

Research Article

Objective gait analysis following total knee arthroplasty with a smart implant directs early intervention with manipulation under anesthesia

John Dundon, MD^{1a}, Patrick M Aubin^{2b}, William Hunter^{3c}

¹ Dundon Orthopedics and Sports Medicine, ² Canary Medical, ³ Canary Medical

Keywords: smart implant, total knee arthroplasty, gait, digital health

<https://doi.org/10.60118/001c.89961>

Journal of Orthopaedic Experience & Innovation

Vol. 5, Issue 1, 2024

Total knee arthroplasty (TKA) is a procedure increasingly in demand. While advancements in surgical techniques and implant designs have led to low complication rates and improved outcomes following TKA, patient satisfaction has not risen commensurately. Routine care may include clinical assessments, physical therapy notes, and patient reported outcome measures, each of which provides a discrete evaluation but may miss significant changes in daily activities.

Here we present the case of a patient who underwent TKA with a tibial implant fitted with an embedded inertial measurement unit capable of providing extensive data on gait kinematics. Despite a successful, well-balanced knee replacement surgery and good clinical outcomes at 2 weeks, by 4.5 weeks post-surgery, she had increased self-reported

^a Dr. John M Dundon is an Orthopedic Surgeon who is Board Certified by the American Board of Orthopedic Surgery. Dr. Dundon has published multiple articles in peer reviewed journals and given national presentations on total hip and knee replacement. He has also published textbook chapters on complex total hip and knee replacement.

Dr. Dundon recently focused his research into healthcare finance reform, implant design, robotics and smart knee technology, revision total joint replacement, as well as multimodal pain management for total hip and knee replacement. He is a member of the American Academy of Orthopedic Surgeons, the American Association of Hip and Knee Surgeons, and the Insall Club.

[Visit John Dundon's Website](#)

[Connect with John Dundon on LinkedIn](#)

[Conflicts of Interest Statement for John Dundon](#)

^b Dr. Aubin's research aims to develop new treatments and technologies that augment human performance and/or improve mobility and function for those affected by disease, age or trauma. By applying advanced artificial intelligence and machine learning techniques to solve challenging problems in orthopedics and rehabilitation he hopes to create devices have a positive impact on patients' lives.

[Visit Patrick Aubin's Website](#)

[Connect with Patrick Aubin on LinkedIn](#)

[Conflicts of Interest Statement for Patrick Aubin](#)

^c A former practicing physician, Bill Hunter has spent his career examining ways to make medical devices safer, "smarter" and more effective. His latest venture, Canary Medical, utilizes implanted sensor technology to enable medical devices to "self-report" on function, activity, wear, complications, and patient outcomes.

Persona IQ, the world's first "smart" orthopaedic implant, combines Zimmer Biomet's market-leading Persona total knee system with Canary's intelligent canturio™ tibial extension. Approved by the FDA in August 2021, Persona IQ passively collects and reports objective metrics such as activity, gait, function, and joint range of motion to patients and their care teams for up to 10 years. A life-long inventor with over 200 patents and patent applications, Dr. Hunter was involved in the discovery and development of the TAXUS® Coronary Drug-Eluting Stent, the Zilver PTX® Peripheral Drug-Eluting Stent, paclitaxel-eluting balloons, and the Quill® barbed wound closure device; products used in over 40M patients and generating revenues of over \$25B.

While in medical school, he co-founded Angiotech Pharmaceuticals (NASDAQ:ANPI), served as CEO (1992-2011), and grew the Company into a profitable, diversified, device company with over 1,400 employees. From 2012-2019, Bill served as CEO of Correvio Pharma Corp (NASDAQ: CORV), an integrated, commercial, specialty pharmaceutical company.

[Visit William Hunter's Website](#)

[Connect with William Hunter on LinkedIn](#)

[Conflicts of Interest Statement for William Hunter](#)

pain scores and her walking speed, stride length and tibial range of motion (ROM) were declining compared to her TKA peers. The patient was called in to the office for evaluation, 3.5 weeks prior to her scheduled 8-week routine follow up. We proceeded with early manipulation under anesthesia, which lead to normalization of her knee ROM. In this case, gait data from the smart implant alerted us to a TKA patient who was failing to progress, prior to her routine follow-up visit. The daily remotely acquired kinematic data was instrumental in the early recognition and intervention. Availability of objective, trended, high-fidelity gait data from smart implants has the potential to identify clinical concerns early, improve efficiency in care, and increase patient and physician engagement in the recovery process.

