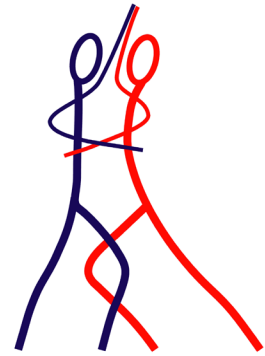# SPINE TANGO  Report
## International 2013

EURO
SPINE

The International Spine Registry
**EuroSpine**

C. Röder, E. Aghayev, E. Munting, T. Pigott, R. Sobottke, A. Mannion, N. Parli

# CONTENTS

2

*Contact:*

*University of Bern*
*Institute for Evaluative Research in Medicine*
*Christoph Röder, MD MPH*
*Stauffacherstr. 78*
*CH-3014 Bern*
*christoph.roeder@memcenter.unibe.ch*

This annual report is digitally available in the literature section of the Spine Tango web page under
www.eurospine.org

# 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. 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 a decade ago by Dieter Grob and Max Aebi, under the auspices of SSE. There has been considerable investment of clinician, academic and financial resource to develop and improve the system. Having achieved international recoginition 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 2-year pilot of a national spine registry using the Spine Tango technology and content as its platform. In 2013 Polish and Belgian Spine Tango modules were launched.

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 two years have seen a significant increase in data entry and a consequent rise in the number of presentations related to this.

Surgeon level data reporting is now a reality in the United Kingdom and is likely to spread to the rest of Europe. 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

$u^b$

UNIVERSITÄT BERN

MEM Research Center

3

## PROFILE

**4**

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 will become available in its already second version in 2015, after a comprehensive field and reliability study. Also, the two new specialist add-on questionnaires for adolesecent scoliosis and degenerative deformities do now 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. 2004 December; 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. 2011 March; 20(3): 369–379.

## REGISTRIES VERSUS RANDOMIZED CONTROLLED TRIALS (RCT)

| | RCT | Registry |
|---|---|---|
| Type of evidence | Efficacy | Effectiveness*, safety |
| Principal question | Can it work? <br> The first step of evidence generation | Does it work? <br> 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)

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
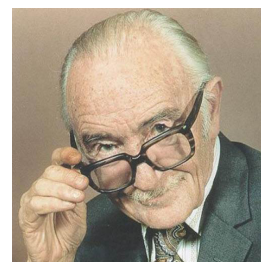
## NEW DEVELOPMENTS

Interfacing clinic information systems with the MEMdoc webservice or webservice client interfaces makes possible importing data like patient demographics or certain clinical or surgical details. In most cases, filling in a complete Spine Tango subform in this automated way is not possible. Consequently, a mechanism for incomplete saving of subforms was introduced, which is also available for the online data entry mode by hand. In case of unknown answers or an interruption of the documentation activity the users can now press a new button "save incomplete" and return to the respective subform later. Only when it is complete, the usual button "save" is pressed which will not only activate the validation but also the completeness check and report errors or missing answers.

**New formlist formats:** the active users may have already seen that the formlists summarizing the key information of each form have been populated with more info. In addition, outcome and pain score values can also be displayed now. The "mouse-over" will display the original question to the listed answer, e.g. "Main Pathology" - degenerative disease. The idea is to have all essential information of a case and its history visible on the formlist so that it can be read like a short summary without having to open up the form itself anymore. If you haven`t seen it yet, log-in and find out!

6

**Form list: 8 form(s)**

Sort by [Intervention date ▾] ▲          [➕ E-Form] [🗎 OMR Form]

Add form to case ➕ 🗎 ⊙

| | | | | | |
|---|---|---|---|---|---|
| 🔒 | 1 | **Core Outcome Measures Index** | | 8 | ✏ 🖶 ▲ |
| | | Neck | | 2 | |
| | | 30.05.2013 | | 7.6 | |
| | | before surgery | | | |

| | | | | | |
|---|---|---|---|---|---|
| 🔒 | 1 | **Neck Disability Index** | | 62.0 | ✏ 🖶 ▲ |
| | | NDI | | | |
| | | 30.05.2013 | | | |
| | | before surgery | | | |

| | | | | | |
|---|---|---|---|---|---|
| 🔒 | 1 | **SPINE TANGO** | degenerative disease | | ✏ 🖶 ▲ |
| | | Surgery 2011 | 1 | | |
| | | | peripheral pain relief; motor | | |
| | | mid lower cervical | improvement; functional | | |
| | | | improvement | | |
| | | 01.06.2013 | uncoforaminotomy | none | |

| | | | | | |
|---|---|---|---|---|---|
| 🔒 | 1 | **SPINE TANGO** | 3 months | functional improvement; motor improvement; peripheral pain relief | ✏ 🖶 ▲ |
| | | Follow-up 2011 | not at work since OP | none | |
| | | mid lower cervical | excellent | none | |
| | | 16.09.2013 | NSAID, Paracetamol (WHO I) | | |

| | | | | | |
|---|---|---|---|---|---|
| 🔒 | 1 | **Neck Disability Index** | | 8.0 | ✏ 🖶 ▲ |
| | | NDI | | | |
| | | 16.09.2013 | | | |
| | | 3 months after surgery | | | |

| | | | | | |
|---|---|---|---|---|---|
| 🔒 | 1 | **Core Outcome Measures Index** | no | 2 | ✏ 🖶 ▲ |
| | | Neck | | 0 | |
| | | 16.09.2013 | very satisfied | 2.15 | |
| | | 3 months | helped a lot | | |

| | | | | | |
|---|---|---|---|---|---|
| 🔒 | 1 | **Core Outcome Measures Index** | no | 2 | ✏ 🖶 ▲ |
| | | Neck | | 0 | |
| | | 15.12.2013 | very satisfied | 1.9 | |
| | | 6 months | helped a lot | | |

| | | | | | |
|---|---|---|---|---|---|
| 🔒 | 1 | **Neck Disability Index** | | 8.0 | ✏ 🖶 ▲ |
| | | NDI | | | |
| | | 15.12.2013 | | | |
| | | 6 months after surgery | | | |

*Figure 1: An example of the new formlist appearence*

## APPLICATION

8

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.

**National and international study network:** the Tango is a technology backbone and currently networks about 45 active hospitals in Europe, North and South America, Australia and Asia. This provides a great opportunity 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".

## DATA ENTRY

There are 6 possible ways data can be transferred to the database (Figure 2):

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.
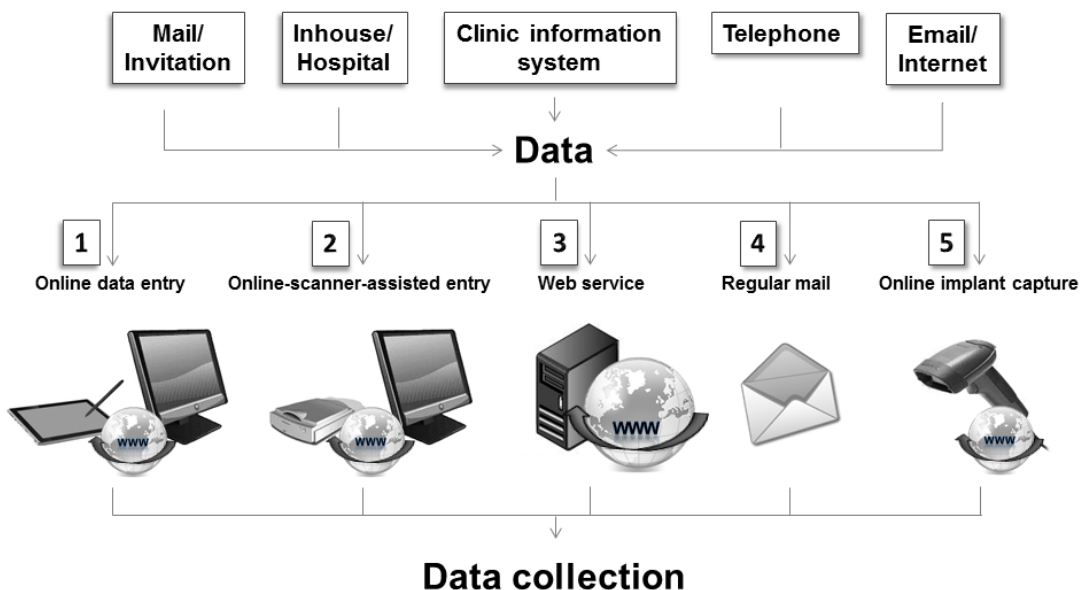
Figure 2: Spine Tango methods of data entry

## 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 3. 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 4 on the next page illustrates the ideal case of a completely documented treatment (6).

11

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
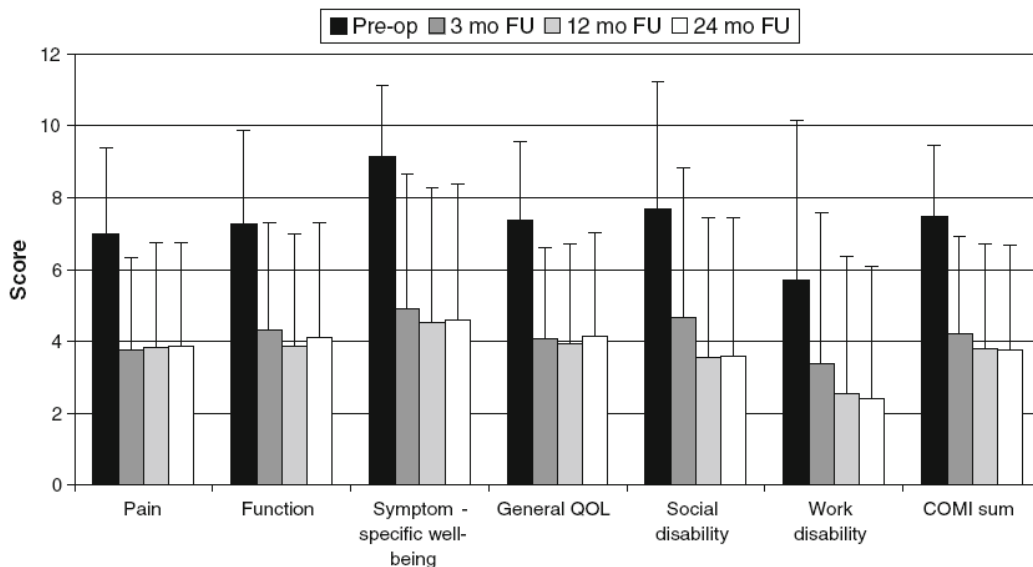
Figure 3: Patient based outcome documentation with the COMI (Core Outcome Measure Index) questionnaires, AF Mannion et al. (2009)(4)
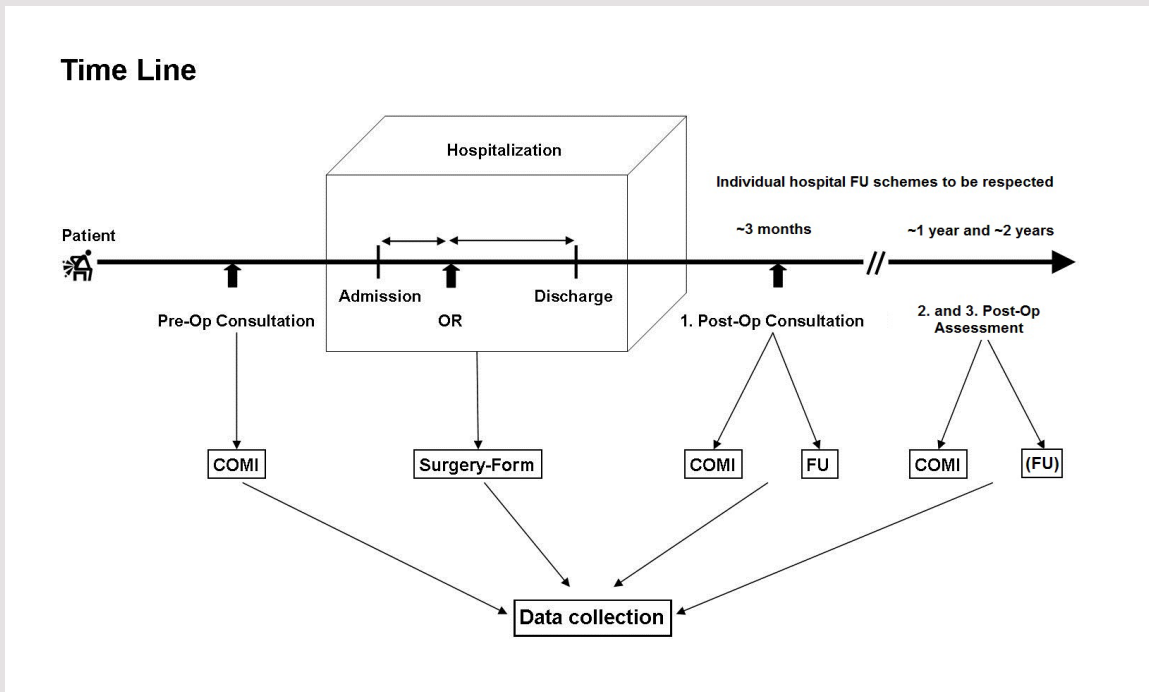
*Figure 4: Timetable of data collection*

**12**

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.
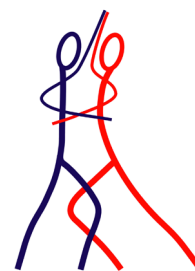
## STATISTICS IN SPINE TANGO

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 recently published (12, 13). A first matching study was just performed and is currently submitted for publication to a journal (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).

13

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. 2012 Mar;21(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. 2011 Jul;20(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. 2009 Aug;18 Suppl 3:386-94.
10. Kleinstück et al. The influence of preoperative back pain on the outcome of lumbar decompression surgery. Spine 2009 May 15;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. 2014 May 20. [Epub ahead of print]
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. 2013 Jul;35(1):E4.
13. Aghayev et al. (2012). Comparative effectiveness research across two spine registries. Eur Spine J. 2012 Aug;21(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?
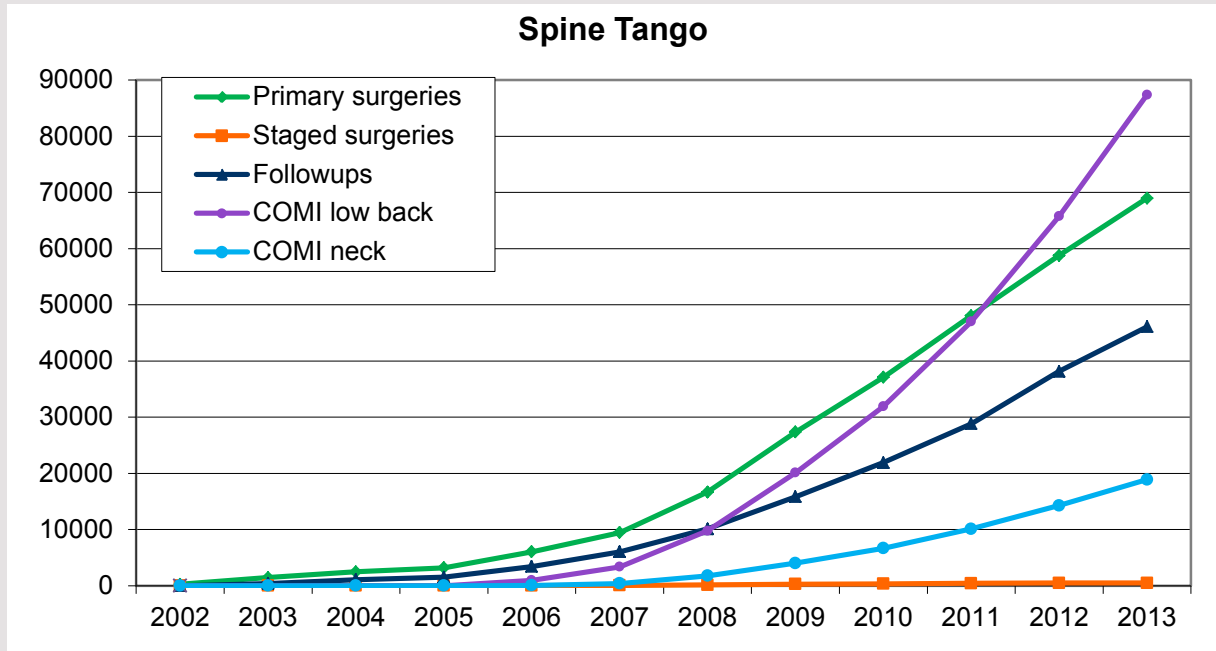
**14**



Figure 5: Growth curves of implemented forms (primary and staged surgery and follow-up) as well as COMI low back and neck over the years.

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 and 2013 is based on these new forms while the previous annual reports covered the complete data pool based on the SSE forms versions 2005 and 2006. For this annual report 2013 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 2013 19'969 new surgeries could be registered with the form version 2011.

Figure 6 shows the age and gender distribution for the patient sample.
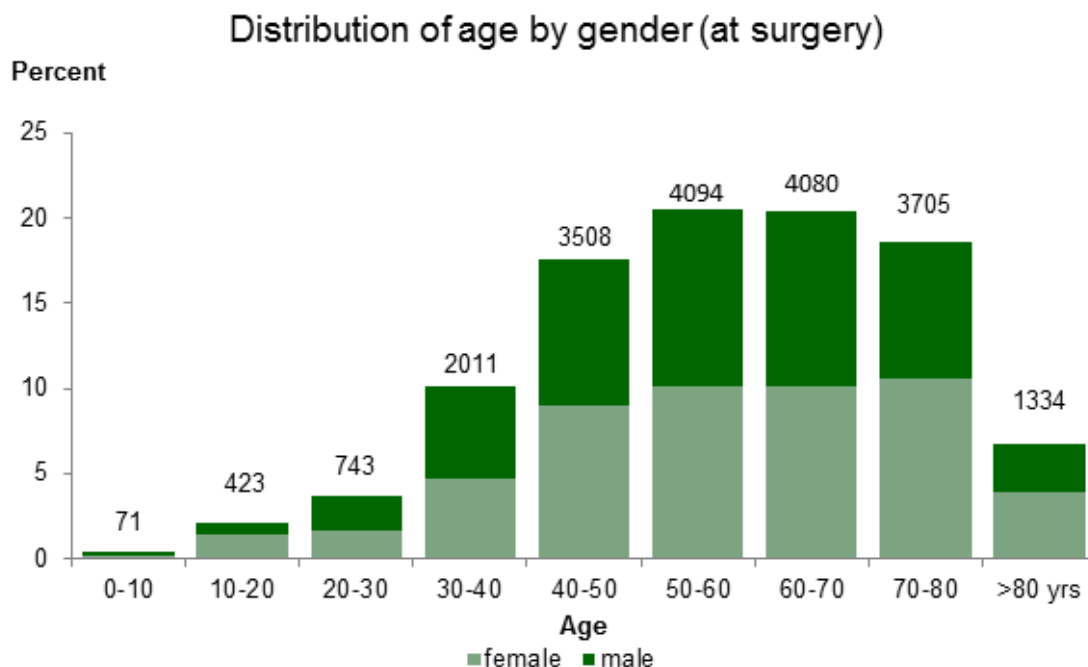


*Figure 6: Distribution of age by gender (at surgery), all cases based on surgery form version 2011 (N=19'969)*

The hospitalization times (length of stay [LOS]) show about 25% of cases with a very short hospitalizations up to two days. The majority of patients is hospitalized between three to five days. However, this distribution may differ depending on healthcare system. In general there is a trend towards shorter hospitalizations over the past years.
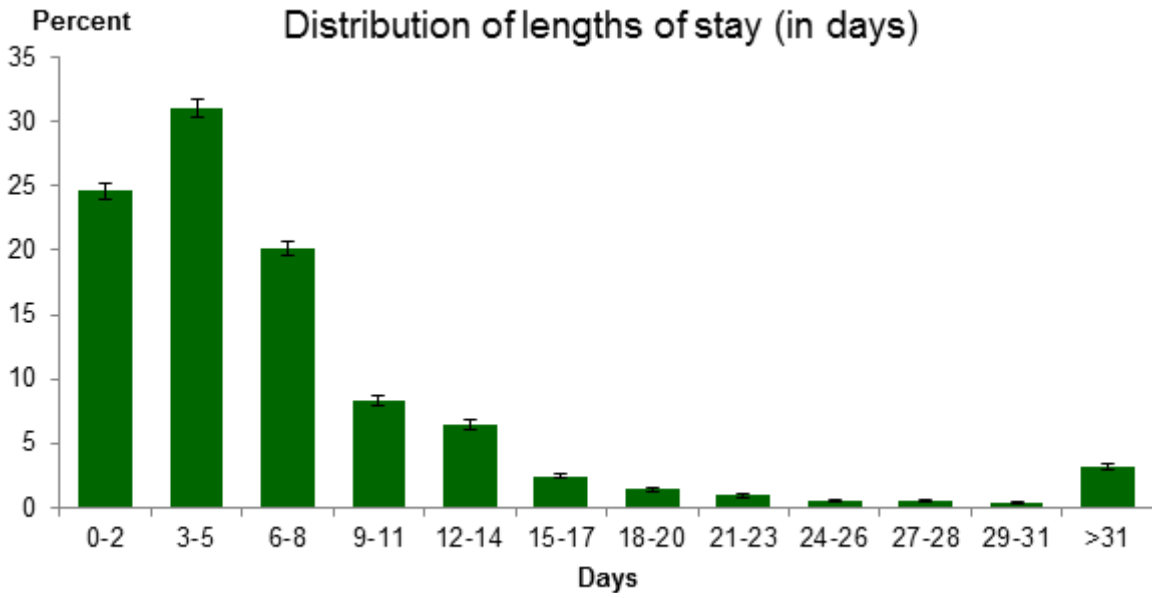


*Figure 7: Length of stay for the surgery form version 2011 (N 19'438)*

Further description of the patient sample can be made with new risk parameters such as body mass index (BMI) and smoking status which are newly evaluated with the 2011 forms.
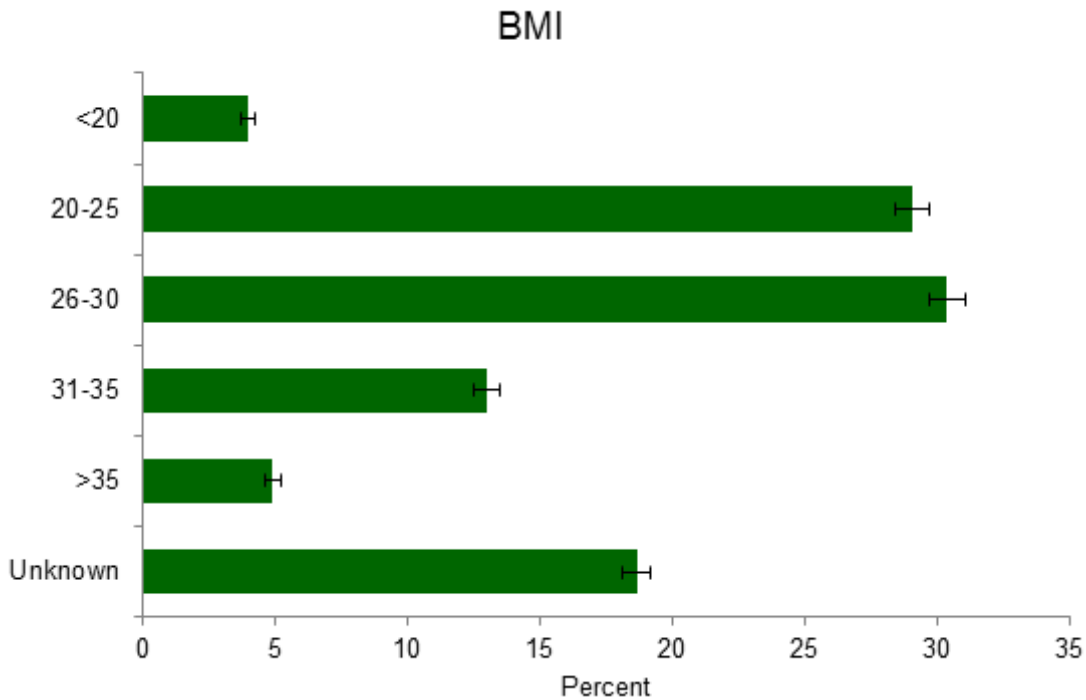


*Figure 8: Distribution of body mass index (BMI), surgery form version 2011 (N= 19'480)*

For BMI the classification underweight: < 20, normal weight: 20 – 25, overweight: 26-30, moderately obese: 31-35 and severely obese: >35 was used for categorization. A total of 48.3% of cases have a BMI over 25 which means they are at least overweight or even obese.

