

Report International 2018 - 2019

Contents

Authors
EUROSPINE & Spine Tango Task Force3
Northgate Public Services3
Statements about Spine Tango4
Foreword by the President5
Advances in 2018 and 20196
About Spine Tango7
Key benefits
Key benefits for individual users8
Key benefits for national spine societies8
Governance9
Data host10
How to join
Participation11
Information security and data protection11
Data capture
A complete case13
Data analysis and research16
Achievements (2018 – 2019)17
Outlook
Selected statistics
World map19
Overall data growth by form type21
Patient characteristics
Main pathologies25
Research
How to publish with Spine Tango data36
Publications (2018-2019)
Publications 2019
Publications 2018
Participants
Austria
Belgium

Germany	
Greece	
Ireland	
Italy	
Nepal	
Poland	
Portugal	
Slovenia	
Spain	40
Switzerland	40
Turkey	41
United Kingdom	41
Images of the Spine Tango registry	41
Contact	43

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Statements about Spine Tango

"Spine Tango is the ideal format to collect standardised diagnostic & treatment data as well as PROMs on both conservative and surgical treatments on a national level. Physicians' forms are sufficiently detailed and COMI is concise enough to enhance response rates. The Spine Society of Belgium has been carefully considering all available options and unanimously decided to collaborate with Spine Tango for its joint-ventures with Belgian Health Authorities."

Bart Depreitere, Spine Society Belgium (SSBe), Belgium

"We have used Spine Tango since 2011 with over 12,000 patients on the system. We have published research, measured our own performance and changed our practice due to the information we have gained from the system. It is a vital part of our everyday practice."

Tim Pigott, Consultant Neurosurgeon, Walton Centre for Neurosurgery, United Kingdom

"As an international registry that captures conservative and surgical treatments, EUROSPINE Spine Tango offers unique research opportunities like multinational data and a large network of global and interprofessional collaborations in Europe and beyond."

Professor M. Nordin, Departments of Orthopedic Surgery and Environmental Medicine, New York University, New York, NY, USA

"Having used Spine Tango and patient outcomes routinely in our secondary care osteopathy service, I believe that the benefits for conservative clinicians are clear. For individual practitioners, the ability to review and analyse your performance in easy steps makes a huge difference to clinical life. Registry participation offers a chance to refine practice based on evidence and performance, and grow as an evidence-based clinician. Once established on the registry, you can publish outcome research and engage with a wider community of spinal clinicians, which makes for a more rewarding career. Yes, there is a commitment in paperwork, but it is less than expected and the benefits are greater."

Samuel Morris, Calderdale Royal Hospital, MSK department, United Kingdom

"Partnering with Spine Tango is an imperative pillar of our strategy to support clinical research, quality assurance of our spinal treatments and their safety and efficacy outcomes. Access to the registry data via the Spine Tango Subscriber Services provides Medtronic with systematic, aggregated Real World Data on our implants and therapies. This data is used for Research & Development, Quality Assurance and Regulatory Compliance, so our users continue to have access to the highest quality spinal implants available."

Floris van de Geijn, Director Medical Communication, Medtronic, Tolochenaz, Switzerland

"To qualify and re-qualify for certification, EUROSPINE Surgical Spine Centres of Excellence (SSCoE) are required to monitor their treatment quality by collecting and evaluating pre- and postoperative data on all spine patients. EUROSPINE's Spine Tango offers powerful generic and customisable registry tools for the documentation and evaluation of spinal treatments. Besides clinical data on surgical interventions, data on implants, clinical scores, patient-reported outcome measures, follow-ups as well as non-surgical treatments can be registered and analysed."

Thomas R. Blattert, Member of the Surgical Spine Centres of Excellence, Schwarzach Orthopedic Clinic, Germany



Everard Munting President of EUROSPINE

Foreword by the President

Improving spinal treatments and quality assurance through evidence-based data

Over the past 17 years, the EUROSPINE Spine Tango registry has grown and evolved into a dynamic and customisable database that provides concrete, evidence-based information on surgical and patient-reported outcomes, implants and devices, and non-surgical treatments.

Spine Tango (ST) was hosted by the University of Bern for the first 16 years, and we sincerely appreciate their trustful collaboration. The change to our new service provider, Northgate Public Services (NPS) in 2019 has enabled Spine Tango to expand its potential by equipping the registry with new tools and a flexible, modular approach, making ST increasingly attractive to individual physicians, hospitals, and national societies, as well as to the MedTech industry.

Despite all these changes, the registry has remained faithful to its mission, namely to:

- Improve spine care by measuring, observing, and comparing the treatment of various spinal pathologies
- Provide performance benchmarking and develop a collective evidence base of treatment effectiveness, patient safety and best practice based on real-life data

The quality of the registry will, however, never be better than the data that are provided to it. Essential is, that both spine care providers – in large numbers – and patients get involved in providing non-selected, non-biased and honest data. Only then will the registry reach its full potential. With this approach, Spine Tango will enable all registry participants and stakeholders to benefit from the collective evidence.

Most importantly, however, the work of the ST registry and its related outcomes are helping to improve the treatment of spinal conditions and thus contributing to the well-being of the patients who are the focus of all our efforts.

Many thanks to all the Spine Tango users who support us.

Also thank you for your interest in Spine Tango and enjoy reading.





