



Cadaveric Testing of a Novel Smart Sensor for Total Knee Replacements

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Abstract

The aim of this research was to prove the functionality of a smart tibial sensor for use during total knee replacements. The accuracy of such device provides surgeons with an objective tool for load balancing in the knee, where currently the joint is balanced based on the surgeon's 'feel' of a balanced knee. Literature surrounding the kinematics and tibiofemoral joint forces through the flexion arc coupled with qualitative feedback from an orthopedic surgeon provided a basis for proving the functionality of the smart-sensor.

Two full body cadavers underwent a cruciate-retaining total knee replacement using Zimmer's Persona Knee System. Varying thicknesses adjusted the height of the tibial smart-sensor between 10 mm to 13 mm in increments of 1 mm. The contact points and loads were observed through the flexion arc (0°, 45°, and 90°). The results found similar results between the literature surrounding both the compartmental forces and contact points throughout the range of motion. Moreover, qualitative feedback determined that the smart-sensor was robust and durable throughout its use in both cadavers demonstrating its potential as a reusable device. Minor adjustments to the graphical user interface would improve the ease of use for the surgical team. This sensor demonstrated the functionality of the smart-sensor through cadaveric testing in predicating both the load and location throughout a range of motion. Continued development of this sensor would provide surgeons with an accurate and robust tool for intraoperative joint balancing which could extend to all joints in the body.

Abbreviations

mm: Millimeter; N: Newtons; kg: Kilograms; TKR: Total Knee Replacement; lbf: Pounds of force; ROM: Range of Motion; GUI: Graphical User Interface

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Introduction

Total Knee Replacement (TKR) surgeries are required in patients with debilitating pain, most commonly from osteoarthritis. The aim of this surgery is to provide patients with a better functioning knee joint to improve quality of life. However, the TKR surgery can be deemed unsuccessful for several reasons, which may require an early revision surgery [1]. Completed a review on 212 revision knee replacements where the top three reasons for revisions were polyethylene wear (25%), aseptic loosening (24.1%), and instability (21.2%). These complications can be attributed to improper tension in the joint. An intraoperative joint load sensor could aid in reducing these complications by balancing the load between the medial and lateral compartments.

To understand results from an intraoperative joint force sensor, it is important to gain a comprehensive background of the joint contact forces and contact points in the knee which were described in the subsequent sections.

Joint contact forces

Joint contact forces from the tibiofemoral joints are responsible for the primary internal forces affecting the knee joint. The tibiofemoral joint contact force is the force on the articulating surface between the tibia and femur. Loads at this joint are a result of external forces such as ground reaction forces, where studies have found that forces in the tibiofemoral joint can reach up to 8.5 times the Body Weight (BW) when walking downhill [2] and can reach 5 to 8 BW during running and side-stepping [3]. Furthermore, the distribution of the force onto the tibia through the medial and lateral compartments are typically not shared evenly. Where it was found that the medial

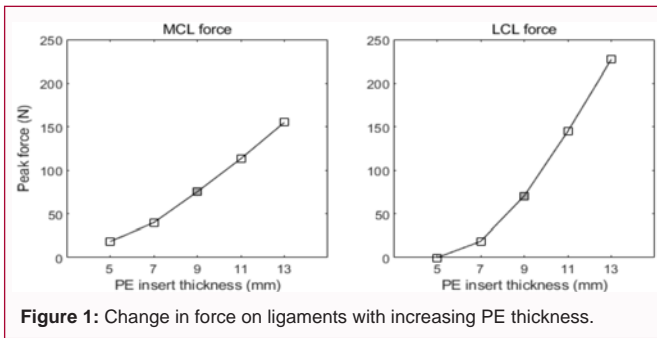


Figure 1: Change in force on ligaments with increasing PE thickness.

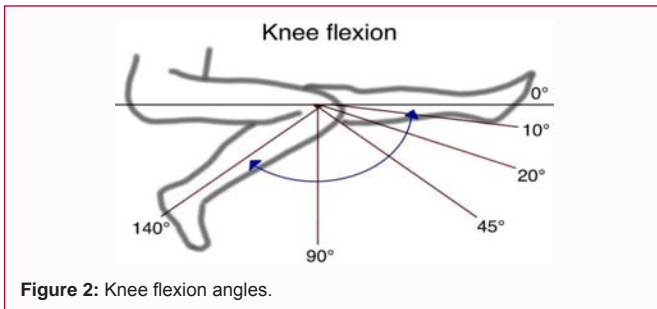


Figure 2: Knee flexion angles.

