Comparative Study of Femoral Sizing between Intraoperative Measurement and CT-Based PSI in Total Knee Arthroplasty

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Background: *Appropriate femoral sizing in total knee arthroplasty (TKA) is an important factor for flexion. An oversized femoral component will decrease flexion gap and postoperative flexion. By using custom cutting blocks technique with computed tomography (CT) imaging to design cutting blocks will help determine sizing of each patient. The differences of femoral sizing between intraoperative measurement and custom cutting blocks technique are still questionable.*
Objective: *To compare femoral component sizing between custom cutting blocks technique and conventional technique.*
Material and Method: *Retrospective cross-sectional study was collected from 2,321 patients underwent primary TKA with the same prosthesis design in Bangkok between January 2012 and December 2012. The population was separated into three groups, group A, 2,053 patients operated by orthopedic surgeons in Bangkok by conventional instrument femoral sizing, group B, 218 patients operated by senior experienced arthroplasty surgeon (Chotanaphuti T) at Phramongkutklao Hospital using the same measurement technique as group A, and group C, 50 patients operated by Chotanaphuti T using custom cutting blocks technique for femoral sizing. The femoral component sizes were assigned from small to large size as number 1 to 6. Chi-square test and Fisher's exact test was used to determine the significant differences between amount of patients of each group.*
Results: *In group A, femoral components were selected in size 1 (n = 157; 8%), 2 (n = 576; 28%), 3 (n = 737; 36%), 4 (n = 431; 21%), 5 (n = 144; 7%), and 6 (n = 8; 0.4%) respectively. In group B, femoral components were selected in size 1 (n = 31; 14%), 2 (n = 55; 25%), 3 (n = 64; 29%), 4 (n = 31; 14%), 5 (n = 37; 18%), and 6 (n = 0; 0%) respectively. In group C, femoral components were selected in size 1 (n = 7; 14%), 2 (n = 19; 38%), 3 (n = 11; 22%), 4 (n = 12; 24%), 5 (n = 1; 2%), and 6 (n = 0; 0%) respectively.*

The most chosen size of group A and B were No. 3, but for group C was No. 2, which was smaller than the first two group by one size. There were statistical difference in group A versus group B ($p<0.0001$), and group B versus group C ($p = 0.009$), but not difference in group A versus group C ($p = 0.096$).
Conclusion: *Custom cutting blocks technique chooses a femoral component closer to knee anatomy of the patients and smaller than intraoperative technique. There are several possible causes, which include variable of level or sagittal angle error of distal femoral bone cut.*

Keywords: *Femoral sizing, Total knee arthroplasty, Custom cutting blocks technique, Conventional technique*

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Total knee arthroplasty (TKA) is one of the most successful operation with excellent durability for advanced osteoarthritis of knee[1]. Appropriate sizing is one of the factor that would help determine clinically success. Femoral component affect flexion gap. There is several factors affect size of femoral component, which could be determined by AP dimension of distal femoral bone cut. Bone-cutting process is a potential source of inaccuracy in TKA process.

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With the use of femoral intramedullary guides in TKA, the placement of entry hole could determine the flexion/extension positions of the femoral component on the femur. Tsukeoka and Lee[2] demonstrated that the amount of the resected bone of the posterior medial condyle decreased 1 mm for every 2 degrees additional flexion from -2, 0, 2, 4 or 6-degree of flexion to the anterior femoral cortex. An anterior drill placement could lead to extension of the femoral component. Mihalko et al[3] had demonstrated that an entry point of deviation just 5 mm anteriorly or posteriorly resulted in a significant amount of flexion or extension. Sparmann et al[4] had reported that the femoral component axis in the sagittal plane was correctly positioned in 80% of the cases with navigation against 22% of cases without navigation

Sagittal cutting error could changes the femoral AP sizing in TKA. Nakahara et al[5] had found that, the AP dimension of the prepared femur was increased by 2 and 3 mm with 3 and 5-degree extension respectively. In addition, the AP dimension of the prepared femur was decreased by 2 and 3 mm, with 3 and 5-degree flexion, respectively. Upsized femoral components make a flexion gap to be tight. It will also decrease a postoperative range of motion. Additionally, it would increase patellofemoral forces in deep knee flexion[6]. It is especially true for women that have ML/AP dimension of distal femur less than men[7,8]. Femoral component overhang of more than or equal 3 mm approximately doubles the odds of clinically important knee pain for two years after TKA[9]. Therefore, for woman, there is a trend to downsize the femoral component when possible, while maintaining a balanced flexion/extension gap. This is the most straightforward method when a femur measures between the two sizes: err toward the smaller on in women[10].

