

Effects of surgical variables in balancing of total knee replacements using an instrumented tibial trial



Peter S. Walker^{*}, Patrick A. Meere, Christopher P. Bell

Department of Orthopaedic Surgery, New York University, Hospital for Joint Diseases, United States

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ABSTRACT

Background: In total knee surgery, typically the bone cuts are made first to produce the correct overall alignment. This is followed by balancing, often using spacer blocks to obtain equal parallel gaps in flexion and extension. Recently an electronically instrumented tibial trial has been introduced, which measures lateral and medial contact forces. The goal of our study was to determine the effect of different surgical variables; changing component sizes, modifying bone cuts, or ligament releases; on the contact forces, as a method to achieve balancing.

Methods: A special rig was designed to fit on a standard operating table, on which tests on 10 lower extremity specimens were carried out. After making bone cuts for a posterior cruciate retaining knee using a navigation system, tibial thickness was determined in extension using the Sag Test. Different Surgical Variables were then implemented, and the changes in the condylar forces were determined throughout flexion using the Heel Push Test. **Results:** condylar forces were found to consist of gravity forces due to the weight of the leg plus forces due to pretension in the collateral ligaments. The pretension force averaged 145 N but there was considerable variation because of ligament stiffness properties. Balancing from an imbalanced state could be achieved with adjustments within only 2° or 2 mm.

Conclusion: The instrumented tibial trial provided force information which indicated which surgical correction options to carry out to achieve balancing. From an initial unbalanced state, relatively small changes could produce balancing, indicating the sensitivity of the procedure.

Clinical Relevance: Non-clinical. This study will assist in the balancing of the knee at total knee replacement surgery.

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1. Introduction

Achieving the ideal alignment of bone cuts, together with ligament balancing, are important goals in total knee surgery. The accuracy of the various bone cuts is usually within 3° of target, with some studies showing that navigation produces more consistency [1,2]. However there is still uncertainty of the basis for the alignment in terms of achieving the optimal results [3–6] and differences between measured resection and gap balancing have been pointed out [7,8]. The complexities of soft tissue balancing have been described and evaluated by many authors, while other balancing options have been specified including adjusting bone cuts and component sizing [9–15]. Generally the emphasis is on achieving equal gaps at 0 and 90° of flexion, with the femoral rotation playing an important role [3,10,16–20]. However, other authors have proposed unequal lateral and medial balancing to better reproduce the normal anatomic situation [21,22].

Various methods have been introduced to improve and quantify the process of balancing, distractors being the most frequently used

[23–26]. The concept of measuring the tibial plateau forces and contact locations at surgery was first demonstrated using pressure sensitive film [27,28]. Recently an electronically instrumented tibial trial component has been introduced, which measured and displayed in real time the forces on the lateral and medial compartments and their locations at all flexion angles [29]. Clinical studies have suggested that correct balancing can improve outcomes in various ways, including the avoidance of postoperative instability and improved flexion [11,12,30–33].

However, there have been few reports of the ideal values of distraction or contact forces in order to achieve ‘correct balancing’. The first such data was provided from a series of cases using a distractor device, where having achieved ideal balancing empirically, average total femoral–tibial compressive forces of 120 N at both 0 and 90° flexion were reported [24]. Whatever the ideal balancing goals, the instrumented tibial trial concept does provide the possibility of reaching a defined goal in a methodical way. At surgery, balancing is usually attempted by ‘surgical variables’ such as ligament releases, changing component sizes, or modifying bone cuts. An instrumented tibial trial can then evaluate the effects of the different surgical variables.

Hence, the primary goal of this laboratory study was to determine the effect of the different surgical variables on the forces on the lateral and medial condyles over a full range of flexion. This would then provide guidelines for which surgical variable would be most effective in

^{*} Corresponding author at: Laboratory for Orthopedic Implant Design, Hospital for Joint Diseases, Suite 1500, 301 East 17th Street, New York, NY 10010, United States. Tel.: +1 212 598 6569; fax: +1 212 598 6096.

E-mail address: Peter.Walker@nyumc.org (P.S. Walker).

achieving balancing from an initial unbalanced state. An associated goal was to evaluate a specific surgical test that would provide the required force data.

