25 Sensor-Based Soft Tissue Balancing in Total Knee Arthroplasty

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Abstract

Total knee arthroplasty (TKA) is a highly successful procedure with utilization expected to grow substantially over the coming decades. However, the revision burden has not concurrently improved, with over 30% of revisions related to technical imperfections (Mulhall KJ, Ghomrawi HM, Scully S, Callaghan JJ, Saleh KJ, Clin Orthop Relat Res 446:45, 2006; Sharkey PF, Hozack WJ, Rothman RH, Shastri S, Jacoby SM, Clin Orthop Relat Res 404:7, 2002; Wylde V, Hewlett S, Learmonth ID, Dieppe P, Pain 152(3):566, 2011). Accurate alignment and soft tissue balancing have been identified as important factors in mitigating these risks. Historically, accuracy relating to soft tissue balance has relied upon surgeon experience and subjective tactile feel. This chapter will explore the utilization of intraoperative sensors related to soft tissue balancing in total knee arthroplasty.

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Keywords

Total knee arthroplasty (TKA) · Intraoperative sensor · Soft tissue balance · Sensor-assisted surgery · Surgical robotics

25.1 Introduction

Total knee arthroplasty (TKA) is one of the most successful and cost-effective joint replacement procedures currently performed. Despite this, risk for failure requiring revision at 10 years postoperatively is nearly 5%, with patients reporting dissatisfaction nearly 20% of the time [4, 5]. Infection, instability, pain, and stiffness have been implicated as the leading causes for revision and dissatisfaction [2, 5, 6]. Requirements for a successful TKA are thought to include both neutral alignment and soft tissue balancing [7, 8]. Recent interest in various alignment parameters on soft tissue balance and potentially improved outcomes (Anatomic, Kinematic) are being investigated [9]. Historically achieving proper soft tissue balance relies heavily upon the surgeon's subjectively perceived tactile feel of ligamentous tension, surgical training, operative experience, and overall skill [10].

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Newly emerging intraoperative load-bearing sensor technology has enabled surgeons to mitigate the inherent drawbacks of subjective knee balancing. This sensor provides dynamic load pressures visualized through a graphical user interface display. The surgeon can visualize the effects of implant rotation and limb alignment on soft tissue balance through a range of motion. The surgeon can receive real-time dynamic information as they adjust rotation, alignment, and the effects of selective soft tissue releases. Knee stability, with inter-compartmental balance, has been shown to be the most important contributor to improved postoperative outcomes, and the ability to visualize objective load data is highly important [4, 11]. There are presently two commercial disposable intra-op devices that utilize load data during a TKA.

25.2 Intraoperative Load-Bearing Sensors

Verasense (Verasense Knee System, Orthosensor Inc., Dania Beach, FL) is a sensorized device that replicates the specific design of the final polyethylene insert. It is implant agnostic and presently compatible with Stryker, Zimmer Biomet, and Smith & Nephew implants. During trialing, the device replaces the standard tibial insert trial. The surgeon utilizes the data through a full range of motion with the patella and capsule reduced. The wireless device measures inter-compartmental load pressures, implant congruency, kinetic rollback, and flexion stability. The pressure differentials, combined with knee position, guide the surgeon on the specific adjustments related to implant rotation, bony realignments, and selective soft tissue releases. The system can be utilized during trialing, cementation, and post-cementation to confirm knee stability in the coronal, rotational, and flexion space, with static and dynamic outputs. The data can be saved and linked to the patients' implant, post-op PROMS, and functional scores (Fig. 25.1).

25.2.1 Benefits of Sensor-Guided TKA

Current projection models show an exponential increase in the incidence of TKA which necessitates the development of new technologies to improve patient outcomes [12, 13]. The use of quantified intra-op data related to knee balance and stability is necessary if we are to address revisions related to imprecise technical factors and patient dissatisfaction in TKAs.

The use of intraoperative sensors was found to significantly improve patient-reported outcomes (Knee Society Score (KSS) and Oxford Knee Score) in a comparative cohort study of 114 patients (57 manual, 57 sensor assisted) who received a primary TKA with a 6-month follow-up [14]. Similarly, in a cohort of 135 sensor-assisted TKA with a minimum 1-year follow-up found excellent KSS and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores of 179.3 and 10.4 in KSS and WOMAC, respectively [11]. Furthermore, soft tissue imbalance is a known contributing factor to many of the complications leading to revision including pain (44%), instability (21%), and joint stiffness (17%) [1–3]. Soft tissue imbalance may be due to the subjective nature and static measurements of manual TKA techniques that rely upon static instruments, surgeon experience, and tactile feel [15, 16]. In a randomized clinical trial (RCT), when blinding surgeons to data outputs, the correlation between their subjective feel of a balanced knee was correct only approximately 50% of the time [17, 18].