INTRODUCTION

Total knee arthroplasty is a high volume, high quality procedure with nearly 900,000 procedures performed annually in the United States and 3,416,000 projected by 2040 (Singh et al. 2019). While complication rates remain low and improvement in patient quality of life years (QALYs) remains high, there is still significant room for improvement (Konopka et al. 2018). Given the high volume of procedures, revision TKA is growing rapidly with over 70,000 reported annually (Upfill-Brown et al. 2022). While patient outcomes are considered good, some studies still report up to 20% of patients are not satisfied with their TKA (Bourne et al. 2010; Noble et al. 2006). With ever improving implants and techniques, the indications for TKA are expanding, leading to a younger, more active population placing further demand and expectations on TKA. With the increase in patient demand and improved implant durability, we are still measuring success and failure in the same antiquated way, using knee range of motion (ROM), physiotherapy (PT) reports, and patient-reported outcome measures (PROMs), which are increasingly being seen as problematic and potentially not accurate in reporting patient outcomes (Halawi et al. 2020).

One objective tool that can measure the patient recovery during the TKA process is Persona IQ, (Zimmer Biomet, Warsaw IN) with the CANARY canturio™ tibial extension (Canary Medical, Vancouver Canada). This smart implant system, which received FDA market release authorization on August 30, 2021, contains an inertial measurement unit (IMU) with a gyroscope and accelerometer. The system utilizes the Canary Health Implanted Reporting Process (CHIRP®) System (Canary Medical, Vancouver, British Columbia), connecting the implant via the cloud to the patient and surgeon. The embedded IMU allows step count, walking speed, distance, stride length, cadence, functional knee range of motion (knee range of motion while walking), and tibia range of motion to be remotely collected, analyzed, and displayed in the form of gait parameters via cloud connectivity to the patient and health care team.

The availability of gait parameter data from a large cohort of patients already implanted with a smart knee allow a patient's daily gait parameters to be plotted as a percentile score, affording the opportunity to see their individual progress in the context of their demographically match TKA peers. The goal of remotely monitoring patients' recovery of gait and activity is to improve efficiency in care, increase patient and physician engagement, and, poten-

tially, prevent impending complications, before they arise or get worse. Clinicians currently lack a consistent and defined, evidence-based algorithm for assessing individual-level recovery after the arthroplasty.

In this case report, we describe a primary TKA patient who was recovering well initially and then declined during the first few weeks following surgery. We were able to identify an issue with her recovery through the use and interpretation of the gait and activity data from a smart implant and proceed with early manipulation under anesthesia (MUA) leading to improvement and normalization of her recovery. MUA procedure is infrequently performed after primary TKA (0.6% in the American Joint Replacement Registry and 2.6% in the Medicare database) (Brigati et al. 2020; Parkulo et al. 2023). There is no consensus on MUA indication, though failure to achieve flexion $\geq 90^\circ$ within 4-8 weeks of TKA is commonly cited (Choi et al. 2015; Bawa et al. 2013). Most studies indicate timing of MUA (i.e., within 3 months of surgery) is important (Parkulo et al. 2023; Kornuijt et al. 2018; Gu et al. 2018; Issa et al. 2014; Cates and Schmidt 2009; Bawa et al. 2013), with pre-surgical knee ROM a commonly-reported prognostic factor (Gu et al. 2018; Choi et al. 2015; Ipach et al. 2011).