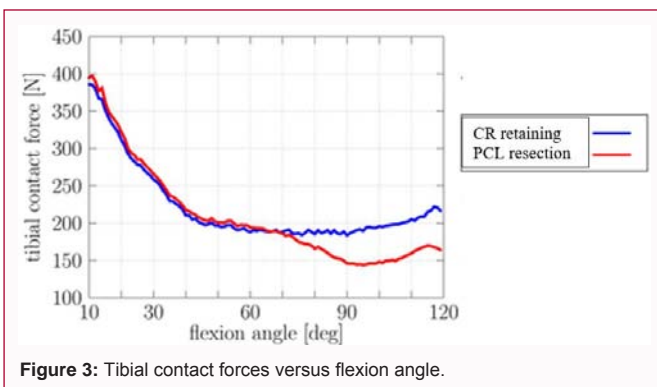


Figure 3: Tibial contact forces versus flexion angle.

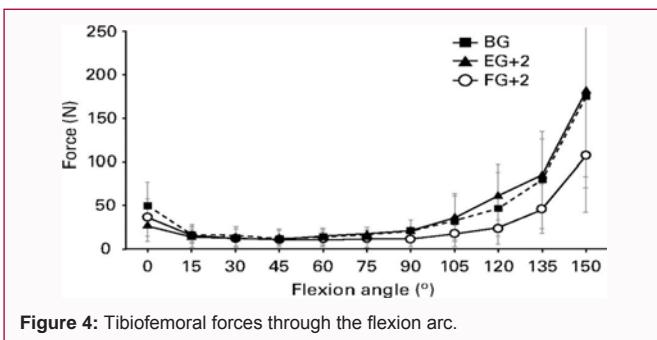


Figure 4: Tibiofemoral forces through the flexion arc.

compartments carried about 60% to 70% of load during walking [4]. This force distribution was also confirmed in clinical practice [5]. However, theoretically having the medial compartment loaded more heavily than the lateral can be detrimental as there would be increased wear on the medial compartment of the joint. This questions whether balancing the load which kinematically would be beneficial is preferred over having a higher load medially which is what is observed in the natural knee.

Contact forces in the knee have the potential to exceed the yield strength of the PE component, which would lead to failure of the component [6-9]. This could be exacerbated by improper joint

tension or balancing set during a TKR operation.

The increase in PE thickness was investigated by a study using a lower extremity model. This study found that increasing the thickness of the PE insert increased the forces in the knee throughout a ROM where the Medial Cruciate Ligament (MCL) and Lateral Cruciate Ligament (LCL) forces increased by 38 N and 74 N, respectively, as PE insert thickness changed from 9 mm to 11 mm [10]. Figure 1 from the research by [10] depicted the increase of forces in the medial and lateral compartment as the PE insert thickness increased.

Tibial contact forces for TKRs are important for soft tissue balancing and implant alignment intraoperatively. Through the flexion arc (Figure 2) forces were measured or modeled in a series of studies to identify patterns in joint forces in the tibiofemoral joint.

In a model of the lower extremity, the tibial contact forces were analyzed based on the flexion angle to observe differences in methods of TKRs. Figure 3 demonstrated that contact forces decreased as the flexion angle increased for two methods of TKRs a Cruciate-Retaining (CR) TKR (blue line) and Posterior Cruciate Ligament (PCL) resection TKR (red line) and there was a slight increase in forces past 45° for the CR-TKR [11].

Moreover, similar observations were made in Figure 3 intraoperatively in a cadaveric test using a self-made force transducer. Results found tibiofemoral forces decreased until around 45° and then increased through the flexion arc [12]. Additionally, Figure 4 depicted the compartmental loads in the knee during the Heel Push (HP) test and Thigh Pull (TP) test as methods of flexing the leg. It can be noted that the loads measured using a self-made sensor behaved similarly through the flexion arc as the previous research adding that the medial loads were larger through the flexion arc for both tests [13].

In summary, joint force tension and balancing can both impact the forces in the knee following a TKR. Identifying the patterns of the forces on the knee at various ranges of motion aid in setting the correct tension and soft tissue balancing during the operation based on previous success.

