



Original research

Dynamic sensor-balanced knee arthroplasty: can the sensor “train” the surgeon?

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ABSTRACT

Background: Dynamic tibial tray sensors are playing an increasing role in total knee arthroplasty (TKA) coronal balancing. Sensor balance is proposed to lead to improved patient outcomes compared with sensor-unbalanced TKA, and traditional manual-balanced TKA. However, the “learning curve” of this technology is not known, and also whether sensor use can improve manual TKA balance skills once the sensor is taken away, effectively “training” the surgeon.

Methods: We conducted a single-surgeon prospective study on 104 consecutive TKAs. In Nonblinded Phase I (n = 49), sensor-directed releases were performed during trialing and final inter-compartmental load was recorded. In Blinded Phase II (n = 55), manual-balanced TKA was performed and final sensor readings were recorded by a blinded observer after cementation. We used cumulative summation analysis and sequential probability ratio testing to analyze the surgeon learning curve in both phases.

Results: In Nonblinded Phase I, sensor balance proficiency was attained most easily at 10°, followed by 90°, and most difficult to attain at 45° of flexion. In Blinded Phase II, manual balance was lost most quickly at 45°, followed by 90°, and preserved for longest at 10° of flexion. The number of cases in the steady state periods (early phase periods where there is a mix of sensor balance and sensor imbalance) for both phases is similar.

Conclusions: A surgeon who consistently uses the dynamic sensor demonstrates a learning curve with its use, and an “attrition” curve once it is removed. Consistent sensor balance is more predictable with constant sensor use.

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Introduction

Recent studies suggest that a balanced total knee arthroplasty (TKA) may lead to better functional outcomes and patient satisfaction [1–5]. Manual coronal plane balance has been achieved primarily through tactile feedback and visual cues. Whether a knee is “balanced” is subjective and is affected by various factors including surgeon training, experience, and surgical volume [6,7].

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Furthermore, unlike joint alignment, cut angles, and magnitude of component rotation, there has not been a widely accepted metric for “balance.” Asymmetric radiographic joint space gapping is but one sign of gross extension space coronal imbalance. There are as yet no comparable markers for finer magnitudes of imbalance and imbalance at varying degrees of flexion.

In recent years, dynamic sensors have played an increasing role in coronal plane balancing. These sensors display tibiofemoral contact points and measure load (or force) to provide real-time intraoperative feedback on whether the knee is truly “sensor-balanced.”

Various authors suggest that sensor-balanced TKA may lead to improved patient satisfaction and patient-reported outcomes [1–5], improved survivorship, and a reduced need for revision [8]. It is thought that by providing a value to nebulous subjective terms such as “loose” or “tight,” the sensor is able to guide decision

Table 1
Demographic and load data between phases.

Characteristic	Nonblinded phase I (n = 49)	Blinded phase II (n = 55)	P value
Female sex	34.7% (17)	45.5% (25)	.264
Age (y)	61.5 ± 7.6	62.7 ± 0.9	.393
BMI (kg/m ²)	32.1 ± 5.7	31.4 ± 6.3	.532
Height (cm)	174.4 ± 10.6	170.8 ± 10.7	.087
Weight (kg)	97.6 ± 18.5	91.4 ± 19.5	.099
Left side (%)	53.1 (26)	45.5 (25)	.439
Medial compartment load (10°) (lbs)	29.2 ± 14.8	26.4 ± 17.3	.379
Medial compartment load (45°) (lbs)	27.8 ± 18.8	24.7 ± 14.1	.330
Medial compartment load (90°) (lbs)	22.0 ± 14.3	25.0 ± 13.1	.279
Lateral compartment load (10°) (lbs)	24.4 ± 11.1	22.3 ± 13.1	.365
Lateral compartment load (45°) (lbs)	23.8 ± 11.4	22.2 ± 15.2	.553
Lateral compartment load (90°) (lbs)	20.2 ± 11.6	21.6 ± 14.5	.586

making and steer the surgeon toward additional soft tissue releases and bony resection.

Elmallah et al [6] established that sensor-balanced TKAs demonstrate lower medial and lateral compartmental loads and lower differences in intercompartmental loads compared to manual-balanced TKAs. What is not known is whether sensor use is able to improve manual TKA balance, or “train” the surgeon. We hypothesize that by converting subjective “looseness” and “tightness” into quantifiable terms (“sensor-balanced” and “sensor unbalanced”), the dynamic sensor may additionally function as a teaching tool and aid the recognition of abnormal coronal balance, improving overall manual TKA skills even in the absence of the sensor.

We hoped to achieve a few objectives in this study. First, we sought to assess a surgeon’s learning curve (LC) with coronal plane balancing using a dynamic sensor to direct soft tissue and bony releases (Nonblinded Phase I). Second, we wanted to determine if following a period of sensor-directed learning, the surgeon could achieve the same balance in the absence of the sensor (Blinded Phase II). In this study, we used cumulative summation (CUSUM) analysis and sequential probability ratio testing to assess the surgeon’s performance during these 2 phases.

Material and methods

We conducted a single-surgeon prospective study at our institution and included the first 100 patients whose TKA procedures

included the use of the dynamic sensor. This cohort of patients represents the senior author’s initial experience with the device, having performed all prior cases using manual balancing. The senior author is a fellowship-trained arthroplasty surgeon with 13 years of clinical experience and performs approximately 800 total joint arthroplasty cases per year.

