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Original Article

How are we addressing ligament balance in TKA? A literature review of revision etiology and technological advancement

Tyler Smith^a, Leah Elson^b, Christopher Anderson^{b,*}, William Leone^c^a Nova Southeastern University, College of Osteopathic Medicine, 3301 College Avenue, Davie, FL 33314, United States^b OrthoSensor Inc., Department of Clinical Research, 1855 Griffin Road, Dania Beach, FL 33004, United States^c Holy Cross Hospital, Leone Center for Orthopedic Care, 1000 NE 56th Street, Fort Lauderdale, FL 33334, United States

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ABSTRACT

Despite technological advances in operative technique and component materials, the total knee arthroplasty (TKA) revision burden, in the United States, has remained static for the past decade. In light of an anticipated exponential increase in annual surgical volume, it is important to thoroughly understand contemporary challenges associated with technologically driven TKA. This descriptive literature review harvested 69 relevant publications to extrapolate patient trends, benefits, costs, and complications associated with computer-assisted surgery, patient specific instrumentation, and intra-operative sensors. Due to additional charges, a steep learning curve, and questionable cost-effectiveness, widespread use of these systems has been limited. Intra-operative sensors are a relatively recent development, and have been shown to improve both soft-tissue balance and overall functional outcomes at a relatively low price and without disrupting operative workflow. The introduction of new technology into the operating suite should be considered carefully, especially with respect to combined clinical efficacy and cost.

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1. Introduction

The demand for total knee arthroplasty (TKA) in the United States is at an all time high.¹ This surge is likely due to a combination of factors, such as a rapidly aging population, the obesity epidemic, and an emerging trend of total knee arthroplasty in younger patients.^{2–6} Traditionally, a large proportion of total knee arthroplasties have been performed

by surgeons with many years of experience, fellowship training, and a high procedural volume.^{3,6} However, with the demand of TKA expected to reach nearly 3.5 million procedures by the year 2030, there is a projected shortage of experienced surgeons, and they will be heavily relied on to meet the increased volume.^{1,5,7} The effect of this inexperience on the revision rate of traditional TKA is a major cause for concern. Total knee arthroplasty has recently surpassed total hip arthroplasty as the most common orthopedic procedure worldwide.⁸

* Corresponding author.

E-mail address: canderson@orthosensor.com (C. Anderson).<http://dx.doi.org/10.1016/j.jcot.2016.04.001>

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The etiology behind the exponential growth of this procedure is multifactorial in nature. Firstly, the population is aging, and the number of Medicare enrollees is rapidly expanding. The number of US citizens older than 65 years of age is expected to double by the year 2030, with a fourfold increase in those 85 and older.² With Medicare covering over two-thirds of all TKA procedures, this represents the single largest proportion of Medicare spending among inpatient procedures.^{9,10} Over the last twenty years the volume of TKAs has increased the greatest among Medicare enrollees and obese patients.^{11,12} One particular impact of these changes will be reflected by a greater prevalence of osteoarthritis. Secondly, by 2025, 40% of the United States population will be affected with osteoarthritis.³⁵ Osteoarthritis results in articular osteophyte formation, ligamentous imbalance, and irreversible joint deformity.¹³ Total knee arthroplasty has proven to be both effective in significantly reducing pain associated with osteoarthritis and significantly more cost effective than prolongation with non-surgical methods.^{14,15} These factors make TKA a highly desirable treatment option.

Several advances in technology have been incorporated into total knee arthroplasty over the past decade. Yet despite these advances, revision rates of TKA are expected to rise.¹ The purpose of this literature review was to investigate the contemporary challenges associated with ligament balance in TKA, as well as the efficacy of three proposed technological solutions including: computer-assisted surgery, patient specific instrumentation, and intra-operative sensors. The three technological implementations were chosen due to their use in over one-third of all total knee arthroplasties performed annually⁷⁰; the investigation of efficacy with respect to ligament balance was chosen due to its large contribution to aseptic complications, post-operatively.²⁰

2. Methods

A literature review was conducted between November 21, 2014 and December 7, 2014. The following keywords were searched: “TKA”, “Total Knee Arthroplasty”, “revision”, “cost”, “economic”, “ligament”, “balance”, and “burden” in the following strings: “Total knee arthroplasty revision”, “revision burden of TKA”, “cost of revision total knee arthroplasty” “cost of revision TKA”, “economic burden of revision total knee arthroplasty”, “economic burden of revision TKA”, “ligament balance in revision TKA”.