The intraoperative sensor mitigates the surgeon's imprecise knowledge of three-dimensional soft tissue stability through real-time dynamic quantitative and objective load data. As described in one study, the sensor outputs allowed for targeted ligament balancing with an average of two to three corrections being needed to achieve ligament balance, thereby decreasing loading variability and ligament imbalance [19]. In addition, studies

Fig. 25.1 Surgeon evaluates implant rollback and soft tissue pressures on computer screen through a full ROM

have shown a significant reduction in the rate of postoperative arthrofibrosis/stiffness and subsequent manipulation under anesthesia when utilizing intraoperative sensor assistance during TKA [14, 20]. Further studies on safe zones of bony alignment (+/− 3 degrees coronal plane) have found that soft tissue balance obtained with 1–2 degrees of bone adjustments may reduce the risk of destabilization from an over-released soft tissue envelope [21, 22].

The sensor can be utilized during revision surgery to help define the root cause of a painful knee where x-rays and work-up are negative. This enables a potentially modified revision leading to less morbidity and economic resource expenditure (Fig. 25.2).

25.2.2 Surgical Technique

The TKA is performed as per the usual fashion, with the sensor being utilized during the trialing phase. After initial trial component placement, the trial tibial insert is substituted with the sensor insert. Shims are used to account for thicker insert sizes.

Tibiofemoral rotational congruency is then evaluated (determined as the position of the tibia in relation to the femoral contact point); positive contact point angles were indicative of internal rotation, while a negative value indicates external rotation. Once congruency is obtained, the patella is then reduced and the capsule closed with towel

Fig. 25.2 Surgeon identifies malrotation and an over-tensioned lateral compartment in a painful TKA. Revision was modified to address both issues and a balanced knee was obtained

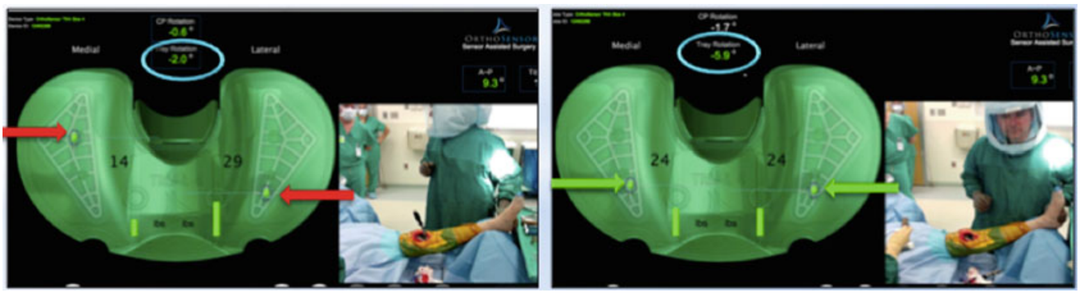

Fig. 25.3 Surgeon rotates the tibia from IR position to obtain congruency and achieves equalized inter-compartmental balance

clips prior to range of motion (ROM) as this has been shown to affect load outputs [23] (Fig. 25.3).

Soft tissue tension is best defined at 10°, 45°, and 90° of flexion, with the hip and leg in a neutral position during ROM. A balanced knee is determined when a mediolateral loading differential of $\leq$15 lbs through the ROM with absolute loading pressures falls between 10 and 40 lbs along with a stable end point (minimal translation <2 mm) on posterior drawer testing [11, 24, 25]. Of note, it is important to reference load pressures during cementation, as elements of imbalance were observed in 44% of patients during initial cementing techniques [26].

25.3 Intraoperative Force Measurement Device

The other commercially available device is the eLIBRA® dynamic knee balancing system (DKBS) (Synvasive Technology, Zimmer® Warsaw, IN). This knee system allows for measured balanced resection utilizing an electronic force measurement device along with an adjustable femoral component device to achieve a symmetrical flexion gap. This system was designed to account for patient variability that may produce irregularities that occur with standard techniques that depend upon empirical anatomical bone landmarks [27]. However, this device does not measure pressures or tensions and is only compatible with Zimmer knee systems and instrumentation.

