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Original research

Relationship between surgical balancing and outcome measures in total knees

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A R T I C L E I N F O

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A B S T R A C T

Background: The purpose of the study was to investigate the accuracy of balancing which could be achieved at total knee surgery and its relation to functional outcomes.
Methods: During surgery, the forces on the medial and lateral plateaus were measured at 10-15 degrees flexion in 101 patients, using an instrumented tibial trial, with equal forces being targeted. Of the initial 101 cases, 71 cases completed all follow-up visits to 1 year. At each follow-up visit, the function was measured using the Knee Society Scoring System, and varus and valgus laxity angles were measured.
Results: The mean medial/(medial + lateral) compartmental force ratio was 0.52, with a standard deviation of 0.09. The total contact force was 217 Newtons, with a standard deviation of 72 Newtons. No correlations were found between the functional scores and the compartmental force ratio or total contact force. However, the mean varus and valgus laxity angles, 2.8 and 2.3 degrees, respectively, were very close to the angles of normal intact knees.
Conclusions: The likely reason for the lack of correlation of function was that the large majority of the balancing ratios were within the range 0.4-0.6 but with a wide spread of functional scores typical of total knee study groups. However, the normal varus and valgus angles achieved at follow-up indicated that equal balancing in early flexion was a reasonable surgical target. Using instrumented tibial trials enabled accurate and consistent balancing values to be achieved, as well as normal varus and valgus laxity angles, which may be important in obtaining optimal outcomes.

Introduction

Soft tissue balancing has frequently been emphasized as an essential step in total knee surgery to achieve smooth motion throughout flexion, produce correct ligament tensions for proprioception, and avoid instability or tightness in any phase of the motion [1-5]. The surgical goals have been described as achieving equal and parallel gaps in extension and flexion, as indicated by spacer blocks or lamina spreaders. A more quantitative approach used a distractor where the angulation of a plate indicated the degree of imbalance [6-8]. Balanced knees were found to have improved proprioception and functional scores. However, the distraction force itself was not correlated with the range of flexion as was expected [9]. A further enhancement in balancing technique was an instrumented tibial trial in which lateral and medial contact forces were monitored over a full flexion range, with balanced knees showing some evidence of higher satisfaction levels [10,11]. Also, balancing using such a device was more accurate than by relying on surgeon feel [12].

The difficulty of achieving accurate medial-lateral balancing over a full flexion range was demonstrated in a study of lower limb specimens in which major changes in the contact forces on the lateral and medial tibial condyles occurred due to small changes in bone cuts or ligament lengths of only 2 mm or 2 degrees [13]. However, in a series of 101 surgical cases, the mean compartment force ratio achieved (medial force/[medial + lateral force]) was 0.52, with a ratio of the range 0.35-0.65 being achieved in 84% of

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cases [14]. Although surgical balancing is clearly required, there is a need for further studies to evaluate the effect which it has on various outcome measures. One important measure is the function itself. However, another important measure is varus and valgus laxity as it relates to stability. To study these aspects, the function and laxity were measured up to 1-year follow-up in patients of the previously reported surgical study [14]. Hence, the purpose of this study was to determine if there was a correlation between the surgical balancing values and the functional scores and whether normal varus and valgus laxity angles were restored.

Material and methods

Terminology

- Medial contact force and lateral contact force, measured with the instrumented tibial trial at surgery.
- Total contact force = (medial + lateral force), measured at 10-15 degrees of flexion.
- Compartmental force ratio (CFR) = (medial force)/(medial + lateral force).
- Varus laxity angle and valgus laxity angle, measured with the smart knee fixture at the different follow-up times.
- Total laxity angle = (varus + valgus angle), measured at 10-15 degrees of flexion.
- Laxity ratio = (varus angle)/(varus + valgus angle).
- Functional score from the Knee Society Scoring System.
- ΔFunction = gain in functional score from preoperative time to a follow-up time.

In this institutional review board–approved study (s16-00,548), 101 consecutive patients from a single surgeon (P.A.M.) were enrolled. The inclusion criteria were age 35-90 years, either male or female, unilateral osteoarthritis, and no major comorbidity that would affect the outcome. During the preoperative assessments, the patients completed the Knee Society Scoring System [15], subdivided into Objective Indicators, Symptoms, Satisfaction, and Functional Activities.

