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ORIGINAL PAPER

Sagittal gap balancing with the concept of a single radius femoral component in posterior cruciate sacrificing total knee arthroplasty with patient-specific instrumentation

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Abstract
Purpose Sagittal gap balancing (relation between flexion and extension gaps) with placement of trial femoral components and reduction of the patella in total knee arthroplasty (TKA) is important, but it is not easy. The purpose of this study was to investigate whether (1) the flexion and extension gaps were equal when a previously suggested three-dimensional planning for a single-radius femoral component (its sagittal centre is matched with flexion-extension axis of knee movement) is executed with patient-specific instrumentation (PSI) and whether (2) PSI was done with good accuracy, which did not affect the first purpose.
Methods Posterior cruciate ligament sacrificed (PS) TKA was performed on 12 joints. Using the patients' pre-operative computed tomography (CT) images, PSI was manufactured to fit on the bony surface of the knee joint and to simultaneously transfer pre-operative planning to the operating room. After osteotomy with PSI, gap measurements were calculated with the knee in flexion and extension. Angle deviations of both components were investigated with postoperative CT images.
Results The flexion gap (mean, 19.1 mm) was larger than the extension gap (mean, 12.3 mm) in all cases. Angle differences between pre- and postoperative alignments were within 3° in all cases.
Conclusions Although PSI executed the pre-operative planning with good accuracy, the flexion gap is always larger than the extension gap. This finding suggests that surgeons may not aim for equal gaps of flexion and extension in PS-TKA.

Keywords Total knee arthroplasty · Sagittal gap balancing · Patient specific instrumentation · Single radius femoral component

Introduction

One of the key elements to ensure a good outcome of total knee arthroplasty (TKA) is correct soft tissue balance in the knee [1]. Sagittal evaluation of intra-operative soft tissue balance is conventionally achieved by measuring the intra-operative gap, which is the distance between osteomized bones at 0° extension (the "extension gap") and 90° flexion (the "flexion gap") of the knee joint [2–4] using a tensor/balancer device. It has also been thought that the "intra-operative gap difference", which is calculated by subtracting the extension gap from the flexion gap [5], should be zero. However, since another intra-operative gap measurement under the condition of placement of a femoral trial component and the reduction of patella was reported in some previous papers [6–8], surgeons need to reconsider how this sagittal gap balancing is controlled. This is because the previous papers [6–8] showed that the gaps under the latter condition are not calculated even if thickness of femoral component and polyethylene insert are added to the former gaps (i.e. tightness of posterior capsule and/or anterior muscles like quadriceps affect gap measuring).

In this context, the author expected that three-dimensional (3D) pre-operative planning might execute equal sagittal flexion and extension gaps under the latter condition. Patient-specific instrumentation (PSI) has been unveiled as one way to execute the 3D pre-operative planning of the measured resection, and it is now widely used [9–12]. It allows fitting of surgical bones and indicates alignment and position of the guide pin for osteotomy or osteotomy itself. When using such a surgical device, bony preparation for the femoral component in the sagittal direction can be controlled without anterior or

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posterior reference. The author previously suggested pre-operative planning of a single-radius femoral component for total knee arthroplasty of posterior cruciate ligament sacrificed type (PS) [13]. The sagittal centre of the femoral component is matched with the single flexion–extension (FE) axis of the knee joint, which is approximated by the transepicondylar axis (TEA) [13]. According to a comparison between the suggested method and a conventionally measured resection method in the paper (Table 1), the sagittal implant centre, by the conventionally measured resection method, was shifted by 2–3 mm from the FE axis. If the author's suggested planning is implemented with PSI, both the posterior and distal distances from the flexion/extension axis should be equal. Then, the extension gap might be equal to the flexion gap under the above more physiological condition, because bilateral collateral ligaments start around the TEA [14].

