EUROSPINE

The international Spine Registry SPINE TANGO

Annual Report

2015

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Table of contents

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 information 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 the society. There has been considerable investment of clinician, academic and financial resources to develop and iteratively further improve the registry. Having achieved international recognition, we would like to encourage national societies and individual partners to join the registry and help collecting collective evidence.

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. Starting from 2017, it is planning to make documentation of all spinal interventions a prerequisite for a certification as a spine centre in Germany. 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 soon. In Switzerland, documentation of all spinal interventions with implants will become mandatory in 2017. Spine Tango will very likely be the system of choice to be used as the template for the Swiss Implant Registry SIRIS. Meanwhile, 16 spine units in Switzerland are already registry participants. The first national Spine Tango-based report is under preparation in Switzerland.

The list of spinal treatments and medical industry are growing, and healthcare authorities today are at times limiting their access 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 with higher evidence studies like RCTs. But the external validity and, therefore, general application of registry findings is often unique, and is what makes the dataset and its clinical and scientific findings so valuable for quality assurance, health service and outcome research. This was demonstrated by an award-winning Spine Tango paper this year (Staub et al. Spine J. 2016 Feb;16(2):136-45).
The registry enables a quick, but detailed implant documentation, which is of great interest for the medical industry and spinal implant suppliers. Spine Tango has developed an implant report including several outcome measures, which is now offered on an individual cost basis.

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 pathologies such as spinal stenosis and degenerative spondylolisthesis have been carried out and are being further refined.
The Spine Tango registry has also reached new levels of technological sophistication. One large spine centre in Italy (Milan) and another one in Germany (Würselen) have programmed 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.

Emin Aghayev, Chair, on behalf of the Spine Tango committee

Profile

Spine Tango enables documentation of the whole spectrum of spinal pathologies and all possible surgical and non-surgical treatment options. The generic approach of the registry is a must to reach the maximum number of participants using a common ‘language’ of documentation (1). This, however, 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. Additional forms, like Spine Tango conservative (2), adolescent scoliosis and degenerative deformities were developed to allow a detailed documentation of conservative and complex deformity cases. Spine Tango is an international, academic project under the auspices of EUROSPINE, the Spine Society of Europe, which aims to enable national societies to organize and operate their part of the Spine Tango as a sub-registry. For that a modern technology called “national module” has been implemented to enhance participation options and to provide the hardware structure for appropriate security measures for patient and user privacy protection. In summary, Spine Tango is a unique applied medical and scientific documentation system, the network of dozens of hospitals, the quality assurance tool, the evidence generator, the template for national registries, and the basis for nested studies.

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.

New Developments

Extended search tool: Besides the simple search tool allowing for searching patients by demographic characteristics, form type and characteristics, and certain form attributes, an extended search tool was developed that includes all questions and answers on all forms which can be used to specify a patient search. The hit list can either show or download the related patients or the related forms.

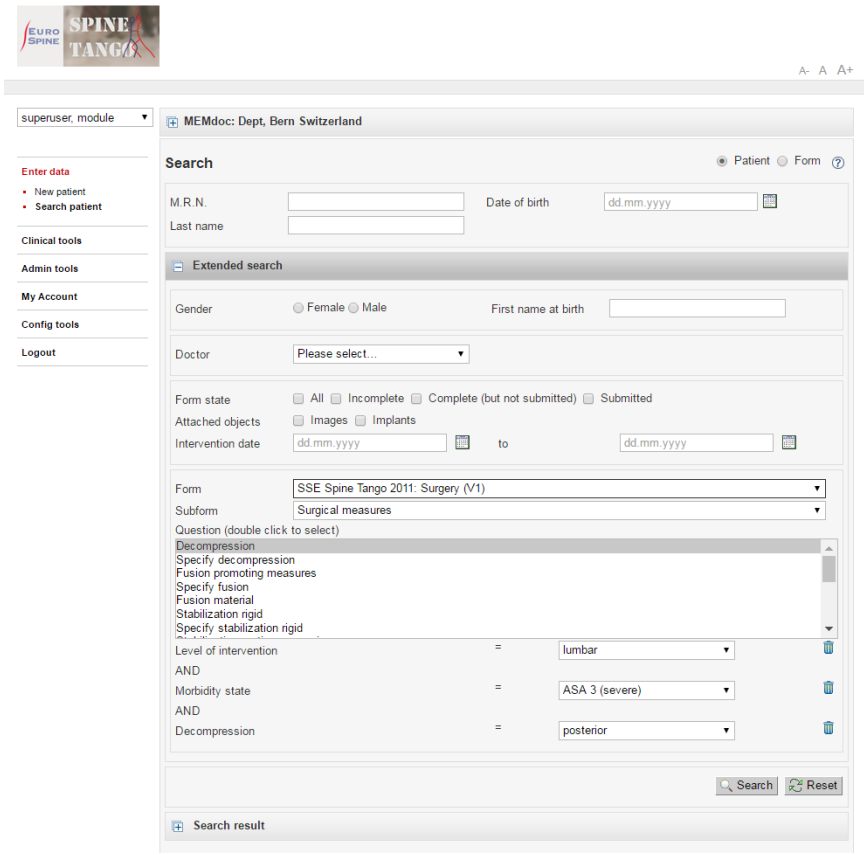

Figure 1: Extended search tool

Implant report: An implant report including several outcome measures was developed and is now offered on the individual cost bases.

Benchmarking report: The previous benchmarking report for the users was based on frequency analyses and pooled all diagnoses together. In 2015 the Spine Tango committee released degenerative diagnosis groups to provide clear discrimination between different entities. These categorizations will now be used in the new, next generation benchmarking report, which will be available by the end of 2016.

New Developments

Follow-up calendar: Follow-up calendar: This is a useful tool for an overview (1) and planning (2) of follow-ups. The calendar allows the user to visualize the performed, pending, and missed appointments as well as “outlier” follow-ups for each case and related forms (1). The calendar is also helpful for planning upcoming follow-ups by defining a time interval in the near or far future and viewing all related follow-ups, the dates they should be performed and the respective forms that need to be administered (2). The study administrator can specify which type of form belongs to which follow-up, and the index form. Among several features of this tool, the physician can distribute patient questionnaires per email, and monitor their status. The questionnaires sent via links have a patient-friendly format and expire after they are used once or after a certain number of days.

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.

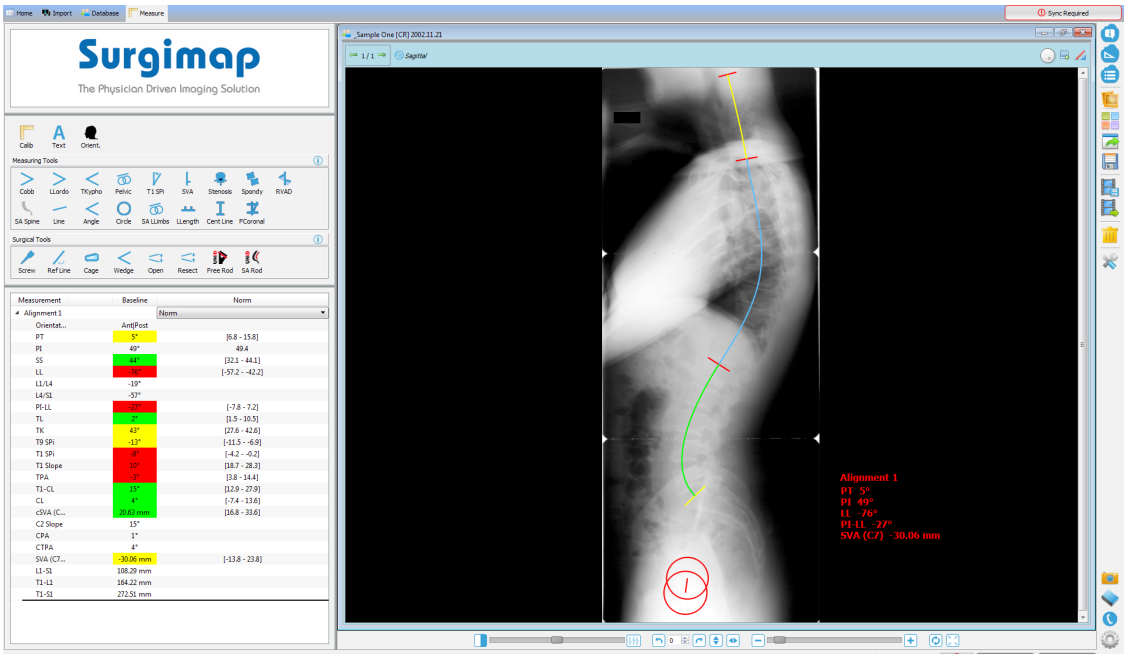

Figure 2: Surgimap measurements (green, red, yellow) for transcription into the database

Application

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

Internal quality control: 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 benchmarking 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.

Health services research: as a sub-discipline of health systems research, this young science is an interdisciplinary field that describes and assesses 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 exploits the systematic and prospective data collection regarding interventions for spinal pathologies and treatment outcomes. While quality assurance is rather used for the purposes of improving ones' own standards of care, outcomes research attempts 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 as 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 will become part of the governmentally mandated Swiss Implant Registry as of 2017.

National and international study network: the registry is a network of about 60 active hospitals in Europe, North and South America, Australia and Asia. This provides great opportunities for national and international multicentre studies that piggyback on the ongoing routine data collection, add some hypothesis based questions and collect extra information/data at the time of primary and follow-up form completion as specified in the 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 available for download on the Spine Tango webpage under "Forms".

Research with Spine Tango

Scientific articles using Spine Tango data are increasingly being published and cited in the peer reviewed literature. Figures 3 and 4 show the results from an ISI Web of Science search of the scientific output and impact of Spine Tango related research over the years. One of the Spine Tango papers received an Outstanding Paper Award from the Spine Journal in 2015.

Staub LP, Ryser C, Röder C, Mannion AF, Jarvik JG, Aebi M, Aghayev E.
Total disc arthroplasty versus anterior cervical interbody fusion: use of the Spine Tango registry to supplement the evidence from randomized control trials.
Spine J. 2016 Feb;16(2):136-45.

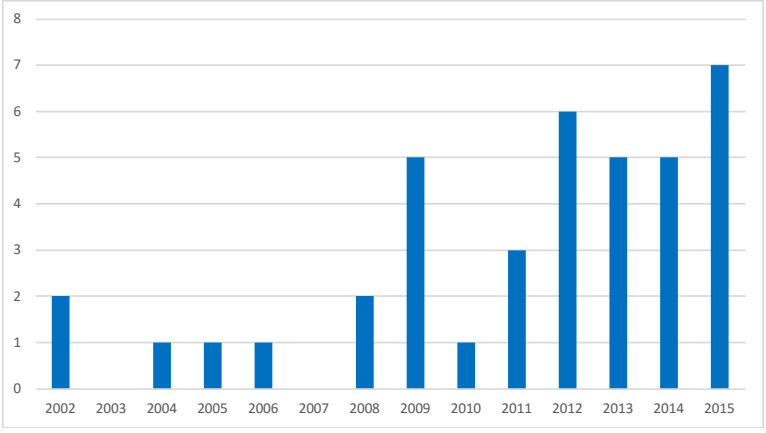

Figure 3: Published items in each year

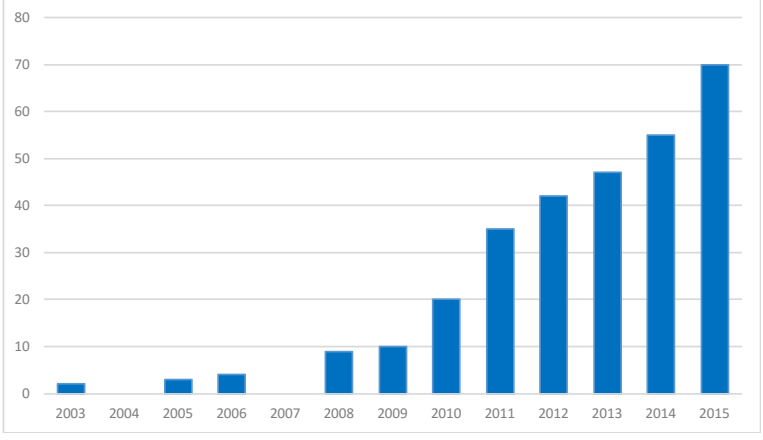

Figure 4: Citations in each year

Results found until 31.12.2015: 39

Sum of the Times Cited: 324	Citing Articles: 222
Sum of Times Cited without self-citations: 253	Citing Articles without self-citations: 192
Average Citations per Item: 8.8	h-index: 12

Reference Web of Science / Thomson Reuters

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 serves as a common agreement between all registry stakeholders for ensuring that the collected data itself is of an acceptable quality and does not compromise the overall goals of the project.

Data entry

There are 6 possible ways data can be transferred to the database (Figure 5):
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 Swiss RDL 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.

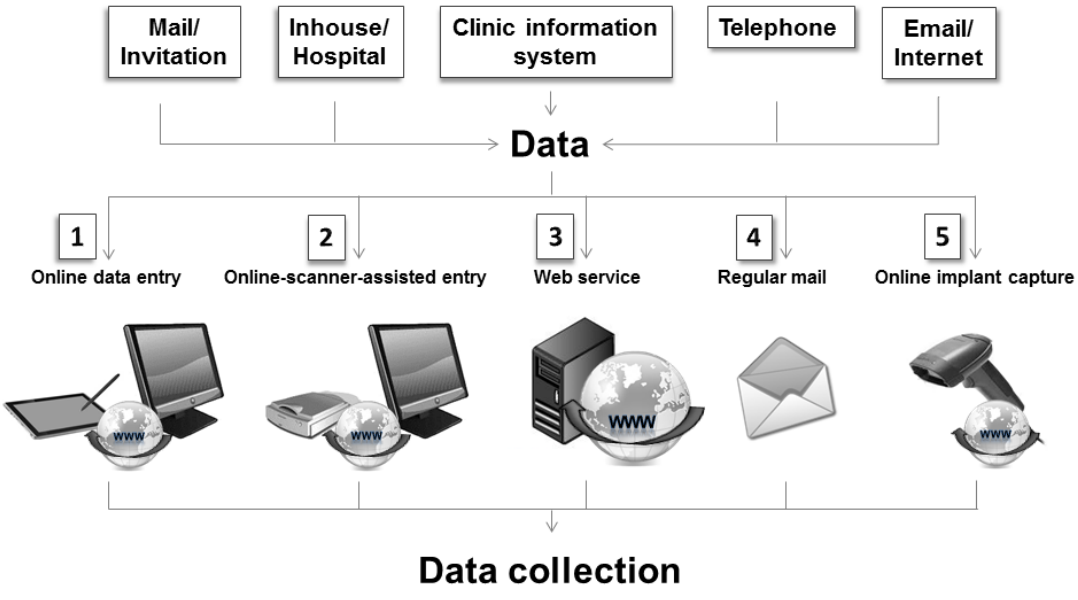

Figure 5: Methods of data entry

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 6. 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 7 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

