A Novel Implant System for Unloading the Medial Compartment of the Knee by Lateral Displacement of the Iliotibial Band

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Background: Medial knee osteoarthritis (OA) typically occurs with excessive mechanical load within the medial compartment, resulting in degeneration of the articular cartilage.

Purpose: A novel extracapsular implant (Latella Knee Implant) has been developed to unload the medial compartment of the knee. The implant displaces the iliotibial band (ITB) over the lateral femoral condyle, thereby increasing its effective moment arm, resulting in a transfer of load from the medial compartment to the lateral compartment of the knee. A cadaveric study was performed to evaluate the effect of altering the moment arm of the ITB on knee biomechanics.

Study Design: Controlled laboratory study.

Methods: A 6-degrees-of-freedom robotic testing system was utilized to measure medial and lateral compartment loads in 8 fresh-frozen cadaveric knees at various ITB loads and knee flexion angles. Measurements were made with and without the implant in place. The system measured the compartment forces at flexion angles between 0° and 30° under 3 simulated loading conditions (300 N quadriceps, 100 N hamstrings, and [1] 0 N ITB, [2] 50 N ITB, [3] 100 N ITB).

Results: Lateral displacement of the ITB between 15 and 20 mm resulted in medial compartment unloading between 34% and 65%.

Conclusion: Unloading the medial compartment with this novel implant has the potential to address the treatment gap for patients with medial knee OA.

Clinical Relevance: Currently, there exists a treatment gap for patients with medial compartment OA who have exhausted conservative management but whose disease and symptoms do not warrant more invasive surgical procedures. An extracapsular implant to unload the medial compartment could fill this treatment gap by providing patients and surgeons with a less invasive option for early to mid-stage OA. Unloading the medial compartment may alleviate pain and improve function, allowing patients with early-stage medial OA to remain active longer prior to considering more invasive options such as arthroplasty.

Keywords: medial osteoarthritis; knee; treatment gap; unloading; moment arm; extracapsular

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Knee osteoarthritis (OA) is a progressive degenerative disease characterized by the breakdown of articular cartilage in the joint, resulting clinically in joint pain and stiffness. In the United States and Europe, 16% of adults older than 45 years suffer from symptomatic knee OA.[21] To alleviate pain and restore function in early-stage OA, conservative therapy includes analgesics, nonsteroidal anti-inflammatory drugs, and nonsurgical treatments such as weight loss, braces, orthotics, steroid injections, and physical therapy. For more severe knee OA, current surgical treatments include minimally invasive interventions like arthroscopic debridement, the effectiveness of which has been questioned,[25] as well as realignment osteotomy and arthroplasty (knee replacement), which involve complex bone-modifying surgery with prolonged recovery times. Hence, there exists a treatment gap for patients who have exhausted conservative OA

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management but whose disease has not advanced enough to warrant highly invasive surgical procedures.[17]

Previous studies have assessed the impact of muscle forces on knee kinematics and force distribution. Kwak et al[16] studied the role of the hamstrings and the iliotibial band (ITB) on knee biomechanics by monitoring alterations in contact locations in the tibiofemoral joint. Both the hamstrings and the ITB were found to be effective anterior and rotational stabilizers of the tibia, with the ITB having a smaller effect. Gadikota et al[10] studied the effect of increased ITB force on tibiofemoral kinematics and force distribution. They concluded that increased ITB force significantly reduced medial compartment force, increased anterior tibial translation and valgus tibial rotation, and decreased internal tibial rotation and medial tibial translation.

The effectiveness of a muscle across a joint is the product of the muscle force and the moment arm of the muscle-tendon unit about the joint's center of rotation. The objective of this study was to determine whether increasing the moment arm of the lateral musculotendinous structures around the knee could alter knee biomechanics. Specifically, the study analyzed the effect on knee biomechanics and medial/lateral compartment loads when the ITB is displaced laterally from the lateral femoral condyle using a novel implant (Latella Knee Implant; Cotera, Inc). A robotic testing system was utilized to evaluate the effect of increasing the moment arm of the ITB on medial/lateral compartment loads and tibiofemoral kinematics in a cadaveric model.

METHODS

A robotic testing system consisting of a 6-degrees-of-freedom robotic manipulator capable of measuring knee kinematics and joint forces has been used in a number of studies[9-11,18,19,33,36,38,40] and is described below. The robotic system was used in this study to measure forces in the medial and lateral side of a cadaveric knee joint at various flexion angles and at various muscle loads (quadriceps, hamstrings, and ITB).

