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Clinical and radiological results of a stemmed medial pivot revision implant in aseptic total knee revision arthroplasty

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Background: Constraint choice in revision total knee arthroplasty depends on the stability of the collateral ligaments and on the severity of bone loss, but the least degree of constraint necessary is recommended. The purpose of this retrospective matched-paired study was to compare clinical results, radiographic outcome and the survival of a stemmed medial pivot revision implant in aseptic revision TKA vs. medial pivot implant in primary TKA.

Methods: Records were reviewed for 69 cases of aseptic revision TKA using Advance® Medial Pivot Stemmed Revision Knee system between 2002 and 2016. These patients were then matched in a 1:2 ratio control group of patients who received a primary TKA with Advance® Medial Pivot system. American Knee Society Score and Visual Analogue Scale pain score were recorded. Alignment, loosening, and incidence of radiolucent lines were evaluated on X-rays. Implant survival was assessed by Kaplan–Meier survival analysis.

Results: The primary TKA group had significant superior AKSS clinical and functional score at baseline (52.3 and 68.2 points, respectively) and at last follow up (84.6 and 68.6 points) compared with the revision TKA group (47.9 and 40.9 points; 78.4 and 59.9 points; $P < 0.05$). No significant difference was observed in the mean change from baseline to last follow up of AKSS score between the two groups ($P > 0.05$). Radiographical outcome and implant survival were similar in the two groups ($P > 0.05$).

Conclusion: The authors support the use of this revision system in knees with collateral ligaments competence and mild-to-moderate bone defect.

1. Introduction

Revision total knee arthroplasty (TKA) is performed with increasing frequency as the population is aging and the number of primary TKA implants is on the rise [1,2]. Unfortunately, although good results and outcomes of these surgeries have been reported [3], about six percent of patients who undergo TKA will require revision in five years [4]. Even with the continuous developments of surgical techniques and implant models, revision TKA rate is predicted to increase by 600% between 2005 and 2030 [5].

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Revision TKA surgery presents numerous challenges, such as adequate management of bone defect and ligamentous instability. Various techniques and devices have been developed to manage the bone defects and obtain adequate fixation including cementation, modular metal augments, bone graft, metaphyseal sleeves and cones and stem component [6,7].

Although the use of higher constrained devices can improve ligamentous instability, this has a negative effect on implant interfaces which may result in earlier loosening and increased polyethylene wear secondary to greater torque on the constraining mechanism.

Constraint choice depends on the integrity and stability of collateral ligaments and other peripheral stabilizers of the knee and on the severity of bone loss. The least degree of constraint necessary is recommended [8–12].

Medial pivot knee design has been developed in order to mimic normal knee kinematics. Compensation for the absent or resected posterior cruciate ligament is accomplished with a medial pivot cruciate substituting insert that possess a mechanical 'stop' to prevent the tibia from anterior subluxation. The medial pivot knee utilizes a 'ball-in-socket' articulating mechanism on the medial side while the lateral side of the insert is less constrained and allows for translation about the medial condyle. Previous studies with medial pivot implant in primary TKA have shown excellent long-term results [13–16].

The purpose of this retrospective matched-paired study was to compare: (1) clinical results, (2) radiographic outcomes, and (3) the survival of a stemmed medial pivot revision implant in aseptic revision TKA vs. medial pivot implant in primary TKA.

2. Materials and methods

2.1. Patient recruitment

After local ethics committee approval (Institutional review board approval obtained by the ethics committee of Verona/Rovigo (IRB: 2614/2019)), 69 non-consecutive patients who had undergone aseptic revision TKA at our institution between 2002 and 2016 by our senior surgeons (E.V. and M.R.) using the Advance® Medial Pivot Stemmed Revision system (MicroPort Orthopedics, Arlington, TN, USA) and had at least two years (range 28–180 months) of follow-up were identified from our arthroplasty database.

The Advance® Medial Pivot Stemmed Revision system is a medial pivot component that offers the possibility to use stems and block or wedge augments to increase stability and fixation in case of bone loss. The implant system is recommended for use in case of mild-to-moderate bone loss and no collateral ligament instability.

