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Modular Augmentation in Varus-Valgus–Constrained Knee Arthroplasty—Do We Need Sleeves to Avoid Femoral Loosening After Excessive Distal Augmentation?

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ABSTRACT

Background: In revision total knee arthroplasty, zonal fixation methods with a combination of augments, press-fit stems, and sleeves are popular. We hypothesized that high distal femoral augmentation with diaphyseal press-fit stems leads to an increased rate of early aseptic loosening and that femoral metaphyseal sleeves improve implant survival. Therefore, we retrospectively investigated implant survival in relation to augment heights and sleeves.
Methods: A total of 136 patients with mean clinical follow-up of 50 months (range, 28-85) who underwent modular total knee arthroplasty and revision total knee arthroplasty with semiconstrained implants between January 2012 and July 2018 were retrospectively evaluated. Implant survival with 4, 8, and 12 mm distal femoral augments was compared to no distal augmentation. Subsequently, a subgroup analysis was performed for femoral sleeve implantation.
Results: We observed an implant survival rate of 97.0%, 87.5%, and 69.2% for 4, 8, and 12 mm distal femoral augmentation, respectively ($P = .73$; $P = .19$; $P = .008$). The implant survival rate with femoral sleeves was 95.8% for the 8 mm augments and 85.7% for the 12 mm augments ($P = .42$; $P = .96$). Without femoral sleeves, the implant survival rate was 78.3% with the 8 mm augments and 50.0% with the 12 mm augments ($P = .02$; $P < .001$).
Conclusion: Higher rates of aseptic femoral loosening were identified for distal femoral augmentation of 8 mm or more without metaphyseal sleeve fixation in semiconstrained implants. Thus, in cases with femoral metaphyseal bone damage requiring high distal femoral augmentation, metaphyseal sleeves should be used to avoid early aseptic femoral loosening.
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The incidence of revision total knee arthroplasty (RTKA) is rising, which is consistent with the increasing number of primary total knee arthroplasty (TKA) being performed. A total of 49,491 RTKA surgeries were performed between 2012 and 2018 in the United States, and this number is estimated to increase to 120,000 RTKA by 2030 [1,2], with aseptic implant loosening being one of the

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most common reasons for late revision surgery [1]. Many cases requiring RTKA are associated with compromised bone stock. Thus, anatomical restoration of the joint line and proper implant fixation can be challenging. Haddad et al proposed a zonal classification system (epiphysis = zone 1, metaphysis = zone 2, diaphysis = zone 3) and suggested a multizone strategy with fixation in at least two zones to achieve good long-term results [3].

To date, fixation in zones 1 and 3 with reconstruction of the epiphysis with modular metal augments and diaphyseal stem fixation is a common approach in RTKA [3]. However, in cases with a severely deficient epiphyseal surface, high distal augmentation may not provide sufficient support in zone 1. In these cases, implant fixation is mainly achieved by a diaphyseal stem. However, the leverage resulting from the insufficient epiphyseal fixation and the strong diaphyseal engagement can subsequently lead to early implant loosening. Consistent with this hypothesis, Lee et al found that there is a correlation between femoral defect size and early aseptic loosening [4]. Furthermore, with increasing defect sizes, the need of higher constrained implants becomes more likely. Even with the implantation of semiconstrained components, a much higher stress at the implant-bone interface must be considered [5]. Additional metaphyseal fixation has therefore been introduced to improve implant fixation and overcome the aforementioned shortcomings [6]. Sleeves as commonly used cementless metaphyseal fixation devices are firmly fixed to the implant and thus provide excellent rotational stability [7]. Promising mid-term results of this method, with a survival rate of 96% after 5 years, have recently been published by Chalmers et al [8].

However, to date, no studies have focused on the distal femoral augmentation height as a measure of the epiphyseal defect size and diaphyseal fixation using press-fit stems with or without metaphyseal fixation in RTKA. We hypothesized that (1) high distal femoral augmentation leads to an increased rate of early aseptic loosening with diaphyseal press-fit stems only and (2) that diaphyseal and metaphyseal fixation improves femoral implant survival. Therefore, we retrospectively investigated implant survival in relation to augment heights and subsequently performed a subgroup analysis in regard to the presence of metaphyseal sleeve implantation.