Eight fresh-frozen human cadaveric knee specimens (4 males, 4 females; age range, 36-50 years; weight range, 49-90 kg; height range, 155-190 cm) were used in the study. Specimens were procured from a tissue bank (MedCure Inc). All specimens were stored at −20°C prior to testing and were thawed at room temperature for 24 hours prior to the experiment. The femur and tibia were truncated approximately 25 cm from the joint line, with all the soft tissues (skin, knee ligaments, joint capsule, and musculature) left intact around the knee. To facilitate fixation of the femur and tibia to the robotic testing system, the femur and tibia were potted in bone cement and secured in thick-walled aluminum cylinders that were attached to the robotic testing system. The quadriceps muscle was separated from the ITB (laterally) and from the sartorius, semimembranous, semitendinous, and gracilis (medially) above the retinaculum. The ITB was separated posteriorly from the biceps femoris. Each muscle was attached to an individual rope by suturing the tendon to the rope using commercially available surgical sutures. Each individual rope was passed through a pulley system and loaded by hanging weights on the free ends of the ropes (Figure 1), which resulted in all the forces being directed vertically downward along the femoral shaft.

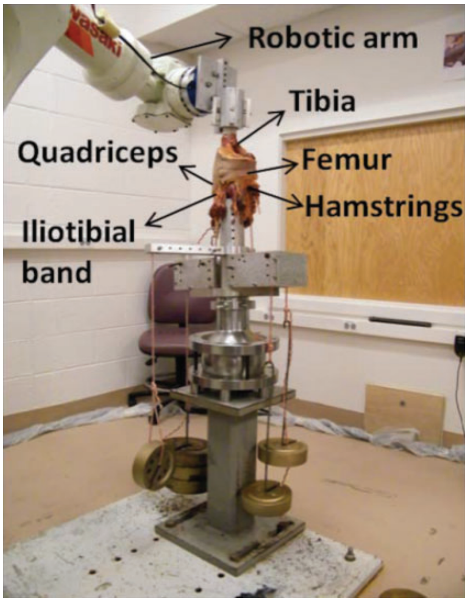

Figure 1. Experimental setup with a cadaveric knee installed on the robotic testing system.

Previous cadaveric studies have estimated that physiologic forces on the ITB during normal gait range from 30 to 90 N.[16,22] In this study, 3 ITB forces (0, 50, and 100 N) were used to cover the range that may be seen during normal gait. Studies using the robotic system have used a range of simulated loading conditions for the quadriceps and hamstring muscles.[9-11,18,19,33,38,40] Although these loads did not simulate physiological conditions, the ex vivo setting facilitates the measurement of joint mechanics under repeatable and controlled conditions. In this study, based on the load capacity of the robotic unit, 3 simulated loading conditions reported previously[10] were used: (1) 300 N quadriceps, 100 N hamstrings, and 0 N ITB; (2) 300 N quadriceps, 100 N hamstrings, and 50 N ITB; and (3) 300 N quadriceps, 100 N hamstrings, and 100 N ITB. The operation of the robotic system to evaluate the tibiofemoral contact forces and kinematics under simulated muscle loads has been reported previously[10] and is described below. Once the knee specimen was mounted on the robotic system and the muscles were loaded, the robotic system minimized the forces and moments at the knee center at each flexion angle by manipulating the tibia. The resultant tibial position at which the forces and moments at the knee center were minimal was recorded as the kinematic response of the tibia for each external loading condition at each flexion angle. After the determination of knee kinematics under the 3 loading conditions, the Latella implant (Figure 2) was implanted under the ITB and the knee kinematics were reassessed for the 3 conditions. The Latella implant is a passive metal implant cast from titanium alloy (Ti6Al4V),

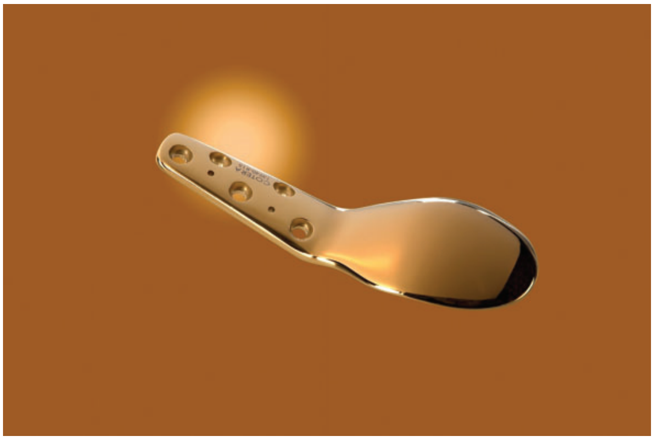

Figure 2. Latella knee implant.

