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Clinical outcome of increased flexion gap after total knee arthroplasty. Can controlled gap imbalance improve knee flexion?

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Abstract

Purpose Increased range of motion (ROM) while maintaining joint stability is the goal of modern total knee arthroplasty (TKA). A biomechanical study has shown that small increases in flexion gap result in decreased tibiofemoral force beyond 90° flexion. The purpose of this paper was to investigate clinical implications of controlled increased flexion gap.

Methods Four hundred and four TKAs were allocated into one of two groups and analysed retrospectively. In the first group ($n = 352$), flexion gap exceeded extension gap by 2.5 mm, while in the second group ($n = 52$) flexion gap was equal to the extension gap. The procedures were performed from 2008 to 2012. The patients were reviewed 12 months postoperatively. Objective clinical results were assessed for ROM, mediolateral and sagittal stability. Patient-reported outcome measures were the WOMAC score and the Forgotten Joint Score (FJS-12).

Results After categorizing postoperative flexion into three groups (poor < 90°, satisfactory 91°–119°, good ≥ 120°) significantly more patients in group 1 achieved satisfactory or good ROM ($p = 0.006$). Group 1 also showed a significantly higher mean FJS-12 (group 1: 73, group 2: 61, $p = 0.02$). The mean WOMAC score was 11 in the first and 14 in the second group (n.s.). Increase in flexion gap did not influence knee stability.

Conclusions The clinical relevance of this study is that a controlled flexion gap increase of 2.5 mm may have a positive effect on postoperative flexion and patient satisfaction after TKA. Neither knee stability in the coronal and sagittal planes nor complications were influenced by a controlled increase in flexion gap.

Level of evidence III.

Keywords Controlled gap imbalance · Total knee replacement · Patient-reported outcome · TKA · TKR

Abbreviations

ROM	Range of motion
TKA	Total knee arthroplasty
BMI	Body mass index
PCL	Posterior cruciate ligament
PROM	Patient-reported outcome measure
PRO	Patient-reported outcome
FJS-12	Forgotten Joint Score

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Introduction

Reduced range of motion (ROM) remains a problem in total knee arthroplasty (TKA). Factors influencing postoperative ROM are preoperative and intraoperative ROM [24], patient age [20], body mass index (BMI) [6], type of prosthesis [21], Insall–Salvati ratio [19] and femoral posterior condylar offset [5].

