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A Step Forward in TKA:
Evidence to Improve Outcomes

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Introduction

Managing proper expectations is a top priority to achieve patient satisfaction after total knee arthroplasty. However, the engineering and design phase of a knee implant and the surgical technique used during the procedure are just as important. Variables such as surgeon learning curve and patellofemoral geometry can greatly affect a patient's ability to return to common daily activities with less pain and minimal downtime.

After many years of careful research and development, the ATTUNE® Knee System (DePuy Synthes Companies) was designed to provide more stability with fewer patellofemoral complications, with improved patient outcomes as the main goal. The device also was designed to be easier to implant than contemporary total knee systems. This supplement reviews the outcomes of several studies that focus on these topics and more, while also highlighting the ATTUNE Knee's early performance within Medicare's new Bundled Payments for Care Improvement initiative under the Affordable Care Act.

I thank the faculty members for their participation and DePuy Synthes Companies for sponsoring this supplement. For more activities on this topic, visit Healio.com/Orthopedics/Education-Lab.

Anthony A. Romeo, MD
Chief Medical Editor
ORTHOPEDICS TODAY

TABLE OF CONTENTS

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Conquering surgeon learning curve one ATTUNE Knee at a time

Ryan M. Nunley, MD

Ryan M. Nunley

According to literature, 10% to 20% of patients are dissatisfied after total knee arthroplasty (TKA).[1-5] These patients represent one of the largest cohorts that may require additional treatment, office visits and/or potential revision surgery in the future. Thus, surgeons often question what can be done to bring TKA outcomes more in line with total hip arthroplasty outcomes.

Engineers and implant manufacturers have been working to improve instrumentation, technology and design features to develop total knee systems that facilitate better surgical procedures to minimize the number of dissatisfied patients. Designers spend much time and research understanding the natural kinematics and native anatomy of the knee to create femoral components that are more stable through the continuum of motion from extension to full flexion. They seek to avoid issues common in contemporary implants, such as instability in midflexion, difficulties with patellofemoral kinematics and anterior flange thickness, that could cause challenges with range of motion and discomfort in patients postoperatively.

The ATTUNE® Knee System (DePuy Synthes Companies) is the result of intensive research and development. In addition to its redesigned patellofemoral components that better replicate the natural knee, the ATTUNE Knee is more applicable to all patients. For example, it offers 10 incremental sizes to fit a wider range of knee anatomies than the standard six sizes offered by most implants. Instead of increasing size by 2 mm, the ATTUNE Knee has polyethylene liners that increase in 1-mm increments to allow surgeons greater versatility in optimizing knee stability without compromising motion. It also comes in narrow options for a more customized fit to bony surfaces.

Learning curve

Literature showing concrete data on learning curve is lacking, so, in my opinion, surgeons may too often rely on anecdotes from colleagues on the ease or difficulty of working with a new knee system. As with any new procedure, there is always the potential to improve one's surgical technique when switching from one knee system to another. Surgeons are faced with subtleties in instrumentation and design features, and, although they may be familiar with the surgical approach, these technically demanding nuances can become worrisome because of the risk for major postoperative complications. It takes time to become accustomed to the fit and fill, the soft tissue balancing and the overall instrumentation to perform arthroplasties in a reproducible, more efficient manner. Not only did designers of the ATTUNE Knee keep a comprehensive fit design in mind, they also designed the knee system in a way that helps minimize surgeon learning curve and provide a surgical workflow that is easier to use, which may help with reproducibility of positioning.

"Literature showing concrete data on learning curve is lacking, so, in my opinion, surgeons may too often rely on anecdotes from colleagues on the ease or difficulty of working with a new knee system."

— RYAN M. NUNLEY, MD

My first entry into using the ATTUNE Knee System was at the request of Brenkel and colleagues, who were gathering data on surgeon learning curve[6] — a secondary outcome measure of a larger, ongoing multicenter study — and how it affects intraoperative and postoperative complications, revision rate and overall outcomes. After obtaining Institutional Review Board approval, candidates for primary TKA were invited and consented to participate in the clinical trial (NCT01754363), for which my colleagues and I enrolled our first 75 cases from the Washington University School of Medicine in St. Louis.

Investigators recruited more than 20 other centers globally whose surgeons were naïve to the new knee system. In addition to participants in the U.S.,

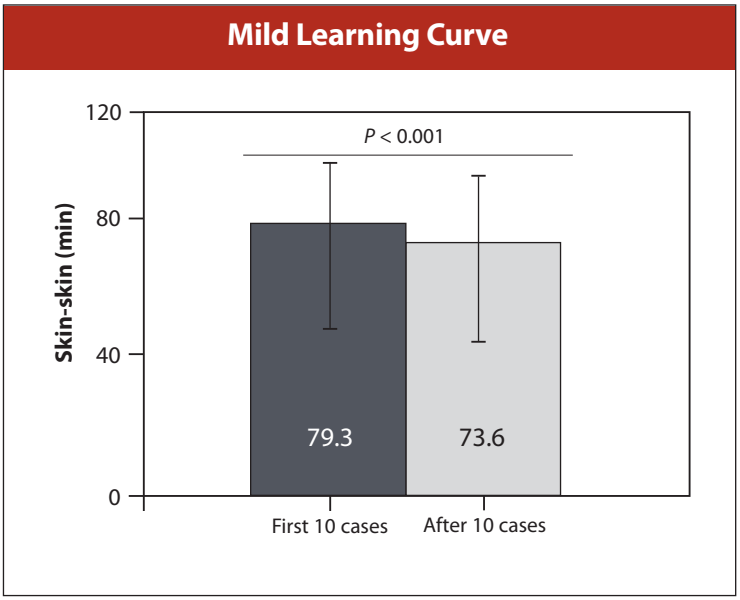

Figure 1. Mean surgical time was reduced by 6 minutes after 10 cases with the ATTUNE Knee System.