Four patients (four TKAs) were deceased at the time of the study, six patients were lost to follow-up and three withdrew consent. A total of 56 consenting patients were eligible for analysis.

These patients were then matched in a 1:2 ratio control group of patients who received a primary TKA with Advance® Medial Pivot system (MicroPort Orthopaedics, Arlington, TN, USA).

Table 1
Demographic and baseline characteristics.

	Revision TKA (n = 56)	Primary TKA (n = 112)	*P*
Age			
Mean (SD)	72.6 (6.6)	70.9 (4.6)	n.s.[a]
Median (range)	72 (61–87)	71 (58–83)	
Gender			
Men, n (%)	21 (38%)	48 (43%)	n.s.[c]
Women, n (%)	35 (62%)	64 (57%)	
Side			
Right, n (%)	23 (41%)	60 (54%)	n.s.[c]
Left, n (%)	33 (59%)	52 (46%)	
Follow-up time			
Mean (SD)	8.8 (4.3)	9.2 (4.12)	n.s.[b]
Median (range)	10.3 (2.3–15)	10.5 (2.3–15)	
AKSS CS			
Mean (SD)	47.9 (11.8)	52.2 (9.3)	0.00021[b]
Median (range)	45 (27–87)	51 (31–85)	
AKSS FS			
Mean (SD)	41 (14.4)	47.1 (1.2)	0.00057[b]
Median (range)	40 (0–90)	45 (15–90)	
VAS			
Mean (SD)	7.2 (1.5)	7.4 (1.2)	n.s.[b]
Median (range)	7 (2–10)	8 (3–10)	
ROM			
Mean (SD)	87° (15°)	94° (13°)	0.00652[b]
Median (range)	90° (50–120°)	95° (60–125°)	

AKSS CS, American Knee Society Score – mechanical; AKSS FS, American Knee Society Score – functional; n.s., not significant; ROM, range of motion; SD, standard deviation; TKA, total knee arthroplasty; VAS, visual analog scale.

[a] *t*-Test.

[b] Mann–Whitney *U*-test.

[c] Chi-squared test.

Matching criteria were age, gender, side and follow-up time (Table 1).

2.2. Surgical procedure

The surgical approach was performed through an anterior midline approach and medial parapatellar exposure of the joint, using previous incisions if present.

In the revision TKA group, bone loss was evaluated after implant removal according to Anderson Orthopedic Research Institute (AORI) classification [17]: nine patients presented AORI 1 bone defects. AORI 2A bone defects were founded in 34 patients while AORI 2B were found in 26 patients.

AORI 1 bone defects were filled with cement, while AORI 2A and 2B bone defects were treated with cemented metal augment wedge-shape at the site of defect. Femoral augments were used in 38 knees while tibial augments were used in 37 knees. No patients of primary TKA group presented significative bone loss.

In both the primary TKA and revision TKA groups, the tibial resection was oriented using an extramedullary alignment rod while femoral alignment was chosen using manual guides based on an intramedullary rod. In all cases, patella was not replaced while posterior cruciate ligament was resected. When femoral and tibial surfaces were obtained, trial components were temporally inserted to test stability and soft tissue release was performed if necessary. All components were cemented.

Femoral and tibial stems were used in all revision cases with a hybrid cementing technique in which cement (Cemex, Tecres S. p.A., Sommacampagna, Italy) was pressurized into the metaphysis and the distal stem was press-fit. Femoral stem length varied from 100 to 140 mm and the mean diameter was 16.3 mm (14–20 mm). Tibial stem length varied from 100 to 140 mm and mean diameter was 12.8 mm (12–16 mm).

2.3. Outcome assessments

Patients were followed up at six months, one year and every two years after surgery.

Clinical evaluation was performed according to the American Knee Society Score (AKSS) system [18], which separately assesses the mechanical (AKSS CS) and functional (AKSS FS) aspects of the knee joint. Radiological evaluation was performed to assess alignment of the limb, position of the component and presence and location of radiolucent lines according to the method described by the Knee Society Total Knee Arthroplasty Roentgenographic evaluation and scoring system [19].

