SPINE TANGO Report
International 2011

The International Spine Registry
EuroSpine

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

INTRODUCTION

Since the year 2000 EuroSpine – The Spine Society of Europe has been developing and enhancing a documentation system for spinal surgery and also for non-surgical spinal treatments in form of a registry. With Spine Tango we are meeting the growing demand to assess the safety and comparative effectiveness of surgical and non-surgical interventions and therapies 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 committee, 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 idea for Spine Tango was proposed a decade ago by Dieter Grob and Max Aebi, under the auspices of the SSE. Developments and participation have constantly progressed since those days. Now, having reached a recognized status we would like to encourage national societies and individual partners to join the registry. A positive signal comes from the German Spine Society DWG, the largest spine society in Europe, which decided to pilot a national spine registry adopting the Spine Tango technology and content to keep it fully compatible with the European endeavor. Health and reimbursement authorities are already limiting the accessibility of some spinal treatment modalities since evidence is lacking in many aspects. Therefore Spine Tango is offered 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.

E. Munting
Chair, on behalf of the Spine Tango committee

PROFILE

Spine Tango enables you to document the whole spectrum of spinal pathologies and the possible surgical and non-surgical treatment options. The generic approach of the Spine Tango documentation system is a must to reach the maximum number of participants using a common web based technology. This, in turn, reduces the potential for customizing the Tango in order to meet the individual expectations of specific users. There are, nevertheless, still a number of possibilities to parameterize the data collection processes according to the various hospital workflows in the user community. To give you the opportunity to document not only the surgical treatments, we have developed Spine Tango Conservative, which is now available in its first version. Spine Tango is an international, non-commercial system under the auspices of EuroSpine, the Spine Society of Europe aiming at enabling national societies to organize and control their own part of the registry. For that a technology called “national module concept” has been implemented to enhance participation options and to provide the hardware structure for appropriate security measures for patient and user privacy protection. The new software release 2012 does further improve these aspects. In conclusion, Spine Tango is a unique applied medical and scientific documentation and technology solution. It is to the benefit of patients, physicians and therapists whilst generating evidence based findings to improve spinal care (1,2).

1. Aebi M, Grob D (2004)
SSE Spine Tango: a European Spine Registry promoted by the Spine Society of Europe (SSE)
Eur Spine J 13: 661-662.
2. Kessler J, Melloh M, Zweig T, Aghayev E, Röder C. (2011)
Development of a Documentation Instrument for the Conservative Treatment of Spinal Disorders in the International Spine Registry Spine Tango.
European Spine Journal, 2011 Mar;20(3):369-79.

NEW DEVELOPMENTS

Spine Tango 2011: the new generation of surgical and non-surgical forms is meanwhile available for all users. New languages like Polish, Turkish, Greek and Russian will become available in their paper based version in the course of the year 2012. The online system still offers menus and content in the five languages English, German, French, Spanish and Italian.

Spine Tango 2011 Dictionaries of Terms and Pathways manual: don`t miss these accompanying documents that provide explanations of all terms used in the surgical and conservative questionnaires and of all new functions of the new software release. They can be found on the front pages of all new Spine Tango modules.

COMI Conservative: paying reference to the surgically focused wording of some of the COMI questions we have made slight changes and created a COMI Conservative version, this also for avoiding an outcome data pool that represents a mix of surgical and conservative treatment results. That way, online statistical queries will be able to clearly distinguish between surgical and non-surgical treatment results. More outcome questionnaires will be offered in their “conservative” version in the future for the same reasons.

New software release: the long awaited new MEMdoc software release is now also available for the Spine Tango user community. Migration of the nearly 50`000 cases and all their followup and outcome forms into the new database had to be performed first, which was a considerable IT effort. The new software offers improved security, better and easier user interfaces, more powerful tools and faster performance.

SSE Spine Tango Pathways
Manual for Entering and Querying Data

APPLICATION

Quality control, health service- , comparative effectiveness - and outcomes research, postmarket surveillance of implants, national and international study network

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

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

Health service research: as a subdiscipline of health systems research, this young science is an interdisciplinary field that describes and causally explains the provision of health services to the diseased and the healthy, contributes to the development of new concepts for delivery of health services and scientifically accompanies their implementation, and evaluates the effectiveness of structures and processes of healthcare delivery under routine day-to-day conditions. The focus of health service research is the “last mile” of the health care system, where the concrete and decisive delivery of care takes place in hospitals, practices and other institutions.

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

Postmarket surveillance of implants: implants play a major role in modern spine surgery and just like in the 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 about 50 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 (figure1)
1. Online data entry via the web-interface using stationary computers or wireless tablet devices (no software to be installed)
2. OMR (Optical Mark Reader) i.e. scanner-assisted entry of paper forms.
3. 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).
In the rectangles multiple methods of gathering patient and physician generated data are shown (by mail, inhouse, outpatient clinics, telephone and new electronic media).
The goal to generate a comprehensive database is achieved by collecting data of the patient layer and the clinic/physician layer. Having created a consistent data set the options of analyses are almost unlimited. Outcome evaluation can now be done in particular.

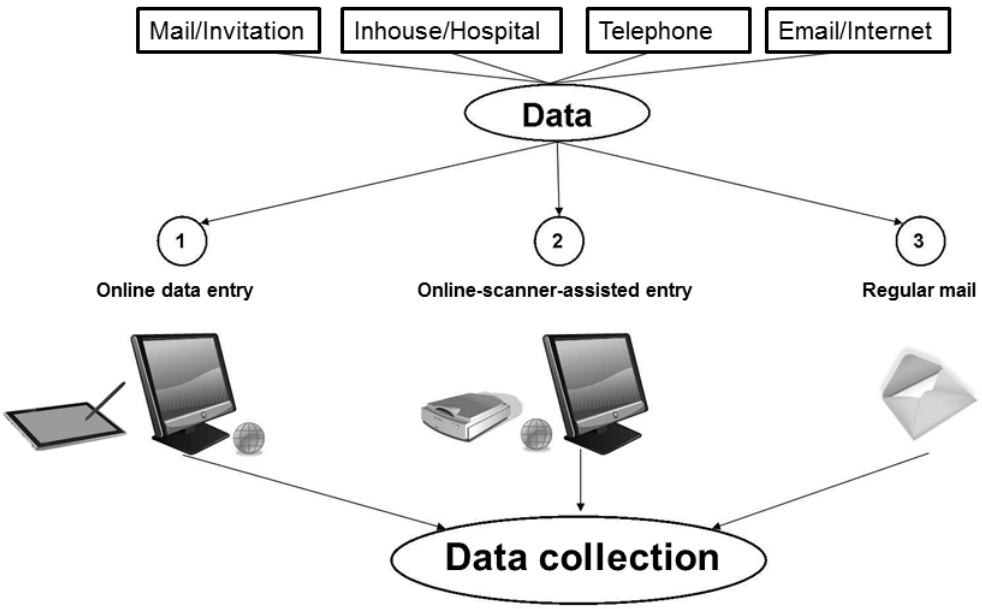

Figure 1: Spine Tango methods of data entry

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 (3). In most cases of spinal surgery, this can be done after a minimum of 3 months after surgery as demonstrated by Mannion et al (4). In accordance with figure 02. EuroSpine encourages one physician and patient based followup in the first year after surgery, ideally later than 3 months postop, and further, at least patient based followups around year one and two after surgery. The registration of complications at any time during the postoperative period is self understood. Patient based outcome documentation with the COMI (Core Outcome Measure Index) questionnaires for neck and back pain has become an essential part of the Spine Tango documentation (5). Figure 03 on the next page illustrates the ideal case of a completely documented treatment (6).

3. Codman, Ernest A. (1916). A Study in Hospital Efficiency. Boston, Mass., privately printed
4. Mannion AF, Porchet F; Kleinstück FS, Lattig F, Jeszenszky D, bartanusz V, Dvorak J, Grob D. (2009) The quality of spine surgery from the patient`s perspective. Part 1: the Core Outcome Measures Index in clinical practice. Eur Spine J. 18 Suppl 3:367-73
5. Mannion AF, Elfering A, Staerkle R, Junge A, Grob D, Semmer NK, Jacobshagen N, Dvorak J, Boos N (2005) Outcome assessment in low back pain: how low can you go? Eur Spine J 14:1014-1026
6. Zweig T, Mannion AF, Grob D, Melloh M, Munting E, Aebi M, Tuschel A, Röder C. (2009) How to Tango – a manual for implementing Spine Tango. Eur Spine J 18 Suppl 3:312-2

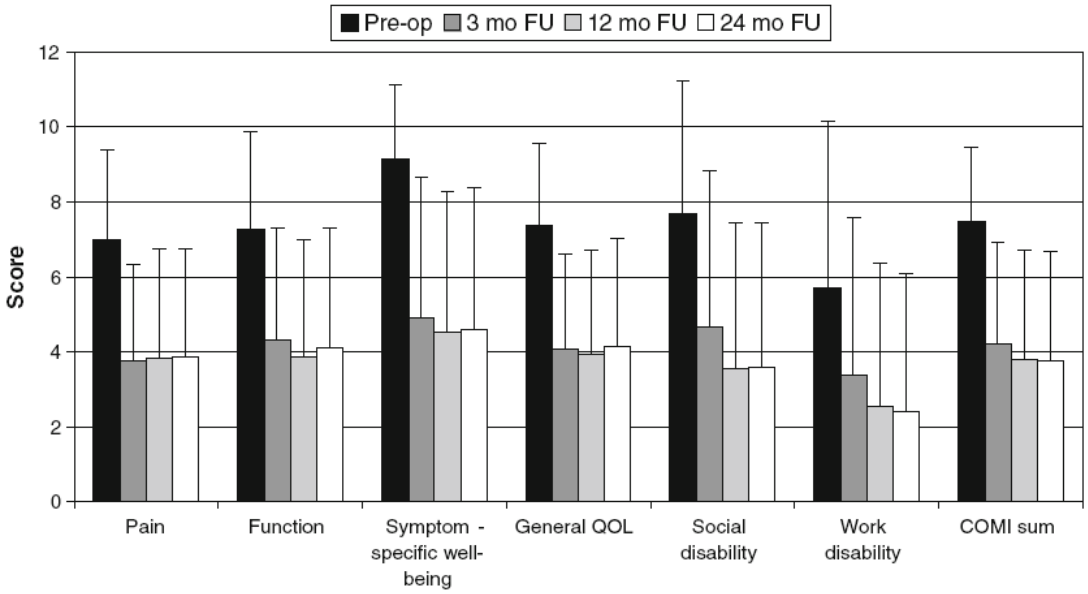

Figure 2: Patient based outcome documentation with the COMI (Core Outcome Measure Index) questionnaires, AF Mannion et al. (2009)(3)

PRE-& POSTOPERATIVE DOCUMENTATION WORKFLOW OF A CASE

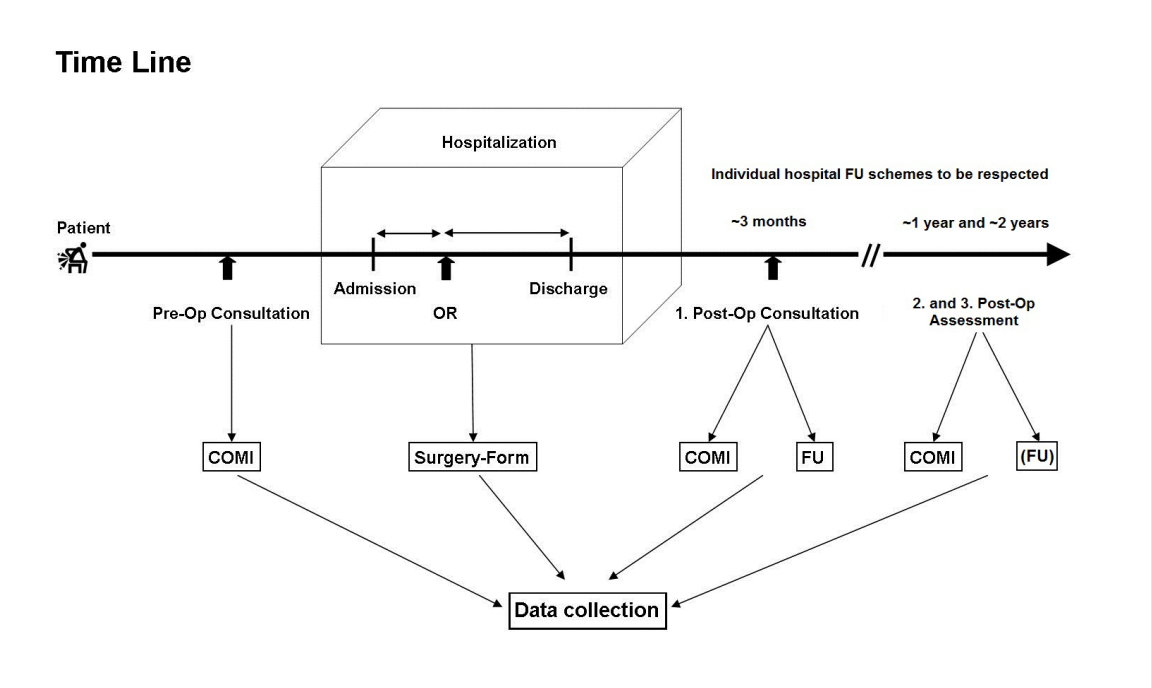

Figure 3: Timetable of data collection

Apart from the preoperative assessment of patients` quality of life and the recording of the surgical intervention, the Spine Tango code of conduct recommends one physician and patient based followup around the 3 months postoperative time interval. In accordance with international standards in the medical literature, an additional and at least patient based followup for the followup intervals 1 year and 2 years is highly desirable. If a surgeon based followup can also be achieved, a perfect outcome documentation is in place.

SPINE TANGO

EURO SPINE — Spine Tango

SURGERY 2011

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Last name	First name	Gender
Street		M.R.N.
Country code Zip code	City	
Social security number		Birthdate (DD.MM.YYYY)

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*
- ..... *please specify*

Format
( ) minimal
( ) **complete**

Level of intervention

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

Admission / Pathology

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** (11) (12) (13) (14) (15) (16) (17) (18) (19) (20)

Main pathology

( ) degenerative disease ( ) fracture/trauma ( ) spondylolisthesis (non degen.) ( ) infection ( ) repeat surgery
( ) non degen. deformity ( ) pathological fracture ( ) inflammation ( ) tumor ( ) other: specify .....

Specification of Main Pathology

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

Degen. disease

Type of degeneration
- ☐ disc herniat./protrusion
- ☐ central stenosis
- ☐ lateral stenosis
- ☐ foraminal stenosis
- ☐ degen. disc disease
- ☐ degen. deformity

Specify grade of spondyl. →
- ☐ degen. spondylolisthesis
- ☐ other instability
- ☐ myelopathy
- ☐ facet joint arthrosis
- ☐ other .....

Specify type of deformity below

Deformity

Type of deformity *Also specify type of degenerative deformity*
( ) scoliosis ( ) combined
( ) kyphosis ( ) other .....

Type of scoliosis
( ) single curve ( ) double curve

Predominant etiology
( ) idiopathic ( ) posttraumatic
( ) congenital ( ) M. Scheuermann
( ) neuromuscular ( ) other .....

(Pathological) Fracture/Trauma

Additional fractures w/different treatments require separate forms

Type of (pathological) fracture/trauma
( ) condylar (C0) ( ) C2 other fracture
( ) C0/1 dissociation ( ) soft tissue injury neck
( ) C1 fracture ( ) fracture C3-L5/S1
( ) C1/2 instability ( ) sacrum fracture
( ) C2 dens fracture ( ) other .....

Dens fracture type
( ) I
( ) II
( ) III

C3-L5/S1 AO fracture type
Type ( ) A ( ) B ( ) C
Group ( ) 1 ( ) 2 ( ) 3
Subgroup ( ) 1 ( ) 2 ( ) 3

Pathological fracture due to ...
( ) osteoporosis
( ) tumor
( ) other .....

Fracture age
( ) fresh fracture
( ) old fracture

In case of tumor, answer questions "Type of tumor" and "Localization" in section "TUMOR"

Spondylolisthesis

Type of spondylolisthesis
( ) Type I (congenital, dysplastic)
( ) Type II (isthmic)
← Type III see type of degeneration
( ) Type IV (traumatic)
( ) Type V (pathologic)
( ) Type VI (postsurgical)

Grade of spondylolisthesis
( ) Grade 0
( ) Grade I
( ) Grade II
( ) Grade III
( ) Grade IV
( ) Spondyloptosis (V)

Inflammation

Type of inflammation
( ) inflammatory arthritis (seropos)
( ) seronegative arthritis
( ) ankylosing spondylitis (M. Bechterew)
( ) other .....

Infection

Infection specification
( ) pyogenic ( ) fungal
( ) parasitic ( ) other .....
( ) tuberculotic

Affected structure(s)
- ☐ spondylitis
- ☐ discitis
- ☐ epidural space
- ☐ paravertebral infection
- ☐ other .....

Tumor

Type of tumor
( ) primary malignant
( ) primary benign
( ) secondary malignant
( ) tumor like lesion
( ) other .....

Localization
- ☐ extraosseous soft tissues
- ☐ intraosseous (superficial)
- ☐ intraosseous (deep)
- ☐ extrasosseous (extradural)
- ☐ extraosseous (intradural)
- ☐ other .....

Specify type of tumor .....

Repeat surg.

Type or reason of repeat surgery
- ☐ hardware removal
- ☐ non-union
- ☐ instability
- ☐ failure to reach therapeutic goals
- ☐ neurocompression
- ☐ postop. infection superficial
- ☐ postop. infect. deep
- ☐ implant malposition
- ☐ implant failure
- ☐ sagittal imbalance
- ☐ adjac. segment pathology
- ☐ other .....

Comments regarding main pathology: .....

In segments, mark cranial VB — SA = sacrum (S2-5) / CO = coccyx

Most severely affected ( ) segment ( ) vertebral body
(C0) (C1) (C2) (C3) (C4) (C5) (C6) (C7) (T1) (T2) (T3) (T4) (T5) (T6)
(T7) (T8) (T9) (T10) (T11) (T12) (L1) (L2) (L3) (L4) (L5) (S1) (SA) (CO)

Extent of lesion (segments/vertebral bodies)
(1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12) (13)
(14) (15) (16) (17) (18) (19) (20) (21) (22) (23) (24) (24)

Additional pathology *(Answer to question "Main pathology" is excluded.)*
- ☐ none
- ☐ degen. disease
- ☐ non-degen. deformity
- ☐ fracture/trauma
- ☐ pathological fracture
- ☐ spondylolisthesis (non-degen.)
- ☐ inflammation
- ☐ infection
- ☐ tumor
- ☐ repeat surgery
- ☐ other: specify .....

Number of previous spine surgeries
(0) (1) (2) (3) (4) (5) (>5)
Answer "0" excludes both "Previous surgery" questions ("at same level" and "at same hospital".)

Previous surgeries at same level
( ) no ( ) yes ( ) partially

Prev. surg. same hospital or surgeon
( ) no ( ) yes ( ) partially

Previous treatment for main pathology (by specialist)
- ☐ none
- ☐ surgical
- ☐ < 3 mon. conservative
- ☐ 3-6 mon. conservative
- ☐ 6-12 mon. conservative
- ☐ > 12 mon. conservative

Risk factors

BMI
( ) < 20 ( ) 31-35
( ) 20-25 ( ) >35
( ) 26-30 ( ) unknown

Current smoker
( ) yes
( ) no
( ) unknown

Presence of flags - low back pain
- ☐ none
- ☐ red
- ☐ yellow
- ☐ orange
- ☐ blue
- ☐ black
- ☐ not assessable/ applicable

Red: Biomedical Factors; serious spinal pathology
Yellow: Psychosocial or behavioral factors
Orange: Abnormal psychological processes indicating psychatric disorders
Blue: Socioeconomic/work factors
Black: Occupational and societal factors

SA = sacrum / CO = coccyx

31.12.2011 / Version v1

SPINE TANGO

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SURGERY
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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** (11) (12) (13) (14) (15) (16) (17) (18) (19) (20)

Therapeutic goals
- ☐ axial pain relief
- ☐ peripheral pain relief
- ☐ functional improvement
- ☐ motor improvement
- ☐ sensory improvement
- ☐ bladder/sex function improv.
- ☐ spinal stabilization
- ☐ stop deformity progression
- ☐ prophylactic decompression
- ☐ cosmetic improvement
- ☐ diagnostic measures
- ☐ other .....

Anterior access
- ○ no anterior access
- ○ transoral
- ○ anterolateral
- ○ cervicothorac. anterolat.
- ○ cervicothorac. w/sternotomy
- ○ thoracotomy
- ○ thoracoabdominal
- ○ retroperitoneal
- ○ transperitoneal
- ○ trans-psoas (XLIF)
- ○ other .....

Components *Description not needed if SEDICO implant tracking is used.*
- ○ none
- ○ with description — **Supplier:** .....
- ○ w/o description — **Article name:** .....

For article numbers or multiple implants use form "Implant documentation" @ www.eurospine.org

Posterior access
- ○ no posterior access
- ○ midline
- ○ paramedian
- ○ posterolateral
- ○ percutaneous
- ○ para-coccygeal (AxiALIF)
- ○ other .....

Surgeon credentials
- ○ specialized spine
- ○ board certif. orthopaedic
- ○ board certified neuro
- ○ orthopaedic in training
- ○ neuro in training
- ○ other .....

Morbidity state
- ○ unknown
- ○ ASA1 (no disturbance)
- ○ ASA2 (mild/moderate)
- ○ ASA3 (severe)
- ○ ASA4 (life threatening)
- ○ ASA5 (moribund)

Technology
- ☐ conventional
- ☐ MISS/LISS
- ☐ loops
- ☐ endoscope
- ☐ CASS
- ☐ microscope
- ☐ neuromonitoring
- ☐ other .....

Operation time
- ○ unknown
- ○ < 1 hr.
- ○ 1-2 hrs.
- ○ 2-3 hrs.
- ○ 3-4 hrs.
- ○ 4-5 hrs.
- ○ 5-6 hrs.
- ○ 6-8 hrs.
- ○ 8-10 hrs.
- ○ > 10 hrs.

Prophylaxis
- ☐ none
- ☐ infection
- ☐ thrombembolism
- ☐ ossification
- ☐ other .....

Blood loss
- ○ unknown
- ○ < 100 ml
- ○ 100 - 500 ml
- ○ 500 - 1000 ml
- ○ 1000 - 2000 ml
- ○ > 2000 ml

Blood transfusion
- ☐ none
- ☐ <2 units
- ☐ >=2 units
- ☐ cell saver
- ☐ unknown

Surgical Measures

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

Decompression
- ☐ none
- ☐ anterior } *specify ...*
- ☐ posterior }

Location in spine, choose at least one!

