



Original Research

Predictive Gap-balancing Reduces the Extent of Soft-tissue Adjustment Required After Bony Resection in Robot-assisted Total Knee Arthroplasty—A Comparison With Simulated Measured Resection

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ABSTRACT

Background: To understand the extent and frequency of soft-tissue adjustment required to achieve mediolateral (ML) balance in measured resection (MR) vs gap-balancing (GB) total knee arthroplasty, this study compared ML balance and joint laxity throughout flexion between the 2 techniques. The precision of predictive GB in achieving ML balance and laxity was also assessed.

Methods: Two surgeons performed 95 robot-assisted GB total knee arthroplasties with predictive balancing, limiting tibial varus to 3° and adjusting femoral positioning to optimize balance. A robotic ligament tensioner measured joint laxity. Planned MR (pMR) was simulated by applying neutral tibial and femoral coronal resections and 3° of external femoral rotation. ML balance, laxity, component alignment, and resection depths were compared between planned GB (pGB) and pMR. ML balance and laxity were compared between pGB and final GB (fGB).

Results: The proportion of knees with >2 mm of ML imbalance in flexion or extension ranged from 3% to 18% for pGB vs 50% to 53% for pMR ($P < .001$). Rates of ML imbalance >3 mm ranged from 0% to 9% for pGB and 30% to 38% for MR ($P < .001$). The mean pMR laxity was 1.9 mm tighter medially and 1.1 mm tighter laterally than pGB throughout flexion. The mean fGB laxity was greater than the mean pGB laxity by 0.5 mm medially and 1.2 mm laterally ($P < .001$).

Conclusion: MR led to tighter joints than GB, with ML gap imbalances >3 mm in 30% of knees. GB planning improved ML balance throughout flexion but increased femoral posterior rotation variability and bone resection compared to MR. fGB laxity was likely not clinically significantly different than pGB.

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Introduction

Poor outcomes and revision in total knee arthroplasty (TKA) have been associated with mediolateral (ML) soft-tissue imbalance [1]. Measured resection (MR) remains the most prevalent technique in TKA despite its reliance on the highly subjective process of manually releasing the soft tissue to achieve ML balance [2]. Gap

balancing (GB), conversely, is a TKA technique which uses the soft-tissue envelope to drive femoral component alignment to achieve ML balance and has been shown to reduce soft-tissue releases [3–6]. The amount of soft-tissue release required to achieve ML and flexion-to-extension (FE) balance after bone resection when performing MR TKA is a fundamental question which has not been fully explored.

Simulation is the only way to directly compare 2 TKA techniques on individual patients. Previous work has simulated TKA using a combination of patient-specific computed tomography data and soft-tissue estimations from the literature [7,8]. However, no studies have been performed using patient-specific soft-tissue

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laxity data to simulate TKA, likely because quantifying soft-tissue laxity has historically been highly invasive [9]. Recently, robotic instrumentation has been introduced, which can quantify joint laxity throughout the arc of flexion [10]. This technology can be used to simulate various surgical techniques on individual patients to explore their effects on joint laxity and balance. This is important clinically as small changes in balance and laxity have been correlated with significant differences in TKA clinical outcomes [11]. A better understanding of how implant alignment impacts soft-tissue balance and laxity can improve intraoperative decision-making.

This study, therefore, aimed to compare how operative planning for MR and GB techniques impact ML balance, FE balance, and joint laxity throughout flexion using intraoperative joint laxity data collected under controlled ligament loading in robot-assisted TKA. This study also reports on the ability of a predictive balance algorithm to predict final laxity using GB. It is hypothesized that ML balance, FE balance, and laxity will be more neutral and less variable in planned GB (pGB) than in simulated planned MR (pMR). Finally, it is hypothesized that ML balance and laxity will be similar between pGB and final GB (fGB).

Material and methods

Patients

Ninety-five consecutive robot-assisted GB TKAs performed by 2 surgeons at 2 centers were retrospectively reviewed after obtaining ethics approval from an independent institutional review board (Bellberry Ltd. approval no. 2020-08-764-A-1). The indication for TKA for all patients was end-stage osteoarthritis. The mean age was 73 ± 9 years, with a BMI of 30 ± 5 kg/m². Thirty-six percent of patients were female. The mean preoperative flexion contracture was $6^\circ \pm 7^\circ$, while the mean preoperative varus alignment was $4^\circ \pm 5^\circ$. Cases were performed between March 2020 and June 2021.