Computer navigation systems also can help in determining the proper implant size as well as alignment. However, it also has many disadvantages, including the cost of the system, more operation times, and the lack of updated clinical studies showing improved survival rate. There have been some reports on periprosthetic fractures through the reference base anchoring holes in the femur and tibia. Currently, there are only limited amount of reports showing improved functional results with computer navigation assisted TKA[11].

Recently, patient with specific approaches to TKA have been introduced to a preoperative imaging (plain radiographs, computed tomography, and magnetic resonance imaging). The images are used to produce cutting blocks specific to a patient's anatomy. Benefits for patient with matched cutting blocks are decreased in operative time, amount of instrumental tray required, and be able to preoperatively plan patient's component size, position, and alignment. In addition, an improvement in postoperative mechanical alignment is expected to be without violation of the intramedullary canal[12].

The objective of the present study is to assess whether the custom cutting blocks technique choose femoral component sizing different from conventional TKA instrumentation.

Material and Method

The Review Board for human research of the Phramongkutklao Hospital had approved the present study. Consent to participate in this research was obtained from all patients. The authors retrospectively reviewed 2,321 patients operated by same prosthesis company design (PFC design, Crucitate Sacrificed, Fixed bearing; Depuy, Inc) in Bangkok between January 2012 and December 2012.

The criteria for inclusion in the present study were as follows: the patients who underwent primary TKA at Phramongkutklao Hospital, suited for implantation using custom cutting blocks; no femoral nails/bone plates extend into the knee, i.e. within 8 cm of joint line; no metal device that could cause CT scatter about the knee and no deformities greater than 15 degrees of fixed varus, valgus or flexion contracture. The patients with previous ipsilateral distal femoral or high tibial osteotomies, ankylosis of the hip joint on the side to be treated, inflammatory arthritis, and previous patellectomy were excluded. All 2,321 primary TKA patients were assigned to one of three groups. Group A (2,053 patients) was treated by using conventional instrumentation (HP instrument, Depuy, Warsaw, Ind) performed by orthopedic surgeons in Bangkok. Group B (218 patients) was treated by using conventional instrumentation (HP instrument, Depuy, Warsaw, Ind) performed by senior experienced arthroplasty surgeon at Phramongkutklao Hospital (Chotanaphuti T). Group C (50 patients) was treated by using custom cutting blocks (TruMatch™ Personalized Solutions; Depuy, Warsaw, Ind).

In Group C, each patient had preoperative 3D CT images imported by proprietary software to planning for amount of bone resections.

At baseline, all groups were comparable of age, sex, and BMI. Data were collected on the chosen size and number of patients in each group.

Proper size of femoral components was assigned from small size to large size as number 1, 2, 3, 4, 5, and 6 respectively. Demographic data are presented as number, percentage, mean, and standard deviation. For data comparison between groups, Chi-square test or Fisher's exact test, and unpaired t-test were used for categorical variables and continuous variables respectively. A p-value less than 0.05 was considered statistically significant. Chi-square test or Fisher's exact test were used to determine significant difference between number of patients of each chosen size in three groups. The analysis was performed with STATA software version 12.1.

Results

Demographic data

Demographic data of 218 patients in Group B who were treated by Chotanaphuti T by conventional instrument and 50 patients in Group C who were treated using custom cutting blocks technique was shown in Table 1.

In Group B, female 191 patients (88%), the mean age of patients was 69.3±5.5 years (range, 58-82 years) and BMI was 25.0±2.1 kg/m^2 (range 20.1-29.4 kg/m^2).

In Group C, female 48 patients (96%), the mean age of patients was 69.7±5.5 years (range, 58-81 years) and BMI was 25.0±2.4 kg/m^2 (range 18.9-30.1 kg/m^2).

In Group A, components were selected in size 1 (n = 157; 8%), 2 (n = 576; 28%), 3 (n = 737; 36%), 4 (n = 431; 21%), 5 (n = 144; 7%) and 6 (n = 0; 0%) respectively.

In Group B, components were selected in size 1 (n = 31; 14%), 2 (n = 55; 25%), 3 (n = 64; 29%), 4 (n = 31; 14%), 5 (n = 37; 18%) and 6 (n = 0; 0%) respectively.

In Group C, components were selected in size 1 (n = 7; 14%), 2 (n = 19; 38%), 3 (n = 11; 22%), 4 (n = 12; 24%), 5 (n = 1; 2%) and 6 (n = 0; 0%) respectively (Table 2).