The study cohort included 99 consecutive patients with 104 consecutive knees undergoing primary TKA between September 2016 and August 2017 with the diagnosis of primary osteoarthritis, post-traumatic arthritis, avascular necrosis, and inflammatory arthritides. We excluded patients with flexion contracture >20°, coronal plane deformity >20°, those requiring revision surgery, hardware removal, and complex primary surgery requiring the use of stems, cones, sleeves, wedges, or augments. Institution review board approval was obtained for this study.

Surgical technique

TKA was performed through a midline incision with medial parapatellar arthrotomy under tourniquet control. Distal femoral and proximal tibial cuts were made using an accelerometer-based surgical navigation system (KneeAlign 2; OrthoAlign, Inc., Aliso Viejo, CA) [9,10]. The senior surgeon has been using this navigation system since its inception, and has 6 years of experience prior to this study. The distal femoral cut was made perpendicular to the mechanical axis, with 3° of flexion. The tibial cut was made perpendicular to the tibial mechanical axis, with 3° of posterior slope. All knees received a cemented posterior-stabilized Journey II BCS knee system (Smith & Nephew Inc., Memphis, TN) and were performed by the senior author.

Dynamic sensor testing

The dynamic sensor (Verasense; OrthoSensor, Dania Beach, FL) was used. Load readings in the medial and lateral tibiofemoral compartments were recorded at 10°, 45°, and 90° of flexion. At each of these flexion angles, the knee was held supported by the surgeon’s hands placed at the ankle and distal thigh, with the patella and foot pointing directly at the ceiling, and with the patella reduced and arthrotomy held provisionally closed using a single towel clip at the level of the superior patellar pole [11]. Care was taken to ensure that the limb was supported in the same fashion in each case.

Definitions

We defined successful coronal balance as mediolateral intercompartmental load difference of ≤15 lbs and unsuccessful balance

Table 2
Nonblinded phase I: demographic data between sensor-balanced and sensor-unbalanced patients.

Characteristic	Sensor-balanced ^a (n = 23)	Sensor-unbalanced ^a (n = 26) ^b	P value
Female sex (%)	34.8 (8)	34.6 (9)	.990
Age (y)	61.8 ± 6.0	61.3 ± 8.8	.819
BMI (kg/m ²)	32.2 ± 6.0	32.1 ± 5.5	.936
Height (cm)	174.9 ± 10.1	173.9 ± 11.1	.750
Weight (kg)	98.2 ± 18.0	97.2 ± 19.3	.852
Left side (%)	39.1 (9)	65.4 (17)	.066

^a Sensor-balanced is defined as ≤15 lbs of mediolateral difference at all 3 tested flexion angles (10°, 45°, and 90°). Sensor-unbalanced is defined as >15 lbs of difference in at least 1 flexion angle.

^b Sensor-unbalanced at all 3 tested angles, n = 3; sensor-unbalanced at 2 of the 3 flexion angles, n = 6; and sensor-unbalanced at 1 of the 3 flexion angles, n = 17.

Table 3
Blinded phase II: demographic data between sensor-balanced and sensor-unbalanced patients.

Characteristic	Sensor-balanced ^a (n = 17)	Sensor-unbalanced ^a (n = 38) ^b	P value
Female sex (%)	41.2 (7)	47.4 (18)	.670
Age (y)	62.7 ± 4.0	62.7 ± 7.3	.987
BMI (kg/m ²)	32.4 ± 8.0	30.9 ± 5.4	.506
Height (cm)	169.9 ± 11.6	171.1 ± 10.4	.695
Weight (kg)	93.6 ± 25.8	90.4 ± 16.3	.642
Left side (%)	29.4 (5)	52.6 (20)	.110

^a Sensor-balanced is defined as ≤15 lbs of mediolateral difference at all 3 tested flexion angles (10°, 45°, and 90°). Sensor-unbalanced is defined as >15 lbs of difference in at least 1 flexion angle.

^b Sensor-unbalanced at all 3 tested angles, n = 9; sensor-unbalanced at 2 of the 3 flexion angles, n = 20; and sensor-unbalanced at 1 of the 3 flexion angles, n = 9.

as load differences >15 lbs [1–3,12]. We defined “sensor-balanced” as ≤ 15 lbs difference in all 3 tested flexion angles (10°, 45°, and 90° flexion) and “sensor-unbalanced” as >15 lbs difference in ≥ 1 flexion angle.

Phase definition: nonblinded phase I—skill acquisition

The sensor was inserted during placement of trial implants. Soft tissue releases were performed as directed by sensor readings with trial components in place using the balancing matrix proposed by Gustke et al [13]. Using this algorithm, additional steps were also adopted if there was symmetric coronal balance but increased absolute load values. As an example, 20–40 lbs load at 10° was addressed with posterior capsular release, while >40 lbs load was addressed with additional distal femoral resection. Final sensor readings were recorded at 10°, 45°, and 90° of flexion with the actual implants cemented in place [14]. Target patient enrollment was 50 TKAs for this phase. This number was derived based on studies showing that the typical LC for a new procedure is 30–50 cases [15]. One patient in phase I was excluded from the final analysis because a different knee system was used to match the TKA on the contralateral side. There were 49 TKAs in this cohort.

