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A New Method for Defining Balance: Promising Short-Term Clinical Outcomes of Sensor-Guided TKA

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ABSTRACT

Recently, technological advances have made it possible to quantify pounds of pressure across the bearing surface during TKA. This multicenter evaluation, using intraoperative sensors, was performed for two reasons: 1) to define "balance" 2) to determine if patients with balanced knees exhibit improved short-term clinical outcomes. Outcomes scores were compared between "balanced" and "unbalanced" patients. At 6-months, the balanced cohort scored 172.4 and 14.5 in KSS and WOMAC, respectively; the unbalanced cohort scored 145.3 and 23.8 in KSS and WOMAC ($P < 0.001$). Out of all confounding variables, balanced joints were the most significant contributing factor to improved postoperative outcomes ($P < 0.001$). Odds ratios demonstrate that balanced joints are 2.5, 1.3, and 1.8 times more likely to achieve meaningful improvement in KSS, WOMAC, and activity level, respectively.

The integrity of a successful total knee arthroplasty (TKA) is dependent on several technical factors, including: appropriate alignment of components, rotational congruency between the prosthetic proximal tibia and prosthetic femoral condyles, and ligamentous balance of the knee joint [1–4].

Technological advances over the last several years have made it possible for the orthopaedic surgeon to ensure correct alignment via digitally-guided bone cuts provided through navigation systems [5,6]. Achieving anatomic rotation, too, can be assessed with the assistance of computed tomography (CT) imaging, or through the use of positional mapping based on referenced landmarks specific to each patient [7]. However, obtaining soft-tissue balance, or even establishing a concrete definition thereof, remains elusive.

Today, "balance" in TKA is determined almost exclusively by the subjectivity of each surgeon and the nebulous "feel" of appropriate ligamentous tension [8–11]. These methods are numerous, variable, and highly subjective [9,12–14]. Surgical experience, fellowship training, and procedural volume play a role in each surgeon's relative skill in balancing a knee properly [15,16]. Patient variables such as BMI, gender, and relative ligament laxity may also affect to the surgeon's perception of balance [17,18].

Soft-tissue imbalance accounts for 35% of early TKA revisions in the United States, manifesting as instability or stiffness, and tibiofemoral incongruency, which could lead to component loosening [2,4,19]. These percentages have not improved despite changes in knee designs and instrumentation. In order to ameliorate the present risks of revision in TKA, refined techniques for assessing and achieving a balanced TKA are essential.

In a rapidly changing economic environment in medicine, coupled with a projected five-fold increase in TKA revision rates by 2030 [20], it is imperative that more empirical and clinical data be used to construct a *scientific* definition of balance. By reducing the subjectivity that has traditionally been relied upon during balancing procedure, clinical outcomes may be improved, and incidence of early revisions reduced, thereby resulting in significant savings in healthcare related costs.

Recently, technology has made it possible to embed microelectronics into the standard tibial trial ("VERASENSE Knee System", Orthosensor, Dania FL) (Fig. 1). This array of sensors provides dynamic, intraoperative feedback regarding tibiofemoral position and quantitative pressure at peak contact points in the medial and lateral compartments during TKA trialing. Kinematic tracking can also be assessed. Utilizing sensor-derived data, displayed on the graphical user interface, the surgeon can now evaluate intercompartmental loading throughout the range of motion (ROM), and correct for soft-

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Fig. 1. Photograph comparing the sensor (in-situ) to the standard tibial trial (foreground).

tissue abnormalities while receiving real-time feedback regarding joint position and the tibiofemoral relationship defined by the contact point location.

A multicenter evaluation has been conducted using these intraoperative sensors. There were two purposes for conducting this study: 1) To attempt to refine the current clinical understanding of "balance" 2) To determine if patients with quantifiably balanced knee joints exhibit improved clinical outcomes during a short-term follow-up interval of 6 months, versus patients with residual imbalance, as measured by the intraoperative sensor system.

Patients/Methods

One hundred and seventy six patients, from eight sites in the United States, have had a PCL retaining or sacrificing TKA performed with the use of the VERASENSE Knee System, used in conjunction with the Triathlon Knee System (Stryker, Mahwah, NJ). Baseline data were obtained, and all patients have subsequently returned for a scheduled 6-month postoperative assessment. Each site received Institutional Review Board approval to enroll patients and all subjects signed a written informed consent document prior to enrollment in the study.

