

## Trial Description

### Title

**Minimally invasive transforaminal lumbar interbody fusion (MIS TLIF) using conventional fluoroscopy and 3D fluoroscopy-based navigation - a prospective, randomized comparative study regarding radiation exposure as well as radiological and clinical results.**

### Trial Acronym

[---]\*

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**In minimally invasive surgery for stabilizing the lumbar spine, implants (screws, rods, spacer) have to be introduced precisely. For this purpose, X-ray-based imaging techniques are used intraoperatively. Conventional X-ray imaging (fluoroscopy) and intraoperative 3D fluoroscopy-based navigation (creating a 3D data set by fluoroscopy for navigation) are established imaging techniques. Since X-rays are ionizing and have potentially damaging effect on tissue, the most economical use of X-rays is crucial.**

**Radiation exposure to patient and operating room staff by these two imaging techniques during minimally invasive stabilization of the lumbar spine (MIS TLIF) has not yet been compared.**

**The aim of this study is to compare "conventional fluoroscopy" and intraoperative "3D Fluoroscopic navigation" in terms of radiation exposure of the patient and the operating room staff as well as the clinical and radiological results in minimally invasive stabilization of the lumbar spine (MIS TLIF) .**

### Brief Summary in Scientific Language

**As part of a posterior stabilization of the lumbar spine, dorsal transpedicular screws have to be implanted in the vertebral body as well as cages into the intervertebral disc space. For this purpose, x-ray-based imaging techniques are used. Since X-rays are ionizing and have potentially damaging effect on tissue, sparse use of X-rays is crucial.**

**The traditional open surgical technique for spinal stabilization (open transforaminal lumbar interbody fusion, OTLIF) includes a long incision in the back, pushing off of the paraspinal musculature and thus provide an open view on the posterior spinal structures in order to introduce the implants. Currently, minimally invasive surgical techniques (minimally invasive transforaminal lumbar interbody fusion, MIS TLIF) are increasingly used. It could be shown that MIS TLIF provides smaller incisions, reduced muscle trauma, infrequently healing disorders and infections, lower intraoperative blood loss, a less frequent application of a wound drainage, a reduced need for opioids, earlier mobilization and an earlier discharge from the hospital compared to OTLIF. Due to the lack of intraoperative visualization of the posterior spine in MIS TLIF, an increased use of x-rays is required, which can lead to an increased radiation exposure of the surgeon,**

**operating room staff, and patient.**

**In addition, the intraoperative 3D navigation is a new development of modern imaging techniques. Goals of the intraoperative 3D navigation are higher accuracy, reduced radiation exposure and possibly shorter operation time. In a cadaver study, MIS TLIF using the navigation-assisted fluoroscopy was found to exhibit less radiation exposure of the operator compared with conventional fluoroscopy. However, there are no systematic comparative studies of the radiation exposure performing MIS TLIF in patients.**

**In the Department of Neurosurgery of the University Hospital in Freiburg, MIS TLIF have been performed routinely for years using the conventional fluoroscopy and 3D fluoroscopy-based navigation. With conventional fluoroscopy, X-ray images can visualize the minimally invasive introduced instruments and implants. With the 3D fluoroscopy-based navigation, an automated intraoperative 3D navigation data set is created from X-ray images. These X-rays were made in the absence of the operating room staff. Subsequently, the minimally invasive introduced instruments can be visualized in the 3D navigation data set on the screen of the navigation system. Herewith, the spine can be instrumented precisely without exposing operating room staff and patient to further X-rays.**

**This study is a comparative study of the radiation exposure of the surgeon, operating room staff and patient, and of the radiological and clinical outcomes in mono- and bisegmental MIS TLIF using the following intraoperative imaging techniques:**

- **Conventional fluoroscopy (FLUORO group)**
- **3D fluoroscopy-based navigation (NAV group)**

