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# Stemmed Versus Nonstemmed Tibia in Primary Total Knee Arthroplasty: A Similar Pattern of Aseptic Tibial Loosening in Obese Patients with Moderate Varus. 5-Year Outcomes of a Randomized Controlled Trial

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## Abstract

Obesity is linked to early tibial tray failure after primary total knee arthroplasty (TKA) for osteoarthritis (OA), especially in patients with preoperative varus. This study compared standard and stemmed tibiae TKAs in patients with class I and II obesity with varus deformity. Between April 2013 and June 2020, a prospective study was conducted including patients with end-stage OA, body mass index between 30 and 40 kg/m$^2$, and varus <15 degrees. Patients were randomly assigned to TKAs with either standard or long-stemmed tibiae and evaluated 5 years after surgery using the Knee Society Scoring (KSS). The knee society and modified radiographic evaluation systems were used for radiological evaluation. In total, 264 TKAs were performed in 264 patients (134 in the standard group and 130 in the stemmed group). The mean preoperative hip–knee–ankle angles for the standard and stemmed groups were $8.2 \pm 3.2$ degrees/varus and $9 \pm 2.9$ degrees/varus, respectively ($p = 0.2$), which improved to $5.1 \pm 3$ degrees/valgus and $5 \pm 3.5$ degrees/valgus after surgery ($p = 0.52$). There was no statistically significant difference between the objective KSS (92 vs. 92.9; $p = 0.84$) and the functioning KSS (73.4 vs. 74.8; $p = 0.28$). There were no aseptic loosening cases or radiographic differences. In-group analysis revealed significant outcomes differences in both groups if preoperative varus was >10 degrees irrespective of the stem design ($p < 0.0001$). Complications occurred in two patients; one with a late infection and one had a stem-related tibial fracture. Standard tibia TKAs yielded comparable results in obese patients to long-stemmed tibias. No aseptic tibial loosening was observed regardless of stem type, and worse clinical outcomes were associated with greater varus.

**Clinical trial registry:** registered at http://www.researchregistry.com (researchregistry5717).

**Level of Evidence** II; a prospective randomized trial.

**Keywords**
- obesity
- primary total knee arthroplasty
- stemmed tibia
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The World Health Organization, in 2000, defined a classification system for obesity based on body mass index (BMI). Normal weight BMI is 18.5 to 24.9 kg/m$^2$ and overweight BMI is 25.0 to 29.9 kg/m$^2$. Classes I, II, and III obesity are defined as the BMI of 30.0 to 34.9 kg/m$^2$, 35.0 to 39.9 kg/m$^2$, and >40.0 kg/m$^2$ respectively.[1] A strong correlation between obesity and the development of knee osteoarthritis (OA) has been revealed.[2] Obesity increases the risk of developing knee OA by 9 to 13% with each additional kilogram of body mass. This rate increases by up to 35% for every 5 kg of weight gained.[3] Owing to the rising rate of obesity in society, an increasing number of overweight and obese patients undergo total knee arthroplasty (TKA).[4] Obese patients underwent TKA at a rate of 31% in 1990, 52% in 2005, and 60% in 2012.[5,6]

Many studies have shown significantly inconsistent results after primary TKA in obese patients.[7–12] Several authors have linked the aseptic loosening of tibial components following TKA to obesity.[13–15] The BMI cut-off linked with this complication is still under discussion. Some studies have reported a BMI cut-off >35 kg/m$^2$,[13,16,17] while others have reported a cut-off >30 kg/m$^2$.[18,19]

Attention has been paid to improving the survival of the tibial components of TKAs in the obese population.[13,14,20] Many factors have been assessed, including tibial stem extension (short or long), keel size, tibial baseplate design, and cement viscosity.[21–26] Variable results were reported using stem extension. Some studies favored the use of standard nonstemmed TKAs,[25,26] while others supported the use of stemmed implants.[21,22]. So, the benefit of stems has not been conclusively shown, and there is no consensus on the use of stems in primary TKA.

