In Vivo Testing of Knee Stability After Rotating-hinge Total Knee Arthroplasty: A Comparison of 2 Knee Systems

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abstract

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Rotating-hinge knee prostheses are used for reconstruction in cases of severe articular compromise and major bone loss. Biomechanical studies revealed that rotating-hinge designs with long and cylindrical pegs are more stable than devices with short and more tapered ones. Twenty-five patients underwent clinical examination using ultrasound, radiographs, and 3 different rating systems to examine the in vivo stability and functional outcome of 2 rotating-hinge knee systems.

Overall, the study revealed that a stable reconstruction could be achieved with both tested devices, with good functional outcome. The results for medial and lateral lift-off during flexion and extension in ultrasonography were comparable, whereas the measured distraction of the Limb Preservation System (LPS/M.B.T.; DePuy, Warsaw, Indiana) was lower compared with the S-ROM Noiles prostheses (DePuy).

The implant, the new formed capsule, and the remaining soft tissues have to maintain joint stability. Soft tissue reconstruction, especially the medial gastrocnemius flap, and the newly formed periprosthetic scar seems to prevent distraction of several millimeters. In addition, determining the lift-off with ultrasonography showed that the shape of the peg does not influence implant’s stability against lateral directed forces.

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Figure: The central rotational stem of the LPS/M.B.T. knee system (DePuy, Warsaw, Indiana) is part cylindrical at the tip and part conical at the base of the polyethylene tray (A), whereas the S-ROM Noiles (DePuy) is truly conical from the tip to the base (stem taper, 5°) (B).
In the past, amputation was the common surgical treatment for malignant bone tumors in distal extremities. Furthermore, arthrodesis or amputation were chosen in revision settings after failed total knee arthroplasty (TKA) with gross bone loss, massive instability, or persistent infection. Limb-salvage surgery using modular or custom-made endoprostheses became an accepted treatment for primary bone tumors or metastases of the extremities. Due to the growing number of revision surgeries for conventional total hip and knee implants, the market for megaprostheses has evolved, and many modular and custom-made prostheses are available.\(^1,5\)

The latest generation of hinged prostheses incorporates a rotating-hinge articulation with a metal-on-polyethylene bearing surface, which allows axial rotation. Surface contact throughout the total range of motion (ROM) leads to the distribution of weight-bearing forces through the femoral condyles. The tibial insert has to handle angular and translational movements. These mechanisms are intended to address the failures of earlier fixed-hinge designs and have produced good short- and mid-term results.\(^5,15\) Nevertheless, because the constraints of the rotating-hinge knee devices decreased, a greater demand is placed on the surrounding soft tissues to maintain stability.

Appropriate coordination of joint laxity and stability is essential for a functional knee. Mild distraction of the knee is observed following endoprosthetic reconstruction of the knee, and investigations showed that instability is most apparent to the patients in flexion when they lift the lower limb out of a seated position or leave the leg dangling.\(^16\) Gustke\(^17\) suggested that instability (flexion–extension gap imbalance) and distraction between the femoral and tibial components can result from soft tissue compromise and ligament laxity.

We performed a study including 25 patients who underwent total femoral, distal femoral, or proximal tibial replacement using the Limb Preservation System (LPS/M.B.T.; DePuy, Warsaw, Indiana) or S-ROM Noiles Rotating Hinge Knee System (DePuy) for tumor or revision indications. The purpose of the study was to compare in vivo stability and functional outcome of these rotating-hinge prostheses. We hypothesized that the LPS/M.B.T. device was more stable than the S-ROM Noiles rotating-hinge knee because of the different shape of the central rotational stem (half cylindrical, half conical vs truly conical). Furthermore, we investigated if soft tissue compromise and/or soft tissue reconstruction would influence implant stability and its impact on distraction. Therefore, clinical and radiographic evaluation were performed, using plain radiographs and ultrasonography. Three rating systems were used to evaluate and compare the functional outcome.

**MATERIALS AND METHODS**

Between January 2003 and December 2008, fifty-five patients (26 men and 29 women) underwent TKA using the LPS/M.B.T. or the S-ROM Noiles rotating-hinge prosthesis at our institution. During the investigation, the LPS/M.B.T. prosthesis was chosen for reconstruction following tumor resections by surgeon preference, whereas the S-ROM Noiles system is still routinely used for revision settings.

Forty-four distal femoral, 8 proximal tibial, and 3 total femoral replacements were performed. Indications were resection of malignancies, primary implantations, and revision TKAs. Mean patient age at surgery was 61 years (range, 14-90 years). Average postoperative follow-up was 32 months (range, 1-73 months).