CASE PRESENTATION

PATIENT

This patient is a 47-year-old female with severe degenerative arthritis. She had failed numerous years of physical therapy, injections, and NSAID use, and we indicated her for right TKA based on physical exam and radiographs ([Figure 1](#)). She was 5'7" tall, 180 pounds, and her preoperative ROM was 10-degree flexion contracture to 115 degrees of flexion for a 105-degree total arc of motion preoperatively. The cemented TKA surgical procedure went well and without complication with robotic balance data as shown ([Figure 2](#)). The surgery was done with patella resurfacing, robotic assist, standard medial parapatellar approach, without a tourniquet. The patient had an IPACK and saphrenous blocks for pain control using 0.25% Marcaine and also underwent intra-articular injection intraoperatively using a Ranawat cocktail. She underwent spinal anesthesia using a chloroprocaine spinal and was discharged home on Tramadol, Percocet, Celebrex and 81 mg Aspirin BID after clearing PT 3 hours post index operation, with a 3x per week PT plan. At her 2-week follow-up visit her ROM was 0 degrees extension and 90 degrees of flexion, pain

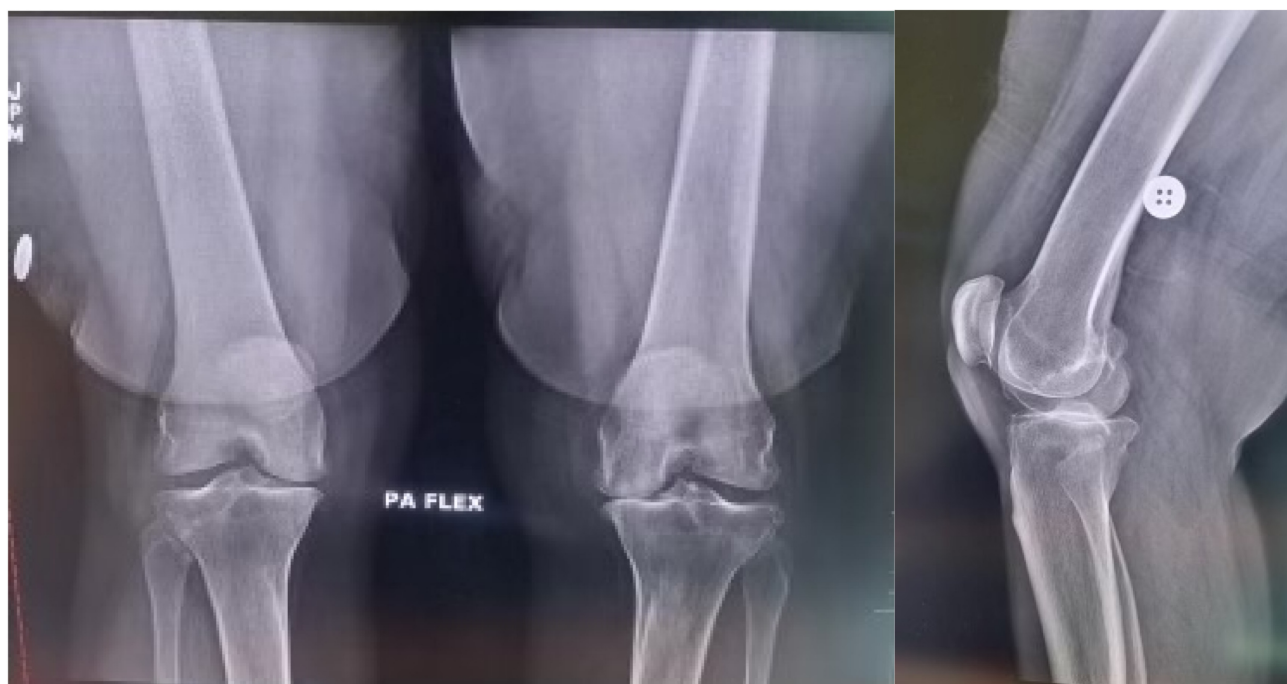


Figure 1. Preoperative flexion PA and lateral showing severe varus arthritis

was controlled and swelling was reasonable, radiographs showed no complications with typical kinematic alignment (Figure 3), she had tapered off narcotics and was progressing in PT and doing well. By 4.5 weeks post surgery, she had increased self-reported pain scores using our post-operative application provided to each patient, and her walking speed, stride length and tibial range of motion percentile scores declined (Figure 4). Consistent with her shorter stride length her cadence was fast (~75th percentile) (Figure 4). Her step count continued to follow the 50th percentile curve, increasing week over week. We called the patient in to the office for evaluation, 3.5 weeks prior to her scheduled routine 8-week follow-up visit. She was increasing her activity and it was causing her pain and swelling. She presented with a stiff knee and decreased ROM. She had a 10-degree flexion contracture and was only able to get to 70 degrees of flexion, significantly worse than at her 2-week visit. In discussion with the patient, we decided to proceed with early MUA. This was done with sedation, a saphrenous block with 0.25% Marcaine and we cycled her knee numerous times to make sure she could obtain full ROM (full extension to 135 degrees flexion). Following the MUA, she was instructed to attend PT 5 days a week for 2 weeks followed by 3 days a week for the following 4 weeks. Following the MUA she did well and by 6 weeks post MUA she had full extension and 125 degrees of flexion, her swelling was greatly improved, and she was walking without a limp.

