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Medial Overhang of the Tibial Component Is Associated With Higher Risk of Inferior Knee Injury and Osteoarthritis Outcome Score Pain After Knee Replacement

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A B S T R A C T

Background: The aim of this prospective multicenter study is to investigate the association among (1) tibial site-specific overhang of medial, anterior, and lateral overhang in relation to Knee Injury and Osteoarthritis Outcome Score pain 1 year after surgery (1 Y KOOS pain) and (2) the malalignment of TKA components including overall malalignment in relation to 1 Y KOOS pain.

Methods: From 10 centers, across 4 continents, 323 patients were enrolled from October 2011 to February 2014. Radiographs were analyzed for tibial overhang on medial, anterior, and lateral site and for overall, tibial, femur, and combined malalignment. A 1 Y KOOS pain score <70 represented an unsatisfactory pain level.

Results: A significant association was observed between medial overhang and 1 Y KOOS pain with a cut-off of <70 ($P = .04$), with an odds ratio of 0.46. No significant associations were observed among the independent variables of lateral and anterior overhang or for overall, tibial, femoral, and combined component malalignment, and the dependent variable of 1 Y KOOS pain <70.

Conclusion: This prospective multicenter study showed a significant association between medial overhang of the tibial component and a 1 Y KOOS pain <70. The related odds ratio was 0.46, which demonstrates that medial overhang may lead to a 54% reduced chance for entering an acceptable pain category 1 year after surgery when receiving a TKA.

To generate biomechanically aligned tracking, optimal load transmission, decreased failure rate, and high functionality after total knee arthroplasty (TKA), it is recommended to aim for accurate fit and alignment of the tibial and femoral components [1,2].

An increasing assortment of tibial components is available to accommodate size and gender specification. Proper fit and alignment should, theoretically, generate both decreased tissue irritation and diminished subsidence due to reduced overhang and undersizing, respectively.

The risk of undersizing is potential subsidence [3–5] shown in both experimental and clinical studies. The impact of oversizing with overhang is debated with inconclusive findings, though with a tendency of nondetrimental impact on functional outcome [4]. Furthermore, different scales exist for grade of overhang. Thus, the influence of overhang continues to be debated, especially medial overhang due to close intra-articular relation to the medical collateral ligament, potentially leading to impingement [6].

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For tibial component alignment, recommendations for coronal placement of the tibial, femoral, and overall alignment exist [7–9], though with a variety of consequences for malalignment if assessed with patient-reported outcome measures (PROMs). Recommendations for sagittal alignment do also exist, including the tibial slope, though based both on experimental animal studies and clinical studies [7].

PROMs are reliable means of assessing postoperative pain and functionality after TKA, albeit the association between component position, especially with overhang and malalignment, in relation to PROMs, continues to be debated. The Knee Injury and Osteoarthritis Outcome Score (KOOS), with an independent subscale of pain, KOOS pain [10], has been used as an independent assessment of pain after TKA [11,12]. Measured dichotomously with questionnaire, a majority of TKA patients have a satisfactory outcome 1 year postoperatively, though approximately 15%-20% have an unsatisfactory outcome if measured with PROMs [13–15]. Thus, clinically it is of great importance to uncover potential predictors for lower outcomes, and component position may contribute to such outcomes.

The aim of this study is to discern if there is an association between tibial component overhang and the Knee Injury and Osteoarthritis Outcome Score pain 1 year after surgery (1 Y KOOS pain), and between malalignment and 1 Y KOOS pain for a TKA group who find themselves less satisfied with TKA 1 year postoperatively.