2.4. Statistical analysis

Descriptive statistics included means, medians, standard deviations, ranges and proportions. Chi-squared test was used to compare binary variables and unpaired *t*-test or Mann–Whitney *U*-test was used to compare independent variables at baseline and follow-up between the primary TKA and revision TKA groups. The confidence level for rejecting null hypotheses was set at 95% ($P < 0.05$). All statistical analyses were performed using R (R: a language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL http://www.R-project.org/).

Regarding our primary outcome with our available sample size and postoperative score standard deviation, this study had 80% power to detect a difference >4 points on the AKSS CS and on the KSS FS at the $P < 0.05$ level. As the minimal clinical important

Table 2
Clinical outcome measures at last follow-up.

	Revision TKA (n = 56)	Primary TKA (n = 112)	*P*
AKSS CS			
Mean (SD)	78.4 (11.7)	84.7 (7.6)	0.00161[a]
Median (range)	82 (50–94)	86 (57–100)	
AKSS FS			
Mean (SD)	59.9 (17.6)	68.6 (9.6)	0.00002[a]
Median (range)	60 (20–100)	70 (45–100)	
VAS			
Mean (SD)	3.1 (1.5)	2.2 (1.3)	0.00010[a]
Median (range)	3 (0–7)	2 (0–7)	
ROM			
Mean (SD)	102° (24°)	113° (10°)	0.00005[a]
Median (range)	105° (0–125°)	115° (90–125°)	
ΔAKSS CS			
Mean (SD)	30.6 (15.7)	32.5 (9.8)	n.s.[a]
Median (range)	34 (−11 to 55)	33 (13–54)	
ΔAKSS FS			
Mean (SD)	18.9 (11.8)	21.6 (8.7)	n.s.[a]
Median (range)	20 (−10 to 45)	20 (0–45)	

AKSS CS, American Knee Society Score – mechanical; AKSS FS, American Knee Society Score – functional; n.s., not significant; ROM, range of motion; SD, standard deviation; TKA, total knee arthroplasty; VAS, visual analog scale.

[a] Mann–Whitney *U*-test.

difference (MCID) of the AKSS CS and AKSS FS have been described to be 5.3 and 5.9 points and 6.1 to 6.4 points, respectively [20], our sample size was sufficient to detect potentially relevant differences regarding this clinical parameters.

The cumulative survival rate of the implants was evaluated using the Kaplan–Meier survival analysis [21] for both groups. Patients with failed TKA were censored at the time of failure and non-failed patients were censored at the time of last clinical contact. The comparison between the two survival curves was performed using long rank test.

3. Results

The demographic and baseline characteristics of the two groups are summarized in Table 1.

The two study groups were homogeneous in terms of demographic characteristics (age, sex, side and follow-up time). The revision TKA group was significantly different from the primary TKA group in baseline AKSS clinical and functional score and range of motion (ROM). No significant difference was detected in baseline visual analog scale (VAS).

3.1. Clinical results

The last follow-up clinical results are shown in Table 2.

The primary TKA group had superior AKSS CS and AKSS FS in comparison with revision TKA group ($P < 0.05$). Similar results were observed in ROM and VAS favoring primary TKA group ($P < 0.05$).

The ΔAKSS CS and ΔAKSS FS (change from baseline score to final postoperative score) was calculated for both groups. The mean changes in AKSS clinical score (ΔAKSS CS) and in AKSS functional score (ΔAKSS FS) after primary TKA were 32.5 points and 21.6 points, respectively, and 30.6 points and 18.9 points, respectively, for the revision TKA group. The difference in AKSS clinical score (ΔAKSS CS) and AKSS functional score (ΔAKSS FS) between the primary and revision groups was not significant ($P > 0.05$).

