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An Extramedullary Spacing Block Technique to Restore Native Coronal Limb Alignment in TKA

Danton S. Dungy, MD and Kayla de Jesus, BS

Background: Historically, the femoral and tibial preparation for a total knee arthroplasty (TKA) are executed in isolation and then soft tissue releases are used to obtain a balanced knee. We present the clinical outcomes associated with a novel surgical method that links the tibial and femoral resections, avoids soft tissue releases, is performed extramedullary, and does not require special scans, robotics, or rapid prototype blocks.

Materials and Methods: We measured hip, knee, ankle alignment radiographs preoperatively and postoperatively on 433 consecutive TKAs performed between November 2016 and August 2019. A new surgical technique called the *l*inked *a*nd *t*ensioned *e*xtramedullary *r*esections (LATER technique) for both extension and flexion gap balancing was utilized without any soft tissue releases.

Results: One hundred thirty-four knees were found to have severe malalignment preoperatively ($\geq$10 degrees of varus or valgus deformities). The average angular correction was 12 degrees toward neutral alignment. Of the entire cohort, 89.2% of patients reported being completely or mostly satisfied. Patients reported "a lot of improvement" or "back to normal" (92.3%).

Conclusions: The LATER technique improves coronal alignment following a complex primary TKA. Contemporary TKA can be balanced without ligament releases. The avoidance of intramedullary violation and soft tissue releases decreased intraoperative blood loss and trauma. This technique also avoids the complexities of navigation, the complications associated with fat embolism, and the manufacturing of rapid prototype blocks. The LATER technique of coronally tensioned alignment is simple to use and has excellent patient-reported satisfaction and improvement scores.

Key Words: LATER technique—spacer block technique—missing link device—coronal alignment—clinical improvement—total knee arthroplasty.

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The overarching goals of total knee arthroplasty (TKA) are pain reduction and limb realignment if a deformity is present, while both patients and surgeons strive for joint stability.[1–4] In addition, implant survivorship of TKA has been associated with balancing the soft tissues around the joint.[5,6]

Unfortunately, there is a lack of consensus in the orthopedic community regarding the appropriate postoperative limb alignment after TKA.[7,8] This variability may contribute to the disparity between the patient-reported satisfaction rates for THA in comparison to TKA, as hip replacement satisfaction continues to consistently score higher than TKA satisfaction.[9–12]

The purpose of this study is to report on the outcomes associated with a newly devised surgical technique that was developed with the following goals: simplicity, reproducibility, and improved patient satisfaction. This novel surgical technique is presented with the intent of balancing coronal malalignment in modern TKA without soft tissue releases, computer-assisted surgery, or robotics.

MATERIALS AND METHODS

Overview

The clinical outcomes of 433 TKAs performed in 337 patients were collected retrospectively in an Institutional Review Board (IRB) approved study. All consecutive patients were included in the study cohort. The surgeries were performed by a single surgeon at 3 facilities: a level 1 trauma center, an orthopedic subspecialty hospital, or same-day home surgery at an ambulatory surgery center. Patients received a combination of cruciate retaining (CR) and posterior stabilized (PS) implants from various implant companies. Each patient's posterior cruciate ligament was assessed intraoperatively, as a tibia-first technique was used. If the posterior cruciate ligament showed continuity, then a CR implant was used; however, if the posterior cruciate was clinically absent or insufficient after tibial resection, then a PS design was implanted. No highly constrained or hinged implant designs were utilized. All surgeries were performed under a tourniquet, all implants were cemented, all patellae were resurfaced, and no drains were utilized. All patients received perioperative antibiotics. Patients were seen for a preoperative visit, a 2- and 6-week follow-up, then an annual evaluation.

Radiographic Criteria

Preoperative and postoperative long-leg imaging was available for the study group once the principal investigator (PI) transitioned to digital radiography; therefore, the surgeries chosen for this study were performed between November 2016 and August 2019. The hip, knee, ankle (HKA) angle of the radiographic coronal alignment was measured according to the method as described by the Knee Society[13] (Figs. 1A, B). A board-certified radiologist performed the measurements using Medstrat Software (Medstrat Inc. 1901 Butterfield Rd. #600 Downers Grove, IL, ECHOS version 3.2.18.0).

