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Research Article

The Satisfied Total Knee Replacement Patient: 3-Year Multicenter Results

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Abstract

Studies have shown that as many as 1 in 5 total knee replacement (TKR) recipients are dissatisfied with the outcome of their surgery. There has also been a large reported disparity between surgeon and patient perception of clinical "success". It has long been shown that surgeon opinion of procedural outcomes is inflated when compared with patient-reported outcomes. Additionally, TKR recipients have consistently reported higher pain levels, greater inhibition of function, and lower satisfaction than total hip replacement recipients. It is imperative that alternative methods be explored with which to improve TKR patient satisfaction. Therefore, the purpose of this prospective multicenter study was to report 3-year patient satisfaction levels following TKR with the use of intraoperative sensors to aid in soft tissue balancing, and to compare these satisfaction results with previous studies of which utilized other surgical modalities.

A total of 129 TKR patients were included in this study. All patients exhibited soft-tissue balance as determined by the sensor output. The definition of quantitative "balance" used was a medial and lateral compartment differential less than 15lbf., as previously reported. At 3-years, 98.3% of patients reported being "satisfied" or "very satisfied". A review of the literature identified no previous reports with a mean level of satisfaction that was greater than the balanced TKR group in this study. These results demonstrate that soft tissue balance via the use of intraoperative sensors may improve patient satisfaction compared to other technologies used during TKR.

Keywords: *Total Knee Replacement; Patient Satisfaction; Intraoperative Sensors; Soft-Tissue Balance*

Introduction

Despite long-term survivorship of contemporary total knee replacement (TKR) components, 1 in 5 recipients of TKR are dissatisfied with their outcomes. Possible reasons for dissatisfaction include limited function or higher pain levels. There is also a discordance between patient expectations and achievable activity levels. One reason for dissatisfaction is a mismatch between patient expectations and achievable activity levels [1]. One possible explanation for this disparity may be due to unique, TKR-related complications associated with soft-tissue imbalance [2-6]. Currently, over 40% of post-operative TKR complications may be attributed to ligament imbalance, including: stiffness, instability, and aseptic component loosening [7-10]. This subtle joint asymmetry may adversely affect biomechanical patterns in gait. Subsequently, impaired gait may contribute to increased pain and decreased function levels – two prominent factors implicated in poor post-operative outcomes [11,12].

Unfortunately, subtle asymmetry in joint balance has been historically difficult for the surgeon to detect. Developments in robotics, computer navigation, and patient specific instrumentation have been made with the hope of rectifying poor patient outcomes. However, none of these surgical modalities were developed with the expressed purpose of capturing the state of soft-tissue balance. Intraoperative sensors have been developed to quantitatively capture, intra-articular medial and lateral compartment loading forces throughout the range of motion. A prospective multicenter, observational study was designed in order to understand mid-term satisfaction levels of patients who have had a quantitatively balanced TKR performed with the use of these sensors. In this study, the investigators evaluated any potential improvement in patient-reported satisfaction following a sensor-assisted TKR, while comparing other satisfaction reports in peer- reviewed literature with the same follow-up period.

Patients and Methods

Mutlicenter Study Group Following IRB approval (NCT01469299), a cohort of 176 eligible patients were recipients of primary TKR in prospective, multicenter study at 8 centers. All patients were implanted with the same total knee system (Triathlon, Stryker Inc., Mahwah, New Jersey), using standard gap balancing or measured resections techniques in most cases. Computer navigation was utilized by two contributing surgeons for initial resections of the distal femur and proximal tibia. Intraoperative sensor technology was used in all

cases for soft tissue balancing (VERASENSE, OrthoSensor Inc., Dania Beach, Florida). VERASENSE is used during the trialing phase of TKR and geometrically replicates the dimensions of the polyethylene tibial trials of the total knee system used (matched via CAD modelling). The sensorized polyethylene insert wirelessly transmits medial and lateral compartment load forces (lbf) to a display screen, which sits outside the sterile field. These compartment load forces enable the surgeon to objectively measure soft tissue balance throughout the full range of motion.

The average demographic profile for this cohort is: 69.7 years of age, a 30.4 kg/m2 BMI, and a gender stratification of 36% male (n = 46) and 64% female (n = 83). In this study, approximately 38% of patients had distal femur and proximal tibia resections performed with the use of computer navigation (Stryker Navigation) (n = 49); while manual cutting guides were used in approximately 62% of patients (n = 80).