coated with titanium nitride, and then polished to a mirror finish. Both materials have a long history of biocompatibility, safety, and durability in orthopaedic devices.[7,27] The implant has no moving parts and remains entirely extracapsular. The implant has a dome-like displacement region to displace the ITB laterally from the lateral condyle. The displacement region is elevated off the lateral condyle (Figure 3) and does not impinge on any of the soft tissues under the ITB such as the lateral ligament and capsule. The Latella implant was inserted through the interval between the ITB and the biceps femoris and attached to the lateral distal femur underneath the ITB using 5 standard 3.5-mm cortical screws. For each specimen, the lateral displacement of the ITB due to the implant was measured after implant placement. Similar to a depth gauge, a K-wire was used to measure the distance by placing it through a small hole in the surface of the dome until it contacted the underlying condyle bone surface.

After kinematics were determined for all conditions, load distribution on the medial and lateral tibial plateaus was measured using piezoelectric pressure sensors (Tekscan, Inc). Each sensor was conditioned, equilibrated, and calibrated prior to load measurement. The sensors were inserted within the tibial and femoral compartment through capsular incisions and secured by suturing the sensor (regions without pressure-sensing elements) to the joint capsule. The capsular incision was appropriately sized, and hence, capsular repair was not required after the sensor was inserted. After the sensors were positioned securely, previously recorded kinematics for all loading conditions were replayed by the robotic system to measure the loads transmitted within the tibiofemoral compartments. During the experiment, the robotic testing system determined the knee joint kinematics from 0° to 45° (2 specimens) and from 0° to 30° (6 specimens). After the initial 2 specimens were tested up to flexion of 45°, the remaining specimens were limited to flexion of 30° since the maximum knee flexion during the stance phase of normal gait has been measured to be approximately 30°.[35]

The results were analyzed statistically using a 1-way tailed paired *t* test. A *P* value less than .05 was considered statistically significant.

RESULTS

In this study, the ITB was displaced from the lateral femoral condyle by attaching the Latella implant to the distal femur of the cadaveric knee specimen, and the mechanical loads on the medial and lateral condyles were measured with and without the implant. For each specimen, the lateral displacement of the ITB due to the implant was measured. The displacement ranged from 15 to 20 mm (Table 1), resulting in a mean unloading of the medial condyle by 34% to 65% (Figure 4). It is interesting to note that the displacement range was relatively small considering the wide range of specimen sizes (eg, height ranging from 155 to 190 cm). It appears that the femoral metaphyseal flare creates a consistent lateral displacement of the lateral femoral condyle, which results in a similar ITB displacement throughout a range of specimen demographics.

Contact Force Analysis

Paired analysis showed medial unloading and an increase in lateral loading across all flexion angles and all 3 muscle loads. Figure 5 shows the medial and lateral loading with the ITB load of 50 N. The asterisk in the plots indicates a statistically significant difference utilizing 1-way tailed paired *t* tests ($P < .05$). Results with the other 2 ITB loading conditions (0 and 100 N) were similar (Figures 6 and 7). In this study, percent mean medial compartment unloading varied more at lower flexion angles than at greater flexion angles for the 3 muscle loading conditions (Figure 8). There was also less unloading at lower flexion angles with ITB loads of 50 and 100 N.

Kinematic Analysis

There was no change in internal/external rotation across flexion angles for all 3 muscle loads (Figure 9). There was more mean anterior translation (Figure 10), mean lateral translation (Figure 11), and mean valgus rotation (Figure 12) across flexion angles and across all 3 muscle loads. The plots shown are for ITB 50 N only since they were similar to the plots of ITB 0 N and 100 N. Paired analysis utilizing 1-way tailed paired *t* tests ($P < .05$) showed that the anterior and lateral translations were statistically significant for most measurements. The valgus rotation was statistically significant at greater flexion angles only.

DISCUSSION

Knee OA typically occurs with excessive mechanical load within the medial compartment of the knee resulting in degeneration of the associated articular cartilage.[32] During the normal gait cycle, the human knee is maximally stressed during the single-leg stance phase. A bending moment due to the ground-reaction force (GRF) directed medially tends to increase the load on the medial compartment. Lateral structures such as the ITB and part of the quadriceps muscles, as well as ligaments such as the lateral