Marco Teli Chair, ST Registry

Tim Pigott EUROSPINE Past President

Advances in 2018 and 2019

Since our last annual report in 2017, Spine Tango has made tremendous technical advances and added powerful new features.

New registry host

Most noteworthy is the transition of the Spine Tango registry host on 1 May 2019 from the University of Bern (who hosted Spine Tango for 16 years) to a state-of-the-art registry platform hosted by UK-based Northgate Public Services (NPS). Factors such as changes to medical device regulations, data protection law and the need for better quality assurance tools led EUROSPINE to launch an international tender in 2018 to identify a registry that could evolve with changing market conditions in terms of user friendliness, functionality, ease of access, scientific output, content and quality of data, and coverage. Furthermore, both regulatory changes and the growing market of implant products indicated a pressing need to register implant data and post-market outcomes.

Five proposals from four European countries were received, including a proposal from the University of Bern. Seven independent reviewers assessed each proposal. After considerable deliberation and review, the contract was awarded to Northgate Public Services (NPS) based on its track record, experience and best-practice approach.

NPS is a professional IT provider specialising in the collection and evaluation of medical data. It hosts several medical registries, including the National Joint Registry (NJR), which is probably the largest orthopaedics registry in the world (more than 3 million patient records), and the Indian Joint Registry (IJR). The registries collect data to help clinicians, regulators and industry deliver evidence-based treatments for patients.

New medical device regulation and cooperation with the MedTech industry

In April 2021, new medical device regulations will be coming into effect that require the capture of lifecycle data for all spinal implants. MedTech companies are therefore seeking collaboration with spinal registries such as Spine Tango. In 2019, Spine Tango and representatives of the leading MedTech companies established a working group to develop an implant library and implant reports. The library enables users to record the implants used

in operations in an accurate and standardised manner. This, in turn, ensures high quality of data and allows monitoring of implant performance.

Cooperation with national spine societies

Spine Tango has continued to strengthen its collaboration with national spine societies. Most notable in this context is the establishment of a collaboration with Swiss specialist societies to implement the Swiss implant registry "SIRIS Spine". SIRIS Spine will be undergoing a pilot phase in 2020 followed by a national rollout in January 2021. More than 70 centres will be participating in SIRIS Spine. In parallel, the Spine Society of Belgium (SSBe), the Association of Spine Surgeons of India (ASSI), the Mexican Spine Society (AMCICO) and the Society of Spine Surgeons of Pakistan (SSSP) are currently conducting their pilots to foster quality assurance in spinal care in their countries.

Furthermore, Spine Tango is developing a collaboration with the American Academy of Orthopaedic Surgeons (AAOS) for further development of implant library.

Special thanks

We would like to express our appreciation to everyone who accompanied Spine Tango through the transition from the University of Bern to NPS, and to those who contributed and are continuing to contribute data to the registry. It is only thanks to the engagement of all these people that the registry is flourishing so well.

About Spine Tango

Spine Tango is an international web-based registry that collects and evaluates data on treatment effectiveness, patient safety and best practice for quality assurance and research on all surgical and non-surgical treatments.

The registry was created and is being continually developed to serve individual users and hospitals, groups of hospitals and national societies.

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 has been hosted by NPS in the UK since May 2019.

The Spine Tango registry was first launched in 2002, while the first web-based version went online in 2004. Today it has grown and expanded with almost 800,000 forms captured by the end of 2019.

Key benefits

Key benefits for individual users

- Common European approach for registering spinal treatments as well as spinal implants to foster a common language (data structure, terms, definitions, outcome measures, industry-supported implant library with implant specifications, etc.)
- Personal research database
- Access to a variety of valuable functions including:
 - User, hospital and national benchmarking reports comparing data to pooled data from other European hospitals
 - Online statistics
- Access to the registry data for research purposes (almost 800,000 forms from five continents) and participation in an international research network
- Ability to register any surgical and conservative spinal treatment in a structured way
- Access to numerous outcome instruments in various languages (COMI, ODI, NDI, EQ3D, SF36, SRS30, etc.)
- Evidence of performance including feedback to users through online statistics and regular benchmarking reports as quality assurance instruments
- Modern and continually-evolving registry platform including:
 - Compliance with the European General Data Protection Regulation (GDPR)
 - Highest standards in information security (ISO27001)
- **Registry platform as a web-application** (the registry may be accessed from any location via the internet)
- Electronic outcome collection using ePROMs (automatically sends forms to patients via email and/or smartphone on a scheduled basis with no administrative burden for hospitals) (coming soon)

Key benefits for national spine societies

- Access to available data, know-how and infrastructure incl. European Implant Library (make it your own)
- Data aggregation to produce statistically robust analyses sooner (e.g. for national surveillance purposes)

- **'Develop once and share' platform features** (access to the European Spine Registry generic services including all existing and future tools and functions at no additional cost)
- Flexible modular approach that allows societies to tailor the registry to their individual needs while ensuring a minimal set of common data
- Ability to create a personalised spine registry based on Spine Tango content and infrastructure (optional)
- Quality assurance and research tool as well as proof of performance
- **Opportunity to develop national best practice standards** in spine care
- **Continuous collaborative development of the registry approach** in accordance with society needs
- A full voting position on the Spine Tango Task Force (Spine Tango steering committee responsible for further development of the registry)
- Innovative financial model (medium-term) based on subscription funding from industry reporting that applies certain income to reduce registry costs, registration costs and/or yield shared profits, after fixed costs have been covered (under development)

Governance

The Spine Tango Task Force (STTF) acts as the registry steering committee and as an advisory group for clinical and methodological questions related to improvements in data collection, development of new forms, reports and all new and ongoing research projects of participating clinics.