Adapted with permission from: Brenkel I, Chang C, Hamilton W, et al. Learning curve with a new primary TKA implant: a worldwide perspective with more than 2000 patients. Poster presented at: British Association for Surgery of the Knee (BASK) 2016 Annual Conference; March 30-31, 2016; Liverpool, England.

"The Bundled Payments for Care Improvement (BPCI) initiative was instituted with a goal of reimbursing health systems based on the quality of care for beneficiaries while also reducing Medicare and Medicaid costs."

— RYAN M. NUNLEY, MD

this study benefitted from accepting centers from countries with large, national joint registries, such as the United Kingdom, Australia and New Zealand, to which we could compare. Patients and physical therapists used the KOOS patient-reported outcomes survey to record patient symptoms, pain, function and quality of life. Intraoperative and postoperative complications were recorded and radiographs were reviewed by an independent reviewer to minimize bias.

Although national joint registries can closely track all patients and, therefore, provide a comprehensive estimate of survivorship from a real-world perspective, registries are not able to track subtler details such as surgical process and extensive patient-reported outcome measures. Investigators were pleased to find that, overall, surgeons rapidly adapted to the technology and intrumentation after approximately 10 cases. When comparing the first 10 cases versus later ATTUNE cases, there was no difference in the incidence of intraoperative knee complications or KOOS scores. There was also a 6-minute reduction after 10 cases in the skin-to-skin surgical time (Figure 1). The study data demonstrated that there were no increased concerns about those initial patients having higher incidence of complications or reoperations.

The ATTUNE Knee in the OR

My personal experience with the ATTUNE Knee System mirrors that which was revealed by Brenkel and colleagues. In my opinion, having instrumentation that allows for better accuracy with cuts and sizing will ultimately help improve outcomes. Although it is too early to determine, it seems rational to think that if a patient is a certain size and instrumentation is less precise, then surgeons have fewer options for components to match that patient's anatomy, thus decreasing the chance of achieving optimal outcomes.

Additionally, many surgeons may say that knee replacement is not just about the bone cuts, but also about the soft tissue balancing to keep ligaments aligned, that make or break the surgery. Because the ATTUNE Knee System has helped me to more accurately reproduce the size of a patient's native anatomy, I can help keep soft tissues less stressed in certain areas and create more tension in others. Therefore, I can provide the appropriate soft tissue balance to help patients achieve full range of motion and stability, while decreasing inflammation and discomfort in the knee.

Quality, not quantity

When considering the attributes total knee systems offer, surgeon learning curve is as important as the components of the knee system, especially in the new bundled payments environment. Under the Affordable Care Act, Medicare is moving away from a traditional fee-for-service (ie, quantity of surgeries) to a value-based system. The Bundled Payments for Care Improvement (BPCI) initiative was instituted with a goal of reimbursing health systems based on the quality of care for beneficiaries while also reducing Medicare and Medicaid costs. This pay-for-performance model provides incentives for physicians and health systems to improve surgical outcomes to reduce length of stay and readmissions, and to improve patient outcomes. Surgeons who perform significantly more procedures yet take less care of their patients will be penalized under the BPCI program.

Total joint surgeons at Washington University School of Medicine in St. Louis operate at two

hospitals; one is part of a voluntary bundled payment program, while the other is part of the mandatory Comprehensive Care for Joint Replacement bundle. Therefore, my colleagues and I have taken several steps over the past several years to improve our quality of perioperative care. For example, we put more emphasis on the preoperative phase to optimize patients' candidacy for surgery, collaborating with patients' specialists on conditions such as poorly controlled diabetes, smoking and obesity. In addition, we now administer tranexamic acid to patients, which has reduced blood loss intraoperatively as well as early in the postoperative period, thus reducing inflammation, pain and distention of the joint capsule and soft tissue. We also introduced abductor canal blocks that provide prolonged analgesia around the knee and surrounding areas to help patients tolerate the pain caused by surgical trauma.

The ATTUNE Knee System has also been helpful in the bundled payment environment because, in my experience, it is friendlier to surrounding soft tissues and better recreates the natural anatomy of the knee. I have come to trust this knee implant and, coupled with collaborative efforts across multiple health care providers for each patient, it has helped me to further reduce the incidence of complications and improve overall outcomes after TKA.

Only time will tell

Bundled payment programs have opened the pathway for surgeons to institute changes that will improve TKA success rates, and, in my opinion, the ATTUNE Knee System fits well within this new environment. Its surgical technique is easy for me to teach to residents and fellows regardless of the patient's anatomy. The mild learning curve associated with the ATTUNE Knee and the intuitively designed components and instruments are features that encouraged me to officially adopt it for my practice. Although the future of TKA looks promising with the ATTUNE Knee, longer follow-up is needed to draw confident conclusions. However, my hope is that surgeons can continue to achieve quality outcomes and minimize or eliminate patient dissatisfaction.

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Modern implant design may reduce clunk and crepitus

Sean D. Toomey, MD

Sean D. Toomey

Primary total knee arthroplasty (TKA) using posterior-stabilized knee components has demonstrated excellent survivorship over the years, yet not all patients are completely satisfied postoperatively because of anterior knee pain and lack of natural function. In fact, more extreme cases of dissatisfaction can lead to additional surgeries, and patellofemoral complications have reportedly been a cause of revision surgery in up to 11.6% of cases.[1-3] One such complication is fibrous peripatellar scar tissue formation after TKA. Patients with this condition often describe grating, grinding or crunching originating from the anterior aspect of the knee.

