EUROSPINE

Spine Tango

Annual Report 2017

Contents

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Introduction

"If you don't measure results, you can't tell success from failure!"
Common knowledge

As opposed to the annual reports in the past, we have decided to stay with the new streamlined format first introduced last year for the 2016 Spine Tango annual report. To reduce redundant information in the publications of EUROSPINE, we would like to point to the society's Annual Report 2017 and encourage you to read there under the section on Spine Tango for further information on achievements, developments and changes throughout 2017.

Back to the saying at the start of this introduction - doubtless medicine is not an "exact" science like mathematics, and as you go deeper into natural sciences you will find theories of uncertainty (Heisenberg's uncertainty principle). None the less we have to measure; and if you don't measure, you will not improve things.

"Truthful words are not always beautiful, beautiful words are not always truthful"
Lao Tzu

With this quote we send our warm thanks and congratulations to all passionate Spine Tango users facing the daily challenge to fill Spine Tango with life. We appreciate their honest documentation of surgical work and sharing data!

EUROSPINE would love to welcome more participants in the registry to have an even more powerful platform in fostering the care of spine and have the arguments supported by data for future tasks.

Enjoy browsing through the data export.

Thomas Zweig, on behalf of the Spine Tango Task Force

About Spine Tango

The idea for an international registry to capture data on spine treatments was proposed almost two decades ago in response to a growing demand for outcome measurement and quality assurance. In 2000, development of Spine Tango began under the auspices of EUROSPINE, the Spine Society of Europe and in collaboration with the Institute for Evaluative Research in Orthopaedic Surgery at the University of Bern, Switzerland. The registry is now hosted at SwissRDL, a centre of excellence at the Institute of Social and Preventive Medicine (ISPM), one of the largest and most renowned institutes at the University. Since the registry was first launched in 2002, it has grown rapidly and expanded in scope with data on more than 113,000 spine surgeries captured by the end of 2017.

Organisation

The Spine Tango Task Force acts as an advisory group for clinical and methodological questions related to improvements in data collection forms, development of new forms, benchmarking projects and all new and ongoing research projects of participating clinics. The underlying principles for participation in the Spine Tango registry are described in the Code of Conduct (1). This document serves as a common agreement between all registry stakeholders for ensuring that the data collected is an acceptable quality and does not compromise the overall goals of the project.

Technical and analytical support for the registry is provided by a dedicated team at the University of Bern. The Spine Tango project team is based within the Swiss medical Registries and Data Linkage (SwissRDL) group at the Institute of Social and Preventive Medicine. They provide expertise in registry development, methodology, epidemiological analysis, statistics, and data linkage.

Application

Spine Tango enables documentation of the entire spectrum of spinal pathologies and corresponding surgical and non-surgical treatment options. The generic approach of the registry enables the maximum number of participants using a uniform 'language' of documentation, but leaves open numerous options for customization (2). There are also a number of possibilities to adapt the data collection process to the various hospital workflows in the user community. Optional add-on forms, such as Spine Tango conservative (3), adolescent scoliosis and degenerative deformities are examples of data collection forms developed to allow a detailed documentation of conservative and complex deformity cases. All current forms are available on the Eurospine website at http://www.eurospine.org/forms.htm.

Spine Tango data has multiple applications that support the aim of improving quality of patient care and outcomes (4).

Internal quality control: The registry enables monitoring treatment and outcomes, capturing key data on patient and pathology characteristics, surgical measures and complications, as well as

physician-based and patient-reported follow-up data. The comprehensive clinic benchmark report can be used for annual performance assessments and comparison with previous years.

External quality control: The ability to compare one's own performance with that of the national or international results in the Tango data pool is an important strength of the registry. Enabling benchmarking possibilities is one of the fundamental goals of Spine Tango. The benchmarking report enables comparison of surgeon or clinic level data with the pooled registry data (5).

Health services research: This inter-disciplinary field describes and assesses the delivery and access to health services with the goal of identifying the most effective way to organize and deliver high quality care and improve patient safety. Spine Tango captures data useful for this type of research including intra- and post-operative complications, rates of repeat surgery, and duration of hospital stay.

Outcomes research: Spine Tango exploits the systematic and prospective data collection for interventions for spinal pathologies and treatment outcomes. While quality assurance is primarily used for the purposes of improving internal standard of care, outcomes research attempts to generate new medical and scientific knowledge.

Post-market surveillance of implants: Implants play a major role in modern spine surgery. Registries are an important tool in evaluating the effectiveness and long-term performance of medical devices after implantation. Spine Tango enables the systematic capture of data for medical devices used in spine surgery and long-term patient outcomes in patient numbers not possible in clinical trials.

International study network: The Spine Tango community is a network of more than 50 active hospitals in Europe, North and South America, Australia and Asia. This provides opportunities to initiate nested multi-centre studies within the ongoing routine data collection. The flexibility of the registry permits the addition of hypothesis-driven questions to data collection forms that can be captured at the time of primary and follow-up form completion.

Data Capture

The goal of generating a comprehensive database is achieved by collecting both patient-level data as well as clinic- and physician-level data.

There are six methods to transfer site data to the Spine Tango database (Fig. 1):

1. Online data entry via the web-interface (no software installation required).
2. OMR (Optical Mark Reader) scanner-assisted entry of paper forms on-site.
3. Data push using web-service interface with clinic information systems.
4. Mailed paper forms to SwissRDL or other partner for OMR scanner-assisted entry.
5. Online implant data capture with handheld barcode scanner with USB or Bluetooth interface. Alternatively, the online supplier catalogues or a section for manual entry of implant data is available.
6. Some centres also employ a hybrid method of online data entry and OMR scanner-assisted entry of paper forms (not shown).