The purpose of this study was first to investigate whether the flexion gap was equal to the extension gap under the above more physiological condition when the above planning for the single-radius femoral component was performed. For this purpose, a patient-specific instrumentation [Prophecy, Wright Medical Technology, Inc. (WMT)] was used. Second, the author measured postoperative orientations of both the femoral and tibial components to investigate whether TKAs in this study were performed with good accuracy.

Materials and methods

A total of 11 patients (12 joints, two males and nine females, average age 76.9 years, range 61–89 years) were enrolled from November 2011 to December 2012. All patients had a pre-operative diagnosis of osteoarthritis. A single surgeon (TH) performed TKAs. The average pre-operative maximum extension angle of the knee was −14.6° (range, −30°–0°), and the average flexion angle was 117.0° (range, 90–130°). The average pre-operative femorotibial angle was 182.9° (range, 178–194°) based on measurements of anteroposterior radiographs of the lower extremity taken at maximum extension in a standing weight-bearing position. This study was approved by the institutional review board, and all patients gave their informed written consent.

Pre-operative CT scanning of the hip, knee, and ankle joints was performed six to ten weeks pre-operatively according to a standard scanning protocol to determine the mechanical axis of the leg and the TEA. Pre-operative CT was transferred to the PSI system (Prophecy, WMT) of the implant company for 3D pre-operative planning. First, in the planning of the femoral component, the TEA was determined. Berger et al. described two different definitions for the TEA: one between the medial and lateral epicondylar crest (the clinical epicondylar axis), and the other between the sulcus of the medial epicondyle and the crest of the lateral epicondyle (the surgical epicondylar axis) [15]. Although the shape of the medial epicondyle resembles a horseshoe [15], it is not detectable in approximately 30 % of examined knees [16, 17]. Thus, we adopted the clinical epicondylar axis in order to standardize the TEA. Next, the femoral mechanical axis (FMA) was defined as a line through the centre of the femoral head and the midpoint between the medial and lateral ends of the TEA in the distal condyle, which was defined as the "knee centre." The centre of the single-radius component (Advance, WMT) [18–20] was matched with the FE axis. This was made by modifying the TEA, in which the TEA was rotated around the knee centre in the coronal plane until it was perpendicular to the FMA. The effect of this modification was likely very small because the previous report by this author [12] showed the average tilt angle required for the TEA to be perpendicular to the FMA was −0.1° (95 % confidence interval [CI]; range, 1.1–0.8°). The implant size was determined according to the radius that was closest to the distance from the FE axis to the distal border of the lateral femoral condyle [13]. The distal distance was then equal to the posterior distance from the FE axis. The femoral component was flexed around the FE axis to avoid anterior notching when the anterosuperior apex of the femoral component dug into the anterior cortex of the femur [13]. The planning of the tibial component involved a proximal osteotomy to make a 3° posterior slope to the anatomic axis. The size of the tibial component was selected by measuring the contour of the osteomized proximal tibia. The component rotation was set to the medial one third of tubercle,

Table 1 Comparison between the author's suggested method and a conventionally measured resection method in three-dimensional pre-operative planning

Determination of three alignments	The author's suggested method	Conventionally measured resection method (Axial alignment is based on TEA)
Coronal	Mechanical axis	Mechanical axis
Axial	Fixed TEA	Parallel with TEA (Anteroposterior position of femoral component can be shifted by anterior or posterior reference when selecting its size)
Sagittal	Mechanical axis	Distal femoral axis (Depended on intramedullary rod)

TEA transepicondylar axis

and the resection level to 11 mm from the lateral side. The author received the planning report as a PDF file with the comments of the engineer from the company (Fig. 1). At this stage, the surgeon could check whether the report reflected the planning and could ask the engineer for modification of the planning in case of any issues. PSI was then manufactured with a polyamide material and delivered to the author's hospital two to three days pre-operatively.

A standard midline incision with a medial parapatellar approach under an air tourniquet at 300 mm Hg was performed in all patients. General anaesthesia was used together with femoral and ischial nerve block. After standard exposure, PSI for the femoral component was placed on the distal femur (Fig. 2).

