Sex-specific versus standard posterior cruciate-substituting total knee prosthesis

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Background
The introduction of sex-specific (SS) knee prosthesis designs was an approach to offer more sizing options and is based on the anatomic sex differences. These SS components were though to provide better fitting to female femora and consequently improve the clinical outcome.
Materials and methods
In the period between February 2011 and March 2013, a prospective superiority randomized controlled clinical trial was conducted to compare the clinical outcome of SS versus the standard posterior stabilized (PS) knee prosthesis in women. The primary outcome measure was the postoperative range of knee flexion, and the secondary outcome measure was the knee function as reflected on the performance of daily activities. The OXFORD Knee Score, Knee Society Score, and Knee Society Score for function were recorded preoperatively and then at 3, 12 months, and annually thereafter. Female patients with degenerative or inflammatory arthritis who were 50 years or older and their knee deformities were totally articular were included. A total of 64 patients with 80 knees were enrolled in this trial, and 40 knees were allocated to each group. Knees in the SS group had total knee arthroplasty using SS knee prosthesis, with SS femoral component (the experimental group), whereas knees in the PS group had standard PS knee design with standard femoral component (the control group). Equal randomization (1 : 1 ratio) was undertaken according to a computer-generated randomization table.
Results
The mean preoperative knee flexion range of motion (ROM) was 110 and 108° in the SS and PS groups, respectively. At the latest follow-up, the mean postoperative knee flexion ROM was 115 and 113° the SS and PS groups, respectively. The mean improvement in the knee flexion ROM in both groups was 5° (range: 0–25), with no statistically significant difference between the two groups. All knees except one had full extension. No statistically significant difference was observed between the two groups when the OXFORD Knee Score, the Knee Society Score, and the Knee Society Score for function were compared.
Conclusion
No clinical advantage was observed in the ROM or function between knees that received SS knee prosthesis when compared with those who received PS knee implants. The SS total knee arthroplasty though designed to provide better fitting to the female distal femur does not provide any clinical advantage over the standard PS knee prosthesis. A logic question is whether a separate implant is required for women or modifications to the knee prostheses geometry and more sizes are required to accommodate all patients?
Level of evidence
Level II.

Keywords:
gender-specific, posterior stabilized, total knee arthroplasty

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Introduction

Total knee arthroplasty (TKA) is a successful procedure with long-term survival of 84% at 15 years [1]. The number of patients undergoing TKA surgery has been continuously increasing and has displayed a higher proportion of female patients [1–3]. Women represent approximately 60% of patients undergoing TKA [4–6].

Morphological data indicated that women tend to have narrower medial to lateral (ML) dimension of their femoral condyles for any given anterior to posterior

dimension. The *Q* angle in female population is significantly greater than in males. Additionally, the anterior femoral condylar anatomy is more pronounced in male knees [7–9].

As women dominate both the population that needs TKA and the currently treated patients' population, there is a strong rationale for evaluating female-specific knee requirements based on sex differences in joint anatomy and kinematics.

The introduction of sex-specific (SS) knee arthroplasty implants is an approach to the ongoing trend across TKA systems to offer more sizing options and was based on the anatomic sex differences. The SS component is designed to better accommodate anatomic differences noted in women with a narrower ML dimension for any given anterior to posterior dimension. In addition, the angle of the trochlear groove was increased and the anterior flange thickness was reduced to better match native female anatomy [10–12].

Although SS implants have theoretical advantages over the standard TKA implants for females, it is unclear whether the change in prosthetic design will be reflected on the clinical outcome. To answer this question, a prospective randomized controlled superiority clinical trial was conducted to detect if there is a superior clinical outcome of the SS compared to the standard posterior stabilized (PS) knee prosthesis in women undergoing TKA.

