

# **Spine Tango** Annual Report 2016

# Contents

# **Authors**

# **Spine Tango Committee**

#### Thomas Zweig, MD

Spine Tango Committee chair Consultant Spine Surgery theSpinecenter (Thun-Bern-Biel) Bern, Switzerland

#### Andrea Luca, MD

IRCCS Istituto Ortopedico Galeazzi Spine Unit III – Adult and Pediatric Deformity Milan, Italy

Anne F. Mannion, PhD Schulthess Klinik Zürich, Switzerland

# Rolf Sobottke, MD, PhD

Rhein-Maas Klinikum GmbH, Zentrum für Orthopädie und Unfallchirurgie Würselen, Germany

# University of Bern, Institute for Social and Preventive Medicine

Kelly Goodwin Burri, MSc Epidemiologist Spine Tango Project Lead SwissRDL – medical Registries and Data Linkage Bern, Switzerland

## Fabio Giudici, MSc Statistician SwissRDL – medical Registries and Data Linkage Bern, Switzerland

# Introduction

Since 2000 EUROSPINE, the Spine Society of Europe, has supported the development and enhancement of a documentation system for spinal surgery. The international registry Spine Tango is the result of this ongoing commitment, and we are proud to present the annual report for 2016.

Spine Tango has clearly matured beyond its initial development phase, as evidenced by the continually increasing number of registry participants. There is also growing interest in using the Spine Tango platform for national spine registries. This trend has culminated in the start of an important project by the German Spine Society (DWG), Europe's largest specialist society for the spine, to create a national registry based on Spine Tango. Registration of all spine surgeries in the DWG registry is now required to become a certified spine center in Germany. With an eye on other national initiatives, we are proud to mention that Belgium will soon start a national registry test period, and similar efforts continue in Switzerland to capture all spinal interventions with implants.

In the following pages, we provide an overview of Spine Tango including data on total surgeries captured, the main pathologies treated, surgical measures used, and outcomes. We also present a more detailed breakdown of key data for two of the most commonly documented pathologies in the registry, lumbar spinal stenosis and disc herniation. This represents just a small sample of the information that can be gleaned from an analysis of Spine Tango data.

There are countless possibilities for further analysis, and our registry participants continue to be very active in generating high-quality scientific output. In 2016 alone, there were 11 studies based on Spine Tango data published in the peerreviewed literature.

On the practical side of things, we would also highlight the ongoing development of registry tools to make the individual surgeon's life easier. Noteworthy examples are the "Follow-up" calendar, automated alerts for electronic patient-based followup forms, and interface solutions to hospital IT systems and data collection tools such as Surgimap.

This report showcases what has been achieved with the support of our highly motivated participants, and will perhaps even inspire you to propose a scientific question of your own. For those of you not active in Spine Tango, we hope it provides the spark to join us in the near future.



Thomas Zweig, on behalf of the Spine Tango committee

# **About Spine Tango**

The idea for an international registry to capture data on spine treatments was proposed almost two decades ago by Prof. Dieter Grob and Prof. Max Aebi 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 (IEFO) and later the Institute for Evaluative Research in Medicine (IEFM) at the University of Bern, Switzerland. The registry is now hosted at SwissRDL, a centre of excellence at the Institute for 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 100,000 primary spine surgeries captured by the end of 2016.

# Organisation

The Spine Tango Committee acts as an advisory group in 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. In January 2016, the IEFM joined the Institute of Social and Preventive Medicine to establish the Swiss RDL, leveraging their combined expertise in registry development, 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 а detailed of documentation 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 interdisciplinary 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 postoperative 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 longterm 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 hypothesisdriven questions to data collection forms that can be captured at the time of primary and follow-up form completion.

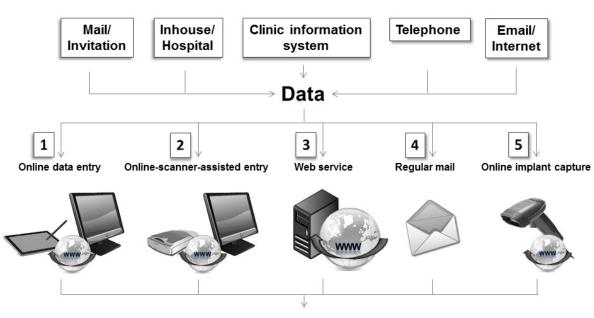
# **Data Capture**

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):

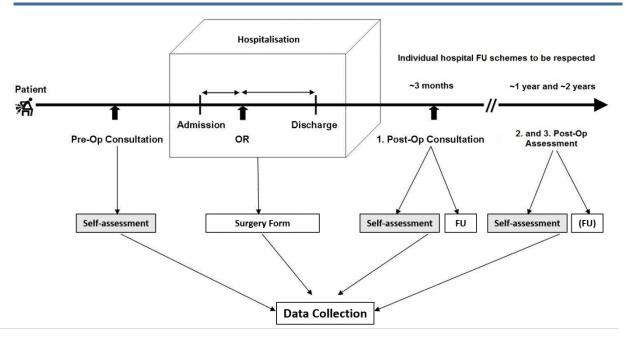
- Online data entry via the webinterface (no software installation required).
- 2. OMR (Optical Mark Reader) scannerassisted entry of paper forms on-site.
- 3. Data push using web-service interface with clinic information systems.
- Mailed paper forms to SwissRDL or other partner for OMR scannerassisted 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.
- 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



**Data collection** 

#### 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 postop. 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 highquality 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 multivariate 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.