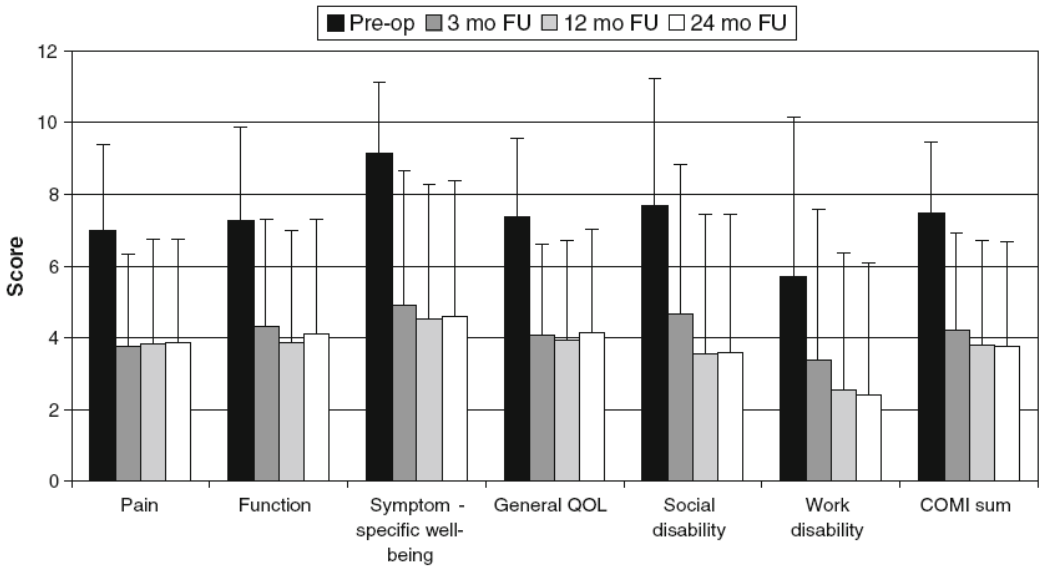

Figure 6: Patient based outcome documentation with the COMI (Core Outcome Measure Index) questionnaires, Mannion et al. (4)

Pre- and postoperative documentation workflow of a case

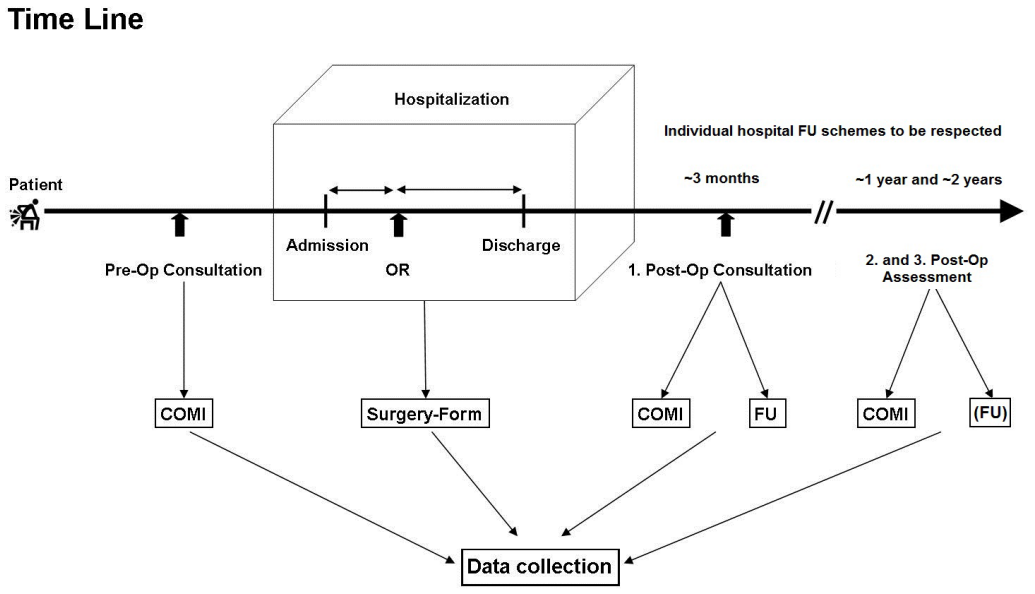

Figure 7: Timeline of data collection

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 methods used 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 have also been published (12, 13). A first matching study was recently performed and received the Outstanding Paper Award from the Spine J (14). In addition to clinical studies, a multitude of reliability and validation studies of the patient COMI form in different languages have been performed and published in the last decade. Furthermore, initial studies investigating 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 continues its work on the description of patient, treatment and outcome characteristics of different diagnostic groups (the so-called Benchmarking Project).

Several professional societies in Europe have expressed their interest in using the Spine Tango registry as a template for their national registries. The common desire in such endeavours is the minimization of Spine Tango documentation. It is a big challenge to find the right balance between the burden of documentation and the informative value (usefulness) of the data. Obviously, the comprehensive assessment of the performance of an implant or a treatment in spine surgery requires the evaluation of several outcomes (for example safety [complications and reoperations], patients' perspective [pain, satisfaction, quality of life], physicians' perspective [achievement of treatment goals], economic perspective [length of hospital stay, surgery time], etc.) as well as an adjustment for the case mix (for example patient age, sex, BMI, duration of symptoms, previous treatment, comorbidity, etc.). Therefore, clearly formulated goals for data collection, an accurate weighing-up of pros and cons for excluding any of the questions, a solid study plan, and a consensus among registry stakeholders are all required.

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 decom - pression 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? Spine J. 2016 Feb;16(2):136-45.

Spine Tango growth curve

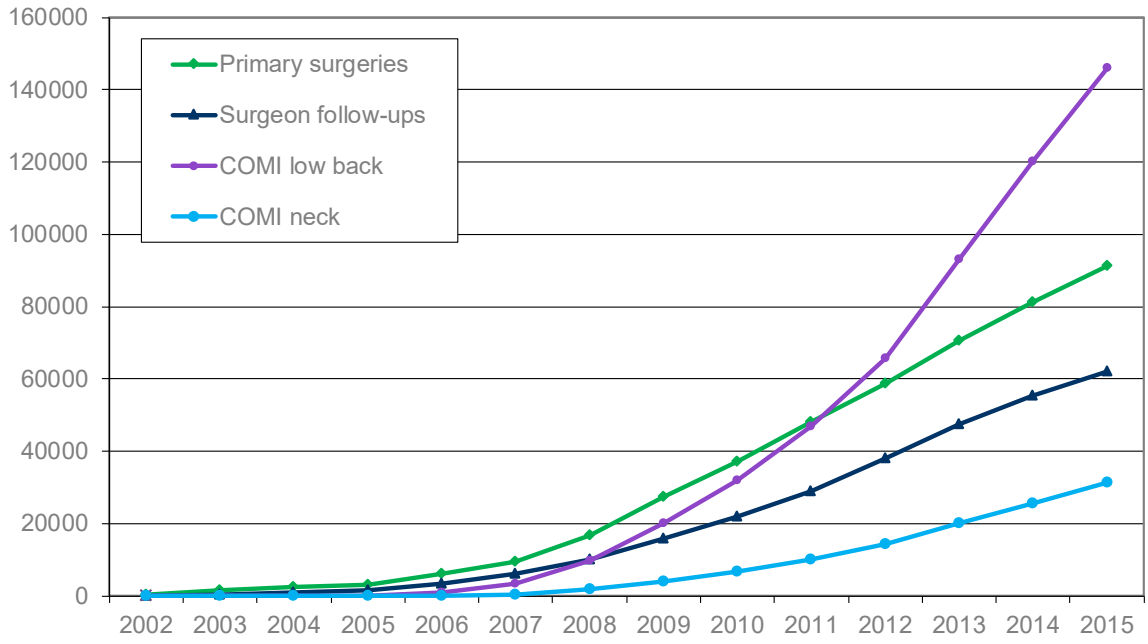

Figure 8: Growth curves of implemented forms (primary surgery and follow-up) as well as COMI low back and neck over the years.

Note: the staged surgeries are not displayed due to low numbers.

SPINE TANGO Statistics

Surgery Form

Part I: Descriptive analysis form version 2011 Surgery Form

The latest Spine Tango form, “version 2011”, has been exclusively used for data collection since January 2012. Consequently, the information gained during the years 2012 - 2015 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 2015 annual report we will exclusively show information collected using the form version 2011.
In total 48`140 surgeries were documented using the 2005 and 2006 versions of the surgery form. By the end of 2015, 43’841 surgeries (10’096 more since 2014) had been registered. Thus, today there are over 90’000 surgeries in total from the form versions 2005, 2006, and 2011.

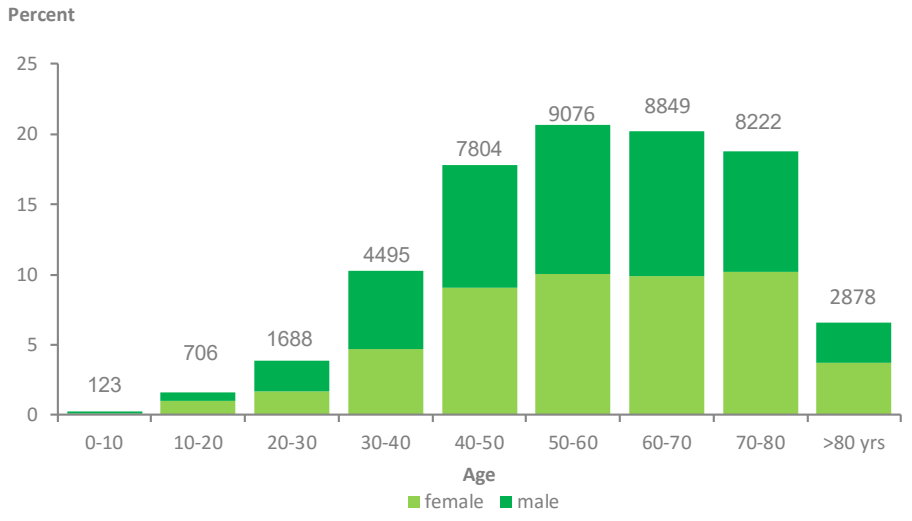

Figure 9: Distribution of age (at surgery) by sex; all patients in the form version 2011 (N=43‘841)

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 and health care systems become visible in that the NHS in the UK seems to promote shorter hospitalizations of up to two days, followed by Belgium where about half of the patients stay no longer than five days. Overall, the majority of patients are hospitalized from between zero and eight days. No adjustment of LOS was made for the case-mix and treatment measures.

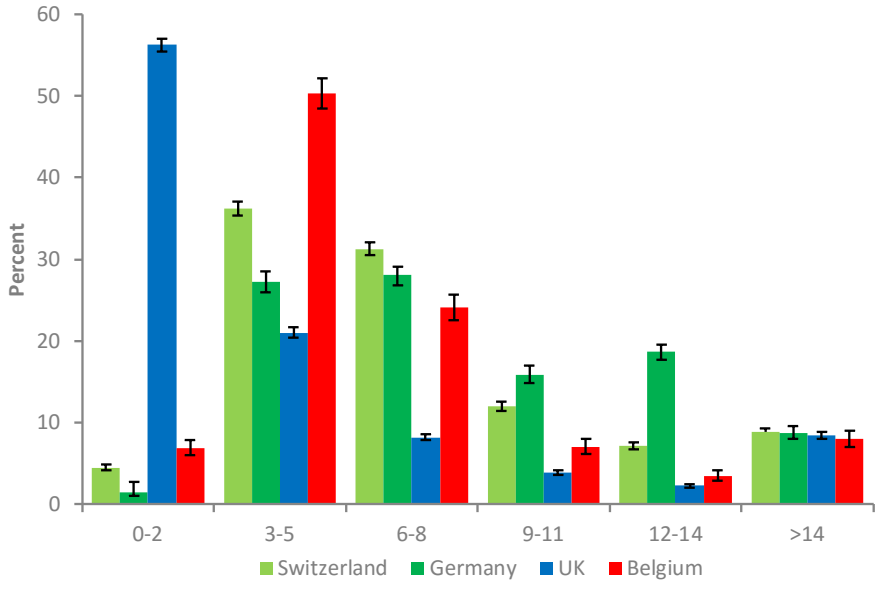

Figure 10: Length of hospital stay; all patients in the form version 2011 (N=37'297)

Admission Subform

Body Mass Index (BMI)

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

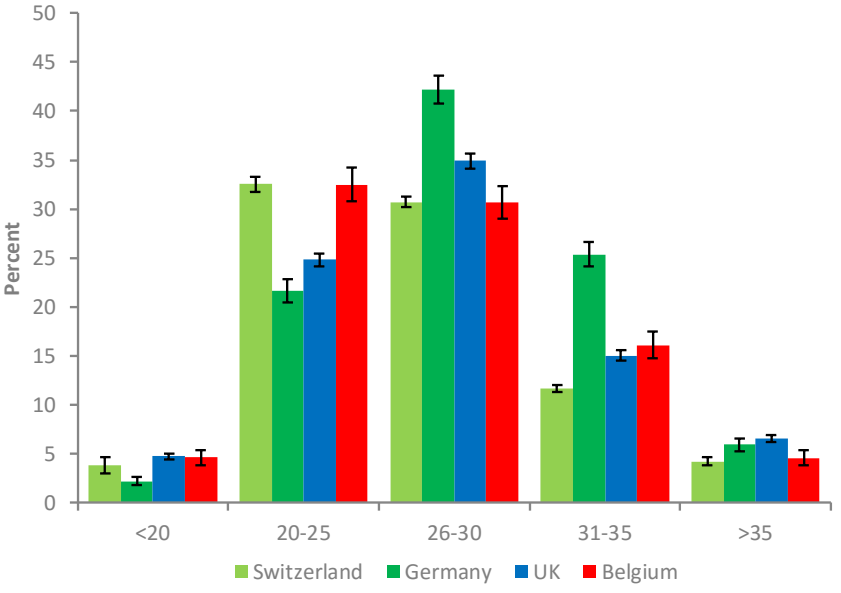

Figure 11: Distribution of body mass index (BMI), all patients in the form version 2011 (N=37'345)

Admission Subform

Smoking status

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

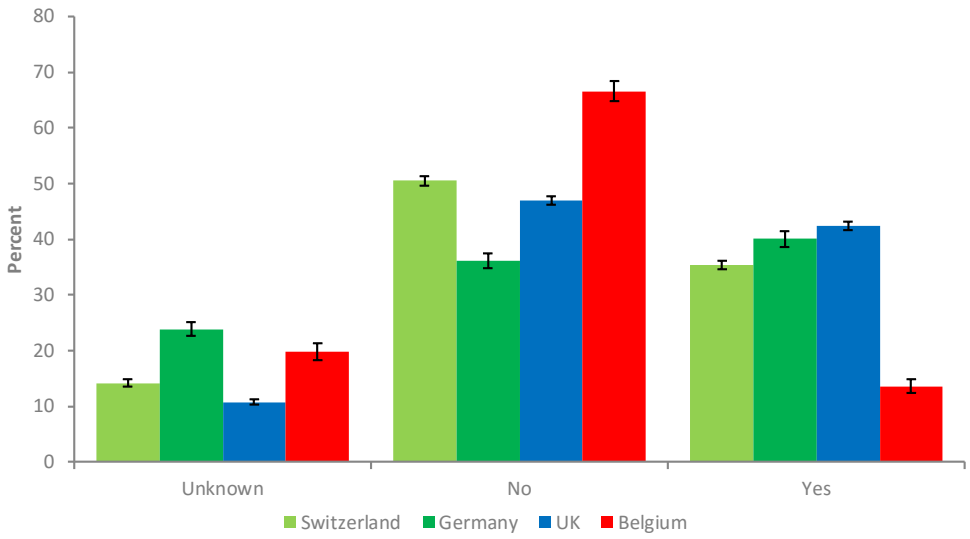

Figure 12: Distribution of current smoking status; all patients in the form version 2011 (N=37'345)

Admission Subform

Risk factors - flags

The flags are a parameter for risk adjustment in the classification/assessment of patients with low back pain (LBP). The psychosocial ("yellow") flags can help e.g. occupational health practitioners to create suitable rehabilitation plans for employees. A brief definition of the different coloured flags 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

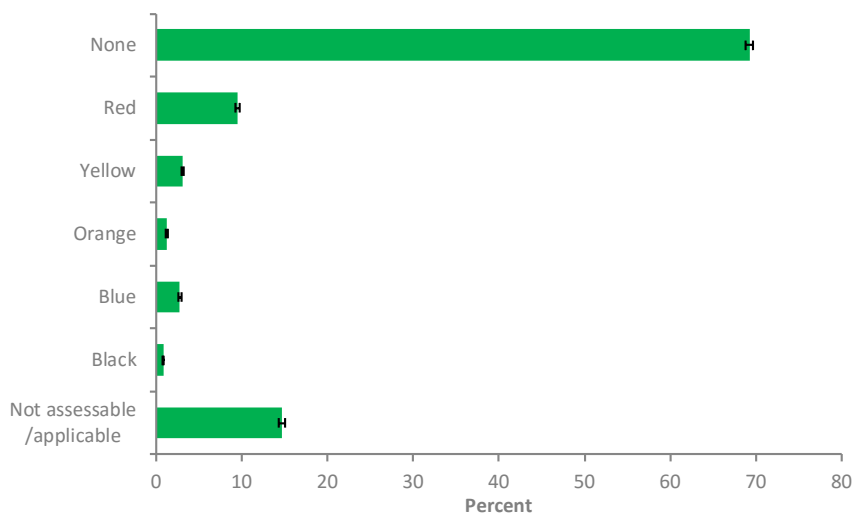

Figure 13: Distribution of risk factors - flags, all patients in the form version 2011 (N=43'128)

Admission Subform

Distribution of main pathology

The proportions of main pathologies have not changed to any relevant extent since the last report. By far the most frequent diagnosis, at about 80%, remains “degenerative disease” followed by “failed/ repeat surgery”, which is stable at around 6%. This combined variable (covering both “failed” and “repeat” surgery) offers response options to describe true treatment failures such as non-union or neurocompression, and also to document reasons for elective repeat surgery such as hardware removal.