Preoperative severe varus deformity was associated with catastrophic tibial baseplate varus failure in obese patients, especially with small tibial sizes.[15] The failure mechanism was found to be due to the failure of the implant–cement interface before the collapse of the proximal medial tibia bone.[27] Under these conditions, the use of stemmed tibial parts was recommended.[14,15]

Our study aimed at prospectively evaluating the use of the standard keeled tibial parts versus the long-stemmed type of the same TKA system in obese patients with moderate varus deformity. The hypothesis was that the use of stemmed tibial components would produce better clinical and radiological results than the standard implants do.

## Material and Methods

### Demographic Data

The institutional board approved a prospective randomized controlled trial between April 2013 and June 2020. The goal was to compare TKA outcomes and complications in obese patients using either standard tibial components or long-stemmed variants. Inclusion criteria were BMI > 30 and < 40 kg/m$^2$ at surgery (obesity class I and II),[1] age between 50 and 70 years, primary OA, and varus deformity less than 15 degrees. Patients outside the age limit or BMI range, secondary or inflammatory OA, previous replacement or reconstructive knee surgery, varus deformity above 15 degrees, valgus deformity, and fixed flexion deformity >10 degrees were excluded. Based on the primary outcome (aseptic tibial loosening), calculating the sample size revealed that 260 sample size patients were needed at a power of 80% (significant 0.05) to identify a significant difference between the two groups.

Demographic data were documented after collecting the target group of the patients, including age, sex, BMI, and comorbidities. The angles of the hip–knee–ankle (HKA) and associated deformities were obtained from a long-leg anteroposterior weight-bearing view and 30 degrees-flexion lateral view X-ray films. A computer software program achieved the randomization of patients into two groups.

After obtaining informed consent, as per the ethical standards of the 1964 Declaration of Helsinki as revised in 2013, 269 patients underwent 269 consecutive primary TKAs. Five patients stopped to continue attendance for regular assessment. At the final follow-up, there were 264 patients: 134 patients in the standard group and 130 patients in the stemmed group (►**Fig. 1**).

### Implant Design

NexGen Complete Knee System, legacy posterior stabilized (LPS) prosthesis (Zimmer, Warsaw, IN) was used. The femoral components were LPS precoated components. In the standard group, the tibial components were monoblock plate, precoated with standard keel (45 mm). The plate was secured to the stem (straight or offset types) with a locking screw in the stemmed group. The stem was 100 mm in length and provided a combined length of 145 mm. Simplex P bone cement (Stryker, Mahwah, NJ) was used for cementation.