Phase definition: blinded phase II—skill assessment

In this phase, coronal plane balancing was performed without the sensor. Directed releases were made by targeting taut

structures in flexion and extension. Only after actual implant cementation was an appropriately sized tibial sensor inserted, with readings again taken at 10°, 45°, and 90° [14]. Sensor readings were recorded by a blinded research investigator. The sensor was then removed and replaced with a similarly sized actual liner without further releases. The surgeon was only made aware of sensor readings at the end of the case. This allowed for only limited learning at the end of the case. A minimum target of 50 TKAs was set to match phase I. There were 55 TKAs in this cohort.

Statistical analysis

Statistical comparisons of categorical variables were made using chi-squared analysis. For continuous data, the Student's *t*-test was performed. An alpha level <0.05 was considered statistically significant. All data analyses were performed using IBM SPSS Statistics 22 (SPSS Inc., Chicago, IL).

CUSUM analysis and sequential probability ratio testing is a method of LC analysis for monitoring the performance of an individual, department, hospital, or hospital network toward a binary outcome [16,17]. National joint registries such as the Scottish Arthroplasty Project employ CUSUM to identify outliers associated with surgeon or implant performance and thus adjust and mitigate risk [17,18].

CUSUM analysis was used to monitor whether coronal plane balance was achieved at 10°, 45°, and 90° of flexion. CUSUM charts were created to display CUSUM values on the y-axis against the

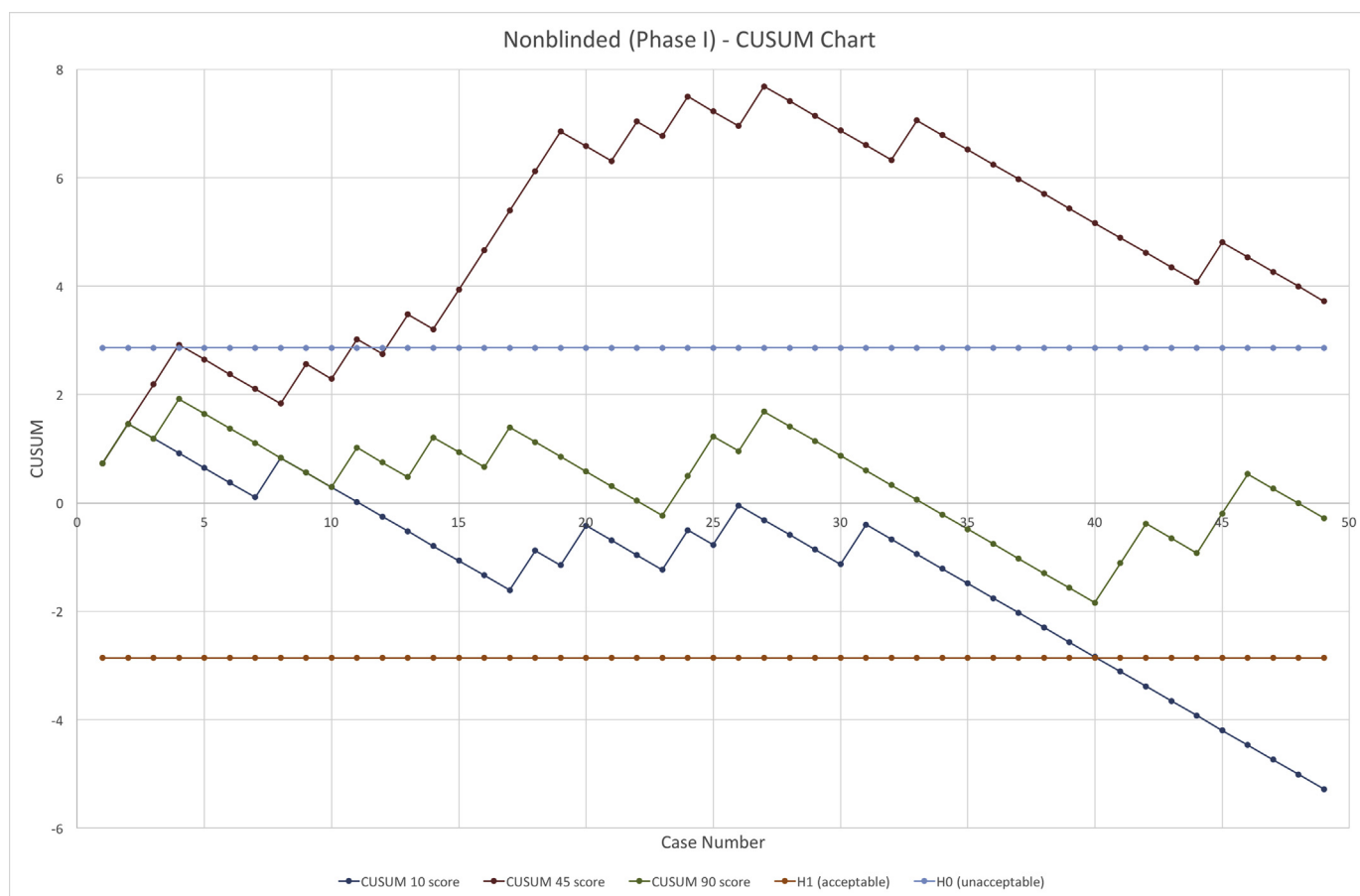


Figure 1. Cumulative summation (CUSUM) chart: Nonblinded Phase I.