Materials and methods

This study has followed the CONSORT statement in recruiting patients, randomization, follow-up, and reporting the outcome. In the period between February 2011 and March 2013, a prospective two-arm parallel-group superiority randomized controlled clinical trial was conducted including 64 female patients with 80 knees who were diagnosed to have advanced knee osteoarthritis. Patients were recruited from the outpatient clinic after obtaining an approval from the Local Medical Ethics Committee before the study. Patients included in the study were given adequate information about the trial before signing a consent form for inclusion. Knees were randomly allocated into two parallel groups. Equal randomization (1 : 1 ratio) was undertaken according to a computer-generated randomization table. Participants were sequentially allocated to the treatment groups in the order in which they were recruited. These patient assignments were prepared by a research statistician and were placed into sequentially numbered opaque sealed envelopes, which were kept by research personnel. These personnel were assigned to open the envelopes and carry out the implementation of assignments and were not involved in the generation and allocation concealment. The envelope was opened before each surgery. Outcome assessor and participants were blinded to the treatment groups. The first group included 40 knees that had TKA using SS knee prosthesis, with SS femoral component (High-Flex Implant; Zimmer Gender Solutions, NexGen, Zimmer Biomet 1800 West Center St.Warsaw, Indiana, USA). The second group included 40 knees that received TKA using standard PS knee design with standard femoral component (LPS Implant; Zimmer NexGen).

Inclusion and exclusion criteria

Female patients with degenerative or inflammatory arthritis who were 50 years or older and their knee deformities were totally articular were included. The exclusion criteria were male patients, knees with valgus deformity, post-traumatic arthritis, patients with a history of previous open knee surgery, in addition to knees with bone defects that required the use of bone graft or metal augments as well as revision procedures.

Preoperative long-leg standing radiographies were performed to evaluate the degree of varus deformity and ascertain the valgus angle required for the distal femoral cut.

The medial parapatellar approach was used in all cases. Standard proximal tibial and distal femoral bone cuts were performed perpendicular to the mechanical axis of the lower limb. The proximal tibial cut incorporated a posterior slope of 7° in the sagittal plane.

Femoral component sizing was performed with a posterior referencing jig, and then, rotation of the femoral components was set at 3° of external rotation. Having completed the distal femoral cut, the size of the femoral component was re-checked. When standard prosthesis was used, the correct size of femoral prosthesis that avoids ML overhanging was chosen. If femoral sizing was in-between two sizes, downsizing was selected to avoid ML overhang; hence, undercover was accepted.

When downsizing was required, some compromise was required and included the surgeon's assessment of the extent of the overhang, flexion and extension gap balance, and remaining anterior bone that could be resected before notching the anterior femoral cortex.

In cases with SS prosthesis, no overhanging was observed. Instead, ML undercover was seen in many cases. No patellar resurfacing was performed in all cases.

Gentamicin-loaded Hi-Fatigue bone cement, 40 g/pack (Zimmer), was used in all cases. Closure of the wound was performed in layers over deep suction drains that were removed within the first 24 h postoperatively. The standard protocol for early mobilization, out of bed from the second postoperative day, and early discharge from the hospital was followed in all patients. The rehabilitation protocol was continued at an outpatient basis for 6 weeks, and then patients were reviewed by the physiotherapist at 2 weeks intervals till the 12th postoperative week. Radiographies were performed postoperatively, then at 3 and 12 months and then annually thereafter.

Outcome measures

The primary outcome measure was the postoperative knee flexion range of motion (ROM), and the secondary outcome measure was the knee function as reflected on the performance of daily activities. This was assessed by OXFORD Knee Score (OKS), Knee Society Score (KSS), and Knee Society Score for function (KSS-F) recorded preoperative, then at 3 and 12 months and then annually thereafter.

Sample size and statistical methods

Based on the assumption that the minimum clinically significant difference in postoperative knee flexion ROM between the two groups is 7°, a sample size of 40 knees in each group was needed to detect a difference using independent sample two-tailed *t*-test with a power of 80% (β=0.20) and a 5% significance level (α=0.05). The independent *t*-test was used to analyze numeric data and the χ^2 test to analyze nonnumeric data. The analysis was performed using SPSS software (SPSS for Windows Release, version 17.0; SPSS Inc., Chicago, Illinois, USA), and significance was accepted at the 95% level.