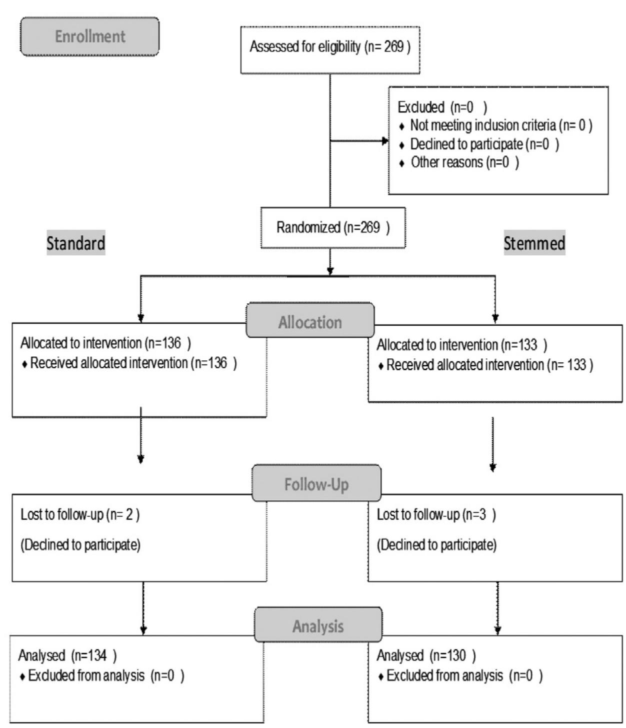


**Fig. 1** CONSORT flow diagram depicting participant flow during the clinical trial.

### Surgical Protocol

All surgeries were performed by the same surgeon (M.M.). Through the anterior incision and medial parapatellar arthrotomy, bone preparation was performed. Two sets of bone cement were used for cementation of the implants (one for each component, i.e., femoral and tibial) in two layers. For nonstemmed tibiae, cementation of the implants was done in two layers, a layer of cement on the implant underside, around the keel, and on the resected bone surface. For stemmed tibia, the intramedullary canal was prepared by sequential reaming to the appropriate length and diameter to accommodate the stem, and finally, a press-fit stem with a diameter corresponding to the size of the last reamer was chosen. After securing the tibial plate to the stem, a layer of cement was placed on the underside of the tibial baseplate, around the keel, and on the resected tibia surfaces. Implantation of the tibial plate and stem was done. Any excess bone cement was removed from the implant/bone interface. Patelloplasty was performed by removing osteophytes from the edges and reshaping the patellar surface to match the femoral component trochlea with patellar rim denervation by electrocautery. Suction drains were used.

### Postoperative Care

Intravenous antibiotic and mechanical and chemical prophylaxis for the thromboembolic disease were given postoperatively. Postoperative X-rays were done on the day of surgery as the index films. The wound drain was removed after 48 hours. At the same time, continuous passive motion was started, and the patients began active knee motion by walking with a walker. Discharge from the hospital occurred after 72 hours. At 14 to 21 days after surgery, stitches were removed. Clinical and radiological assessments were done at 6 weeks, 12 weeks, 6 months, 1 year, and then, annually for at least 5 years for every case.

### Follow-Up Assessment

Clinical evaluation was done by the Knee Society Scoring (KSS) system.[28] The radiological evaluation was performed by the Knee Society roentgenographic evaluation scoring[29] and the modified radiographic evaluation systems[30] to identify and evaluate radiolucent lines (RLLs). Early radiological tibial loosening (progressive RLLs >2 mm, osteolysis, or tilting of the component) has been recorded. The radiological results were assessed independently by two surgeons (E.I. and E.M.). As per the study protocol, any patient with suspected implant loosening was assessed by C-reactive protein and white blood cells, bone scans, computed tomography scan, joint aspiration, and fluoroscopic assessment of prosthesis stability. Evaluations were conducted for each patient at 6 weeks, 12 weeks, 6 months, 1 year, and every year for at least 5 years.

### Statistical Analysis

Data were coded and entered using the Statistical Package for the Social Sciences version 25 (IBM Corp., Armonk, NY). Data were analyzed using the mean, standard deviation, minimum, and maximum in continuous data, using the frequency (count) and relative frequency (percentage) for categorical data. Comparisons between continuous variables were made using the nonparametric Mann–Whitney test. The nonparametric Friedman test and Wilcoxon signed-rank test were applied to compare serial measurements within each patient. For comparing categorical data, chi-square ($X^2$) test was performed. Fisher's exact test was used instead when the expected frequency was <5. A *p*-value of less than 0.05 was considered statistically significant. Curves of survival were performed according to Kaplan–Meier principles and compared with a nonparametric log-rank test.

**Table 1** Demographic data

| | Standard group | Stemmed group | *p*-Value |
|---|---|---|---|
| No. of patients | 134 | 130 | 0.935 |
| Male/female | 46/88 (34%/66%) | 44/86 (33%/67%) | 0.368 |
| Age mean in years (range) | $57 \pm 4$ (52–63) | $57 \pm 2$ (53–64) | 0.355 |
| BMI mean in $kg/m^2$ (range) | $35.15 \pm 3.3$ (31–37) | $35.56 \pm 3.35$ (32–36.5) | 0.820 |

Abbreviation: BMI, body mass index.

