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KNEE ARTHROPLASTY

Gap-balancing technique combined with patient-specific instrumentation in TKA

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Abstract

Introduction Combining patient-specific instrumentation (PSI) with a balancer device in total knee arthroplasty (TKA) to achieve functional femoral rotational alignment is a novel technique. The primary goal of this study was to introduce a new method to combine PSI with a gap-balancing technique and to determine the impact of the technique on rotation of the femoral component.

Materials and methods Twenty-five primary TKAs (15 women, 10 men) were prospectively studied. All TKAs involved PSI with an associated gap-balancing device. Front plane alignment was performed intraoperatively with the PSI, followed by rectangular, symmetrical extension and creation of a flexion gap using the balancer device to set the femoral rotation.

Results Femoral component rotation was between 3° internal and 6° external rotation versus the transepicondylar axis. There were no postoperative signs of patellofemoral dysfunction. In no cases was the resulting joint line displacement >3 mm. The mean elevation was 1.2 ± 0.9 mm (range 0–3). The leg axis was straight in all cases (±3°), at a mean of 1.6° ± 1.0° varus (range 0°–3° varus).

Conclusions PSI was with the gap-balancing technique was successfully used without affecting anatomical alignment. With the balancer device, PSI can be used more widely than techniques based solely on landmarks, as the soft-tissue tension can be taken into account, thus virtually eliminating flexion instabilities.

Keywords Total knee arthroplasty · Patient-specific instrumentation · Gap-balancing · Extension-first technique · Balancer device

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Introduction

Rotation of the femoral components in total knee arthroplasty (TKA) affects flexion stability and tibiofemoral and patellofemoral kinematics [1–3]. The potential consequences include: an asymmetrical flexion gap [4, 5]; contractures [6]; persistent instability, particularly in flexion with lift-off [7–9]; unilateral wear of the polyethylene inlay [10]; postoperative pain [11]; and early implant failure [5, 12–14].

The optimum femoral rotation has not been consistently described in the literature. The rotational alignment of the femoral component [4, 15] is either anatomical (measured-resection technique) or references the soft tissue (gap-balancing technique). The gold standard for the measured-resection technique, which has hitherto been used with patient-specific instrumentation (PSI), is the femoral component alignment parallel to the transepicondylar axis, or 0°–3° from the posterior condylar line [16–19]. Rotational adjustment deviations of up to 6° are, however, not an uncommon feature when using the gap-balancing technique [20], and a symmetrical flexion gap is crucial to its success [18, 19]. Comparable clinical results are reported with both techniques [21–23].

A key criticism of the gap-balancing technique is that component alignment is based on the proximal tibial cut and there is thus a risk that initial alignment errors will be carried through to all subsequent cuts [24, 25]. With the development of PSI, anatomically referenced cutting blocks can be produced preoperatively based on MRI or CT data, which improve alignment [17, 26–29]. All currently used PSI systems are, however, bone-referenced, and it is therefore not possible to take functional parameters into account. In some cases, planned workups have had to be stopped [30–33]. Studies have shown that PSI deviated from the surgical plan in up to 50 % of cases, partially because femoral rotation could not be controlled and it was not possible to achieve a rectangular flexion gap with symmetrical tissue tension [30–32].

PSI with the gap-balancing technique is currently being explored, although the impact on rotational alignment of the femoral component is unclear. For the current study, it was hypothesized that, when used correctly, kinematic femoral alignment in combination with PSI leads to deviation from anatomical alignment, while it adequately restores stability, range of motion, joint line, as well as alignment of the leg axis.

Materials and methods

In a prospective study, 25 primary TKAs (15 women, 10 men) were performed with PSI (Visionaire, Smith & Nephew Inc., Memphis, TN) and an associated gap-balancing device (Visionaire; Fig. 1). The study was approved by the local ethics committee (S1(a)/2013). Patients scheduled to undergo resurfacing for primary or secondary gonarthrosis and who had provided their written consent were enrolled. Patients aged under 18 years at the time of surgery, those with rheumatoid arthritis or post-traumatic arthrosis, and those who did not give their consent were excluded. The average age of the study population was 67.6 ± 6.7 years. The preoperative leg axis was between 18° varus and 15° valgus.

