

SPINE TANGO Report

International 2009



The International Spine Registry
EuroSpine

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INTRODUCTION

Since the year 2000 EuroSpine – The Spine Society of Europe has been developing and enhancing a documentation system for spinal surgery in form of a registry. With Spine Tango we are meeting the growing demand to assess the safety and efficacy of all surgical interventions of the spine. Only few other fields in medicine are under comparable scrutiny. Reacting to these tendencies, endeavors of pioneer clinicians and the Spine Tango team, in collaboration with the Institute for Evaluative Research in Medicine of the University of Bern, have led to the implementation of the only international spinal registry to date. The constantly growing number of Spine Tango participants indicates that the system has overcome its development period. Now, having reached a recognized status we would like to encourage national societies and individual partners to join the registry. Health authorities will increasingly limit the accessibility of our treatment modalities if we do not fulfill the demanded standards. Therefore we are offering Spine Tango as a common language to make our services visible and transparent. With a constantly increasing activity in the registry we would like to inform you about its history, its objectives and its current status.

M. Aebi

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^b
**UNIVERSITÄT
BERN**

NEW DEVELOPMENTS

Spine Tango Conservative: for the past two years we have been working on a documentation instrument for the non-surgical spinal therapies in order to complement the registry and make possible the assessment of all spinal treatments within the framework of one and the same registry. A first version of Spine Tango conservative was tested on a series of patients in 2009 and the results of this study are meanwhile available in the literature. Also, after another round of refinements and a validation study the first official version of the questionnaire will go live in early 2011

Spine Tango Pathways: we undertook a major effort for making available a comprehensive manual explaining all functionalities of the Tango in an easy, mostly picture based, way. This manual is meanwhile available for download on the front page of all Spine Tango modules.

Spine Tango Newsletter: you may have gotten it already. The newsletter wants to inform about latest developments, findings, publications and activities related to the Tango.

New software release: in fall/winter 2010 a completely redesigned software will displace the current Spine Tango program. Increased patient and user security, new features and more comfortable data handling are expecting the user community.



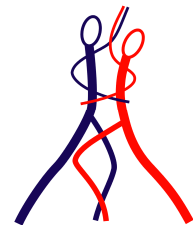
SSE Spine Tango Pathways Manual for Entering and Querying Data



Newsletter

EuroSpine - Spine Tango





PROFILE

Spine Tango enables you to document the whole spectrum of spinal pathologies and the possible surgical and soon also the non-surgical treatment options. The generic approach of the Spine Tango documentation system is a must to reach the maximum number of participants using a common web based technology. This, in turn, reduces the potential for customizing the Tango in order to meet the individual expectations of specific users. There are, nevertheless, still a number of possibilities to parameterize the data collection processes according to the various hospital workflows in the user community. To give you the opportunity to document not only the surgical treatment, we have developed Spine Tango Conservative, which is currently being validated. It is due to be released in early 2011.

Spine Tango is an international, non-commercial system under the auspices of EuroSpine aiming to enable national societies to control their own part of the registry. For that a technology called "national module concept" has been implemented to enhance participation options and to provide the hardware structure for appropriate security measures for patient and user privacy protection. In conclusion, Spine Tango is a unique applied medical and scientific documentation and technology solution. It is to the benefit of patients and physicians whilst generating evidence based findings to improve spinal care (1).

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1. Aebi M, Grob D (2004)
SSE Spine Tango: a European Spine Registry promoted by the Spine Society of Europe (SSE)
Eur Spine J 13: 661-662. DOI 10.1007/s00586-004-0868-0



APPLICATION

Quality control, outcomes research, postmarket surveillance of implants, national and international study network

Internal quality control: assuming that you have a complete data collection Spine Tango enables you to monitor all types of surgery during a specific period, observing the date and duration of operation, patient characteristics and outcomes (patient and physician based).

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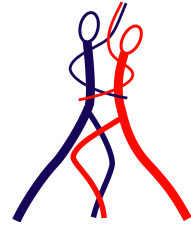
External quality control: Benchmarking, the comparison of own performance with that of the national or international results in the Tango is a powerful management tool because it overcomes "paradigm blindness." Paradigm blindness can be summed up as the mode of thinking, "The way we do it is the best because this is the way we've always done it." Benchmarking opens organizations to new methods, ideas and tools to improve their effectiveness. It helps overcome resistance to change by presenting successful methods of problem solving that are different to the ones currently employed. Enabling benchmarking possibilities is one of the fundamental goals of the Spine Tango venture.



Outcomes research: this aspect is actually just taking a different view for the same basic activity, i.e. the systematic and prospective collection of key data regarding interventions and outcomes for and of spinal pathologies. While quality assurance is rather used for the purposes of improving ones` own standards of care, outcomes research wants to generate new medical and scientific knowledge and make it available in the peer-reviewed literature.

Postmarket surveillance of implants: implants play a major role in modern spine surgery and just like in the domains of total joint arthroplasty their true performance can only be evaluated by systematically following the devices after implantation and documenting their outcomes in large clinical databases like the Tango.

National and international study network: the Tango is a technology backbone and currently networks over 40 active hospitals in Europe, North and South America, Australia and Asia. This provides a great opportunity for national and international multicenter studies that piggyback on the ongoing routine data collection, add some hypothesis based questions and collect this extra information for the time of primary and followup data collection as specified in the joint study protocol.



DATA ENTRY

There are **4 possible ways** forms and questionnaires can be transferred to the database (Fig. 1)

- ① Online data entry via the web-interface (no software to be installed)
- ② OMR (Optical Mark Reader) i.e. scanner-assisted entry of paper forms
- ③ Paper based data capture with mailing to the IEFM or other partner institutions for OMR scanner-assisted entry of paper forms
- ④ Hybrid method of online data entry and OMR scanner-assisted entry of paper forms (not pictured)

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In the rectangles multiple methods of gathering patient and physician generated data are shown (per mail, in house, outpatient clinics, telephone and new electronic media). The goal to generate a comprehensive database is achieved by collecting data of the patient layer and the clinic/physician layer. Having created a consistent data set the options of analyses are almost unlimited. Outcome evaluation can now be done in particular.

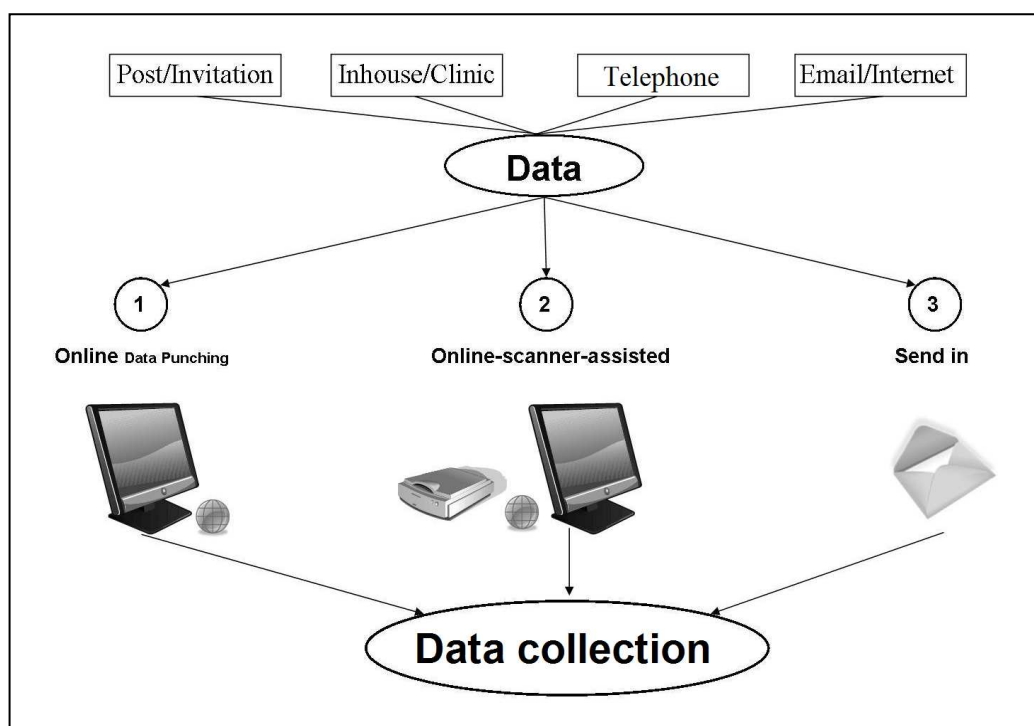


Fig. 1: Spine Tango methods of data entry

A COMPLETE CASE

Following Ernest Codman's "end result system" the result of a surgical intervention should be recorded if the outcome can be considered as definitive (2). In most cases of spinal surgery, this can be done after a minimum of 3 months after surgery as demonstrated by Mannion et al (3). Compare with Fig. 02. EuroSpine encourages one physician and patient based followup in the first year after surgery, ideally later than 3 months postop, and a second, at least patient based followup around year two after surgery. The registration of complications at any time during the postoperative period is self understood. Patient based outcome documentation with the COMI (Core Outcome Measure Index) questionnaires for neck and back pain has become an essential part of the Spine Tango documentation (4). The figure 03 on the next page illustrates the ideal case of a complet documented treatment (5).

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2. Codman, Ernest A. (1916). A Study in Hospital Efficiency. Boston, Mass., privately printed

3. Mannion AF, Porchet F; Kleinstück FS, Lattig F, Jeszenszky D, bartanusz V, Dvorak J, Grob D. (2009) The quality of spine surgery from the patient's perspective. Part 1: the Core Outcome Measures Index in clinical practice. Eur Spine J. 18 Suppl 3:367-73

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

5. Zweig T, Mannion AF, Grob D, Melloh M, Munting E, Aebi M, Tuschel A, Röder C. (2009) How to Tango – a manual for implementing Spine Tango. Eur Spine J 18 Suppl 3:312-2

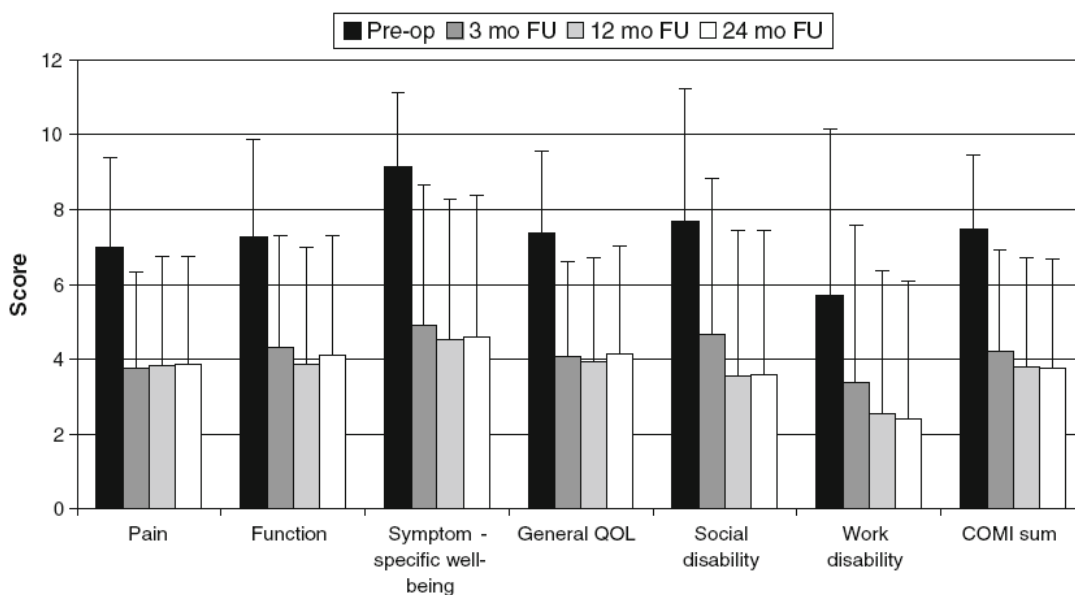


Fig. 2: Patient based outcome documentation with the COMI (Core Outcome Measure Index) questionnaires, AF Mannion et al. (2009)(3)

Pre- & postoperative documentation workflow of a case

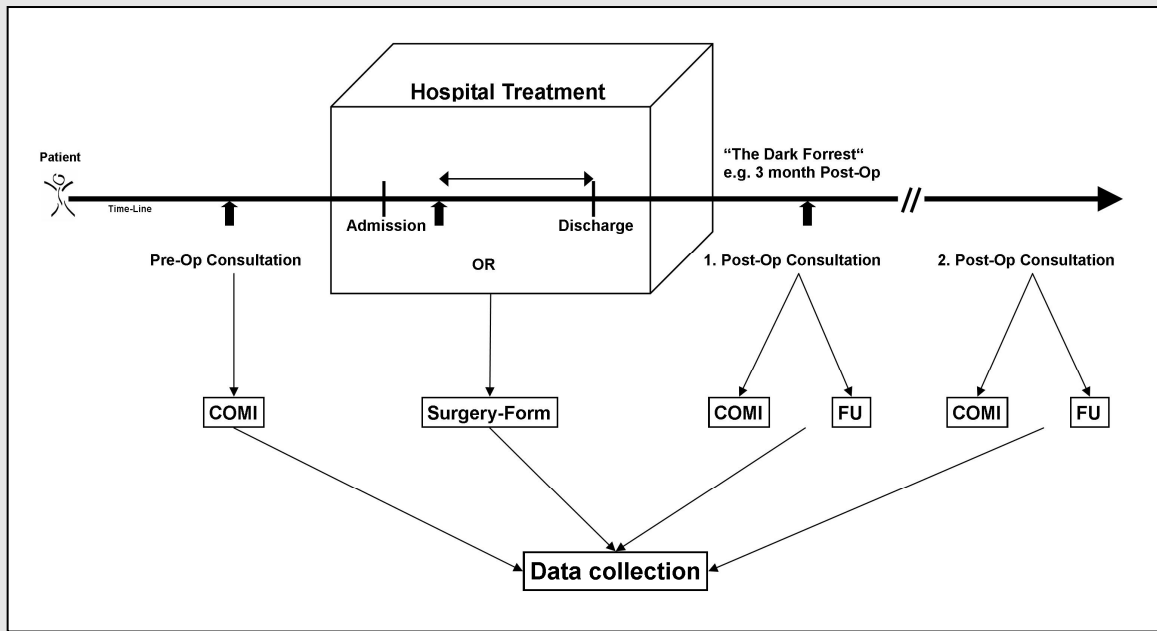


Fig 3: Timetable of data collection

Surgery form front side

SPINE TANGO

SURGERY

2006

Directions

- Use a #2 soft pencil for marking.
- Text answers must be entered with the web interface.
- All questions must be answered unless otherwise indicated.
- Completely fill in boxes to record answers.

Question types

only 1 answer allowed multiple answers allowed

mandatory questions

Level of procedure

upper cervical cervicothoracic thoracic thoraco-lumbo-sacral lumbo-sacral coccyx

mid lower cervical cervico-thoraco-lumbar thoracolumbar lumbar sacral

Admission / Pathology

Day: [C1] [C2] [C3] [C4] [C5] [C6] [C7] [C8] [C9] [C10] [C11] [C12] [C13] [C14] [C15] [C16] [C17] [C18] [C19] [C20] [C21] [C22] [C23] [C24] [C25] [C26] [C27] [C28] [C29] [C30] [C31]

Month: [C1] [C2] [C3] [C4] [C5] [C6] [C7] [C8] [C9] [C10] [C11] [C12] Year: [00] [01] [02] [03] [04] [05] [06] [07] [08] [09] [10] [11] [12] [13] [14] [15] [16]

Main pathology

degenerative disease fracture/trauma spondylolisthesis infection failed surgery

deformity pathological fracture inflammation tumor other: specify

Specification of Main Pathology *Only answer questions related to Main Pathology ("other" requires no specification).*

<p>Degenerative Disease</p> <p>Type of degeneration</p> <p><input type="checkbox"/> black disc <input type="checkbox"/> spondylarthrosis</p> <p><input type="checkbox"/> disc degeneration <input type="checkbox"/> spinal stenosis</p> <p><input type="checkbox"/> disc herniation <input type="checkbox"/> adjacent segment degen.</p> <p><input type="checkbox"/> spondylolysis <input type="checkbox"/> other</p>	<p>Spondylolisthesis</p> <p>Type of spondylolisthesis</p> <p><input type="checkbox"/> Type I (congenital, dysplastic)</p> <p><input type="checkbox"/> Type II (isthmic)</p> <p><input type="checkbox"/> Type III (degenerative)</p> <p><input type="checkbox"/> Type IV (traumatic)</p> <p><input type="checkbox"/> Type V (pathologic)</p> <p><input type="checkbox"/> Type VI (postsurgical)</p>	<p>Grade of spondylolisthesis</p> <p><input type="checkbox"/> Grade 0</p> <p><input type="checkbox"/> Grade I</p> <p><input type="checkbox"/> Grade II</p> <p><input type="checkbox"/> Grade III</p> <p><input type="checkbox"/> Grade IV</p> <p><input type="checkbox"/> Spondylolysis (V)</p>
<p>Deformity</p> <p>Type of deformity</p> <p><input type="checkbox"/> scoliosis <input type="checkbox"/> combined</p> <p><input type="checkbox"/> kyphosis <input type="checkbox"/> other</p> <p>Type of scoliosis</p> <p><input type="checkbox"/> single curve <input type="checkbox"/> double curve</p> <p>Predominant etiology</p> <p><input type="checkbox"/> idiopathic <input type="checkbox"/> posttraumatic</p> <p><input type="checkbox"/> congenital <input type="checkbox"/> M. Scheuermann</p> <p><input type="checkbox"/> neuromuscular <input type="checkbox"/> other</p> <p><input type="checkbox"/> degenerative</p>	<p>Inflammation</p> <p>Type of inflammation</p> <p><input type="checkbox"/> inflammatory arthritis (seropos)</p> <p><input type="checkbox"/> seronegative arthritis</p> <p><input type="checkbox"/> ankylosing spondylitis (M. Bechterew)</p> <p><input type="checkbox"/> other</p>	<p>Infection</p> <p>Infection specification</p> <p><input type="checkbox"/> pyogenic <input type="checkbox"/> fungal Affected structure(s)</p> <p><input type="checkbox"/> parasitic <input type="checkbox"/> other</p> <p><input type="checkbox"/> tuberculous <input type="checkbox"/> spondylitis</p> <p><input type="checkbox"/> <input type="checkbox"/> discitis</p> <p><input type="checkbox"/> <input type="checkbox"/> spondylodiscitis</p>
<p>(Pathological) Fracture/Trauma</p> <p><i>Additional fractures w/ different treatments require separate forms.</i></p> <p>Type of (pathological) fracture/trauma</p> <p><input type="checkbox"/> condylar (C0)</p> <p><input type="checkbox"/> C0/1 dissoziation</p> <p><input type="checkbox"/> C1 fracture</p> <p><input type="checkbox"/> C1/2 instability</p> <p><input type="checkbox"/> C2 dens fracture</p> <p>Dens fracture type</p> <p><input type="checkbox"/> I</p> <p><input type="checkbox"/> II</p> <p><input type="checkbox"/> III</p> <p>Pathological fracture due to ...</p> <p><input type="checkbox"/> osteoporosis</p> <p><input type="checkbox"/> tumor</p> <p><input type="checkbox"/> other</p> <p><i>(In case of tumor, answer questions "Type of tumor" and "Localization" in section "TUMOR")</i></p>	<p><input type="checkbox"/> C2 other fracture</p> <p><input type="checkbox"/> soft tissue injury neck</p> <p><input type="checkbox"/> fracture C3-L5/S1</p> <p><input type="checkbox"/> sacrum fracture</p> <p><input type="checkbox"/> other</p> <p>C3-L5/S1 AO fracture type</p> <p><input type="checkbox"/> A1 <input type="checkbox"/> B1 <input type="checkbox"/> C1</p> <p><input type="checkbox"/> A2 <input type="checkbox"/> B2 <input type="checkbox"/> C2</p> <p><input type="checkbox"/> A3 <input type="checkbox"/> B3 <input type="checkbox"/> C3</p> <p>Fracture age</p> <p><input type="checkbox"/> fresh fracture</p> <p><input type="checkbox"/> old fracture</p>	<p>Tumor</p> <p>Type of tumor</p> <p><input type="checkbox"/> primary malignant</p> <p><input type="checkbox"/> primary benign</p> <p><input type="checkbox"/> secondary malignant</p> <p><input type="checkbox"/> tumor like lesion</p> <p><input type="checkbox"/> other</p> <p>Specify type of tumor</p> <p>Localization</p> <p><input type="checkbox"/> vertebral body</p> <p><input type="checkbox"/> posterior bony elements</p> <p><input type="checkbox"/> extradural</p> <p><input type="checkbox"/> intradural extramedullary</p> <p><input type="checkbox"/> intradural intramedullary</p> <p><input type="checkbox"/> other</p>
<p>Failed surg.</p> <p>Type of failed surgery</p> <p><input type="checkbox"/> non-union <input type="checkbox"/> postop. infection <input type="checkbox"/> frontal imbalance</p> <p><input type="checkbox"/> instability <input type="checkbox"/> implant failure <input type="checkbox"/> other</p> <p><input type="checkbox"/> neurocompression <input type="checkbox"/> sagittal imbalance</p>		