PSI for the femoral component guided both the surgeon's placement of the pins for the distal cutting block and where to make the holes to set the chamfer for intercondylar osteotomy. PSI for the tibial component was then placed on the proximal tibia to position the pins for the horizontal cutting block and determine the rotation of the tibial component.

A tensor/balance device [6–8] was used to make the intraoperative gap measurements with the trial femoral component following osteotomies. This device consists of two plates that are connected to the main body via an offset arm. The upper plate has a surface tray and seesaw plate, and is free to seesaw under the relative balance between the medial and lateral soft tissues. The lower plate is controlled by two pins with a depth of 4 mm, and put on the osteomized tibial plane, where the centre of the anterior side of the lower plate is placed at 1-mm posterior to the centre of the anterior side of the proximal tibia (i.e. normal position of the tibial component). The surface of the lower plate has two slight concavities in which the two condyles of the trial femoral component fit. These concavities control the tibio-femoral position in both the sagittal and coronal planes, reproducing the joint constraint and alignment that will occur after the prostheses are implanted. In surgery a torque driver was used to apply a constant 30-pound distracting force between the two plates. This distracting force was chosen on the basis of the author's previous study [8]. Gap distance (in mm) was evaluated with the patella reduced with the trial patellar component in place. Intraoperative gap measurements were performed at an extension of 0° and a flexion of 90°.

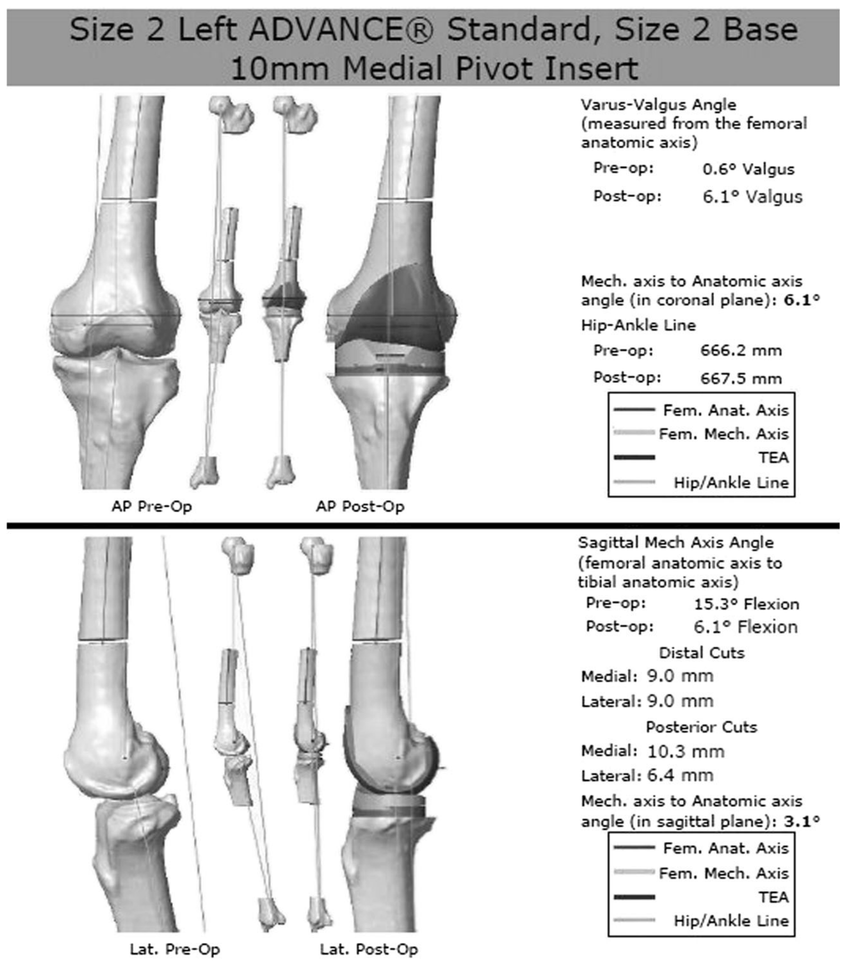

Fig. 1 A report of a three-dimensional preoperative plan for total knee arthroplasty