Patients were considered for enrollment in this study if they were eligible for primary TKA, with a diagnosis of: osteoarthritis, avascular necrosis, rheumatoid or other inflammatory arthritis, or posttraumatic arthritis. Patients less than 50 years of age were excluded. Other exclusion criteria included: prior TKA, ligament insufficiencies, prior surgeries such as ACL or PCL reconstructions, posterolateral reconstructions, osteotomies, or repair of tibia plateau fractures.

For this evaluation, patients were evaluated preoperatively, intraoperatively, at 6 weeks, and at 6 months postoperatively (although data will continue to be collected annually, up to 3 years following surgery or until a revision procedure is reported).

Two patient-reported outcomes measures were inventoried at each clinical evaluation point, including the American Knee Society Score (KSS), and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). For all patients, at all intervals, standard weight-bearing plain radiographs were taken, including anteroposterior, lateral, and sunrise patellar or merchant views. At all intervals, varus/valgus and anteroposterior stability, extension lag, anatomic alignment, and ROM were also recorded.

Intraoperatively, knee joints were accessed through a medial parapateller, subvastus or midvastus approach. The surgeons performed standard cuts for the distal femur and proximal tibia, either with or without the use navigation, at their discretion. Some surgeons used a measured resection technique for femoral cuts; others used a gap balancing technique for femoral rotation.

With the trial components for the tibia and femur in place, the standard polyethylene trial was inserted and the knee was reduced. The knee was assessed manually to confirm that the joint was not excessively tight or loose in the coronal or sagittal planes, in extension and flexion. Once the appropriate tibial insert size was determined, the corresponding VERASENSE sensor was activated, and registration was verified. During the activation process, the patella was cut and patellar button applied. The VERASENSE sensor was then inserted after the appropriate shim was affixed to its undersurface to replicate the thickness of the standard trial that was used during initial assessment. The VERASENSE Knee System replicates the exact geometry of the standard tibial trial insert in order to obtain information related to the knee design and to minimize any error introduced by nonconforming geometry. It also allows closure of the medial capsule to ensure appropriate soft tissue tension during evaluation of the knee joint.

Prior to soft-tissue evaluation, tibial tray rotation was visually quantified using the sensors. The mid to medial third of the tibial tubercle was used as a reference to set initial tibial tray rotation. As per surgeon preference a pin was placed in either an anteromedial or anterolateral position to stabilize any translational motion during rotational correction. With the VERASENSE sensor inserted, the knee was taken into extension. The tibial baseplate was rotated until the medial and lateral femoral contact points were seen as parallel on the graphic user interface (GUI) and a second pin was added. This was a critical step, as malrotation can significantly impact soft-tissue tension.

Once appropriate rotation was achieved, balance of the knee was assessed in three positions: full extension (0–10 degrees), mid-flexion (45 degrees), and in 90 degrees of flexion. Visible varus-valgus stress testing was performed in extension, as well as at 10 and 45 degrees of flexion to assess any laxity present in the collateral ligaments. With the capsule closed, medial and lateral load measurements and center of load were documented at 10, 45, and 90 degrees of flexion. It is important while assessing compartment pressure that no axial compression is applied across the joint. A posterior drawer was applied in 90 degrees of flexion with the hip in neutral rotation to evaluate stability of the posterior cruciate ligament (PCL). Flexion balance was achieved when femoral contact points were within the mid-posterior third of the tibial insert (Fig. 2A), symmetrical rollback was seen through ROM, intercompartmental loads were balanced, and central contact points displayed less than 10 mm of excursion across the bearing surface during a posterior drawer test. A tight flexion gap during surgery creates excessive pressures in flexion and the peak contact point resided more posteriorly on the tibial insert (Fig. 2B). This was corrected through recession of the PCL or, in some instances, by increasing the tibial slope. PCL laxity was identified via the excessive anteroposterior excursion of the femoral contact points across the bearing surface, during a posterior drawer test (Fig. 2C). Surgical correction required a thicker tibial insert, anterior-constrained insert, or a conversion to a posterior-stabilized knee design. Soft-tissue releases and/or "pie crusting" techniques were performed for coronal asymmetric imbalance, as necessary, until the desired balance was achieved.

