SPINE TANGO Report
International 2009

The International Spine Registry
EuroSpine

C. Röder, M. Neukamp, G. Perler, M. Melloh, T. Zweig, E. Munting, M. Aebi

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INTRODUCTION

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

M. Aebi
NEW DEVELOPMENTS

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

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

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

New software release: in fall/winter 2010 a completely redesigned software will displace the current Spine Tango program. Increased patient and user security, new features and more comfortable data handling are expecting the user community.
Spine Tango enables you to document the whole spectrum of spinal pathologies and the possible surgical and soon also the non-surgical treatment options. The generic approach of the Spine Tango documentation system is a must to reach the maximum number of participants using a common web based technology. This, in turn, reduces the potential for customizing the Tango in order to meet the individual expectations of specific users. There are, nevertheless, still a number of possibilities to parameterize the data collection processes according to the various hospital workflows in the user community. To give you the opportunity to document not only the surgical treatment, we have developed Spine Tango Conservative, which is currently being validated. It is due to be released in early 2011.

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

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

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

**External quality control:** Benchmarking, the comparison of own performance with that of the national or international results in the Tango is a powerful management tool because it overcomes "paradigm blindness." Paradigm blindness can be summed up as the mode of thinking, "The way we do it is the best because this is the way we've always done it." Benchmarking opens organizations to new methods, ideas and tools to improve their effectiveness. It helps overcome resistance to change by presenting successful methods of problem solving that are different to the ones currently employed. Enabling benchmarking possibilities is one of the fundamental goals of the Spine Tango venture.
Outcomes research: this aspect is actually just taking a different view for the same basic activity, i.e. the systematic and prospective collection of key data regarding interventions and outcomes for and of spinal pathologies. While quality assurance is rather used for the purposes of improving ones` own standards of care, outcomes research wants to generate new medical and scientific knowledge and make it available in the peer-reviewed literature.

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

National and international study network: the Tango is a technology backbone and currently networks over 40 active hospitals in Europe, North and South America, Australia and Asia. This provides a great opportunity for national and international multicenter studies that piggyback on the ongoing routine data collection, add some hypothesis based questions and collect this extra information for the time of primary and followup data collection as specified in the joint study protocol.
There are 4 possible ways forms and questionnaires can be transferred to the database (Fig. 1)
① Online data entry via the web-interface (no software to be installed)
② OMR (Optical Mark Reader) i.e. scanner-assisted entry of paper forms
③ Paper based data capture with mailing to the IEFM or other partner institutions for OMR scanner-assisted entry of paper forms
④ Hybrid method of online data entry and OMR scanner-assisted entry of paper forms (not pictured)

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

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


Fig. 2: Patient based outcome documentation with the COMI (Core Outcome Measure Index) questionnaires, AF Mannion et al. (2009)(3)
Pre- & postoperative documentation workflow of a case

Fig 3: Timetable of data collection
The year on the form indicates the developmental version.
### SPINE TANGO

**SURGERY**

#### Surgery

- **Day**: C1, D2, E3, F4, G5, H6, I7, J8, K9, L10, M11, N12, O13, P14, Q15, R16, S17, T18, U19, V20, W21, X22, Y23, Z24
- **Month**: C1, D2, E3, F4, G5, H6, I7, J8, K9, L10, M11, N12, O13, P14, Q15, R16, S17, T18, U19, V20, W21, X22, Y23, Z24
- **Year**: C1, D2, E3, F4, G5, H6, I7, J8, K9, L10, M11, N12, O13, P14, Q15, R16, S17, T18, U19, V20, W21, X22, Y23, Z24

#### Surgeon credentials
- c: board certified, orthopaedic
- c: board certified, neuro
- c: board certified, spine
- c: orthopaedic in training
- c: neuro in training
- c: other

#### Goal of surgery
- □: pain relief
- □: functional improvement
- □: neurological improvement
- □: cosmetic improvement
- □: diagnostic measures
- □: other