2. Methods and materials

A test rig was developed for mounting lower body specimens to a standard operating table (Fig. 1). The pelvis was fixed to the base of the rig and a surgical boot was firmly strapped to the foot. A spherical bearing fixed to the heel of the boot was attached to a low friction carriage which advanced towards the hip along a slide rail, to flex and extend the knee with no constraints. To maintain the leg in a vertical plane, chocks were used to prevent foot rotation. For specific tests, fixtures on the rig allowed the leg segments to be supported at a required flexion angle, to maintain the thigh and lower leg in a vertical plane, to prevent axial rotation of the femur, and to be correctly positioned medio-laterally. A total of 10 leg specimens were tested, of which two were used for experimental development.

Once the specimen was mounted, navigation trackers were fixed to the femur and tibia. A subvastus medial approach was then used for surgical exposure. The bone cuts were made for the insertion of a posterior cruciate retaining total knee (Triathlon, Stryker Orthopaedics, Mahwah, NJ) using an optical navigation system (Stryker Navigation, Kalamazoo, MI). The frontal plane cuts were perpendicular to the mechanical axes of the respective bones, while the tibia was cut at 5° posterior slope in the sagittal plane. The femoral rotation was 3 to 4° external to the epicondylar axis, verified by Whiteside’s line and the posterior condylar line. The trial femoral component and tibial baseplate were inserted, the latter rotationally aligned initially to the medial third of the tibial tubercle.

The wireless instrumented tibial trial was then introduced (OrthoSensor Knee Balancer, OrthoSensor, Inc., Sunrise, FL), of a thickness so that the knee just reached full extension when the foot was lifted up from the table. This procedure was called the Sag Test. For

this and all subsequent tests, the vastus medialis and medial arthrotomy incision were closed with towel clips. In order to assess the rotational position of the tibial component, the foot was oriented vertically, and was manually pushed along the horizontal rail such that the knee flexed from 0 to 120°, with the leg moving in a vertical plane. This procedure was termed the Heel Push Test. The anterior–posterior (AP) locations of the contact points were observed and the rotational position of the tibial component was adjusted if necessary to produce uniform locations of the contact points on the lateral and medial sides. The tibial baseplate was then pinned in place to define its position for all subsequent tests.

A surgical variable (Fig. 2) was selected based on the initial output data. For example if there was a consistently higher medial than lateral force during flexion, a two degree tibial varus angle was applied by stuffing the lateral side with a two millimeter wedge. The Heel Push Test was then repeated. The difference in the output data caused by the surgical variable (in this case, the two degree tibial varus) was then determined. This principle of differences was used throughout the sequential testing to determine the effect of each surgical variable. The order of applying the surgical variables was based mainly on the output data from the preceding test. The method was to move towards and away from a balanced state with each variable. All variables could not be applied to every knee due to situations when the contact forces became zero, or were excessive in certain flexion ranges.

3. Results

3.1. Analysis of Heel Push Test

The leg is represented in Fig. 3, where the hip is a fixed pivot, the foot slides horizontally along the slide rail, and a heel push force is applied. The forces between the femur and tibia are shown as a force JF down the axis of the tibia, which would be measured by the instrumented tibial trial, and a shear force, JF is the sum of the lateral and medial forces. The weights of the thigh and lower leg are WT and WS, acting at the distances shown.

This equation for the total joint force JF (Fig. 3) predicts that the forces will be small at higher flexion angles, but increase rapidly as the flexion angle becomes about 15°. The