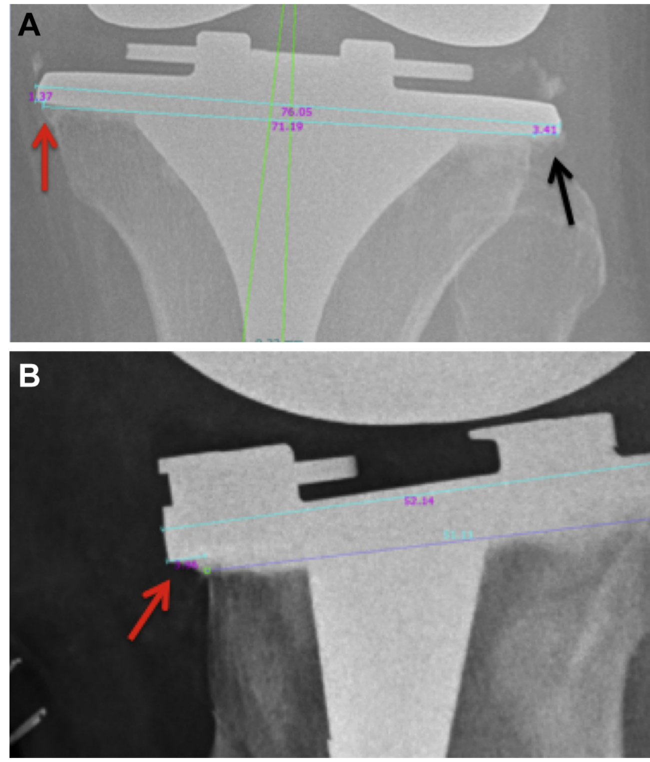

Fig. 1. (A) Measurement of medial (red arrow) and lateral (black arrow) overhang. (B) Measurement of anterior (red arrow) overhang.

Method

This prospective multicenter was conducted at 10 centers in 4 continents. A total of 323 patients undergoing unilateral TKA were enrolled. One hundred twelve patients were enrolled in Europe from 3 centers (2 centers in Denmark and 1 in Sweden); 98 patients in the United States from 4 centers (Massachusetts, California, Wisconsin, and Tennessee), 81 patients from Asia all from 2 South Korean centers, and 32 patients from 1 center in Australia (Sydney). All patients consented to be followed up postoperatively at 0.5, 1, 3, 5, 7, and 10-year intervals. All centers' participating surgeons were experts in the field of TKA, and perform a high volume of surgeries annually. All surgical procedures were conducted between October of 2011 and February of 2014.

The study was Institutional Review Board approved and managed by 1 center in the United States.

The inclusion criteria were a painful and disabled knee joint resulting from osteoarthritis or traumatic arthritis where one or more compartments are involved.

The exclusion criteria were either absolute or relative. Absolute contraindications included infection, sepsis, osteomyelitis, and failure of a previous joint replacement. Relative contraindications included uncooperative patient or patient with neurologic disorders who are incapable of following directions, severe osteoporosis, metabolic disorders which may impair bone formation, osteomalacia, vascular insufficiency, muscular atrophy, neuromuscular disease, and incomplete or deficient soft tissue surrounding the knee.

For all surgical procedures, performed either by measured resection or a hybrid technique (measured resection and gap balancing), patients received Vitamin E diffused highly cross-linked polyethylene (E1) in a Vanguard Knee Replacement (Zimmer Biomet Holdings, Inc, Warsaw, IN). The tibial bearings were available in various levels of constraint required and appropriate constraint was determined by the surgeon: 140 knees received cruciate retaining and 183 received posterior stabilized implants. All the Vanguard Knees in this study were cemented.

Patient data were collected prospectively with a variety of patient demographics including age, gender, body mass index (BMI), as well as surgical variables including anesthesia type, blood loss, side, skin approach, incision length, and tourniquet time. Postoperative radiographs were collected and analyzed for component positioning. All radiographic analyses were performed according to a standardized image protocol to optimize reproducibility and minimize rotation. Preoperative and 1 Y KOOS pain score were used to evaluate the association between pain and component positioning. The acceptable timeframe for the postoperative film was a maximum of 6 weeks postoperatively.

An external orthopedic surgeon conducted the radiographic analysis, focusing on component position and overhang. This surgeon did not have any surgical engagement in the study.

Overhang was defined as any portion of the tibial tray that exceeded the tibial bone with a subsequent categorical outcome of either (1) overhang or (2) nonoverhang representing perfect fit or undersizing. The reason for this dichotomous outcome, with any proportion of overhang more than 0 mm being counted as overhang, was the approach that any overhang is nonintended. Medial/lateral overhang was measured on the anterior/posterior (AP) postoperative radiographs and anterior overhang was measured on lateral view (Fig. 1A and 1B). Posterior overhang was not included in the analysis since a minor rotation of the postoperative radiograph can generate overlay of posterior condyles with great uncertainty of the true posterior component position with risk of misclassification.