Fig. 1. Methods of data entry

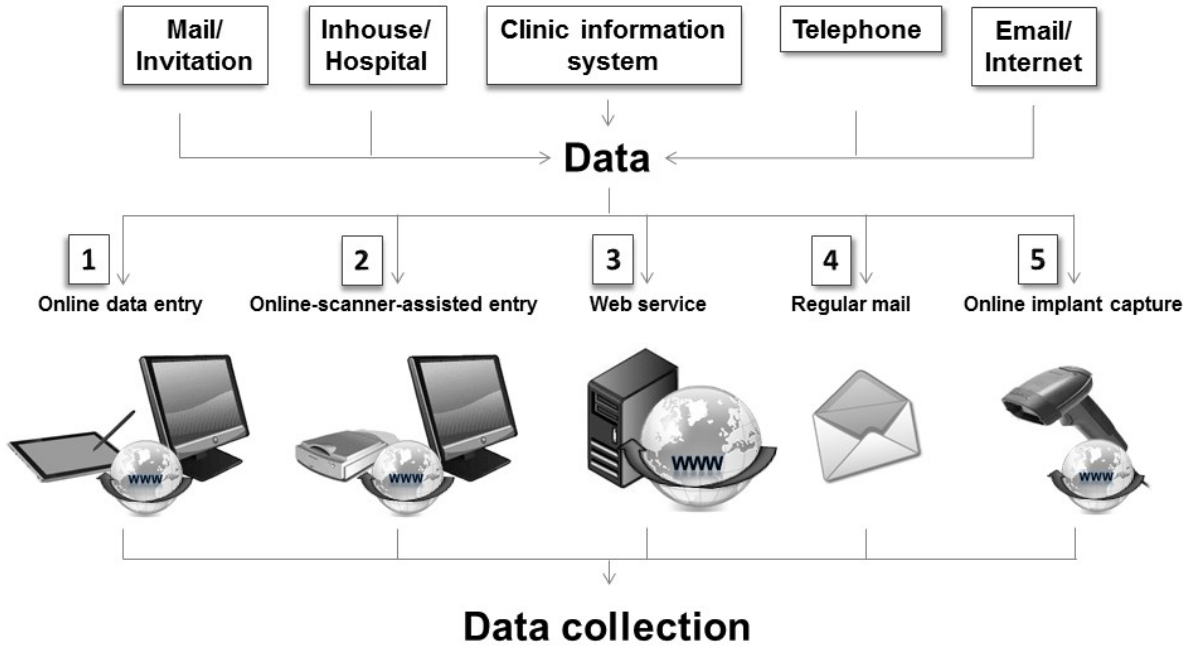
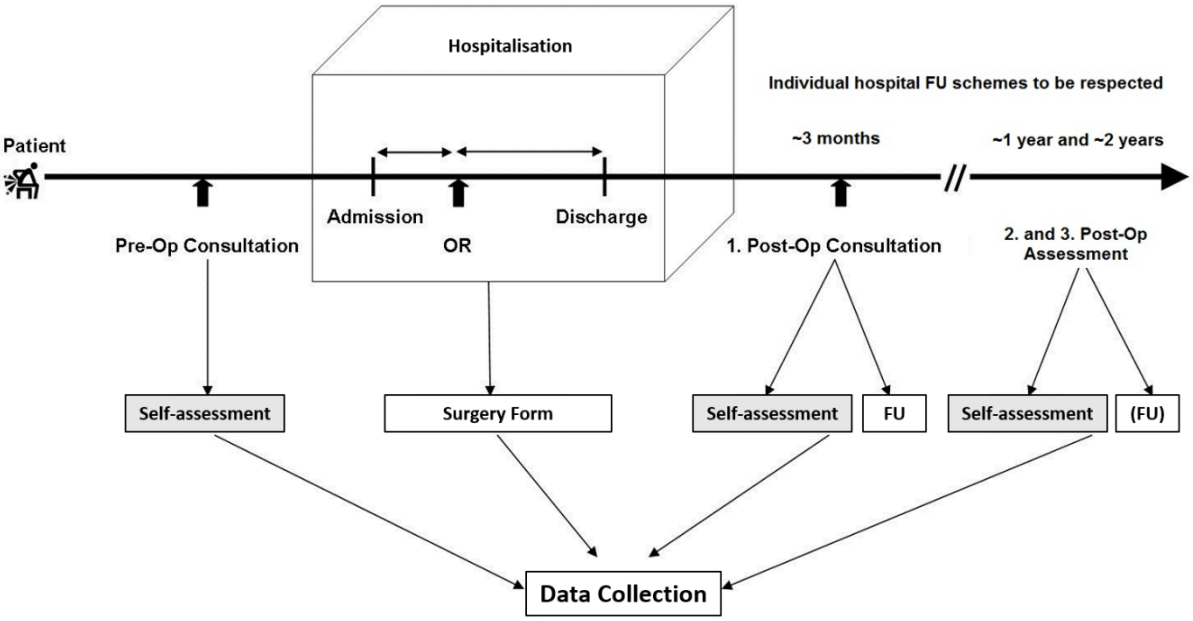


Fig. 2. Timing of data collection for a complete Spine Tango case



A Complete Case

The result of a surgical intervention should be recorded when the outcome can be considered definitive (6). In most spinal surgery cases, assessment 3 months after surgery predicts well outcomes at later follow-up (7). Figure 2 illustrates the steps leading to the capture of a completely documented treatment (8).

EUROSPINE encourages one physician and one patient-reported follow-up in the first year after surgery, ideally later than three months after surgery. Further patient follow-ups at one and two years after surgery are strongly encouraged with documentation of complications possible at any time during the postoperative period.

Patient reported outcomes captured both pre- and post-operatively with the Spine Tango Patient Self-Assessment form, which includes the Core Outcome Measure Index (COMI) for neck and back problems, have become an essential part of the Spine Tango documentation (9).

Data Analysis and Research

Spine Tango supports meaningful data analysis to further scientific knowledge and improve the quality of patient care. To this end, all users have access to epidemiological and statistical expertise from SwissRDL at the University of Bern. The utility of the data is evident in the high-quality scientific output and increasing interest in using Spine Tango as a model for national spine registries.

Scientific articles using Spine Tango data are increasingly published and cited in the peer reviewed literature, as well as being recognized as outstanding contributions to scientific knowledge (10). Various statistical methods are utilized in Spine Tango research, including descriptive analyses for data exploration, parametric and non-parametric tests, uni- and multi-variate linear and logistic regression analyses (11–14). and inverse probability of treatment weighting using the propensity score (15). Comparative effectiveness research studies across different spine registries have also been published (16,17). In addition to clinical studies, a multitude of reliability and validation studies of the patient Core Outcome Measures Index (COMI) in different languages have been performed and published in the last decade (18–25).

Several professional societies in Europe have expressed interest in using Spine Tango as a template for national registries. The common desire in such endeavours is to minimize the burden of Spine Tango documentation through streamlining and automating processes for data collection.

The comprehensive assessment of the performance of an implant or treatment in spine surgery requires the evaluation of several outcomes as well as an adjustment for the case mix. Depending on the scientific question, outcomes of interest could include those related to safety (complications and reoperations), the patient's perspective (pain, satisfaction, quality of life), the physician's follow-up (achievement of treatment goals), or an economic perspective (length of hospital stay, surgery time). Variables used to adjust for case mix can include age, sex, BMI, duration of symptoms, previous treatment, and any co-morbidity. Clearly formulated goals for data analysis defined in a detailed study plan, and a consensus among registry stakeholders are all required.

2017 Achievements and Outlook

Achievements

- Users documented 12,071 new surgeries for a total of 114,096, a 12% growth since 2016.
- The registry added 71 new user accounts and 21 new departments, for a total of 159 users submitting at least 1 data form in 2017.
- Seven peer-reviewed papers based on registry data were published.
- Spine Tango received a Scientific Exchange grant from the Swiss National Science Foundation to support an expert workshop for the revision of the conservative treatment data collection form. Development of the new 2017 Surgery form was completed and launched in January 2018.
- The third Spine Tango User Meeting (STUM 2017) with the theme "*Registries and Industry*" was held in conjunction with the EUROSPINE annual meeting in Dublin.
- Results of the first Spine Tango User Survey were presented at the STUM 2017.