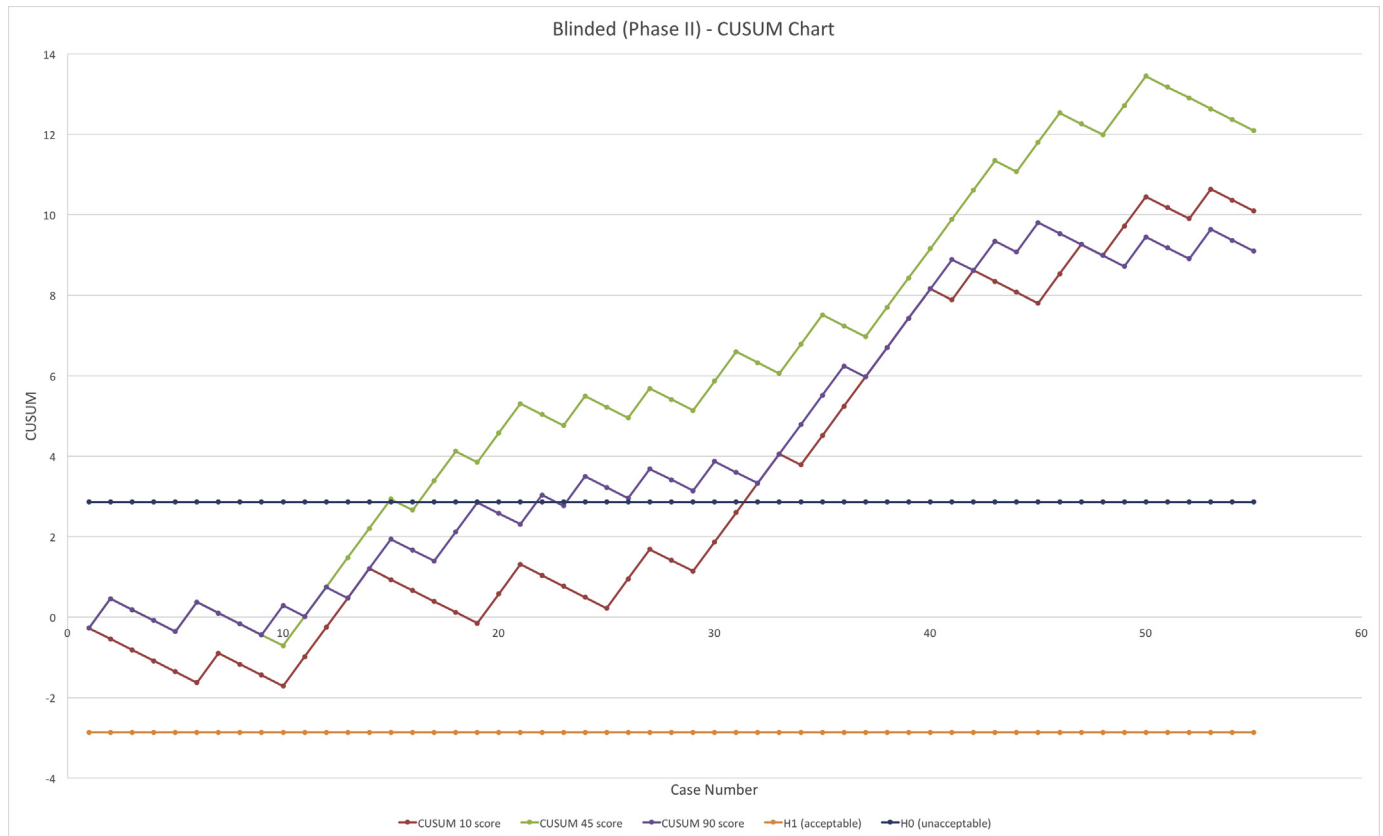


Figure 2. CUSUM chart: Blinded Phase II.

number of procedures on the x-axis. Details of the CUSUM method can be found in [Appendix I](#).

CUSUM graphs were plotted to depict performance, with CUSUM 10, CUSUM 45, and CUSUM 90 depicting results at 10°, 45°, and 90°, respectively. The CUSUM graph decreases with each success and an acceptable performance will demonstrate a horizontal or down-sloping line. Conversely, the graph increases with each failure and an unacceptable performance will show an up-sloping line. We used horizontal control lines to help draw conclusions regarding the acceptability of the performance. We can then draw conclusions regarding prior performance at points where the graph crosses control lines.

If the graph crosses the acceptable control line (h_1) from above, a positive performance indicator was met (good prior performance, GPP). If the graph crosses the unacceptable control line (h_0) from below, a negative performance indicator was met (poor prior performance, PPP).

Results

Demographic data

The mean patient age was 62.1 ± 7.0 years. Female patients comprised 40.4%. The mean preoperative patient height was 172.5 ± 10.7 cm and the mean preoperative patient weight was 94.3 ± 19.2 kg. The mean preoperative body mass index (BMI) was 31.7 ± 6.0 kg/m². The left knee was involved in 49% of cases. Between phases, there was no difference in sex, age, height, weight, and BMI ([Table 1](#)). Two patients in Nonblinded Phase I and 3

patients in Blinded Phase II underwent sequential bilateral TKA (single anesthetic).

