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Femoral component sizing in Oxford Unicompartmental Knee Replacement: Existing guidelines do not work for Indian patients.

Abstract

Oxford Unicompartmental knee replacement (OUKR) has shown excellent long-term clinical outcomes as well as implant survival when used for correct indications with optimal surgical technique. Anteromedial osteoarthritis is highly prevalent in Indian patients and OUKR is the ideal treatment option in such cases. Uncertainty prevails about the best method to determine femoral component size in OUKR. Pre-operative templating has been shown to be inaccurate, while height and gender based guidelines based on European population might not apply to the Indian patients. Microplasty instrumentation introduced in 2012 introduced the sizing spoon which has the dual function of femoral component sizing and determining the level of tibia cut. We aimed to check the accuracy of sizing spoon and also determine whether the present guidelines are appropriate for use in the Indian patients. 130 consecutive Oxford mobile bearing medial cemented UKR performed using the Microplasty instrumentation were included. The ideal femoral component size for each knee was recorded by looking for overhang and underhang in post-operative lateral knee radiograph. The accuracy of previous guidelines was determined by applying them to our study population. Previously published guidelines (which were based on Western population) proved to be accurate in only 37% of cases. Hence, based on the demographics of our study population, we formulated modified height and gender based guidelines, which would better suit the Indian population. Accuracy of modified guidelines was estimated to be 74 %. The overall accuracy of sizing spoon (75%) when used as an intra-operative guide was similar to that of modified guidelines. Existing guidelines for femoral component sizing do not work in Indian patients. Modified guidelines

and use of intra-operative spoon should be used to choose the optimal implant size whilst performing OUKR in Indian patients.

Keywords - knee replacement, unicompartmental knee replacement, prosthesis fitting, osteoarthritis, body height.

Introduction

Unicompartmental knee replacement (UKR) has proven to be an effective remedy for medial compartment osteoarthritis of the knee [1-5]. Excellent medium and long term results have been published [1-5]. Long term success depends on accurate component alignment and sizing [6,7]. Nearly half of the knees undergoing Total Knee Replacement (TKR) are candidates for UKR as well [8].

The Oxford medial UKR was first introduced in 1976 and has undergone substantial changes in the instrumentation and new sizes have been introduced to better match patient anatomy [9,10]. This evolution is driven by the desire to achieve consistent implant positioning as well as optimal sizing, and accelerate rehabilitation. The currently used Microplasty instrumentation is designed to implant the components through a minimally invasive approach while ensuring accurate positioning [9,11,12].

Uncertainty prevails about the best method to determine the femoral component size in Oxford medial Unicompartmental Knee Replacement (OUKR) because of considerable discrepancies among the presently used methods [13]. Height and gender based guidelines have been used out of experience in European population [13]. The inventory of popular TKR and UKR is based on anthropometric measurements in Caucasian knees [14,15]. However, due to the differences in anatomy between Caucasian and Indian knees, these guidelines might not apply to Indian or Asian population in general [14,16]. The anthropometric measurements in Indian knees have been shown to be smaller than Caucasian knees [16]. This variation is more pronounced in females as compared to males [16].

Bothra et al have showed that pre-operating templating has only slight to moderate inter-observer and intra-observer reliability in determining the ideal femoral size [17]. Similarly, Kasis et al have shown poor inter-observer reliability of templating [18]. Hence, the accuracy

of the pre-operative templating to determine the size of the femoral component is questionable and it is not routinely recommended [9]. Both have shown that the accuracy did not improve with surgeon's experience. Also, the Microplasty instrumentation for OUKR recommends the use of a sizing spoon to assess the size of femoral component during surgery. The femoral sizing spoon is used to assess the size of femoral component during surgery. It captures the medial condyle and restores proper ligament tension. When inserted, it is pulled upfront to hug the posterior condyle, and the space between anterior lip of the spoon and the denuded bone should be 3-5 mm to compensate for the thickness of eroded articular cartilage [9]. Although sizing spoon is said to accurately determine the femoral size [9], most authors still rely on x -ray templating and height to select the size. The accuracy of the spoon has not been reported in the literature so far, neither has been the accuracy of height and gender based guidelines in Indian patients undergoing OUKR. A study by Tu et al [19] in Chinese population has found Fawzy et al's guidelines [13] to be inaccurate for use in Asian population. They reported an accuracy of only 51.1 % and suggested modified guidelines for use in Asian population.

The aim of this study was three-fold – 1. To verify the reliability of existing height and gender based guidelines [13, 19] for the Indian population. 2. To check the accuracy of femoral sizing spoon in determining size of femoral component. 3. In case of discrepancy, formulate new guidelines.