Exclusion criteria for recruitment into this study included patients < 50 years of age, previous TKR, fixed varus/valgus deformity greater than 15 degrees or flexion contracture greater than 20 degrees, ligament insufficiencies, prior soft-tissue surgeries (e.g. PCL reconstructions), osteotomies or any record of tibial plateau fractures. Patients were assessed pre-operatively, intraoperatively, six weeks, six months, and at annual intervals up to three years. Since the last report by Gustke., *et al.* 47 of the 176 eligible patients voluntarily withdrew from the research or were lost to follow-up (for varying reasons unrelated to their outcomes, i.e., disinterest in continuing to be seen annually) [24]. Thus, 129 patients were analyzed to evaluate patient reported satisfaction following sensor-assisted TKR.

The patients included in this analysis must have met the intraoperative balancing criteria previously reported by Gustke., *et al.* [14], wherein the medial and lateral compartmental load differential could not exceed 15 lbf. Of this group, there were no reported revision surgeries or procedure related complications that warranted hospital readmission. The satisfaction questionnaire was administered during the annual visits. The questionnaire contains 7 questions on a 5-point Likert scale (1 = worst outcome ('false' or 'very unsatisfied'); 5 = best outcome ('true', or 'very satisfied')), and previously received face validation [26]. Quantitative scores were stratified into five qualitative categories: "very dissatisfied", "dissatisfied", "neutral", "satisfied", "very satisfied", via questionnaire scores in 7- point increments, up to the maximum overall score of 35 points. All patients fully completed the satisfaction survey. In order to reduce potential answering bias, the questionnaire was completed by the patient prior to seeing the surgeon for follow-up.

Systematic Literature Review

A systematic review of existing literature on patient satisfaction following TKR was conducted. The protocol for harvesting comparative literature, indexed in PubMed, was as follows: 1) combinations of the following strings were queried, separately, by two contributing authors: "satisfaction total knee navigation", "satisfaction total knee computer assisted", "satisfaction total knee patient specific instrumentation", "satisfaction total knee 3 year", "satisfaction total knee 2 year", "satisfaction total knee customized", "satisfaction total knee patient specific cutting"; 2) the timeframe of publications accepted by the authors, for the purposes of reasonable comparison, was between January 2007 and October 2016 – this timeframe was established based on reported consistency in revision burden over time [14]; 3) the clinical follow-up reported in the included publications must have been a minimum of 2 years and a maximum of 3 years; and 4) studies with post-operative collection of satisfaction data with a statistical description of patients who were 'satisfied' to 'very-satisfied'. Only the studies that met the above criteria were included in this analysis.

All statistical analyses were performed using SPSS – Version 23 (IBM, Armonk, NY). In order to compare the mean satisfaction among navigated versus non-navigated patients in the multicenter study, an independent t-test was conducted. Significance levels were preemptively set at an α-level of 0.05. For the systematic review, owing to the high likelihood of heterogeneous collection methods, survey tools, and patient demographics, only descriptive data was described. Mean satisfaction data was evaluated in each study, and was stratified by surgical modality, where necessary.

Results

Multicenter Study Group At 3 years, 98.3% of the sensor-assisted cohort reported being "satisfied" to "very satisfied", as indicated by the combined total score of each satisfaction survey. There was no significant difference in satisfaction levels between patients with and without the use of computer navigation (P = 0.607). The average subscore for each question is shown in figure 1.

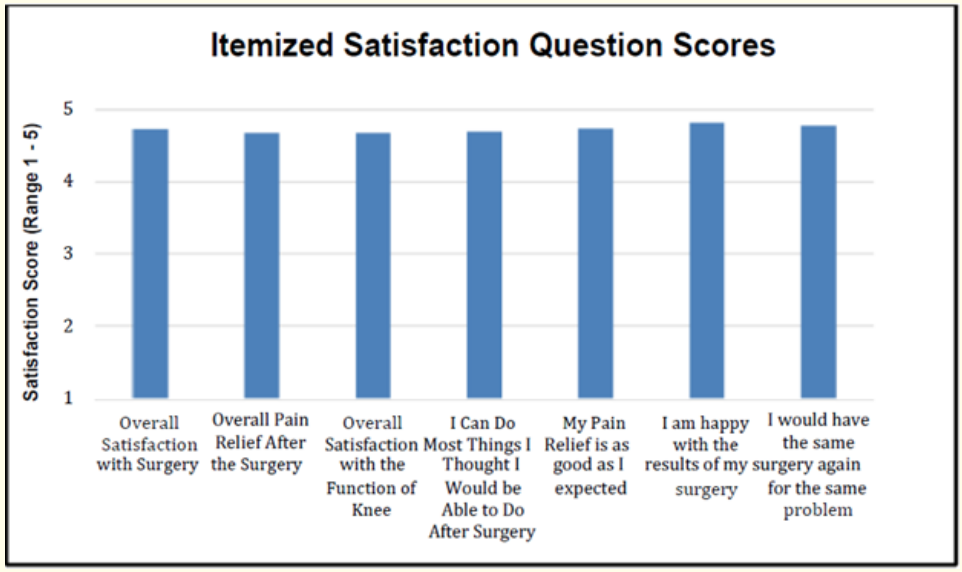

Figure 1

The total number of studies retrieved via the strings used in this systematic review was 1,875. Based on exclusion and inclusion criteria outlined in the review protocol, 8 studies were included in the final analysis (Figure 2) [15-22].