Of the initial 55 patients, 11 died due to their underlying disease or an unrelated cause, 5 were lost to follow-up, and 14 did not participate in our investigation. In total, 25 patients were investigated (mean follow-up, 38 months; range, 11-67 months). Demographic data of the patients divided by the used hinged tibial insert are shown in Table 1. The LPS/M.B.T. hinged tibial insert was used in 12 patients and the S-ROM Noiles polyethylene insert was used in 13 patients.

**Prostheses/Inlays**

The LPS/M.B.T. knee system is a comprehensive modular implant system designed to facilitate limb-sparing surgery. The central rotational stem of the LPS/M.B.T. knee system is part cylindrical at the tip and part conical at the base of the polyethylene tray (Figure 1A). The S-ROM Noiles rotating-hinge prosthesis is used for reconstruction in cases of ligamentous instability or multiple revision settings. The peg’s design is truly conical from the tip to the base, with a stem taper of 5° (Figure 1B).

**Physical Examination and Scoring Systems**

For functional evaluation, the active and passive total ROM and the clinical stability of the implant in extension (medial and lateral lift-off) were tested. Three different rating systems were used to assess functional outcome: Knee Society Score, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score, and Musculoskeletal Tumor Society (MSTS) score.

**Radiographic Evaluation**

No rating system was used for radiographic evaluation. Anteroposterior and lateral radiographs in extension were examined for any signs of loosening (changes in implant position, migration, and radiolucent lines), instability, or malalignment (Figures 2A, B).

In addition, conventional radiographs and fluoroscopy of the knee made with a C-arm were taken from the lateral view in knee flexion. Both uptakes were made with a reference ball (diameter, 25 mm for plain radiographs and 17 mm for fluoroscopy) to determine the distraction of the hinged tibial insert (Figures 2B, C). For the radiographs, the patients sat on the edge of the examination table with the
knee in flexion (90°). The leg was dangling, and the distraction of the inlay was produced by the force of gravity.

Ultrasonography of the knee was performed with a 9-MHz device (Siemens Elegra; Siemens AG, Erlangen, Germany) to quantify the medial and lateral lift-off distances in flexion and extension. This technique was used because it has been shown to be a reliable method with no additional radiation burden. The ultrasound head was positioned on the medial and lateral side of the knee until the echo of the hinged insert was detected (Figure 3A). The ultrasound response of bone and metal was reported previously and differs from the distinct hyperechogenic signal of the hinged tibial insert. On freeze images, the medial and lateral distance between the femoral and tibial component were measured in flexion and extension (Figure 3). These measurements were repeated with varus and valgus stress to cause medial and lateral lift-off (Figure 3A). To determine the medial and lateral lift-off distances in each position, the measured distances in neutral position were subtracted from the measured distances made with varus or valgus stress.

For statistic analysis, the PASW Statistics 16.0 program (SPSS Inc, Chicago, Illinois) was used, and P<.05 was considered statistically significant.
Bivariate data analyses were performed to determine the Pearson correlation coefficient, and analysis of variance (ANOVA) was performed to determine significant differences between the hinged tibial insert groups.

The study was approved by the Ethics Committee of the Medical University of Graz, and informed consent was obtained from all patients.

**RESULTS**

**Physical Examination/Function/Stability**

The active total ROM for the LPS/M.B.T. inlay ranged from 30° to 125° (mean, 94°), whereas the average passive mobility was 95° (range, 30°-125°). The active total ROM for the S-ROM Noiles hinged tibial insert ranged from 80° to 120° (mean, 103°), whereas the passive ROM ranged from 80° to 130° (mean,
108°). Overall, the total ROM was satisfying in both implant groups, except for 2 patients with a LPS/M.B.T. device, whose active and passive flexion were limited to 30° and 50° due to extensive soft tissue compromise following tumor resection. Nevertheless, ANOVA comparing the ROM of both devices showed no significant difference between the active \((P= .275)\) and passive \((P= .161)\) ROMs.

Clinical stability was tested in extension with an applied varus and valgus stress. The mean results for medial and lateral lift-off were 1° (range, 0°-5°) and 2° (range, 0°-4°), respectively, for the LPS/M.B.T. hinged insert and 1° (range, 0°-3°) each for the S-ROM Noiles hinged tibial insert. Comparing the lift-off of both implants showed no significant difference between the medial \((P= .857)\) or the lateral \((P= .477)\) lift-off.

**Scoring Systems**

Patients who had distal femoral or proximal tibial replacement with a LPS/M.B.T. hinged insert had a mean WOMAC score of 20 points (range, 1-43 points). Patients treated with an S-ROM Noiles hinged tibial insert had a mean WOMAC score of 19 points (range, 0-88 points). The different outcomes between the groups were not statistically significant \((P= .957)\).

