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Elucidation of the association between additional distal femoral resection and extension angle improvement following the actual surgical steps with the Robot-TKA system

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1. INTRODUCTION

Total knee arthroplasty (TKA) is a common surgical intervention that improves activities of daily living in patients with knee osteoarthritis (KOA) and rheumatoid arthritis [1]. Knee flexion contracture, which frequently causes post-operative contracture, is commonly observed with KOA progression. Stronger quadriceps tension than usual is required to prevent knee buckling, which causes quadriceps fatigue during daily activities, in knee contracture cases [2]. Additionally, post-operative contracture results in leg length discrepancy, causing unstable gait and contracture deformity in the contralateral knee. Therefore, post-operative contracture is not only a factor in poor outcomes on the operated side [3], but it also contributes to fatigue in the contralateral side [4] and trunk imbalance [5].

Efforts are made to resolve the contracture through soft tissue techniques during TKA to prevent post-operative contracture in cases with pre-operative flexion contracture. Initially, osteophytes, which cause the contracture, are removed, and posterior joints are released to improve posterior tightness. Additional distal femoral resection may be performed if contracture persists despite these efforts. Notably, distal femoral resection should be avoided as much as possible because it elevates the joint line, consequently causing anterior knee pain, mid-flexion instability, and decreased range of motion (ROM) after TKA [6, 7]. It should only be considered when absolutely necessary. However, the extent to which contracture improves through additional bone resection remains unknown.

Several studies have investigated the association between additional bone resection and flexion contracture improvement in living knee [8-10]. After completing the four-corner cut in human knees, they simulated a flexion contracture by adding an augment to the distal femur, which mimics insufficient distal bone resection. They retrospectively evaluated the amount of additional bone resection needed at the distal femur and the degree of improvement in the flexion contracture based on the amount of augmentation added to the distal femur and the angle of the flexion contracture. However, no studies have evaluated the additional amount of bone resection and the angle of contracture improvement following the actual surgical steps.

Robot-assisted TKA (Robot-TKA) and computer assisted navigation systems, which allows for precise bone cutting and balance evaluation, has been performed in recent years. Several studies have demonstrated superior accuracy of the navigation systems when compared to conventional methods [11-

13]. Robot-TKA has been reported to increase the accuracy of bone resections and reduce the number of alignment outliers in TKA [14]. The ROSA Knee System (Zimmer Biomet, Warsaw, IN, USA) is a robotic system that incorporates robotic placement of the cutting jigs and dynamic ligament balance evaluation [15, 16]. The average difference between the mechanical axes measured on the pre-operative radiograph and by the navigation system composed of the ROSA Knee system during surgery was 0.2° with standard deviation of 0.8° [17]. The average difference among planned, validated and measured angles and the amount of resection using ROSA Knee system was 1 mm or under 1 degree with standard deviation under 1 in coronal and sagittal plane [18]. Furthermore, the arm-type Robot-TKA, which attaches the cutting guides using an arm, allows additional distal femoral bone resection, which is difficult to manually perform, after completing the bone-cutting step. Thus, an accurate distal femoral resection is possible with arm-type Robot-TKA.

Therefore, we could accurately perform and evaluate contracture improvement through distal femoral resection following the actual surgical steps with the Robot-TKA system. This study aimed to elucidate the association between additional distal femoral resection and extension angle improvement following actual TKA procedure with the Robot-TKA system for the first time.

2. Material and method

2.1. Subjects

XXX University Institutional Review Board approved the protocol of this prospective study (020-0341) performed following the tenets of the Declaration of Helsinki. The participants signed written informed consent for study participation. This study received no specific grant from funding agencies in the public, commercial, or not-for-profit sectors. The study was conducted from January 2021 to June 2021 at XXX University Hospital. A total of 14 consecutive patients (14 knees) underwent TKA during this period. The exclusion criteria were cases requiring a constrained implant due to significant knee instability or bone defects. Hence, two cases that underwent semi-constrained TKA and one case that underwent constrained TKA were excluded. As a result, 11 patients were enrolled into this study. Demographic data of the patients are shown in Table 1. The range of motion of the knee joint in patient demographics were measured using

goniometer as a part of physical examination. ROSA Knee System (Zimmer Biomet, Warsaw, IN, USA) were used for Robot-TKA. at ROSA Knee System [18]. All patients used the posterior-stabilized (PS) Persona knee implant system.