DISCUSSION

We achieved a well-balanced primary TKA surgery, as evidenced in the robotic data, and good two-week clinical outcomes, as assessed at a routine follow-up visit, yet this patient started showing both a decline in objective gait

metrics, detected by a change in the patient recovery trajectory, and a noted change in comparison to the normalized patient cohort, shortly after 4 weeks post-surgery. The change in slope of the patient recovery trajectory prompted a phone call, that prompted an office visit and discussion, which prompted an early intervention. This previously unavailable objective data provides an opportunity to understand real-world activities of daily living more comprehensively and detect concerns between routine follow-up visits. In the case of our patient, kinematic data combined with clinical data provided via the patient app in the early post-op period let us know that she was not progressing and prompted early evaluation and the decision to perform MUA.

Early identification and treatment of potential complications is pivotal to both patient recovery and care cost effectiveness. Identifying patients at risk for functional impairment, before revision surgery is needed, has been hindered by both an absence of objective outcome data and the resource-intensive nature of gait analysis in a clinical setting. In this case report we describe a patient who underwent primary TKA with an implant containing embedded sensor technology within the tibial stem that transmitted high fidelity, daily gait data following surgery. The smart implant has the potential to record *in vivo* data that can track recovery and provide adjunctive information that assists in clinical decision-making. Unlike traditional in-office performance outcome measures to quantify physical function at discrete timepoints, smart orthopedic devices can provide unprecedented, daily data over long periods (10 years). The smart implant permits remote monitoring of patient gait in their own environment, performing daily activities that are important to them. Data provided by smart sensors are continuous and readily available, making patient mon-

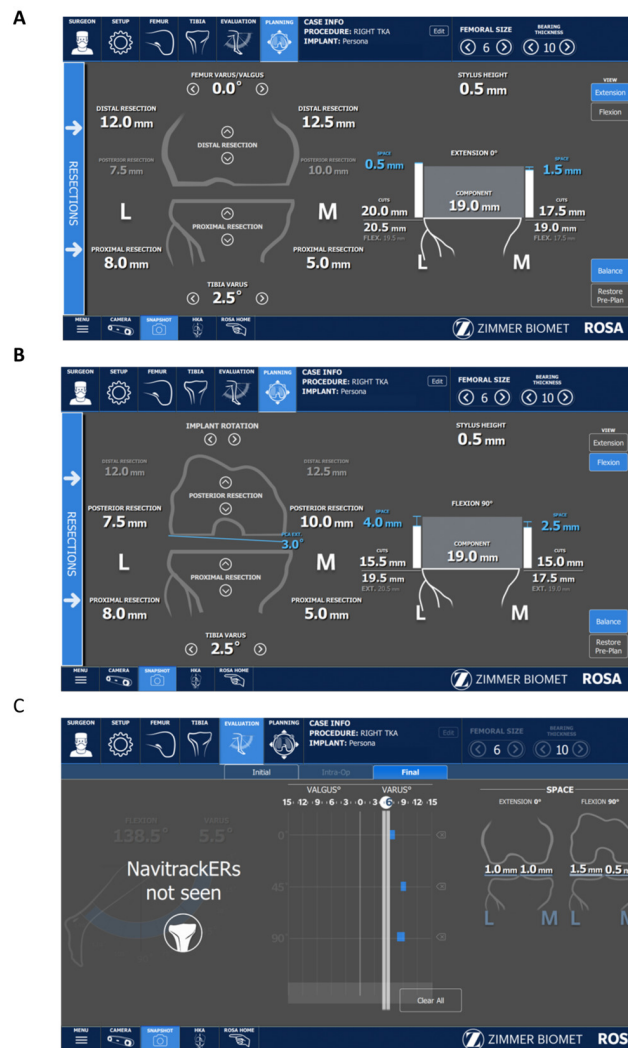


Figure 2. Intraoperative planning showing planned extension gaps (A), flexion gaps (B), and final balance (C) in 0, 45, and 90 degrees.

itoring significantly easier and less costly than measurements performed in traditional gait labs.

