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Direct, Cementless, Metaphyseal Fixation in Knee Revision Arthroplasty With Sleeves—Short-Term Results

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ABSTRACT

Different options for implant fixation in revision TKA exist. Small series have been published on direct cementless fixation with sleeves. The objective of this study was to analyze the short- and mid-term results of sleeve-fixation in a large revision TKA series. In this prospective study 121 patients with 193 sleeves (119 tibial and 74 femoral) were included. Mean follow-up was 3.6 years (2–6.1 years). Analysis included clinical and radiographic assessment. ROM, KSS and Functional Score improved significantly. Fourteen patients (11.4%) underwent operative re-revision during the follow-up period. Direct cementless fixation in the metaphysis by sleeves is a promising option for implant fixation in revision TKA, both on the tibial and femoral side.

TKA revision is of increasing relevance in daily practice and will become even more relevant in coming years [1,2]. Different reasons for failure exist. While infection is the most common cause for early failure, aseptic implant loosening and polyethylene wear as well as instability are relevant for late failure [3,4]. In almost all revisions bone defects are one of the problems to address during surgery and a solid fixation of the revision implant in compromised bone stock can be challenging [5]. While in primary TKA the fixation is mainly at solid bone cuts on the joint surface (zone 1), in revisions this zone is mostly compromised and can therefore not be reliably used. Based on the concept of zonal fixation, additional fixation in the diaphysis (zone 3) and/or metaphysis (zone 2) is recommended [6].

For fixation at the diaphysis, cemented and cementless stems can be used, both having individual advantages and disadvantages. Cemented stems have a good initial and long-term fixation leading to good mid- and long-term survival rates [7]. Due to the cement however, they are often difficult to remove. Another shortcoming is that they are not canal-filling and implants may therefore mal-align. A further important problem over time is the effect of strain shielding and thus bone resorption at the metaphysis [8]. Because of these problems cementless stems became more popular. However, limitations of this fixation option also need to be known. The mainly polished titanium stems do not provide osseous integration. Thereby they do not give long term stability, which can be observed radiographically with a high rate of radiolucent lines around the stems [7]. Another problem of straight, canal-filling stems can be misguidance into pre-existing mal-alignment in all bones with canal geometry deviations (varus/valgus bowing of the tibia, or antecurvatum of the femur). Furthermore, in up to 10% of cases, these canal-filling cementless stems can cause stem pain at its tip [9–11]. Considering all the advantages and disadvantages of cemented and cementless stems to date, no final recommendation regarding the optimal fixation technique of a stem, the optimal stem length and thickness can be made [12] and additional concepts for fixation should be considered.

One additional zone for fixation is the metaphysis. In cemented stems it is automatically used, in cementless stem fixation, however, the metaphysis is bypassed. The only direct cementless fixation option at the metaphysis is provided by sleeves. Indirect fixation at the metaphysis can be performed with cementless cones and additional cemented stem fixation. The concept of sleeves in a rotating hinge knee has been known for decades and good results have been reported [13,14]. Recently, sleeves have become more frequently used, because they can now be combined with all kinds of constraint levels from PS, VVC up to a rotating hinge. The concept of the sleeve is based on Wolf's law of 1896, with stress distribution into the metaphysis stimulating bone growth towards the sleeve. With this fixation close to the joint, stems might become less relevant and fulfil only the role of guidance for alignment and further for support for bony integration of the sleeve in the first 3 months. Although the midterm results of the first published studies are promising [15–17], until now only smaller series with the main focus on the tibial sleeves have been published.

The objective of this study, therefore, was to analyze the clinical and radiological midterm results of tibial and of femoral sleeves in a larger

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series. Further, a special focus was paid to the failure analysis of the meanwhile failed and revised revision implants.

Methods

Between February 2007 and October 2011, 156 patients underwent aseptic knee revisions with complete exchange of the implant at our institution. Preoperative CRP values, cell-count and 14 day cultivation of synovial aspiration remained negative. Out of these 156 patients 121 could be re-evaluated (18 died, 17 could not be reached). In these 121 patients 119 tibial sleeves and 74 femoral sleeves were implanted. In 117 of the 119 tibial sleeves and in 25 patients out of 74 femoral sleeves additional stems were applied. This led to 2 cases of stemless fixation of the tibia and 49 of the femur. In 73 cases the surgery was the first revision, in 31 the second and in 17 third or more revision. Seventy-seven patients were female and 34 were male. The sleeves used varied from the smallest up to the biggest size. Majority was 37, 45 and 53 mm in the tibia and 31, 34, and 40 mm in the femur. In 3 cases a thick tibia tray (2×15 mm and 1×25 mm) was used in order to raise the joint line of the tibia. The mean follow-up was 3.6 years, minimum follow-up 2 years, and maximum follow-up was 6.1 years. All patients underwent follow-up within the local and later national register. Time-points were 3 months, 6 months, one year and afterwards every year. Approval of the Ethics Committee and written consent of the patients prior to surgery were obtained.

Low grade infection and acute infection were exclusion criteria. The main reasons for aseptic revision in our study were instability (41 cases), malalignment (24 cases) and loosening (23 cases). Other reasons were polyethylene wear (15 cases), trauma (4 cases), stiffness because of mechanical problems (9 cases), implant failure (3 cases) and pain (2 cases). In some cases more than one problem was identified. However, only the dominant reason was selected.