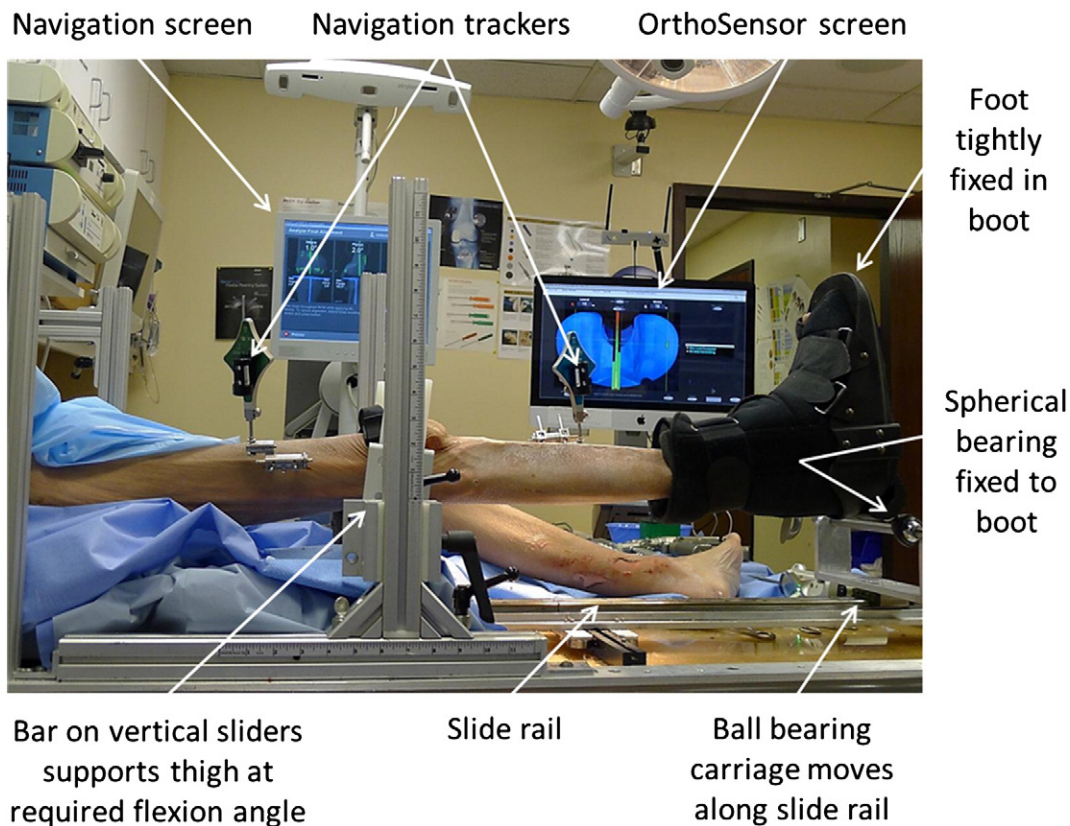


Fig. 1. The test set-up for carrying out the experiments on the lower limb. The custom-made rig was fixed to a standard operating table.

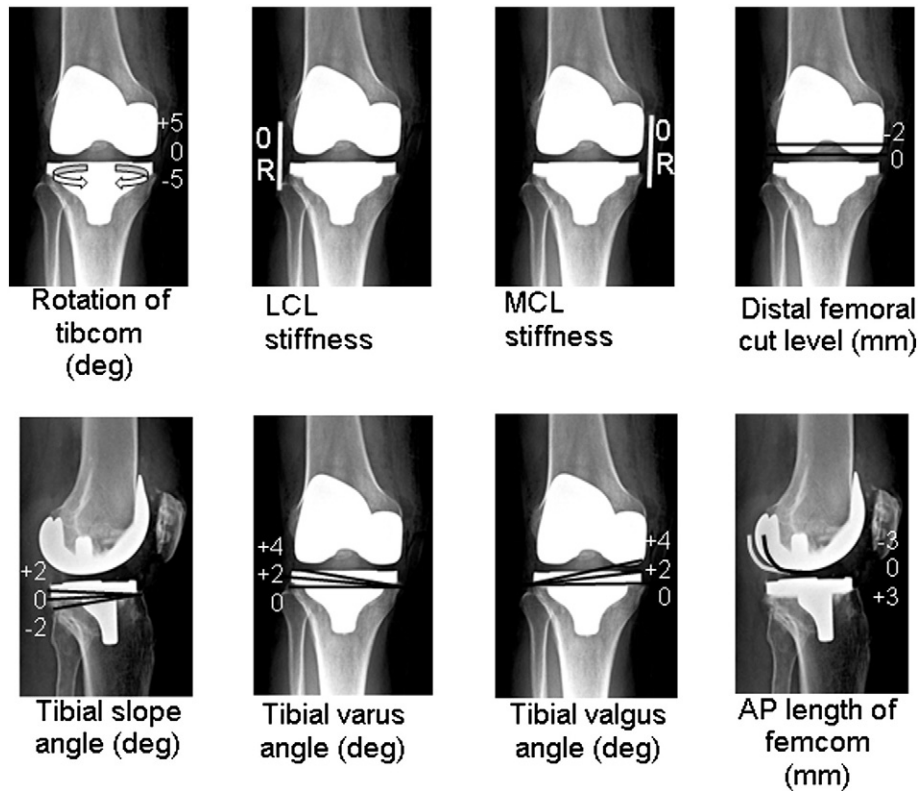


Fig. 2. The surgical variables which were tested to determine the changes in the condylar force values. Spacers and wedges were used for the distal femur and proximal tibia. For the LCL and PCL, the variables were unaltered (0) and released (R). The numerical values are the changes relative to the initial status.

analysis breaks down at low flexion because soft tissue forces are not accounted for. The results for the total joint force JF plotted against angle of flexion F from 15 to 120° flexion are shown for the average male leg size and weight (Fig. 4, full black line) [34]. The curve (full black line) represents the force on the tibial surface due entirely to the weight of the leg, without accounting for soft tissue forces. Any forces in excess of those values would be due to soft tissue tensions. The curve will vary for each individual leg depending on its weight.