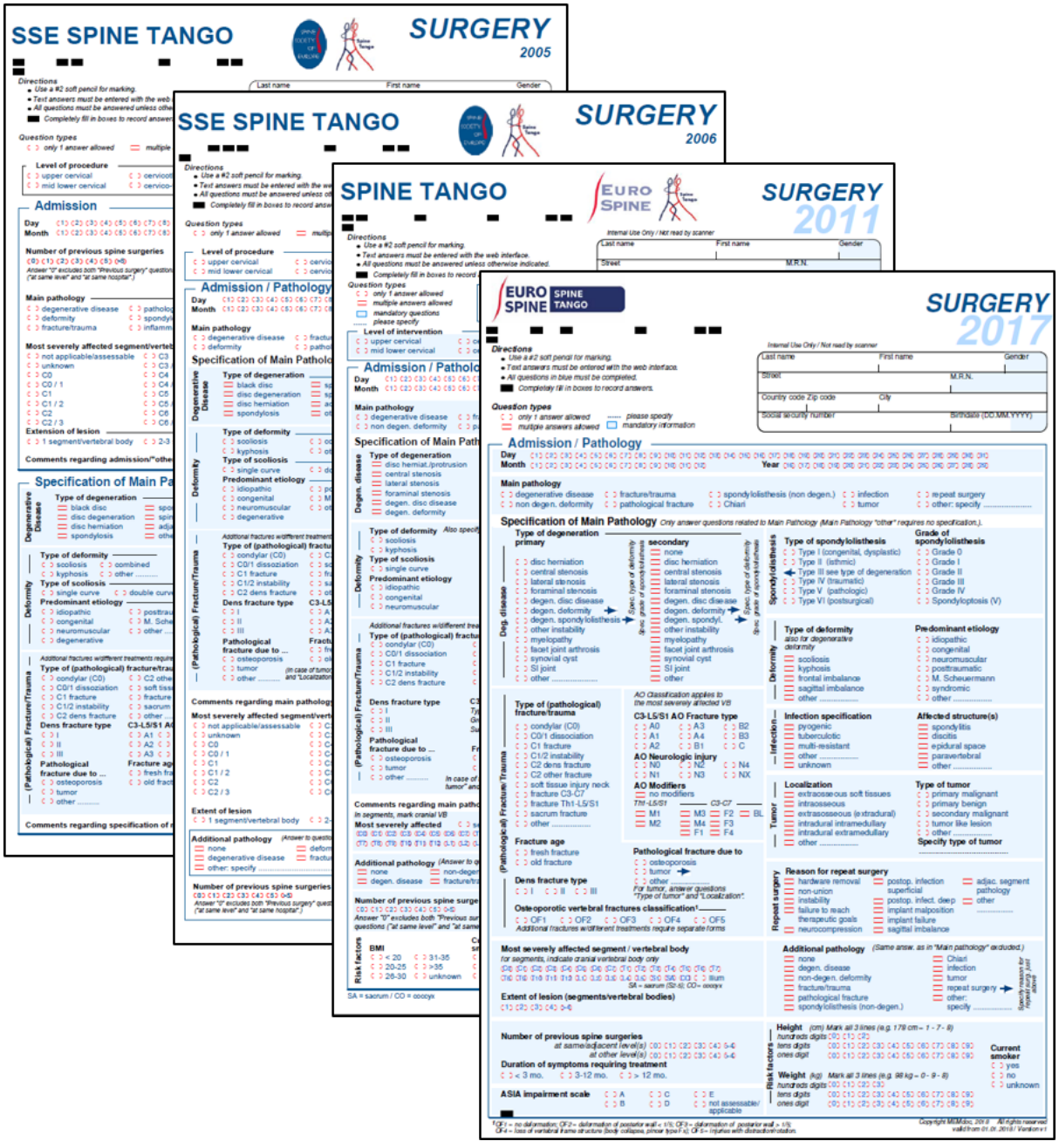
Outlook

In late 2017, the Spine Tango Committee was transformed into a Task Force. Previously the committee has served as an advisory group for clinical and methodological questions related to the improvement and development of content (forms), the acquisition and activation of new country modules, and new and ongoing research projects. The change to a Task Force will provide a more flexible structure for tackling the more demanding tasks of the future.

As the leading spine registry in Europe for documenting the effectiveness of techniques and treatments for spine disorders, Spine Tango is evolving rapidly. In the coming year, the Spine Tango Task Force will focus on implementing new content, improving data quality, and continued system developments.

Our specific goals include:

- Establish mid- and long-term collaboration between Spine Tango and industry in light of recent changes in regulations for medical devices and implants.
- Complete the design, testing and release of the updated version of the Conservative Treatment data collection form.
- Develop new quality reporting tools, including a new data validation report for clinics.
- Develop and implement tablet and smart phone versions of Spine Tango.


SSE SPINE TANGO
SURGERY
2005
SSE SPINE TANGO
SURGERY
2006
SPINE TANGO
EURO SPINE
SURGERY
2011
EURO SPINE
SPINE TANGO
SURGERY
2017

Registry Statistics

Registry Development

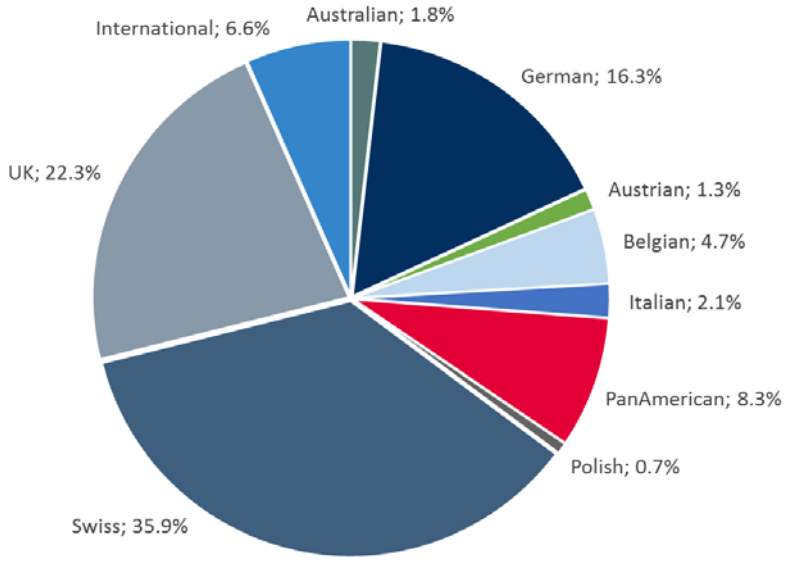
Since its inception in 2002, Spine Tango has expanded to become truly international in scope with users based across Europe and around the globe. While the majority of participating hospitals are found in Europe, users also contribute data in Australia, United States, South America, Asia and the Middle East. Fig. 3 shows the relative distribution of country and regional modules based on the proportion of submitted surgical cases.

The use of national and regional registry modules allows Spine Tango the flexibility to meet national registry needs and differing data protection requirements Responsible authorities in the US and UK have accepted the registry's distributed server concept. There are nine regional/national registry modules available and the international module to accommodate users regardless of where they are located in the world.

The first Spine Tango national/regional modules were launched in 2005. The first modules launched were the Austrian, Swiss and International modules; German and PanAmerican modules followed in 2006, Italy in 2008, and Australia and Great Britain in 2010. The Polish module launched in 2013, with data available from 2010 onwards due to migration of active users from the international module. A similar situation exists for the Belgian module that was launched in 2014, with retrospectively migrated data available from 2008 (Fig. 4).

The registry content has evolved over time beginning with pilot versions launched in 2000 and 2002, followed by the 2005 Surgery version that was mature enough for a broader application. Major revisions were completed in 2006, 2011 and 2017 to reflect continuing advances in spine surgery.