Contact points

In the knee the femur articulates with the tibia. Through the flexion arc these contact points change to allow for deep flexion by femoral rollback of the femur on the tibia. Figure 5 depicts the contact points in the normal knee where through flexion arc the contact points in the lateral compartment move more posteriorly compared to the medial compartment [14]. Femoral rollback can be seen as the contact points in the medial and lateral compartments shift posteriorly between 120° and 140°.

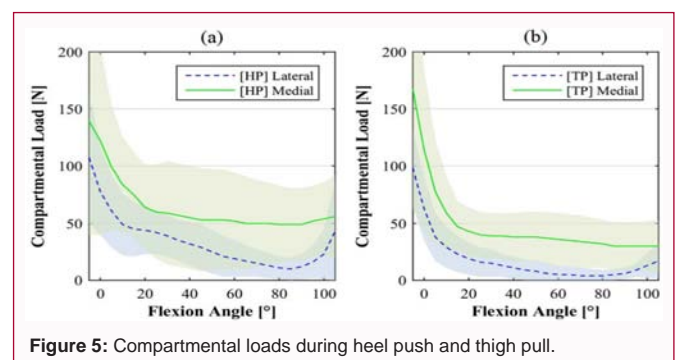


Figure 5: Compartmental loads during heel push and thigh pull.

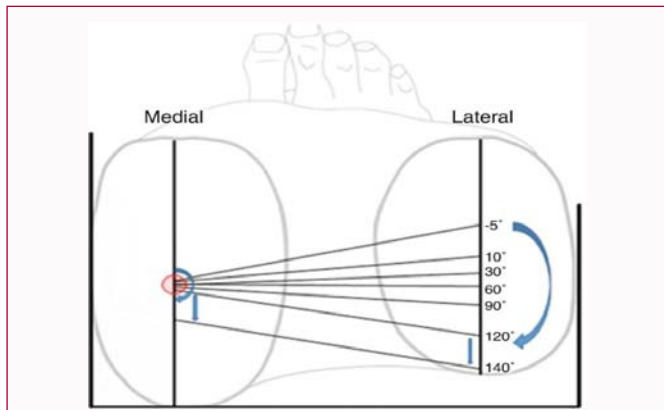


Figure 6: Contact points in the normal knee through the flexion arc.

This behavior was similar in the TKR knee. A similar behavior was observed through a retrospective study of TKRs where the contact points were depicted in Figure 6. This study focused on the gait cycle post TKR and depicted the contact area shifting posteriorly through the flexion arc, which was more dramatic in the lateral compartment [15].

Another study observed intraoperative contact points using VERASENSE [16]. The image from this study, Figure 7, was of the left leg so the image was flipped vertically to be compared to Figure 6. It can be noticed from these figures that the contact points during and after a TKR through the flexion arc were similar.

In conclusion, the current literature surrounding the contact points in the tibiofemoral joint show a shifting from an anterior position to posterior through the flexion arc [14-20], which provides context to the intraoperative contact point readings in this research. Moreover, the general positions and patterns were observed because of subjectivity of the values based on the collection method (sensor, gait analysis, or computational modeling) and surgical procedure.

Methodology

An intraoperative smart sensor was developed using AI to accurately measure the forces in the knee. The sensor was tested in cadavers which occurred at Glasgow University in Scotland on June 27th, 2023. Since the sensor created in this research was the only sensor compatible with Zimmer’s Persona Knee System, qualitative results were discussed based on expected outputs and trends in the joint load and the kinematic pivot patterns. The normal knee and TKR kinematic and kinetic patterns were described in the previous sections, which provided context to the cadaveric results. Additionally, surgeon’s comments and concerns were discussed based on several factors

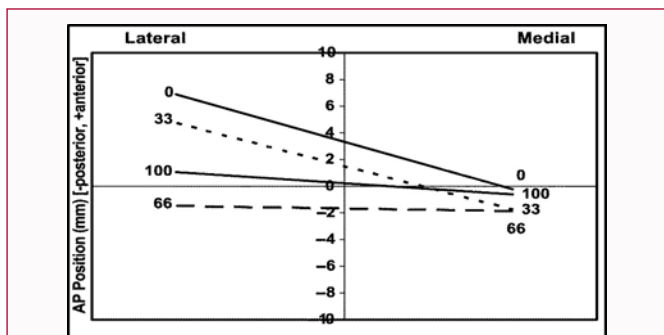


Figure 7: Contact points after a TKR through the flexion arc.