- ☐ discectomy partial/total
- ☐ vertebrectomy partial
- ☐ vertebrectomy full
- ☐ osteotomy
- ☐ laminotomy
- ☐ hemi-laminectomy
- ☐ laminectomy
- ☐ facet joint resec. partial
- ☐ facet joint resection full
- ☐ sequestrectomy
- ☐ flavectomy
- ☐ flavotomy
- ☐ foraminotomy
- ☐ laminoplasty
- ☐ uncoforaminotomy
- ☐ other .....

Fusion promoting measu.
- ☐ none
- ☐ anterior } *specify ...*
- ☐ posterior }

Location in spine, choose at least one!

- ☐ interbody fusion (A-IF)
- ☐ interbody fusion (PLIF)
- ☐ interbody fusion (TLIF)
- ☐ interbody fusion (XLIF)
- ☐ other interbody fusion
- ☐ posterolat. fusion
- ☐ posterior fusion
- ☐ other .....

Fusion material
- ☐ none
- ☐ autol. bone harvested
- ☐ autol. bone locally procured
- ☐ allog. bone
- ☐ bone subst.
- ☐ cement
- ☐ BMP or similar
- ☐ other .....

Stabilization rigid
- ☐ none
- ☐ anterior } *specify ...*
- ☐ posterior }

Location in spine, choose at least one!

- ☐ interbody stabil. with cage
- ☐ interbody stabil. with auto-/allograft
- ☐ vertebral body replacement by cage
- ☐ vertebral body replacment by auto-/allograft
- ☐ plates
- ☐ pedicle screws with rod
- ☐ facet screws
- ☐ transarticular screw C1-C2
- ☐ laminar hooks with rod
- ☐ pedicle hooks with rod
- ☐ lateral mass screw with rod
- ☐ odontoid screws
- ☐ laminar screws
- ☐ other .....

Stabil. motion preserving
- ☐ none
- ☐ anterior } *specify ...*
- ☐ posterior }

Location in spine, choose at least one!

- ☐ disc replacement
- ☐ dynamic stabilizat.
- ☐ interspin. spacer
- ☐ other .....

Percutan. measures
- ○ none
- ○ post. } *specify ...*

Choose one!

- ☐ facet block
- ☐ root block
- ☐ discography
- ☐ vertebroplasty
- ☐ kyphoplasty
- ☐ epidural injections
- ☐ other .....

Other surgical measures
- ○ no
- ○ yes

Specify yes: .....

Extent of surgery - indicate as: *(from cranial to caudal)*
SA = sacrum (S2-5) / CO = coccyx
- ○ segments
- ○ vertebral bodies

from (C0) (C1) (C2) (C3) (C4) (C5) (C6) (C7) (T1) (T2) (T3) (T4) (T5) (T6) (T7) (T8) (T9) (T10) (T11) (T12) (L1) (L2) (L3) (L4) (L5) (S1) (SA) (CO)
to (C0) (C1) (C2) (C3) (C4) (C5) (C6) (C7) (T1) (T2) (T3) (T4) (T5) (T6) (T7) (T8) (T9) (T10) (T11) (T12) (L1) (L2) (L3) (L4) (L5) (S1) (SA) (CO)

Intraop surgical complications
- ☐ none
- ☐ nerve root damage
- ☐ spinal cord damage
- ☐ dura lesion
- ☐ vascular injury
- ☐ fx vertebral structures
- ☐ other .....
- ☐ not documented

Surgical measures during index surgery
- ☐ none
- ☐ suture/glue
- ☐ other .....

Intraop general complications
- ☐ none
- ☐ anaesthesiological
- ☐ cardiovascular
- ☐ pulmonary
- ☐ thrombembolism
- ☐ death
- ☐ other .....
- ☐ not documented

Hospital stay

Postop surgic compl. before discharge
- ☐ none
- ☐ epidural hematoma
- ☐ other hematoma
- ☐ radiculopathy
- ☐ CSF leak / pseudomeningocele
- ☐ motor dysfunction
- ☐ sensory dysfunction
- ☐ bowel / bladder dysfunction
- ☐ wound infection superficial
- ☐ wound infection deep
- ☐ implant malposition
- ☐ implant failure
- ☐ wrong level
- ☐ other .....
- ☐ not documented

Postop general compl. before discharge
- ☐ none
- ☐ cardiovascular
- ☐ pulmonary
- ☐ cerebral
- ☐ kidney / urinary
- ☐ liver / GI
- ☐ thrombembolism
- ☐ death
- ☐ other .....
- ☐ not documented

Re-intervention after index surgery
- ☐ none
- ☐ hematoma evacuation
- ☐ suture / glue
- ☐ hardware removal
- ☐ hardware re-implantation
- ☐ abscess drainage
- ☐ (further) decompression
- ☐ other .....
- ☐ not documented

Hospital stay
- ☐ uneventful
- ☐ ICU > 2 days
- ☐ extended stay

Status of surg. complications
- ○ resolved
- ○ improved
- ○ persisting

Therapeutic goals upon discharge
- ○ achieved
- ○ partially achieved
- ○ not achieved

FU foreseen
- ○ no
- ○ yes

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** (11) (12) (13) (14) (15) (16) (17) (18) (19) (20)

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

31.12.2011 / Version v1

SPINE TANGO

EURO SPINE

FOLLOW-UP 2011

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
- ..... please specify
- ☐ 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
Social security number | Birthdate (DD.MM.YYYY)

Level of intervention

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

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** ○11○ ○12○ ○13○ ○14○ ○15○ ○16○ ○17○ ○18○ ○19○ ○20○

Follow up interval
○ ○ 6 weeks ○ ○ 3 months ○ ○ 6 months ○ ○ 1 year ○ ○ 2 years ○ ○ other (yrs.) .....
(Ex. 4 months=0.33 yrs. (4/12))

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

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

Therapeutic goals/measures achieved
☐ none ☐ axial pain relief ☐ peripheral pain relief ☐ functional improvement ☐ motor improvement ☐ sensory improvement ☐ bladder/sex function improvement ☐ spinal stabilization ☐ stop deformity progression ☐ prophylactic decompression ☐ cosmetic improvement ☐ diagnostic measures ☐ other .....

Therap. goals/measures partially achieved
☐ none ☐ axial pain relief ☐ peripheral pain relief ☐ functional improvement ☐ motor improvement ☐ sensory improvement ☐ bladder/sex function improvement ☐ spinal stabilization ☐ stop deformity progression ☐ prophylactic decompression ☐ cosmetic improvement ☐ diagnostic measures ☐ other .....

Therapeutic goals/measures not achieved
☐ none ☐ axial pain relief ☐ peripheral pain relief ☐ functional improvement ☐ motor improvement ☐ sensory improvement ☐ bladder/sex function improvement ☐ spinal stabilization ☐ stop deformity progression ☐ prophylactic decompression ☐ cosmetic improvement ☐ diagnostic measures ☐ other .....

Medication for spinal surgery/pathology
☐ none ☐ NSAID,Paracetamol (WHO I) ☐ weak opiates (WHO II) ☐ strong opiates (WHO III) ☐ steroids ☐ antidepressives ☐ vitamin B complex ☐ antibiotics ☐ other .....

Overall outcome (examiner)
○ ○ not applicable ○ ○ excellent ○ ○ good ○ ○ fair ○ ○ poor

Rehabilitation
☐ none ☐ home-based ☐ outpatient rehab / physio ☐ inpatient rehab / physio ☐ other .....

Decision
○ ○ no further follow-up ○ ○ further follow-up ○ ○ revision foreseen ○ ○ 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
☐ sensory dysfunction ☐ motor dysfunction ☐ bowel / bladder dysfunction ☐ non-union ☐ implant failure ☐ instability ☐ CSF leak / pseudomeningocele ☐ wound infection superficial ☐ wound infection deep ☐ spondylitis ☐ discitis ☐ epidural hematoma ☐ extravertebral hematoma ☐ wrong level ☐ implant malposition ☐ recurrence of symptoms ☐ graft complication ☐ sequelae anaesthesia ☐ adjac. segment pathology ☐ recurrent tumor ☐ decompensation of spine ☐ cardiovascular ☐ gastrointestinal ☐ central nervous system ☐ fx vertebral structures ☐ thrombembolism ☐ 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 .....

Spine Tango COMI
Patient self-assessment

EURO SPINE — Spine Tango

Compatible with SGS SWISSspine register

Low Back 2008

Internal Use Only
Not read by scanner

Last name | First name | Gender

Street | M.R.N.

Country Code | Zip Code | City

Social security number (ADI no.) | Birthdate (DD.MM.YYYY)

Directions

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

Examination interval

○ before surgery	○ 3 months	○ 2 years	
○ 4 weeks	○ 6 months	○ 3 years	
○ 6 weeks	○ 9 months	○ 4 years	*e.g. 4 months*
○ 2 months	○ 1 year	○ 5 years	*= 4 months/12 months*
		○ 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?

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

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

	0	1	2	3	4	5	6	7	8	9	10	
no pain	○	○	○	○	○	○	○	○	○	○	○	**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 = Core Outcome Measures Index

01.02.2009

Spine Tango COMI — **Patient self-assessment** *Low back*

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: .....

SPINE TANGO

EURO SPINE — Spine Tango

CONSERVATIVE THERAPY 2011

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*

Internal Use Only
Not read by scanner

Last name | First name | Gender
Street | M.R.N
Country code | Zip code | City
Social security number (ADI no.) | Birthdate (DD.MM.YYYY)

☐ Mandatory information

Level of intervention

( ) neck / cervical ( ) mid back / thoracic ( ) low back / lumbar / sacral ( ) ilio-sacral ( ) cervico-thoraco-lumbar

Anamnesis

Intake 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** (11) (12) (13) (14) (15) (16) (17) (18) (19) (20) *(Intake date is optional)*

Type of setting
( ) outpatient
( ) inpatient

Main reason for seeking care
( ) diagnostic findings (ICD)
( ) functional limitations (ICF)
( ) diagnostic findings and functional limitations

Diagnosis validated with
☐ anamnesis ☐ CT
☐ clinical evaluation ☐ laboratory
☐ X-ray ☐ other .....
☐ MRI

Presence of flags*
☐ none ☐ blue
☐ red ☐ black
☐ yellow ☐ unable to assess
☐ orange
red flag = patient grade IV

Patient classification
( ) Grade 0 ( ) Grade III
( ) Grade I ( ) Grade IV
( ) Grade II ( ) unable to assess

grade 0 = no symptoms
grade I = symptoms; no further care recommended
grade II = symptoms; no radicular signs, treatment recommended
grade III = symptoms; radicular signs, treatment recommended
grade IV = red flags

Diagnostic findings *ICD nomenclature (ICD 9 and 10 codes automatically generated by system)*
☐ disc disorder w/o myelopathy
☐ disc disorder with myelopathy
☐ spinal stenosis
☐ degenerative disc disease
☐ nerve root compression/ radiculopathy
☐ postlaminectomy syndrome
☐ muscle strain
☐ sciatica
☐ spondylolysis/spondylolisthesis (acquired)
☐ spondylolysis/spondylolisthesis (congenital)
☐ pregnancy backache
☐ collapsed vertebra
☐ compression fracture
☐ ankylosing spondylitis
☐ scoliosis (idiopathic)
☐ pain
☐ other .....

Specification of limitations in activities and participation (ICF)
☐ handling stress and other psychological demands
☐ changing basic body positions
☐ maintaining a body position
☐ lifting and carrying objects
☐ hand and arm use
☐ walking
☐ driving
☐ toileting
☐ dressing
☐ doing housework
☐ assisting others
☐ family relationship
☐ acquiring, keeping and terminating a job
☐ remunerative employment
☐ work and employment, other specified and unspecified
☐ community life
☐ recreation and leisure
☐ sleep functions
☐ exercise tolerance function
☐ other .....

Duration of current episode
( ) < 6 weeks ( ) > 12 weeks
( ) 6 weeks - 12 weeks

History of complaint
( ) recurrent episode → *if recurrent*
( ) first episode

Sought care
( ) yes → *if yes*
( ) no

Received treatment
( ) yes
( ) no

Treatment history for current complaint
☐ no treatment before
☐ pain medication
☐ exercise therapy
☐ manual therapy
☐ physical measures
☐ psychological intervention
☐ occupational medicine measures
☐ multidisciplinary treatments
☐ invasive pain therapy
☐ spine surgery
☐ other .....

Number of previous spine surgeries
( ) 0 ( ) 2 ( ) >3
( ) 1 ( ) 3

Region(s) of previous spine surgeries
☐ cervical ☐ lumbar / sacral
☐ thoracic

Number of previous therapy sessions during the last 12 months *according to patient information*
( ) unknown ( ) 1 -9 ( ) 19 -27
( ) none ( ) 10 - 18 ( ) > 27

Intake medication for current complaint
☐ none
☐ NSAID
☐ weak opioids
☐ strong opioids
☐ other analgesics
☐ muscle relaxants
☐ sleep promoting drugs
☐ SSRI (Selective Serotonin Reuptake Inhibitor)
☐ tricyclic antidepressants
☐ anxiolytics
☐ anticonvulsants
☐ neuroleptics
☐ other .....

Spinal comorbidities
( ) yes
( ) no

Other musculoskeletal comorbidities
( ) yes
( ) no

Systemic comorbidities
( ) yes →
( ) no

Number
( ) 1-3
( ) >3

Therapy

Start of therapy
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** (11) (12) (13) (14) (15) (16) (17) (18) (19) (20)

Therapist credentials
☐ MD/physician
☐ physiotherapist
☐ chiropractor
☐ osteopath
☐ occupational therapist
☐ pain specialist (non MD)
☐ massage therapist
☐ acupuncturist
☐ manual therapist
☐ psychologist
☐ other .....

***Flags**
Red: Biomedical Factors; serious spinal pathology
Yellow: Psychosocial or behavioral factors
Orange: Abnormal psychological processes indicating psychatric disorders
Blue: Socioeconomic/work factors
Black: Occupational and societal factors

31.12.2011 / Version v1

SPINE TANGO

CONSERVATIVE THERAPY

Course of therapy / therapeutic measures for current episode

Medication

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

- ☐ NSAID
- ☐ other analgesics
- ☐ weak opioids
- ☐ strong opioids
- ☐ muscle relaxants
- ☐ sleep promoting drugs
- ☐ SSRI (Selective Serotonin Reuptake Inhibitor)
- ☐ tricyclic antidepress.
- ☐ anxiolytics
- ☐ anticonvulsants
- ☐ neuroleptics
- ☐ other .....

Non-invasive therapies

Therapy setting
- ○ one to one
- ○ group
- ○ one to one and group

Exercise therapy
- ○ no
- ○ yes *specify* →

- ☐ strength
- ☐ flexibility
- ☐ muscular endurance
- ☐ cardiovascular endurance
- ☐ balance
- ☐ postural control
- ☐ coordination
- ☐ stability
- ☐ other .....

Manual therapy
- ○ no
- ○ yes *specify* →

- ☐ mobilization
- ☐ manipulation
- ☐ techniques for soft tissues
- ☐ stretches
- ☐ neuromeningeal mobil.
- ☐ visceral techniques
- ☐ trigger point treatment
- ☐ craniosacral techniques
- ☐ massage
- ☐ other .....

Physical modalities
- ○ no
- ○ yes *specify* →

- ☐ interferential power
- ☐ thermo therapy
- ☐ short-wave diathermy
- ☐ shockwave therapy
- ☐ TENS
- ☐ ultrasound
- ☐ lumbar orthosis
- ☐ laser therapy
- ☐ traction
- ☐ other .....

TENS = Transcutaneous Electrical Nerve Stimulation

Psychological intervention
- ○ no
- ○ yes *specify* →

- ☐ psychotherapy
- ☐ relaxation / meditation therapy
- ☐ cognitive therapy
- ☐ behavioral therapy
- ☐ counseling
- ☐ other .....

Occupational medicine measures
- ○ no
- ○ yes *specify* →

- ☐ ergonomic measures
- ☐ occupational retraining / vocational rehabilitation
- ☐ work reintegration / return to work programs
- ☐ work hardening
- ☐ other .....

Multidisciplinary treatments
- ○ no ○ yes *specify* →

- ☐ physiotherapist
- ☐ occupational therapist
- ☐ psychotherapist
- ☐ physician
- ☐ chiropractor
- ☐ osteopath
- ☐ other .....

Invasive therapies

Invasive pain therapy
- ○ no
- ○ yes *specify* →

- ☐ facet block
- ☐ root block
- ☐ epidural infiltration
- ☐ epidural catheter
- ☐ pain pump
- ☐ medullary stimulation
- ☐ IDET
- ☐ IRT
- ☐ radiofrequency therapy
- ☐ cryodenervation of facets
- ☐ alcohol denervat. of facets
- ☐ neural therapy
- ☐ acupuncture
- ☐ ISJ infiltration
- ☐ other .....

End of therapy

End of therapy

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** ○11 ○12 ○13 ○14 ○15 ○16 ○17 ○18 ○19 ○20

Therapeutic complications
- ☐ none
- ☐ unexpected pain exacerbation
- ☐ muscle strain
- ☐ fall
- ☐ heart attack/angina
- ☐ burn
- ☐ asthma attack
- ☐ nerve root damage
- ☐ cauda equina damage
- ☐ spinal cord damage
- ☐ bleeding in spinal canal
- ☐ bleeding outside spinal canal
- ☐ dura lesion
- ☐ wound infection
- ☐ electrode malposition
- ☐ electrode dislocation
- ☐ other .....

Measures taken for complications
- ☐ none
- ☐ cons. pharmacological
- ☐ conservative functional
- ☐ prolonged inpatient stay
- ☐ surgical intervention
- ☐ referral to other speciality
- ☐ emergency room
- ☐ other .....

Number of sessions received
- ○ unknown
- ○ 1 -9
- ○ 10 - 18
- ○ 19 -27
- ○ > 27

Completed treatment
- ○ yes
- ○ no

Reasons for non-completed treatment
- ○ unknown
- ○ medical
- ○ insurance
- ○ work
- ○ personal
- ○ other

Referral for further treatment
- ☐ none
- ☐ rheumatology
- ☐ physical medicine
- ☐ spine surgery
- ☐ pain management
- ☐ psychology
- ☐ other .....

End of therapy - patient reassessment

Patient classification
- ○ Grade 0
- ○ Grade I
- ○ Grade II
- ○ Grade III
- ○ Grade IV
- ○ unable to assess

Presence of flags
- ☐ none
- ☐ red*
- ☐ yellow
- ☐ orange
- ☐ blue
- ☐ black
- ☐ unable to assess

Goals and achievements: GA goal achieved - GP goal partially achieved - GN goal not achieved - NG not a goal

GA	GP	GN	NG		GA	GP	GN	NG		GA	GP	GN	NG	
☐	☐	☐	☐	handling stress and other psychological demands	☐	☐	☐	☐	toileting	☐	☐	☐	☐	work and employment, other specified and unspecified
☐	☐	☐	☐	changing basic body pos.	☐	☐	☐	☐	dressing					
☐	☐	☐	☐	maintaining a body position	☐	☐	☐	☐	doing housework					
☐	☐	☐	☐	lifting and carrying objects	☐	☐	☐	☐	assisting others	☐	☐	☐	☐	community life
☐	☐	☐	☐	hand and arm use	☐	☐	☐	☐	family relationship	☐	☐	☐	☐	recreation and leisure
☐	☐	☐	☐	walking	☐	☐	☐	☐	acquiring, keeping and terminating a job	☐	☐	☐	☐	sleep functions
☐	☐	☐	☐	driving	☐	☐	☐	☐	remunerative employm.	☐	☐	☐	☐	exercise tolerance funct.
										☐	☐	☐	☐	other .....

Global outcome (therapist)
- ○ excellent
- ○ good
- ○ fair
- ○ poor

Global change assessment (therapist)
- ○ much worsened
- ○ slightly worsened
- ○ unchanged
- ○ slightly improved
- ○ much improved

* *Patient grade IV*

Examiner .....

Spine Tango COMI
Patient self-assessment

EURO SPINE — Spine Tango

Compatible with SGS SWISSspine register

Low Back conservative 2008

Internal Use Only
Not read by scanner

Last name | First name | Gender

Street | M.R.N.

Country Code | Zip Code | City

Social security number (ADI no.) | Birthdate (DD.MM.YYYY)

Directions

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

Examination interval

○ before treatment	○ 3 months	○ 2 years	
○ 4 weeks	○ 6 months	○ 3 years	
○ 6 weeks	○ 9 months	○ 4 years	*e.g. 4 months*
○ 2 months	○ 1 year	○ 5 years	*= 4 months/12 months*
		○ 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?

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

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

	0	1	2	3	4	5	6	7	8	9	10	
no pain	○	○	○	○	○	○	○	○	○	○	○	**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 = Core Outcome Measures Index

Spine Tango COMI ***conservative***

Patient self-assessment
Low back

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 21 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 21 days

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

8a Did any **complications** arise as a consequence of your treatment **in our institution** (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 treatment in our institution**, have you had any **further** treatment(s) on your lumbar spine (back) **in our or in other institutions?**

- ☐ 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 institution**?

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

11 Overall, how much did the **treatment in our institution** help your back problem?

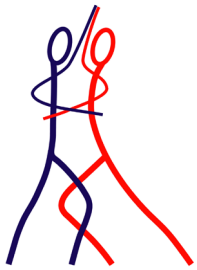
- ☐ helped a lot
- ☐ helped
- ☐ helped only little
- ☐ didn't help
- ☐ made things worse

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: .....



EPITOME OF AVAILABLE DATA

Overview (Pool)

Benchmarking: USA vs. German speaking countries vs. Benelux & Scandinavia vs. “Others”

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

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

STATISTICS AND COMMENTS

A study of the weighting and frequency of statistical reports was published by Windish in JAMA in 2007 (7). 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 close to 50.000 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 various types of spondylolisthesis.

7. 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.

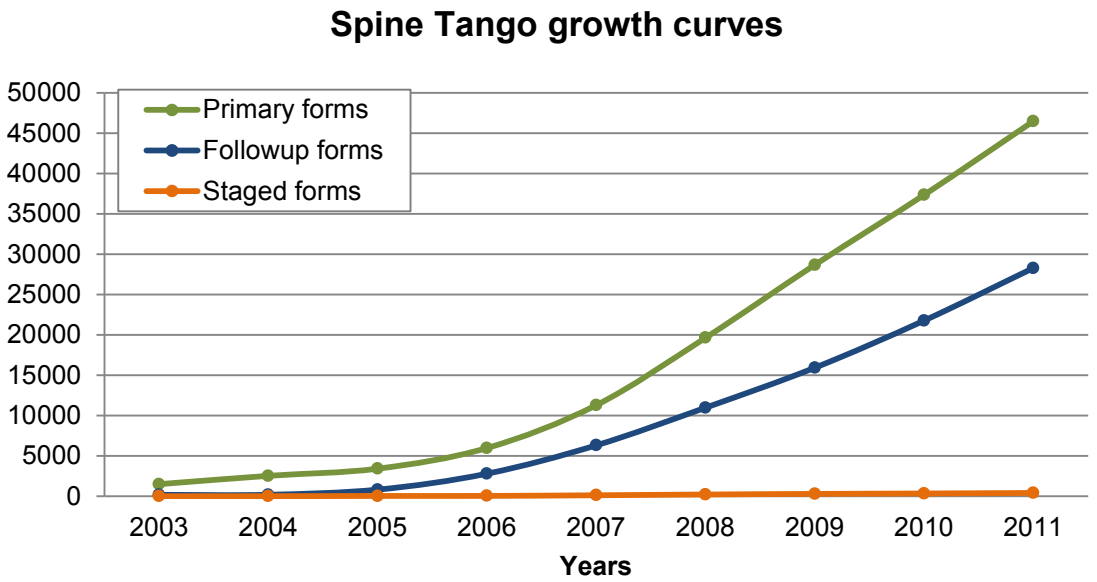


Figure 4: Growth curves of implemented forms (primary and staged surgery and followup) over the years.