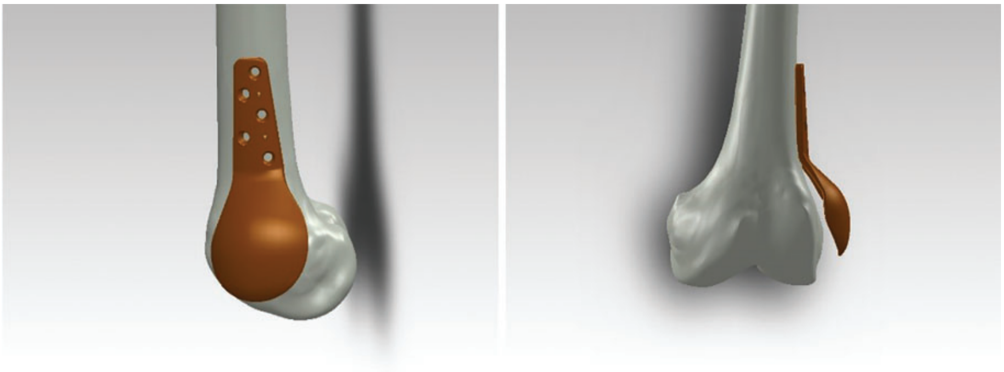

Figure 3. Illustration of Latella knee implant mounted on the lateral femur.

TABLE 1
Specimen Donor Demographics[a]

Specimen	Sex	Age, y	Weight, kg	Height, cm	ITB Displacement, mm
1	M	41	59	168	15
2	F	36	73	168	19
3	M	38	55	175	20
4	F	50	89	163	20
5	M	49	90	190	20
6	F	50	56	168	20
7	M	38	49	170	16
8	F	37	73	155	19

[a] F, female; ITB, iliotibial band; M, male.

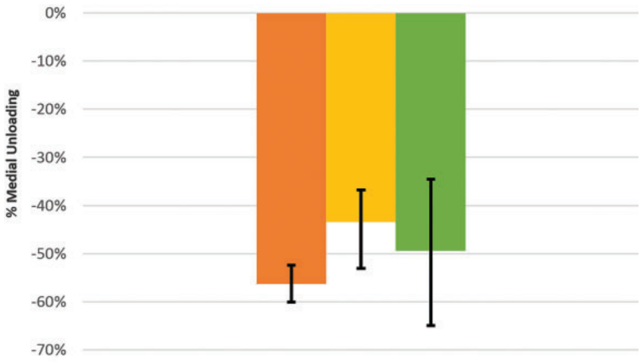

Figure 4. Mean medial condyle unloading due to the Latella knee implant under a range of muscle loading conditions over the measured knee flexion range of 0° to 30°. Error bars represent minimum and maximum values. Orange, iliotibial band (ITB) 0 N; yellow, ITB 50 N; green, ITB 100 N.

collateral ligament and the capsule, resist this bending moment and provide a lateral resistance to opening of the lateral side of the joint. When the bending moment due to the GRF increases due to varus knee malalignment or increased body weight, a greater percentage of the joint reaction force is borne by the medial compartment. This excessive mechanical loading can lead to cartilage degeneration and, ultimately, medial OA. A study to estimate medial and lateral contact loads in patients with knee OA and matched controls using an electromyography modeling approach has shown that subjects with OA have greater absolute medial load than controls and maintained a greater percentage of their total load on the medial compartment.[15]

The results of this study suggest that by displacing the ITB from the lateral femoral condyle and increasing its muscle moment arm, the load within the knee can be redistributed. The effectiveness of a muscle across a joint is the product of the muscle force and the moment arm of the muscle-tendon unit about the joint's center of rotation. Mechanical leverage of muscles across a joint is enhanced through sesamoid bones, such as the patella, which increase the muscle moment arm. A study evaluating the mechanical function of the patella has shown that the removal of the patella reduces the effectiveness of the quadriceps muscle by 30%.[13] Similarly, an implanted device may displace muscles and/or tendons around a joint to increase the moment arm of the applied muscle forces. For patients with medial OA, by lateralizing the lateral soft tissues and increasing their moment arm, a portion of the load on the medial compartment can be transferred to the lateral compartment, thereby restoring a more normal balance of loads within the joint. Hence, the resultant force (combination of the medial and lateral compartment loads) in the knee during normal gait (shown by the green arrow in Figure 13), is in effect moved laterally away from the medial side of the knee.

The medial unloading observed with no ITB force (0 N) indicates the role of other lateral structures attached to the ITB over the lateral condyle in unloading the medial compartment. Cadaveric studies have shown that various structures other than the ITB will cross the location of the implanted Latella device, including the attachment of the vastus lateralis (VL) to the ITB.[23] Becker et al[1] reviewed the anatomy of the VL and identified 4 distal attachment areas: supralateral border of the patella, lateral intermuscular septum, ITB, and rectus tendon. Out of 10 specimens, 7 specimens had clear attachment of the VL to the ITB. The portion of the VL inserting into the ITB was 1.2% to 5.8% of the total VL cross-sectional area, implying that a portion of the total VL force is transmitted through the ITB. Since the quadriceps muscle was loaded in all conditions in this study, it is likely that a portion of that load was being transferred to the ITB even when the ITB was not loaded independently.