Based on our data, there was no difference between the revision group and the primary group in terms of survivorship 15 years after surgery (94.1%, 95% confidence interval (CI) 94.8% to 87.8%, versus 89.8% 95% CI 96.9%% to 78.4%; $P = 0.55$) (Figure 1).

3.2. Radiographic assessment

Radiological assessment was undertaken for all patients at final follow-up.

No difference was noted on prosthesis alignment between revision TKA group and primary TKA group (3.6° of varus versus 2.9° of varus; $P > 0.05$). Similar results were observed in radiolucent lines analysis. Non-progressive radiolucent lines measuring less than one millimeter were identified in nine patients (15.8%) in the revision TKA group and in 13 (8.6%) patients in the

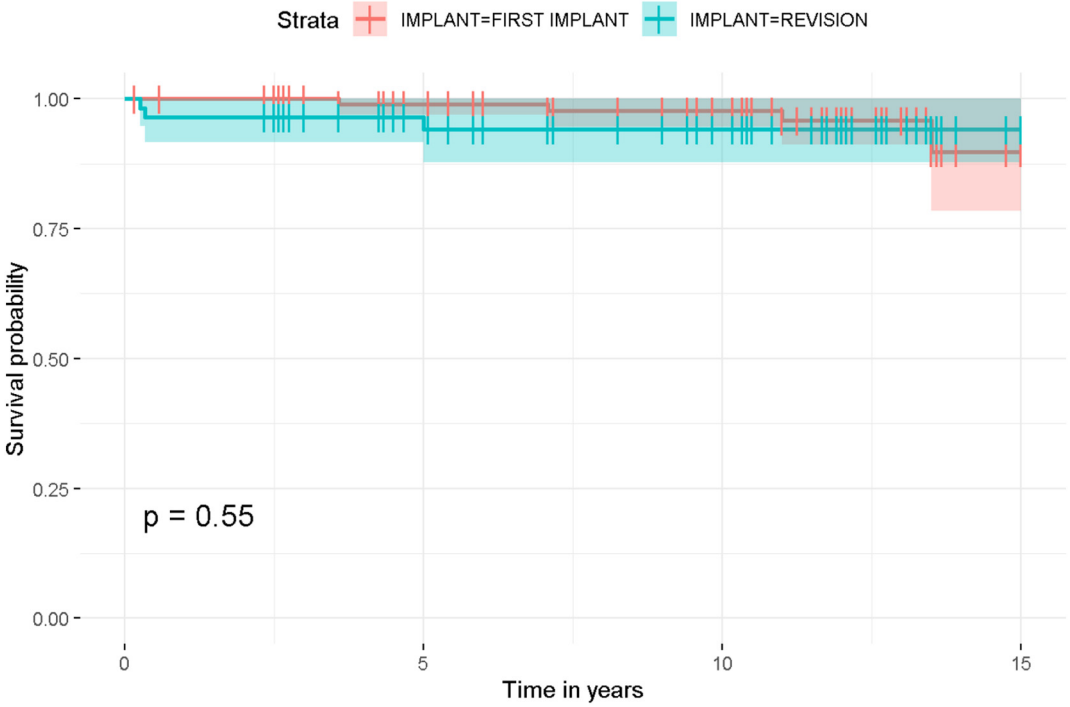

Figure 1. Kaplan–Meier survival estimates.

primary TKA group ($P > 0.05$). Radiolucent line >2 mm around the entire circumference of the prosthesis with the subsidence of the component was observed in one patient in the revision TKA group and in two patients of the primary TKA group.

3.3. Complications

In the revision TKA group, one aseptic loosening was observed (five years after surgery) for which a re-revision with hinge implant was necessary, while two patients (three and four months, respectively, after surgery) developed a deep prosthetic infection. In the primary TKA group, one patient developed deep prosthetic infection (four years after surgery), two patients aseptic loosening due to polyethylene wear (11 and 13 years after surgery) and one a periprosthetic fracture with loosening (seven years after surgery). All of them needed further revision surgery.

4. Discussion

The most important finding of this study was that improvement of AKSS between the two groups was similar from baseline to final follow-up both for clinical and functional outcome.