Surgical Technique

The surgical exposure was created through a medial parapatellar approach without any additional soft tissue releases. The first step in the technique was to remove the marginal osteophytes that surround the distal femur and proximal tibia (Fig. 2). Then, an extramedullary tibia-first technique was used. An attempt was made to resect the tibia at 0 degree of varus/valgus with a 3-degree posterior slope as this was the angle of the manufacturer's cutting guide.

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East Valley Regional Institutional Review Board approved study.

The Principal Investigator, D.S.D., is the CEO of Sterling Innovations, LLC and the creator of the LATER technique, the Missing Link Device, and has patented the Missing Link Device and the specialized spacer blocks. K.d. J. declares that there is nothing to disclose.

For reprint requests, or additional information and guidance on the techniques described in the article, please contact Danton S. Dungy, MD, at dungy13@gmail.com or by mail at 2121 W. Chandler Blvd, #110, Chandler, AZ 85224. You may inquire whether the author(s) will agree to phone conferences and/or visits regarding these techniques.

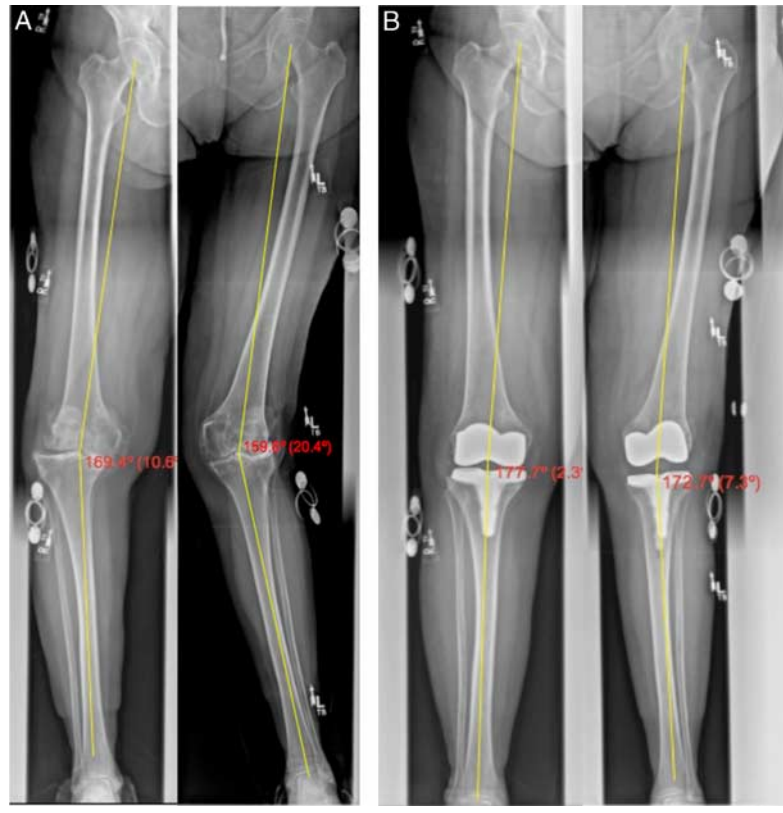

FIGURE 1. A, Severe valgus (20.4 degrees left knee) and varus (10.6 degrees right knee) malaligned knees, a so-called "wind-swept" deformity preoperatively. B, Postoperative radiographs of (A) showing improved coronal alignment (20.4 to 7.3 degrees valgus left knee and 10.6 to 2.3 degrees varus right knee) and patient-reported outcomes revealed "back to normal" (level of improvement: 4) and "completely satisfied" (patient satisfaction: 6).