Table 1. Pre-operative patient demographics.

	n=11
Age (years)	68.6 (SD 13.4, range 49 to 88)
Sex (Female/Male)	5/6
Diagnosis (OA/RA)	8/3
ROM (°)	
Extension angle	−5.0 (SD 8.3, range −25 to 0)
Flexion angle	109 (SD 16.8, range 79 to 131)
Flexion contracture (greater than 10°/less than 10°)	3/8
HKA (°)	−4.1 (SD 10.8, range −19.2 to 11.3)

Continuous variables are presented as the mean (standard deviation with range).

OA, osteoarthritis; RA, rheumatoid arthritis; ROM, range of motion; HKA, hip–knee–ankle angle

2.2. Radiographic evaluation

Hip–knee–ankle angle (HKA) was evaluated on full-length lower limb standing anteroposterior radiography. We also evaluated the passive extension angles using stress lateral radiograph of the full-length lower limb before and 14 days after surgery. A stress lateral radiograph, including the femoral head, knee joint, and ankle, under an extension force of 15 N to the front of the distal femur to maximize knee extension, was used to measure the passive extension angle (Figure 1A, 1B). This evaluation was performed for two main reasons: 1) to measure the extension angles in the mechanical axis similar to those measured by the intra-operative navigation system, and 2) it was considered that a measure of passive extension angle using a stress lateral radiograph can reflect intra-operative findings, as there was a possibility of limited active extension due to pain two weeks after surgery.

We conducted a stress lateral radiograph on 8 volunteers twice with a 3-day to evaluate the test-retest

reliability and intra-rater reliability using the Intraclass Correlation Coefficient (ICC). ICC (3,1) was used for the test-retest reliability of the stress lateral radiograph. The initial measurements of the 8 volunteers were re-evaluated by the same evaluator (R.H) after a 3-day interval. ICC (3,1) was used to assess the reliability of measurements on lateral radiograph. The ICC for the test-retest reliability and for intra-rater reliability was 0.78 and 0.89, respectively.

The coronal inclination of the femoral and tibial components in the component alignment was defined as θ angle (optimum: 90) and β angle (optimum: 90), respectively, as previously reported [22]. Similarly, the sagittal inclination of the femoral and tibial components was defined as γ angle (optimum: 0) and δ angle (optimum: 87), respectively [22]. Two independent investigators (K.I. and Y.K.) measured these angles on pre-operative and post-operative radiographs to minimize any observation bias. Intraclass correlation coefficients (ICC) were used to assess the degree of agreement within a rater or between raters. The ICC for intra- and inter-observer variability was 0.85 and 0.82, respectively.

2.3. Surgical techniques

One surgeon (K.I.) performed all surgical procedures. The air tourniquet was inflated to 280 mmHg intra-operatively under general anesthesia. All patients underwent anterior incision with a medial parapatellar approach. All cases used the PS Persona knee implant system (Zimmer Biomet, Warsaw, IN, USA) as the prosthesis. We cut the distal femur and proximal tibia perpendicular to the mechanical axis with a navigation system. The amount of initial distal femoral resection was differentiated according to the degree of prior flexion contracture measured at pre-operative physical examination using goniometer. Those with pre-operative flexion contractures of $>10^\circ$ were cut 9.0 mm from the distal femur surface, while those with pre-operative flexion contractures of $<10^\circ$ were cut 7.0 mm. The amount of bone resection on the tibial side was performed perpendicular to the functional axis and 10 mm from the joint surface, accounting for the thickness of the implant, regardless of the degree of prior flexion contracture. In the present cases, the mechanical medial proximal tibial angle (MPTA) was less than 90 degrees in all instances. Consequently, the amount of resection on the lateral side was greater than that on the medial side in every case. We used the posterior femoral condylar precut technique to evaluate the impact of additional bone resection alone on flexion contracture improvement [19-21]. The posterior femoral condyle was temporally cut smaller with this technique than the measured resection technique, thereby creating a

