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Original article

Revision of total knee arthroplasty with press-fit condylar SIGMA TC3-mobile bearing system and porous metaphyseal sleeves in type AORI type II and III bone defects. A long-term follow-up study

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Abstract. *Background and aim:* Revision total knee arthroplasty(rTKA) is a challenging and expensive treatment for orthopedic surgeons who have to deal with poor bone quality and bone loss. This study aims to retrospectively evaluate the clinical and radiological results of patients undergoing rTKA and porous metaphyseal sleeves in AORI type II and III bone defects. *Methods:* We conducted a retrospective series of continuous patients treated for mechanical failure of TKA. All patients with aseptic loosening of TKR underwent revision arthroplasty. We included only patients with AORI type IIa/b and III bone defects. The Septic revision or other grades of bone defect or patients lost at follow-up or with less than 2 years follow-up were excluded. We evaluated knee function with Oxford Knee Score (OKS) pain with Visual Analogue Scale (VAS) and range of motion (flex-ext), while radiological evaluation was performed to evaluate any sign of loosening. *Results:* The mean preoperative OKS was 13.85 +/- 5.39 (range 5 -22), and it improved to 33.89 +/- 3.98 (range 20 - 40) (p<0.00001). The mean preoperative VAS was 7.77 +/- 1.33 (range 5 - 9), and it improved to 1.89 +/- 0.92 (range 0 - 4) (p<0.00001). ROM improved from 62.23° +/- 13.71° (range 40° - 90°) to 100.53° +/- 6.93° (range 90° - 120°) (p<0.00001). No signs of loosening or implant migration were reported. *Conclusions:* Metaphyseal sleeves made knee revision in large bone defects reliable and effective with good results. Good implant stability was reached in all the cases treated with metaphyseal sleeves. (www.actabiomedica.it)

Key words: Revision arthroplasty, Aseptic loosening, bone defects, metaphyseal sleeve

Revision total knee arthroplasty (rTKA) is a challenging and expensive treatment for orthopedic surgeons dealing with poor bone quality and bone loss in the proximal tibia and distal femur portion (1).

The amount and extent of bone loss during rTKA are complex problems requiring several reconstructive techniques to treat bone defects (2,3).

Due to different and complex treatment options, some help in the treatment strategy could be provided by Anderson Orthopaedic Research Institute (AORI) (4).

AORI type II bone defect could be effectively managed with a revision implant, and cement could fill the bone defect. In some cases, cancellous bone graft or augmentation could be necessary to restore the joint line and provide better knee stability (3,5).

In AORI type III bone defects, more complex fixations should be adopted with structural allografts, trabecula metal sleeves or cones, or, in extreme cases, custom-made components or mega prosthesis implants (4,6).

Porous metaphyseal sleeves already showed promising results in reconstructing significant bone defects in rTKA (7,8).

Due to extensive bone loss, the conventional implant could not be suitable to correct joint residual instability, and a constrained implant should be used to address this issue (9).

This study aims to retrospectively evaluate the clinical and radiological results of patients undergoing rTKA with press-fit condylar (PFC) Sigma TC3-mobile bearing system and porous metaphyseal sleeves in AORSI type II and III bone defects.

Materials and methods

We conducted a retrospective series of continuous patients treated for aseptic loosening of TKA (Figure 1).

Figure 1. Failed total knee arthroplasty with loosening and dislocation of prosthesis components in anteroposterior (a) and lateral (b) view.

All patients with aseptic loosening of TKR who underwent revision arthroplasty from January 2012 to December 2016 were included in the study. In order to obtain a homogeneous group, we included only patients with AORI type IIa/b and III bone defects. The septic revision or other grades of bone defect or patients lost at follow-up (less than 2 years) were excluded.

In all cases, a press-fit condylar (PFC) Sigma rotating platform TC3 (Depuy Synthes, Warsaw) was used during revision with femoral and tibial metaphyseal sleeves (Figure 2).