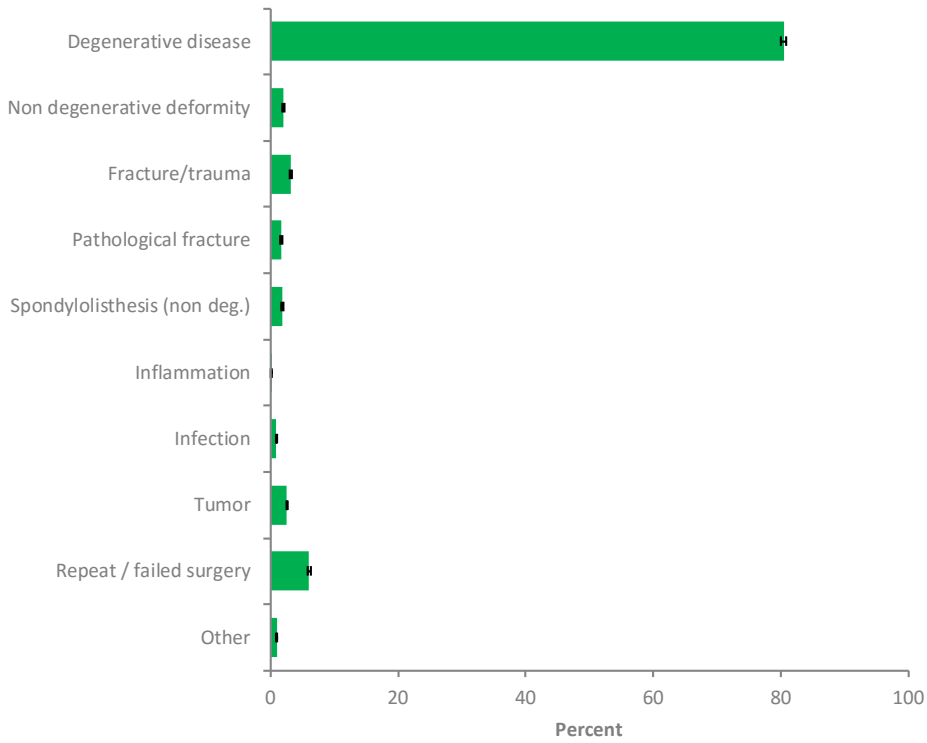

Figure 14: Distribution of main pathology; all patients in the form version 2011 (N=43’841)

Admission Subform

Specification of degenerative diseases

Figure 15 shows the distribution of the response categories for the main pathology “degenerative disease” (N.B. multiple pathologies can be indicated so the figures do not add up to 100%). Disc herniation is the single most frequent type of degenerative disease documented, but if all types of spinal stenosis are combined (central, lateral and foraminal), then stenosis is even more common.

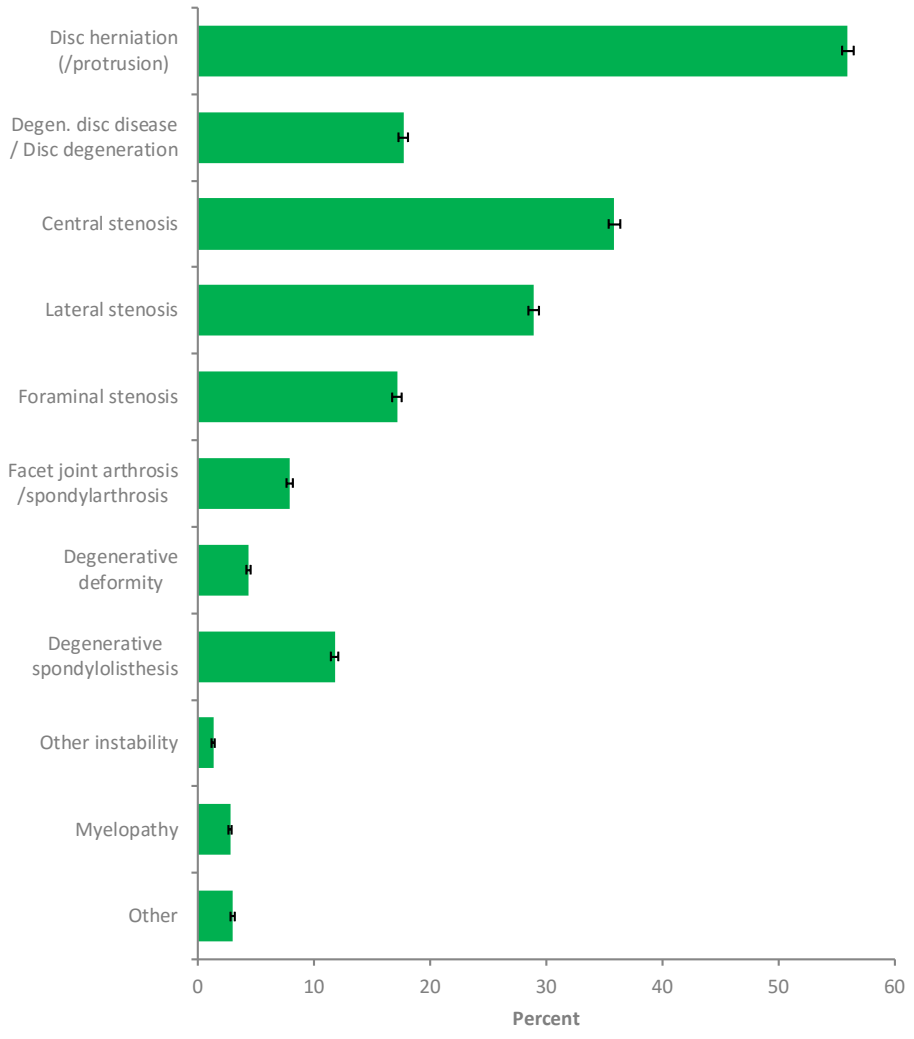

Figure 15: Specification of degenerative disease in the form version 2011 (N=35’244)

Admission Subform

Specification of spondylolisthesis

Four out of five patients with spondylolisthesis suffer from a degenerative type. The isthmic type makes up about 15%, and the congenital type about 4%.

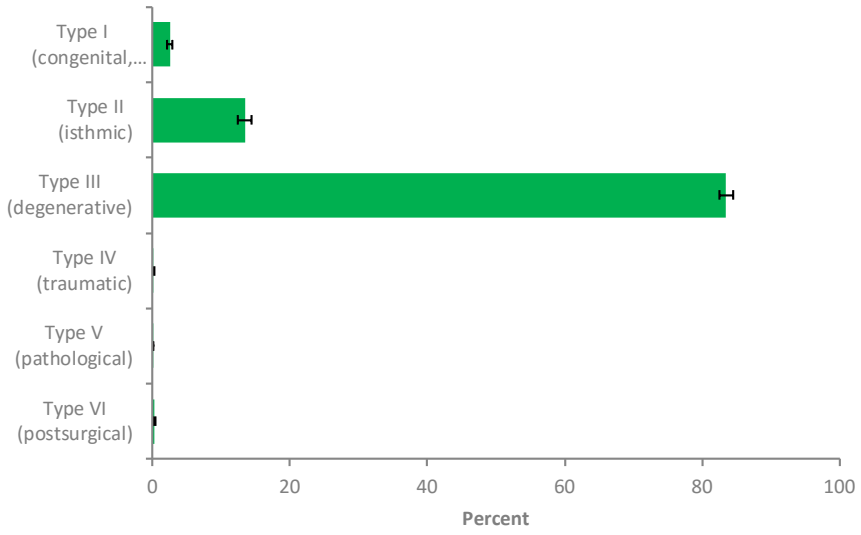

Figure 16: Distribution of type of spondylolisthesis in the form version 2011 (N= 4'969)

Age distribution by sex

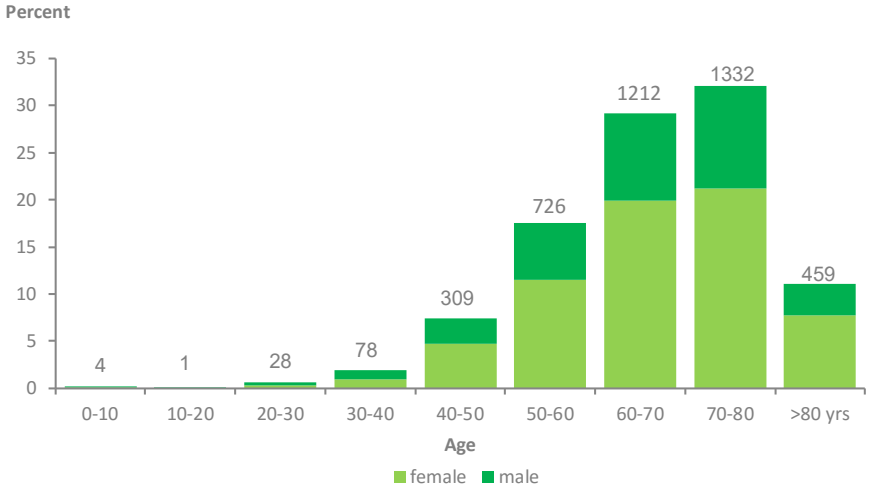

Figure 17: Distribution of age (at surgery) by sex; patients with type I spondylolisthesis (congenital, dysplastic)

Admission Subform

Age distribution by sex

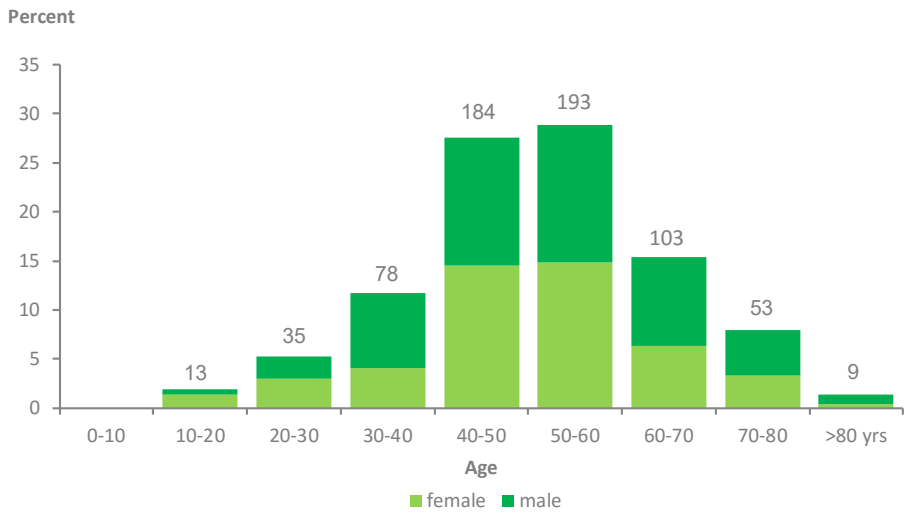

Figure 18: Distribution of age (at surgery) by sex, patients with type II spondylolisthesis (isthmic)

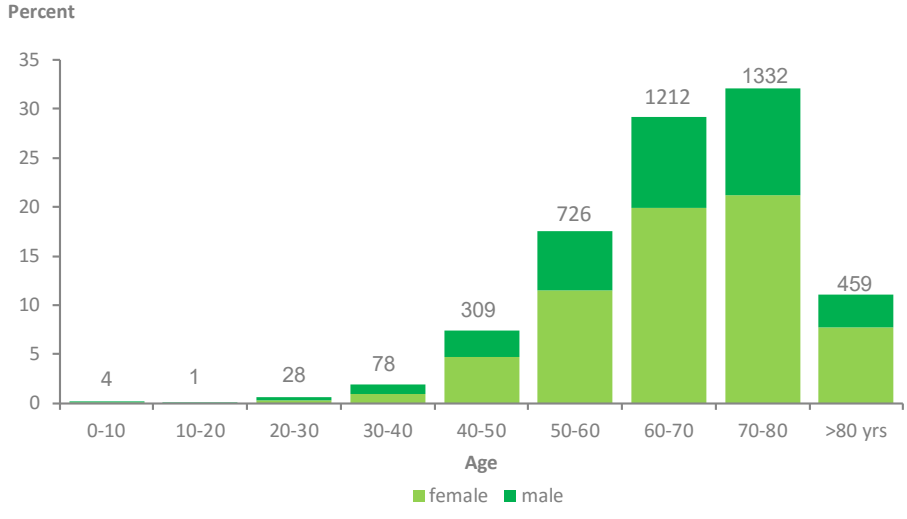

Figure 19: Distribution of age (at surgery) by sex, patients with type III spondylolisthesis (degenerative)

The age and sex distribution is relatively normal for patients with congenital/dysplastic and isthmic spondylolisthesis, whilst the degenerative type is clearly skewed towards older patients. Degenerative spondylolisthesis affects women about 2-3 times more often than it does men.

