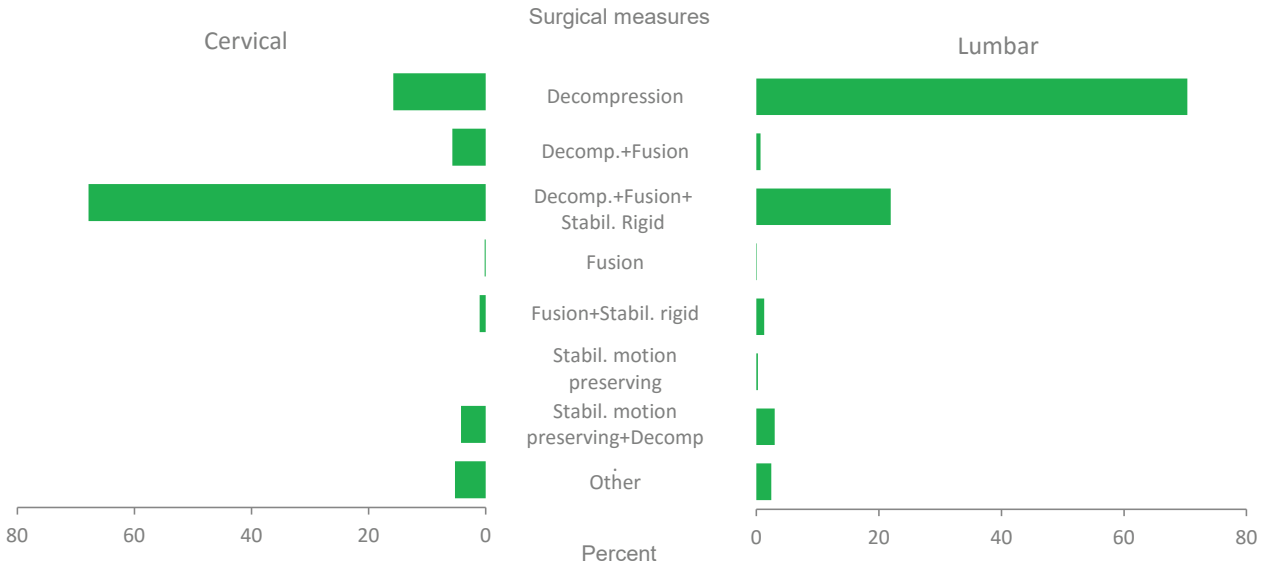


Figure 28: Specification of fusion promoting measures, surgery form version 2011 (N= 13'237)

Surgical Measures Subform

Specification of fusion promoting measures and materials

Contrasting the cervical and lumbar fusion promoting measures it becomes obvious how the A-IF (anterior interbody fusion) dominates the cervical surgery. There must be a terminology gap in the ST surgery form since the second most frequent cervical fusion promoting measure is specified as “other”. On the other hand, four measures dominate the lumbar surgery: TLIF, PLIF, posterolateral fusion and the A-IF. “Other” fusion promoting measures are basically not documented in the lumbar interventions.

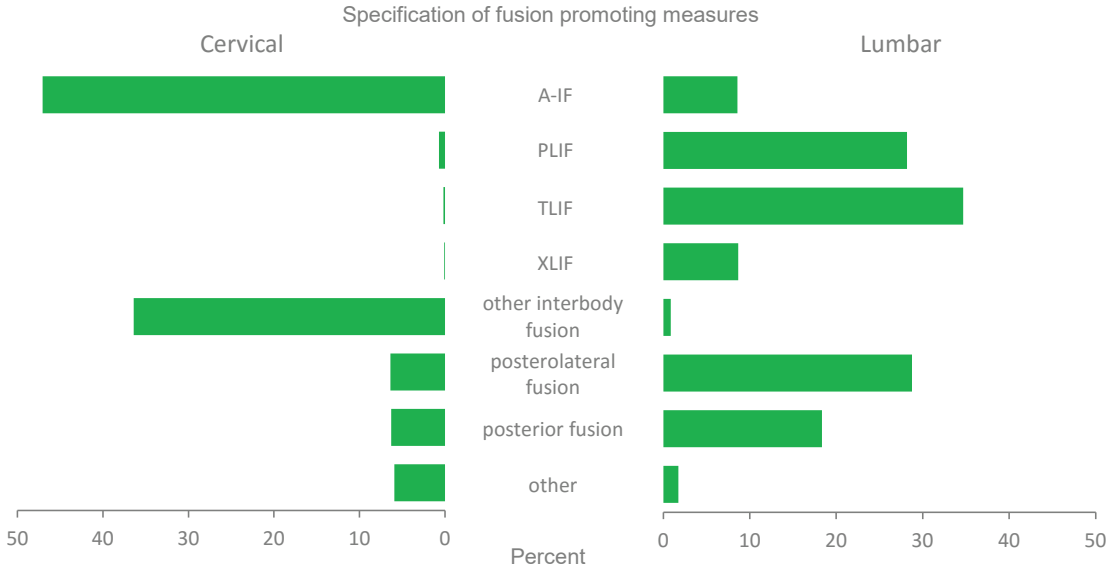


Figure 29: Specification of fusion promoting measures, surgery form version 2011 (N= 13’237)

Locally procured autologous bone is the most frequently used fusion material in the cervical and the lumbar interventions. Bone substitute (cervical) and harvested autologous bone (lumbar) come in second place, and harvested autologous bone (cervical) and bone substitute (lumbar) in third place.

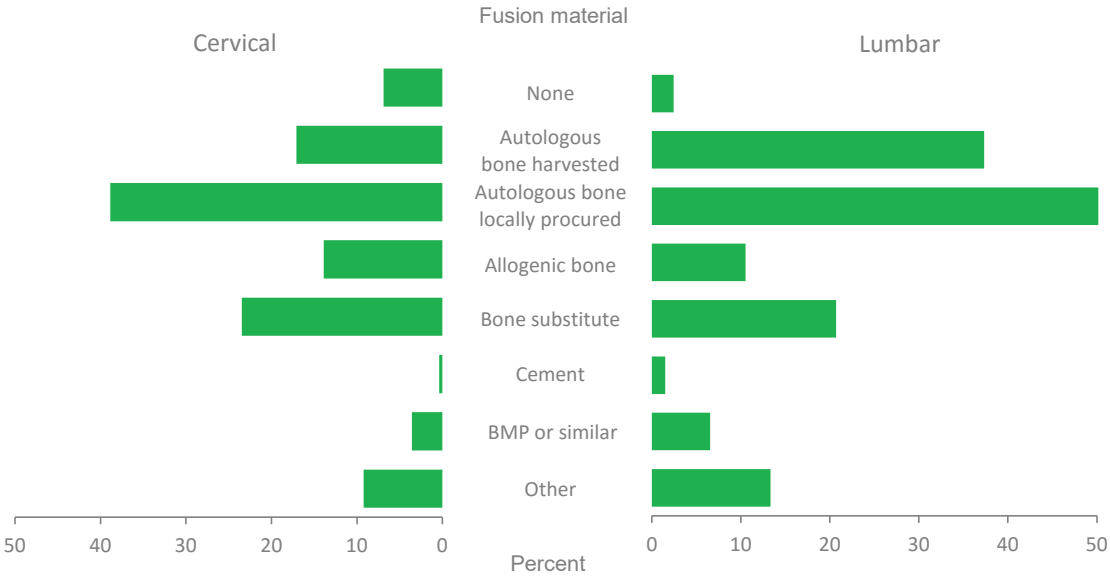


Figure 30: Specification of fusion material, surgery form version 2011 (N= 13’237)

Surgical Measures Subform

Intraoperative complications

The surgical complications are divided into intraoperative complications and complications occurring during hospitalization before discharge.For intraoperative complications which are shown in figure 31 a dura lesion remained the most frequent complication with 4.7%, which is almost unchanged compared with the last report. No intraoperative surgical complications occurred in 94% of cases, in 0.4% they were not documented.