Patients underwent clinical and radiological examinations. We evaluated knee function with Oxford Knee Score (OKS), pain with Visual Analogue Scale (VAS), and range of motion (calculated as

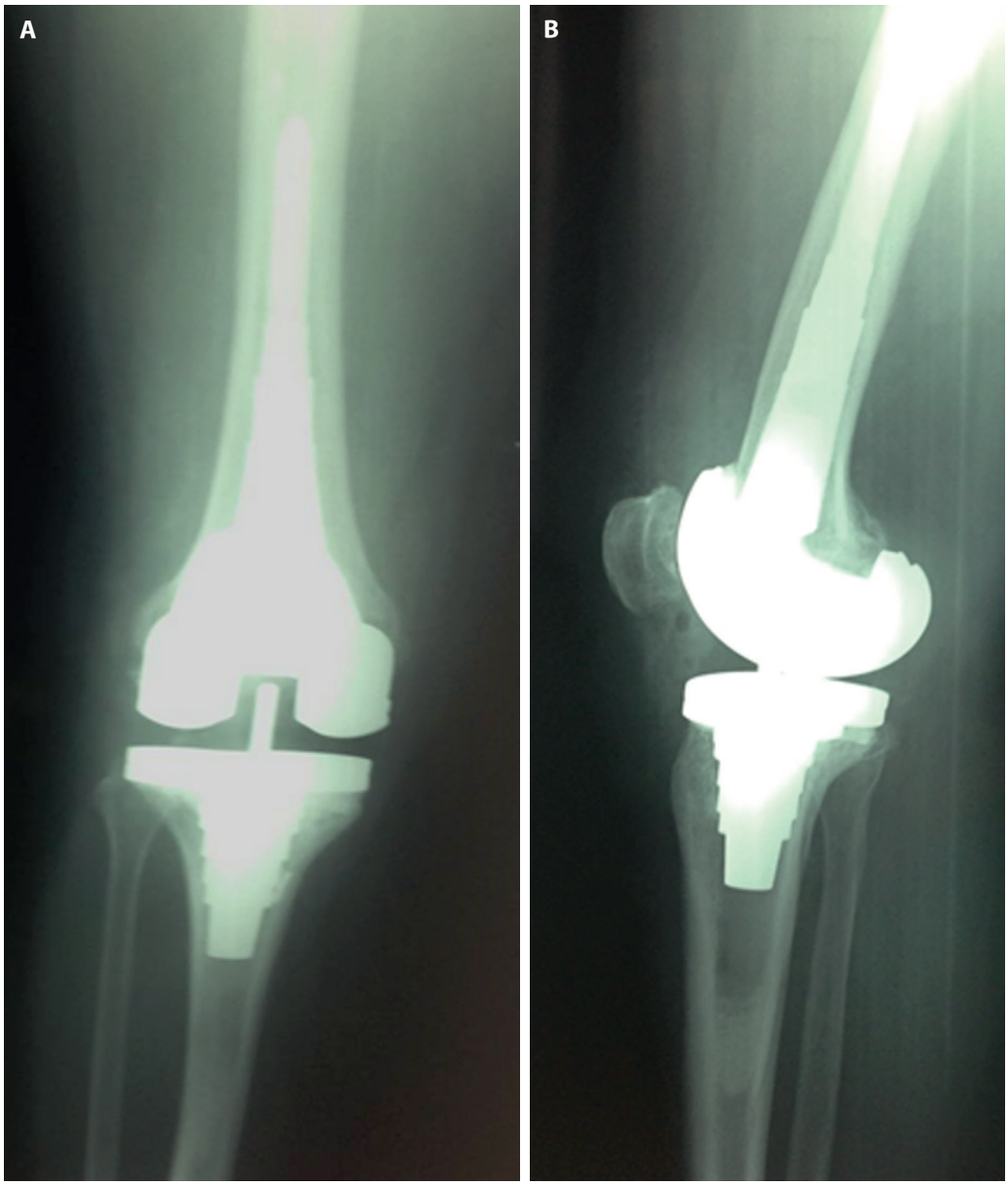

Figure 2. Revision arthroplasty of a failed primary TKA with PFC Sigma TC3 prosthesis in anteroposterior (a) and lateral (b) view.

flexion-extension gap). At the same time, radiological evaluation was performed to evaluate any sign of loosening or prosthesis mobilization (radiolucent lines, changing position).