Although Insall and colleagues first observed this scar tissue overgrowth in 1982,[4] Hozack and colleagues further defined its occurrence in 1989 as patellofemoral crepitus and clunk syndrome caused by a discrete fibrous nodule developing at the junction of the suprapatellar bursa and the quadriceps tendon.[5] When scar tissue impinges on the femoral implant, it creates a clunking sensation when the knee moves from extension into flexion. The pathophysiology is most prevalent in patients implanted with a posterior-stabilized total knee design,[6] with incidence ranging from 0% to 21%.[7,8]

Crepitus or clunk typically occurs sometime between 2 months to 2 years after TKA. Many factors contribute to the risk for its development, which may affect patient clinical outcomes. Differences in surgical technique, such as patellar and femoral component positioning; patellar sizing, thickness and tilt; joint line elevation; tibial tray placement; and surgical approach (eg, using a mini-subvastus vs. a medial parapatellar approach) are all associated with clunk and crepitus incidence.[5] Femoral component design, such as anterior flange geometry and trochlear groove geometry, are also contributing causes.[9] Specifically, the posterior-stabilized knee features an intercondylar box configuration for its post and cam mechanisms, which is more conducive to synovial tissue entrapment than in cruciate-retaining implants.[3,10]

Although patellofemoral crepitus and clunk occur somewhat infrequently, the true prevalence remains under significant debate, which is likely because of a combination of subjective issues. For example, the definitions of clunk and crepitus can vary among physicians, leading to lack of reporting clarity and potentially skewing outcomes measurement data. In addition, surgeons disagree on the nature of the syndrome from patient to patient (ie, whether a patient is symptomatic vs. asymptomatic). Since identifying patellofemoral crepitus and clunk syndrome as a postoperative symptom that can adversely affect a patient's total knee experience, physicians have focused on improving patient outcomes by eradicating this source of anterior knee pain, even though this complication can usually be treated successfully through open or — as is my preference, arthroscopic debridement.

Previous studies

The pathophysiology of patellar noise is incompletely understood, but prior studies have attempted to identify design factors that are predisposed to crepitus or clunk. Conrad and Dennis examined 60 SIGMA® Posterior-Stabilized Total Knee Systems (DePuy Synthes Companies) with the proprietary P.F.C.® Knee design, all which required arthroscopic nodule removal for crepitus, and compared them with a control group.[10] Their study revealed implant design and surgical technique factors that increased the risk for developing patellofemoral crepitus and clunk, such as shortened patellar tendon length, the use of smaller patellar components, decreased patellar composite thickness and an increased posterior femoral condylar offset. In a similar study, Costanzo and colleagues identified 75 cases of patellar clunk brought on by thicker preoperative patella, smaller patellar components and longer patellar length.[11]

Previously published literature has also included flexion greater than or equal to 110° as a predictor of clunk and crepitus.[12,13] Specifically, Peralta-Molero and colleagues studied 500 semi-TKAs using the Genesis II total knee system (Smith & Nephew) and reported an incidence of patellofemoral crepitus and clunk in 34 knees, six of which required arthroscopic

debridement.[13] They also concluded that for every degree of increasing postoperative flexion, the likelihood of developing clunk or crepitus increased by 4.2%.[13]

The ATTUNE Knee and incidence of patellofemoral complications

Throughout my career, I have implanted more than 2,500 SIGMA Total Knee Systems. Although overall outcomes have been quite positive, I was concerned by the incidence of patellofemoral issues, which were mostly related to soft tissue entrapment. Approximately 14% of my patients experienced some form of patellofemoral symptoms, including patellar grind, clunk and/or crepitus or audible squeaking. Seven percent of them remained symptomatic despite attempts of conservative care, and required subsequent arthroscopic debridement.

When the ATTUNE® Knee System (DePuy Synthes Companies) received its regulatory approval, I learned that engineers had modified the standard total knee design by updating femoral, tibial and patellar component designs with a focus on improving patellofemoral joint function. My colleagues and I then participated in two worldwide, multicenter prospective studies (NCT01497730 and NCT01746524) to evaluate the SIGMA Knee System and, to a lesser degree, other leading knee brands — the Triathlon total knee system (Stryker) and the NexGen knee (Zimmer Biomet) — against the ATTUNE Knee. Given that the theoretical design advantages of any new implant system must be demonstrated in vivo, our overall goal was to evaluate whether improvements in functional performance of primary TKA were being addressed with the new design. We hypothesized that these modifications and enhancements to the patellofemoral geometry may positively influence the patient experience by reducing the overall incidence of crepitus and clunk and, thus, the subsequent need for secondary surgery (Table 1). This hypothesis is supported by other literature stating the ATTUNE posterior-stabilized TKA demonstrated less patellofemoral crepitus incidence than other products examined in the study.[14]

Methods and study design

When developing our study design, my colleagues and I took steps to ensure the greatest chance of reporting accurate incidence of any complication, especially when compared to other published retrospective database reviews, which appears to be the most frequently reported study design on this topic. For example, each site included an assigned research coordinator who reviewed all medical records to ensure that any reported adverse event in a patient's medical record was also reported as an adverse event to study personnel. Research coordinators also contacted patients to reduce the number of patients lost to follow-up.

For the two studies, surgeon investigators collected incidence of patellofemoral complications, including crepitus — either asymptomatic or symptomatic — and patellar clunk. They were instructed via study training to report all noises originating from the front of the knee as well as any anterior patellofemoral symptoms in general — grinding, popping and more. Crepitus

Table 1. Demographics and length of follow-up for posterior-stabilized knees.

Demographics	Current PS Products (n = 422)	ATTUNE (n = 584)
Age (mean ± SD), years	65.3 ± 8.6	65.6 ± 8.0
Gender	61.9% female	59.1% female
BMI (mean ± SD)	32.0 ± 6.4	32.0 ± 6.1
Diagnosis	98.3% OA	99.0% OA
Length of follow-up (mean ± SD), years	1.95 ± 0.71	1.23 ± 0.66

Abbreviations: PS, posterior-stabilized; SD, standard deviation; BMI, body mass index; OA, osteoarthritis.
Data accurate as of July 2016.