Nonblinded phase I vs blinded phase II: load data and component sizes

There were no statistically significant differences in mean medial or lateral compartment load between phases ([Table 1](#)). There were no statistically significant differences in femoral or tibial component size, or polyethylene thickness between phases ($P = .142$, $P = .672$, and $P = .987$, respectively).

Sensor-balanced vs sensor-unbalanced groups: demographic data

There were no statistically significant differences between sensor-balanced and sensor-unbalanced patients in terms of sex, age, BMI, height, or weight ([Tables 2 and 3](#)).

CUSUM analysis

Nonblinded phase I

Successful balance with CUSUM 10 was achieved by case 31 with successful balance thereafter (all downslope). By case 40, the curve achieved GPP ([Fig. 1](#)).

With CUSUM 90, there were successes and occasional imbalances, and the curve never achieved GPP (remained between the control lines).

With CUSUM 45, there was short success after case 4, but overall deterioration (upslope), achieving PPP at case 11. After case 19, there are attempts at correction (downslope).

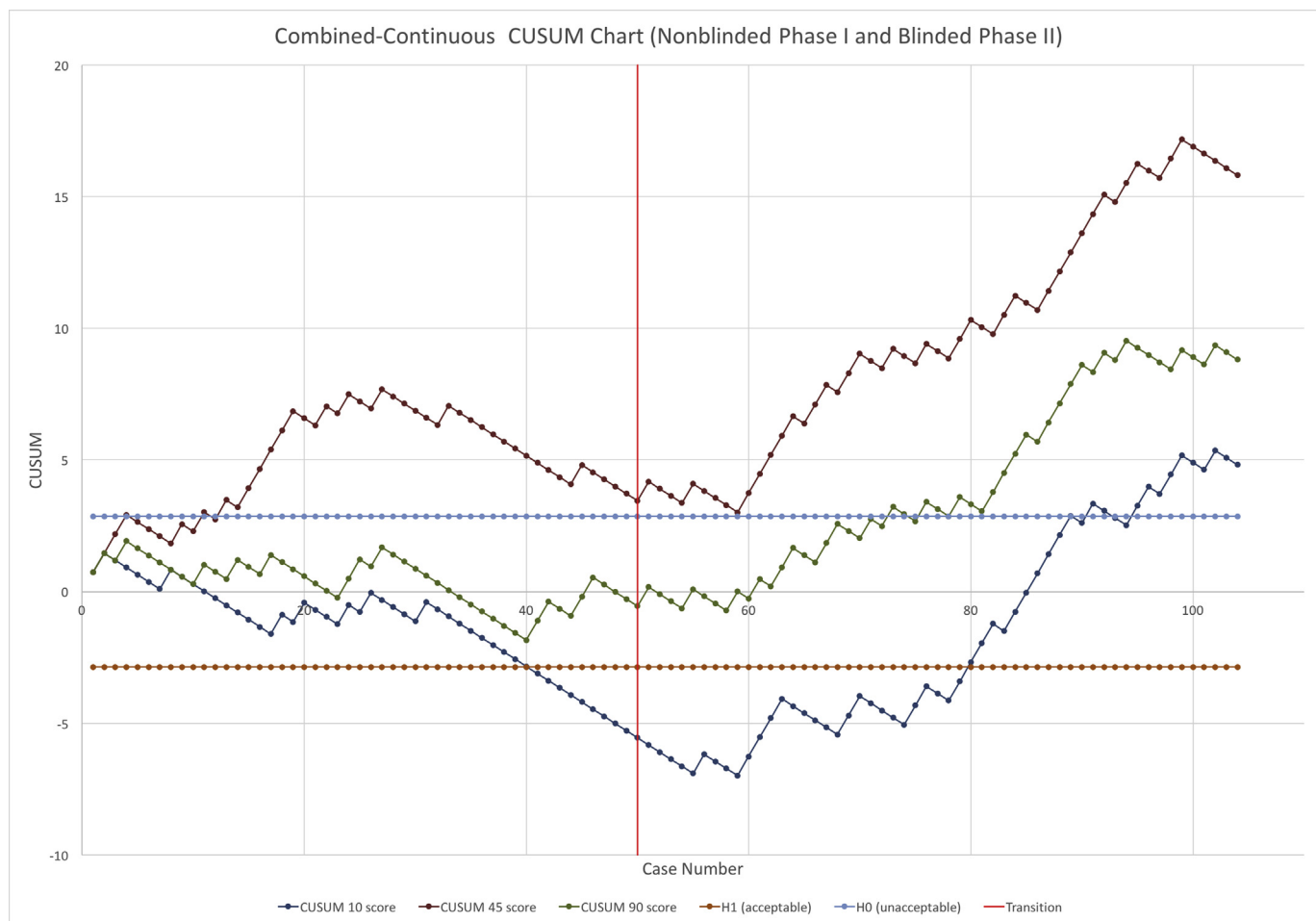


Figure 3. Combined continuous CUSUM chart: Nonblinded Phase I and Blinded Phase II.

Blinded phase II

With CUSUM 10, there was an initial mix of success and imbalance (horizontal line), with later deterioration (upslope), reaching PPP at case 32, and more deterioration later (Fig. 2).

The CUSUM 90 was similar with slow deterioration (upslope), reaching PPP at case 22, and continued deterioration thereafter (upslope).