Comments regarding main pathology:

Most severely affected segment/vertebral body

<input type="checkbox"/> not applicable/assessable	<input type="checkbox"/> C3	<input type="checkbox"/> C7	<input type="checkbox"/> Th4	<input type="checkbox"/> Th8	<input type="checkbox"/> Th12	<input type="checkbox"/> L4
<input type="checkbox"/> unknown	<input type="checkbox"/> C3 / 4	<input type="checkbox"/> C7 / Th1	<input type="checkbox"/> Th4 / 5	<input type="checkbox"/> Th8 / 9	<input type="checkbox"/> Th12 / L1	<input type="checkbox"/> L4 / 5
<input type="checkbox"/> C0	<input type="checkbox"/> C4	<input type="checkbox"/> Th1	<input type="checkbox"/> Th5	<input type="checkbox"/> Th9	<input type="checkbox"/> L1	<input type="checkbox"/> L5
<input type="checkbox"/> C0 / 1	<input type="checkbox"/> C4 / 5	<input type="checkbox"/> Th1 / 2	<input type="checkbox"/> Th5 / 6	<input type="checkbox"/> Th9 / 10	<input type="checkbox"/> L1 / 2	<input type="checkbox"/> L5 / S1
<input type="checkbox"/> C1	<input type="checkbox"/> C5	<input type="checkbox"/> Th2	<input type="checkbox"/> Th6	<input type="checkbox"/> Th10	<input type="checkbox"/> L2	<input type="checkbox"/> S1
<input type="checkbox"/> C1 / 2	<input type="checkbox"/> C5 / 6	<input type="checkbox"/> Th2 / 3	<input type="checkbox"/> Th6 / 7	<input type="checkbox"/> Th10 / 11	<input type="checkbox"/> L2 / 3	<input type="checkbox"/> sacrum (S2-5)
<input type="checkbox"/> C2	<input type="checkbox"/> C6	<input type="checkbox"/> Th3	<input type="checkbox"/> Th7	<input type="checkbox"/> Th11	<input type="checkbox"/> L3	<input type="checkbox"/> coccyx
<input type="checkbox"/> C2 / 3	<input type="checkbox"/> C6 / 7	<input type="checkbox"/> Th3 / 4	<input type="checkbox"/> Th7 / 8	<input type="checkbox"/> Th11 / 12	<input type="checkbox"/> L3 / 4	

Extent of lesion

1 segment/vertebral body 2-3 segments/vertebral bodies 4-5 segments/vertebral bodies >5 segments/vertebral bodies

Additional pathology *(Answer to question "Main pathology" is excluded.)*

none deformity pathological fracture inflammation tumor

degenerative disease fracture/trauma spondylolisthesis infection failed surgery

other: specify

Number of previous spine surgeries [C0] [C1] [C2] [C3] [C4] [C5] [C6]

Answer "0" excludes both "Previous surgery" questions ("at same level" and "at same hospital")

Previous surgeries at same level	Previous treatment for main pathology	
<input type="checkbox"/> no <input type="checkbox"/> yes <input type="checkbox"/> partially	<input type="checkbox"/> none <input type="checkbox"/> 3-6 mon. conservative	
Previous surgeries at same hospital	<input type="checkbox"/> surgical <input type="checkbox"/> 6-12 mon. conservative	
<input type="checkbox"/> no <input type="checkbox"/> yes <input type="checkbox"/> partially	<input type="checkbox"/> < 3 mon. conservative <input type="checkbox"/> > 12 mon. conservative	

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Surgery form back side

SPINE TANGO

SURGERY

Page 2 of 2

Internal Use Only - Not read by scanner

Surgeon Assistant

Surgery

Day (1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12) (13) (14) (15) (16) (17) (18) (19) (20) (21) (22) (23) (24) (25) (26) (27) (28) (29) (30) (31)
 Month (1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12) Year 00 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16

SURGICAL PROCEDURE

Surgeon credentials <input type="checkbox"/> specialized spine <input type="checkbox"/> board certif. orthopaedic <input type="checkbox"/> board certified neuro <input type="checkbox"/> orthopaedic in training <input type="checkbox"/> neuro in training <input type="checkbox"/> other	Goal of surgery <input type="checkbox"/> pain relief <input type="checkbox"/> functional improvement <input type="checkbox"/> neurological improvement <input type="checkbox"/> cosmetic improvement <input type="checkbox"/> diagnostic measures <input type="checkbox"/> other
Morbidity state <input type="checkbox"/> unknown <input type="checkbox"/> ASA1 (no disturbance) <input type="checkbox"/> ASA2 (mild/moderate) <input type="checkbox"/> ASA3 (severe) <input type="checkbox"/> ASA4 (life threatening) <input type="checkbox"/> ASA5 (moribund)	Anterior access <input type="checkbox"/> no anterior access <input type="checkbox"/> transoral <input type="checkbox"/> anterior <input type="checkbox"/> anterolateral <input type="checkbox"/> cervicothorac. anterolat. <input type="checkbox"/> cervicothorac. a.lat. w/sternotomy
Technology <input type="checkbox"/> conventional <input type="checkbox"/> MISS/LISS <input type="checkbox"/> loops <input type="checkbox"/> microscope	Blood loss <input type="checkbox"/> unknown <input type="checkbox"/> none <input type="checkbox"/> < 500 ml <input type="checkbox"/> endoscope <input type="checkbox"/> CASS <input type="checkbox"/> other
Components <input type="checkbox"/> yes <input type="checkbox"/> no	Operation time <input type="checkbox"/> unknown <input type="checkbox"/> < 1 hr. <input type="checkbox"/> 1-2 hrs. <input type="checkbox"/> 2-3 hrs. <input type="checkbox"/> 3-4 hrs. <input type="checkbox"/> 4-5 hrs. <input type="checkbox"/> 5-6 hrs. <input type="checkbox"/> 6-8 hrs. <input type="checkbox"/> 8-10 hrs. <input type="checkbox"/> > 10 hrs.

Supplier: Article No:
 Article name:

Surgical Measures

Note: "anterior" / "posterior" refers to location of MEASURES in the spine, NOT to access!

Decompression <input type="checkbox"/> none <input type="checkbox"/> anterior } specify ... <input type="checkbox"/> posterior } <small>Location in spine, choose at least one!</small>	<input type="checkbox"/> discectomy <input type="checkbox"/> vertebrectomy partial <input type="checkbox"/> vertebrectomy full <input type="checkbox"/> other <input type="checkbox"/> osteotomy <input type="checkbox"/> laminotomy <input type="checkbox"/> hemi-laminectomy	<input type="checkbox"/> laminectomy <input type="checkbox"/> facet joint resection partial <input type="checkbox"/> facet joint resection full <input type="checkbox"/> flavectomy <input type="checkbox"/> foraminotomy <input type="checkbox"/> sequestrectomy
Fusion <input type="checkbox"/> none <input type="checkbox"/> anterior } specify ... <input type="checkbox"/> posterior } <small>Location in spine, choose at least one!</small>	<input type="checkbox"/> interbody fusion between adjct. vertebrae (ant. appr.) <input type="checkbox"/> interbody fusion between adjct. vertebrae (post. appr.) <input type="checkbox"/> interbody fusion between dist. vertebrae (ant. appr.) <input type="checkbox"/> interbody fusion between dist. vertebrae (post. appr.)	Fusion material <input type="checkbox"/> none <input type="checkbox"/> autol. bone <input type="checkbox"/> allog. bone <input type="checkbox"/> bone subst. <input type="checkbox"/> cement <input type="checkbox"/> other
Stabilization rigid <input type="checkbox"/> none <input type="checkbox"/> anterior } specify ... <input type="checkbox"/> posterior } <small>Location in spine, choose at least one!</small>	<input type="checkbox"/> interbody stabil. with cage (ant. approach) <input type="checkbox"/> interbody stabil. with cage (post. approach) <input type="checkbox"/> vertebral body replacement by cage <input type="checkbox"/> plates <input type="checkbox"/> pedicle screws with rod	<input type="checkbox"/> pedicle screws with plate <input type="checkbox"/> facet screws <input type="checkbox"/> transarticular screw <input type="checkbox"/> laminar hooks with rod <input type="checkbox"/> pedicle hooks with rod <input type="checkbox"/> lateral mass screw with rod <input type="checkbox"/> lateral screw with plate <input type="checkbox"/> odontoid screws <input type="checkbox"/> other
Stabil. motion preserving <input type="checkbox"/> none <input type="checkbox"/> anterior } specify ... <input type="checkbox"/> posterior } <small>Location in spine, choose at least one!</small>	<input type="checkbox"/> disc replacement <input type="checkbox"/> dynamic stabilizat. <input type="checkbox"/> other Percutan. measures <input type="checkbox"/> none <input type="checkbox"/> disc post. } specify ... <small>Choose one!</small>	<input type="checkbox"/> facet block <input type="checkbox"/> root block <input type="checkbox"/> discography <input type="checkbox"/> vertebroplasty <input type="checkbox"/> kyphoplasty <input type="checkbox"/> other

Other surgical measures
 no
 yes } specify ...
Choose one!

Surgical notes

Discharge

Day (1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12) (13) (14) (15) (16) (17) (18) (19) (20) (21) (22) (23) (24) (25) (26) (27) (28) (29) (30) (31)
 Month (1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12) Year 00 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16

(Answer "none" in both "Surgical" and "General complications" excludes all remaining questions.)

Surgical complications <input type="checkbox"/> none <input type="checkbox"/> wrong level <input type="checkbox"/> nerve root damage <input type="checkbox"/> cauda equina damage <input type="checkbox"/> spinal cord damage <input type="checkbox"/> bleeding in spinal canal <input type="checkbox"/> bleeding outside spinal canal <input type="checkbox"/> malposition of implant <input type="checkbox"/> dural lesion <input type="checkbox"/> wound infection <input type="checkbox"/> implant failure <input type="checkbox"/> other	General complications <input type="checkbox"/> none <input type="checkbox"/> anaesthesiological <input type="checkbox"/> cardiovascular <input type="checkbox"/> pulmonary <input type="checkbox"/> cerebral <input type="checkbox"/> kidney/urinary <input type="checkbox"/> liver/GI <input type="checkbox"/> death <input type="checkbox"/> other
Measures taken <input type="checkbox"/> none <input type="checkbox"/> intervention during surgery <input type="checkbox"/> re-intervention after surgery <input type="checkbox"/> conservative medical <input type="checkbox"/> conservative functional <input type="checkbox"/> extended hospital stay <input type="checkbox"/> other	Surgical intervention/re-intervention <input type="checkbox"/> none <input type="checkbox"/> hematoma evacuation <input type="checkbox"/> abscess drainage <input type="checkbox"/> metal removal <input type="checkbox"/> re-implantation <input type="checkbox"/> refusion <input type="checkbox"/> suture <input type="checkbox"/> other

Comments regarding discharge

Status of Complications
 Surgical resolved improved persisting
 General resolved improved persisting

Abbreviations:
 MISS = Minimally Invasive Spine Surgery; LISS = Less Invasive Spine Surgery; CASS = Computer-Assisted Spine Surgery

12

COMI (low back)

patient based assessment, front side

Spine Tango COMI Patient self-assessment



Low Back 2008

Directions

- Use a #2 soft pencil for marking.
- Only one answer per question allowed
- Completely fill in boxes to record answers.
- Mandatory informations

Internal Use Only
Not read by scanner

Last name		First name		Gender
Street			M.R.N.	
Country Code	Zip Code	City		
Occupation	Birthdate (DD.MM.YYYY)		Telephone	

Examination interval

- | | | | |
|---|-----------------------------------|---|----------------------|
| <input type="checkbox"/> before surgery | <input type="checkbox"/> 3 months | <input type="checkbox"/> 2 years | |
| <input type="checkbox"/> 4 weeks | <input type="checkbox"/> 6 months | <input type="checkbox"/> 3 years | |
| <input type="checkbox"/> 6 weeks | <input type="checkbox"/> 9 months | <input type="checkbox"/> 4 years | e.g. 4 months |
| <input type="checkbox"/> 2 months | <input type="checkbox"/> 1 year | <input type="checkbox"/> 5 years | = 4 months/12 months |
| | | <input type="checkbox"/> other: years | = 0.33 year |

Back problems can lead to back pain and/or pain in the legs/buttocks, as well as to sensory disturbances such as tingling, 'pins and needles' or numbness in any of these regions.

1 Which of the following problems troubles you **the most**? Please tick **ONE BOX only**.

- back pain
- leg/buttock pain
- sensory disturbances in the back/leg/buttocks, e.g. tingling, 'pins and needles', numbness
- none of the above

2 For the following 2 questions (2a and 2b) we would like you to indicate the severity of your pain, by ticking the appropriate box (where "0" = no pain, "10" = worst pain you can imagine). There are separate questions for **back pain** and for **leg pain (sciatica)/buttock pain**.

2a How severe was your **back pain** in the last week?

no pain 0 1 2 3 4 5 6 7 8 9 10 **worst pain that I can imagine**

2b How severe was your **leg pain (sciatica)/buttock pain** in the last week?

no pain 0 1 2 3 4 5 6 7 8 9 10 **worst pain that I can imagine**

3 During the **past week**, how much did your back problem **interfere with your normal work** (including both work outside the home and housework)?

- not at all
- a little bit
- moderately
- quite a bit
- extremely

4 If you had to spend **the rest of your life with the symptoms you have right now**, how would you feel about it?

- very satisfied
- somewhat satisfied
- neither satisfied nor dissatisfied
- somewhat dissatisfied
- very dissatisfied

5 Please reflect **on the last week**. How would you rate your quality of life?

- very good
- good
- moderate
- bad
- very bad

Please go to the next page...

COMI (low back)
patient based assessment, back side

Spine Tango COMI

**Patient self-assessment
Low back**

page 2 of 2

6 During the past 4 weeks, how many days did you cut down on the things you usually do (work, housework, school, recreational activities) because of your back problem?

- none
- between 1 and 7 days
- between 8 and 14 days
- between 15 and 21 days
- more than 22 days

7 During the past 4 weeks, how many days did your back problem keep you from going to work (job, school, housework)?

- none
- between 1 and 7 days
- between 8 and 14 days
- between 15 and 21 days
- more than 22 days

Answer the following questions only if you are completing this questionnaire AFTER the operation

8a Did any complications arise as a consequence of your operation in our hospital (e.g. problems with wound healing, paralysis, sensory disturbances)?

- no
- yes → please describe these:

8b How bothersome were these complications?

- not at all bothersome
- slightly bothersome
- moderately bothersome
- very bothersome
- extremely bothersome

9 Since the operation in our hospital, have you had any further operation(s) on your lumbar spine (back) in our or in other hospitals?

- no
- yes, but at a different level of the spine.
- yes, at the same level of the spine (same segment)

10 Over the course of treatment for your back problem, how satisfied were you with your overall medical care in our hospital?

- very satisfied
- somewhat satisfied
- neither satisfied nor dissatisfied
- somewhat dissatisfied
- very dissatisfied

11 Overall, how much did the operation in our hospital help your back problem?

- helped a lot
- helped
- helped only little
- didn't help
- made things worse

Date Day 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
 Month 1 2 3 4 5 6 7 8 9 10 11 12 Year 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19

Signature:

Follow-up physician based, single sided

SPINE TANGO



FOLLOW-UP 2006

Directions

- Use a #2 soft pencil for marking.
- Text answers must be entered with the web interface.
- All questions must be answered unless otherwise indicated.
- Completely fill in boxes to record answers.