#### Morbidity state
- c: unknown
- c: ASA 1 (no disturbance)
- c: ASA 2 (mild disturbance)
- c: ASA 3 (severe disturbance)
- c: ASA 4 (life threatening)
- c: ASA 5 (moribund)

#### Anterior access
- □: no anterior access
- □: transoral
- □: anterior
- □: anterolateral
- □: cervicothorac. anterol.
- □: cervicothorac. a. lat. w/ sternotomy
- □: other

#### Posterior access
- □: no posterior access
- □: midline
- □: paramedian
- □: posterior lateral
- □: other

#### Technology
- □: MISS/LISS
- □: loops
- □: microscope
- □: endoscope
- □: CASS
- □: other

#### Components
- □: yes
- □: no

#### Surgical Measures

**Decompression**
- □: none
- □: anterior
- □: posterior
- □: specify...

**Fusion**
- □: none
- □: anterior
- □: posterior
- □: specify...

**Stabilization rigid**
- □: none
- □: anterior
- □: posterior
- □: specify...

**Stabil. motion preserving**
- □: none
- □: anterior
- □: posterior
- □: specify...

#### Blood loss
- c: 0-50 ml
- c: 50-100 ml
- c: 100-200 ml
- c: 200-300 ml
- c: > 300 ml
- c: 1-2 hrs
- c: > 2 hrs
- c: > 3 hrs

#### Operation time
- c: < 4-6 hrs
- c: > 6-8 hrs
- c: > 8-10 hrs
- c: > 10 hrs

#### Supplier: __________________________ Article No: __________________________

#### Article name: __________________________

#### Surgical intervention/re-intervention
- □: none
- □: metal removal
- □: suture
- □: hematoma evacuation
- □: re-implantation
- □: other

#### Measures taken
- □: conservative
- □: surgical
- □: other

#### Status of Complications
**Surgical**
- □: resolved
- □: improved
- □: persisting

**General**
- □: resolved
- □: improved
- □: persisting

#### Comments regarding discharge


---

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

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Spine Tango COMI
Patient self-assessment

Examination interval
- before surgery
- 4 weeks
- 6 weeks
- 2 months
- 3 months
- 6 months
- 9 months
- 1 year
- 2 years
- 3 years
- 4 years
- 5 years
- 6 months
- 12 months
- other: years

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' and numbness in any of these regions.

1. Which of the following problems troubles you the most? Please tick ONE BOX only.
   - back pain
   - leg/buttock pain
   - sensory disturbances in the back/leg/buttocks, e.g. tingling, 'pins and needles', numbness
   - none of the above

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

2a. How severe was your back pain in the last week?
   - no pain
   - 0
   - 1
   - 2
   - 3
   - 4
   - 5
   - 6
   - 7
   - 8
   - 9
   - 10
   - worst pain that I can imagine

2b. How severe was your leg pain (sciatica)/buttock pain in the last week?
   - no pain
   - 0
   - 1
   - 2
   - 3
   - 4
   - 5
   - 6
   - 7
   - 8
   - 9
   - 10
   - worst pain that I can imagine

3. During the past week, how much did your back problem interfere with your normal work (including both work outside the home and housework)?
   - not at all
   - a little bit
   - moderately
   - quite a bit
   - extremely

4. If you had to spend the rest of your life with the symptoms you have right now, how would you feel about it?
   - very satisfied
   - somewhat satisfied
   - neither satisfied nor dissatisfied
   - somewhat dissatisfied
   - very dissatisfied

5. Please reflect on the last week. How would you rate your quality of life?
   - very good
   - good
   - moderate
   - bad
   - very bad

Please go to the next page...
**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?

- [x] 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)?

- [x] 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)?

- [x] no
- [ ] yes → please describe: .................................................................

---

**8b** How bothersome were these complications?

- [x] 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?

- [x] 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?

- [x] 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?