temporary small flexion gap. This enables the easy removal of the posterior osteophyte, thereby releasing the posterior soft tissue. Additionally, the femoral precut trial was effective in evaluating the extension and flexion gaps for the same gap space by the final bone resection. The posterior capsular procedure performed after the posterior femoral condylar precut was varied based on the degree of flexion contracture. Three patients with pre-operative physical examinations showing more than 10° of flexion contracture, 9 mm of the distal femur equivalent to the thickness of the implant was resected. It was considered that these cases (3 cases) had posterior tightness. We measured knee extension angle after posterior osteophytes removal and the posterior capsule release were performed. In cases with less than 10° (8 cases), 7 mm of the distal femur was resected. Knee extension angle was measured after posterior osteophytes removal without the posterior capsule release (Figure 2). The posterior osteophytes were confirmed to be removed only by visual inspection and palpation, without the use of the intra-operative fluoroscopy. The amount of additional distal femoral resection was decided by following steps. A spacer with the same thickness as the combined thickness of the tibia tray and the thinnest insert (10 mm for this implant) was placed on the tibial resection surface. If full extension was not achieved at this point, we determined the thickness of the spacer that allows for full extension using the navigation system. The difference between this thickness that allows for full extension and 10 mm was taken as the additional bone resection amount (Figure 3). After the additional resection, no further resection of bone spurs or dissection of soft tissue was carried out. Femoral rotation was determined to keep the medial flexion-extension gap between 0.0 and 2.0 mm, referring surgical epicondylar axis. The final distal femoral resection was then performed, and all components were implanted. The final measurement of kinematics,

such as flexion-extension knee ROM, was performed after patellar reduction (Figure 2).