Alternatives, such as wearable sensors, can be limited by inaccurate alignment of the sensor relative to anatomical landmarks (Cuesta-Vargas, Galán-Mercant, and Williams 2010; Poitras et al. 2019), reported noise, variability and drift in the real-world setting (Matijevich et al. 2020), the potential for loose fixation to the patient, and challenges with consistent patient use so that daily data is collected over weeks. Patients frequently stop using wearables as time from surgery increases (Hermesen et al. 2017; Lyman et al. 2020).

As value-based care initiatives continue to concentrate on patient satisfaction, patient-focused PROMs are becoming common in clinical settings and can provide information on patient functional recovery and satisfaction. Their scientific and diagnostic utility depends largely on what information is captured, how complete the information is, how inclusive they are, and how representative they are of the patient population at large. However, their usefulness may be limited by their subjectivity and reliance on pain rather than movement as a metric of success (Terwee et

al. 2006; Stevens-Lapsley, Schenkman, and Dayton 2011). Also, the association has been reported to be weak between PROMs and an existing standard for functional outcomes, standardized tests (e.g., the 400m walk pace, chair stand and 20 m pace tests) (Hill et al. 2023).

The daily spatial-temporal gait metrics transmitted from each patient's implant allow both patient and physician to chart individual progress throughout recovery for seven gait metrics (including distance). The kinematic data also become meaningful and diagnostic in the context of a large group of existing patients with smart implants. For example, to see if a patient with a smart implant is on schedule with their recovery, the individual's data for each gait parameter is compared to estimates of the 5th through 95th percentile values within their appropriate cohort (i.e., men <65y or ≥65y; women <65y or ≥65y). The patient can immediately see how they are progressing relative to others in their cohort TKA. In the case of our patient, we could see that, relative to other women less than 65 years old, she failed to progress normally early after surgery and we intervened with an MUA. There is no validated clinical prediction tool to estimate a patient's recovery trajectory, though



Figure 3. Two-week post-op radiographs showing no complications with typical kinematic alignment, the left knee was performed at a separate date.