Admission Subform

Aetiology of deformity

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

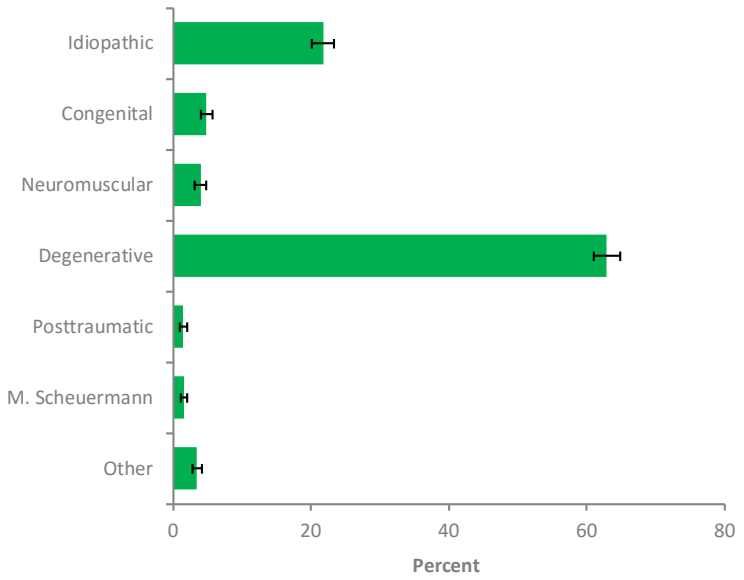

Figure 20: Distribution of predominant aetiology of deformity fin the forms version 2011 (N= 2‘445)

Age distribution by sex

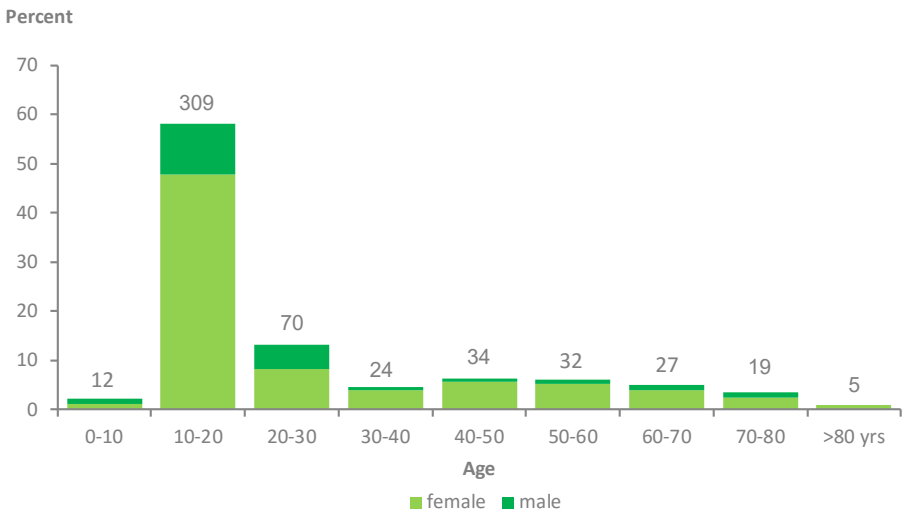

Figure 21: Distribution of age (at surgery) by sex; patients with idiopathic scoliosis

Admission Subform

Age distribution by sex

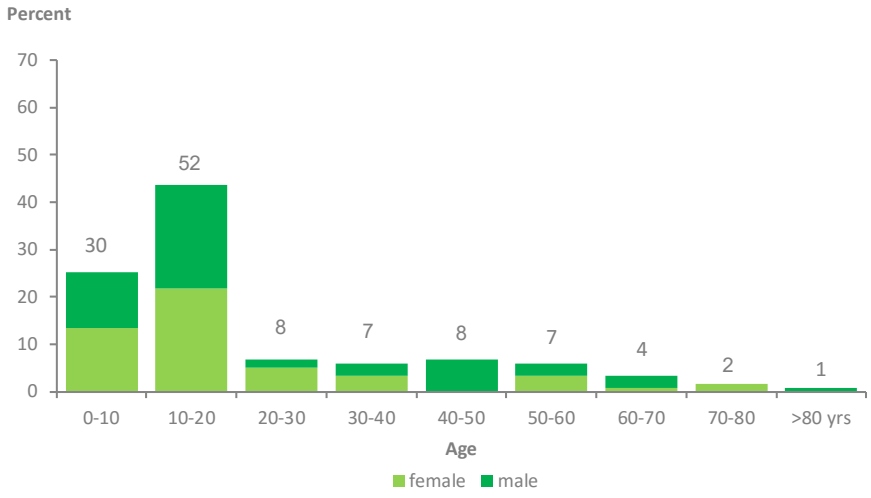

Figure 22:Distribution of age (at surgery) by sex; patients with congenital deformity

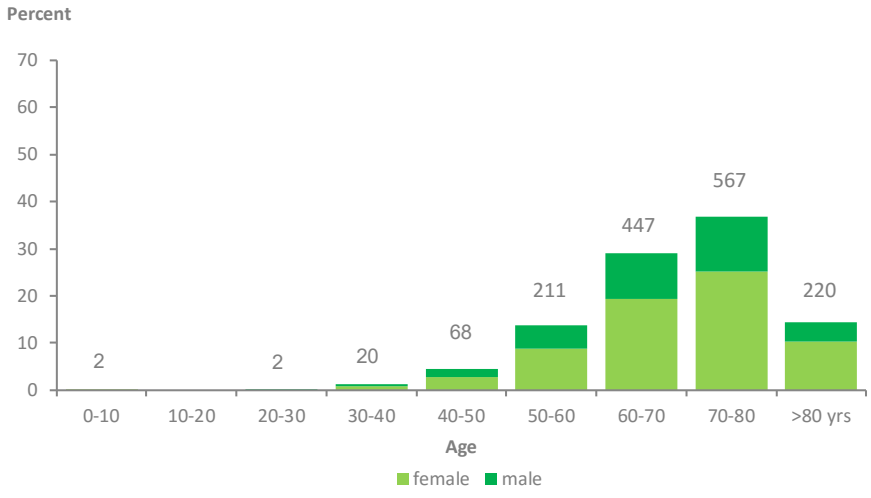

Figure 23: Distribution of age (at surgery) by sex; patients with degenerative deformity

Admission Subform

Type of repeated / failed surgery

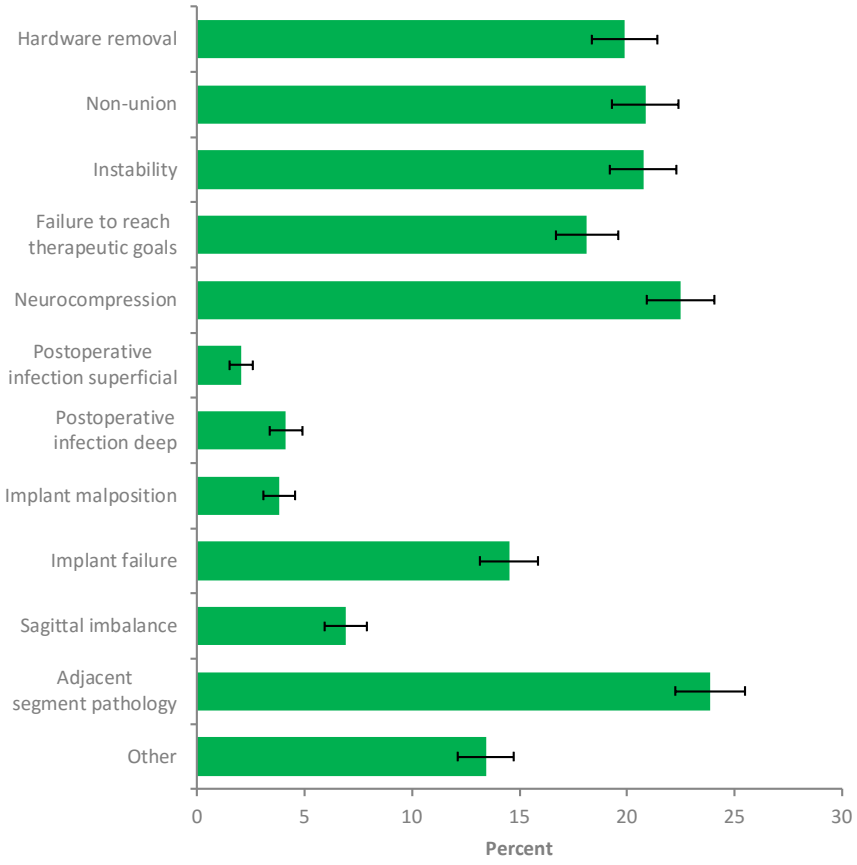

Figure 24: Type of failed/ repeated surgery for the surgery form version 2011 (N=2'646)

About 6% of cases (N=2'641) recorded in 2012 - 2015 were repeat surgeries. Since this 2015 report, adjacent segment pathology has now become for the first time the most frequent reason for a reintervention (23.9%), followed by neurocompression, non-union, and instability. Hardware removal was performed in about 20% of cases. This surgical measure does not necessarily imply a failed index surgery, which is why the field is now referred to as just "repeat" surgery. Failure to reach the initial therapeutic goals was given as a reason for repeat surgery in 18% of cases.

Surgery Subform

Therapeutic goals / goals of surgery

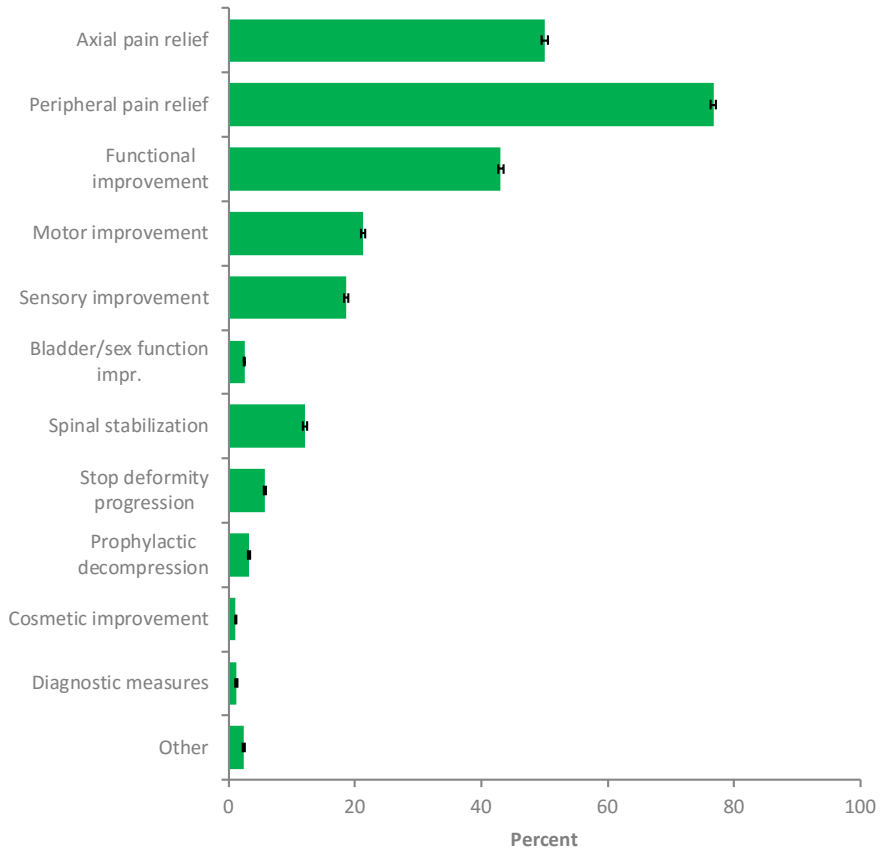

Figure 25: Distribution of therapeutic goals/ goals of surgery for the surgery form version 2011 (N=43'841)

The therapeutic goals can be more precisely defined in the form version 2011. Pain relief has now been split into axial and peripheral pain relief to consider back/neck and leg/arm pain separately. The therapeutic goal (multiple options can be indicated) is peripheral pain relief in approximately four out of five patients and axial pain relief in almost half, followed by functional improvement in about 40%.

Surgical Measures Subform

Specification of surgical measures for the degenerative diseases

A comparison of the surgical measures for the degenerative spinal diseases shows that, in the lumbar spine, simple decompression procedures predominate followed by decompression with instrumented fusion; for the cervical spine, the pattern is reversed, with the majority of procedures being decompression with instrumented fusion, and next most common, simple decompression. All other surgical measures and their combinations are rather rare.

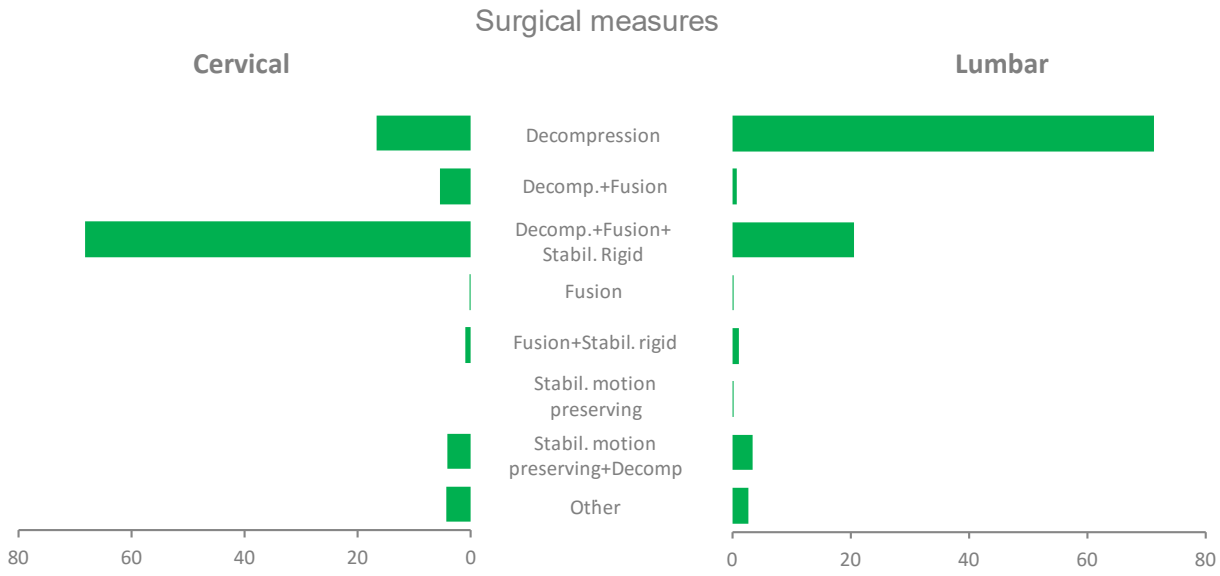

Figure 26: Specification of fusion promoting measures; all patients form version 2011 (N=35'244)

Surgical Measures Subform

Specification of fusion promoting measures and materials

In comparing the cervical and lumbar fusion-promoting measures A-IF (anterior interbody fusion) clearly dominates in cervical spine surgery (over 50%), whilst TLIF, PLIF, posterolateral fusion and posterior fusion are each relatively common in lumbar spine surgery. The proportions of “A-IF” and of “X-LIF” are just under 10% for the lumbar interventions.

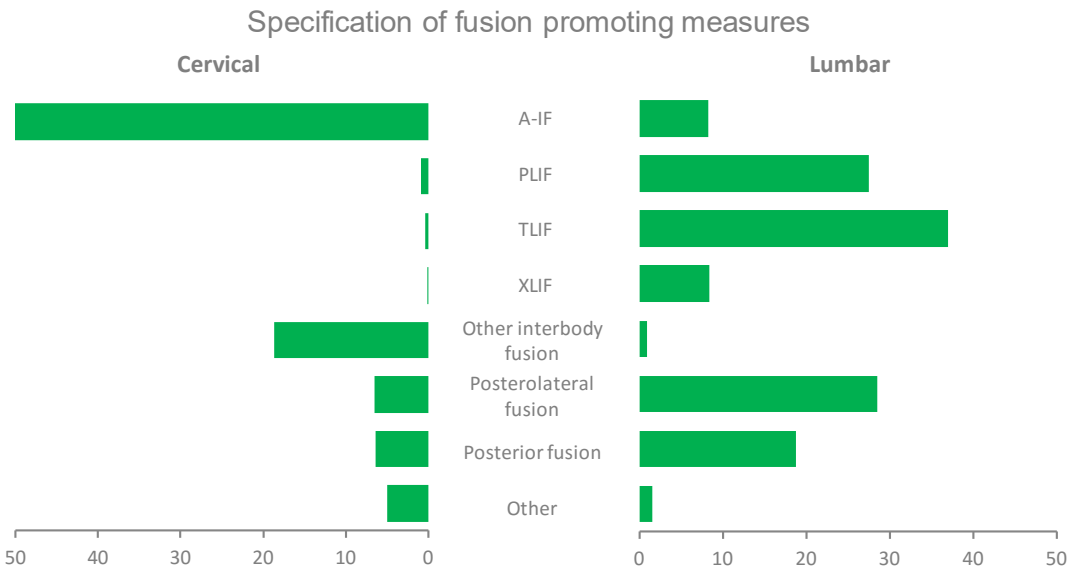

Figure 27: Specification of fusion promoting measures, surgery form version 2011 (N=35’244)

Locally procured autologous bone is the most frequently used fusion material in both cervical and lumbar interventions, followed by bone substitute and harvested autologous bone.