Surgical technique

Both surgeons used the same robot-assisted TKA system with a predictive GB workflow (OMNIBotics; Corin Group, UK) and cruciate-retaining (CR) implant (Unity CR; Corin Group) for call cases. Both surgeons had 2–4 years of experience with surgical robotics in knee arthroplasty prior to this study. The knee was exposed through a parapatellar approach, optical tracking arrays

were fixed to the femur and tibia, and the bone anatomy was registered using imageless bone morphing 3D reconstructions. The preoperative kinematics, coronal deformity in the fully extended position, and the opening of the knee under manually applied varus and valgus stress throughout the range of motion were recorded by the robotic system. The tibial resection was then planned, limiting the resection to 3° varus depending on the correctability of the hip-knee-ankle angle under valgus stress. The tibial resection was performed using a navigated adjustable cutting guide, and the final resection achieved was stored by the system probe.

A digital joint tensioner (BalanceBot; Corin Group, UK) was then inserted into the joint to collect laxity data throughout flexion during an initial balance assessment with forces ranging from 70 to 90 N per side, as shown in Figure 1a [10,12]. These initial balance assessment data were used as an input for a predictive gap planning software program which virtually placed the femoral component, rendering a postoperative gap prediction throughout flexion. Femoral sizing, anteroposterior positioning, flexion, rotation, valgus, and distal and posterior resection depths were all adjusted by the operating surgeon to optimize ligament balance throughout the flexion cycle, as seen in Figure 2a. Femoral resections were then executed using the robotic cutting guide [12,13]. After femoral resection, the digital tensioner was inserted again to collect a final laxity assessment throughout flexion (Fig. 1b and c). Laxity was defined as the tibial insert thickness subtracted from the gap between the resected tibia and femoral component. Planned laxity was calculated using the tibial insert thickness selected during the femoral planning stage. Final laxity was calculated using the implanted tibial insert thickness.

Any bony recuts or soft-tissue releases performed beyond the normal exposure procedure were recorded.

MR simulation

MR was an ideal candidate for simulation because the workflow uses bony landmarks to reference all resections, which are accurately acquired using the surgical navigation system. pMR was performed for each of the 95 GB cases post-hoc by importing the intraoperative data into a dedicated simulation software tool that emulated the robotic system planning software (provided by the manufacturer of the robotic system). The tibial and femoral resections were then virtually performed using the robotic

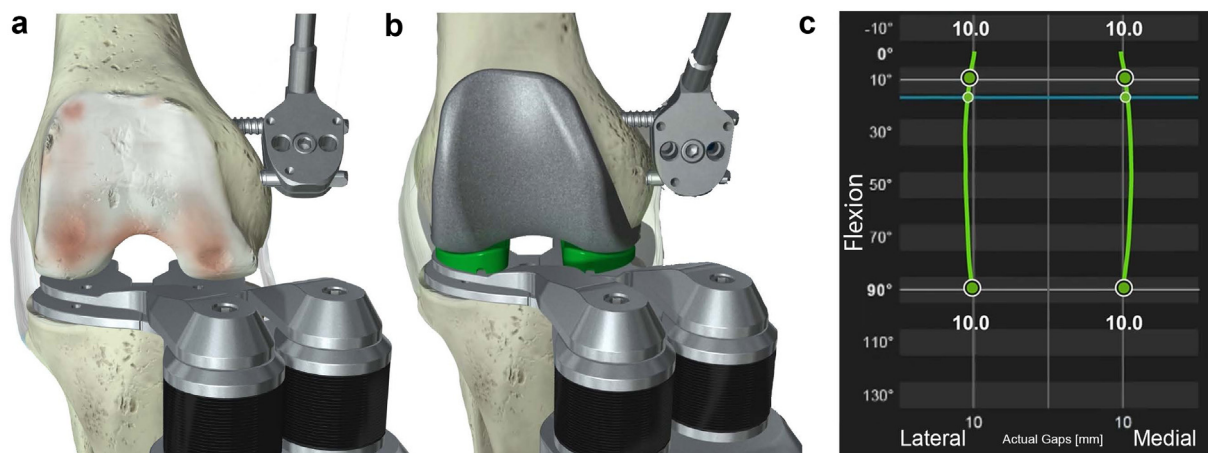


Figure 1. The digital joint tensioning device utilizes independent medial and lateral active spacing units which are controlled via the navigation system to measure joint gaps throughout the flexion range. Joint tension is selected by the surgeon. (a) Gap data collected after tibial resection are used for predictive balance. (b) Final gap data are collected with the femoral trial in place. (c) The system provides a visual representation of the joint gaps throughout the flexion range.