# **2016 Achievements and Outlook**

# Achievements

- Captured 13,967 new surgeries for a total of 102,025, a 16% increase over 2015
- Added 41 new user accounts and 24 new departments, for a total of 829 active submitting data in 13 countries
- Published eleven peer-reviewed papers with two further papers accepted
- Developed 2017 Surgery form, representing the most mature spine registry content
- German Spine Society (DWG) adopted the 2017 Surgery form for their national spine registry, launching on 1 January 2017

- Held the second Spine Tango User Meeting (STUM 2016) with over 50 participants, in conjunction with the EUROSPINE general meeting in Berlin
- Developed a new implant report for industry comprised of all relevant implant data (including standard Tango outcome parameters)
- Upgraded the follow-up calendar to email patients a link to a patient form for remote data entry with the aim of increasing follow-up rates
- Developed new benchmarking reports for users comparing single centre data to the pooled data by pathology

# Outlook

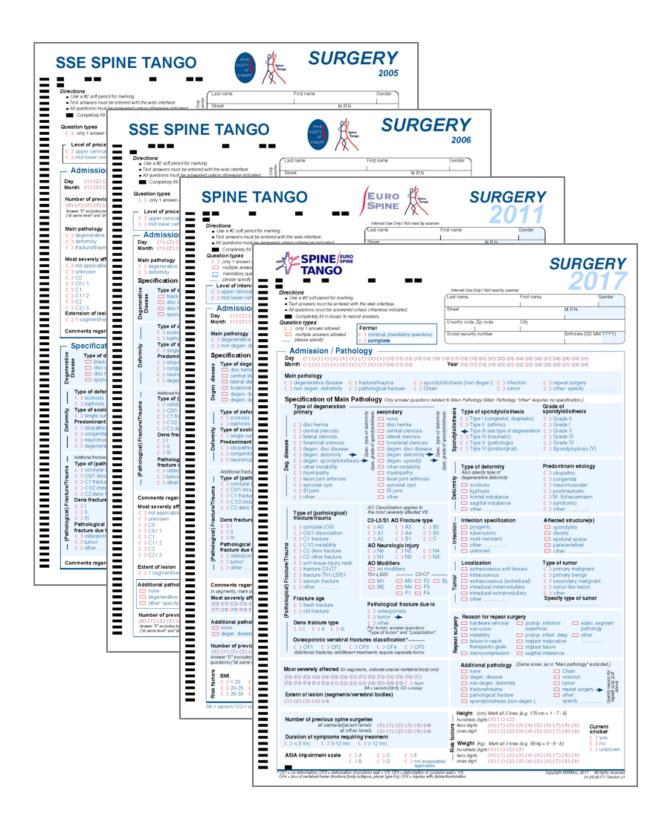
In the coming year, we plan to continue improving Spine Tango, making the registry more versatile and comprehensive. Our goals in the coming year include:

- Complete testing and release Version 2017 of the Surgery form
- Prioritise further development of the conservative form, with a workshop planned to finalize a revised form for implementation
- Carry out a registry users survey to better understand user needs and further improve the registry

 Initiate a dialog with industry to better understand how we can meet future regulatory changes together

With the release of the 2017 data collection forms, data compatibility across current and retired form versions will also be a focus. We will evaluate methods and tools that will aid data analysts wishing to merge multiple versions of the different forms.

Spine Tango is evolving quickly. We will continue improving Spine Tango, making the registry more versatile and comprehensive than ever.



# **Registry Statistics**

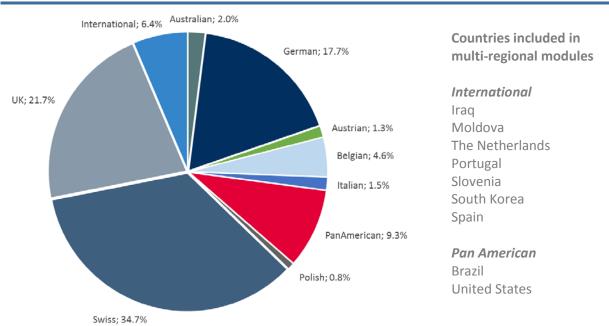
# **Registry Development**

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 modules registry 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 for a broader application. Major revisions were completed in 2006 and 2011 to reflect continuing advances in spine surgery.



#### Fig. 3. Overview of Spine Tango modules and contributing countries

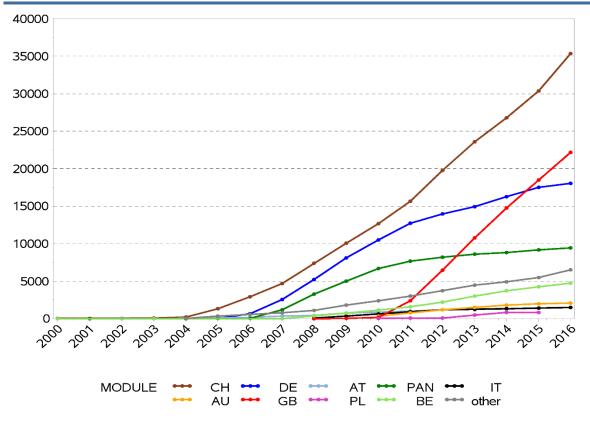


Fig. 4. Registry growth – submitted Surgery forms by module

The 2011 Surgery form has been used exclusively for data collection since January 2012. 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 (55,896 surgeries up to end of 2016). Before 2012, the 2005 and 2006 Surgery forms were used for 46,129 surgeries. As of the end of 2016, there were over 100,000 surgeries submitted in total from the three form versions (Fig. 5).