Preoperatively, all patients underwent MRI (Optima MR 360 1.5 T, GE Health Care, Little Chalfont, UK) and long-standing (lower extremity) radiographs. The production of the PSI, as well as the patient-customized cutting blocks for the femur and tibia, were then planned. The objective was to achieve a neutral mechanical axis for the femur and tibia, 4° flexion in the sagittal plane for the femoral component, a 3° posterior slope for the tibial component and a femoral rotation ±2° parallel to the surgical transepicondylar axis. Planning was reviewed and confirmed by the surgeon in each case. Age, gender, weight, body mass index, American Society of Anesthesiologists classification (physical status classification) and the planned femoral rotation based on the transepicondylar axis were all recorded preoperatively.

All patients underwent a medial parapetallar approach and were implanted with a cemented Journey BCS Posterior Stabilized TKA (Smith & Nephew Inc., Memphis, TN) by the first author. The proximal tibial and the distal femoral cuts were first carried out using the PSI. Soft-tissue balancing was performed by first setting the extension gap with the balancer device and, where appropriate, gradually releasing the ligament to achieve a symmetrical extension gap [34–36]. The balancer device was used to distract the femur from the proximal tibia. Following each release step with the balancer device, the extension gap was measured until a symmetrical extension gap was achieved. The values established for the extension gap tension were subsequently applied to the flexion gap. The rotation of the

Fig. 1 The Visionaire gap-balancing device with a spreader to determine the rotation of the femoral component

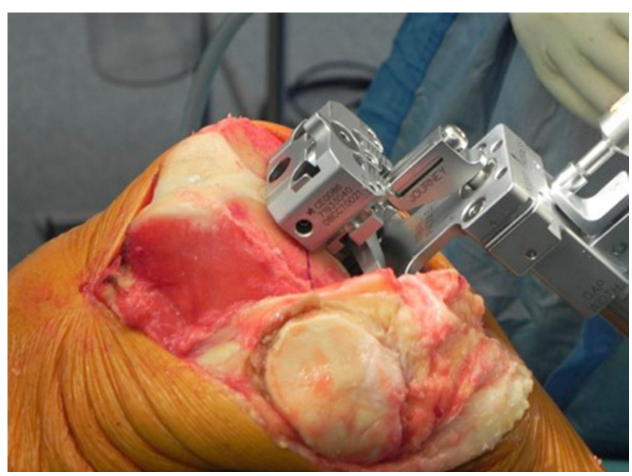

Fig. 2 The balancer device in the flexion gap. The rotation of the femur was adjusted based on the soft-tissue tension to achieve a *rectangular* flexion gap

femur was adjusted based on the soft-tissue tension to achieve a rectangular flexion gap (Fig. 2). The pinholes for the 5-in-1 block were drilled over the balancer device. Next, the final bone cuts were made and implant placement was performed as instructed by the manufacturer. The patella was not replaced in any of the cases, nor was lateral release required to correct patellar tracking.

Clinical examinations were carried out 3 months post-operatively to assess stability (extension and mid-flexion), patellofemoral pain and joint range of motion. Mid-flexion instability was defined as 30°–45° of flexion [37]. Radiological follow-up examinations were performed using a CT (Philips Brilliance CT 6 No. 44639207). Femoral rotation and joint line displacement were assessed. Femorotibial joint line height restoration was determined radiographically using the ratio of the adductor tubercle to joint line distance and the femoral width [38].

The mechanical leg axis (hip–knee angle (HKA) [39]) was measured on a long-standing (lower extremity) radiograph. Radiographs were taken in neutral rotation of the leg. The X-ray beam was centered between the two knees. Mechanical axis of the lower limb was measured using digital radiographs and special software (PACS, Carestream Health, Rochester, US). All postoperative measurements were performed by an independent physician.