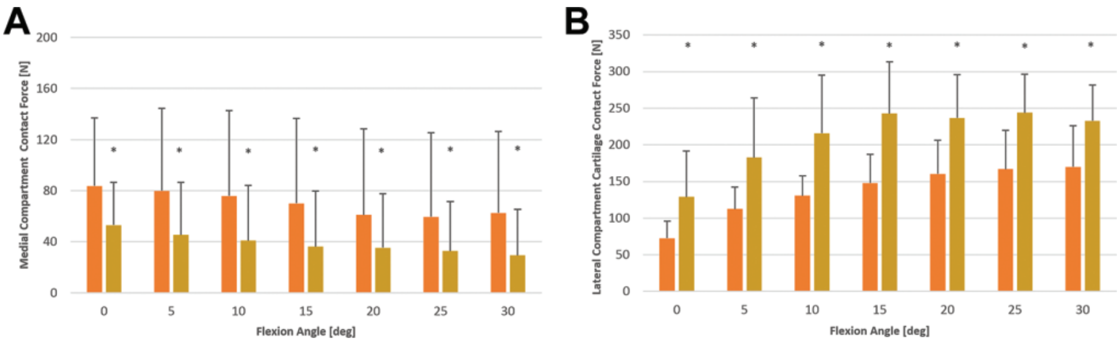

Figure 5. (A) Medial and (B) lateral compartment contact forces with an iliotibial band load of 50 N. Error bars represent standard deviation. Orange, native knee; gold, implanted knee. *Statistically significant.

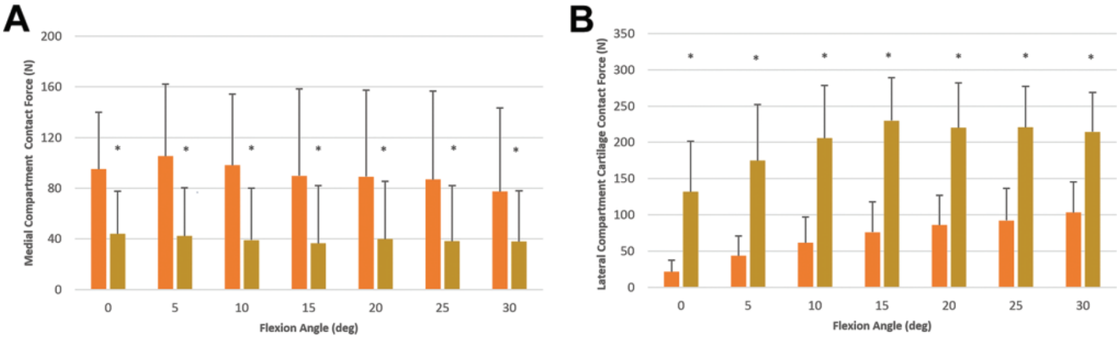

Figure 6. (A) Medial and (B) lateral compartment contact forces with an iliotibial band load of 0 N. Error bars represent standard deviation. Orange, native knee; gold, implanted knee. *Statistically significant.

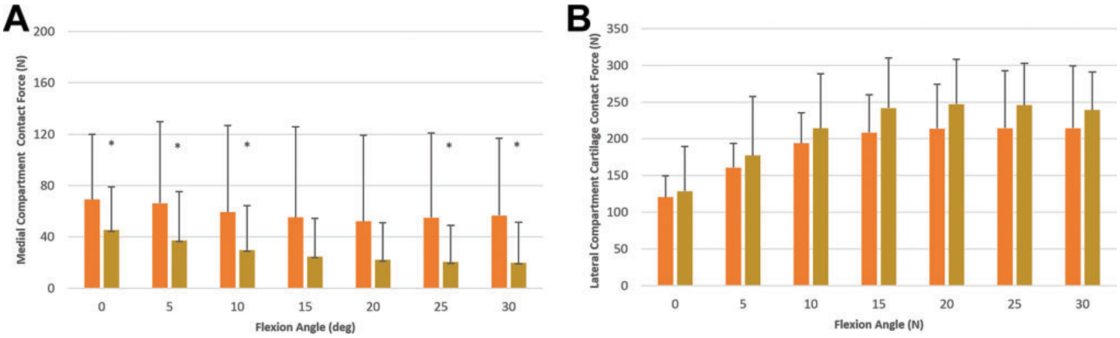

Figure 7. (A) Medial and (B) lateral compartment contact forces with an iliotibial band load of 100 N. Error bars represent standard deviation. Orange, native knee; gold, implanted knee. *Statistically significant.