- [x] helped a lot
- [ ] helped
- [ ] helped only little
- [ ] didn’t help
- [ ] made things worse

---

Date

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<th>Month</th>
<th>Day</th>
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<td>10</td>
<td>13</td>
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</tbody>
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Signature: ........................................................................

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# Follow-up

**physician based, single sided**

## Follow-up

### SPINE TANGO

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

### Question types

- **only 1 answer allowed**
- **multiple answers allowed**
- **mandatory information**

### Level of procedure

- **upper cervical**
- **mid lower cervical**
- **cervico-thoracic**
- **cervico-thoraco-lumbar**
- **thoracic**
- **thoraco-lumbo-sacral**
- **lumbo-sacral**
- **coccygeal**

### Follow-up

#### Day
- **5 weeks**
- **3 months**
- **6 months**
- **other yrs.**

#### Month
- **1**
- **2**
- **3**
- **4**
- **5**
- **6**
- **7**
- **8**
- **9**
- **10**
- **11**
- **12**

#### Year
- **0**
- **1**
- **2**
- **3**
- **4**
- **5**
- **6**
- **7**
- **8**
- **9**
- **10**

#### Follow up interval

- **not at work since OP**
- **started partially, same job**
- **fully retrained**
- **resumed work, but quit again**
- **withdrawn from labor force**

#### Surgery goals/Measures achieved

- **pain relief**
- **functional improvement**
- **neurological improvement**
- **cosmetic improvement**
- **diagnostic measures**
- **other**

#### Surgical goals/Measures partially achieved

- **pain relief**
- **functional improvement**
- **neurological improvement**
- **cosmetic improvement**
- **diagnostic measures**
- **other**

#### Surgical goals/Measures not achieved

- **pain relief**
- **functional improvement**
- **neurological improvement**
- **cosmetic improvement**
- **diagnostic measures**
- **other**

#### Medication

- **none**
- **steroids**
- **antidepressives**
- **antibiotics**
- **other**

#### Rehabilitation

- **home-based**
- **outpatient rehab / physio**
- **other**

#### Overall outcome (examiner)

- **not applicable**
- **good**
- **poor**
- **excellent**
- **fair**

#### Decision

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

### 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 disturbance**
- **motor disturbance**
- **sphincter disturbance**
- **non-union**
- **implant failure**
- **instability**
- **liquit fistula**
- **superficial wound infection**
- **deep subfascial wound infection**
- **spondylitis**
- **/discitis**
- **wrong segment**
- **malposition of implant**
- **recurrence of symptoms**
- **graft complication**
- **sequela asaesthesia**
- **internal medicine**

#### Therapeutic consequences

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

#### Individual consequences

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

### Comments regarding follow-up

### Comments regarding complications

---

**Examiner**

---

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### SPINE TANGO

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

#### Question types
- ☐ only 1 answer allowed
- ☐ multiple answers allowed

### Level of therapy
- ☐ upper cervical
- ☐ cervicothoracic
- ☐ thoracic
- ☐ thoraco-lumbo-sacral
- ☐ lumbo-sacral
- ☐ coccyx
- ☐ mid lower cervical
- ☐ cervico-thoraco-lumbar
- ☐ thoracolumbar
- ☐ lumbar
- ☐ sacral
- ☐ isch

### Admission / Pathology
- ☐ inpatient
- ☐ outpatient

#### Main pathology
- ☐ functional pathology
- ☐ structural pathology
- ☐ functional & structural pathology

#### Specification of main pathology
- Only answer questions related to Main Pathology.

### FUNCTIONAL DISEASE

#### Type of functional disease
- ☐ arthritic blockade
- ☐ myosclerosis
- ☐ muscular hypotony
- ☐ muscular shortening
- ☐ muscular insufficiency
- ☐ rhabdomyopathy
- ☐ paralysis
- ☐ segmental instability
- ☐ segmental dysfunction
- ☐ whiplash
- ☐ hypermobility
- ☐ pseudoradicular syndrome
- ☐ cranial dysfunction
- ☐ other