The objectives of the internationally-composed STTF are to develop and implement strategies to further develop the registry, increase its value for the users and stakeholders: patients, insurance companies, MedTech companies and health authorities.

STTF members: Marco Teli (chair, surgery, UK), Emin Aghayev (registries, CH), Bart Depreitere (surgery, BE), Jiří Dvořák (sport medicine, CH), Josef G. Grohs (surgery, AT), Beat Leimbacher (delegate of ExCom, CH), Andrea Luca (surgery, IT), Samuel Morris (osteopathy, UK), and Pedro dos Santos (surgery, PT).

Data host

Technical and analytical support for the registry is provided by a dedicated team at Northgate Public Services (NPS). The project team is based in the UK and provides expertise in registry development, methodology, epidemiological analysis, statistics, and data linkage.

NPS has been the technology and implementation service provider for the National Joint Registry (NJR) in the UK for over 16 years. The NJR is probably the largest orthopaedics registry in the world with more than 3 million patient records. NPS hosts a number of other medical registries such as the National Vascular Registry (NVR) and the Indian Joint Registry (IJR) – all of which collect data to help clinicians, regulators and industry deliver evidence-based treatments for patients.

For more information, please visit:

- <u>News: Evidence to improve outcomes for spinal patients with EUROSPINE registry</u>
- Information on NPS and NPS Registry Solutions

How to join

Form

The Spine Tango registry is a EUROSPINE member benefit. If you are not currently a member and your department or hospital does not have a EUROSPINE member on staff, you may still use Spine Tango provided that you or one staff member of your department or hospital become a EUROSPINE member within one year of your Spine Tango registration.

Individual users and hospitals can join the registry in 3 steps:

 Step 1
 Step 2
 Step 3

 Jownload and complete the Hospital/User Registration
 Download, read, complete and sign the General Terms
 Send both co to

Download, read, complete and sign the <u>General Terms</u> <u>& Conditions</u> (see <u>help</u> for assistance).

Send both completed forms to <u>spinetango@eurospine.org</u>.

Once EUROSPINE has received your registration request, EUROSPINE will approve it and provide you (and your colleagues in the case of multiple users) with your account details. Then you can start using the registry.

For more information, please visit EUROSPINE - New Users

Participation

The underlying principles for participation in the Spine Tango registry are described in the <u>General Terms & Conditions</u>.

Information security and data protection

The secure and confidential handling of patient and clinical data is a fundamental part of the Spine Tango service provided by NPS. In delivering services to their clients, NPS manages confidential data relating to millions of citizens and patients in the UK and overseas. This not only involves technical solutions to protect the data, but also robust processes and procedures surrounding data access, based upon legislation and industry best practice. Given the nature of the data processed by NPS, security and governance are afforded the highest priority.

Spine Tango is compliant with the *European General Data Protection Regulation* (GDPR) with the highest standards in information security applied (ISO27001).

In certain instances, personal health information may be provided to organisations in some countries where the GDPR does not apply. Where this is the case, EUROSPINE will enter into individual data-sharing agreements based on the requirements of the GDPR. This will ensure that the data are afforded the necessary levels of information governance and security.

Furthermore, it is the responsibility of the individual or organisation (the 'Participant') to ensure that all necessary agreements are obtained from their institution (and can be made available on demand) in respect to any local laws, guidelines, 'best practice', ethical requirements, etc. In particular, the Participant is explicitly responsible for obtaining and documenting each patient's informed consent for the use of the patient's data for the purposes of research and quality assurance in the registry. The participant must also warrant that all necessary consents and approvals required for processing all information relating to an identified or identifiable natural person to be processed under this agreement have been obtained.

Upon registration of a new patient, the registry platform requires a confirmation that informed patient consent has been obtained.

For more detailed information on data security please read the <u>FAQs on Data Protection and</u> <u>Information Security</u>.



Data capture

The goal of generating a comprehensive database is achieved by collecting both patient data and clinical / physicians' data.

The four following data entry methods (or combinations thereof) are currently used for Spine Tango (Figure 2):

- 1. Online data entry via 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
- 4. Online implant data capture with handheld barcode scanner



Figure 2. Methods of data entry

A complete case

The result of a surgical intervention should be recorded when the outcome can be considered definitive. In most spinal surgery cases, assessment three months after surgery predicts outcomes well at later follow-up¹. Figure 3 and Figure 4 illustrate the steps leading to the capture of a fully-documented treatment².

¹ 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.

² 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.



Figure 3. Timing of data collection for a complete Spine Tango case

EUROSPINE encourages one physician- and one patient-reported follow-up in the first year after surgery, ideally more 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 documentation³.

³ 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.