Fig. 3. Overview of Spine Tango modules and contributing countries – 2017

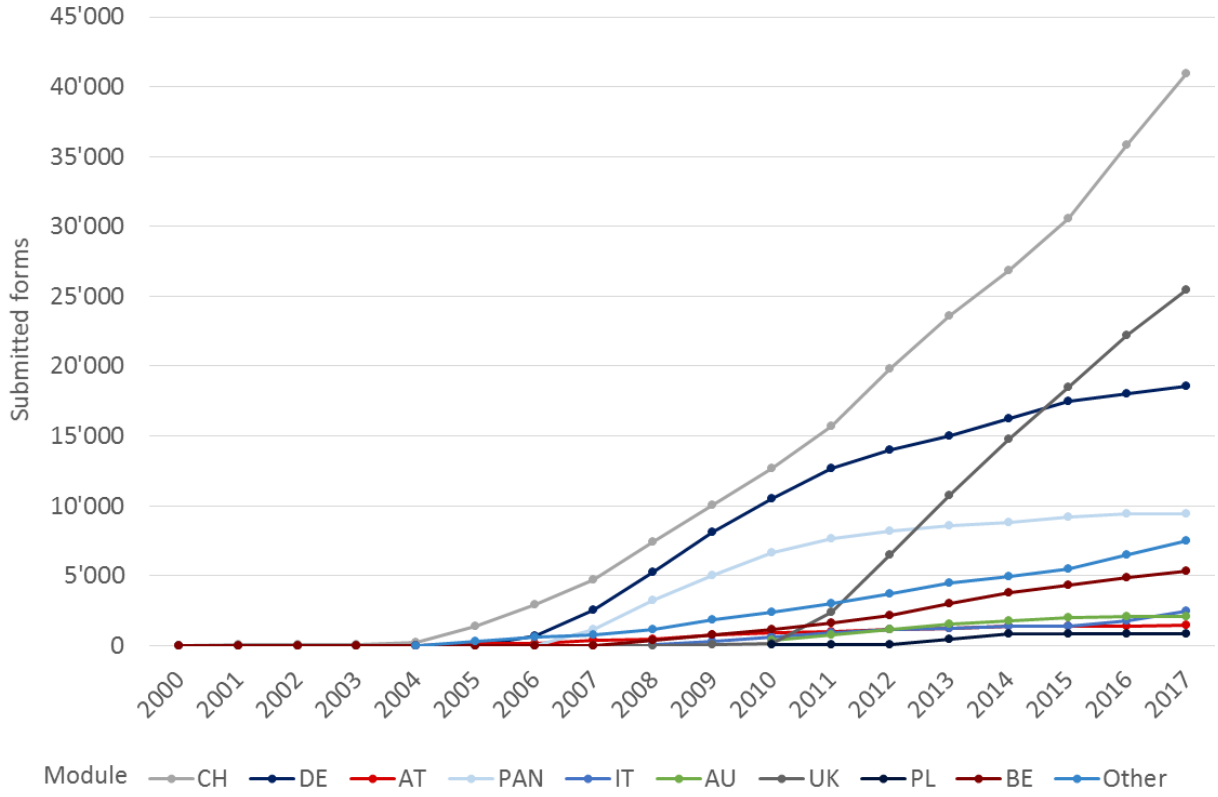


Countries included in multi-regional modules

International
Iraq
Moldova
The Netherlands
Portugal
Slovenia
South Korea
Spain

Pan American
Brazil
United States

Fig. 4. Registry growth – submitted Surgery forms by module



The 2011 Surgery form was used exclusively for data collection from January 2012 until December 2017. This time period has also seen the fastest growth of the registry. Consequently, more than half of all surgeries submitted to the registry use the 2011 Surgery format (67,966 surgeries until end of 2017). Before 2012, the 2005 and 2006 Surgery forms were used for 46,130 surgeries. By the end of 2017, just over 114,000 total surgeries had been submitted to the registry from the three form versions (Fig. 5). The new 2017 Surgery forms were only implemented in January 2018 and are not included here.

Significant changes were implemented with the 2011 data collection form. Therefore not all data elements are compatible across all form versions. For this reason, descriptions of some specific pathologies in this annual report are limited to data collected in the 2011 format.

Fig. 5. Submitted surgeries by form version

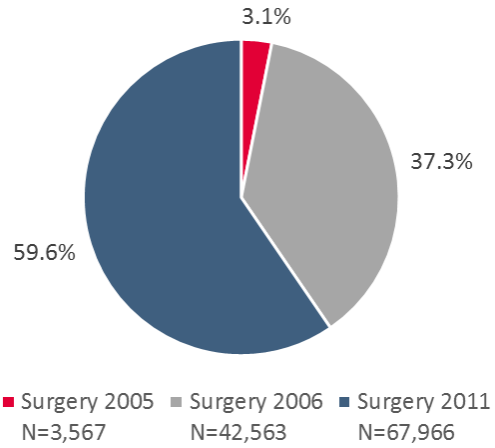
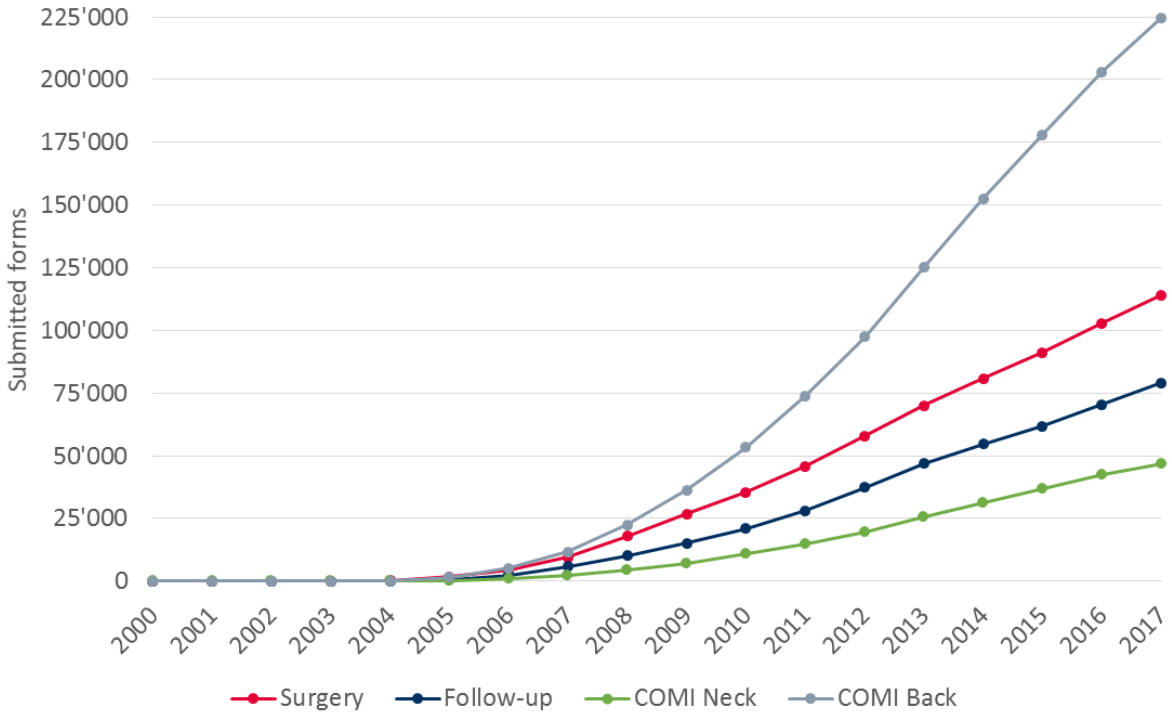


Fig. 6. Registry growth –submitted Surgery forms per year



In addition to the primary surgery forms, Spine Tango utilizes data collection instruments for surgeon follow-up, and COMI (neck and back) to capture patient-reported outcomes (Fig. 6). Many of the forms are available in multiple languages and specialty add-on and quality of life (QoL) related questionnaires are also available. All available forms can be found at: http://www.eurospine.org/forms.htm.

All together more than half a million data collection forms have been submitted to the registry.

Patient Characteristics

Patient characteristics have not changed substantially between different Surgery form versions (Table 1). The average patient is 57 years old at the time of surgical intervention; and the distribution between men and women is fairly even. The majority of cases document interventions for lumbar pathologies. The distribution of main pathologies has not changed to any relevant extent since the last report. The most frequent diagnosis remains "degenerative disease" at about 80%, followed by "repeat or failed surgery," which is stable at around 6%. This combined variable includes both "failed" and "repeat" surgeries, and offers response options to describe treatment failures such as non-union or neurocompression, and also to document reasons for elective repeat surgery.