Figure 2. Femoral planning screens for pGB (a) and pMR (b). Femoral component adjustments are made using the computer system, and a predictive balance and laxity plan are provided throughout flexion.

system planning software. The tibial varus resection was set to neutral (0°) to the tibial mechanical axis. The default resection from the high side of the proximal tibia was set to the tibial implant construct thickness of 9 mm, and if necessary, it was increased to ensure a minimum of 2 mm was resected off the low side. Distal femoral valgus and external rotation were set to neutral (0°) to the mechanical axis and 3° external to the posterior condylar axis. The maximum distal and posterior femoral resections were set to the thicknesses of the femoral condyles of the implant. The thinnest tibial insert was selected by default. If medial and lateral laxities at 10° and 90° were all greater than 1 mm, the tibial insert thickness was increased until the laxity in at least 1 of the 4 regions was within 1 mm. The robotic planning software then provided the laxity data for pMR based on these virtual inputs (Fig. 2b).

Data analysis

Planned resection angles and depths were recorded for pGB and pMR. Medial and lateral extension and flexion space resections were calculated by combining the tibial and femoral resection depths from each compartment. Total extension and total flexion space resections were calculated by averaging the total medial and total lateral resections for each space.

ML balance, medial and lateral laxity, external femoral rotation, femoral valgus, tibial varus, medial and lateral resections from the proximal tibia, distal femur, and posterior femur were compared between pGB and pMR. Medial and lateral extension and flexion, along with total extension and flexion space resections, were also compared between pGB and pMR. ML balance and lateral and medial laxity were compared between pGB and fGB.

Statistical analysis

All data were considered normally distributed (Kolmogorov-Smirnov test of ML balance and resection thickness rejected alternative hypothesis, $P > .05$ in all cases). Welch's unequal variances t -tests, variance tests (F -tests), Chi-squared tests, and Fishers exact tests were used where appropriate in comparing balance and laxity among groups. Statistical analyses were conducted using the R Environment for Statistical Computing (version 4.1.0) [14]. Statistically significant differences are indicated in figures by “****”/“†††” = $P \leq .001$; “***”/“††” = $P \leq .01$; “**”/“†” = $P \leq .05$; with “*” and “†” denoting t - and F -tests, respectively. A prospective matched-pair means power analysis was performed. Using an alpha of 0.05, beta of 0.8, a joint gap balance standard deviation of 1.5 mm with equal sampling ratio, and a threshold joint balance difference of 0.75 mm, a minimum of 45 participants were required.

Results

pGB vs Simulated measured resection (pMR)

pMR had greater ($P \leq .030$) and more variable ($P < .001$) ML imbalance throughout flexion, with standard deviations at least 2 times greater than pGB (Fig. 3 and Table 1). This resulted in pMR having a higher percentage of knees with a planned ML imbalance >2 mm at 10° (53% vs 18%), 45° (46% vs 12%), and 90° (50% vs 3%) and >3 mm at 10° (38% vs 9%), 45° (34% vs 3%), and 90° (30% vs 0%), $P < .001$.

Because pMR showed greater imbalance than pGB, further analysis was performed to investigate the types of imbalances associated with this technique. pMR had more knees which were 2 mm tighter medially than laterally in extension and flexion ($P < .001$) (Fig. 4a). There were also more pMR knees where the lateral side was 2 mm tighter than the medial side in flexion ($P = .018$; Fig. 4a). pMR also had more knees with FE imbalance than pGB. pMR had more knees 2 mm tighter in extension than flexion medially and laterally ($P \leq .032$; Fig. 4b). There were also more pMR knees 2 mm tighter in flexion than extension medially and laterally ($P < .001$; Fig. 4b).

pGB laxity was greater but less variable than pMR medially and laterally throughout flexion ($P \leq .001$; Fig. 4a and Table 2). pGB laxity was tighter medially than laterally at 45° ($P = .001$), but not at 10° and 90° ($P = N.S.$). pMR laxity was tighter medially than laterally at 10° ($P = .017$), 45° ($P < .001$), and 90° ($P = .006$). The mean pMR medial laxity was at least 2 mm tighter than the implant construct throughout the range.

pGB planned to resect more tibial varus ($P < .001$), more distal medial femur ($P < .001$), and more posterior lateral femur ($P = .036$) than pMR (Table 3). pGB planned for more total resection than pMR from the medial extension space by 1.2 mm ($P = .003$) and from the total extension space by 0.5 mm ($P = .024$; Table 3).