Figure 4. Process of data collection from the spinal surgery to the reports

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 our data host, NPS. 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 being published and cited in peerreviewed literature, and recognised as outstanding contributions to scientific knowledge⁴. Various statistical methods are utilised in Spine Tango research, including descriptive analyses for data exploration, parametric and non-parametric tests, uni- and multi-variate linear and logistic regression analyses^{5,6,7,8} and inverse probability of treatment weighting using the propensity score⁹. Comparative effectiveness of research studies across different spine registries have also been published^{10,11}. In addition to clinical studies, a multitude of reliability and validation studies

⁴ 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.

⁵ 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.

⁶ 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.

⁷ 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.

 ⁸ 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.
 ⁹ Munting E, Röder C, Sobottke R, Dietrich D, Aghayev E. Patient outcomes after laminotomy,

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

¹⁰ Burkhardt J-K, Mannion AF, 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 corpectomy. Neurosurg Focus. 2013;35(1):E4.

¹¹ 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.

of the patient Core Outcome Measures Index (COMI) in different languages have been performed and published in the last decade^{12,13,14,15,16,17,18,19}.

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.

Achievements (2018 – 2019)

In 2018, EUROSPINE appointed a **new contractor**, Northgate Public Services (NPS), to host EUROSPINE's Spine Tango registry. The registry launched at NPS for all users on 1 May 2019, with all legacy data migrated to NPS.

EUROPSINE succeeded in establishing an **implant library**, which enables the accurate documentation of implants used in surgery in addition to a later evaluation. Built on a model similar to that used in the UK's National Joint Registry, device manufacturers can now easily upload and maintain reference data on their implants, which then forms the basis of a comprehensive implant library of over 165,000 distinct implants. Thus, the library incorporates a mechanism for updates and continuous further development. The implant library will soon include a classification of implant types, enabling implant analysis and comparison across like-for-like devices and within product families.

¹² 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.

 ¹³ 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.
 ¹⁴ 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.

¹⁵ Qiao J, Zhu F, Zhu Z, Xu L, Wang B, Yu Y, et al. Validation of the Simplified Chinese version of the Core Outcome Measures Index (COMI). Eur spine J. 2013;22(12):2821–6.

¹⁶ 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.

¹⁷ 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.

¹⁸ Van Lerbeirghe J, Van Lerbeirghe J, Van Schaeybroeck P, Robijn H, Rasschaert R, Sys J, Parlevliet T, Hallaert G, Van Wambeke P, Depreitere B. Cross-cultural adaptation and validation of the Dutch version of the core outcome measures index for low back pain. Eur Spine J. 2018 Jan;27(1):76-82.

¹⁹ 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.

This development enables Spine Tango to play a key role in supporting the MedTech industry in their compliance to the new European Medical Device Regulations (MDR).

In collaboration with the MedTech industry, Spine Tango has begun developing **implant reports**. This type of report is needed for implant manufacturers to meet regulated requirements on post-market surveillance.

A new **benchmarking hospital report** has been created and is currently under further development. This report provides valuable feedback to the hospital, serves as evidence of the hospital's performance, enables monitoring of treatment efficiency, and compares hospital patient populations, treatments and treatment outcomes to those of all other hospitals.

In 2019, EUROSPINE participated in and won the tender for Swiss Implant Registry "SIRIS Spine". SIRIS Spine will be undergoing a pilot phase in 2020 followed by a national rollout in January 2021. More than 70 centres will be participating in SIRIS Spine.

Information portfolios for hospitals and implant suppliers have been developed.

Today, Spine Tango is more present than ever in different **media channels** such as LinkedIn, YouTube, and Twitter to approach a broader audience.

FAQs on data protection and information security have been created.

An **information leaflet for patients**, which informs patients about the Spine Tango registry has been created.

Training new users is now easier with the <u>video tutorials</u> on the Spine Tango webpage and on YouTube.

To improve efficiency, each member of the **Spine Tango Task Force** (STTF) has taken on a specific role and responsibilities (e.g. Society Officer, Financial Officer or Science Officer).

Furthermore, a considerable amount of conceptual work has been done in the background. The STTF has developed "**models on collaboration** with Spine Tango" for national societies, and standard procedures for new users joining the registry, termination of a user's participation, and **research requests**. The Spine Tango **webpage** at EUROSPINE has been **reorganised** and all documents listed above are available online.

Finally, many resources have been invested into **re-defining the requirements for the features** of the registry (e.g. **benchmarking reports, search feature, export feature, online statistics**, etc.) to further develop them and increase their value for users.

Outlook

Having proven that the registry is stable, reliable, and flexible under the new service provider NPS, new features are continually being added and available features further developed to increase the value of the registry for users and increase accessibility to a wider audience.

In 2020, the user interface of the registry should be made multilingual to include English, French, and German. Further languages are coming soon.

Spine Tango is in talks with several national spine societies who have expressed an interest in using Spine Tango as the registry tool for their national registries. EUROSPINE hopes that the number of spine societies that use Spine Tango will increase in the future. Among others, Spine Tango aim to establish a close collaboration with the German Spine Society and the American Academy of Orthopaedic Surgeons.

Future developments to Spine Tango platform to come onstream in the coming year include the development of an online reporting service and the implementation of an ePROMs service. The online reporting service will provide users with the ability to conduct interactive analyses of their Spine Tango data to supplement Spine Tango Hospital Reports. The ePROMs solution will provide a simple method for collecting data directly from patients over a longer period and, thus, improve outcomes analyses.

Spine Tango wants to further develop and strengthen the user feedback system to include online statistics and reporting.