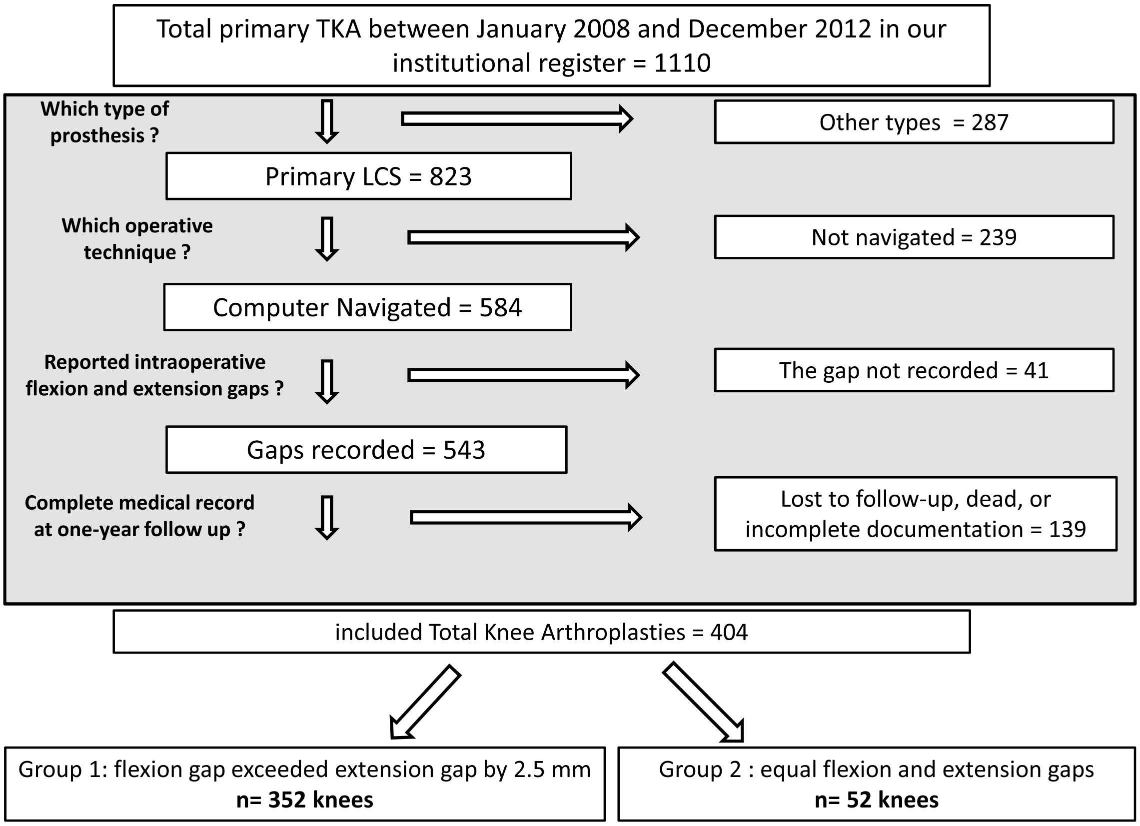

Fig. 1 Number of TKAs meeting the inclusion criteria

Restoring equal flexion and extension gaps is a widely accepted surgical goal and has been thought to be important for well-functioning TKA. It has also been attributed to reducing the incidence of stiffness [10] or instability [20]. However, a biomechanical cadaver study [15] showed that a small and controlled increase (2 mm) in the flexion gap resulted in decreased tibiofemoral force beyond 90° of passive knee flexion without affecting medial and lateral ligament strain. These biomechanical findings suggest that increased flexion gap might result in better postoperative ROM while not influencing knee stability. Several clinical comparative studies have also indicated increased patient satisfaction in slightly lax knees [7, 17]. However, most of these studies did not intentionally increase the flexion gap, and little clinical research has been published to evaluate the above cadaver findings. Therefore, further investigation of the clinical effects of an intentionally increased flexion gap focusing on ROM, knee stability and patient-reported outcome measures (PROMs) is needed. The hypothesis of the current study was that increased flexion gap would result in increased postoperative flexion.

Materials and methods

Our analysis was based on data available from the TKA registry at the Kantonsspital St. Gallen (Switzerland). Consecutive patients from 2008 to 2012 who underwent primary TKA were prospectively followed and considered for this study. The study design was a retrospective analysis of the prospectively collected data. Inclusion criteria were: computer navigation (Vector Vision, CT-free, opto-electronic, passive marker navigation system, Brain-Lab, Munich, Germany), ligament balancing, primary TKA, the same type of prosthesis (mobile-bearing, posterior cruciate ligament (PCL) sacrificing prosthesis LCS, DePuy Low Contact Stress Complete Knee System, Leeds, UK), reported intraoperative flexion and extension gaps and complete medical record at 1-year follow-up. A total of 1110 knee replacements could be identified. Inclusion criteria were met in 404 knees (363 patients, 41 of them received bilateral TKA; Fig. 1). The knees were divided into two groups according to the difference between flexion and extension gaps. In 352 knees flexion gap exceeded extension gap by 2.5 mm (group 1), while 52 knees had equal flexion and extension gaps (group 2). The mean age of the patients at the time of the operation was 69 years (ranging from 50 to 89 years). There were 222 female (mean age 69, SD 10), and 141 male (mean age 69, SD 9) patients. The patients did not differ regarding age, sex distribution and preoperative ROM between the two groups.

The decision to create equal flexion and extension gaps or not was taken by the surgeon at the time of surgery. Measurements were obtained in extension and at 90° of flexion using the navigation system with a spring-loaded sensor tensor joint spacer (CAS Ligament Tensor DePuy Orthopaedics). The gaps after resection were confirmed manually with standard spacer blocks measuring 10 mm in extension and 12.5 mm in flexion for a 10-mm inlay. A gap difference of 2.5 mm was intentionally created in group 1. Most consultants at the department adopted the increased flexion gap protocol over the years, which explains the larger patient numbers in the first group.