Materials and Methods

130 consecutive Oxford mobile bearing medial cemented UKR in 103 patients performed in a single centre by a single senior surgeon from January 2014 to December 2015 were included in this study. All surgeries were performed using the Microplasty instrumentation using

standard surgical technique [9]. Ethical clearance was obtained from institutional review board.

The size of the femoral component was determined pre-operatively by using the height and gender based criteria laid down by Fawzy et al [13]. Intra-operatively, the medial femoral condyle sizer (spoon) was used to restore the ligament tension and determine the size of the femoral component [5]. In case of any discrepancy among the two, the senior surgeon relied on the spoon for sizing the femoral component.

Apart from deciding the femoral size, the spoon has another important function of tensioning the medial compartment. Every size spoon (extra-small, small, medium, large, and extra-large) is available in 1 mm, 2 mm and 3 mm thickness options. Usually 1 mm spoon provides adequate tensioning. The ligament tension is deemed to be sufficient when the spoon can be freely twisted 20 degrees in both directions. This is important as the level of tibial cut will depend on the thickness of the spoon, as a thicker spoon will remove lesser tibia [9].

The component sizing was assessed on post-operative true lateral radiographs according to the criteria laid down by the Oxford Group [9]. Component which was flush with the posterior condyle or smaller was considered underhang, up to 2 mm overhang beyond bony confines of the posterior margin of medial femoral condyle was considered ideal, and posterior projection of the femoral component beyond 2 mm was considered significant overhang. Figure 1 shows a case with femoral component overhang, and figure 2 shows a case with underhang. The size of tibial component was measured intra-operatively by overlaying the tibial bone cut onto the reversed tibial tray of opposite side. Two independent observers calculated the overhang or underhang, and in case of any discrepancy, the senior author was consulted and his observation was taken as final. The accuracy of the sizing was calculated for both the methods and compared. When there was overhang or underhang (on

117 post-operative radiographs), the ideal size for that knee was taken to be one size down or one 118 size up respectively. The accuracy of the two methods was compared using Fisher's exact 119 test. Similarly, the accuracy of Tu et al's guidelines were tested in our population.

120

121 **Results**

122 There were 28 males (34 knees) and 75 females (96 knees). The overall mean height of the 123 cohort was 158.8 cm (SD 8.4; range 144-178 cm), while the mean height of males and

124 females was 162.2 cm (SD 8.1 cm; range 152 -178 cm) and 157.6 cm (SD 8.2; range 144-176 125 cm) respectively. The femoral size was checked in post-operative radiographs to determine 126 the accuracy of the spoon, and ideal size was recorded in 97 knees, i.e. overall accuracy was 127 74.6 %. Underhang was found in 10 knees (7.7 %) and overhang in 23 knees (17.7 %). The 128 ideal size for each knee was recorded.

129 Fawzy et al's guidelines were applied to our population to test their accuracy. Overall

130 accuracy was found to be low (36.9 %). Tu et al's guidelines were similarly tested. Although 131 slightly better than European guidelines, the accuracy was still found to be low (47.7 %).

132 Based on the demographic characteristics of our study population, we modified these 133 guidelines to better suit our population (Table 1).

134 Table 2 compares the accuracy of sizing spoon, Fawzy et al guidelines, Tu et al guidelines 135 and our guidelines. Table 3 depicts the statistical analysis comparing the four methods.

136 Interestingly, there were 4 female knees (4.2 % of female knees) in which even extra small 137 size showed overhang. As current inventory does not provide for such a small knee, the ideal 138 size for these cases was taken as extra small for the ease of calculations.

Relationship of size of tibial implants with femoral implants was also analysed. All the femur sizes were used with multiple tibial sizes making it highly unreliable for predicting the femur size. (Table 4)

Discussion

Guidelines described by Fawzy et al [13] and Tu et al [19] proved to be inaccurate when applied to our study population, while the accuracy of modified guidelines was similar to that of spoon. Hence, these guidelines can be safely applied to the Indian patients.

Phase I and Phase II of Oxford medial UKR had only one size femoral component, corresponding to the medium size of the current inventory [6]. It implies that all patients receiving Oxford medial UKR till 1998 received a single size femur irrespective of height and gender. Still the 20-year survival rate of Oxford Phase I and II medial UKR was reported to be 92 % [13], which is similar to the best reported TKR survival. But the practice of implanting the same size femur in all patients irrespective of height and gender faced criticism [19]. Phase III was introduced in 1998, which included five femoral sizes, an anatomic tibial tray, and instruments which allowed implantation through a minimally invasive surgical (MIS) approach [9,10,13]. The femoral sizing was based on pre-operative templating and height and gender based guidelines. Microplasty instrumentation was introduced in 2012 with the aim of improving the alignment of the femoral component as well as reducing the risk of tibial recut [9]. The femoral sizing spoon was introduced as a part of the Microplasty instrumentation with the dual function of femoral sizing as well as a guide to determine the level of horizontal tibial cut. However, the reliability of sizing spoon has not yet been evaluated in any study.