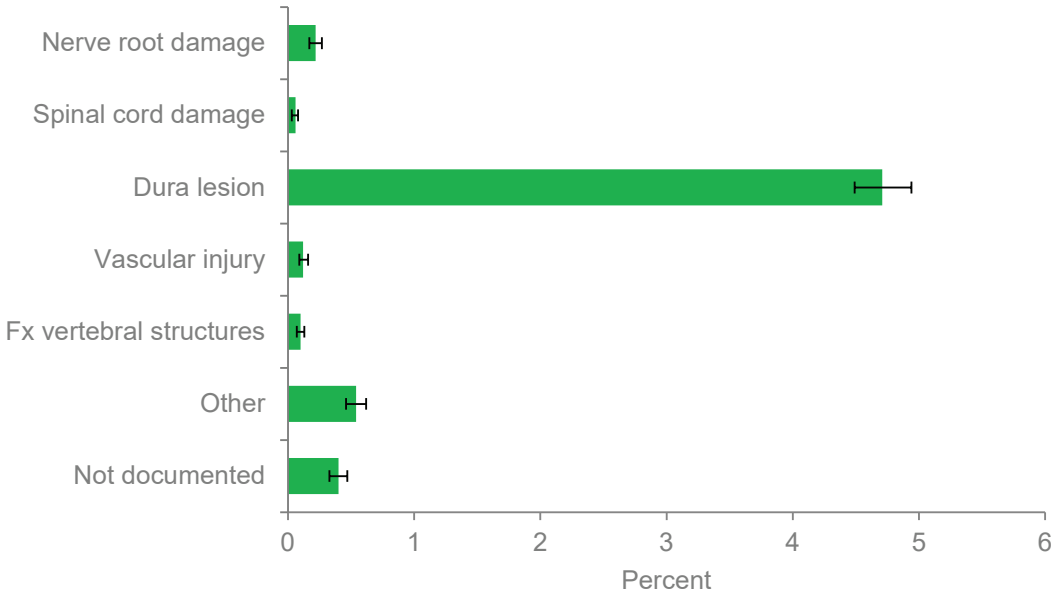


Figure 31: Distribution of intraoperative surgical complications, excluded was the answer "none", surgery form version 2011 (N= 33'745)

Hospital Stay Subform

Surgical complications before discharge

Postoperative complications which occurred during hospitalization are shown in figure 32. Their distribution is very stable over time. The most frequent complications were motor dysfunction with 0.9%, sensory dysfunction with 0.7% and radiculopathy with 0.5%. Even though a dura lesion was the most frequent complication during surgery, a CSF leak/ pseudomeningocele occurred in only 0.5% of cases. In 0.6% of cases the complications before discharge were not documented, in 95.1% of cases no postoperative complications occurred.

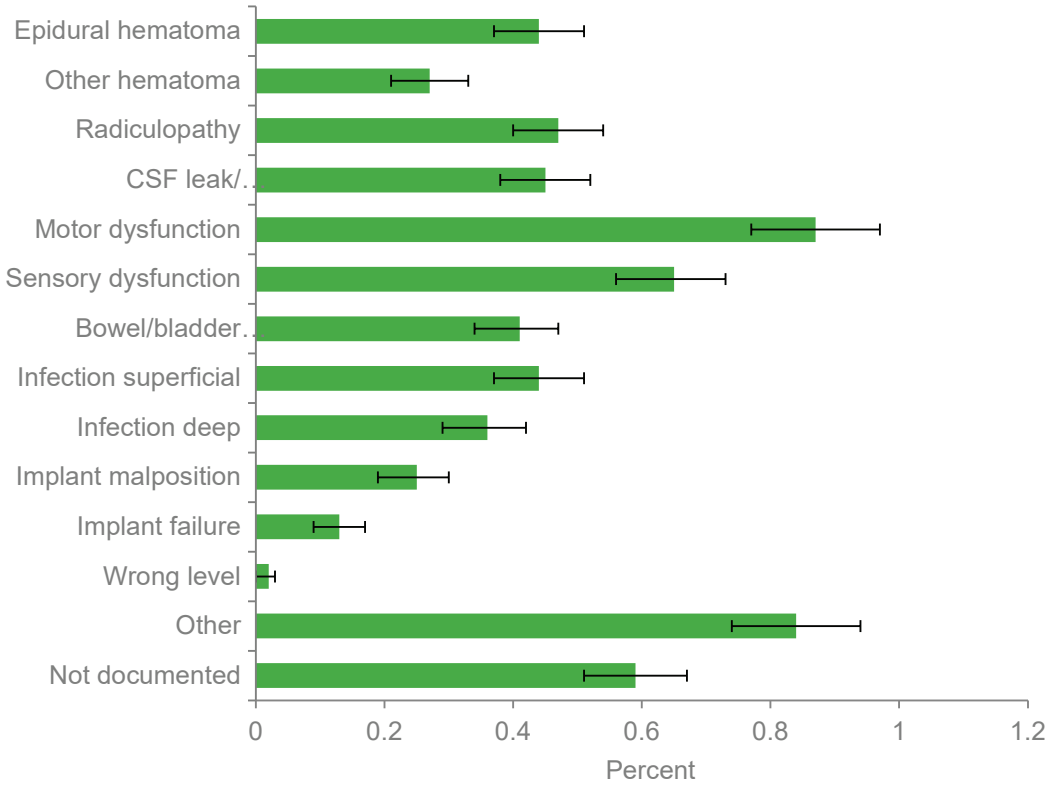


Figure 32: Distribution of surgical complications before discharge, excluded was the answer "none", surgery form version 2011 (N= 33'743)

Hospital Stay Subform

Status of complications

The status of complications at discharge refers to all cases with an intra and/ or postoperative complication at hospitalization. For the sample based on the form version 2011 2'990 cases with complications were documented. In 63.5% of those cases the complications were resolved at discharge, in 6.9% they were persisting.