Material and Methods

Patients

A total of 148 patients who underwent complex TKA and RTKA with a semiconstrained modular implant design at a single academic center between January 17, 2012 and July, 20 2018 were retrospectively identified. In total, 136 patients with mean clinical follow-up of 50 months (range, 28-85) were included in the study (See Fig. 1). Patient characteristics are shown in Table 1. RTKA was performed in 32 cases for periprosthetic joint infection requiring reimplantation with a two-stage approach, in 34 cases for aseptic loosening after primary TKA, in 47 cases for instability, in 2 cases for periprosthetic fractures, and in 8 cases for polyethylene wear. Primary TKA with the respective modular, semiconstrained implant was performed in 25 cases with osteoarthritis and severe varus-valgus instability. The augment height was determined to restore the joint line and to provide axial and rotational stability in accordance to the femoral Anderson Orthopaedic Research Institute (AORI) classification, whereby the potentially lowest augment height was selected: in type I defects, 4-8 mm augments and in type II/III defects, 8-12 mm augments were applied. If the remaining metaphyseal bone stock was insufficient for axial and rotational implant stability, metaphyseal sleeves were utilized in AORI type I to III defects. Implant survival with the respective distal

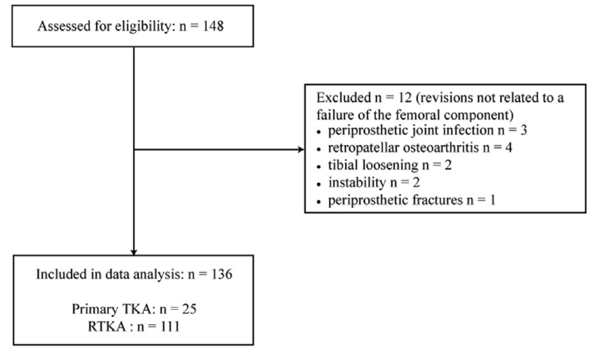

Fig. 1. Flowchart of patient inclusion. TKA, total knee arthroplasty; RTKA, revision total knee arthroplasty.

femoral augment heights was compared to no distal augmentation. Subsequently, a subgroup analysis was performed comparing the respective augment heights to no distal augmentation depending on the presence of a metaphyseal sleeve fixation.

Surgical Procedure

Two senior arthroplasty surgeons performed the RTKA procedures using medial parapatellar arthrotomy and a semiconstrained revision knee arthroplasty system (PFC Sigma TC3 Knee System, Revision MBT, Fa. DePuy Synthes Warsaw). Adequate epiphyseal contact and restoration of the joint line were established with modular metal augments measuring 4 mm, 8 mm, and 12 mm in height.

In cases with a severe cavitary bone defect in the femoral metaphysis, additional sleeve fixation was performed. The sleeve was prepared until axial and rotational stability was achieved. In all cases, cementless press-fit stems were used.

Statistical Analyses

Fisher's exact tests were performed for all dichotomous variables. The log-rank test was performed for the Kaplan–Meier survivorship curves to estimate the survivorship until revision due to aseptic loosening. Values of $\alpha < 0.05$ were considered to indicate statistical significance. Statistical analyses were performed using GraphPad Prism 8.0 (GraphPad Software, Inc).

Results

In total, we observed 13 cases of aseptic loosening in 136 cases with modular, semiconstrained knee arthroplasties, all having diaphyseal press-fit stems. Mean time to aseptic femoral loosening was 23 months (range, 2-43). Three cases of femoral loosening occurred in 76 cases with no or 4 mm distal femoral augmentation and 10 cases of femoral loosening in 60 cases with 8 mm or 12 mm distal femoral augmentation, respectively ($P = .013$).