Planned GB vs final GB

ML imbalance was similar between fGB and pGB at 10° and 45° ($P = N.S.$), but not at 90° where fGB was greater ($P = .007$), more

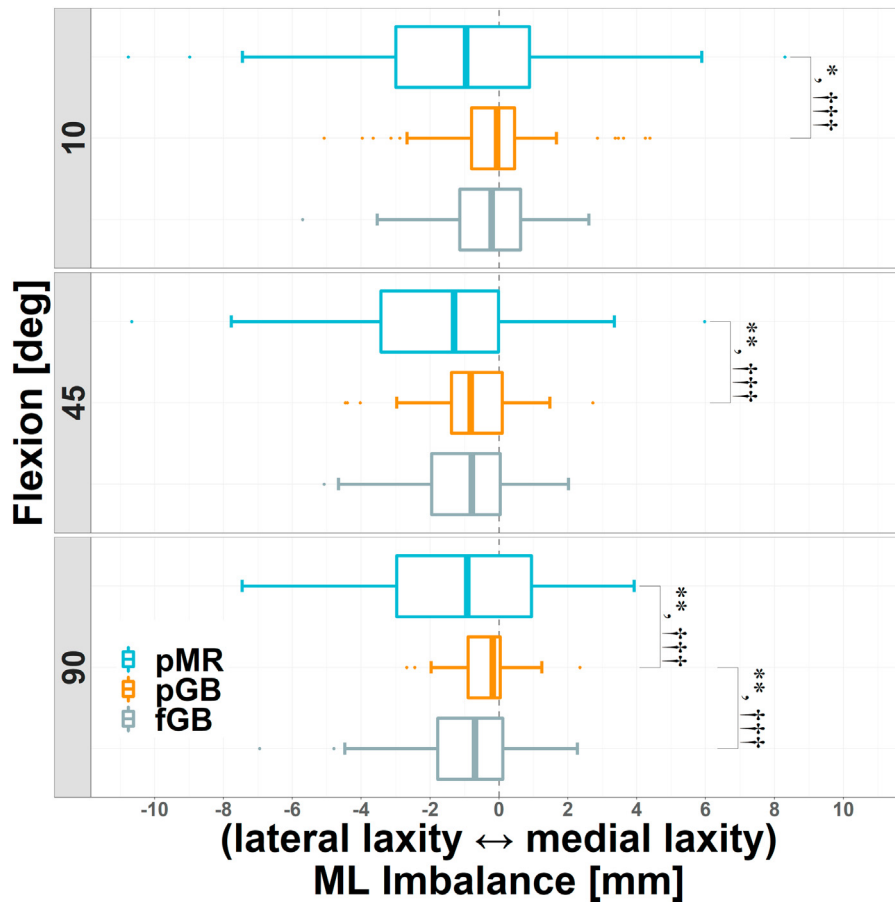


Figure 3. pMR (blue), pGB (orange), and fGB (gray) ML imbalance shown with negative values representing relative lateral laxity. */ $\dagger = P \leq .05$; **/ $\dagger\dagger = P \leq .01$; ****/ $\dagger\dagger\dagger = P \leq .001$.

Table 1
ML imbalance values, mean ± SD (range).

Flexion	pMR	pGB	fGB	pMR vs pGB		pGB vs fGB	
				t-test	F-test	t-test	F-test
10°	-1 ± 3.4 (-10.8 to 8.3)	-0.2 ± 1.6 (-5.1 to 4.4)	-0.3 ± 1.4 (-5.7 to 2.6)	0.030	< 0.001	0.590	0.301
45°	-1.7 ± 2.8 (-10.7 to 6)	-0.8 ± 1.2 (-4.5 to 2.7)	-0.9 ± 1.5 (-5.1 to 2)	0.004	< 0.001	0.394	0.048
90°	-1.2 ± 2.6 (-7.5 to 3.9)	-0.4 ± 0.8 (-2.7 to 2.4)	-0.9 ± 1.6 (-7 to 2.3)	0.005	< 0.001	0.007	< 0.001