The need for further development of the surgery form will be assessed soon and the form revised if needed.

Selected statistics

World map

The Spine Tango registry and the majority of participating hospitals are based in Europe. Hospitals from many other countries are also currently participating (or have previously participated) in the registry, as illustrated in the following three maps. This international distribution demonstrates the need for a common language in the registration of spinal treatments and their outcomes, which in turn will lead to the standardisation of spinal care and improved efficiency.

All following maps are based on registry data collected up to 31 December 2019.



Figure 5. Global overview of origin of participants in the registry



Figure 6. Global overview of submitted forms by country



Figure 7. Overview of submitted forms of the participants by country in Europe

Overall data growth by form type

The number of documented forms in the registry increases each year. The number of forms in 2019 was visibly lower than in previous years. This is probably related to the change of host and the transition phase, which led to the loss of some participants.



Figure 8. Surgery forms



22

Figure 9. COMI forms (both surgery and conservative COMI)





Figure 11. EQ3D forms



Patient characteristics

The figures presented in the following tables are based on 131,410 surgeries documented up to 31 December 2019.

Category	Characteristic	Percent
	< 40	15.5%
	40-49	17.2%
Age	50-59	20.5%
	60-79	39.9%
	> 80	6.9%
Condor	Male	48.3%
Gender	Female	51.7%
	No	48.3%
Smoker*	Yes	13.6%
	Unknown	38.1%
	< 20	4.4%
	20-25	26.8%
	26-30	33.1%
DIVII	31-35	15.8%
	> 35	6.4%
	Unknown	13.4%
Number of	1	60.6%
Segments	2	26.4%
Affected	3	6.9%
	> 3	6.1%
Previous	0	71.1%
Surgeries (Any	1	19.1%
	> 1	9.2%
Lever	Unknown	0.6%

Table 1. Patient characteristics overview (*these characteristics were documented in the 2011 and 2017 forms only and their proportions are calculated based on the number of those 85,207 forms.)

Main pathologies

The most frequent pathology seen in the registry is degenerative disease with around 78%, followed by repeat surgery with 4.1% and other less frequent pathologies.

Main Pathology	Percent	Count
Degenerative Disease	77.8%	102,268
Repeat Surgery	4.1%	5 <i>,</i> 389
Fracture / Trauma	3.7%	4,915
Spondylolisthesis (Non-Degenerative)	3.2%	4,194
Non-Degenerative Deformity	2.6%	3,469
Pathological Fracture	2.5%	3,247
Tumour	2.4%	3,125
Failed Surgery	1.5%	1,983
Other	1.0%	1,318
Infection	1.0%	1,258
Inflammation	0.2%	244
TOTAL	100.0%	131,410

Table 2. Main pathologies tabular overview



Figure 13. Main pathologies bar chart overview

Regarding the levels of intervention, the majority of the cervical surgeries take place at C5 (6.5%), followed by C6 (4.4%). Thoracic levels are rather rare with Th12 as the most frequent thoracic level at 1.6%. The three most treated levels are L4 (31.2%) followed by L5 (21.4%) and L3 (12.2%).



Figure 14. Levels of intervention

Descriptive analysis of selected pathologies

The authors of this annual report elected to describe some key characteristics of patient groups undergoing surgical treatment for one of the two most frequent pathologies: disc herniation and spinal stenosis.

Disc herniation

40% of all documented surgeries in Spine Tango (N=53,043) were related to the treatment of disc herniation. The following Table 3 describes characteristics of this patient population.

Patient characteristics

Mean Age		52
<40	22.24%	11,797
40-49	25.71%	13,637
50-59	22.73%	12,058
60-79	26.30%	13,948
>=80	3.02%	1,603
Gender		
Male	52.40%	27,796
Female	47.60%	25,247
Smoker (2011 & 2017 only)		
Yes	9.91%	5,258
No	28.84%	15,300
Unknown	29.51%	15,655
Median BMI (2011 & 2017 only)		27.34
< 20	2.58%	1,368
20-25	18.42%	9,768
26-30	22.70%	12,041
31-35	10.03%	5,322
>35	4.35%	2,305
Unknown	10.20%	5,409
Number of Segments Affected		
1	76.70%	40,683
2	18.60%	9,864
3	3.29%	1,743
>= 3	1.42%	753
Previous Surgeries (Any Level)		
0	78.03%	41,388
1	16.30%	8,647
>1	5.49%	2,912
Unknown	0.18%	96

Table 3. Patient characteristics disc herniation

Surgical measures

The following Figure 15 demonstrates proportions of key surgical measures over a time period of 15 years between 2005 and 2019. The distribution of the individual surgical measures remained rather stable over this time period with a slight but visible reduction of motion preserving stabilisation in the last seven years.



Proportion of Surgeries by Surgical Measure by Year

Figure 15. Proportion of surgeries by surgical measure by year

Complications

General complications were rather rare with the leading complication of kidney and urinary tract in 0.25% of the surgeries (Figure 16).



General Complications for Herniated Disc Cases

Figure 16. General complications for herniated disc cases

Surgical complications were more frequent with dural lesions documented in 2.85% of the surgeries (Figure 17). The next most frequent complications were neurological with motor disfunction, radiculopathy and sensory disfunction in 0.37%, 0.31% and 0.31%, respectively.