The keywords and strings collectively resulted in 304 publications. 64 were excluded due to duplications, and 171 did not meet inclusion criteria. The final number of publications included in this literature review was 69 (Fig. 1).

3. Results

3.1. Etiology of TKA Failure

While total hip arthroplasty revision rates have steadily declined over the past several years, the revision rate for TKA is projected to increase fivefold by 2030 despite improvements in infection control, surgical methods, innovative

Fig. 1 – Flowchart of article selection for qualitative analysis of literature.

prosthesis designs, and accelerated rehabilitation programs.^{1,4,16–18} “Early” revision is typically defined as occurring within five years of the primary procedure, and is considered a devastating failure for both the patient and physician.¹⁹ Fehring et al. found that as many as 63% of TKA failures occur within the first five years.¹⁹ Of these early failures, 35% can be attributed to soft tissue imbalances.²⁰

Ligamentous alignment and component attenuation are intrinsically linked.¹³ Imbalance may manifest as stiffness, instability, prosthetic loosening, tibiofemoral incongruity, or as defects in patellofemoral tracking.^{13,21} In a study by Babazadeh et al., 86% of knees with asymmetrical component wear lacked ligamentous balance. This study also found that balanced knees have a significantly lower rate of prosthetic loosening. Micromotion in an asymmetric joint may result in accelerated osteoclast activity leading to osteolysis and component loosening or failure.¹³ Sharkey et al. reviewed the etiology of revision in 781 failed TKAs and determined that aseptic loosening was most common cause along with a significant number of revisions due to instability (Fig. 4).^{20,22} If all total knee replacements exhibited proper soft-tissue balance, the rate of early failures would improve by 40%, and the overall TKA failure rate by 25%.¹⁹

3.2. Balance as a determinant of function

Soft-tissue imbalance has been shown to be a significant determinant of post-operative pain and range of motion. Idiopathic pain is thought to be secondary to abnormal mechanical stress in an unbalanced joint. This requires muscles and tendons to work excessively in an attempt to dynamically stabilize the joint when it cannot be stabilized throughout the arc of motion by peri-articular soft tissue alone.²³ Kumar et al. found that malalignment resulted in significant deficits in proprioception, wound complications, infection, post-operative hematomas, and post-operative joint function.²⁴ Patient outcomes are standardized by using WOMAC (Western Ontario and McMaster Universities Arthritis Index) and KSS (Knee Society Knee Scoring System) scores to assess patient and physician reported functional status. Gutske et al. showed that balanced knees resulted in significantly higher KSS scores, reporting scores of 172 versus 142 for unbalanced groups.²¹ Additionally, the difference between pre-operative and 6 month post-operative KSS scores was 63.8 versus 42.6 in the balanced versus unbalanced groups, respectively.²¹ Balanced joint state was revealed to be

the variable exhibiting the most drastic effect on KSS and WOMAC scores, and therefore functional outcome.²¹

Balanced joint state was also shown to be associated with greater post-operative activity levels.²¹ This is particularly relevant to the rising trend of young patients undergoing TKA for relief of pain and improvement in function.²⁵ In recent years, the largest rates of increase in primary TKA were in patients age <45 and 45–64.⁴ Young patients place a greater demand on their prosthetics due to greater activity levels, and are more likely to develop component wear and failure secondary to aseptic loosening.^{26–29} The biomechanics of a balanced joint state are likely associated with a cascade of effects. Decreased post-operative pain likely leads to greater participation in physical therapy, therefore accelerated activity levels, and improved overall patient satisfaction.²¹