13.8 % of patients receiving spinal surgery were labeled as currently smoking, in 38.4% of cases the smoking status was unknown.
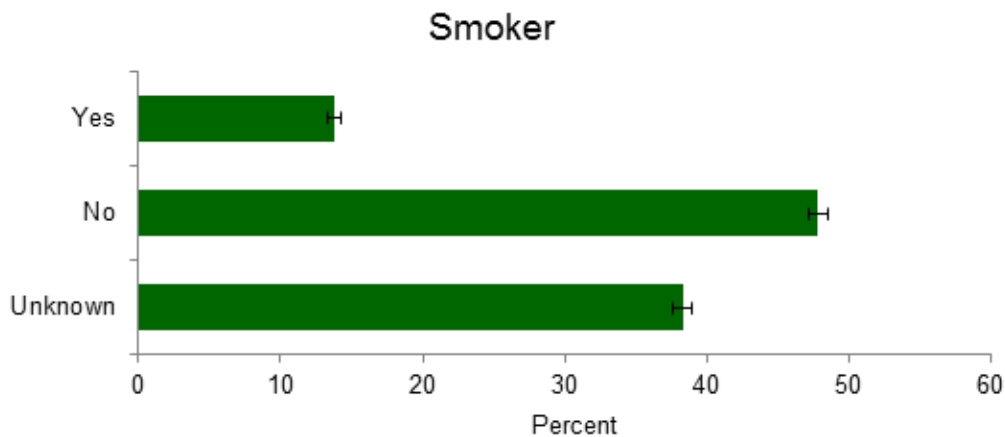


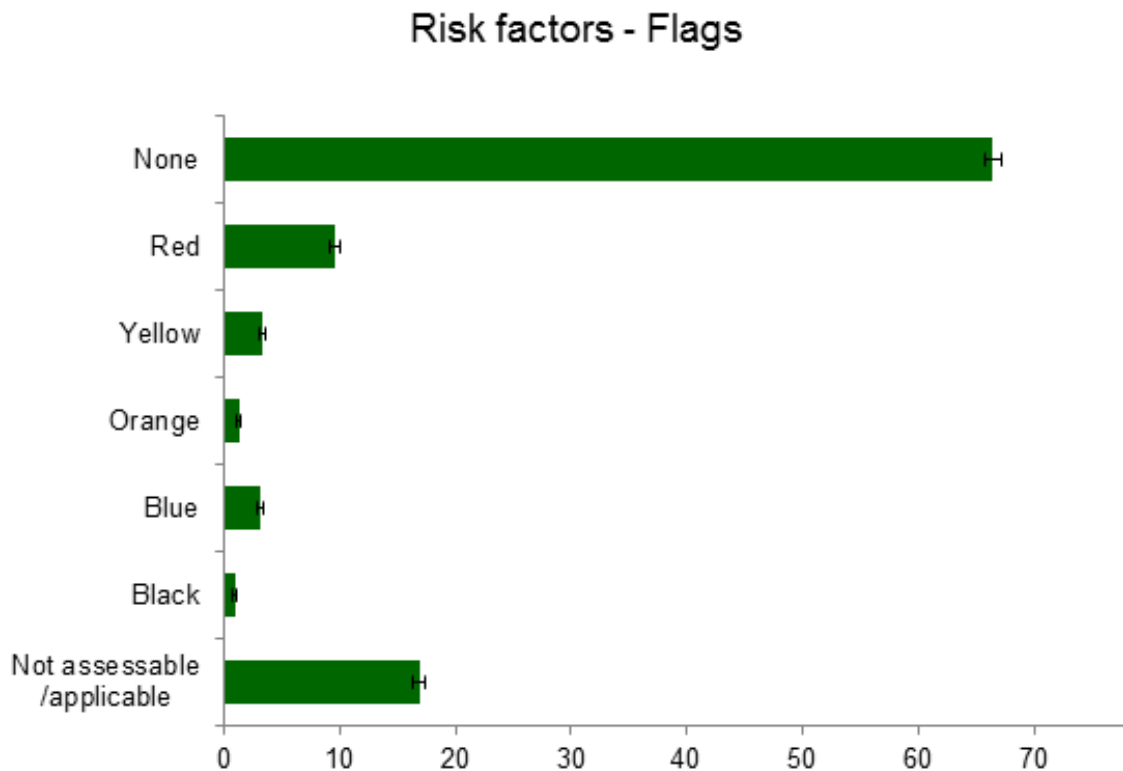*Figure 9: Distribution of current smoking status, surgery form version 2011 (N= 19'480)*



*Figure 10: Distribution of risk factors - flags, all patients with surgery form version 2011 (N= 19'787)*

The flags are an additional new parameter. 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 1.

*Table 1: Description of flag types*

| 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 |

Degenerative disease remains by far the most frequent main pathology in the form version 2011 with 76.5%. The second most frequent "pathology", though not a true one, are the failed and repeat surgeries adding up to 6.4%. 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.
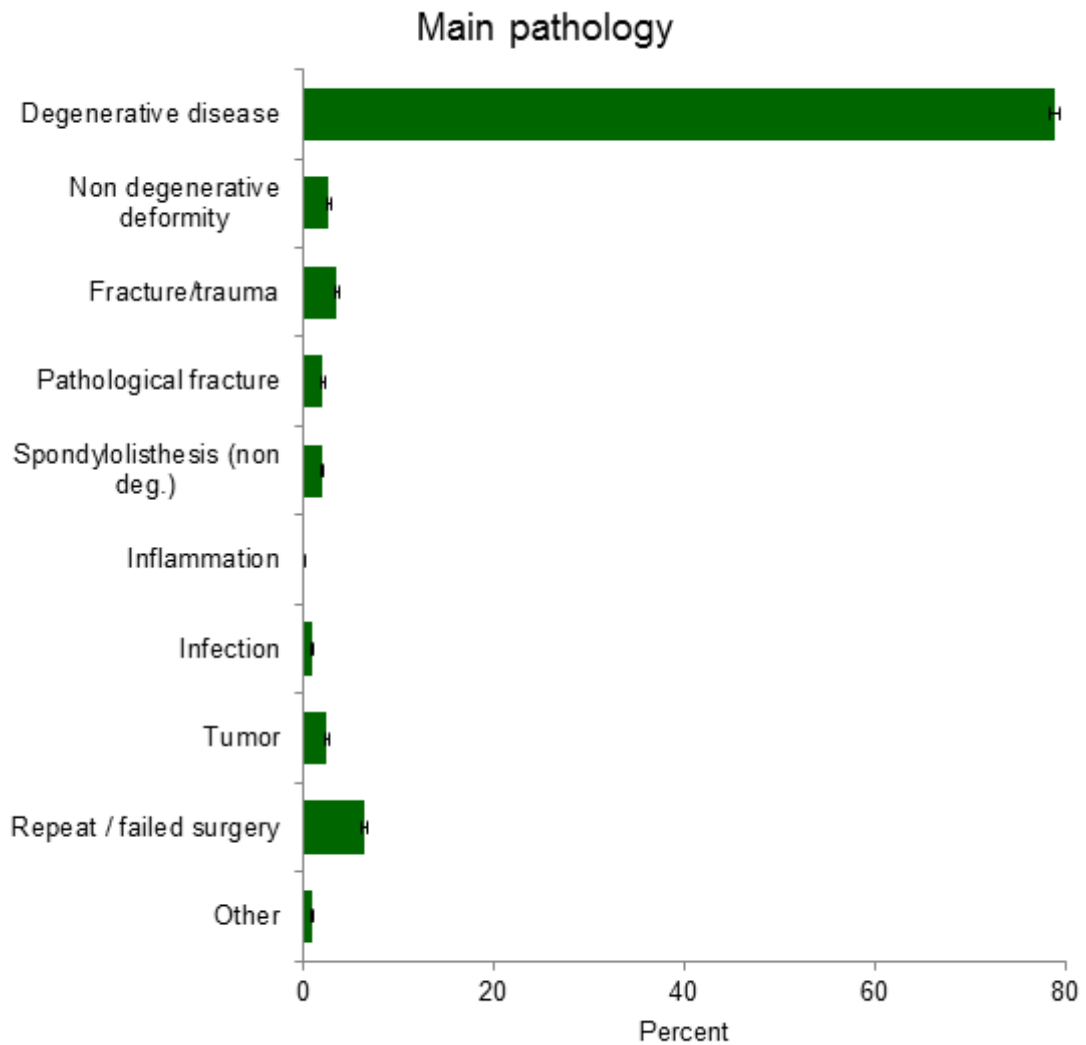
18

## Main pathology



*Figure 11: Distribution of main pathology for the surgery form version 2011 (N= 19'970)*

Fig. 12 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.
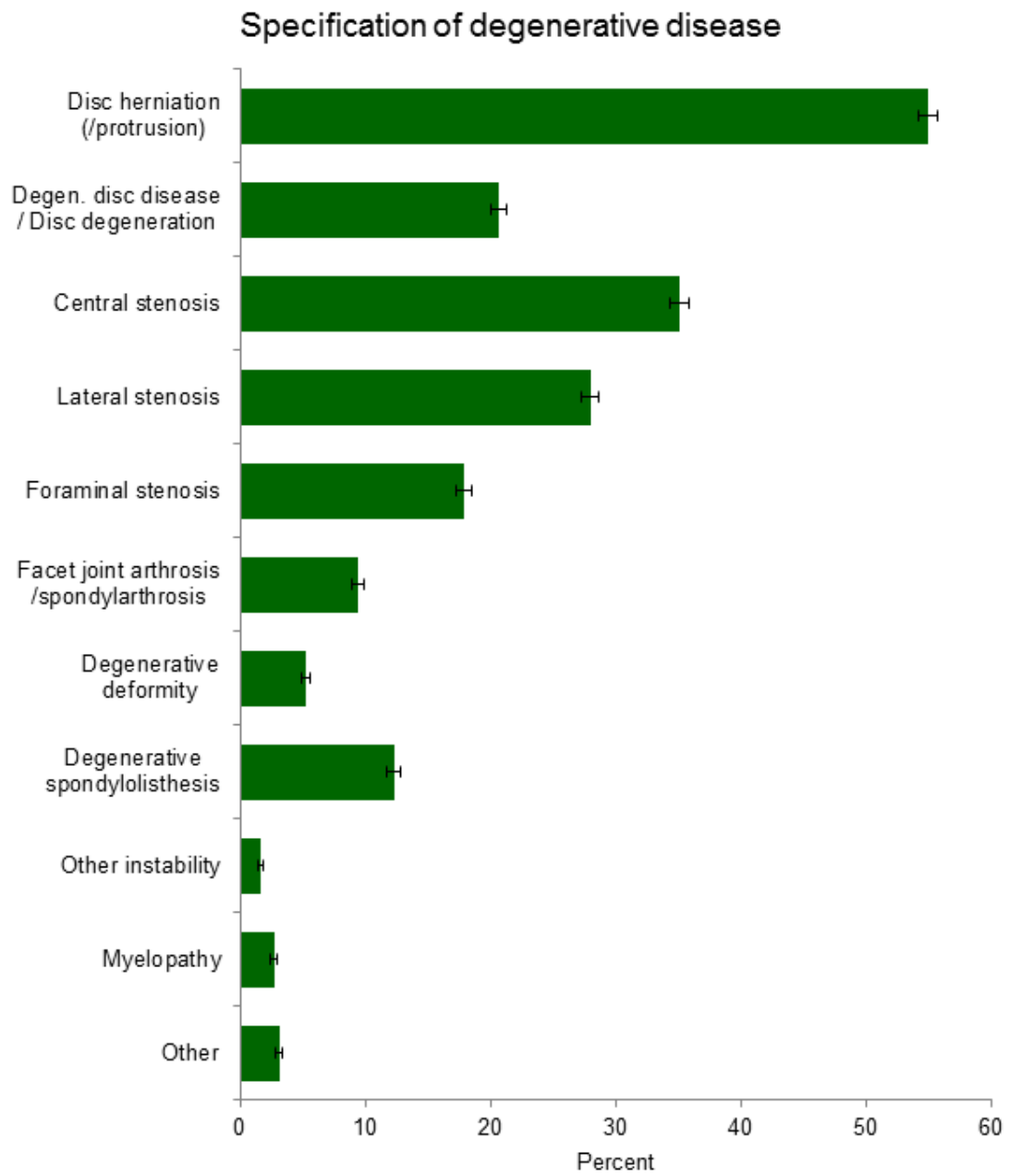
## Specification of degenerative disease



Figure 12: Specification of degenerative disease for the surgery form version 2011 (N= 15'743)

20

The age distribution shows at what ages the two pathologies typically occur and that disc herniation is a disease of the mid to late forties while the stenosis patients are in their late sixties or early seventies.
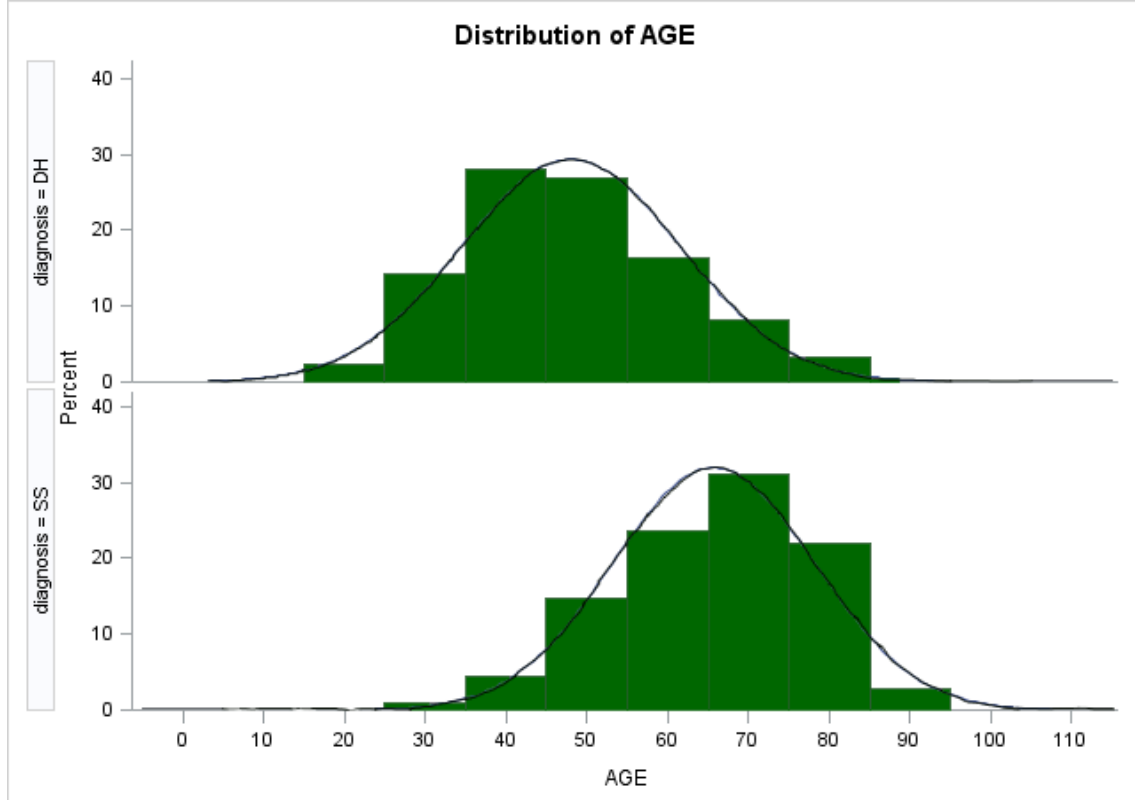


*Figure 13: Age distribution of the two most frequent degenerative pathologies at the time of surgery DH (N= 7'056), SS (N= 5'847)*

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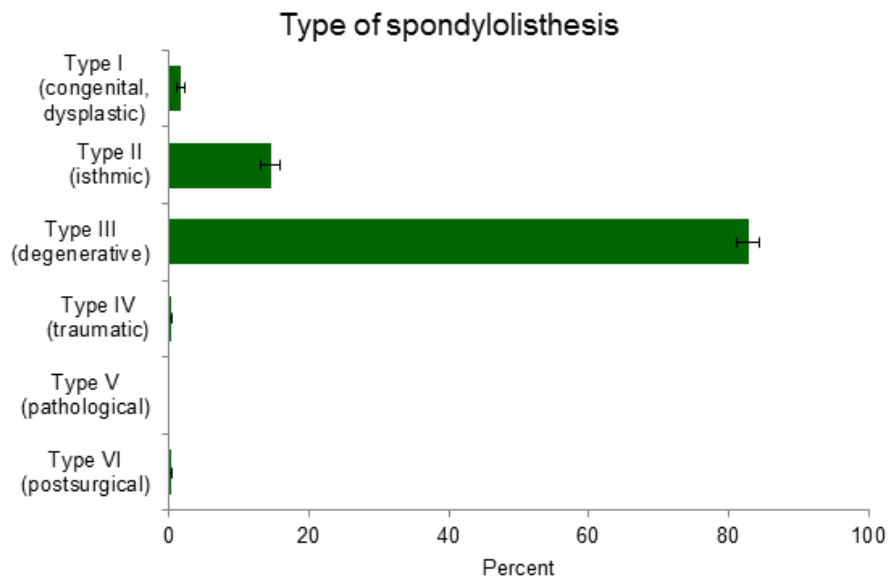


*Figure 14: Distribution of type of spondylolisthesis for the surgery form version 2011 (N= 2'333)*
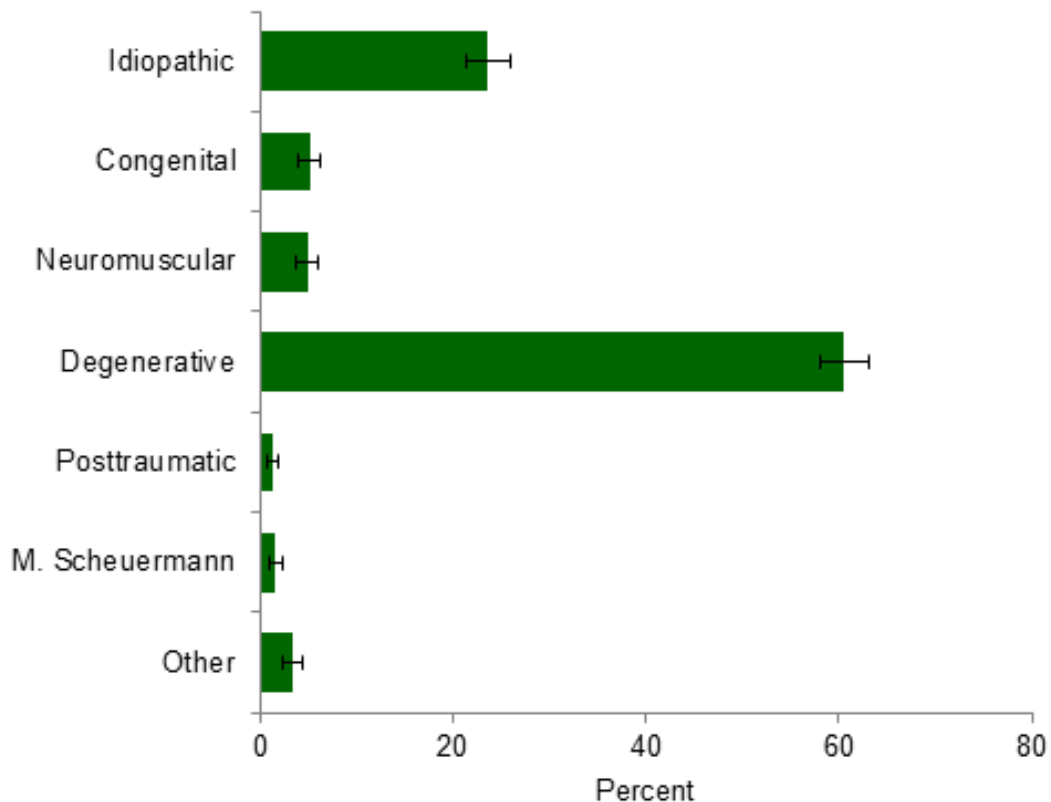
The classification of the degenerative spondylolisthesis is now (in the version 2011) included into the specification of degenerative disease as main pathology which gives the possibility to declare further degenerative pathologies which can be seen later in fig. 15.