Negative values indicate greater lateral ML imbalance. Bold values indicate statistical significance.

variable ($P < .001$), and had more knees with >2 mm of imbalance (21% vs 3%, $P < .001$; Fig. 3 and Table 1).

fGB laxity was greater than pGB medially and laterally at 10° ($P < .001$), 45° ($P < .001$), and 90° ($P \leq .026$; Fig. 5b and Table 2). fGB laxity was greater laterally than medially at 10° ($P < .001$) and 45° ($P < .001$) but not at 90° ($P = N.S.$). The mean fGB laxity was greater than pGB from 10° to 90° medially (0.7 ± 1.4 vs -0.2 ± 1.4 , $P < .001$) and laterally (1.6 ± 1.6 vs 0.4 ± 1.5 , $P < .001$; Fig. 5b).

Discussion

The most important findings of this study were that pMR had greater and more variable ML imbalance, more FE imbalance, and tighter and more variable laxity throughout flexion than pGB. Additionally, fGB laxity was consistently greater than pGB although this difference was on average within 1 mm.

The impact of prioritizing neutral alignment and relying on soft-tissue releases to achieve ML balance on outcomes remains controversial. Ponder et al. found that knees with soft-tissue releases reported significantly worse Knee injury and Osteoarthritis Outcome Scores at 6 months (symptoms, Activities of Daily Living, Quality of Life) and at 12 months (Activities of Daily Living), and Peters et al. showed that valgus knees with releases underperformed

(Knee Society Score) compared with those without releases [15,16]. In this study, pGB produced a more balanced soft-tissue envelope throughout flexion, while pMR had relative lateral imbalance throughout flexion. pMR also reported more patients with >3 mm of ML imbalance throughout flexion, occurring in 38% and 30% of knees in extension and flexion, respectively. Blakeney et al. reported similar results for MR with ML imbalances >3 mm in extension and flexion occurring in 33% and 34% of knees, respectively, [7]. In this study, 4 releases occurred in GB in 4 separate cases, 1 posterior capsule and 3 posterior cruciate ligament releases, for an overall release rate of 4% (4/95). The release rate for MR has been reported at over 60% in varus knees alone [17]. In a study of 101 MR TKAs performed with computer navigation, Meere et al. found that 63 incidences of soft-tissue releases were required to achieve ML balance following bone resection [18]. The pMR results indicate that more frequent soft-tissue releases would be required to achieve ML balance compared to pGB. Fifty-five percent (52/95) of pMR knees in the present study would require soft-tissue adjustment to be within 3 mm of ML balance at 10°, 45°, or 90°, compared to 11% (10/95) in pGB.

ML balance targets have been shown to directly affect patient outcomes. Keggi et al. showed improved Knee injury and Osteoarthritis Outcome Scores for GB posterior cruciate-sacrificing knees