3.3. The subjectivity of balance

Soft-tissue balance has traditionally been achieved by the surgeon's sensation of ligamentous tension throughout various ranges of flexion, extension, varus, and valgus testing. This acquired “feel” of balance is highly dependent on surgical experience, fellowship training, and procedural case volume.^{21,30} Variations in patient age, gender, BMI, and disparities in ligamentous laxity from patient-to-patient all affect soft-tissue balance. This methodology is subjective in nature, and likely contributes to the alarming number of imbalance related complications and revisions.²¹ As primary TKA volume is expected to surge 673% by 2030, there is an expected shortage of physicians qualified with this acquired “feel” of balance.^{1,7} This will likely result in an overflow of TKA procedures for younger, less experienced physicians.⁷ A 2004 study by Katz et al. determined that over 10% of TKAs are performed in institutions in which there are a total of less than 25 TKAs per year. Additionally, they determined that only 25% of TKAs are preformed in centers where >200 TKAs are performed annually.³⁰ This data further suggests a nationwide lack of surgeon experience as TKA volumes rapidly rise. This dilemma may exacerbate the current projections, which expect the revision rate to double by 2015 and increase five fold by 2030.¹

3.4. Economic implications endemic to revision TKA

Revision TKA is associated with higher hospital expenses, implant and surgical charges, and greater overall resource consumption than primary TKA.⁵ The costs of TKA revision are approximately 60% higher than primary TKA, and are only 65% as cost-effective. The higher costs are primarily driven by greater length of stay and three fold greater implant cost.^{31–34} The economic burden of hospital charges for revision TKA was 2.7 billion in 2012.¹¹ Extrapolating for a five fold increase in revision rate by 2030, the economic burden is expected to near 13 billion in hospital charges alone.^{1,35} Medicare reimbursement rates for revision TKA have been decreasing steadily for the past several years, a discrepancy that will only contribute to the financial burden that costly revision procedures place on the health care system.^{36,37}

Revision TKA is also detrimental to a patient's return to employment. Return to work decreased after revision TKA to 78% versus 98% following primary TKA.^{7,38–40}

Additionally, the average elapsed time before a patient does return to work is approximately 9 weeks following primary TKA versus 3 months following revision TKA.⁴⁰ The average indirect cost of revision TKA is estimated to be nearly \$10,500 due to lost labor, productivity, and physical and mental suffering.^{23,41}

3.5. Technology as a solution

The rapid expansion of total knee arthroplasty during the last two decades has paralleled the golden age of technology in medicine. As revision surgery continues to place a rising financial burden on the health care system, modern technological advances in TKA methodology may offer a solution. However, in order to achieve implementation into accustomed use, emerging techniques must prove to be both safe and cost-effective.

3.5.1. Computer assisted surgery

Computer assisted surgery (CAS) or “navigation” was first developed in an attempt to increase the accuracy of bony resection and alignment while improving clinical performance in TKA. This system operates by placing bony pin markers that register physical anatomic landmarks with computer software in order to create a three-dimensional model of the patient's morphology. This software allows for exact anatomical mapping developed to improve the accuracy of bony resection and component positioning.⁴² The use of CAS has gained popularity in recent years, yet has failed to operatively surpass conventional methods of TKA due to a variety of reasons. While many authors agree that CAS does improve alignment, there is a lack of literature to support any differences in KSS scores or patient satisfaction, suggesting no improvement in functional or clinical improvement.^{42–48,67} Other studies suggest time-consuming registration of landmarks, risks of pin loosening, a steep learning curve, and higher costs are limiting factors.^{49,50} Navigation is associated with an additional cost of \$1500 per case, and is only likely to be cost-effective in high volume institutions where it is least likely to be necessary.^{51–53} At high volume centers, in which 250 TKAs are performed each year, CAS requires a reduction in the annual revision rate by 2.5% to establish cost-effectiveness. At low volume centers, in which only 25 TKAs are performed each year, a 13% reduction in revision rate is necessary.⁶⁴ Concerns of cost-effectiveness, improvements in functional outcome, prolonged OR and tourniquet times, and higher procedural cost have limited the expansion of CAS in TKA.⁴⁶