## Results

### Clinical Results

The mean follow-up of all patients was $6.1 \pm 0.7$ years (range 5.1–7.2 years). The standard group included 134 patients with a mean age of $57 \pm 4$ years and a mean BMI of $35.15 \pm 3.3\ kg/m^2$. The stemmed group included 130 patients with an average age of $57 \pm 2$ years and a mean BMI of $35.56 \pm 3.35\ kg/m^2$. ►**Table 1** shows the demographic data for both groups.

The standard group's preoperative mean objective KSS score was $56.20 \pm 7.08$, and a mean functional score was $50.90 \pm 5.88$. The mean objective score for the stemmed group was $53.70 \pm 9.97$, and the mean functional score was $50.75 \pm 6.8$. There was a statistically significant improvement in postoperative KSS scores for each group ($p < 0.05$), still the stemmed group had slightly better figures; however, the difference between the groups was not statistically significant, as shown in ►**Table 2**.

The in-group analysis showed that the final outcome was more favorable with preoperative varus deformity less than 10 degrees irrespective of the stem design. In the nonstemmed group, the mean objective KSS was $92.1 \pm 2$ in patients with less than 10 degrees of preoperative varus deformity compared with $88.6 \pm 2.7$ if the preoperative varus was more than 10 degrees and the difference was statistically significant ($p < 0.001$). The same values were detected in the stemmed group. By comparing the patients with preoperative varus >10 degrees of the two groups, both had similar outcomes as shown in ►**Table 3**.

 

**Table 2** KSS for both groups

| KSS mean | Standard | | Stemmed | | $p$-Value[a] |
|---|---|---|---|---|---|
| | Preoperative | Postoperative | Preoperative | Postoperative | (postoperative results) |
| Objective (range) | 56.2 ± 7 (39–72) | 92 ± 2 (88–95) | 53.7 ± 10 (34–70) | 92.5 ± 2(89–96) | 0.841 |
| Functional (range) | 50.9 ± 5.88 (39–68) | 73.4 ± 5.1(67–81) | 50.8 ± 6.8 (35–60) | 74.8 ± 5(63–82) | 0.289 |

Abbreviation: KSS, Knee Society Score.
[a]$p$-Value between the postoperative results of the two groups.

**Table 3** In-group analysis according to the preoperative varus degree

| Group | Nonstemmed | Nonstemmed | $p$-Value | Stemmed | Stemmed | $p$-Value |
|---|---|---|---|---|---|---|
| Preoperative varus | < 10 degree of varus | >10 degree of varus | | <10 degrees of varus | >10 degrees of varus | |
| Objective KSS | 92.1 ± 2 | 88.6 ± 2.7 | <0.0001 | 92.6 ± 1.9 | 88 ± 3 | <0.0001 |

Abbreviation: KSS, Knee Society Score.

## Radiological Results

For the standard group, the mean preoperative HKA was 8.2 ± 3.2 degrees of varus (ranging from 5 to 14.5 degrees of varus), which improved postoperatively to 5.1 ± 3.2 degrees of valgus (ranging from 3 to 7 degrees). Comparable results were recorded for the stemmed group with the mean preoperative HKAs being 9 ± 2.9 degrees of varus (ranging from 5 to 14 degrees of varus), which improved to 5 ± 3.5 degrees of valgus ($p$-value = 0.834; ►**Fig. 2**).

Changes in the components alignments between the two groups were subtle during the follow-up. A mean 1-degree change in tibial tray position was reported in the standard group between the immediate postoperative film and the final follow-up. No other changes in the position of the components have been reported.