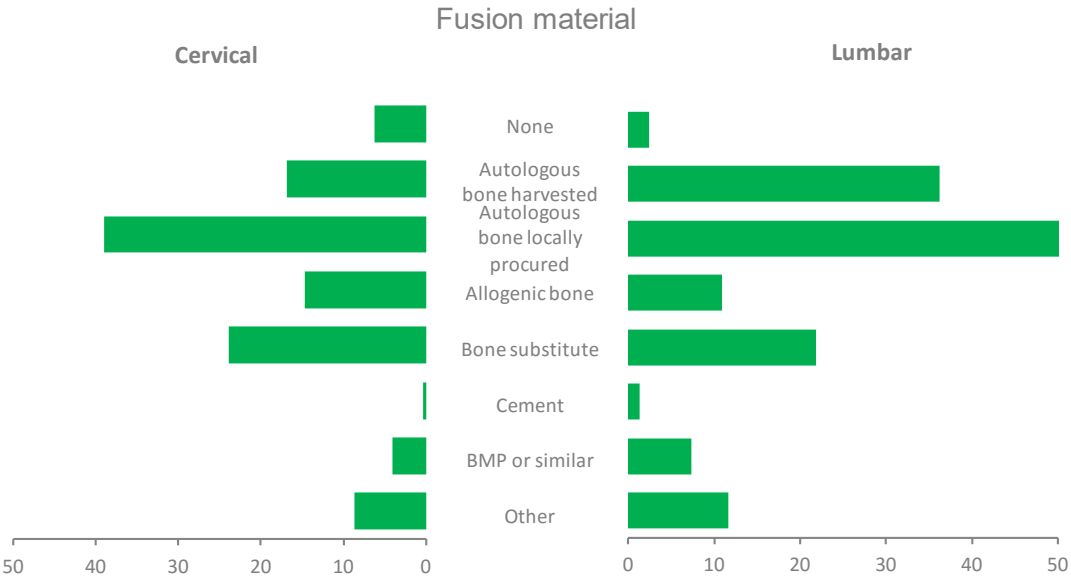

Figure 28: Specification of fusion material, surgery form version 2011 (N=35’244)

Surgical Measures Subform

Surgical complications are divided into intraoperative complications and complications occurring during the hospitalization before discharge.

Intraoperative complications

For intraoperative complications, which are shown in figure 29, dural tear remained the most frequent complication at 4.8%. This is almost unchanged compared with the last annual report. No intraoperative surgical complications occurred in 94% of cases, and in 0.3% complications were not documented.

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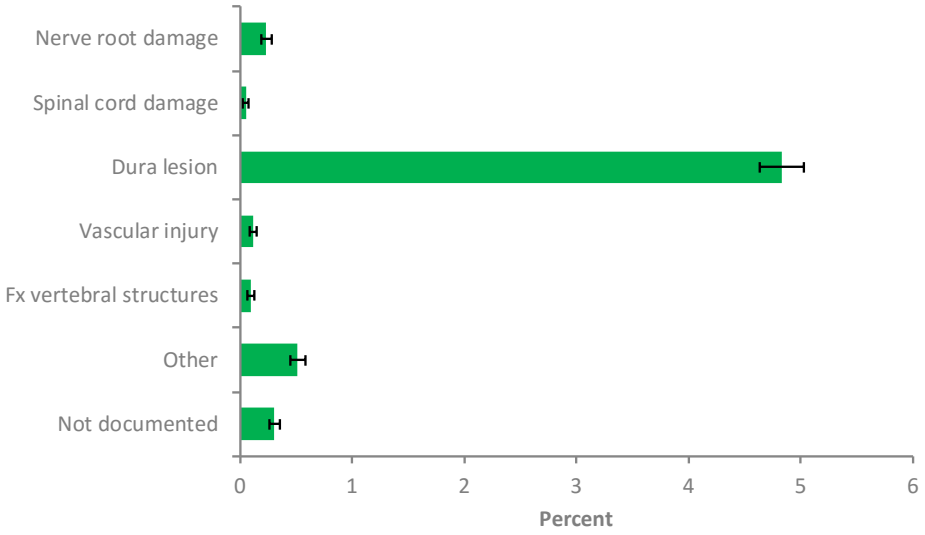

Figure 29: Distribution of intraoperative surgical complications, excluded was the answer "none", surgery form version 2011 (N=43'841)

Hospital Stay Subform

Surgical complications before discharge

Postoperative complications that occurred during hospitalization are shown in figure 30.
Their distribution is very stable over time. The most frequent complications were motor dysfunction (0.8%), sensory dysfunction (0.8%), 'other' complications (0.8%) and radiculopathy (0.5%). Even though a dural tear was the most frequent complication during surgery, a CSF leak/ pseudomeningocele occurred in only 0.4% of cases. In 95.1% of cases no postoperative complications occurred and in 0.6%, complications before discharge were not documented.

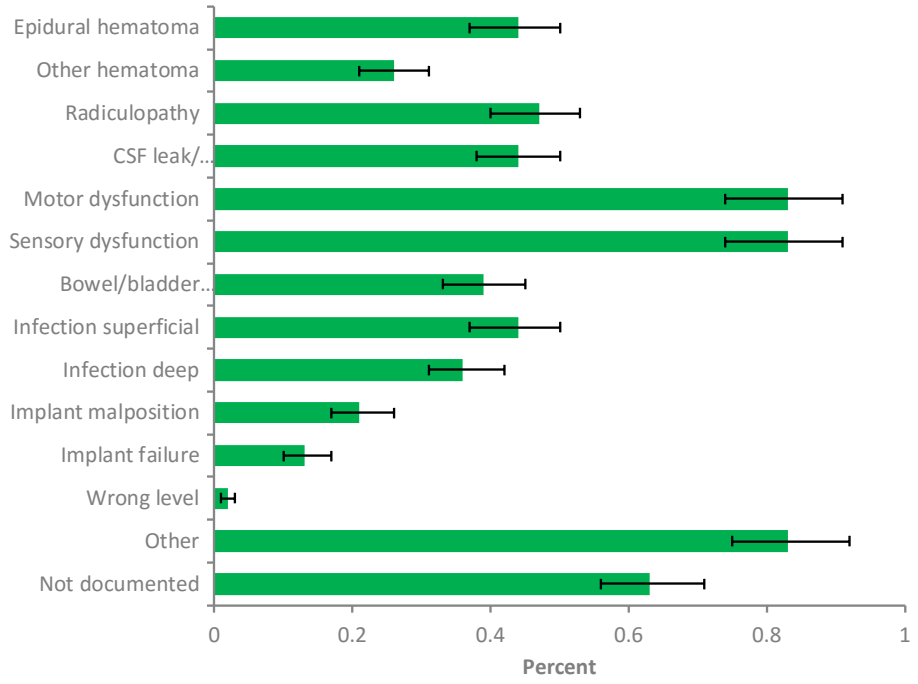

Figure 30: Distribution of surgical complications before discharge, excluded was the answer "none", surgery form version 2011 (N=43'841)

Hospital Stay Subform

Status of complications

The status of complications at discharge refers to all cases with an intra and/or postoperative complication during the hospitalization. Overall, 3’865 cases with complications were documented. In 64.8% of those cases the complications were resolved before discharge, and in 6.7% they persisted.
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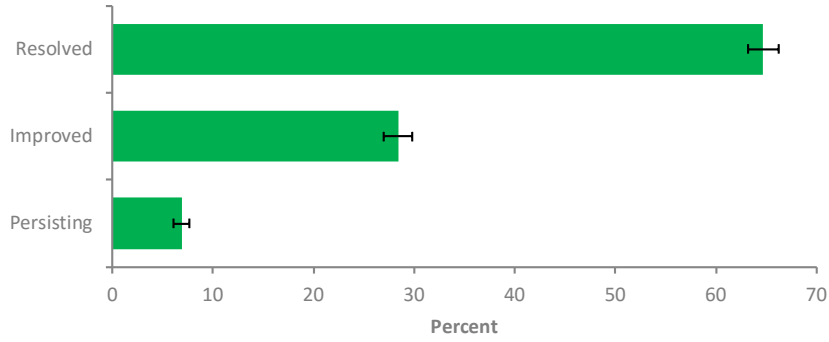

Figure 31: Status of complications at discharge for patients with an intraoperative complication and/ or a complication before discharge; form version 2011 (N=3’865)

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 or 3 months after surgery. The literature suggests that at least the mid-term outcomes at three months give a reliable indication of the final outcome (4, 15). 6-month, and 1-year or longer follow-ups are strongly recommended, but remain a major challenge of any routine care registry. The current mean follow-up time for the physician-based follow-up form is 6 months.

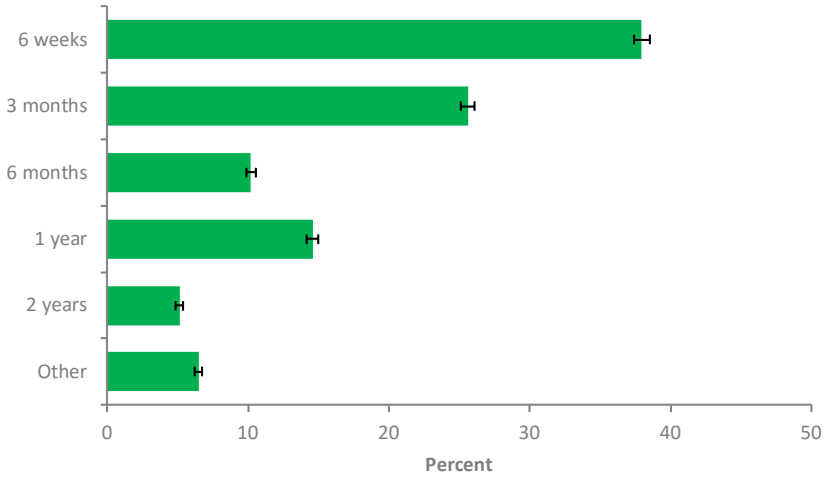

Figure 32: Distribution of followup interval; followup form version 2011 (30'513 forms for 18'373 patients)

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

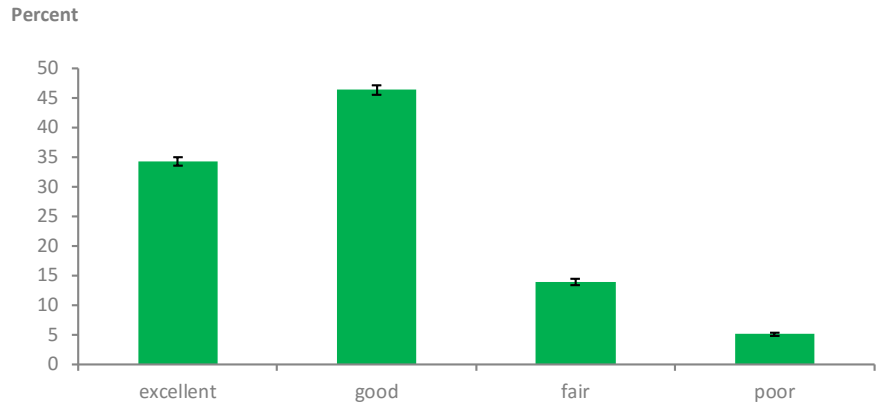

Figure 33: Physician based overall outcome (surgeon); follow-up form version 2011 (N=30'513)

If we collapse the 4-point surgeon based outcome rating into a binary format, approximately 4 out of 5 cases have a desirable outcome for elective surgery (excellent or good), while 1 out of 5 cases do not (fair or poor).

Follow-up Form

Surgical goals – pain relief and functional improvement

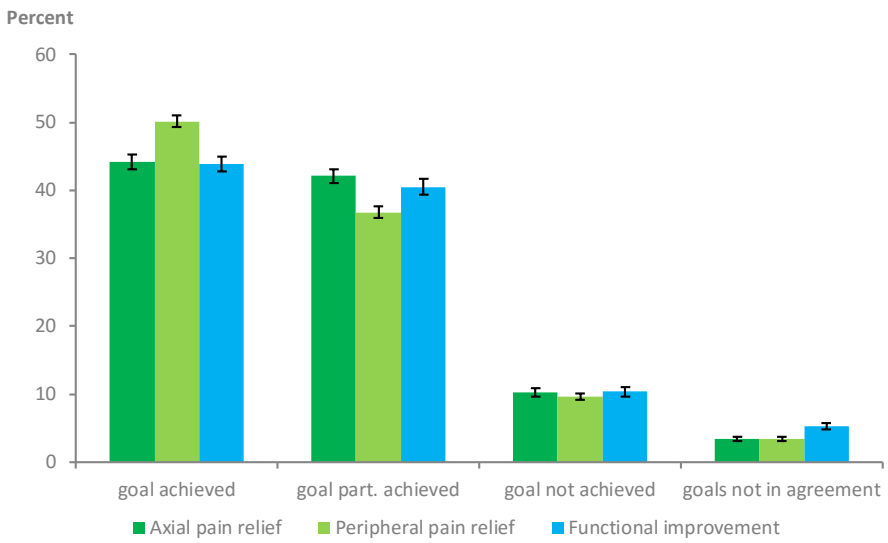

Figure 35: Achievement of the surgical goals axial (N=8‘878) and peripheral (N=13‘152) pain relief and functional improvement (N=7‘643); followup form version 2011

The three most frequent therapeutic goals of surgery are peripheral pain relief, axial pain relief and functional improvement. The above figure shows the extent to which these goals are achieved. Peripheral pain relief is the goal most commonly achieved. In about half of all cases the surgeons indicate complete goal achievement and in just under 40%, at least partial achievement. Axial pain relief and functional improvement are slightly more difficult to achieve, although these goals are still completely or partially achieved in more than 80% of patients for whom they were relevant. In about 10% of patients, none of the goals are achieved.

Follow-up Form

Surgical goals – neurological improvement / additional goals

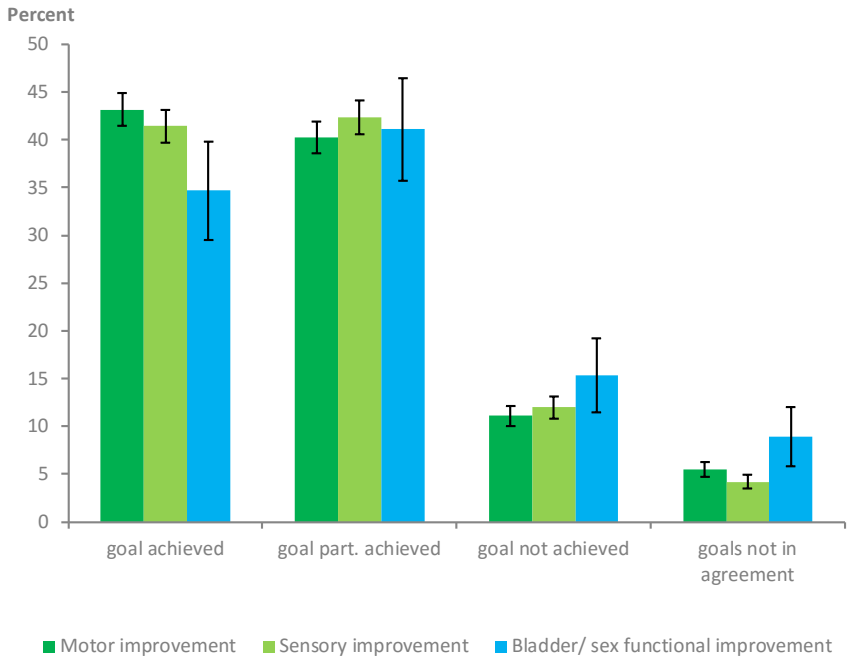

Figure 36: Achievement of the surgical goals motor improvement (N=3'330), sensory improvement (N=3'101) and bladder/sex function improvement (N=326); followup form version 2011

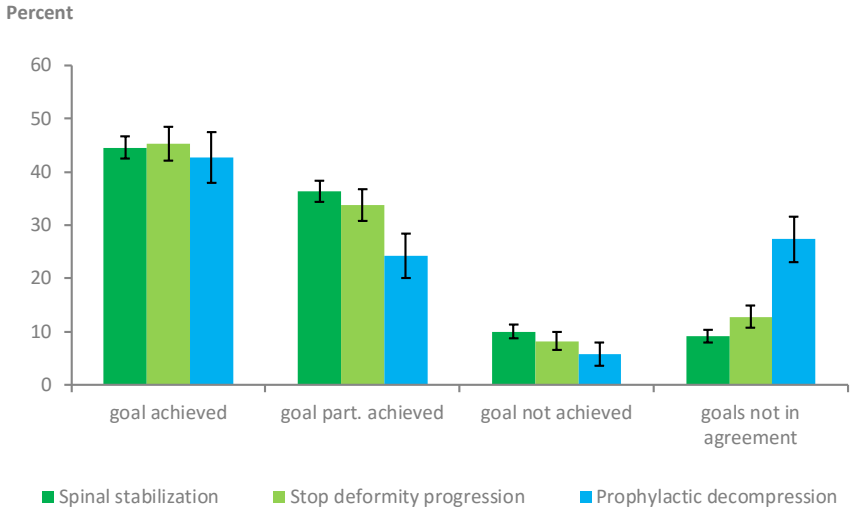

Figure 37: Achievement of additional surgical goals (spinal stabilization (N=2'177), stop deformity progression (N=943) and prophylactic decompression (N=413); followup form version 2011

PART II: The Spine Tango Benchmarking Project (surgical complications)

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 safe?" is also of outmost importance, even for the most efficacious or effective treatments. Patients and payers are very interested in the safety of a therapy per se, but also in the hands of an individual healthcare provider. Some therapies may be generally safe or unsafe, whereas others may show a larger variation of complication rates between centres. Disc herniation and spinal stenosis, which make up about two thirds of all degenerative diseases recorded with Spine Tango, as well as degenerative spondylolisthesis have each been assessed regarding perioperative (intra- and postoperative prior to discharge) surgical complications using funnel plots, stratified by location in the spine and type of surgery. **No further case mix adjustments were made, such as for the extent of surgery or number of previous surgeries.** This second part of the 2015 annual report highlights the most frequently seen treatments for these pathologies — decompression alone and decompression with instrumented fusion — and their associated complication rates.