Question types

- only 1 answer allowed multiple answers allowed
 mandatory information

Internal Use Only
Not read by scanner

Last name		First name		Gender	
Street			M.R.N.		
Country code	Zip code	City			
Occupation		Birthdate (DD.MM.YYYY)		Telephone	

Level of procedure

- | | | | | | |
|---|---|--|---|---------------------------------------|---------------------------------|
| <input type="checkbox"/> upper cervical | <input type="checkbox"/> cervicothoracic | <input type="checkbox"/> thoracic | <input type="checkbox"/> thoraco-lumbo-sacral | <input type="checkbox"/> lumbo-sacral | <input type="checkbox"/> coccyx |
| <input type="checkbox"/> mid lower cervical | <input type="checkbox"/> cervico-thoraco-lumbar | <input type="checkbox"/> thoracolumbar | <input type="checkbox"/> lumbar | <input type="checkbox"/> sacral | |

Follow-up

Day 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

Month 1 2 3 4 5 6 7 8 9 10 11 12 Year 00 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16

Follow up interval

- 6 weeks 1 year
 3 months 2 years
 6 months other (yrs.)
- (Ex. 4 months=0.33 yrs. (4/12))

Work status

- not at work since OP resumed work, different job housewife
 started partially, same job has been dismissed child/student
 fully reintegrated retired since OP other
- resumed work, but quit again retired before OP

Only comment on those goals/measures which were indicated for the "Goal of surgery" question on the "SURGERY" form.

Surgical goals/measures achieved

- none
 pain relief
 functional improvement
 neurological improvement
 cosmetic improvement
 diagnostic measures
 other

Surgical goals/measures partially achieved

- none
 pain relief
 functional improvement
 neurological improvement
 cosmetic improvement
 diagnostic measures
 other

Surgical goals/measures not achieved

- none
 pain relief
 functional improvement
 neurological improvement
 cosmetic improvement
 diagnostic measures
 other

Medication

- none steroids antibiotics
 NSAIDs antidepressives other
- opiates vitamin B complex

Overall outcome (examiner)

- not applicable good poor
 excellent fair

Rehabilitation

- none outpatient rehab / physio other
- home-based inpatient rehab / physio

Decision

- no further follow-up revision foreseen
 further follow-up other primary intervention foreseen

Comments regarding follow-up

Complications

Complications

- no (Answer "no" excludes all remaining questions.)
 yes

Time

- early, Op-day - 28 days postop
 sub-acute, 2 - 6 months
 late, > 6 months

Type

- | | | |
|--|--|---|
| <input type="checkbox"/> sensory disturbance | <input type="checkbox"/> liquor fistula | <input type="checkbox"/> malposition of implant |
| <input type="checkbox"/> motor disturbance | <input type="checkbox"/> superficial wound infection | <input type="checkbox"/> recurrence of symptoms |
| <input type="checkbox"/> sphincter disturbance | <input type="checkbox"/> deep subfascial wound infection | <input type="checkbox"/> graft complication |
| <input type="checkbox"/> non-union | <input type="checkbox"/> spondylitis | <input type="checkbox"/> sequelae anaesthesia |
| <input type="checkbox"/> implant failure | <input type="checkbox"/> discitis | <input type="checkbox"/> internal medicine |
| <input type="checkbox"/> instability | <input type="checkbox"/> wrong segment | <input type="checkbox"/> other |

Therapeutic consequences

- none
 non-operative inpatient
 non-operative outpatient
 reintervention
 other

Individual consequences

- none
 increased pain
 prolonged impairment
 reduced social activities
 permanent impairment
 other

Examiner

Comments regarding complications

Conservative Therapy draft

front side

SPINE TANGO



CONSERVATIVE THERAPY

Directions

- Use a #2 soft pencil for marking.
- Text answers must be entered with the web interface.
- All questions must be answered unless otherwise indicated.
- Completely fill in boxes to record answers.

Question types

- only 1 answer allowed multiple answers allowed

Level of therapy

- upper cervical cervicothoracic thoracic thoraco-lumbo-sacral lumbo-sacral coccyx
 mid lower cervical cervico-thoraco-lumbar thoracolumbar lumbar sacral ISJ

ISJ = ilio sacral joint

Admission / Pathology

Date Day 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
 Month 1 2 3 4 5 6 7 8 9 10 11 12 Year 00 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16

Therapy outpatient inpatient

Main pathology

- functional disease
 structural disease
 functional & structural disease

Specification of structural disease

- degenerative disease inflammation
 deformity other
 spondylolistesis

Diagnosis validated with

- anamnesis
 clinical evaluation
 X-ray
 layer picture
 laboratory
 other

Specification of main pathology Only answer questions related to Main Pathology

FUNCTIONAL DISEASE

Type of functional disease

- articular blockade
 myosclerosis
 muscular hypot.
 muscular shortening
 muscular insufficiency
 malposition
 paralysis
 segmental instability
 segmental dysfunction
 whiplash
 hypermobility
 pseudoradicular syndrome
 cranial dysfunction
 visceral dysfunction
 other

STRUCTURAL DISEASE

Degenerative disease

- black disc discopathy
 segmental instability disc herniation

Type of deformity

- scoliosis
 kyphosis
 other

Predominant etiology

- idiopathic
 degenerative
 M. Scheuermann
 other

Spondylolistesis

Type of ...

- unknown
 Type I (congenital, dyspl.)
 Type II (isthmic)
 Type III (degenerative)
 Type IV (traumatic)
 Type V (pathologic)
 Type VI (postsurgical)

Grade of ...

- unknown
 Grade 0
 Grade I
 Grade II
 Grade III
 Grade IV
 Spondyloptosis (V)

Inflammation

- inflammatory arthritis spondylarthropathies
 infectious other

Duration of disease W = Weeks, M = Months

- < 6 W 4-6 M > 12 M
 6 W - 3 M 7-12 M

Number of previous spine operations for same pathology and spinal level(s)

- none 1 2 3 >3

Number of previous therapy sessions during the last 12 months according to patient information

- unknown 10 - 18
 none 19 - 27
 1 - 9 > 27

Other

- chron. pain disease CRPS (M. Sudeck) radicular syndrome
 fibromyalgia muscular disease other
 soft tissue lesion, neck neuromuscular disease

Medication at admission

- none sleep promoting drugs
 NSAID SSRI
 other analgetics tricyclic antidepressants
 weak opioide anxiolytics
 strong opioide anticonvulsants
 muscle relaxants neuroleptics

Flags*

- unknown
 red
 yellow
 orange
 blue
 black

WHO Scheme

- Level 1 Level 2 Level 3

Comments regarding main pathology

Therapy

Beginning of therapy

Date Day 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
 Month 1 2 3 4 5 6 7 8 9 10 11 12 Year 00 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16

Therapist credentials

- orthopedic surgeon osteopathic phys.
 neurosurgeon physiotherapist
 rheumatologist ergotherapist
 physical doctor pain therapist
 chiropractician other

Goals of functional therapy

- none functional improvement diagno. measures
 pain relief neurological improvement other

Goals of structural therapy

- none functional improvement diagno. measures
 pain relief neurological improvement other

*Flags Red: Biomedical Factors; serious spinal pathology
 Yellow: Psychosocial or behavioral factors
 Orange: Abnormal psychological processes

Blue: Socioeconomic/work factors
 Black: Occupational and societal factors

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 07.04.2009

Conservative therapy draft back side

SPINE TANGO

CONSERVATIVE THERAPY

Page 2 of 2

Therapeutic Measures

Invasive pain therapy
 no
 yes *specify* →

<input type="checkbox"/> facet block	<input type="checkbox"/> medullary stimulation	<input type="checkbox"/> cryodeneration of facets
<input type="checkbox"/> root block	<input type="checkbox"/> IDET	<input type="checkbox"/> alcohol denervat. of facets
<input type="checkbox"/> epidural infiltration	<input type="checkbox"/> IRT	<input type="checkbox"/> neural therapy
<input type="checkbox"/> epidural catheter	<input type="checkbox"/> radiofrequency therapy	<input type="checkbox"/> acupuncture
<input type="checkbox"/> pain pump		<input type="checkbox"/> ISJ infiltration <input type="checkbox"/> other

Pain medication
 none
 Current medication...
 continued
 discontinued
 added/modified *spec.* →

<input type="checkbox"/> NSAID	<input type="checkbox"/> muscle relaxants	<input type="checkbox"/> anxiolytics
<input type="checkbox"/> other analgetics	<input type="checkbox"/> sleep promoting drugs	<input type="checkbox"/> anticonvulsants
<input type="checkbox"/> weak opioide	<input type="checkbox"/> SSRI	<input type="checkbox"/> neuroleptics
<input type="checkbox"/> strong opioide	<input type="checkbox"/> tricyclic antidepressants	

Physiotherapy
 no
 yes *specify* →

<input type="checkbox"/> strength training	<input type="checkbox"/> endurance training	<input type="checkbox"/> stabilisation training
<input type="checkbox"/> therapy for scoliosis	<input type="checkbox"/> neurorehabilitation	<input type="checkbox"/> other

Manual therapy
 no
 yes *specify* →

<input type="checkbox"/> mobilisation	<input type="checkbox"/> stretches	<input type="checkbox"/> trigger point treatment
<input type="checkbox"/> manipulation	<input type="checkbox"/> neuromeningeal mobil.	<input type="checkbox"/> craniosacral techniques
<input type="checkbox"/> techniques for soft tissues	<input type="checkbox"/> visceral techniques	<input type="checkbox"/> massage
		<input type="checkbox"/> other

Physical modalities
 no
 yes *specify* →

<input type="checkbox"/> interference power	<input type="checkbox"/> shockwave therapy	<input type="checkbox"/> lumbar orthosis
<input type="checkbox"/> thermo therapy	<input type="checkbox"/> TENS	<input type="checkbox"/> laser therapy
<input type="checkbox"/> diathermy	<input type="checkbox"/> ultrasound	<input type="checkbox"/> other

Group programmes
 no
 yes *specify* →

<input type="checkbox"/> back training program	<input type="checkbox"/> pain management	<input type="checkbox"/> MTT group programmes
<input type="checkbox"/> cognitive behavioural therapy	<input type="checkbox"/> ADL (activities of daily living)	<input type="checkbox"/> other

Psychological intervention
 no
 yes *specify* →

<input type="checkbox"/> cognitive behaviour therapy	<input type="checkbox"/> relaxation therapy	<input type="checkbox"/> other
<input type="checkbox"/> psychotherapy	<input type="checkbox"/> coping strategies	

Occupational medicine measures
 no
 yes *specify* →

<input type="checkbox"/> ergonomic measures	<input type="checkbox"/> work reintegration	<input type="checkbox"/> work hardening
<input type="checkbox"/> occupational retraining		<input type="checkbox"/> other

Other therapeutic measures
 no
 yes *specify* →

Therapist's notes

End of therapy

Date of end of therapy
 Day C 1) C 2) C 3) C 4) C 5) C 6) C 7) C 8) C 9) C 10) C 11) C 12) C 13) C 14) C 15) C 16) C 17) C 18) C 19) C 20) C 21) C 22) C 23) C 24) C 25) C 26) C 27) C 28) C 29) C 30) C 31)
 Month C 1) C 2) C 3) C 4) C 5) C 6) C 7) C 8) C 9) C 10) C 11) C 12) Year 00) 01) 02) 03) 04) 05) 06) 07) 08) 09) C 10) C 11) C 12) C 13) C 14) C 15) C 16)

General complications *Answer "none" in "Therapeutic" and "General complications" excludes "Measures taken" and "Status of complications".*
 none yes

Therapeutic complications
 none
 nerve root damage
 cauda equina damage
 spinal cord damage
 bleeding in spinal canal
 bleeding outside spinal canal

Measures taken
 none
 cons. pharmacological
 conservative functional
 prolonged inpatient stay
 operative Intervention
 other

Status of complications
General resolved improved persisting
Therap. resolved improved persisting

Consultation
 rheumatology
 physical medicine
 orthopedy
 spine surgery
 other

Further scheduled measures
 none
 other conservative therapy
 surgical intervention

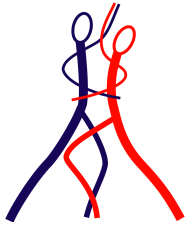
Achieved goals of therapy

	functional disease				structural disease			
	a	p	n		a	p	n	
pain relief	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
functional improvement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
neurological improvement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
diagnostic measures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*a = achieved
 p = partially achieved
 n = not achieved*

Comments regarding end of therapy

Therapist



EPITOME OF AVAILABLE DATA

Overview (Pool)

Data from the

Surgery form: demographic data, distribution and specification of diagnosis, different details related to main pathology, complications

Followup form: followup interval, overall outcome, achievement of surgical goals

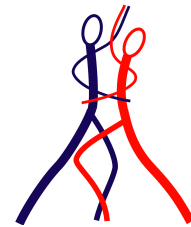
Short exemplary analysis on Total Disc Replacement (Pool):

Level of procedure,

Demographic data,

Type of degeneration,

VAS (COMI)



STATISTICS AND COMMENTS

A study of the weighting and frequency of statistical reports was published by Windish in JAMA in 2007 (6). This work comprises the study of 239 original articles in 6 journals (American Journal of Medicine, Annals of Internal Medicine, BMJ, JAMA, Lancet, New England Journal of Medicine) with regard to statistical evaluation. 91.6% of the articles included descriptive statistics and 50.2% were compiled from simple statistical methods. Multivariate analyses were used for 68.6% of the cases. All the above mentioned methodologies can be used in Spine Tango. The Spine Tango international pool offers over 30.000 eligible cases. The number of entries increases constantly. Below you will find a short summary of all the documented surgeries in Spine Tango followed by a detailed assessment of the patient subgroup with dynamic stabilization of the cervical and lumbar spine using disc arthroplasty.

19

6. Windish D, Huot SJ, Green ML (2007).
Medicine Residents' Understanding of the Biostatistics and Results in the Medical Literature;
JAMA. 2007;298(9):1010-1022.

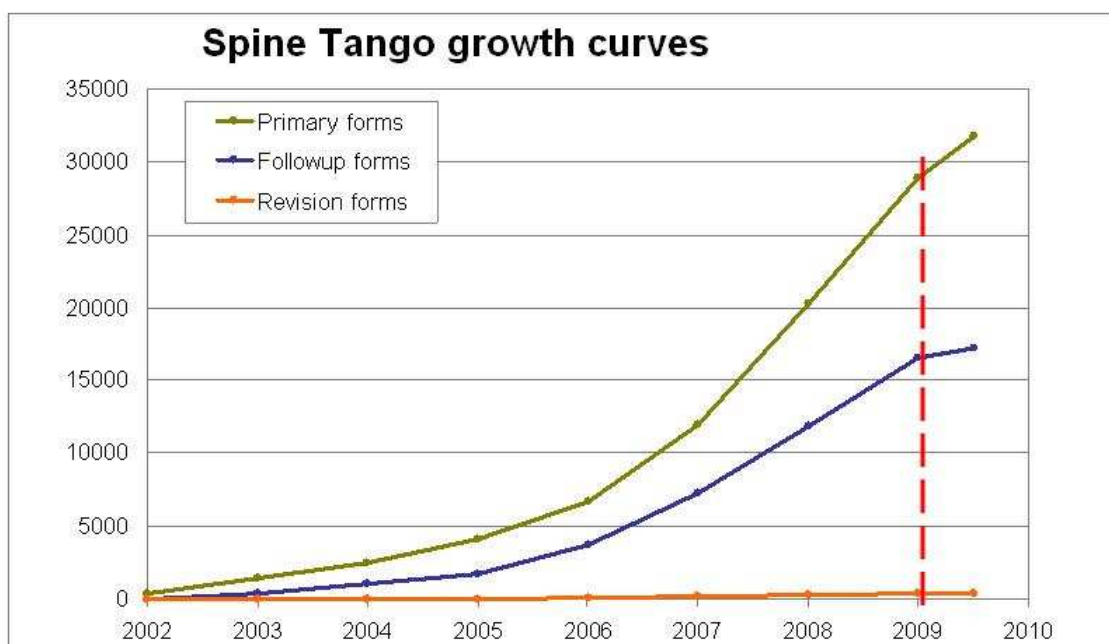


Fig 4: Growth curves of implemented forms (primary and revision surgery and followup) over the years.

Data from the surgery form
Demographic data - distribution of diagnosis

The following graphics are based on the international Spine Tango data pool using all submitted forms until the end of the year 2009. Only form versions 2005 and 2006 were considered. They added up to 24327 surgeries.

Distribution of age (at surgery)

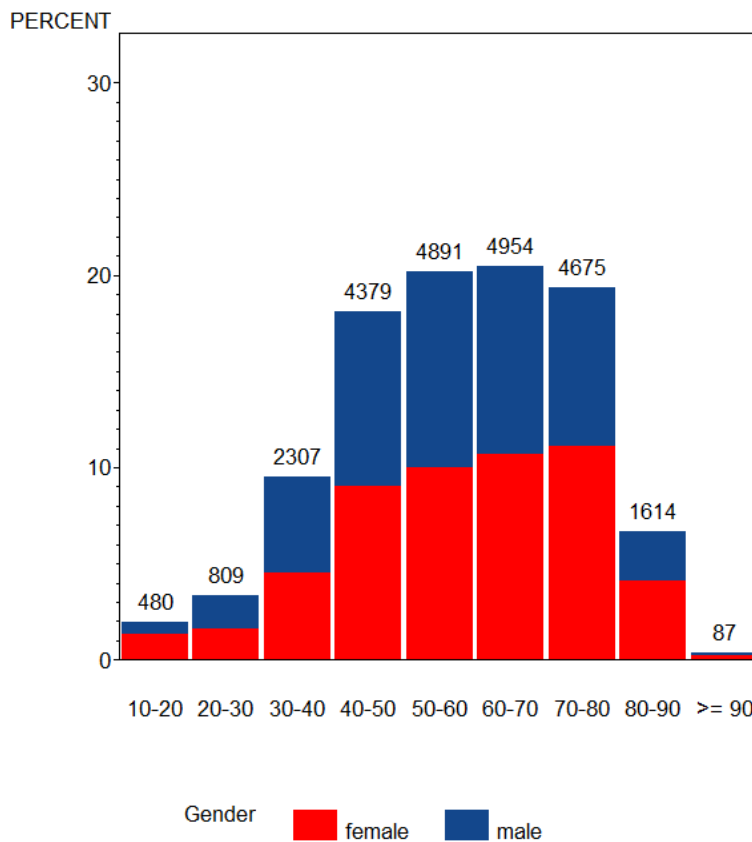


Fig 5: Demographic data - distribution of age and gender (surgery form)

Figure 5 shows that the majority of spinal interventions happen in the four life decades between an age of 40 and 80 years.

For females the majority of surgeries happen in patients aged 70-80 years. The male main group is between 50-60 years old (n= 2473) and makes up 21.3% of all surgeries in males.