Two patients underwent revision due to femoral loosening without distal femoral augmentation (3.0%). The revision rate due to aseptic femoral loosening following distal femoral augmentation was 4.7% with 4 mm augments, 12.8% with 8 mm augments, and 30.8% with 12 mm augments. We observed an implant survival rate of 97.0% with 4 mm augments, a rate of 87.5% with 8 mm augments, and a rate of 69.2% with 12 mm augments after a mean follow-up of 50 months (range 28-85) ($P = .73$; $P = .19$; $P = .008$) (See Fig. 2).

The distribution of distal femoral augments with and without femoral sleeves is demonstrated in Table 2. Ten of 13 cases (77%) of femoral loosening occurred when no sleeve was used for

Table 1
Patient Characteristics, Follow-Up, and Implant Survival After Revision Total Knee Arthroplasty.

Characteristics	
Total of VVC implantations, n	148
Included, n	136
Men, n (%)	62 (45.6)
Women, n (%)	74 (54.4)
Mean age at VVC implantation, y (range)	68 (36-86)
Mean follow-up, mo (range)	50 (28-85)

VVC, varus-valgus–constrained implant.

Table 2
Count and Distribution of Distal Femoral Augments With and Without Femoral Sleeves.

Amount of Augmentation	Total (n)	Sleeve n (%)	No Sleeve n (%)
None	43	8 (18.6)	35 (81.4)
4 mm	33	8 (24.2)	25 (75.8)
8 mm	47	24 (51.1)	23 (48.1)
12 mm	13	7 (53.8)	6 (46.2)
Total	136	47 (34.6)	89 (65.4)

metaphyseal fixation ($P < .01$): one case without distal augmentation and one case with 4 mm distal augmentation, as well as 5 cases with 8 mm distal augmentation and three cases with 12 mm distal augmentation. The remaining 3 cases of femoral loosening with femoral sleeve occurred in one case without distal augmentation, one case with 4 mm distal augmentation, and one case with 12 mm distal augmentation. Significantly more cases of femoral loosening were observed without sleeves and distal femoral augmentation with the 8 mm and 12 mm augments ($P = .02$; $P < .001$). The implant survival rate with femoral sleeves was 95.8% for the 8 mm augments and 85.7% for the 12 mm augments after a mean follow-up of 50 months (range, 28-85) ($P = .42$; $P = .96$). Without femoral sleeves, the implant survival rate was 78.3% with the 8 mm augments and 50.0% with the 12 mm augments after a mean follow-up of 50 months (range, 28-85) (See Fig. 3).

Discussion

The most important findings in this study are that in semiconstrained RTKA, (1) the rate of aseptic femoral loosening is significantly higher in cases with high distal femoral augmentation (8 mm and 12 mm) and diaphyseal press-fit stems only and (2) that an additional metaphyseal sleeve can significantly improve implant survival in such defects.

Metal augments are intended to improve the bone-implant contact to provide axial and rotational stability. Furthermore, metal augmentation permits joint line restoration [9,10]. Metal augmentation is currently recommended for AORI type II and III defects up to 20 mm and heterogeneous mid-term results were observed [9,11–13]. Patel et al demonstrated a 92% implant survival rate after 11 years using 4-8 mm metal augments in 102 patients who had tibial and femoral AORI type II defects [14]. However, the authors indicated that implant fixation was achieved by the use of long stems with strong diaphyseal engagement. Therefore, these results cannot be solely attributed to epiphyseal fixation using metal augments. Furthermore, Wood et al reported a survival free of revision for aseptic loosening of 98% using RTKA with press-fit stems and augments at a mean 5-year follow-up (range, 2-12). Sah et al demonstrated a survivorship free of aseptic loosening of 90% at mean 10 years (range, 24-126 months) with RTKA with press-fit stems and augments [15]. Similarly, Peters et al reported no revisions due to aseptic loosening in a mean follow-up of 49 months (range, 24-132) after RTKA with press-fit stems and augments. However, the authors of the latter 3 studies indicated metaphyseal cement fixation but did not specify the extent of augmentation. Therefore, the low rate of aseptic loosening in these studies can neither be attributed strictly to epiphyseal nor diaphyseal fixation.