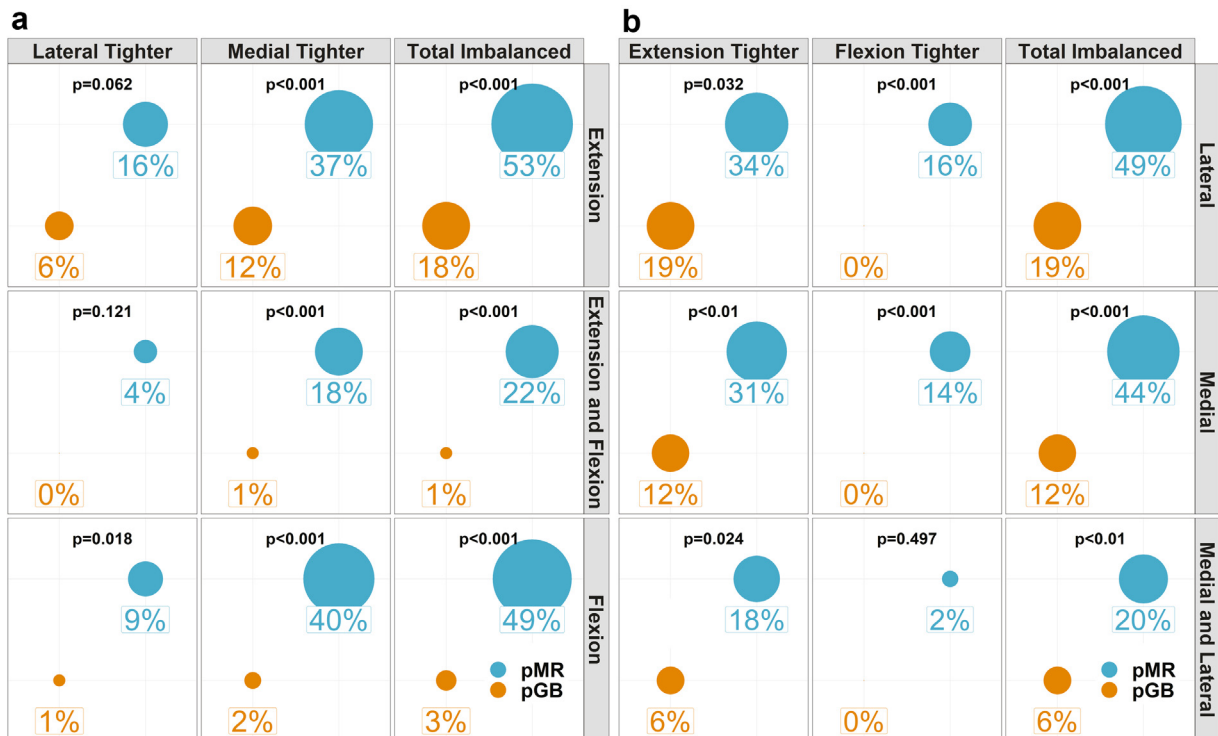


Figure 4. Bubble plots showing rates of ML (a) and FE (b) imbalance >2 mm for pGB and pMR. P values from Fisher's exact test.

Table 2
Lateral and medial laxity values, shown as mean \pm SD (range), and statistical test results for pGB, pMR, and fGB.

Flexion	Lateral laxity			pMR vs pGB		pGB vs fGB	
	pMR	pGB	fGB	t-test	F-test	t-test	F-test
10°	-2 \pm 2.8 (-8.5 to 6.8)	-0.7 \pm 1.8 (-7.7 to 4.2)	0.2 \pm 1.7 (-3.5 to 5.1)	<0.001	<0.001	<0.001	0.668
45°	-0.7 \pm 2.3 (-6.3 to 5.2)	0.5 \pm 1.6 (-5.7 to 4.9)	1.9 \pm 1.8 (-2.7 to 8.2)	<0.001	<0.001	<0.001	0.286
90°	-0.8 \pm 3 (-8.2 to 8)	0.3 \pm 1.4(-3.4 to 5.1)	1.3 \pm 1.8 (-2.6 to 5.3)	0.001	<0.001	<0.001	0.038
Flexion	Medial laxity			pMR vs pGB		pGB vs fGB	
	pMR	pGB	fGB	t-test	F-test	t-test	F-test
10°	-3 \pm 3 (-10.8 to 3.2)	-0.9 \pm 1.7 (-6.4 to 4.5)	-0.1 \pm 1.4 (-4.7 to 3.4)	<0.001	<0.001	<0.001	0.132
45°	-2.4 \pm 2.7 (-9.1 to 3.1)	-0.2 \pm 1.6 (-5.3 to 5)	1 \pm 1.5 (-2.8 to 4)	<0.001	<0.001	<0.001	0.697
90°	-2 \pm 2.8 (-7.8 to 5.4)	-0.1 \pm 1.3 (-4.8 to 5.3)	0.4 \pm 1.6 (-2.7 to 3.9)	<0.001	<0.001	0.026	0.044

Significant results shown in bold.

with ultracongruent inserts with ML imbalance <1.5 mm throughout the range [19]. In the present study, pGB had significantly less patients with <2 mm and <3 mm of ML imbalance throughout flexion compared to pMR. Without releases to improve the balance, the literature suggests that the pMR group would report worse outcomes. Keggi et al. used a cruciate-sacrificing technique with deep dish inserts which may not directly translate to the PCL-retaining CR knees in this study which may restore more native kinematics such as a looser lateral flexion gap [19–21].