Following the 2010 annual report format the following descriptive analysis is based on data of the international Spine Tang pool. Enclosed were all submitted and completed forms versions 2005 and 2006 until the end of the year 2011. The division into four subgroups according to language or geographic regions was maintained: German speaking countries, USA, Scandinavia-Benelux and "Others".

The German speaking group is counting 33 hospitals by the end of 2011 and includes 12 hospitals from Switzerland, 18 from Germany and three from Austria. The US-group is represented by three centers. In the Scandinavia/Benelux group we combined four Belgian hospitals two Finnish and one hospital from the Netherlands. The "Other"-group is comprised of 14 hospitals from different countries. These hospitals are located in Italy (5), Australia (2), UK (2), Mexico, Poland, Singapore, Brazil and Slovenia.

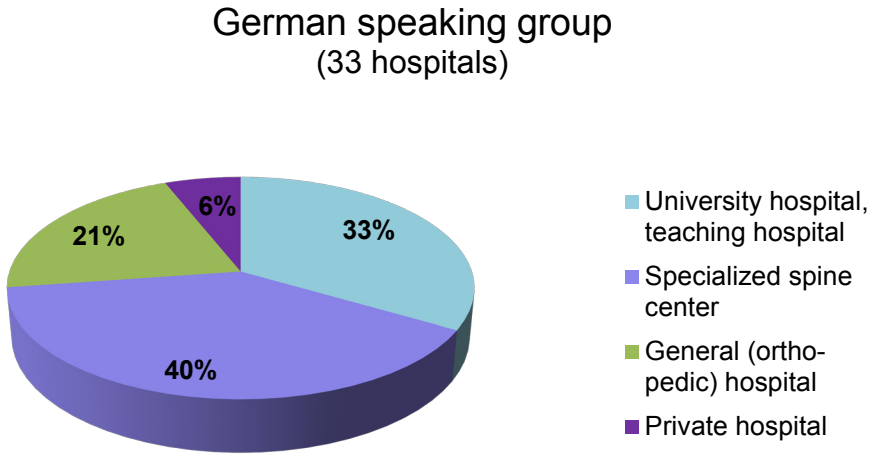


Figure 5: Hospital classification, German speaking group, (33 hospitals)

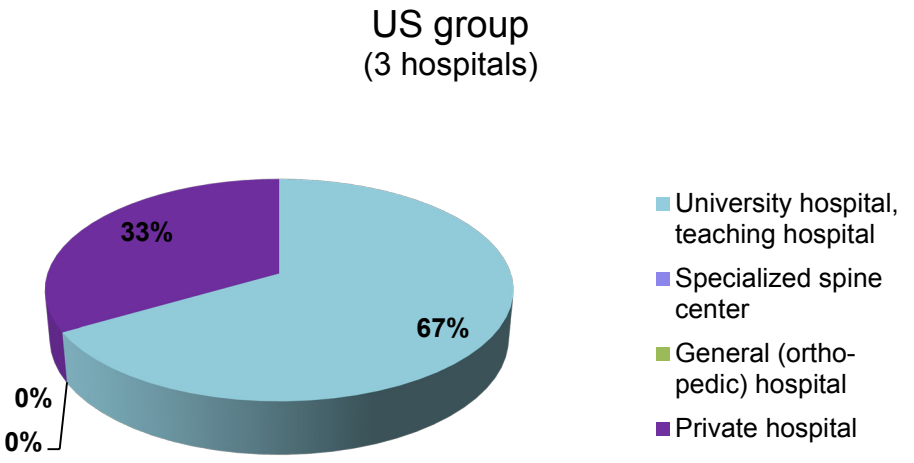


Figure 6: Hospital classification, US group, (3 hospitals)

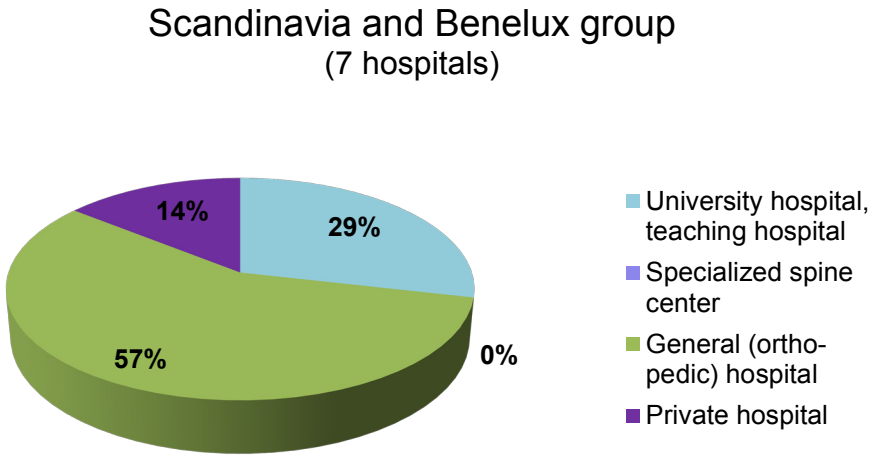


Figure 7: Hospital classification, Scandinavia and Benelux group, (7 hospitals)

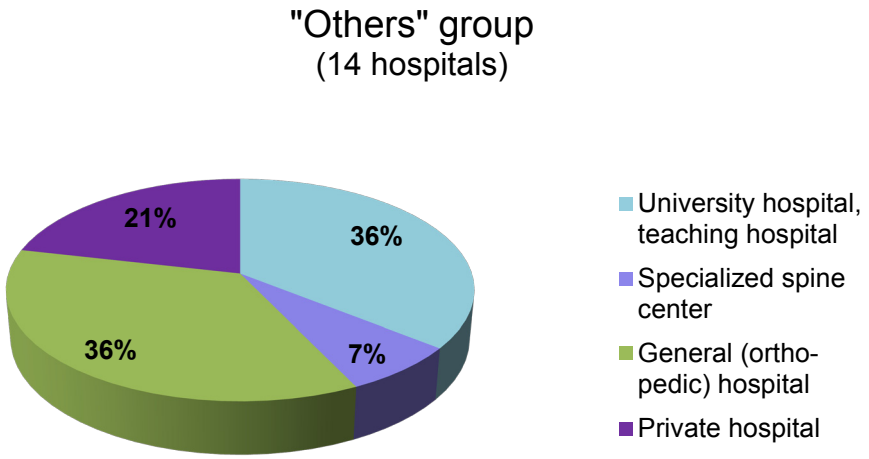


Figure 8: Hospital classification, "Other" group (14 hospitals)

For a more detailed description of the group members the hospitals and centers were classified into the categories: university hospital or teaching hospital, specialized spine center, general or orthopedic hospital and private hospital. The distribution of these categories within the single groups are shown in the figures 5-8.

In the German speaking group specialized spine centers make up the largest part with 40% (13) followed by 11 university and/or teaching hospitals. In the US group two of the three hospitals are university/ teaching hospitals. The Scandinavian and Benelux group has the highest fraction of general or orthopedic hospitals with over 50%. In the "Others"-group the distribution of the classifications is given by five university/ teaching hospitals, five general or orthopedic hospitals, three private hospitals and one specialized spine center. Differences according to the classifications within the groups may also be caused by different health care systems and nomenclatures.

Until the end of 2011 (surgery date) 43988 intrventions could be detected in the database. 27960 in the German speaking group, 2841 in the Scandinavian and Benelux group,7058 in the US group and 6129 in the group “Others”. The figures 9-12 show the distribution of age and gender at surgery for each group.

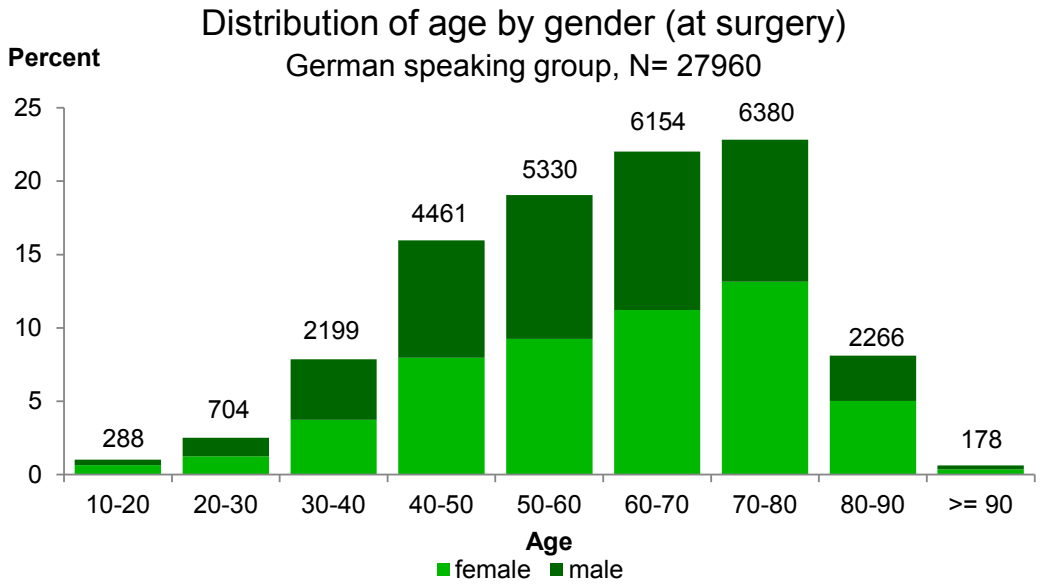


Figure 9: Distribution of age by gender (at surgery), German speaking group, (N= 27960)

In all groups the majority of spinal surgeries are performed at an age between 40 and 80 years. This can easily be explained by the fact that degenerative diseases are the most frequent main pathology as visible in fig. 13 on page 22. Compared to the “Others” groups Scandinavia and Benelux show a relative higher percentage of younger patients (8.9% at and age between 10 to 20 years). In this group one of the hospitals is specialized in deformity surgery in younger patients.

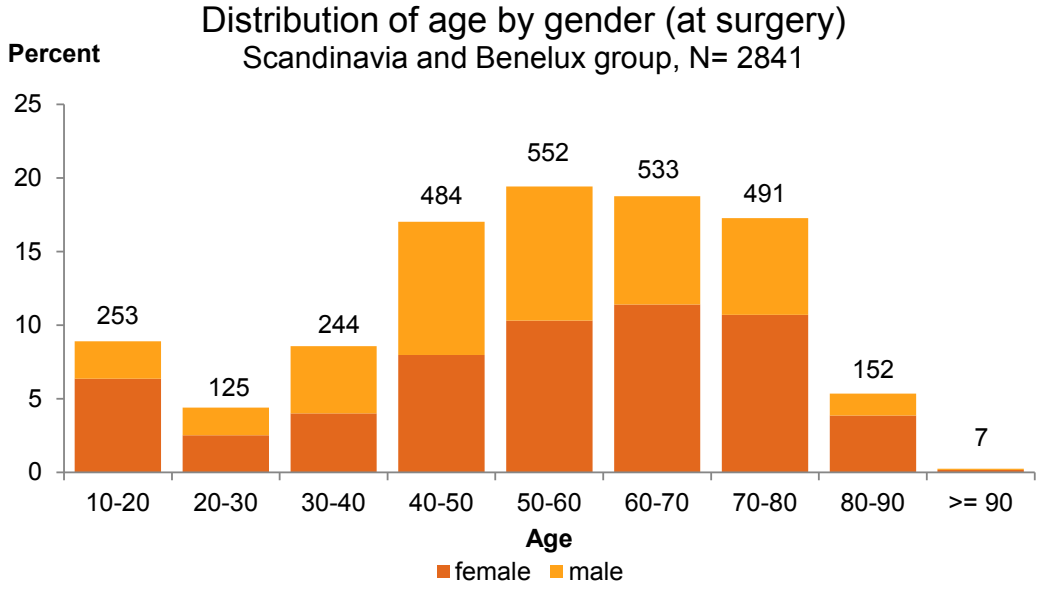


Figure 10: Distribution of age by gender (at surgery), Scandinavia and Benelux group, (N=2841)

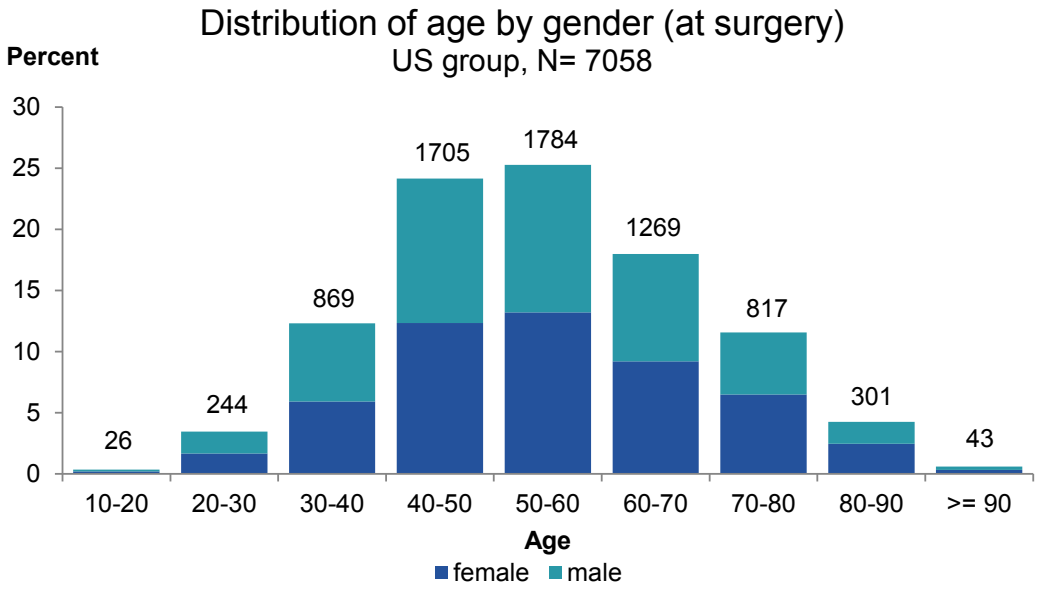


Figure 11: Distribution of age by gender (at surgery), US group, (N= 7058)

In the German speaking group the age distribution shows an older population compared to the "Others" groups with an age maximum between 60 and 80 years (44.8%) where for example the US and the "Others" group have their maximum between 40 and 60 years with 49.4% and 39.6%.

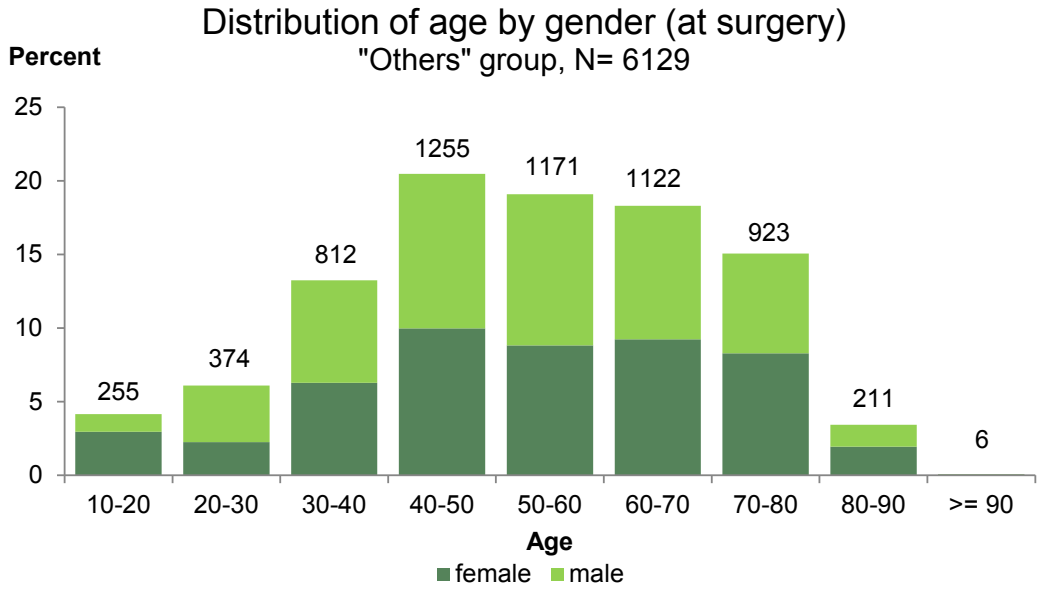


Figure 12: Distribution of age by gender (at surgery), "Others" group, (N=6129)

Numbers of surgeries have considerably risen since the end of 2010, especially in the German speaking group by over 5000 surgeries (2010: 22522 surgeries). They were almost doubled in the „Others" group (2010: 3313 surgeries).

Distribution of main pathology (surgery form)

Degenerative disease as main pathology is clearly dominating the field in all four groups with 75.2% in the German speaking group, 69.0% in the Scandinavian and Benelux group, 78.1% in the US group and 71.8% in the “Others” group.

Failed surgery as main pathology is more often detected in the Scandinavia and Benelux group with 7.6% compared to 2.4 - 4% in the “Others” groups. A similar effect can also be seen in reporting complications. This is largely explainable with the different surgical spectrum in this region as mentioned above.

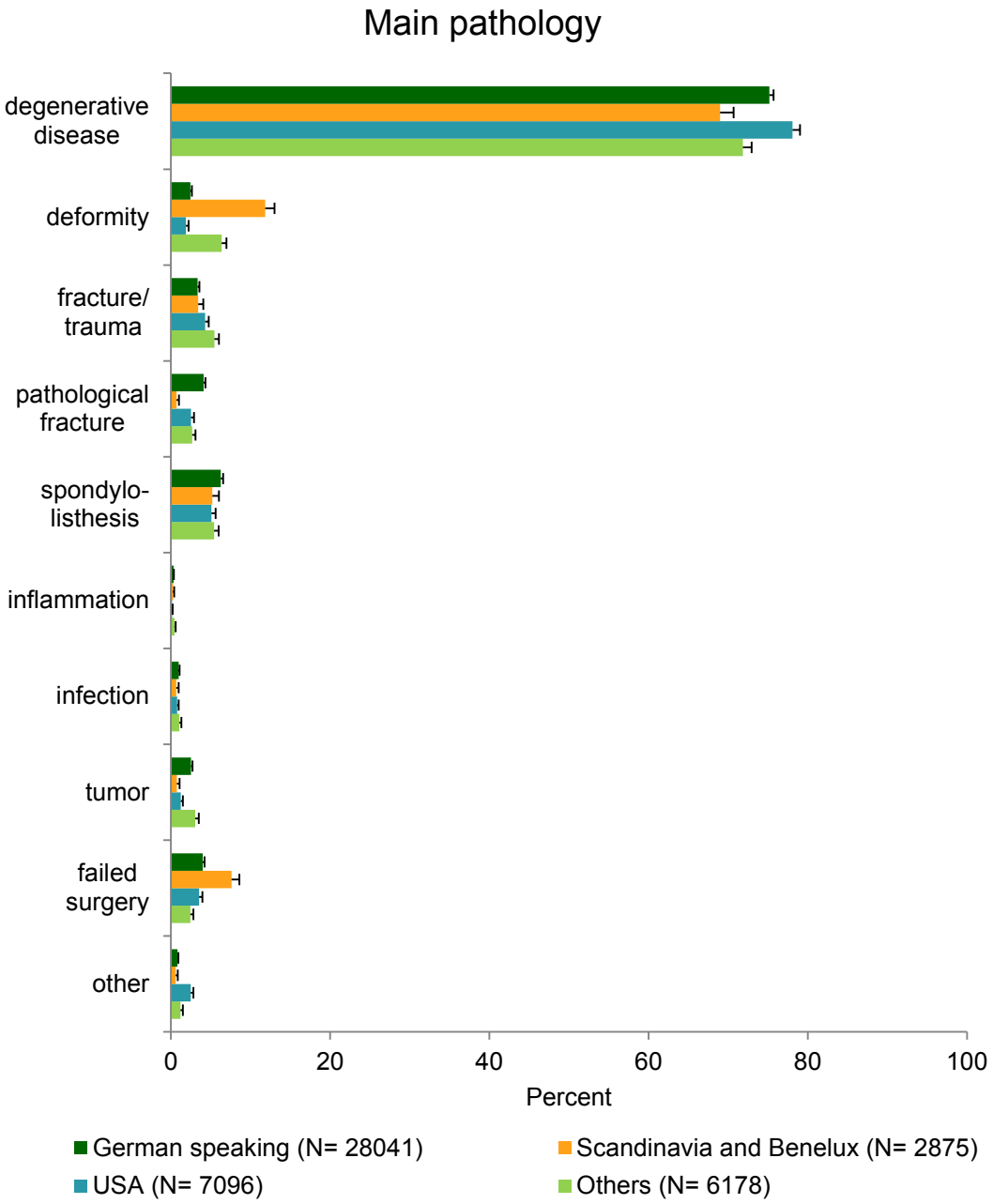


Figure 13: Distribution of the main pathology for the four groups (surgery form)

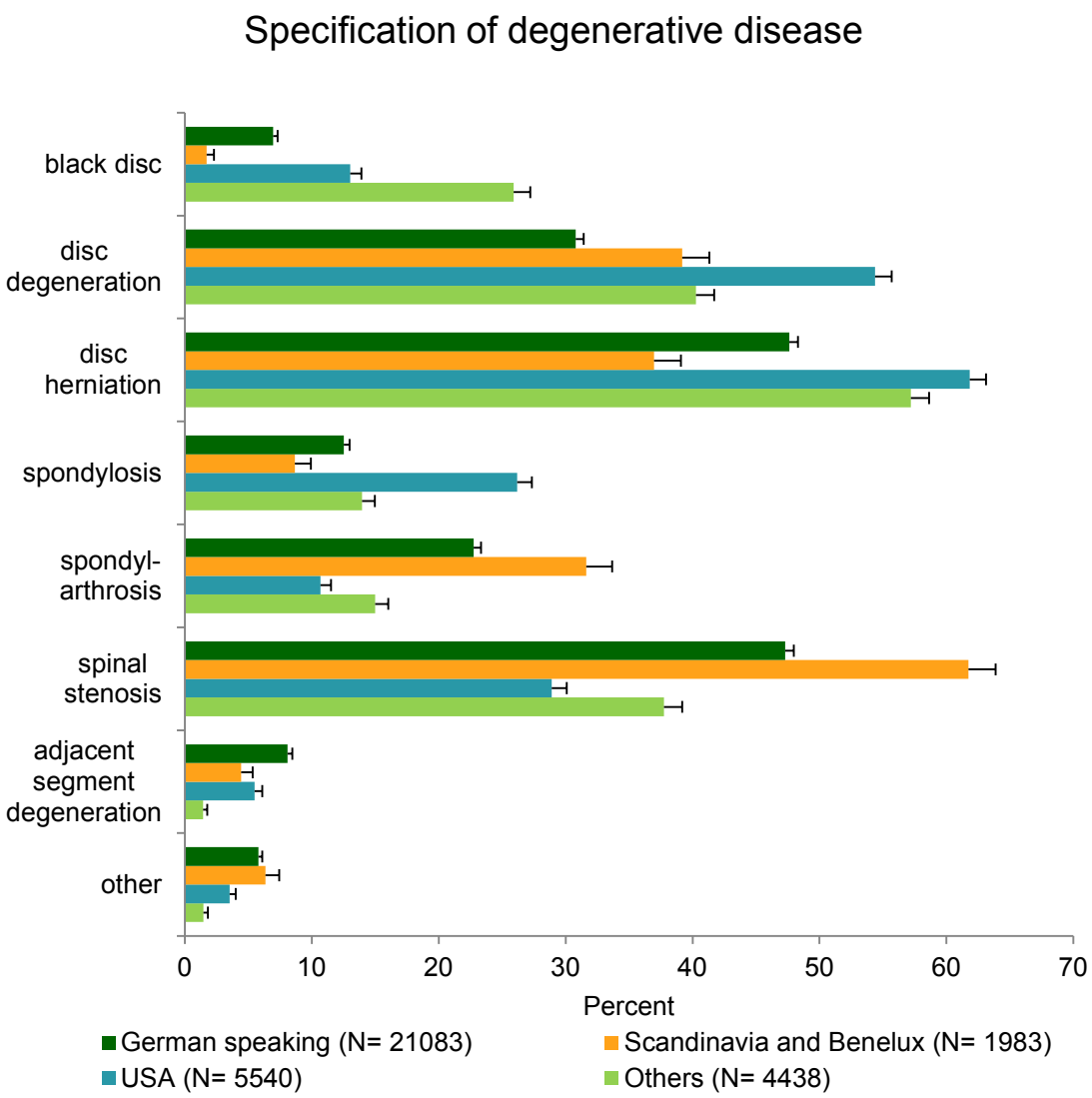


Figure 14: Specification of degenerative disease for the four groups (surgery form)

Fig. 14 gives more details on specifications of degenerative diseases.