Adapted with permission from: Toomey SD, Himden S, Shah J, Daccach J, Lesko J, Hamilton WG. Comparing the incidence of patellofemoral complications in a new total knee arthroplasty system vs. currently available products in two, worldwide, multicenter, prospective clinical studies. Paper presented at: American Association of Hip and Knee Surgeons 26th Annual Meeting. November 10-13, 2016; Dallas, TX.

Table 2. Kaplan-Meier cumulative incidence rate of symptomatic crepitus only.

	1-year Kaplan-Meier Cumulative Incidence Rate (95%)	2-year Kaplan-Meier Cumulative Incidence Rate (95%)
Current PS Products (n = 422)	2.53% (1.37% - 4.65%) n = 369	3.14% (1.79% - 5.47%) n = 244
ATTUNE PS (n = 584)	0.78% (0.29% - 2.06%) n = 391	1.21% (0.47% - 3.08%) n = 102

Abbreviation: PS, posterior-stabilized.

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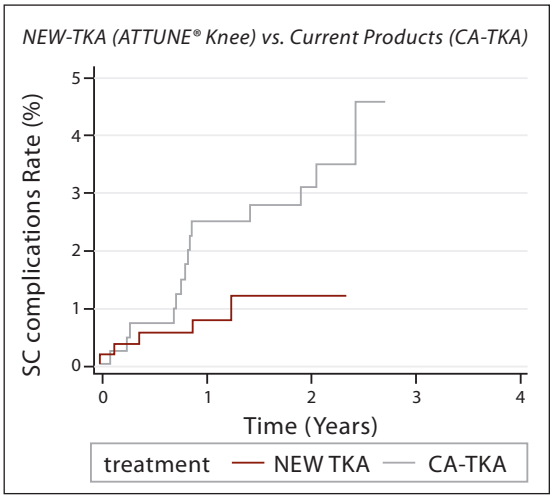

Figure. Kaplan-Meier plot of cumulative incidence rate of symptomatic crepitus only.

Abbreviation: CA-TKA, currently available TKA systems

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was identified on physical examination as the presence of consistent audible grinding or crunching localized to the front of the knee when patients extended their knees from the flexed position. Symptomatic crepitus excluding clunk was noted as an event in which patients were aware of pain and/or discomfort, which could be verified during examination. Finally, clunk was demonstrated as patellar catching with a visible popping of the patella at a discrete point in arc of motion.

Study weaknesses

Investigators identified several weaknesses that may have affected study results. For example, this was a nonrandomized, case-control study design with the three mentioned total knee systems, for which patients were enrolled 1 to 2 years before the ATTUNE Knee System became available. It is conceivable that changes in surgical technique or perioperative protocols over that time may have slightly influenced the incidence of crepitus or clunk. However, my colleagues and I believe this is unlikely given the close sequential timing of the two cohorts, the consistency of our perioperative protocols during this time frame and the fact that the same surgeons implanted both the ATTUNE Knee and control knees.

Another potential weakness may be associated with the differences in definitions of crepitus and clunk from surgeon to surgeon, and from center to center. However, training was provided to investigators before the study to minimize that possibility. Last, other than to define incidence of patellofemoral complications, my colleagues and I did not take radiographic measurements or examine patient characteristics that may have better clarified the etiology of crepitus and clunk. We plan for this to be an emphasis of a future study.

Results

My colleagues and I reported a cumulative incidence rate of symptomatic crepitus of 3.14% with the SIGMA Total Knee and 1.21% with the ATTUNE Knee, of which two patients required arthroscopic debridement (Table 2 and Figure).[15] The Triathlon and NexGen knees represented approximately 15% of the knees in the first group, but yielded no reports of patellofemoral symptoms. Our odds ratio analysis of interim data for other products examined in this study and the ATTUNE Knee indicate no statistically significant difference in crepitus and/or clunk based on high flexion vs. low flexion, contrary to Peralta-Molero and colleagues' findings. However, our results

indicate that patients with higher postoperative flexion using other products examined in this study had approximately four times higher odds of developing crepitus and/or clunk than those with lower flexion, while the odds remained the same in both flexion groups for the ATTUNE Knee.[14]

Although the complication rates are low with both implants, the trend toward reducing patellofemoral complications is very reassuring. Our study shows that directed effort toward modifying implant design can improve patient outcomes, and further follow-up in both studies will help to confirm this trend.

Personal experience with the ATTUNE Knee

I have implanted more than 650 posterior-stabilized ATTUNE Knees and, based on postoperative clinical observations and patient outcome tracking measures, I find this knee system's performance promising. My patients tend to regain range of motion more quickly than with other systems I have used previously. However, this finding also may be influenced by adjustments in my postoperative pain management protocols, including the incorporation of multimodal anesthesia, peri-articular injections and postoperative peripheral nerve catheters provided for my patients' overall total knee experience.

One other advantage to the ATTUNE Knee System is that it offers more implant sizes, not only in the anterior/posterior dimension, but also in the medial/lateral dimension. The implant features a 1-mm incremental change in tibial polyethylene thickness size, which, in my opinion, may help dial in stability to a greater degree during surgery. Additionally, having this flexibility in component size and tibial insert thickness has improved my ability to optimize both component sizing and soft tissue balancing.

Conclusion

Based on our clinical studies and my early personal experience, I have confidence that the ATTUNE Knee System offers a quality design that appears to reduce patellofemoral crepitus and clunk syndrome and improve overall outcomes for study participants and my patients alike. Also, I now perform far fewer arthroscopic follow-up surgeries than in the past. Incidence of patellar grind, clunk and crepitus has decreased to approximately 2.5% for my patients with the ATTUNE Knee, with 1% of those patients requiring postoperative arthroscopic surgeries. My colleagues and I are currently working on a subsequent paper comparing only the SIGMA Knee with the ATTUNE Knee, and we hope to add to existing data on patellofemoral complications.