During the testing of the 10 knees using the Heel Push Test, ranges of force–flexion curves were obtained before and after the implementation of different surgical variables. The colored curves in Fig. 4 were selected based on an average lateral:medial or medial:lateral force ratio of less than 2.5:1, over the flexion range. For each curve, the calculated force due to the weight of the leg was subtracted, leaving only the force due to the soft tissue tension. The mean of these corrected curves was then determined (Fig. 4, dashed line). The mean soft tissue tension value was close to 145 N (32.5 lbf) for the whole flexion range.

3.2. The effect of the Surgical Variables

From an initial status, implementing a surgical variable led to a change in the Output Data. Several surgical variables were tested on each knee. The mean values of the force changes on the lateral and medial condyles after different surgical variables were measured (Fig. 5). For a 2 millimeter distal femoral cut, a 2 millimeter thicker tibial spacer was used to preserve extension. As a result, the condyle forces in low flexion were little changed, but the forces in high flexion were increased. For 2 millimeter lateral stuffing, the lateral forces increased and the medial forces decreased. The opposite was the case for medial stuffing, but with a large medial increase. Increasing the tibial slope had little effect, possibly due to the contact points not displacing posteriorly a large amount. On the other hand a decreased slope achieved with a 2 millimeter wedge caused large force increases in both flexion ranges. An increase in the femoral component size with the same anterior and distal contours but 3 mm of additional posterior condylar offset, showed a large increase in the total condylar force.

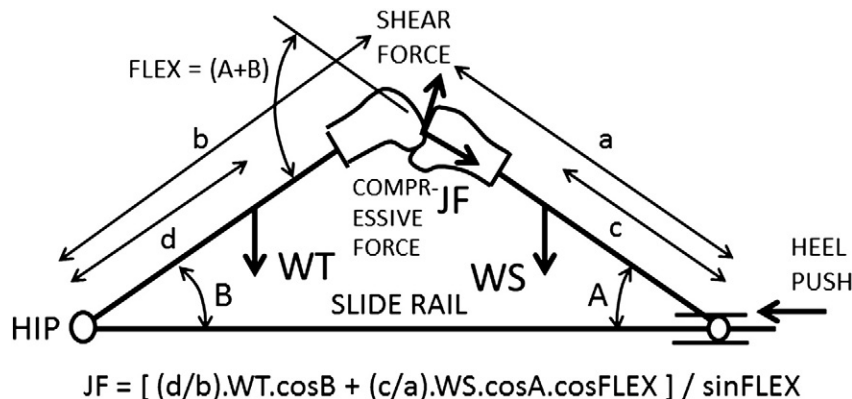


Fig. 3. Analysis of the Heel Push Test. The joint compressive force (JF) due to the weight of the thigh (WT) and lower leg (WS) is calculated, from the equation.

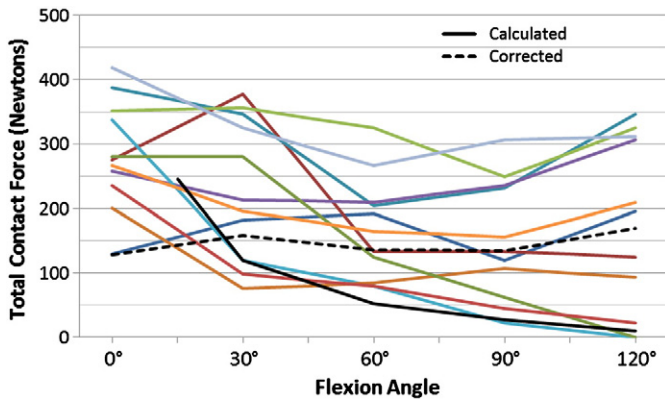


Fig. 4. Force–flexion curves (colored) in the Heel Push Test where the medial:lateral or lateral:medial force ratio averaged less than 2.5:1 for the flexion range. The theoretical curve for the weight of the average male leg is shown (full black line). The mean soft tissue tension forces for the knees, corrected for the weights of the legs, are shown (dashed black line).