In total, 18 of 134 standard-group patients (11%) and 14 of 130 stemmed-group patients (11%) showed RLLs. These lines were observed in the first year, being less than 2 mm in width and nonprogressive. Most RLLs were observed in zone 1 (12 standard-group patients and 10 stemmed-group patients), and fewer were observed in zone 4 (six standard-group patients and four stemmed-group patients; ►**Fig. 3**). No radiolucency around the keel or stem was observed. The gross displacement of any component was not detected.

## Complications

One patient in the standard group, 7 months after surgery, had a late hematogenic infection, and we made debridement with a change in polyethylene liner followed by 6 weeks of IV antibiotics. Another patient in the stemmed group sustained a proximal intraoperative tibial fracture during stem insertion, which was fixed with two cancellous screws (►**Fig. 4**). For this patient, weight-bearing was deferred to 6 weeks and partial weight-bearing was allowed after complete bone healing (approximately 13 weeks). She was a 69-year-old female with a markedly osteoporotic tibia. The final objective score was 85, having a functional score of 68. The survival rate of tibial components was 100% for both the standard and stemmed implants during the mean follow-up (►**Fig. 5**).

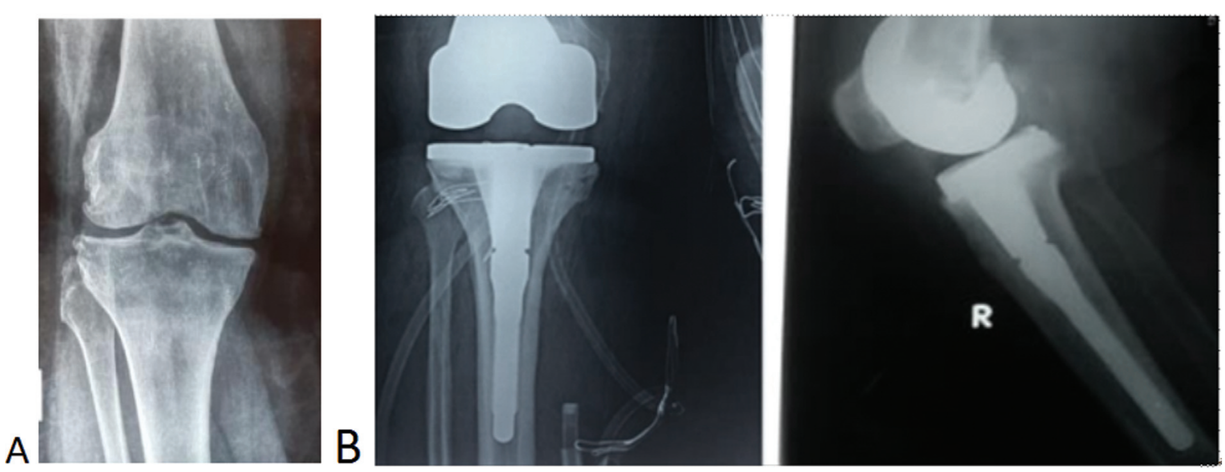


**Fig. 2** Preoperative **(A)** and postoperative **(B)** X-ray of 59-year-old female (BMI = 32 kg/m$^2$) with the stemmed tibial component. BMI, body mass index.

 