The CUSUM 45 curve was also similar, reaching PPP at case 17, with continued deterioration thereafter (upslope).

Transition period analysis

To illustrate trends between phases, the 2 phases were plotted as continuous graph with a vertical red line (case 50, the first case of phase II) indicating the transition point (Fig. 3).

The CUSUM 10 curve demonstrated good balance at the end of Nonblinded Phase I into the first 5 cases of Blinded Phase II (downslope). Thereafter, there was gradual deterioration (upslope), reaching PPP at case 91.

The CUSUM 90 curve remained between control lines at the end of Nonblinded Phase I into the first 10 cases of Blinded Phase II, with progressive deterioration thereafter (upslope).

The CUSUM 45 curve demonstrated improvement at the end of Nonblinded Phase I (downslope). However, after case 59, there was deterioration (upslope).

Side-by-side analysis

For each flexion angle, CUSUM curves from both phases were plotted side-by-side to allow comparison of the absolute case numbers in the steady state and learning/attrition periods (Figs. 4–6).

The CUSUM 10 curves demonstrated successes (downslope) and imbalances (upslope) until case 30 (Fig. 4). After this, the curves diverged. There was improvement (downslope) in Nonblinded Phase I (darker curve) and deterioration (upslope) in Blinded Phase II (lighter curve).

The CUSUM 90 curves had successes (downslope) and imbalances (upslope) until case 17 (Fig. 5). After this, the curves diverged. There was improvement (downslope) in Nonblinded Phase I (darker curve) and deterioration (upslope) in Blinded Phase II (lighter curve).

The CUSUM 45 curves demonstrated progressive deterioration (upslope) after case 10 (Fig. 6). There was an attempt at recovery (downslope) in Nonblinded Phase I (darker curve) but only deterioration (upslope) in Blinded Phase II (lighter curve).

Bilateral TKA

In Nonblinded Phase I, cases 5–6 and 41–42 represent bilateral TKA. The first pair showed overall improvement in all 3 CUSUM



Figure 4. Comparison of CUSUM 10 scores between phases.

curves, while the second pair showed improvement in only CUSUM 10 and 45.

In Blinded Phase II, cases 8–9, 16–17, and 18–19 represent bilateral TKA. The first pair showed overall improvement in all 3 CUSUM curves. The second pair showed improvement only in CUSUM 10 and 90. The third pair showed improvement only in CUSUM 10 and 45.

Discussion

CUSUM analysis is a useful sequential analysis method that can detect changes in performance and provide useful LC analysis when learning a new procedure or technology [19]. As a result of the real-time nature of this technique, when applied in the manner described in Nonblinded Phase I, it can be used to demonstrate increasing proficiency.

Conversely, it can also be used to identify slow degradation in a process thought to be under control and alert the surgeon to deviations in established technique, or attrition of an established skill, as shown in Blinded Phase II. Results from this phase suggest that once the sensor is taken away, the skill level previously attained undergoes attrition at a similar rate. It is reasonable to expect that performing coronal balance releases without sensor guidance (blinded), the surgeon may regress back to baseline over time.

Our study yielded a few important findings. First, the “learning” and “attrition” curves in Nonblinded Phase I and Blinded Phase II, respectively, were almost mirror images of each other. Each curve comprised 2 periods: (1) a “steady state” horizontal period, with an

equal number of successes and failures (indicating neither consistent learning nor consistent attrition), followed by (2) a period of accelerated learning or attrition.

Second, the “steady state” periods at 10° and 90°, prior to the period of rapid learning/attrition, were similar in Nonblinded Phase I (learning) and Blinded Phase II (attrition, 30 cases and 17 cases, respectively). This implied that the surgeon picked up and underwent progressive loss of skill after a similar number of cases (learning and attrition, respectively).

Third, the absolute number of cases in the steady state during Blinded Phase II is indicative of the difficulty level of coronal balance at that degree of flexion. Coronal plane balance is easiest to achieve and takes longest to “lose” in extension, and is only “lost” after 30 cases (Fig. 4). Balance at 90° is more difficult (and easier to “lose”) and this skill is “lost” after only 17 cases (Fig. 5). Balance at 45° is most challenging and we see deterioration after only 10 cases (Fig. 6).

Fourth, the difficulty in achieving balance at 45° of mid-flexion is further highlighted by the lack of a clear LC in Nonblinded Phase I, which was marked by upward deterioration even with the sensor (Fig. 6) that becomes even more marked once the sensor is taken away. Although extension stability is a function of posterior capsular tension, and stability at 90° is owed to collateral ligament tension, mid-flexion stability is a more challenging concept thought to be contributed to by different factors, some of which are not as easily addressed by algorithmic releases [20].