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.

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 enquired about surgical complications without discriminating between the time of occurrence (intraoperative or postoperative), 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 lumbar disc herniation, degenerative spondylolisthesis, and spinal stenosis (Table 1). The definition of cervical diagnosis groups is under work yet. 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 centres 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 rates with 95% confidence intervals (funnel) are shown.

Results

Cervical disc herniation treated with decompression and instrumented fusion
2`872 patients from 35 hospitals were included in the analysis (Fig. 38). The average perioperative surgical complication rate was 2.6%. The proportion of incidental dural tears was 0.7%. The surgery appears to be generally safe regarding perioperative surgical complications with essentially no outlier hospitals. Higher variation between low caseload-hospitals can be anticipated due to heterogeneity in case mix.

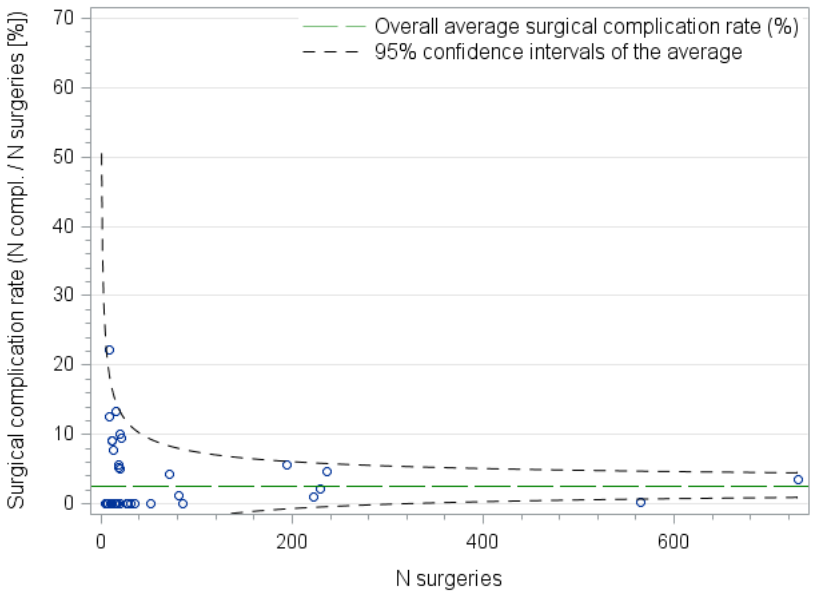

Figure 38: Cervical disc herniation treated with decompression and instrumented fusion.

Cervical spinal stenosis treated with decompression and instrumented fusion

385 patients from 17 hospitals were included in the analysis (Fig. 39). The average perioperative surgical complication rate was 11.7%. The average complication rate for this procedure and underlying pathology is much higher compared with disc herniation. The proportion of incidental dural tears was 1.6%, and hence does not explain the overall higher surgical complication rate. The most frequent surgical complication type was motor or sensory dysfunction (3.7%).

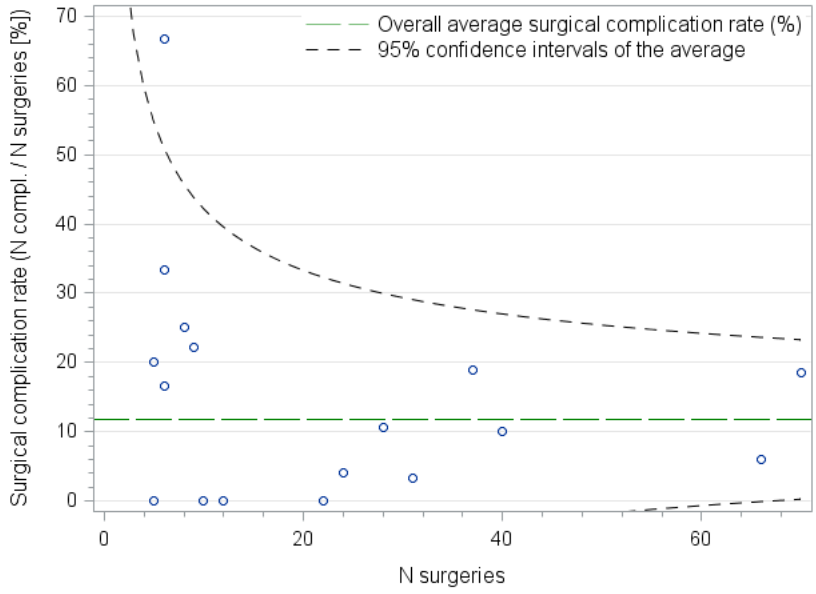

Figure 39: Cervical spinal stenosis treated with decompression and instrumented fusion.

Cervical spinal stenosis treated with decompression alone

779 patients from 14 hospitals were included in the analysis (Fig. 40). The average perioperative surgical complication rate was 4.7%, which is lower than that for decompression with instrumented fusion for the same main pathology. The proportion of incidental dural tears was 0.9%.

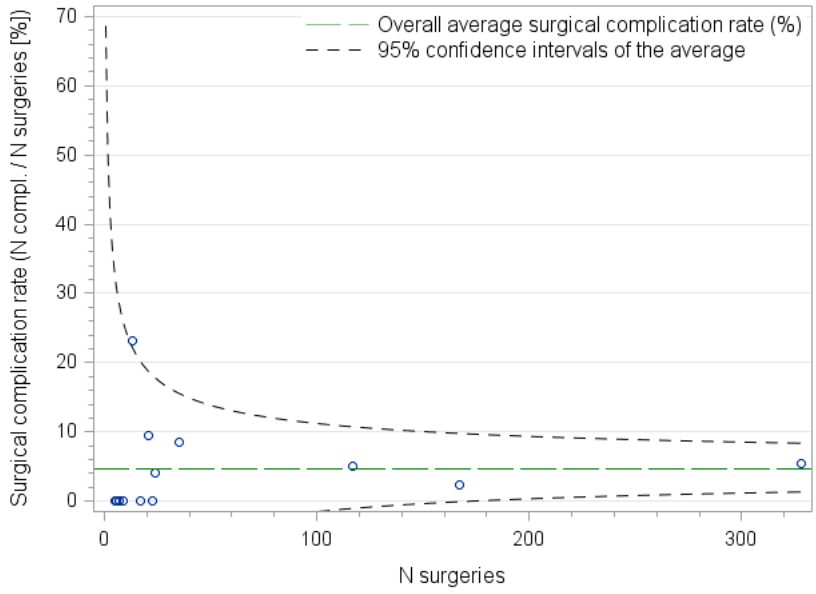

Figure 40: Cervical spinal stenosis treated with decompression alone.

Lumbar disc herniation treated with decompression alone

16`431 patients from 63 hospitals were included in the analysis of this most frequent pathology and type of surgery (Fig. 41). The average perioperative surgical complication rate was 4.6% and almost all hospitals were inside the average with 95% confidence intervals with three close-to-average outliers. The proportion of incidental dural tears was 3.2%. The procedure seems to show no relevant differences between the various participating centres and surgeons.

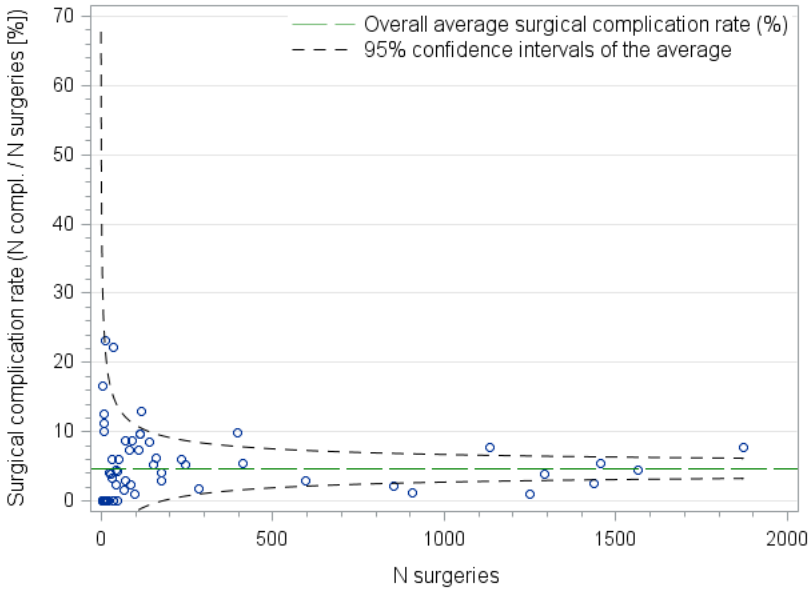

Figure 41: Lumbar disc herniation treated with decompression alone.

Lumbar degenerative spondylolisthesis treated with decompression alone

1`674 patients from 32 hospitals were included in the analysis (Fig. 42). With an average 12.2% of surgical complications, this pathology and surgery is most prone to surgical complications. Their clinical relevance may be less dramatic and this needs to be analysed in detail to allow meaningful interpretation. A relatively high rate of incidental durotomy of 9.0% is documented in this subgroup, which is known for this pathology. However, variation of complication rates was considerable.

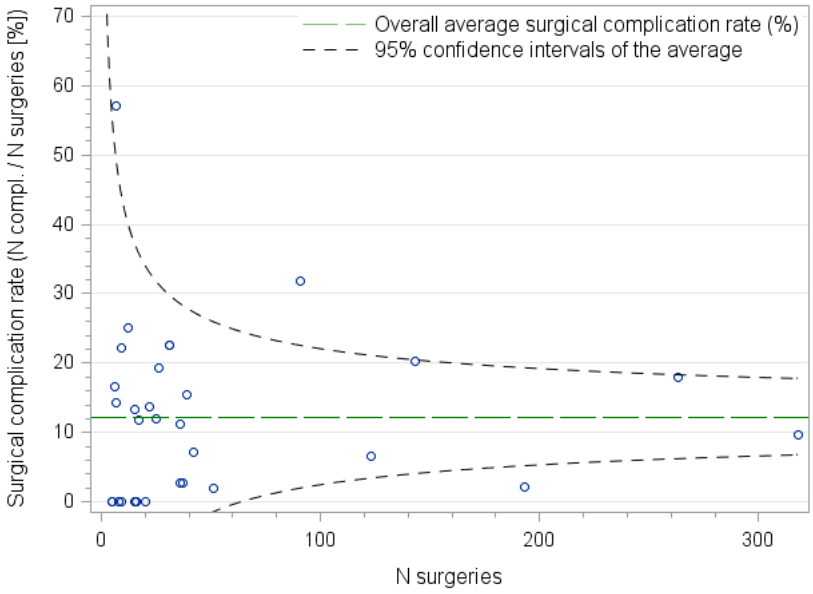

Figure 42: Lumbar degenerative spondylolisthesis treated with decompression alone.

Lumbar degenerative spondylolisthesis treated with decompression and instrumented fusion
3'559 patients from 49 hospitals were included in the analysis (Fig. 43). With an average 9.4% of perioperative surgical complications, this procedure displayed slightly lower complication rates than for simple decompression alone, which appeared to be mostly the result of a lower rate of incidental durotomy (5.1%). Kleinstück et al. (Eur Spine J. 2012 Feb;21(2):268-75) compared fusion and decompression for this pathology. They interpreted the higher incidental durotomy rate in the decompression group as follows: Possible reasons for the slightly higher rate of intra/perioperative complications in the decompression group might include the greater age and slightly greater comorbidity of the patients, and the fact that decompression surgery without fusion is carried out with less resection of the bony elements and hence in a more limited space than in decompression and instrumented fusion, where (because fusion is being added anyway) the exposure is usually more generous and resection can be performed more liberally without the risk of causing increased instability.

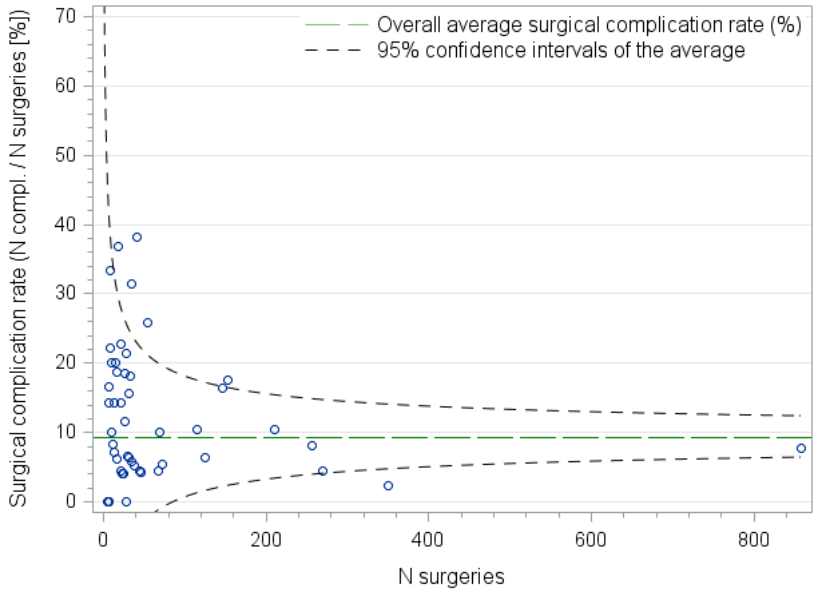

Figure 43: Lumbar degenerative spondylolisthesis treated with decompression and instrumented fusion.

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

12`766 patients from 55 hospitals (decompression alone) and 2`634 patients from 43 hospitals (decompression and instrumented fusion) were included in the analysis (Figs. 44, 45). Complication rates were identical at 10.1%. However, the rate of incidental dural tears was higher after decompression alone (7.8%) than after decompression and instrumented fusion (5.3%). Also, more hospital outliers were observed after decompression alone representing both higher and lower than average rates.