During surgery, the bone cuts were carried out with the aid of a navigation system (Stryker Navigation System; Stryker Inc., Mahwah, NJ). Instrumented tibial trials (VERASENSE; Orthosensor Inc., Dania Beach, FL) were used to obtain the medial and lateral forces, and the knee was balanced as accurately as possible by soft tissue releases and, in some cases, by adjustments to bone cuts [14]. The latter was to avoid excessive soft tissue releases, but the limb alignment was always maintained within 2 degrees of mechanical alignment, as monitored by the navigation system. The contact forces on the lateral and medial condyles were recorded in real time as the heel-push test [13] was carried out from extension to full flexion.

Postoperative evaluations were carried out at 4 weeks, 3 months, 6 months, and at a minimum of 1-year follow-up. At each time point, varus and valgus angles were measured using a “smart knee fixture” (Fig. 1) with the knee at 10-15 degrees of flexion [16], and the laxity ratios were calculated. Measurement in flexion of 90 degrees was avoided due to the difficulty in controlling amid rotation of the femur.

The fixture consisted of plastic pads interfaced with the sides of the thigh and shank joint above and below the knee. Bands of the stretch sensor material (Danfoss PolyPower, Nordberg, Denmark) spanned from the femoral to tibial pads. Computer software determined the increase or decrease in length. To carry out a varus or valgus test, a force dynamometer (ergoFET; Hoggan Health, Salt Lake City, UT) was used at the ankle to apply a moment of 10 Nm at the knee, accounting for shank length. The width across the lateral and medial stretch sensors, measured using a caliper, was used in the calculation of the varus or valgus angle from the stretch sensor length values.

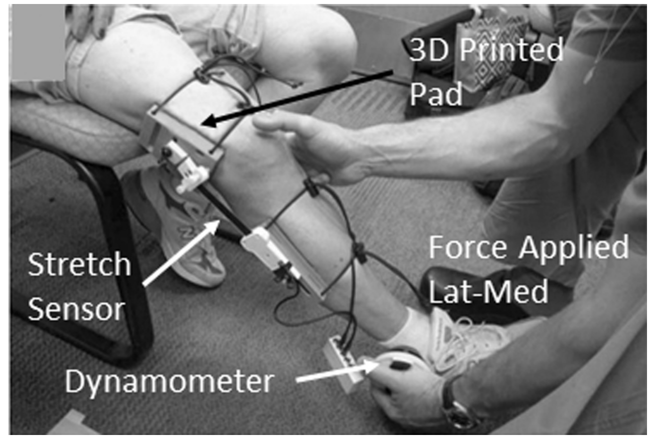

Figure 1. The “smart knee fixture” used to determine the varus and valgus angles at the knee when a moment of 10 Nm was applied at the ankle.

The method was validated by fluoroscopy studies of the right and left legs of 2 volunteers (institutional review board–approved study) where 5 different moments were applied at each of 10, 20, and 30 degrees of flexion. Angles were measured on the radiographic images using a software program and compared with values from the smart knee fixture. The Bland-Altman plot gave a mean difference in absolute values of 0.02 degrees with 95% of differences between ±0.35 degrees. This was considered sufficiently accurate for our clinical study.

Results

The mean ages were 71 years for men (range: 50-87) and 69 years for women (range: 52-87). The body mass index was 29.9 for men and 30.6 for women. The initial numbers of knees were reduced over the time of the study from the original 101 to 71 due to lack of attendance at designated follow-up times and failure to complete all sections of the Knee Society Score form. Table 1 gives a summary of the values for the different parameters for the 71 cases both at the time of surgery and at different follow-up times. For the functional scores over time, there was a slight reduction from preoperative period to 1 month after operation, and thereafter, there was a steady increase up to 1 year. The ΔFunction score paralleled this, with an almost constant difference in value of about 40 points. The varus angle increased from 1 month up to 6 months but then reduced slightly at 1 year. The valgus angle showed a similar behavior, but the value was consistently 0.5-1.0 degrees less than the varus angle.

The values for the CFR were converted to the difference from the target value of 0.5. Hence, a CFR of 0.5 would be 0.0, a CFR of 0.4 or 0.6 would be 0.1, and so on. The functional scores were plotted against the differences (Fig. 2). The differences were clustered toward 0.0, with only 10% greater than 0.15. The functional scores were then plotted against the total contact force, which might give an indication whether there was an association between the 2 (Fig. 3). There was a wide range of each variable but no correlation apparent. The varus and valgus angles at 1 year were plotted against the lateral and medial forces at surgery, respectively (Fig. 4). The rationale was that a tight lateral side should result in a small varus laxity angle and a tight medial side, in a small valgus angle. Again, there were no correlations apparent. However, the means and standard deviations of the varus and valgus laxity angles were

Table 1
Results of the compartmental force ratio (CFR), total contact force at surgery, and the laxity ratio (LR) for preoperative time and at the 4 different follow-up times.