3.5.2. Patient specific instrumentation

Patient specific instrumentation (PSI) was developed as an alternative to computer assisted surgery by combining the benefits of CAS with the improved efficiency of a patient specific system.⁵⁴ PSI was designed to potentially improve alignment and component accuracy, eliminate outliers and variations in positioning, and establish restoration of a neutral mechanical axis with improved OR times.^{54,55} This software creates patient specific cutting blocks using pre-operative MRI or CT based images. This custom block is then used intra-operatively incorporating anatomic parameters that are unique to each patient. Custom cutting blocks have displayed

improved OR times and exceptional restoration of mechanical axis.^{54–57} Lombardi et al. presented results of 54 TKAs performed using PSI and found that all cases displayed accurate component positioning and satisfactory restoration of mechanical axis.⁴⁹ In addition, Watters et al. determined that PSI saved an additional 28 min of OR time versus conventional TKA, and an additional 67 min versus CAS.⁵⁸ This time reduction is largely due to fewer required surgical trays, and may allow for an increased operative caseload and therefore improve the cost-effectiveness of PSI. However, while computer-assisted surgery allows for confirmation of cut accuracy and subsequent intra-operative corrections, PSI does not.⁵⁴ The accuracy of pre-operative planning is a factor that largely influences the cost-effectiveness and surgical efficiency of PSI, as rechecking cut thickness, component sizing, and component positioning all add time and disrupt operative flow.⁵⁹ Sassoon et al. performed a systematic review of 22 controlled studies and determined that although PSI showed a consistent reduction in the number of surgical trays used, this efficiency was negated by the prevalence of times in which PSI-generated preoperative plans needed to be altered intra-operatively.⁵⁹ Along with an additional cost of over \$1000 per case and additional patient radiation exposure, variations in literature supporting the clinical accuracy of PSI have limited routine use.^{56,57,59–61}

3.5.3. Intra-operative sensors

The use of intra-operative sensors is a relatively recent development in the field of orthopedics, yet has already shown signs of promise, both operatively and clinically. Microelectronic sensors embedded into the tibial tray allow for dynamic, in vivo evaluation of joint loading and peak center of load location. Tibiofemoral contact points are displayed by a graphical interface that exhibits a quantitative analysis correlating intercompartmental pressures throughout full range of motion. This enables the surgeon to receive real-time feedback of component positioning and torque, adjusting any imbalance with additional bony resection or soft-tissue corrections.^{62,63} Wasielewski et al. reported on the first smart tibial trial in 2004 and determined that intra-operative sensors displayed greater sensitivity and were able to detect subclinical compartment abnormalities that were not detected by the surgeon's feel.^{62,63} The majority of these subclinical abnormalities occurred in flexion, where variables such as leg size and the surgeon's ability to stabilize the knee can make a qualitative assessment of balance difficult.⁶² Disposable and intended for single use, this technology is relatively inexpensive at less than \$1000 USD per case.⁶⁴ In addition, because the sensors are embedded in the tibial tray there are no supplementary operative steps and therefore no disruption in workflow.⁶⁴ Sensor-assisted TKA has also demonstrated a trend toward post-operative weight loss when compared to conventional TKA.⁶⁵ This is likely due to greater WOMAC, KSS, and activity level scores reported with patients receiving sensor-assisted TKA.²¹ The greatest limitation of this technology includes the fact that measured pressures and load are detected in an open-chain, non weight-bearing state without surrounding muscle contraction.^{62–64} Soft-tissue balance is likely variable with weight-bearing activities, so the use of intra-operative sensors may serve as a relative

rather than absolute measurement of joint balance until further analysis is completed.^{62–64} There is limited research regarding the use of sensor-assisted TKA, however nearly all of the research depicts favorable outcomes. Additionally, the cost-effectiveness of this technology has yet to be extensively investigated. This technology provides enhanced sensitivity and additional insight into joint balance, and may be ideal for low volume centers in which surgeons may lack the acquired “feel” for soft-tissue balance.

4. Discussion

The rapid expansion of total knee arthroplasty over the last decade has been primarily driven by an increase in per capita utilization.¹¹ Figs. 2 and 3 illustrate the exponential nature of current primary and revision TKA projections through 2030. An aging population, worsening obesity epidemic, and high prevalence of osteoarthritis make TKA a desirable treatment, especially for young patients.^{3,7,66} TKA at a younger age may prevent disease progression and comorbidities associated with inactivity, such as obesity, diabetes mellitus, and heart disease among others.⁷ Subsequently, patients may prevent costly health related expenses in the future related to these associated comorbidities.⁷ However, TKA components in younger patients are more inclined to wear, at an accelerated pace, because of increased activity and impact.^{26–29} This may lead to an increased demand of complex, costly revision procedures. One study predicted that by 2020 the demand for orthopedic procedures will increase by 23%, while the supply of orthopedic surgeons will increase by only 2%.⁶ The number of graduating orthopedic residents interested in adult reconstructive careers is declining, as demonstrated by the number of unfilled positions and closing fellowship programs.^{1,3,6,68} The expansion of TKA utilization will place a heavy burden on orthopedic surgeons nationwide, and younger, less experienced physicians without arthroplasty fellowship training will be called upon to support the rising demand.^{3,6} Ten percent of total knee arthroplasties are currently performed in institutions in which less than 25 TKAs are performed annually, and 75% are performed in institutions with fewer than 200 annual TKA procedures.³⁰ The expected shortage of physicians qualified with an acquired “feel” of ligamentous balance