Placement of the implant under the ITB results in a slight increase in the length of the ITB. Based on the reported length of the ITB,[8] it is estimated that this length would increase by 1% to 2% due to the Latella implant. Studies evaluating the impact of stretching of the ITB have measured increases of 9% to 11% without impacting its function.[8] In addition, as shown in Figure 1, the surface of the Latella knee implant is polished to a mirror finish to mitigate any risk of ITB irritation. Long-term clinical studies have demonstrated the safety of implantation of condylar plates at the same anatomical site as the Latella knee implant.[14,28] Failures of condylar plates in clinical studies are primarily caused by lack of osteosynthesis (bone healing), which is not a failure mode for the Latella knee implant.

Reduction of mechanical load on the medial condyle by 10% has been shown to provide clinical benefits in terms of reduced pain and improved function. Christensen et al[2] concluded, based on a meta-analysis of randomized controlled trials, that unloading the knee by a 10% reduction in body weight resulted in a 28% improvement in knee function. Pollo et al[29] demonstrated that a medial load reduction of 11% to 17% can be achieved by valgus bracing. While studies have demonstrated that this bracing

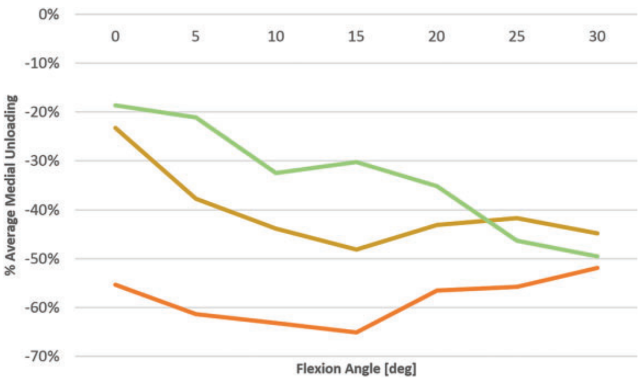

Figure 8. Mean medial compartment unloading as a function of flexion angle. Orange, iliotibial band 0 N; gold, ITB 50 N; green, ITB 100 N.

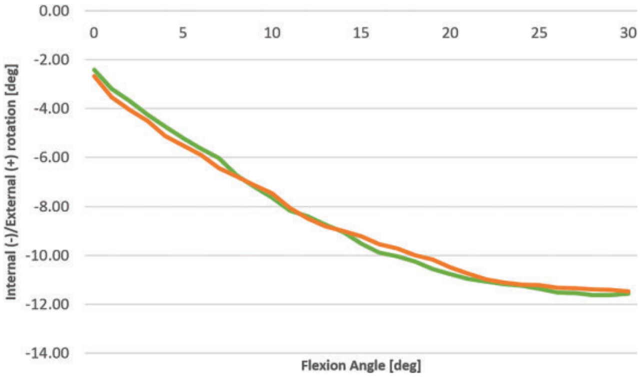

Figure 9. Internal (–)/external (+) rotation as a function of flexion angle with an iliotibial band load of 50 N. Green, native knee; orange, implanted knee.

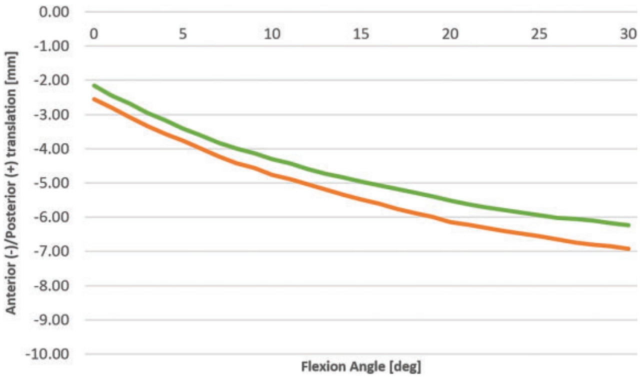

Figure 10. Anterior (–)/posterior (+) translation as a function of flexion angle with an iliotibial band load of 50 N. Green, native knee; orange, implanted knee.