The specification of types of degeneration is a multiple choice question so combinations of the single specifications can occur.

The most often recorded specifications are spinal stenosis and disc herniation in the German speaking group with 47.3% and 47.6%. For the Scandinavian and Benelux group spinal stenosis was found to be the most frequently specification with 61.7%. The US group most frequently specified disc herniation with 61.7% and disc degeneration with 39.2%, similar to the “Others” group with 57.2% of disc herniation and 40.3% of disc degeneration. There are other relatively high percentages like black disc with 25.9% in the “Others” group, 26.2% of spondylosis in the US-Group and 31.6% of spondylarthrosis in the Scandinavian and Benelux group.

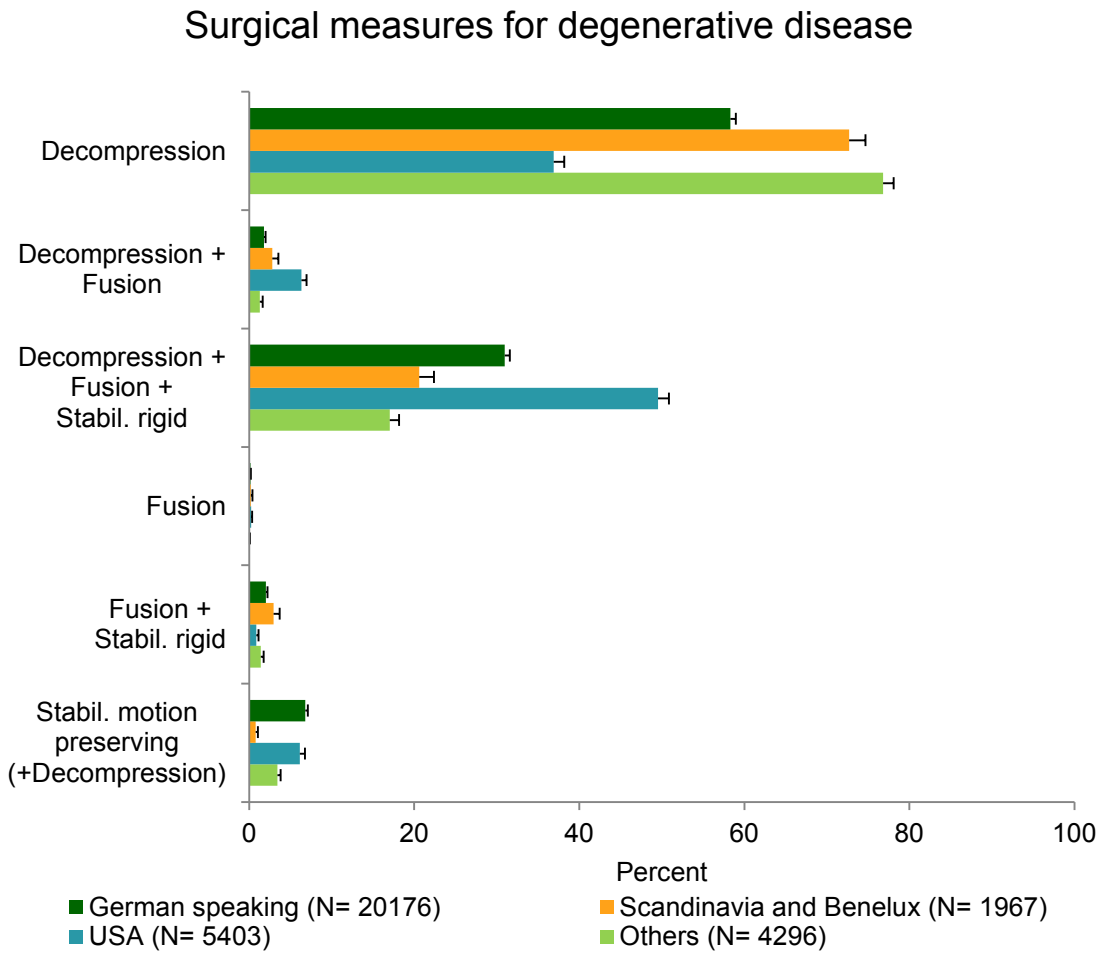


Figure 15: Surgical measures performed for degenerative disease as main pathology, for the four groups (surgery form)

In patients with degenerative disease decompression alone was the most frequently performed technique in the German speaking group (58.3%), the Scandinavian and Benelux group up (72.2%) and the “Others” group (76.8%). In the US group only 36.9% of the patients with degenerative disease were treated this way; rather decompression in combination with fusion and rigid stabilization was performed most often in this group (49.5%).

Motion preserving stabilization with or without decompression had lower application in the Scandinavian and Benelux group and the “Others” group. In combination with decompression or alone the motion preserving technique was performed in 6.8% of cases in the German speaking group and in 6.1% in the US-group.

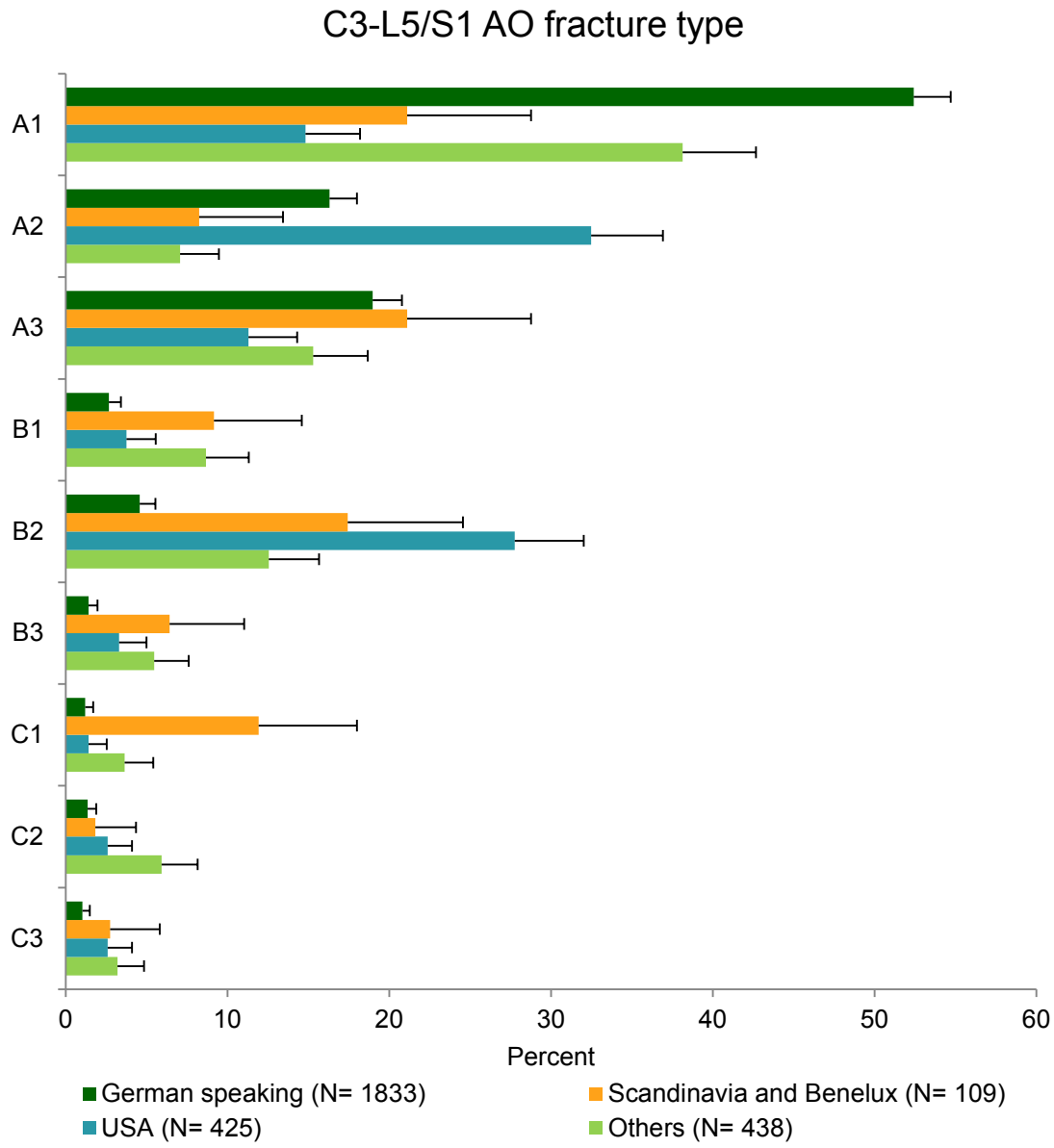


Figure 16: AO fracture types in patients with C3-L5/S1 fracture, for the four groups (surgery form)

The distribution of the AO fracture types is shown in figure 16. Most often described is type A followed by type B and type C. Type A1 is most frequent in the German speaking group (52.4%) and in the "Others" group (38.1%). Scandinavian and Benelux countries show a relatively equal distribution of the fracture types A1 and A3 with 21.1% each and 17.4% of Type B2; C1 is represented with 11.9% in this group. The US group shows the highest distribution of type A2 fractures with 32.5% and B2 types with 27.8%.

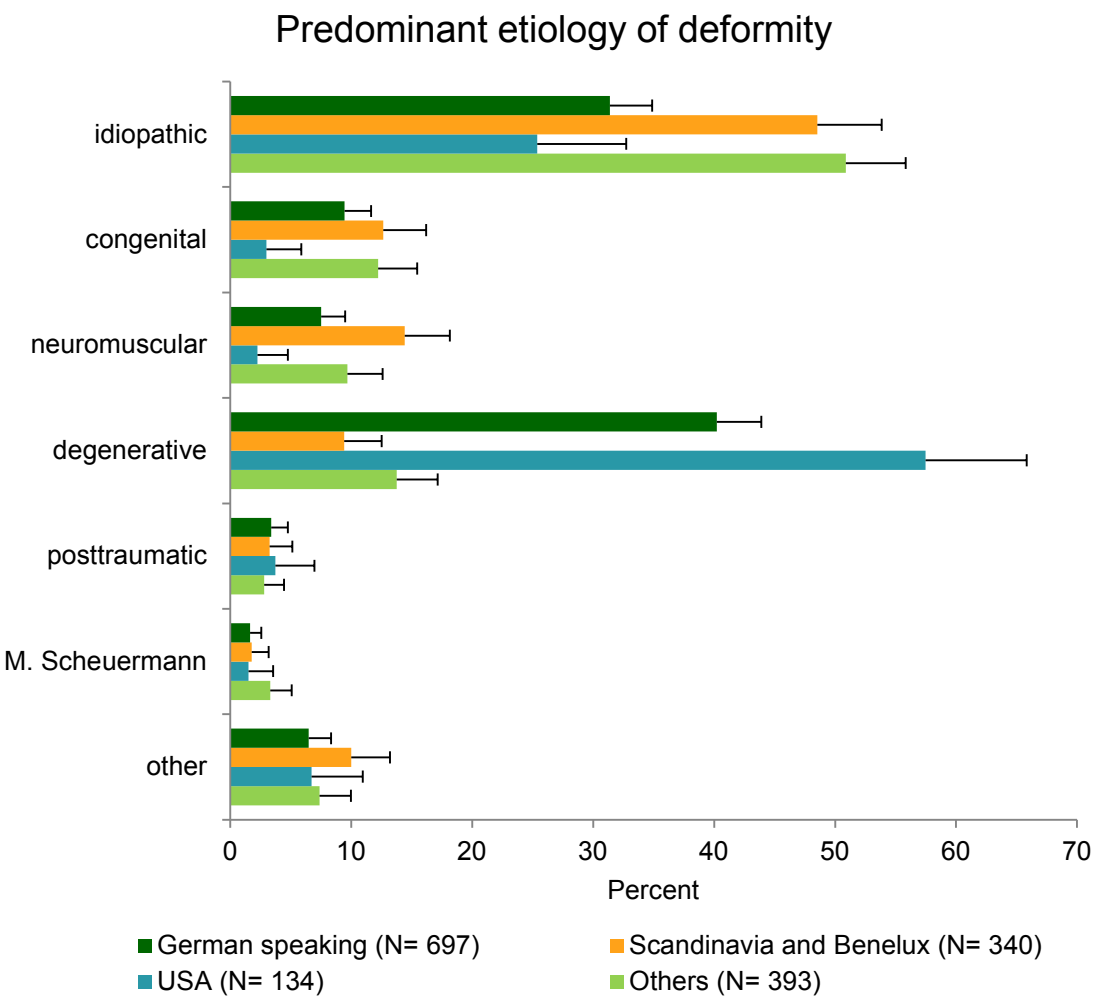


Figure 17: Predominant etiology of deformity, for the four groups (surgery form)

The predominant etiology of deformity is shown in figure 17.

For the German speaking countries and the US group the dominating etiology is the degenerative one with 40.2% and 57.5%. For the Scandinavian and Benelux group and the “Others” group idiopathic etiology of deformity is determined as the most frequent one with 48.5% and 50.9%.

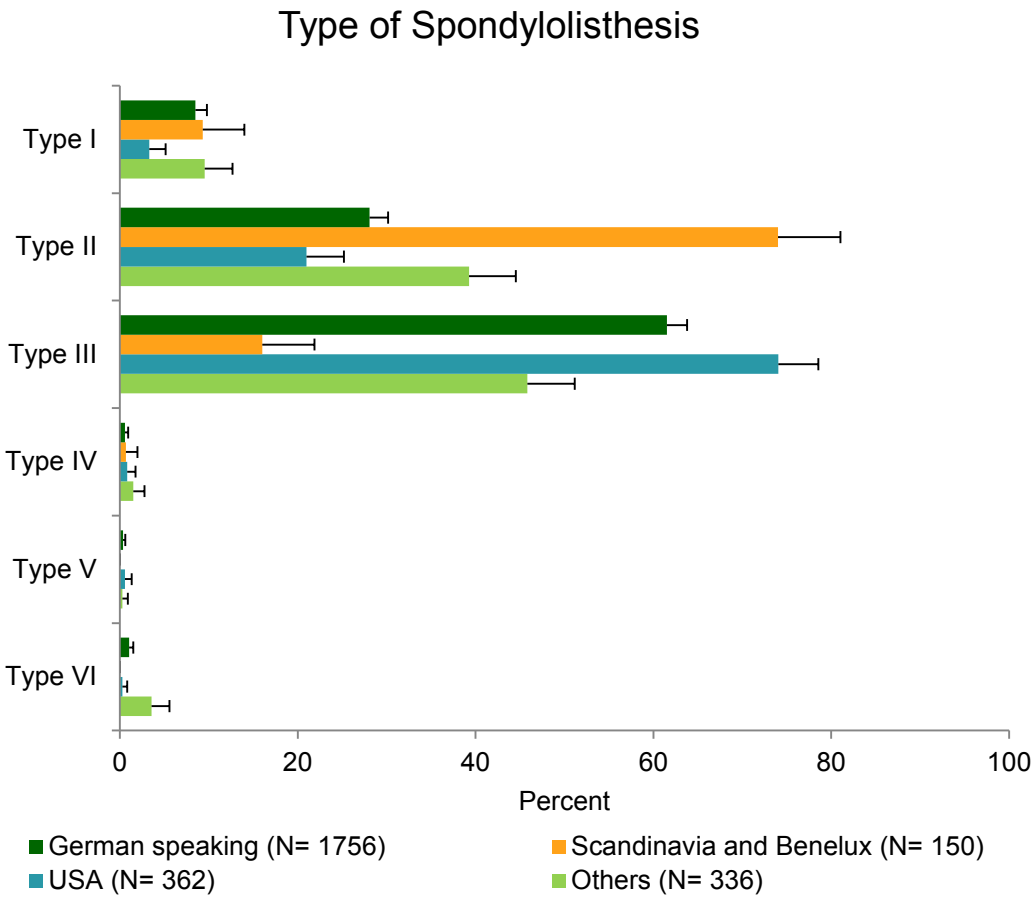


Figure 18: Type of spondylolisthesis , for the four groups (surgery form)

Figure 18 gives the distribution of the spondylolisthesis types for all four groups. In the German speaking group and the US group degenerative spondylolisthesis is the most common one with over 50% (61.5% and 74.0%). In the “Others” group degenerative (Type III) and isthmic (Type II) spondylolisthesis are the most frequent types with 45.8% and 39.3%. In contrast in the Scandinavian and Benelux group 74% of the spondylolisthesis was specified as isthmic spondylolisthesis. Congenital dysplastic spondylolisthesis (Type I) was recorded in less than 10% (3.3%-9.5%) in all four groups. Type IV, V and VI were very infrequently specified.

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 main pathology (surgery form)

The grade distribution for every group for the three most frequent types of spondylolisthesis (degenerative, congential and isthmic) are shown in the following figures. For the congenital spondylolisthesis the case number is very low except for the German speaking group, therefore comparisons cannot be made.

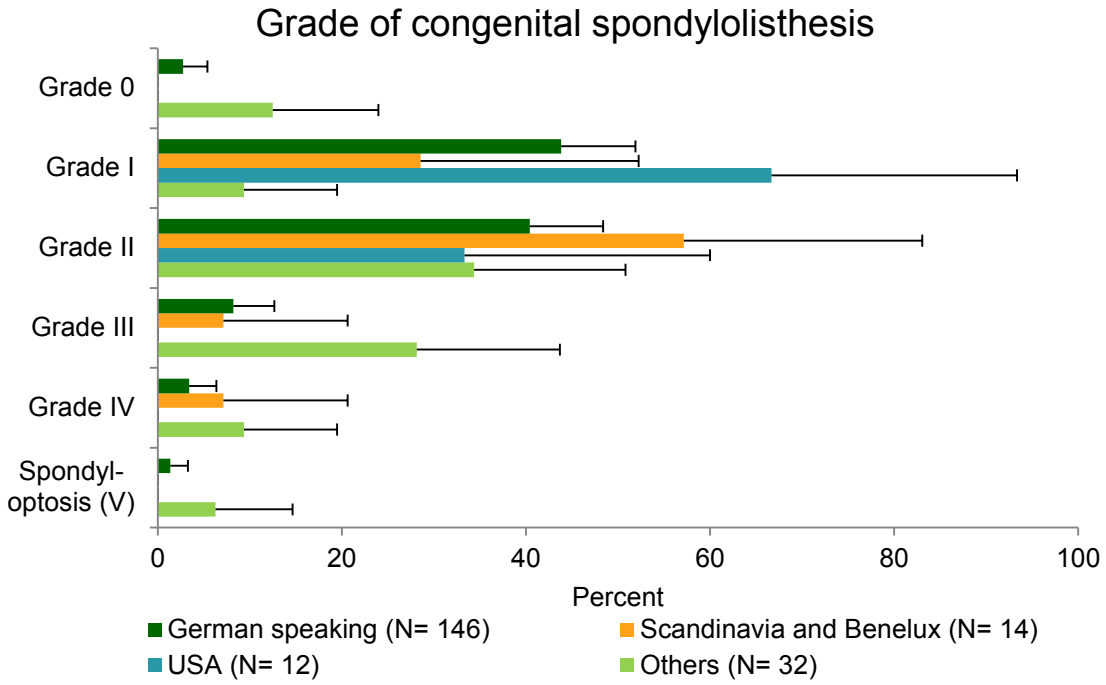


Figure 19: Grade of congenital spondylolisthesis, for the four groups, (surgery form)

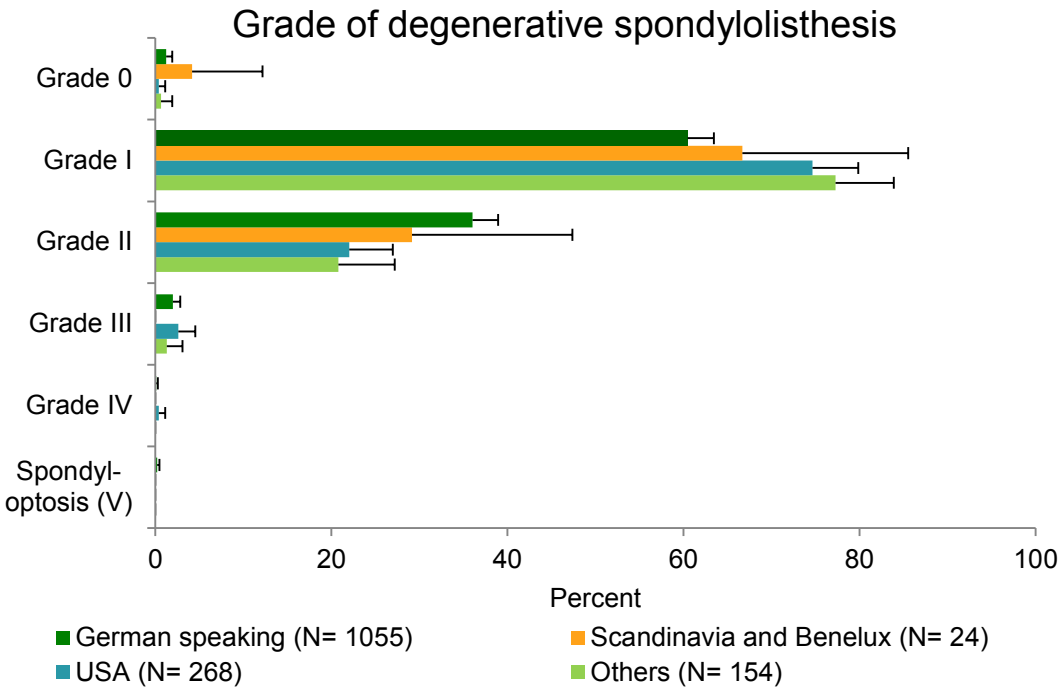


Figure 20: Grade of degenerative spondylolisthesis, for the four groups, (surgery form)

With the exception of the Scandinavian and Benelux group the highest case load is found for degenerative spondylolisthesis. The grade of spondylolisthesis shows a homogeneous distribution for all groups as shown in fig. 20. The most common grade is grade I with over 60% in all groups followed by grade II with 20 - 36%.