Stiffness is a leading cause for poor joint function, patient dissatisfaction, and ultimately revision surgery following TKA [22–26]. Joint stiffness after TKA can result from excessive tension in the collateral ligaments. In this study, medial and lateral laxity throughout flexion were tighter and more variable in pMR than those in pGB. This indicates MR would require more frequent manual adjustments, either through bony recuts or soft-tissue releases, to avoid undesirable joint stiffness. The consistent laxity observed in pGB is likely due to the digital joint tensioner being used in combination with a predictive laxity algorithm which provides accurate joint gap data throughout flexion [10].

fGB laxity was greater than but consistently within 1 mm of pGB, which indicates the joint space may be opening during femoral resection. This could be due to several factors such as osteophyte removal and soft-tissue distraction [27]. Bellemans et al. also showed that stress relaxation occurs during TKA, which can increase the mean laxity by 1 mm medially and laterally [28]. However, a 1-mm difference in overall laxity is likely not clinically significant. This is supported by research showing that while small

differences in insert thickness may affect outcomes at 4 months, no differences in outcomes were observed after 12 months [29].

This study has limitations. Retrospective analyses are susceptible to various biases. To limit these, a consecutive group of TKA patients were selected from both surgeons. Another limitation of this study was the potential of surgeon-specific technique preferences affecting the results. However, both surgeons used a standardized technique with the same robotic system and the same CR implant. The optimal distraction force for evaluating laxity and balance is unknown, and therefore, the 70–90 N range used in the present study is a limitation. Patient-specific distraction forces based on individual ligament properties may be more suitable. However, 70–90 N has been demonstrated to be safe clinically and has been confirmed to result in suitable postoperative stability by experienced surgeons [30,31]. A limitation, but also a strength, was that 1 single-radius implant was used by both surgeons. Consequently, the results may not be replicated using multiradius implant designs. Finally, the results from pMR were reported without considering soft-tissue releases which would directly impact final laxity and balance. Because of this, pGB was used as the comparator instead of fGB, as pGB also excludes the effects of final soft-tissue releases.

This is the first study to compare ML balance and laxity between two TKA techniques by performing one and simulating another using patient-specific laxity data. pMR was less balanced and had a higher percentage of knees requiring soft-tissue adjustment to balance the joint within 2 mm and 3 mm, compared to pGB. fGB laxity and balance were not likely clinically significantly different

Table 3
Tibial, femoral, and total/combined resection values, shown as mean \pm SD (range), for pGB and pMR with t- and F-test P values.

Measure	pGB	pMR	t-Test	F-Test
Tibial varus (°)	1 \pm 1 (-1.2 to 3)	0 \pm 0 (0-0)	<0.001	<0.001
Lateral tibia (mm)	8.7 \pm 2.2 (2 to 13.1)	9.1 \pm 1.7 (2.9-15)	0.162	0.025
Medial tibia (mm)	6.1 \pm 2 (-1.4 to 10.2)	5.6 \pm 2.5 (1.7-9)	0.152	0.037
Femoral valgus (°)	0.1 \pm 2 (-4 to 7)	0 \pm 0 (0-0)	0.759	<0.001
External femoral rotation (°)	3.1 \pm 2.4 (-4 to 8)	3 \pm 0 (3-3)	0.796	<0.001
Distal lateral femur (mm)	7.5 \pm 2 (2 to 12)	7.3 \pm 2 (0.5-9)	0.539	0.898
Distal medial femur (mm)	9 \pm 1.1 (6 to 12)	8.3 \pm 1.2 (2.8-9)	<0.001	0.393
Posterior lateral femur (mm)	7.3 \pm 2.2 (2 to 13)	6.8 \pm 0.3 (5.9-7.7)	0.036	<0.001
Posterior medial femur (mm)	9.5 \pm 1.2 (7 to 13)	9.5 \pm 0.4 (8.6-10.7)	0.954	<0.001
Total extension lateral (mm)	16.2 \pm 3.2 (4.2 to 22.6)	16.4 \pm 3.2 (3.7-23)	0.706	1.000
Total extension medial (mm)	15.1 \pm 2.3 (7.6 to 19.1)	13.9 \pm 3.2 (5.5-18)	0.003	0.005
Total flexion lateral (mm)	16 \pm 3.1 (6.6 to 22.1)	15.9 \pm 1.7 (10-21.7)	0.822	<0.001
Total flexion medial (mm)	15.6 \pm 2.1 (8.6 to 19.2)	15.2 \pm 2.4 (10.9-19.1)	0.168	0.226
Total extension (mm)	15.7 \pm 1.8 (10.3 to 20.2)	15.2 \pm 1.3 (10.9-17.7)	0.024	0.001
Total flexion (mm)	15.8 \pm 2 (10.4 to 20.2)	15.5 \pm 1 (13.6-17.4)	0.233	<0.001

Significant results shown in bold.