Distribution of diagnosis

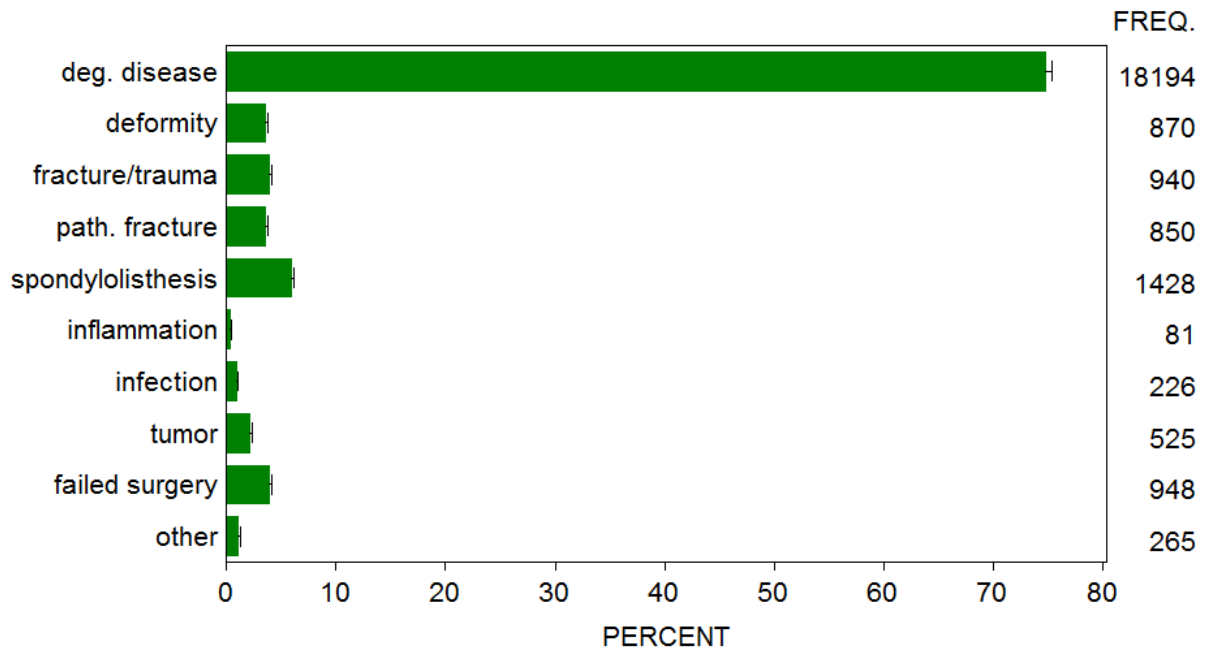


Fig 6: Distribution of diagnosis (surgery form)

Three quarters of all patients suffered from a degenerative disease as main pathology. The types of degenerative diseases with their distribution are shown below (Fig. 7). The most frequently checked fields were disc herniation, spinal stenosis and disc degeneration. Please note the multiple choice format of this question. There was an average of 1.4 answers per case.

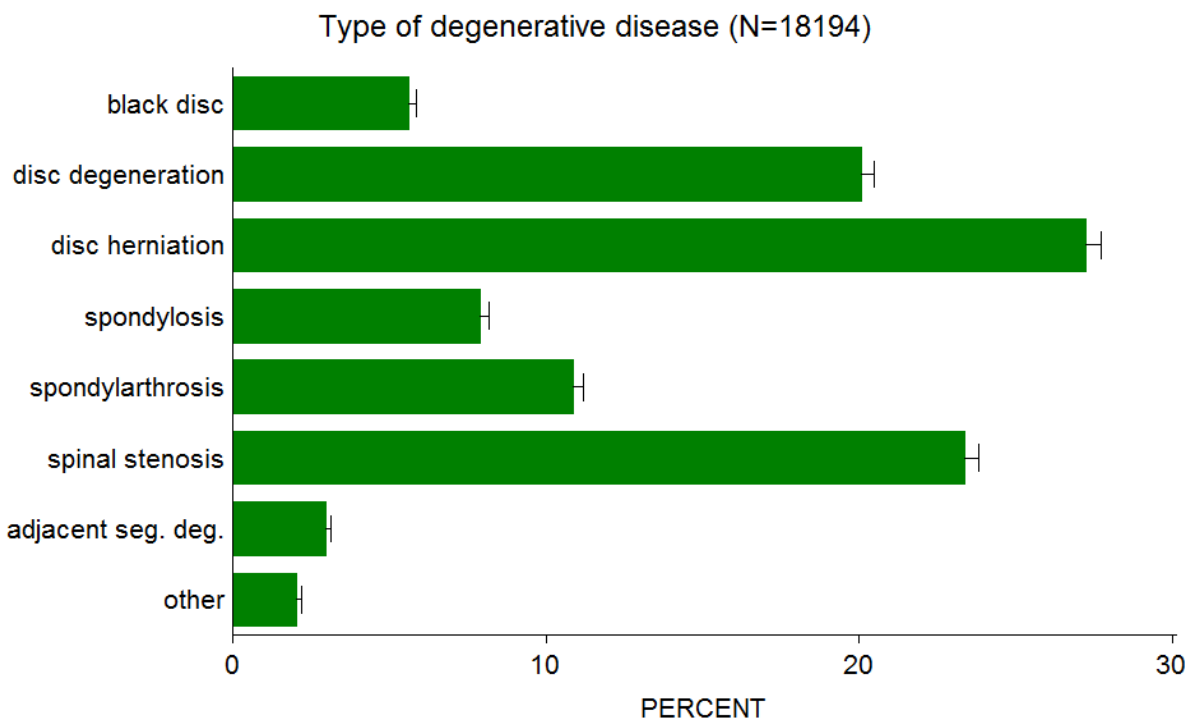


Fig 7: Type of degenerative disease (surgery form)

Different details related to the main pathology
(surgery form)

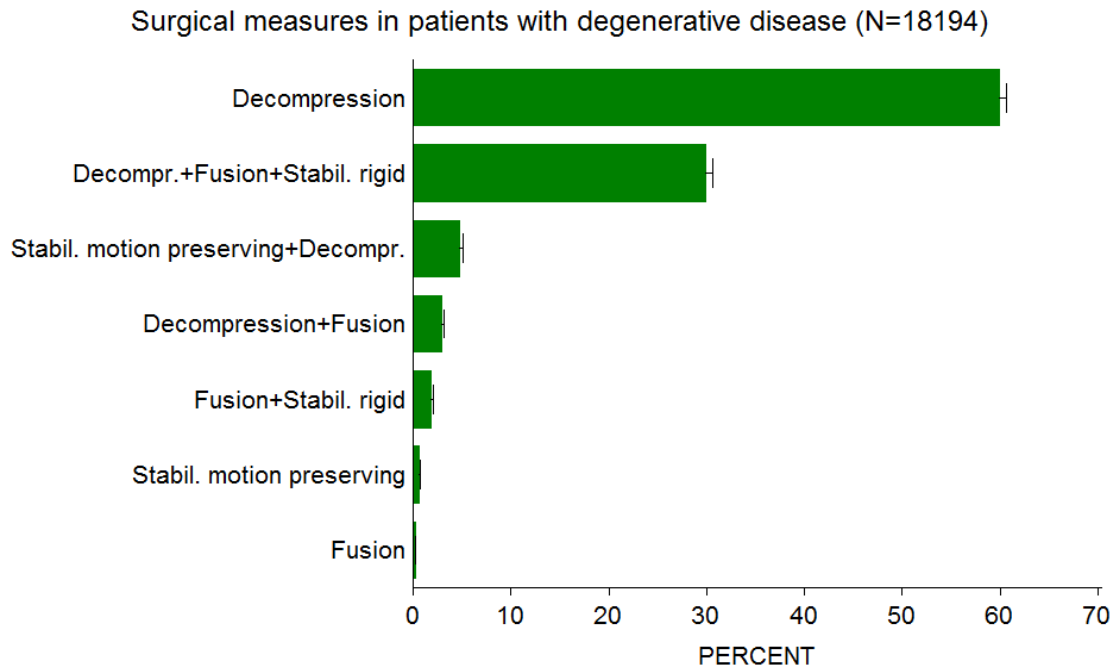


Fig 8: Surgical measures for degenerative disease (N=18194) (surgery form)

The most frequently performed surgical measure in patients with degenerative disease was the sole posterior decompression.

Of the 930 documented fractures in the surgery form, 56 were classified as C2 dens fractures (6%) (not shown).

The most frequent trauma were C3-L5/S1 fractures (N=805) with the distribution of the AO fracture types shown below (Fig. 9)

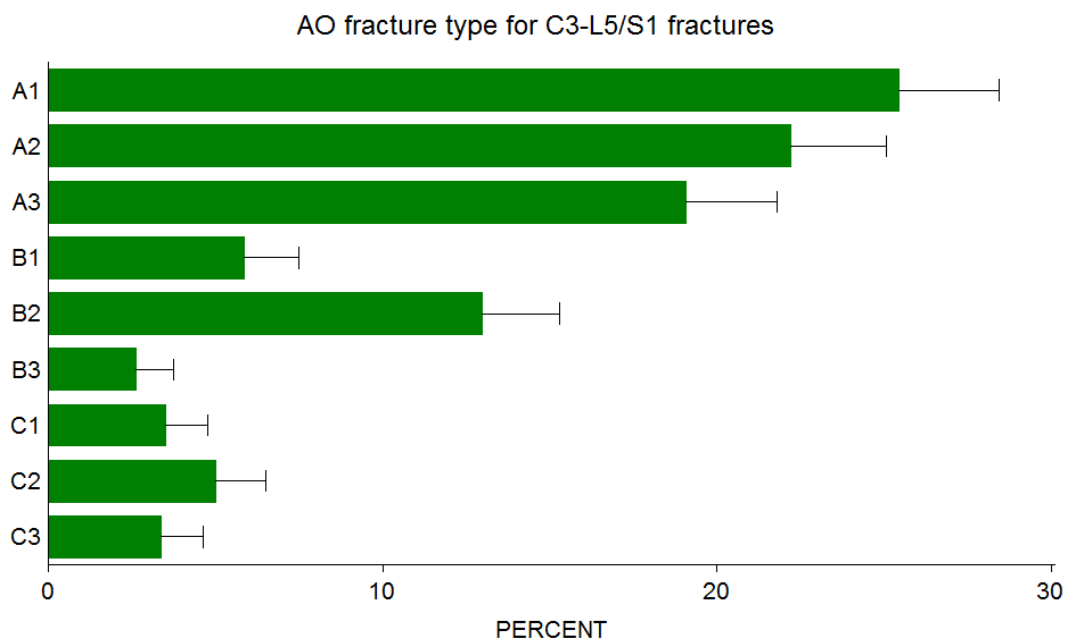


Fig 9: AO fracture types in patients with C3-L5/S1 fracture (N=805) (surgery form)

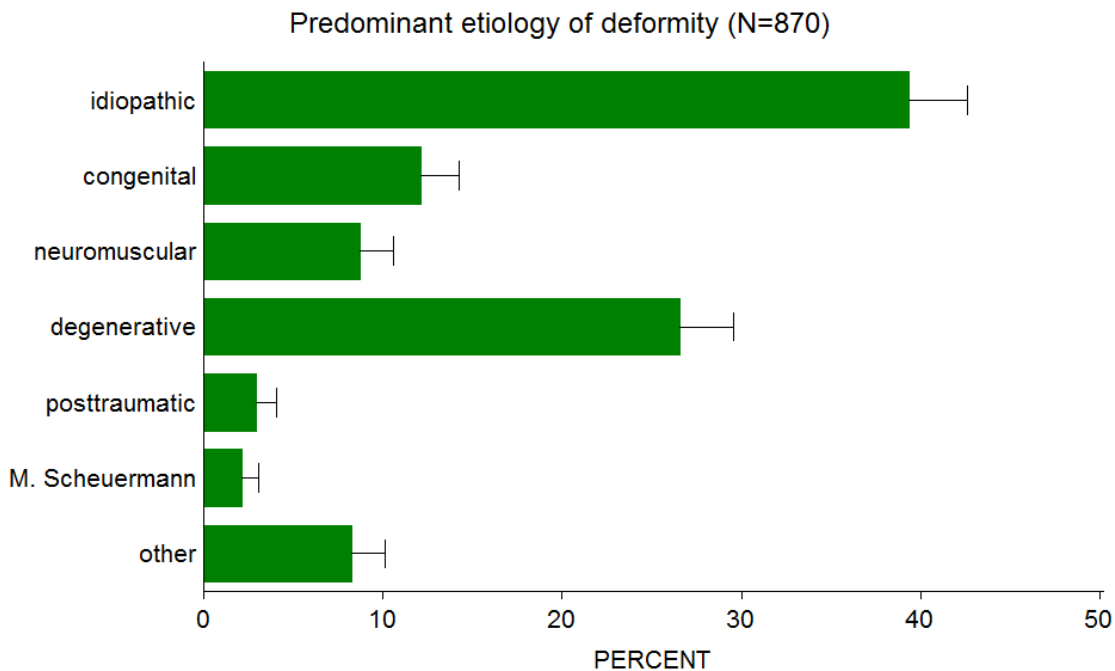


Fig 10: Predominant etiology of deformity (N=870) (surgery form)

There are 870 documented deformity cases in the database. The predominant etiology is shown in fig. 10 with idiopathic and degenerative etiologies as the most common ones.

Most of the spondylolisthesis cases have a degenerative etiology (n=811), followed by the isthmic type (n=464).

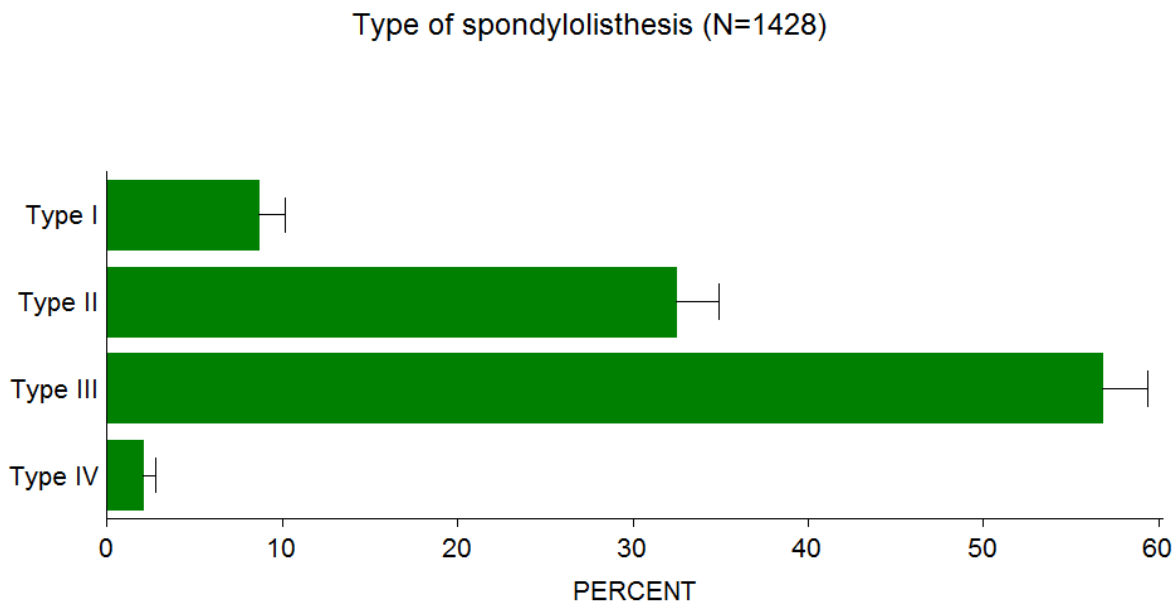


Fig 11: Type of spondylolisthesis (N=1428)(surgery form)

Tab 1: Classification of the various types of spondylolisthesis of Neugebauer & Newman, adapted by Wiltse et al.

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

Different details related to the main pathology
(surgery form)

Following we show the distribution of the spondylolisthesis grade for the three most frequent types (Fig 12-14). In Type I (congenital, dysplastic) spondylolisthesis Grade II dominates whereas in the degenerative spondylolisthesis cases Grade I is most frequent with over 60%.

Grade distribution of congenital, displastic spondylolisthesis (N=121)

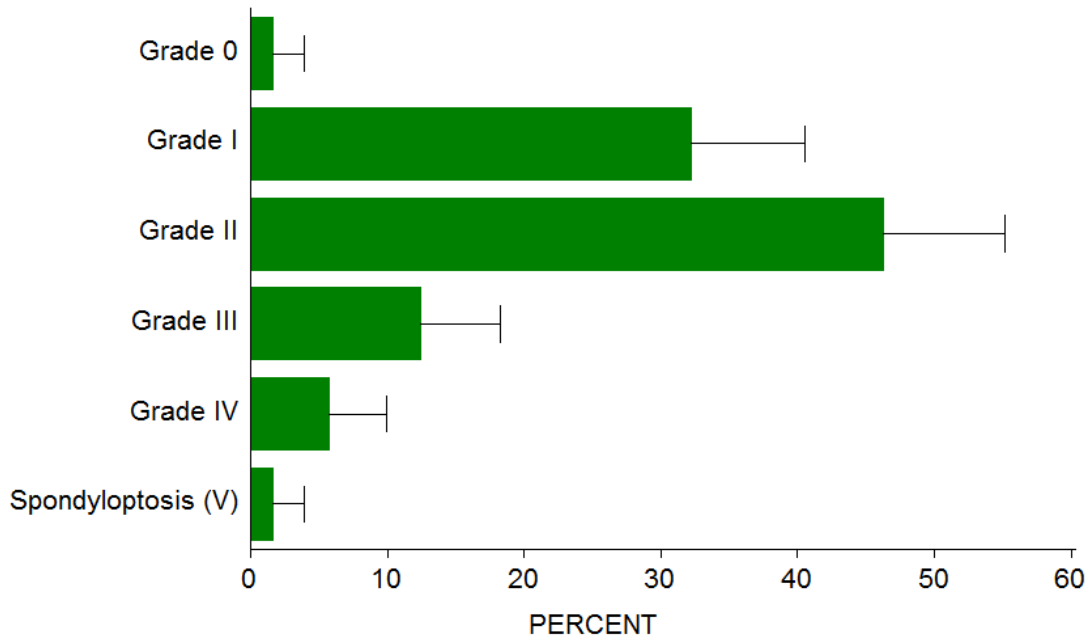


Fig 12: Grade of congenital spondylolisthesis (N=121) (surgery form)

Grade distribution of isthmic spondylolisthesis (N=453)

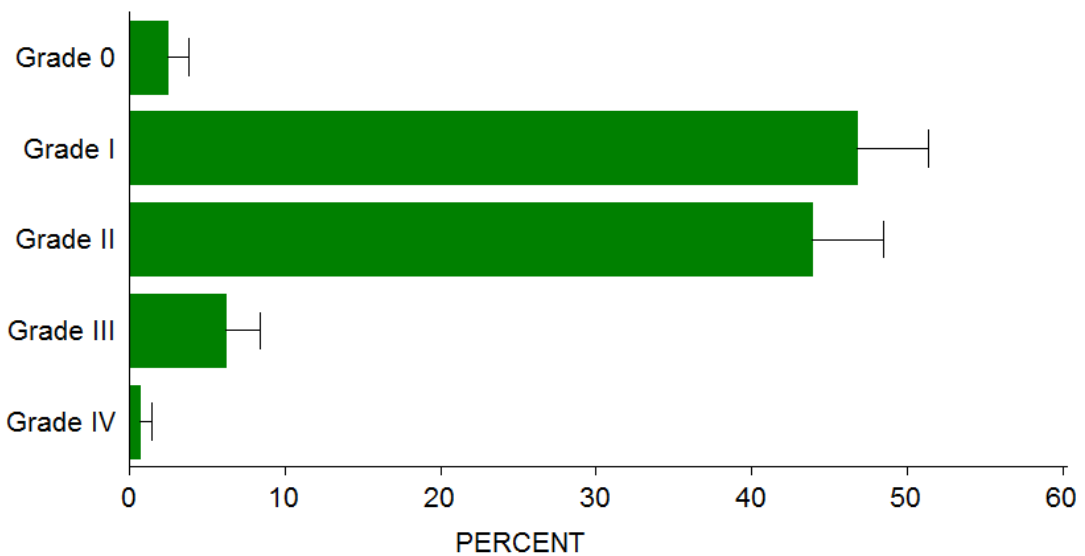
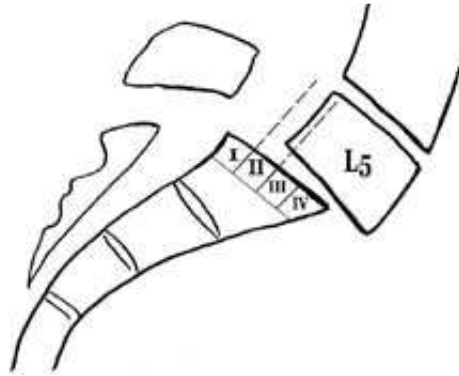


Fig 13: Grade of isthmic spondylolisthesis (N=453) (surgery form)

Tab. 2: Classification of spondylolisthesis according to Meyerding:

Grade 0	Lysis of pars without slip
Grade I	0-25% slip
Grade II	25-50% slip
Grade III	50-75% slip
Grade IV	> 75% slip
Grade V	spondyloptosis



Meyerding classification: now also shown in the new Spine Tango “Dictionary of Terms” on the Spine Tango web page.

