KNEE

Increased satisfaction after total knee replacement using sensor-guided technology

The aim of this prospective multicentre study was to report the patient satisfaction after total knee replacement (TKR), undertaken with the aid of intra-operative sensors, and to compare these results with previous studies. A total of 135 patients undergoing TKR were included in the study. The soft-tissue balance of each TKR was quantified intra-operatively by the sensor, and 18 (13%) were found to be unbalanced. A total of 113 patients (96.7%) in the balanced group and 15 (82.1%) in the unbalanced group were satisfied or very satisfied one year post-operatively (p = 0.043).

A review of the literature identified no previous study with a mean level of satisfaction that was greater than the reported level of satisfaction of the balanced TKR group in this study. Ensuring soft-tissue balance by using intra-operative sensors during TKR may improve satisfaction.

Cite this article: Bone Joint J 2014;96-B:1333–8

Since the formal assessment of satisfaction following joint replacement began in the 1990s, studies of satisfaction following total knee replacement (TKR) have yielded varying results.1-3 Surgeons assess the results of surgery more highly than patients.4-7 Also, patients who undergo TKR consistently report higher levels of pain, greater impairment of function, and lower levels of satisfaction than those who undergo total hip replacement (THR).8-11

A number of explanations for these findings have been suggested. Satisfaction correlates closely with function.12-14 Dissatisfaction may reflect the failure of the surgeon to manage the expectations of the patient prior to surgery.15 It is likely that both factors contribute to dissatisfaction.16,17

Interventions to improve satisfaction following TKR are an important area of research. The aim of this study was to report the satisfaction, one year post-operatively, in a group of patients who underwent sensor-assisted TKR, and to compare these findings with previous studies reporting satisfaction following TKR.

Patients and Methods

Following ethical approval, 135 patients (135 knees) who met the appropriate inclusion criteria from eight institutions were enrolled into a prospective multi-centre study. All patients underwent TKR of a single design (Triathlon, Stryker Inc., Mahwah, New Jersey), and implanted using the Versense Knee System (OrthoSensor Inc., Dania Beach, Florida).

The Versense device is a sensor system which replaces the tibial insert trials used during surgery. The geometry of the sensor corresponds to that of the standard tibial trial insert. By using the sensor in combination with one of a number of gradated shims, a construct can be made up to the required thickness of the trial component. The sensor is composed of a microprocessor and integrated nanosensor system, which wirelessly transmits real-time data to a portable graphic display unit, which then launches the Versasense application. The sensor measures and localises peak load at the medial and lateral tibiofemoral interfaces.18 Loading data may be captured intra-operatively through a full range of movement (ROM) using the sensor system.

Patients undergoing unilateral TKR for osteoarthritis, avascular necrosis, inflammatory arthropathy or post-traumatic arthritis were eligible for inclusion in the study. We excluded patients aged < 50 years, those undergoing revision TKR, those who had undergone previous ipsilateral knee surgery, such as ligament reconstruction or osteotomy, those with contralateral TKR, and those with a tibial plateau fracture or ligamentous insufficiency.

Patients were evaluated pre-operatively, intra-operatively, and at six-months and one-year post-operatively. At each interval, kinematic data including varus/valgus and anteroposterior stability, the presence of a flexion contracture or extension lag, anatomical alignment and ROM
were recorded, and a satisfaction survey was completed at the one year interval.

For the purposes of this study, a new satisfaction questionnaire was devised. Questions were selected if they had been used in at least three studies published previously, to allow comparison with previous studies and to ensure that each question had been validated. Following the construction of the questionnaire, it was reviewed and approved by nine independent reviewers. Of the nine reviewers, four were orthopaedic surgeons and five were clinical research associates (KAG, MWR, GJG, GJJ).

The final questionnaire included seven domains, assessing the satisfaction following surgery and whether the result met the patient’s expectations (Fig. 1). Each domain was answered on a five point Likert scale, with one point representing the worst result (‘false’ or ‘very unsatisfied’) and five points representing the very best (‘true’, or ‘very satisfied’); this is similar to other questionnaires of this type.10,12-15,17,19

Questionnaires were scored on an additive, point-per-answer basis, giving an overall score of between 7 (the worst possible score) and 35 points. The overall score was categorised into five possible outcomes: very dissatisfied (1 to 7 points), dissatisfied (8 to 14 points), neutral (15 to 21 points), satisfied (22 to 28 points), or very satisfied (29 to 35 points). All patients fully completed the satisfaction survey.

The questionnaire was completed by the patient with the assistance of a research co-ordinator, during the one-year follow-up appointment, prior to seeing the surgeon. TKR was performed using medial parapatellar, subvastus or midvastus approaches, with or without navigation, and using measured resection or gap-balancing techniques. Based on the findings at surgery and the preference of the surgeon, both posterior stabilised and cruciate-retaining components were used, and the patella was resurfaced in all patients.