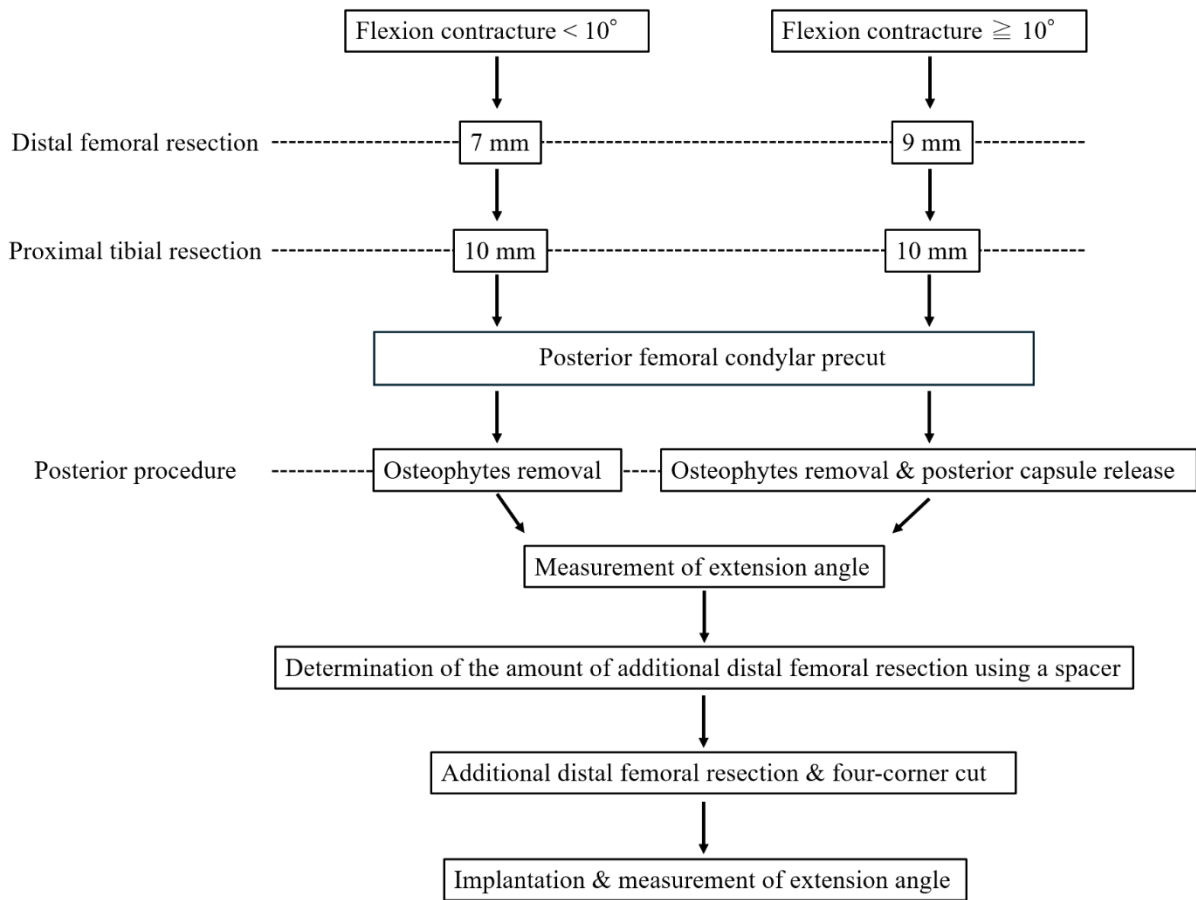


Figure 2. Flowchart for the variation in surgical techniques based on differences in flexion contracture

2.4. Intra-operative evaluation

Intra-operative flexion contracture correction angle relative to the amount of the additional distal femoral resection was calculated as the primary outcome measure. Correlations were then evaluated for the correction angle relative to the amount of additional resection. Secondary outcome measures were bone resection thickness of the initial and additional distal femur in intra-operative evaluation. Further, flexion-extension ROM was immediately measured before the wound closure.

2.5. Statistical analysis

JMP Pro version 15.2 was used for statistical analyses. The significance level was set at $P = .05$. Descriptive data were presented as mean (standard deviation) with range, and inferential

statistics were reported as mean with standard error. The relationship between the correction angle of flexion contracture and the amount of additional distal femoral resection was summarised by the Pearson correlation coefficient and the use of linear regression. A paired t-test was used to compare pre- and post-operative values. In a previous study that investigated the relationship between knee extension angle and the thickness of the augment using a digital camera, linear regression analysis yielded an R² value of 0.71 [23]. The minimal sample size was calculated as 6 based on this result with a power of 0.80 and an α of 0.05 (power analysis using g*power 3.1).

3. Results

Table 1 shows patient demographic data. This study included 5 males and 6 females with a mean age of 68.6 years (standard deviation 13.4 years) with a range of 49 to 88 years. KOA was diagnosed in 8 patients and rheumatoid arthritis in 3 patients. The mean pre-operative extension ROM was -5.0° (8.3°) with a range of -25° to 0°) and flexion ROM was 109.1° (16.8°) with a range of 79° to 131°). Three patients had pre-operative flexion contracture greater than 10° and eight had less than 10° . The mean pre-operative HKA was 4.1° varus (10.8°) with a range of 19.2° varus to 11.3° valgus).