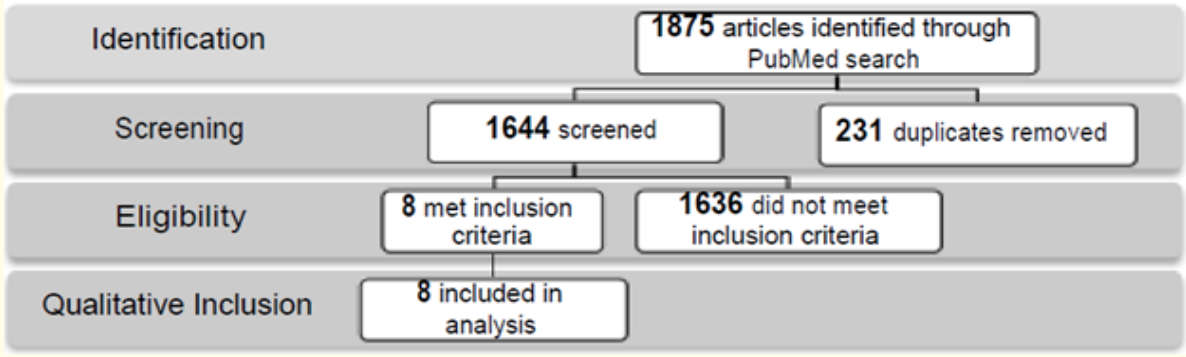

Figure 2

Overall, the total patient population (as a sum of the 8 included studies) included 2,585 knees. The overall, average follow-up period was approximately 2.4 years. The type of questions asked in this 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. An itemized accounting of each study demographic distribution and follow-up period (specific also by surgical modality type, where applicable) is seen in table 1. Note: several authors evaluated more than one group of patients – each patient group has been broken out and reported separately.

Authors	Follow-Up	Satisfaction Level
Keudell., *et al.* (manual)	3 years	87.0%
Jacobs., *et al* (manual)	3.5 years	90.5%
Liow., *et al* (robot)	2 years	93.5%
Liow., *et al.* (manual)	2 years	89.7%
Nam., *et al.* (PSI)	3 years	88.7%
Nam., *et al.* (manual)	3 years	89.5%
Martin., *et al.* (CT-navigation)	2 years	90.4%
Martin., *et al.* (imageless navigation)	2 years	67.0%
Merle-Vincent., *et al.* (manual)	2 years	89.8%
Spencer., *et al.* (navigation)	2 years	86.7%
Spencer., *et al.* (manual)	2 years	83.3%
Singisetti., *et al.* (navigation)	2 years	87.4%

Table 1: *Follow-up and Findings: Systematic Review Results.*

The average satisfaction reported in this literature review, at a 2-3 year postoperative follow-up, was 87%. One outlier exists in the literature, exhibiting 67% satisfaction for imageless navigation (Martin., *et al.*) which may be due to small sample size. When compared to the multicenter study group, at 3 years, the average satisfaction rate in this literature review is 11.3% lower (87% vs. 98.3%). The highest reported satisfaction in this literature review is 4.8% lower than the multicenter study group rate (93.5% vs. 98.3%) (Figure 3).

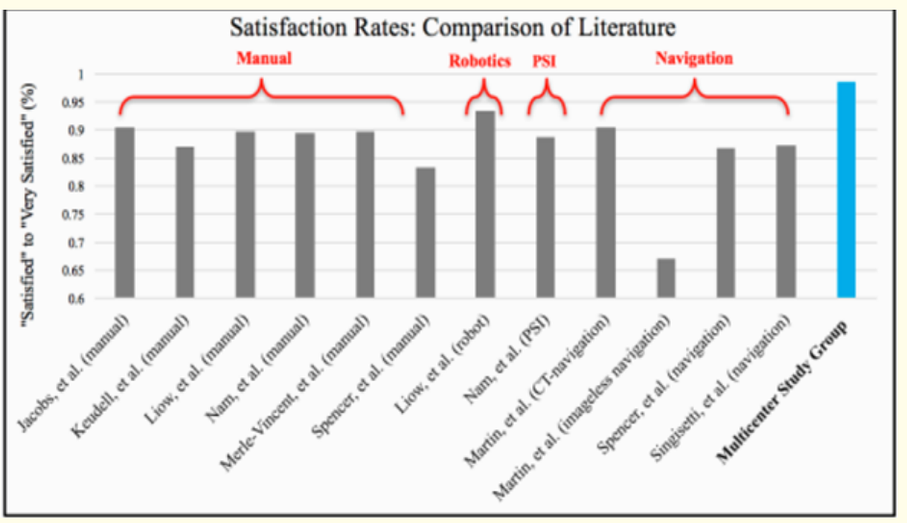

Figure 3:

Discussion

This study represents the first report of mid-term outcomes of patients following sensor-assisted TKR. The results in this evaluation are in agreement with previous publications, at shorter follow-up intervals, that suggest patients with quantifiably balanced soft-tissues outperform those with either non- quantifiably balanced, or imbalanced, joints [12,23,24]. To the authors' knowledge, the 3-year satisfaction levels exhibited by this multicenter study group are the highest reported among all TKR recipients, in literature, to-date. There are several reasons which may explain the trend seen in this group of sensor-assisted TKR patients. First, it is well-known that subtle soft-tissue imbalance is difficult for surgeons to detect manually. Therefore, having access to objective real-time balancing data at surgery may have allowed the surgeons to correct any residual imbalance outside of their traditional surgical techniques. Second, surgeon-applied force, during manual testing, varies between surgeons [25]. As such, this large variability may manifest as different perceptions of what is classified as "soft-tissue balance". However, the quantified data used in this study allows for the standardization of the definition of

balance. Third, it has been shown in literature that surgeons who use sensor guidance, during TKR, frequently make 1-2 additional surgical corrections beyond standard of care to achieve a well-balanced knee. Elmallah., *et al.* demonstrated that having access to quantified loading data led to a series of additional soft-tissue and component orientation corrections during sensor-assisted TKR, compared to traditional gap-balancing methods alone, wherein the surgeon was blinded to sensor data [26]. Fourth, utilizing quantified data to make informed corrections to the knee joint may mitigate pain and/or correct anatomic factors that can inhibit function. It has already been reported that pain and function are both prominent contributors to patient-reported satisfaction, therefore relying on objective loading data may assist the surgeon in correcting for states of asymmetry and overloading not detected with manual techniques. Taken together, sensor assistance may standardize soft-tissue balancing practices and decrease the proportion of imbalanced outlier knees.

The data harvested in the systematic literature review is partly in agreement with patient reported dissatisfaction levels of roughly 20 - 25% following TKR [27]. However, the average rate of satisfaction in this systematic review is a little higher, and was calculated to be 87%. The reason for this may be twofold: 1) the authors chose to include literature surrounding innovative technologies that have already been shown to increase patient-reported outcomes over manual techniques, and 2) Five of the eight reports used were published in the last 3 years, wherein the implementation of newer physical therapy protocols and post-operative regiments may have contributed to higher satisfaction [17-19,23,24].

There are several limitations in this study: 1) there is a lack of homogeneity in the methodology used to capture patient satisfaction among studies, and thus lack of robust statistical analyses available; 2) this study was neither randomized or blinded, which may have introduced assessment bias associated with the use of novel technology. However, the systematic literature review is meant to serve as a mode of comparison, and the low risk of bias in the studies collected make them appropriate for usage in this manner; 3) The multicenter study cohort is relatively small when compared to the total knees captured in the systematic literature review. However, it would be large enough – if variance and distribution of the systematic literature group could be determined – to compare statistically. The results from this study demonstrate that higher satisfaction in TKR may be achievable via the standardization of soft-tissue management. Incorporating intraoperative sensors for balancing into surgical workflow has demonstrated higher satisfaction levels compared to other surgical modalities used during TKR, for the same follow-up interval. This study, and its predecessors, have consistently shown clinically meaningful post-operative results for patients undergoing sensor-assisted TKR. While these trends toward increased satisfaction are promising, further studies should be directed at evaluating the long-term benefits of sensor-assisted TKR.

Declarations

The study received IRB approval by Western Institutional Review Board on September 27, 2011 (Protocol Number 20110927). All participating subjects were consented to participate in this research. No patient identifying information is reported within this manuscript. The results are reported in aggregate. Drs. Kenneth Gustke and Gregory Golladay are consultants and received royality payments from OrthoSensor, Inc. Dr Martin Roche serves as the Chief Medical Officer and is a board member for OrthoSensor, Inc. Dr. Roche also receives royalty payments from OrthoSensor, Inc. All authors have participated in this research enthusiastically and approved the content of this manuscript.

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