To put this data into perspective, the force increases due to a 1 millimeter increase in length of the lateral or medial collateral are shown (Fig. 5, right), taking data from force elongation tests of the collaterals [35]. Two force ranges are shown: the soft region up to the toe of the force–elongation curve and the subsequent stiff region. The former represents an elongation in the range of 0–2 mm, the latter an elongation of 3–5 mm. This data explains the relatively large changes in either the lateral or medial condyle force when the frontal plane slope of the tibia was modified by only 2°, equivalent to about 2 mm of collateral length change. A decrease in sagittal tibial slope had a similar effect, in this case on both of the condyles together.

4. Discussion

In this study we investigated the use of an instrumented tibial trial which measured and displayed the lateral and medial condyle forces as an indicator of balancing. An important feature of the system is that the forces are measured with the actual implant trial components [36] which differentiate it from the distractor approach. In principle the force values obtained and their locations, can be interpreted to indicate what corrections would be needed to obtain a balanced state. These corrections, which we termed ‘surgical variables’, included ligament releases, adjustments to bone cuts, or a change of component sizes. Two

surgical tests were used in the experiments. The Sag Test determined the required tibial insert thickness, which would then determine the overall magnitude of the forces during flexion due to the tensions in the soft tissues, primarily the collaterals. The Heel Push Test determined the forces during the full flexion range and indicated whether a lateral–medial imbalance was uniform throughout flexion, and whether there was an increase or decrease in the forces from extension to flexion.

The combined condyle force in the Heel Push Test, subtracting the calculated force due to the weight of the leg, averaged 145 N, representing soft tissue tension. The value is similar to the 120 N determined for balanced knees in a previous study [24]. This magnitude of force implied that the elongation of each collateral ligament producing the pretension forces was in the range of 2–3 mm. This placed the ligaments at the start of the stiff part of their force–elongation curves. This explains the important finding in our study, that a change in tibial frontal plane angle of only 2°, equivalent to an increase of approximately 2 mm at the lateral or medial side, produced relative medial–lateral force changes which would compensate for any initial imbalance. This would also indicate the small amount of ligament release that would be needed to achieve balancing, consistent with a progressive ‘pie crusting’ approach [37]. Hence, balancing is very sensitive to adjustments of only 1–2 mm.

Regarding the Surgical Tests, the Heel Push Test proved to be simple to carry out, and covered the whole flexion range. It was necessary to slide the heel along a track to maintain the leg in a vertical plane, which was achieved by attaching a simple fixture to the operating table. The condyle forces recorded in this test were shown to include the weight of the thigh and lower leg, with a greater effect in lower flexion angles. In order to isolate the soft tissue forces only, the gravity forces from the weight of the leg had to be subtracted. A similar test but supporting the weight of the leg with a hand at the posterior of the knee may result in only soft tissue forces, but this was not methodically tested in the present study.

The problem of identifying how to correct an imbalanced state was addressed by applying a surgical variable and determining the force changes from an initial state. This would provide the ‘signature’ for that particular variable. Looseness in flexion could be addressed by an additional distal femoral resection, but the effect was not major, whereas decreasing the tibial slope had a much larger effect. In contrast increasing the tibial slope had little effect. A previous study reported