Next, the exposed proximal tibial metaphyseal bone was protected with a metallic plate (Fig. 3). Then, a novel *l*inked *a*nd *t*ensioned *e*xtramedullary *r*esection (LATER) technique was utilized. More specifically, the collateral ligaments are tensioned equally, medially and laterally, with calibrated Scott femoral tibial tensioners (Innomed Inc., Savannah, GA) to a measured amount of ~25 to 30 ft/lb (2.5 to 3 indicator gauge on the tensioners) in 0 degree extension (Fig. 4A). Once the extension gap was tensioned, a newly developed jig called the Missing Link Device (Sterling Innovations LLC, Scottsdale, AZ) was used to link the previously created tibial resection to affix the distal femoral resection block at the level of the femoral notch with the limb in full extension (Fig. 4B). The Missing Link Device was disconnected, the knee was flexed, and the distal femoral resection was completed without intramedullary violation. This created a balanced rectangular extension gap without any soft tissue releases.

From the sagittal plane, the newly created rectangular extension gap is actually a trapezoidal space, not rectangular; thus, standard spacer blocks would have the surgeon assessing mediolateral stability in a 3-degree flexed position, instead of full extension. Therefore, a unique trapezoidal spacer block was created to allow assessment of the extension gap in full extension at 0 degree (Fig. 5).

The extension gap was measured in mm per the appropriate spacer block (typically 17 to 23 mm), then the same tension was applied medially and laterally in the flexion space at 90 degrees to produce external rotation (ER) of the femoral component using posterior referencing gap balancing technique to create the

FIGURE 2. Displaced medial collateral ligament secondary to "tenting," not contracture, can return to its native position after the removal of marginal osteophytes and the meniscus. Arrow pointing at tenting medial collateral ligament.

FIGURE 3. Flat metallic protective plate for the resected proximal tibial exposed metaphyseal bone.

rectangular flexion gap that matched the size and shape of the extension gap. Several implant companies offer instrumentation that allow tensioning while the knee is flexed (Fig. 6).

Data Collection

We then evaluated postoperative long-leg radiographs to reassess HKA angular alignment during the 2-week follow-up visit.

We collected patient demographic data such as age, gender, and body mass index. We also looked at several other inpatient and outpatient parameters such as: opioid utilization by reviewing the state-run controlled substance prescription monitoring program, length-of-stay, 30-day readmissions, and any adverse outcomes. Finally, KOOS Jr, patient satisfaction rates and levels of improvement were assessed using 6-point and 4-point Likert scales, respectively (Tables 1, 2).

RESULTS

Of the 433 TKAs, 89 had incomplete data (59 incomplete radiographic visualization of the lower extremity, 26 lost to follow-up, 3 deceased, and 1 could not stand for preoperative imaging), leaving 344 TKAs with complete data. Two hundred ten had normal alignment (< 10 degrees varus/valgus) and 134 were malaligned. Forty-eight patients underwent bilateral surgeries within the study period, of which 31 had complete data (62 TKAs). Three hundred twelve procedures were performed in an inpatient hospital setting, 31 in an outpatient ambulatory surgery center setting, and 1 in an orthopedic specialty hospital. The clinical follow-up ranged from 12 to 46 months. The mean age at the time of surgery was 67 and ranged from 46 to 94 years old. The average body mass index in the normal alignment group was 31.7 and was similar in the malaligned group at 31.2. (range: 21.7 to 44.0). One hundred forty-two knees received a CR designed implant, the remaining 202 knees received a PS implant. Patients received implants from