Dural Lesion -				2.85%
Other-	0.55%			
Motor Dysfunction -	0.37%			
Radiculopathy -	0.31%			
Sensory Dysfunction -	0.31%			
Epidural Hematoma -	0.19%			
Bowel / Bladder Dysfunction -	0.16%			
Nerve Root Damage -	0.15%			
CSF Leak / Pseudomeningocele -	0.14%			
Other Hematoma -	0.12%			
Wound Infection Superficial -	0.11%			
Wound Infection Deep	0.07%			
Vascular Injury -	0.04%			
Implant Malposition -	0.04%			
Implant Failure -	0.03%			
Fracture Vertebral Structures -	0.03%			
Spinal Cord Damage -	0.02%			
Wrong Level	0.01%			
Recurrent Nerve Paresis -	0.01%			
	0.0%	1.0%	2.0%	3.0%

Surgical Complications for Herniated Disc Cases

Figure 17. Surgical complications for herniated disc cases

Outcomes - COMI

In 36% of all patients a baseline COMI form and a 3-month postoperative or later COMI form were documented. The following Figure 18 to Figure 20 demonstrates the average preoperative and postoperative axial and peripheral pain levels as well as COMI score with 95% confidence intervals over the last 15 years. The curves were not adjusted by patient characteristics, surgical measures and follow-up interval, which are assumed to be relatively stable. Nevertheless, the figures have a descriptive character only and a conclusive interpretation requires more granular investigations.

Over this time period the preoperative axial pain has steadily increased from about 5 points to 6.5 points, while the postoperative axial pain has steadily increased from 3 to 4 points. This finding of increasing preoperative axial pain points to a stable but steadily improving treatment indication. This is very positive. The increasing postoperative axial pain over the years demonstrates, however, that a better treatment indication does not necessarily result in a better postoperative axial pain level. Nevertheless, a trend for slightly higher pain relief is still seen in the last years.



Preoperative and Postoperative Axial Pain in Disc Herniation Cases by Year

Figure 18. Preoperative and postoperative axial pain in disc herniation cases by year

Over this time period the preoperative peripheral pain has steadily increased from about 6.7 points to 8 points, while the postoperative peripheral pain has steadily increased from 3 to 4 points. This finding of increasing preoperative peripheral pain points also to a stable but steadily improving treatment indication, which is very positive. The increasing postoperative peripheral pain over the years demonstrates again that a better treatment indication does not necessarily result in a better postoperative peripheral pain level.



Preoperative and Postoperative Peripheral Pain in Disc Herniation Cases by Year

Over this time period the preoperative pain remained very stable at 8 points, while the postoperative COMI score has steadily increased from 3.5-4 points to 4.5 points. The

increasing postoperative COMI score reflects a higher level of postoperative disability, which is a not favourable finding.



Preoperative and Postoperative COMI Score in Disc Herniation Cases by Year

Figure 20. Preoperative and postoperative COMI score in disc herniation cases by year

Spinal stenosis

50.2% of all surgeries documented in Spine Tango (N= 65'818) were related to the treatment of spinal stenosis. The following Table 4 describes characteristics of this patient population.

Patient characteristics

Mean Age		65.5
<40	4.67%	3,075
40-49	10.49%	6,902
50-59	19.58%	12,890
60-79	55.05%	36,236
>=80	10.20%	6,715
Gender		
Male	49.44%	32,540
Female	50.56%	33,278
Smoker (2011 & 2017 only)		
Yes	8.88%	5,843
No	37.96%	24,984
Unknown	30.22%	19,887
Median BMI (2011 & 2017 only)		28.36
< 20	2.32%	1,529
20-25	17.12%	11,265
26-30	26.29%	17,301
31-35	13.72%	9,030
>35	5.32%	3,501
Unknown	12.29%	8,088
Number of Segments Affected		
1	47.63%	31,350
2	35.25%	23,202
3	11.60%	7,636
>= 3	5.52%	3,630
Previous Surgeries (Any Level)		
0	80.36%	52,893
1	13.73%	9,035
> 1	5.69%	3,742
Unknown	0.22%	148

Table 4. Patient characteristics spinal stenosis

Surgical measures

The following Figure 21 demonstrates proportions of key surgical measures over a time period of 15 years between 2005 and 2019. The distribution of individual surgical measures changed over this time period. The proportion of decompression alone has grown from approx. 40% initially to over 70% of all surgeries in the last years. The proportion of instrumented fusion has steadily decreased from approx. 40-45% in 2005 to approx. 20-25% in the last three years. The proportion of motion preserving stabilisation has remained mostly stable in around 5% of surgeries, but decreased in the last three years.



Proportion of Surgeries by Surgical Measure by Year

Complications

General complications were rather rare with the leading complication of kidney and urinary tract in 0.63% of the surgeries (Figure 22).





Surgical complications were more frequent with dural lesions documented in 5.28% of the surgeries (Figure 23). The next most frequent complications were neurological with motor disfunction, epidural hematoma, sensory disfunction and radiculopathy in 0.76%, 0.59%, 044% and 0.42%, respectively.