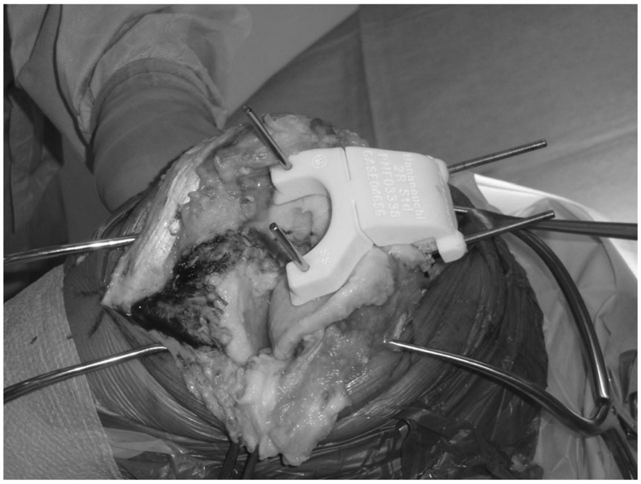

Fig. 2 Patient-specific instrumentation (PSI) for femoral osteotomy is fit onto the surface of the distal femur. The surgeon inserts several pins for bone preparation through PSI into the femur

Computed tomography (CT) of the TKA knees was performed three weeks postoperatively to assess whether TKAs in this study were performed with good accuracy. The postoperative evaluation was performed with computer software (3-D template, KYOCERA Medical Corporation, Osaka, Japan). Multi-planar views (coronal, sagittal, and axial) with a changing orthogonal coordinate system and any digitally reconstructed plain radiographs (DRR) on each view were acquired. The pre-operative coordinate system for the femoral component was established on the postoperative CT images by finding the TEA. The difference in angles between the pre- and postoperative alignments of the femoral components was measured in all patients. The author also checked for a notch or gap of the anterior apex of the femoral component on the sagittal DRR view in order to investigate whether the sagittal position of the femoral component was extremely shifted anteriorly or posteriorly from that in the pre-operative planning (e.g. the extremely posterior shift of the femoral component makes the flexion gap shorten). Differences in angles between pre- and postoperative alignments of the tibial components of all patients were measured by establishing a postoperative coordinate system for the tibial component in the same manner as was done for the femoral component.

To compare the intra-operative gaps at an extension of 0° and a flexion of 90°, a paired t-test was conducted using statistical software (StatView 5.0; SAS Institute Inc., Cary, NC). The intra-operative gap difference was also measured by subtracting the extension gap from the flexion gap.

Results

The flexion gap was significantly larger than the extension gap (p=0.00012). The average extension gap was 12.3 mm (standard deviation (SD), 3.3 mm; range, 8–19 mm). The average flexion gap was 19.1 mm (SD, 2.2 mm; range, 15–22 mm). The intraoperative gap difference (flexion gap minus extension gap) was consistently a positive value (range, 2–12 mm), and on average 6.8 mm (SD, 4.0 mm).

The postoperative CT analysis showed angle differences between pre- and postoperative alignments were within 3° in all cases (Table 2). No cases were found to have an anterior notch or gap of the femoral component.

Discussion

This study sought to (1) investigate whether the flexion gap was equal to the extension gap in PS-TKAs with 3D pre-operative planning by the author's concept of a single-radius femoral component and (2) measure postoperative evaluations of both the femoral and tibial components to indicate the TKAs with PSI were performed with good accuracy.