#### Structural Disease

#### Degenerative disease
- ☐ discopathy
- ☐ disc herniation
- ☐ spondylolisthesis

#### Spondylolysthesis

#### Type of degenerative disease
- ☐ spondylolisthesis
- ☐ kyphosis
- ☐ other

#### Predominant etiology
- ☐ idiopathic
- ☐ degenerative
- ☐ M. Scheuermann
- ☐ other

#### Other
- ☐ trauma, pain syndrome
- ☐ fibromyalgia
- ☐ soft tissue lesion, neck
- ☐ CPPD (pseudogout)
- ☐ muscular disease
- ☐ neuromuscular disease

#### Inflammation
- ☐ inflammatory arthritis
- ☐ spondylarthropathies
- ☐ infectious
- ☐ other

#### Medication at admission
- ☐ muscle relaxants
- ☐ pain relievers
- ☐ corticosteroids
- ☐ antiinflammatory
- ☐ antidepressants
- ☐ anticoagulants
- ☐ anticonvulsants
- ☐ neuroleptics

#### WHO Scheme
- ☐ Level 1
- ☐ Level 2
- ☐ Level 3

#### Therapy

#### Beginning of therapy
- ☐ January
- ☐ February
- ☐ March
- ☐ April
- ☐ May
- ☐ June
- ☐ July
- ☐ August
- ☐ September
- ☐ October
- ☐ November
- ☐ December

#### Year
- ☐ 2021
- ☐ 2022
- ☐ 2023
- ☐ 2024
- ☐ 2025

#### Therapist credentials
- ☐ orthopedic surgeon
- ☐ neurosurgeon
- ☐ osteopath
- ☐ physiotherapist
- ☐ traumatologist
- ☐ physical doctor
- ☐ nutritionist
- ☐ other

#### Goals of functional therapy
- ☐ functional improvement
- ☐ pain relief
- ☐ other

#### Goals of structural therapy
- ☐ functional improvement
- ☐ pain relief
- ☐ other
## Therapeutic Measures

### Invasive pain therapy
- [ ] facet block
- [ ] root block
- [ ] epidural infiltration
- [ ] epidural catheter
- [ ] pain pump
- [ ] radiofrequency therapy
- [ ] cryodenervation of facets
- [ ] alcohol de nervs.
- [ ] neural therapy
- [ ] acupun

### Pain medication
- [ ] NSAID
- [ ] muscle relaxants
- [ ] muscle relaxants
- [ ] sleep promoting drugs
- [ ] SSRIs
- [ ] anti convulsants
- [ ] neurotics

### Physiotherapy
- [ ] strength training
- [ ] endurance training
- [ ] stabilisation training
- [ ] therapy for scoliosis
- [ ] neurorehabilitation

### Manual therapy
- [ ] mobilisation
- [ ] stretches
- [ ] neuromeningeal mobil
- [ ] visceral techniques
- [ ] trigger point treatment
- [ ] craniosacral techniques
- [ ] massage
- [ ] other

### Physical modalities
- [ ] laser therapy
- [ ] ultrasound
- [ ] other

### Group programmes
- [ ] back training program
- [ ] pain management
- [ ] ADL (activities of daily living)
- [ ] other

### Psychological intervention
- [ ] cognitive behaviour therapy
- [ ] relaxation therapy
- [ ] coping strategies

### Occupational medicine measures
- [ ] ergonomic measures
- [ ] work reintegration
- [ ] work hardening

### Other therapeutic measures
- [ ] occupational retraining
- [ ] other

### Therapist’s notes

---

**End of therapy**

Date of end of therapy

Day  
Month  
Year  

General complications
- [ ] none
- [ ] yes

Therapeutic complications
- [ ] none
- [ ] cauda equina damage
- [ ] spinal root damage
- [ ] bleeding in spinal canal
- [ ] bleeding outside spinal canal

Achieved goals of therapy

<table>
<thead>
<tr>
<th>Functional disease</th>
<th>Structural disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>a</td>
<td>b</td>
</tr>
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Status of complications
- [ ] general
- [ ] unaffected
- [ ] resolved
- [ ] other

Consultation
- [ ] physical therapy
- [ ] orthopedy
- [ ] spine surgery
- [ ] other

Further scheduled measures
- [ ] other conservative therapy
- [ ] surgical intervention

Therapist: ..................................................