Patient data were analysed descriptively. The mean and standard deviation were used to analyze continuous variables, while numbers and percentages were used for group variables. Outliers in the displacement of the joint line (>5 mm) [40] and the alignment of the leg axis (>3°) [41] were defined. Data were analyzed using Stata 12.1 (Stata Corporation, College Station, TX).

Results

Demographic data are provided in Table 1. In all cases, the TKA was implanted with PSI, and the balancer device was used for gap balancing, as planned. Additionally, all knees received the pre-planned insert and femoral size. In two cases, a tibial component one size smaller than planned was used. There were no intraoperative complications. In four TKAs, a first-degree soft-tissue release was carried out in extension. The time required to balance the flexion and extension gap averaged 2 min.

On follow-up examination, ligament stability was achieved in extension and in mid-flexion (gapping <2 mm) in all knee joints. Patellofemoral pain was not reported. Mean flexion improved from 99.2° ± 8.4° preoperatively to 108.4° ± 9.4° at 12 weeks.

Six (24 %) femoral components were aligned into internal rotation (1°–3°) with gap-balancing. Femoral rotation was as planned in three (12 %) cases, while, in the remaining 16 (64 %) cases external rotation resulted (1°–5°; Fig. 3). The rotation of the femoral components was between 3° internal rotation and 6° external rotation (Fig. 3).

The average joint line displacement was 1.2 ± 0.9 mm (range 0–3) proximal. No outliers >5 mm were recorded.

Table 1 Preoperative study group data

	N = 25
ASA[§] (1-2-3)	40–48–12
Age* (years)	67.6 ± 6.65
Gender[§] (f–m)	60–40
Weight (kg)*	85.0 ± 6.52
BMI (kg/m^2)*	28.0 ± 6.52

ASA American Society of Anesthesiologists, *BMI* body mass index

* Mean ± standard deviation; [§] proportion of patients in %

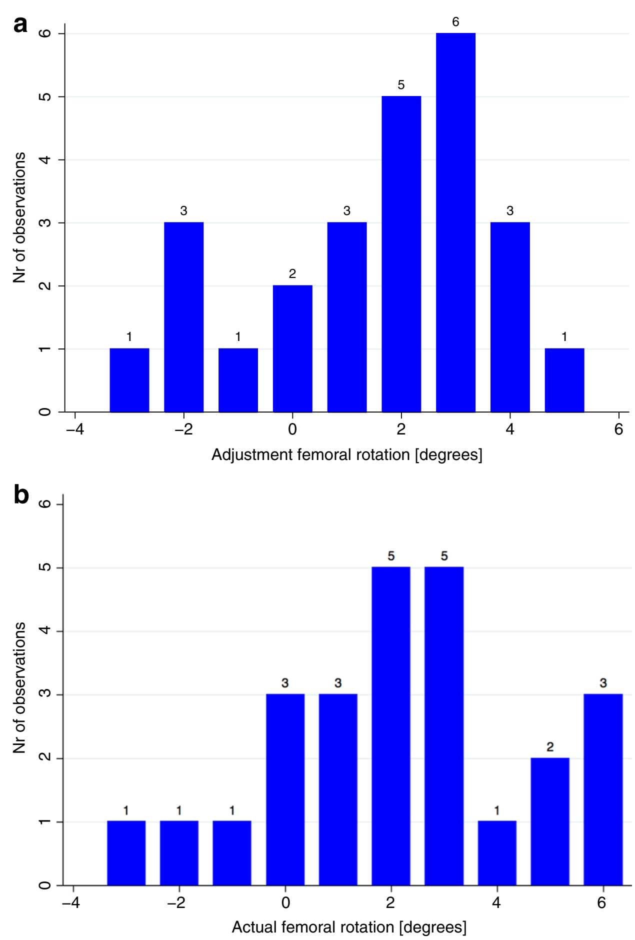

Fig. 3 Femoral rotation with gap-balancing deviation from the planned rotation, established with landmarks (**a**) and the actual femoral rotation (**b**). − Internal rotation, + external rotation of the femoral components versus the surgical transepicondylar axis