3.1. Intra-operative evaluation

The thickness of the initial and additional distal femur bone resection was 8.8 mm (1.8 mm) with a range of 7.4 to 12.7 mm and 1.9 mm (0.7mm) with a range of 1.0 to 3.3 mm. Similarly, the knee extension angles before and after the additional distal femoral resection were -4.1° (3.7°) with a range of -10.9° to 0.6° and 0.1° (2.9°) with a range of -2.0° to 5.1° , respectively. The additional distal femoral resection demonstrated a linear relationship ($R^2 = 0.56$; $P = 0.008$) of an average of 2.0° with standard error (SE) of 0.6° of flexion contracture correction per millimeter (Figure 4).

3.2. Post-operative evaluation

The mean passive extension angle measured by using a stress radiograph improved from -12.2° (8.8°)

204 with a range of -27.2° to 0.2°) to -3.0° (4.2°) with a range of -13.3° to 2.2° ($P = 0.009$) and HKA
205 improved from -4.1° (10.8°) with a range of -19.2° to 11.3°) to -0.5° (1.6°) with a range of -2.9° to 2.8°
206 ($P = 0.253$) (Table 2). The mean coronal inclinations were 89.3° (1.2°) with a range of 87.5° to 90.0° and
207 89.3° (0.9°) with a range of 87.7° to 90.1° and the mean sagittal inclinations were 2.2° (0.6°) with a range
208 of 0.9° to 2.9°) and 87.7° (0.9°) with a range of 86.5° to 89.0° of the femoral and tibial components,
209 respectively. Regarding outliers, no cases deviated for $>3.0^{\circ}$ from the optimum angle. The follow-up
210 reported no cases of major adverse events.

	Pre-operative value			Post-operative value			Change of the angle			p-value
	mean	SD	range	mean	SD	range	mean	SD	range	
Passive extension angle using a stress lateral radiograph	-12.2	8.8	-27.2 – 0.2	-3.0	4.2	-13.3 – 2.2	9.2	9.5	-7.2 – 29.4	0.009
HKA	-4.1	10.8	-19.2 – 11.3	-0.5	1.6	-2.9 – 2.8	3.6	9.9	-8.3 – 16.4	0.253
CIFC (θ)				89.3	1.2	87.5 – 90.0				
CITC (β)				89.3	0.9	87.7 – 90.2				
SIFC (γ)				2.2	0.6	0.9 – 2.9				
SITC (δ)				87.7	0.9	86.5 – 89.0				

222 Table 2. Pre- and post-operative radiographic evaluation.

223 All measurements are in degrees. HKA, hip–knee–ankle angle

224 The coronal and sagittal inclinations of the component were previously defined by Song et al. [24]

225 CIFC, Coronal inclination of the femoral component; CITC, Coronal inclination of the tibial component; SIFC, Sagittal inclination of the

226 femoral component; SITC, Sagittal inclination of the tibial component

4. Discussion

This study primarily aimed to clarify the flexion contracture correction angle relative to the amount of additional distal femoral resection following the actual surgical steps with the Robot-TKA system. The most important finding of this study was that an additional 1.0 mm distal femur bone resection in PS-type TKA causes a 2.0° improvement in knee extension angle within an additional resection range of 1.0mm to 3.3mm.

Several studies revealed the association between distal femoral bone resection and improvement in contracture. Studies that used cadaveric knees and evaluated the angle with a goniometer reported that 2-mm additional bone resection resulted in a 9° improvement in contracture [8]. Another study that used cadaveric knees and evaluated the angle with a digital camera revealed a 1.8° change per 1 mm of resection [23]. A study that utilized a navigation system with CR-TKA reported a 10° improvement with a 3.55 mm resection [10]. Furthermore, a study that used PS-TKA and assessed the ROM with the navigation system revealed a 2.2° change per 1 mm of resection [9]. However, all these studies evaluate the association between the amount of extension and the degree of contracture angle by adding an augment to the distal femur only after proceeding to the stage of placing the tibiofemoral implant trial following the usual surgical steps. Reportedly, simply shifting the implant in the distal direction after creating the extension knee changes the protrusion position of the posterior condyles [25], indicating that the amount of shift in the distal direction did not reflect the extension gap improvement. Therefore, the use of an augment to change the position of the distal femoral implant may not faithfully reflect what occurs in actual TKA.