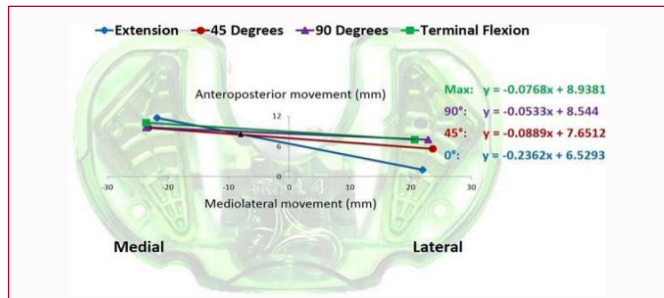


Figure 8: Contact points during a TKR through the flexion arc.



Figure 9: Cadaver with sensor.

including the useability of the device, compatibility with Zimmer’s Persona Shim System, and other factors.

Surgical procedure

The surgical procedure was performed in conjunction with a surgical training session organized by Zimmer Biomet. This involved surgical trainees performing TKRs on cadavers under the supervision of orthopedic surgeons. The cadavers used in this research underwent a right knee Cruciate Retaining (CR) TKR while using Zimmer’s Persona Knee System (Figure 8). This Zimmer Specific sensor was used in two full body cadavers. In accordance with Scotland’s ethical procedures surrounding the human tissue the identity was concealed and no photographs of the cadavers were taken. The following Figure 9 was a cadaveric knee used with VERASENSE which provides an idea of what the knee looked like with the sensor made in this research inserted.

To investigate the function of the Zimmer Specific sensor intraoperatively the sensor replaced the tibial spacer as seen in Figure 10. The laptop and relevant electronics were placed on a trolley next to the cadaver during the use of the sensor.

During a TKR surgeons will insert tibial spacers of varying thicknesses and feel if the proper tension has been achieved. Therefore, during the intraoperative use of the Zimmer Specific sensor the thicknesses of the shims were increased (10 mm-13 mm) to observe the impacts of the tensioned soft tissue on the contact forces through the compartments. Additionally, the knee was moved through a ROM (0°/10°, 45°, and 90°) and with varus and valgus stresses applied to ensure that the values reflected what was expected at the orientations in the passive state. When thicker shims were inserted, the knee did not reach full extension of 0° and therefore full extension was reached at 10°. Figure 11 depicts the Zimmer Specific sensor with the 13 mm thickness shim being inserted which was one of the 4 variable thicknesses.