---
Overview (Pool)

Data from the

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

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

Short exemplary analysis on Total Disc Replacement (Pool):

Level of procedure,

Demographic data,

Type of degeneration,

VAS (COMI)
A study of the weighting and frequency of statistical reports was published by Windish in JAMA in 2007 (6). This work comprises the study of 239 original articles in 6 journals (American Journal of Medicine, Annals of Internal Medicine, BMJ, JAMA, Lancet, New England Journal of Medicine) with regard to statistical evaluation. 91.6% of the articles included descriptive statistics and 50.2% were compiled from simple statistical methods. Multivariate analyses were used for 68.6% of the cases. All the above mentioned methodologies can be used in Spine Tango. The Spine Tango international pool offers over 30,000 eligible cases. The number of entries increases constantly. Below you will find a short summary of all the documented surgeries in Spine Tango followed by a detailed assessment of the patient subgroup with dynamic stabilization of the cervical and lumbar spine using disc arthroplasty.


Fig 4: Growth curves of implemented forms (primary and revision surgery and followup) over the years.
The following graphics are based on the international Spine Tango data pool using all submitted forms until the end of the year 2009. Only form versions 2005 and 2006 were considered. They added up to 24327 surgeries.

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

For females the majority of surgeries happen in patients aged 70-80 years. The male main group is between 50-60 years old (n= 2473) and makes up 21.3% of all surgeries in males.
Three quarters of all patients suffered from a degenerative disease as main pathology. The types of degenerative diseases with their distribution are shown below (Fig. 7). The most frequently checked fields were disc herniation, spinal stenosis and disc degeneration. Please note the multiple choice format of this question. There was an average of 1.4 answers per case.
The most frequently performed surgical measure in patients with degenerative disease was the sole posterior decompression.

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

The most frequent trauma were C3-L5/S1 fractures (N=805) with the distribution of the AO fracture types shown below (Fig. 9).
Tab 1: Classification of the various types of spondylolisthesis of Neugebauer & Newman, adapted by Wiltse et al.

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>congenital, dysplastic</td>
<td>IV</td>
<td>traumatic</td>
</tr>
<tr>
<td>II</td>
<td>isthmic</td>
<td>V</td>
<td>pathological</td>
</tr>
<tr>
<td>III</td>
<td>degenerative</td>
<td>VI</td>
<td>postsurgical</td>
</tr>
</tbody>
</table>

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

There are 870 documented deformity cases in the database. The predominant etiology is shown in fig. 10 with idiopathic and degenerative etiologies as the most common ones. Most of the spondylolisthesis cases have a degenerative etiology (n=811), followed by the isthmic type (n=464).

Fig 11: Type of spondylolisthesis (N=1428) (surgery form)
Following we show the distribution of the spondylolisthesis grade for the three most frequent types (Fig 12-14). In Type I (congenital, dysplastic) spondylolisthesis Grade II dominates whereas in the degenerative spondylolisthesis cases Grade I is most frequent with over 60%.

