Smith+Nephew CORI◊ Digital Tensioner for total knee arthroplasty (TKA): ligament tensioning and assessment prior to bone resections

Haas SB;[1] Chow J;[2] Nathwani D;[3] AlBelooshi A;[4] Jennings S;[5] Waters TS;[6] Ettinger M;[7] Bollars P;[8] Van den Berg JL;[9] Rama S;[10] Tuli N;[10] Signorelli J[11]

[1]Hospital for Special Surgery, New York, NY; [2]Chow Surgical, LLC, Phoenix, AZ; [3]Imperial Healthcare NHS Trust, Charing Cross & St. Mary's Hospitals, London, UK; [4]Orthocure Medical Center, Dubai, UAE; [5]The London Clinic, London, UK; [6]London Hip & Knee Ltd; [7]Orthopedic University Clinic, Oldenburg, Germany; [8]St. Trudo Hospital, Sint-Truiden, Belgium; [9]Busamed Paardevlei Hospital, Somerset West, South Africa; [10]Smith+Nephew, Pittsburgh, PA; [11]Memorial Medical Center, Ashland, WI.

Foreword from Steven B. Haas, MD, MPH

Dr. Steven Haas received his education and training at Harvard, Cornell and the University of Rochester. He is the Chief of the Knee Service at the Hospital for Special Surgery in New York, speaks extensively both nationally and internationally on knee topics, and has authored more than 100 orthopaedic publications. Cutting-edge technologies employed by Dr. Haas include robotic-assisted joint replacement, patient-specific instrumentation and accelerometer-based computer navigation.

"The CORI Digital Tensioner has been designed to achieve an elusive goal of personalized soft tissue management during total knee arthroplasty. This technology takes what we've historically done by feel and applies an objective and consistent measure of the load and the gaps, translating these data into a language we already understand without any change to workflow. The ability to obtain these measurements throughout the stressed range of motion (ROM) in an anatomically natural state – prior to any bone resection – means that measurements will more accurately represent a patient's optimal ligament tension characteristics and truly personalize implant placement for patient-specific needs."

Summary

- The CORI Digital Tensioner is the first connected solution to quantify joint laxity prior to making bone resections, with a robotic system[1,2]
- A surgeon-defined, quantifiable force is produced by the CORI Digital Tensioner to distract the knee joint and tension the ligaments, in turn providing objective gap data for procedure planning and execution[1]
- The CORI Digital Tensioner has been shown to lead to improved tensioning repeatability and consistency, compared to manual technique

Introduction

There are varying definitions of what constitutes a well-balanced knee.[3,4] Nevertheless, there is consensus among orthopaedic surgeons that TKA outcomes are highly contingent on soft tissue management.[3,4] One of the goals of TKA surgery is to therefore provide a well-balanced soft tissue envelope that surrounds a well-aligned and well-fixed implant.[5] Patients with well-balanced knees after TKA have reported improved post-operative outcomes, including Knee Society Score, Western Ontario and McMaster Universities Osteoarthritis Index, and Forgotten Joint Score.[6,7]

Optimal soft tissue balance can be broadly defined as equal and symmetrical flexion and extension gaps.[8,9] In practice, achieving soft tissue alignment and balancing can be more challenging than achieving good bone alignment.[10] When a patient has a mal-aligned, imbalanced knee after undergoing TKA, the likelihood of TKA failure increases.[11,12] Surgeons face the additional challenge of accurately assessing laxity intra-operatively. When patients' soft tissues are in a relaxed, non-loaded state it can be difficult for surgeons to extrapolate loaded weight-bearing performance.[10,13,14]

Historically, surgeons have relied on experience and manual, intra-operative feel to assess joint laxity.[12,15,16] Balance is achieved by adjusting implant sizing, implant alignment and soft tissue release.

However, these adjustments are often subjective.[12,16,17] The force manually applied by the surgeon to distract the joint varies among surgeons and cases.[17] This can result in variation in insert thickness choice, implant position and joint laxity for the same knee among surgeons.[18,19]

Recently, sensor-guided knee balancing, which involves the intra-operative use of a pressure sensor to inform soft tissue balancing, has been introduced to TKA surgery.[4,12] These electronic sensors are used after bone resection.[7] Surgeons must therefore commit to a tibia cut before considering ligament laxity, and prior to reviewing the surgical plan.[20] As a result, surgeons have been limited in their ability to predict natural ligament balance through the full ROM.[8] This may lead to compromises in gap balancing and restoration of the joint line, disrupting the natural kinematics of the knee.