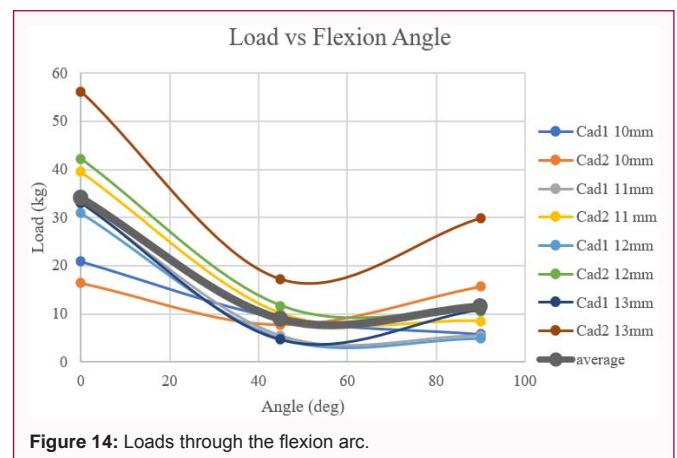
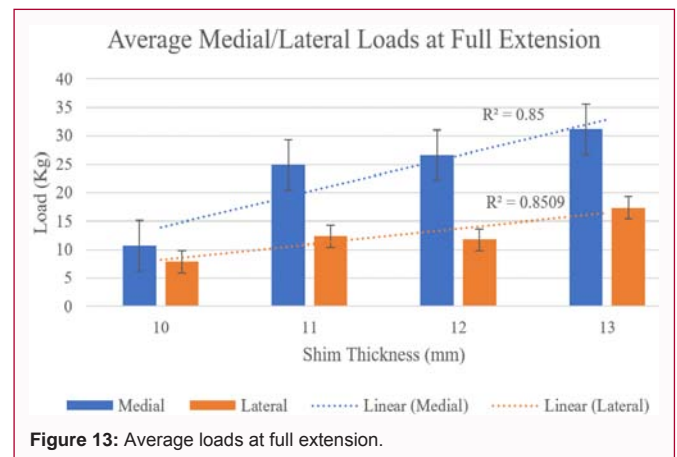
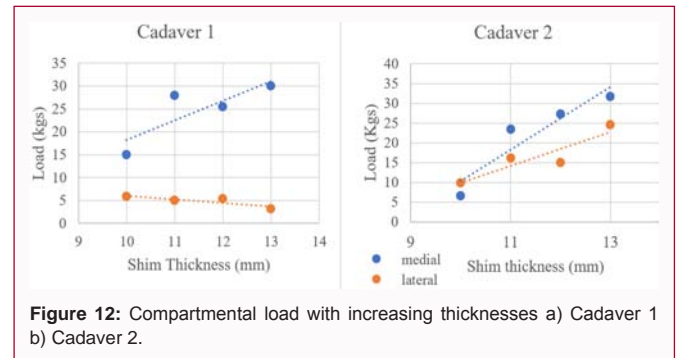
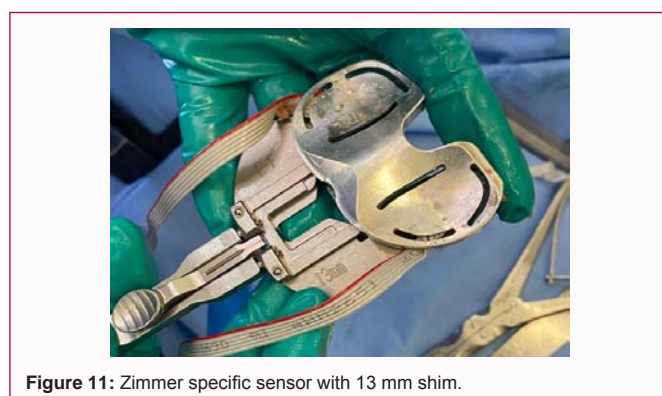
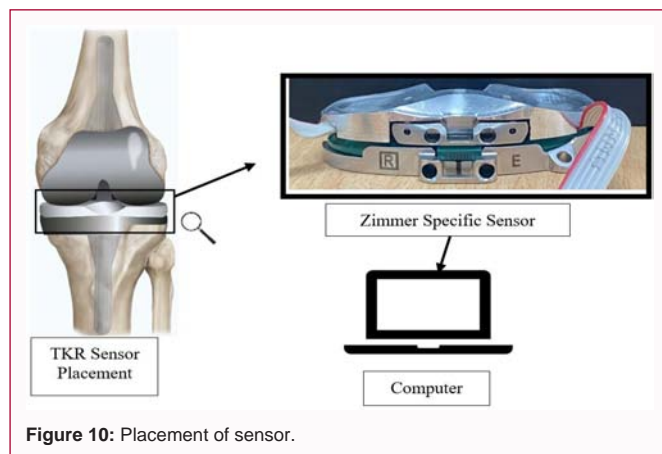
Results and Discussion

The cadavers were both tested with the 10 mm, 11 mm, 12 mm and 13 mm shim inserts twice at different degrees of flexion (0°/10°, 45°, and 90°). The load and location predications were averaged and recorded. Since the in-service loads were unverifiable with a sensor that could measure loads with the Persona Knee System, characteristics of the general performance were described. Depending on the quality of the replacement, performed by the surgical trainees, the following trends may be observed from the load values in the knee.

Compartmental loads

Firstly, as the shims increased in thickness the loads observed in both compartments increased accordingly. Figure 12a, 12b depicted the changes in load measurements in the medial and lateral compartments at 0°/10° when the shim thickness was increased from 10 mm to 13 mm in increments of 1 mm for both cadavers. Increasing the thickness of the shim should increase the load in the compartments since the soft tissue was not altered during this process. This finding was substantiated by research which found an increase in tibiofemoral forces when the polyethylene insert thicknesses were increased [10]. This was the case for all compartments and both cadavers except for the lateral compartment in Cadaver 1 which remained mostly the same with the increasing thicknesses.

Moreover, the average of the results from both cadavers in full extension with the increasing shim size was compared which was also done in research by [21] using a sensor. The results were comparable, the results in [21] used thicknesses from 10 mm to 16 mm in 1 mm increments, however, in this study ranges from 10 mm to 13 mm were used. The plot can be seen in Figure 13. The R² values for the linear relationship were 0.88-Lateral, 0.97-Medial in the study



by [21] and 0.85 for both medial and lateral compartments in this study. This implied that the sensor was able to register the increase in compartmental loads that would be expected as the thicknesses of the insert increased.