Fawzy et al [13] reported accurate selection of femoral size in 67 % cases by using pre-operative templating. 33 % were one size out, none were two sizes out. Based on their experience, they formulated a height and gender based table for prediction of femoral component size. The accuracy of their method was 75% when applied to their study population, with 25% being one size out and none two sizes out. However, when applied to our study population, its accuracy was 40%, with 58.5% being one size out and 1.5% two sizes out. Hence, their table is not applicable to Asian population. Most common size in Fawzy et al's study was medium (54 % cases), while in our study most common size was extra small for females and small for males. Fawzy et al also mentioned tibial implant size as a predictor for femur size, although with a low accuracy (56%). However, we did not consider tibial implant size as a criteria for predicting femur component size as femur sizing is done before the tibial size determination during the surgery. Also, the tibial component size can change during the surgery if tibial re-cut is required, however, the femur component size cannot change during the surgery.

The inapplicability of Fawzy's guidelines in Asian population has been acknowledged in the past by Tu et al [19]. They used intra-operative image intensifier to judge the correct size of femoral component. Although intra-operative use of fluoroscopy to assess component size can be employed, it is not practical and may not be available in all the hospitals. In addition, it increases surgical time and is associated with unnecessary exposure to radiation. When applied to our population, Tu et al's guidelines proved to be inaccurate with accuracy of 47.1 % in males and 48 % in females, with an overall accuracy of 47.7 %. In their study, if overhang or underhang was detected on intra-operative imaging, the authors undersized or oversized the femur respectively. Another potential problem with Tu's technique is the way instruments work. Trialling of the femoral component is done after the medial condyle has been prepared, and this preparation depends on the sizing of the femoral component [9]. As

each femoral size has different radius of curvature, there is a separate set of instruments used for bone preparation for each size. Hence when a different trial is placed upon distal femur prepared according to some other size, it may not sit properly on the bone surface. This may also alter the posterior overhang of the femur, potentially inducing bias in the authors' interpretation of sizing. On further analysis of Tu et al's guidelines, we noticed they have recommended size small for a wide range of heights (150-169 cm) and used it for 83% of patients. Whereas, in our study extra small femoral implant was found to be ideal for 62 % females and 29.4 % males, 53.8 % overall.

An interesting observation in our study was that 4 female knees (4.2% of female knees, 3.1% overall) showed overhang even with the smallest available size. Their heights ranged from 144 – 146 cm (Mean 145 cm). This observation has also been made in Korean population by Kim et al. They reported a similar finding in 6 females (18.7 % of female knees, 16.2 % overall). This finding was not observed in Tu et al's report. It might be possible that this figure may increase to a more significant value with future studies involving larger number of patients. Probably, the inventory needs to be expanded.

Kim et al [20] compared overhang between Oxford medial UKR (Phase III) and Miller-Galante II UKR. The incidence of posterior overhang of femoral component was significantly more in Oxford Group (51.4 %) as compared to M-G II group (4.3 %, $p < 0.001$). The authors used pre-operative templating to size of Oxford UKR, which explains the high incidence of incorrect sizing. However, this did have not have any effect on the functional results. In our study, the average OKS (Oxford Knee Score) at one-year follow-up was 40.1 in accurately sized group, while it was 39.6 in inaccurately (overhang/underhang) sized group (p value = 0.59). Hence, our study also shows that incorrect sizing does not affect function.

Considering the fact that posterior overhang of femur has not been shown to affect clinical outcomes till now, one might question the logic of this study. But it is undeniable that every surgeon will aim for accurate sizing, and to achieve this the criteria used for sizing must be accurate to minimize the number of outliers. According to the Oxford Group, one size out femur is acceptable but two sizes out is unacceptable.

Certain pitfalls in relation to sizing with the spoon must be kept in mind. Presence of posterior osteophytes or where partial thickness cartilage loss is present may overestimate the size. On the other hand, bone loss over the medial condyle may underestimate the size. In general, it is recommended to use the pre-operative sizing guide (based on patient's height and gender) as a reliable method to estimate femoral component size. Further checks using the spoons (intra-operatively) will help the surgeon to confirm correct component size.