Table 2: Neugebauer & Newman classification of the various types of spondylolisthesis, adapted by Wiltse et al.

| Type I | congenital, dysplastic | Type IV | traumatic |
|--------|------------------------|---------|-----------|
| Type II | isthmic | Type V | pathological |
| Type III | degenerative | Type VI | postsurgical |

With the ageing society many more degenerative compared with idiopathic, congenital or neuromuscular deformities are surgically treated. For these types of interventions, two new specialist add-on forms are newly available in Spine Tango.



Figure 15: Distribution of predominant aetiology of deformity for the surgery forms version 2011 (N= 1'378)

Fig. 16 demonstrates the new possibilities of the description of additional degenerative pathologies in patients with deg. spondylolisthesis and deg. deformity. The foraminal stenosis and facet joint arthrosis seem to occur more often in patients with deg. deformity compared to patients with deg. spondylolisthesis.
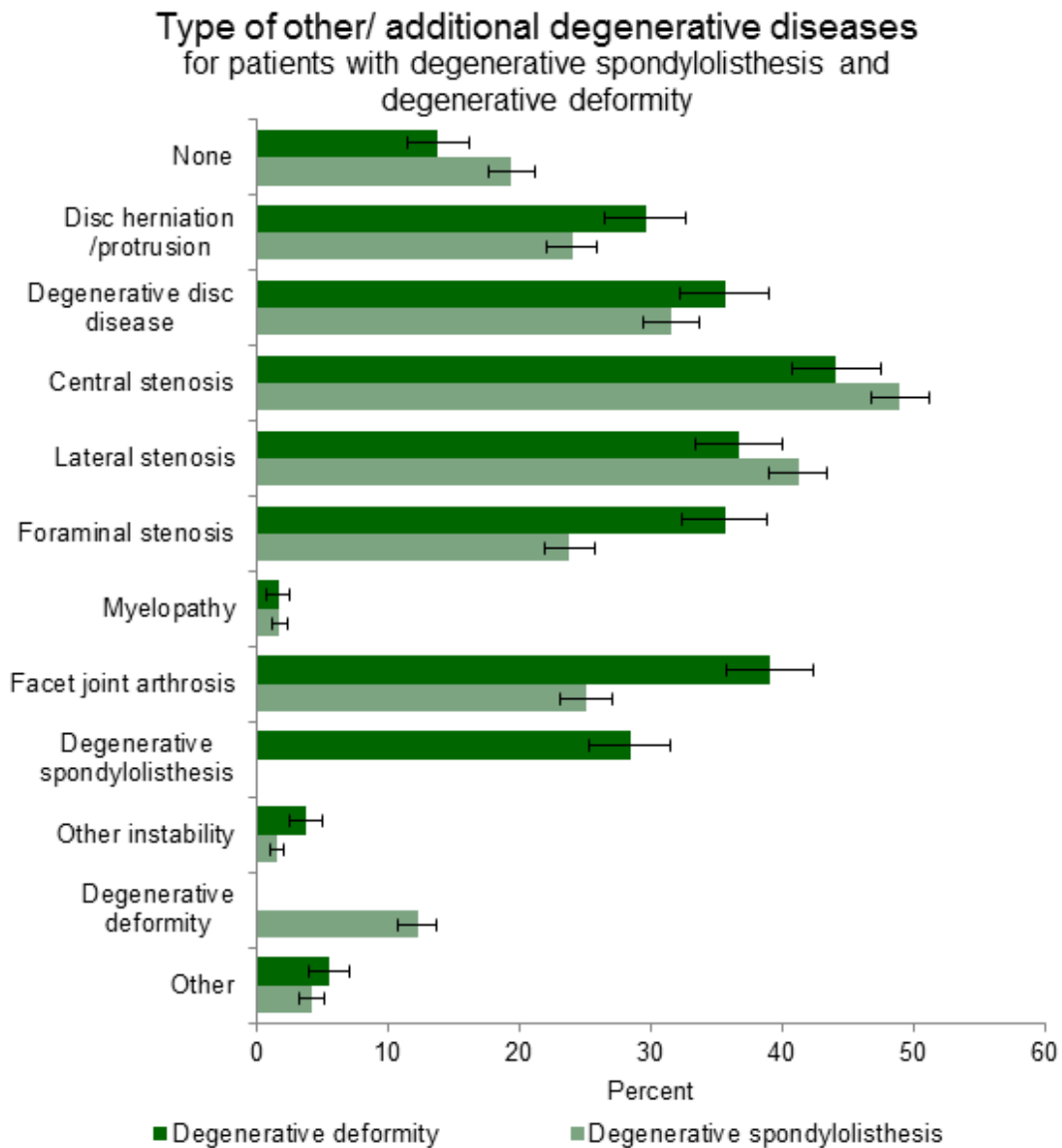


Figure 16: Distribution of type of other/additional degenerative diseases for patients with degenerative spondylolisthesis (N=1'931) and degenerative deformity (N=834), surgery form version 2011

The parameter failed surgery was renamed to repeat surgery and some more specifications were added in the version 2011. The postoperative infection can now be further specified into superficial or deep infection. Other new specifications are hardware removal, failure to reach therapeutic goals, implant malposition and adjacent segment pathology.
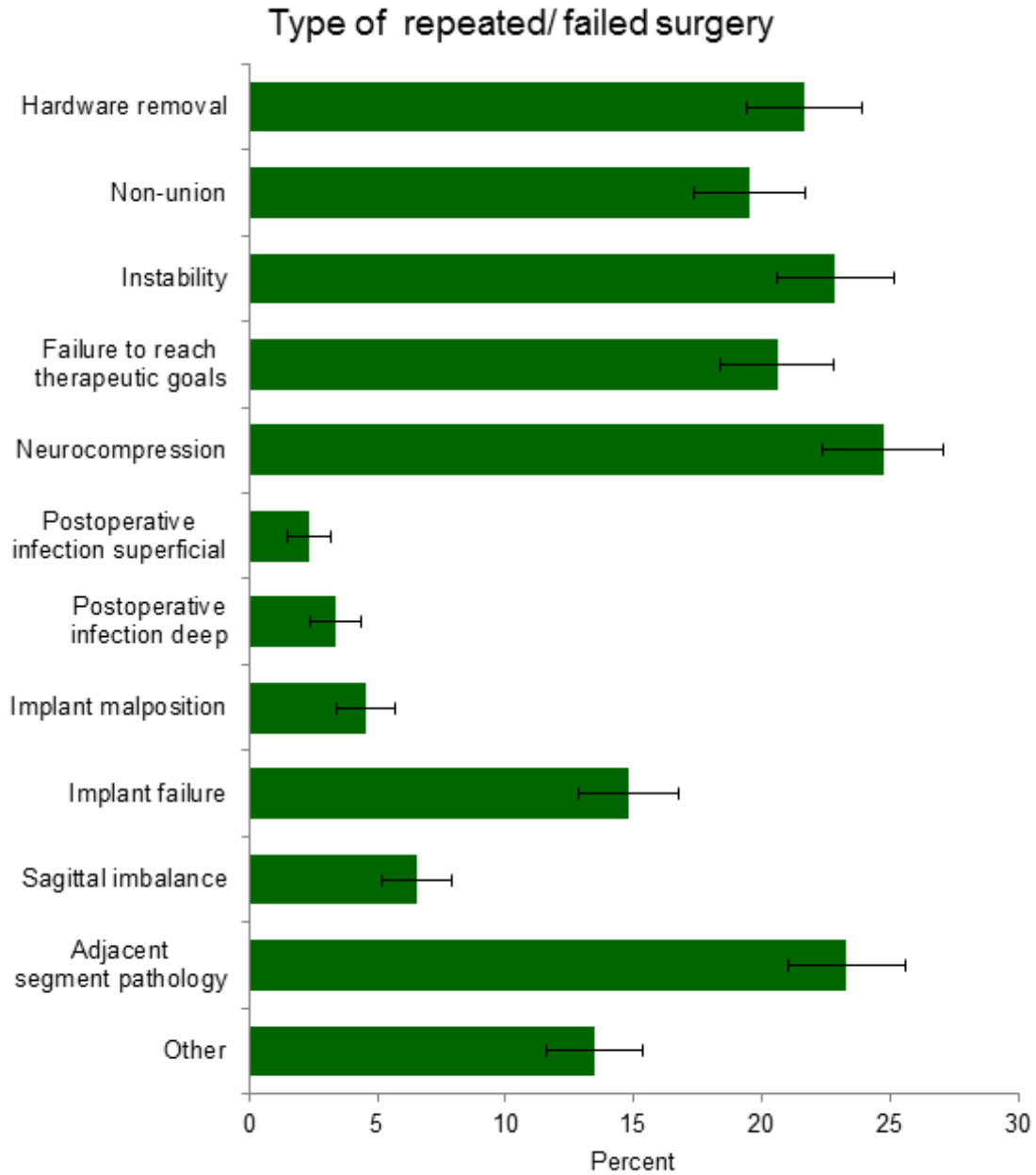
**24**



*Figure 17: Type of failed/ repeated surgery for the surgery form version 2011 (N= 1'283)*

About 10% of cases (N=1'283) recorded in 2012 and 2013 were repeat surgeries.
Hardware removal covered 21.7% of cases, and adjacent segment pathology another 23.3%. These specifications do not necessarily imply a failed index surgery, which explains the new variable name.
Failure to reach the initial therapeutic goals was given as a reason for repeat surgery in 20.6% of cases.

The parameters "Affected structures of infection" and "Localization of tumor" were newly defined. The former forms considered only the disc and vertebra as affected structure of infection. The new answer possibilities in the version 2011 also take the epidural space and the paravertebral soft tissue into account.
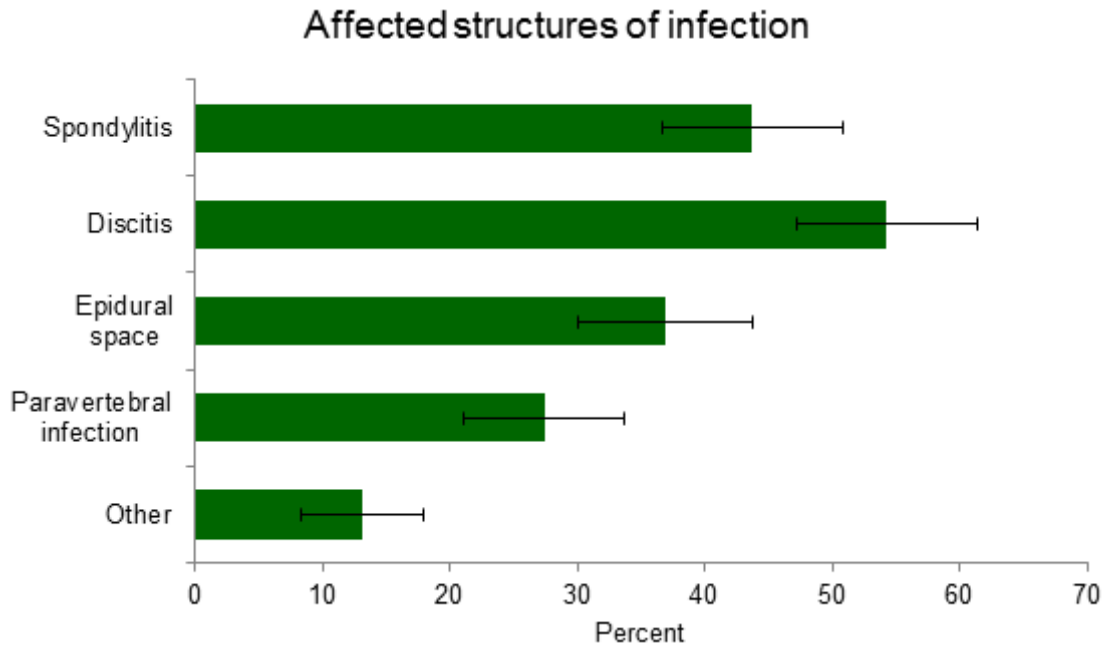
## Affected structures of infection



*Figure 18: Distribution of affected structures of infection, surgery form version 2011 (N=190)*
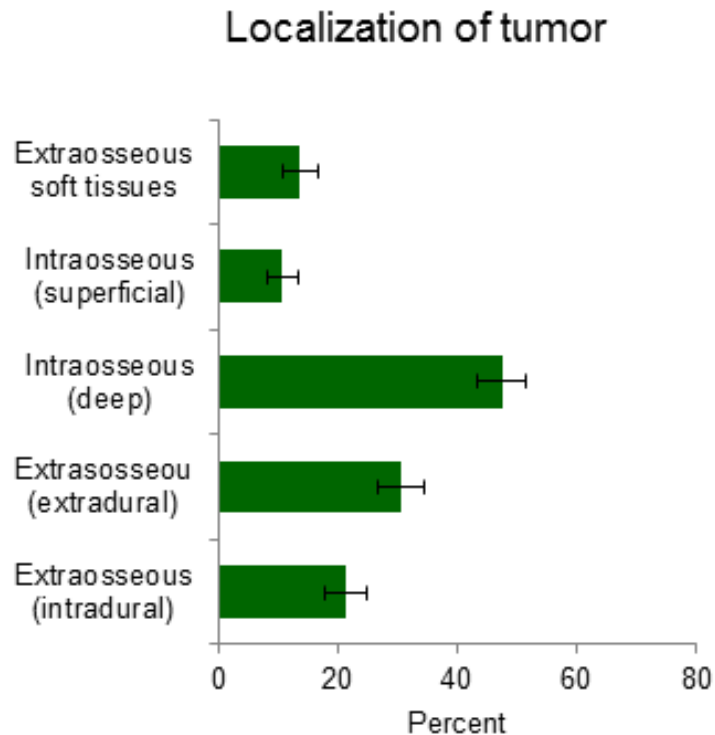
## Localization of tumor



*Figure 19: Distribution of localization of tumor for the surgery form version 2011 (N= 551)*
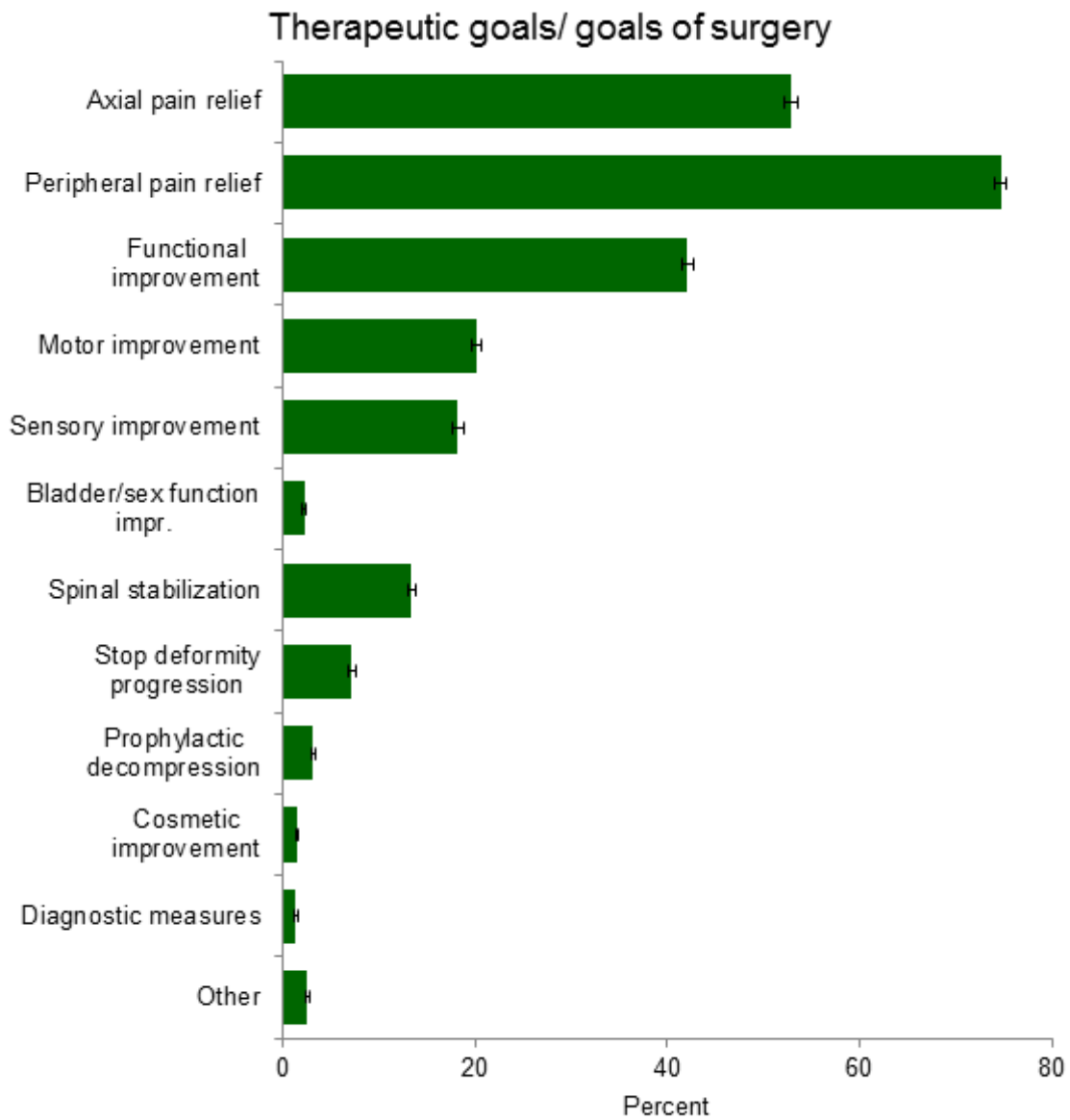
## Therapeutic goals/ goals of surgery



*Figure 20: Distribution of therapeutic goals/ goals of surgery for the surgery form version 2011 (N= 19'969)*

The therapeutic goals can be more precisely defined in the form version 2011. Pain relief was splitted 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.