The results of the first part of the Knee Society Score, assessing the function of the knee, were satisfying in both groups. Mean score was 86 points (range, 65-100 points) for patients with the LPS/M.B.T. inlay, and mean score was 87 points (range, 51-100 points) for patients with the S-ROM Noiles hinged tibial insert.

The second part of the Knee Society Score, evaluating the functional parameters of walking, stair stepping, and walking aid use, showed worse results compared with the first part. Most patients had deductions for using walking aids, such as canes or crutches. The maximum score for the LPS/M.B.T. inlay was 100 points, and the worst result was 45 points (mean, 70 points). Mean results of the S-ROM Noiles group were worse than the results of the LPS/M.B.T., with a mean score of 60 points (range, 0-100 points). The differences between the groups were not statistically significant for the first \((P= .768)\) or second part \((P= .395)\) of the Knee Society Score. Mean percentage rating of the total score of 30 points was 76% (range, 40%-100%) in the LPS/M.B.T. group and 70% (range, 17%-97%) in the S-ROM Noiles group. Overall, statistical analysis comparing the results of MSTS score revealed no significant differences between the groups \((P= .484)\).

**Radiographic Evaluation**

On anteroposterior and lateral radiographs, some radiolucent lines we observed around the femoral and tibial intramedullary stems of some patients, but no further signs of loosening or instability were observed (Figures 2A, B). Nevertheless, all components were stable. Average distraction measured on the radiographs was 0.8 mm (range, 0-3.7 mm) for the LPS/M.B.T. hinged tibial insert and 1.0 mm (range, 0.5-4.7 mm) for the S-ROM Noiles insert (Figure 1C). Analysis of variance of the mean results showed no significant differences between the inserts \((P= .664)\) (Table 2). Measurements with the C-arm resulted in a range of distraction between 0 to 7.1 mm (mean, 1.3 mm) for the LPS/M.B.T. insert and 0 to 9.7 mm (mean, 2.1 mm) for the S-ROM Noiles insert. However, the \(P\) value of the ANOVA comparing the measured distraction of the 2 groups was not significant \((P= .433)\) (Table 2). Nevertheless, a significant correlation existed between the distraction measured on the plain radiographs and the C-arm radiographs \((LPS/M.B.T. Pearson, 0.947; P< .001)\) (S-ROM Noiles Pearson, 0.787; \(P= .001)\).

Measuring the medial and lateral lift-off distances with ultrasonography showed comparable results for both devices (Table 2). The measurements in exten-
sion showed a significant correlation between medial and lateral lift-off distance for the S-ROM Noiles implant (Pearson, 0.768; \( P = .002 \)), whereas the lift-off distances during flexion revealed a significant correlation for the LPS/M.B.T. device (Pearson, 0.701; \( P = .011 \)). Analysis of variance comparing the medial and lateral lift-off distances during flexion and extension revealed results that were not significant (Table 2).

**Mechanical Failure**

Although clinical and radiographic evaluations showed that a stable reconstruction with good functional outcome could be achieved with both tested devices, 5 dislocations occurred in 3 of 55 patients. One dislocation was traumatic, 1 prosthesis dislocated due to a loosened femoral component, and 3 prostheses dislocated after fracture of the metal yoke inside the hinged tibial insert (Figure 4). All yoke fractures of the LPS/M.B.T. hinged insert occurred at the transition zone from the conical to the cylindrical part (Figure 4E). As a consequence, the hinged tibial insert was changed in all cases, and the extensor mechanism was reconstructed in 2. After a second dislocation due to a yoke fracture in 1 patient, the manufacturer modified the metal yoke, and no further complications occurred during a follow-up period of 9 months.

**DISCUSSION**

The current study testing the in vivo stability and functional outcomes of the LPS/M.B.T. and the S-ROM Noiles rotating-hinge devices showed no significant differences between these implants, despite their different-shaped central rotational stems. Furthermore, determining the distraction of the peg also showed no significant differences (Table 2). However, based on the results of statistical analysis, the study may have been underpowered.

The functional result of limb-salvage procedures for tumoral and non-neoplastic indications depends on the extent of bone and soft tissue resection, the used reconstructive technique, the prosthesis design, and the cooperation of the patient.\(^{3,14,19}\) Renard et al\(^{20}\) described a significantly better functional outcome after limb-salvage surgery compared with ablative procedures (\( P = .0001 \)), whereas a comparison of different limb-salvage procedures (endoprosthetic reconstruction vs arthrodesis vs rotationalplasty) produced no significant differences.