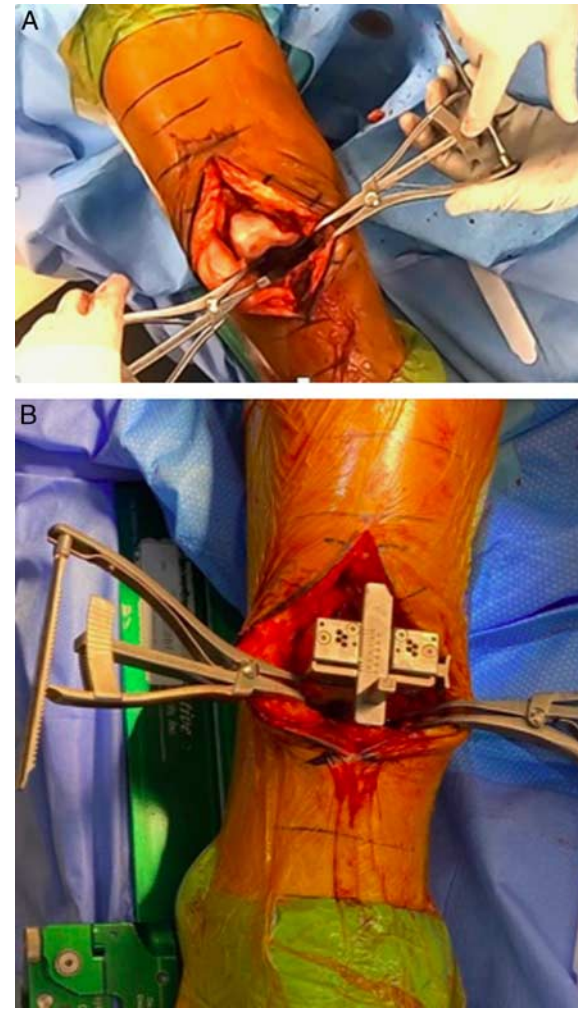

FIGURE 4. A, Equally tensioned medial and lateral compartments while the knee is fully extended. B, With the linked and tensioned extramedullary resection technique the Missing Link Device connects the anticipated distal femoral resection to the previously created proximal tibial resection resulting in a balanced rectangular extension gap without the traumatic release of soft tissues.

ZimmerBiomet (Warsaw, IN), Exactech (Gainesville, FL), Smith & Nephew (Memphis, TN), Johnson & Johnson/DePuy (Warsaw, IN), and DJO (Austin, TX). There were no transfusions, nor neurovascular injuries.

The final cohort had 258/344 preoperative varus deformity. The severe preoperative deformities (> 10 degrees) were unequally distributed by sex, 59% were women; however, 65% of the entire 344 TKAs were performed in women. The average preoperative alignment in the normal cohort was 3.2 degrees (varus) which resulted in an average postoperative alignment of 1.0 degrees (varus). Whereas, the mean preoperative angular valgus malalignment was 13.8 degrees (range: 10 to 26.6 degrees deformity) and the varus malalignment was 12.3 degrees (range: 10 21.2 degrees deformity). The resultant mean postoperative alignment in the malalignment subgroups was 5 degrees valgus and 1 degrees varus, respectively.

The average coronal angular correction in the normal alignment cohort was 2.2 degrees; whereas, the mean coronal alignment correction in the malaligned group was 8 and 13

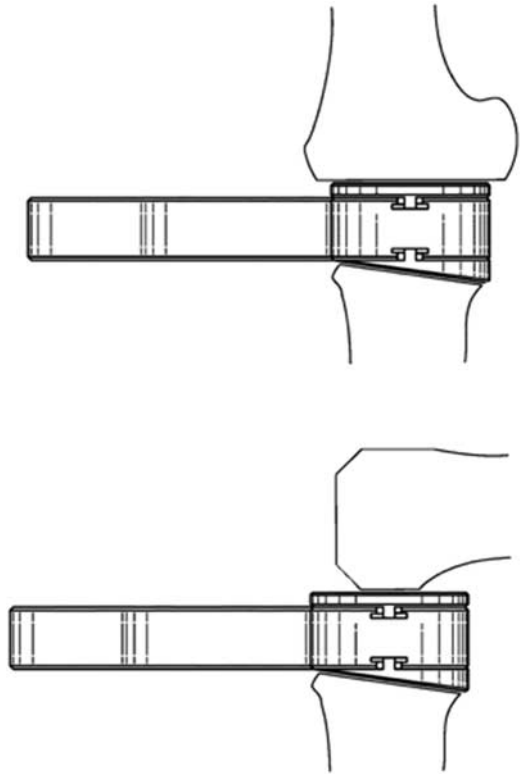

FIGURE 5. Sagittal schematic diagram showing the femur and tibial create a trapezoidal shape when compared with the rectangular shape created in the coronal plane. A specialized spacer block with a 0 degree shim on the femoral side and a 3 degree shim on the tibial side was used to confirm M/L stability in full extension and flexion.

degrees, in the valgus and varus cohorts, respectively. Bilateral TKA patients' preoperative alignment difference side-to-side averaged 4.4 degrees (range: 30.4 to 0 degrees), while postoperative alignment was found to be within 2.9 degrees of each other (range: 10 to 0.2 degrees). The mean angular correction with the LATER technique was 8.2 degrees (Figs. 7A, B).