Fig. 2 – Generated from published data^{41,43} illustrating projections for revision TKA from 2005 to 2030.

Fig. 3 – Generated from published data^{41,43} illustrating projections for primary TKA from 2005 to 2030.

may, in turn, lead to further expansion of already troublesome revision rates.^{7,21} Revision surgeries require greater technical skill and are associated with inferior outcomes, especially revisions due to aseptic stiffness.^{32,69} Revision TKA consumes nearly double the resources of a primary procedure and may cost up to twice the amount of a primary procedure.^{5,35,53} The economic burden of hospital charges for revision TKA was 2.7 billion in 2012 alone.³⁵ Patients are less likely to return to work following revision TKA, and indirect costs due to lost labor, reduced productivity, caretaker expenses, and physical and mental suffering contribute to this economic burden (Figs. 4 and 5).^{7,23,38–41}

Recent technological advances have addressed the concerns of revision surgery and have made strides to target accurate alignment and correct for ligamentous instability (Tables 1–3). Yet inconsistent results in literature, additional charges, a steep learning curve, and questionable cost-effectiveness have limited widespread use of systems such as computer-assisted surgery and patient specific instrumentation.^{31,42,45,47,49,50,55–57,61} Intra-operative sensors are a relatively recent development, and have been shown to improve

Fig. 4 – Generated from published data^{41,62,63} displaying reported reasons for revision (overall) associated with imbalance. CR, cruciate retaining; PS, posterior stabilizing.

Fig. 5 – Annual growth of primary TKA with relative stability of revision burden. Generated from published data,¹³ more recent data not readily available.

both soft-tissue balance and overall functional outcomes at a relatively low price and without disrupting operative workflow.^{21,62–65} The literature regarding the use of intra-operative sensors is limited and has yet to thoroughly analyze its cost-effectiveness, but the studies that do exist have shown signs of

Table 1 – Pros and cons of computer-assisted surgery.

Pros	Cons
<ul style="list-style-type: none"> • Provides quantitative data for surgeons to make objectively based alignment decisions • Decreases component positioning outliers • May help as a training tool for resident surgeons 	<ul style="list-style-type: none"> • Increases operative time • Registration process of markers introduces additional complexity to the procedure • Navigation hardware and software is costly and may require regular maintenance

Table 2 – Pros and cons of patient specific instrumentation.

Pros	Cons
<ul style="list-style-type: none"> • Less instrument trays are necessary • No complex registration process • No extraneous equipment in the operating room • Shorter operating room times 	<ul style="list-style-type: none"> • Extra costs associated with pre-operative imaging • Extra radiation exposure to patient for imaging • Cutting jigs may exhibit inaccuracy, which may impact operating room efficiency

Table 3 – Pros and cons of intra-operative sensors.

Pros	Cons
<ul style="list-style-type: none"> • Quantified, real-time feedback regarding joint balance and rotational alignment • Does not disrupt surgical workflow • Disposable, single-patient use 	<ul style="list-style-type: none"> • Limited availability for specific constraint designs • Captures non-weight bearing kinetics • Non-implantable; does not track kinetics for duration of component lifetime

promise. With an expected 5-fold increase in revisions by 2030, the financial burden associated with institutions performing revision procedures is a major cause for concern.^{1,4,35} Without a method of intervention, the current probability of revision surgery is primarily dependent on the surgeon's capacity to obtain appropriate balance.

Conflicts of interest

Authors CA and LE are agents of OrthoSensor, Inc.; Author WL is a paid consultant for Stryker and OrthoSensor, Inc.

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