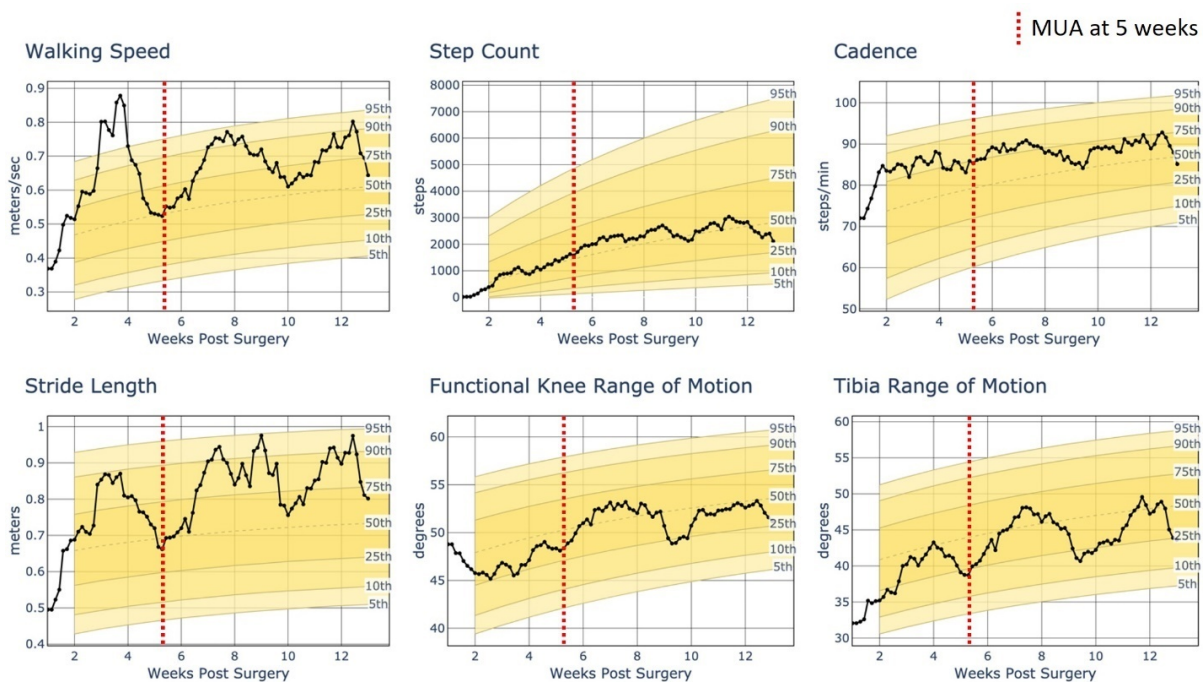


Figure 4. Canary™ Recovery Curves™ showing decrease in stride length, functional and tibial range of motion and increased cadence leading to manipulation under anesthesia at 5 weeks. At twelve-weeks the knee ROM returns to average.

post TKA knee flexion guidelines have been reported (Ebert, Munsie, and Joss 2014) and Kittelson et al. published a reference chart for flexion active ROM to assess postoperative recovery for individual patients relative to others who have previously undergone TKA surgery (Kittelson et al. 2020). Implantable, smart sensor technology represents a new era, allowing clinicians to monitor individual patient recovery, alone or in the context of a peer cohort, set appropriate individual recovery goals and, potentially, avoid adverse events.

CONCLUSIONS

Herein we presented a case of an early intervention with MUA following TKA. The need for an MUA was detected early in the post-recovery period, prior to routine follow-up, by smart sensor technology in the implant. Remote monitoring with the smart implant has the potential to improve patient compliance, increase physician and patient

engagement, and provide data critical for an early intervention that impacts recovery, as exemplified by this patient.

.....

ACKNOWLEDGMENT

The authors wish to acknowledge and thank Katie Miller, MS, and Max Gill, MBA, for thoughtful review of the manuscript and Jane Bailly, PhD, for editorial assistance.

Submitted: October 12, 2023 EDT, Accepted: November 08, 2023 EDT



This is an open-access article distributed under the terms of the Creative Commons Attribution 4.0 International License (CCBY-NC-ND-4.0). View this license's legal deed at <https://creativecommons.org/licenses/by-nc-nd/4.0> and legal code at <https://creativecommons.org/licenses/by-nc-nd/4.0/legalcode> for more information.