On the other hand, increased rates of aseptic loosening have been reported in RTKA using press-fit stems and distal femoral augmentation as well [16–18]. Hockmann et al demonstrated in a 5-year follow-up (range, 61-104 months) of 54 cases treated with augmented RTKA that isolated distal metal augmentation in femoral and tibial AORI type II or III defects did not effectively address bone loss and was associated with 59% of the demonstrated implant failures [18]. Shannon et al investigated 63 RTKA with press-fit stems and epiphyseal augmentation and reported 10% revisions for aseptic loosening at a mean 5-year follow-up (range, 2-10) [16]. Similarly, Bottner et al investigated 33 patients who had press-fit stems and epiphyseal augmentation and reported a 9% revision rate for aseptic loosening at a mean follow-up of 38 months (range, 24-109) [17]. Interestingly, both latter authors as well did not comment on the respective heights of the augmentation. Thus, previous studies missed to identify the correlation between augment heights and site of loosening so that it remains unclear to what extent femoral bone deficiency can be appropriately treated with metal augments.

Besides epiphyseal and diaphyseal fixation techniques, the metaphysis serves as a viable zone for implant fixation as well. Various techniques, such as those involving tantalum cones or

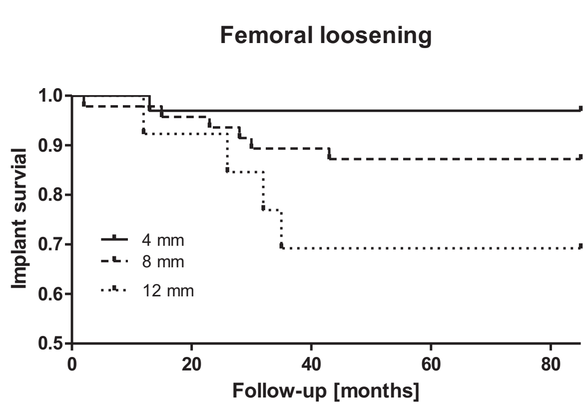

Fig. 2. Kaplan–Meier curve of femoral implant survival for semiconstrained RTKA according to distal femoral augment height ($P = .03$).

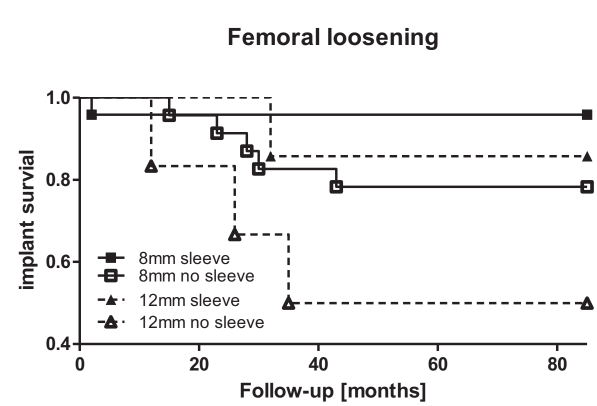

Fig. 3. Kaplan–Meier curve of femoral implant survival for semiconstrained RTKA with distal femoral augmentation (8 mm and 12 mm) with and without femoral sleeve fixation ($P = .03$).

sleeves, have been validated. Metaphyseal sleeves are a promising treatment for AORI type II or III defects [19]. Roach et al reviewed the short- and mid-term outcomes reported in 12 studies including 1,617 sleeve implantations performed between 2005 and 2017 and concluded that the results were promising, with a total rate of aseptic loosening of only 0.8%. In 61.7% of these procedures, AORI type IIB or more severe cases were identified [19]. Hernandez et al reported that aseptic loosening did not occur in a prospective study with 134 RTKA surgeries performed with sleeves in mild-to-moderate bone defects within a maximum follow-up period of 8.9 years (range, 24-107 months). Hernandez et al classified the femoral bone defects as AORI type IB defects in 70 patients, type IIA defects in 30 patients, and type IIB defects in 34 patients [20]. Chalmers et al evaluated the most cases treated by sleeve implantation, including 393 sleeves (144 femoral, 249 tibial). A total of 67% of the femoral sleeves were implanted for AORI type IIB or III defects [8]. The authors reported a 5-year survivorship free of revision for femoral aseptic loosening of 96%. Given this low rate of loosening in these related studies, femoral metaphyseal fixation using sleeves is considered to provide excellent implant, irrespective of the extent of bone deficiency [8,12,19,21]. Interestingly, sleeves are commonly implanted with a press-fit stem, and the favorable results of the studies mentioned above are attributed to the use of both a sleeve and a stem [8,20,22]. Therefore, the excellent outcomes are likely attributed to two-zone fixation.