Results

In the period between February 2011 and March 2013, 76 female patients with 92 knees who were diagnosed to have advanced knee osteoarthritis were assessed for participation in this trial (Fig. 1). A total of 12 patients were excluded (Table 1). The remaining 64 patients with 80 knees were included. No patient was lost or excluded during follow-up. The mean age of the overall cohort of patients included at the time of surgery was 63 years (range: 50–72). Overall, 42 right and 38 left knees were resurfaced. Moreover, 48 patients had a unilateral procedure, whereas 16 patients had bilateral knee replacement, and 14 patients of these had a SS flex-prosthesis on one side and standard PS on the other side, giving the chance to ask for patients' preference.

No difference in the patients' BMI was observed between the two groups, as the mean BMI for the SS group of patients was 33.25±3 kg/m^2, whereas the BMI for patients on the standard PS group was 33.5 ±3 kg/m^2 (mean±STD). Overall, 90% of the patients included in this study were classified as obese (BMI>30 kg/m^2), whereas 4% were morbid obese and 6% were overweight, with no difference between the groups.

The mean preoperative varus deformity in the SS group of patients was 11±5° (range: 5–20°); similarly, the varus deformity in the standard PS group of patients was 11±5° (range: 0–20°). These varus deformities were corrected in both groups with a mean postoperative knee valgus alignment of 5°. These differences in limb alignment between preoperative and postoperative measurements were highly significant (P<0.001).