26

## Prophylaxis
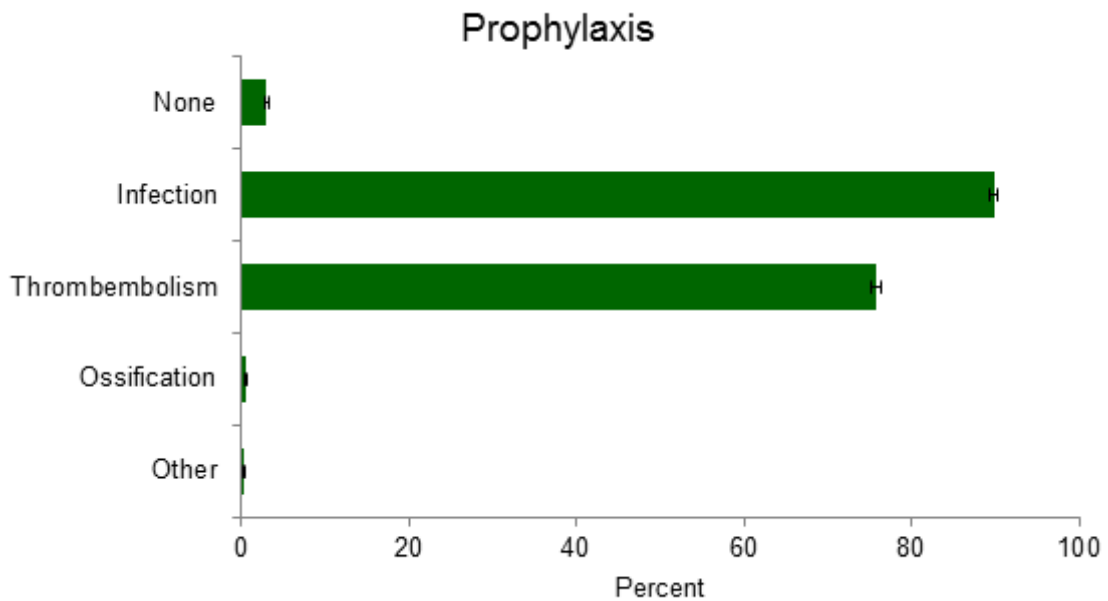


*Figure 21: Distribution of type of prophylaxis, surgery form version 2011 (N= 19'474)*

Prophylaxis is a new question in the form version 2011. Infection prophylaxis was performed in 89.8% of cases, thromboembolic prophylaxis in 75.8% of cases.
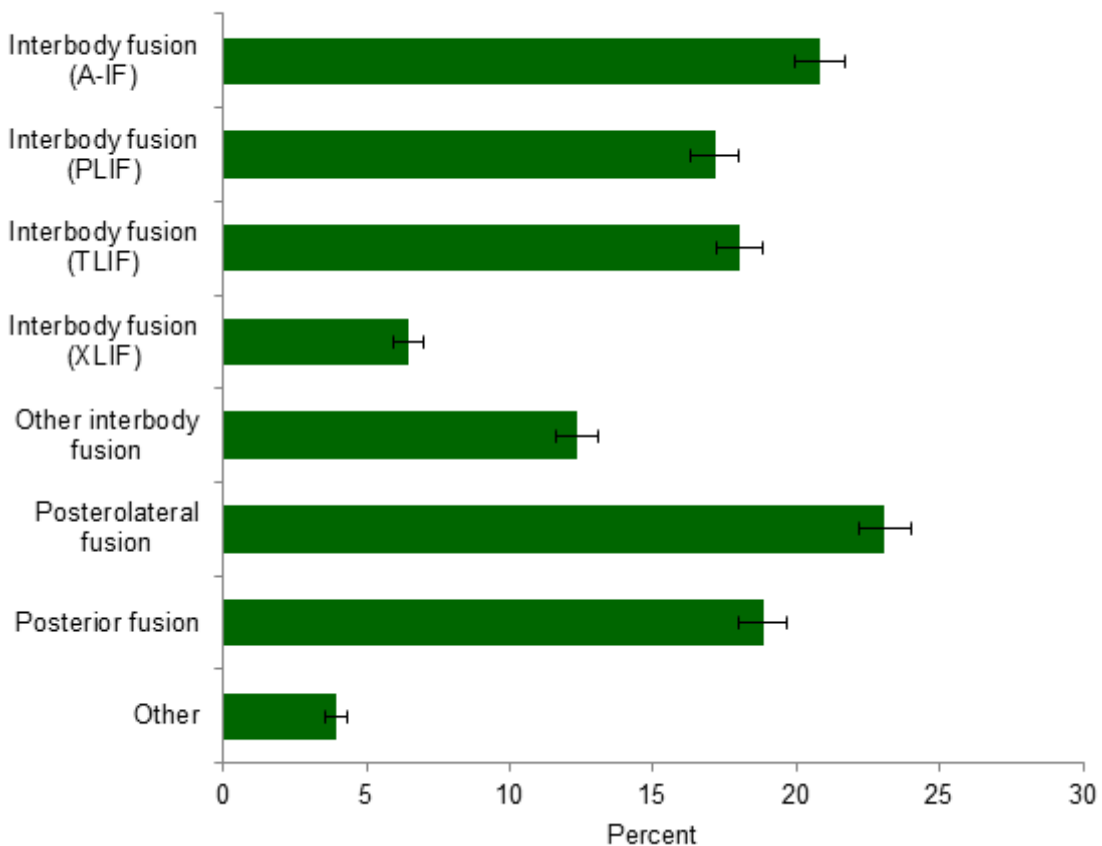
## Specification of fusion promoting measures



*Figure 22: Specification of fusion promoting measures, surgery form version 2011 (N= 8'343)*

The fusion promoting measures can now be more precisely specified in terms of the different types of interbody fusion. The most frequently performed interbody fusions are A-IF and TLIF with 20.8% and 18.0%. A PLIF was carried out in 17.2% and an XLIF in 6.5% of cases where a fusion was performed. The posterolateral fusion was the most frequently performed fusion promoting measure in total with nearly 23.1%.
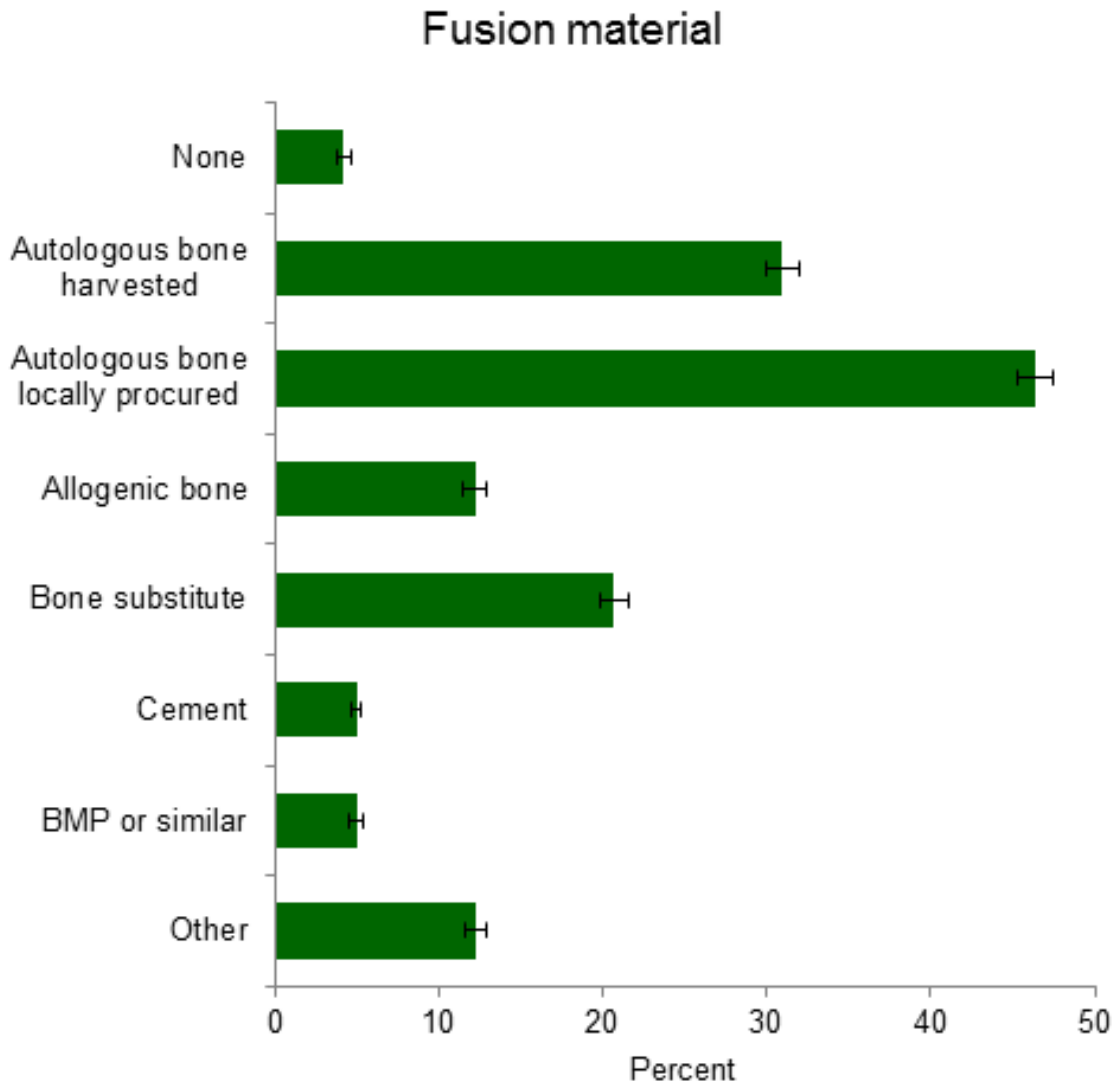
## Fusion material



*Figure 23: Specification of fusion material, surgery form version 2011 (N= 8'343)*

The specification of the fusion material was also redesigned. Especially for autologous bone it can now be distinguished whether the bone was locally produced e.g. during decompression or whether the bone was harvested e.g. pelvic crest biopsy.

The surgical complications are now divided into intraoperative complications and complications occurring during hospitalization before discharge.

For intraoperative complications which are shown in fig. 24 the dura lesion was the most frequent complication with 4.6%. No intraoperative surgical complications occurred in 93.8% of cases, in 0.6% of cases they were not documented.

## Intraoperative surgical complications
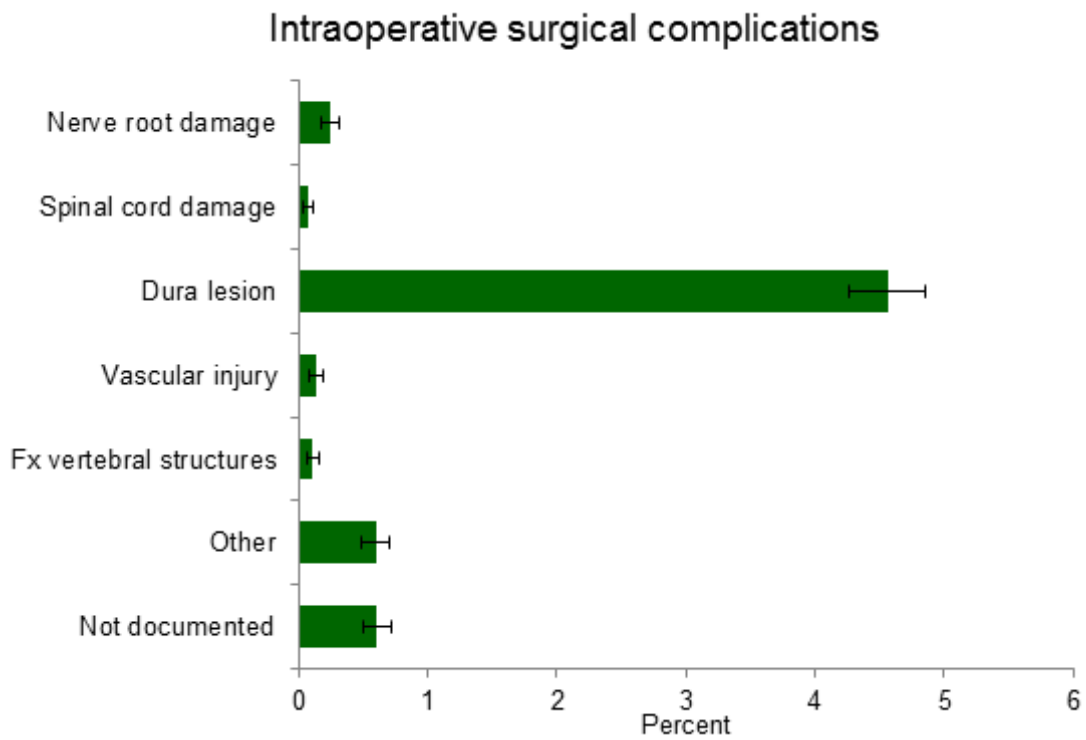


Figure 24: Distribution of intraoperative surgical complications, excluded was the answer "none", surgery form version 2011 (N= 19'970)

29

Postoperative complications which occurred during hospitalization are shown in figure 25.
The most frequent complications were motor dysfunction with 0.9%, sensory dysfunction with 0.8% and radiculopathy with 0.6%. Even though a dura lesion was the most frequent complication during surgery, a CSF leak/ pseudomeningocele occurred in only 0.4% of cases. In 0.6% of cases the complications before discharge were not documented, in 95.1% of cases no postoperative complications occurred.
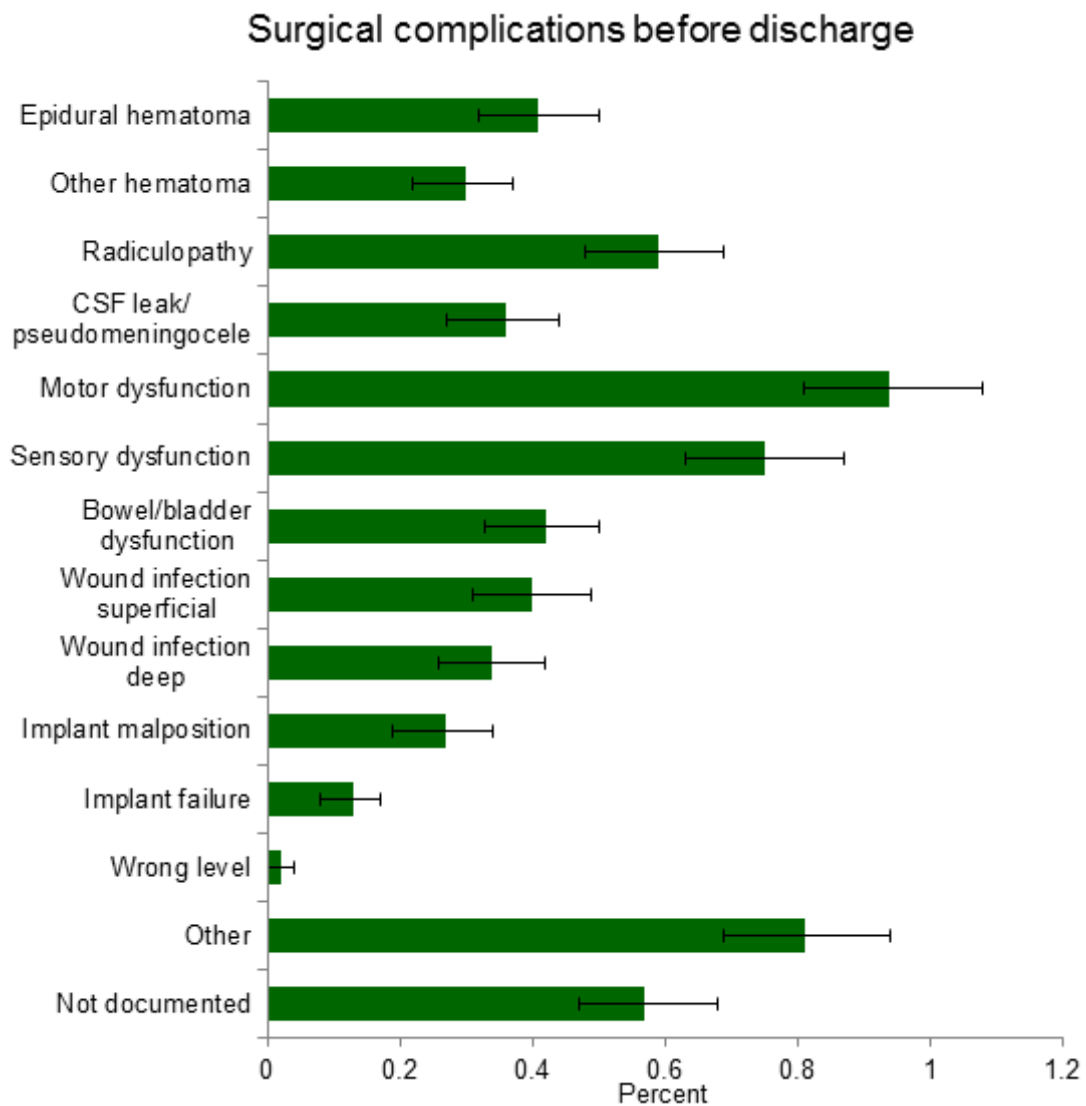
30



*Figure 25: Distribution of surgical complications before discharge, excluded was the answer "none", surgery form version 2011 (N= 19'969)*

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 1'777 cases with complications were documented. In 62% of those cases the complications were resolved at discharge, in 8.7% they were persisting.

## Status of complications at discharge
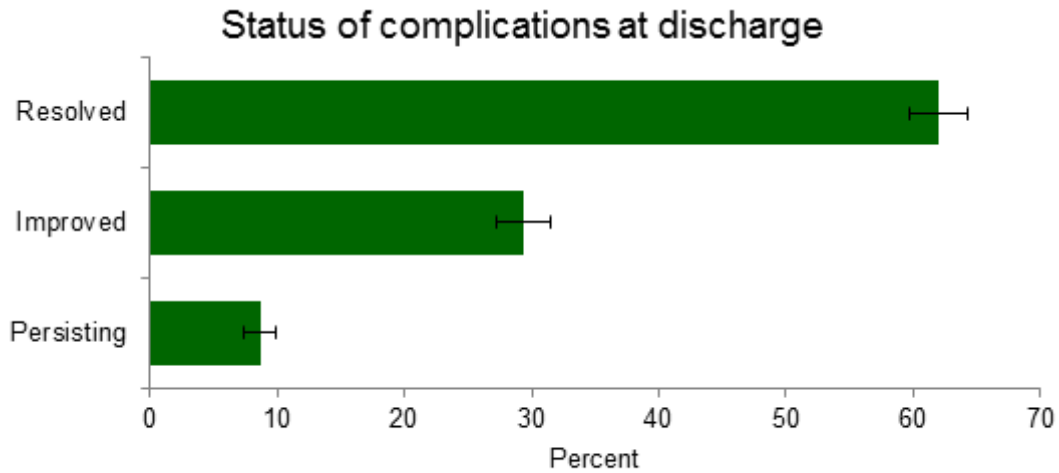
*Figure 26: Status of complications at discharge for patients with an intraoperative complication and/ or a complication before discharge, for surgery form version 2011 (N= 1'777)*

A new question is the foreseen follow-up. This parameter was added to have the opportunity to calculate realistic follow-up rates. In 94.3% of cases at least one follow-up was foreseen.

## Follow-up foreseen at discharge
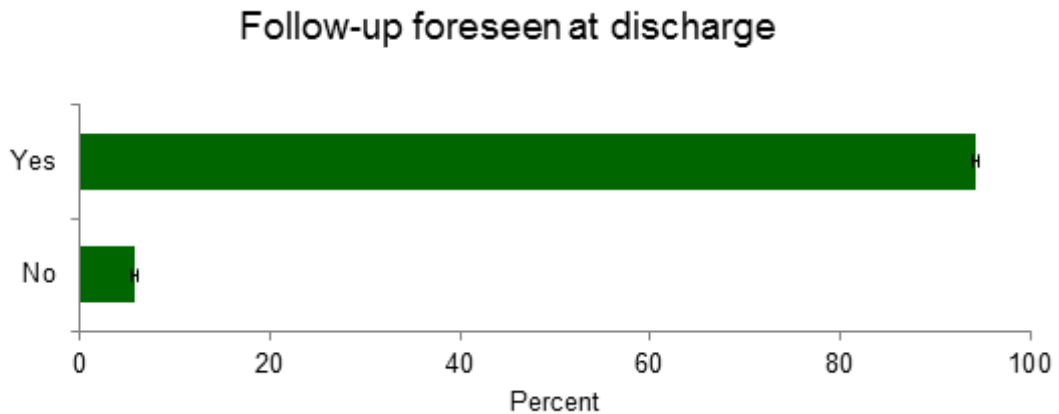
*Figure 27: Followup foreseen, surgery form version 2011 (N=19'433)*

31

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.

**32**



Figure 28: Distribution of followup interval for the followup form version 2011 (17'502 forms for 8'357 patients)

Form version 2011: 17'502 FUs / 8'357 patients: current mean FU at 169.7 days, if last available FU is considered. Due to the young age of the form version, the mean FU times will most likely increase in the future. Also, the 2011 followups referring to cases operated before January 1st 2012 (documented with 2006 surgery form versions) were not considered for this analysis.

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. 2009 (18 Suppl) 3:367-73
15.   Strömqvist B et al. (2013). Swespine: the Swedish spine register: The 2012 report. Eur Spine J. 2013 Apr;22(4):953-74.

*Figure 29: Physician based overall outcome (surgeon) for the surgery form version 2011 (N=8'762)*

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.
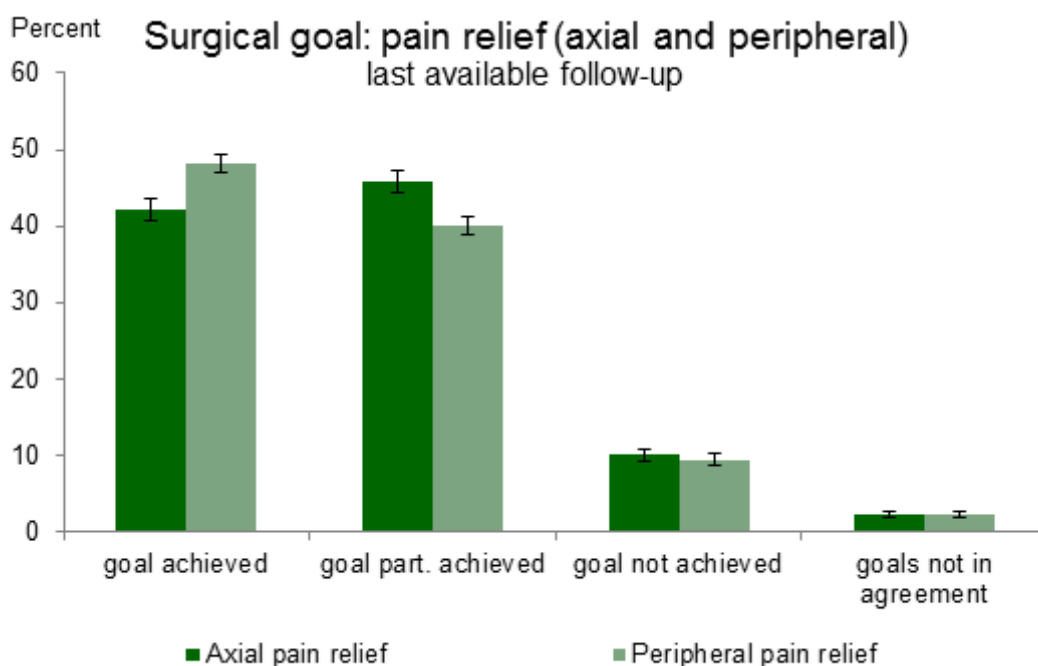


*Figure 30: Achievement of the surgical goal pain relief (axial and peripheral) for the followup form version 2011*

Peripheral pain relief seems the easier to achieve or partially achieve surgical goal compared with axial pain relief. However, the non-achiever rates are basically the same.