25.3.1 Benefits of Force Measurement TKA Flexion Gap

The force measurement system is designed to address intraoperative flexion instability with objective dynamic measurements of inter-compartmental soft tissue forces allowing patient-specific femoral component rotation [28]. In a study of 75 force measurement-assisted TKA patients, postoperative cone beam computed tomography (CBCT) found that there was optimal orientation of the femoral component with a mean of 2.18° of external rotation [29]. This study also found an improvement in KSS clinical and functional scores (preoperative means of 48.35 and 47.53; postoperative means of 88.03 and 91.2 ($p < 0.001$ for both aspects)) [29].

25.3.2 eLIBRA Surgical Technique

The TKA is approached as per the surgeon's usual preferred technique with a modified trial femur and sensor inserted following the distal femur and proximal tibia resections with care to reducing the patella. Alternatively, the force plate may also be inserted under the trial insert or gap spacer paddle. The femoral posterolateral implant is then adjusted to obtain load pressures. The sensors are outfitted with force transducers on both the medial and lateral sides which are represented on a graphical user interface (Fig. 25.4).

The values depicted can range from 1 through 20 with each unit representing approximately 15 newtons (3.4 lbs of force). Following adequate symmetrical balancing, the femoral rotation is marked, the trial femoral block is inserted, and the TKA is completed as usual. The force plate can be used under the tibial trial for final evaluation.

25.4 Robotic- and Sensor-Assisted Surgery Synergy

The future integration of sensors that quantify the patient's soft tissue tension, and knee stability through a full range of motion, enables the robot to make incremental implant and bone readjustments to allow true customization of a patient's total knee soft tissue balance and alignment.

25.5 Conclusion

Intraoperative load-bearing sensors deliver real-time dynamic and objective load-bearing data to the surgeon through a full range of motion. This assists the surgeon in accurately and consistently balancing the knee during TKA. The surgeon can now minimize subjective decisions that can lead to inconsistent surgical