Generally, soft-tissue releases were performed using "pie crusting" techniques, as described by Bellemans, et al, to correct coronal asymmetric imbalance, as necessary, until balance was achieved [8]. With this technique, multiple punctures were made to the medial

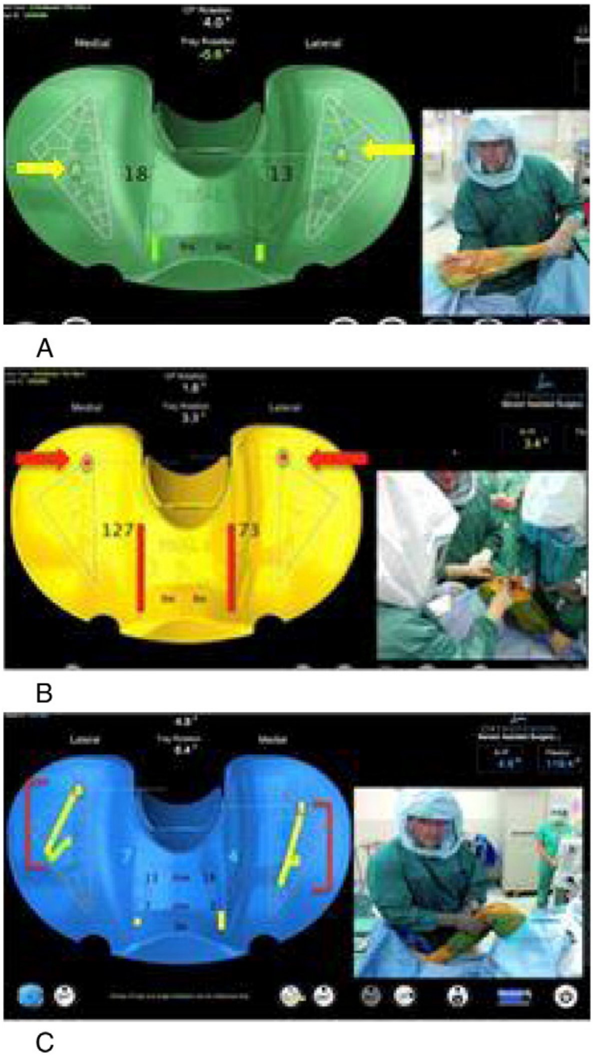

Fig. 2. Screen capture from three intraoperative scenarios, demonstrating: optimal sagittal plane balance as indicated by the symmetric positioning of the femoral contact points in the mid-third of the sensor (A); excessive posterior tension as indicated by the posterior position of the femoral contact points (B); and excessive laxity as indicated by the excursion of femoral contact points, across the sensor surface, during a posterior drawer test (C).

collateral ligament (MCL), using a 19-gauge needle or #11 blade, to progressively stretch the MCL or the lateral structures until the intercompartmental pressures were deemed acceptable by the individual surgeon (Fig. 3). This technique is performed gradually, allowing the knee to flex and extend after several punctures to allow the ligament to stretch and re-tension. The surgeons documented all soft-tissue releases performed. Final load measurements were recorded prior to cementing the components.

Analysis of the data was performed using SPSS version 21 (SPSS Inc., Chicago, IL). Comparative statistics were run between outcomes data stratified by two groups: those with a "balanced" joint, and those with an "unbalanced" joint. Analysis of variance (ANOVA) was used to assess the difference between each group, with post-hoc t-tests to demonstrate significance. Separate analyses were performed to evaluate power of sample sizes and any correlative effect that demographic/clinical variables may have had on patient outcomes. All variables that could have contributed to improved postoperative outcomes were combined in a multivariate logistic regression model, as per best fit analyses. This allowed us to control for any simultaneous confounding effects. Odds ratios were calculated for each group of patients to evaluate the probability of influence in postoperative outcomes. Significance was defined as a P-value <0.05.