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

**Fig 13: Grade of isthmic spondylolisthesis (N=453) (surgery form)**
Tab. 2: Classification of spondylolisthesis according to Meyerding:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Lysis of pars without slip</td>
</tr>
<tr>
<td>I</td>
<td>0-25% slip</td>
</tr>
<tr>
<td>II</td>
<td>25-50% slip</td>
</tr>
<tr>
<td>III</td>
<td>50-75% slip</td>
</tr>
<tr>
<td>IV</td>
<td>&gt; 75% slip</td>
</tr>
<tr>
<td>V</td>
<td>Spondyloptosis</td>
</tr>
</tbody>
</table>

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

Fig 14: Grade of degenerative spondylolisthesis (N=786) (surgery form)
Different details related to the main pathology
(surgery form)

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

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

**Type of inflammation (N=81)**

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

The most frequently affected structures with infection as main pathology are spondylodiscitis (71.7%). Discitis occurred in 10.05%, spondylitis in 18.3%.
Fig 17: Surgical complications (of 23928 patients), excluded was answer “none” (surgery form)

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

Fig 18: General complications (of 23472 patients, excluded was answer “none” (surgery form))
Data from the followup form
Distribution of followup interval / overall outcome

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

![Distribution of followup interval](image)

**Fig 19: Distribution of followup interval (followup form)**

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

![Overall outcome (examiner)](image)

**Fig 20: Overall outcome, examiner (followup form)**
Figure 21 shows the distribution of achieved surgical goals/measures from 13,9840 followups, stratified by followup interval. The first group of follow-ups is analysed without reference to the indicated surgical goals of the index surgery (figures 21-23), the second group with reference to the index surgery (figures 24-26).
Looking at non-achieved surgical goals, pain relief slightly decreases over time as the most prominent problem. In contrast, neurological problems seem to improve with delay in some cases since the early rates of non-achieved neurological problems are more than halved after two years.

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

Fig 24: Goal of surgery: pain relief
The evaluation of pain relief, functional improvement and neurological improvement as outcome in relation to the preoperatively determined goals shows a stable distribution over time for each parameter.
An exemplary analysis of **Disc Replacement** using the Spine Tango data pool

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

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

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

![Distribution of level of procedure](image)

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

The age and gender distribution of the cervical and lumbar group is given in figures 28 and 29. The mean age for the patients with cervical disc arthroplasty is 47.7 years, for the lumbar disc arthroplasty 42.7 years. In the cervical group 53.7% of patients are female, in the lumbar group 47.2%.
Fig. 30: Type of degeneration for patients with cervical disc replacement (N=523)

The specification of degenerative disease in patients with total disc replacement showed a predominance of disc herniation and disc degeneration in the cervical group (N=523).
In contrast to cervical disc replacement, in the lumbar group the main specification of degenerative disease was disc degeneration with 81.2%. In accordance with treatment recommendations, lumbar disc herniation as underlying disease was less frequently documented.
In the cervical group (blue) there is a pain score reduction from 5.7 to 3.0 points in neck and from 6.8 to 2.9 points in arm pain. The mean followup time was 160 days.

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

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

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

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neck pain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>preop</td>
<td>274</td>
<td>5.7</td>
<td>6.0</td>
</tr>
<tr>
<td>postop</td>
<td>216</td>
<td>3.0</td>
<td>2.0</td>
</tr>
<tr>
<td>Arm pain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>preop</td>
<td>274</td>
<td>6.8</td>
<td>7.5</td>
</tr>
<tr>
<td>postop</td>
<td>216</td>
<td>2.9</td>
<td>2.0</td>
</tr>
</tbody>
</table>
In the lumbar group (orange) there is a pain score reduction from 6.7 to 4.0 points in back and from 5.0 to 3.2 points in leg pain. The mean follow-up time was 212 days.