34



*Figure 31: Achievement of the surgical goal neurological improvement (motor, sensory, bladder and sex function) for the followup form version 2011*

The main focus of neurological improvement lies on motor and sensory function, which is equally likely achieved. Improvement of bladder and sexual function is a less frequently desired goal, but also one that is more difficult to achieve.
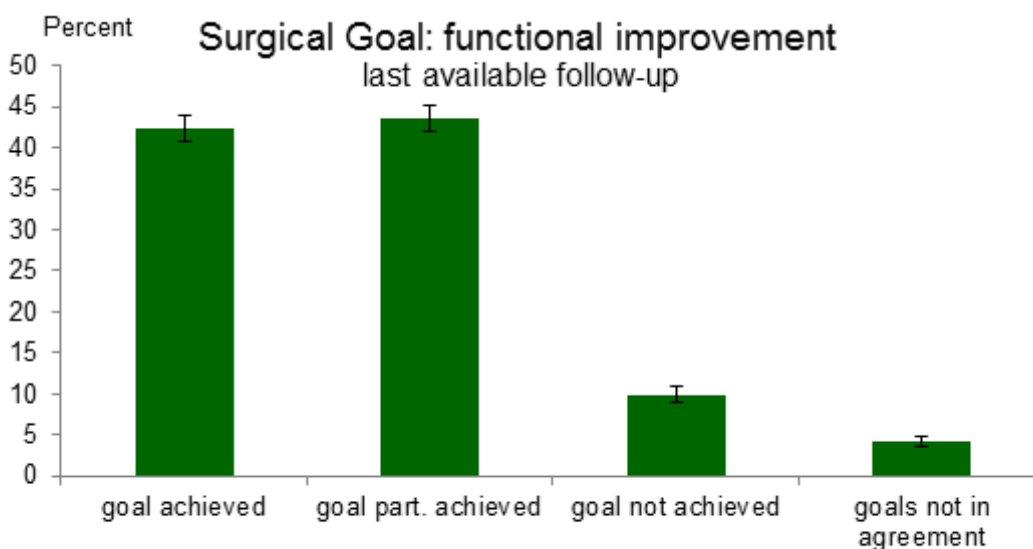
*Figure 32: Achievement of the surgical goal functional improvement for the followup forms version 2011*

In only about 1 out of 10 patients, a functional improvement could not be achieved.
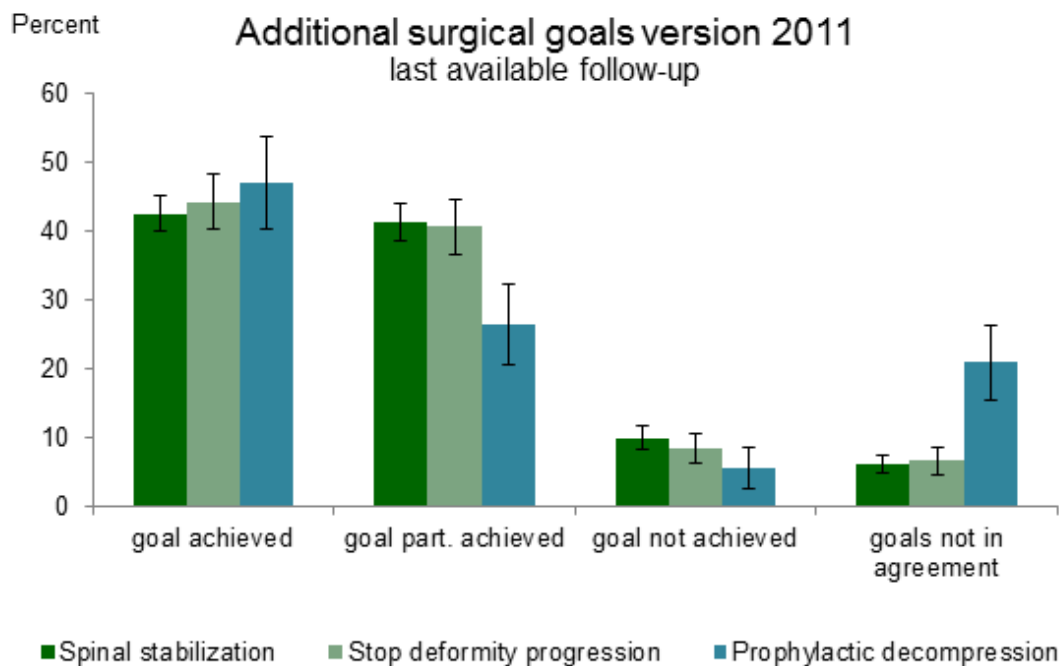


*Figure 33: Achievement of additional surgical goals (spinal stabilization (N=1'349), stop deformity progression (N=611) and prophylactic decompression (N= 215) for the followup form version 2011*

Spinal stabilization and stopping deformity progression are equally likely to achieve as surgical goals, and in the majority of patients they are completely or partially achieved. A prophylactic decompression is not a frequent goal, but it seems one of the easiest goals to achieve or partially achieve.

**Lumbar spinal stenosis – the most frequent treatment types and their comparative outcomes in clinical practice**

**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 an intervention 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 surgical spinal interventions "do" work in day-to-day clinical settings. Disc herniation and spinal stenosis, making up about two thirds of all degenerative diseases recorded with Spine Tango, are the first pathologies the benchmarking project will assess. This second part of the 2013 annual report highlights the three most frequently seen treatments for lumbar spinal stenosis which are decompression, decompression with rigid stabilization and intended fusion, and decompression with posterior dynamic stabilization. Due to the large extent of the complete analysis, only some highlights are shown on the following pages.

**Materials and Methods**

*Spine Tango forms*
The last three iterations of the surgery form were used in the analysis: 'Surgery 2005', 'Surgery 2006' and 'Surgery 2011'. The register supports the linkage of the physician based data to outcome data, largely documented by the patients themselves. Treated patients are asked to complete a Core Outcome Measures Index (COMI) questionnaire. The COMI form is the official patient-based outcome instrument of the Spine Tango registry. It was based on a proposal by Deyo et al [18].

Inclusion criteria and patient sample
The Spine Tango database was screened on December 1st 2013 for the diagnosis of degenerative lumbar spinal stenosis (LSS) without concomitant degenerative spondylolisthesis. The inclusion criteria were lumbar and lumbo-sacral location and mainly affected segment between L1/2 and L5/S1, no previous surgical treatment, at least one surgical follow-up between 3 and 30 months postoperative, baseline and at least one follow-up COMI assessment between 3 and 30 months postoperative, and known ASA (American Society of Anaesthesiologists) status. The complete selection algorithm is shown in table 1. The inclusion criteria resulted in 1'376 patients from 31 hospitals from Australia, Belgium, Germany, Switzerland, UK and the USA.

*Table 3: Selection algorithm.*

| Selection | N |
|---|---|
| 'Surgery 2005' primary forms submitted | 3'570 |
| 'Surgery 2006' primary forms submitted | 42'020 |
| 'Surgery 2011' primary forms submitted | 16'027 |
|  |  |
| 'Surgery 2005' with LSS, without spondylolisthesis and previous surgery | 491 |
| 'Surgery 2006' with LSS, without spondylolisthesis and previous surgery | 4'819 |
| 'Surgery 2011' with LSS, without spondylolisthesis and previous surgery | 2'468 |
|  |  |
| All primary forms with LSS, without spondylolisthesis and no previous surgery | 7'778 |
|  |  |
| All primary forms with LSS, without spondylolisthesis and no previous surgery, with at least 1 physician-based follow-up (3-30 months) | 1'841 |
|  |  |
| All primary forms with LSS, without spondylolisthesis and no previous surgery, with at least 1 physician-based follow-up, with baseline COMI, with at least 1 COMI follow-up (3-30 months), without patients with unknown ASA | 1'376 |

*Analyses*

*I.     Representativeness of patient sample*

To explore a potential selection bias, the final patient sample (n=1'376) was compared with all other patients with LSS (n=6'402) regarding their demographics. Representativeness was largely given, but the analysis is not shown.

*II.     Treatment types*

The main surgical treatment types were selected for all further analyses. The proportions of the various decompression, instrumented fusion and posterior dynamic stabilization types were analysed. Univariate comparisons of patient characteristics of the main treatment types were performed. General linear modelling with Bonferroni adjustment was used for comparisons of continuous co-variates and the Chi-square test was used for comparing proportions.

*III.     Predictors for desired outcomes*

The outcome measures were 1) achievement of minimum clinically relevant change (MCRC) in back pain of 2 NPS points, 2) achievement of MCRC in leg pain of 2 NPS points, 3) achievement of MCRC in COMI score of 2 points, and 4) occurrence of a surgical complication (not shown). For an adjusted analysis of predictors of outcomes a multivariate logistic regression was built. The quantitative relationships between the studied covariates in the regression model are expressed as odds ratios (OR) with 95% Wald confidence intervals (CI95%).

*IV.      Sensitivity analysis*

To explore the potential influence of large hospitals on the prediction of the desired outcome considering the respective treatment type the above mentioned multivariate logistic regression analyses were carried out for the complete sample (=31 hospitals) and again excluding the three hospitals with the highest patient numbers (=28 hospitals) (not shown).

*V.      Achievement of the main treatment goals*

Descriptive, graphical and statistical comparisons of the frequency of achievement of main treatment goals were performed. The Chi-square test was used for comparison of proportions of achievement of goals between the treatment groups. The following treatment goals were regarded as the main ones: pain relief, functional and neurological improvement.

*VI.      Patient- and physician-based rating of treatment outcome*

Descriptive and graphical comparisons of the patient-based perception of the treatment effect (helped a lot, helped, helped only little, didn't help, made things worse), and physician based appreciation of the treatment outcome (excellent, good, fair, poor) were performed (physician based assessment not shown).

*VII.      Main COMI domains at baseline and at the last available COMI follow-up*

The spider graphs were created for the main COMI domains: function, symptom-specific well-being, quality of life, and social and work disability. Median pre- and postoperative answers, ranging from 1 – the best to 5 – the worst possible answer, were displayed for each domain.

*VIII.      Course of postoperative change*

Course of postoperative change for the main treatment types was displayed and analysed if patients had the following four COMI forms: baseline, 3-month and  1-year follow-ups. This requirement resulted in 513 patients. General linear modelling was used for comparisons of back and leg pain and COMI score at the different time points. For pairwise comparison between the treatment types in the generalized linear models a Bonferroni adjustment was applied.

**Results**

*I.      Description of surgical measures*

Three procedures (surgical measures) alone or in combination with other procedures were:
 1) decompression alone (n=803; 58.4%),
2) decompression with an instrumented fusion (n=357; 25.9%), and
3) decompression with posterior dynamic stabilization (n=172; 12.5%).

All the other numerous combinations of surgical measures accounted for 3.2% of the total (n=44) and were excluded from the analysis.
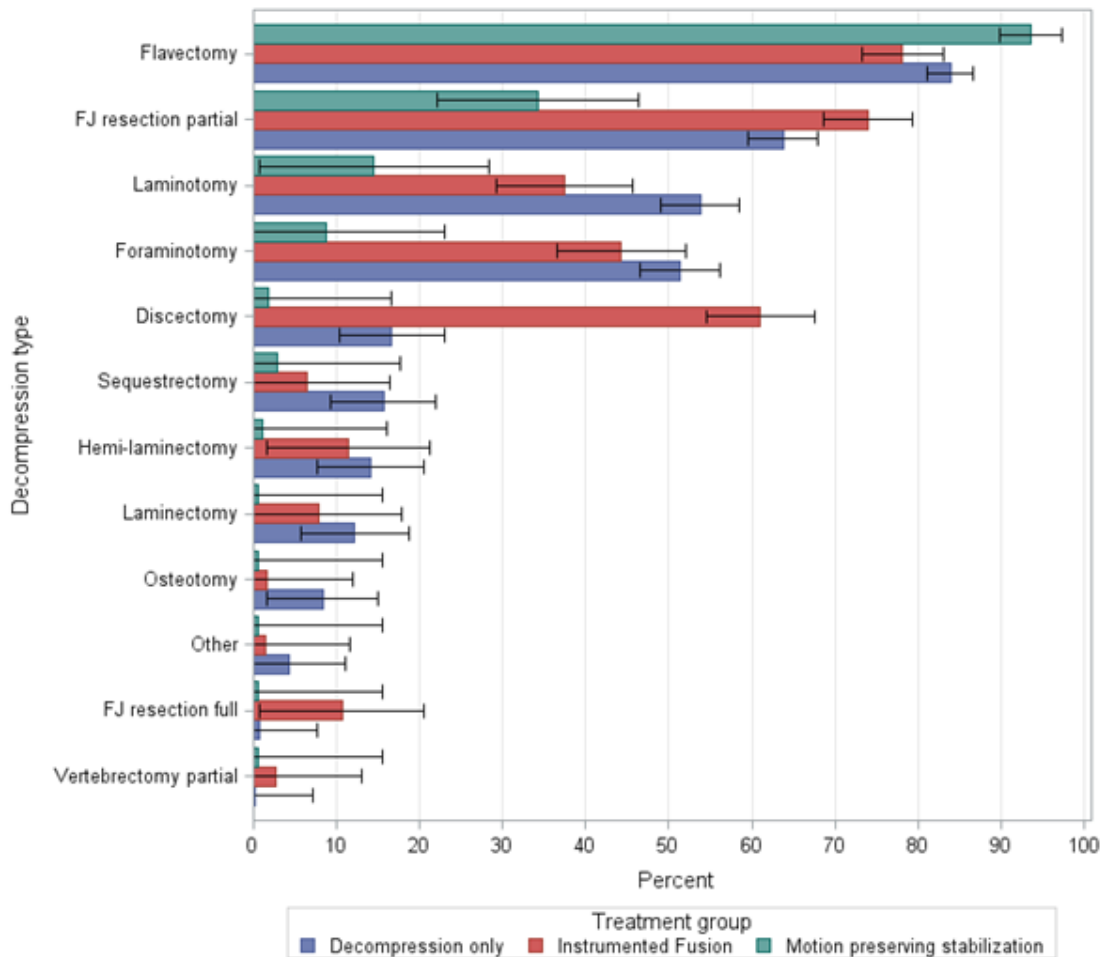
Figure 34: Types of decompression used in the three treatment groups.

The postoperative COMI intervals were significantly different between the groups, but were all within 12-15 months after surgery and therefore not different to a clinically relevant extent.

Looking at the proportion of patients with an achievement of MCRC, instrumented fusion and posterior dynamic stabilization appeared to be more beneficial for back pain relief than sole decompression, and posterior dynamic stabilization seemed superior to decompression and instrumented fusion with regards to relief of leg pain. The dynamic stabilization group appeared to have more rigid selection criteria with regard to leg pain level and function (COMI score). These parameters are the highest at baseline and the lowest postoperatively in comparison with the other treatment groups. However, this group represented less morbid patients with a lesser proportion of additional degenerative diseases, less involved segments and a shorter duration of previous conservative treatment.

A decompression alone appeared less beneficial for back pain relief, but also for leg pain relief despite high preoperative leg pain levels in this group. Consequently, the improvement and achievement of the MCRC in COMI score was lower than in the other groups. Categorized pain relief and COMI score improvements are shown in figure 35 and 36. The three treatment types performed similarly with regard to the categorized unadjusted pain relief and COMI score improvement, and particularly for COMI score improvement. The curves of instrumented fusion and posterior dynamic stabilization are slightly shifted to the right reflecting more potential achievement of MCRC in pain and in COMI score.

**40**
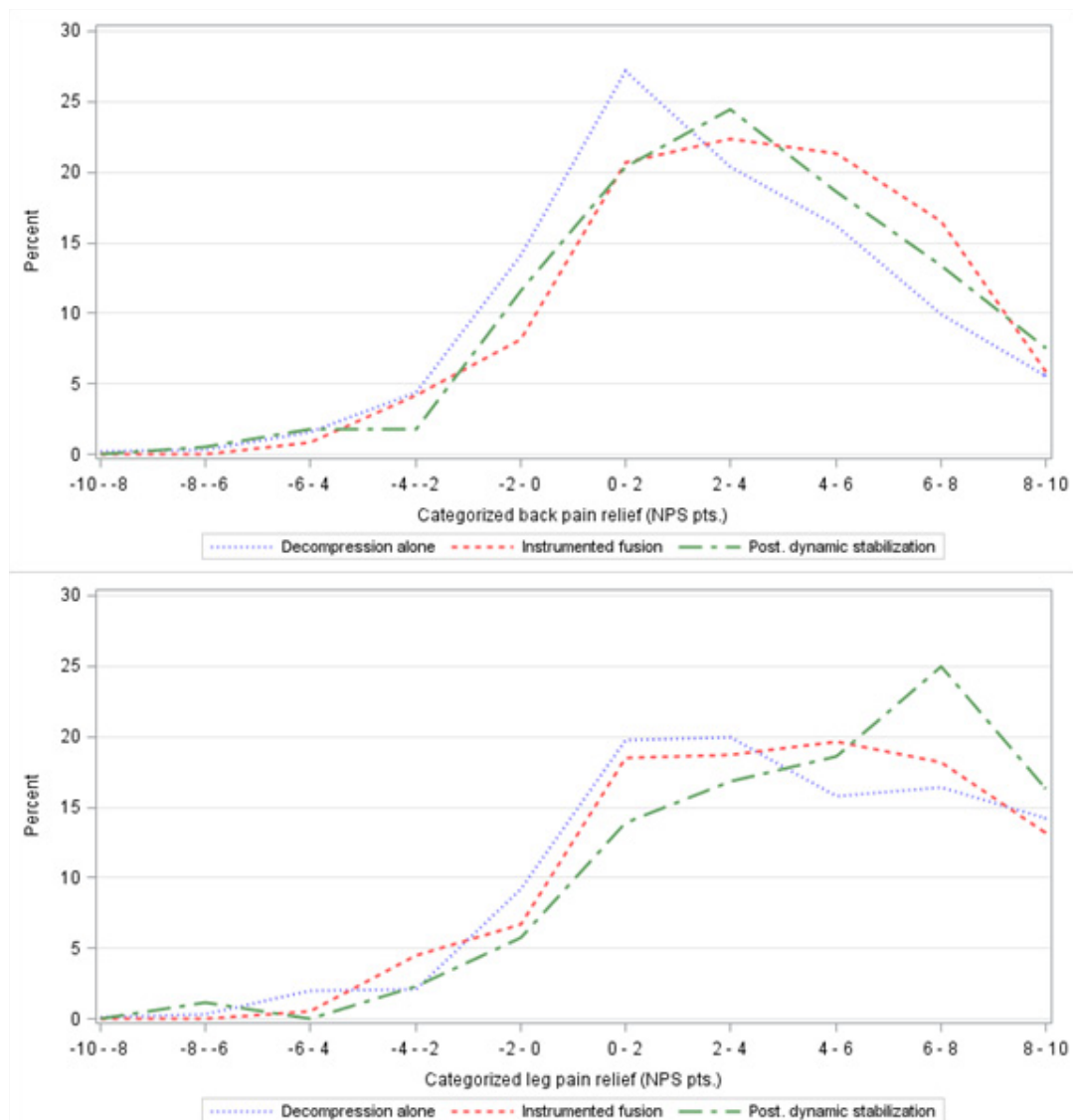


*Figure 35: Categorized pain relief for the three treatment groups.*
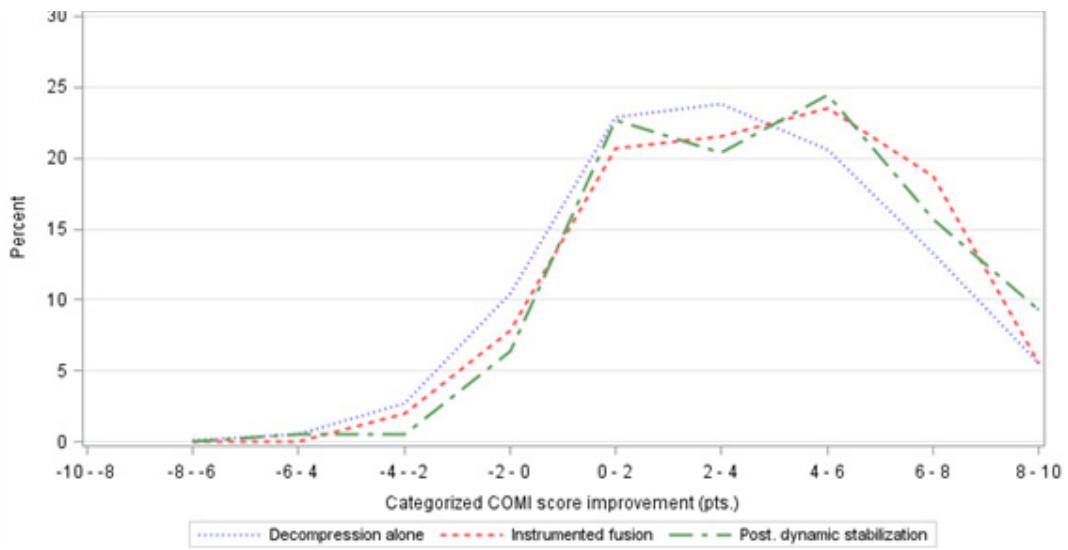
*Figure 36: COMI score improvements for the three treatment groups.*
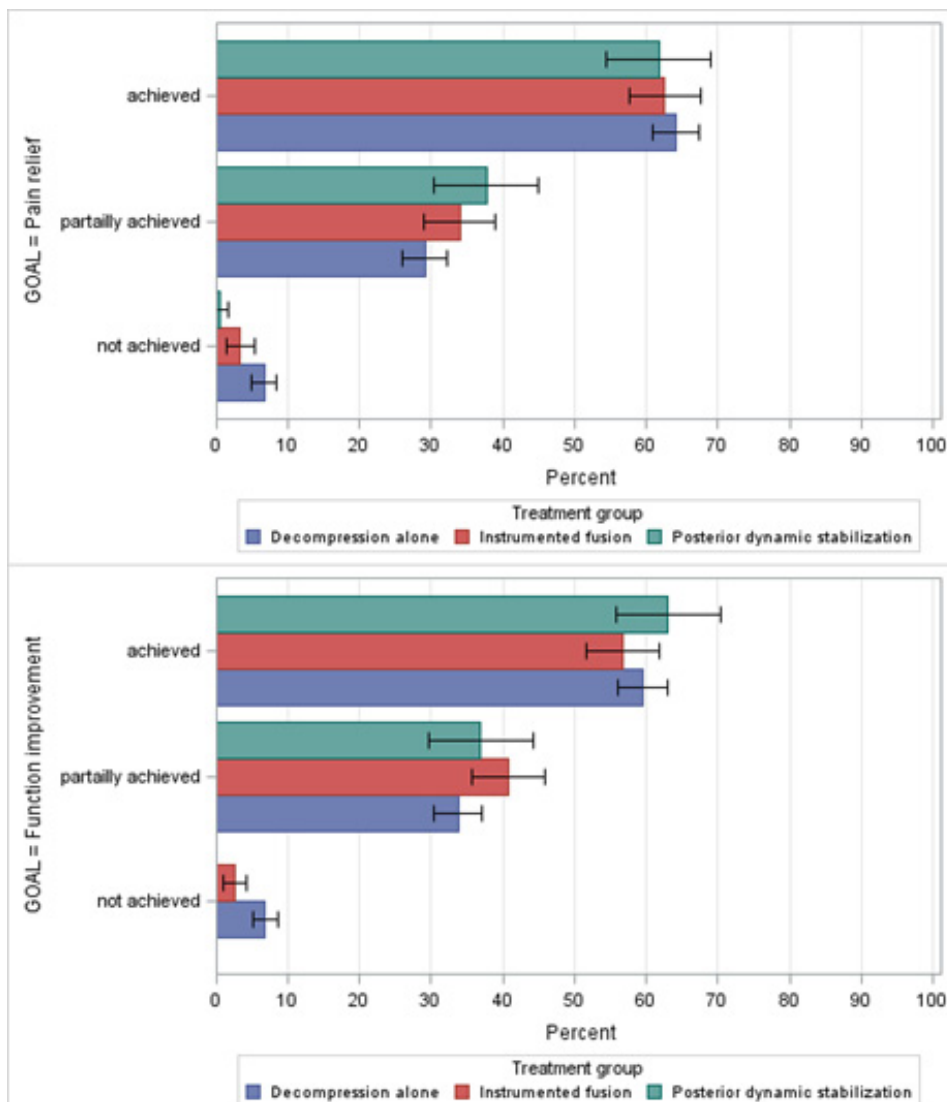
## II.     Achievement of the main treatment goals