**Fig. 3** Radiolucent line at tibial area 1 (arrow) after 11 months of index surgery.

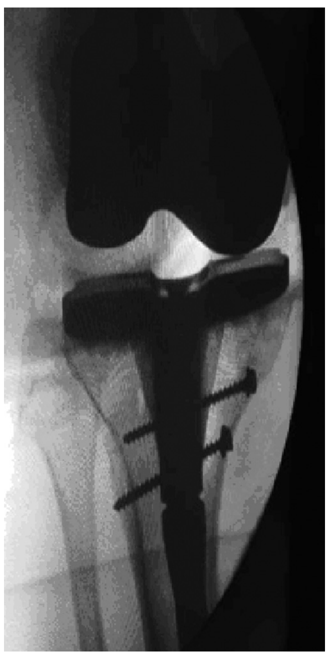

**Fig. 4** Intraoperative fluoroscopic photo after fixation of the crack of the proximal tibia by screws.

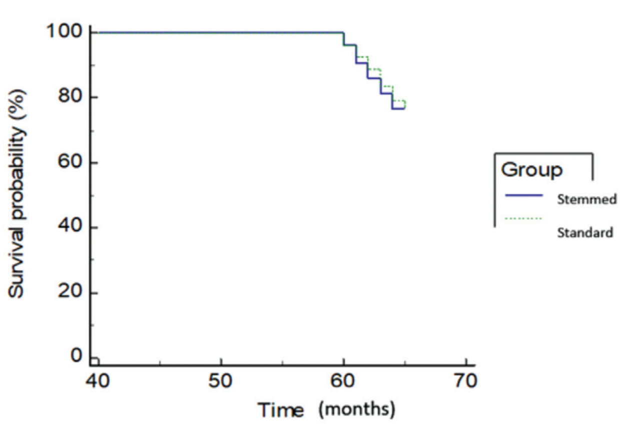


**Fig. 5** Kaplan–Meier curve for implant loosening during the follow-up (60 months).

## Discussion

The most important finding from this study was that standard tibia TKA in obese patients with moderate varus in a 5-year follow-up period provided similar clinical and radiographic results to long-stemmed TKA. This study analyzed two groups: a group that underwent TKA with nonstemmed standard tibial parts of 45-mm keel and a group with long-stemmed tibial parts of 145-mm length. At the final follow-up, the postoperative outcomes were slightly better in the stemmed group, but there was no statistical significance. There was no gross displacement of any TKA components to suggest aseptic loosening. No cases underwent a revision for aseptic loosening.

The mechanisms of aseptic loosening of tibial implants in obese patients are likely due to increased stress on the tibial implant and abnormal kinematics of the knee with catastrophic varus collapse.[14,31,32] Preoperative weight loss, the use of a larger tibial component, and a tibial stem extension can reduce stress on the proximal tibia. Because the size of the tibial component is limited by anatomy, efforts to reduce tibial stress may depend primarily on the preoperative weight loss and the use of tibial stem extensions.[33]

Long-stemmed tibial components were used to improve primary tibial survival.[13,14,25] The involvement of the stems enhances the rigidity of the components to endure bending forces.[26] Finite element analysis revealed that the use of stem extension also reduces stress on the cement–device interface, which reduces micromotion and improves implant stability.[34] Such benefits come at the expense of some drawbacks, including stress shielding, the possibility of periprosthetic fracture, complicated revision, and pain of the stem tip.[22] Stem-related periprosthetic fractures could be confronted. Our study had a case of intraoperative tibial fracture during stem insertion.

Short-stemmed tibial TKAs have been evaluated. Fournier et al, in a retrospective study, compared 35 TKAs with short-stemmed tibiae (combined length of the baseplate and the stem = 70 mm) versus 105 TKAs with standard implants. The mean BMI was 34 kg/m$^2$ for both groups, and the mean follow-up was 52 months (minimum of 2 years). Seven patients with tibial failures in the standard group (6.6%) versus no tibial loosening in the stemmed group ($p < 0.001$) were recorded. This study recommended using short-stemmed TKA for obese patients.[22] Garceau et al, in another study, compared the use of short-stemmed (combined length = 75 mm) TKAs with a nonstemmed group, using BMI > 40 kg/m$^2$ as a point of stratification. The 5-year survival of the stemmed group was 100% with BMI below or above 40 kg/m$^2$, while in the nonstemmed group, 94.5% 5-year survival with BMI < 40 kg/m$^2$ was recorded but 4-year survival was 71.4% if the BMI was > 40 kg/m$^2$. A marked discrepancy in the survival toward the short-stemmed group was recorded.[23] Nevertheless, on the contrary, the cost-effectiveness of using a tibial stem in each patient of this population with BMI above 35 kg/m$^2$ should be considered for more selective criteria for implanting tibial stems.[35]