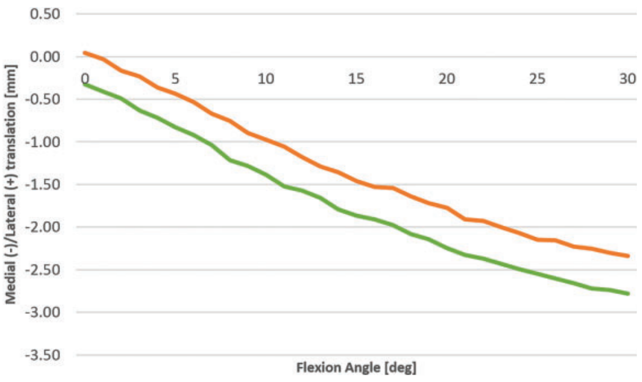

Figure 11. Medial (–)/lateral (+) translation as a function of flexion angle with an iliotibial band load of 50 N. Green, native knee; orange, implanted knee.

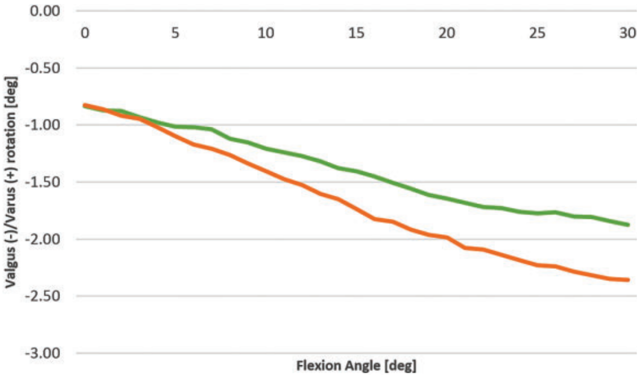

Figure 12. Valgus (–)/varus (+) rotation as a function of flexion angle with an iliotibial band load of 50 N. Green, native knee; orange, implanted knee.

provides significant pain relief, lack of patient compliance due to discomfort and side effects remains a challenge.[30] The unloading of 34% to 65% observed in this robotic cadaveric model suggests that displacement of the ITB has the potential to provide clinically beneficial unloading of the medial compartment.

Surgical redistribution of load within the knee is currently accomplished via a high tibial osteotomy or a distal femoral osteotomy. This is typically performed to reduce the load in the medial compartment, transferring the load to the lateral compartment. Based on cadaveric studies reported in the literature, osteotomy of the knee unloads the medial condyle by 6.6% to 40.2%,[26] 52% to 97%,[24] and 54% to 92%,[34] which is similar to the range of unloading reported here. Clinical studies of high tibial osteotomies have reported long-term success over 5 to 10 years,[37] indicating that the load transfer does not adversely affect the lateral compartment. However, due to the invasiveness of the procedure, postsurgical complications (eg, bone nonunion, delayed union, and loss of alignment), and extended rehabilitation, it is not a commonly performed procedure.[12] Additionally, a high tibial osteotomy also increases the technical difficulty of performing a subsequent total knee replacement.[37]

Another device, an extracapsular partial load-absorbing implant, designed to redistribute loads within the knee joint has been reported by Clifford et al.[4] The implant

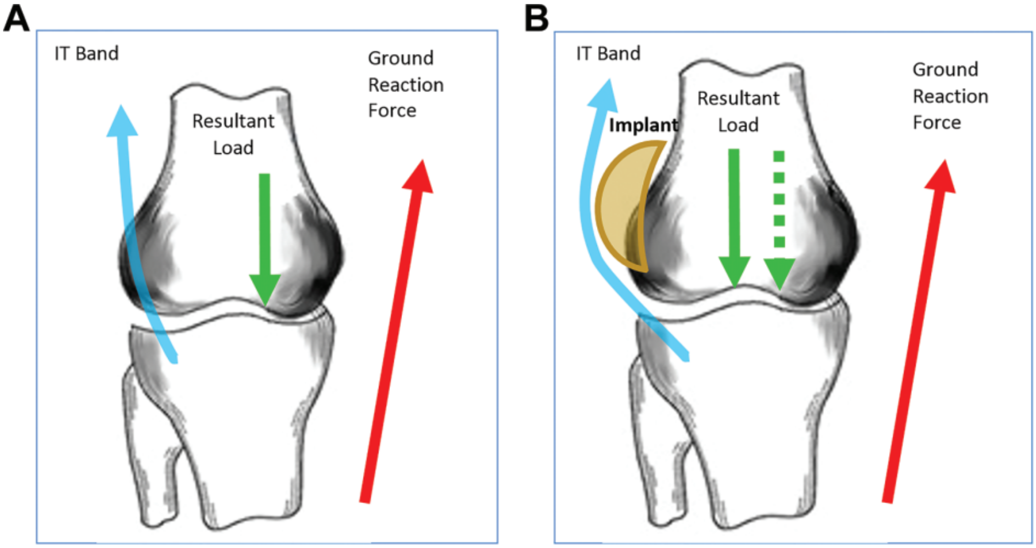

Figure 13. Schematic demonstrating the shift in the resultant force (green arrow) from the medial side to the lateral side due to the Latella knee implant. (A) Native knee; (B) implanted knee. IT, iliotibial.