All surgeries were done by the first or third author using the same tibia first, gap balanced technique. After diaphyseal reaming (for alignment) metaphyseal broaching was performed. The tibia joint line and height of the broach were determined with respect to the fibula head. The first sleeve that gave rotational and axial stability was selected as the final one in order to preserve bone. Seventy percent bone-coverage of the sleeve was defined to be minimum to achieve bony integration. The bone support of the tibia base plate (zone 1) was stated to be not that relevant because primary fixation was defined in the metaphysis or diaphysis (Fig. 1). On the femoral side the sleeve was prepared with respect to the distal bone-resection line. Again the first sleeve that gave rotational stability was selected to be implanted.

In all cases the DePuy (Warsaw) PFC Sigma mobile bearing revision tibia tray was used. In 77 patients a posterior stabilized insert, in 27 a TC3 insert (VVC constraint), and in 17 a rotating hinge was implanted.

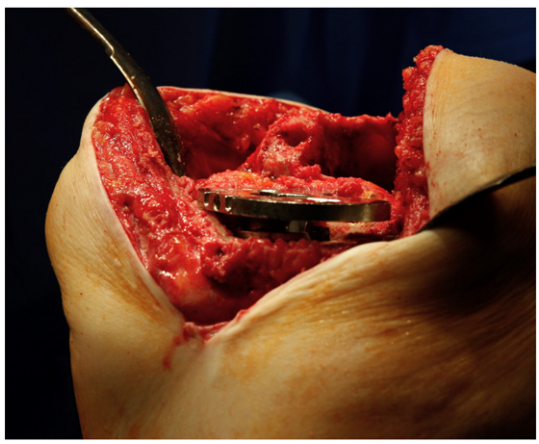

Fig. 1. Trial tibial component without epiphyseal bone contact.

In all cases original implant surface (femoral shield and tibia baseplate) was cemented. This was performed to seal bone surface and therefore reduce initial bleeding and to deliver antibiotics initially (Gentamycin + Clindamycin, Copal®). This cement-layer is not supposed to provide long-term implant fixation.

Mean age was 74.0 ± 9 years, body height was 165.5 ± 9.9 cm and weight was 90.0 ± 20.1 kg, leading to a mean BMI of 32.9 ± 6.9.

In all cases at least a type 2 defect (AORI classification) [18] on the tibia side was found (77 × type 2a and 37 × type 2b) and in 7 cases a type 3 defect. On the femoral side the type 3 defect was observed in a higher number of cases (28), and the rest were type 2b defects.

The follow-up included clinical examination, American Knee Society score and radiological analysis. All patients were asked whether they suffered from tibial or femoral stem pain. The clinical examination included ROM and stability testing in extension, mid-range and flexion.

The radiological analysis included measurement of leg axis and zonal analysis of implant fixation regarding the Gruen Zones. Special focus was paid to the osseous integration around the sleeves at the porous coated surface. In all cases of re-revision the failure mode was analyzed.

Statistics

Preoperative range of motion and American Knee Society score were compared with those obtained at the post-OP. Statistics were obtained using t-test and Mann-U test [19] using the sigma plot 11.0 software (Systat Software, Inc.).

Intraoperative complications occurred in two cases leading to a fracture of the anterior, distal cortex of femur during femoral broaching. A circular wire was placed in these cases before implantation of original femoral implant. These two patients did not show any loosening signs in the follow-up radiographs nor was the postoperative protocol adjusted. No additional complications were observed. The medial tibia plateau fracture shown in Fig. 5 occurred due to implant migration after implant failure.

Results

ROM was significantly improved from 89° ± 6° pre-operatively to 114° ± 4° postoperatively ($P < 0.01$). AKS was also significantly improved from 88 ± 18 preoperatively to 147 ± 23 postoperatively ($P < 0.01$). The functional knee score as a subsection of the AKS improved from 52 ± 18.9 preoperatively to 68.8 ± 23.3 points ($P < 0.01$) postoperatively.

Stem pain on the tibia side was found in 2 patients (1.7%) and in 1 patient on the femoral stem tip (1.4%). In one patient with tibia stem pain a loosening of the tibial implant was found in a later revision. No pain was recorded at the tip of the tibial or femoral sleeve in the stemless revisions.

Radiological analysis showed restoration of leg axis in almost all cases within the 3° corridor (98.4%). Mean leg axis was changed from 2.1° ± 2.2° varus preoperatively to 0.6 ± 0.3° varus postoperatively. Majority (96.4 %) of the sleeves showed good osseo-integration in both planes (Figs. 2 and 3). In 7 patients radiolucent lines could be found around the coated area of the sleeves (5 femoral and 2 tibial) (Fig. 4). Three of those have been without clinical symptoms so far. The other 4 sleeves have been revised due to persistent pain and aseptic loosening.

Fourteen revisions have been performed until the follow-up. This corresponds to an overall revision rate of 11.4% after 3.6 years. Four of these revisions were done for infection (3.3%). Majority of aseptic revisions were performed for biomechanical reasons (4.1% = 5 cases). Three of these 5 patients showed ligament instability as major revision cause, 1 malalignment and 1 extensor mechanism failure. In 2 patients a failure of the implant was found. In both cases, the implant was broken at the junction between stem and sleeve (Fig. 5). Both cases showed insufficient osseo-integration of the sleeve in combination with malalignment and excellent stem fixation leading to low stress high cycle fatigue (ETQ analysis report by the manufacturer).