We were able to obtain patient-reported outcomes in 249/344 (72.3% response rate). Overall patient satisfaction was found to be 89.2%. Moreover, 92.3% of patients reported "a lot of improvement" or "back to normal." Ten of 344 patients reported dissatisfaction secondary to persistent pain, tightness, and stiffness. The average raw KOOS Jr. score obtained at a minimum of 1 year follow-up was 3.6 which equated to an adjusted score of 81.8.

TABLE 1. Four-point Likert Scale Used for the Determination of Patients' Level of Improvement After Total Knee Arthroplasty

Level of Improvement "How Much Has the Knee Replacement Improved Your life?"	
0	No improvement or worse
1	A little improvement
2	A moderate amount of improvement
3	A lot of improvement
4	Back to normal/complete improvement

There were no revision arthroplasties performed on this study group for loosening, wear, nor instability; however, we did encounter adverse outcomes in a small group of patients. Three patients were noted to have readmissions within 30 days postoperatively. More specifically, 1 patient had metabolic acidosis secondary to rhabdomyolysis and underlying liver cirrhosis. The other 2 recovered fully from a gastrointestinal bleed and leukopenia, respectively. Meanwhile, 5 patients did undergo additional knee surgery. First, the patient with liver cirrhosis cited above also developed persistent postoperative bleeding secondary to a coagulopathy, which led to wound healing issues. This same patient then developed an infection, was treated with a 2-stage revision, had recurrent infection and ultimately an above the knee amputation. Four of the remaining patients sustained disruption of the medial arthrotomy repair postoperatively, 3 within the first 90 days and 1 chronic addressed surgically over a year postoperatively for patellar realignment. Finally, 1 patient underwent manipulation under anesthesia postoperatively and ultimately achieved 0 to 125 degrees range of motion.

DISCUSSION

The purpose of this study is to present a novel surgical method that can improve both radiographic alignment (an average of 8.2 degrees correction) and patient-reported outcomes ($>89.2\%$ improvement and $>79.3\%$ satisfaction rates) while simplifying the execution of modern TKA. We have found that the data supports the following: (1) the technique is applicable to both CR and PS knee implant designs; (2) the technique is open-platform, meaning that it can be used universally with several contemporary knee replacement systems; (3) a balanced knee replacement construct is created without ligament releases in malaligned arthritic knees; (4) there is decreased blood loss when compared with IM-guided TKA alignment and (5) finally, there is improved patient-reported outcomes when specifically looking at overall satisfaction and improvement comparable to that of THA.

FIGURE 6. Examples of flexion gap balancer instrumentation as offered from DJO and Exactech, respectively.

TABLE 2. Six-point Likert Scale Used for the Determination of Patients' Satisfaction After Total Knee Arthroplasty

Patient Satisfaction "How Satisfied Are You With Your Knee Replacement?"	
0	Completely dissatisfied
1	Mostly dissatisfied
2	Somewhat dissatisfied
3	Neither dissatisfied nor satisfied
4	Somewhat satisfied
5	Mostly satisfied
6	Completely satisfied

Multiple implant companies were used during this study for varying reasons: match the contralateral implant, a patient reported history of metal sensitivity, or facility directed implant availability. This strengthens the concept that this is indeed an open-platform technique.