Complications were also reported.

Surgical technique

We performed a medial parapatellar approach to obtain proper and adequate exposure; four times tibial tubercle osteotomy was performed. The polyethylene insert was removed first, followed by the femoral and tibial components. All membranes were removed along with cement residues, especially in the anchoring areas of the sleeves and in cases of septic failure.

Judet myolysis (10) of the quadriceps was performed systematically to enhance the mobility of the knee. The next step was the assessment of gaps and bone loss.

Firstly, the tibia was prepared: handheld reamers were used in progressive size until cortical contact was obtained in the diaphysis at the desired stem length. The broach prepared the tibial metaphysis to accept the sleeve: the right size sleeve should fill the metaphyseal bone defect and achieve contact with the residual cancellous bone. Completely overlapping was the prepayment on the femoral side.

If necessary, the height of the tibia and femur were adjusted using different sleeves to restore the joint line properly. Once the sleeve size and height are chosen, a trial reduction is performed with the assembled components.

The flexo-extension gaps are tested, and any soft tissue release is performed if necessary.

The final components are assembled with the correct rotational orientation of the sleeves previously determined on the tibial implant.

Statistical analysis

Continuous variables were reported as mean, standard deviation, and range. STATA13 software (StataCorp LLC, College Station, Texas, USA) was used for statistical analysis. Student t-test and Wilcoxon test were used to evaluate differences in clinical scores before treatment and the last follow-up. The level of significance was set as $p<0.05$.

Results

Forty-seven patients (47 knees), 30 female and 17 males, were reviewed at an average follow-up of 69 months +/- 7.73 months (range 60 - 88). Main demographic characteristics, cause of failure, and extension of bone defects were reported in Table 1.

The mean preoperative OKS was 13.85 +/- 5.39 (range 5 -22) and improved to 33.89 +/- 3.98 (range 20 - 40). The mean preoperative VAS was 7.77 +/- 1.33 (range 5 - 9) and improved to 1.89 +/- 0.92 (range 0 - 4). ROM improved from 62.23° +/- 13.71° (range 40° - 90°) to 100.53° +/- 6.93° (range 90° - 120°) (Tab. 2).

Causes of failure were aseptic loosening (15), implant instability (17), malrotation (3), stiffness (5), or failed unicompartmental knee arthroplasty (7) due to neglected unrecognized intraoperative fracture, loosening and progressive deformity with prosthetic mobilization. In 40 patients (85.11%), it was the first rTKA,

Table 1. Main demographic characteristics of patients included in the study.

Patients	**Sample**
Male	17
Female	30
Age (age +/- SD)	71,34 +/- 5,63
AORI type iia	5
AORI type iib	26
AORI type III	16
First revision	40
Subsequent revision	7
Follow up(months)	69 +/- 7,73

Table 2. Pre and postoperative Oxford Knee Score, VAS, and ROM.

Scores	**Preoperative**	**Postoperative**	**P**
OKS	13,85 +/- 5,39	33,89 +/- 3,98	< 0,00001
VAS	7,47 +/- 1,33	1,83 +/- 0,92	< 0,00001
ROM	62,23 +/- 13,71	100,53 +/- 6,93	< 0,00001

while in 7 patients (14.89%), it was the second revision attempt.