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

<table>
<thead>
<tr>
<th>Lumbar group</th>
<th>Back pain</th>
<th>N</th>
<th>Mean</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>preop</td>
<td>87</td>
<td>6.7</td>
<td>7.0</td>
</tr>
<tr>
<td></td>
<td>postop</td>
<td>59</td>
<td>4.0</td>
<td>3.0</td>
</tr>
<tr>
<td>Leg pain</td>
<td>N</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>preop</td>
<td>87</td>
<td>5.0</td>
<td>5.0</td>
</tr>
<tr>
<td></td>
<td>postop</td>
<td>59</td>
<td>3.2</td>
<td>3.0</td>
</tr>
</tbody>
</table>

![VAS: Back pain](image1)

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

![VAS: Leg pain](image2)

**Fig 35: VAS scores pre- and postoperative for back pain, lumbar group (patients with TDA)**
Figure 36 displays the growth curves of the various national modules. The different starting dates of the modules need to be considered (Swiss/International: 2005, Austrian 2005, German: 2006, North American: 2007, Brazilian/ South American: 2008; Italian: 2008; Mexican: 2008)
The latest newcomers are an Australian and British module. Both are not yet available via www.Eurospine.org, but already have clinics entering data.

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

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

Each module server contains a local MySQL database, an Apache web server and the custom MEMdoc-Module application. This server can sit within the same clinic as the user or in some remote location depending on the needs of the group hosting the module. The physical and network security of this server is left up to the hosting entity. Some groups choose to restrict access to the module to users within the local subnet while others allow open access from anywhere. The module database contains all user and clinic information as well as the basic demographic data of patients. No medical data is stored on the module server.
All users from every MEMdoc-Module make their initial connection to the MEMdoc central server that houses the core MEMdoc application as well as all clinical study definitions. The MEMdoc application then recognizes the URL of the connection to determine which MEMdoc-Module to utilize and delivers the appropriate custom module application to the user’s web browser. Each time a user requests data the application contacts both the local MEMdoc-Module and MEMdoc central database (Oracle) to seamlessly integrate the data from each for display. Newly entered data is likewise split so that only internal numeric identifiers for the user, patient, clinic, department and module are stored on the MEMdoc central database. All medical data is retrieved from and stored directly to the MEMdoc central server and linked to the module by these internal identifiers. Medical data never passes through the MEMdoc-Module server and is never stored on the MEMdoc-Module server. The birth year and gender of each patient are the only pieces of personal information stored on the MEMdoc central data for performing pooled statistics.

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

The following hardware is recommended for a MEMdoc-Module:

- Midrange Tower- or 19” Rack server
- CPU Intel Quad Core, Xeon or AMD Opteron
- RAM > 2 GB
- Hardware RAID 1 or 5
- Linux (Debian 5)
<table>
<thead>
<tr>
<th>Language</th>
<th>SF-36</th>
<th>EQ-5D</th>
<th>SRS-22</th>
<th>Oswestry</th>
<th>COM Patient Assessment Back</th>
<th>COM Patient Assessment Neck</th>
</tr>
</thead>
<tbody>
<tr>
<td>English</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Spanish</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>French</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>German</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Forms used in the SSE Spine Tango Registry 01.01.2010

Table 5: Available questionnaires in the SSE Spine Tango Registry
PUBLICATIONS

Papers in peer reviewed journals


Oral presentations


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

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


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


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


Awards

Best Poster Award

Sobottke R, Zweig T, Röder C, Eysel P; Delank KS, Aghayev E Wirbelsäulenchirurgie im Alter: Wie riskant ist die operative Therapie der lumbalen Spinalkanalstenose (LSS) in Abhängigkeit vom Patientenalter. [Spine Surgery in elderly patients: how risky is the operative treatment of lumbar spinal stenosis depending on patient age.] 4th Annual Conference, DWG (German Spine Society), Munich 2009
Christoph Röder, MD PhD MPH
Senior Researcher, Spine Tango Coordination
Institute for Evaluative Research in Medicine
University of Berne, Switzerland

Michal Neukamp, MD
Spine Tango Support & Research
Institute for Evaluative Research in Medicine
University of Berne, Switzerland

Gosia Perler
Statistics
Institute for Evaluative Research in Medicine
University of Berne, Switzerland

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

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

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

Max Aebi, MD, Dhc, FRCSC
Professor and Director
Institute for Evaluative Research in Medicine
University of Berne, Switzerland