For isthmic spondylolisthesis grade I and grade II are nearly equally distributed with 43-56% and 34-48% throughout the four groups. All other grades are much less frequent with <10% in all groups.

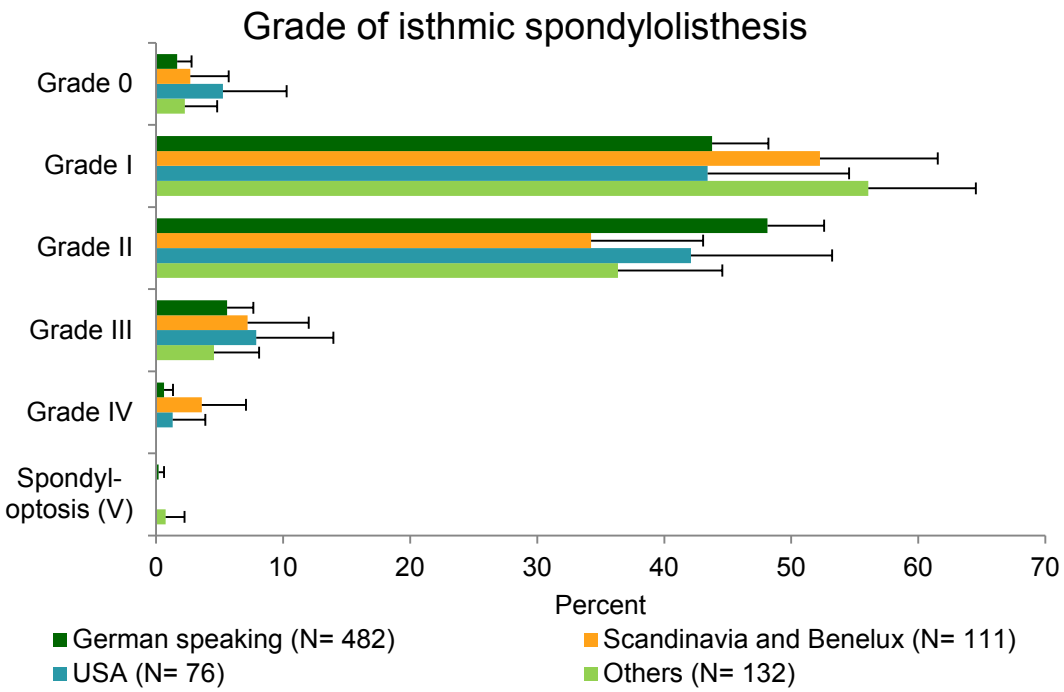
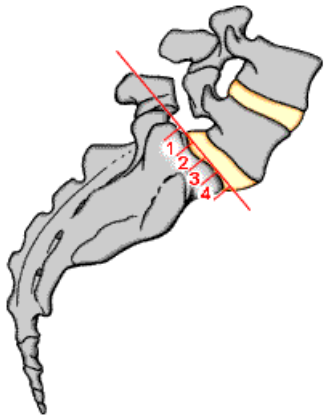


Figure 21: Grade of isthmic spondylolisthesis, for the four groups, (surgery form)

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

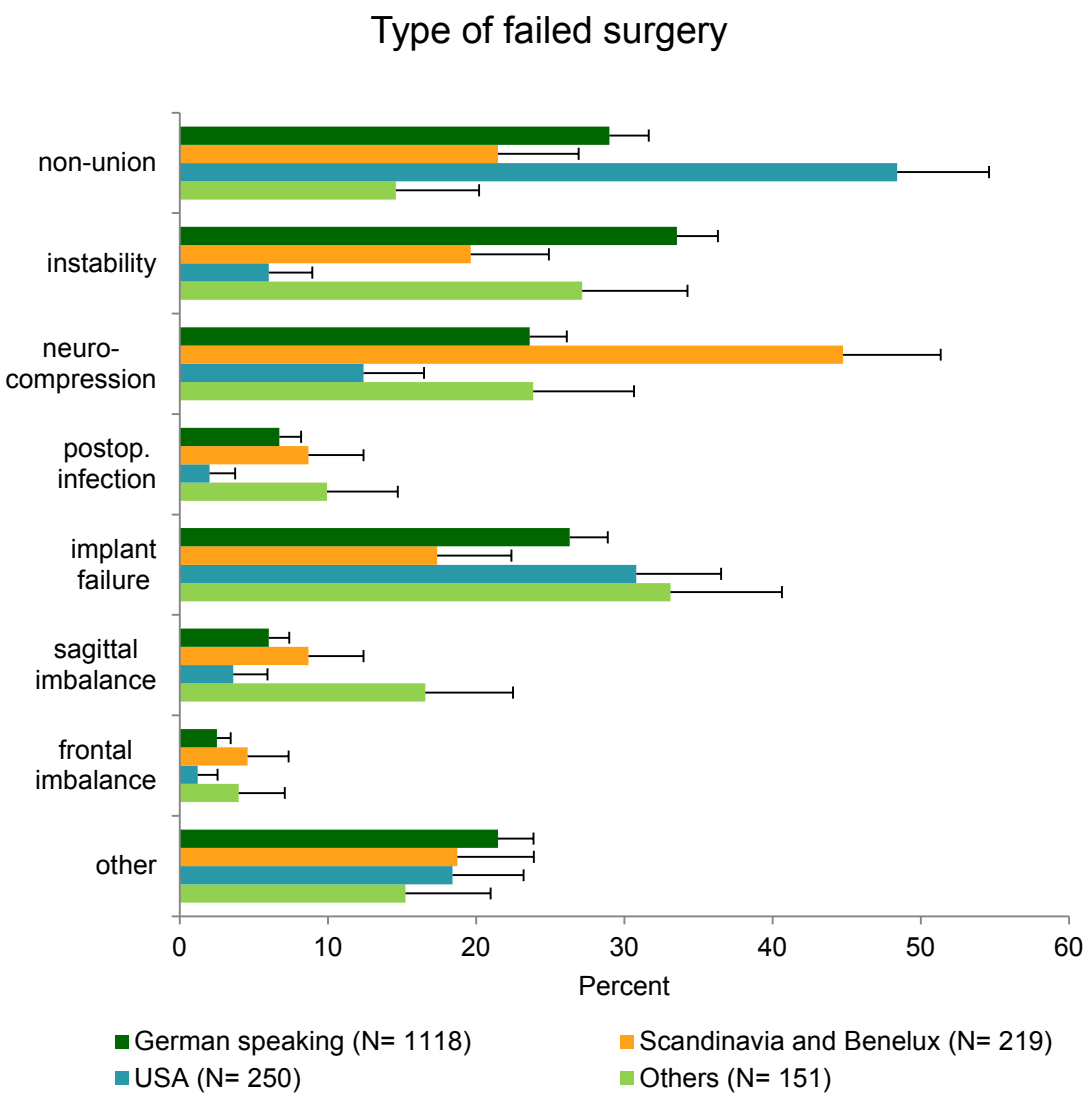


Figure 22: Type of failed surgery, for the four groups, (surgery form)

The main diagnosis “failed surgery” could be found 1738 times until the end of 2011 compared with 1321 counts in the year before. The distribution pattern has not changed much since last year. For the German speaking group instability is the most frequent reason for revision surgery with 33.5% followed by nonunion (28.9%), implant failure (26.3%) and neurocompression (23.6%). In Scandinavian and Benelux countries neurocompression dominates the reason for revision surgeries with 44.7%. In the US nearly half of the revision surgeries are performed due to nonunion (48.4%). Implant failure (33.1%), instability (27.2%) and neurocompression (23.8%) are the three most common types of failed surgeries in the “Others” group.

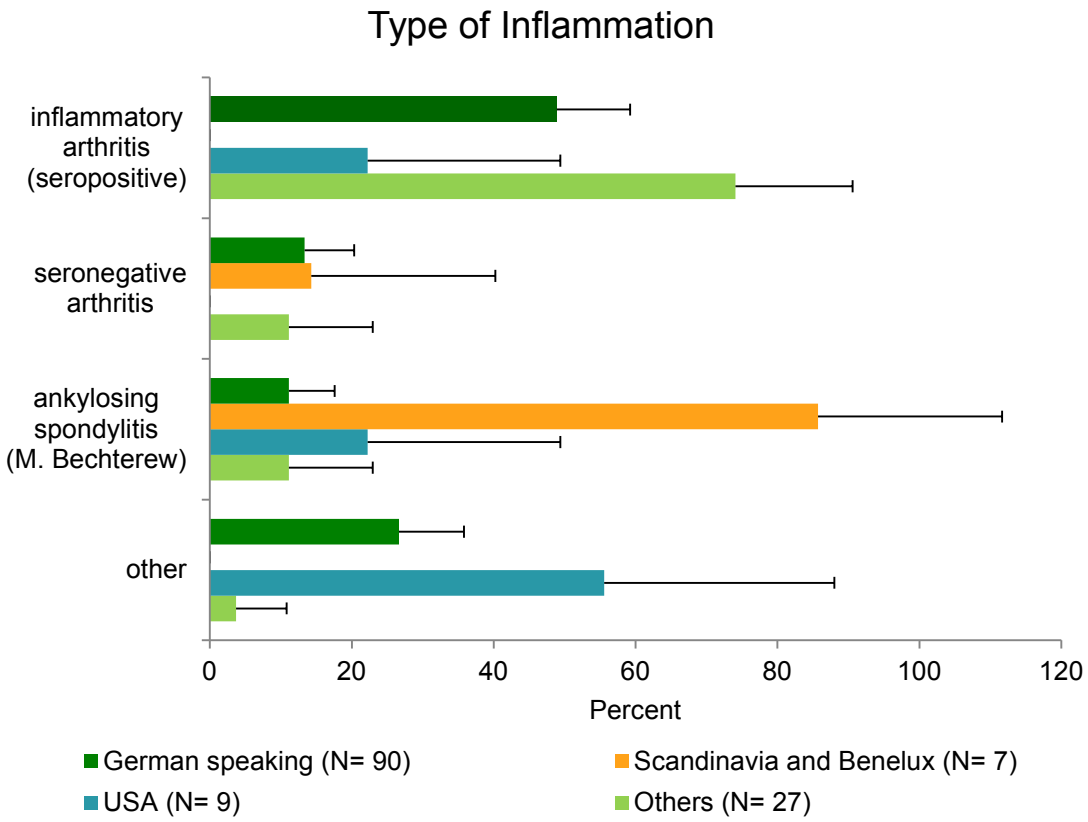


Figure 23: Type of inflammation/infection, for the four groups, (surgery form)

133 cases of inflammation as main pathology with surgical intervention could be found in the database. The overall low numbers and large confidence intervals do not allow any sound conclusions yet.

Complications (surgery form)

The following figures show the distribution of the surgical and general complications. The answer “none” is not shown; it was the most frequent answer with 95.8% in the German speaking group, 87.9% in the Scandinavian and Benelux group, 98.4% in the US group and 93.3% in the “Others” group. Combining all patients in the Spine Tango database a complication rate of 4.7% can be calculated.

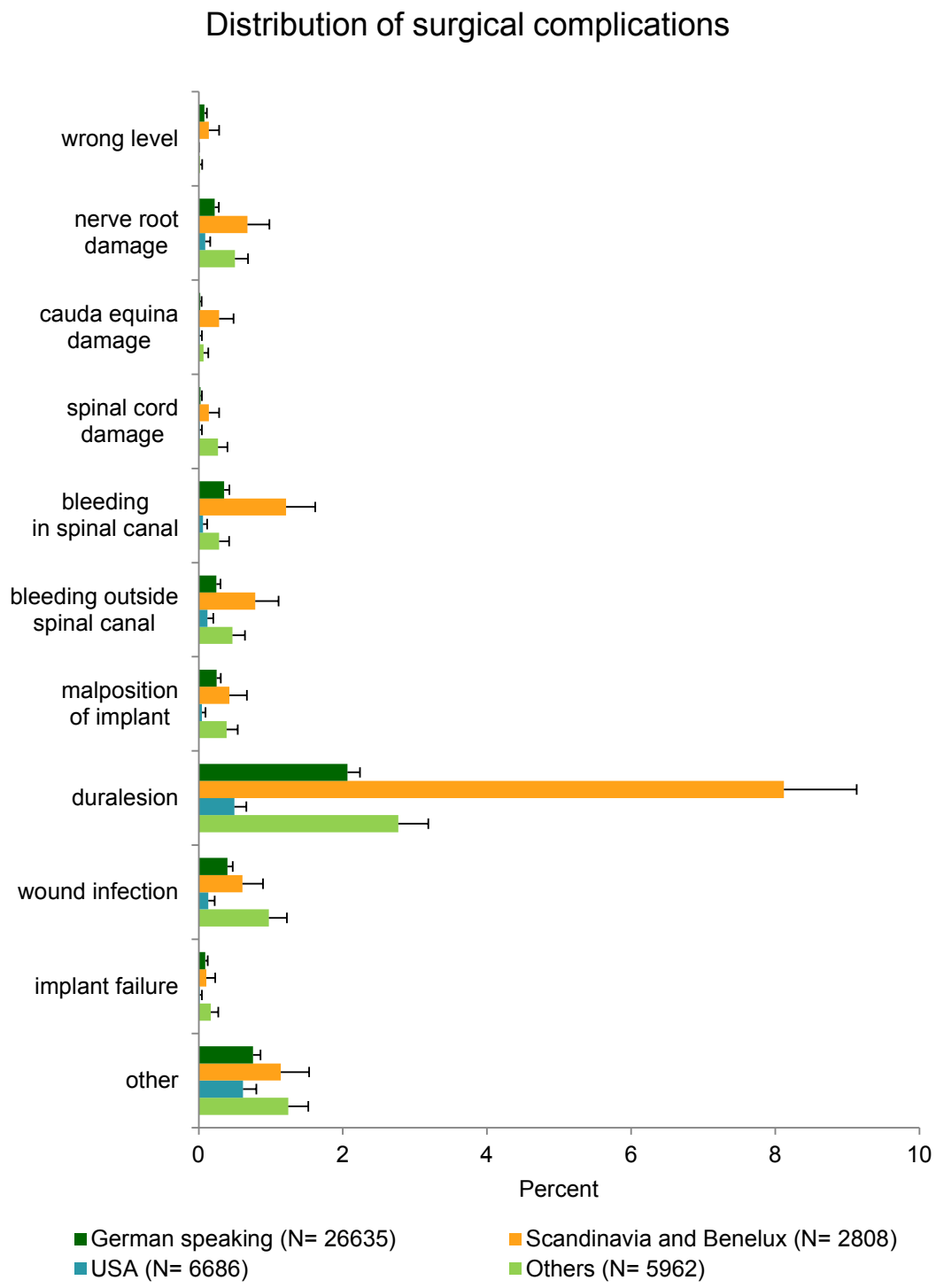


Figure 24: Surgical complications for the four groups, excluded was the answer “none” (surgery form)

Complication reporting is the weakest point of any data collection without written adherence to a code of conduct or monitoring mechanisms. These concepts are unfortunately introduced with delay to the Spine Tango community due to changing strategies of the Excom. Moreover, the different dura lesion rates are most probably explained by strict or less strict interpretations of a dura lesion. Anything from a superficial dural lesion, to a tear, up to a leakage or a revision procedure for a leakage can be deemed a “duralesion” that is worth being recorded. The Spine Tango dictionary of terms proposes definitions for all items and helps to harmonize the understanding, interpretation and capture of such events.

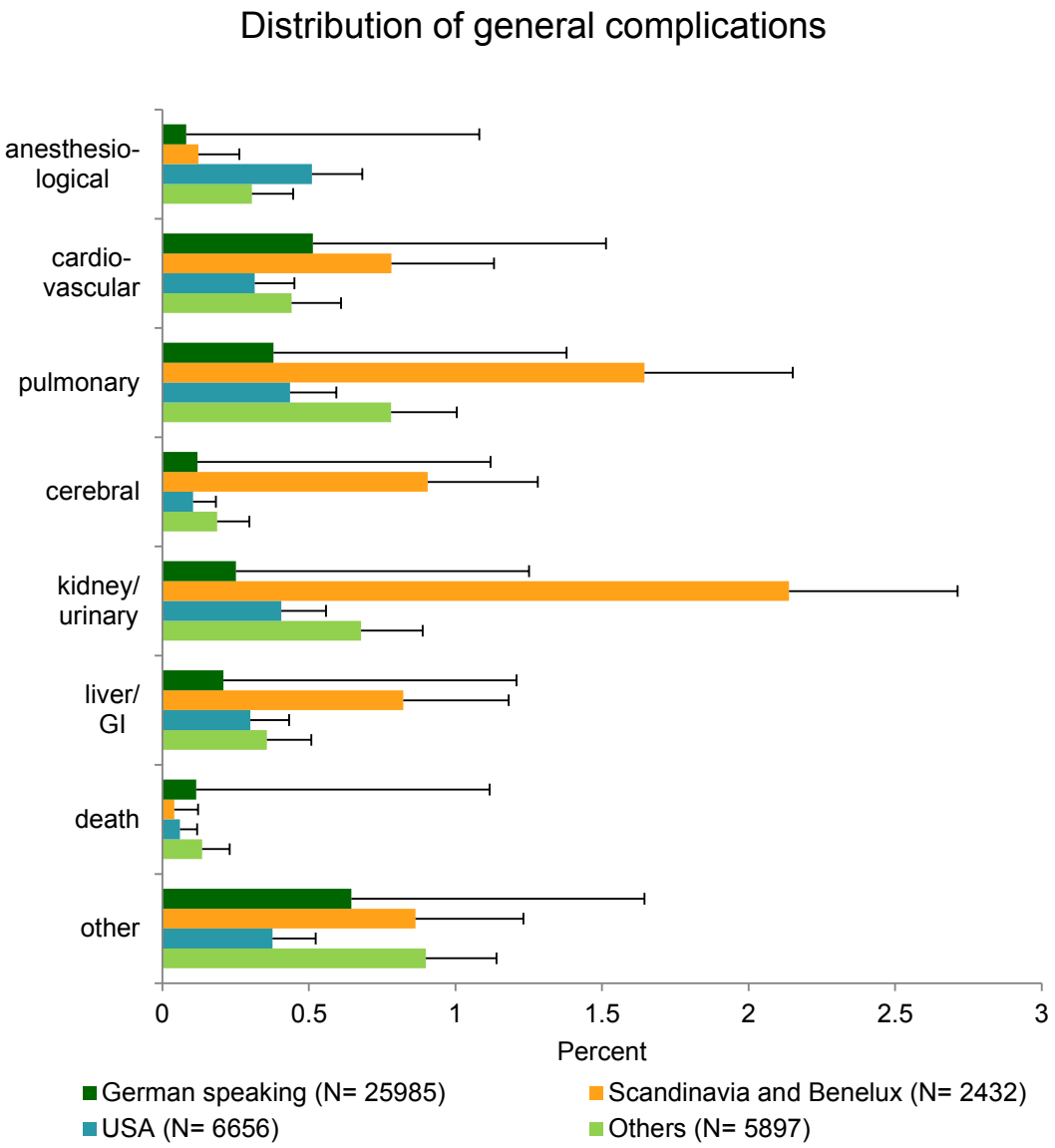


Figure 25: General complications for the four groups, excluded was answer “none” (surgery form)

The percentage of patients without any general complications (answer “none” not shown) for the four groups are the following: German speaking group: 98.0%, Scandinavian and Benelux group: 93.5%, US group: 97.9% and “Others” group: 96.8%.

In the following section we refer to the Spine Tango follow up form.
Figure 26 shows the distribution of the followup forms for each group. A general decrease of documented followups over time is obvious in all groups.
The best percentage of long-term followups is represented by the Scandinavian and Benelux group with 23.9% at 6 months, 16.2% 1 year postoperative and 6.4% 2 years postoperative.
In the US group the most frequent followups are reported after 6 weeks with 60.1%.