Because significant changes were implemented with the 2011 data collection form, 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.

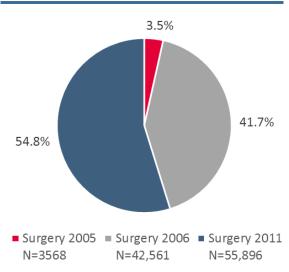
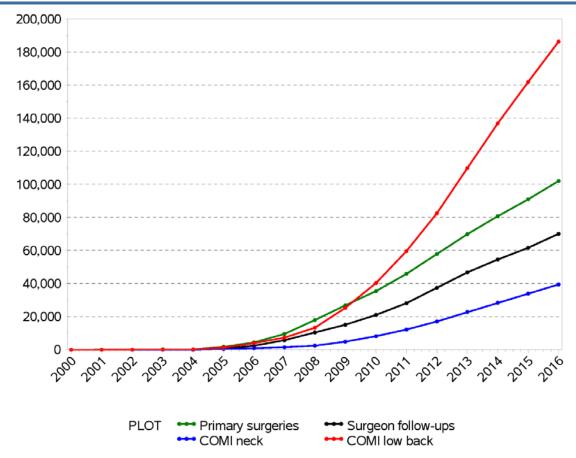


Fig. 5. Submitted surgeries by form version



#### 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 patientreported 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 forms can be found online at http://www.eurospine.org/forms.htm.

## **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.

	v2005	v2006	v2011
	n (%)	n (%)	n (%)
Age (years ± SD)	56.8 (± 17.6)	57.0 (± 16.8)	56.8 (± 16.5)
Gender			
Female	1954 (54.8)	22,250 (52.3)	28,437 (50.9)
Male	1614 (45.2)	20,311 (47.7)	27,459 (49.1)
Level of intervention			
Neck	411 (11.5)	7577 (17.8)	10241 (18.3)
Back	3157 (88.5)	34,984 (82.2)	45,655 (81.7)
Main pathology			
Degenerative disease	2537 (71.1)	31,603 (74.3)	44,896 (80.3)
Non-degenerative deformity	223 (6.3)	1578 (3.7)	1062 (1.9)
Fracture/Trauma	123 (3.4)	1572 (3.7)	1977 (3.5)
Pathological fracture	86 (2.4)	1512 (3.6)	1017 (1.8)
Spondylolisthesis (non-degenerative)	308 (8.6)	2459 (5.8)	964 (1.7)
Inflammation	24 (0.7)	113 (0.3)	78 (0.1)
Infection	30 (0.8)	402 (0.9)	500 (0.9)
Tumour	66 (1.8)	1012 (2.4)	1405 (2.5)
Repeat/failed surgery	150 (4.2)	1808 (4.2)	3484 (6.2)
Other	21 (0.6)	500 (1.2)	513 (0.9)
Previous treatment for main pathology			
None	528 (14.8)	4829 (11.3)	13,670 (24.5)
Surgical	345 (9.7)	2570 (6.0)	4288 (7.7)
< 3 months conservative	466 (13.1)	7723 (18.1)	7736 (13.8)
3-6 months conservative	524 (14.7)	6927 (16.3)	8848 (15.8)
6-12 months conservative	521 (14.6)	6534 (15.4)	7721 (13.8)
> 12 months conservative	1303 (36.5)	12,351 (29.0)	12,264 (21.9)
Number of previous spine surgeries			
None	2424 (67.9)	30,213 (71.0)	40,086 (71.7)
1	716 (20.1)	8417 (19.8)	10,626 (19.0)
2	248 (7.0)	2413 (5.7)	3137 (5.6)
3	96 (2.7)	820 (1.9)	1104 (2.0)
4	39 (1.1)	335 (0.8)	434 (0.8)
5	16 (0.4)	145 (0.3)	152 (0.3)
>5	29 (0.8)	216 (0.5)	357 (0.6)

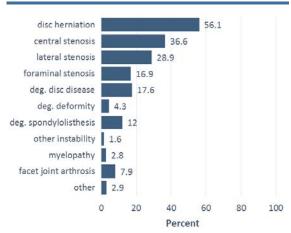
## Table 1. Patient characteristics by Spine Tango Surgery version

\*Surgery 2005: N=3568; Surgery 2006: N=42,561; Surgery 2011: N=55,896 total submitted forms.

# **Main Pathologies**

#### Degenerative Diseases

Disc herniation is the single most frequent type of degenerative disease documented, with more than half (56.1%) of all degenerative disease cases reporting this specification (Fig. 7). Central stenosis was the second most commonly reported degenerative disease (36.6%), and if all types of spinal stenosis are combined (central, lateral and foraminal), then stenosis is more prevalent than disc herniation, reported in 82.4% of cases.



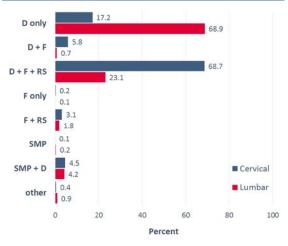
#### Fig. 7. Specification of degenerative disease

Version 2011 data. N=44,896. 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

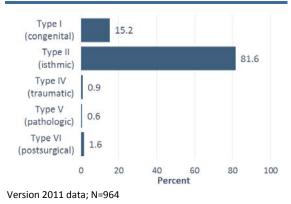


Version 2011 data. N=44,896. D=decompression, F=fusion, RS=rigid stabilisation, SMP=stabilisation-motion preserving.