This is in contrast with previous reports in the literature comparing the outcomes between revision and primary TKA [22]. One possible explanation for this difference is that this revision system ensures a low degree of constraint but at the same time allows management of bone loss and the achievement of good stability and fixation of the prosthesis components.

Higher degrees of constrained devices, such as semi-constrained or hinged prostheses, lead to increased stress across the fixation interface that may result in earlier aseptic loosening and increased polyethylene wear secondary to greater torque on the constraining mechanism. Several studies recommended the use of the least degree of constraint possible in revision TKA. Low degree-constrained implant may be appropriate when collateral ligaments of the knee are intact and bone defect is not extensive [8–12]. Medial pivot is a low constraint design featured by a 'ball-in-socket articulation' with a stable endpoint in the medial compartment. The lateral condyle is less constrained to facilitate rolling from anterior to posterior, in order to better mimic the physiological kinematics of the normal knee. The design aim is to avoid the paradoxical anterior slide of the femoral condyles and the 'mid-flexion instability' [12,23,24]. Compared with traditional posterior stabilized (PS) prostheses, that incorporate a cam-post mechanism to resist the anterior movement of the femur, medial pivot implants achieve anterior–posterior stability by the high congruency of the medial compartment. Moreover, the use of medial pivot implants compared with the other prostheses designs such as PS or constrained condylar knee (CCK) allows greater preservation of bone stock. This feature might become relevant in case of re-revision.

The use of primary implants in revision TKA shows worse results and survival rates compared with revision implants [25] because of the inability of such implants to manage an altered bone stock thus leading to a diminished fixation of prosthesis components to bone and earlier aseptic loosening.

This revision system offers the possibility to use stems and block or wedge augments to increase stability and fixation in case of bone loss.

In our study, we treated AORI 1 bone defects with cementation and observed no aseptic loosening. This technique is recommended for small bone defects such as AORI 1 and has shown good long-term results when bone defects are <20 mm [26,27].

We treated AORI 2A and 2B bone defects with cemented metal augment wedge-shape at the site of defect and observed one case of component loosening. Modular metal augments provide stable and durable knee revisions with limited peripheral bone defects up to 20 mm deep, avoiding further resection of host bone. Patel et al. performed a total of 102 revision TKAs in patients with AORI 2 defects with cemented metal augments and observed 92% survival at 11 years [28].

Biomechanical studies have supported the use of both cemented and press-fit stems in enhancing stability and fixation in the setting of revision TKA. Stems act synergistically with metaphyseal structural support and help to reduce micromotion by bypassing deficient or damaged areas to gain fixation [29–31].

However, the optimal method of stem fixation in revision TKA continues to be debated. Cemented stems provide immediate fixation but may increase stress shielding of the metaphyseal bone. Furthermore, cemented stems can be challenging to remove in case of re-revision.

Hybrid stems offer better alignment and ease of revision with better bone preservation, but they can result in end-of-stem pain. In a recent meta-analysis regarding fixation of cemented versus non-cemented stems in revision TKA, no difference was found in rates of failure, revision or aseptic loosening [30].

To our knowledge this is the first study that analyzes the outcome of a medial pivot design revision knee system in revision TKA. AKSS and pain outcomes observed in this study are comparable with what has been previously reported in other revision TKA studies.

Se-Yyun Cho et al. [32] reviewed a cohort of 30 patients who underwent revision TKA with PS, condylar constrained or fully constrained prosthesis with a minimum two years of follow-up. They reported in the PS group a mean AKSS clinical score and a mean AKSS functional score of 78 and 79, respectively, while mean ROM was 94°. Laskin and Ohnsorge [33] retrospectively reviewed 58 patients who underwent revision TKA with a PS implant. At minimum four years of follow-up, 52 of the 58 patients had anteroposterior instability of less than five millimeters. In addition, five years after surgery, implant survival was 96%. Whaley et al. [34] analyzed 38 revision TKAs performed with cemented PS posterior with a mean follow-up of 10.1 years. The Knee Society pain score averaged 17 points before revision and improved to 51 points at last follow-up whereas the function score averaged 48 points before revision and improved to 57 at last follow-up. Eleven-year component survival was 95.7%.