This study has several unique strengths. Although most studies have focused on patient-sided outcome measures, none have

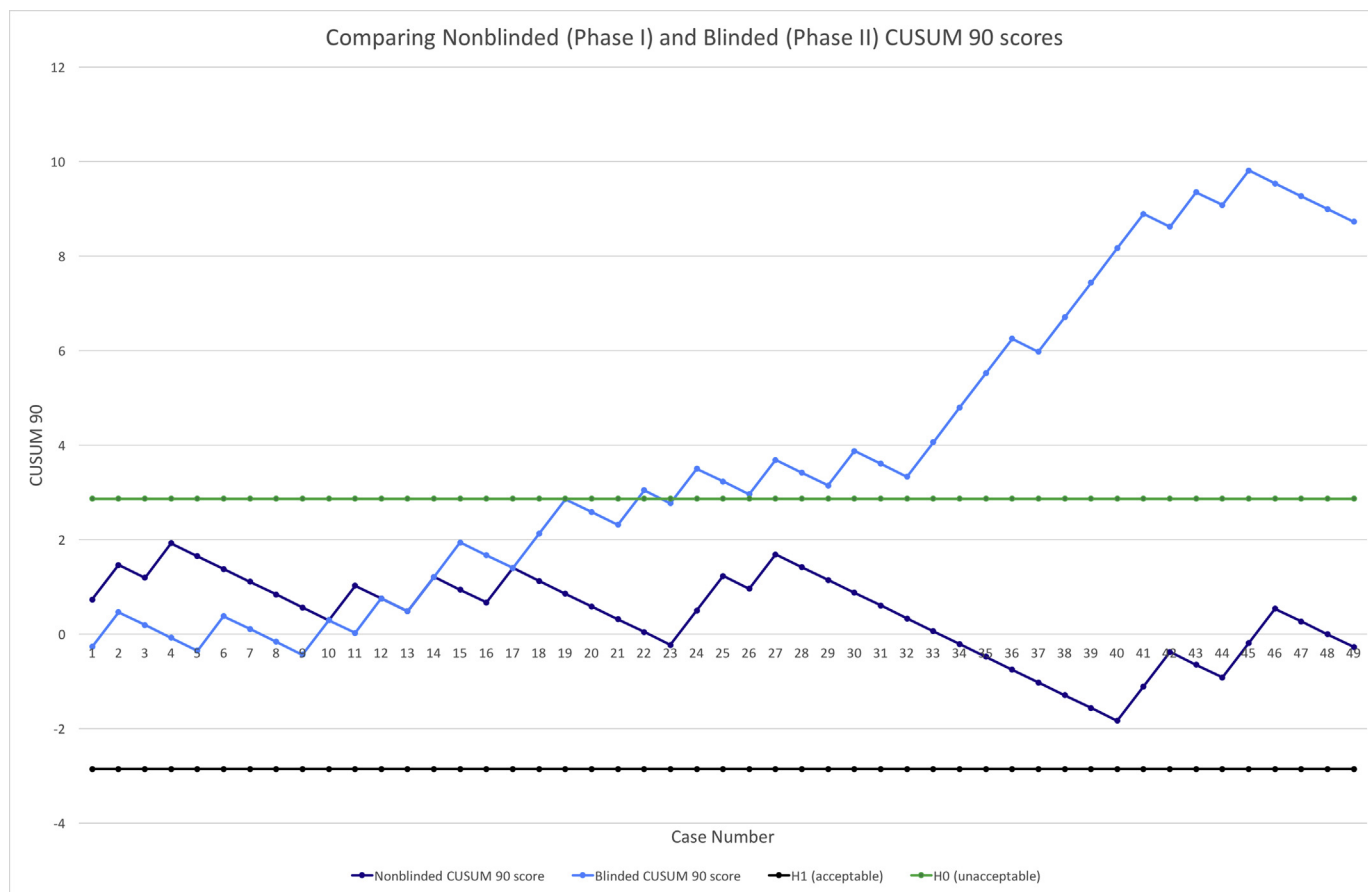


Figure 5. Comparison of CUSUM 90 scores between phases.

examined the surgeon-sided implications and the use of this technology in surgeon education. To our knowledge, this is the first study documenting the use of the sensor in surgeon training. It was neither the intention of this study to address patient outcomes between phases, nor between sensor-balanced and unbalanced patients. Another strength is that this study tracks the learning and attrition curves of a single, experienced, high-volume arthroplasty surgeon at a single institution using a consistent, methodical surgical technique, an algorithmic approach to ligament balancing, and the identical implant system for each case in a series of consecutive patients. In so doing, it controls for the variability in technique and implant choice that is apt to plague multiuser studies.

There are some limitations. First, we did not examine the subjective difficulty of individual cases nor the magnitude of deformity correction necessary. Second, the sequential nature of patient enrollment and consecutive phases precluded the use of randomization for group allocation. Third, sensor readings are influenced by limb position and rotation. We attempted to minimize these random errors by involving only a single senior surgeon and replicating the identical procedure with each iteration. Fourth, there are inherent tactile differences between trial components (Phase I) and actual implants (Phase II). Trial components may demonstrate more “play” as they are not bonded to bone, unlike actual components. Users may have a differing experience depending on how the sensor is incorporated into surgical workflow (trial phase, or both trial and final implant phases). Fifth, we acknowledge that one of the unique strengths of this study, its

single-surgeon design, is also a limitation as the learning and attrition curves of a single, experienced, high-volume surgeon may not immediately translate to surgeons in general. Different patterns may emerge when repeating this study on surgeons with different training, experience, and case volumes. Data collection is currently underway at our institution to determine if these curves translate to arthroplasty trainees and other first-time users of the technology. Sixth, in this pilot study, we were unable to determine the effects of a prolonged Nonblinded Phase I, involving more patients, longer time period, or both. Further investigations will reveal if a longer Nonblinded Phases I will produce (1) the same steady state/attrition rate in Blinded Phase II, (2) a longer steady state and slower attrition, or (3) skill proficiency and permanence. Seventh, while the 15 lbs threshold quoted in the literature remains the most commonly quoted mediolateral differential threshold, Meneghini et al [21] found improved activity levels with a <60 lbs differential. With greater use of sensor technology, our understanding of the ideal mediolateral differential threshold may continue to evolve.