Grade distribution of degenerative spondylolisthesis (N=786)

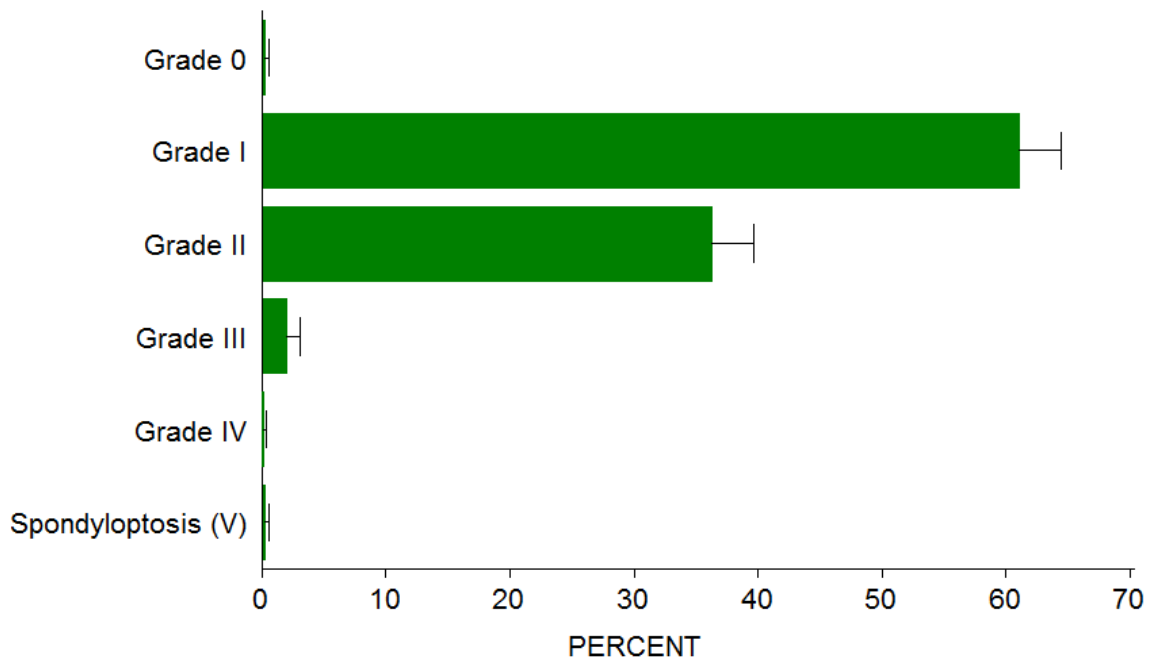


Fig 14: Grade of degenerative spondylolisthesis (N=786) (surgery form)

Different details related to the main pathology (surgery form)

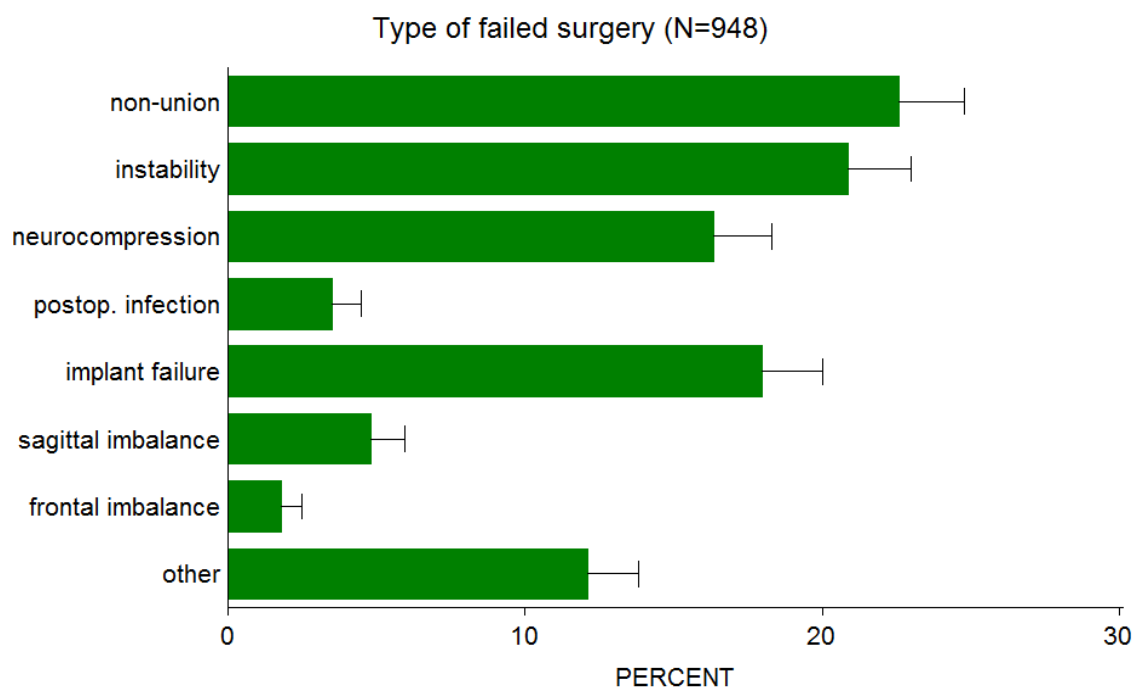


Fig 15: Type of failed surgery (N=948) (surgery form)

948 failed surgeries were documented in the database until the end of 2009. Since this is a multiple choice question the most frequent specifications were non-union (22.6%), instability (20.7%), implant failure (18.0%) and neurocompression (16.3%). Repeat surgeries for postoperative infections were documented in 49 patients (3.5%).

Type of inflammation (N=81)

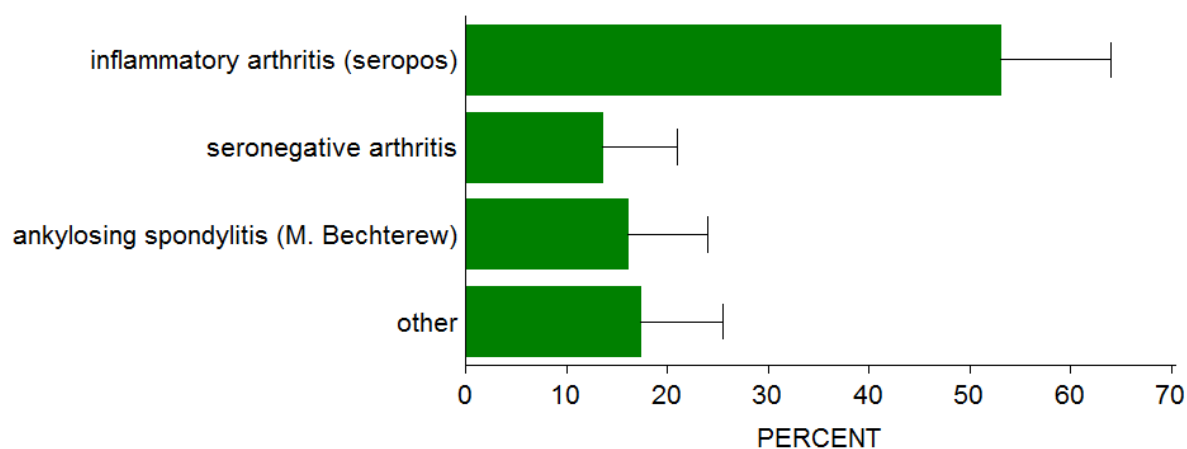


Fig 16: Type of inflammation/infection (N=81) (surgery form)

The most frequently affected structures with infection as main pathology are spondylodiscitis (71.7%). Discitis occurred in 10.05%, spondylitis in 18.3%.

Complications (surgery form)

Distribution of surgical complications (N=23928)

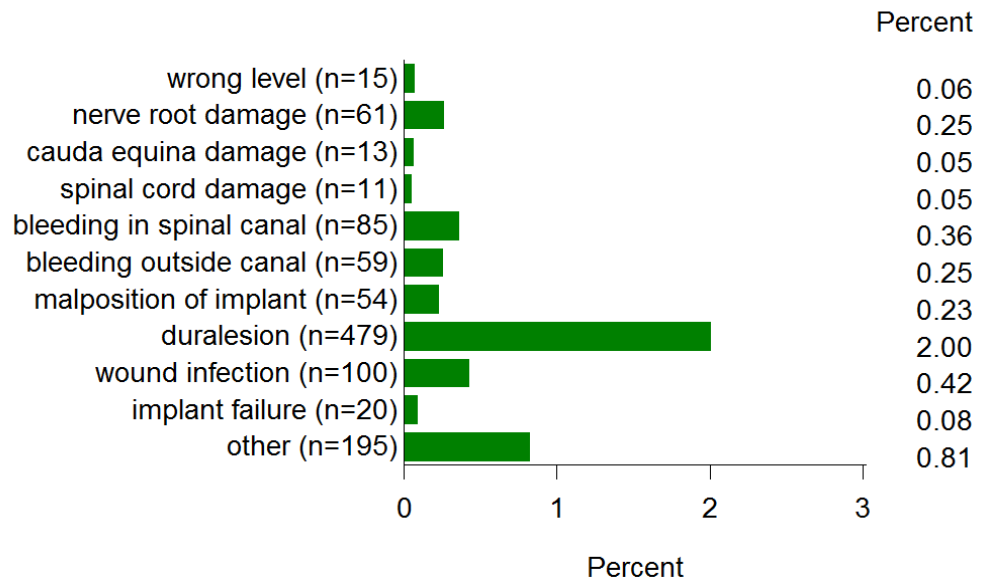


Fig17: Surgical complications (of 23928 patients), excluded was answer "none" (surgery form)

Figures 17 and 18 show the distribution of surgical and general complications, excluding the answer "none". 95.5% of the 23928 patients had no surgical complications, 97.2% (of 23472 patients) had no general complications. The most frequent surgical complication was a dura lesion with 2%.

Distribution of general complications (N=23472)

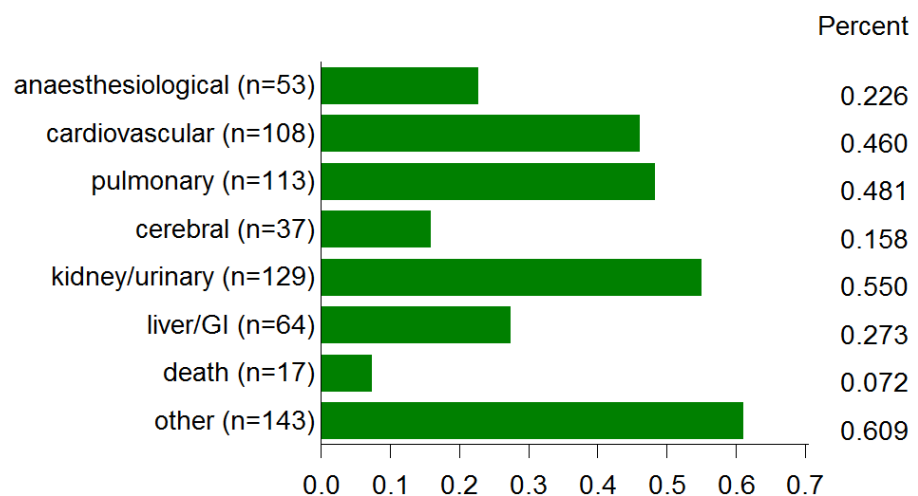


Fig 18: General complications (of 23472 patients , excluded was answer "none" (surgery form))

Data from the followup form
Distribution of followup interval / overall outcome

In figure 19 the distribution of the interval of 14943 followups is shown. 59.7 % of the follow ups were recorded 6 weeks or 3 months after surgery, only 19.6% at 1 year or later after surgery.

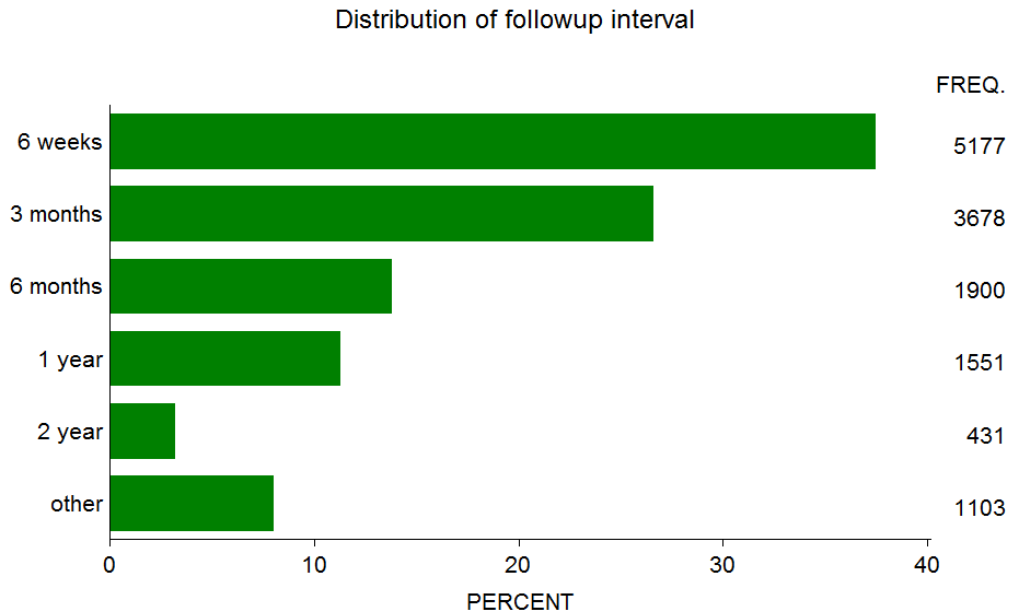


Fig 19: Distribution of followup interval (followup form)

The distribution of the overall outcome from the surgeon's point of view shows that the percentage of excellent results rises over time, at the expense of mainly good results. Fair results stay quite stable, whereas poor results slightly increase with longer followup intervals.