Smith+Nephew CORI◊ Digital Tensioner

The CORI Digital Tensioner communicates directly with the CORI Surgical System, providing automated gap data collection, and assists surgeons in providing consistent varus and valgus stress during gap assessment before making bone resections.[1,2,21]

During gap balancing, force is applied to the medial and lateral knee joints, while stretching the ligaments throughout the ROM of the knee. The CORI Surgical System user interface allows the surgeon to specify their preferred target force value (50±10N, 100±10N, or 150±10N).[1,22] These force settings have been identified to support optimal ligament tension, based on testing and published literature.[22,23] The CORI Surgical System only automatically collects gap data when the reading from the CORI Digital Tensioner is within the specified force range (±10N of the target value, Figure 1).

The CORI Surgical System workflow is maintained with the use of CORI Digital Tensioner technology. When the CORI Digital Tensioner is connected, the surgeon can switch between using the CORI Digital Tensioner or a manual technique by selecting the corresponding option on the touchscreen.

Figure 1. Case image of the gap assessment screen using the CORI Digital Tensioner to achieve a target force value of 100N through ROM as indicated by a green bar

Cadaveric and clinical studies involving a global representation of surgeons have been conducted to assess the effect of the Smith+Nephew Tensioner technology on the repeatability of stressed ROM measurements. This report summarises the cadaveric study and preliminary results from the clinical study.

Cadaveric study

Seven arthroplasty surgeons participated in a cadaveric laboratory study.[24] Using a single cadaver, each surgeon tensioned the same knee three times manually, and three times using Smith+Nephew Tensioner technology. For the manual technique, surgeons selected the approach with which they were most familiar: surgeons 3 and 7 opted for a manual technique, and the other five surgeons for a z retractor. When using the Tensioner technology, the surgeons continually incremented the force setting by 10N (from 100N) until the gap profile using the Tensioner was similar to that of the manual technique. This resulted in a force setting of 140N±40N,* closely replicating the average gap profile of the manual technique.

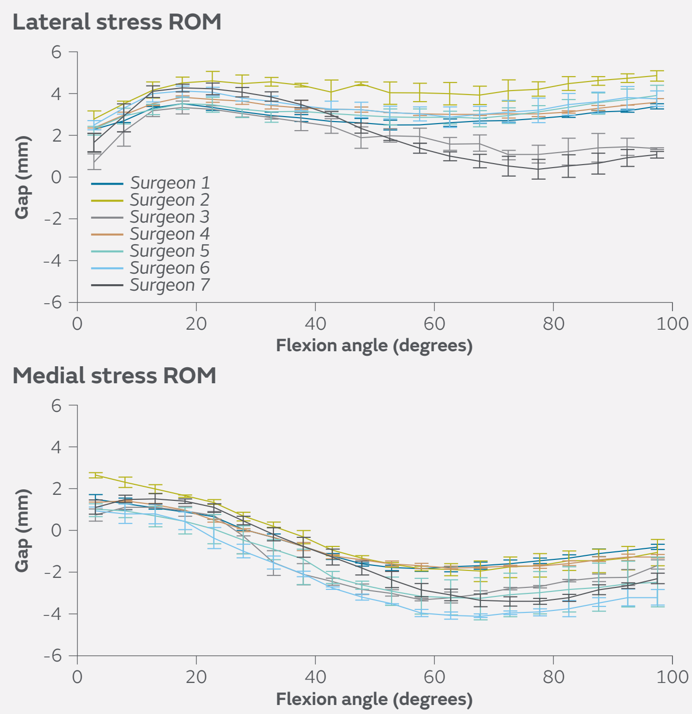

Figure 2. Comparison of average (mean) measured gaps collected during stressed ROM for manual lateral and medial gap assessment by seven individual surgeons in the cadaveric study†

SD reported for every five degrees of flexion. Error bars represent intra-surgeon variability