Following standard femoral and tibial resection, and with the trial components in place, the standard tibial trial was inserted and the knee reduced. The knee was assessed to confirm that the joint was not excessively tight or loose in the coronal and sagittal planes and a tibial trial insert was selected. Once the size of the appropriate tibial component was determined, the corresponding Verasense sensor was activated, and registration was verified. During the activation process, the patella was cut and the patellar button was applied. The sensor was then inserted with the appropriate shim to match the thickness of the trial component.

Rotation of the tibial component was assessed visually using the mid- to medial-third of the tibial tubercle as a reference point. The tibial baseplate was stabilised using an anteromedial or anterolateral pin. With the sensor inserted, the knee was extended. The tibial baseplate was rotated about the stabilising pin until the femoral contact points were seen to be parallel on the graphical user interface (GUI). At that point, a second pin was added to stabilise the tray.

Balance of the components was assessed at full extension (0° to 10°), at mid-flexion (45°), and in 90° of flexion. Subjective varus-valgus stress testing was performed in extension and at 10° and 45° of flexion to assess laxity or excessive tension in the collateral ligaments. With the capsule closed, medial and lateral load measurements and the centre of load were documented at 10°, 45°, and 90° of flexion, with no axial compression applied across the joint. A posterior drawer test was applied at 90° of flexion, with the hip in neutral rotation to evaluate stability of the posterior cruciate ligament (PCL), which could be visually confirmed by observing the extent of translation of the femoral contact point across the bearing surface, as shown by the sensor system. Flexion balance was achieved when the sensor recorded femoral contact points in the mid to posterior third of the tibial component, rollback was seen through the ROM, medial and lateral compartment loads were
equal, and central contact points displayed < 10mm of excursion across the bearing surface during the posterior drawer test (Fig. 2). If the flexion gap was tight (demonstrated by excessive pressures when the femoral contact position was posterior on the tibia), the PCL was recessed or the tibia was re-cut with additional slope. If the PCL was lax (demonstrated by excessive excursion or anterior translation of the femoral contact points), a thicker or anterior-constrained tibial component was used, or the TKR was converted to a posterior-stabilized design. Soft-tissue releases and/or ‘pie crusting’ techniques were performed, as necessary, until the desired balance was achieved. During ‘pie crusting’, multiple punctures were made in the ligaments exhibiting tension, using a 19-gauge needle or number 11 blade, to lengthen the ligaments incrementally until the pressures in the medial and lateral compartments were similar. All soft-tissue releases were documented. Final load measurements were recorded prior to cementing the components.

These criteria were chosen based on previous biomechanical studies, previous studies demonstrating inferior outcomes in patients with a difference in loading of > 20 lb between the compartments, the observation of experienced surgeons within the study that these differences of load corresponded to 2 mm of opening on stress of the varus/valgus (as recorded by navigation systems) and the observation, made during the study, that patients meeting these criteria tended to have superior post-operative outcome scores. The criteria were only established while the study was in progress. While balancing was performed in later cases with the aim of achieving this standard, earlier cases were balanced by the surgeons in their standard fashion. As a result, several early TKRs were unbalanced according to these criteria. These formed a group which was compared with balanced TKRs in the final analysis.

A systematic review of existing literature regarding patient satisfaction was performed. Using PubMed, combinations of the following keywords were queried, separately, by two contributing authors (CRA, LCE): ‘satisfaction’, ‘TKR’, ‘satisfied’, ‘total knee arthroplasty’, ‘one year’, ‘patient-reported satisfaction’, and ‘post-operative satisfaction’, via the following strings, “satisfaction total knee arthroplasty,” “satisfaction TKR,” “patient reported satisfaction total knee arthroplasty,” “patient reported satisfaction TKR,” “patient reported satisfaction total knee arthroplasty one year,” “patient reported satisfaction TKR one year,” “post-operative satisfaction total knee arthroplasty”, “post-operative satisfaction TKR,” “satisfied TKR,” “satisfied total knee arthroplasty,” “satisfied total knee arthroplasty one year,” and “satisfied TKR one year”. All literature was searched between December 2013 and January 2014.

Inclusion criteria were: studies with all patients undergoing primary TKR; studies with post-operative collection of satisfaction data; statistical description of patients who were ‘satisfied’ to ‘very satisfied’. Studies were only included in the review if both assessors (CRA, LCE) agreed that all criteria were met.

**Statistical analysis.** Analyses were performed using SPSS, version 21 (IBM Inc., Armonk, New York). Repeated measures ANOVA analyses (as determined by a positive Mauchly’s sphericity test) were executed to contrast the satisfaction data one year post-operatively. These data were stratified by two groups: those with a ‘balanced’ joint, and those with an ‘unbalanced’ joint. The Brown-Forsythe meta-analysis (df = 11) of literature was performed to evaluate the typical proportion of reported patient satisfaction, post-TKR statistically. The meta-analysis average is based on weighted means. Significance for all analyses was defined as p < 0.05.
Results

Overall, 18 of the 135 TKRs (13%) were unbalanced and most of these procedures were undertaken early in the study period, prior to establishment of the balancing criteria. No patient with an unbalanced TKR had any adverse anatomical features prior to surgery. There was no statistically significant difference between the demographic data of patients with a balanced TKR and those with an unbalanced TKR (Table I).