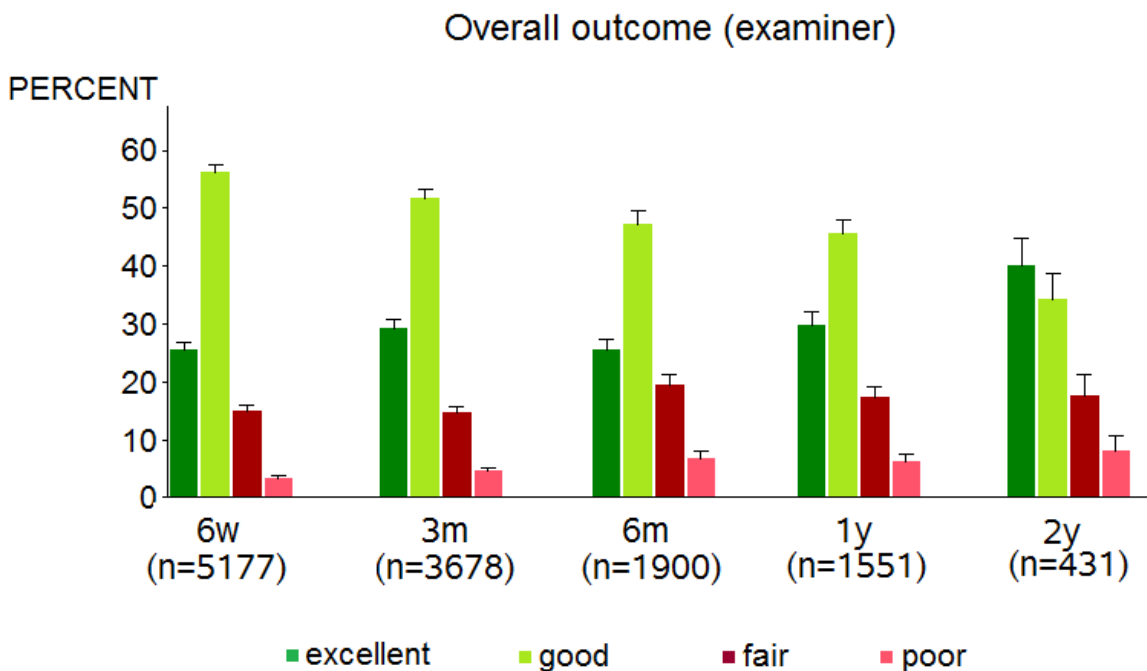


Fig 20: Overall outcome, examiner (followup form)

Achievement of surgical goals (followup form)

Surgical goals/measures achieved

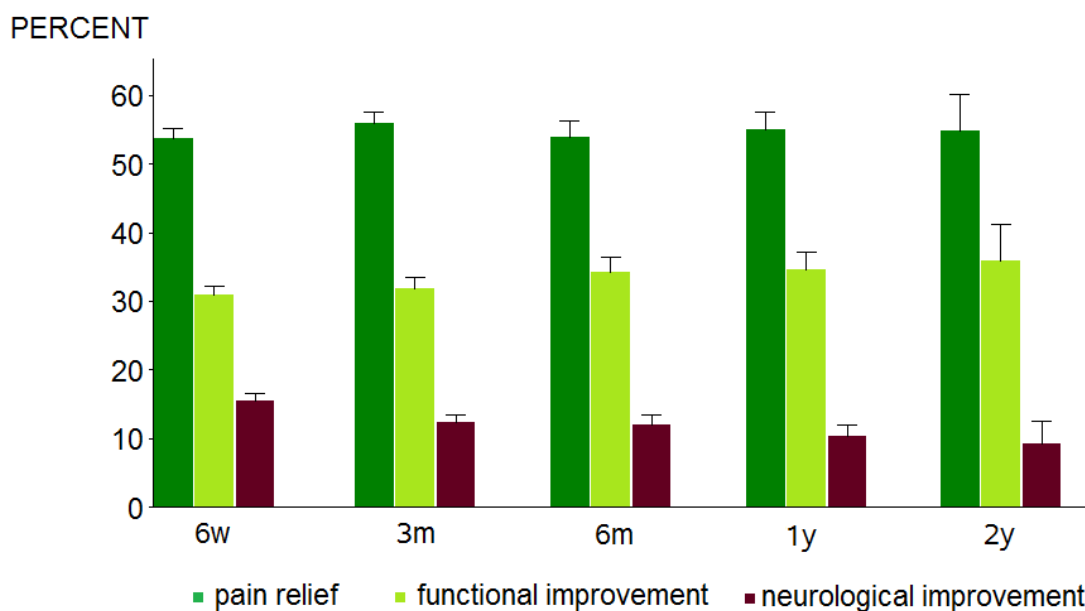


Fig 21: Surgical goals /measures achieved (followup form)

Figure 21 shows the distribution of achieved surgical goals/ measures from 13gg840 followups, stratified by followup interval. The first group of follow-ups is analysed without reference to the indicated surgical goals of the index surgery (figures 21-23), the second group with reference to the index surgery (figures 24-26).

Surgical goals/measures partially achieved

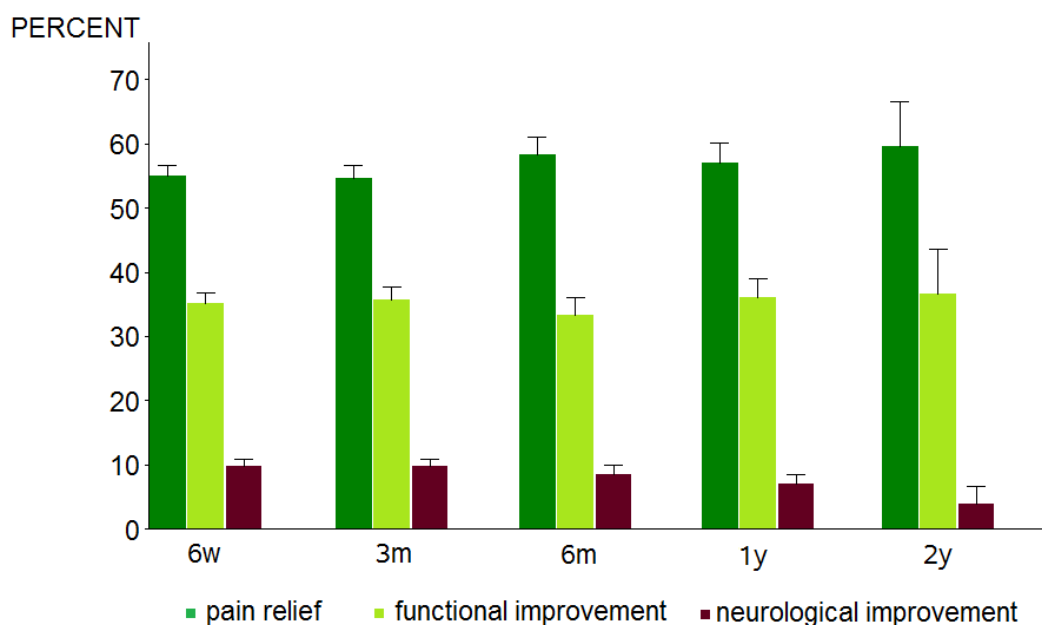


Fig 22: Surgical goals /measures partially achieved (followup form)

Achievement of surgical goals (followup form)

Surgical goals/measures not achieved

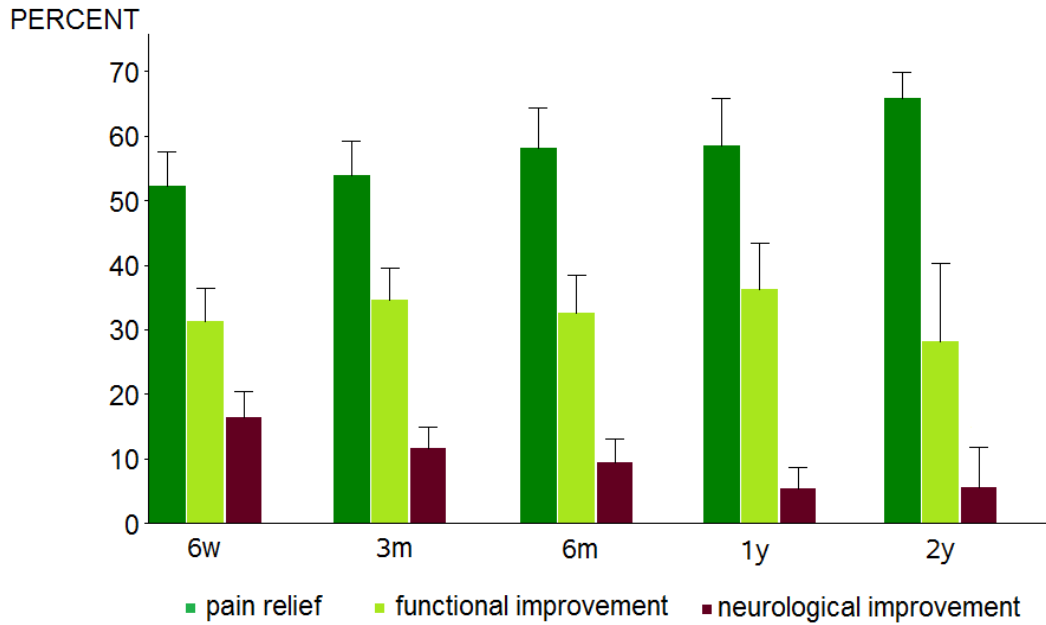


Fig 23: Surgical goals /measures not achieved (followup form)

Looking at non-achieved surgical goals, pain relief slightly decreases over time as the most prominent problem. In contrast, neurological problems seem to improve with delay in some cases since the early rates of non-achieved neurological problems are more than halvened after two years.

Goal of surgery: pain relief

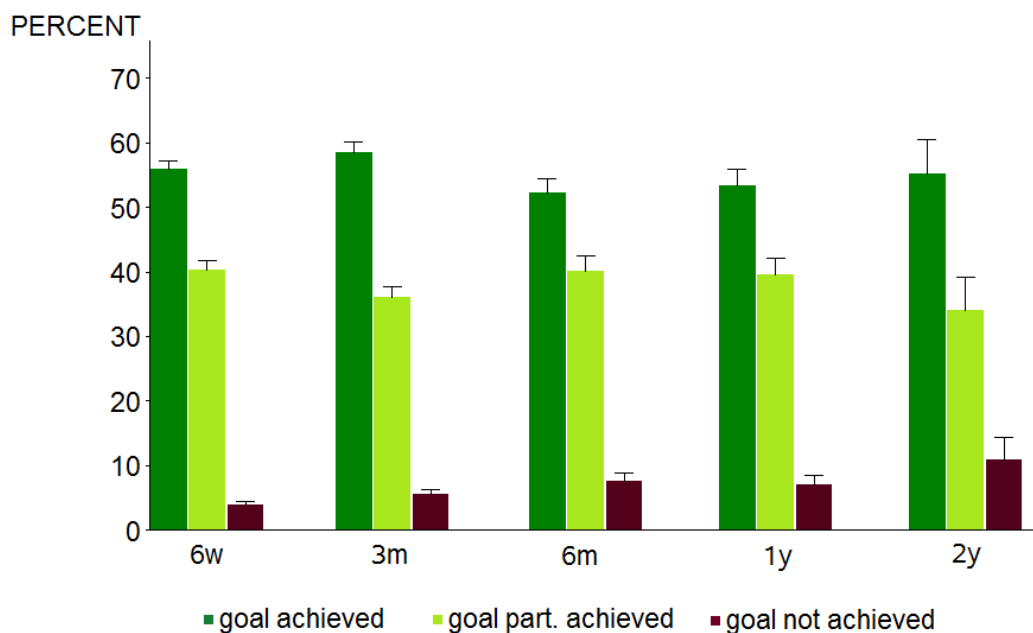


Fig 24: Goal of surgery: pain relief

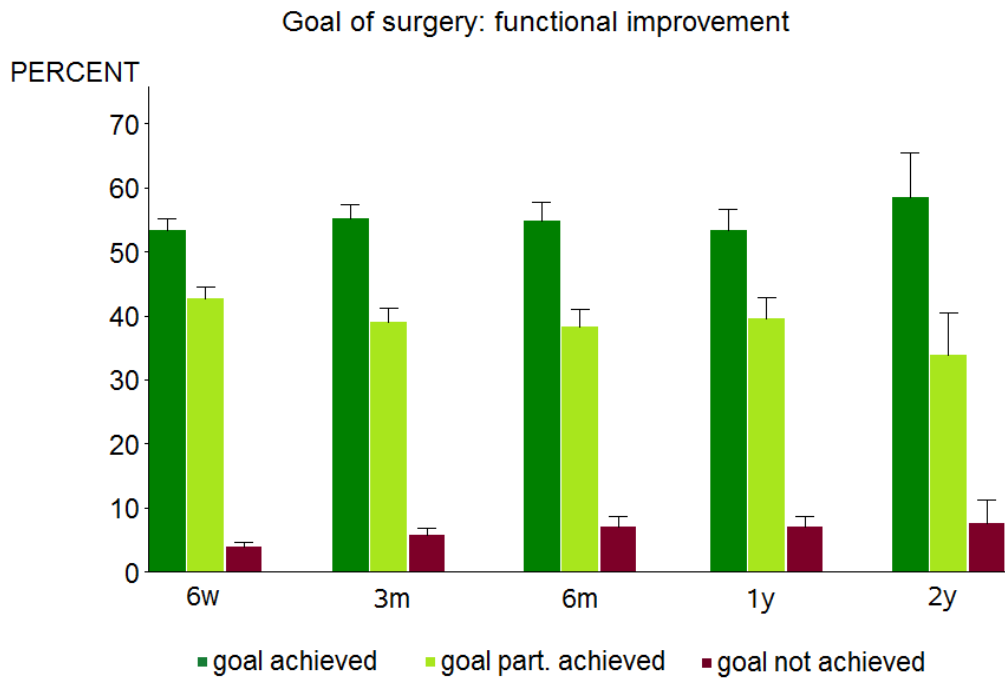


Fig 25: Goal of surgery: functional improvement

The evaluation of pain relief, functional improvement and neurological improvement as outcome in relation to the preoperatively determined goals shows a stable distribution over time for each parameter.

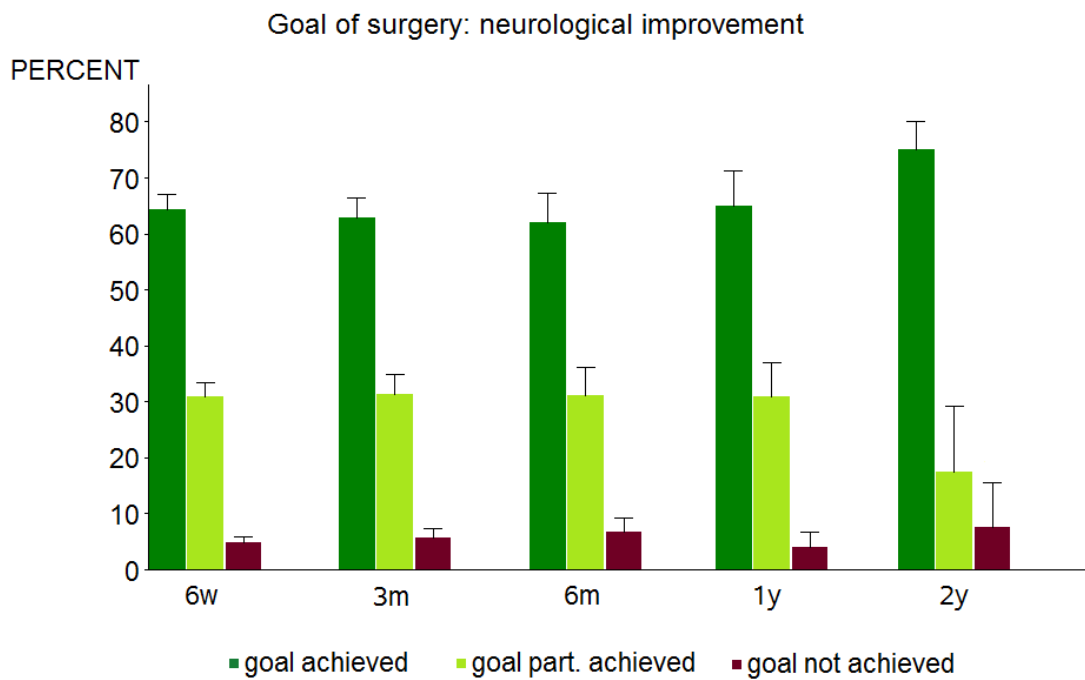


Fig 26: Goal of surgery: neurological improvement

An exemplary analysis of **Disc Replacement** using the Spine Tango data pool

In the management of discogenic back pain total disc replacement was introduced for preventing degenerative changes which occur in segments adjacent to fusions. It aims at maintaining segmental motion and eliminating pain (7). For achieving these goals the indications and contraindications have to be strictly respected.

By the end of 2009 we could identify 794 documented total disc replacements in the Spine Tango data pool. In the following part we show a short analysis of these interventions and some important outcome parameters.

As visible in figure 27 we stratified patients into two groups depending on the location of the operation. The cervical group (blue) counts 529 disc arthroplasties where nearly all (96.2%) are located in the mid-lower C-spine. The lumbar group (yellow) includes 265 disc arthroplasties with 44.5% located between L1-L5 and 54.0% in L5/S1.

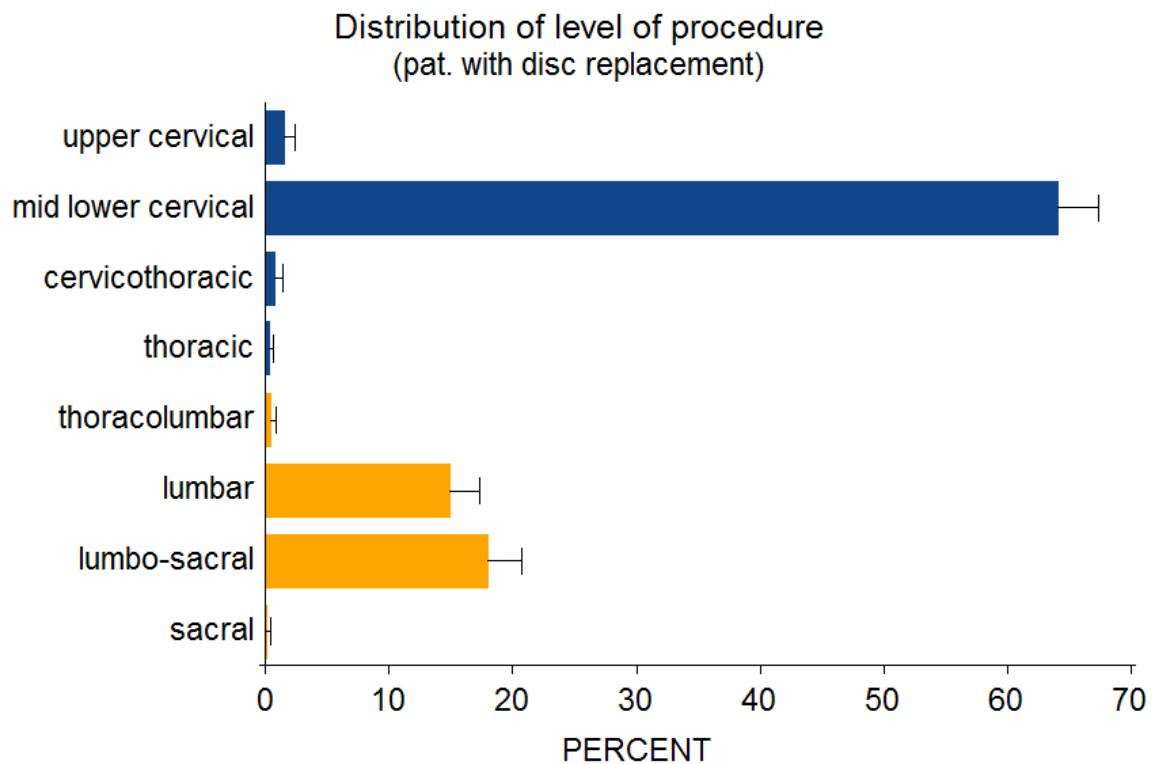


Fig. 27: Distribution of age (patients with disc replacement)

Demographic data (patients with Disc Replacement)

The age and gender distribution of the cervical and lumbar group is given in figures 28 and 29. The mean age for the patients with cervical disc arthroplasty is 47.7 years, for the lumbar disc arthroplasty 42.7 years. In the cervical group 53.7% of patients are female, in the lumbar group 47.2%.