Parameter	Pr-op	Pr-op	In-op	In-op	1 m	1 m	3 m	3 m	6 m	6 m	12 m	12 m
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
CFR			0.52	0.09								
TF			216.8	71.6								
Varus					1.99	1.03	2.35	0.99	2.93	1.11	2.68	1.04
Valgus					1.67	0.65	1.77	0.73	2.20	1.00	1.98	0.72
Lax R	0.52	0.13			0.54	0.13	0.56	0.10	0.57	0.11	0.57	0.10
Symp	9.7	5.3			15.0	5.4	17.8	5.1	19.3	4.5	20.9	4.1
Satis	15.8	8.4			22.8	8.1	28.7	7.8	31.5	6.4	37.0	4.5
Func	40.6	15.7			36.9	15.8	57.0	19.1	67.9	17.1	80.0	15.2
ΔFunc					−4.2	18.3	15.3	20.6	27.0	18.0	39.4	16.3

ΔFunc, postoperative function − preoperative function; CFR, compartmental force ratio = medial/(medial + lateral) force; Func, function score; In-op, intraoperative; Lax R, laxity ratio = varus/(varus + valgus); m, month; Pr-op, preoperative; Satis, satisfaction score; SD, standard deviation; Symp, symptoms score; TF, total force (Newtons). The Knee Society Scores are shown including the functional scores and the ΔFunction.

almost identical with the values for normal nonoperated knees as measured in a group of older test subjects [17]. The mean varus and valgus angles in that study were 2.8 ± 1.3 and 2.3 ± 0.9 degrees, respectively; the values in our study were 2.6 ± 1.0 and 2.0 ± 0.8 degrees.

A Spearman Rank's test was used to determine the correlation between the CFR and total contact force with the Knee Society scores of symptoms, satisfaction, function, and ΔFunction. All correlations observed were not significant ($P > .05$). The total contact force score with respect to function ($r = -0.04$; $P = .79$), ΔFunction ($r = 0.14$; $P = .31$), satisfaction ($r = -0.098$; $P = .443$), and pain ($r = 0.073$; $P = .561$) was not significant. When the CFR was compared with all factors similarly, function (-0.08; $P = .52$), ΔFunction ($r = 0.04$; $P = .77$), satisfaction ($r = -0.156$; $P = .211$), and pain ($r = 0.002$; $P = .99$) had r values that were also not significant. In addition, a correlation between varus and medial angle ($r = 0.016$; $P = .91$) as well as between valgus angle and lateral force ($r = 0.028$; $P = .84$) showed no correlation between variables.

Discussion

The lack of correlation between the balancing force ratio and the functional score can be interpreted in different ways. The wide range of scores indicates that there are many factors involved, not the least of which is the general condition of the patient. But, balancing is one of many surgical factors that could have an influence. In this study, we only analyzed the balancing at 10-15 degrees of flexion, and although this would be applicable to the most frequent activity of walking, it does not wholly cover the full scope of function. The large majority of CFRs were close to the ideal value of 0.5, equal lateral and medial forces, with only a few outliers, so this level of balancing may have been sufficient so as not to affect the functional scores in a major way.

The other parameter that could possibly affect the function is the total contact force, which is one measure of how loose or tight the joint was. In a study of bilateral total knee arthroplasty, it was found that patients preferred the looser knee over the tighter one, although statistical significance was not achieved [18]. At surgery, the tightness is not controlled directly, but a major factor is the thickness of the tibial component which is selected based on reaching full extension [19]. In this series of patients, there was a wide range of total contact forces ranging from 100 to 400 Newtons, but there was no correlation with the functional score. This large range would most likely be explained by the range of sizes of knees and the varying stiffnesses of the collateral ligaments [4].