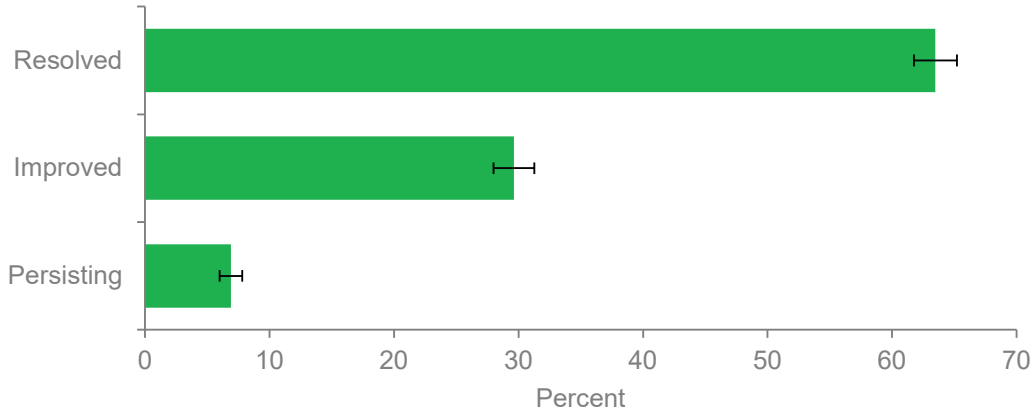
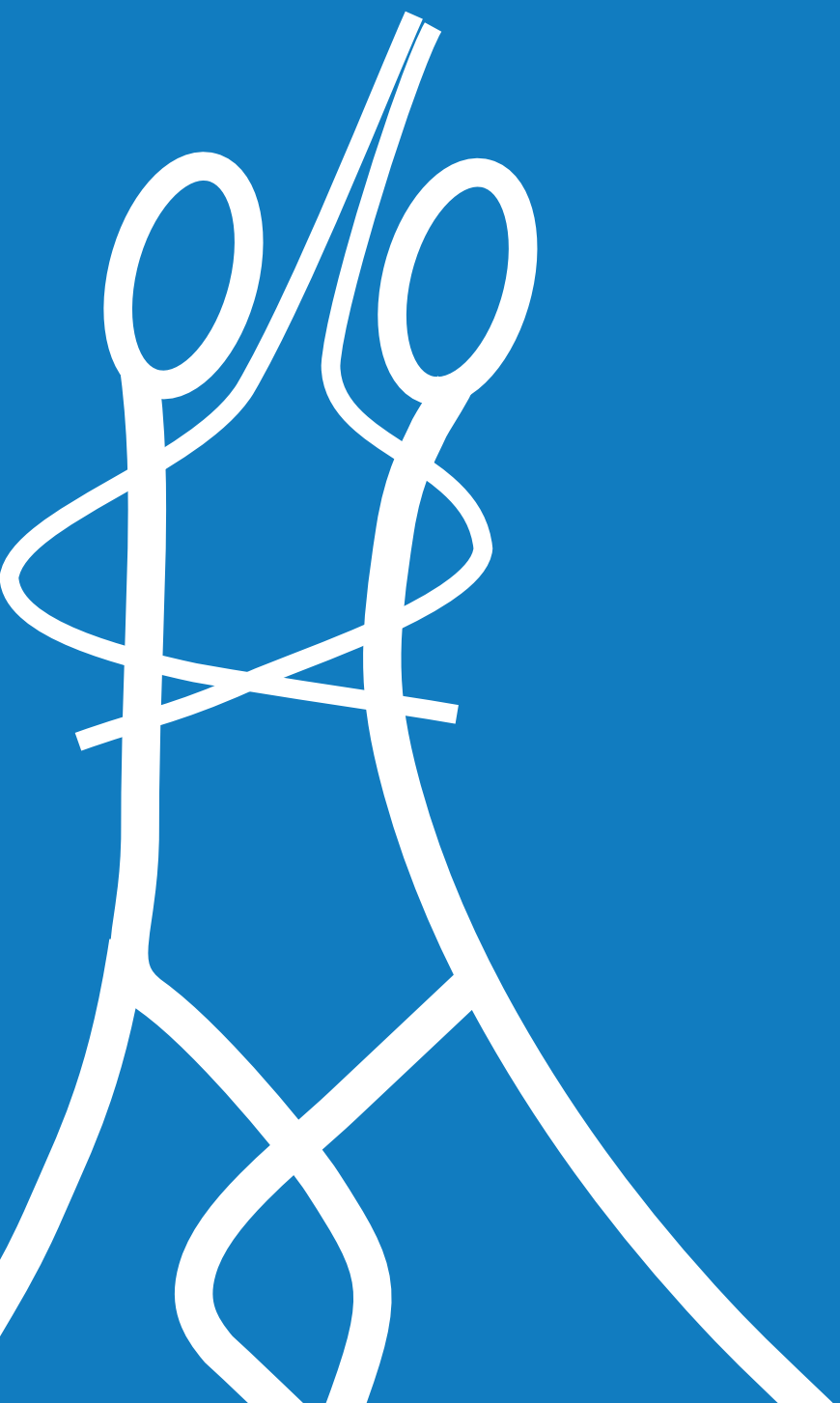


Figure 33: Status of complications at discharge for patients with an intraoperative complication and/ or a complication before discharge, for surgery form version 2011 (N= 2'990)

SPINE TANGO Statistics

Followup Form



Follow-up Form

Distribution of follow-up interval

In the following section we refer to the Spine Tango follow-up form 2011.
The majority of documented follow-ups in the routine clinical setting are captured at 6 weeks and 3 months after surgery. The literature suggests that at least the mid-term outcomes at three months can basically be considered as the final outcomes (Mannion et al. (4); Strömqvist et al. (15)). 6-month, 1-year and longer follow-ups are strongly recommended, but remain a major challenge of any routine care registry.

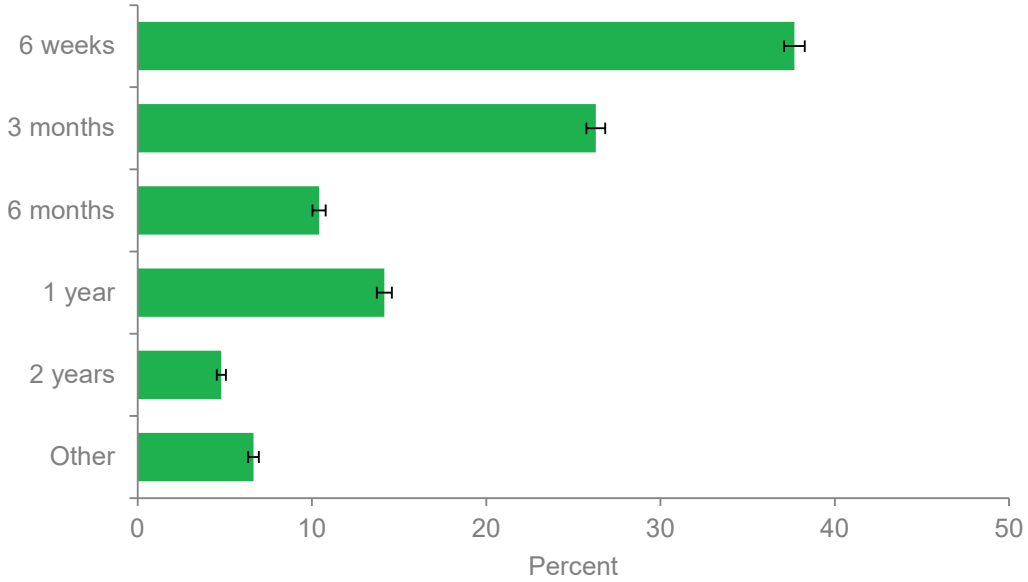


Figure 34: Distribution of followup interval for the followup form version 2011 (24'973 forms for 15'721 patients)

Form version 2011: 24'973 FUs /15'721 patients. The current mean FU time improved from 169.7 days (2013 report) to 210.9 days, if last available FU is considered.