Failure mechanisms for TKAs have shifted from implant-related issues, such as polyethylene wear, to instability and malalignment. Thiele and colleagues found that in 358 revision TKAs, the cause for additional surgery 42.5% of the time was either instability (21.8%) or malalignment (20.7%).[14] Because of this, the classic mechanical alignment (MA) method of TKA has been challenged by the kinematic alignment (KA) as presented by Howell who reports a decreased length of stay 1.3 days versus 3.1 days for MA-TKA; lower 30-day readmission 1.5% compared with 2.5%; and, 1% versus 2.7% major complications.[15]

Although there are differences between the MA-TKA and KA-TKA, the commonality of the tibia and femur being addressed in isolation is similar for both techniques. This also applies to the adoption of any current robotic or navigated methods to perform contemporary TKAs. Whereas, the LATER technique differs from these methods because it uses tensioning and linking before bone resection in both flexion and extension. This achieves the desired equal rectangular extension and flexion gaps without soft tissue injury. Also, the LATER technique does not align the limb to a predetermined angular measurement as dictated by the MA-TKA, nor is it based on measured resections as described in the KA-TKA. Instead, the goal of the LATER technique is to create a neutral tibial mechanical axis and then build the femoral resection off the individual patient's soft tissue envelope. This novel method may be a solution to address the findings of Bellemans and colleagues who reported the "normal" limb alignment of 500 healthy male and female subjects ranged from 9 degrees of varus to 9 degrees of valgus in a Bell-shaped distribution (Fig. 7B).[16]

Similar to Kizaki et al[17] who conducted a recent meta-analysis looking at almost 4000 patient specific-TKAs which found that there was a decrease in blood loss secondary to the avoidance of intramedullary violation, we too concluded that

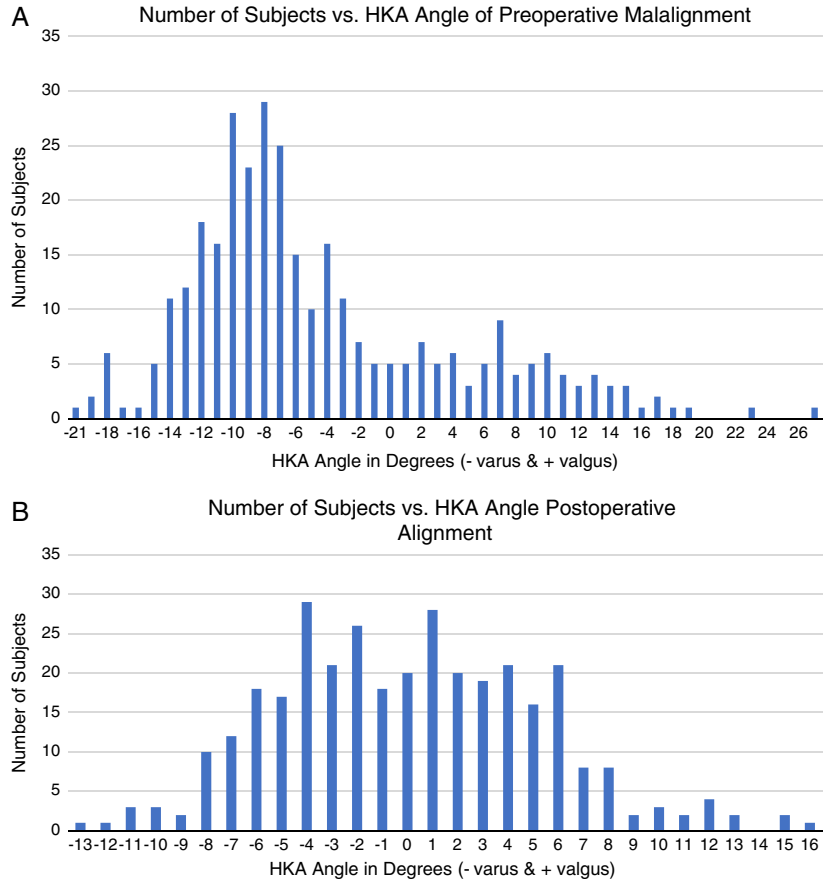

FIGURE 7. A, Negative numbers represent a varus malalignment, while positive integers are equated to a valgus malalignment. B, Negative numbers represent a varus alignment correction, while positive integers are equated to a valgus alignment correction. HKA indicates hip, knee, ankle.