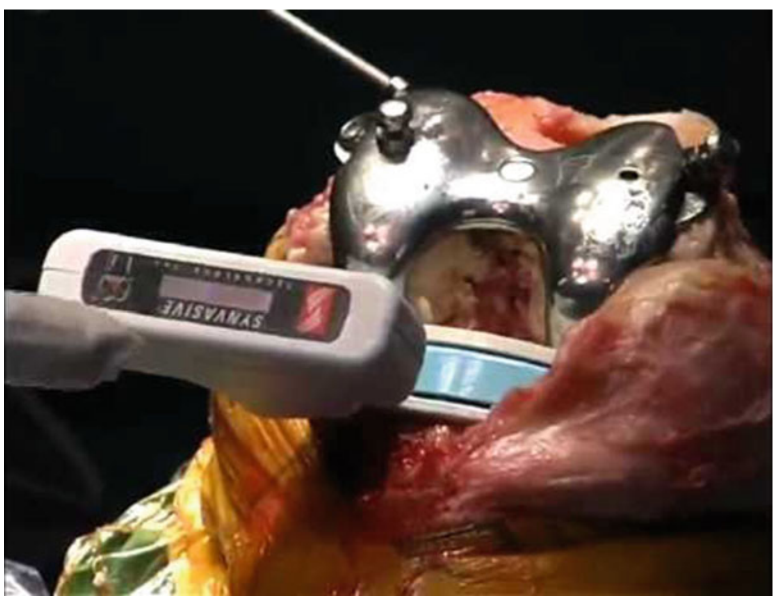

Fig. 25.4 *eLIBRA* device

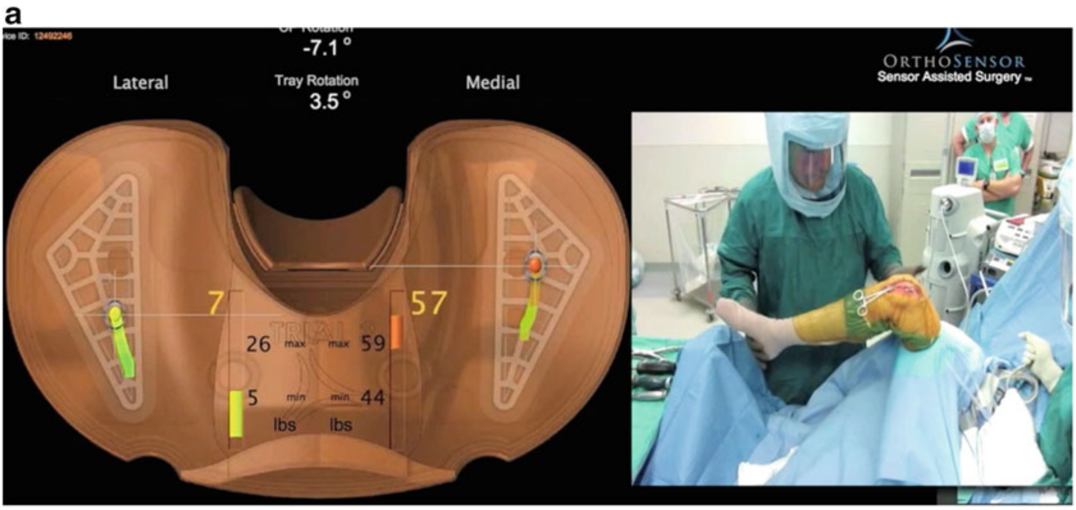

Fig. 25.5 Sensor depicts an over-tension MCL in flexion

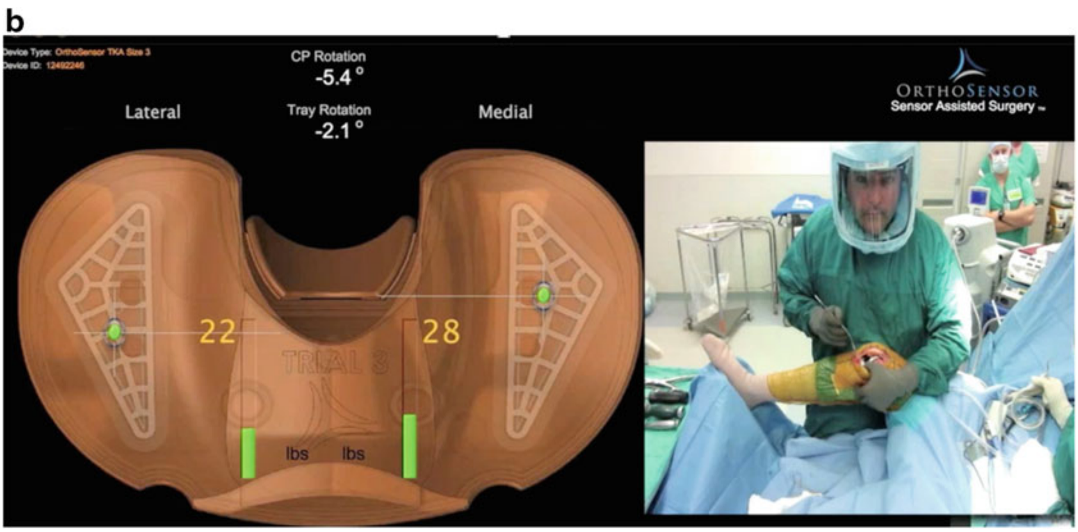

Fig. 25.6 Surgeon dynamically pie-crusts the anterior MCL until inter-compartmental balance is obtained

outcomes. The knowledge of the implant design and how the implants need to be coupled in a congruent manner through a full range of motion enables the surgeon to minimize malrotation as a confounding variable. The safety of pie-crusting to selectively elongate the soft tissue enables the surgeon to titrate their releases with resultant real-time soft tissue tension outputs [30, 31] (Figs. 25.5a and 25.5b).

The evolution of robotics into the TKA field now enables surgeons to perform accurate bony adjustments while obtaining soft tissue balance within known acceptable alignment parameters. This is the first step to customize our surgery to the individual's specific alignment and soft tissue signatures. Knowledge of the knee's kinetics (force + motion) in three planes will continue to evolve the mastery of our surgical techniques to achieve our evolving data endpoints (Fig. 25.6).

As machine learning advances, surgeons will be provided consistent zones and outputs, with data-driven techniques to improve our outcomes and potentially match our patient expectations.

Fig. 25.7 Computer screen displays the alignment, gaps, rotation, and kinetic rollback of the knee during surgery

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