Surgical Complications for Spinal Stenosis Cases

Figure 23. Surgical complications for spinal stenosis cases

Outcomes - COMI

In 42.8% of all patients, a baseline COMI form and a 3-month postoperative or later COMI form were documented. The following Figure 24 to Figure 26 demonstrates the average preoperative and postoperative axial and peripheral pain levels as well as COMI score with 95% confidence intervals over the last 15 years. The curves were not adjusted by patient characteristics, surgical measures and follow-up intervals, which are assumed to be relatively stable. Nevertheless, the figures have a descriptive character only and a conclusive interpretation requires more granular investigations.

Over this time period the preoperative axial pain has steadily increased from about 5.5 points to slightly more than 6 points, while the postoperative axial pain has slightly fluctuated around 4 points mark. This finding of increasing preoperative axial pain points to a stable but marginally improving treatment indication. The stable postoperative axial pain is rather a neutral finding pointing out that changes in the treatment strategy did not result in worthening or improving postoperative axial pain.



Preoperative and Postoperative Axial Pain in Spinal Stenosis Cases by Year

Figure 24. Preoperative and postoperative axial pain in spinal stenosis cases by year

Over this time period the preoperative peripheral pain has steadily increased from about 6.5 points to 7.5 points, while the postoperative peripheral pain has steadily increased from 3.5 to 4 points. The increase of preoperative peripheral pain level of the years is slightly higher than that of the postoperative pain level, which points to a slightly higher pain reduction achieved in the last years.



Preoperative and Postoperative Peripheral Pain in Spinal Stenosis Cases by Year

Figure 25. Preoperative and postoperative peripheral pain in spinal stenosis cases by year

Over this time period the preoperative remained very stable at 7.5 - 8 points and the postoperative COMI score remained rather stable between 4.5 and 5 points.



Preoperative and Postoperative COMI Score in Spinal Stenosis Cases by Year

Figure 26. Preoperative and postoperative COMI score in spinal stenosis cases by year

Research

How to publish with Spine Tango data

As a participant of the Spine Tango registry, you have access to Spine Tango data for research purposes. The access to data is bound to specific studies and is granted following approval of the study protocol. A template for the study protocol can be found <u>here</u>. The protocols should be sent to <u>spinetango@eurospine.org</u>.

Once we have received the completed study protocol, the following steps will be required to access the requested data:

- 1. The STTF will review the protocol in terms of scientific accuracy, good clinical and epidemiological practice, methods, and appropriateness of the analysis based on the Spine Tango data.
- 2. You will receive feedback from the STTF either approving your protocol, advising that you make some adjustments to the study, or requesting clarification on some points.
- 3. Once the protocol has been approved by the STTF, an analysis will be conducted by EUROSPINE or you will be provided with data, depending on the study protocol and some other factors.

Publications (2018-2019)

The following list includes publications released between 1 January 2018 and 31 December 2019.

Publications 2019

- [Derived from the data of the European Spine Registry: Spectrum of Spine Surgery in Switzerland] Aghayev E, Jeszenszky D, Benneker L, Heini P, Maestretti G, Trouillier HP, Külling F, Otten P. Swiss Med Wkly. 2019;19(49–50):803–807
- Medium-term outcome of posterior surgery in the treatment of non-tuberculous bacterial spinal infection.
 Aljawadi A, Sethi G, Imo E, Arnall F, Choudhry MN, George KJ, Tambe A, Verma R, Yasin MN, Mohammed S, Siddique I.
 J Orthop. 2019 Jun 19;16(6):569-575.
- Back Pain and Its Change After Surgery in Adolescents and Young Adults With Idiopathic Scoliosis.
 Fekete TF, Mannion AF, Haschtmann D, Loibl M, Kleinstück FS, Jeszenszky DJ. Spine Deform. 2019 Sep;7(5):754-758.
- Does neck pain as chief complaint influence the outcome of cervical total disc replacement? Finkenstaedt S, Mannion AF, Fekete TF, Haschtmann D, Kleinstueck FS, Mutter U, Becker HJ, Bellut D, Porchet F. Eur Spine J. 2019 Nov 16.
- Pooling and patient satisfaction in non-instrumented lumbar decompressive surgery. Halliday J, Holsgrove D. Br J Neurosurg. 2019 Feb;33(1):8-11.
- Non-medical factors significantly influence the length of hospital stay after surgery for degenerative spine disorders.
 Mai D, Brand C, Haschtmann D, Pirvu T, Fekete TF, Mannion AF. Eur Spine J. 2019 Nov 16.
- Comparative study of multilevel posterior interbody fusion plus anterior longitudinal ligament release versus classic multilevel posterior interbody fusion in the treatment of adult spinal deformities.
 Sabou S, Lagaras A, Verma R, Siddique I, Mohammad S.
 J Neurosurg Spine. 2019 Apr 5:1-7.
- Concomitant back pain as a predictor of outcome after single level lumbar microdecompressive surgery - A study of 995 patients.
 Sethi G, Aljawadi A, Choudhry MN, Fischer B, Divecha HM, Leach J, Arnall F, Verma R, Yasin N, Mohammad S, Siddique I. J Orthop. 2019 Aug 14;16(6):478-482.

- Surgical training in spine surgery: safety and patient-rated outcome. Waisbrod G, Mannion AF, Fekete TF, Kleinstueck F, Jeszenszky D, Haschtmann D. Eur Spine J. 2019 Apr;28(4):807-816.
- The clinical and radiological outcomes of multilevel posterior lumbar interbody fusion in the treatment of degenerative scoliosis: a consecutive case series with minimum 2 years follow up.
 Sabou S, Carrasco R, Verma R, Siddique I, Mohammad S.