Working Definition of "Balance"

For the purposes of this evaluation, a definition of soft-tissue "balance" was quantitatively assessed using GUI feedback from the VERASENSE system. In order to classify a knee joint as being "balanced" two criteria must have necessarily been met. Firstly, the joint must have exhibited stability in the sagittal plane (typically determined by a stable end-point with the application of a posterior drawer test, while not exhibiting gross posterior cruciate ligament (PCL) tension leading to excessive rollback or anterior lift off of the tibial component). Secondly, a difference in pounds of pressure between the medial and lateral compartments of the tibial plateau must not have exceeded 15 lb (i.e., a medial load of 14 lb and lateral load of 21 lb exhibits an intercompartmental difference of 7 lb; this joint is classified as "balanced" in the coronal plane). The decision to choose 15 lb as the upper limit for balance was made based on: 1) Biomechanical research on condylar pressures in a passive state [21]; 2) Intraoperative observations by experienced surgeons that quantified 2 mm of opening with varus/valgus stress and load changes coupled with navigation; 3) Significant drop-offs, observed in this study, in postoperative, patient-reported outcome scores in patients with intercompartmental loading differences exceeding 20 lb.

Results

Patient Profile

A total of 176 patients (176 knees) enrolled in the multicenter study had reached the 6-month follow-up interval when outcome data were evaluated. Of the full cohort 13% were "unbalanced"; 87% were "balanced". All unbalanced patients remained so due to intraoperative surgeon discretion: In many cases, patients exhibited excessive loading (exceeding 100 lb) in the medial compartment,

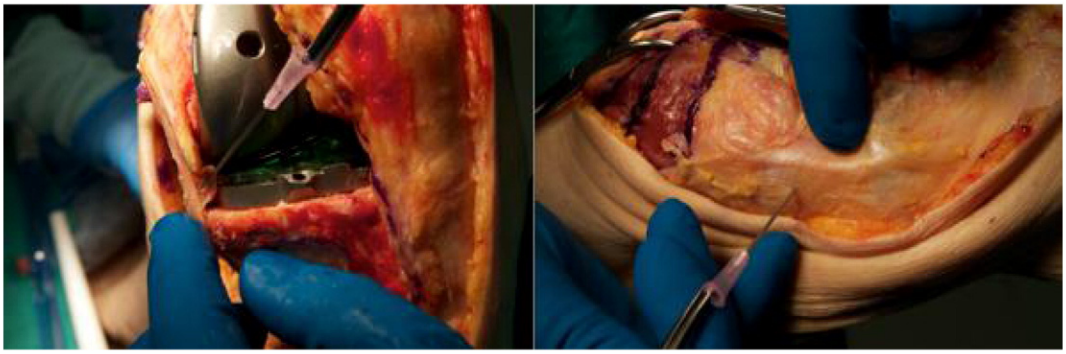

Fig. 3. Photograph of MCL pie-crusting technique with a 19-gauge needle.

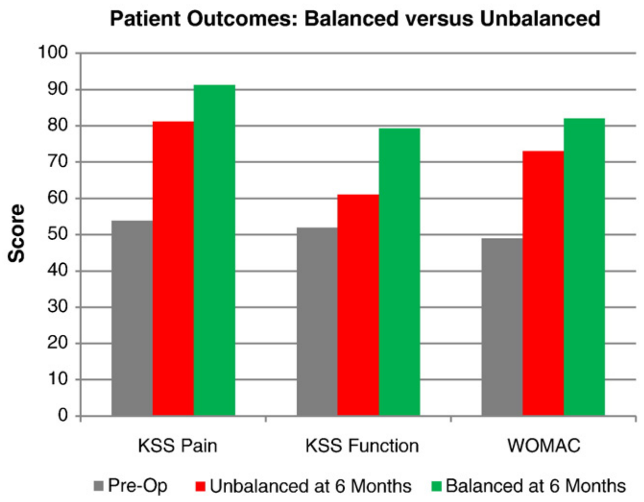

Fig. 4. Bar graph showing comparative trends in average patient-reported outcomes scores (preoperatively, and at 6 months), between the "balanced" and "unbalanced" groups.

