Navigational predictors in determining the necessity for collateral ligament release in total knee replacement

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The requirement for release of collateral ligaments to achieve a stable, balanced total knee replacement has been reported to arise in about 50% to 100% of procedures. This wide range reflects a lack of standardised quantitative indicators to determine the necessity for a release. Using recent advances in computerised navigation, we describe two navigational predictors which provide quantitative measures that can be used to identify the need for release. The first was the ability to restore the mechanical axis before any bone resection was performed and the second was the discrepancy in the measured medial and lateral joint spaces after the tibial osteotomy, but before any femoral resection.

These predictors showed a significant association with the need for collateral ligament release (p < 0.001). The first predictor using the knee stress test in extension showed a sensitivity of 100% and a specificity of 98% and the second, the difference between medial and lateral gaps in millimetres, a sensitivity of 83% and a specificity of 95%. The use of the two navigational predictors meant that only ten of the 93 patients required collateral ligament release to achieve a stable, neutral knee.

The achievement of balance in total knee replacement (TKR) requires careful bony resection and appropriate soft-tissue release. Failure to release contracted ligaments adequately may result in instability and secondary accelerated wear of the components. This may account for the recommendation that collateral ligament release should be performed for all TKRs undertaken without navigation. Others have suggested, however, that soft-tissue release is necessary only in 50% to 76% of TKRs. This wide range reflects the lack of quantitative data for defining the necessity for such ligament release. Poorly-judged excessive release could also result in instability.

With recent advances in computerised navigation software, quantitative measures for soft-tissue balancing, the identification of the mechanical axis and the range of movement in the knee during the operation are available in real time. It has been shown that alignments to within 1° and soft-tissue balance within 1 mm are attainable. We have investigated the ability of these real-time data to indicate the need for and extent of any ligament release without recourse to extra bony resection or compromise of alignment in TKR.

Patients and Methods
We enrolled 100 consecutive patients in the study irrespective of weight, severity of deformity or age. They had advanced arthritis of the knee and CT-free, OrthoPilot 4.2 (Aesculap, Tuttlingen, Germany) computer-assisted navigated primary TKR was planned. All patients gave informed consent approved by the Institutional Review Board. Seven patients were excluded, five because the operation was cancelled and two because of incomplete collection of data. This left 93 patients in the study. All had end-stage arthritis of the knee; three had rheumatoid, one systemic lupus and 89 osteoarthritis. There were 87 men and six women with a mean age of 68 years (44 to 85) and a mean body mass index of 36 (18 to 50). The Columbus TKR (Aesculap) with a deep dished polyethylene insert, designed to accommodate both the cruciate-sacrificing and cruciate-retaining techniques, was used for all patients. However, we preserve the PCL initially and released it only when deemed necessary for balance. In eight (8.6%) the posterior cruciate ligament was sacrificed.

The pre-operative deformity was determined before the first bone cut using computerised navigation to define the mechanical axis. The system used a non-image kinematics analyser to locate the centre of the hip, knee and ankle by active optical localisers attached to temporary femoral and tibial bicortical screws approximately 12 cm from the joint line, using two infrared cameras attached to a computer.
and a monitor. The axes were defined as varus in 66 patients and valgus in 27 with an overall range of 18° of varus to 13° of valgus.

We defined stable knee in extension as having a medial to lateral unidirectional deflection angle of ≤ 2° from a mechanical axis of 0°, or a total arc of ≤ 4°. A neutral knee was defined as having a mechanical axis of 0° ± 2° which included a possible computerised navigation error of ± 1°.

Utilising this protocol, two navigational predictors were used to determine whether they could accurately reflect the need for release of a collateral ligament and still achieve a stable neutral TKR. The first was used when a medial/lateral stress test could not correct the pre-operative varus/valgus deformity. The stress testing was performed before the skin incision had been made. The surgeon stressed the knee and attempted to correct the deformity to a reading of 0° on the computerised navigation. If such a reading could not be achieved, the deformity was deemed to be uncorrectable. At this stage large osteophytes may prevent correction giving a false-positive reading for the first predictor. However, once these are excised, and a repeat test indicates that the deformity is correctable, this may be taken to predict that collateral ligament release is not necessary.

The second predictor was used after all the osteophytes had been removed, the first predictor had been evaluated, and the proximal tibial osteotomy performed at 0° in the coronal and sagittal planes, but before resecting the femur. In this second step collateral ligament release was considered to be necessary when the difference between the medial and lateral gap measured ≥ 5 mm. A Ligament Tensioner (Braun, Tuttlingen, Germany) with two independent pads was used to measure the medial and lateral gaps in extension and at 90° of flexion. It was predicted that when the lateral gap was greater than the medial by > 4 mm, that is a difference between the gaps ≥ 5 mm, the medial collateral ligament would require release in a progressive manner until the gaps became equal. Similarly, when the medial gap was greater, the lateral collateral ligament would require release in a step-like fashion. The computer demonstrated that when the difference between the medial and lateral gaps in extension was not > 4 mm, a mechanical axis of 0° was achievable with a total deflection arc of ≤ 4° in keeping with the definition of a neutral, stable knee. However, to balance a discrepancy in the medial and lateral gaps at 90° of knee flexion, when the difference between the medial and lateral gaps was ≤ 4 mm, adjustment of femoral rotation of ≤ 5° was undertaken to equalise the gaps and to correct the deformity without any collateral ligament release and without additional bony resection. This intervention was referred to as adjusted femoral resection. Any femoral external rotation was restricted to ≤ 5° to avoid deleterious effects on patellar tracking. If by adhering to this protocol the difference in the medial and lateral flexion gaps remained ≥ 5 mm, a collateral ligament release was undertaken to avoid notching or maltracking of the patella which would otherwise occur with high angles of external rotation of the femoral component.