Table 1. Patients' demographic data

Variable	Group B (n = 218)	Group C (n = 50)	p-value
Female	191 (88%)	48 (96%)	0.13
Age (years), mean ± SD	69.3±5.5	69.7±5.5	0.64
Body mass index (BMI), mean ± SD	25.0±2.1	25.0±2.4	1.00

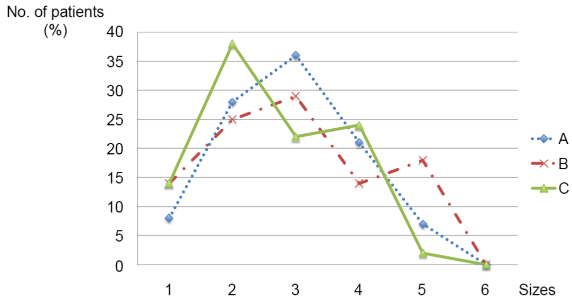

Fig. 1 The number of patients (%) and femoral sizing (1, 2, 3, 4, 5 and 6) in each group.
A = patient operated by orthopedic surgeons in Bangkok using conventional technique (n = 2,053)
B = patient operated by Chotanaphuti T using conventional technique (n = 218)
C = patient operated by Chotanaphuti T using custom cutting blocks technique (n = 50)

The graph was plotted in Fig. 1. The most chosen size of Group A and B were No. 3, but for Group C was No. 2, which was smaller than the first two groups by one size. There were statistical difference between Group A versus Group B ($p<0.0001$), and Group B versus Group C ($p = 0.009$), but not difference between Group A versus Group C ($p = 0.096$).

Discussion

There are several methods to measure femoral component size. The preoperative templating from plain radiographs could predict the exact size of the femoral prosthesis in only 49% of the cases(13). If the current preoperative digital templating technique was used, the authors could predict the femoral prosthesis size in 83% of the cases(14).

Recently, patient-specific instrumentation (PSI) approaches to TKA has been introduced, in which

Table 2. The number of population (%) and femoral sizing (1, 2, 3, 4, 5 and 6) in each group

Size of femoral component	Group A [number of patients (%)]	Group B [number of patients (%)]	Group C [number of patients (%)]
1	157 (8)	31 (14)	7 (14)
2	576 (28)	55 (25)	19 (38)
3	737 (36)	64 (29)	11 (22)
4	431 (21)	31 (14)	12 (24)
5	144 (7)	37 (18)	1 (2)
6	8 (0.4)	0 (0)	0 (0)
Total	2,053 (100)	218 (100)	50 (100)
Median (min-max)	Size 3 (1-6)	Size 3 (1-5)	Size 2 (1-5)

preoperative imaging (plain radiographs, computed tomography, and magnetic resonance imaging) are used to produce cutting blocks specific to a patient's anatomy. Benefits of patient-matched cutting blocks include decreasing in operative time, amount of instrument tray required, and able to preoperatively plan a patient's component size, position, and alignment. The computerized preoperative plan from PSI was able to correctly predict the size of the implanted femoral component in 95.5% of the cases[15]. In addition, an improvement in postoperative mechanical alignment is expected, without violation of the intramedullary canal, which may reduce blood loss and cardiac-related complications because fewer emboli are placed into the venous system than with placement of intramedullary rod[11]. However, there are questions remain regarding patient outcomes and the cost-effectiveness associated with patient-specific cutting block technology. Nowadays, there is no study comparing femoral sizing determined by custom cutting block and conventional technique. The present article will review the evolution of surgical techniques in TKA, the development of patient-specific cutting blocks, surgical considerations, and the literature associated with this new technology[12].

Due to several factors, conventional intra-operative femoral sizing has many errors. From the present study, there are statistical significances between Group B and Group C, and Group A and Group B, but not between Group A and C. However, Group A and B mostly chose size 3, but size mostly chosen by Group C was size 2. The authors could interpret that custom cutting block technique tends to choose femoral component one size smaller than conventional intraoperative measurement, and show statistically significant between two methods performed by one surgeon (Chotanaphuti T).

There were several limitations in the present study. First, because the study was retrospective chart reviewed, the authors did not have the demographic data of Group A (the data abstained from the product company by personnel communication). The authors assume there were no significant differences between Group B and C. Second, most population were women that had ML/AP dimension of distal femur less than men[7,8]. For most women, there was trend to downsize the femoral component when possible, while maintaining a balanced flexion/extension gap. This was the most straightforward method when a femur measures between two sizes, it would cause error toward the smaller on a woman[10]. Third, the sample of Group A was much larger than Group B and C, which might affect statistical calculated results.