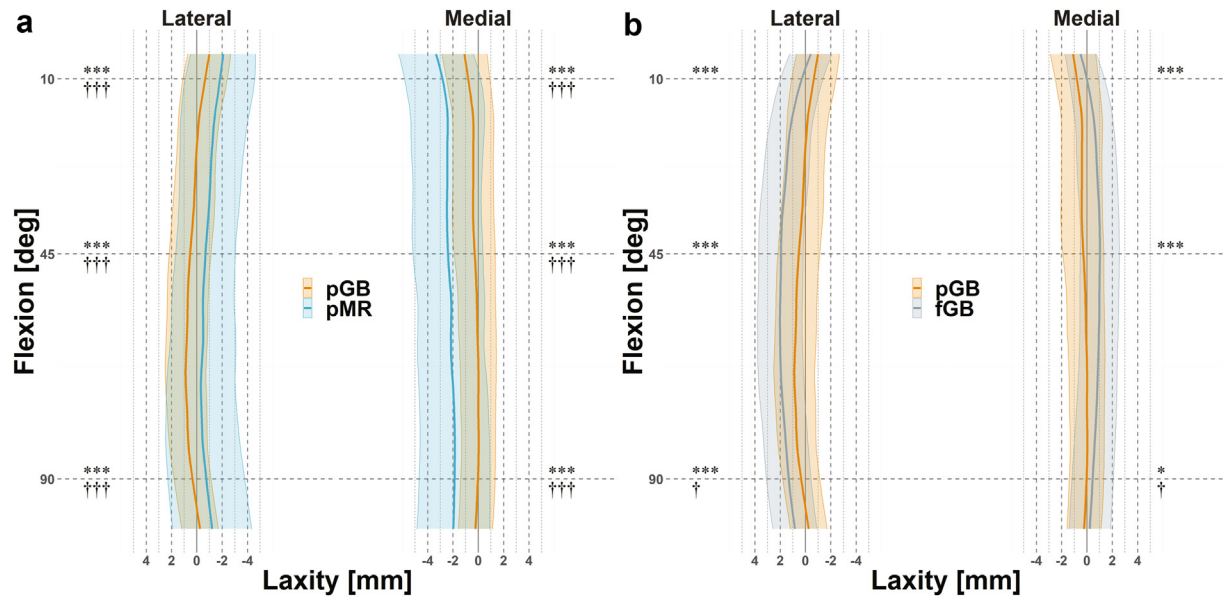


Figure 5. (a) Laxity profile comparison between pGB (orange) and pMR plan (blue). (b) Laxity profile comparison between pGB and fGB (gray). Solid lines represent mean laxity, and shaded areas represent ± 1 SD. */† = $P < .05$; **/†† = $P < .01$; ***/††† = $P < .001$.

than pGB. The results highlight the variability in ML balance and FE balance, as well as the increased tightness and variability in laxity associated with MR. These are valuable data for clinicians as they show just how sensitive ML balance and laxity are to surgical technique.

Conclusions

ML imbalance was greater and more variable in pMR than in pGB. At least 30% of pMR knees were projected to require soft-tissue adjustment to balance the joint within 3 mm, which was significantly more than the number of pGB knees. Laxity was tighter and more variable in pMR than in pGB. Despite fGB laxity being consistently greater than pGB, the difference was not likely clinically significant.

Conflicts of interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: A. D. Orsi is a paid employee of Corin Group. C. Plaskos is a paid employee of Corin USA and Omni, has stock or stock options in Corin USA and Omni, and is a part of the International Society of Computed Assisted Orthopedic Surgery Annual Meeting Scientific Review Committee. E.A. Wakelin is a paid employee of Corin Ltd. J. Sullivan receives royalties from; is in the speakers' bureau of or gave paid presentations for; and is a paid consultant for Corin. J. Sullivan has stock or stock options in Johnson & Johnson and Stryker. S. Gupta is in the speakers' bureau of or gave paid presentations for Corin, Stryker and Johnson & Johnson; is a paid consultant for Corin and Johnson & Johnson; receives research support from Corin and Stryker; is in the editorial or governing board of the Journal of American Orthopaedic Surgeons (JAAOS) and The Bone & Joint Journal (BJJ); and is an NSW Orthopaedic Association Executive Board Member.

For full disclosure statements refer to <https://doi.org/10.1016/j.artd.2022.03.025>.

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