More than 70% of submitted cases are for primary surgery, followed by about 20% with one prior spine surgery (which only partially captures revisions). Data also show that a large proportion of patients have more than 12 months of conservative treatment before their surgery.

Table 1. Patient characteristics by Spine Tango Surgery version, cut-off 31 December 2017

	v2005 n (%)	v2006 n (%)	v2011 n (%)
Age (years ± SD)	56.8 (± 17.6)	57.0 (± 16.8)	57.0 (± 16.5)
Gender			
Female	1954 (54.8)	22,251 (52.3)	34,649 (51.0)
Male	1613 (45.2)	20,312 (47.7)	33,317 (49.0)
Level of intervention			
Neck	411 (11.5)	7577 (17.8)	12,349 (18.2)
Back	3156 (88.5)	34,986 (82.2)	55,616 (81.8)
Main pathology			
Degenerative disease	2537 (71.1)	31,603 (74.3)	54,314 (79.9)
Deformity*	223 (6.3)	1580 (3.7)	1062 (1.9)
Fracture/Trauma	123 (3.4)	1572 (3.7)	2523 (3.7)
Pathological fracture	86 (2.4)	1512 (3.6)	1336 (2.0)
Spondylolisthesis*	308 (8.6)	2459 (5.8)	1174 (1.7)
Inflammation	24 (0.7)	113 (0.3)	90 (0.1)
Infection	29 (0.8)	402 (0.9)	625 (0.9)
Tumour	66 (1.9)	1012 (2.4)	1639 (2.4)
Repeat/failed surgery	150 (4.2)	1808 (4.2)	4309 (6.3)
Other	21 (0.6)	500 (1.2)	622 (0.9)
Previous treatment for main pathology			
None	528 (14.8)	4829 (11.3)	16,357 (24.1)
Surgical	345 (9.7)	2571 (6.0)	5225 (7.7)
< 3 months conservative	466 (13.1)	7723 (18.1)	9362 (13.8)
3-6 months conservative	524 (14.7)	6927 (16.3)	10,633 (15.6)
6-12 months conservative	521 (14.6)	6534 (15.4)	9434 (13.9)
> 12 months conservative	1303 (36.5)	12,352 (29.0)	15,097 (22.2)
Number of previous spine surgeries			
None	2424 (67.9)	30,214 (71.0)	48,585 (71.5)
1	715 (20.1)	8418 (19.8)	12,902 (19.0)
2	248 (7.0)	2413 (5.7)	3898 (5.7)
3	96 (2.7)	820 (1.9)	1401 (2.1)
4	39 (1.1)	335 (0.8)	553 (0.8)
5	16 (0.4)	145 (0.3)	186 (0.3)
>5	29 (0.8)	216 (0.5)	441 (0.6)

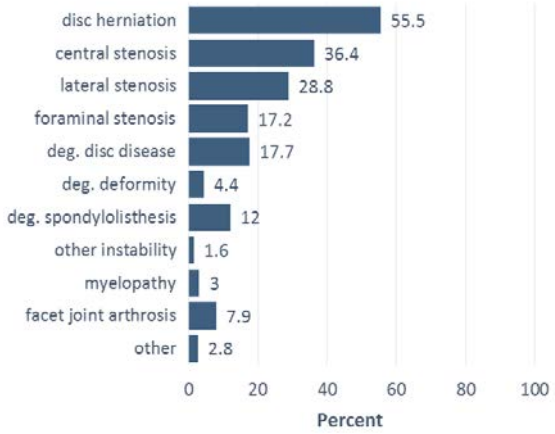
Surgery 2005: N=3567; Surgery 2006: N=42,563; Surgery 2011: N=67,966 total submitted forms.
***Deformity and spondylolisthesis categories include both degenerative and non-degenerative cases in 2005 and 2006 Surgery versions. From 2011, degenerative cases for both pathologies are captured under degenerative disease.**

Main Pathologies

Degenerative Diseases

Disc herniation is the single most frequent type of degenerative disease documented, with more than half (55.5%) of all degenerative disease cases reporting this specification (Fig. 7). Central stenosis was the second most commonly reported degenerative disease (36.4%), and if all types of spinal stenosis are combined (central, lateral and foraminal), then stenosis is more prevalent than disc herniation, being reported in 82.4% of cases.

Fig. 7. Specification of degenerative disease

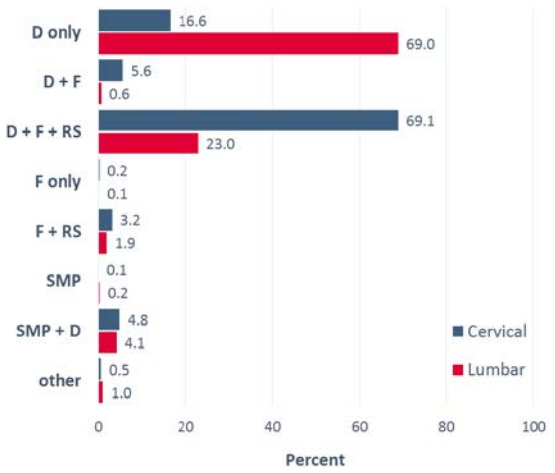


Version 2011 data. N=67,966. Note multiple pathologies can be indicated so the figures do not add up to 100%.

A comparison of surgical measures used to treat degenerative spinal diseases shows that, in the lumbar spine, simple decompression procedures predominate followed by decompression with instrumented fusion (Fig. 8).

Unsurprisingly for the cervical spine, the pattern is reversed, with the majority of procedures being decompression with instrumented fusion, and next most common, simple decompression or decompression with fusion. All other surgical measures and their combinations are rather rare.

Fig. 8. Specification of surgical measures

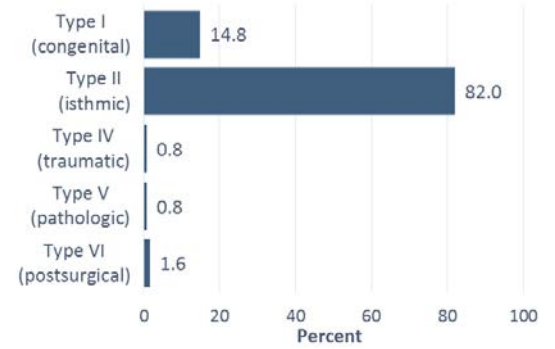


Version 2011 data. N=67,966. D=decompression, F=fusion, RS=rigid stabilisation, SMP=stabilisation-motion preserving.

Spondylolisthesis (non-degenerative)

In four out of five patients with spondylolisthesis the etiology is degenerative (Type III spondylolisthesis). Of the non-degenerative cases, the most common etiologies are isthmic at 82.0% and congenital/dysplastic at 14.8% (Fig. 9).

Fig. 9. Specification of non-degenerative spondylolisthesis



Version 2011 data; N=1174

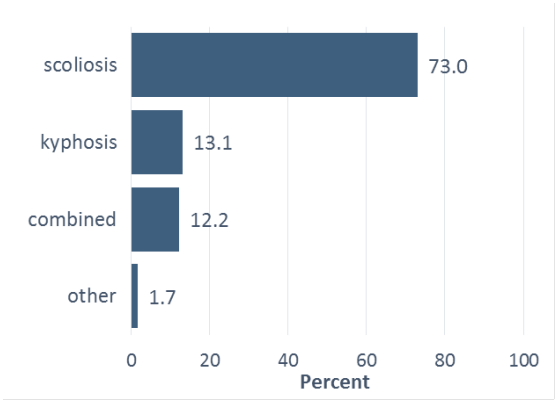
Fracture/Trauma

Fracture patients are the third largest group captured in the registry at 5.7% of submitted cases. This category includes both trauma and pathological fractures. A trauma add-on form should improve future documentation of fracture cases.