ROM was measured using a goniometer with 1° scale, but the recorded results were rounded at 5° due to measurement and parallax error. Means have been calculated from those values and rounded to integer values, corresponding to the precision of the initial goniometer measurement scale. All measurements were taken by a single study nurse. The knees were further allocated according to maximal passive flexion: poor (<90°), satisfactory (91°–119°) or good (>120°). Anteroposterior stability was clinically evaluated at 90° of knee flexion by the study nurse and subdivided in tight (0–5 mm), middle (6–10 mm) and lax (>10 mm). Mediolateral stability was also clinically evaluated with the knee under varus and valgus stress at 30° of knee flexion. The knees were allocated into five groups: rigid (0°), firm (1°–5°), slightly lax (6°–10°), lax (11°–15°) and unstable (>15°) mediolateral opening.

The patient-reported outcome (PRO) was evaluated using the WOMAC score (Western Ontario and McMaster Universities Arthritis Index) [4] and the Forgotten Joint Score (FJS-12) [3]. The WOMAC is a widely used tool to determine outcome and consists of 24 questions covering 3 dimensions: pain (five questions), stiffness (two questions) and function (17 questions). The score ranges from 0 to 100 (higher scores indicating poor results). The FJS-12 is a recently published PROM to assess joint awareness in hips and knees during various activities of daily living [3]. It uses a five-point Likert response format, consisting of 12 equally weighted questions with the raw score transformed to range from 0 to 100 points. High scores indicate good outcome, i.e. a high degree of being able to forget about the affected joint in daily life. In its validation study [3] it showed a low ceiling effect and high internal consistency (Cronbach's ∝ 0.95) and discriminated well for well-functioning patients.

Informed consent was obtained from all individual participants included in the study. The study was approved by the Ethics Committee of Kanton St. Gallen (ref. no. EKSG 15/39).

Statistical analysis

Contingency tables were created to prove the interrelation between gap difference and postoperative flexion, and anteroposterior and mediolateral stability. Chi-square statistics were used to determine statistical significance (*p* value). The arithmetic mean, standard error and standard deviation were calculated for flexion measurements, FJS-12 and WOMAC scores, respectively. There was a 95 % confidence interval. The *F* test and *t* test were used for calculating the *p* value. Statistical significance was defined overall as p value <0.05.

Results

Range of motion

The mean postoperative flexion in group 1 was 115° ± 11°; in group 2: 113° ± 14° (n.s.). The knees were further subdivided according to the maximal passive postoperative flexion: poor (≤90°) satisfactory (91°–119°) good (≥120°). A significantly ($p = 0.006$) higher percentage achieved satisfactory (48.3 vs. 46.2 %) or good (48.3 vs. 40.4 %) flexion in group 1 compared to group 2 (Fig. 2). Thirty-four knees (9.7 %) had flexion contracture of 5° and 9 knees (2.6 %) flexion contracture of 10° in group 1. In group 2 there were 8 knees (15 %) with 5° and 1 knee (1.9 %) with flexion contracture of 10° (n.s., Fig. 3). There was an overall incidence of hyperextension of 2.7 %. In group 1 the incidence was 2.9 %, while in group 2 it was 1.9 % (n.s., Fig. 4).

Stability

One knee (0.3 %) showed sagittal translation of >10 mm, five (1.4 %) 6–10 mm and 346 (98.3 %) <5 mm in group 1. In group 2 this was 0, 2 and 98 %, respectively (n.s., Fig. 5). Mediolateral laxity of 1°–5° in group 1 was 87 and 85 % in group 2. Eight knees (2.3 %) showed mediolateral laxity of 5–10° in group 1 and none in group 2 (n.s., Fig. 6).

PROMs: WOMAC and FJS-12

The WOMAC and FJS-12 were assessed 1 year postoperatively. The mean WOMAC score was 11 for group 1 and 14 for group 2 with a 95 % confidence interval. There was no statistical significance (n.s.). The FJS-12 was significantly higher in group 1 (73) than in group 2 (61; $p = 0.02$; Fig. 7, Table 1).