consists of 2 titanium bases fixed medially to the distal femur and proximal tibia, with a spring absorber interposed between ball joints on the 2 bases. In a cadaveric gait simulation study, the femorotibial forces in the medial compartment during the stance phase were reduced by 31 pounds when the device was implanted.[5] Zhao et al[41] estimated that the medial and lateral load in the knee during gait are 1.2 and 1.0 times body weight (BW), respectively. Hence, a 31-pound load reduction would result in a 26% medial load reduction in an individual with 100-pound BW and a 10% reduction in an individual with 250-pound BW. While the device was evaluated in a different cadaveric model, these values are similar to the range of unloading reported in this study. In addition, early clinical use of this system has included reports of soft tissue irritation, metallosis,[31] and fracture,[3] demonstrating the challenges of deploying complex implants with moving parts across the knee joint.

While the controlled cadaveric study used to evaluate the Latella knee implant provided a means to assess the potential impact of muscle moment arm on joint load distribution, the limitations of the model must be noted. The model used here utilizes fixed muscle loads during knee flexion, which is not physiologically accurate. Muscle loads are expected to vary based on the activity and degree of knee flexion. Since the actual ITB load has not been reported in the literature, assumptions were made about the range of ITB loads. In this model, the muscles around the knee were isolated from the neighboring joints (hip and ankle). Any change to the ITB could alter the biomechanics of the hip or the ankle, thereby altering the observed effect within the knee. Similarly, any long-term change in ITB force due to displacement by the Latella implant could also alter the load distribution in the knee.

Additionally, the kinematic measurements reported here are based on a nonweightbearing model. Body weight has an impact on knee kinematics,[20] and a study comparing a weightbearing model with this nonweightbearing robotic model has noted differences in the measured kinematics.[39]

During normal gait, actual muscle forces as well as the ratio of the muscle forces (quadriceps, hamstrings, and ITB) vary through the flexion range. In this model, the muscle forces (and ratio of muscle forces) were fixed through the flexion range. While the muscle forces and ratios probably varied from normal knee biomechanics, we measured substantial levels of medial compartment unloading through all loading conditions within previously described physiologic ITB loads. Hence, it is likely that for various combinations of muscle forces at different flexion angles, the degree of medial unloading is within the range we measured.

There exists a treatment gap for patients who have exhausted conservative OA management but whose disease has not advanced enough to warrant highly invasive surgical procedures.[6] The Latella knee implant could fill this treatment gap by providing patients and surgeons a less invasive, potentially reversible option for early to mid-stage OA. In comparison with more invasive bone-modifying surgical procedures (eg, high tibial osteotomy, unicondylar or total knee arthroplasty), the Latella knee implant is a simpler surgical procedure. Since the entire implant is extracapsular and the procedure does not involve cutting bone, there is the potential for fewer significant postsurgical complications (eg, bone nonunion). Additionally, the Latella knee implant is designed to be removable, hence, potentially allowing the surgeon and patient to consider any of the other surgical options in the future.

Based on the results of this cadaveric study, unloading the medial compartment by displacing the ITB laterally may be a means of treating medial OA. Unloading the medial compartment may alleviate pain and improve function, allowing patients with early-stage medial OA to remain active longer prior to considering more invasive options like arthroplasty. Clinical studies are currently underway (Clinicaltrials.gov: NCT02002637, NCT02343705, NCT02608957) to evaluate the safety and efficacy of the Latella knee implant in treating medial knee OA. Currently, the Latella knee implant is used exclusively for clinical investigations in the European Union. It is limited by federal law to investigational use in the United States.

CONCLUSION

Mechanical leverage of muscles across a joint is enhanced through sesamoid bones (eg, patella), which increase the muscle moment arm. Similarly, an implanted device may be used to displace muscles and/or tendons around a joint to increase the moment arm of the applied muscle forces. In the knee, the load can be redistributed by laterally displacing the ITB over the lateral femoral condyle and increasing its muscle moment arm. In a robotic cadaver model, displacement of the ITB by 15 to 20 mm using the Latella knee implant was shown to unload the medial condyle by 34% to 65%. Unloading the medial compartment with the Latella knee implant has the potential to address the treatment gap for patients with medial knee OA by reducing pain and improving function.

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