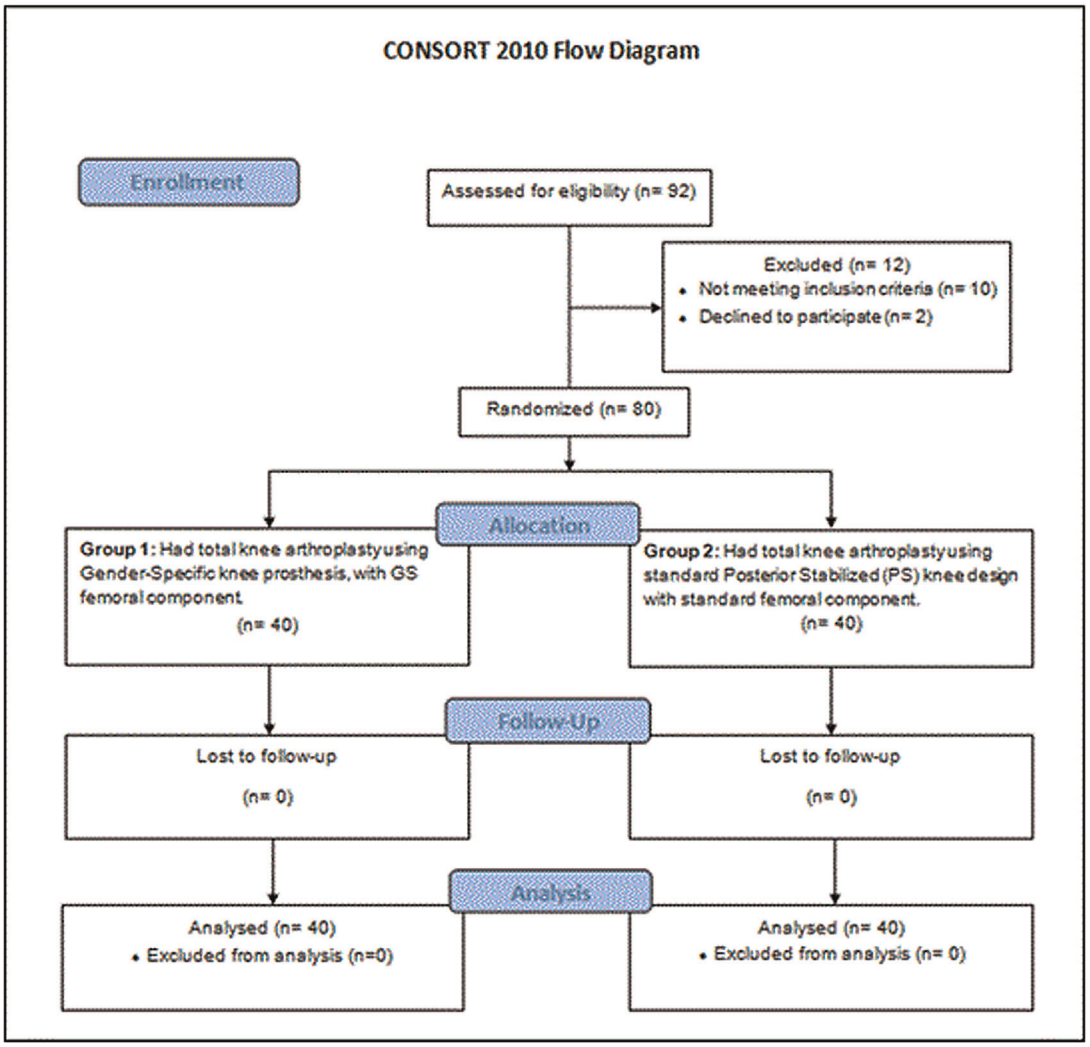
ROM

In this series, the mean preoperative range of knee flexion in the supine position was 110 and 108° in the SS and PS groups, respectively. At the latest follow-up, the mean postoperative knee flexion was 115 and 113°, respectively. The mean improvement in the knee flexion ROM in both groups was 5° (range: 0–25°), with no statistically significant difference between the two groups. However, fixed flexion deformity (FFD) was present in many patients preoperatively. The mean preoperative FFD was 1.25±3.19 (range: 0–10) in the SS group and 2.75±6.38 (range: 0–25) in the PS group (mean±STD). All patients except one had full extension. Therefore, a significant improvement in the arc of motion was achieved, but no significant change in the mean knee flexion was observed in both groups.

KSS

The mean preoperative KSS scores were 27 and 25 points in the SS and standard implant groups, respectively. The mean postoperative KSS scores were 83 and 84 points, respectively. Hence, the mean improvement in KSS scores was 55 and 59 points, with no statistically significant difference between two groups. The changes in KSSs can be attributed to the dramatic reduction or elimination of pain postoperatively.

Figure 1



CONSORT (Consolidated Standards of Reporting Trials) flow diagram for the study.

KSS-F

In this study, the mean preoperative KSS-F scores were 28 and 26 points for the SS and PS groups, respectively, with a significant improvement to 83 and 82 points postoperatively. The mean improvement between preoperative to postoperative KSS-F scores was 54 and 56 points. However, no statistically significant difference was observed between the two groups.

OKS

The mean preoperative OKS for the SS group was 10.8 points (range: 7–14), whereas the mean postoperative score was 40.8 points (range: 25–45) ($P<0.001$). Similarly, the mean preoperative OKS for the PS group was 9.6 (range: 7–14) and the mean postoperative score was 40.3 points (range: 25–43) ($P<0.001$). Meanwhile, no difference in the preoperative or postoperative scores was observed between the two groups.

The mediolateral coverage of the distal femur by the prosthesis was recorded. In the SS group, an undercover of greater than 2 mm from the medial and lateral sides of the distal femur was observed in 70% of the knees (28/40). In contrast, the standard PS prosthesis achieved better ML coverage of the distal femur with under coverage only seen in four knees (10%) (Figs. 2 and 3). In none of the cases, overhang of the prosthesis was permissible.

In this study, the early clinical outcome for the knees with a SS NexGen LPS-Flex-prosthesis was similar to those for the knees with a standard NexGen LPS prosthesis. Negligible differences in terms of patient satisfaction and preference were found between the two prostheses in the 14 patients who had SS implant and PS on the other side.

Discussion

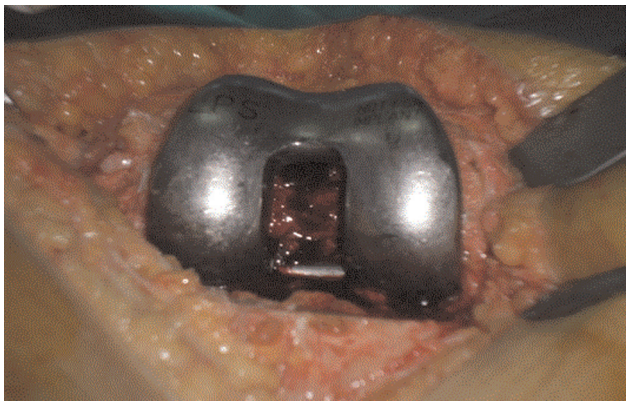
This study has investigated the question of whether a SS knee prosthesis can produce a better clinical outcome on female patients when compared with a