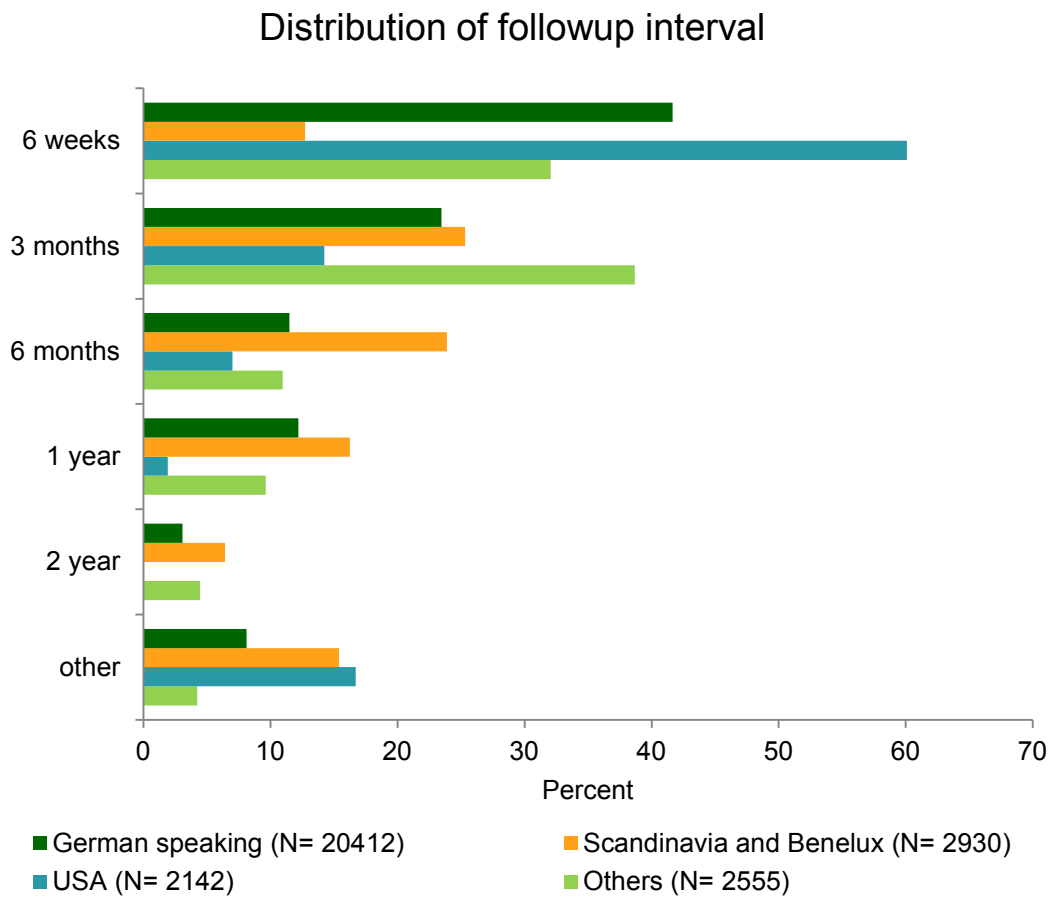


Figure 26: Distribution of followup interval (followup form)

Figures 27-29 show the overall outcome from the examinator's point of view for three different time followup intervals. The 3 and 6 month followup groups have good sample sizes and allow the conclusion that the majority of outcomes are rated as excellent or good in the eyes of the surgeons even if the 6 month followups show a slight increase in "fair" ratings, especially in the German speaking group. Longer-term followups of 1 year are increasingly visible in this language region and will allow for better outcome assessments in the future.

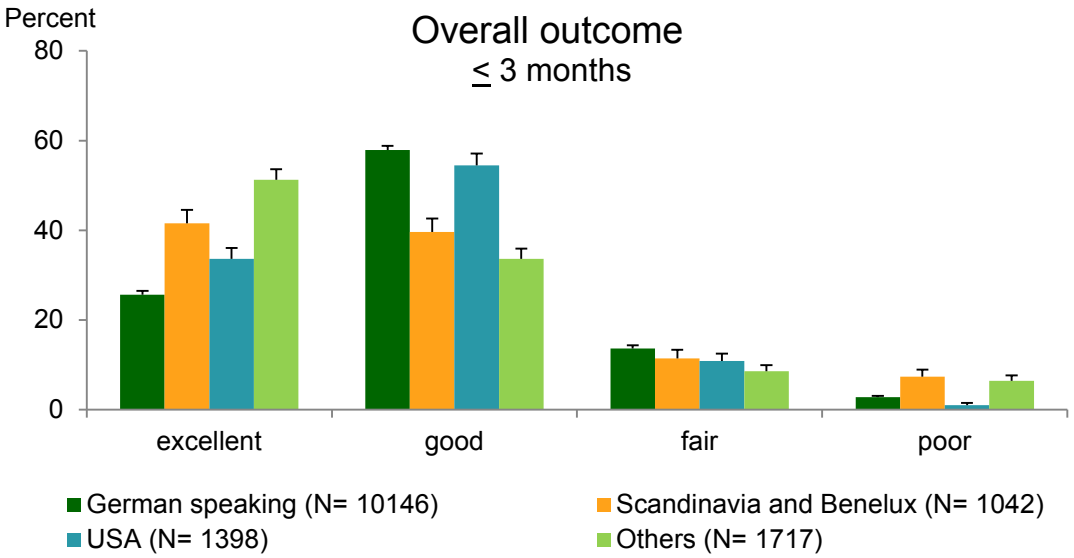


Figure 27: Overall outcome (surgeon) for all four groups at a followup < 3 months (followup form)

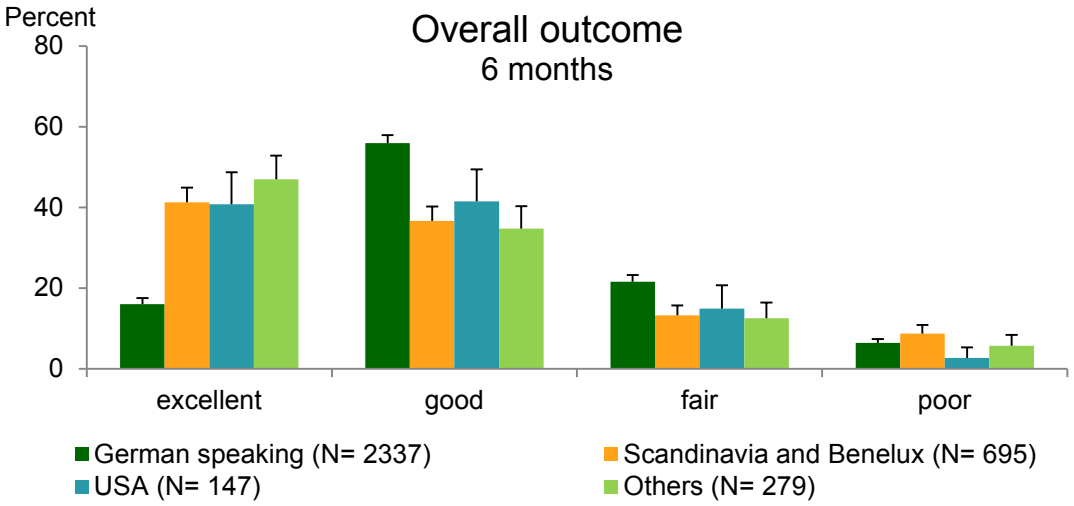


Figure 28: Overall outcome (surgeon) for all four groups at a followup of 6 months (followup form)

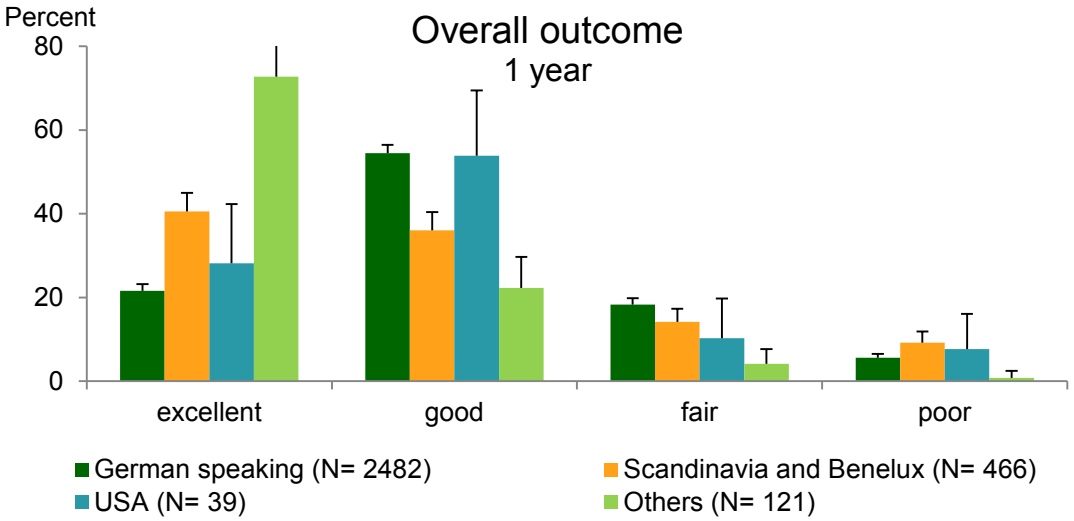


Figure 29: Overall outcome (surgeon) for all four groups at 1 year followup (followup form)

Surgical goals – pain relief (followup form)

The following pages show the achievement of surgical goals according to the different followup intervals. Achieved pain relief as surgical goal shows high percentages in all four groups (around 45-80% depending on the followup interval). The highest values are achieved in the “Others” group (80.5% at 6 months FU), the lowest in the German speaking group with 43.0% also at 6 months FU. The subjectivity of the physician based outcomes is well known and must be considered in this context.

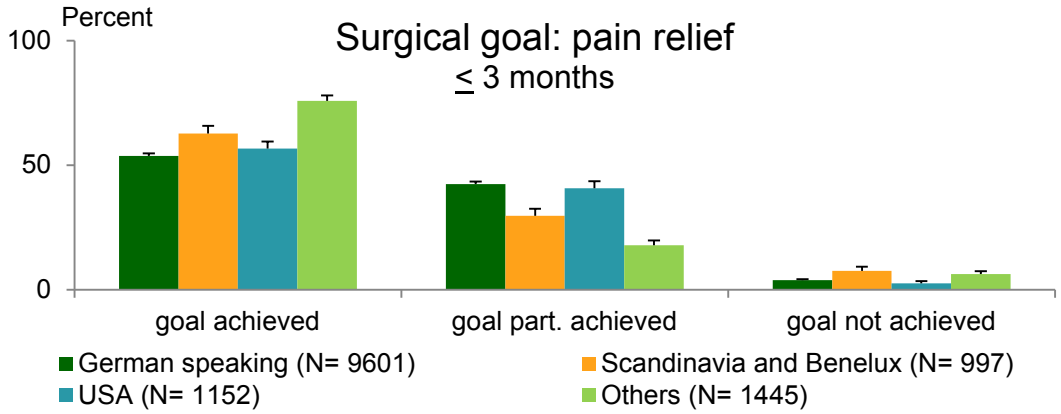


Figure 30: Surgical goal: pain relief for all four groups at a followup < 3 months (followup form)

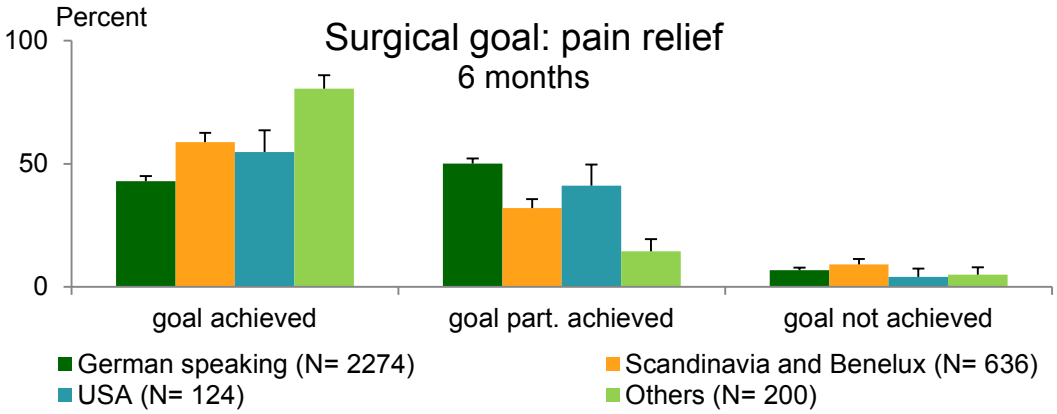


Figure 31: Surgical goal: pain relief for all four groups at a followup of 6 months (followup form)

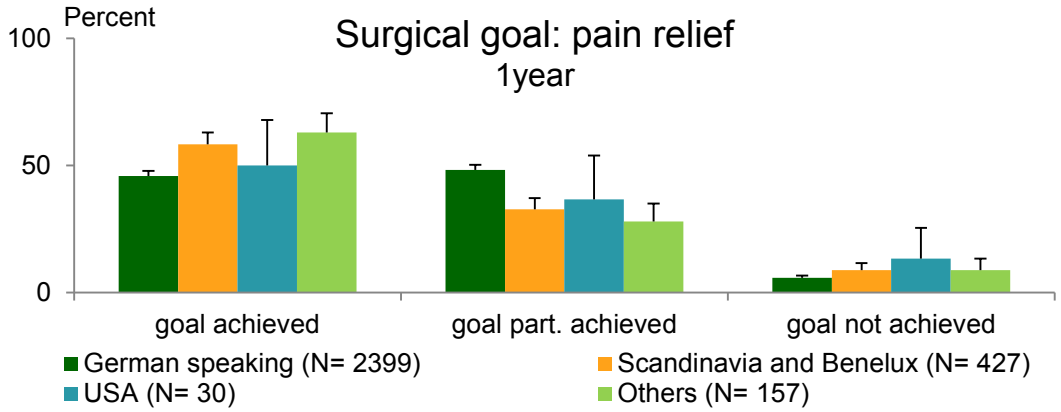


Figure 32: Surgical goal: pain relief for all four groups at a followup of 1 year (followup form)

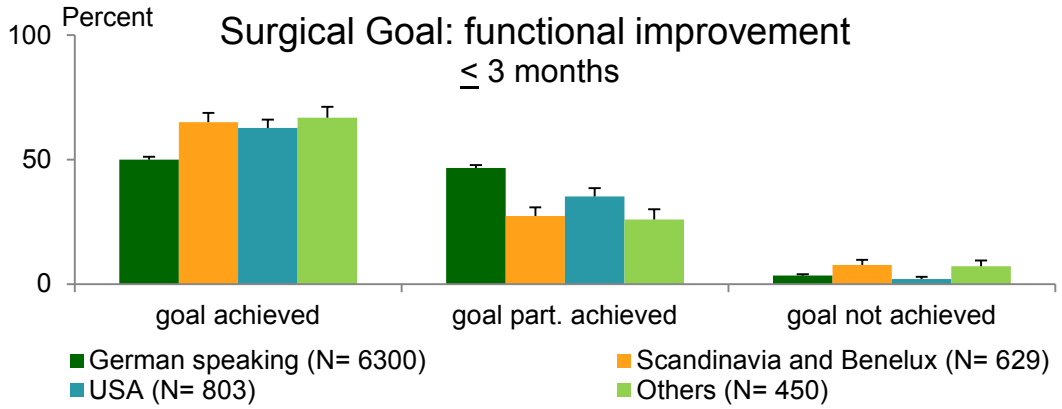


Figure 33: Surgical goal: functional improvement for all four groups at a followup <3 months (followup form)

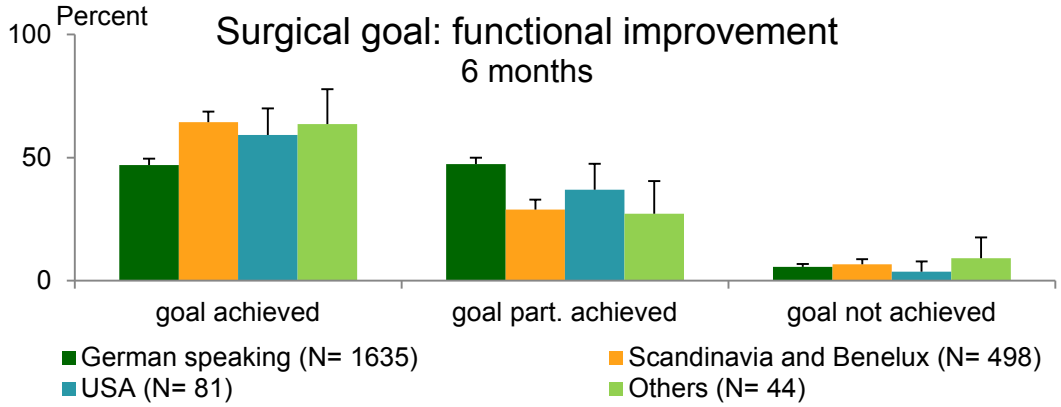


Figure 34: Surgical goal: functional improvement for all four groups at a followup of 6 months (followup form)

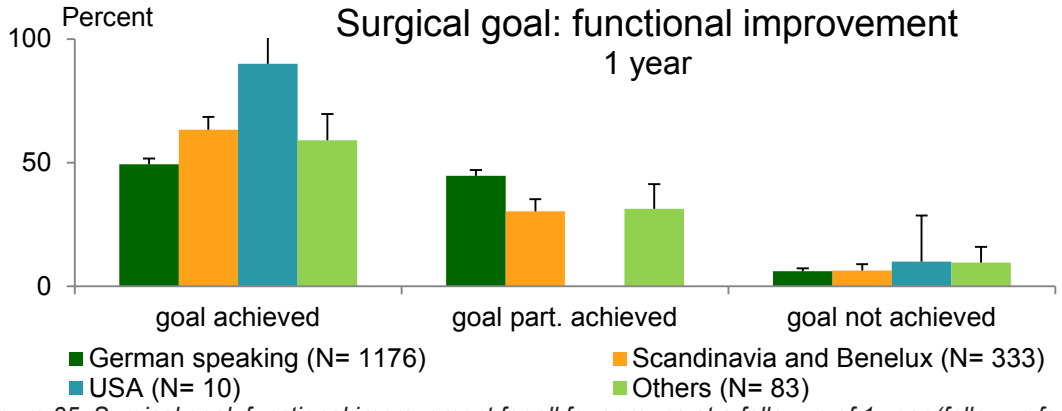


Figure 35: Surgical goal: functional improvement for all four groups at a followup of 1 year (followup form)

Functional improvement as an achieved surgical goal showed the lowest rates in the German speaking group (47.0%) at 6 months FU but with a higher percentage as partially achieved goal. For the “Others” groups the distribution is quite similar with achievement of functional improvement in around 60%. Functional improvement as not achieved goal is comparable to pain relief with low distribution in all four groups. Due to very low numbers of observations in the 1 year follow up interval the US group cannot be included in any interpretations at this time point.

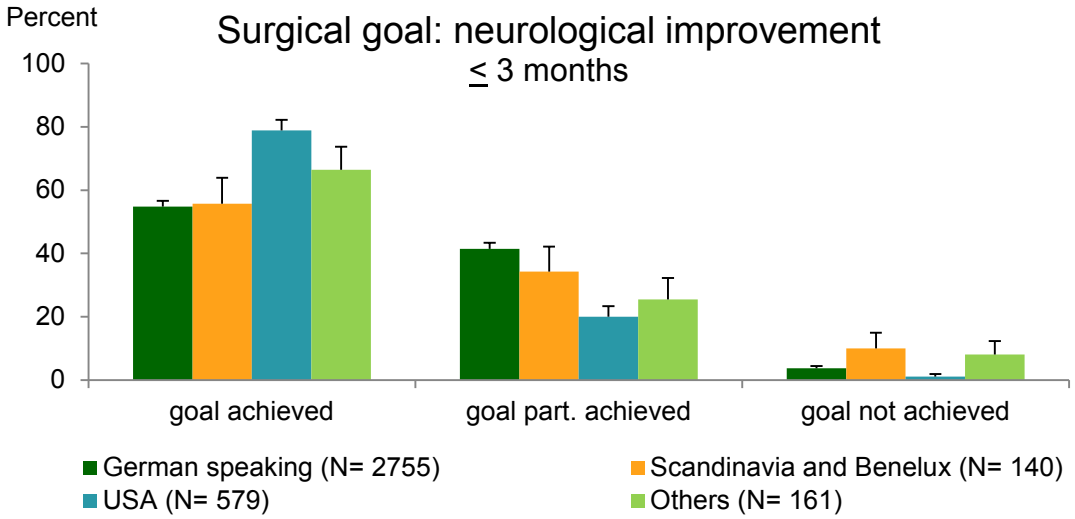


Figure 36: Surgical goal: neurological improvement for all four groups at a followup<3 months (followup form)

Only the German speaking group has a sufficient number of long term followups (1 year) to conclude that achievement of neurological improvement rises from about 50% at 6 weeks to 60% at one year. Especially the US group seems to have more favorable neurological improvement at 6 weeks, but later followups are too low in numbers to assess the further course of the neurological status of patients.

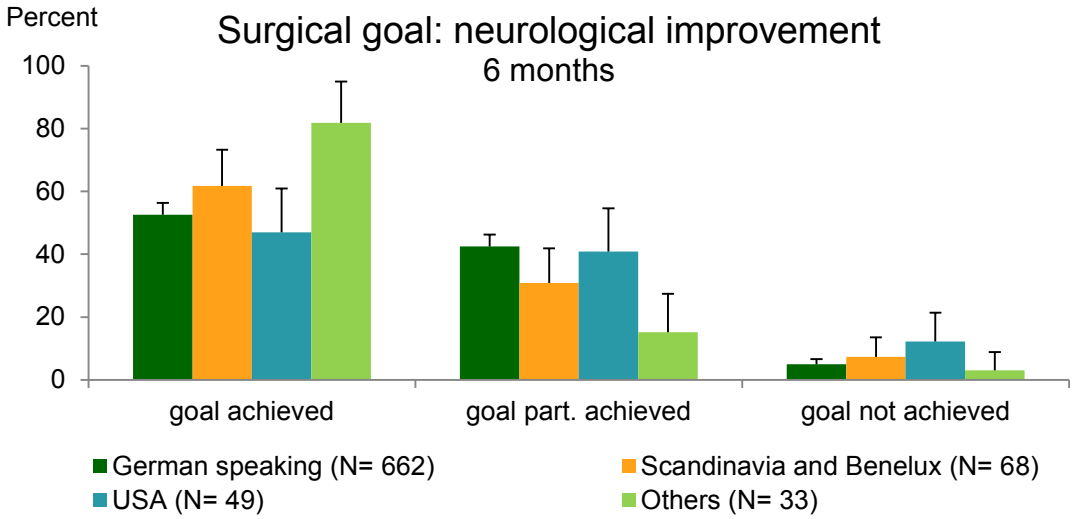


Figure 37: Surgical goal: neurological improvement for all four groups at a followup of 6 months (followup form)

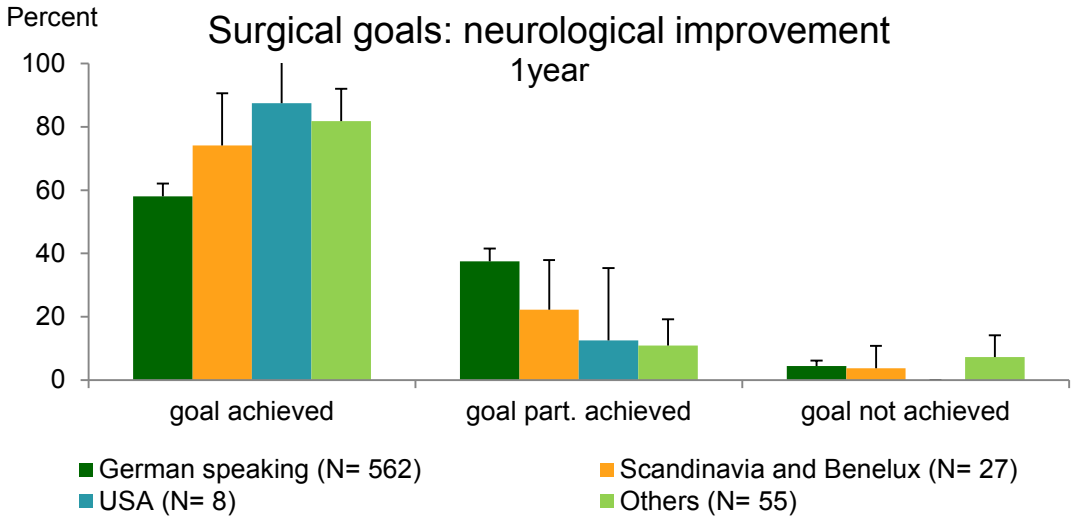


Figure 38: Surgical goal: neurological improvement for all four groups at a followup of 1 year (followup form)

PREFACE

The Spine Tango benchmarking project aims at creating benchmarks, i.e. reference values for patient characteristics, treatment practices and outcomes. Reference values shall be representative for the typical patient profile, treatment practice given a certain pathology, and the outcome that can typically be expected when a typical patient with a specified diagnosis receives a certain treatment. These benchmarks shall then serve for comparison of individual participants, their patients, treatments and outcomes with the reference values generated by the respective peers.