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High-tech biomechanics yield promising data on anatomic patellar geometry

Kevin B. Shelburne, PhD

Kevin B. Shelburne

Patient satisfaction after total knee arthroplasty (TKA) depends on the restoration of natural strength, range of motion and a return to normal activities in a timely fashion with minimal pain. However, as may commonly occur after knee surgery, patients often lose quadriceps strength and efficiency during the acute recovery phase after TKA, making it more necessary for patients to adjust the way they perform common activities of daily living, such as walking, descending stairs and kneeling. Moreover, for some patients, these adjustments in movement performance persist long after recovery.

Although surgeons have several implant options from which to choose, identifying a design that will best restore successful function through recovery of quadriceps efficiency requires sophisticated kinematic measurements of body motion. Conventional experiments performed in motion laboratories may not provide the data necessary to understand how implant design interacts with loading conditions, muscle activity and strains inside the knee to best enable a patient to execute common tasks.

The Human Dynamics Laboratory

The Center for Orthopaedic Biomechanics at the University of Denver receives grants from organizations such as the National Science Foundation, the NIH and implant manufacturers to apply their sought-after tools for research on joint mechanics, patient-specific motion and musculoskeletal modeling. Unlike conventional biomechanics laboratories, our Human Dynamics Laboratory is one of only a handful of worldwide facilities that combines sophisticated computer modeling with advanced joint and gait experimentation techniques in vivo, including high-speed stereo radiography (HSSR), always with the primary goal of improving patient outcomes.

Although some motion labs use single-plane fluoroscopy technology, our lab uses biplanar radiography that allows us to study the patellofemoral joint on a 3-D level at high frame rates, and with great accuracy. Combining multiple measurement techniques allows my colleagues and me to generate real-time kinematics of patients' motion at the joints. We also measure muscle activity, body poses and the forces patients create on the ground while performing ordinary activities such as walking and kneeling, and during simple knee flexion and extension. As a key part of this whole-body functional portrait, the HSSR system uses low-dose pulsed X-ray to provide a detailed view of bone and joint motion at the knee down to a sub-millimeter level. These data are used to build patient-specific computer models that aid in determining how various knee systems perform in vivo, thus providing biomechanical engineers and manufacturers the information necessary to design implants that more closely resemble the natural knee.

In vivo mechanics with the ATTUNE Knee

It had previously been hypothesized that the knee reconstruction itself, regardless of implant design, does not produce natural mechanics to a sufficient degree to allow for proper restoration of complete function.[1] Other comparisons of patellofemoral kinematics for medialized dome and medialized anatomic patellofemoral geometries have shown differences at the sagittal plane during flexion,[2] but no prior evidence existed on how these differences affected natural mobility.

The Center for Orthopaedic Biomechanics developed a protocol to examine the mechanics of two posterior-stabilized, rotating-platform ATTUNE Knee Systems (DePuy Synthes Companies). My colleagues and I performed a head-to-head comparison of medialized dome and medialized anatomic patellofemoral resurfacing geometries using combined measurements from our HSSR system and patient-specific computer models of patella function.[3] The hypothesis was that the anatomic design would better replicate natural motion of the patella, specifically in its flexion angle in the sagittal plane, because it was designed with natural mo-

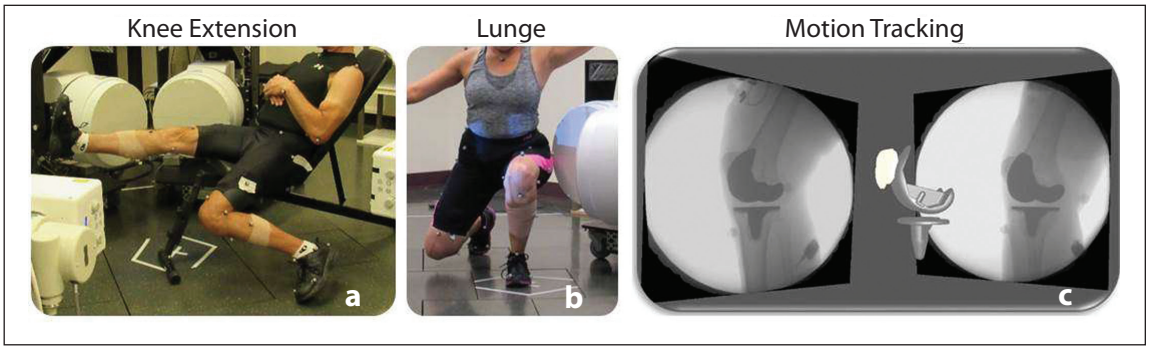
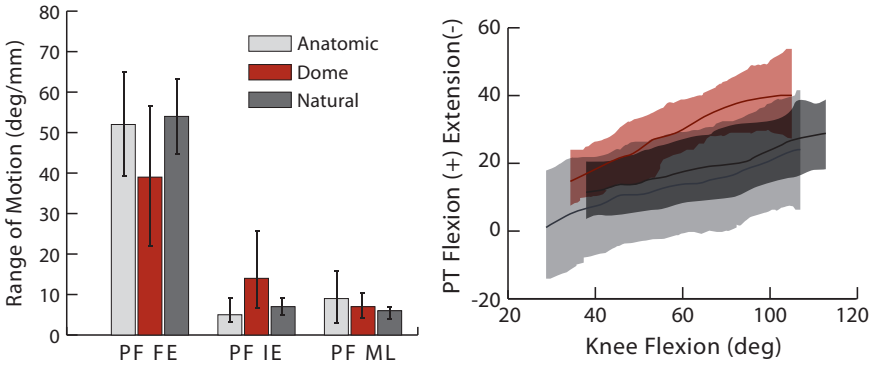


Figure 1. High-speed stereo radiography capture of knee extension (a) and lunge (b). Bone and implant motion tracking (c).