A total of 127 patients (94.1%) were ‘satisfied’ or ‘very satisfied’ one year post-operatively. A total of 113 patients (96.7%) whose TKR was balanced were satisfied or very satisfied as were 15 (82.1%) of those whose TKR was unbalanced. This difference was statistically significant (repeated measures ANOVA analysis; p = 0.043).

In order to understand what these satisfaction data indicated within the context of the satisfaction expected for most TKR patients, an extensive literature search and meta-analysis was performed.

In total, 196 publications were retrieved using the selected keywords, and 12 publications met the inclusion criteria, representing 33,775 international patients who had undergone TKR. The mean follow-up period for the assessment of satisfaction was 19 months, with one study reporting satisfaction at a mean of three months and one reporting it at a mean of six years. The type of questions asked in the assessment of satisfaction were common among all publications, including: the levels of pain, function, global satisfaction, and if the patient would elect to have the same surgery again.

The data were non-normal in distribution, and thus a Brown–Forsythe test was used to test its homogeneity. The results yielded a highly statistically significant amount of homogeneity (B–F = 3.048; homogeneity < 0.001; df = 11) indicating that the data relating to satisfaction could be reasonably compared across all studies.

It was found that a weighted mean of 81% of TKR patients, as reported in the included meta-analysis literature, were satisfied or very satisfied one year post-operatively.
‘satisfied’ or ‘very satisfied’. This represents a 16% decrease from the balanced cohort evaluated in this study (p = 0.001). The mean satisfaction reported in the literature was more in agreement with the unbalanced cohort (82.1%). Figure 3 shows the comparison of all studies collected from literature, with the two groups of patients reported in this study.

Discussion

Patient satisfaction is an important measure of success following joint replacement. The reason patients who undergo TKR have lower levels of satisfaction than those who undergo THR is not clear. 12-17

In this study, we found that patients who have soft-tissue balance after TKR, as verified by sensors intra-operatively, had significantly higher satisfaction than those who do not, one-year post-operatively (p < 0.043).

In the systematic review, 81% of patients were found to be ‘satisfied’ or ‘very satisfied’ following TKR. This number is lower than the patients with balanced TKR in this study, and is similar to those with an unbalanced TKR. The highest reported level of satisfaction in the evaluated literature was 90.3%, 4 which was lower than those with a balanced TKR in this study. While the weighted mean follow-up reported in the literature is slightly longer than that of the patients in this study (19 months vs 12 months; 3 months to 6 years), levels of satisfaction remain relatively stable following the first year, in the absence of revision surgery. 7

One of the strengths of this study is the use of a satisfaction questionnaire to assess function and pain, as well as whether pre-operative expectations were met. Both of these criteria for satisfaction contribute to the opinions of patients about the success of their TKR. 12-16 By using a similar 5-level Likert scale to those which have been used previously, we were able to compare these results with similar studies.

There were weaknesses in this study. First, no validated satisfaction score was available at the time of enrolment of the patients and although the satisfaction questionnaire was constructed specifically for the study, it has not been formally validated. Secondly, there was significant heterogeneity in terms of age, gender, ethnicity, and/or BMI amongst the studies which were included in the systematic review. These factors may in part explain the differences observed between the patients who underwent sensor-assisted TKR and those in previous studies. As a result, no meta-analysis was attempted: the aim of the systematic review was simply to obtain a better general understanding of satisfaction following TKR. Likewise, not all the studies in the systematic review included the results one-year post-operatively and may not have been directly comparable with the current study. However, 70% of the papers included in the systematic review reported satisfaction one-year post-operatively, and previous studies suggest that levels of satisfaction remain static with the passage of time 1 and therefore the results would be comparable.

None of the surgeons participating in this study had previously used the Triathlon (Stryker) device. This raises the possibility that the poor satisfaction in the patients with an unbalanced TKR, most of whom were enrolled earlier in the study, may have been related to the learning curve, rather than whether or not the TKR was balanced.

The study was neither blinded nor randomised, which may have introduced assessment bias associated with the use of novel technology.

These results suggest that accurate balancing of the soft tissues in TKR may lead to higher levels of satisfaction. No other study in the literature review reported higher levels of satisfaction than that reported in those with a balanced TKR. While these trends towards higher satisfaction are promising, the tools for assessing satisfaction remain imprecise. Satisfaction is based not just on physical gains or limitations, but is strongly affected by the patient’s psychological state amongst other factors. 25-27 The development of more sophisticated outcome measures may allow more accurate assessment of satisfaction in patients undergoing TKR.

We would like to thank the support of the following people for their invaluable assistance in our research: K. Kops, L. Behrend, M. Padley, M. Liendo, and P. Carter.

The author or one or more of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article.

This article was primary edited by A. Liddle and first proof edited by J. Scott.

References