#### 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 81.6% and congenital/dysplastic at 15.2% (Fig. 9).

#### Fig. 9. Specification of spondylolisthesis



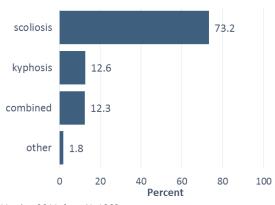
Fracture/Trauma

Fracture patients are the third largest group captured in the registry, but at 5.3% are underrepresented. This category includes both trauma and pathological fractures. A trauma add-on form in development should improve future documentation of fracture cases.

#### Non-degenerative Deformity

The most common non-degenerative deformity is scoliosis (73.2%) (Fig. 10). The predominant etiology of the nondegenerative deformity cases was idiopathic (59.1%), followed by congenital (13.1%)and neuromuscular (10.2%)causes.



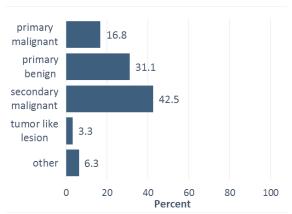


Version 2011 data; N=1062

#### Tumour

Tumours were documented as the main pathology in 1405 cases (2.5%). The type of tumours are specified in Fig. 11. Secondary malignant tumours were the most commonly documented tumour between 2012 and 2106 accounting for 42.5% of cases.





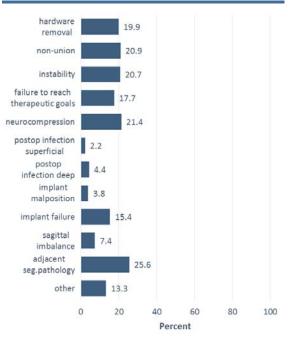
Version 2011 data; N=1552

#### 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. 3484 (6.2%) submitted cases were for repeat surgeries.

The reasons for repeat surgery were fairly evenly distributed (Fig. 12). Adjacent segment pathology has become the most frequent reason for a reintervention (25.6%), followed by neurocompression (21.4%), non-union (20.9%), and instability (20.7%). Hardware removal was performed in 19.9% of cases. Failure to reach the initial therapeutic goals was given as a reason in 17.7% of repeat surgery cases.



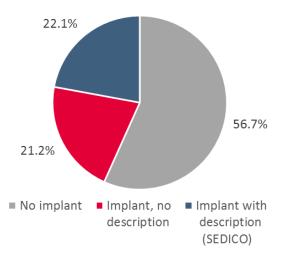


Version 2011 data; N=3484. Note multiple reasons can be indicated so the figures do not add up to 100%.

## **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 longterm performance.





Version 2011 data. N=55,896

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, 51% provided a description (product name, manufacturer, and description) of the respective devices. Implant failure was documented as the reason for a repeat surgery in 538 (15.4%) 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 2684 (4.8%) cases. Sensory dysfunction was most common at follow-up, reported in 391 cases (1.3%).

Timing	Complication	n (%)
Intraoperative	Dura lesion	2684 (4.8%)
	Nerve root damage	135 (0.2%)
	Vascular injury	65 (0.1%)
Postop before discharge	Motor dysfunction	440 (0.8%)
	Sensory dysfunction	332 (0.6%)
	Radiculopathy	256 (0.5%)
Follow-up	Sensory dysfunction	391 (1.3%)
	Recurrence of symptoms	352 (1.2%)
	Motor dysfunction	281 (0.9%)

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

Version 2011 data. N=55,896.

# **Treatment Outcomes**

## **Outcome Measurement**

Several data collection instruments are available to capture treatment outcomes; the most commonly used forms are presented in Table 3. 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. Utilization of PROMS 2012-2016

Form	Count	%*
ST COMI Neck	42,220	43.0
ST COMI Back	198,134	43.2
Oswestry Disability Index	80,709	6.3
Neck Disability Index	1,286	2.1
EuroQoL: EQ-5D	60,459	7.5
SF 36	22,489	0.2

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

# **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.

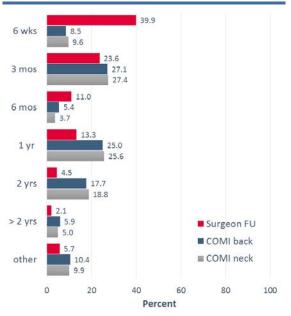
The proportion of surgical cases up to 2016 with at least one submitted surgical follow-

up was 39%. Of the submitted surgeonbased follow-up forms, most documented outcomes at 6 weeks (39.9%) or 3 months (23.6%) after surgery (Fig. 14).

# **Patient-Reported Outcomes**

To evaluate patient-reported outcomes it is necessary to capture data prior to surgery (baseline) and at least 3 months after surgery. Overall 43% of surgical cases have both a baseline and at least one follow-up Spine Tango COMI form. The completeness of PROM assessment also differs by the main pathology. Cases of non-degenerative spondylolisthesis had the most complete (51.6%), COMI assessment while fracture/trauma (17.4%) and infection (11.6%) were least complete. Of the submitted COMI follow-up forms, most document outcomes at 3 months (27%) and 1 year (25%) 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 23,958 cases documented with the Surgery versions 2006 and 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" according to this consensus document.

#### Patient Characteristics

The average age of patients undergoing surgery for disc herniation was 48 years (Table 4). Most patients were undergoing their first spine surgery, and had undergone up to 12 months of conservative treatment before surgery. The majority of surgeries were in the lumbar region (80.5%).