Non-degenerative Deformity

The most common non-degenerative deformity is scoliosis (73.0%) (Fig. 10). The predominant etiology of the non-degenerative deformity cases was idiopathic (60.3%), followed by congenital (12.0%) and neuromuscular (10.0%) causes.

Fig. 10. Type of non-degenerative deformity

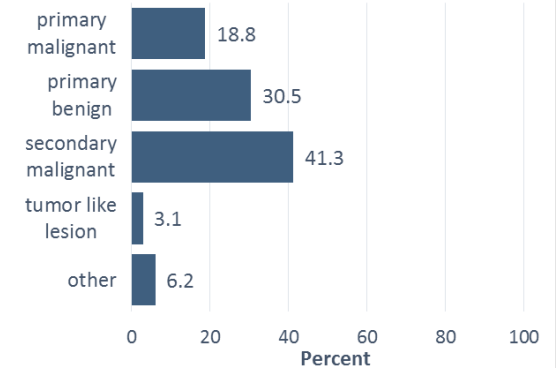


Version 2011 data; N=1062.

Tumour

Tumours were documented as the main pathology in 1639 cases (2.4%). The type of tumours are specified in Fig. 11. Secondary malignant tumours were the most commonly documented tumour between 2012 and 2017 accounting for 41.3% of cases.

Fig. 11. Tumour specification



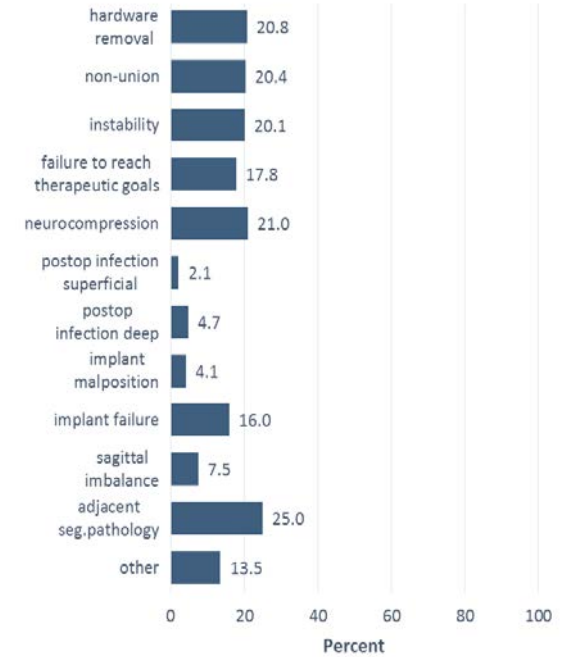
Version 2011 data; N=1639.

Repeat Surgery

Repeat surgery does not necessarily imply a failed index surgery, which is why the field previously referred to as "failed" surgery was revised to simply "repeat" surgery with the implementation of the 2011 Surgery form. 4,309 (6.3%) submitted cases were for repeat surgeries.

The reasons for repeat surgery were fairly evenly distributed (Fig. 12). Adjacent segment pathology remains the most frequent reason for a reintervention (25.0%), followed by neurocompression (21.0%), hardwared removal (20.8%), and non-union (20.4%). Failure to reach the initial therapeutic goals was given as a reason in 765 repeat surgery cases.

Fig. 12. Type or reason for repeat surgery

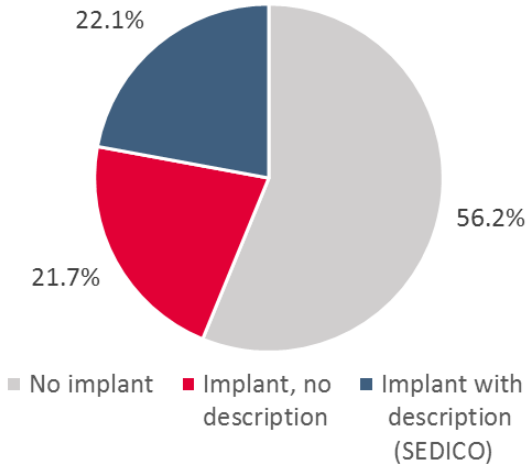


Version 2011 data; N=4309. Note multiple reasons can be indicated so the figures do not add up to 100%.

Implant Data

Implants play a major role in modern spine surgery. Spine Tango enables the capture of data for medical devices used in spine surgery to evaluate effectiveness and long-term performance.

Fig. 13. Surgeries with implant data



Version 2011 data. N=67,966

Implant related data documented in Spine Tango includes the product name, lot number and manufacturer. Additionally, implant failure is documented as a possible reason for a repeat surgery, as well as a complication post-operatively before discharge and at follow-up.

The use of implants was reported in just over 40% of submitted surgery cases (Fig. 13). Of these cases, 50% provided a description (product name, manufacturer, and description) of the respective devices. Implant failure was documented as the reason for a repeat surgery in 691 (16.0%) cases (Fig. 12), and rarely as a complication at any time point.

Complications

Surgical and general complications can be reported at three main time points, intraoperative, postoperative before discharge, and at follow-up visits. The overall prevalence of complications is low, with only 5% of cases reporting any surgical complication (Table 2). Dura lesion was the most common intraoperative surgical complication, reported in 3189 (4.7%) cases. Sensory dysfunction was most common at follow-up, reported in 497 cases (1.3%)

Table 2. Most commonly reported complications reported perioperative and at follow-up

Timing	Complication	n (%)
Intraoperative	Dura lesion	3189 (4.7)
	Nerve root damage	161 (0.2)
	Vascular injury	73 (0.1)
Postop before discharge	Motor dysfunction	542 (0.8)
	Sensory dysfunction	411 (0.6)
	Radiculopathy	347 (0.5)
Follow-up	Sensory dysfunction	497 (1.3)
	Recurrence of symptoms	464 (1.2)
	Motor dysfunction	362 (1.0)

Version 2011 data. N=67,966.

Treatment Outcomes

Several data collection instruments are available to capture treatment outcomes, both from the patient's and the surgeon's perspective.

Patient-Reported Outcomes

The two most widely used instruments for patient reported outcomes are the Spine Tango patient assessment including the Core Outcome Measures Index (or COMI) for low back and the Oswestry Disability Index (Table 3). To evaluate patient-reported outcomes it is necessary to capture data prior to surgery (baseline) and at least 3 months after surgery. Overall 44.6% of surgical cases have both a baseline and at least one follow-up Spine Tango COMI form for lower back.

Table 3. Utilization of PROMS 2012-2017

Form	Count	%*
ST COMI Neck	46,249	44.5
ST COMI Back	221,753	44.6
Oswestry Disability Index	87,652	5.7
Neck Disability Index	1,561	2.2
EuroQoL: EQ-5D	90,571	8.1
SF 36	18,772	0.1

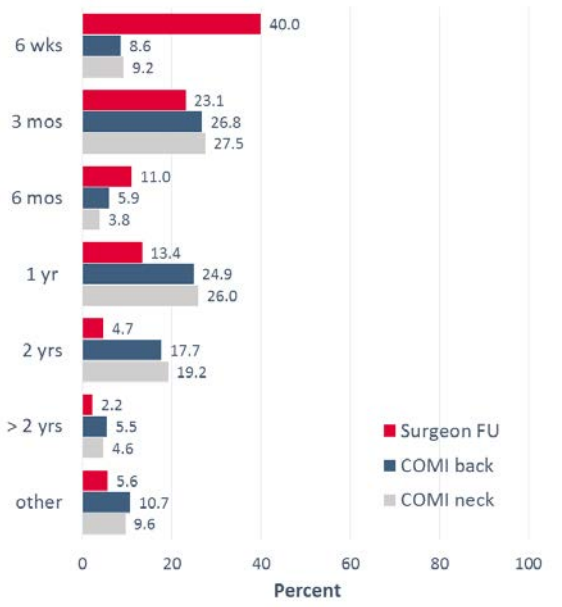
*% is proportion of cases associated with a baseline measure and at least 1 follow-up for the given form (necessary for analysis).