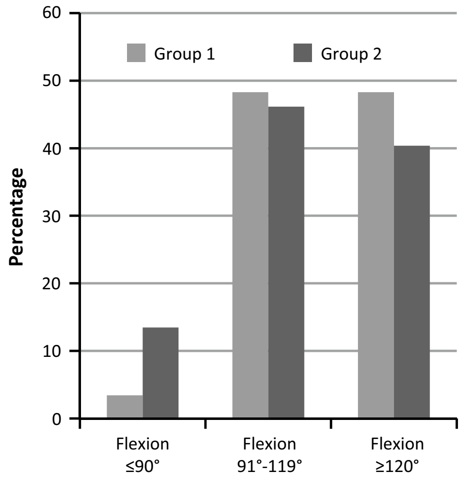

Fig. 2 Postoperative flexion

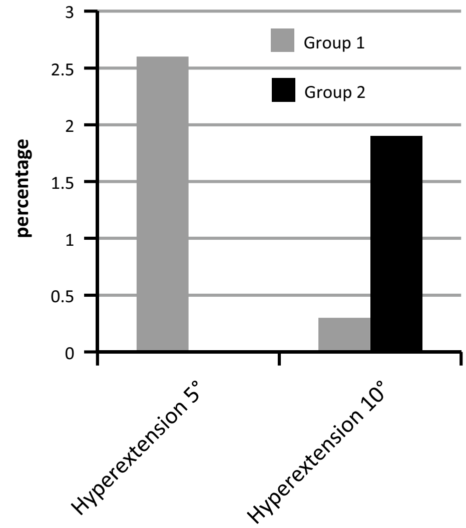

Fig. 4 Hyperextension

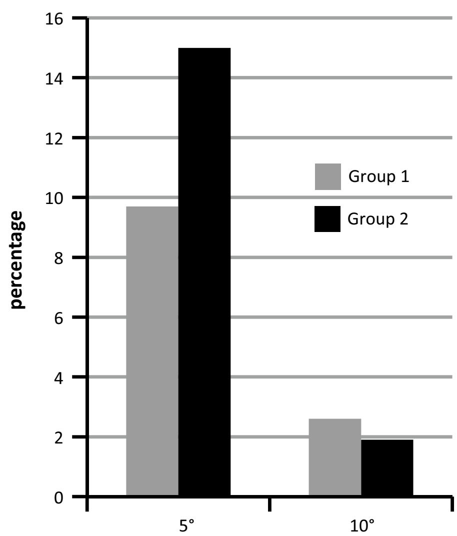

Fig. 3 Flexions contracture

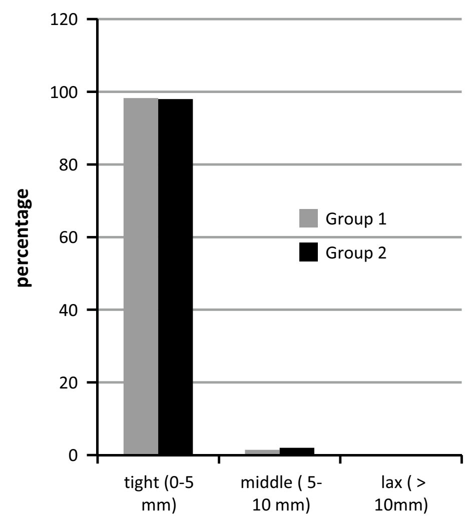

Fig. 5 Anteroposterior stability

Discussion

The most important finding of the present study was that controlled increase in flexion gap resulted in better ROM and improved PRO when measured with the FJS-12.

Equal flexion and extension gaps are considered the ultimate goal in TKA surgery. This paradigm was also incorporated into the design of most computer navigation systems and patient-specific instruments. Although navigation has enhanced the accuracy of the component position and overall leg alignment [13, 16], it did not improve patient satisfaction or ROM in most studies [12, 18]. Latest techniques including partially navigated modified gap-balancing techniques [2], PCL preservation [25] and newer implants like custom fit [23] or high-flex implants [1] could not achieve a significant improvement in PRO or ROM either.