Conclusions

In conclusion, our preliminary data show that the sensor does indeed train the surgeon. With CUSUM, one can see learning and attrition curves with and without the sensor. Proficiency of sensor balance is attained earliest at 10°, then 90°, and is most challenging at 45°. In the absence of the sensor, balance skill at 45° is first to deteriorate, then 90°, with 10° being the last to deteriorate.

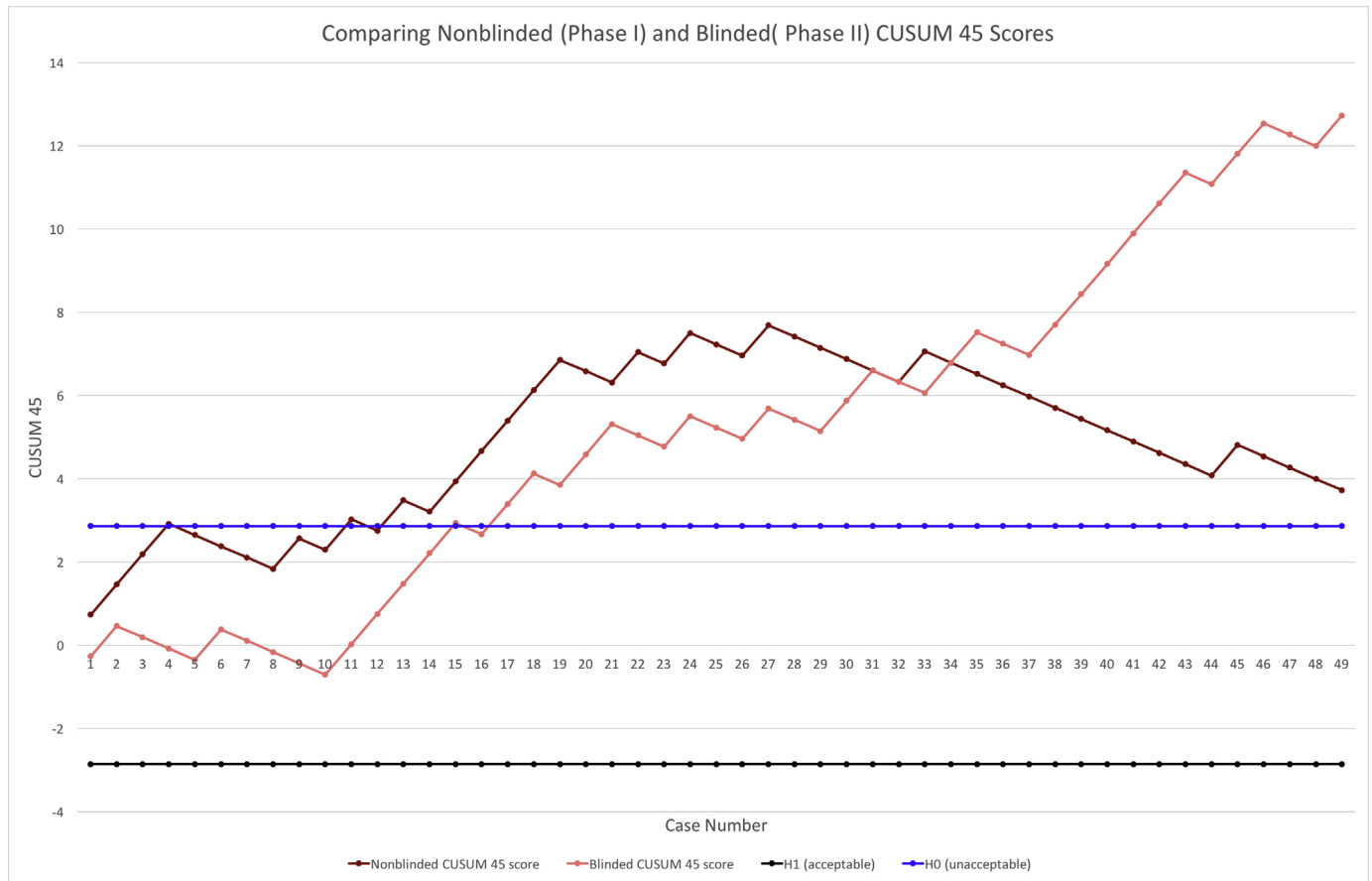


Figure 6. Comparison of CUSUM 45 scores between phases.

This demonstrates that while balancing technique can indeed be “trained” by the sensor, the benefits of training are transient and are lost once the sensor is taken away, suggesting that consistent sensor balance is more predictable with constant sensor use.

However, there are multiple unexplored parameters that can affect the LC in a TKA. The choice of sensor balance parameters, use or lack of use of navigation for bone cuts, as well as choice of kinematic vs mechanical axis alignment could be potentially significant variables that have not been accounted for. Larger multisurgeon studies may help address these unanswered questions.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.artd.2019.03.001>.

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