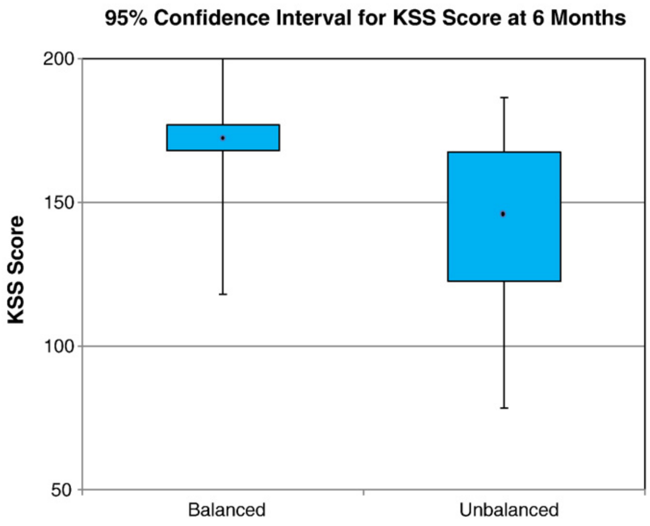

Fig. 5. Comparative boxplots of KSS scores at 6 months for "balanced" and "unbalanced" groups. Dots represent mean; boxes represent 95% confidence interval; vertical whiskers represent minimum and maximum.

lateral compartment, or both. Oftentimes, after a succession of ligamentous release, the surgeon chose to keep the patient in an unbalanced state (as defined by this study), rather than compromise stability as a result of further release.

The mean age at surgery for the unbalanced cohort was 72 ± 7 years; mean age at surgery for the balanced cohort was 69 ± 8 years. The average BMI for the unbalanced group was 31 ± 6.4; the average BMI for the balanced group was 30 ± 5.3. The average female-to-male ratio for both groups was approximately 2:1. An ANOVA comparison of means for demographic variables showed that there was no significant difference, in any of the above categories, between the two group profiles.

Descriptive Statistics

Of the 176 patients who underwent sensor-assisted TKA, 97% had a primary diagnosis of osteoarthritis. The average preoperative ROM for all patients was 114°, and 63% exhibited a preoperative varus alignment with an average anatomic alignment of 5.1°.

In order to measure improvement in clinical performance of the balanced versus unbalanced groups, patient-reported outcomes scores were used for comparison. All statistics that follow are based on this comparison method. The short-term follow-up interval for all patients is 6-months. All improvements in score are based on preoperative reports, the means of which were approximately the same in both groups, with no statistical difference ($P = .603$): total KSS = 105 ± 24.6; total WOMAC = 47 ± 14.8.

ANOVA means comparison of KSS score at 6 months yielded 172.4 for the balanced group; 145.3 for the unbalanced group ($P < 0.0001$) (Fig. 4). The 95% confidence intervals were 168–177 and 123–168 for the balanced group and unbalanced group, respectively (Fig. 5). The change between preoperative and 6-month KSS score was 63.8 for the balanced group; 42.6 for the unbalanced group ($P = .046$).

ANOVA means comparison for WOMAC did not reach significance ($P = .073$). While the means between the two groups were markedly different (14.5 for balanced; 23.8 for unbalanced), the balanced and unbalanced patients exhibited high standard deviations (16.9 and 11.2, respectively) which contributed to the non-significant P-value.

Regression Analyses

Because KSS scores exhibited a highly significant difference in means comparison, a linear regression model was applied and yielded a predictive value of $P = 0.032$.

Multivariate binary logistic regression analyses were performed for both KSS and WOMAC scores at 6 months. Variables run in these analyses included: age at surgery, BMI, gender, preoperative ROM, preoperative alignment, change in activity level (preoperative to 6 months), and joint state (balanced versus unbalanced). For KSS and WOMAC, both step-wise and backward multivariate logistic regression analyses were calculated to be best fit models with similar significance ($P < 0.001$). Ultimately, the step-wise model was used.

The binary model revealed that the variable exhibiting the most significant effect of improvement on KSS and WOMAC score was balanced joint state ($P = 0.001$; $P = 0.004$). Joint state was the most highly significant variable; this demonstrated similar levels of significance throughout all possible combinations of variables included in the model ($P = 0.001$). Joint state was also observed to be the sole significant factor in patient-reported outcome score improvement ($P < 0.001$). Interestingly, there was also a concurrent significance observed with activity level ($P = 0.005$). However, activity level was not significant on its own. This leads to the conclusion that a balanced joint state results in a higher activity level (Fig. 6). This would make activity level more of a dependent variable, rather than a predictor. Thus, it was pulled from the regression and evaluated, along with KSS and WOMAC scores at 6 months, with odds ratios.