Table 1 Differences between the two groups

Parameters	Sex-specific NexGen LPS-flex (*N*=40)	Standard NexGen LPS (*N*=40)	*P* value
Age distribution	62.7 years (50–70 years)	63.2 years (56–72 years)	0.74 (NS)
Side of arthroplasty	22 right, 18 left	20 right, 20 left	0.75 (NS)
BMI	33.25 kg/m^2	33.45 kg/m^2	0.84 (NS)
Follow-up duration	30 months (24–38)	32.6 months (24–40)	0.90 (NS)
Mean preoperative flexion	110° (85–140)	108° (9 –130)	0.65 (NS)
Mean postoperative flexion range	115° (100–140)	113° (100–130)	0.56 (NS)
Mean postoperative flexion improvement	5° (0–25)	5° (0–25)	0.90 (NS)
Mean preoperative KSS score	27 points (20–40)	25 points (20–35)	0.30 (NS)
Mean postoperative KSS score	83 points (50–90)	84 points (55–95)	0.58 (NS)
Mean postoperative KSS score improvement	55 points (25–65) HS improvement ($P<0.001$)	59 points (35–70) HS improvement ($P<0.001$)	0.26 (NS)
Mean preoperative Oxford score	10.8 points (7–14)	9.6 points (7–14)	0.09 (NS)
Mean postoperative Oxford score	40.8 points (25–45)	40.3 points (25–43)	0.70 (NS)
Mean Oxford score improvement	29 points (17–33) HS improvement ($P<0.001$)	30 points (18–35) HS improvement ($P<0.001$)	0.51 (NS)
Perioperative blood loss (drain)	525 ml (350–900)	530 ml (300–950)	*0.92* (NS)

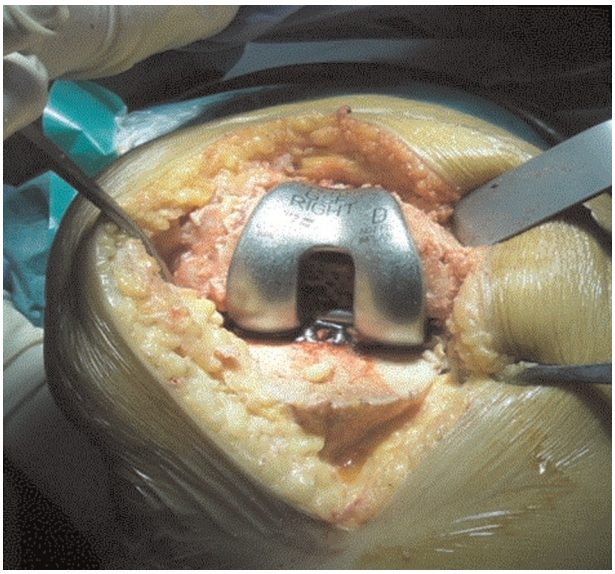
KSS, Knee Society Score.

Figure 2



Standard prosthesis trial size D.

Figure 3



Sex-specific prosthesis trial size D for the same patient showing under coverage of medial side.

standard unisex implant. The results of this series have clearly showed no clinical advantage of using the SS flex knee prosthesis over the standard PS implant.

In both groups, female patients had improved quality of life in terms of reduction of their pain, walking distance, correction of deformity, as well as significant improvement of OKS, KSS, and KSS-F scores following knee arthroplasty. However, negligible differences in terms of patients' satisfaction or even preference between the two prostheses 'in the 14 bilateral cases with SS implant in one side and PS on the other side' was recorded.