*Figure 37: Achievement of the main physician-based treatment goals after different measures.*
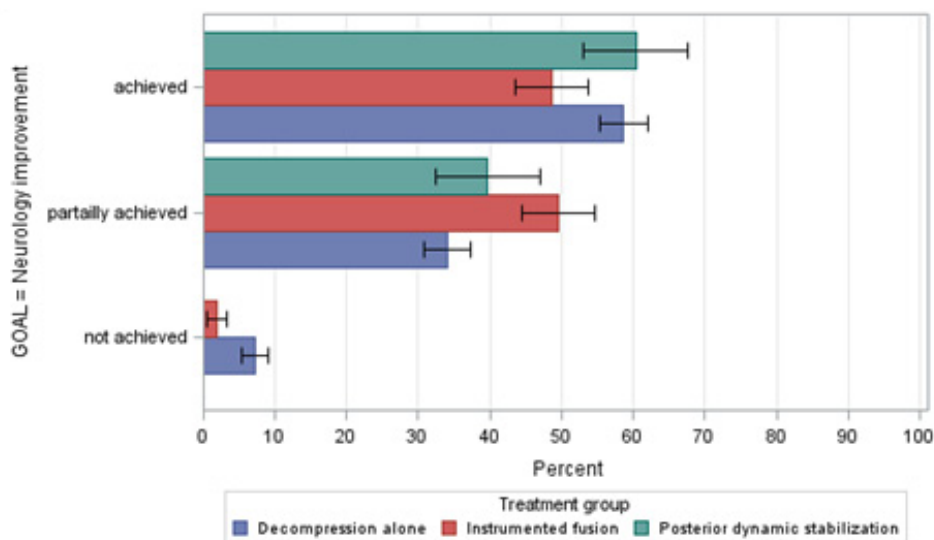
*Figure 38: Achievement of the main physician-based treatment goals after different measures.*

The proportions of 'achieved', 'partially achieved' and 'not achieved' goals were significantly different between the subgroups for all three main goals (p<0.003). The comparison of proportions of 'achieved' main physician-based goals between the three groups showed comparable results between 61.2% - 64.2% for pain relief, between 56.7% - 63.1% for functional improvement and between 48.6% - 60.3% for neurological improvement (Fig. 37 and 38). However, the comparison of proportions of 'not achieved' goals resulted in higher variations between 0.59 – 6.7% for pain relief, 0 -6.8% for functional improvement and 0 -7.3% for neurological improvement. The proportions of patients with 'not achieved' goals were the smallest in the group with dynamic stabilization, and the largest in the group with decompression alone for all the three mains goals.

III.      *Patient-based and physician-based perceptions of  treatment outcome*

Analysis of the patient-based perception of the treatment effect demonstrated that 72.9% of the decompression patients, 81.2% of the instrumented fusion patients and 85.5% of the dynamic stabilization patients were of the opinion that the treatment had helped a lot or had helped (Fig. 39). 10.8% of the decompression patients, 6.2% of the instrumented fusion patients, and 2.9% of the dynamic stabilization patients stated that the treatment had not helped or had made things worse. Notably, none of the dynamic stabilization patients stated that the treatment had made things worse in contrast to the other treatment options.

**Overall, how much did the operation help your back problem?**
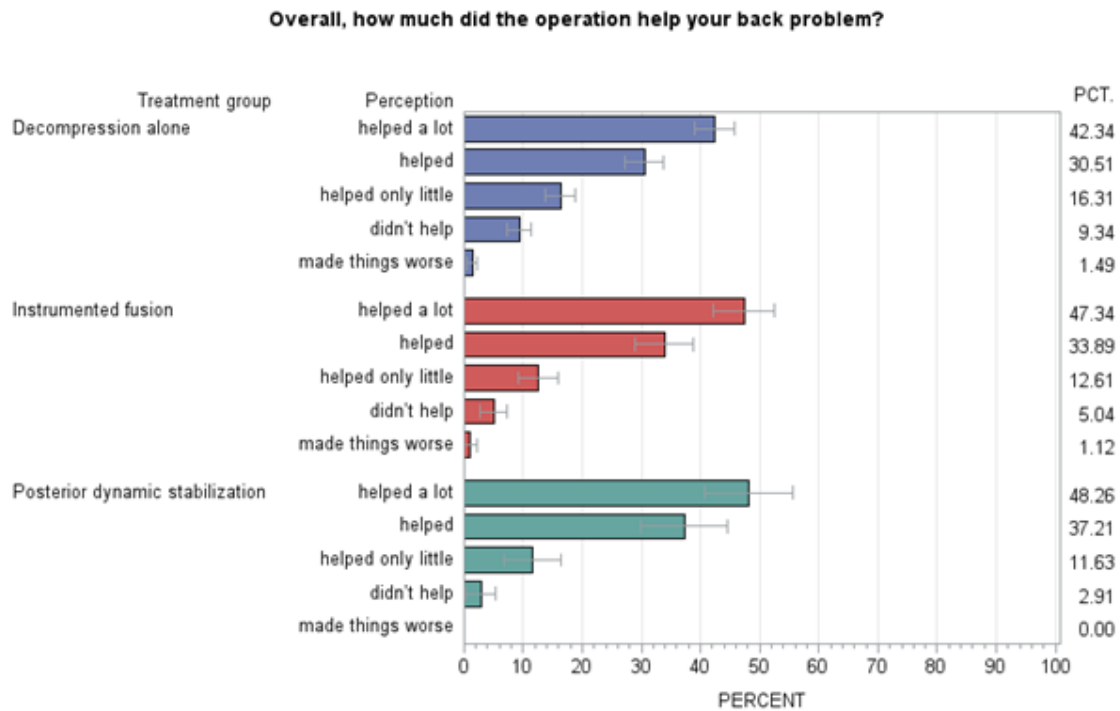


*Figure 39: Patient-based perception of the treatment effect according to COMI forms.*

According to the physician-based assessment of the treatment outcome, 73.1% of the decompression patients, 81.5% of the instrumented fusion patients and 97.7% of the dynamic stabilization patients had excellent or good outcomes. Interestingly, in only 4.1% of the dynamic stabilization cases physicians rated the outcome as excellent, and in 93.6% as good (no figures shown).

*IV.     Main COMI domains at baseline and at the last available  follow-up*
Median-answer-based spider charts demonstrated the same baseline and postoperative status for the COMI domains in all treatment groups (Fig. 40). At baseline, social disability and symptom-specific well-being were of major concern for all patients. Less of concern, but still poor were the domains work disability, function and quality of life. The last two domains improved by one category only. The social disability improved by two categories; symptom-specific well-being and work disability by three categories.

43

COMI domains pre- and postop for decompression alone



COMI domains pre- and postop for intrumented fusion



COMI domains pre- and postop for motion preserving stabilisation
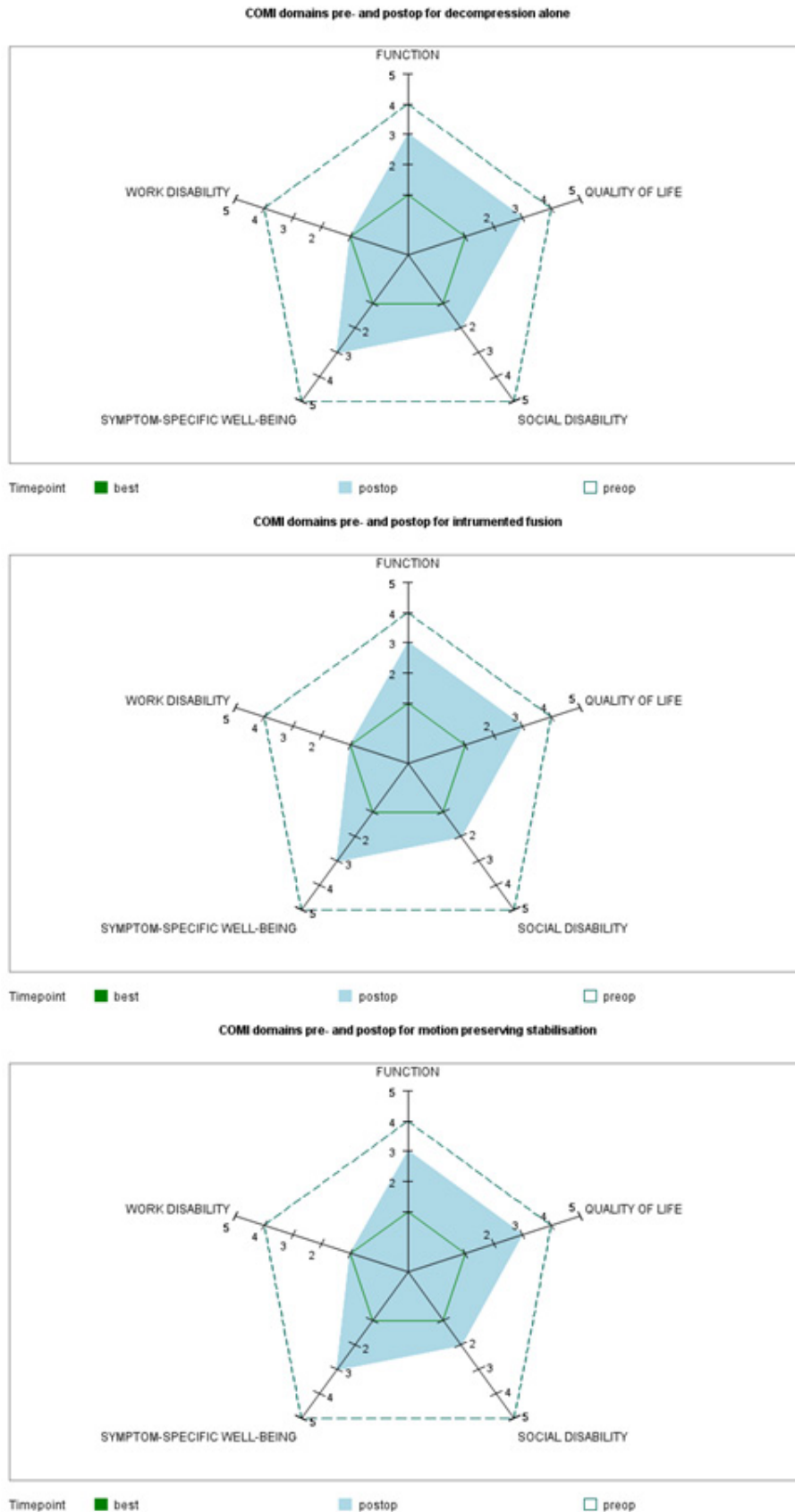


Figure 40: Main COMI domains pre- and postoperative for the three treatment groups.

*V.      Course of postoperative change*

There were 513 patients with a 3-month and 1-year follow-up. Of these, 263 had received decompression alone; 199, instrumented fusion; and 51, posterior dynamic stabilization. Figures 41 - 43 show the course of change in pain and COMI scores over time.

With Bonferroni adjustments for pairwise comparisons back pain at baseline was not significantly different between the treatment groups (p>0.41). No significant difference was seen also at 3-month follow-up (p>0.06). The group with posterior dynamic stabilization (2.1 points) was significantly different from the group with decompression alone (4.0 points; p<0.001) and from the instrumented fusion group (3.3 points; p=0.013) at the 1-year follow-up. At this follow-up also the instrumented fusion group had significantly lower back pain than the decompression alone group (p=0.015). The pre- to postoperative improvement of back pain to either follow-up was significant in each treatment group (p<0.001 for all comparisons) (Fig. 41).

45
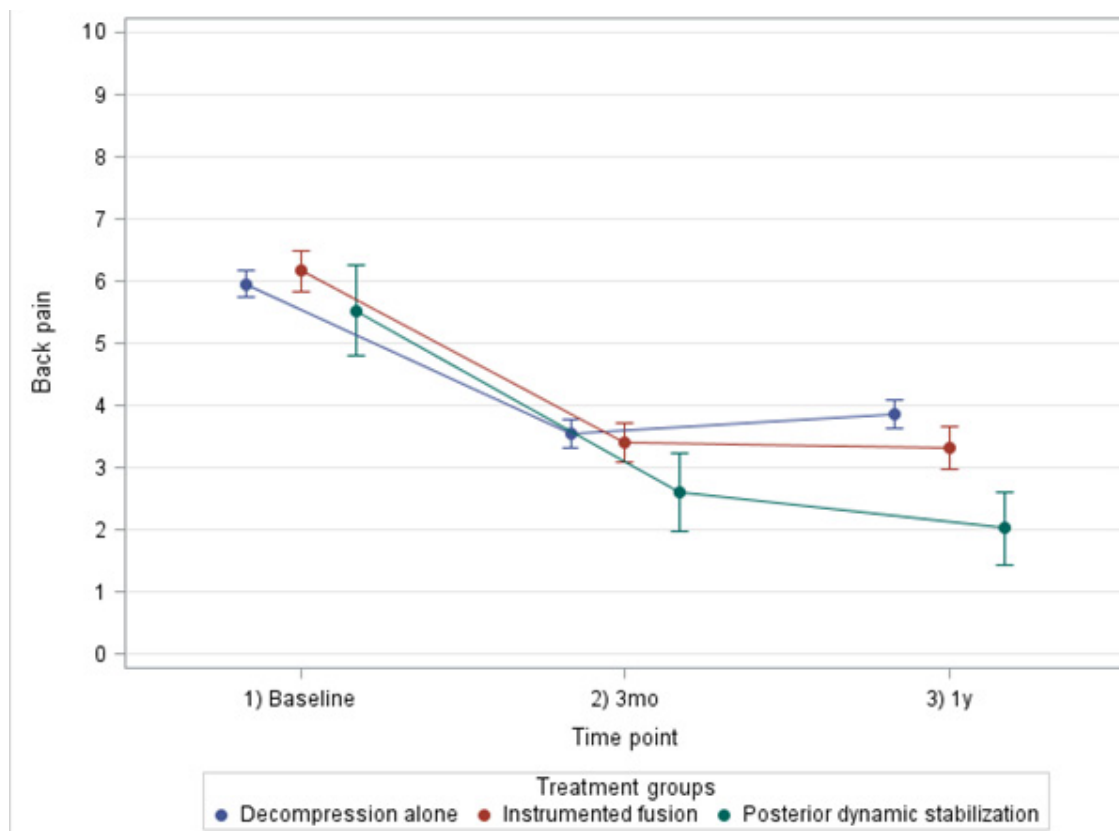


*Figure 41: Pre- and postoperative back pain at different time points (decompression alone N=140, instrumented fusion N=96, posterior dynamic stabilization N=51).*

A similar picture was revealed for the course of postoperative leg pain (Fig. 42). There were no significant differences in leg pain at baseline between the groups (p>0.05). At the 3-month follow-up the postoperative leg pain in the posterior dynamic stabilization group (2.1 points) was significantly lower than that in the instrumented fusion group (2.8 points; p<0.001) or that in the decompression alone group (3.7 points; p<0.001). The two latter groups were not significantly different from each other (p=0.32). Patients in either group had rather constant postoperative leg pain levels between the 3-month and the 1-year follow-ups. The posterior dynamic stabilization group had a significantly lower leg pain (2.2 points) than that in the instrumented fusion group (3.0 points; p<0.001) or that in the decompression alone group (3.8 points; p<0.001), whereas the instrumented fusion and the decompression alone groups were not significantly different from each other (p=0.27). The pre- to postoperative improvement of leg pain to either follow-up was significant in each treatment group (p<0.001 for all comparisons) (Fig. 42).

**46**



*Figure 42: Pre- and postoperative leg pain at different time points (decompression alone N=140, instrumented fusion N=96, motion preserving stabilization N=51).*

Regarding the course of change in COMI score, similarly as for pain, baseline COMI score was not significantly different between the groups (p=1.0) (Fig. 43). Also at the 3-month follow-up the COMI score was not significantly different between the groups (p>0.10).