In the current study, the functional outcome and scoring systems revealed good to excellent results for the LPS/M.B.T. and S-ROM Noiles devices (Table 2). Similar to an earlier series, slightly better function was found in patients treated for nontumor conditions compared with patients treated for neoplasms.\(^{21}\) In addition, revision procedures in tumor patients gave poorer results than in nontumor patients. Overall, total ROM was excellent in both implant groups, except for 2 patients with a LPS/M.B.T. device whose active and passive flexion was limited to 30° and 50° due to extensive soft tissue compromise following tumor resection. Wiganowicz et al\(^{22}\) found a reduction in functional rating after revision procedures, whereas several other investigators reported that a second revision procedure does not cause deterioration.\(^{3,10,14,20,23-30}\)

The clinical stability test in extension showed low varus–valgus angulation for both implants, and the measurements with ultrasonography in flexion and extension showed that both rotating-hinge devices were robust against varus and valgus stress, despite the more tapered peg of the S-ROM Noiles hinged tibial insert (Figure 1; Table 2).

Nevertheless, medial or lateral instability is common following TKA. Ligamentous imbalance, component malalignment or loosening, and polyethylene wear are the most frequent reasons for this complication.\(^{31}\) Several repair techniques and treatment options have been described, including immobolizers, braces, or orthoses as nonoperative management.\(^{31}\) Further opportunities to enhance joint stability are the advancement of the collateral ligaments and muscle or tendon transfers.\(^{32-36}\) Moreover, collateral ligament insufficiency can be treated with soft tissue reconstruction or with implants that provide inherent stability in the coronal plane.\(^{37}\) Overall, the minimum amount of constraint combined with ligament reconstruction should be used to achieve joint stability in cases of ligament deficiency, but rotating-hinge knee prostheses remain a viable option.\(^{2}\)

Determining the distraction of the peg with plain and C-arm radiographs resulted in a lower distraction of the LPS/M.B.T. peg compared with the S-ROM Noiles...
device, although this difference was not statistically significant (Table 2).

In 2003, Eckardt et al. performed a biomechanical analysis testing the stability and the maximum amount of distraction until dislocation of 7 rotating-hinge knee devices. This study showed that implant designs with long, untapered central rotational stems produced the best results (higher stability and lower risk of dislocation). Therefore, they recommended devices with a long (>5 cm) cylindrical peg or an effective mechanical antidislocation feature. However, the current study showed that there are only some millimeters of distraction in vivo; therefore, angular laxity plays a minor role in cases of stable joint reconstruction.

Dislocation of a rotating-hinge knee prosthesis is a serious but rare complication. Of 55 initial joint reconstructions in the current series, 5 dislocations occurred in 3 patients (Figure 4). One explanation for breakage of the yoke could be thrashing due to high axial load during flexion, combined with several millimeters of distraction and posterior dislocating forces. However, it could be an ordinary failure in its fabrication. As a consequence of this failure, the manufacturer modified the hinged tibial insert, and no further complications occurred.

Schwarzkopf et al reported 2 cases of fractured LPS/M.B.T. metal yokes. They hypothesized that the fatigue fractures were caused by a cantilever effect due to extreme laxity of the knee combined with nonrotatory motion at the insert–base plate interface. This could also be a further explanation for the fractures in the current series. Kawai et al. also related 2 tibial yoke fractures of the Finn Rotating Hinge Knee (Biomet, Warsaw, Indiana) and 1 fractured tibial bearing insert. As a consequence, the yoke was thickened approximately 50%, and no further complications occurred. Several other authors reported dislocated rotating-hinge knee prostheses, but in the majority of cases, dislocation occurred due to breakage of any prostheses component or fatigue of the tibial antidislocation device. All authors reported excessive flexion gap instability and posterior dislocating forces to be responsible for the mechanical failure, indicating the importance of the ligamentous balance, especially the flexion gap.

The current study had several limitations. First, a small number of patients were enrolled in the study and split into 2 subpopulations. Second, we did not perform a power analysis, but the current study seems to be underpowered; therefore, the data may be less persuasive. Third, no preoperative scores could be compared with postoperative scores. The data can be used to compare the postoperative outcomes.

**CONCLUSION**

Both tested rotating-hinge devices provided outstanding stability with good functional outcomes. The implant and its intrinsic stability, the newly formed peri-prosthetic capsule, and the remaining soft tissues have to maintain joint stability. Soft tissue reconstruction, especially the medial gastrocnemius flap, which was used in several cases, seems to prevent distraction of several millimeters, particularly in tumor cases. The shape of the peg does not influence the implant’s stability against lateral-directed forces. 

**REFERENCES**


Feature Article