Critical analysis for the improvement in knee scores should highlight two parameters: pain and ROM. Pain has improved in most patients from severe (score 0 in KSS) to mild or no pain (score 45 or 50 in KSS); this would then be reflected on the improvement of different daily activities and patients' satisfaction with the procedure. Therefore, elimination of pain could be considered a leading cause for the significant changes seen in different scores. The second parameter was the ROM. Although the TKA procedures have eliminated the FFD with an improvement in the overall arc of motion, no significant gain in knee flexion was seen neither in the SS high flex nor the PS groups. This may be explained by the high BMI for patients involved in this study, as 94% of them were classified as obese or morbidly obese.

The anatomic differences between male and female knees have been studied by various authors, and clear morphologic differences regarding mediolateral and anteroposterior dimensions between genders were recorded [7–9,13]. These anatomic differences encouraged the design of a SS knee prostheses that would better match the unique female anatomy of the distal femur [10–12]. It was thought that the development of a SS knee prosthesis would be reflected on the clinical outcome of knee arthroplasty in females. However, in line with the current results, other reports could not identify any extra benefits from using the SS designs in women [14].

A SS knee prosthesis was advocated based on specific assumptions. First, women have inferior results following TKA when compared with men. Second, anatomic differences between sexes could not be addressed by the standard prosthesis designs. A number of clinical studies have refuted the idea that women have worse outcomes than men using traditional total knee designs [15–17]. Indeed, some studies suggested that women achieved essentially the same or even better results than men [18,19].

A systematic review by Merchant *et al.* [14] found no systematic anatomic differences between women's and men's knees that could justify a female-specific knee prosthesis. It is argued that anatomic differences between male and female knees are a reflection of the smaller average height and size of women bones, not by sex differences.

A recent study by Bellemans *et al.* [20] showed that the shape of the knee is not only dependent on sex but also on the morphotype of the patient. In their study, three groups of patients were defined according to their anatomic configurations: endomorph, ectomorph, or mesomorph. Patients with a short and wide morphotype (endomorphs) had, irrespective of sex, greater mediolateral versus anteroposterior ratios and thus wider knees. In contrast, another group of patients with long and narrow morphotypes (ectomorphs) had narrower knees. Therefore, the variability of knee shape can partially be explained by the morphotype of the patient, not only their sex.

In addition to the variability of the morphotypes, racial differences appear to exist in the anatomy of the distal femur. Almost all prosthetic implants have been designed and manufactured to accommodate the knee anatomy of western white population, and there is some doubt about the application of these systems to other races especially Asians [21–25].

In this study, the standard prosthesis provided better fitting of the distal femur in Egyptian women than SS prosthesis in terms of mediolateral coverage of the femur. The aspect ratio of the distal part of the femur was closer to that of the standard prosthesis than it was to the SS prosthesis.

Theoretically, the higher incidence of undercover in the SS group, which exposed more cancellous bone than with the standard prostheses, could be a source of higher perioperative blood loss and may induce increased osteolysis from wear debris [7,26]. However, perioperative blood loss was not significantly different in both groups, and osteolysis needs longer follow-up to be evaluated.

With the SS prosthesis, the anterior condylar height is lowered and the patellar sulcus is recessed to avoid a so-called 'overstuffed' patellofemoral joint that allows increased postoperative knee ROM. However, the mean ROM after knee arthroplasty was indistinguishable between SS and PS groups. Similar results were observed in clinical studies on patients who had bilateral TKR comparing SS on one side to standard prosthesis on the contralateral side [26–29].

Another design feature of the SS prosthesis is the trochlear groove angle of the femoral component, which is increased by ~3° in order to replicate the distinct *Q* angle, thereby enhancing patellar tracking. In this study, the patellar tilt angle did not differ significantly between the two groups either preoperatively or postoperatively. None of the knees in either group had subluxation or dislocation of the patella or needed intraoperative lateral retinacular release.

Improvement in clinical outcomes following knee arthroplasty is usually measured by score scales that have a ceiling effect and limited ability to differentiate between highly functioning arthroplasty patients. More sensitive outcome scores may be needed [30,31].

Conclusions

The SS TKA though designed to provide better fitting to the female distal femur does not provide any clinical advantage over the standard PS knee prosthesis. A logic question is whether a separate implant is required for women or modifications to the knee prostheses geometry and more sizes are required to accommodate all patients?

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Nil.

Conflicts of interest

There are no conflicts of interest.

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