In the present study, since the posterior and distal distances from the modified TEA (i.e., the FE axis) to the condylar borders of the implanted femur must be equal, the sagittal shifting of the femoral component in the conventional measured resection method by anterior or posterior reference while size selection of the femoral component can be avoided. However, the results in the present study showed that the intra-operative gap difference was always positive (mean, +6.8 mm; range, 2–12 mm; SD, 4.0 mm). Therefore, the author considers the suggested 3D pre-operative planning of the single radius femoral component in PS-TKA with patient-specific instrumentation cannot provide equal sagittal flexion and extension gaps. In other words, if surgeons follow a pre-operative plan by single flexion–extension movement of the knee joint, surgeons should not aim at equal gaps of flexion and extension in PS-TKA.

The intra-operative gap difference (mean, 6.8 mm) in the present study was slightly larger than in the author's previous study (mean, 4.7 mm) which was done with measured resection, but without PSI [8]. However, in some cases of the

Table 2 Accuracy of patient-specific instrument for total knee arthroplasty in this study

Component	Average error	Absolute error
Femoral component		
Coronal	−0.3±1.4 (−2.7–1.3)	1.1±0.8 (0–2.7)
Sagittal	1.8±1.3 (−0.7–2.9)	1.9±1.1 (0.4–2.9)
Axial	0.8±1.2 (−1.5–2.9)	1.2±0.8 (0–2.9)
Tibial component		
Coronal	0.3±1.5 (−2.4–2.8)	1.3±0.7 (0.4–2.8)
Sagittal	0.6±1.4 (−1.3–2.9)	1.2±0.8 (0–2.9)
Axial	1.2±.17 (−2.1-2.9)	1.9±0.7 (0.9–2.9)

Values are mean±standard deviation (range)

Table 3 Effect of posterior cruciate ligament (PCL) in previous reports

Study	Subject (joint)	Measurement	Component	Effect (mm)			Navigation	Patellae position	Tensor (value)	Osteotomy
				Extension	Flexion	Gap difference				
1) Cutting of PCL[a]										
Mihalko et al. [28]	Cadavers (12)	Osteomized bone gaps	–	−1.4	5.3	6.7	–	Eversion	Maximal manual Distraction	M[f]
Kadoya et al. [29]	Patients (33)	Osteomized bone gaps	–	0.9	4.6	3.7	–	Eversion	V-STAT (Zimmer, 40lb)	M
Park et al. [30]	Patients (30)	Component gaps	E. motion (B. Braun Aescrap)	0.9[b]	4.0[b]	3.1	+	Eversion	No name (200Nm)	M
Chaiyakit et al. [31]	Patients (16)	Component gaps	PFC Sigam or LCS M(Depuy)	0.2[b]	1.7[b]	1.5	+	Reduction	Knee Balancer (Depuy, 150Nm)	M
Matthew et al. [32]	Cadavers (10)	Component gaps	Triathlon (Stryker)	–0.8	0.5	1.3	+	Reduction	V-STAT (Zimmer, 22N)	M
Schnurr et al. [33]	Patients (50)	Component gaps	PFC Sigam (Depuy)	0.6[b]	1.1[b]	0.5	+	Reduction	Sensor Tensor (Depuy, 150Nm)	M
2) Difference[c] between CR[d] and PS[e]										
Matsumoto et al. [21]	Patients (CR 50; PS 20)	Component gaps	NexGen CR and LPS Flex (Zimmer)	−1.4	3.5	4.9	+	Reduction	Offset Repo-tensor (Zimmer, 40lb)	M
		Component gaps	NexGen CR and LPS Flex (Zimmer)	−1.5	2.6	4.1	+	Eversion	Offset Repo-tensor (Zimmer, 40lb)	M
Matsumoto et al. [22]	Patients (CR 25; PS 25)	Component gaps	NexGen CR and LPS Flex (Zimmer)	−0.1	4.3	4.4	+	Reduction	Offset Repo-tensor (Zimmer, 40lb)	M
		Component gaps	NexGen CR and LPS Flex (Zimmer)	0	2.0	2.0	+	Reduction	Offset Repo-tensor (Zimmer, 40lb)	M
Matsumoto et al. [23]	Patients (CR 19; PS 22)	Component gaps	NexGen CR and LPS Flex (Zimmer)	−1.7	3.7	5.4	+	Reduction	Offset Repo-tensor (Zimmer, 40lb)	M
Matsumoto et al. [24]	Patients (CR 80; PS 40)	Component gaps	E. motion (B. Braun Aescrap)	−0.7	3.7	4.4	+	Reduction	Offset Repo-tensor (Zimmer, 40lb)	G[g]
Oka et al. [26]	Patients (CR 25; PS 25)	Component gaps	NexGen CR and LPS Flex (Zimmer)	−1.3	4.7	6.0	+	Reduction	Offset Repo-tensor (Zimmer, 40lb)	M
Nishizawa et al. [27]	Patients (CR 20; PS 20)	Component gaps	NexGen CR and LPS Flex (Zimmer)	−2.7	2.2	4.9	+	Reduction	Offset Repo-tensor (Zimmer, 40lb)	M
Matsumoto et al. [25]	Patients (CR 45; PS 90)	Component gaps	E. motion (B. Braun Aescrap)	−0.1	2.8	3.1	+	Reduction	Offset Repo-tensor (Zimmer, 40lb)	G
	Patients (CR 20; PS 100)	Component gaps	NexGen CR and LPS Flex (Zimmer)	−0.2	4.3	4.5	+	Reduction	Offset Repo-tensor (Zimmer, 40lb)	M