#### 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, stratified by cervical or lumbar region. A comparison of the surgical measures for herniated disc shows that, in the lumbar spine, simple decompression procedures predominate (94.9% of cases); for the cervical spine, the majority of procedures include decompression in combination with instrumented fusion and rigid stabilization (71.8% of cases).

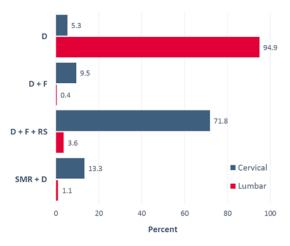
#### **Table 4. Patient characteristics**

	10()	
	n (%)	
Age (years ± SD)	48 (± 13.7)	
Gender		
Female	11132 (46.5)	
Male	12826 (53.5)	
BMI		
≤ 25	4592 (34.2)	
26-30	4586 (34.2)	
> 30	2534 (18.9)	
Unknown	1711 (12.7)	
Previous treatment for ma	ain pathology	
None	4431 (18.5)	
Surgical	913 (3.8)	
< 3 mos. conservative	7114 (29.7)	
3-12 mos. conservative	8051 (33.6)	
> 12 mos. conservative	2821 (11.8)	
Number of previous spine surgeries		
None	19696 (82.2)	
1	3373 (14.1)	
2	648 (2.7)	
≥ 3	39 (0.3)	

#### 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 466 (1.9%) of cases. Over 2730 person-years of follow-up were recorded for this sub-group, recurrence of symptoms was the most common complication reported.





N=4189 cervical cases; N=11,192 lumbar cases with complete surgical measures data. D=decompression, F=fusion, RS=rigid stabilisation, SMP=stabilisation-motion preserving.

#### Outcomes - COMI

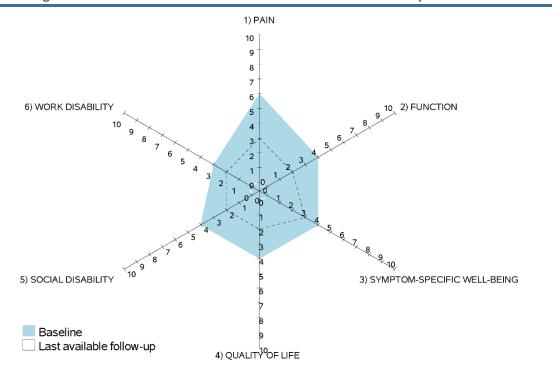
12,934 (67%) patients with a herniated disc in the lumbar region had both a baseline and at least 1 follow-up COMI back score. The average time of follow-up was 15.2 months after surgery. The mean change in COMI score was 3.5 (from a mean baseline

#### Table 5. Most common complications

Complication	n (%)
Perioperative	
Dural lesion	466 (1.9)
Radiculopathy	48 (0.2)
Motor dysfunction	42 (0.2)
Sensory dysfunction	42 (0.2)
Follow-up	
Recurrence of symptoms	102 (1.1)
Sensory dysfunction	99 (1.0)
Other	82 (0.9)

score of 7.8) 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 12,934 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 10,400 cases were documented over the 10-year period from 2006 to 2016. 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 more than 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 72% of patients, followed by decompression in combination with instrumented fusion and rigid stabilization in 22%.

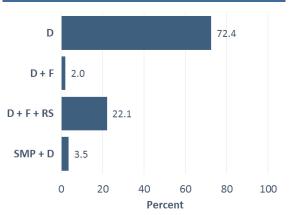
#### Complications

The most common complications reported perioperatively and at follow-up after surgery for lumbar spinal stenosis are Table presented in 7. Overall. complications were reported in less than 2% of cases. Dural lesion was the most frequently reported surgical complication reported following surgery in 145 (1.4%) of cases. Over 1,848 person-years of followup were recorded for this sub-group, capturing the most common complications of sequelae anaesthesia, sensory dysfunction, and superficial wound infection.

#### Table 6. Patient characteristics – LSS

	<u>n (%)</u>	
Age (years ± SD)	67.3 (± 11.9)	
Gender		
Female	5363 (51.6)	
Male	5037 (48.4)	
BMI		
≤ 25	266 (25.6)	
26-30	400 (38.5)	
> 30	255 (24.5)	
Unknown	118 (11.4)	
Previous treatment for main pathology		
None	734 (7.1)	
Surgical	385 (3.7)	
< 3 mos. conservative	930 (8.9)	
3-12 mos. conservative	3979 (38.2)	
> 12 mos. conservative	3974 (38.2)	
Missing	398 (3.9)	
Number of previous spine surgeries		
None	7734 (74.4)	
1	1907 (18.3)	
2	509 (4.9)	
≥ 3	250 (2.4.)	

#### Fig. 17. Surgical measures – LSS



Version 2006 % 2011. N=7,978. D=decompression, F=fusion, RS=rigid stabilisation, SMP=stabilisation-motion preserving.