Reprinted with permission from: Azhar A, Mannen E, Smoger L, Laz P, Rulkoetter P, Shelburne K. Evaluation of in vivo mechanics for medialized dome and anatomic patellofemoral geometries during knee extension and lunge. Paper presented at: International Society for Technology in Arthroplasty's 29th Annual Congress. October 5-8, 2016; Boston, MA.

tion in mind. In addition, because optimal strength is determined by how the patella transfers load in the quadriceps and how much contact force is created within the implant, we speculated whether this would translate into better quadriceps efficiency.

Ten self-described active patients who were satisfied with their outcomes at least 1 year after unilateral or bilateral TKA were recruited from Colorado Joint Replacement in Denver — five with medialized dome and five with medialized anatomic patellar components. We focused on two activities of daily living — lunges and seated knee extension — for all patients. The seated knee extension provides measurements of patella function through a large knee range of motion without the high loads of weightbearing, whereas the lunge (Figure 1) enables us to examine function under muscle loading conditions that can far exceed patient bodyweight. In addition, we tested the full capabilities of each implant with other common activities such as walking and turning, stepping down and rising from a chair.



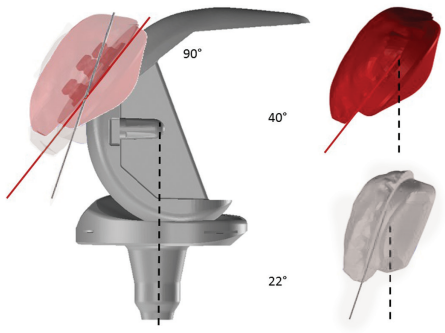


Figure 2. Results of specimen-specific computational model of the lunge measured in the laboratory. The total range of motion for patellofemoral (PF) flexion-extension (FE), internal-external (IE) and medial-lateral (ML) motions (upper left), averaged across subjects ±1 standard deviation. Flexion of the patella relative to the tibia for natural knees, medialized dome and medialized anatomic implants (upper and lower right).

Adapted with permission from: Azhar A, Mannen E, Smoger L, Laz P, Rulkoetter P, Shelburne K. Evaluation of in vivo mechanics for medialized dome and anatomic patellofemoral geometries during knee extension and lunge. Paper presented at: International Society for Technology in Arthroplasty's 29th Annual Congress. October 5-8, 2016; Boston, MA.

Study results

Using in-house data of natural knee mechanics as baseline, early results show that, compared with the medialized dome design, the motion of the ATTUNE Knee medialized anatomic geometry more closely resembles that of the natural knee.[3] As natural knee flexion increases during an activity such as the lunge, patellar flexion increases as well in a consistent way. Patients with the anatomic patella exhibited more patellar flexion during lunge activities (16° ± 3° from 40° to 100°), similar to the performance of the natural knee. The range of motion of between the natural and anatomic patella was also similar in internal/external rotation or 'tilt.' (Figure 2). Kinematics also showed an improved moment arm length for medialized anatomic over medialized dome geometries, which may enable more knee torque from the quadriceps.

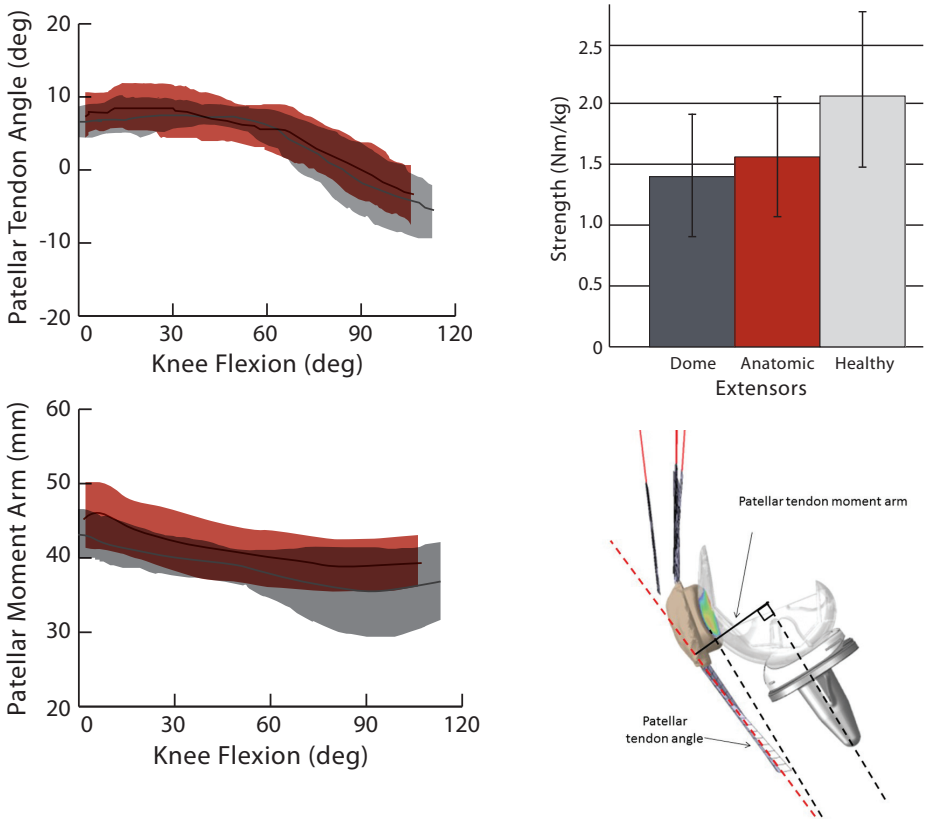


Figure 3. Comparison of mean (line) and ±1 standard deviation (shaded) of patellar tendon angle (upper left) and moment arm (lower left) during the seated knee extension showing similar behavior of the natural and implanted knee. Comparison of maximum knee extension torque between natural and implanted knees (upper and lower right).