FIGURE 8. A, Preoperative anteroposterior and lateral radiographs of a patient with posttraumatic osteoarthritis with retained hardware after ACL reconstruction. B, Postoperative imaging of the knee with retained femoral hardware secondary to an extramedullary femoral resection. ACL indicates anterior cruciate ligament.

there was decreased blood loss with the extramedullary technique. We also theorize that the lack of soft tissue releases may have prevented additional blood loss and contributed to less swelling and potentially earlier range of motion. Another advantage of the extramedullary technique was that retained hardware was not an issue in our cohort (Figs. 8A, B).

The lack of soft tissue releases may contribute to the superior patient satisfaction rates. Our findings are similar to those reported for hip arthroplasty by Hamilton et al[18] who found that the satisfaction rate for THA was 91% when compared with TKA at 81%. Our satisfaction rate of 89.2% was superior to the historically reported TKA rate of 81%.[19] Equally, our patient reported improvement rate of 92.3% is encouraging. Preoperative patient expectations, persistent knee pain, and decreased activity are among the leading causes of patient dissatisfaction after a TKA.[4,19,20] We postulate that our cohort patients' knees felt like their native knees and performed in a more physiological manner because the soft tissue was less

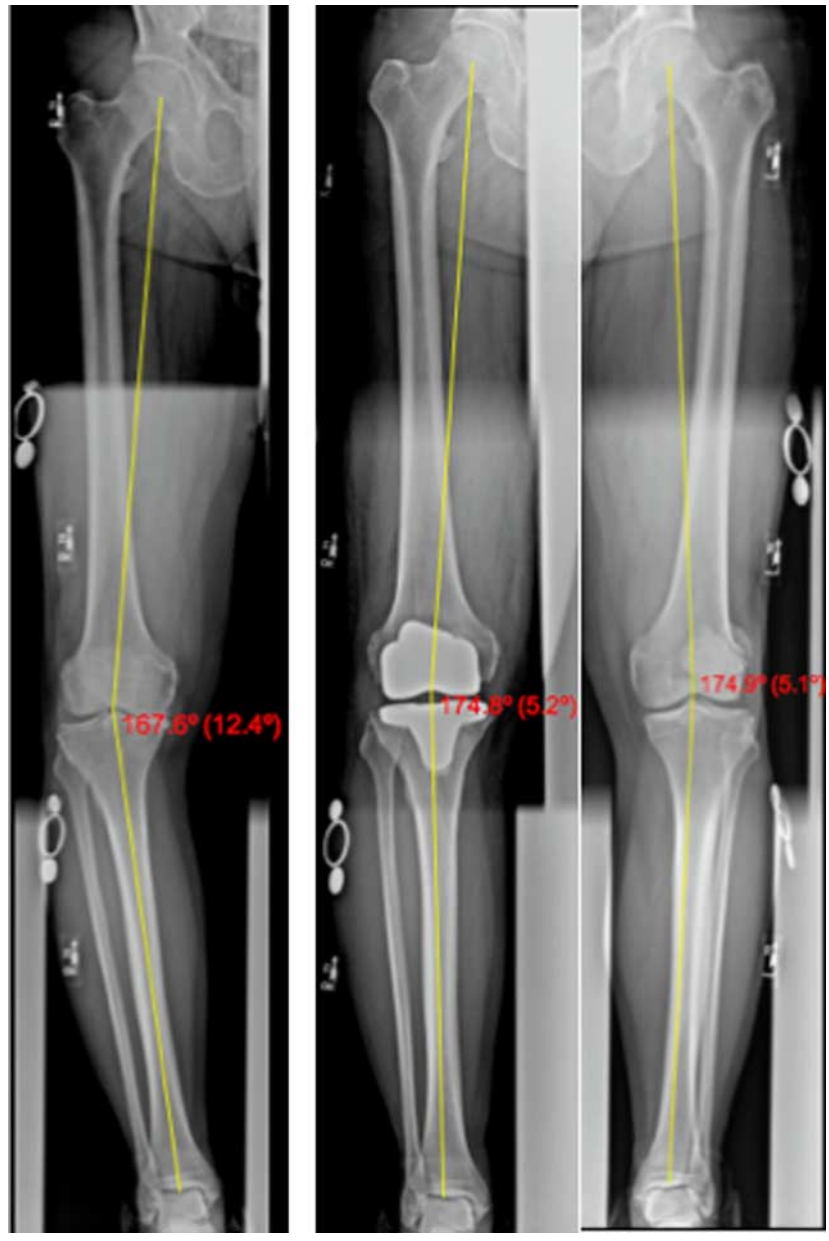

FIGURE 9. A preoperative long-leg radiograph showing an hip, knee, ankle angle of 12 degrees of varus. Postoperative imaging shows that the new limb alignment using the *l*inked *a*nd *t*ensioned *e*xtramedullary *r*esections (LATER) technique for total knee arthroplasty has brought the limb back to the same alignment of the nonarthritic knee, 5 degrees of varus. Level of improvement: 4; patient satisfaction: 6.

traumatized with the LATER technique. This method may be returning the knee to the prearthritic alignment (Fig. 9).

There are some limitations to our study. First, there is no direct comparison made to another cohort group who underwent either MA-TKA or KA-TKA. Unfortunately, the PI has evolved the LATER technique over several years and the quality of data available before contemporary electronic health records is inadequate for us to present a matched group for comparison. We encourage other surgeons to perform knee replacement surgery with the LATER technique and develop additional research data.

Next, the measurement of radiographic alignment via the HKA angle can be influenced by several factors such as internal and ER of the limb and patient position.[21] Malrotation of the limb during long-leg radiographs could lead to falsely under or over-measurement of the varus or valgus alignment of the limb.[22,23] Fortunately, the same radiology technologist performed all of the imaging and followed a protocol attempting to keep all of the patients' feet pointing forward (neutral internal rotation and ER).