In measuring the varus and valgus laxity angles, it was found that the mean varus angle of 2.8 degrees was higher than the mean valgus angle of 2.3 degrees. Comparing these values with those of normal knees is not easy because the available data on normal intact knees and on total knee patients show variable results. This has been attributed to the differences in patient groups including age, sex, and follow-up time and to the measurement parameters including the equipment used, the moment applied, and the flexion angle [20]. One study comparable to ours measured the angles in extension and flexion on older patients with an average age of 62 years, measuring angles radiographically, which is expected to be accurate [17]. Their applied moment however was 15 Nm, which is higher than our moment of 10 Nm; however, in both cases, the collaterals have already passed the loose toe region and are in the stiff part of the force-elongation curve [21,22].

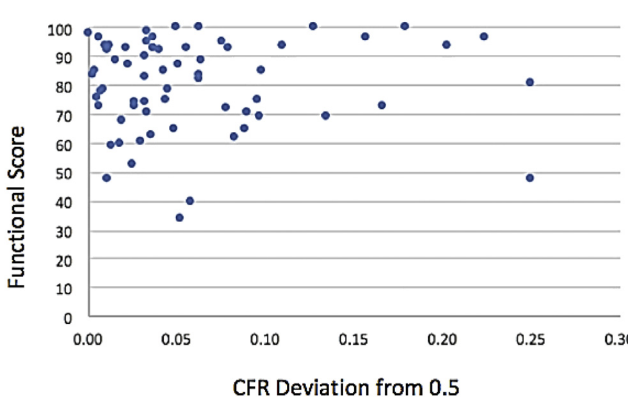

Figure 2. The functional score at 1 year plotted against the deviation of the compartmental force ratio (CFR) from 0.5 (eg, A CFR of 0.4 and 0.6 have a deviation of 0.1). There was no correlation.

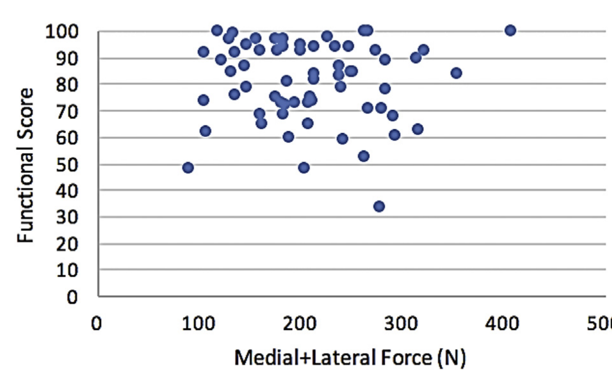

Figure 3. The functional score at 1 year plotted against the total contact force at surgery. There was no correlation.

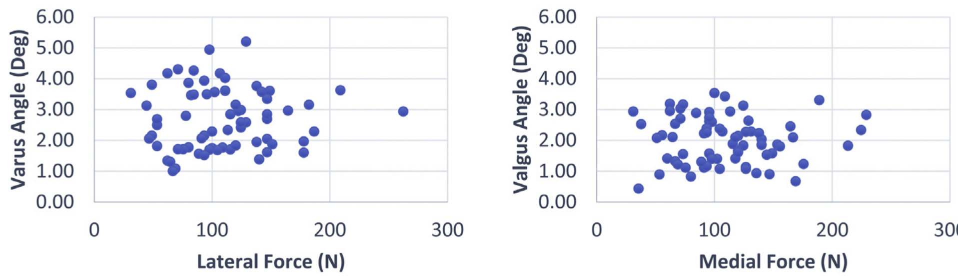

Figure 4. The varus laxity angle plotted against the lateral contact force, and the valgus laxity angle plotted against the medial contact force. There was no correlation.

We limited the moment to 10 Nm, which is well below the elongation limit of the collaterals. The means and standard deviations in both varus and valgus were almost identical between our study and the literature study on intact knees. In other studies, the mean varus and valgus angles were 3.5 and 3.2 degrees in 49 normal subjects [23], which are only slightly higher than those in our study. In 42 patients who underwent total knee surgery, the mean varus angle was 2.9 degrees, and the mean valgus angle was 2.5 degrees [24], which were comparable to those of our study. Hence, it is reasonable to conclude that the varus and valgus laxity angles measured on total knees in our study were comparable with values in normal intact knees. However, for individual knees, without laxity data of the knees in their normal condition, it is not possible to determine whether each knee was restored to its own normal laxity values after the total knee surgery. Furthermore, there was no correlation of the laxity angles with the functional score.