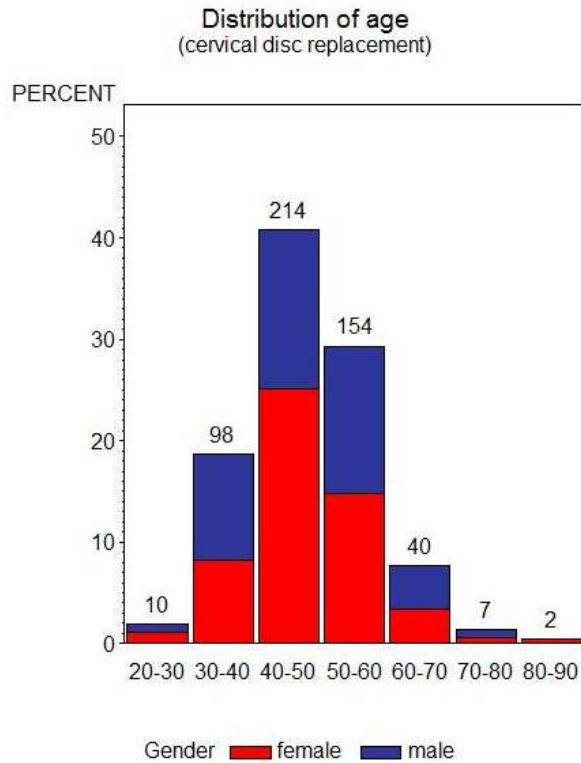


Fig. 28: Demographic data (patients with cervical disc replacement)

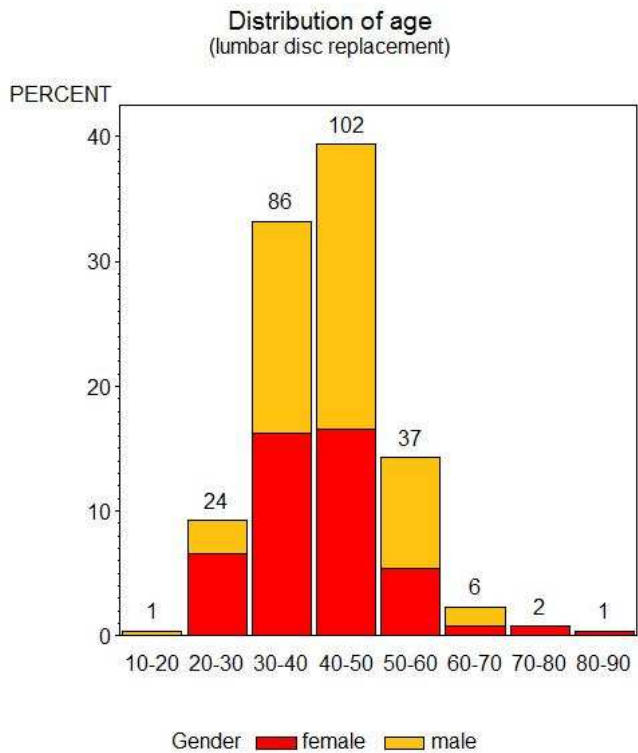


Fig. 29: Demographic data (patients with lumbar disc replacement)

Type of degeneration
(exemplary analysis for Disc Replacement)

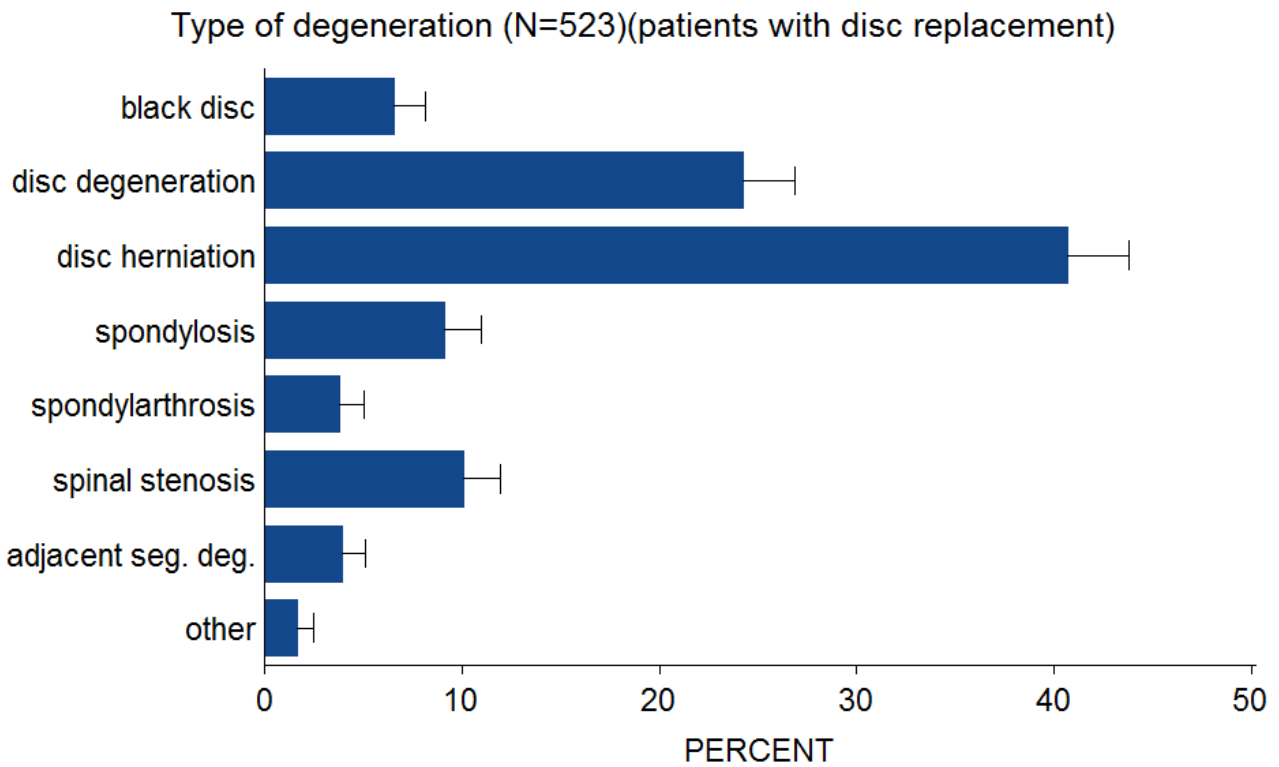


Fig. 30: Type of degeneration for patients with cervical disc replacement (N=523)

The specification of degenerative disease in patients with total disc replacement showed a predominance of disc herniation and disc degeneration in the cervical group (N=523).

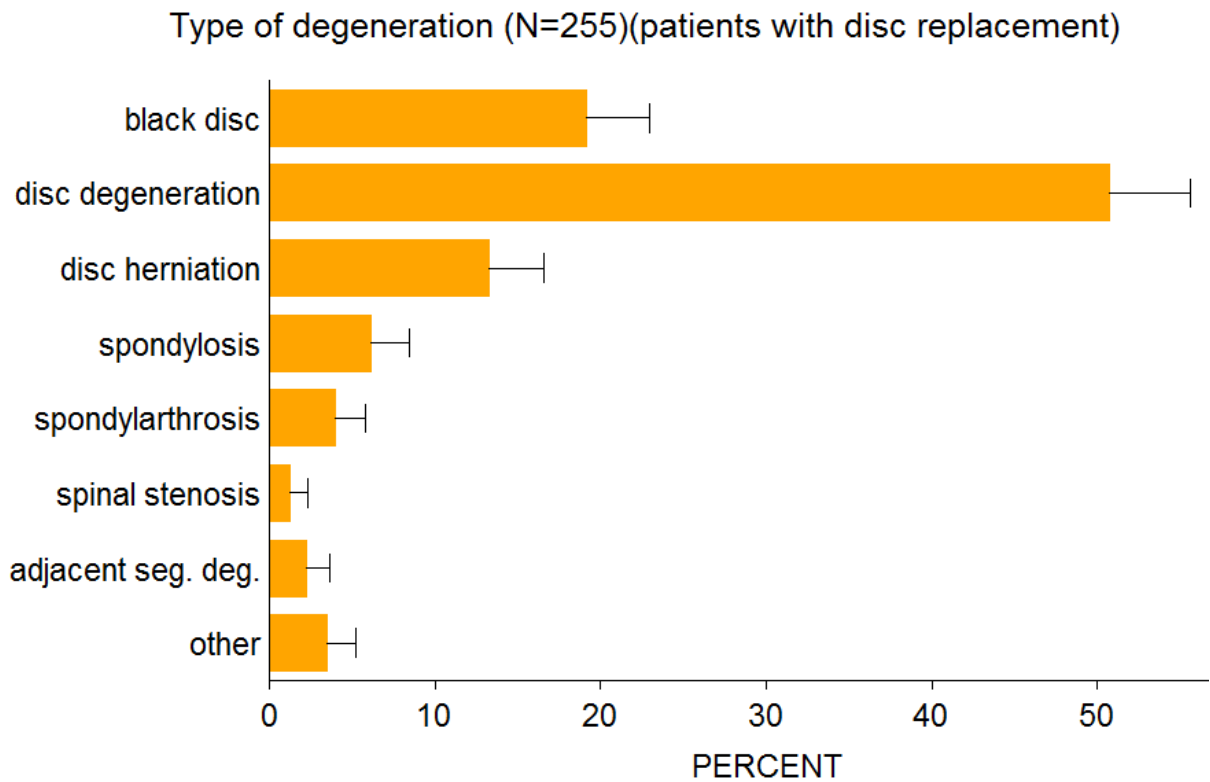
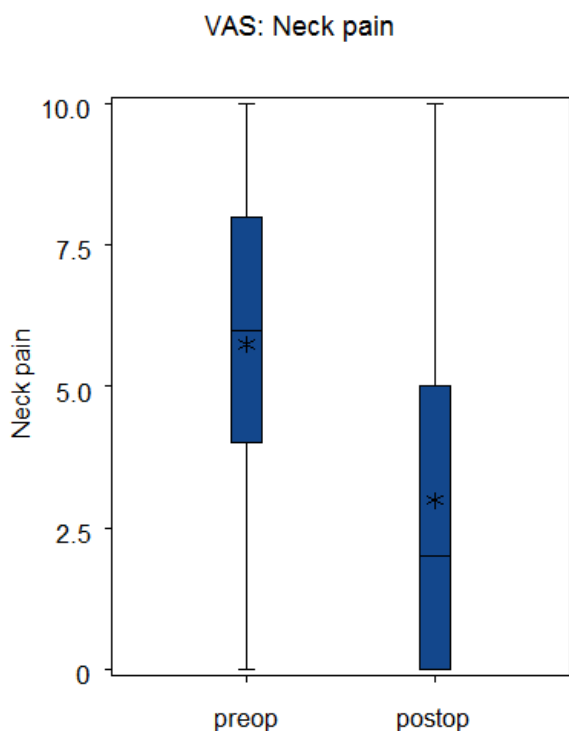


Fig. 31: Type of degeneration for patients with lumbar disc replacement (N=255)

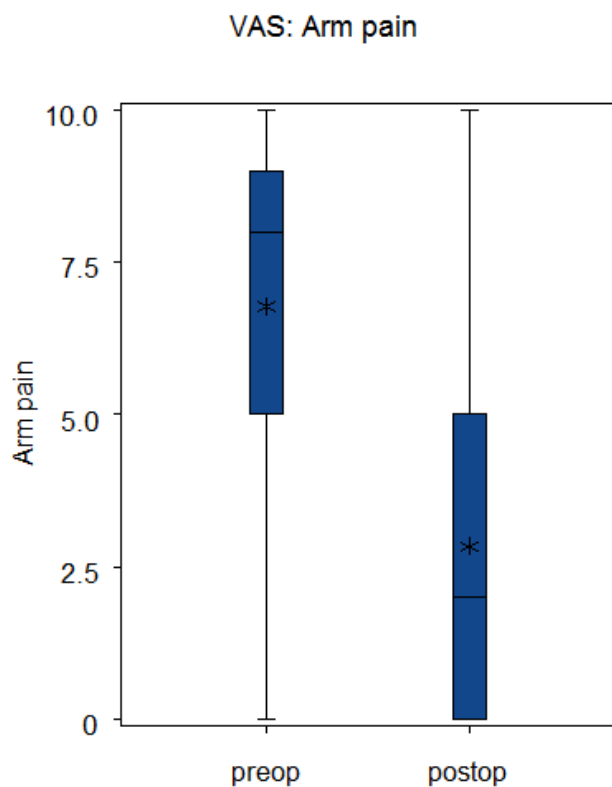
In contrast to cervical disc replacement, in the lumbar group the main specification of degenerative disease was disc degeneration with 81.2%. In accordance with treatment recommendations, lumbar disc herniation as underlying disease was less frequently documented.

Outcome (COMI)
(Disc Replacement)



In the cervical group (blue) there is a pain score reduction from 5.7 to 3.0 points in neck and from 6.8 to 2.9 points in arm pain. The mean followup time was 160 days.

Fig 32: Pre- and postoperative VAS scores for neck pain, cervical group (patients with TDA)



Tab 3: Pre- and postoperative VAS scores for neck and arm pain, cervical group (patients with TDA)

Cervical group (COMI)			
Neck pain	N	Mean	Median
preop	274	5.7	6.0
postop	216	3.0	2.0
Arm pain	N	Mean	Median
preop	274	6.8	7.5
postop	216	2.9	2.0

Fig 33: Pre- and postoperative VAS scores for arm pain, cervical group (patients with TDA)

In the lumbar group (orange) there is a pain score reduction from 6.7 to 4.0 points in back and from 5.0 to 3.2 points in leg pain. The mean followup time was 212 days.

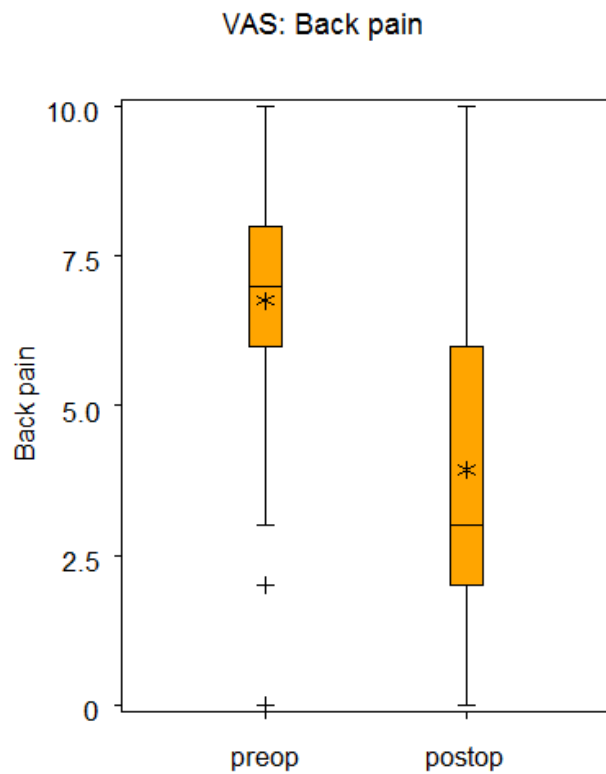


Fig 34: Pre- and postoperative VAS scores for leg pain, lumbar group (patients with TDA)

Tab 4: Pre- and postoperative VAS scores for back and leg pain, lumbar group (patients with TDA)

Lumbar group			
Back pain	N	Mean	Median
preop	87	6.7	7.0
postop	59	4.0	3.0
Leg pain	N	Mean	Median
preop	87	5.0	5.0
postop	59	3.2	3.0

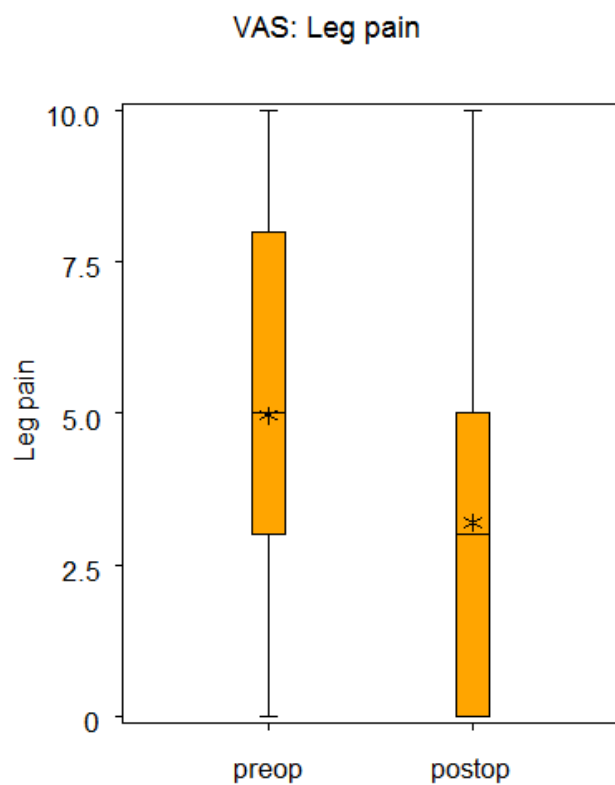
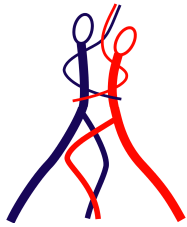


Fig 35: VAS scores pre- and postoperative for back pain, lumbar group (patients with TDA)



PARTICIPANTS/ MODULE ANALYSIS

Figure 36 displays the growth curves of the various national modules. The different starting dates of the modules need to be considered (Swiss/International: 2005, Austrian 2005, German: 2006, North American: 2007, Brazilian/ South American: 2008; Italian: 2008; Mexican: 2008)

The latest newcomers are an Australian and British module. Both are not yet available via www.Eurospine.org, but already have clinics entering data.