Any discrepancy in the flexion and extension gaps may be corrected by femoral resection, because the proximal tibial cut affects both gaps, while the distal femoral cut determines the extension gap. In addition, the size of the femoral component selectively determines the flexion gap. Therefore, a larger femoral component can be used to fill a larger gap at 90° of flexion to match a smaller gap found at full extension without overfilling the joint and disrupting patellar tracking. Conversely, a smaller femoral component could be used to increase the flexion gap to balance a larger extension gap without any alteration in the extension gaps. Flexion-extension gap asymmetry was accepted if it was restored to within 2 mm.

Using the navigated distal femoral cutting block without any intra-medullary component, each degree of external rotation with the knee flexed at 90° would produce an increase of 1 mm to 2 mm in the medial flexion gap, with or without an equivalent decrease in the lateral gap and vice versa for internal rotation of the cutting block. Following this method if asymmetry persisted between the medial and lateral sides of more than 4 mm (≥ 5 mm) then collateral ligament release was required according to the techniques of Whiteside8 and Matsueda et al,14 while monitoring the effect using the computerised navigation to avoid excessive release. This is described in detail in Figure 1.

Collateral ligament release was considered to be complete once a mechanical axis of 0° was obtained in full extension, which itself was recorded with the leg elevated and supported by the heel. Full flexion was recorded by placing the hips into maximum flexion and allowing the knee to flex fully under the influence of gravity. All the measurements were performed under the supervision of the senior author (SH) who was experienced in navigated TKR. Data obtained from the OrthoPilot software, were recorded on a computer spreadsheet (Excel, Windows XP, Microsoft, Redmond, Washington).

Statistical analysis. Multiple logistic regression was performed on the data obtained for patients requiring collateral ligament release with navigational predictor 1 and navigational predictor 2 using SigmaStat version 2.03 software (SPSS Inc., Chicago, Illinois) with statistical significance set at p ≤ 0.05. The likelihood ratio test statistic was calculated to assess model agreement with the data. A 2 × 2 contingency table was constructed for each predictor with the number of patients for collateral release indicated or not indicated in rows, and columns for collateral ligament release performed or not performed. The sensitivity, specificity and the positive predictive and negative predictive values were calculated using an internet-based program, Stats Calculator, Toronto, Canada) (Tables I and II).

Results
All 93 patients were aligned and balanced post-operatively irrespective of the severity of the pre-operative deformity. Following the protocol, as indicated by the predictors, only ten (10.75%) required collateral ligament release.
The stress predictor, if relied on alone, identified 12 patients with uncorrectable deformity requiring ligament release. However, after excision of the osteophytes full correction was achieved in two of these 12 patients when the stress test was repeated (Table I).

The difference in measured medial and lateral gaps in both extension and flexion, as determined by the Ligament Tensioner device as a predictor indicated that 14 of the 93 patients would need a release since these patients had a difference in their gaps of ≥ 5 mm. However, four of the 14 patients had grossly abnormal femoral condyles, in two because of hypoplasia of the lateral femoral condyle, in one because of malunion of the medial femoral condyle and in one because of marked bony defects from osteochondritis desicicans affecting the medial femoral condyle. Since adjusted femoral resection corrected these deformities, no collateral ligament release was necessary and these four patients may be considered to have false-positive results using this predictor of a ligament release. Again, this resulted in ten of 93 patients with asymmetrical medial and lateral gaps of ≥ 5 mm which needed ligament release. However, we noted two patients who had a difference in the medial and lateral gaps of < 5 mm but they had an uncorrectable deformity in extension and required collateral ligament release. These two patients were considered to have false-negative results. The sensitivity and specificity of predictor 1 were 100% and 98%, respectively and for predictor 2, 83% and 95%, respectively. Therefore, the predictors were reliable and accurate as long as bone-deforming factors were taken into consideration.

Multiple logistic regression showed agreement of predictor 1 (correlation coefficient 20.639) and predictor 2 (correlation coefficient 0.565) and the outcome of the collateral ligament release performed at operation (likelihood ratio test statistic 51.556, p < 0.001). The odds ratio (OR) for predictor 1 approached infinity with a 95% confidence interval (CI) of 0.00 to infinity. For predictor 2, the OR was 0.569 with a 95% CI of 0.00518 to 62.36. In other words the logistic regression model showed a statistically significant association between the use of the navigational

** performing the release 2 cm at a time while monitoring the mechanical axis by the computer until zero mechanical axis is achieved.