#### Table 7. Most common complications – LSS

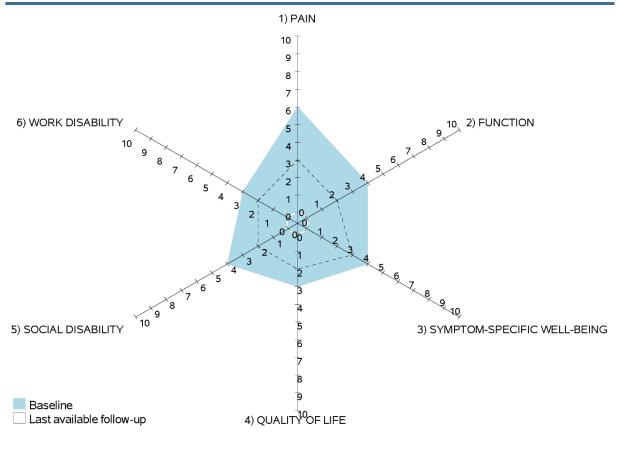
Timing	Complication	n (%)
Perioperative	Dural lesion	145 (1.4)
	Epidural hematoma	16 (0.2)
	CSF leak/pseudomeningocele	15 (0.1)
Follow-up	Sequelae anaesthesia	91 (1.7)
	Sensory dysfunction	72 (1.4)
	Wound infection superficial	67 (1.3)

#### Outcomes - COMI

7185 (69%) patients with LSS had both a baseline and at least 1 follow-up COMI score. The average time of last follow-up was 2 years. The mean change in COMI score was 3.3 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 wellbeing, social disability, work disability, function, quality of life, and pain) are presented for 7,185 cases in Fig. 18.

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



# **Participants**

Active departments with cases submitted between 1 January 2014 and 31 December 2016

# Australian module

Royal Adelaide Hospital, Adelaide

St. Andrew's Hospital, Adelaide

## Austrian module

LKH Graz, Universitätsklinik für Orthopädie, Graz

Universitätsklinik für Orthopädie Medizinische Universität Wien, Vienna

## **Belgian module**

Clinique Edith Cavell, Orthopédie, Bruxelles

Clinique Saint-Pierre, Anesthesiologie, Ottignies

Clinique Saint Pierre, Orthopédie, Ottignies

Cliniques Universitaires St. Luc, Orthopédie, Bruxelles

Grand Hôpital de Charleroi, Orthopédie, Charleroi

## German module

Gemeinschaftspraxis für Orthopädie und Neurochirurgie, Hof

Krankenhaus der Barmherzigen Brüder, Wirbelsäulenzentrum Trier, Trier

Uniklinik Köln, Neurochirurgische Klinik, Köln

Uniklinik Köln, Klinik für Orthopädie und Unfallchirurgie, Köln

Universitätsklinikum Greifswald, Orthopädische Klinik, Greifswald

## Italian module

Clinica Cellini, Chirurgia Vertebrale, Torino

IRCCS Galeazzi, CVCO, Milano

Istituto Ortopedico Galeazzi, Milano

Istituto Ortopedico Galeazzi, Chirurgia Vertebrale 2, Milano

Istituto Ortopedico Galeazzi, Chirurgia Vertebrale 3, Milano

Policlinico Universitario Agostino Gemelli, Neurochirurgia, Roma

## Pan-American module

Centro Medico Puerta de Hierro, Columna, Zapopan Jalisco, Mexico

Christiana Spine Center, Newark, USA

HGZ IMSS, Ortopedia, Hermosillo, Mexico

Hospital das Clínicas de Ribeirão Preto, Biomecânica Medicina e Reabilitação do Aparelho Locomotor, Ribeirão Preto, Brazil

## Polish module

General Hospital Torun, Department of Neurosurgery, Torun

Medical University of Silesia, Department of Neurosurgery and Neurotraumatology, Bytom

Orthopaedic and Traumatology Clinic, Poznan

SCM Polanica, Neurosurgery, Polanica-Zdroj

Uniwersytecki Szpital Kliniczny, Klinika Ortopedii i Traumatologii, Wrocław

WCM, Oddział Neurochirurgii, Opole

Wojewódzki Szpital Specjalistyczny, Neurochirurgia, Jastrzębie-Zdrój

#### Swiss module

Berit Paracelsus Klinik AG, Wirbelsäulenzentrum, Speicher

Bethesda Spital, Neurochirurgie, Basel

Centre de la Douleur Riviera, Neurochirurgie, Vevey CHUV, Rhumatologie, Lausanne

CHUV, Unite spinale, Lausanne

Clinica Ars Medica, Spineticino, Lugano

Clinique Cecil, Neurocentre, Lausanne

Clinique Générale de Fribourg, Neurochirurgie, Fribourg

Das Rückenzentrum, Wirbelsäulenmedizin, Thun

Hôpital Cantonal Fribourg, Orthopédie, Fribourg

Inselspital, Neurosurgery, Bern

Kantonsspital Liestal, Wirbelsäule, Liestal

Kantosspital St. Gallen, Klinik für Orthopädische Chirurgie und Traumatologie, St. Gallen

Klinik Linde, Spine Division, Biel

Klinik Permanence, Wirbelsäule, Bern

Klinik Sonnenhof, Wirbelsäulenchirurgie -Orthopädie Sonnenhof, Bern

Klinik St Anna Hirslanden, Neuro- und Wirbelsäulenzentrum, Luzern

Salem Spital, Orthopädie, Bern

Salem Spital, Wirbelsäulenchirurgie, Bern

Salem Spital, Neurochirurgie, Bern

Schulthess Klinik, Wirbelsäulenzentrum, Zürich

Spital Sonnenhof, Orthopädie, Bern

Spitalzentrum Oberwallis, Orthopädie, Brig

Universitätsklinik für Orthopädie -Inselspital, Wirbelsäulenchirurgie, Bern

#### United Kingdom module

Nuffield Oxford Center, Oxford Royal Derby Hospital, Derby Nottingham University Hospitals NHS Trust, Nottignham The Walton Centre, NHS Foundation Trust, Liverpool