To date, only one reported study has investigated the relationship between bone resection and contracture improvement by performing additional bone resection from a contracted knee, similar to our study [26]. This previous study used cadaver knees and assessed bone resection using PS-TKA and a robotic system. They reported a 3.6° improvement, from a 10° contracture to 6.4° , with a 2 mm additional bone resection [26]. Performing additional bone resection from a state of knee contracture was not contradictory to an actual surgical step. However, whether or not a contracted knee created by posterior joint capsule suturing could replicate the condition of an actual contracted knee remains debatable.

This study has several strengths. First, it includes living knee specimens. Second, it incorporates precise

bone resection with a robotic system and accurate ROM evaluation with a navigation system. Further, the study follows the actual surgical steps by performing additional bone resection from the contracture knee. Furthermore, the precut technique implementation allows easier posterior access and osteophyte removal [19], thereby eliminating their effect on the extension angle. Therefore, the observed improvement of 2.0° per 1 mm in flexion contracture during PS-TKA is considered a value that reflects the achievable outcomes in real surgical procedures.

The extension gap rarely becomes tight during the final trial due to the distal femoral bone resection equivalent to the implant thickness when performing TKA on a knee without contracture. However, the distal femoral bone was typically resected as usual following the implant thickness in knees with severe contracture, and the four-corner cuts proceeded and the trial components were inserted after confirming the extension gap with a gap spacer, which causes an insufficient extension gap. Manually performing additional distal femoral bone resection became difficult in such cases since the procedure had already reached the four-corner cuts. Consequently, the implant was inserted as it was, thereby creating flexion contracture. This could occur when the extension gap was already borderline tight during the confirmation with the gap spacer and was believed to be caused by the difference between the bone gap and implant gap due to the prominence of the implant's posterior condyle. Hence, cutting a larger amount of the distal femur than usual when performing TKA on a contracted knee was frequently practiced. The amount of additional resection during the initial distal femoral bone resection largely depended on the surgeon's experience. Furthermore, a larger amount of distal femur was initially resected in some cases, followed by gradual bone spur removal and posterior capsule tightness release during the subsequent steps of the surgery, causing a looser extension gap and a thicker insert. However, this should be avoided as much as possible by the potential joint line elevation [6]. This study used a precut method that involved a specialized thin posterior component trial, which enabled precutting of the posterior aspect to facilitate a posterior approach [19-21]. This allowed bone spur removal and posterior capsule dissection before the four-corner cuts and enabled implant gap evaluation. The utilization of the precut technique is believed to prevent unpredictable extension gap insufficiency and unnecessary joint line elevation, as mentioned above.

Accurately performing additional bone resection was challenging based on the distal femoral bone resection surface after completing the four-corner cuts with manual techniques. This was because of the

small surface area of the distal femoral bone resection. However, precise additional distal femoral resection could be easily achieved using a robot, regardless of the bone resection surface area. The desired gap is obtained based on the results of this study when the extension implant gap was smaller than intended at the final trial stage even without using the precut technique by proceeding with the four-corner cuts as usual and completing soft tissue dissection. Robot-TKA was considered useful for its potential to prevent post-operative flexion contracture.