Table 2 Clinical and radiographic outcome data ($n = 25$)

	Mean ± SD	Range
Preoperative flexion	99.2° ± 8.4°	90°–120°
Flexion at 12 weeks	108.4° ± 9.4°	95°–130°
HKA (°)	1.6 ± 1.0	0–3
Joint line displacement (mm)	1.2 ± 0.9	0–3

SD standard deviation, *HKA* hip–knee angle

The mean leg axis was 1.6° ± 1.0° varus (range 0°–3° varus) versus the neutral mechanical axis. No outliers with >3° deviation were recorded (Table 2).

Discussion

In the current study, rotational values of the femoral components using the gap-balancing technique were within the range considered typical for this technique (3° internal rotation to 6° external rotation versus the transepicondylar axis) [18], but deviated from anatomical alignment. Using the balancer device meant that it was possible to take the individual tissue conditions into account while using PSI. Proper leg axis alignment was achieved in all cases. The joint line was only marginally raised in the study population.

The use of PSI allowed alignment of the tibial component in this study, with no deviations >1.5° compared to planning. Similar accuracy of primary bone cuts has been described for PSI by other authors [17, 26–28, 42]. Reliable use of the gap-balancing technique with a sufficiently accurate tibial cut is therefore ensured. Femoral rotation is more accurate if it has already been balanced in extension, and avoids secondary rotational malalignment of the femoral component due to a varus or valgus malalignment of the tibial component [43, 44]. Raising the joint line by up to 5 mm is then possible without having a detrimental effect [40, 45–47]. In our study, there was no relevant displacement of the joint line >3 mm, at 3 mm in two cases, 2 mm in five cases, and <2 mm in the remaining 18 knees. Restoration or preservation of the natural joint line, considered to be a key factor in successful TKA, was thus achieved [40, 46, 48].

Elevation of the joint line affects the patellofemoral joint specifically by increasing contact forces and thereby contributing to pain, instability, wear and impaired function [40, 47]. The literature reports femoropatellar complication rates of 2–7 % following primary TKA [4, 49, 50]. Functional impairment and an increased risk of revision are also reported [46]. Postoperative clinical effects or complications, such as mid-flexion instability, patellofemoral pain syndrome, or contractures, due to raising the joint line were not observed in the study cohort.

It was possible to carry out the surgical technique in all cases without complications. In the event of rotations >6°, the literature advises that lateral ligament instability should be assessed. Any further rotation of the femoral component may lead to suboptimal patellar tracking with anterior knee pain, kinematic restrictions, crepitation, overexertion and excessive wear of the polyethylene surfaces [19, 34, 51]. With the exception of two tibial components that were downsized following the removal of exophytes, the planned implants were used in all cases. There were no other deviations from the surgical plan described in the literature, nor were there any requirements to abandon the planned workups because a balanced gap was not achieved, as has been reported elsewhere in the literature [30–32].

A right-angled flexion gap with symmetrical ligament tension was achieved in all cases. The postoperative leg axis was 1.6° varus on average (range 0°–3° varus). A neutral [13] or slightly varus [52] leg axis of 0° to 1°–2° varus are considered to be ideal, whereas deviations of >3° are considered a risk factor for implant failure [13, 53].

Limitations of the current study include the lack of a control group, the relatively short follow-up period, and the small, heterogeneous, study population. Moreover, an a priori power analysis was not conducted. Consequently, our findings should be interpreted with caution.

In conclusion, the gap-balancing technique was successfully applied in combination with PSI in 25 knees. The balancer device takes into account individual soft-tissue tension, and can be used in PSI by surgeons who prefer the gap-balancing technique. However, only prospective comparative long-term studies can determine whether this technique is well-suited for TKA.

Compliance with ethical standards

Conflict of interest Preparation of this manuscript was supported by Smith & Nephew GmbH, Marl, Germany. Smith & Nephew had no involvement in the collection, analysis or interpretation of the data, in the writing of the report or in the decision to submit the results for publication.

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