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Moment arm is a measure of the quacriceps muscle's 'lever arm' that produces extension torque at the knee. To further investigate the potential impact of these kinematic differences, maximum extension torque was measured with the subjects seated in a dynamometer. For these early results, the data show that patients with the anatomic design have greater knee extensor strength (Figure 3).

Conclusion

What role the ATTUNE Knee plays in quadriceps strength has yet to be fully determined. However, my colleagues and I are optimistic that quadriceps efficiency appears to be better with anatomic patellar designs when interpreting these in vivo results within the context of experimental in vitro results.[4-5] Currently, 16 knees with the medialized dome geometry and 16 with the medialized anatomic geometry are now enrolled in our study, with early results similar to what we have previously shown. Although an additional 6 months to 1 year of study may be needed to draw more concrete conclusions, the medialized anatomic patellar configuration is promising in its ability to mimic natural motion while possibly providing more quadriceps efficiency. In my opinion, all patients participating in our study seemed pleased with the ATTUNE Knee System and the functionality it provides.

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Early PROMs data trending positive for the ATTUNE Knee

Mark Clatworthy, MBChB, FRACS

Mark Clatworthy

Orthopedic surgeons rely heavily on both clinical and patient-reported outcomes data when deciding which knee implants to adopt for their practices. With patient satisfaction at the top of any surgeon's priority list, national and international knee registry data are critical in choosing the implant that meets patients' many demands. Furthermore, patient-reported outcome measures (PROMs) help close the surgeon–patient communication gap between perceived and actual levels of satisfaction after total knee arthroplasty (TKA).

Recognizing the lack of accurate and beneficial local joint information available to surgeons — especially in the southern hemisphere — the New Zealand Orthopaedic Association founded the New Zealand National Joint Registry in 1997. In April 1999, the registry began collecting data on orthopedic practice characteristics, surgeon characteristics, implant survivorship, revision rates and patient-reported outcomes. It provides a more holistic perspective than the implant failure rates that most other countries' registries had previously collected, and its data can be added to the wealth of other registry and PROMs data worldwide to build a robust record of implant performance over time.

As of 2015, more than 100 public and private hospitals in New Zealand participate in the registry and report on knee, hip, shoulder and elbow data, representing 100% of the eligible population. To collect patient-specific data, every participating hospital in the registry uses the Oxford Knee Score (OKS) questionnaire, which is a simple 12-point survey specific to knee replacement procedures. Distributed at 6 months to 20% of the TKA population who have received contemporary implants — and to 100% of patients with an ATTUNE Knee — it helps capture the relative ease or difficulty of performing daily tasks before and after TKA, including walking, kneeling and rising from a seated position.

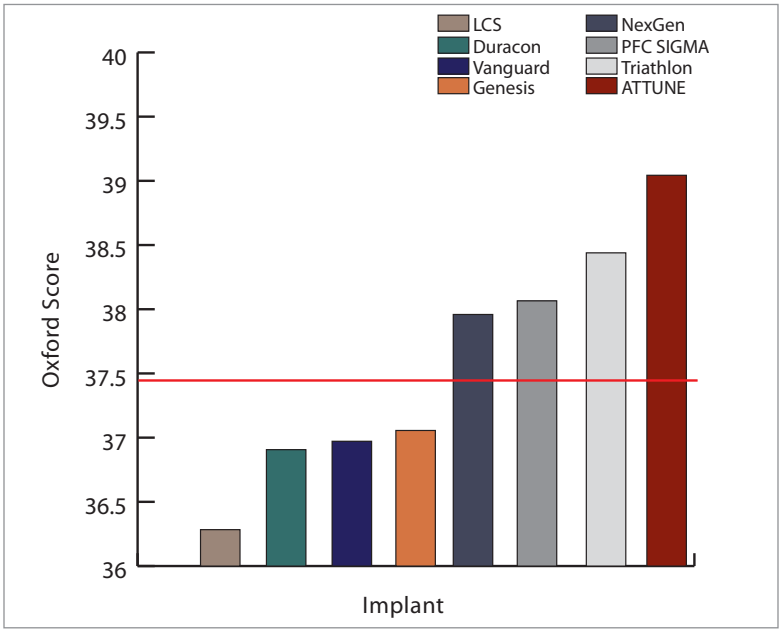

Figure 1. Comparison of Oxford Knee Scores as reported in the New Zealand National Joint Registry.

Adapted from data published in: Rothwell A, Hobbs T, Frampton C, Taylor J, Muir D, Mohammed K. The New Zealand Joint Registry Seventeen-year Report: January 1999 to December 2015. New Zealand Orthopaedic Association; October 2016.

The OKS is scored from 0 to 48 points, with 48 points representing the best possible outcome. Once a year, registry participants receive surgeon-specific OKS scores, survival rates and benchmarking data to allow comparisons with the mean of the country. For compliance purposes, surgeons are required to present this data to colleagues, which is a useful research tool when comparing the survival rates and PROMs performance of various implant designs.

The latest data show that the ATTUNE Knee has the highest mean OKS score of 39.1 (Figure 1) and a 25% reduction in the number of poor and fair scores.[1] The ATTUNE Knee scores are only slightly lower than total hip arthroplasty scores — 39.1 vs. 40.4, respectively.[1] In addition, infections typically occur in the early life of a new implant, thus making revision rates higher. However, the 2-year revision rate is low for the ATTUNE Knee.[1]

continued on page 15

Table. Comparison of early clinical outcomes of the ATTUNE Knee CR RP and SIGMA CR150 RP Knee. Data are reported as mean.