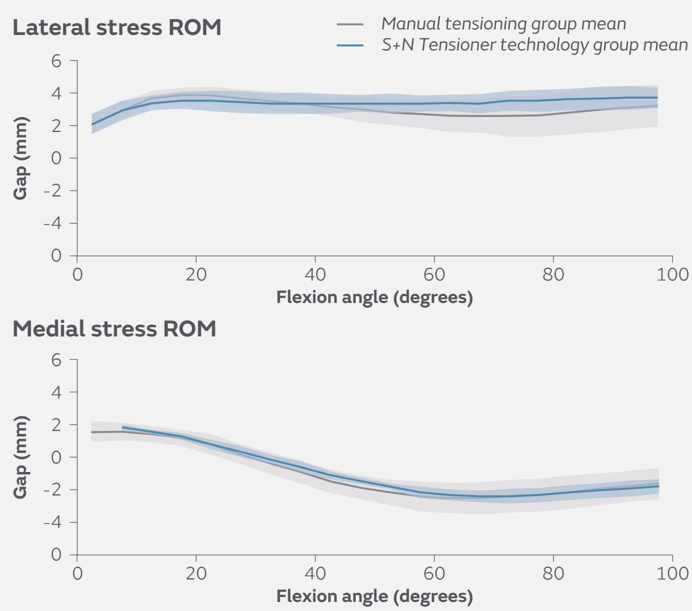

Figure 3. Comparison of surgeon group mean of lateral and medial manual tensioning versus the Smith+Nephew Tensioner technology in the cadaveric study†

SD reported for every five degrees of flexion

*The force setting for this study was selected prior to finalizing the setting selections for the commercial product (50±10N, 100±10N, 150±10N). †Gaps are calculated using the distance between the femur and tibia implants at their system-derived initial locations throughout the stressed ROM collection. Planned gaps are predictive. As illustrated in Figures 2 and 3, negative gap values are possible if the planned positions of the implants overlap at specific areas in the collected stressed range. Negative gap values, therefore, indicate tightness in the resulting joint.

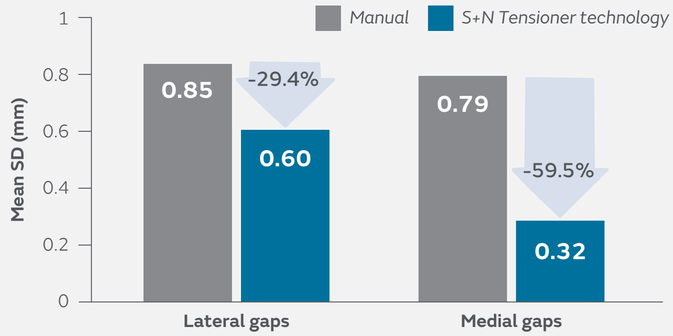

Figure 4. Change in mean SD for lateral and medial gaps across full ROM with manual tensioning versus the Smith+Nephew Tensioner technology in the cadaveric study

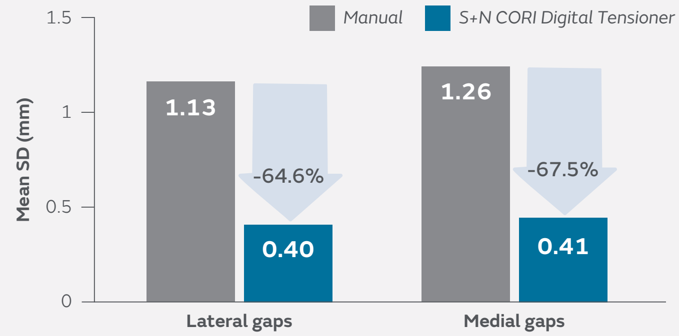

Figure 5. Change in mean SD for lateral and medial gaps across full ROM with manual tensioning versus the CORI Digital Tensioner in the clinical study

When using the manual tensioning technique, there was inconsistency in measured gaps collected during stressed ROM both among surgeons (inter-surgeon variability) and for each surgeon (intra-surgeon variability), as illustrated in Figure 2. Results on the lateral side of the knee show two distinct trends corresponding to surgeons who opted for a z retractor and surgeons who opted for a manual technique. A z retractor helps to provide more mechanical leverage and to stress the ligaments in deeper flexion, compared to tensioning without a z retractor. This trend was not observed on the medial side, perhaps because the lateral side is looser and therefore may be associated with higher variability in measured gaps.