Some surgeons may consider another limitation of the LATER technique is not knowing the precise numbers related to the various resections and angles for distal femoral implant positioning. We are comfortable not knowing these numbers because one of the goals of the LATER technique is to create a balanced knee every time, which we believe has contributed to improved patient satisfaction.

Next, there may be concern that this technique will not work in the severely malaligned knee with a fixed deformity. This is the precise reason such a challenging cohort of malaligned knees was identified and found to have similar outcomes as a normal alignment subgroup.

We believe that the only limitation to using the LATER technique is the absence of either or both collateral ligaments. Equally, we did not have an opportunity to perform this LATER technique in a patient with a severe flexion contracture.

Finally, there were a handful of patellar issues postoperatively. Although this study did not research the specific amount of ER on the femoral component via computed tomography scan, a balanced rectangular flexion gap was created based off of the resected tibia. We attribute these failures to the PI transiently switching the suture used to repair the arthrotomy during the reported time frame from a running looped 0 PDS to a newly released barbed suture that was FDA-approved for fascial closure. An examination of all TKA patients who underwent surgery by the PI from 2011 until the cohort group in 2016 and since late-2018 showed no medial arthrotomy disruptions. This window of issues can be attributed to a change in the medial arthrotomy repair, not the technique which has been used for several years prior and has shown no re-emergence after switching back to the original closure technique.

Future studies should aim to determine the distal femoral implant rotation with the LATER technique; cost-effectiveness of the Missing Link Device compared with navigation, robotics, and preoperative scans such as magnetic resonance imaging or computed tomography; preoperative versus postoperative limb alignment in patients who undergo TKA for isolate patellofemoral arthritis; and, finally, postoperative limb alignment compared with a nonarthritic contralateral knee as seen in Figure 9. It is possible that this technique may be closer to achieving the "forgotten knee" as described by Eymard and colleagues.[24,25]

CONCLUSION

The new LATER technique has been shown to improve coronal alignment following a complex primary TKA. We have also found that the knee can achieve coronal balance without ligament releases. The method's benefits of avoiding intramedullary violation have shown decreased intraoperative trauma and blood loss. With no special preoperative scans (computed tomography/magnetic resonance imaging) and avoiding the complexities of navigation, the LATER technique of coronally tensioned alignment is simple to use and easily reproducible

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