4. Mannion AF et al. (2009). The quality of spine surgery from the patient`s perspective. Part 1: the Core Outcome Measures Index in clinical practice.
Eur Spine J. (18 Suppl) 3:367-73

15. Strömqvist B et al. (2013). Swespine: the Swedish spine register: The 2012 report.
Eur Spine J. 22(4):953-74.

Follow-up Form

Overall outcome / surgical goals

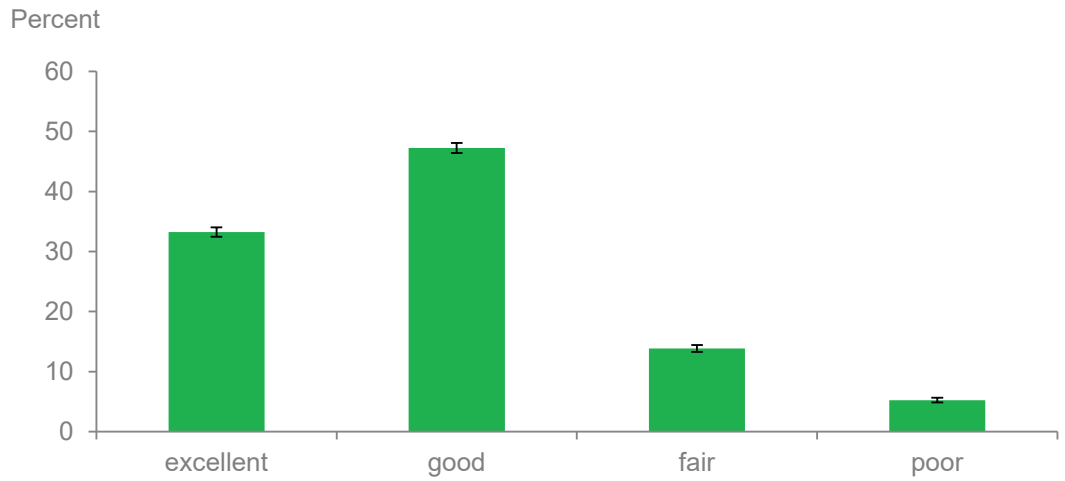


Figure 35: Physician based overall outcome (surgeon) for the surgery form version 2011 (N=24'973)

Converting the surgeon based outcome rating into a binary format, about 4 out of 5 cases have a desired outcome, and 1 out of 5 cases has an undesired outcome.

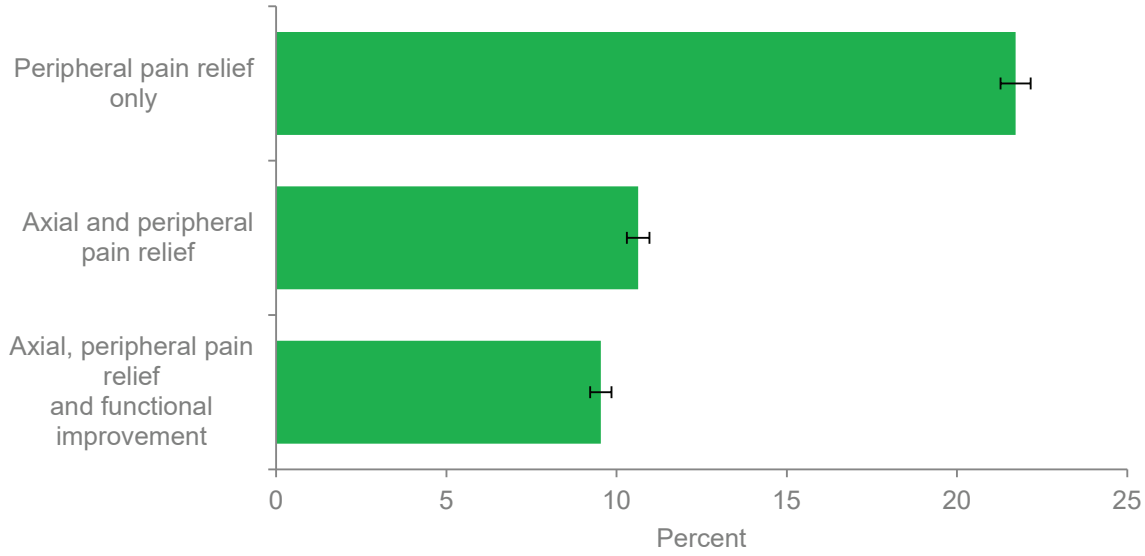


Figure 36: Cluster analysis of the most frequent combinations of surgical goals

The three most frequent combinations of therapeutic goals are peripheral pain relief only, a combination of peripheral and axial pain relief, and functional improvement in addition to peripheral and axial pain relief.

Follow-up Form

Surgical goals – pain relief and functional improvement

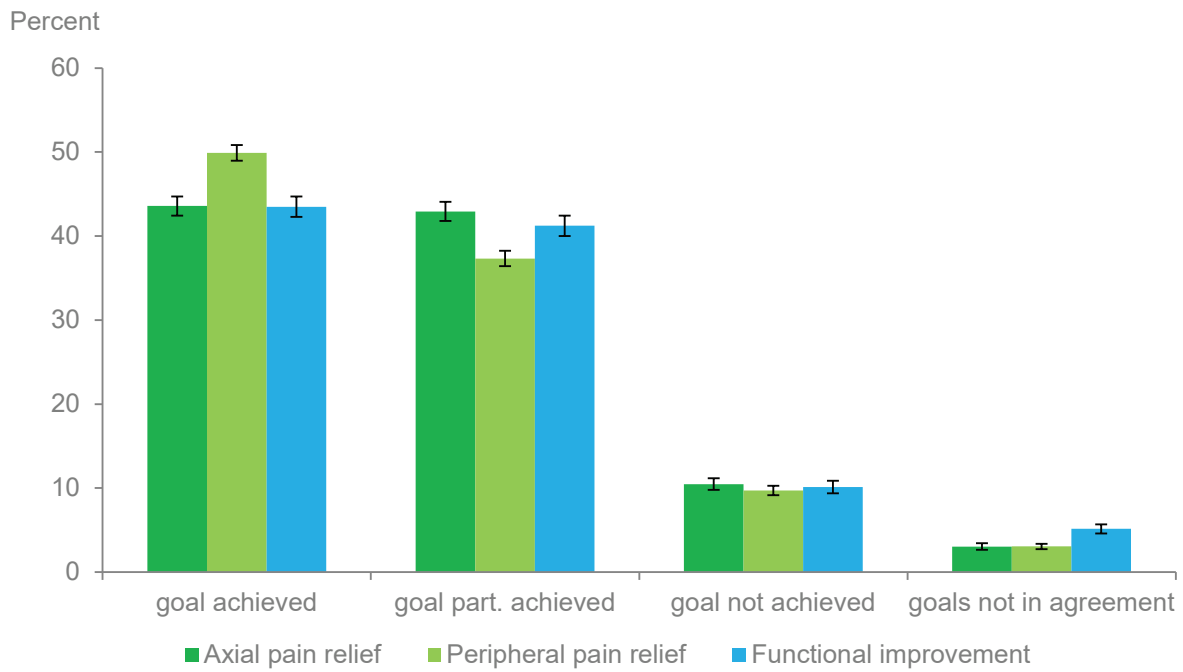


Figure 37: Achievement of the surgical goals pain relief and functional improvement for the followup form version 2011.

According to the aforementioned cluster analysis the figure shows pain relief and functional improvement and the extent to which these goals are achieved. Peripheral pain relief is the best achieved surgical goal and in about half of all cases the surgeons indicate a complete goal achievement and in just under 40% an at least partial achievement. Axial pain relief and functional improvement are slightly more difficult to achieve. In a little under 90% these goals are completely or partially achieved. In about 10% of patients pain relief and functional improvement are not achieved.