Figure 37 shows an overview of the Spine Tango participating clinics and their country of origin till the end of 2009. The current numbers show the ongoing growth with e.g. 17 clinics in Germany, 13 in Switzerland, 3 in South America etc. (status quo July 2010)

Growth rates of the various Spine Tango modules

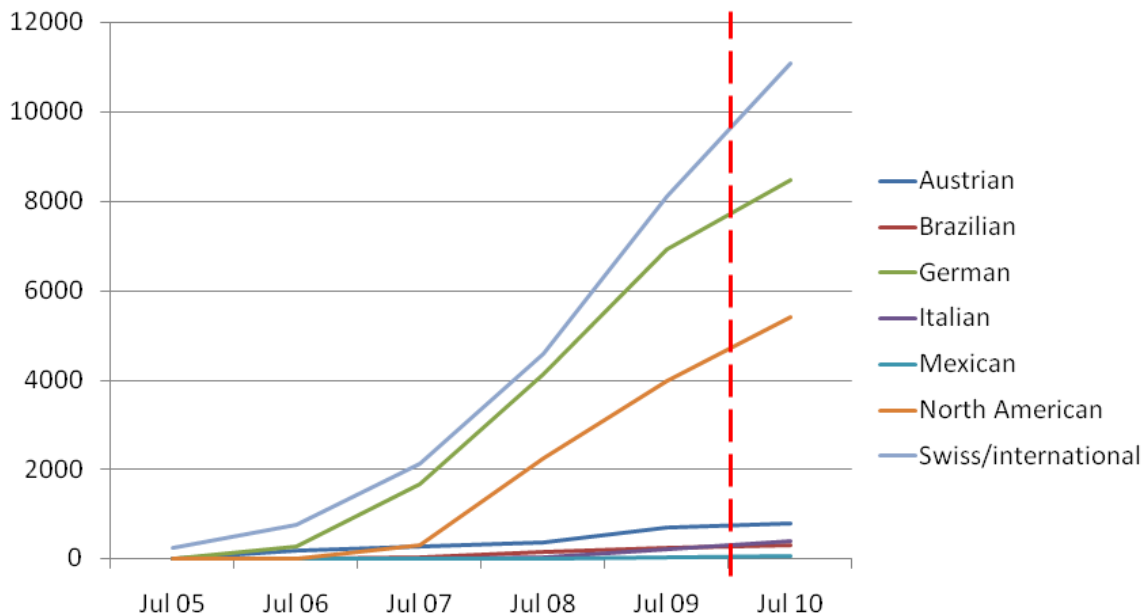


Fig 36: Growth curve (number of cases of the single Spine Tango modules over the years)

Spine Tango cases per participating countries (clinics)

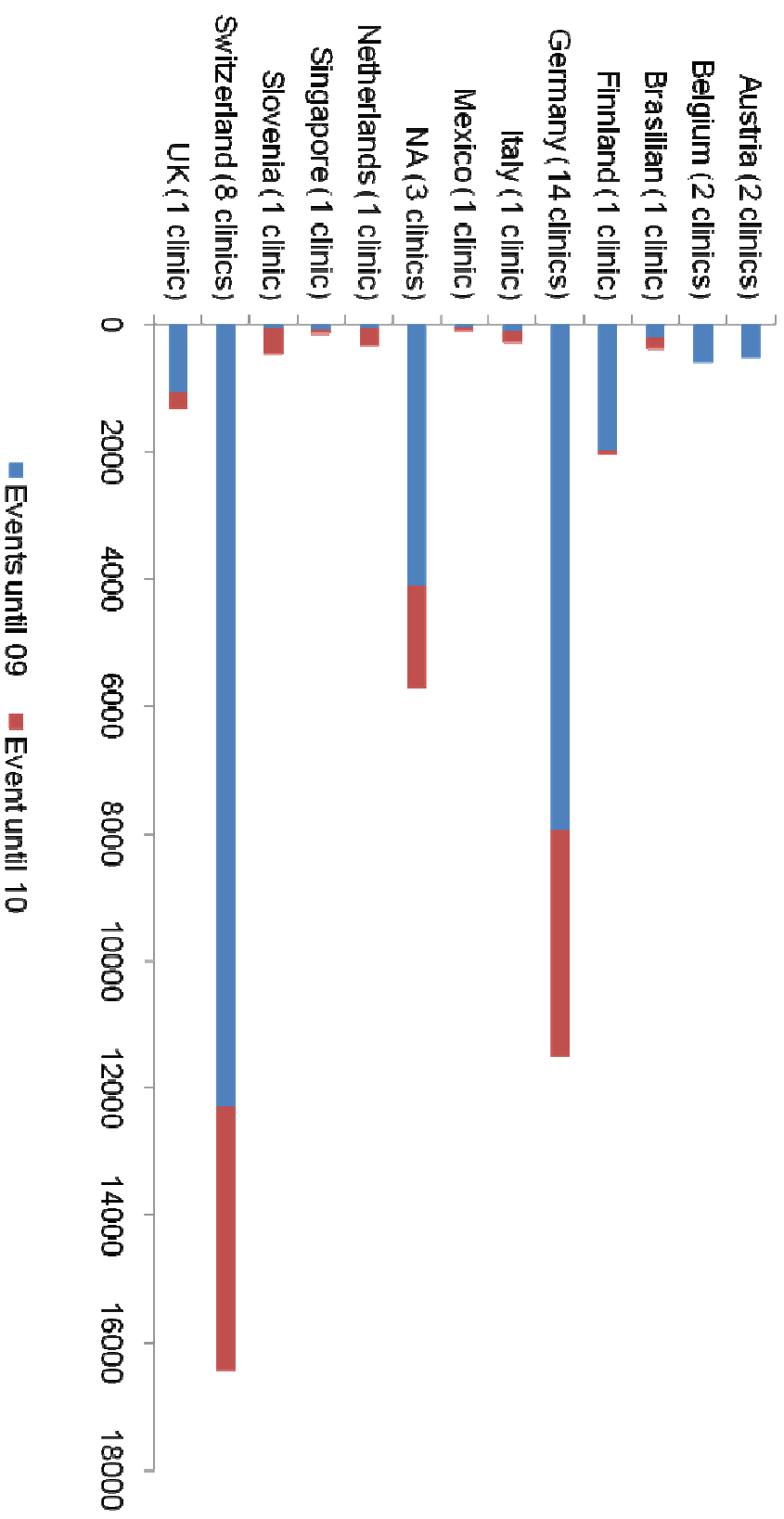
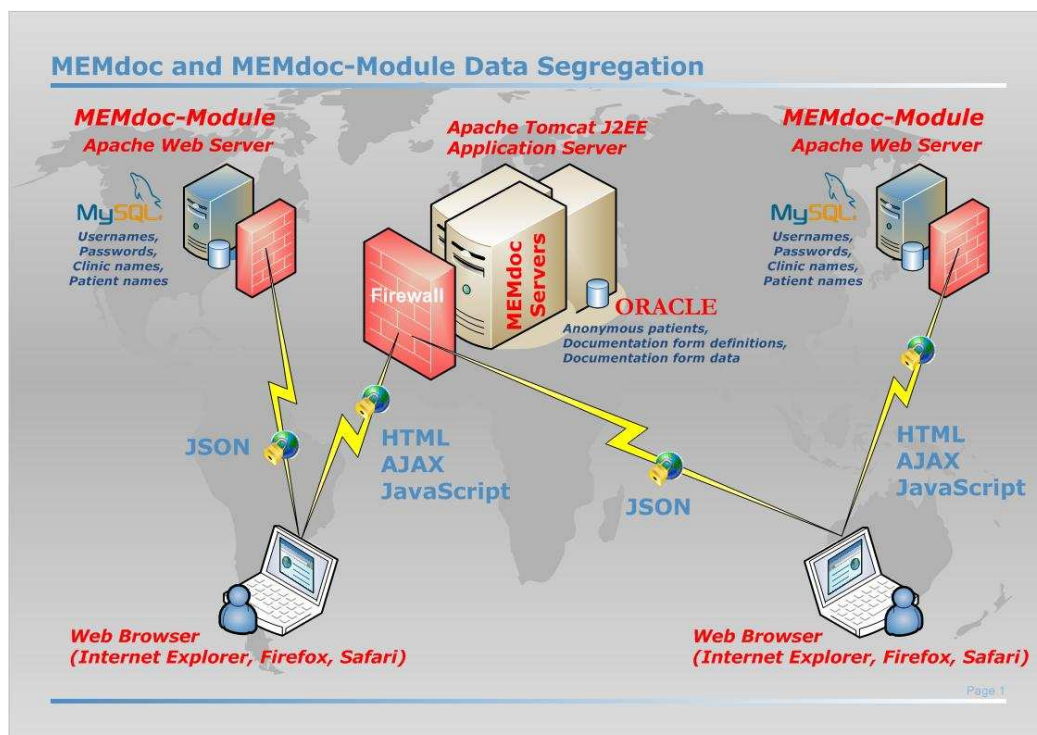


Fig. 37: Overview of the Spine Tango participating clinics according to their country of origin with case

SECURITY

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

Each module server contains a local MySQL database, an Apache web server and the custom MEMdoc-Module application. This server can sit within the same clinic as the user or in some remote location depending on the needs of the group hosting the module. The physical and network security of this server is left up to the hosting entity. Some groups choose to restrict access to the module to users within the local subnet while others allow open access from anywhere. The module database contains all user and clinic information as well as the basic demographic data of patients. No medical data is stored on the module server.



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

The physical and network security of all the MEMdoc servers is maintained by IEFM (Institute for Evaluative Research in Medicine) at the MEM Research Center. This includes the MEMdoc central (web) server and the MEMdoc database server. All servers are physically housed at the MEMcenter in Bern in a dedicated, locked, climate controlled and monitored server room. The network is protected by a Sonicwall Pro 2040 firewall with real-time gateway anti-virus, anti-spyware, anti-span and intrusion prevention. The firewall only allows access to the servers via ports 80, 443, 8080 and 22 (SSH). Web security is controlled by a DigiCert certified SSL web server certificate with 256-bit encryption. Each server is continuously monitored to log all connections and to detect any suspicious activity. Additionally, any modules that are hosted within IEFM fall within the same security parameters.

The following hardware is recommended for a MEMdoc-Module:

- Midrange Tower- or 19" Rack server
- CPU Intel Quad Core, Xeon or AMD Opteron
- RAM > 2 GB
- Hardware RAID 1 or 5
- Linux (Debian 5)



AVAILABLE QUESTIONNAIRES

Table 5: Available questionnaires in the SSE Spine Tango registry (01.01.2010)

Forms used in the SSE Spine Tango registry 01.01.2010		implemented	in process	mandatory	multilingual	online available					OMR paper forms						
						english	german	french	italian	spanish	english	german	french	italian	spanish	portugese	danish
SSE SPINE TANGO	Surgery 2006	✓			✓	✓					✓	✓	✓	✓			
SSE SPINE TANGO	Surgery staged 2006	✓			✓	✓					✓	✓	✓	✓			
SSE SPINE TANGO	Follow-up 2006	✓			✓	✓					✓	✓	✓	✓	IP		
SSE SPINE TANGO	conservative 2009	✓			✓	✓	✓				✓	✓	✓	✓			
SSE SPINE TANGO	COMI patient assessment neck	✓			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
SSE SPINE TANGO	COMI patient assessment back	✓			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
SSE SPINE TANGO	Oswestry 2.1	✓			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
SSE SPINE TANGO	SRS-22 Scoliosis Patient Questionnaire	✓			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
SSE SPINE TANGO	EuroQol EQ-5D	✓			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
SSE SPINE TANGO	SF-36 Health Survey	✓			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		

IP = in process

PUBLICATIONS

Papers in peer reviewed journals

Grob D, Porchet F, Kleinstück FS, Lattig F, Jeszenszky D, Luca A, Mutter U, Mannion AF. A comparison of outcomes of cervical disc arthroplasty and fusion in everyday clinical practice: surgical and methodological aspects. *Eur Spine J.* 2010 Feb;19(2):297-306. Epub 2009 Oct 31.

Grob D, Bartanusz V, Jeszenszky D, Kleinstück FS, Lattig F, O'Riordan D, Mannion AF. A prospective, cohort study comparing translaminar screw fixation with transforaminal lumbar interbody fusion and pedicle screw fixation for fusion of the degenerative lumbar spine. *J Bone Joint Surg Br.* 2009 Oct;91(10):1347-53.

Röder C, Staub L, Dietrich D, Zweig T, Melloh M, Aebi M. Benchmarking with Spine Tango: potentials and pitfalls. *Eur Spine J.* 2009 Aug;18 Suppl 3:305-11.

Grob D, Mannion AF. The patient's perspective on complications after spine surgery. *Eur Spine J.* 2009 Aug;18 Suppl 3:380-5.

Lattig F, Grob D, Kleinstueck FS, Porchet F, Jeszenszky D, Bartanusz V, O'Riordan D, Mannion AF. Ratings of global outcome at the first post-operative assessment after spinal surgery: how often do the surgeon and patient agree? *Eur Spine J.* 2009 Aug;18 Suppl 3:386-94. Epub 2009 May 22.

Zweig T, Mannion AF, Grob D, Melloh M, Munting E, Tuschel A, Aebi M, Röder C. How to Tango: a manual for implementing Spine Tango. *Eur Spine J.* 2009 Aug;18 Suppl 3:312-20. Epub 2009 Jun 28. Review.

Porchet F, Bartanusz V, Kleinstueck FS, Lattig F, Jeszenszky D, Grob D, Mannion AF. Microdiscectomy compared with standard discectomy: an old problem revisited with new outcome measures within the framework of a spine surgical registry. *Eur Spine J.* 2009 Aug;18 Suppl 3:360-6. Epub 2009 Mar 3. Review.

Kleinstück FS, Grob D, Lattig F, Bartanusz V, Porchet F, Jeszenszky D, O'Riordan D, Mannion AF. The influence of preoperative back pain on the outcome of lumbar decompression surgery. *Spine (Phila Pa 1976).* 2009 May 15;34(11):1198-203.

Oral presentations

Zweig T, Aghayev E, Melloh M, Sobottke R, Aebi M, Roeder C. Comparison of physician based vs patient based outcome after posterior lumbar fusion, EuroSpine 2009, Warsaw, Poland, 21-24 October 2009

Melloh M, Zweig T, Aghayev E, Röder C, Theis JC. Evaluative comparison of physician-based vs. patient-based outcomes in posterior lumbar fusion. NZOA Annual Scientific Meeting, Wellington, 18-21 October 2009

Zweig T, Aebi M, Aghayev E, Domanja S, Melloh M, Röder C, Predictors of dural tears in posterior spinal fusion in the lumbar spine - an analysis based on data of spine tango EFORT, 10th Congress, Vienna, Austria, 3-6 June 2009

Aghayev E, Zweig T, Aebi M, Aghayev E, Melloh M, Staub L, Röder C, Evaluative comparison of patient based versus physician based outcome in posterior lumbar fusion - an analysis based on the "Spine Tango" registry. EFORT, 10th Congress, Vienna, Austria, 3-6 June 2009

Sobottke R, Csecsei G, Delank K, Eysel P, Aghayev E, Zweig T, Röder C, How risky is spinal surgery in the elderly? International Society for the Study of the Lumbar Spine (ISSLS) 36th Annual Meeting, Miami/Florida, USA, 4-8 May 2009

Zweig T, Aghayev E, Melloh M, Sobottke R, Galbusera F, Aebi M, Röder C, An analysis of the surgical treatment of lumbar spinal stenosis (LSS) – Procedures, outcomes, influential factors. International Society for the Study of the Lumbar Spine (ISSLS) 36th Annual Meeting, Miami/Florida, USA, 4-8 May 2009

Zweig T, Aghayev E, Melloh M, Röder C, Physician- vs. patient based outcome after posterior lumbar fusion in the Spine Tango Registry. International Society for the Study of the Lumbar Spine (ISSLS) 36th Annual Meeting, Miami/Florida, USA, 4-8 May 2009

Zweig T, Medical registries: A tool for clinical evaluation for medical devices, focus on Spine Tango. Medical Device Clinical Congress (MDCC), Köln, 29 April 2009

Melloh M, Aghayev E, Staub LP, Zweig T, Röder C, Barz T, Rieger PS, Theis JC. Predictive Factors of Physician-based Outcomes after Posterior Lumbar Fusion. . Spine Society of Australia Annual Scientific Meeting, Brisbane, 17 – 19 April 2009

Melloh M, Staub LP, Röder C, Aghayev E, Zweig T, Barz T, Rieger PS, Theis JC. Co-variates of Length of Hospital Stay in Posterior Spinal Fusion. . Spine Society of Australia Annual Scientific Meeting, Brisbane, 17 – 19 April 2009

Zweig T, Aebi M. Wirbelsäulenregister der EuroSpine, Nutzen und Chancen für die Wirbelsäulen- und Alterschirurgie. 3. Alterstrauma-Kongress der DGU, Münster, 3-4 April 2009

Posters

Zweig T, Aghayev E, Melloh, Domanja S, Sobottke R, Aebi M, Roeder C. Predictors of dura lesions in posterior fusion of the lumbar spine - a study based on data of international „Spine Tango“ registry, EuroSpine 2009, Warsaw, Poland, 21-24 October 2009

Melloh M, Staub L, Röder C, Aghayev E, Zweig T, Theis JC, Challenges in establishing an international spine registry. International Society for the Study of the Lumbar Spine (ISSLS) 36th Annual Meeting, Miami/Florida, USA, 4-8 May 2009

Melloh M, Aghayev E, Staub L, Zweig T, Barz T, Theiss JC, Predictive factors for in physician based outcomes after posterior lumbar fusion. International Society for the Study of the Lumbar Spine (ISSLS) 36th Annual Meeting, Miami/Florida, USA, 4-8 May 2009

Melloh M, Staub L, Röder C, Aghayev E, Zweig T, Theis JC, Benchmarking in spinal surgery. International Society for the Study of the Lumbar Spine (ISSLS) 36th Annual Meeting, Miami/Florida, USA, 4-8 May 2009

Melloh M, Staub L, Röder C, Aghayev E, Zweig T, Theis JC, Co-variables of length of hospital stay in posterior spinal fusion. International Society for the Study of the Lumbar Spine (ISSLS) 36th Annual Meeting, Miami/Florida, USA, 4-8 May 2009

Zweig T, Aghayev E, Melloh M, Sobottke R, Galbusera F, Aebi M, Röder C, Predictors of dura lesions in posterior lumbar fusion – A study based on data of the International Spine Tango Registry. International Society for the Study of the Lumbar Spine (ISSLS) 36th Annual Meeting, Miami/Florida, USA, 4-8 May 2009

Awards

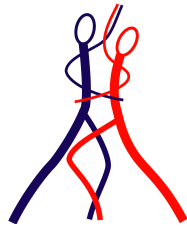
Best Poster Award

Sobottke R, Zweig T, Röder C, Eysel P; Delank KS, Aghayev E

Wirbelsäulenchirurgie im Alter: Wie riskant ist die operative Therapie der lumbalen Spinalkanalstenose (LSS) in Abhängigkeit vom Patientenalter.

[Spine Surgery in elderly patients: how risky is the operative treatment of lumbar spinal stenosis depending on patient age.]

4th Annual Conference, DWG (German Spine Society), Munich 2009



Christoph Röder, MD PhD MPH
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Gosia Perler
Statistics
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University of Berne, Switzerland

Markus Melloh, MD, MPH
Orthopaedic surgeon, EuroSpine (Past Fellow)

Thomas Zweig, MD
Orthopaedic surgeon, EuroSpine (Past Fellow)

Everard Munting, MD
Chair Spine Tango Committee, EuroSpine
Clinique Saint Pierre
Ottignies, Belgium

Max Aebi, MD, Dhc, FRCSC
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2019/10/15