In conclusion, the results of the present study demonstrate that custom cutting blocks technique tends to choose femoral component one size smaller than intraoperative technique by single arthroplasty surgeons in the same population, who underwent primary TKA. There are several possible causes, which include variable of level or sagittal angle error of distal femoral bone cut. There would be necessity for further study in order to improve accuracy and eliminate outlying for conventional instrument. Since the authors only performed TKA with posterior cruciated-sacrificed (PS) design with the cutting of posterior cruciated ligament (PCL) affect flexion more than extension gap[16], it might not have clinical significance. Yet, it could still have a clinical significance in cruciated-retaining (CR) design. Finally, it would be best to have further study to compare the significant difference in sizing measurement from these two techniques in the same patient in the future to determine if it had any clinically significant.

What is already known on this topic?

There are several methods to measure femoral component size. The preoperative templating from plain radiographs could predict the exact size of the femoral prosthesis only 49% of the cases. The current preoperative digital templating technique could predict up to 83% of the cases.

Recently, patient-specific instrumentation (PSI) approaches to TKA have been introduced, in which preoperative imaging (plain radiographs, computed tomography, and magnetic resonance imaging) are used to produce cutting blocks specific to a patient's anatomy. Benefits of patient-matched cutting blocks include a decrease in operative time, amount of instrument tray required, and be able to preoperatively plan a patient's component size, position, and alignment. The computerized preoperative plan from PSI was able to correctly predict the size of the implanted femoral component in 95.5% of the cases.

In addition, an improvement in postoperative mechanical alignment is expected, without intruding of the intramedullary canal, which may reduce blood loss and cardiac-related complications because fewer emboli are placed into the venous system than with placement of intramedullary rod. However, there are questions remain regarding patient outcomes and the cost-effectiveness associated with patient-specific cutting block technology. Nowadays, there is no study compared femoral sizing determined by custom cutting block and conventional technique.

What this study adds?

The custom cutting blocks technique tends to choose femoral component one size smaller than intraoperative technique by single arthroplasty surgery in the same population, who underwent primary TKA. There are several possible causes, which include variable of level or sagittal angle error of distal femoral bone cut. There would be necessity for further study in order to improve accuracy and eliminate of outlying for conventional instrument. Since the authors have only performed TKA with posterior cruciated-sacrificed (PS) design with the cutting of posterior cruciated ligament (PCL) affect flexion more than extension gap, it might not have clinical significance. Yet, it could still have a clinical significance in cruciated-retaining (CR) design.

Potential conflicts of interest

None.

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การศึกษาเปรียบเทียบขนาดของข้อเข่าเทียมส่วน femoral component โดยการวัดด้วยเครื่องมือมาตรฐานในขณะผ่าตัดเทียบกับการวัดด้วยคอมพิวเตอร์สแกนในการออกแบบบล็อกผ่าตัดเฉพาะบุคคล

สารเดช เขื่องศิริกุล, ธนันท์ สมิทธารักษ์, ธไนนิธย์ โชตนภูติ

ภูมิหลัง: *การเลือกขนาดของ femoral component ที่เหมาะสมเป็นปัจจัยที่สำคัญในงอเข่าได้มากหรือน้อย ภายหลังการผ่าตัดเปลี่ยนข้อเข่าเทียมหากเลือกขนาดใหญ่เกินไปอาจมีผลให้งอเข่าได้น้อย การวัดด้วยเครื่องมือมาตรฐานในขณะผ่าตัดมีความคลาดเคลื่อนได้มาก ปัจจุบันมีเทคโนโลยีที่สามารถวัดขนาดของข้อเข่าเทียมที่จะใช้ได้ตั้งแต่ก่อนผ่าตัดโดยใช้การวัดด้วยคอมพิวเตอร์สแกนเพื่อออกแบบบล็อกแบบเฉพาะบุคคลสำหรับการตัดกระดูกให้มีขนาดใกล้เคียงกับกายวิภาคของผู้ป่วยแต่ละราย อย่างไรก็ตามยังคงมีคำถามว่าขนาดของ femoral component ที่ได้จากการวัดทั้งสองวิธีดังกล่าวมีความแตกต่างกันหรือไม่*

วัตถุประสงค์: *เพื่อเปรียบเทียบขนาดของข้อเข่าเทียมส่วน femoral component ที่ได้จากการวัดด้วยเครื่องมือมาตรฐานในขณะผ่าตัดเทียบกับการวัดด้วยคอมพิวเตอร์สแกนในการออกแบบบล็อกผ่าตัดเฉพาะบุคคล*