The completeness of PROM assessment also differs by the main pathology. Cases of non-degenerative spondylolisthesis had the most complete COMI assessment (51.5%), while infection (14.1%) was least complete. Of the submitted COMI back follow-up forms, most document outcomes at 3 months (26.8%) and 1 year (24.9%) after surgery (Fig. 14).

Surgeon Follow-up

The surgeon-based follow-up form captures whether the goals of surgery were achieved, partially achieved or not achieved, any complications arising since surgery or a previous follow-up, and the need for further follow-up or revision surgery. The proportion of surgical cases up to 2017 with at least one submitted surgical follow-up was 67%. Of the submitted surgeon-based follow-up forms, most documented outcomes at 6 weeks (40.0%) or 3 months (23.1%) after surgery (Fig. 14).

Fig. 14. Follow-up interval by type of form



Descriptive Analysis of Selected Pathologies

Disc Herniation

Disc herniation was the most common degenerative diagnosis reported, with 12,649 cases (lumbar region) documented with the Surgery version 2011. For the purpose of analysis, an algorithm was previously developed by the Spine Tango Registry Committee to characterise patients into one unique diagnosis category (as multiple types of degeneration may be reported for an individual case on the surgery form) (26). Data presented here are for cases categorized as "disc herniation" for the lumbar region according to this consensus document.

Patient Characteristics

The average age of patients undergoing surgery for disc herniation was just over 50 years (Table 4). Most patients were undergoing their first spine surgery, and had undergone up to 12 months of conservative treatment before surgery.

Surgical Measures

To be classified as having "disc herniation", patients had to have undergone discectomy or sequesterectomy. Further characterisation of the surgical measures used for disc herniation are presented in Fig. 15. A comparison of the surgical measures for herniated disc shows that in the lumbar spine simple decompression procedures clearly predominate (94.9% of cases). Decompression in combination with instrumented fusion and/or rigid stabilization or motion preserving stabilization accounted for fewer than 5% of cases.

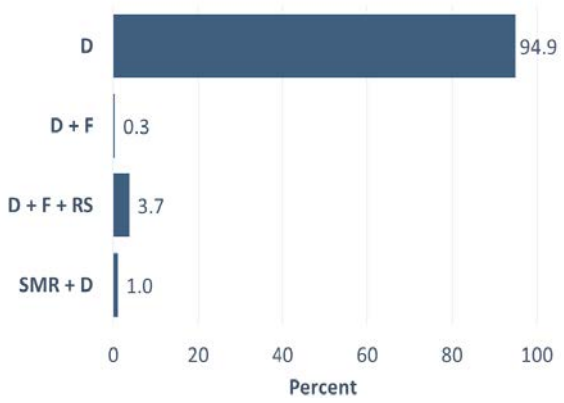
Table 4. Patient characteristics

	n (%)
Age (years ± SD)	50.5 (± 14.6)
Gender	
Female	5,467 (43.2)
Male	7,182 (56.8)
BMI	
≤ 25	2,437 (31.8)
26-30	2,732 (35.7)
> 30	1,540 (20.2)
Unknown	946 (12.3)
Previous treatment for main pathology	
None	2,474 (19.6)
Surgical	608 (4.8)
< 3 mos. conservative	4,156 (32.9)
3-12 mos. conservative	3,928 (31.1)
> 12 mos. conservative	1,192 (9.4)
Missing	291 (2.2)
Number of previous spine surgeries	
None	9,967 (78.8)
1	2,127 (16.8)
2	409 (3.2)
≥ 3	146 (1.2)

Complications

The most common complications reported perioperatively and at follow-up after surgery for disc herniation are presented in Table 5. Overall, complications were rare. Dural lesion was the most frequently reported surgical complication reported following surgery in 342 (2.7%) of cases. During follow-up for this sub-group, recurrence of symptoms was the most commonly reported complication (1.6%).

Fig. 15. Surgical measures



N=12,516 lumbar cases with complete surgical measures data. D=decompression, F=fusion, RS=rigid stabilisation, SMP=stabilisation-motion preserving.

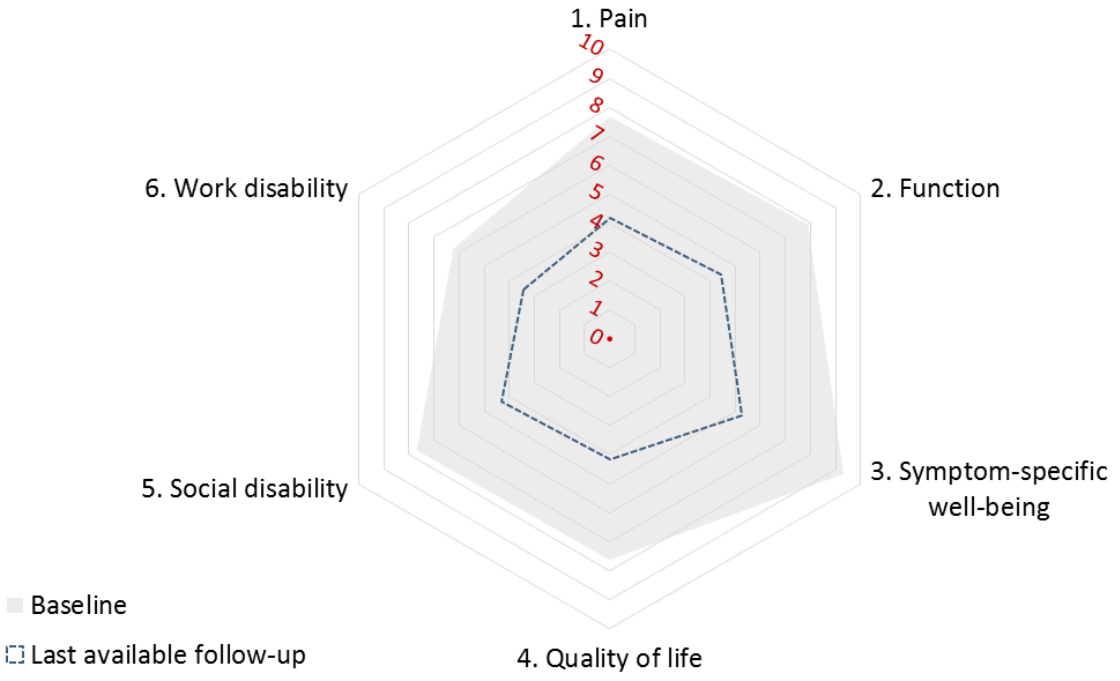
Table 5. Most common complications

Complication	n (%)
Perioperative	
Dural lesion	342 (2.7)
Radiculopathy	36 (0.3)
Motor dysfunction	28 (0.2)
Bladder dysfunction	25 (0.2)
Follow-up	
Recurrence of symptoms	73 (1.6)
Sensory dysfunction	43 (0.9)
Wrong level	38 (0.8)

Outcomes - COMI

7,914 (62%) patients with a herniated disc in the lumbar region (2011 Surgery data) had both a baseline and at least 1 follow-up COMI back score. The average time of follow-up was 15.4 months after surgery. The mean change in COMI score was 3.5 (from a mean baseline score of 7.9) at the last available follow-up. The average change in each of the 6 items of the COMI back score (pain, function, symptom-specific well-being, quality of life, social disability, and work disability) are presented for all cases in Fig. 16.