Loads through the Flexion Arc

Secondly, following a TKR the contact forces decreased significantly as the flexion angle increased to 45° then slightly increased to 90° evidenced by various research [11-13,22-25]. Therefore, observing the total load difference between 0°/10° and 90° provided good insight into the potential function of the sensor. Figure 14 depicted the average of each cadaver for all shim inserts, as well as the total average which followed the trends described above.

Intercompartmental load balancing

Another kinematic observation was that the loads may be higher medially than laterally throughout the flexion arc, however this was

Table 1: Balancing with differing shim thicknesses.

Thickness	Cad1	Cad2
10 mm	9.00 kg	3.35 kg
11 mm	23.00 kg	7.25 kg
12 mm	20.10 kg	12.25 kg
13 mm	26.90 kg	7.25 kg

Balanced ≤ 6.80 kg
 $6.80 \text{ kg} <$ moderately unbalanced ≤ 13.60 kg
 $13.60 \text{ kg} \leq$ severely unbalanced

Table 2: Varus/Valgus stress tests.

	Varus		Valgus	
	Medial	Lateral	Medial	Lateral
Cadaver 1	24.10 kg	3.00 kg	0.80 kg	42.20 kg
Cadaver 2	34.45 kg	2.10 kg	7.85 kg	46.65 kg

Table 3: Load difference from suggested load differential.

Thickness	Cad1	Cad2
10 mm	+2.20 kg	-3.45 kg
11 mm	+16.20 kg	+0.45 kg
12 mm	+13.20 kg	+5.45 kg
13 mm	+20.10 kg	+0.45 kg
Total	+51.70 kg	+2.90 kg

based on the surgeon’s ability to balancing the knee. When averaging all flexion angles the loads were higher medially than laterally for both cadavers, which was observed in studies using VERASENSE and independent load sensor [13,22,26,27].

The intercompartmental load difference provided insight into the balancing of the knee joint. VERASENSE developers and literature surrounding joint balancing found that the intercompartmental load difference should be ≤ 6.80 kg (66.70 N or 15lbf) [27-29]. The mediolateral compartmental difference was tabulated in Table 1. Since the cadavers underwent a TKR performed by surgical trainees using standard tools it was expected the joint would be unbalanced. The results in Table 1 reflected the experience of the surgical trainees.

Varus-Valgus stress tests

Surgeons often perform varus-valgus stress tests to uncover the condition of the surrounding knee stabilizers, which is often performed at 30° [30]. With the varus-valgus stress test the loads should be much greater in one compartment when the leg is pulled varus or valgus (to the medial or lateral compartment) respectively. This was observed when testing both cadavers by applying varus and valgus forces to the knee at 30° as seen in Table 2. Cadaver 1 was performed with the 12 mm insert and Cadaver 2 with a 10 mm insert.

It was observed that the medial forces were slightly lower than the lateral when the varus/valgus forces were applied respectively. This could be because the soft tissue was tighter laterally meaning more force was required by the surgeon to move the leg in varus direction. This was dependent on the surgeon’s bone cuts and gap balancing [31].

Location predictions

The location predictions were dependent on how the surgeon

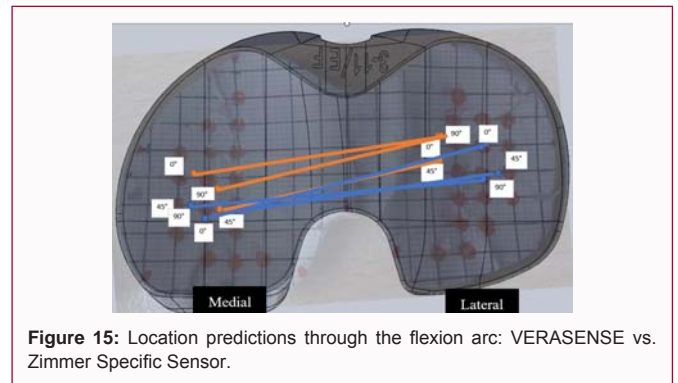


Figure 15: Location predictions through the flexion arc: VERASENSE vs. Zimmer Specific Sensor.