Follow-up Form

Surgical goals – neurological improvement / additional goals

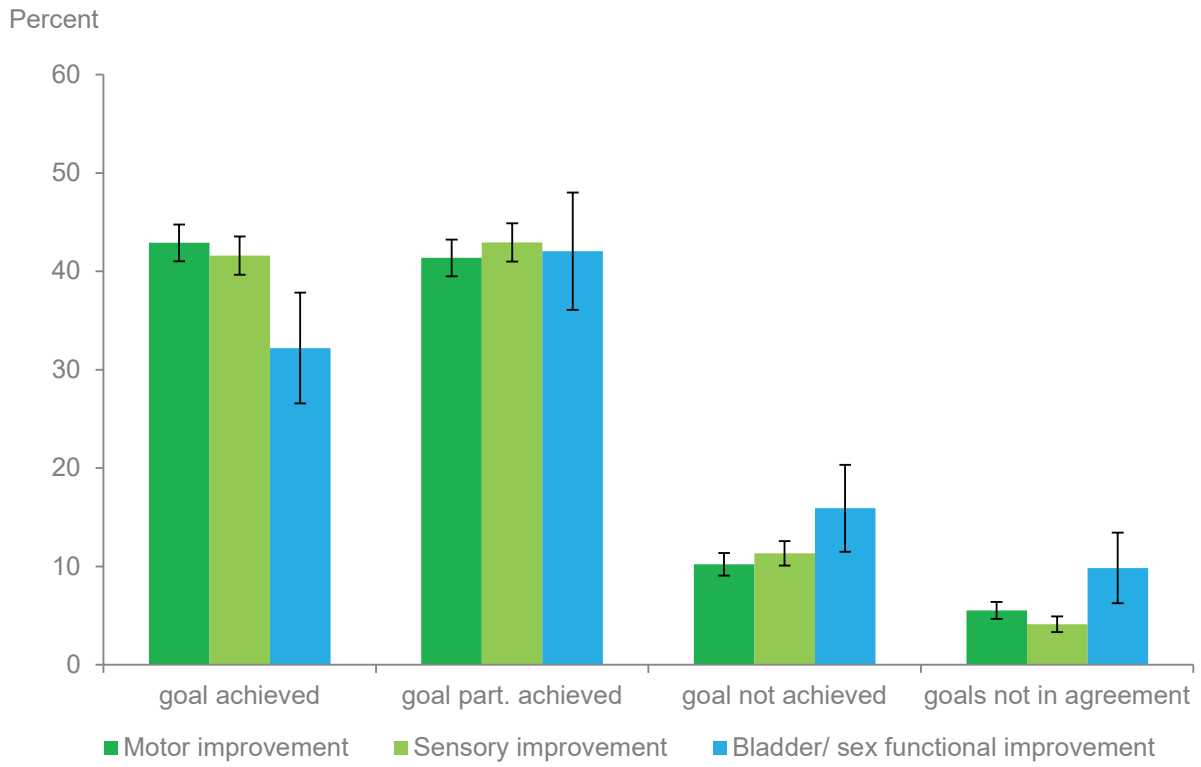


Figure 38: Achievement of the surgical goals motor improvement (N=2681), sensory improvement (N= 2473) and bladder/sex function improvement (N= 264) for the followup forms version 2011

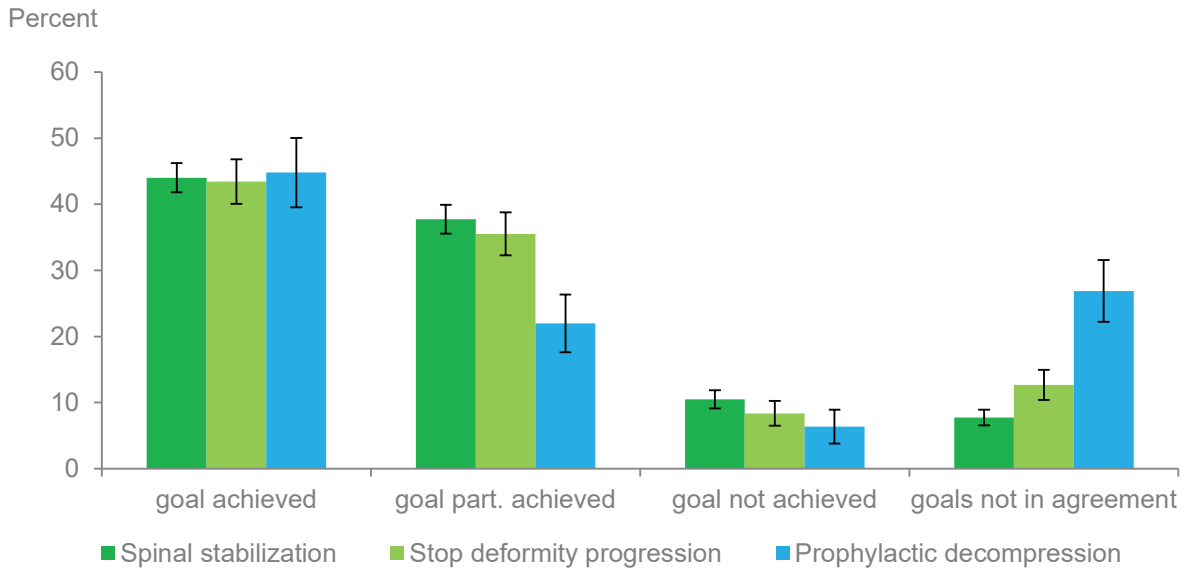


Figure 39: Achievement of additional surgical goals (spinal stabilization (N=1'924), stop deformity progression (N=836) and prophylactic decompression (N= 346) for the followup form version 2011

PART II: The Spine Tango Benchmarking Project

Perioperative surgical complications in selected pathologies and interventions. A comparison of Spine Tango participants.

Introduction

The objective of the Spine Tango benchmarking project is to create reference values for patient characteristics, treatment practices and their outcomes. Cochrane noted that the results of such registry analyses demonstrate high external validity, i.e. generalizability, because they more adequately reflect the true heterogenic nature of health service delivery and its outcomes [16]. Three simple questions summarise Cochrane's scheme: can it work (efficacy)? Does it work (effectiveness)? Is it worth it (cost effectiveness)? Even if a surgery is successful in a study, it may not succeed similarly in normal everyday care [17]. Consequently, the Spine Tango benchmarking project aims to analyse the most frequently encountered treatments for the most common degenerative diseases of the spine, in order to find out if and to what extent spinal surgeries "do" work in day-to-day clinical settings. However, the question "Is it save?" is also of outmost importance, even for the most efficacious or effective treatments. Patients and payers are highly interested in the safety of a therapy per se, but also in the hands of an individual healthcare provider. Some therapies may be generally save or unsave, others may show a larger variation of complication rates between centers. Disc herniation and spinal stenosis, making up about two thirds of all degenerative diseases recorded with Spine Tango, and degenerative spondylolisthesis in addition are the pathologies that were assessed regarding perioperative (intra- and postoperative until discharge) surgical complications using funnel plots, thereby stratifying by location in the spine and type of surgery. No further case mix adjustments like for the extent of lesion or for previous surgeries were made. This second part of the 2014 annual report highlights the complication rates of these pathologies and the most frequently seen treatments for them, which are decompression alone and decompression with instrumented fusion.

Materials and Methods

The last three versions of the surgery form were used in the analysis: 'Surgery 2005', 'Surgery 2006' and 'Surgery 2011'. Since the 2005 and 2006 forms only asked for surgical complications without discriminating between intraoperative and postoperative ones, the intra- and postoperative complications recorded on the 2011 form version were pooled. Based on the consensus of the Spine Tango Registry Committee, detailed inclusion and exclusion criteria were defined for cervical and lumbar disc herniation, degenerative spondylolisthesis, and spinal stenosis (see *http://www.eurospine.org/forms.htm*). These criteria were applied to form distinct degenerative diagnosis subgroups. The only additional exclusion criterion used was a number of treated cases per hospital below 5. Patient populations and the number of treating centers are listed for the individual diagnosis subgroups below. Perioperative surgical complication rates per treating hospital were displayed using funnel plots accounting for the caseload of the hospital. Average surgical complication rate with 95% confidence intervals (funnel) are shown.