Fig. 16. Change in COMI back score from baseline to last available follow-up – disc herniation



Lumbar Spinal Stenosis

Lumbar spinal stenosis is one of the most commonly documented diagnoses in Spine Tango. A total of 10,646 cases were documented over the period from 2011 to 2017 (Surgery 2011 version). Data presented here are for cases categorized as "lumbar spinal stenosis without spondylolisthesis" according to the Spine Tango consensus document defining diagnosis subgroups in degenerative disease (26).

Patient Characteristics

Patients undergoing surgery for LSS had a mean age of 67 years (Table 6). Most were undergoing their first spine surgery, and had undergone between 3 and 12 months of conservative treatment before surgery.

Surgical Measures

Further characterisation of the surgical measures used to treat LSS are presented in Fig. 17. A comparison shows that simple decompression procedures predominate in about 73% of patients, followed by decompression in combination with instrumented fusion and rigid stabilization in 22%.

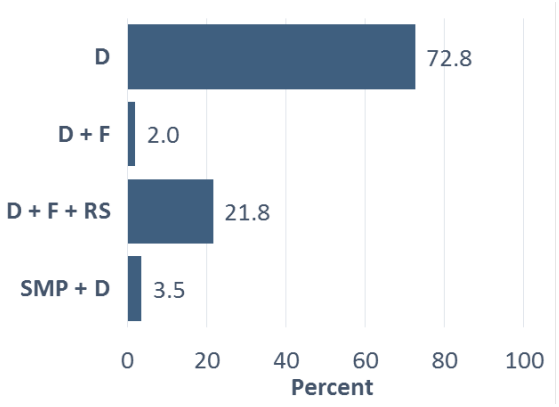
Complications

The most common complications reported perioperatively and at follow-up after surgery for lumbar spinal stenosis are presented in Table 7. Overall, complications were reported in less than 2% of cases. Dural lesion was the most frequently reported surgical complication reported following surgery in 165 (1.5%) of cases. The most common complications at follow-up were sequelae anaesthesia, sensory dysfunction, and superficial wound infection.

Table 6. Patient characteristics – LSS

	n (%)
Age (years ± SD)	67.2 (± 12.0)
Gender	
Female	5,471 (51.4)
Male	5,175 (48.6)
BMI	
≤ 25	319 (24.9)
26-30	489 (38.2)
> 30	308 (24.0)
Unknown	164 (12.8)
Previous treatment for main pathology	
None	784 (7.4)
Surgical	387 (3.6)
< 3 mos. conservative	949 (8.9)
3-12 mos. conservative	4070 (38.3)
> 12 mos. conservative	4050 (38.0)
Missing	402 (3.8)
Number of previous spine surgeries	
None	7942 (74.6)
1	1935 (18.2)
2	515 (4.8)
≥ 3	254 (2.4)

Fig. 17. Surgical measures – LSS



Version 2006 & 2011. N=8,149. D=decompression, F=fusion, RS=rigid stabilisation, SMP=stabilisation-motion preserving.

Table 7. Most common complications – LSS

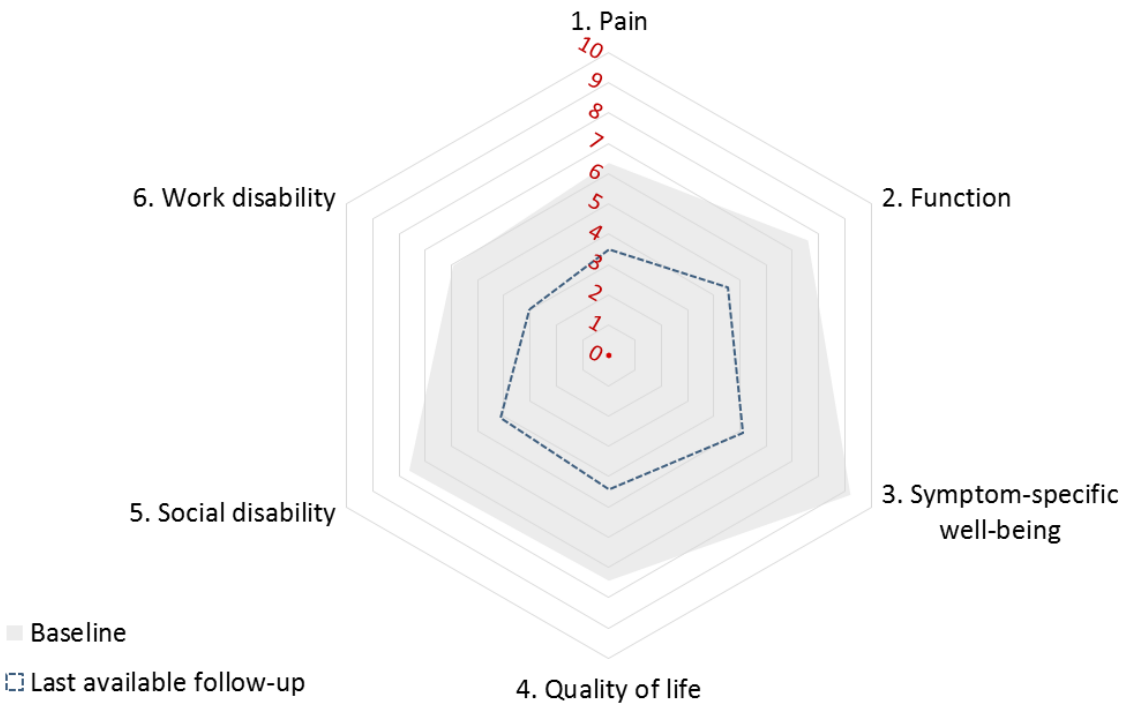
Timing	Complication	n (%)
Perioperative	Dural lesion	165 (1.5)
	Epidural hematoma	16 (0.2)
	CSF leak/pseudomeningocele	16 (0.2)
Follow-up	Sequelae anaesthesia	91 (1.7)
	Sensory dysfunction	77 (1.4)
	Wound infection superficial	67 (1.2)

Outcomes - COMI

7,295 (68.5%) patients with LSS had both a baseline and at least 1 follow-up COMI score. The average time of last follow-up was 2.1 years. The mean change in COMI score was 3.2 points (from a mean baseline score of 7.6) at the last available follow-up.

The average change in each of the 6 items of the COMI score (symptom-specific well-being, social disability, work disability, function, quality of life, and pain) are presented for all cases in Fig. 18.

Fig. 18. Change in COMI back score from baseline to last available follow-up – LSS



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2017 Publications

1. **Becker HJ, Nauer S, Porchet F, Kleinstück FS, Haschtmann D, Fekete TF, Steurer J, Mannion AF.** A novel use of the Spine Tango registry to evaluate selection bias in patient recruitment into clinical studies: an analysis of patients participating in the Lumbar Spinal Stenosis Outcome Study (LSOS). Eur Spine J. 2017 Feb;26(2):441-449.

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3. **Gabel CP, Cuesta-Vargas A, Qian M, Vengust R, Berlemann U, Aghayev E, Melloh M.** The Oswestry Disability Index, confirmatory factor analysis in a sample of 35,263 verifies a one-factor structure but practicality issues remain. Eur Spine J. 2017 Aug;26(8):2007-2013.

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