In the interpretation of these results, one factor which stands out is the lack of correlations between the functional outcome, the CFR, the total contact force, and the varus-valgus laxity at follow-up. The consensus on obtaining a balanced knee at surgery is based more on factors such as avoiding pain and instability rather than on function. In terms of balancing, previous studies showed relationships with proprioception [9] and satisfaction [10,11]. Satisfaction is generally related to pain relief and ability to carry out normal everyday activities, as well as to functions, although in many studies, it is treated as a single domain entity [25]. The most common reason for dissatisfaction in about 20% of patients overall was persistent pain. It is possible that in knees that are well balanced, there is a lower pain incidence due to the avoidance of excessively loose or tight soft tissues in the flexion range. If this is the case, consistency of accurate balancing would be an advantage, justifying the use of quantitative methods of measuring and achieving balancing [26,27]. An additional factor is that the contact forces are measured over a full flexion range rather than only at 0 degree and 90 degree flexion. Another outcome measure that could possibly be applied to balancing is the forgotten joint score, being the ability to forget the artificial knee in everyday life, resulting in the highest satisfaction [28].

Although the ideal range of the balancing force ratio is unknown, the ability to achieve consistent values between 0.35 and 0.65 in most cases seems a reasonable starting point. Our study has shown that this is achievable using an instrumented device at surgery. It should be noted however that although most authors emphasize equal medial-lateral balancing, possibly with some lateral loosening in flexion [2], this does not wholly agree with recent data from normal knees which showed higher medial than lateral contact forces throughout flexion, both decreasing with the flexion angle [29]. It may be that equal balancing is more suitable for symmetric total knee designs, particularly PS types, whereas an anatomic pattern is best suited to anatomic total knee designs [16]. The surgical technique itself might influence the balancing goals [30,31]. The actual values of the balancing forces can be compared with those of a recent study [32]. These authors reported that over 50% of their balanced values of (lateral + medial) force were in the range of 20-40 lbf (89-178N), averaged from 10, 45, and 90 degrees of flexion. This is consistent with our average force of 217N, considering that our value was at 10-15 degrees of flexion, whereas force values diminish steadily with the flexion angle [29]. Within the balancing range achieved of 0.35 to 0.65, differences in outcomes were not found, whereas the number of cases outside that range was too few to be statistically represented as an unbalanced group. The absence of a control group of unbalanced knees remains a limitation of the study.

In our study, one consequence of achieving a well-balanced knee in most cases was normal mean values for the varus and valgus angles, including approximately half a degree higher varus than valgus angle. As for the CFR, it is possible that this may relate more to satisfaction rather than to the functional score. This was the case in a study of 94 total knees, in which the postoperative varus-valgus laxity was measured at 6 months using a Telos device and the Knee Society Scores were determined [33]. There was no correlation between the varus-valgus laxity and score. In addition, the lateral or medial lift-off was measured radiographically during treadmill walking, but there was no correlation between the lift-off and varus or valgus angles. However, under certain conditions, imbalance can result in lift-off during activity [34].

The present study is a clinical follow-up to a previous surgical study of 101 cases in which balancing was carried out using an instrumented tibial spacer and the medial and lateral contact forces were measured, from which a CFR was calculated. The expectation was that there would be a correlation between the functional score and the ratio, but none was found. Also, the varus and valgus angles were measured at 1-year-plus follow-up to determine if these related to the balancing force values. Again, no direct relation was found. The major limitation of the study was that due to the balancing method used, the balancing was close to the target of equal medial and lateral forces in most cases. Also, a single surgeon experienced in the use of instrumented tibial trials carried out the procedure in all the cases. A power analysis was not carried out, which might have revealed that a much higher number of cases would be needed for significance in any event. The original 101 cases were reduced to 71 during the course of the study, which is not unusual for a large city hospital, but it did reduce the amount of data. The use of the smart knee fixture device may have introduced some error in the varus and valgus angles, although a careful validation study did show that maximum errors would be less than 0.4 degrees. Muscle effects in possibly reducing the laxity angles were ruled out; an electromyographic study showed minimal muscle activity when the varus and valgus moments were applied slowly and smoothly.

Conclusions

The main conclusions of the study, which could be applicable to total knee surgery, were that the use of an instrumented device to achieve balancing at surgery can achieve consistent medial and lateral contact force values; that the balancing target can be chosen as equal medial and lateral forces or modified for a particular total knee design or surgical technique; and that for equal balancing, normal varus and valgus laxity angles are achieved at follow-up.

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