Results

Cervical disc herniation treated with decompression and instrumented fusion

2`335 patients from 32 hospitals were included in the analysis (Figure 40). Average perioperative complication rate was 2.4%. The proportion of incidental dura lesions was 0.5%. The therapy appears as generally save regarding perioperative complications with basically no outlier hospitals. Higher variation between low caseload-hospitals can be anticipated due to heterogeneity in case mix.

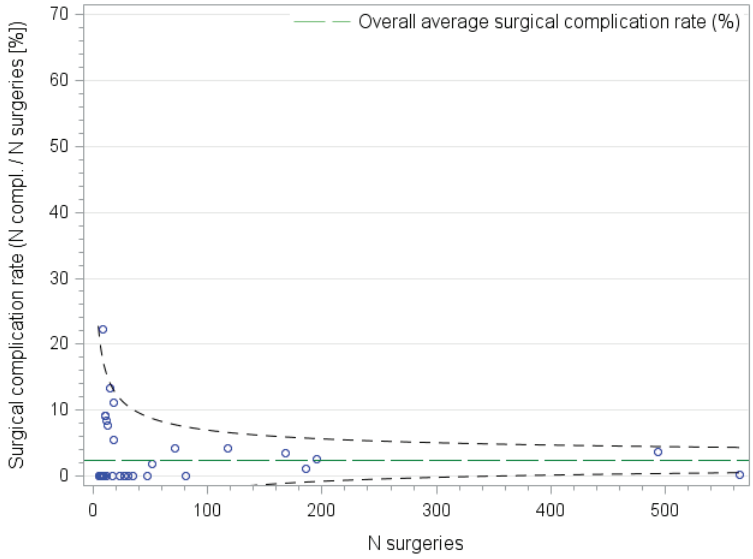


Figure 40: Cervical disc herniation treated with decompression and instrumented fusion.

Cervical spinal stenosis treated with decompression and instrumented fusion

333 patients from 16 hospitals were included in the analysis (Figure 41). Average perioperative complication rate was 10.5%. It becomes obvious that the average complication rate of this procedure and underlying pathology is much higher compared with, cervical disc herniation. The proportion of incidental dura lesions was 1.2%, thus, not explaining the high overall complication rate. However, the complication rates are much more scattered among the participating hospitals which hints at a greater influence of the individual surgeon on the safety of this type of surgery.

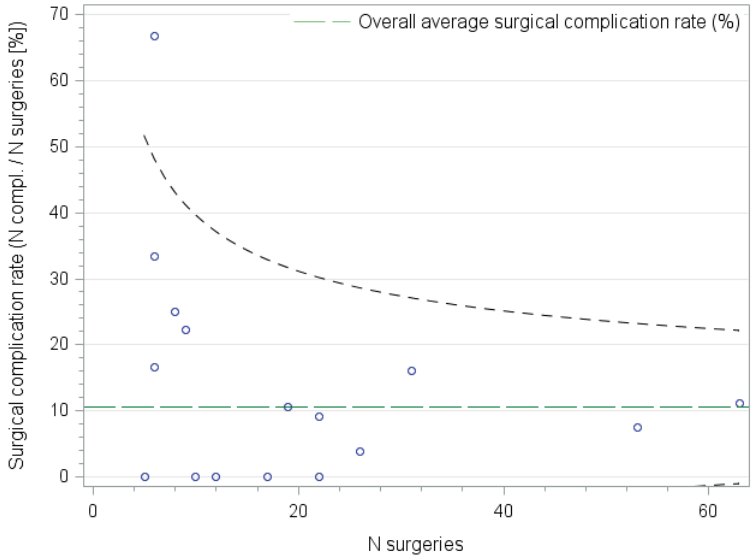


Figure 41: Cervical spinal stenosis treated with decompression and instrumented fusion.

Cervical spinal stenosis treated with decompression alone

585 patients from 12 hospitals were included in the analysis (Figure 42). Average perioperative complication rate was 3.9%, which is lower than that after decompression accompanied with instrumented fusion for the same pathology. The proportion of incidental dura lesions was 0.3%.

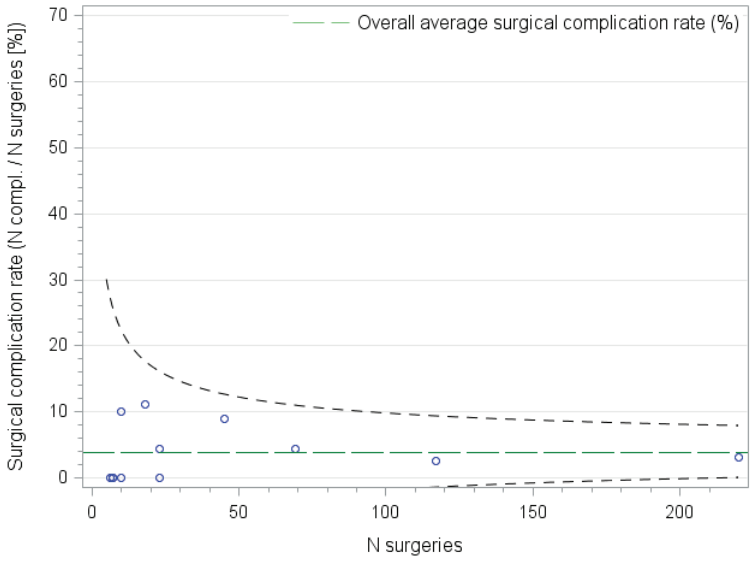


Figure 42: Cervical spinal stenosis treated with decompression alone.

Lumbar disc herniation treated with decompression alone

13`917 patients from 58 hospitals were included in the analysis of this most frequent pathology and surgery on the spine (Figure 43). Average perioperative complication rate was 4.5% and almost all hospitals were inside the average with 95% confidence intervals with three close-to-average outliers. The procedure seems generally sufficiently save with no relevant differences between the various participating centers and surgeons.

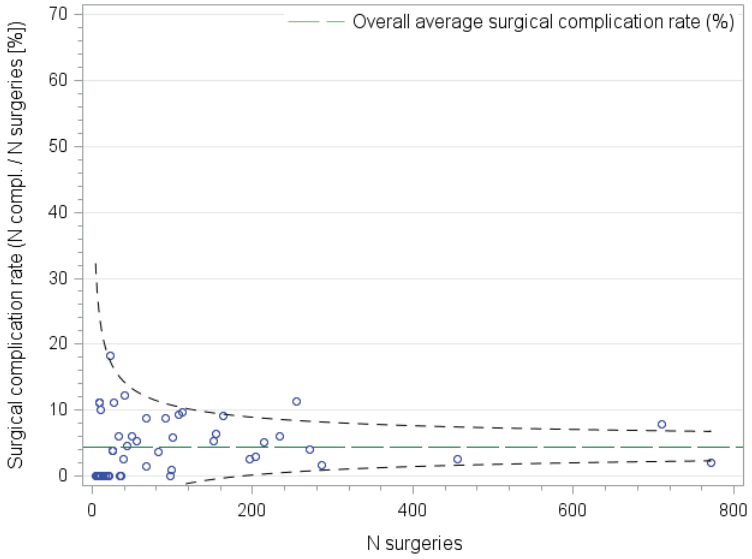


Figure 43: Lumbar disc herniation treated with decompression alone.