Salford Royal NHS Foundation Trust, Manchester

Salford Royal NHS Trust, Salford

## International module

Hospital Sant Pau, Cirugía Ortopédica y Traumatología, Barcelona, Spain

Hospital São João, Neurosurgery, Porto, Portugal

Hospital Universitario Virgen de la Arrixaca, Departamento de Cirugia Ortopedica y Traumatologia, El Palmar Murcia, Spain

Jadria Private Hospital, Spine, Baghdad, Iraq

Medical Center Haaglanden, Department of Neurosurgery, VA Den Haag, the Netherlands

Nizhny Novgorod Research Institute of Traumatology and Orthopedics, Neurosurgery, Nizhny Novgorod, Russia

Orthopaedic Hospital Valdoltra, Spine surgery and paediatric orthopaedics, Ankaran, Slovenia

SCTO, Spine surgery department, Chinsinau, Moldova

University Clinic Orthopedics, Orthopedic clinic, Ljubljana, Slovenia

University Hospital Antwerp, Department of Neurosurgery, Edegem, Belgium

Wooridul Spine Hospital, Neurological surgery, Seoul, South Korea

# **2016 Publications**

- Morris S, Booth J, Hegarty J. Spine Tango registry data collection in a conservative spinal service: a feasibility study. Eur Spine J. 2016 Sep;25(9):2984-92.
- Ferlic PW, Mannion AF, Jeszenszky D, Porchet F, Fekete TF, Kleinstück F, Haschtmann D. Patient-reported outcome of surgical treatment for lumbar spinal epidural lipomatosis. Spine J. 2016 Nov;16(11):1333-1341.
- van Hooff ML, Mannion AF, Staub LP, Ostelo RW, Fairbank JC. Determination of the Oswestry Disability Index score equivalent to a "satisfactory symptom state" in patients undergoing surgery for degenerative disorders of the lumbar spine-a Spine Tango registrybased study. Spine J. 2016 Oct;16(10):1221-1230.
- Greiner-Perth R, Sellhast N, Perler G, Dietrich D, Staub LP, Röder C. Dynamic posterior stabilization for degenerative lumbar spine disease: a large consecutive case series with long-term follow-up by additional postal survey. Eur Spine J. 2016 Aug;25(8):2563-70. Erratum in: Eur Spine J. 2016 Aug;25(8):2571.
- Fekete TF, Haschtmann D, Kleinstück FS, Porchet F, Jeszenszky D, Mannion AF. What level of pain are patients happy to live with after surgery for lumbar degenerative disorders? Spine J. 2016 Apr;16(4 Suppl):S12-8.
- Beyer F, Geier F, Bredow J, Oppermann J, Schmidt A, Eysel P, Sobottke R. Nonoperative treatment of lumbar spinal

stenosis. Technol Health Care. 2016 Jul 27;24(4):551-7.

- Zehnder P, Aghayev E, Fekete TF, Haschtmann D, Pigott T, Mannion AF. Influence of previous surgery on patient-rated outcome after surgery for degenerative disorders of the lumbar spine. Eur Spine J. 2016 Aug;25(8):2553-62.
- Staub LP, Ryser C, Röder C, Mannion AF, Jarvik JG, Aebi M, Aghayev E. Total disc arthroplasty versus anterior cervical interbody fusion: use of the Spine Tango registry to supplement the evidence from randomized control trials. Spine J. 2016 Feb;16(2):136-45.
- Marbacher S, Mannion AF, Burkhardt JK, Schär RT, Porchet F, Kleinstück F, Jeszenszky D, Fekete TF, Haschtmann D. Patient-Rated Outcomes of Lumbar Fusion in Patients with Degenerative Disease of the Lumbar Spine: Does Age Matter? Spine (Phila Pa 1976). 2016 May;41(10):893-900
- Pochon L, Kleinstück FS, Porchet F, Mannion AF. Influence of gender on patient-oriented outcomes in spine surgery. Eur Spine J. 2016 Jan;25(1):235-46.
- Kleinstueck FS, Fekete TF, Jeszenszky D, Haschtmann D, Mannion AF. Adult degenerative scoliosis: comparison of patient-rated outcome after three different surgical treatments. Eur Spine J. 2016 Aug;25(8):2649-56.

# References

- 1. Spine Tango Registry Committee. Spine Tango Code of Conduct [Internet]. [cited 2017 Sep 1]. Available from: http://www.eurospine.org/cm data/ SpineTango\_Code\_of\_Conduct.pdf
- Aebi M, Grob D. SSE Spine Tango: a European Spine Registry promoted by the Spine Society of Europe (SSE). Eur Spine J. 2004;13:661–2.
- Kessler JT, Melloh M, Zweig T, Aghayev E, Röder C. Development of a documentation instrument for the conservative treatment of spinal disorders in the International Spine Registry, Spine Tango. Eur Spine J. 2011;20(3):369–79.
- Stey AM, Russell MM, Ko CY, Sacks GD, Dawes AJ, Gibbons MM. Clinical registries and quality measurement in surgery: A systematic review. Surgery. 2015;157(2):381–95.
- Röder C, Staub L, Dietrich D, Zweig T, Melloh M, Aebi M. Benchmarking with Spine Tango: potentials and pitfalls. Eur Spine J. 2009;18(Suppl 3):S305– 11.
- Codman E. A Study in Hospital Efficiency. Boston: Privately printed.; 1916.
- Mannion AF, Porchet F, Kleinstück FS, Lattig F, Jeszenszky D, Bartanusz V, et al. 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):S367–73.
- Zweig T, Mannion AF, Grob D, Melloh M, Munting E, Tuschel A, et al. How to Tango: A manual for implementing Spine Tango. Eur Spine J.