Outcome Measures	ATTUNE CR RP Knee (n = 40 knees)	SIGMA CR150 RP Knee (n = 40 knees)	Significance
Preoperative flexion, deg	114.0° (10.3°)	111.8° (12.7°)	$P > .05$, NS
Discharge flexion, deg	101.4° (8.2°)	98.6° (11.0°)	$P > .05$, NS
Discharge ROM (flexion minus extension), deg	100.5° (8.3°)	96.4° (11.8°)	$P > .05$, NS
2-week flexion, deg	113.0° (8.6°)	106.1° (9.5°)	$P < .001$
6-week flexion, deg	121.1° (6.0°)	115.0° (9.6°)	$P = .002$
Days to 90° flexion	2.1 (1.0)	1.9 (1.1)	$P > .05$, NS
Percent unable to achieve 90° flexion at discharge	0%, 0/40 knees	15%, 6/40 knees	$P = .026$, trending
Days to functional independence	2.4 (0.6)	2.4 (0.6)	$P > .05$, NS
Days to perform an SLR	1.8 (1.2)	2.0 (1.2)	$P > .05$, NS
Percent unable to perform an SLR at discharge	5%, 2/40 knees	7.5%, 3/40 knees	$P > .05$, NS
Days to ride exercise bike	3.3 (0.6)	3.1 (0.6)	$P > .05$, NS
Percent unable to ride exercise bike at discharge	5%, 2/40 knees	15%, 6/40 knees	$P > .05$, NS
Days to lap ward	2.4 (0.5)	2.5 (0.7)	$P > .05$, NS
Days to master stairs	2.9 (0.4)	3.0 (0.8)	$P > .05$, NS
Days to crutch use	2.3 (0.5)	2.6 (0.6)	$P = .018$, trending
Discharge VAS pain at rest	0.4 (0.6)	0.8 (1.1)	$P = .048$, trending
Discharge VAS pain with exercise	3.9 (1.8)	4.5 (2.0)	$P > .05$, NS
VAS functional score (0-10)	6.6 (1.5)	5.3 (1.5)	$P < .001$
Discharge days	4.3 (0.7)	4.5 (0.6)	$P > .05$, NS
Days to reach criteria for discharge	3.3 (0.5)	3.6 (0.8)	$P = .048$, trending

Numbers in parentheses denote the standard deviations.

A P value between .01 and < .05 is noted as trending. A P value < .01 is statistically significant.

Abbreviations: CR, cruciate-retaining; RP, rotating-platform; NS, not significant; ROM, range of motion; SLR, straight leg raise; VAS, visual analogue scale

Adapted with permission from: Clatworthy M. DePuy Synthes Companies. An early outcomes study of the ATTUNE® Knee System vs. the SIGMA® CR150 Knee System [white paper]. *Warsaw, IN: 2015.*

continued from page 13

Early evidence of patient satisfaction

Before the release of the ATTUNE Knee System (DePuy Synthes Companies), I preferred using the SIGMA Knee System (DePuy Synthes Companies). Although the SIGMA Knee performed well overall for my patients, there were some issues with the patellofemoral joint, and patients occasionally exhibited instability. The ATTUNE Knee System was designed to address these patellofemoral joint issues and enable more stability by modifying the curvature of the femoral component, thus theoretically providing patients with better function for daily activities. Engineers and designers alike had anticipated the implant would decrease length of hospital stay, time to return of motion and anterior knee pain.

In 2015, I published an internal prospective study outlining 2- and 6-week clinical outcomes from my last 40 patients with SIGMA CR150 Rotating-platform Knee Systems vs. my first 40 ATTUNE Cruciate-retaining, Rotating-platform Knees.[2] The Brainlab computer-assisted TKA technique (Brainlab AG) with a gap-balanced approach was used for all 80 patients. Additionally, in-hospital physiotherapists, who recorded 20 key motion-related and functional postoperative measures such as range of motion, flexion, days to discharge and time to lap our ward, were blinded to the type of implant each patient received.

At 2 weeks and 6 weeks, patients with ATTUNE Knees had significantly more flexion compared with patients implanted with SIGMA Knees.[2] In addition to pain at rest trending lower for the ATTUNE Knee vs. the SIGMA Knee upon hospital discharge ($P = 0.48$), I noted and continue to monitor other trending factors including percent of patients unable to achieve 90° flexion at discharge, time until patients can walk with crutches, and time until patients meet discharge criteria (Table).[2]

I also participated in two worldwide, multicenter prospective studies (NCT01497730 and NCT01746524) comparing several configurations of the ATTUNE Knee with contemporary knee systems, primarily the SIGMA Knee.[3,4] After investigators obtained Ethics Committee approval and informed patient consent, 1,137 patients were implanted with ATTUNE Knees and 845 patients were implanted with other leading knee brands. At Middlemore Hospital, 67 SIGMA Knees and 95 ATTUNE Knees were enrolled.

PROMs data were collected from the KOOS, OKS, Patient Knee Implant Performance and EuroQol-5D-3L scoring systems and measured early postoperatively at a minimum of 1 and 2 years. Investigators noted statistically significant improvements in daily activities, pain, symptoms and function during sports and recreational activities for the ATTUNE Knee compared with contemporary implants.[3,4] These interim results suggest better overall performance, and longer follow-up is ongoing and necessary.

In addition to the benefits for surgeons already detailed, these improvements in PROMs scores and length of stay have advantages to hospitals in terms of reduced overall costs for patients because of reduced morbidity, faster mobilization and potentially faster return to normal activities.

Conclusion

To date, the New Zealand Joint Registry has shown that a one-unit drop in OKS scores at 6 months predicts a 9.9% increase in revision rates over 2 years.[5] The latest data show that the ATTUNE Knee System has the highest OKS score of all TKAs currently used in New Zealand. Furthermore, our various studies at Middlemore Hospital have shown improved early outcomes with the ATTUNE Knee over contemporary knee systems. In terms of patient satisfaction, this may mean fewer early revision procedures, based on previously published data.[5] In my experience, my patients implanted with ATTUNE Knee have a stable knee with less pain and fewer patellofemoral problems. Most importantly, it is a knee that my patients and I can trust.

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