Standard tibial TKA was studied by Parratte et al in a randomized controlled trial of 120 patients. Patients were stratified into four groups: BMI of 30 to 35 kg/m$^2$ and BMI > 35 kg/m$^2$ with tibial implants either without stems or a 100-mm stem. The study did not find any significant differences between the treated groups of patients regarding aseptic loosening.[25] Crawford et al supported using the standard design in which a standard tibial tray was fixed by a high viscosity bone cement, with a mean follow-up of 5.4 years. The mean BMI of the patients was 41.7 kg/m$^2$. In this study, only one patient developed aseptic tibial loosening after 1.6 years and was revised by a 40-mm stem extension (combined length of 80mm).[21] Steere et al obtained a similar result in a cohort study of 178 primary TKAs (posterior-stabilized and cemented implants) with BMI > 35 kg/m$^2$, showed the comparison between TKAs with a 30-mm short-stemmed extension with nonstemmed TKAs, did not detect aseptic loosening in both groups after a mean follow-up of 36 months.[26]

Martin et al noted that preoperative varus deformity might also be associated with aseptic tibial varus collapse. They recommended using stemmed TKAs in patients who meet the following *three* combined criteria: a preoperative severe varus, BMI >35 kg/m$^2$, and small tibial trays (lower 50% of implant sizes).[15] Samy et al mentioned the same recommendation to stemmed TKAs in morbidly obese patients with severe preoperative varus deformity. These conclusions supported the outcome of our study by using the standard tibial TKAs in obese patients with limited varus deformity; however, the previous studies did not define a cut-off for the varus degree before using stemmed TKAs.[36]

In this study, standard nonstemmed TKAs were used in obese patients, with BMI < 40 kg/m$^2$ and varus deformity <15 degrees, yielding comparable results to long-stemmed tibial design and providing results that may favor the use of standard tibial implants in a similar group of patients to avoid stem-related complications and improve the cost-effectiveness. However, the degree of preoperative varus deformity above 10 degrees was associated with less favorable outcomes in both groups but no increase in radiographic evidence of loosening.

This study has several limitations. A longer follow-up will be necessary to establish more substantial results. Strict patient selection—primary OA, age, BMI, and degree of deformity—is another weakness. We excluded patients with very severe varus deformities and valgus deformities, trying to minimize the variables that could affect the outcomes and longevity of the implant to evaluate the lucid effect of obesity on the behavior of the implant. Another limitation is that this study's results do not address whether stem tibia would decrease the risk of loosening in the setting of morbid obesity BMI > 40 or more severe varus deformities. In addition, because the failure rate of TKAs increases with time, a longer follow-up is needed to understand whether stem fixation decreases the risk of later failure in this group of patients.

## Conclusion

In patients with class I and II obesity and a varus deformity <15 degrees, the use of a standard tibial tray had similar clinical and radiographic outcomes compared with stemmed tibial components indicating that the use of stem did not appear to provide any statistically significant improvement in outcomes. Besides, stem-related complications have been avoided. However, preoperative varus deformity may be more detrimental for expecting better outcomes in this population of patients irrespective of the stem design. This study may affect the choice of TKA implants in treating these groups of patients. As the cost of health care continues to increase and there is more interest in cost control, this study supports the use of standard tibial implants in this category of patients.

### Ethical Approval
This study was approved by the Institutional Committee Board in April 2012.

### Authors' Contributions
M.M.M. is a treating surgeon and was responsible for the revision of the manuscript draft.
M.M.E. was responsible for study design, data collection, material preparation and analysis, and revision of the manuscript draft.
E.I.I was responsible for study design, data collection, results analysis, statistical calculation and figures construction, and manuscript writing.

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### Conflict of Interest
None declared.

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