Three females suffered from anterior knee pain within the first eight months of rTKA, and a patient underwent patella prosthesis approximately 1 year from revision. A male patient suffered from early acute infection due to *Staphylococcus aureus* and needed debridement and liner replacement and 6 weeks of antibiotic therapy. At the same time, another male patient was treated with a 2-stage revision for an Escherichia coli late acute infection secondary to cystitis approximately 3 years after rTKA. The two patients completely remitted their symptoms after the early and late acute infection revision.

No patients included in the study died during follow-up. At the final follow-up, the X-ray showed an excellent osteointegration of the sleeves. Mild pain persisted in the patient undergoing patella prosthesis: the patient underwent a subsequent knee revision for the malrotation of femoral and tibial components.

Discussion

Revision of TKA is very challenging, needing the surgeon to plan surgical intervention accurately. Several options are available to manage bone defects. Allografts, tantalum cones, metaphyseal sleeves, modular stems, or mega prostheses are valuable options for managing bone defects according to the AORI classification (11).

In type II and III AORI bone defects, new material and technique development brought new alternatives to manage bone defects. Mancuso et al. highlighted that in those cases, metaphyseal sleeves offer reliable results in implant stability (12).

Our cases showed significant pain relief, no postoperative loosening, and a good range of motion after revision surgery. According to other studies in the literature, the clinical results of our study were considered good results, and they were similar to the results of revision arthroplasty of several authors (13–15).

Several studies have already evaluated metaphyseal sleeves with different follow-up times, patient numbers, and results in septic and aseptic revisions (16–19). From a functional point of view, our research showed comparable results with those of other studies (20,21). Moreover, another strength of our study is the relatively homogeneous group of patients included for AORI grades of bone defects (grade II and III) (4,11), while usually, authors included all AORI grade bone defects in their studies.

After treatment, none of our patients suffered from implant mobilization or loosening. In literature, the rate of loosening ranged from approximately 10% to 41.5% (13–15); in those studies, however, patients also suffered from septic loosening, which was one of the exclusion criteria of our article, while patients shared similar bone defects. The pain level was lower after treatment than reported in the literature; the absence of loosening or mobilization of the implants in our research could explain this. However, it must be noted that rTKA could suffer from the same problem as primary TKA, such as infection, malrotation of the tibial or femoral component, or anterior knee pain (22,23). In our research, 2 patients suffered from prosthesis infection, and 1 needed revision with anterior knee pain and a further revision for component malrotation.

In the study of Dalury et al., 40 knees were evaluated after rTKA. The Authors reported a small percentage of revision failure (2.5%) with implant loosening and migration, but more interestingly, they reported good implant fixation due to metaphyseal bone ingrowth (18). Bloch et al. confirmed the same outcome from medium and long-term follow-ups (24).

Our study has several limitations. The relatively low number of patients included, the lack of a control group, and the retrospective nature of our study could be a source of bias. Although our follow-up is relatively long, it is not homogeneous, exposing the implant to a possible risk of loosening.

Conclusions

Metaphyseal sleeves made knee revision in AORI II and III bone defects reliable and effective with good results. In our series, most patients achieved good clinical outcomes, a good range of motion, and no sign of implant loosening or migration. Good stability of the implants was reached in all the cases treated.

Conflict of Interest: Each author declares that he or she has no commercial associations (e.g., consultancies, stock ownership, equity interest, patent/licensing arrangement, et.) that might pose a conflict of interest in connection with the submitted article

Author Contributions: Study design F.Z., A.P., D.P. Data collection F.Z., A.P., D.P., V.C., S.C. Writing of manuscript F.F., G.C. Statistical analysis F.F. Revision of manuscript G.C., F.Z., E.P. Approval of final version of anuscript F.Z., A.P., D.P., V.C., S.C., E.P., F.F., G.C. Submission of manuscript F.F.

Ethics Approval and Consent to Participate: All patents involved in the study gave their informed consent to participate in the study. All procedures involving human participants were in accordance with the 1964 Helsinki Declaration and its later amendments. The study was approved by the local Research Ethics Committee US-CLV n° 2022/00128.

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