The decompression alone group remained unchanged and the two other treatment groups showed further improvement of the COMI score until 1-year follow-up, which was the highest in the posterior

dynamic stabilization group (0.9 points) than in the instrumented fusion group (0.5 points). At the 1-year follow-up, the posterior dynamic stabilization group had significantly lower COMI score (3.0 points) than the decompression alone (4.7 points; p<0.001), but not significantly different from the instrumented fusion (3.9 points; p=0.08) group. At this follow-up, the COMI score in the instrumented fusion group also was significantly lower than that in the decompression alone group (p=0.002). The pre- to postoperative improvement of COMI score to either follow-up was significant in each treatment group (p<0.001 for all comparisons) (Fig. 43).
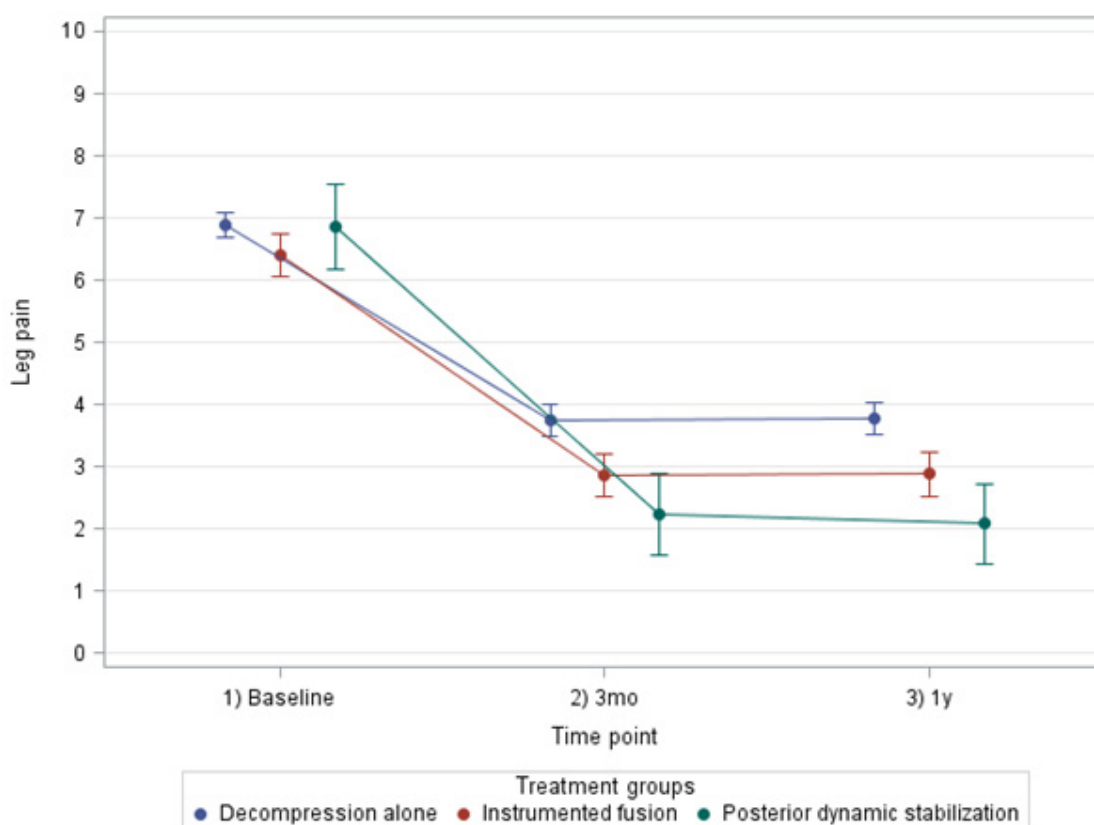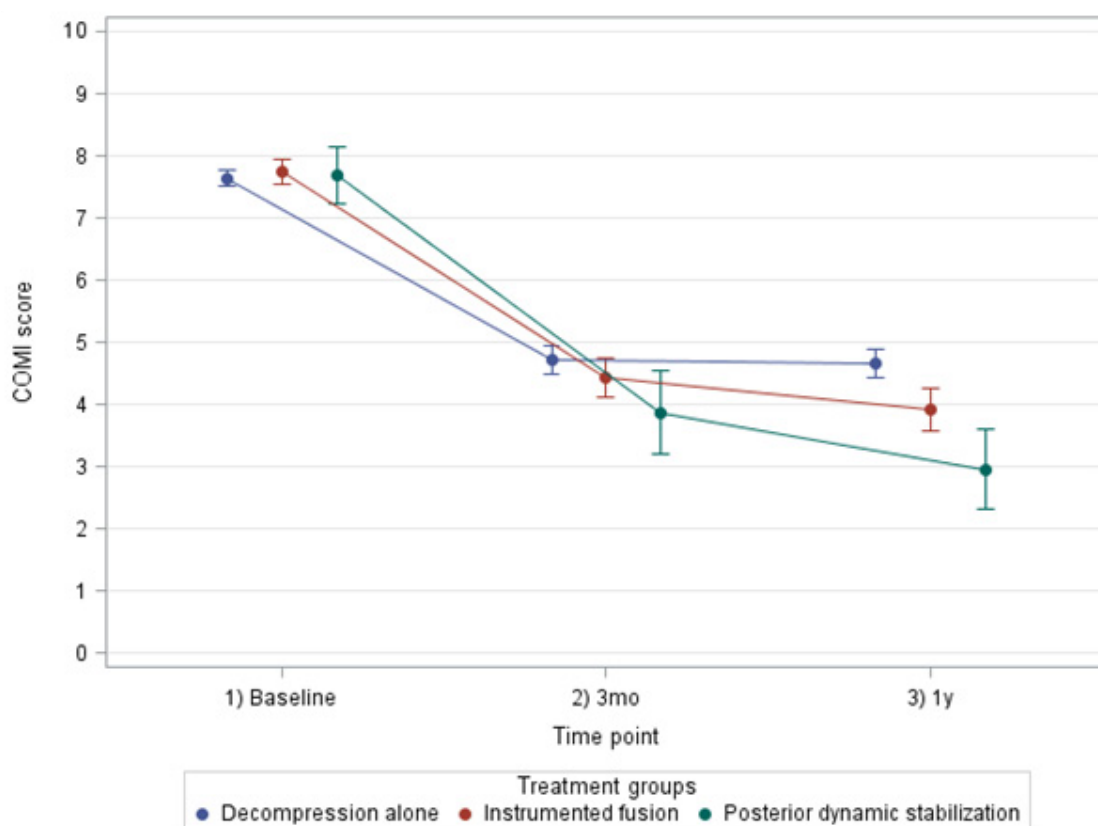


*Figure 43: Pre- and postoperative COMI score at different time points (decompression alone N=203, instrumented fusion N=199, motion preserving stabilization N=51).*

**References**

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.
18. Deyo RA, Battie M, Beurskens AJ, Bombardier C, Croft P, Koes B, Malmivaara A, Roland M, Von Korff M, Waddell G (1998). Outcome measures for low back pain research. A proposal for standardized use. Spine 23:2003-2013
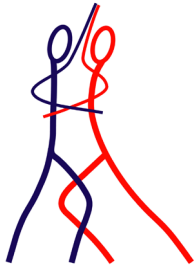
Figure 44 displays the cumulative growth curves of the various national modules. The different starting dates of the modules need to be considered (Swiss/International 2005, Austria 2005; Germany 2006; North America 2007; Brazil/South America 2008; Italy 2008; Mexico 2008; Great Britain 2010; Australia 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.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.

The hospital classification of all active 45 Spine Tango clinics actively documenting in 2013 can be seen in figure 45. The highest proportion is made up by university or teaching hospitals with 42%.

Figure 46 shows an overview of the Spine Tango participating hospitals and their country of origin until the end of 2013. We divided their total case load into primary forms, follow-up forms and COMI forms.

**48**

## Growth rates of the various Spine Tango modules
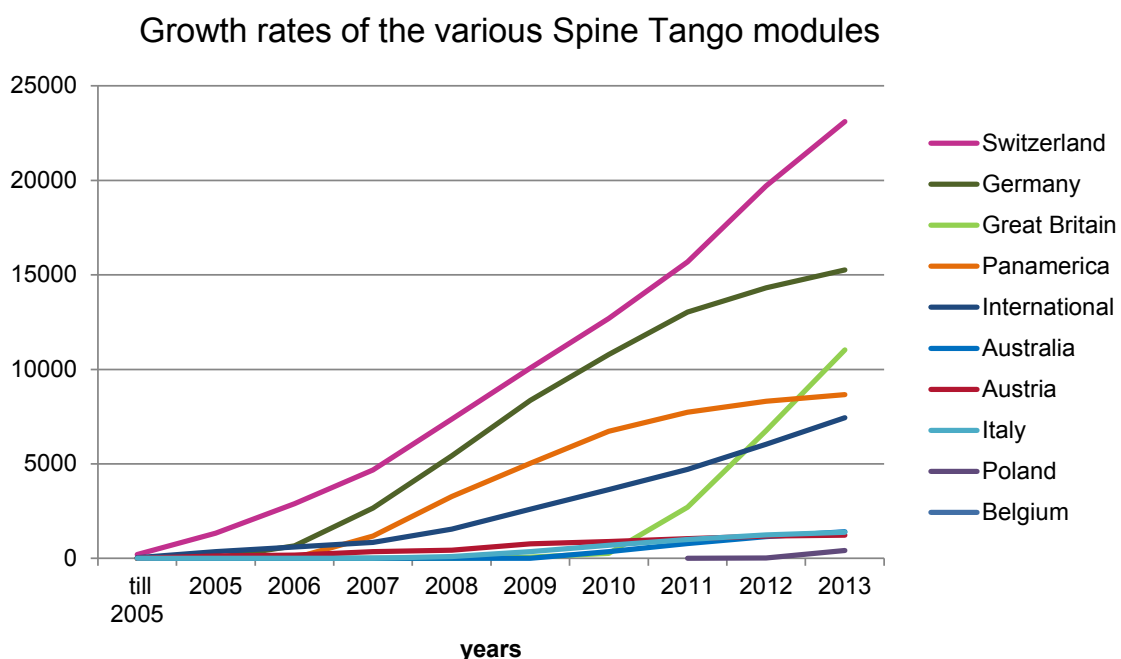


*Figure 44: Growth curves (number of cases of the single Spine Tango modules over the years)*

# Hospital classification
## 45 Spine Tango clinics



- University hospital
- Specialized spine center
- General hospital
- Private hospital

42%
24%
16%
18%
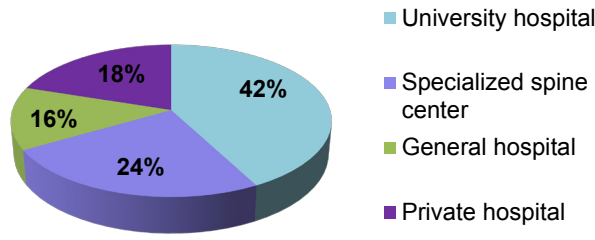
*Figure 45: Hospital classification for the 45 clinics actively documenting the 2011 forms.*



Spine Tango 2011 forms per participating country (active hospitals) by the end of 2013

- Surgery forms
- Follow-up forms
- COMI forms

Australia (2 hospitals)
Austria (2 hospitals)
Belgium (5 hospitals)
Brazil (1 hospital)
Germany (6 hospitals)
Italy (2 hospitals)
Poland (4 hospital)
Slovenia (1 hospital)
Spain (1 hospital)
Switzerland (16 hospitals)
UK (4 hospitals)
USA (1 hospital)
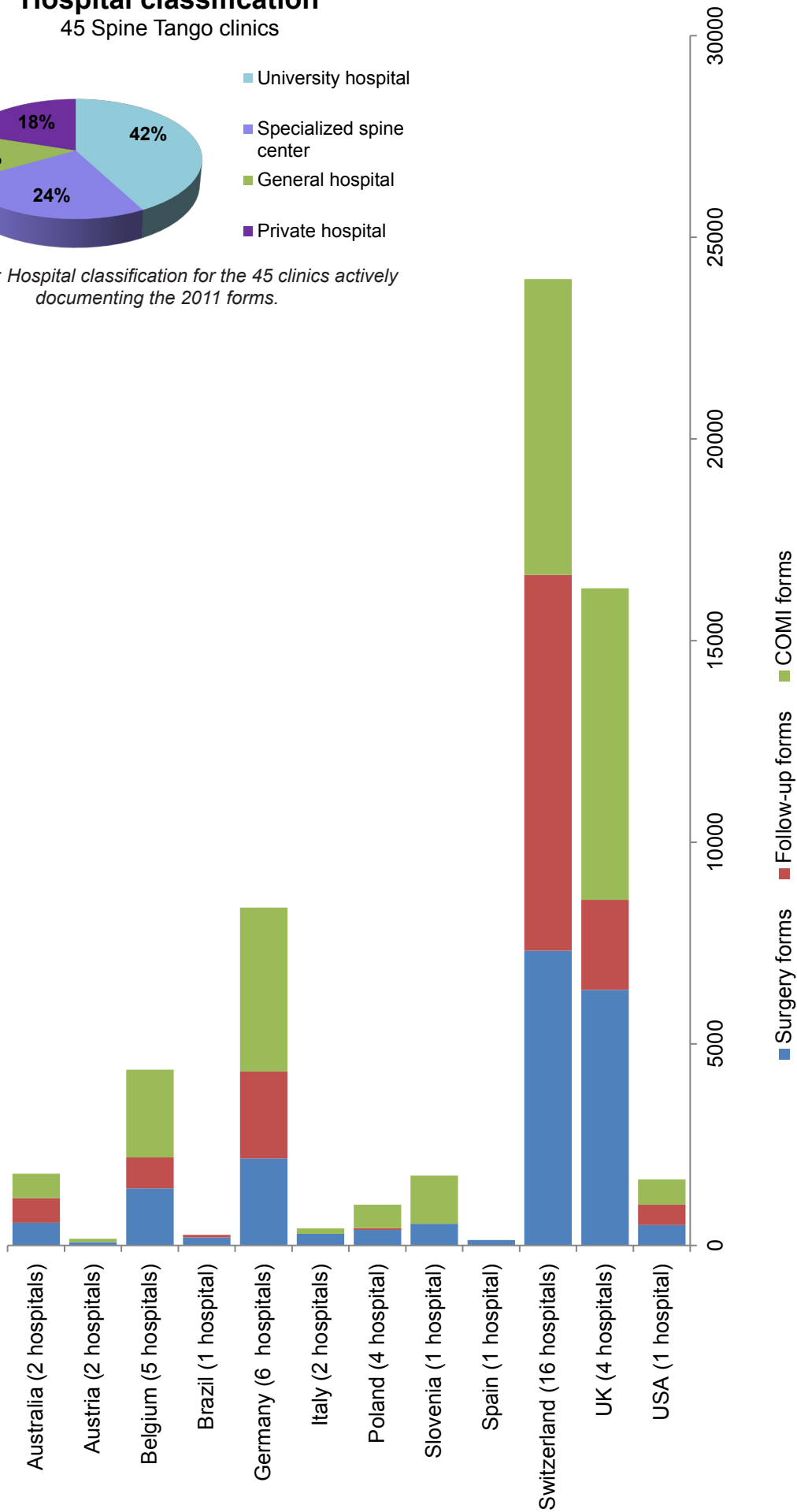
*Figure 46: Overview of the Spine Tango participating hospitals according to their country of origin with case load divided into primary forms 2011, follow-up forms and COMI forms until the end of 2013.*

49

## SECURITY

The model of the MEMdoc and MEMdoc-Module system is designed around the principle of data separation. The MEMdoc central server, housed at the MEM Research Center (MEMcenter) in Bern, hosts the main application and the central database containing all study definitions and clinical study data.  Satellite MEMdoc-Module servers located throughout the world store all personal data about users, institutions and patients. At the core of the system is an innovative architecture in which the web browser of the client is used as a hub to seamlessly segregate and integrate the data between the MEMdoc-Module and the MEMdoc central server. This design provides tightly integrated communication between the servers while increasing the security and privacy of both systems. This has been accomplished using a light weight JSON server and incorporation of SSL encryption on each module. Flexible data sharing options have been designed to restrict or expand data access to suit individual needs.  Finally, data consistency is controlled through systematic validation of received data and a rollback in case of errors.

Each module server contains a local MySQL database, an Apache web server and the custom MEMdoc-Module application. This server can sit within the same clinic as the user or in some remote location depending on the needs of the group hosting the module. The physical and network security of this server is left up to the hosting entity. Some groups choose to restrict access to the module to users within the local subnet while others allow open access from anywhere.



MEMdoc and MEMdoc-Module Data Segregation and Web Service
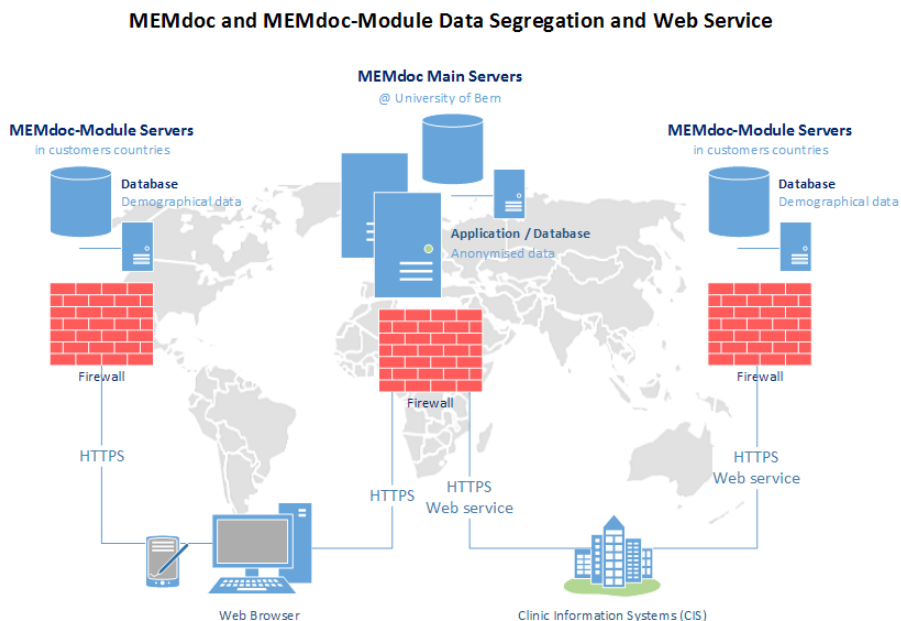
The module database contains all user and clinic information as well as the basic demographic data of patients. No medical data is stored on the module server.

All users from every MEMdoc-Module make their initial connection to the MEMdoc central server that houses the core MEMdoc application as well as all clinical study definitions. The MEMdoc application then recognizes the URL of the connection to determine which MEMdoc-Module to utilize and delivers the appropriate custom module application to the user's web browser. Each time a user requests data the application contacts both the local MEMdoc-Module and MEMdoc central database (Oracle) to seamlessly integrate the data from each for display. Newly entered data is likewise split so that only internal numeric identifiers for the user, patient, clinic, department and module are stored on the MEMdoc central database. All medical data is retrieved from and stored directly to the MEMdoc central server and linked to the module by these internal identifiers. Medical data never passes through the MEMdoc-Module server and is never stored on the MEMdoc-Module server. The birth year and gender of each patient are the only pieces of personal information stored on the MEMdoc central database for performing pooled statistics.

The physical and network security of all the MEMdoc servers is maintained by IEFM (Institute for Evaluative Research in Medicine) at the MEM Research Center. This includes the MEMdoc central (web) server, the MEMdoc database server and the MEMdoc statistics (SAS) server. All servers are physically housed at the MEMcenter in a dedicated, locked, climate controlled and monitored server room. The network is protected by a Sonicwall NSA 3500 firewall with real-time gateway anti-virus, anti-spyware, anti-spam and intrusion prevention. The firewall only allows access to the servers from the outside via port 443. Additional access is restricted to connections from within the MEMcenter. Web security is controlled by a DigiCert certified SSL web server certificate with 256-bit encryption on the MEMdoc central server and on each satellite module. Each server is continuously monitored to log all connections and to detect any suspicious activity. Additionally, any modules that are hosted at the MEMcenter fall within the same security parameters.

The following hardware is recommended for a MEMdoc-Module:
☐ Processor (1 CPU) Intel Xeon 3500 / AMD Opteron
☐ Memory 4 GB RAM
☐ Hard drive (2 drives) 250 GB, Sata or SAS
☐ RAID-Controller with battery backup unit (Raid 1)
☐ Debian 6
or a virtual machine with comparable performance

## IMPLANT CAPTURE

Application flow and features, although much appreciated by users, are secondary to easy and flexible data collection methods. With this in mind the MEMdoc application has expanded data collection facilities for all forms of medical data including image and implant data. OMR (optical mark recognition), a proven technology for data collection, has long been a staple of the MEMdoc application and has been expanded and simplified in Release 4 with support for both Windows and Mac users from all popular web browsers. Image capture has been extended with a redesigned image upload function that allows multiple uploads for a single case as well as simplified image retrieval for subsequent analyses and presentations. The SEDICO (secure data integration concept) implant capture tool, previously only available to users documenting on the MEMdoc central server, is now available to MEMdoc-Module users. Users who do not use the SEDICO interface can now use an inexpensive hand-held barcode reader to scan implant barcodes directly into the recorded questionnaires. Finally, access to the ever growing list of online suppliers and products has been enhanced with a faster search engine and the ability to segregate products by category and anatomical location of use.
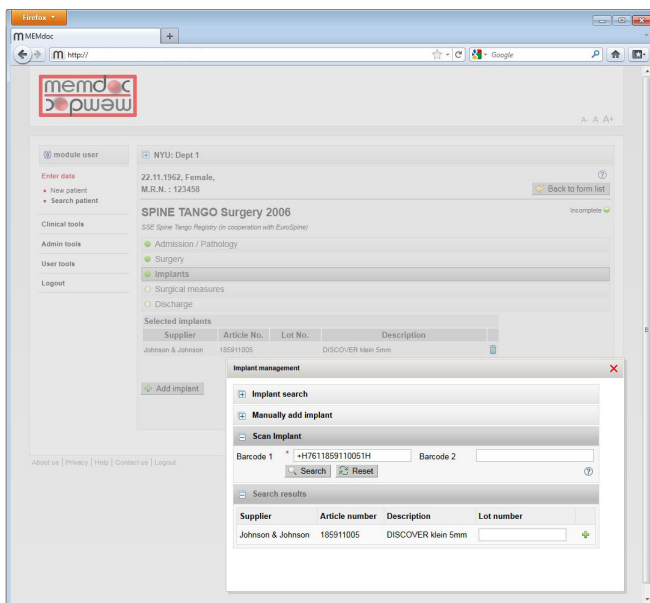
$u^b$

*b*
UNIVERSITÄT
BERN

MEM Research Center

While one of the major advantages of the MEMdoc system lies with its web-based access that allows contributions from users around the world to create a global data pool, IEFM is keenly aware that MEMdoc is not the only documentation solution available.  Users of other systems, however, may still want to contribute to a nationally endorsed data pool like Spine Tango housed exclusively on MEMdoc.  To this end IEFM developed the MEMdoc Web Service.  This tool provides an interface that can be integrated into existing hospital information systems (HIS) and virtually any third-party data collection system to facilitate data entry, reduce physician workload and decrease data entry errors.  Through our web service, applications can request the latest version of the definition of our data collection forms along with the complete set of validation rules.  It is then up to the third-party application to collect the data and apply the rules.  Once the data is collected it can then be contributed to the MEMdoc central repository.  We developed such a system to ensure that the data received from external sources was of the same quality as that recorded directly on MEMdoc.  Hence, redundant data entry is reduced while the value of the collected information is increased via silent synchronization of local data with a central instance. Such an interface between commercial systems and an academic documentation portal is unique and the combination of the advantages of both approaches goes beyond the current state of art of medical documentation.

## Forms used in Spine Tango Registry - 01.09.2014

| | Forms | multilingual | online available | | | | | | OMR paper forms available | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | english | german | french | italian | spanish | polish | 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 4: Available questionnaires in the SSE Spine Tango registry (01.09.2014)*

## PUBLICATIONS

PAPERS IN PEER REVIEWED JOURNALS

**Mannion AF, Fekete TF, O'Riordan D, Porchet F, Mutter UM, Jeszenszky D, Lattig F, Grob D, Kleinstueck FS**
The assessment of complications after spine surgery: time for a paradigm shift?
Spine J. 2013 Jun;13(6):615-24.

**Burkhardt JK, Mannion AF, Marbacher S, Dolp PA, Fekete TF, Jeszenszky D, Porchet F**
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. 2013 Jul;35(1):E4.