Lumbar degenerative spondylolisthesis treated with decompression alone

1`481 patients from 31 hospitals were included in the analysis (Figure 44). With an average 12.6% of perioperative surgical complications this pathology and surgery represents the most prone to surgical complications. Their clinical relevance may be less dramatic and need to be analyzed in detail for an accurate interpretation. A particularly high rate of incidental dura lesions of 9.0% is documented in this subgroup. In 63.9% the dura lesion was associated with an intervention during or a reintervention after surgery. However, variation of complication rates was considerable even between centers with higher case load and a ≥20% perioperative complication rate seems to be also possible.

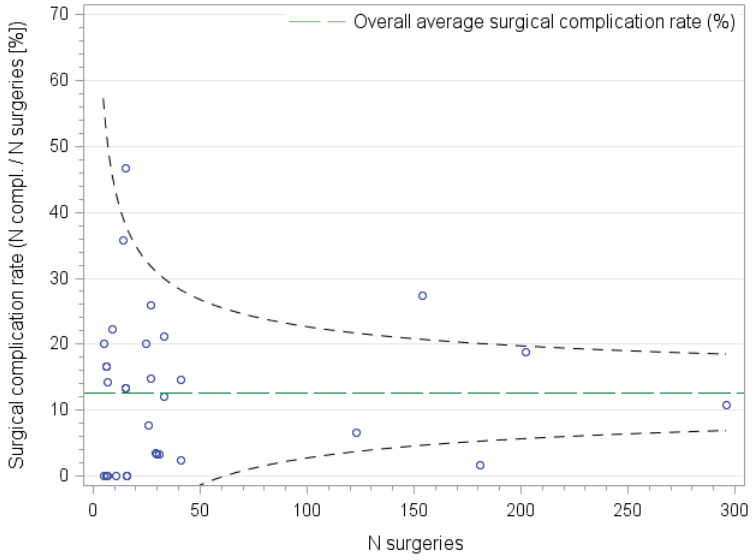


Figure 44: Lumbar degenerative spondylolisthesis treated with decompression alone.

Lumbar degenerative spondylolisthesis treated with decompression and instrumented fusion

2`811 patients from 47 hospitals were included in the analysis (Figure 45). With an average 9.5% of perioperative surgical complications this procedure displayed slightly lower complication rates than the sole decompressive treatment. The incidental dura lesion rate was 4.9%, while 89.1% of them were associated with an intervention during or a reintervention after surgery.

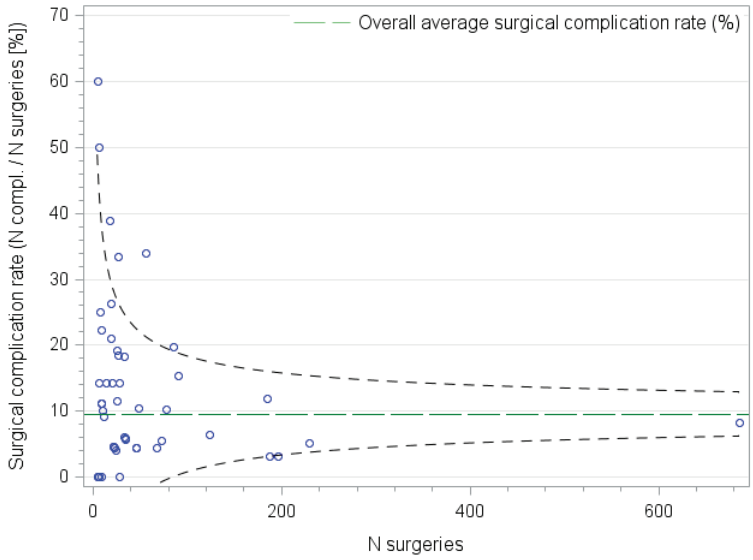


Figure 45: Lumbar degenerative spondylolisthesis treated with decompression and instrumented fusion.

Lumbar spinal stenosis treated with decompression alone versus treatment with decompression and instrumented fusion

10`631 patients from 51 hospital (decompression alone) and 2`298 patients from 38 hospitals (decompression and instrumented fusion) were included in the analysis (Figures 46, 47). Complication rates were well comparable with 9.6% and 9.8%, respectively. However, incidental dura lesion rate was higher after decompression alone (7.3%) than after decompression and instrumented fusion (5.0%). Also, more hospital outliers were observed after decompression alone representing both higher and lower than average rates.

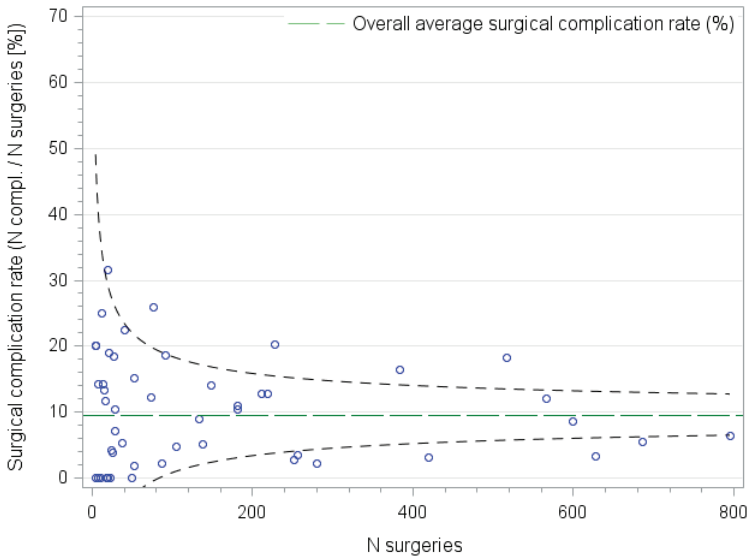


Figure 46: Lumbar spinal stenosis treated with decompression alone.

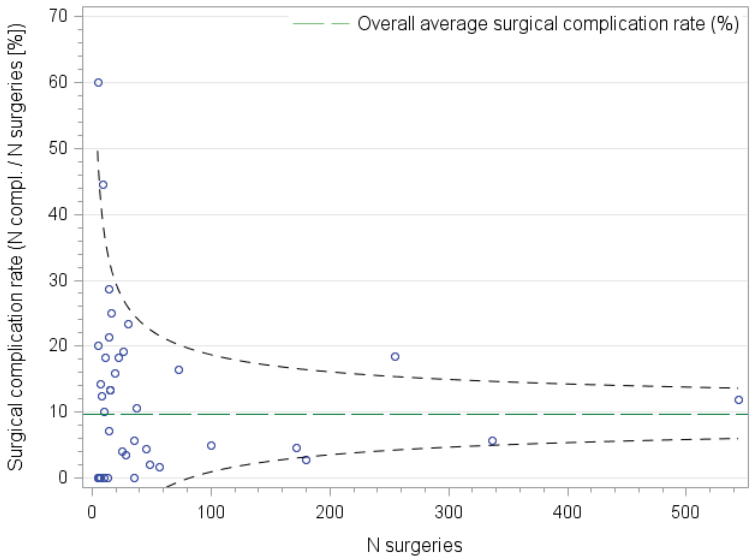


Figure 47: Lumbar spinal stenosis treated with decompression and instrumented fusion.

16. Cochrane AL (1972). Effectiveness and Efficiency. Random Reflections on Health Services. Reprinted in 1999 for Nuffield Trust by the Royal Society of Medicine Press, London

17. Jarvinen TL, Sievanen H, Kannus P, Jokihaara J, Khan KM (2011). The true cost of pharmacological disease prevention. BMJ 342:d2175.