[a] Investigation of increase of gap by cutting PCL

[b] Since the paper expressed medial and lateral values, average of both values is described.

[c] Investigation of difference between the measurements with CR or PS

[d] Total knee arthroplasty with retaining of PCL

[e] Total knee arthroplasty with cutting of PCL

[f] Measured resection

[g] With gap technique

previous study, the rotational position of the femoral component was based on an external rotation of 3° to the posterior condylar line. Therefore, the author cannot clarify the difference between the current and the previous studies. In addition, as in other similar studies, previous reports [21–27] by Matsumoto et al. show that the flexion gap was bigger than the extension gap in PS-TKAs even with a gap control technique [24, 25]. Therefore, the author thinks that the effect of cutting PCL on flexion and/or extension gaps is bigger than the effect of the sagittal shift of the femoral component in the antero-posterio direction. Even so, the extent of the effect of cutting PCL on flexion and/or extension gaps is varied [21–33] (Table 3). Range of increasing gap by cutting PCL was −1.4–0.9 mm in extension, 0.5–5.3 mm in flexion, and 0.5–6.7 mm in the intra-operative gap difference. In addition, differences between cruciate-retaining (CR) and PS-TKAs of the intra-operative gap difference was 2.0–6.0 mm. Further studies to investigate how a proper pre-operative planning is determined for good sagittal gap balancing under the more physiological condition are needed.

Other papers are currently attempting to investigate the accuracy of PSI using long-standing radiographs [34] or CT scout images in the coronal plane [35], with plain radiographs in the sagittal plane [36, 37] and axial CT images for post-evaluation of axial rotation [36, 37]. However, accuracy of PSI used in the present study (Prophecy) has not been reported. This study first showed that this PSI system can provide good accuracy and which angle deviations of both components were within 3°. In addition, no cases were found to have an anterior notch or gap of the femoral component. Therefore, the results of the flexion and extension gaps in the present study were not so affected by the accuracy of this PSI system.

This study contained some limitations. First, the number of the patients was very small. This small sample size is counter-balanced by the benefits of a prospective study done by a single surgeon with one type of implant. Second, postoperative change in gaps could not be expected since only the intra-operative gaps were measured. However, it has been shown that soft tissue balance implemented during TKA persisted five years postoperatively [23].

In conclusion, this study showed that the flexion gap is always larger than the extension gap under a constant distraction force, even if the sagittal centre of the single-radius femoral component was matched with the flexion-extension axis using patient-specific instrumentation. This finding suggests that surgeons should not aim at equal gaps of flexion and extension in PS-TKA.

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