The AP radiographs were analyzed for overall, femoral, and tibial malalignment. Standing full-length lower limb radiographs were not feasible and instead the anatomical tibiofemoral axis was used, determined on short films; the tibiofemoral axis has previously been evaluated for this purpose [9,16]. Four categories of malalignment on the AP view were determined: overall, femoral, tibial, and combined. These were defined as <2.5 or >7.5 valgus for overall; <2 valgus or >7 valgus for femoral; and >3 varus or >3 valgus for tibial. Combined malalignment was defined as both tibial and femoral malalignments, described by the aforementioned criteria. The chosen levels of malalignment were extracted from the value of relative consensus of alignment [7–9]. The result was stated categorical as either malaligned or aligned for the 4 categories.

Postoperative radiographs were analyzed with mdesk Version 3.4.0.0 software (RSA Biomedical AB, Sweden). Size was standardized and calibrated using the distal tibial peg, insensitive to rotation [17].

To accommodate the aim of elaborating on predictors for lower outcome after TKA, especially unacceptable pain, the independent subscale of KOOS pain was employed. This subscale has been validated as an independent scale to evaluate knee pain following TKA [18]. Thus, any 1 Y KOOS pain score <70 was used to represent unsatisfactory pain; however, this cut-off defined neither a complete failure nor a clinically acceptable pain level. This cut-off was based on follow-up studies 1 year after knee surgery [19–21], thus 1 Y KOOS pain <70 representing not acceptable pain and >70 representing intermediate and acceptable pain.

The preoperative value of PROMs impacts the postoperative outcome [22–25], which was adjusted by including preoperative KOOS pain as an independent variable in the analysis.

Statistics

Patient characteristics are displayed as mean (with standard deviation [SD]) or count (percent). Multiple logistic regression was used to assess the association among independent variables, overhang, malalignment, and preoperative KOOS pain, and the dependent variable of <70 for 1 Y KOOS pain score. A *P*-value of .05 was considered significant. Odds ratio (OR) described the degree of association and was adjusted for gender, age, BMI, and the preoperative KOOS pain.

The fit of the models was evaluated by the Hosmer-Lemeshow goodness-of-fit test.

All analyses were done in R 3.0.2 software and Hosmer-Lemeshow goodness-of-fit test was done using the Hosmer test from the ResourceSelection package.

Results

Of the 323 patients enrolled in the study, 68.4% (211) were women, mean BMI was 30.7 kg/m^2 (SD 8.2), and the mean age was 66.0 years (SD 8.2).

All the included patients had 1 Y KOOS pain, 292 had postoperative AP films and 286 had lateral films. All 292 AP films and 286 lateral films qualified for analysis of medial/lateral and anterior overhang, respectively. Of the 292 postoperative AP films, 286 qualified for analysis of overall, tibial, and femoral malalignment, whereas 6 films were insufficiently short for assessment. For KOOS pain, 320 patients had preoperative KOOS pain value and 298 patients had 1 Y KOOS pain value. Lost to follow-up with missing both 1 Y KOOS pain and images were 37 patients (11%).

A total of 53 (18.0%), 92 (32.2%), and 17 (5.8%) patients were observed with medial, lateral, and anterior overhang, respectively, when measured on the dichotomous scale of overhang vs nonoverhang.

Significant association was observed between medial overhang and 1 Y KOOS pain <70 ($P = .04$, OR 0.46, confidence interval 0.21-0.97). No significant associations were found for anterior and lateral overhang and the outcome of 1 Y KOOS pain (Table 1).

Table 1
Overhang and 1 Y KOOS Pain Adjusted for Pre-KOOS Pain.