วัสดุและวิธีการ: *ทำการทบทวนเวชระเบียนของผู้ป่วยที่ได้รับการผ่าตัดใส่ข้อเข่าเทียมยี่ห้อและชนิดเดียวกัน 2,321 ราย ที่กรุงเทพมหานคร ในช่วงเดือนมกราคม พ.ศ. 2555 ถึง เดือนธันวาคม พ.ศ. 2555 โดยแบ่งผู้ป่วยออกเป็น 3 กลุ่ม กลุ่ม A คือผู้ป่วย 2,053 ราย ที่ถูกผ่าตัดด้วยเทคนิคแบบมาตรฐานโดยศัลยแพทย์ข้อเข่าทั่วไปในกรุงเทพ, กลุ่ม B คือผู้ป่วย 218 ราย ที่ถูกผ่าตัดด้วยเทคนิคแบบมาตรฐานโดยศัลยแพทย์ผู้นิพนธ์, กลุ่ม C คือผู้ป่วย 50 ราย ที่ถูกผ่าตัดด้วยเทคนิคการวัดด้วยคอมพิวเตอร์สแกนในการออกแบบบล็อกผ่าตัดเฉพาะบุคคลโดยศัลยแพทย์ผู้นิพนธ์ จากนั้นจึงนำจำนวนผู้ป่วยในแต่ละกลุ่มที่ถูกเลือกใช้ขนาดของ femoral component ที่แตกต่างกันตั้งแต่เบอร์ 1-6 จากเล็กไปใหญ่มา plot กราฟ และลงตารางเพื่อให้เห็นความแตกต่างของการเลือกขนาดของ femoral component ของแต่ละกลุ่มและนัยสำคัญทางสถิติ*

ผลการศึกษา: *ในผู้ป่วยกลุ่ม A, ขนาดของ femoral component ที่ถูกเลือกเป็น size 1 (n = 157; 8%), 2 (n = 576; 28%), 3 (n = 737; 36%), 4 (n = 431; 21%), 5 (n = 144; 7%) and 6 (n = 8; 0.4%) ตามลำดับในผู้ป่วยกลุ่ม B, ขนาดของ femoral component ที่ถูกเลือกเป็น size 1 (n = 31; 14%), size 2 (n = 55; 25%), size 3 (n = 64; 29%), size 4 (n = 31; 14%), size 5 (n = 37; 18%) และ size 6 (n = 0; 0%) ตามลำดับ ในผู้ป่วยกลุ่ม C, ขนาดของ femoral component ที่ถูกเลือกเป็น size 1 (n = 7; 14%), 2 (n = 19; 38%), 3 (n = 11; 22%), 4 (n = 12; 24%), 5 (n = 1; 2%) และ 6 (n = 0; 0%) ตามลำดับ เมื่อนำมาวิเคราะห์ทางสถิติพบว่าการเลือก size ของกลุ่มที่ถูกผ่าตัดด้วยเทคนิคต่างกันโดยศัลยแพทย์คนเดียวกันมีความแตกต่างอย่างมีนัยสำคัญโดยที่กลุ่ม B เทียบกับกลุ่ม C ได้ p-value = 0.009 โดยขนาดเฉลี่ยของการวัดด้วยคอมพิวเตอร์สแกนในการออกแบบบล็อกผ่าตัดเฉพาะบุคคลมีแนวโน้มที่จะเล็กกว่าเทคนิคแบบมาตรฐาน โดยที่ค่าเฉลี่ยในการเลือก size ของกลุ่ม A และ B พบว่าส่วนใหญ่เลือก size 3 (36% และ 29% ตามลำดับ) ในขณะที่ค่าเฉลี่ยในการเลือก size ของกลุ่ม C ส่วนใหญ่เลือก size 2 (38%)*

สรุป: *ขนาดของ femoral component ที่ได้จากการวัดด้วยคอมพิวเตอร์สแกนในการออกแบบบล็อกผ่าตัดเฉพาะบุคคลมีแนวโน้มที่จะเล็กกว่าเทคนิคการวัดด้วยเครื่องมือมาตรฐานในขณะผ่าตัดโดยศัลยแพทย์คนเดียวกัน อาจมีหลายปัจจัยที่ทำให้การวัดด้วยเครื่องมือมาตรฐานในขณะผ่าตัดไม่เที่ยงตรงเท่าที่ควร อย่างไรก็ตามจำเป็นต้องทำการศึกษาเปรียบเทียบในผู้ป่วยเป็นรายต่อรายเพิ่มเติมต่อไปรวมถึงศึกษาถึงความสำคัญทางคลินิก*