When comparing manual tensioning methods with Smith+Nephew Tensioner technology, a reduction in the variability of measured gaps collected during stressed ROM was observed (Figure 3).

The mean within-group standard deviation (SD) across the full ROM was calculated to compare the variability of the manual technique and the Smith+Nephew Tensioner technology. There was a 29.4% reduction in variability for the lateral collections and a 59.5% reduction in variability for the medial collections when using the Tensioner, compared with the manual technique (Figure 4). These results suggest that using Smith+Nephew Tensioner technology supports a consistent approach to tensioning, resulting in decreased inter- and intra-surgeon variability.

Clinical study

A prospective, pre-market, clinical study is currently in progress to further evaluate the repeatability of the gap balancing workflow using the CORI◊ Surgical System and the CORI Digital Tensioner.[25] During each of the four initial single-surgeon surgeries, the surgeon repeated three stressed ROM collections using a manual technique and three using the CORI Digital Tensioner, prior to bone resection. A CORI Digital Tensioner force setting of 100N±10N was chosen by the surgeon and used in all cases and collections. A tolerance of 10N was chosen for this study after surgeon feedback indicated that this tolerance was sufficiently easy to use, while potentially leading to decreased variability in gap collections, as compared to a tolerance of 40N in the cadaveric study.

A reduction in variability in measured gaps during stressed ROM was observed with the CORI Digital Tensioner, compared to the manual technique.

The mean within-group SD across the full ROM was calculated to compare the single-surgeon repeatability of the manual technique and the CORI Digital Tensioner. There was a 64.6% reduction in variability for the lateral collections and a 67.5% reduction in variability for the medial collections when using the CORI Digital Tensioner, compared with the manual technique (Figure 5). These preliminary results suggest that using the CORI Digital Tensioner supports a consistent approach to tensioning, resulting in decreased intra-surgeon variability.

Conclusions

The clinical and cadaveric studies compared the use of the Smith+Nephew Tensioner technology with manual techniques, prior to making bone resections. Results from the seven surgeons participating in the cadaveric study showed reductions in intra- and inter-surgeon variability and preliminary results from the single surgeon participating in the clinical study demonstrated reductions in intra-surgeon variability, across lateral and medial stressed ROM when using the Smith+Nephew Tensioner technology.

Thus, the data from these studies demonstrate consistent and repeatable tensioning when using the Smith+Nephew CORI Digital Tensioner. The Smith+Nephew CORI Digital Tensioner for use with the CORI Surgical System should be considered by surgeons who seek an objective tool to support consistent and repeatable joint balancing and alignment during TKA.