	1 Y Films	Overhang	% Overhang	Odds Ratio	Confidence Interval	*P*-Value
Medial	292	53	18.0	0.46	0.21-0.97	.04
Lateral	292	92	32.2	0.76	0.34-1.69	.50
Anterior	292	17	5.8	1.43	0.27-7.56	.60
Pre-KOOS pain				1.06	1.03-1.09	.009

1 Y KOOS pain, Knee Injury and Osteoarthritis Outcome Score pain 1 year after surgery.

Regarding malalignment, 53 (18.5%), 42 (14.8%), 54 (18.9%), and 11 (3.8%) patients were observed with overall, tibial, femoral, and combined malalignment, respectively. No significant associations were observed between any of the 4 categories of malalignment and 1 Y KOOS pain <70 (Table 2).

None of the analyzed films gave evidence of subsidence, osteolysis, or fracture. Three patients were revised within the first 3 months: 2 due to postoperative infection and 1 due to instability after 2, 6, and 10 weeks, respectively.

Discussion

The main finding in this prospective multicenter study is a significant and clinically relevant association between medial overhang and a 1 Y KOOS pain outcome <70 with an OR of 0.46. This demonstrates that postoperative medial overhang may lead to a 54% reduced chance for entering an acceptable pain (KOOS >70) category 1 year after surgery when receiving a TKA. A total of 18% were observed with medial overhang in this study.

This study is the first to evaluate overhang and malalignment in relation to 1 Y KOOS pain in a multicenter prospective cohort study including 4 continents. Furthermore, it is the first study to elaborate on site-specified overhang with medial, lateral, and anterior in contrast to pooled cumulated overhang.

For overhang, previous studies have elaborated on the association to various PROMs ranging from no association to significant association [4,26,27]. In a recent prospective study of 154 TKAs, no association was found neither for major (≥3 mm) or minor (<3 mm) overhang in relation to Oxford Knee Score (OKS) and Western Ontario & McMaster Universities Osteoarthritis Index score 1 and 4 years after TKA; however, no distinction was done regarding location of overhang with total overhangs of 18%. A study in unicompartmental knee, with identical size classification of overhang (≥3 mm vs <3 mm), found no association between minor medial overhang and OKS after 1 year, but significant association between major overhang and OKS 4 years after surgery [26]. In a retrospective study of 532 TKAs, severity of overhang had no association to OKS [27]. Another retrospective single center study with 114 consecutive TKA patients found that overhang, grouped into mediolateral and anteroposterior overhang, generated no significant difference in 1 Y KOOS pain [28]. However, patients with mediolateral overhang had a significant, but small, reduction in knee flexion. These studies were actually an updated earlier study by the same author in which both femur and tibia mediolateral oversizing were investigated [29].

Thus, overall, the studies on the impact of overhang are limited and do not contain distinction for site-specified overhang in TKA, despite intra-articular located medical collateral ligament and risk of impingement [6]. This could potentially dilute a significant site-specific signal from medial overhang when pooling all data for overhang.

Table 2
Malalignment and 1 Y KOOS Pain Adjusted for Pre-KOOS Pain.

	1 Y Films	Malalignment	% Malalignment	Odds Ratio	Confidence Intervals	*P*-Value
Overall	286	53	18.5	0.57	0.23-1.45	.24
Tibial	284	42	14.8	1.32	0.11-15.39	.83
Femur	286	54	18.9	1.61	0.16-16.69	.69
Combined	286	11	3.8	1.07	0.91-1.25	.40

1 Y KOOS pain, Knee Injury and Osteoarthritis Outcome Score pain 1 year after surgery.

For the observed significant association in this study, it is reasonable to discuss the clinical relevance and to which extent medial overhang should be avoided in favor of potential undersizing and subsidence [3,4]. The limited literature including our findings for overhang cannot rationalize a medial undersizing if only nonfitting trays are available. Rather, when a perfect fit is not feasible, at least avoid a medial overhang when choosing a tibial component. The choice of a dichotomous scale of overhang vs nonoverhang is intended in terms of surgical usability since it is easy to assess intraoperatively, and since any overhang is unintended.