**Do you plan to share individual participant data with other researchers?**

[---]\*

**Description IPD sharing plan**

[---]\*

## Organizational Data

- DRKS-ID: **DRKS00004514**
- Date of Registration in DRKS: **2012/11/08**
- Date of Registration in Partner Registry or other Primary Registry: [---]\*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **431/12 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

## Secondary IDs

- Other Secondary-ID: [---]\*

## Health condition or Problem studied

- ICD10: **M53.26** - [generalization **M53.2: Spinal instabilities**]
- ICD10: **M43.16** - [generalization **M43.1: Spondylolisthesis**]
- ICD10: **M43.17** - [generalization **M43.1: Spondylolisthesis**]
- ICD10: **M43.06** - [generalization **M43.0: Spondylolysis**]
- ICD10: **M47.26** - [generalization **M47.2: Other spondylosis with radiculopathy**]

## Interventions/Observational Groups

- Arm 1: **Conventional fluoroscopy (FLUORO group)**
- Arm 2: **3D fluoroscopy-based navigation (NAV group)**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Randomized controlled trial**
- Blinding: [---]\*
- Who is blinded: [---]\*
- Control: **Active control (effective treatment of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

## Primary Outcome

**Radiation exposure of the surgeon, operating room staff and patient per monosegmental MIS TLIF in the FLUORO and NAV group (measured with dosimeters)**

## Secondary Outcome

- **Radiation exposure of patients with bisegmental MIS TLIF in the FLUORO and NAV group**
- **Radiation exposure of the surgeon, operating room staff and patient depending on the body mass index (BMI) of patients in the FLUORO and NAV group**
- **Radiation exposure of the surgeon, operating room staff and patient per MIS TLIF with or without cement augmentation**
- **Clinical outcome (examination findings, questionnaires), fusion rate (follow-up, 12 months)**
- **Comparison of the accuracy of pedicle screws in the FLUORO and NAV group**
- **Comparison of the parameters of the sagittal balance (C7 plumb line, segmental / lumbar lordosis, pelvic tilt, sacral slope, pelvic incidence) between follow-up (12**

**months) and preoperatively in the FLUORO and NAV group in lateral X-rays**

## Countries of recruitment

- **DE Germany**

## Locations of Recruitment

- University Medical Center **Neurochirurgische Klinik, Freiburg im Breisgau**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/02/07**
- Target Sample Size: **55**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

## Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

## Additional Inclusion Criteria

- **Full age to competent patients with planned mono- or bisegmental MIS TLIF between LWK 2 and SWK 1 due to degeneration and / or instability including spondylolisthesis Meyerding grade I and II.**
- **Both imaging techniques are considered suitable for MIS TLIF.**
- **No improvement in symptoms for at least 3 months under conservative treatment.**
- **Pain score (VAS for low back pain) of at least 3/10.**

## Exclusion criteria

- **Previous surgery in the affected or directly adjacent vertebral segment.**
- **Spondylodiscitis, traumatic instability, osteoporotic vertebral fractures, neoplastic disease of the operating segment(s), spondylolisthesis Meyerding grade III and IV.**
- **Indication for stabilization > 2 segments.**
- **One of the imaging techniques is not considered suitable for MIS TLIF.**
- **Scoliosis with a Cobb angle > 10 ° in the operating segment(s).**

## Addresses

### ■ Primary Sponsor

**Neurochirurgische Universitätsklinik Freiburg**  
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### ■ Contact for Scientific Queries

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## Sources of Monetary or Material Support

### ■ Institutional budget, no external funding (budget of sponsor/PI)

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■ **Private sponsorship (foundations, study societies, etc.)**

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## Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2016/11/25**

## Trial Publications, Results and other documents

- Paper **Studienprotokoll**
- Paper **PubMed - Abstract**
- Paper **PubMed - Abstract**

\* This entry means the parameter is not applicable or has not been set.

\*\*\* This entry means that data is not displayed due to insufficient data privacy clearing.