A problem in the Spine Tango data pool is the heterogeneity of data donators, the relatively uncontrolled data entry and the potential influence of healthcare systems on the benchmarks. Hence, instead of simply using the complete data pool for generating a benchmark, the distribution of data for a certain co-variate must be carefully assessed, and those participants and their patients must be excluded that are obviously aberrant from the benchmark that the rest of the data forms. The reasons for these aberrancies may or may not be or become obvious upon further data analysis.

The benchmarking project will only include patients with degenerative diseases since they form the majority of cases in spinal surgery and also in the Spine Tango datapool.

Table 03: Epidemiology (age) for spinal surgery patients with degenerative disease.

	Regional age for considered clinics				Overall age (all regions)		
Diagnosis	German speaking	Scandina-via & Benelux	USA	Other	N clinics >30 cases	N considered clinics	Age
Black disc or disc degeneration	51.9	44.1	50.3	48.3	19	12	50.9
Disc herniation only	50.1	46.0	46.6	46.3	42	23	47.0
Adjacent segment degeneration	66.7	60.1	56.6	-	14	8	62.7
Spinal stenosis+ disc herniation	63.8	54.5	59.7	60.4	12	5	59.4
Spinal stenosis + spondylarthrosis	69.4	68.4	68.3	65.6	13	11	69.2
Spinal stenosis only	68.6	63.8	62.9	66.0	37	23	66.7
Spondylarthrosis	59.4	60.7	61.9	-	10	7	59.7
Spinal stenosis + disc hern.+ spondylarth.	67.7	65.6	51.1	65.9	10	5	65.6
Degenerative spondylolisthesis	65.0	-	67.1	60.4	13	9	65.4
All others	59.0	53.4	59.2	48.6	17	11	58.9

The epidmiology of spinal surgery patients with degenerative diseases shows that only in very few pathologies like spinal stenosis with spondylarthrosis or spondylarthrosis alone (orange fields) there is an internationally similar age at which patients are operated. In most other pathologies the healthcare system seems to have an important impact on the timing of surgery and therefore national age benchmarks are required.

The female:male ratio in most degenerative diseases is around 50% +- 5%, with the exception of degenerative spondylolisthesis, where about two thirds of patients are women (table not shown). As opposed to the age distribution, the sex distribution is more homogeneous across the region groups and hence international benchmarks can be created for most degenerative pathologies.

The two most important surgically treated degenerative diseases in the benchmarking sample are disc herniation and spinal stenosis, making up about two thirds of all degenerative diseases. Hence, the following further analyses will focus on these two most relevant pathologies.

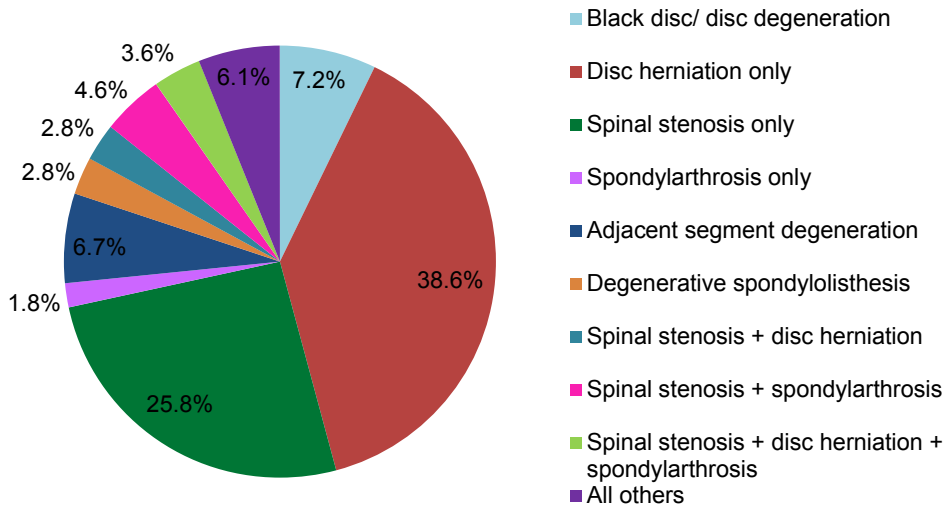


Fig. 39: Proportions of different degenerative diseases in the complete benchmarking sample

OUTCOME INFORMATON

The most important outcome information that can be derived directly from the surgery forms are the surgical and general complications. In the following analysis we focus on the by far most frequently reported surgical complication, which is the dura lesion.

Table 04: dura lesion rates in the degenerative Spine Tango data pool

DURALESION	Frequency	Percent
no	23095	97.71
yes	542	2.29

The proportion of reported dura lesions in the benchmarking sample ranges from 0% - 13.36% in the surgeries for degenerative diseases. The average proportion is 2.29%. The dura lesion rate does not only serve as an indicator for intraoperative complication rates, it does also serve for identifying possible candidates for the code of conduct principles, i.e. an honest and invariable documentation of each and every (even minor) complication.
Since case mix can have a considerable influence on surgical complication rates, a statistical model must be built that considers and adjusts for the most important influential co-variates on dura lesion rates. In the following model, age, gender, type of degeneration, location of pathology, extent of lesion and previous surgeries were statistically adjusted for.

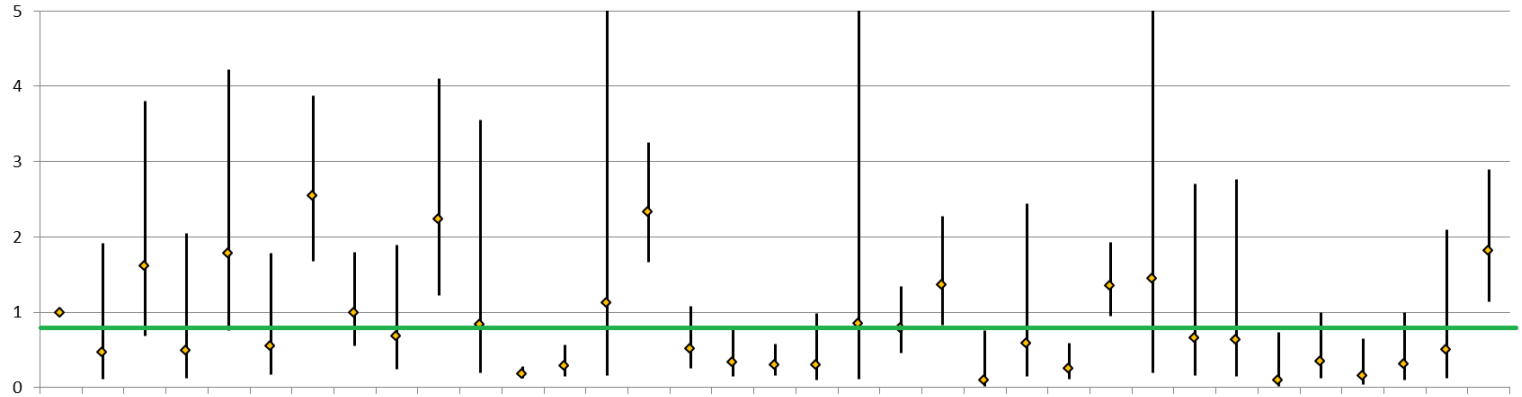


Figure 40: The adjusted odds (a measure of risk or probability) for a dura lesion in surgeries for degenerative diseases

The participating hospital contributing the largest case load to the benchmarking sample was used as the reference hospital (first dot) with an odds ratio=1. The benchmark (green line) for an adjusted dura lesion risk in the sample is about OR=0.8 compared with the reference hospital. The majority of participants lies within the benchmark (line of confidence interval crossing green line). The five centers with the highest (documented) dura lesion rates are well known Spine Tango participants. Their cumulated average dura lesion rate is 6.96% which corresponds much better with published data in the literature.

Cervical disc protrusion is the first pathology being assessed in the benchmarking project. The strict inclusion criteria left 415 cases for evaluation (upper or mid-lower cervical location, main pathology = degenerative disease, specification of main pathology = disc herniation, no stenosis, pre- and postop COMI available, preop arm pain ≥ 4 points, no previous surgery). Distribution of surgical measures shows that only two surgical techniques have a sufficiently high case load for further analysis. These are decompression combined with motion preserving stabilization and decompression combined with fusion and rigid stabilization.

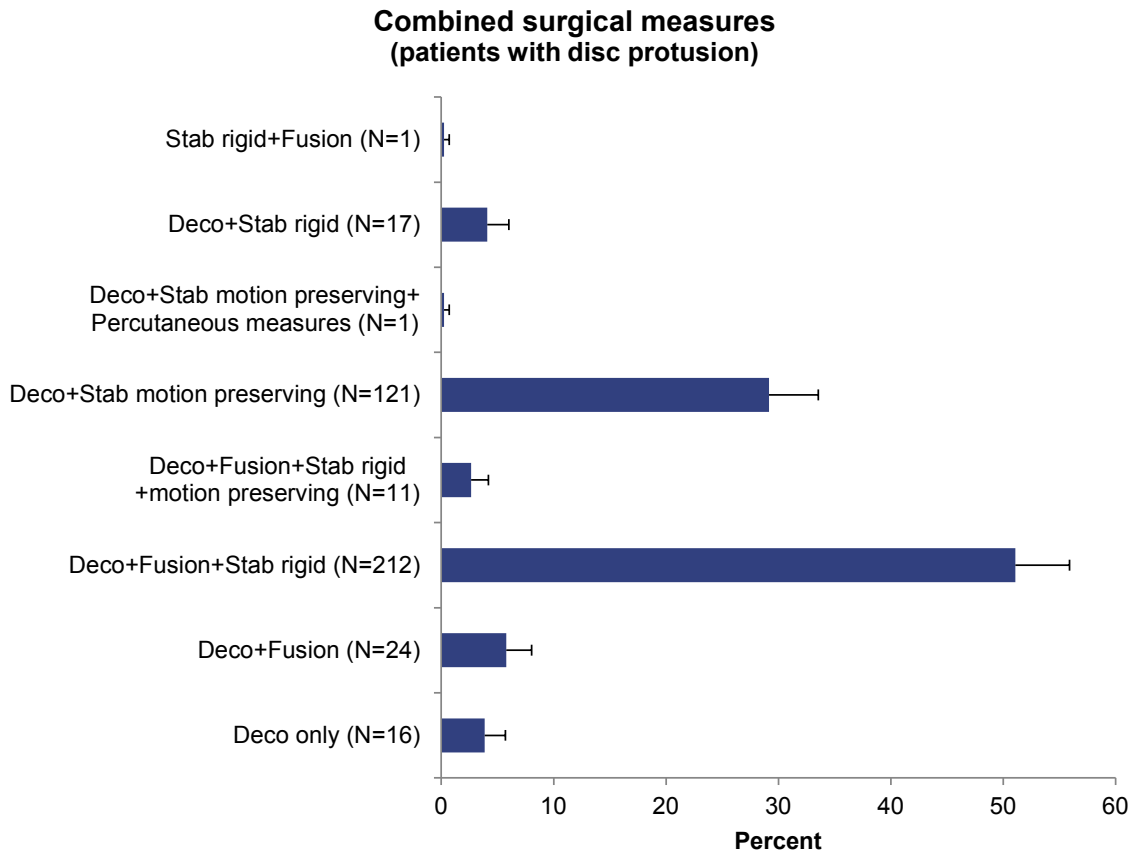


Figure 41: Distribution of combined surgical measures in patients with disc protrusion.

Table 05: Age for the two most frequent surgical measures combinations

Surgical measures	N	Minimum	Median	Maximum	Mean	Std Dev
Decompression + Fusion + Stabilization rigid	212	23.8	48.2	81.7	48.4	9.4
Decompression + Stabilization motion preserving	121	25.5	46	66.3	46.4	7

After a mean followup time of 5 months (range 1-17 months) the achievement, partial achievement or non-achievement of the surgical goals for decompression with fusion and rigid stabilization looks as displayed in figure 42.

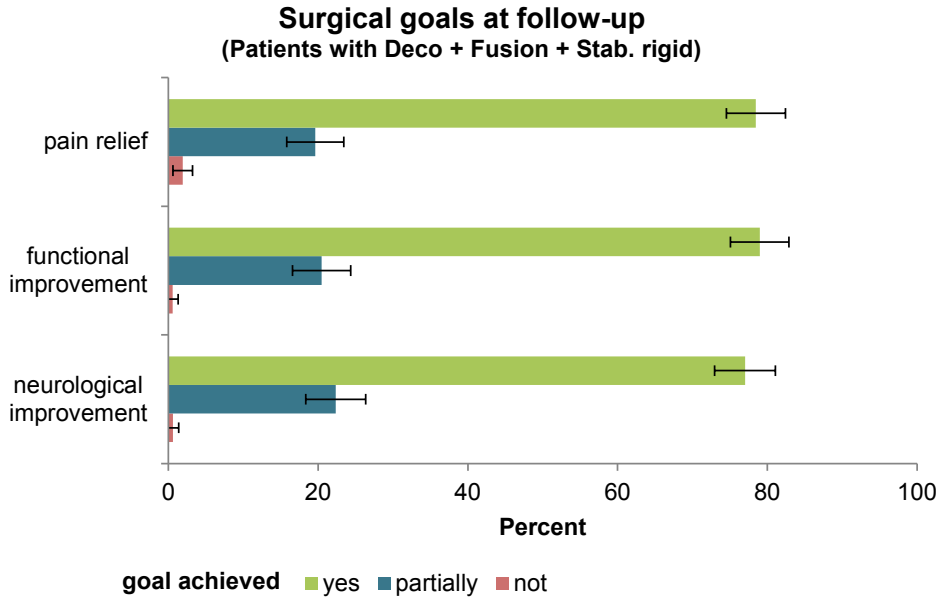


Figure 42: Achievement of surgical goals at follow up for decompression in combination with fusion and rigid stabilization.

After a mean followup time of 7 months (range 1-18 months) the achievement, partial achievement or non-achievement of the surgical goals for decompression with motion preserving stabilization looks as displayed in figure 43.

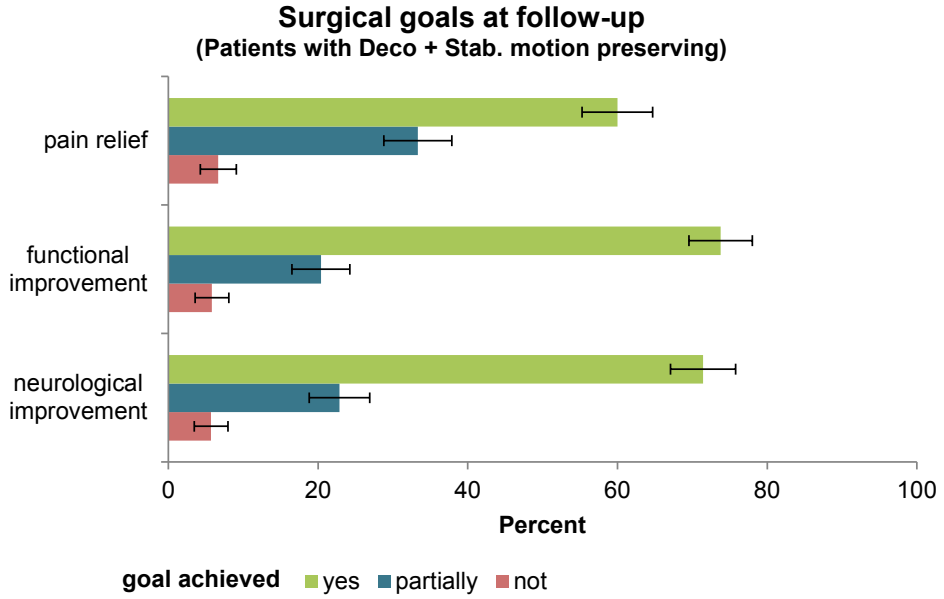


Figure 43: Achievement of surgical goals at follow up for decompression with motion preserving stabilization.

The according evaluation of the overall treatment results of the two types of interventions by the surgeon are displayed in figure 44.
Despite an almost 20% higher rate of achieved pain relief in the fused cases, surgeons rate the outcome as excellent in 39% in the disc arthroplasty group compared with only 26% in the fusion group.

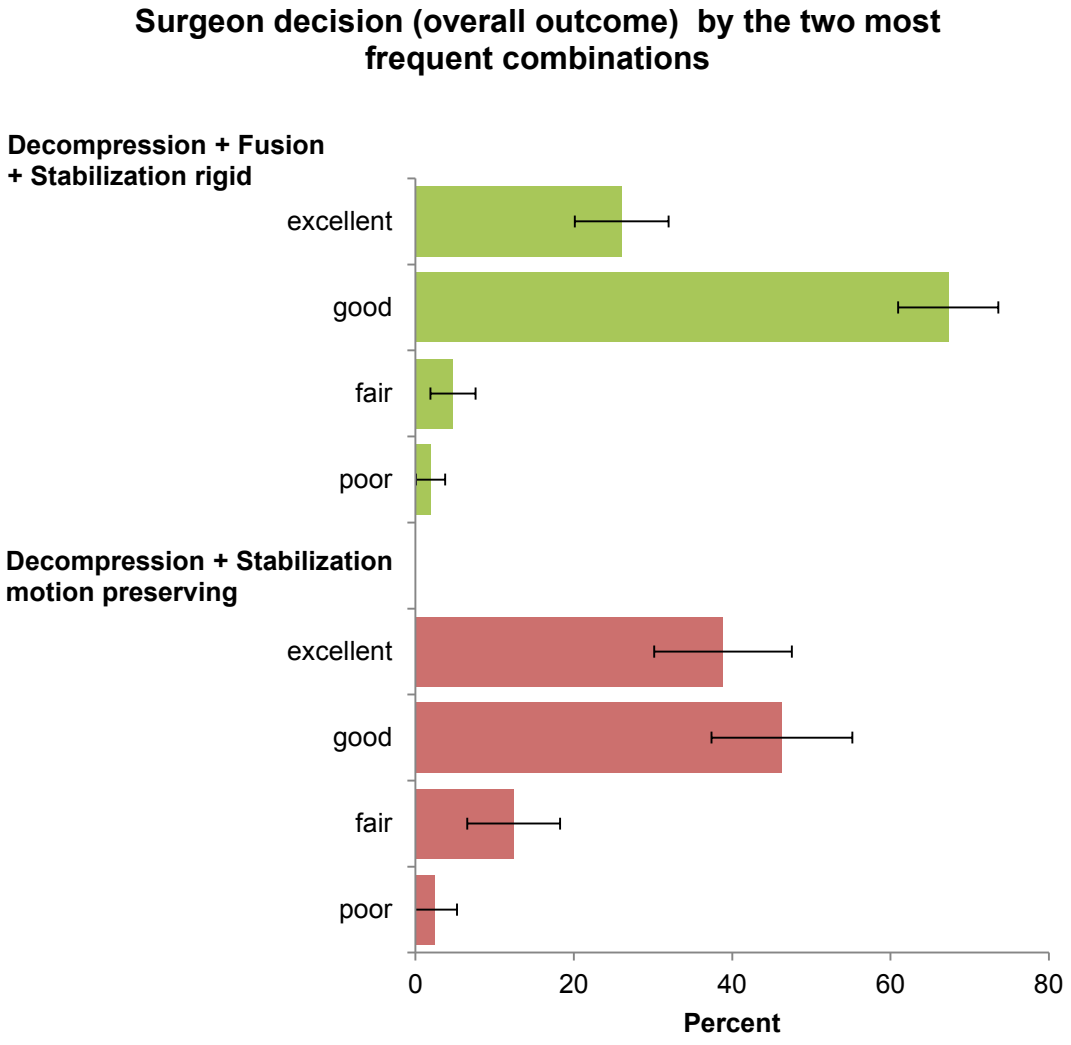


Figure 44: Surgeon decision by the two most frequent combinations of measures.

Figure 45 shows the minimum clinically relevant change (MCRC) for neck pain (two points - dashed line) that is achieved with the two surgical techniques.

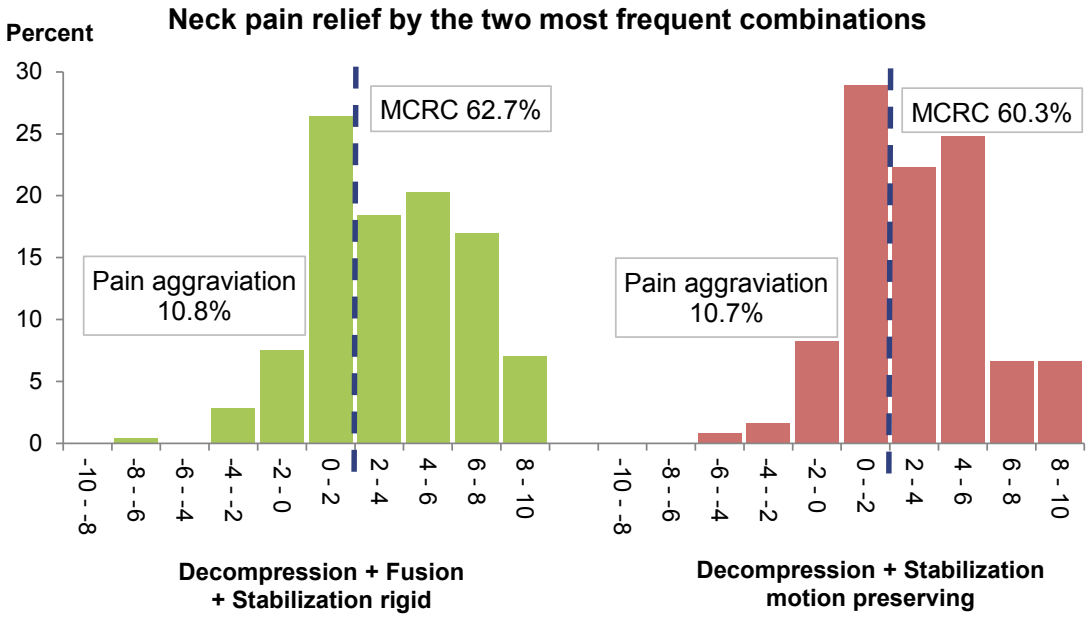


Figure 45: Neck pain relief by the two most frequent combinations of surgical measures

Figure 46 shows the minimum clinically relevant change (MCRC) for arm pain (two points - dashed line) that is achieved with the two surgical techniques.