For malalignment no association was found for 1 Y KOOS pain >70. This is aligned with prior studies; no difference for 218 TKAs in functional scores (Western Ontario & McMaster Universities Osteoarthritis Index and 36-item short form health survey (SF-36)) for malaligned and aligned TKA in a minimum 5-year follow-up study [30]. One study even found a better outcome with slightly varus configuration [31] and additionally 2 studies with 15 years of follow-up found no difference in revision rate between overall malalignment and alignment for 501 and 398 TKAs [32,33]. However, 2 other cohort studies showed significant increased revision rate for malalignment in 6070 primary TKAs with a follow-up time of 8 years [8,9]. Existing well-conducted evidence has shown a marked increase failure rate when the second component, to attain alignment, is inserted to compensate an initiated malalignment [8]. In our study, 7 of total 11 combined malalignments were combined tibial varus malposition and femoral valgus malposition generating an overall alignment, though with no association to 1 Y KOOS pain <70. However, it is important to preserve caution for the conclusion due to a low number of combined malalignments and therefore the risk of type II mistakes.

The KOOS pain subscale has previously been validated for TKA [18], and has been used independently to evaluate pain after TKA [11,12]. Assessing patient outcome after TKA with the KOOS pain score appears to be a suitable measure due to higher responsiveness and to a lower ceiling effect compared to other PROMs [34]. Therefore, KOOS pain appears to be an appropriate measure for the remaining 17%-20% of TKA patients that, despite a good surgical result, ends up not fully satisfied after TKA measured with PROMs [13,14]. Hence, this study aimed to trace predictors for *not acceptable pain* with a cut-off of 70 for 1 Y KOOS pain. This cut-off for KOOS pain of 70 was anchored to earlier studies: (1) a follow-up study after other knee surgery in which mean KOOS pain score was 77 for undecided intermediate pain, 57 for nonacceptable pain, and 88 for acceptable pain 12 months postoperatively [19]; (2) in a Swedish population study with a sample of 840 subjects (all adults), the mean KOOS pain was 78.6 (73.1-84.1) and 87.8 (84.0–91.4) for female and male, respectively, in the age group of 55-74, and (3) also in a large Swedish study with a random sample of 10,000, 25% had knee pain and 15% had clinical knee osteoarthrosis within the age of 56-84 (mean of 70). Thus, KOOS pain of 70 appears to be a *reasonable* cut-off for unacceptable pain after TKA surgery; the value is lower than undecided intermediate pain (1), higher than nonacceptable pain (1), and for a population sample, within the relevant age category, KOOS pain score was well above the chosen cut-off, however not entirely painless (2), possibly explained by the significant minority of subjects with osteoarthritis-related symptoms in the same population and age groups (3).

Finally, observing the divergent impact of medial overhang in perspective with existing literature might ask if the chosen implant could be a confounder. The implants and instrumentation are in general uncomplicated to apply and have shown no inferiority in comparison to other implant types [35].

Strengths and Limitations

The obvious strength is the methodological setup with a prospective multicenter study with a tentative high external validity. For the internal validity and thereby the assessment of how causal the observed significant effect is, the temporal precedence and covariation is present although it can be argued that other factors may explain a part of the association. Furthermore, this study is the first to look at isolated medial overhang with both a high number of TKAs and medial overhangs (event). However, no power calculation was performed prior to this study due to the explorative character of this study. This could potentially lead to type II errors.

The KOOS pain cutoff value for *not acceptable pain* could be discussed, however with a dichotomous outcome of KOSS pain 1 Y <70 representing not acceptable pain and >70 representing intermediate and acceptable pain, the cut-off primarily serves to explore for predictors in the minority of patients with low outcome in line with the explorative character of this study.

The large number of surgeons involved, conditioned by the multicenter study, could be argued to be a bias in the study. The counter argument is that all centers were high-volume TKA centers and had experience with the KOOS scale prior to the trial, which both contribute to an increased external validity.

In cases where osteophytes could not be distinguished clearly from the tibial cortex, it may cause an overhang going undetected. If this is the case our estimate of overhang may be slightly underestimated.

The possibility of evaluating the impact of an eventual component malrotation in relation to overhang and malalignment requires a computed tomography scan [1], which was not possible in this study. It is a clear limitation for this study. In general, there is a need of studies for which the rotation is included in the attempt of predicting component factor which affect PROMs.

Conclusion

In this prospective multicenter study, a significant association was shown between medial overhang and a 1 Y KOOS pain <70, demonstrating a 54% reduced chance for entering an acceptable pain category 1 year after surgery if medial overhang is present after receiving a TKA.

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