Despite these promising results of the use of both, sleeves and stems, it remains unclear to what extent the combination of distal augmentation and sleeve implantation affects implant stability overall. When osteointegration takes place, the sleeves bear the axial load, provide rotational stability, and protect the epiphysis [19]. However, whether distal augmentation exerts an additional effect on stability has not yet been investigated. Previous studies regarding epiphyseal metal augments and metaphyseal fixation are scarce, and most studies concerning femoral sleeves did not state whether metal augments were used [19,21,22]. Fedorka et al evaluated the outcomes of 79 sleeve implantations and specified femoral augmentation in 30 cases treated with femoral sleeves. However, the authors did not report any interactions between the augments and sleeves [23]. The indication for distal femoral augmentation is therefore still controversial and thus remains ultimately in the hands of the surgeon. We like to highlight that an increase in the distal femoral augmentation height leads to a decrease in the relative height of the femoral box, leading to decreased rotational stability and potentially to early femoral loosening. Hockman et al postulated that reducing the contact area between bone and implant can lead to higher failure rates, particularly of the femoral component [18]. In this context, Chen and Krackow et al demonstrated that filling tibial bone defects with rectangular metal wedges into a stepped pattern resulted in improved rigidity and rotational stability [24]. In the present study, improved rotational stability was achieved by additional sleeve fixation, which led, in accordance with the aforementioned hypothesis, to improved implant survival.

Unfortunately, an evidence-based treatment algorithm for the various femoral components has not yet been established. Aggarwal et al recently discussed the currently available management options for patients undergoing RTKA and recommended to consider metal augmentation only in specific cases: The authors proposed that femoral metal augmentation may be adequate in semiconstrained implants with stems in elderly and low-demand patients with AORI type I and II defects up to 20 mm because they will unlikely fail in low-demand patients [12]. Similarly, Rosso et al recently recommended that metal augmentation should be reserved for AORI type II and III defects with sufficient bone stock in which durable fixation in zone 3 can be achieved. In patients with sclerotic or osteoporotic bone, however, the authors recommend considering metaphyseal fixation already in AORI type I defects [25]. Chalmer et al stated that the severity of preoperative bone loss classified by the AORI system does not significantly affect the rate of revision due to aseptic loosening if sleeves were applied [8]. Our results support this hypothesis: However, this effect is much more apparent with larger defects in the meta-epiphysis (8 and 12 mm augments) than with minor defects in the epiphysis. Therefore, we consider the use of sleeves for minor femoral defects to be optional.

We acknowledge that the present study has several limitations, including its retrospective nature. First, only one implant system was examined within a single hospital, which limits the generalizability of the results. Biases regarding implant design or the surgical techniques used cannot be excluded. Second, selection bias regarding the components used may be present. Although the indications for the femoral components were specified, the choice of augments and sleeves ultimately depended on the surgeon's judgment intraoperatively. Third, despite the strength of the overall large patient population, the specific subgroups were relatively small due to the relatively low incidence of aseptic femoral loosening in this cohort. The small subgroup sizes potentially limit the validity of the present study.

In conclusion, higher rates of aseptic femoral loosening were identified for high distal femoral augmentation of 8 mm or more without metaphyseal sleeve fixation. Thus, in femoral AORI type II and III cases requiring high distal femoral augmentation, a metaphyseal sleeve should be implanted to avoid early aseptic femoral loosening.

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