REFERENCES

- Bawa, Harpreet S., Glenn D. Wera, Matthew J. Kraay, Randall E. Marcus, and Victor M. Goldberg. 2013. "Predictors of Range of Motion in Patients Undergoing Manipulation after TKA." *Clinical Orthopaedics & Related Research* 471 (1): 258–63. <https://doi.org/10.1007/s11999-012-2591-1>.
- Bourne, Robert B., Bert M. Chesworth, Aileen M. Davis, Nizar N. Mahomed, and Kory D. J. Charron. 2010. "Patient Satisfaction after Total Knee Arthroplasty: Who Is Satisfied and Who Is Not?" *Clinical Orthopaedics & Related Research* 468 (1): 57–63. <https://doi.org/10.1007/s11999-009-1119-9>.
- Brigati, David P., James Huddleston, David Lewallen, Richard Illgen, Heena Jaffri, Diane Ziegenhorn, Dena S. Weitzman, and Kevin Bozic. 2020. "Manipulation Under Anesthesia After Total Knee: Who Still Requires a Revision Arthroplasty?" *The Journal of Arthroplasty* 35 (6): S348–51. <https://doi.org/10.1016/j.arth.2020.03.009>.
- Cates, H E, and J M Schmidt. 2009. "Closed Manipulation after Total Knee Arthroplasty: Outcome and Affecting Variables." *Orthopedics* 32 (6): 398. <https://doi.org/10.3928/01477447-20090511-10>.
- Choi, Ho-Rim, John M. Siliski, Henrik Malchau, and Young-Min Kwon. 2015. "Effect of Repeated Manipulation on Range of Motion in Patients with Stiff Total Knee Arthroplasty." *Orthopedics* 38 (3): e157–62. <https://doi.org/10.3928/01477447-20150305-51>.
- Cuesta-Vargas, Antonio I, Alejandro Galán-Mercant, and Jonathan M Williams. 2010. "The Use of Inertial Sensors System for Human Motion Analysis." *Physical Therapy Reviews* 15 (6): 462–73. <https://doi.org/10.1179/1743288x11y.0000000006>.
- Ebert, Jay R., Claire Munsie, and Brendan Joss. 2014. "Guidelines for the Early Restoration of Active Knee Flexion after Total Knee Arthroplasty: Implications for Rehabilitation and Early Intervention." *Archives of Physical Medicine and Rehabilitation* 95 (6): 1135–40. <https://doi.org/10.1016/j.apmr.2014.02.015>.
- Gu, Alex, Adam J. Michalak, Jordan S. Cohen, Jeffrey G. Stepan, Neil D. Almeida, Alexander S. McLawhorn, and Peter K. Sculco. 2018. "Prognostic Factors That Predict Failure of Manipulation under Anesthesia for the Stiff Total Knee Arthroplasty: A Systematic Review." *Journal of Orthopaedics* 15 (3): 842–46. <https://doi.org/10.1016/j.jor.2018.08.003>.
- Halawi, Mohamad J., Walter Jongbloed, Samuel Baron, Lawrence Savoy, Mark P. Cote, and Jay R. Lieberman. 2020. "Patient-Reported Outcome Measures Are Not a Valid Proxy for Patient Satisfaction in Total Joint Arthroplasty." *The Journal of Arthroplasty* 35 (2): 335–39. <https://doi.org/10.1016/j.arth.2019.09.033>.
- Hermesen, Sander, Jonas Moons, Peter Kerkhof, Carina Wiekens, and Martijn De Groot. 2017. "Determinants for Sustained Use of an Activity Tracker: Observational Study." *JMIR mHealth and uHealth* 5 (10): e164. <https://doi.org/10.2196/mhealth.7311>.
- Hill, Brandon G., Shivesh Shah, Wayne E. Moschetti, and Peter L. Schilling. 2023. "Do Patient-Reported Outcomes Reflect Objective Measures of Function? Implications for Total Knee Arthroplasty." *The Journal of Arthroplasty* 38 (7): S162–S168.e3. <https://doi.org/10.1016/j.arth.2023.04.049>.
- Ipach, Ingmar, Falk Mittag, Julia Lahrmann, Beate Kunze, and Torsten Kluba. 2011. "Arthrofibrosis after TKA - Influence Factors on the Absolute Flexion and Gain in Flexion after Manipulation under Anaesthesia." *BMC Musculoskeletal Disorders* 12 (1): 184. <https://doi.org/10.1186/1471-2474-12-184>.
- Issa, Kimona, Samik Banerjee, Mark A. Kester, Harpal S. Khanuja, Ronald E. Delanois, and Michael A. Mont. 2014. "The Effect of Timing of Manipulation under Anesthesia to Improve Range of Motion and Functional Outcomes Following Total Knee Arthroplasty." *Journal of Bone and Joint Surgery* 96 (16): 1349–57. <https://doi.org/10.2106/jbjs.m.00899>.
- Kittelson, Andrew J., Jordi Elings, Kathryn Colborn, Thomas J. Hoogbeem, Jesse C. Christensen, Nico L. U. van Meeteren, Stef van Buuren, and Jennifer E. Stevens-Lapsley. 2020. "Reference Chart for Knee Flexion Following Total Knee Arthroplasty: A Novel Tool for Monitoring Postoperative Recovery." *BMC Musculoskeletal Disorders* 21 (1): 482. <https://doi.org/10.1186/s12891-020-03493-x>.
- Konopka, Joseph F., Yuo-yu Lee, Edwin P. Su, and Alexander S. McLawhorn. 2018. "Quality-Adjusted Life Years After Hip and Knee Arthroplasty: Health-Related Quality of Life After 12,782 Joint Replacements." *JBJS Open Access* 3 (3): e0007. <https://doi.org/10.2106/jbjs.oe.18.00007>.
- Kornuijt, A., D. Das, T. Sijbesma, L. de Vries, and W. van der Weegen. 2018. "Manipulation under Anesthesia Following Total Knee Arthroplasty: A Comprehensive Review of Literature." *Musculoskeletal Surg* 102 (3): 223–30. <https://doi.org/10.1007/s12306-018-0537-9>.
- Lyman, Stephen, Chisa Hidaka, Kara Fields, Wasif Islam, and David Mayman. 2020. "Monitoring Patient Recovery After THA or TKA Using Mobile Technology." *HSS Journal* 16 (S2): 358–65. <https://doi.org/10.1007/s11420-019-09746-3>.
- Matijevich, Emily S., Leon R. Scott, Peter Volgyesi, Kendall H. Derry, and Karl E. Zelik. 2020. "Combining Wearable Sensor Signals, Machine Learning and Biomechanics to Estimate Tibial Bone Force and Damage during Running." *Human Movement Science* 74 (December): 102690. <https://doi.org/10.1016/j.humov.2020.102690>.
- Noble, Philip C, Michael A Conditt, Karon F Cook, and Kenneth B Mathis. 2006. "The John Insall Award: Patient Expectations Affect Satisfaction with Total Knee Arthroplasty." *Clinical Orthopaedics and Related Research* 452 (November): 35–43. <https://doi.org/10.1097/01.blo.0000238825.63648.1e>.