Participants / Module Analysis

Figure 48 displays the cumulative growth curves of the various national modules. The different starting dates of the modules need to be considered (Swiss/International 2005, Austria 2005; Germany 2006; North America 2007; Brazil/South America 2008; Italy 2008; Mexico 2008; Great Britain 2010; Australia 2010). During 2012 the North American, Brazilian and Mexican modules have been combined to the Pan American Module. The Swiss/ International module was divided into one Swiss and one International module. The Polish module was launched in 2013, but due to migration of active users from the international module there is data from 2011 onwards in the Polish module database.A similar situation exists for the Belgian module which was launched in 2014. The Australian and British modules are both not available via www.eurospine.org because of national data privacy regulations, but the contact persons for these modules are displayed on the Spine Tango web page.

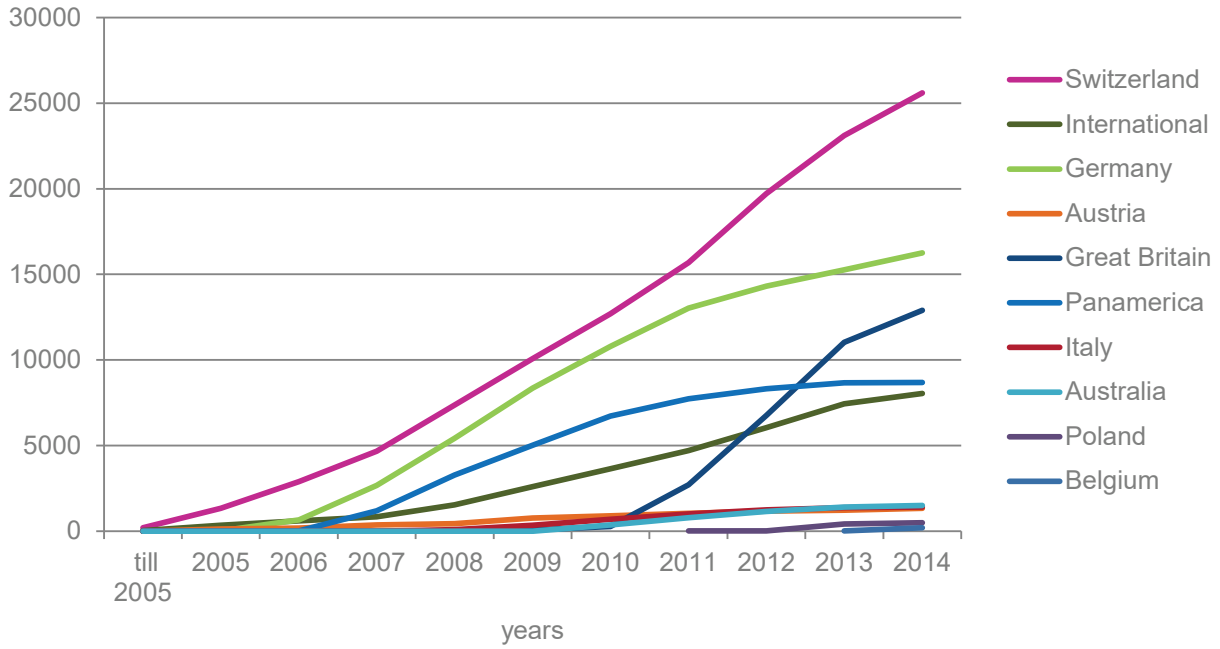


Figure 48: Growth curves (number of cases of the single Spine Tango modules over the years)

The hospital classification of all active 39 Spine Tango clinics actively documenting in 2014 can be seen in figure 49. The highest proportion is made up by university or teaching hospitals with 42%.

Figure 50 shows an overview of the Spine Tango participating hospitals and their country of origin until the end of 2014. We divided their total case load into primary forms, follow-up forms and COMI forms.

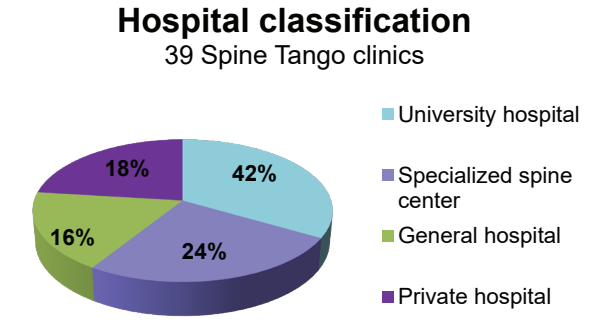


Figure 49: Hospital classification for the 39 clinics actively documenting the 2011 forms.

Figure 50: Overview of the Spine Tango participating hospitals according to their country of origin with case load divided into primary forms 2011, follow-up forms and COMI forms until the end of 2014.

Forms used in Spine Tango Registry - 01.08.2015		multilingual	online available						OMR paper forms available										
			english	german	french	italian	spanish	polnish	english	german	french	italian	spanish	portuguese	turkish	polish	greek	dutch	russian
Registry Forms																			
Spine Tango	Surgery 2011	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓		✓
Spine Tango	Staged 2011	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓		✓
Spine Tango	Follow-up 2011	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓		✓
Spine Tango	Conservative treatment 2011	✓	✓	✓					✓	✓									
Spine Tango	Adult deformity add-on	✓	✓	✓					✓	✓									
Spine Tango	Adolescent scoliosis add-on	✓	✓	✓					✓	✓									
Patient Forms																			
Spine Tango	Core Outcome Measures Index: COMI Neck	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓			
Spine Tango	Core Outcome Measures Index: COMI Back	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓			
Spine Tango	Core Outcome Measures Index: COMI Neck Conservative	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓						
Spine Tango	Core Outcome Measures Index: COMI Back Conservative	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓						
Spine Tango	Oswestry Disability Index ODI 2.1	✓	✓	✓	✓	✓	✓		✓	✓	✓		✓	✓	✓	✓		✓	
Spine Tango	Neck Disability Index NDI	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓			✓			
Spine Tango	Scoliosis Research Society: SRS 30	✓	✓	✓	✓				✓	✓	✓								
Spine Tango	EuroQol™: EQ-5D™	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓						
Spine Tango	RMQ - Low Back and Disability Questionnaire	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓					✓	
Spine Tango	SAQ Spinal Appearance Quesitonnaire	✓	✓	✓					✓	✓									
Examination Forms																			
Spine Tango	Examination: ASIA Score (Beta)		✓																

OMR = Optical Mark Reader

Table 3: Available questionnaires in the SSE Spine Tango registry (01.08.2015)

Publications 2014

Papers in peer reviewed Journals

Al-Mahfoudh R, Qattan E, Ellenbogen JR, Wilby M, Barrett C, Pigott T.
Applications of the ultrasonic bone cutter in spinal surgery - our preliminary experience. Br J Neurosurg. 2014 Jan;28(1):56-60.

Bellut D, Mutter UM, Sutter M, Eggspuehler A, Mannion AF, Porchet F.
Back pain in patients with degenerative spine disease and intradural spinal tumor: what to treat? when to treat? Eur Spine J. 2014 Apr;23(4):821-9.

Mannion AF, Fekete TF, Porchet F, Haschtmann D, Jeszenszky D, Kleinstück FS.
The influence of comorbidity on the risks and benefits of spine surgery for degenerative lumbar disorders. Eur Spine J. 2014 Apr;23 Suppl 1:S66-71.

Kleinstueck FS, Fekete TF, Jeszenszky D, Haschtmann D, Mannion AF.
Adult degenerative scoliosis: comparison of patient-rated outcome after three different surgical treatments. Eur Spine J. 2014 Aug 8. [Epub ahead of print]

Murray NJ, Demetriades AK, Rolton D, Nnadi C.
Do surgeon credentials affect the rate of incidental durotomy during spine surgery. Eur Spine J. 2014 Aug;23(8):1767-71.

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