References

1. Smith+Nephew 2022. Optimus TKA Tensioner Gap Assessment Verification Report. Internal Report. 10059269 REV A.
2. Smith+Nephew 2022. Tensioner Design Verification Test Report. Internal Report. TR100123 REV A.
3. Deep K. Collateral ligament laxity in knees: what is normal? *Clin Orthop Relat Res*. 2014;472:3426–3431.
4. Gustke KA, Golladay GJ, Roche MW, Elson LC, Anderson CR. A new method for defining balance: promising short-term clinical outcomes of sensor-guided TKA. *J Arthroplasty*. 2014;29:955–960.
5. Rossi R, Bruzzone M, Fantino G, Dettoni F, Bonasia DE, Castoldi F. Primary total knee arthroplasty: surgical technique. In: Rossi R, Bruzzone M, eds. Soft tissue balancing in primary total knee arthroplasty. Turin: Edizioni Minerva Medica; 2012:1–12.
6. Gustke KA, Golladay GJ, Roche MW, Elson LC, Anderson CR. Primary TKA patients with quantifiably balanced soft-tissue achieve significant clinical gains sooner than unbalanced patients. *Adv Orthop*. 2014;2014:628695.
7. Golladay GJ, Bradbury TL, Gordon AC, Fernandez-Madrid IJ, Krebs VE, Patel PD, Suarez JC, Higuera Rueda CA, Barsoum WK. Are patients more satisfied with a balanced total knee arthroplasty? *J Arthroplasty*. 2019;34:S195–S200.
8. Shalhoub S, Lawrence JM, Keggi JM, Randall AL, DeClaire JH, Plaskos C. Imageless, robotic-assisted total knee arthroplasty combined with a robotic tensioning system can help predict and achieve accurate postoperative ligament balance. *Arthroplast Today*. 2019;5:334–340.
9. Risitano S, Indelli PF. Is "symmetric" gap balancing still the gold standard in primary total knee arthroplasty? *Ann Transl Med*. 2017;5:325.
10. Wilton TJ. Use of a tensiometer at total knee arthroplasty. In: Bellemans J, Ries MD, Victor JM, eds. Total knee arthroplasty: a guide to get better performance. Heidelberg: Springer Berlin; 2005:212–216.
11. Sharkey PF, Lichstein PM, Shen C, Tokarski AT, Parvizi J. Why are total knee arthroplasties failing today-has anything changed after 10 years? *J Arthroplasty*. 2014;29:1774–1778.
12. Meneghini RM, Ziemba-Davis MM, Lovro LR, Ireland PH, Damer BM. Can intraoperative sensors determine the "target" ligament balance? Early outcomes in total knee arthroplasty. *J Arthroplasty*. 2016;31:2181–2187.
13. Walker PS, Meere PA, Bell CP. Effects of surgical variables in balancing of total knee replacements using an instrumented tibial trial. *Knee*. 2014;21:156–161.
14. Watanabe T, Muneta T, Sekiya I, Banks SA. Intraoperative joint gaps and mediolateral balance affect postoperative knee kinematics in posterior-stabilized total knee arthroplasty. *Knee*. 2015;22:527–534.
15. Muller JH, Van der Merwe W. Primary principles in soft tissue balancing. In: Matsuda SL, Lustig S, Van der Merwe, W, eds. Soft tissue balancing in total knee arthroplasty. Berlin: Springer Nature; 2017:41–48.
16. Elmallah RK, Mistry JB, Cherian JJ, Chugthai M, Bhave A, Roche MW, Mont MA. Can we really "feel" a balanced total knee arthroplasty? *J Arthroplasty.* 2016;31:102–105.
17. Chang MJ, Lim H, Lee NR, Moon YW. Diagnosis, causes and treatments of instability following total knee arthroplasty. *Knee Surg Relat Res*. 2014;26:61–67.
18. Elmasry SS, Sculco PK, Kahlenberg CA, Mayman DJ, Cross MB, Pearle AD, Wright TM, Westrich GH, Imhauser CW. Arthroplasty surgeons differ in their intraoperative soft tissue assessments: a study in human cadavers to quantify surgical decision-making in TKA. *Clin Orthop Relat Res*. 2022;480:1604–1615.
19. Lekkreusuwan K, Scior W, Graichen H. Influence of implant design and individual joint laxity on in vivo medio-lateral stability of the knee. *Clin Surg*. 2021;6:3050.
20. Lee MC. PS: Gap technique. In: Matsuda SL, Lustig S, Van der Merwe, W, eds. Soft tissue balancing in total knee arthroplasty. Berlin: Springer Nature; 2017:59–64.
21. Smith+Nephew 2022. Tensioner KPC: Tensioner Calibration Check. Internal Report. TR100116 REV B.
22. Völlner F, Weber T, Weber M, Renkawitz T, Dendorfer S, Grifka J, Craiovan B. A simple method for determining ligament stiffness during total knee arthroplasty in vivo. *Scientific Reports*. 2019;9:5261.
23. Wilson WT, Deakin AH, Payne AP, Picard F, Wearing SC. Comparative analysis of the structural properties of the collateral ligaments of the human knee. *J Orthop Sports Phys Ther*. 2012;42:345–351.
24. Smith+Nephew 2022. Tensioner Whitepaper Supporting Evidence. Internal Report. 10073166 REV A.
25. Smith+Nephew 2022. CORI TENSIONER .2020.04 Study Cases. Preliminary Analysis Report REV B.

Smith & Nephew, Inc. 1450 Brooks Road, Memphis, TN 38116, USA.

**Developed by Evidence Communications,
Global Clinical & Medical Affairs
www.smith-nephew.com**