Odds ratios were calculated based on meaningful clinical improvement in KSS scores, WOMAC scores, and activity levels at 6 months. Based on literature review, "meaningful improvement" for KSS scores were anything greater than 50 points; WOMAC scores greater than 30 points; and gains in activity level greater than or equal two 2 lifestyle levels (from lowest score to highest: sedentary, semi-sedentary, light labor, moderate labor, heavy labor) [22,23]. Scores from the unbalanced group were used as the reference point.

The odds ratio for balanced joint state and improved KSS score was 2.5, with a positive coefficient (95% CI). This suggests a high probability of obtaining a meaningful improvement in KSS with a balanced knee joint, over those who do not have a balanced knee. The odds ratio for balanced joint state and improved WOMAC score was 1.3, with a positive coefficient (95% CI). Again, this suggests a favorable probability that patients with a balanced state will achieve a meaningful improvement in WOMAC score, over those that do not have a balanced knee. Finally, the odds ratio for balanced joint state and improved activity level was 1.8, with a positive coefficient (95% CI). This also suggests a favorable probability of meaningful gains in activity level in those with a balanced knee, versus those with an unbalanced knee (Table 1).

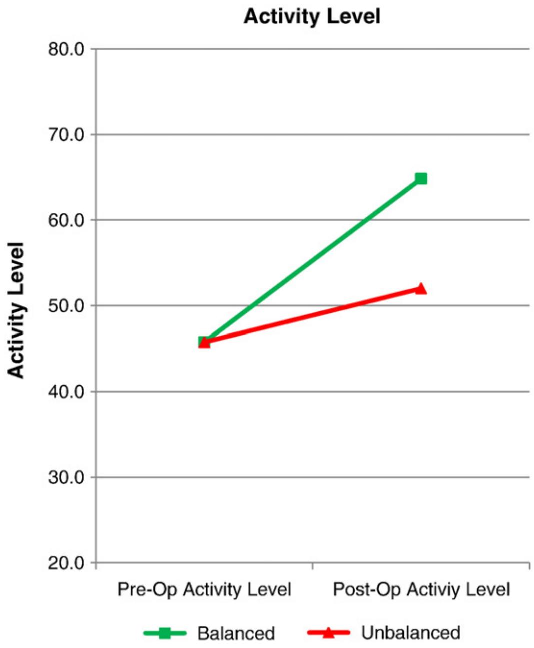

Fig. 6. Comparative line graph showing average improvement in activity level, from preoperative to 6-month interval, between "balanced" and "unbalanced" groups.

Discussion

Traditionally, soft-tissue "balance" during TKA has been determined exclusively by the subjective assessment of each surgeon. However, these imprecise methods contribute to 35% of reasons for revision, based on imbalance-related complications [2,4,19]. In light of the anticipated five-fold increase of annual revision procedures projected by 2030, it is desirable to prevent these premature failures [20]. Thus, it is imperative that balance be defined, and corrections executed, based on empirical data.

With recent technological advances, it is now possible to dynamically track joint kinetics via tibial inserts embedded with microelectronics. One such wireless tool, the VERASENSE Knee System, allows the surgeon to observe kinetics across the bearing surface, through dynamic motion, and with the capsule closed.

This multicenter study, using VERASENSE intraoperatively, has provided a unique opportunity to observe the short-term clinical outcomes of patients with a *quantifiably* balanced knee versus those who have *quantifiably* unbalanced knees. The results of these clinical outcomes, at 6 months, are promising.

Postoperatively, balanced patients (mediolateral intercompartmental loading difference ≤ 15 lb through a range of motion) showed greater improvement in mean values than unbalanced patients, in both KSS and WOMAC scores. KSS scores, at 6 months, were 172.4 versus 145.3 for balanced and unbalanced patients, respectively ($P < 0.0001$). For WOMAC, at 6 months, balanced patients averaged 14.5 and unbalanced averaged 23.8 (in WOMAC scoring scale, the lower score indicates greater improvement).

Table 1
Odds Ratios: Likelihood of Balanced Patients Achieving Clinically Meaningful Improvement Over Unbalanced Patients.

Variable (Score Change Between Preop and 6 mo)	Odds Ratio
KSS ($\Delta > 50$ pts)	2.5
WOMAC ($\Delta > 30$ pts)	1.3
Activity level ($\Delta > 40$ pts)	1.8

The results of the linear regression analysis, with respect to KSS score, suggest that balanced knees not only improve postoperative outcomes, but do so predictably on a pound-for-pound basis ($P = .032$).