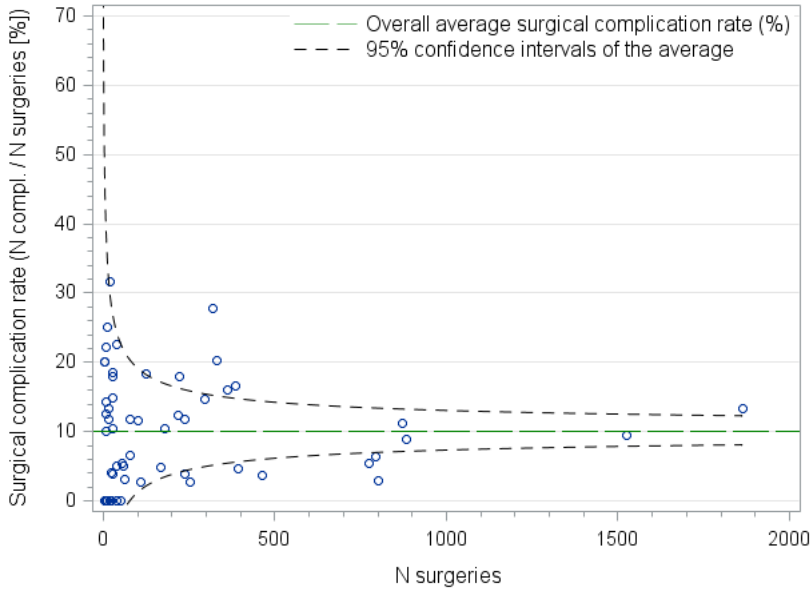

Figure 44: Lumbar spinal stenosis treated with decompression alone.

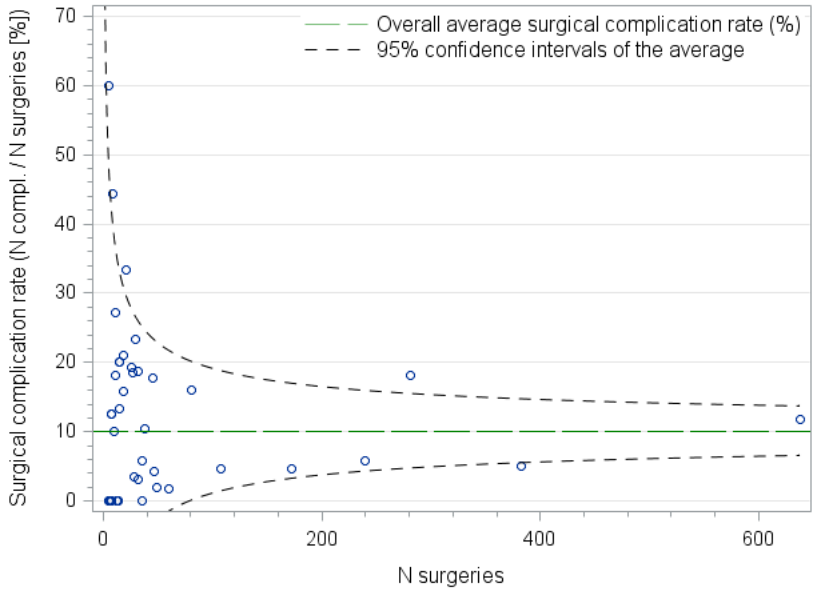

Figure 45: Lumbar spinal stenosis treated with decompression and instrumented fusion.

PART III: Trends in spine surgery

Introduction

The idea of looking at trends over the years in various patient characteristics and surgical procedures is becoming increasingly popular. After 11 years of Tango data collection with reasonably high annual numbers we therefore sought to carry out some initial trend analyses. We chose four of the most frequently documented degenerative diagnoses (lumbar spinal stenosis without spondylolisthesis, lumbar degenerative spondylolisthesis, and lumbar and cervical disc herniation) and analysed the trends in patient age, proportion of female patients, length of hospital stay, fusion, motion preserving stabilization, surgical complications, average axial and peripheral pain relief, and COMI score.

The observation period was from 2005 to 2015, inclusive (11 years). Annually, on average 1546 patients with one of the four aforementioned diagnoses from an average of 20 departments were documented. The average annual follow-up rate for COMI (one baseline and at least one postoperative COMI) was 46%.

We do not present the p-values for the trends, as the majority of the trends were statistically significant, and since we consider the clinical importance to be higher than the statistical significance of the observed differences.

Any interpretation of the trend analyses should be carried out with caution, since the coverage of the pooled data is unknown and many other annual differences, such as the number and type of hospitals contributing data, patient and treatment characteristics of the contributed cases etc., may explain the variation.

Patient age

The Figure 46 demonstrates a slight decrease (of approx. 4 years during the 11 years of observation) in patient age in LSS without spondylolisthesis and in lumbar degenerative spondylolisthesis, and a slight increase (approx. by 4 years) in patient age in cervical disc herniation. Patient age in lumbar disc herniation was relatively stable. Interestingly, patients with LSS without spondylolisthesis and in lumbar degenerative spondylolisthesis had a very similar average age of between 65 and 70 years over the whole period of observation. For both lumbar and cervical disc herniation the average age was approximately 50 years.

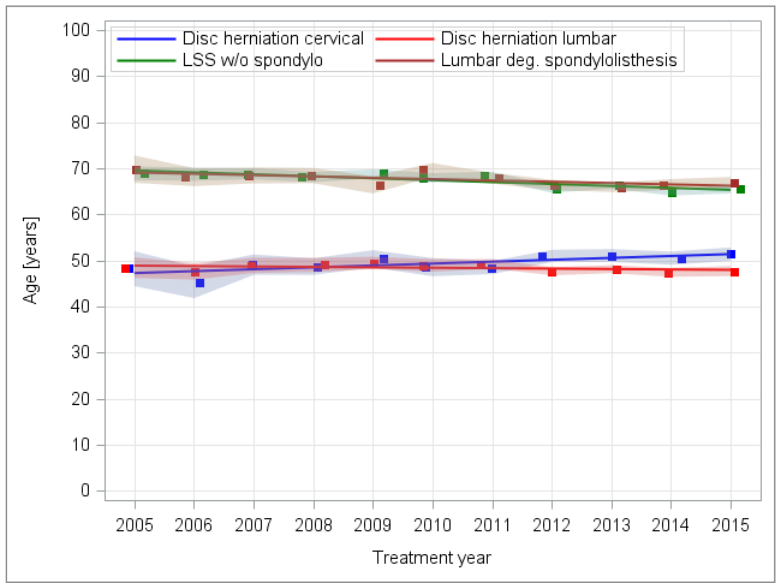

Figure 46. Trends in patient age (regression line, and 95% confidence intervals [95%CI] as a transparent band)

Patient sex

The proportion of female patients was relatively stable for all four diagnoses although there were slight trends (<=10%) for an increase in lumbar disc herniation and decrease in LSS without spondylolisthesis.

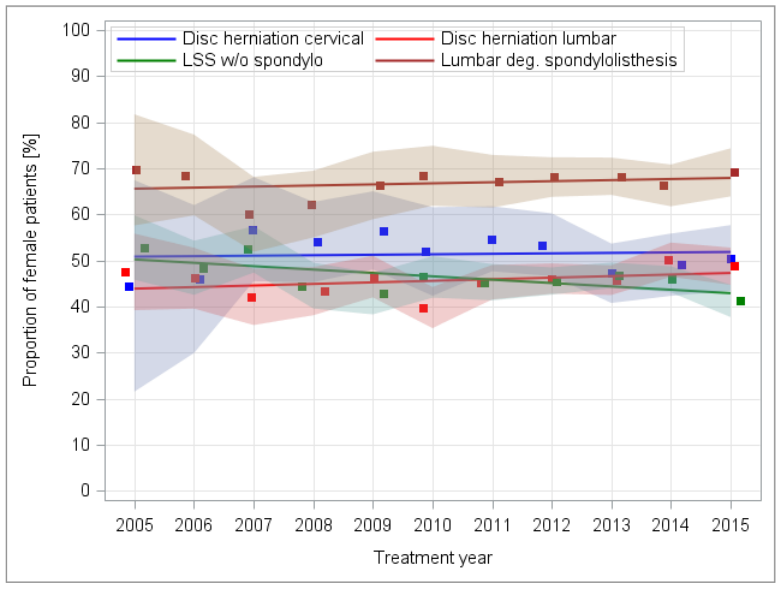

Figure 47. Trends in proportions of female patients (regression line, and 95%CI as a transparent band)

Length of hospital stay

The was a clear decrease in length of hospital stay for all four diagnoses. The two largest decreases took place in lumbar deg. spondylolisthesis and LSS without spondylolisthesis (between on average 12 days in 2005 and 6 days in 2015 and between 11 days in 2005 and 4 days in 2015, respectively). The length of hospital stay after a disc herniation reduced from 6 days in 2005 to 3 days on average in 2015 for both cervical and lumbar surgery.

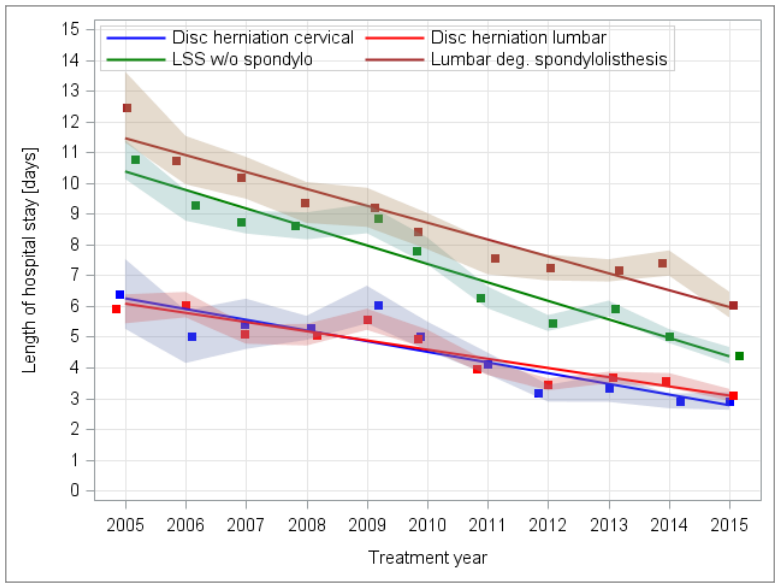

Figure 48. Trends in length of hospital stay (regression line, and 95%CI as a transparent band)

Treatment

The rates of fusion procedures for cervical disc herniation increased markedly from 50% in 2005 to 92% in 2015. Over the same time period, fusion procedures for LSS without spondylolisthesis decreased from 35% to 10%, while the rates for lumbar disc herniation (5% on average) and lumbar degenerative spondylolisthesis (65%) were rather stable.

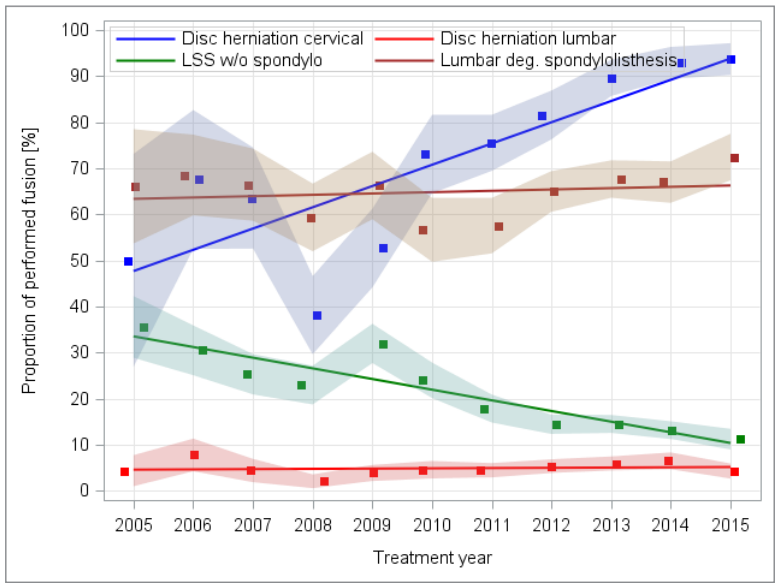

Figure 49. Trends in rates of fusion procedures (regression line, and 95%CI as a transparent band)

There was a notable decrease in the rate of motion preserving stabilisation used to treat cervical disc herniation from 45% in 2005 to 5% in 2015, and there was a slight trend for this type of treatment to increase over the same time period from 0.5% to 4% in LSS without spondylolisthesis. No visible trend was seen for motion preserving stabilisation in lumbar disc herniation and lumbar degenerative spondylolisthesis.

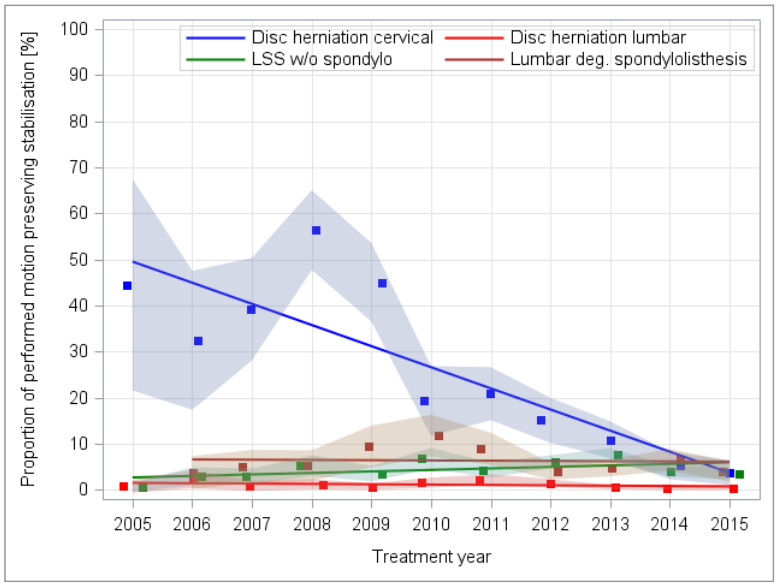

Figure 50. Trends in rates of motion preserving stabilisation (regression line, and 95%CI as a transparent band)

Complications

No visible trend was recognizable for annual surgical complication rates. The treatment of lumbar degenerative spondylolisthesis and LSS without spondylolisthesis was associated with an average surgical complication rate of approximately 10%; for lumbar disc herniation the figure was 5% and for cervical disc herniation, 3%.

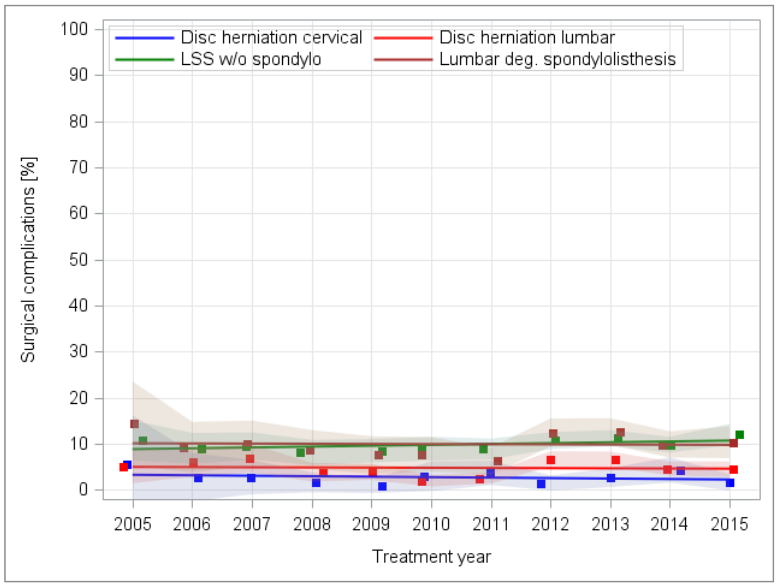

Figure 51. Trends in surgical complication rates (regression line, and 95%CI as a transparent band)

Axial and peripheral pain and COMI score

There was a visible increase in the average intensity of baseline axial pain (four upper regression lines) and a slightly less steep increase in its relief (four lower regression lines) in patients undergoing surgery for LSS without spondylolisthesis, degenerative spondylolisthesis and lumbar disc herniation. The cervical disc herniation group showed an increase in the average intensity of axial pain at baseline accompanied by a slight trend for a decrease in its relief. This latter observation is rather worrying.