*** Every degree of femoral rotation approximates to 1 mm to 2 mm of gap correction. External rotation of the femoral component will increase the medial flexion gap. Internal rotation of the femoral component will increase the lateral gap.

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**Table I.** Sensitivity and specificity of predictor 1 in a 2 × 2 Table

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**Table II.** Sensitivity and specificity of predictor 2 in a 2 × 2 Table

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Fig. 1

Flow chart showing the sequence of collateral ligament release (second predictor) in a) varus and b) valgus knees (Δ, difference between; MCL, medial collateral ligament; LCL, lateral collateral ligament; M, medial; L, lateral).

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**Fig. 1**

Flow chart showing the sequence of collateral ligament release (second predictor) in a) varus and b) valgus knees (Δ, difference between; MCL, medial collateral ligament; LCL, lateral collateral ligament; M, medial; L, lateral).
predictors and the need for collateral ligament release to obtain a correctly aligned balanced TKR.

For all 93 patients the mechanical axis was restored to $0^\circ \pm 2^\circ$ (SD 0.11) which represented a change from the pre- to post-operative alignment of a mean of 3.11° (SD 5.7; Fig. 2). Additionally all patients showed improvement in extension and flexion with a mean improvement in extension of 4.14° (SD 3.5) and in flexion of 10.07° (SD 6.23; Fig. 3). The post-operative varus/valgus stress test for stability of the knee performed at the end of the operation showed a mean medial/lateral unidirectional deflection in extension of 1.43° ($0^\circ$ to $4^\circ$ total arc) from the mechanical axis of $0^\circ$.

**Discussion**

The success of TKR depends on many variables, with soft-tissue balancing being both the most crucial and challenging.5,6 Historically, Freeman et al,3,15 and Insall, Griffin and Scuderi16 promoted the concept of gap measurement when balancing the replaced knee. Subsequently, in vivo kinematic fluoroscopic studies have examined the results of soft-tissue balancing17 as have gait studies.18,19 However, the lack of quantitative standardisation of soft-tissue release at operation has resulted in some unpredictability in outcome.6-8 It has been reported that the most common cause of revision of TKR is loosening and soft-tissue instability which also causes further symptoms in 10% to 20% of all revisions.20,21 Persistent pain because of flexion instability when the replaced knee is stable in extension has also been reported.22 However, advances in computerised navigation have allowed the best alignment of the component and stability to be determined.10,23 This enables soft-tissue balancing to be a more predictable task in TKR.11,12,24 In our series when our predictor methods were used, a reduction in the need for collateral ligament release was associated with achieving a mechanical axis of $0^\circ$ with a stable knee of $\leq 4^\circ$ of total arc deflection. This represented a marked reduction in the need for soft-tissue release compared with historical data in the non-navigated TKR literature.6-8 Part of the explanation for a higher rate of soft-tissue release in non-navigated TKR may be the temptation to undertake early collateral ligament release in all deformed knees during the exposure to achieve a neutral knee. By applying our navigational predictors we find it unnecessary to perform such early ligament release.

Our study has some limitations since none of our patients had a pre-operative deformity of more than $20^\circ$ from the mechanical axis, but we anticipate that our predictors will still be applicable in more severe deformity, but with a greater proportion requiring collateral ligament release. Our patients were primarily male, but we are unaware of any studies which identified differences in balancing techniques between men and women. Our protocol relied on cutting the tibia first at $0^\circ$ in both the coronal and sagittal planes, thereby limiting it to implants in which the tibial slope was accommodated within the polyethylene insert. Cutting the femur first can deprive the surgeon of many choices which the computer can readily calculate such as balancing the knee by adjustable femoral cuts.10 Additionally, our data came from one computer software source (OrthoPilot), and we do not know if they can be reproduced using other software or if comparable software is available to measure the gaps in real time. Another limitation was that the first predictor relied on manual stress testing to assess mediolateral instability. This might have
involved variability in the exertion despite being undertaken by one surgeon with extensive experience and repeated a number of times during the procedure. We achieved a mechanical axis of 0° (SD 0.11) with a total deflection arc of ≤ 4°. Whether these ‘stable’ knees will continue to be within the deflection arc of ≤ 4° in the long term remains unknown to which end follow-up continues.

Our definition of a stable, balanced knee with a mechanical axis of 0° ± 2° with a total varus/valgus deflection arc ≤ 4° is similar to previous definitions used in navigated TKR.16,25-28 Thus standardisation can be established as more comparative data are published.

The two predictors we tested were found to be reliable and to reduce the rate of collateral ligament release, which is consistent with the findings of a similar study.25 Our data support the use of the two predictors as a reliable measure to determine the need for and the extent of release to achieve a mechanical axis of 0° with a stable knee showing a unidirectional deflection of ≤ 2°.

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References