Step-wise multivariate logistic regression analyses show that, when calculating the effect of all possible confounding variables (including: age at surgery, BMI, gender, preoperative ROM, preoperative alignment, change in activity level (preoperative to 6 months), and joint state (balanced versus unbalanced)), balanced soft-tissue is the most highly significant variable that has contributed to the vast improvement in patient-reported outcomes ($P = 0.001$). Not only is this variable the most significant, but its significance is consistent throughout all combinations of variables tested.

Activity level was an anomalous variable during the regression analyses. While it showed significance when paired with balanced knees alone, it was highly non-significant on its own, or when combined with any other variable. This is suggestive that there is a relationship between activity level and joint balance, though perhaps not as two variables. Based on the significance values associated with activity level and balanced joint state, activity level was found to be best represented as a dependent measure (just as KSS and WOMAC scores). As such, joint balance was also the most highly significant variable in improving activity level ($P = 0.005$).

This relationship between activity level and a balanced knee may be part of a cascade effect among clinical outcomes (Fig. 7). A balanced joint may contribute to more favorable biomechanics. This, in turn, may lead a patient to perform better in postoperative physical therapy than an unbalanced patient. This improved performance may also decrease pain levels, which would potentially lead to the increased activity levels observed in this study. Furthermore, increased activity levels may lead to higher patient satisfaction, manifesting as the significantly improved KSS and WOMAC scores also observed in this study.

The odds ratios observed in this study are also promising. When defining a "meaningful improvement" in clinical outcomes, balanced patients were 2.5 times, 1.3 times, and 1.8 times more likely to obtain meaningful improvement than unbalanced patients in KSS, WOMAC, and activity level respectively.

There were limitations to this study. Firstly, we did not have a control group. The primary design of the multicenter evaluation was intended to be observational. Because 13% of patients remained unbalanced (due to surgeon discretion) we were given the opportunity to compare the two groups. Whether or not this unbalanced group is representative of traditional, non-sensor guided TKA is unknown. Secondly, the number of unbalanced patients was much smaller than balanced patients. While power analyses did confirm that comparisons could be reasonably made, an equal proportion of patients in each group would have been more favorable. Thirdly, none

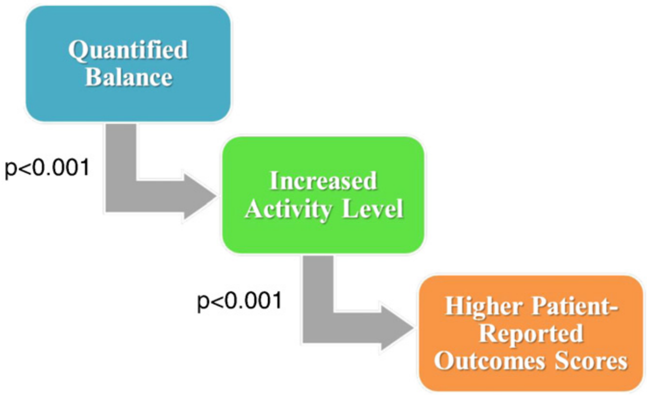

Fig. 7. Flow chart indicating correlation/cascade effect between balance, activity level, and improved outcomes scores.

of the 8 surgeons participating in this study are experienced Stryker Triathlon users. Despite an inherent learning curve associated with using unfamiliar components and instrumentation, there is a chance that clinical outcomes may be better improved with seasoned users. However, the highly favorable clinical results achieved with balanced knees suggest that the learning curve for surgeons may be compressed when using the VERASENSE system. It also holds promise as a technical aid for lower-volume surgeons in whom a subjective feel may be less refined and also as a teaching tool in the academic setting.

As the numbers of primary TKA patients continue to increase, so, too, will the need for less experienced surgeons to perform TKAs, leading to a larger potential for surgeon error. Soft-tissue balancing is one of the only remaining aspects of TKA that has not yet benefitted from quantified metrics. The effects of implant design, rotation, and alignment on soft-tissue balance can now be defined and their effects on short and long-term outcomes can be evaluated. This study has begun to elucidate aspects of what has, thus far, only been based on intuition: a balanced knee leads to better clinical outcomes.

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