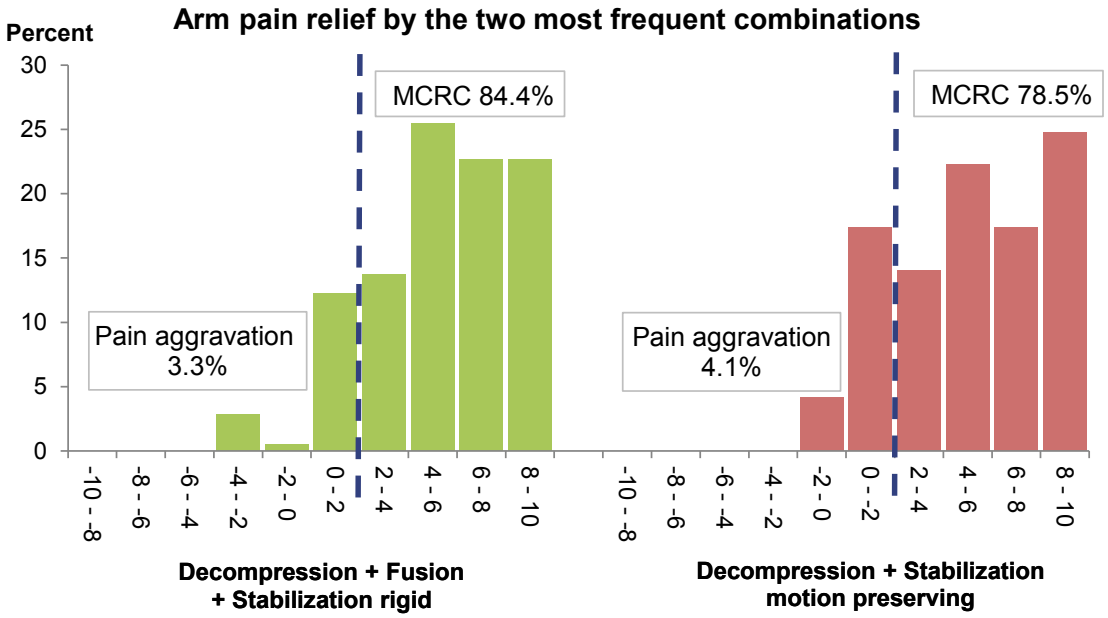


Figure 46: Arm pain relief by the two most frequent combinations of surgical measures.

Figures 47 and 48 show the pre- to postoperative changes of the COMI items for the two surgical interventions whereby 5 represents the worst and 1 the best outcome. The dashed line is the preoperative state, the blue area is the postoperative state, the central green line is the ideal state.

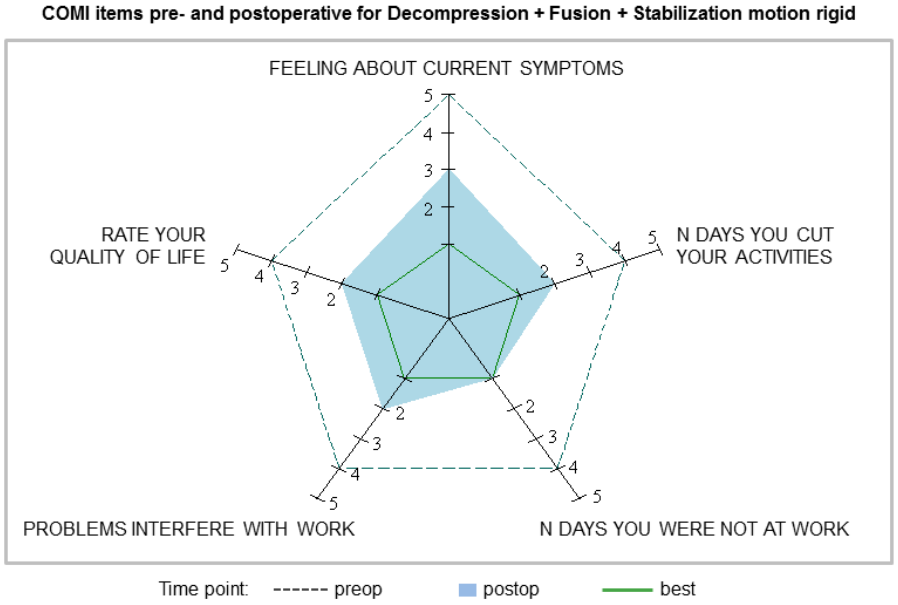


Figure 47: COMI items pre- and postoperative for decompression with fusion and stabilization rigid.

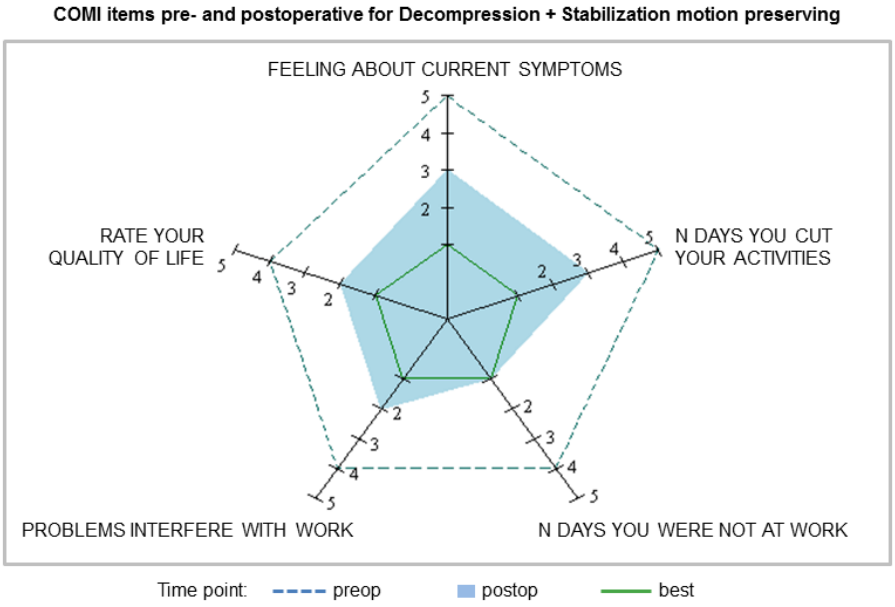


Figure 48: COMI items pre- and postoperative for decompression with stabilization motion preserving.

We built three logistic regression models with the MCRC in neck pain, arm pain, and COMI score as primary outcomes. The following covariates were fed into the model: age, gender, ASA status, extension of lesion, duration of previous non-surgical treatment, preoperative neck and arm pain levels, preoperative COMI score, surgical measures, surgeon credentials. Table 06 shows the significant predictors that were revealed.

Table 06: Significant predictors for each MCRC in neck pain, arm pain and COMI score.

Significant predictors for MCRC in neck pain (2 VAS points)					
Variable	Effect	OR	LCI95%	UCI95%	p-value
Neck pain	for each additional VAS point	1.363	1.212	1.532	<.0001
Significant predictors for MCRC in arm pain (2 VAS points)					
Variable	Effect	OR	LCI95%	UCI95%	p-value
Neck pain	for each additional VAS point	0.803	0.681	0.948	0.0096
Arm pain	for each additional VAS point	1.403	1.146	1.717	0.0011
Significant predictors for MCRC in COMI score (2 score points)					
Variable	Effect	OR	LCI95%	UCI95%	p-value
Neck pain	for each additional VAS point	0.778	0.675	0.896	<0.001
COMI score	for each additional score point	1.443	1.149	1.814	0.002
Surgeon credentials	Spine surgeon vs neurosurgeon	2.679	1.311	5.476	0.024

OR = odds ratio; LCI95% = lower 95%-confidence interval; UCI95% = upper 95%-confidence interval

Neck pain was the only significant predictor for neck pain relief of at least two points. For each additional point of preoperative neck pain the odds to achieve the MCRC in neck pain increased by 1.363.

Neck pain and arm pain were significant predictors for arm pain relief of at least two points. For each additional point of preoperative arm pain the odds to achieve the MCRC in arm pain increased by 1.403. In contrast, for each additional point of preoperative neck pain, the odds to achieve the MCRC in arm pain relief de-creased by 0.803.

Neck pain, COMI score (range 0 (best) – to 10 (worst) points), and surgeon credentials were significant predictors for COMI score improvement of at least two points. For each additional point of preoperative neck pain the odds to achieve the MCRC in COMI score de-creased by 0.778. In contrast, for each additional point of preoperative COMI score, the odds to achieve the MCRC in COMI score increased by 1.443. Finally, surgeons labeling themselves as spine surgeons had an odds ratio of 2.679 to achieve the MCRC in COMI score as outcome for their patients, compared with neurosurgeons.

Table 07: OR for reaching MCRC in dynamic stabilization compared to fusion as gold standard with OR=1.

	OR	CI 95%	p-value
MCRC in neck pain	1.16	0.63-2.14	0.63
MCRC in arm pain	0.61	0.30-1.23	0.17
MCRC in COMI score	1.00	0.53-1.88	0.99

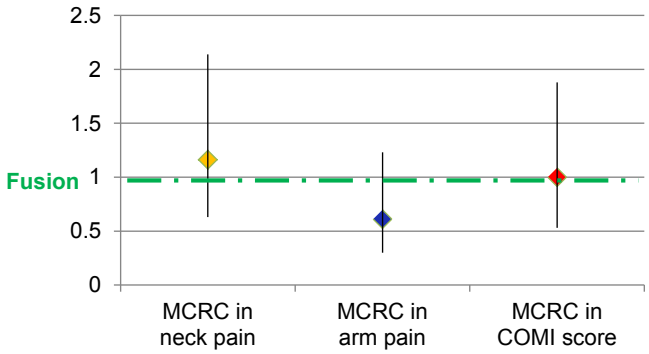


Figure 49: Odds ratio for the achievement of minimum clinically relevant change in neck pain (2 points), arm pain (2 points) and COMI score (2 points) for Deco+Stab motion preserving in comparison to Deco+Fusion+Stab rigid (gold standard OR=1)

There were too few complications recorded in this patient sample in order to analyze the influence of the surgical technique or calculate a separate rate of surgical complications for the aforementioned selected participants. Also, stratification by region and its effects could not be assessed yet. More and more equally distributed cases are necessary for such an analysis.

PARTICIPANTS/ MODULE ANALYSIS

Figure 50 displays the cumulative growth curves of the various national modules. The different starting dates of the modules need to be considered (Swiss/International 2005, Austria 2005; Germany 2006; North America 2007; Brazil/South America 2008; Italy 2008; Mexico 2008; Great Britain 2010; Australia 2010).

The Australian and British modules are both not available via www.eurospine.org because of national data privacy regulations, but the contact persons for these modules are displayed on the Spine Tango web page.

Figure 51 shows an overview of the Spine Tango participating hospitals and their country of origin until the end of 2011. We divided their total case load into primary forms and followup forms.

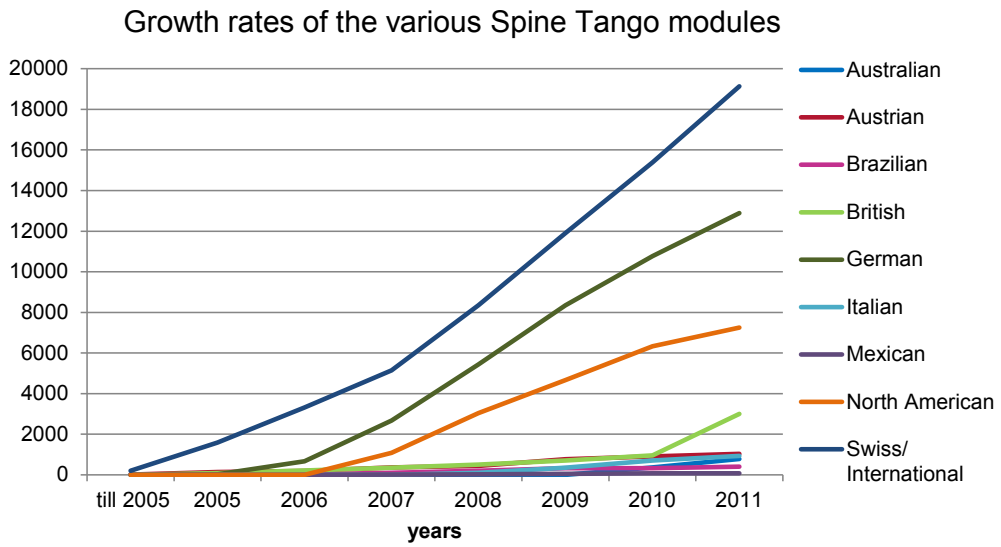


Figure 50: Growth curves (number of cases of the single Spine Tango modules over the years)

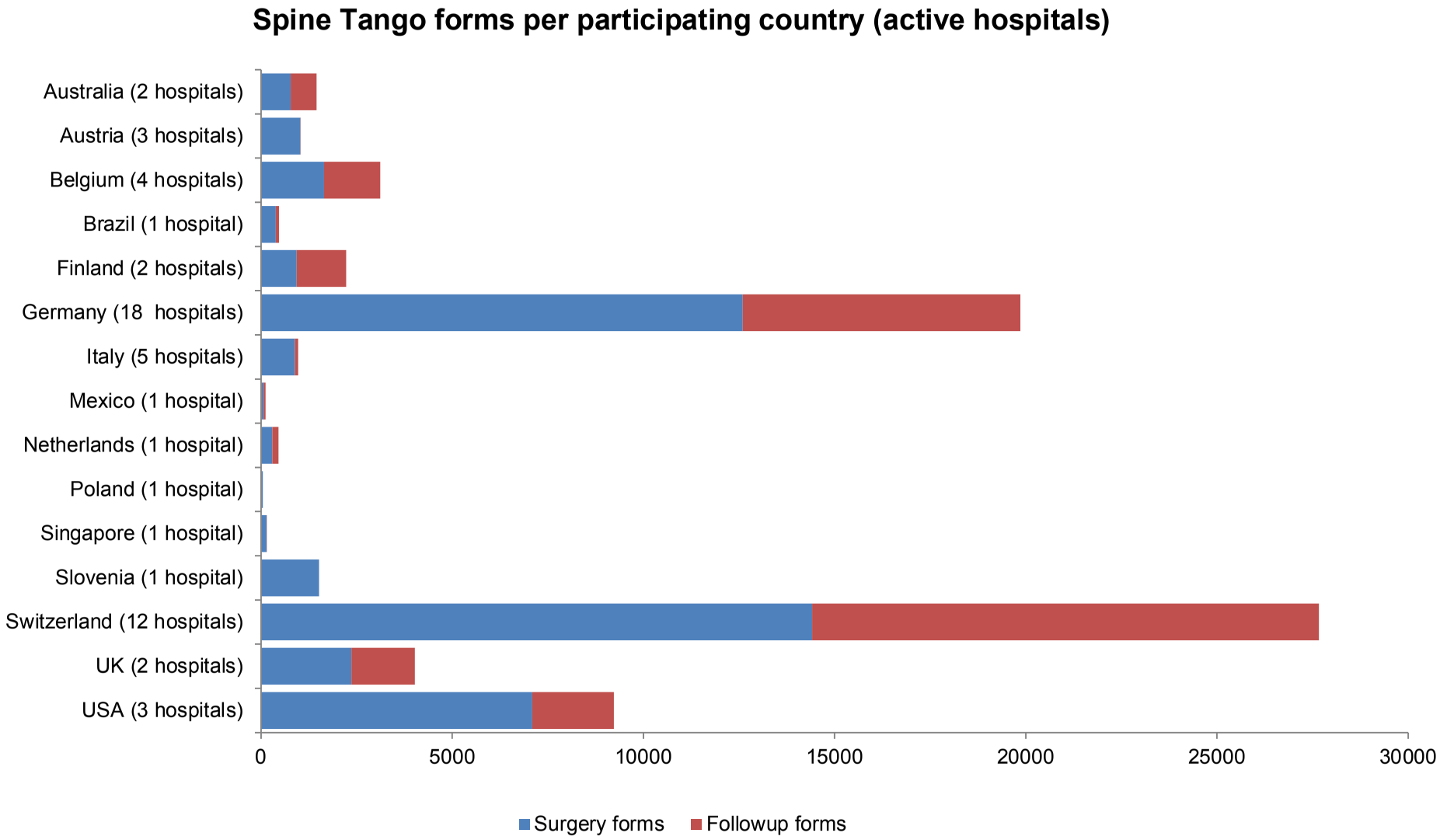
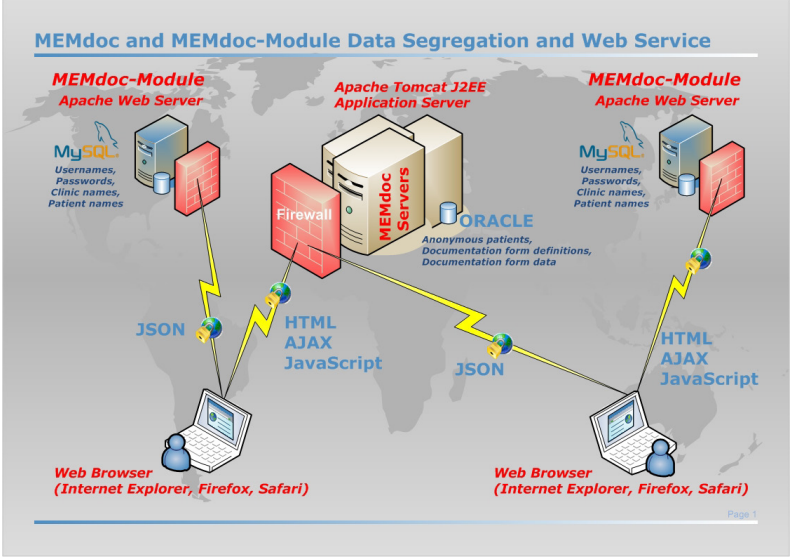


Figure 51: Overview of the Spine Tango participating hospitals according to their country of origin with case load divided into primary forms and followup forms until the end of 2011.

SECURITY

The model of the MEMdoc and MEMdoc-Module system is designed around the principle of data separation. The MEMdoc central server, housed at the MEM Research Center (MEMcenter) in Bern, hosts the main application and the central database containing all study definitions and clinical study data. Satellite MEMdoc-Module servers located throughout the world store all personal data about users, institutions and patients. At the core of the system is an innovative 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 database for performing pooled statistics.

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

The following hardware is recommended for a MEMdoc-Module:

- Processor (1 CPU) Intel Xeon 3500 / AMD Opteron
- Memory 4 GB RAM
- Hard drive (2 drives) 250 GB, Sata or SAS
- RAID-Controller with battery backup unit (Raid 1)
- Debian 6

or a virtual machine with comparable performance

Table 8: Available questionnaires in the SSE Spine Tango registry (01.01.2012)

			online available					OMR paper forms available										
Forms used in Spine Tango Registry - 01.01.2012		multilingual	english	german	french	italian	spanish	english	german	french	italian	spanish	portuguese	turkish	polish	greek	hungarian	russian
Registry Forms																		
Spine Tango	Surgery 2006	✓	✓					✓	✓	✓	✓	✓						
Spine Tango	Staged 2006	✓	✓					✓	✓	✓		✓						
Spine Tango	Follow-up 2006	✓	✓					✓	✓	✓		✓						
Spine Tango	Surgery 2011	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		IP	IP	IP	IP	IP
Spine Tango	Staged 2011	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		IP	IP	IP	IP	IP
Spine Tango	Follow-up 2011	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		IP	IP	IP	IP	IP
Spine Tango	Conservative treatment 2011	✓	✓	✓				✓	✓									
Patient Forms																		
Spine Tango	Core Outcome Measures Index: COMI Neck	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		IP		IP	IP
Spine Tango	Core Outcome Measures Index: COMI Back	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		IP		IP	IP
Spine Tango	Core Outcome Measures Index: COMI Neck Conservative	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓						
Spine Tango	Core Outcome Measures Index: COMI Back Conservative	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓						
Spine Tango	Oswestry Disability Index ODI 2.1	✓	✓	✓	✓		✓	✓	✓	✓		✓			IP		IP	
Spine Tango	Neck Disability Index NDI	✓	✓	✓	✓		✓	✓	✓	✓		✓						
Spine Tango	Scoliosis Research Society: SRS 30	✓	✓	✓	✓			✓	✓	✓								
Spine Tango	EuroQol™: EQ-5D™	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓					IP	

IP = in process

OMR = Optical Mark Reader

PUBLICATIONS

PAPERS IN PEER REVIEWED JOURNALS

Sobottke R, Aghayev E, Röder C, Eysel P, Delank S, Zweig T
Predictors for surgical, general and follow-up complications in lumbar spinal stenosis relative to patient age
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BOOK CHAPTERS

Meyer F., Hopf C., Aebi M., Röder C.
Das DWG Wirbelsäulenregister in Kooperation mit Spine Tango, der europäischen Initiative.
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ABSTRACTS IN PEER-REVIEWED JOURNALS

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ORAL PRESENTATIONS

June 2011

Aghayev E, Detzner M, Moulin P, Röder C, on behalf of the SWISSspine and the Spine Tango Registry Groups
Benchmarking across spine registries: Comparison of pain alleviations after lumbar TDA and ALIF with stratification by surgeon and by disc prosthesis
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Proceedings of the NASS 26th Annual Meeting; The Spine Journal 11 (2011), 170S

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Prospektive monozentrische Analyse minimalinvasiver oder endoskopischer Mikrodiskektomien bei lumbaler Bandscheibenherniation mit assoziierter Radikulopathie in drei unterschiedlich vorbehandelten Patientengruppen
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DISSERTATION

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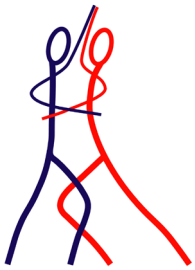

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