J Spine Surg. 2019 Dec;5(4):520-528.

Publications 2018

- Dynamic Posterior Stabilization versus Posterior Lumbar Intervertebral Fusion: A Matched Cohort Study Based on the Spine Tango Registry. Bieri KS, Goodwin K, Aghayev E, Riesner H-J, Greiner-Perth R. J Neurol Surg A Cent Eur Neurosurg. 2018;79(3):224-230.
- Minimally invasive stabilization of the fractured ankylosed spine: a comparative case series study.
 Brooks F, Rackham M, Williams B, Roy D, Lee YC, Selby M.
 J spine Surg (Hong Kong). 2018;4(2):168-172.
- Shaping conservative spinal services with the Spine Tango Registry. Morris S, Booth J. Eur Spine J. 2018;27(3):543-553.

Participants

The following is a list of hospital departments that submitted forms to the Spine Tango registry based on surgeries dated between 1 January 2018 and 31 December 2019.

Austria

• Universitätsklinik für Orthopädie Wien (Vienna) - Universitätsklinik für Orthopädie und Unfallchirurgie (Dept)

Belgium

- CHwapi Tournai Clinic Neurosurgery
- Clinique Edith Cavell Bruxelles Orthopédie
- Clinique Saint-Pierre Ottignies Orthopaedic Surgery
- Clinique Saint-Pierre Ottignies Neurosurgery

- Cliniques Universitaires Saint-Luc Bruxelles Orthopédie
- Heilig Hart Ziekenhuis Lier Neurosurgery, physical medicine and rehabilitation, algology
- ZNA Middelheim Antwerp Neurosurgery

Germany

• Kliniken HochFranken - Orthopadie und Neurochirurgie

Greece

• General Hospital of Argolida Argos - Orthopedic Department

Ireland

• Beaumont Hospital - Department of Neurosurgery

Italy

- Istituto Ortopedico Galeazzi Milano Reparto 1
- Istituto Ortopedico Rizzoli Bologna -Spine Deformity Unit
- Istituto Ortopedico Rizzoli Bologna Oncologic and Degenerative Spine Surgery Unit
- Policlinico Universitario Agostino Gemelli Roma Neurochirurgia

Nepal

• Hospital for Advanced Medicine and Surgery HAMS

Poland

• General Hospital Toruń - Department of Neurosurgery

Portugal

Hospital São João Porto - Neurosurgery

Slovenia

- Orthopaedic Hospital Valdoltra Ankaran Department for Spine Surgery and Paediatric Orthopaedics
- University Clinic Orthopedics Ljubljana Orthopedic Clinic

Spain

- Madrid College of Chiropractic San Lorenzo de El Escorial Centro Quiropractico
- Hospital Quironsalud Madrid Pozuelo de Alarcon Orthopedic Trauma

Switzerland

- Berit Paracelsus Klinik AG Speicher Wirbelsäulenzentrum
- Bethesda Spital Basel Neurochirurgie
- Centre Hospitalier Universitaire Vaudois Lausanne Service de rhumatologie
- Centre Hospitalier Universitaire Vaudois Lausanne Unite spinale
- Clinica Ars Medica Gravesano Spine
- Clinica Ars Medica Lugano Spine
- Clinique Cecil Lausanne Neurocentre
- Clinique Generale de Fribourg Neurochirurgie
- Das Rückenzentrum Thun Wirbelsäulenmedizin
- Hirslandenklinik Birshof Münchenstein Wirbelsäulenzentrum
- Hopital Cantonal Fribourg Orthopädie
- Kantonsspital Liestal Wirbelsäule
- Kantosspital St Gallen Klinik für orthopädische Chirurgie und Traumatologie
- Klinik Permanence Bern Wirbelsäule
- MediSpine WirbelsäulenZentrum Biel-Seeland Wirbelsäule
- Salem Spital Bern Neurochirurgie
- Salem Spital Bern Wirbelsaulenchirurgie
- Salem Spital Bern Orthopädie
- Schulthess Klinik Zürich Wirbelsaulenzentrum
- Klinik Sonnenhof Bern Spez. Wirbelsaulenchirurgie + Orthopadie Sonnenhof
- Universitätsklinik für Orthopädie Inselspital Bern Wirbelsäulenchirurgie

Turkey

• Gazi University Faculty of Medicine Ankara - Department of Neurosurgery

United Kingdom

- Salford Royal NHS Foundation Trust Department of Neurosurgery
- Salford Royal NHS Foundation Trust Spinal Department
- The Walton Centre NHS Foundation Trust Department of Neurosurgery

Images of the Spine Tango registry

The following screen shots are from the web interface of the ST registry.

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Powerful search function to find patients, questionnaires and implants:

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Guided documentation procedures with indications of missing or inappropriate data:

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Surgery	Admission date*						
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Hospital stay	Main pathology*						
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	Degenerative disease						
	Type of degeneration - primary*						
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	Type of degeneration - secondary*						
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The surgery and conservative forms, as well as key patient-reported outcome measure forms, can be found <u>here</u>.



EUROSPINE, the Spine Society of Europe Seefeldstrasse 16 8610 Uster-Zürich Switzerland

Robert Conrad Registry Manager <u>spinetango@eurospine.org</u>