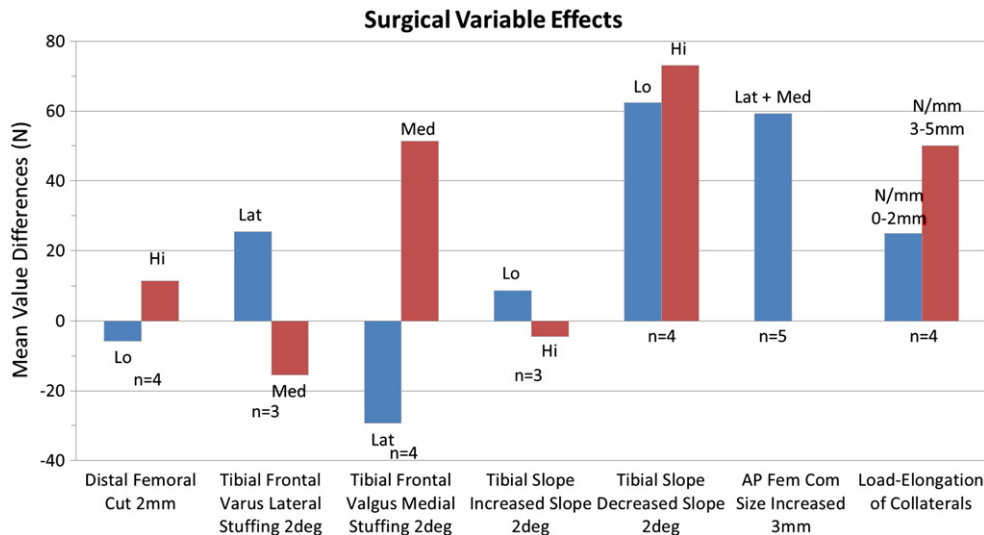


Fig. 5. The mean differences in the condyle forces in the Heel Push Test caused by implementing different surgical variables (Fig. 2). Lo = low flexion range 0–60°. Hi = high flexion range 60–120°. Lat + Med = combined lateral and medial forces. Collateral ligament stiffness in the initial soft region (0–2 mm) and the subsequent stiff region (3–5 mm) is taken from reference [36].

such effects for both posterior cruciate retaining (CR) and posterior stabilized (PS) knees [38]. Interestingly, increasing the AP dimensions of the femoral component caused an increase in condyle forces throughout flexion. Although increasing the femoral component size is impractical in a surgical setting, it did emphasize that from the point of view of maximizing the flexion range, a larger posterior femoral condyle offset is an advantage [39,40].

Regarding the significance of balancing, in gait and other activities, the axial compressive forces are in the range of 2.5–4.0 times body weight [41,42]. The frontal plane moments are affected by the alignment of the leg, muscle actions, and the individual's gait pattern. The magnitude of these moments and functional forces is around an order of magnitude greater than the soft tissue pretensions of approximately 145 N. Hence, it is likely that passive imbalance within certain limits is unlikely to affect load-bearing function itself, at least in terms of varus–valgus and AP stability. However, in the swing phase, the axial compressive forces have been measured at only a fraction of body weight, comparable to the soft tissue pre-tension forces. Hence for an unbalanced knee the relative position of the femur on the tibia in the swing phase, and at the time of heel strike, could result in an unstable phase until the femur and tibia reach equilibrium determined largely by the geometry of the total knee components. Such instability has been detected in the varus–valgus and anterior–posterior directions using accelerometers [43,44].

Our study was limited in several ways. Due to using only 10 knee specimens and the few separate tests that could be performed on each, the data cannot be used for a statistically valid analysis of force changes for each surgical variable, which would be better carried out in a clinical study with a large number of arthritic patients. Nevertheless we were able to identify overall trends, and to determine the sensitivity of the condylar forces to small gap or angular changes. Our models oversimplified the soft tissue structures and the changes in balancing which could be achieved by various releasing strategies [37]. Also we did not specifically account for the effect of the posterior cruciate, for which an AP drawer test would be applicable [45]. Studies have shown the variation in the force–elongation properties of different parts of the collaterals [35,46,47] and in the variation of the actual varus and valgus angles on lift-off [20]. These factors emphasize the patient-specific nature of balancing. This highlighted the sensitivity of the balancing process but also indicated the range within which the correction procedures need to be carried out. Finally, we have reported here only results from the Heel Push Test. We did obtain data from varus–valgus, anterior–posterior, and internal–external rotation tests. The data obtained supplemented the Heel Push Test and will be reported separately.

In conclusion, we studied the application of an instrumented tibial trial for achieving balancing of a total knee replacement. The variations in condylar forces between different knees emphasized that there was no universal set of values that would apply to all, but that a systematic approach could lead to a balanced knee within acceptable limits. The balancing procedures appeared to be sensitive to changes within two millimeters and two degrees, whether from corrections made to soft tissues, bone cuts, or component sizing. The condylar forces of the passive knee were an order of magnitude less than those in function and hence balancing is expected to have a larger effect in the swing phases of activity rather than in the stance phases.

5. Conflict of interest

Dr. Walker and Dr. Meere have received consulting payments for participation in workshops organized by OrthoSensor Inc., the manufacturer of the device which is the subject of this paper. OrthoSensor Inc. provided partial funding for the study, monitored through the Sponsored Programs Administration of New York University Medical Center. Other funding was directly from the Department of Orthopedic Surgery.

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