This study has several limitations. First, the rotational alignment of the femoral and tibial components was not evaluated. However, the component malrotation may cause a mismatch of the femorotibial components and maltracking of the patella component. Therefore, the component malrotation was considered to not affect the extension angle, which was the primary outcome of this study. Second, the assessment period in this study was limited to 2 weeks after TKA, which may be too early. However, a previous study that examined ROM up to one year after TKA revealed that the extension angle immediately post-operatively was equivalent to that observed pre-operatively even if a full extension is achieved intra-operatively [27]. Subsequently, the extension angle demonstrated improvement in 6–12 months. In this study, although a full extension was achieved intra-operatively, about 4° of flexion contracture was observed post-operatively. Considering that the average difference among planned, validated angles and the amount of resection using ROSA Knee System was under 1 mm or 1° with a standard deviation under 1 mm or 1° in the sagittal plane [18], the post-operative ROM reported in this study may not reflect the intra-operative and the final ROM due to the early evaluation time. Third, the flexion contracture improvement obtained in this study was only valid in limited range. The current study revealed that an additional 1.0 mm of distal femoral resection in PS-type TKA improves knee extension angle by 2.0° within an additional resection range of 1.0mm to 3.3mm. Therefore, it is unknown to mention whether the same contracture improvement can be obtained with an additional resection amount beyond this range. However, this study is the first to report the association between the amount of additional distal femoral resection and flexion contracture correction following the steps of actual TKA techniques. Further, our results can help surgeons by providing intra-operative tips during TKA procedures.

5. Conclusions

The analysis based on the method of contracture improvement following the steps of actual TKA

techniques indicated that a 1.0-mm distal femoral resection enhances extension by 2.0° (SE 0.6°) within an additional resection range of 1.0 mm to 3.3 mm in PS-TKA. This provided surgeons the information about the required amount of additional distal femoral resection for flexion contracture improvement during TKA, thereby potentially reducing the risk of joint line elevation associated with excessive additional resection.

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Declarations of Conflict interest

The authors declare no conflicts of interest.

Acknowledgments

None.

Informed consent

All study participants provided their full written informed consent for participation in this clinical research before the operative procedure.

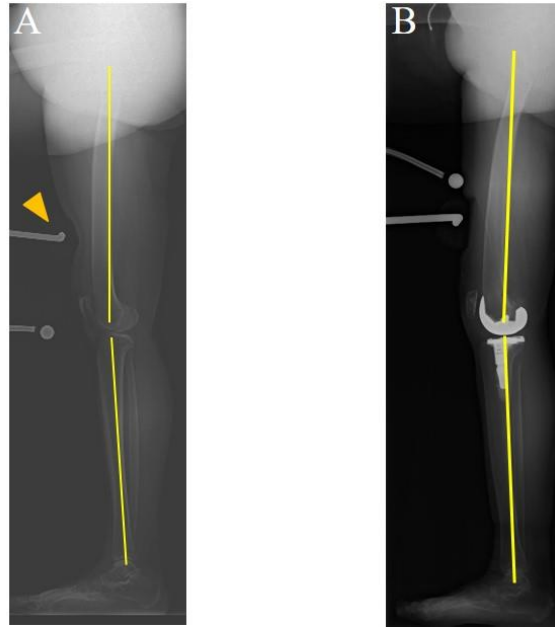


Figure 1. Stress radiographs showing pre- and post-operative knee extension angles. (A) Measurement of the pre-operative knee extension angle as the mechanical axis of the femur and lower leg using lateral stress radiographs, including the femoral head, knee, and ankle. An extension force of 15 N was applied to the front of the distal femur (arrowhead) to maximize the knee extension. (B) Post-operative knee extension angle. The knee extension angle was evaluated as a pre-operative procedure.