External validation of our guidelines is definitely needed before being put to widespread use.

Conclusions

Existing guidelines for femoral component sizing do not work in Indian patients. Our recommended guidelines work in 3 out of 4 cases and these along with use of spoons intra-operatively will help the surgeon decide optimal femoral component size in the Indian patients undergoing Oxford UKR.

Conflict of Interest statement: One of the authors is a paid consultant with Zimmer-Biomet, receives Institutional support from Depuy and Zimmer-Biomet and is involved in medico-legal work with Kennedy's Law. (Disclosure form attached).

Source of funding: None

Figure Captions:

Figure 1: An example of femoral component overhang.

Figure 2: An example of femoral component underhang.

Table legends:

Table 1: Modified height and gender based guidelines for Indian patients.

Table 2: Accuracy of sizing spoon, previous guidelines and modified guidelines.

Table 3: Statistical analysis comparing different methods.

Table 4: Table showing relationship of femoral size with tibial size, and comparison with Fawzy et al's [13] outcome.

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Table 1 – Modified height and gender based guidelines for Indian patients.

Femur size	Males	Females
XS	< 155 cm	<160 cm
S	155-165 cm	160-170 cm
M	166-175	>170 cm
L	>175 cm	-
XL	-	-

Table 2 – Accuracy of sizing spoon, previous guidelines and modified guidelines.

Accuracy	Sizing spoon	Fawzy et al table [13]	Tu et al table [19]	Our table
Males	Ideal – 23/34 (67.6%) Overhang – 9/34 (26.5%) Underhang – 2/34 (5.9%)	Ideal – 9/34 (26.5%) Overhang – 24/34 (70.6%) (2 were two sizes out) Underhang – 1/34 (2.9%)	Ideal – 16/34 (47.1%) Overhang – 10/34 (29.4%) Underhang – 8/34 (23.5%)	Ideal – 28/34 (82.3%) Overhang – 4/34 (11.8%) Underhang – 2/34 (5.9%)
Females	Ideal – 74/96 (77.1%) Overhang – 14/96 (14.6%) Underhang – 8/96 (8.3%)	Ideal – 39/96 (40.6%) Overhang – 57/96 (59.4%) Underhang – 0/96 (0%)	Ideal – 46/96 (48%) Overhang – 49/96 (51%) Underhang – 1/96 (1%)	Ideal – 68/96 (70.8%) Overhang – 19/96 (19.8%) Underhang – 9/96 (9.4%)
Overall	Ideal – 97/130 (74.6%) Overhang – 23/130 (17.7%) Underhang - 10/130 (7.7%)	Ideal – 48/130 (36.9%) Overhang – 81/130 (62.3%) Underhang – 1/130 (0.8%)	Ideal – 62/130 (47.7%) Overhang – 59/130 (45.4%) Underhang – 9/130 (6.9%)	Ideal – 96/130 (73.8%) Overhang – 23/130 (17.7%) Underhang – 11/130 (8.5%)

Table 3 – Statistical analysis comparing different methods.

		p value (Fisher's exact test)
Spoon versus Fawzy et al [13]	Males Females Overall	**0.0014** **< 0.0001** **< 0.0001**
Spoon versus Our table	Males Females Overall	0.2624 0.4111 1.0000
Our table versus Fawzy et al [13]	Males Females Overall	**< 0.0001** **< 0.0001** **< 0.0001**
Spoon versus Tu et al [19]	Males Females Overall	0.1407 **<0.0001** **<0.0001**
Tu et al [19] versus Fawzy et al [13]	Males Females Overall	0.1306 0.3834 0.1025
Our table versus Tu et al [19]	Males Females Overall	**0.0047** **0.0019** **<0.0001**

*$p < 0.05$ considered to be statistically significant

Table 4: Table showing relationship of femoral size with tibial size, and comparison with Fawzy et al's [13] outcome.

Femur size	Tibia size (Males)	Tibia size (Females)	Fawzy et al [13]
Extra small	A (50 %), B (20 %), C (20 %)	A (29.7 %), B (54.7 %)	A
Small	B (35.7 %), D (50%),	A (37 %), B (44.4 %)	A, B
Medium	D (40 %), E (40%)	B (20 %), C (60 %), D (20 %)	C, D
Large	C (33.3 %), D (66.7 %)	N/A	E
Extra large	N/A	N/A	F

N/A – not applicable

Figure 1: An example of femoral component overhang.

488x643mm (72 x 72 DPI)

Figure 2: An example of femoral component underhang.

536x948mm (72 x 72 DPI)