In a clinical comparative study on bilateral TKAs, Kuster et al. [17] showed that patients favoured the laxer to the tighter knees, indicating that a certain laxity in TKA might feel more normal. This lead to a cadaver study [15], which showed that increased flexion gap could have a positive effect on postoperative flexion and ligament strain without affecting knee stability. The present clinical study supports this biomechanical finding. Its novelty lies in being the first study presenting the clinical results of a "controlled" and intentional gap imbalance.

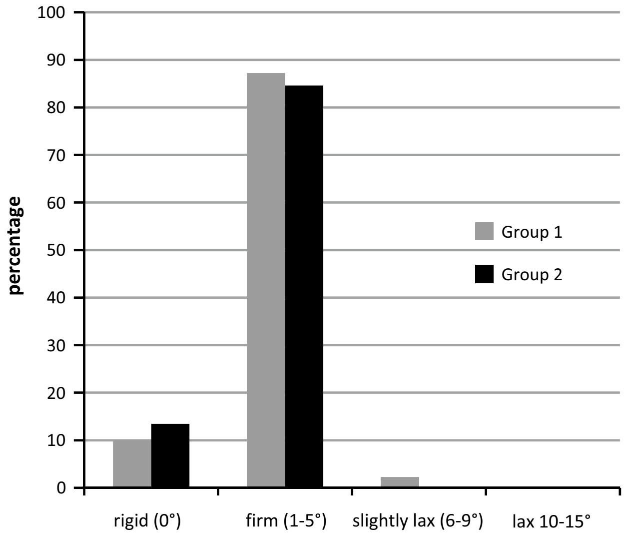

Fig. 6 Mediolateral stability

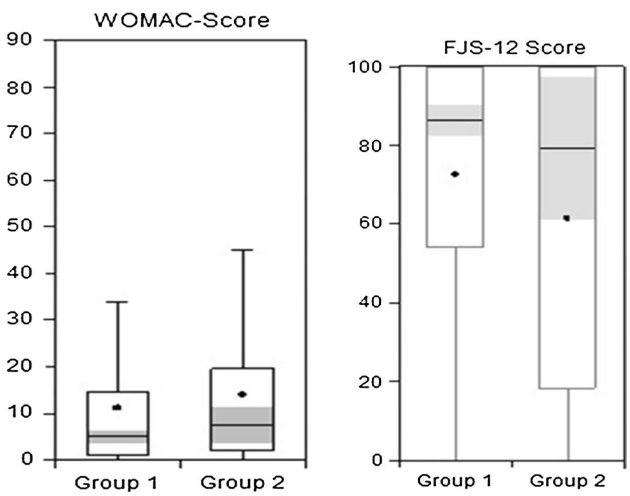

Fig. 7 Box plot for WOMAC and FJS-12 data

Table 1 Mean FJS-12 and WOMAC scores

	Group 1 (flexion gap > extension gap)	Group 2 (flexion gap = extension gap)	
FJS-12	73	61	$p = 0.02$
WOMAC score	11	14	n.s.

However, some prior reports on the impact of gap imbalance could not find a clear advantage of an increased flexion gap [9, 14, 20]. Minoda et al. [20] found no correlation between gap imbalance and knee flexion, while Higuchi et al. [14] found a positive correlation between gap difference and postoperative flexion but only for fixed-bearing knee prosthesis. Fujimoto et al. [9] reported no significant influence of increased flexion gap in postoperative WOMAC score. Possible explanations for the conflicting results are operative technique, design and different outcome parameters.

Regarding operative technique, in the two randomized controlled studies by Higuchi et al. [14] and Minoda et al. [20] the gap difference was not the primary outcome parameter but rather a secondary observation in cases of non-optimal balance. The gap difference was either small 0.8 mm (±1.3 for mobile-bearing and ±1.9 for fixed-bearing group) [20] or the gaps were not symmetrical in the medial and lateral joint spaces [14]. In both studies the gap difference was not a primary intraoperative goal, while in the present study the difference was intentional and with appropriate adjustments to the bone cuts and navigation-controlled ligament balancing over the whole ROM. Hence, the patients in group 1 always showed a flexion gap difference of 2.5 mm, which was symmetrical at the medial and lateral joint spaces.