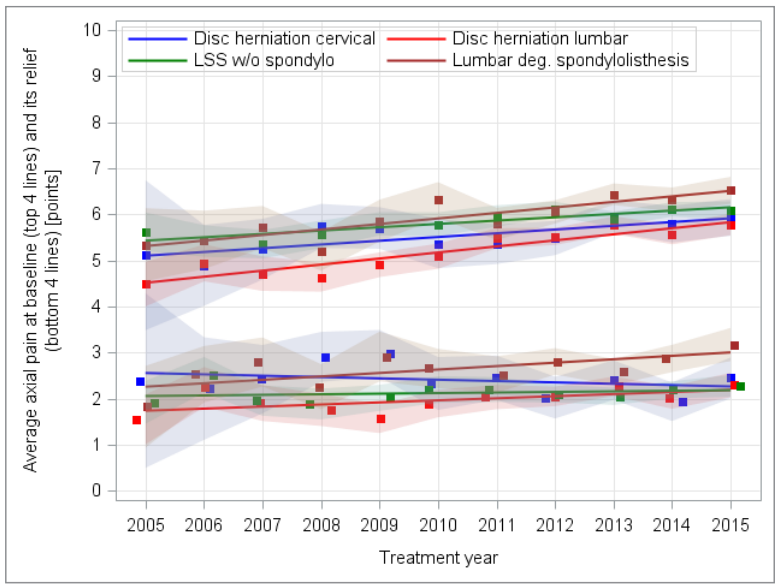

Figure 52. Trends in baseline value and in relief of axial pain (regression line, and 95%CI as a transparent band)

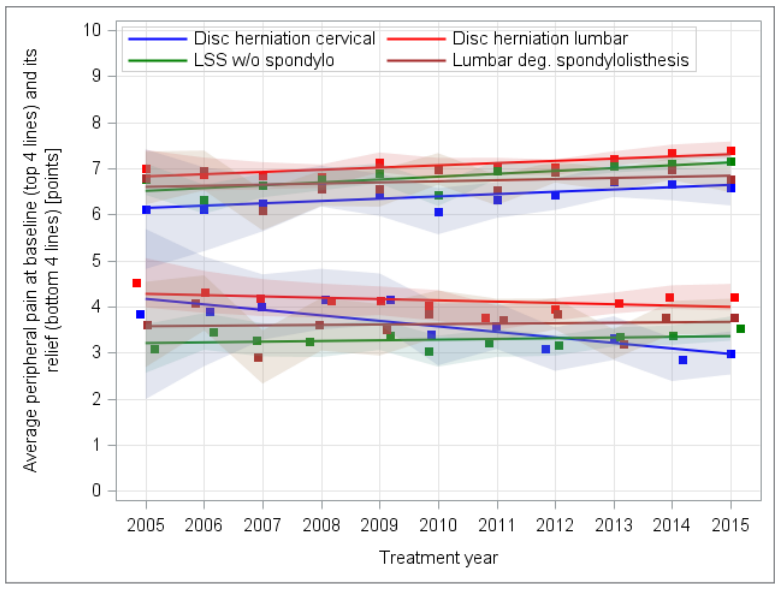

Figure 53. Trends in baseline value and in relief of peripheral pain (regression line, and 95%CI as a transparent band)

There was a visible increase in the average intensity of baseline peripheral pain (four upper regression lines) and a stable behaviour for its postoperative relief (four lower regression lines) for LSS without spondylolisthesis and for degenerative spondylolisthesis. The lumbar disc herniation group showed an increase in the average intensity of peripheral pain at baseline accompanied by a slight trend for a decrease in its relief. The cervical disc herniation group showed an increase in the average intensity of peripheral pain at baseline accompanied, however, by a clear trend for a decrease in its relief (between 4.2 point in 2005 and 3.0 points in 2015), which is worrying.

The values for the COMI at baseline (four upper regression lines) were stable over time for all diagnoses, except for a slight decrease in patients with cervical disc herniation. However, while the postoperative improvement (four lower regression lines) in COMI score was relatively stable over time for LSS without spondylolisthesis and for degenerative spondylolisthesis, it decreased by about 1 point for lumbar disc herniation, and by almost 2 points for cervical disc herniation (i.e. showed less improvement by these amounts) over the years.

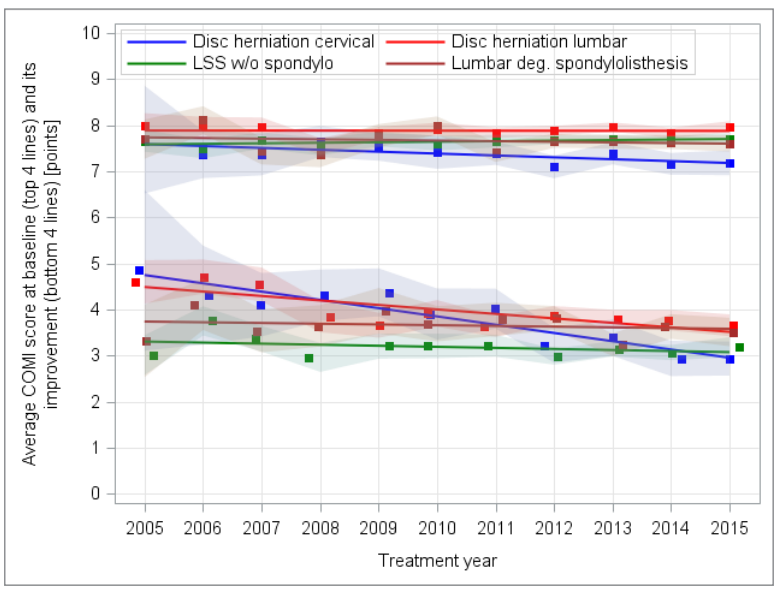

Figure 54. Trends in baseline value and in improvement of COMI (regression line, and 95%CI as a transparent band)

In summary, for the four diagnoses under investigation, the observed trends demonstrate a relatively stable patient collective in terms of patient age and sex, and a clearly decreased length of hospital stay. The considerable increase in the rate of fusion procedures and decrease in motion preserving procedures in cervical disc herniation is accompanied by a higher preoperative axial and peripheral pain, but shows a slight reduction of axial pain relief, and a marked reduction of peripheral pain relief and of COMI score improvement over time. The reduction over time in the rate of fusion procedures for LSS without spondylolisthesis is associated with a reduction in general complication rates. In lumbar disc herniation, there appears to be a slight reduction in the extent of peripheral pain relief and in COMI score improvement over the years, with no visible trend in relation to the proportion of fusion procedures carried out. In degenerative spondylolisthesis, there were clear trends for a decrease in general complication rates and an increase in axial pain relief.

Participants / Modules

Figure 55 displays the cumulative growth curves of the 9 national modules and the international module. The different starting dates (including retrospectively migrated data) of the modules need to be considered (Austria 2005; International 2005; Switzerland 2005; Germany 2006; Panamerica 2006; Italy 2008; Belgium 2008; Great Britain 2010; Australia 2010; Poland 2010). The Polish module was launched in 2013, but due to migration of active users from the international module there is data from 2010 onwards in the Polish module database. A similar situation exists for the Belgian module which was launched in 2014, but the data from Belgian hospital are available since 2008 onwards. 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.

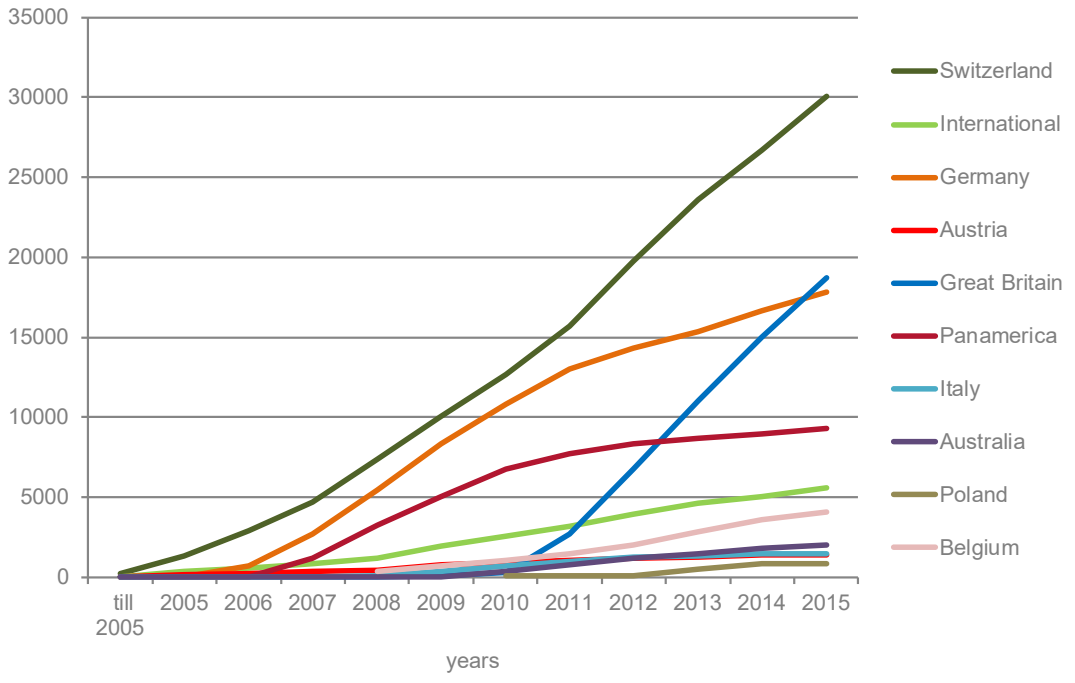

Figure 55: Growth curves (number of cases of the single Spine Tango modules over the years)

The hospital classification of all active 59 Spine Tango departments actively documenting in 2015 can be seen in figure 55. The highest proportion is made up by university or teaching hospitals with approximately 42%.

Figure 56 shows an overview of the Spine Tango participating hospitals and their country of origin until the end of 2015. We stratified their submitted forms into primary forms, surgeon follow-up forms and COMI forms.

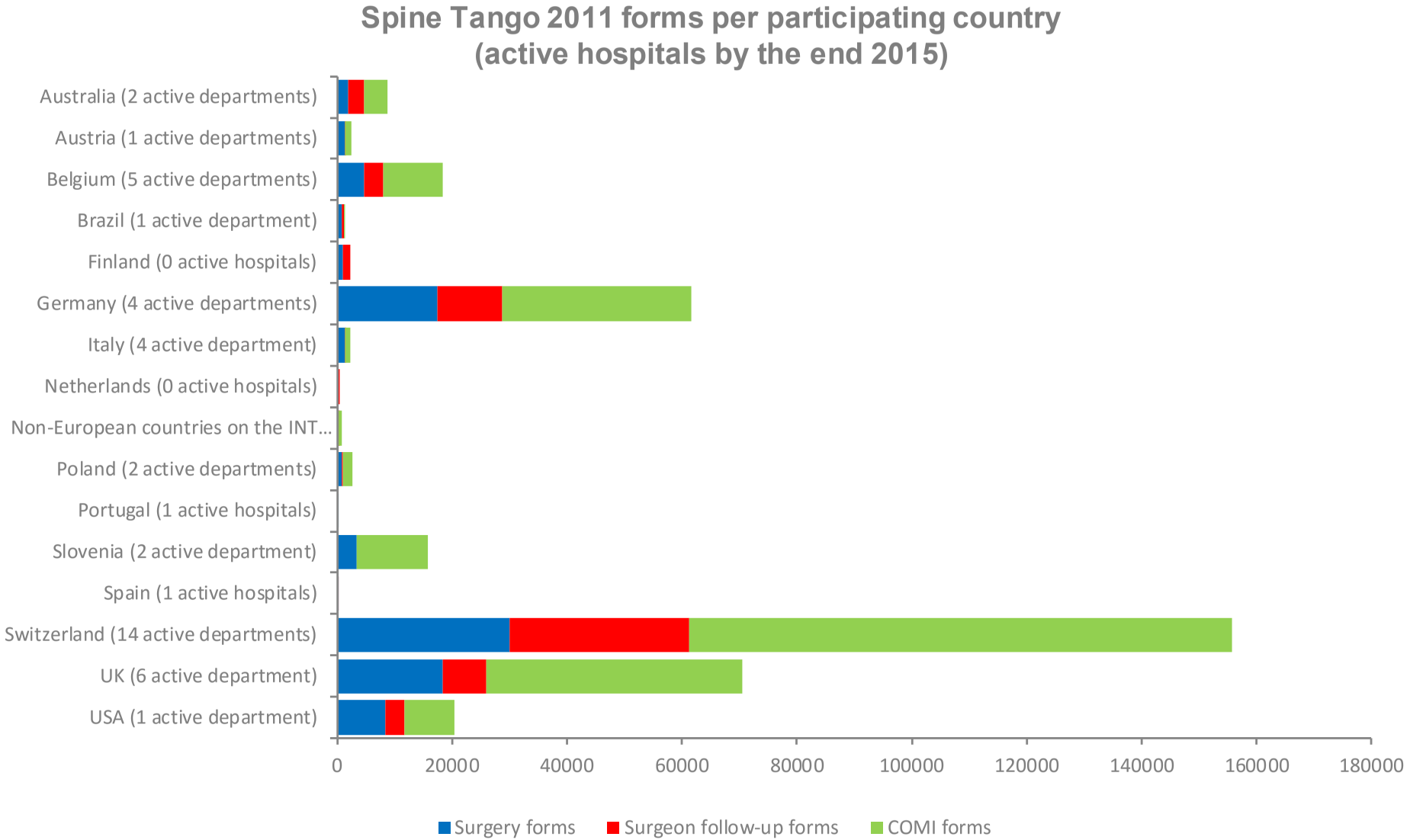

Figure 56: Overview of the Spine Tango participating hospitals according to their country of origin with case load divided into primary forms 2011, follow-up forms and COMI forms until the end of 2015

Forms used in Spine Tango Registry - 01.08.2015		multilingual	online available: english	online available: german	online available: french	online available: italian	online available: spanish	online available: polnish	OMR paper forms available: english	OMR paper forms available: german	OMR paper forms available: french	OMR paper forms available: italian	OMR paper forms available: spanish	OMR paper forms available: portuguese	OMR paper forms available: turkish	OMR paper forms available: polish	OMR paper forms available: greek	OMR paper forms available: dutch	OMR paper forms available: 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 2015

Papers in peer reviewed Journals

Rischke B, Zimmers KB, Smith E.
Viscoelastic Disc Arthroplasty Provides Superior Back and Leg Pain Relief in Patients with Lumbar Disc Degeneration Compared to Anterior Lumbar Interbody Fusion.
Int J Spine Surg. 2015 Jul 1;9:26.

Röder C, Baumgärtner B, Berlemann U, Aghayev E.
Superior outcomes of decompression with an interlaminar dynamic device versus decompression alone in patients with lumbar spinal stenosis and back pain: a cross registry study.
Eur Spine J. 2015 Oct;24(10):2228-35.

Pochon L, Kleinstück FS, Porchet F, Mannion AF.
Influence of gender on patient-oriented outcomes in spine surgery.
Eur Spine J. 2016 Jan;25(1):235-46.

Reinshagen C, Ruess D, Molcanyi M, Redjal N, Walcott BP, Goldbrunner R, Rieger B.
A novel translaminar crossover approach for pathologies in the lumbar hidden zone.
J Clin Neurosci. 2015 Jun;22(6):1030-5.

Burkhardt JK, Mannion AF, Marbacher S, Kleinstück FS, Jeszenszky D, Porchet F.
The influence of cervical plate fixation with either autologous bone or cage insertion on radiographic and patient-rated outcomes after two-level anterior cervical discectomy and fusion.
Eur Spine J. 2015 Jan;24(1):113-9.

Munting E, Röder C, Sobottke R, Dietrich D, Aghayev E.
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. 2015 Feb;24(2):358-68.

Lattig F, Fekete TF, Kleinstück FS, Porchet F, Jeszenszky D, Mannion AF.
Lumbar facet joint effusion on MRI as a sign of unstable degenerative spondylolisthesis: should it influence the treatment decision?
J Spinal Disord Tech. 2015 Apr;28(3):95-100.

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