2009;18(Suppl 3):312-20.

- Mannion AF, Elfering A, Staerkle R, Junge A, Grob D, Semmer NK, et al. Outcome assessment in low back pain: how low can you go? Eur Spine J. 2005;14:1014–26.
- Staub LP, Ryser C, Röder C, Mannion AF, Jarvik JG, Aebi M, et al. Total disc arthroplasty versus anterior cervical interbody fusion: use of the Spine Tango registry to supplement the evidence from randomized control trials. Spine J. 2016;16(2):136–45.
- 11. Sobottke R, Aghayev E, Röder C, Peer E, Delank SK, Zweig T. 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;21:411–7.
- Kleinstueck FS, Fekete T, Jeszenszky D, Mannion AF, Grob D, Lattig F, et al. The outcome of decompression surgery for lumbar herniated disc is influenced by the level of concomitant preoperative low back pain. Eur Spine J. 2011;20:1166–73.
- Lattig F, Grob D, Kleinstueck FS, Porchet F, Dezsö A, Ae J, et al. Ratings of global outcome at the first postoperative assessment after spinal surgery: how often do the surgeon and patient agree? Eur Spine J. 2009;18(Suppl 3):S386–94.
- Kleinstück FS, Grob D, Lattig F, Bartanusz V, Porchet F, Jeszenszky D, et al. The Influence of Preoperative Back Pain on the Outcome of Lumbar Decompression Surgery. Spine (Phila Pa 1976). 2009;3434(11):1198–203.
- 15. Munting E, Röder C, Sobottke R,

Dietrich D, Aghayev E. Patient outcomes after laminotomy, hemilaminectomy, laminectomy and laminectomy with instrumented fusion for spinal canal stenosis: a propensity score-based study from the Spine Tango registry. Eur Spine J. 2015;24:358–68.

- 16. J-K, AF. Burkhardt Mannion Marbacher S, Dolp PA, Fekete TF, Jeszenszky D, et al. A comparative effectiveness study of patient-rated and radiographic outcome after 2 types of decompression with fusion for spondylotic myelopathy: anterior cervical discectomy versus Neurosurg corpectomy. Focus. 2013;35(1):E4.
- Aghayev E, Henning J, Munting E, Diel P, Moulin P, Röder @bullet C. Comparative effectiveness research across two spine registries On behalf of the SWISSspine and Spine Tango Registry groups. Eur Spine J. 2012;21:1640–7.
- Genevay S, Marty M, Courvoisier DS, Foltz V, Mahieu G, Demoulin C, et al. Validity of the French version of the Core Outcome Measures Index for low back pain patients: a prospective cohort study. Eur spine J. 2014;23(10):2097–104.
- Storheim K, Brox JI, Løchting I, Werner EL, Grotle M. Cross-cultural adaptation and validation of the Norwegian version of the Core Outcome Measures Index for low back pain. Eur spine J. 2012;21(12):2539– 49.
- 20. Miekisiak G, Banach M, Kiwic G, Kubaszewski L, Kaczmarczyk J, Sulewski A, et al. Reliability and validity of the Polish version of the Core Outcome Measures Index for the neck. Eur spine J. 2014;23(4):898–903.
- Qiao J, Zhu F, Zhu Z, Xu L, Wang B, YuY, et al. Validation of the SimplifiedChinese version of the Core Outcome

Measures Index (COMI). Eur spine J. 2013;22(12):2821–6.

- Klemencsics I, Lazary A, Valasek T, Szoverfi Z, Bozsodi A, Eltes P, et al. Cross-cultural adaptation and validation of the Hungarian version of the Core Outcome Measures Index for the back (COMI Back). Eur spine J. 2016;25(1):257–64.
- Nakhostin Ansari N, Naghdi S, Eskandari Z, Salsabili N, Kordi R, Hasson S. Reliability and validity of the Persian adaptation of the Core Outcome Measure Index in patients with chronic low back pain. J Orthop Sci. 2016;21(6):723–6.
- 24. Van Lerbeirghe J, Van Lerbeirghe J, Van Schaeybroeck P, Robijn H, Rasschaert R, Sys J, et al. Cross-cultural adaptation and validation of the Dutch version of the core outcome measures index for low back pain. Eur spine J. 2017;
- 25. Mohammadi HR, Azimi P, Zali A, Montazeri A. An outcome measure of functionality and pain in patients with low back disorder: A validation study of the Iranian version of Core Outcome Measures Index. Asian J Neurosurg. 2015;10(1):46.
- 26. Spine Tango Registry Committee. Spine Tango: Definitions of diagnosis subgroups in degenerative disease [Internet]. [cited 2017 Sep 1]. Available from: http://www.eurospine.org/cm\_data/ def\_of\_degen\_patho.pdf

# $u^{\scriptscriptstyle b}$

b UNIVERSITÄT BERN





# Contact

University of Bern Institute for Social and Preventive Medicine SwissRDL - medical Registries and Data Linkage Finkenhubelweg 11 CH-3012 Bern

Kelly Goodwin Burri, MSc Spine Tango Project Lead spine.tango@ispm.unibe.ch www.swissRDL.unibe.ch