**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. 2013 Dec 31. [Epub ahead of print]

**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. [Epub ahead of print 2013 Jul 10].

ORAL PRESENTATIONS

**Fairbank JC, van Hooff ML,  Mannion AF**
Determination of the Oswestry Disability Index (ODI) score equivalent to a "satisfactory symptom state".
British Association of Spine Surgeons, Norwich, UK
13th - 15th of March 2013

**Fairbank JC, van Hooff ML,  Mannion AF**
What score on the Oswestry Disability Index indicates a satisfactory symptom state?
International Society for the Study of the Lumbar Spine, Scottsdale, Arizona, USA
13th - 17th of May 2013
Swiss Society of Orthopaedics and Traumatology, Lausanne, Switzerland
26th - 28th of June 2013
Swiss Medical Weekly 143, Suppl 198, p. 17S.

**Burkhardt J-K, Mannion AF, Marbacher S, Dolp PA, Fekete TF, Jeszenszky D, Porchet F**
A comparative effectiveness study of patient-rated and radiographic outcome after two types of decompression with fusion for spondylotic myelopathy: anterior cervical discectomy (ACDF) versus corpectomy (ACCF).
Sociedad Espanola de Neurocirugia, San Sebastian, Spain
14th - 17th of May 2013
Deutsche Gesellschaft für Neurochirurgie, Düsseldorf, Germany
26th -29th of May 2013
Swiss Federation of Clinical Neuro-Societies, Montreux, Switzerland
05th - 07th of June 2013
World Federation of Neurosurgical Societies, Seoul, Korea
08th -13th of September 2013
Eurospine, The Spine Society of Europe, Liverpool, UK
2nd - 4th of October 2013

**Kleinstueck F, Buddenberg P, Fekete TF, Porchet F, Jeszenszky D, Mannion AF**
The patient's perspective on the outcome of surgery for lumbar degenerative scoliosis.
Swiss Society of Orthopaedics and Traumatology, Lausanne, Switzerland.
26th - 28th of June 2013
Swiss Medical Weekly 143, Suppl 198, p. 15S.

**Röder C**
Benchmarking with Spine Tango: potentials and pitfall.
European Spine Journal "Spine Sciences' State of the Art Forum", Geneva.
13th of September 2013

**Mannion AF**
The quality of spine surgery from the patient's perspective.
Spine Sciences State of the Art Forum  Geneva, Switzerland
13th - 14th of September 2013

**Mannion AF**
Rating of global outcome after spinal surgery: how often do the surgeon and patient agree?
Spine Sciences State of the Art Forum  Geneva, Switzerland
13th - 14th of September 2013

**Sobottke R, Siewe J, Kalhausen T, Eysel P, Röder C, Aghayev E**
Predictors for quality of life improvement and pain relief in lumbar spinal stenosis relative to patient age: A Spine Tango registry based study.
Eurospine Congress, Liverpool 2013, UK
2nd - 4th of October 2013
Eur Spine J 2013;22(5):S713

**Fairbank JC, van Hooff ML, Mannion AF**
What is the maximum level of disability on the Oswestry Disability Index that most patients could live with?
Eurospine, The Spine Society of Europe, Liverpool, UK
2nd - 4th of October 2013

**Mannion AF, Kleinstueck FS, Jeszenszky D, Porchet F, Haschtmann D, Fekete TF**

What level of pain are patients happy to live with after surgery for lumbar herniated disc?

Society for Back Pain Research, London, UK

14th - 15th of November 2013

**Ferlic P, Fekete TF, Kleinstuck FS, Porchet F, Mannion AF, Jeszenszky D, Haschtmann D**

Patientenrelevante klinische Ergebnisse der chirurgischen Dekompression bei lumbaler epiduraler Lipomatose.

Deutscher Wirbelsäulenkongress, 8. Jahrestagung der Deutschen Wirbelsäulengesellschaft, Frankfurt am Main, Deutschland

5th - 7th of December 2013

POSTER PRESENTATIONS

**Munting E, Röder C, Sobottke R, Aghayev E**

Predictors for dural lesions requiring surgical measures in the treatment of lumbar spinal stenosis:

Comparison of a single center with the reliable and all other Spine Tango clinics

Eurospine Kongress, Liverpool (UK)

2nd -4th of October 2013

Eur Spine J 2013;22(5):S723

**Zweig T, Melloh M, Aghayev E, Röder E**

Impact of the conservative therapy-interval on the surgery outcome of the lumbar disc herniation.

8. German Spine congress, Frankfurt am Main (Germany)

5th -7th of December

## Authors

Christoph Röder, MD MPH
Spine Tango Committee, EuroSpine
Associate Professor, Director
Institute for Evaluative Research in Medicine
University of Berne, Switzerland

Emin Aghayev, MD MSc
Spine Tango Committee, EuroSpine
Senior lecturer, Group Head Evaluative Clinical Research
Institute for Evaluative Research in Medicine
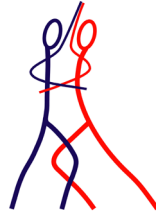University of Berne, Switzerland

Everard Munting, MD
Forner Chair Spine Tango Committee, EuroSpine
Head of Orthopaedics, Clinique Saint Pierre
Ottignies, Belgium

Tim Pigott, MD
Chair Spine Tango Committee, EuroSpine
Head of Neurosurgery, Walton Centre for Neurology and Neurosurgery
Liverpool, United Kingdom

Rolf Sobottke, MD
Spine Tango Committee, EuroSpine
Head of Orthopaedics, Würselen Hospital
Aachen, Germany

Anne Mannion, PhD
Spine Tango Committee, EuroSpine
Head of Spine Research, Schulthess Clinic
Zurich, Switzerland

Nina Parli, cand. med
Scientific assistant
Institute for Evaluative Research in Medicine
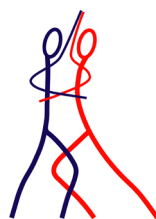University of Berne, Switzerland

58

# CODE OF CONDUCT

for Participation in the

Spine Tango Registry

**Table of contents**

## I.    Mission Statement

a) The registry should facilitate the collection of high quality data describing the outcome of spine surgery.

b) The data should be collected honestly and as completely as possible.

c) The means of data collection and the methods of auditing that are put in place to ensure the validity of the data should be transparent to all involved.

## II.    Definitions

*Spine Tango Registry*

Spine Tango Registry is an internet based documentation and register system dedicated to quality assurance and outcome assessment in the field of spinal care.

*Database*

The database is the result of the collection of independently gathered data through the Spine Tango Registry, arranged in a systematic or methodical way and individually accessible.

*IEFM*

Institute for Evaluative Research in Medicine.

*Participants*

Participants are defined as individuals or groups of individuals complying with the Code described herein.

A "Participant" can be either an individual or a group of individuals constituting a unit or department. An individual should be a member of Eurospine-SSE (in any one of the approved membership categories). Participants practicing outside Europe should be member of another recognized scientific society, or a corresponding member of Eurospine.

For groups, at least one person in the group should be a member of Eurospine-SSE or another recognized society.  For participants practicing in Europe, Eurospine-SSE membership should be obtained within 12 months of acceptance of the agreement on Code of Conduct.

*Spine Tango Registry Dictionary of Terms*

Refers to documents published on each ST module front page.

*COMI*

Core Outcome Measures Index.  Refers to:
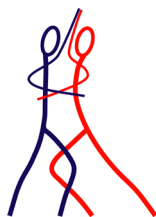
Deyo RA, Battie M, Beurskens AJHM, Bombardier C, Croft P, Koes B, Malmivaara A, Roland M, Von Korff M, Waddell G. Outcome Measures for Low Back Pain Research: A Proposal for Standardized Use. Spine. 1998;23(18):2003-2013.

Mannion AF, Elfering A, Staerkle R, Junge A, Grob D, Semmer NK, Jacobshagen N, Dvorak J, Boos N. Outcome assessment in low back pain: how low can you go? Eur Spine J. 2005;14(10):1014-1026III. Spine Tango Registry

Mannion AF, Porchet F, Kleinstueck 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

Mannion AF,Porchet F, Kleinstueck FS, Lattig F, Jeszenszky D, Bartanusz V, Dvorak J, Grob D (2009) The quality of spine surgery from the patient's perspective: Part 2. Minimal clinically important difference for improvement and deterioration as measured with the Core Outcome Measures Index. Eur Spine J 18 (Suppl 3): 374-9

## III.     Spine Tango Registry

### III.A.    Background

In the late 1990s Prof. Dieter Grob was asked by the cantonal government of Zurich, Switzerland, to conduct an outcome study of the results of surgical interventions on the spine. The investigation was completed and the data provided to the sponsor. There was no further feedback or consequences as a result of this study.

This triggered the idea of conducting similar projects with a specialist society like Eurospine, the Spine Society of Europe and keep full control of the data.

In 2000, Prof. Max Aebi took over the direction of MEM-CED, the Maurice E. Müller Center for Education and Documentation. This institute, which had a research focus on medical registries, multicenter studies and outcomes research, was later integrated into the University of Berne as the Institute for Evaluative Research in Medicine (IEFM).

In cooperation with experts from Eurospine, the Spine Tango content and technology was developed at the IEFM, where its database and administrative center is located.

### III.B.    Instruments

Being initially a purely surgical registry, Spine Tango has been developed around one core questionnaire for primary and revision surgeries. It is accompanied by a second and very similar questionnaire
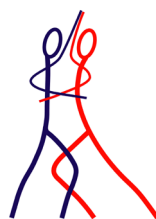
for staged surgery and a short follow-up questionnaire.

All instruments are available in a scanable paper and online format and follow the three golden rules for medical registries: simplicity, simplicity, simplicity. The forms can be completed in a minute or less and are suitable for documentation of all spinal pathologies, levels, accesses and surgical techniques. There has been a significant shift in political and consumer requirements for validated surgical outcomes. With this in mind the Core Outcome Measures Index (COMI), originally proposed by R. Deyo et al. (1998), was developed by a group at the Schulthess Klinik and at Balgrist Hospital, Zurich (AF Mannion, D Grob, N Boos et al.) for back and neck pain (two separate instruments) and is now officially recommended as the outcome instrument of choice for the Spine Tango community. Similar to the physician-based documentation, the COMI is short ,comprehensive and easy for patients to fill in. Since the superiority of surgical versus conservative treatment is still unclear for many spinal disorders, a working group has developed the "Spine Tango conservative form", a documentation form for the most important non-surgical treatment options (Kessler JT et al, ESJ 2011 Mar;20(3):369-79). This will enlarge the potential user base of Tango, making it a diagnostic endeavor with possibilities to compare surgical and non-surgical treatments and their outcomes using one and the same registry.

## IV.     Parties

This agreement is established between Eurospine, The Spine Society of Europe, the Participants of the Spine Tango Registry and IEFM.

## V.     General Code of participation

All "Participants" in the Spine Tango Registry shall adhere to the Participant Agreement.

All participants shall provide a signed agreement to the conditions and standards set out herein. All participants shall be responsible in ensuring that all necessary agreements are obtained from their institution (and produced on demand) in respect to any local laws, guidelines, "best practices", ethical requirements, infrastructure etc.

The underlying rationale for each requirement (highlighting how it is intended to promote/advance the overall quality of the registry) are, after the statement of each rule, indicated in square brackets.

### V.A.     Requirements for Participants

•      All participants shall irrevocably and for an indefinite period provide their data to Spine Tango. For the avoidance of doubt each participant hereby agrees by their participation to accept that data cannot be withdrawn/removed at a later date, irrespective of that Participant withdrawing for any reason from Spine Tango. Only data entered and subsequently found to be "fraudulent" will be removed from the data pool. If such data has already been used in existing publications, and have markedly
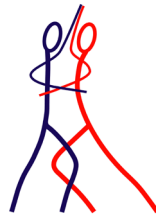
influenced those published findings, this shall be addressed as an addendum in the relevant journal or publication. [The reason for insisting on the retention of all data in the registry is that any scientific papers that have been published, based on a given data set, must be readily accessible and available should inspection be requested by the publishing journal. Although an electronic copy of the specific dataset will be stored separately in the database, the original data must be traceable within the registry at all times.]

• All Participants must agree to a common language for completion of the Spine Tango forms in accordance with the definitions given in the Spine Tango Registry Dictionary of Terms. Constructive comments and feedback on the dictionary is encouraged and welcomed, especially if Participants encounter any inconsistencies or ambiguities. [Adherence to the Spine Tango Dictionary of Terms is important to ensure consistent and systematic data collection, and to avoid any wording/phrasing from being interpreted differently by different users.]

• If it is available in their native language, all Participants are strongly encouraged to use the Core Outcome Measures Index (COMI) as their patient-orientated outcome instrument. This instrument has been validated in many languages, and is short and practical for use in daily clinical practice. [We recommend the consistent use of this instrument for all Participants because it is a practical and valid tool and its use will facilitate benchmarking between centers.]

• All Participants shall be required to indicate the methodology and means (e.g Clinic Information System, Operating Room report, personal agenda, billing procedure) by which they will verify the number of cases they have operated upon or treated in a given year at their personal convenience. The data source selected shall be a matter for the Participant subject to that source being considered "legitimate" by the Spine Tango Registry. [The annual number of cases will permit calculation of compliance with submitted documentation of each user, to give them a key performance indicator for future improvement and/or to form the basis of their application to ultimately become an Accredited Spine Tango Participant]

• Participants shall be required to accept and agree to on-site auditing by an independent party contracted by the EuroSpine-SSE Spine Tango Committee. Such independent auditor will be bound to medical confidentiality. [Auditing of the Spine Tango registry data, to include verification of the proportion of all cases submitted and the accuracy of the specific data entered, is essential to ensure that the data is trustworthy. Auditing is a prerequisite of any high quality registry.]

• In the case of proven fraudulent behavior the Participant's entire data set will be removed from the registry and their current and previous participation terminated forthwith. Their name will be deleted from the published list of Participants, for all years. This step will only be taken after an investigation by the Eurospine –SSE Executive Committee. The investigation shall take such form as the Executive Committee shall in its absolute discretion determine. It will be a positive duty for all
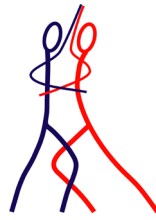
Participants, if so requested, to assist the Executive Committee in the investigation of such matters. [Honesty, truthfulness and integrity is expected and demanded of all Participants. However to retain external credibility and accountability, it is essential that decisive action is taken where such conditions are breached. Strict adherence to and enforcement of this rule is essential in order to ensure the integrity of the dataset, and its value to other Participants and the Society.]

• Participants and their administrative assistants should agree to share their expertise and know-how about Spine Tango with other Participants/ administrators. [Fostering an atmosphere of open exchange, support and assistance from other users is expected to benefit the whole Spine Tango community.]

• The Participants are free to cease participation at any time. His/her name will remain on the year-list of Participants and accredited Participants published on the website for the years corresponding to the periods of their Participation.

On-site start-up assistance and online assistance

On-site start-up assistance will be provided in terms of setting-up and training in the use of the system. Based on circumstances (e.g. travel distance, time involved, accommodation, etc) charges for this may apply.

Electronic assistance is available to all Participants upon request.

### V.B.    Specific requirements for Accredited Participants

A Participant will be acknowledged by the Eurospine-SSE and IEFM as an "Accredited Spine Tango Participant" if they comply with the completion rates for data input described below. The final decision for recognition as an "Accredited Spine Tango Participant" will be made by the Spine Tango Committee based on the data completion compliance.

Accredited Participants must obtain the following compliance rates:

Minimum 80% case documentation rate. A "case" is defined as a preoperative COMI form, the surgical intervention form, and at least one postoperative COMI and physician follow-up form at an interval of 3 months after surgery or later. For the non-surgical participants, a "case" is defined as a pre-treatment COMI form, the conservative treatment form and an end of treatment assessment with a COMI form.

• Where Accredited Participants already have a system in place that relies on other established outcome questionnaires (e.g. Oswestry, RMDQ, etc.) they will not be compelled to change to the COMI; however, where feasible, they will be encouraged to use the COMI in addition to their own chosen outcome instrument(s) and must

as a minimum include two 0-10 pain scales for axial pain and referred pain. [Having at least one instrument in common between all centers (pain scale) will facilitate comparison. It may also allow some sort of "calibration" of the data collected using outcome instruments other than the COMI.]

Participants may proactively apply to become accredited after a minimum of 12 months' participation
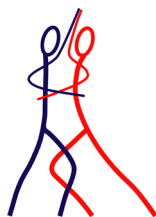
in the Spine Tango Registry. If they believe that they have reached the necessary standards and that these can be maintained in the long term, a document (e.g. hospital`s or department`s annual report) credibly indicating the annual surgical or treatment volume and an informal application letter must be sent to the ST committee head. If compliance is deemed inadequate, assistance will be offered in an attempt to remedy the shortcoming.

Accreditation will be affirmed on an annual basis.

**VI.      Benefits for all Participants in the Spine Tango Registry**

*Consistent and accurate in-house data collection*

The Participant has a personal database of their own activity for inter alia, quality assurance, outcome research or implant postmarket surveillance, for example.  Furthermore, they will have the satisfaction of knowing that their work in contributing to the Spine Tango data pool will be useful to the wider community even if of limited or no value to the Participant.

*Online statistics, Benchmarking*

Basic online descriptive statistics regarding ones own performance and comparison with the anonymous data pool ("benchmarking") of all other Participants can be obtained using the Spine Tango online statistics tool, without the need for any statistical software or data handling knowledge.

*Raw data exports*

The Spine Tango Registry database permits the exporting of a Participant's own raw data at any time, allowing the Participant to perform further statistical analyses beyond those offered by the online statistics.

*Annual report*

The data center in Berne provides an individual annual report by email or in the participant`s user account

*Statistical/epidemiological services*

Members of the Spine Tango community can make use of the statistical/epidemiological and methodological expertise of the IEFM in Berne or other Spine Tango expert members.

Registration of the requested analysis/study at the IEFM will be required. To ensure high quality data analyses and interpretation, and efficient use of the available personnel and resources, a structured and brief study protocol summary will have to besubmitted. The template is available on the Spine Tango web page under "Forms"
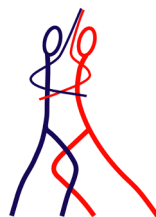
1)

Accredited participants are treated in a prioritized mode and have exclusive access to the pool of accredited data for an even more valid and high quality benchmark.

*Implant capture*

Thanks to a sophisticated implant interface, Participants can record their implants by manually adding them to the surgery form, by making use of electronic supplier catalogues, or by using the MEMdoc or GHX barcode scanners. A personal "Implant Notebook" can also be created with the most frequently used implants of the respective user.

*Imaging system*

The Spine Tango Registry system offers an online imaging interface for uploading, storing and viewing image files.

*Promotional material*

Participants will receive Spine Tango brochures as promotional material for patients, insurance companies, referring physicians, etc. (informing about the aims of Spine Tango, its accreditation procedure, and the value and kudos associated with your participation).

### VI.A     Additional Benefits for Accredited Participant of Spine Tango

*Accreditation*

•        Yearly accreditation with a certificate confirming status as "Eurospine, the Spine Society of Europe Spine Tango Accredited Participant".

•        All accredited Participants will be listed on the Eurospine website and Spine Tango website, on an annual basis and for each year.

•        Use of logo indicating status of "Eurospine, the Spine Society of Europe Spine Tango Accredited Participant" to be placed on official letterheads, website, etc. of the Participant's/Participants' institution.

*Benchmarking*

•        Offline Statistics concerning Participants performance and comparison with the Accredited Pool.
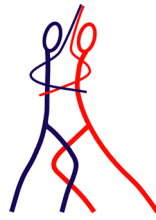
## VII. Scientific publication of the Spine Tango data

### VII.A. Participants' rights and duties

• Each user may use their own data as they deem appropriate for the purposes of scientific publication. This also applies for groups of users that wish to use their combined data for inter alia hospital, multicentre, or on a national basis.

• Should a Participant have a proposal for a paper that requires/involves data from the whole data pool, a summary of the proposed "study/analysis" shall initially be submitted for approval to the Spine Tango committee.

• If approved, the major Participants contributing the data (≥20%) for the proposed "study" will be invited to co-author the paper, conditional upon their effective contribution to the work (i.e., the writing of the manuscript).

• The first author shall be the judge of "effective contribution" and the subsequent rights of authorship. Should a dispute arise in relation to "effective contribution" the Spine Tango Committee shall be the final arbiter whose decision shall be final and binding upon the parties

• The Spine Tango group should be acknowledged as "participating investigators" and reference should be made to the web page where the names of all Accredited Participants are indicated (according to the recommendations of Tornetta P, Siegel J, McKay P, Bhandari M. Authorship and Ethical Considerations in the Conduct of Observational Studies 2009; J Bone Joint Surg Am. 2009;91:61-67. doi:10.2106/JBJS.H.01538).

### VII.B. Third parties (industry, insurance companies, political bodies, societies, etc).

• Should an individual or organization (the above being a non exhaustive list) wish to investigate or pose a question which involves utilizing the whole data pool, they shall initially submit to the Eurospine Spine Tango Committee an outline and/or justification of the enquiry or proposed issue for approval.

• If such approval is forthcoming, a report containing the requested information will be provided by the Eurospine Spine Tango Committee. Individual raw data shall under no circumstances be released, and the released data will comprise only a summary addressing the specific enquiry.

• The third party using Spine Tango pool data will be invited to make a donation to the project depending on the number of cases that are of use for the respective data analysis.

## VIII. User fee

In order to contribute to the upkeep of the registry, as of 1.1. 2014 an annual user fee of EUR 1000 per center and registered surgeon will be introduced.  The maximum annual fee per center will be EUR 2500. Accredited participants will receive a 50% reduction. In justified cases (e.g. socio-economically poor countries), a fee reduction or waiver may be granted.