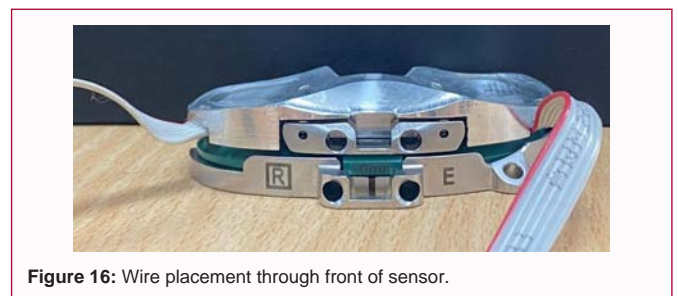


Figure 16: Wire placement through front of sensor.

was holding the leg and the overall laxity in the joint. The average of all location predictions was plotted to Figure 15 and compared with research conducted by [16] on VERASENSE. The orange in Figure 15 represented the predictions found in this research where the blue was from the research conducted by [16] and transposed on to the Zimmer Specific sensor. Since the implants were not the same size the locations were estimated onto the Zimmer Specific sensor as accurately as possible. One similarity was that the lateral location predictions were more anterior to the medial compartment. This was consistent to what was known about the kinematic pivot patterns in the knee [14-20].

Qualitative analysis

The cadaveric testing provided valuable insight into the qualitative performance of the sensor with the unique perspective of an experienced orthopedic surgeon. The Graphical User Interface (GUI) included drawings of the surface of the tibial insert which were identical to what the surface of the sensor looked like. Moreover, the Cartesian-coordinate system was aligned with the training points to increase the consistency between what the sensor was predicting and what the surgeon saw. Due to the distance that the surgeon stood from the screen elements of the GUI were enhanced later to make the use of the system easier for the surgeon. The other features like zeroing the device were noted to be easy to use by a technician during the surgery.

Moreover, since this was a working prototype, the wires emerged from the front of the sensor while the skin and tissue from the front of the knee covered the sensor including the wires. The positioning of the wires from the front of the sensor can be seen in Figure 16. However, despite this the wires were durable and from the surgeon’s perspective and did not cause interference with his work. Additionally, the shims were easily exchangeable and there were no problems with the sensor throughout of the cadaveric testing including with the electronics, GUI, or physical compatibility with the Persona Knee System.

It was evident that the sensor was durable and robust as

demonstrated by being able to withstand the high loads from varus and valgus stresses, in excess of 391 N (40 kg). Additionally, the sensor was not handled with extreme care and was able to withstand being pulled and pushed in and out of the knee joint without being damaged. The knee (femoral implant) was able to glide smoothly over the surface of the sensor throughout the ROM. For the final design, a plastic coating should be used over the sensor to prevent tissue and liquid from entering the electronics. However, the sensor was water resistant, so it was able to be used for the several hours that the cadaveric testing occurred without damage to the electronics. The coating would make the sensor easier to clean and reusable through sterilization and would allow for quicker insertion of varying shim thicknesses, by removing the need to thoroughly wipe down the sensor. This would in turn decrease the already short addition of the sensor to the operation time.

Moreover, in terms of the accuracy of the results it was noted that during the cadaveric testing the surgeon observed that the Cadaver 2 felt more balanced than Cadaver 1. This was reflected by the results in Table 2 where the literature suggested an intercompartmental load difference of ≤ 6.80 kg (66.70 N or 15lbf) [27-29]. Table 3 reflected the distance of the load difference from the suggested load differential where the Cadaver 2 was significantly more balanced than Cadaver 1 ($p < 0.05$) and the total was +51.70 kg greater than maximum suggested load difference of 6.80 kg for Cadaver 1 and + 2.90 kg for Cadaver 2.

Conclusion

In conclusion, the cadaveric testing provided valuable insight into the real-time performance of the sensor for both load and location predications. The use of AI in this sensor has notably enhanced its sensing capabilities in terms of the robustness and accuracy. Despite the absences of a direct comparative sensor, the existing literature surrounding kinematic and kinetic patterns of the knee and TKRs provided an argument for the successful use of the sensor intraoperatively. Moreover, the perspective of an orthopedic surgeon with experience using VERASENSE offered valuable commentary on the useability and performance of the sensor. Collectively, the cadaveric testing suggested the success of the sensor for intraoperative use. The ongoing development and refinement of the sensor could allow for a sustainable and repeatable tool for surgeons to balance joints effectively and extend the application to other joint in the body.

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