

PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

**Navigation of TKA:
Rotation of components and clinical results in a prospectively randomized study**

Trial Acronym

Navigation TKA

URL of the trial

[---]*

Brief Summary in Lay Language

The value if navigation for knee arthroplasty is to be evaluated.

Brief Summary in Scientific Language

Abstract:

Background:

Navigation was introduced into Total Knee Arthroplasty (TKA) to improve accuracy of component position, function and survival of implants. This study was designed to assess the outcome of navigated TKA in comparison with conventional implantation with the focus on rotational component position and clinical mid-term results.

Methods:

In a prospectively randomized single-blinded approach, 90 patients with primary gonarthrosis were assigned to three different groups. 30 patients each were assigned to NexGen LPS without and with navigation (groups 1 and 2), and 30 patients to navigation with the Stryker Scorpio PS (group 3). Clinical outcome was assessed by a blinded observer applying the Knee Society Score (KSS) and a visual analogue scale. CT scans and radiographs were conducted prior to, and 12 weeks after index surgery.

Results:

79 patients were available for clinical evaluation at 3 ± 0.4 years follow-up. Four implants had to be revised for early loosening or infection (4.4%). Four patients had died and three patients were not able to follow the invitation for clinical assessment. Functional results in the KSS were significantly lower after navigated TKA. Operation time and incisions with navigation were significantly longer. Significantly less radiological outliers with navigation were found for coronal alignment of the femur, only.

Conclusion:

In this series, no beneficial effect for navigation in TKA could be shown assessing clinical data, as functional results in the presented series seemed to be lower after navigated TKA. The clinical mid- to long-term value of navigation remains to



be evaluated in larger patient series or meta-analyses at longer follow-up.

Organizational Data

- DRKS-ID: **DRKS00000430**
- Date of Registration in DRKS: **2010/11/26**
- 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.: **69/01** , **Ethik-Kommission des Fachbereichs Medizin der Philipps-Universität Marburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **M17.1 - Other primary gonarthrosis**

Interventions/Observational Groups

- Arm 1: **TKA NexGen non-navigated**
- Arm 2: **TKA NexGen navigated**
- Arm 3: **TKA Scorpio navigated**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: **Single blind**
- Who is blinded: [---]*
- Control: **Active control**
- Purpose: **Prognosis**
- Assignment: **Parallel**
- Phase: **N/A**
-



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Phase: **N/A**

Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

Primary Outcome

Analysis of Rotation of components in CT 3 Months postOP

Secondary Outcome

Survival of implants at 10 years

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2001/08/06**
- Target Sample Size: **90**
- 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

Indication for TKA

Exclusion criteria

Unwilling or unable to give informed consent.

Addresses

■ Primary Sponsor

**Klinik für Orthopädie und Rheumatologie
Baldingerstrasse
35043 Marburg
Germany**

Telephone: **+4964215863691**

Fax: **+4964215867007**

E-mail: **heyse at med.uni-marburg.de**

URL: **http://www.ukgm.de/ugm_2/deu/203.html**

■ Contact for Scientific Queries

**Klinik für Orthopädie und Rheumatologie
Mr. Dr. Thomas Heyse
Baldingerstrasse
35043 Marburg
Germany**

Telephone: **+4964215863691**

Fax: **+4964215867007**

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Sources of Monetary or Material Support

- **Institutional budget , no external funding (budget of sponsor/PI)**

Klinik für Orthopädie und Rheumatologie

Mr. Dr. Jan Schmitt

Baldingerstrasse

35043 Marburg

Germany

Telephone: **+4964215863691**

Fax: **+4964215867007**

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Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

- 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.