- Parkulo, Travis D., Elive F. Likine, Kevin L. Ong, Heather N. Watson, Langan S. Smith, and Arthur L. Malkani. 2023. "Manipulation Following Primary Total Knee Arthroplasty Is Associated With Increased Rates of Infection and Revision." *The Journal of Arthroplasty* 38 (3): 567-572.e1. <https://doi.org/10.1016/j.arth.2022.09.027>.
- Poitras, Isabelle, Frédérique Dupuis, Mathieu Biemann, Alexandre Campeau-Lecours, Catherine Mercier, Laurent Bouyer, and Jean-Sébastien Roy. 2019. "Validity and Reliability of Wearable Sensors for Joint Angle Estimation: A Systematic Review." *Sensors* 19 (7): 1555. <https://doi.org/10.3390/s19071555>.
- Singh, Jasvinder A., Shaohua Yu, Lang Chen, and John D. Cleveland. 2019. "Rates of Total Joint Replacement in the United States: Future Projections to 2020–2040 Using the National Inpatient Sample." *The Journal of Rheumatology* 46 (9): 1134–40. <https://doi.org/10.3899/jrheum.170990>.
- Stevens-Lapsley, Jennifer E., Margaret L. Schenkman, and Michael R. Dayton. 2011. "Comparison of Self-Reported Knee Injury and Osteoarthritis Outcome Score to Performance Measures in Patients after Total Knee Arthroplasty." *PM&R* 3 (6): 541–49. <https://doi.org/10.1016/j.pmri.2011.03.002>.
- Terwee, Caroline B., Rienk M.A. van der Slikke, Rob C. van Lummel, Rob J. Benink, Wil G.H. Meijers, and Henrica C.W. de Vet. 2006. "Self-Reported Physical Functioning Was More Influenced by Pain than Performance-Based Physical Functioning in Knee-Osteoarthritis Patients." *Journal of Clinical Epidemiology* 59 (7): 724–31. <https://doi.org/10.1016/j.jclinepi.2005.11.019>.
- Upfill-Brown, Alexander, Peter P. Hsiue, Troy Sekimura, Brendan Shi, Seth A. Ahlquist, Jay N. Patel, Micah Adamson, and Alexandra I. Stavrakis. 2022. "Epidemiology of Revision Total Knee Arthroplasty in the United States, 2012 to 2019." *Arthroplasty Today* 15 (June):188-195.e6. <https://doi.org/10.1016/j.artd.2022.03.004>.