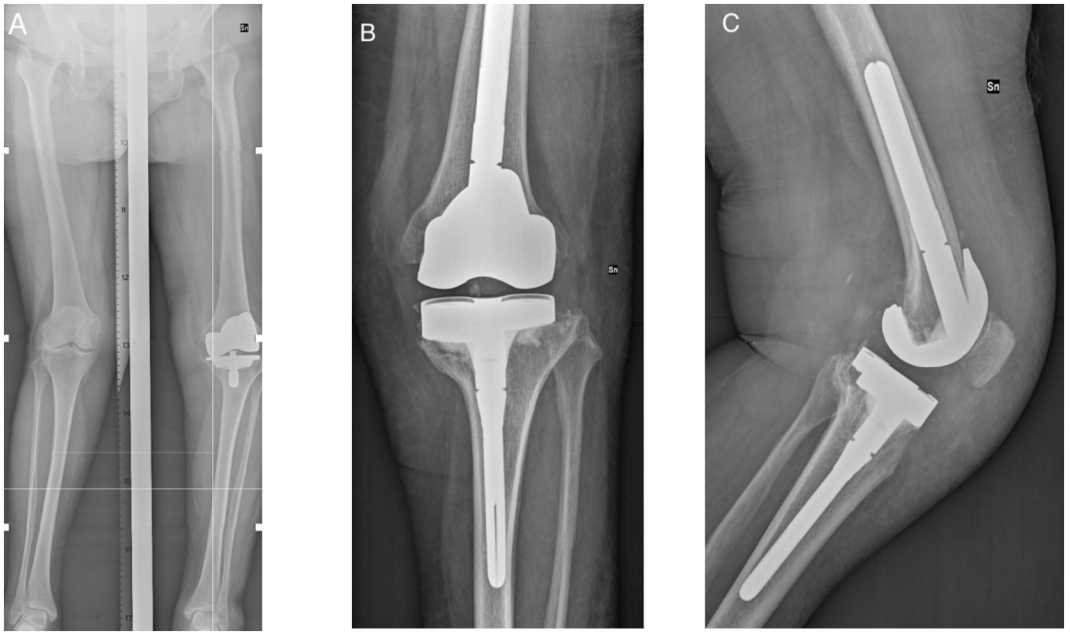

Figure 2. Preoperative orthostatic lower limb X-ray (a) of a failed total knee arthroplasty demonstrating polyethylene wear and distal femoral and tibial osteolysis. Four-year postoperative anteroposterior (b) and lateral (c) radiographs demonstrating reconstruction with a stemmed medial pivot revision implant.

This study has some weaknesses. Firstly, the use of this revision knee system was strictly limited to patients with intact collateral ligaments and minimal bone defects. In this subgroup of patients, the surgical procedure was less complex than surgery in knees with major ligamentous damage and bone loss. Secondly, survival analysis had to be interpreted with caution for the population inhomogeneity and for the high number of censored patients over the years (Figure 1) and results cannot thus be reliably extended to larger patient populations (Figure 2). In particular, only 52% (29 out of 56) and 57% (64 out of 112) of patients reached 10 years of follow-up, respectively, in revision and primary TKA groups. Future studies with more homogeneous patient population and longer follow-up are necessary to gain more insight into implant survival rate.

5. Conclusion

The results of our study show that, in selected cases, stemmed medial pivot revision implant can provide comparable radiographical results and survival at a mean of 8.8 years and with a maximum follow-up of 15 years compared with primary medial pivot TKA implant. Although primary TKA has higher AKSS, the relative improvement, as measured by the AKSS, between primary TKA and revision TKA group is similar. We support the use of this system in knees with collateral ligaments competence and mild-to-moderate bone defects that can be managed with stems and augment wedges.

Declaration of competing interest

The authors declare that they have no conflict of interest.

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