Concerning prosthesis design, the biomechanical investigation [15] as well as the present data is only valid for a PCL sacrificing, mobile-bearing prosthesis with deep-dished high conforming inlay, such as the LCS mobile-bearing prosthesis (DePuy Low Contact Stress Complete Knee System, Leeds, UK). Higuchi et al. [14] used a PCL retaining prosthesis (P.F.C. DePuy Orthopaedics Inc., Warsaw, IN, USA) as did Fujimoto et al. [9] (Scorpio NRG CR TKA System, Stryker Orthopaedics, Mahwah, NJ), while Minoda et al. 2014 [20] investigated a posterior stabilized prosthesis (Vanguard PS for the fixed-bearing group and Vanguard RP for the mobile-wearing group) with a post-cam mechanism.

Evaluating the gap impact on flexion, Higuchi et al. [14] (116° ± 14°) and Minoda et al. [20] (129° ± 10°) compared mean values for postoperative flexion and did not find a significant correlation to gap difference for mobile-bearing prosthesis. However, the analysis of the mean value for postoperative knee flexion might not fully represent the influence of the gap difference. In the present study, the number of patients achieving a satisfactory or good ROM was statistically significant but not the difference in mean passive flexion. It is well known that patients with a ROM below 100° experience problems in daily activities such as stair climbing, squatting or even sitting. Hence it is an important finding that fewer patients with increased flexion gap were in this unsatisfactory flexion group.

The fear that a greater flexion gap could result in instability in deep flexion was not confirmed and postoperative knee laxity did not differ between the two groups. Slight laxity could be favourable as it has been shown to improve patient-reported results [7, 17].

Finally the appropriate choice of outcome measurements seems to be important to distinguish between well and very well-functioning knee replacements. An interesting finding of this study was that we could measure a significant ($p = 0.02$) improvement of PRO evaluated with the FJS-12, which could not be detected by the WOMAC score. Even though results for patients with higher flexion gap tended to be slightly better in the WOMAC score (11 vs. 14), this difference was not statistically significant ($p = 0.22$). In the 2015 study of Fujimoto et al. [9] the influence of gap difference in PRO was examined as well. The total WOMAC score, while also smaller for patients with increased gap (17 vs. 22), showed no statistical significance, which agrees with our results.

The FJS-12 on the other hand was able to detect subtle subjective differences in favour of the higher flexion gap group. This quality of FJS-12 has already been acknowledged and discussed in other studies [3, 11, 26]. The FJS-12 was found to be a more responsive and discerning measure for PRO [26]. The reason for the increased discriminatory power of FJS-12 in well-performing patients probably indicates that it is a more sensitive construct. A "forgotten joint" (i.e. the lack of awareness of the affected joint during various activities of daily living) is very hard to accomplish [11], and therefore, there is a lower ceiling effect compared to other scores such as WOMAC [3]. The difference between the two groups in the present study was more than 10 points, which we consider a clinically relevant improvement.

The present study has several limitations. The group allocation of the knees was not randomized. The decision was made by the surgeon at the time of surgery without specific criteria. Furthermore, most surgeons at our department have adopted an increased flexion gap for their routine knee arthroplasty. Hence the difference in size between the two groups was considerable, which could have skewed the results. Regarding measurement techniques, the anteroposterior stability was measured clinically rather than with a knee laxity testing device, which reduces the objectivity of the measurements. It is, however, noteworthy that all measurements were taken by a single study nurse. The follow-up was 1 year only. This period should be enough for the majority of the patients to reach their maximum flexion [22, 24], as well as to reach an almost final stable condition regarding patient satisfaction and knee stability [8]. A longer follow-up might be necessary to establish the safety of such surgical technique changes. Finally the results are valid for a specific prosthesis design only (deep-dish mobile-bearing). Therefore, the results of the current study require further validation in randomized trials for different surgical designs and long-term follow-up.

Conclusions

The clinical relevance of this study is that it provides additional evidence for the importance of controlled flexion gap increase as one factor to improve flexion and PRO after a PCL sacrificing deep-dish TKA.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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