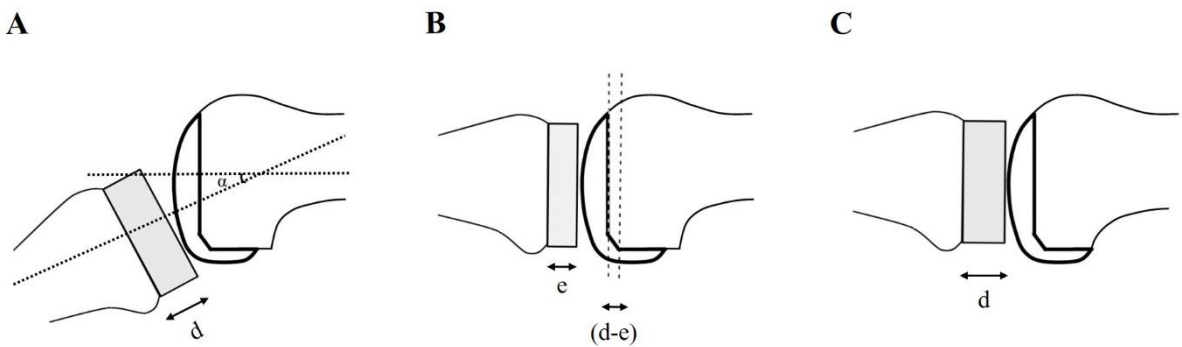


Figure 3. Schematic drawing of additional distal femoral resection. (A) The spacer, which is equal to the thickness of the tibial tray and the thinnest insert, was placed on the tibial resection surface. Full extension has not been achieved, and flexion contracture was observed. The extension angle was measured with navigation as the flexion contraction angle (α). The thickness of the spacer (d). (B) The thickness of the insert that allowed for full extension was measured (e). The amount of additional distal femoral resection was set as ($d-e$). (C) Full extension is achieved with the thinnest spacer after additional distal femoral resection.

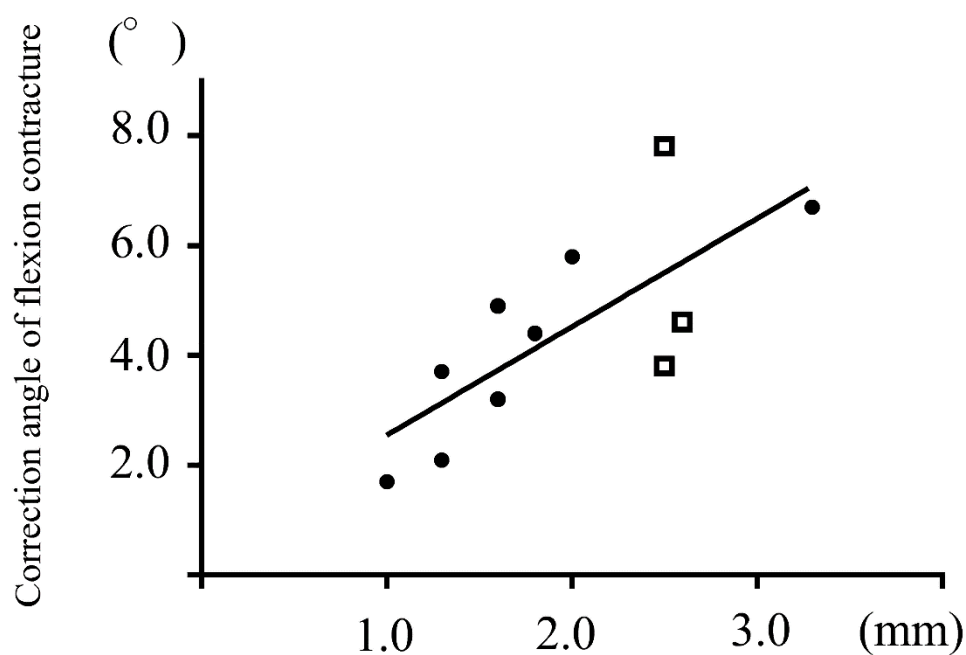


Figure 4. Association between intra-operative correction angle of flexion contracture and the amount of additional distal femoral resection. A linear association was observed with a mean correction of 2.0° (SE 0.6°) of flexion contracture per millimeter of additional distal femoral resection ($R^2 = 0.56$; $P < 0.01$). Cases with pre-operative flexion contracture greater than 10° were represented by black squares, while cases with less than 10° were represented by black circles.

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