

# Triathlon<sup>®</sup> Total Knee System Clinical evidence



## Introduction

Over the past decade, a wealth of clinical data around the world has largely supported the enhanced survivorship<sup>1, 2, 4, 5</sup> and functional outcomes<sup>4,7</sup> of the Triathlon Total Knee System. This compendium features the most representative clinical evidence of Triathlon design including:

## Triathlon Primary Knee System



### Survivorship

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Australian Orthopaedic Association National Joint Replacement Registry

Orthopaedic Data Evaluation Panel (ODEP), National Joint Registry for England, Wales, Northern Ireland

Scott et al. "Excellent 10-year patient-reported outcomes and survival in a single radius, cruciate-retaining total knee arthroplasty" *Knee Surgery, Sports Traumatology, Arthroscopy*

Mistry et al. "Long-term survivorship and clinical outcomes of a Single Radius Total Knee Arthroplasty" *Surgical Technology International*



### Function

9

Larsen et al. "Quantitative, comparative assessment of gait between single radius and multi radius Total Knee Arthroplasty designs" *The Journal of Arthroplasty*

Shimizu et al. "In vivo movement of femoral flexion axis of a single radius Total Knee Arthroplasty" *The Journal of Arthroplasty*



### Patient Reported Outcome Measurement (PROM)

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Cook et al. "Functional outcomes used to compare single radius and multi radius of curvature designs in Total Knee Arthroplasty" *The Journal of Knee Surgery*

Hamilton et al. "Implant design influences patient outcome after Total Knee Arthroplasty. A prospective double-blind randomized controlled trial." *The Bone & Joint Journal*



### Constraint options

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Scott et al. "Prospective randomized comparison of posterior-stabilized versus condylar-stabilized total knee arthroplasty: final report of a five-year study" *The Journal of Arthroplasty*

Martin et al. "Coronal alignment predicts the use of semi-constrained implants in contemporary total knee arthroplasty" *The Knee*

Worhacz et al. "Comparing the efficacy of the total stabilizing and posterior stabilizing knee prostheses in obese and preobese females: a retrospective cohort study." *The Journal of Knee Surgery*



### Component positioning and fit

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Hitt et al. "Use of a flexible intramedullary rod and its influence on patient satisfaction and femoral size in total knee arthroplasty" *Journal of Long-Term Effects of Medical Implants*

Hampf et al. "What is the prevalence of femoral component overhang in Total Knee Arthroplasty?" *International Society for Technology in Arthroplasty 31st Annual Congress*

# Triathlon Total Knee System

## Clinical evidence



### Wear resistance

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Abdel et al. "Randomized Clinical Trial of Conventional vs. Highly Cross-Linked Polyethylene in Total Knee Arthroplasties" 2016 American Association of Hip and Knee Surgeons Annual Meeting  
Meneghini et al. "Multicenter study of highly cross-linked vs. conventional polyethylene in Total Knee Arthroplasty" The Journal of Arthroplasty



### Biologic fixation

22

Miller et al. "Results of cemented vs. cementless primary Total Knee Arthroplasty using the same implant design" The Journal of Arthroplasty  
Cohen et al. "Early clinical outcomes of a new cementless Total Knee Arthroplasty Design" Orthopedics

## Triathlon TS Revision Knee System



### Survivorship

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Gwam et al. "Short- to mid-term outcomes of revision total knee arthroplasty patients with a total stabilizer knee system." Journal of Arthroplasty



### Function

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Hamilton et al. "Aseptic revision knee arthroplasty with total stabilizer prostheses achieves similar functional outcomes to primary total knee arthroplasty at 2 years: a longitudinal cohort study" The Journal of Arthroplasty





### Component positioning

30

Samson et al., "Optimizing posterior condylar offset and joint line restoration in revision total knee arthroplasty using a contemporary implant system." Techniques in Orthopaedics

## Survivorship

In joint registries and ODEP

Joint registry	10+ year survivorship <sup>1,2</sup> (including failure for all cause)
 2018 Australian Orthopaedic Association National Joint Replacement Registry	96.2% for cemented Triathlon primary knee system 96.0% for cementless Triathlon primary knee system
 2018 National Joint Registry for England, Wales, Northern Ireland	97.0% for cemented Triathlon primary knee system 96.0% for Triathlon with CR X3 insert

### Orthopaedic Data Evaluation Panel (ODEP)<sup>3</sup>

The Orthopaedic Data Evaluation Panel (ODEP) is an independent organization in the UK that provides ratings for arthroplasty implants based on implant performance in National Joint Registries and peer-reviewed publications. The number, 3, 5, 7, 10, and 13 represent length of follow up in years. The letters, A\*, A and B represent the quality of data. A represent strong evidence, B represent acceptable evidence, and A\* represents very strong evidence above A and B.

	Triathlon components	ODEP rating
<b>Cemented</b>	CR femur with CR insert Conventional polyethylene	10A*
	CR femur with CR insert X3 polyethylene	10A
	CR femur with CS insert Conventional polyethylene	10A
	PS femur with PS insert Conventional polyethylene	10A
	PS femur with PS insert X3 polyethylene	7A*
<b>Cementless</b>	CR femur with CR insert Conventional polyethylene	10A
	CR femur with CR insert X3 polyethylene	7A
	CR femur with CS insert X3 polyethylene	7A
	Triathlon Tritanium Baseplate and Metal-Backed Patella	Pre-Entry A*

ODEP rating accessed as April 2019. Latest ODEP ratings can be found at [www.odep.org.uk](http://www.odep.org.uk).

## Survivorship



In clinical studies

### Study

Excellent 10-year patient-reported outcomes and survival in a single radius, cruciate-retaining Total Knee Arthroplasty

### Authors

Chloe E. H. Scott, Katrina R. Bell, Richard T. Ng, Deborah J. MacDonald, James T. Patton, Richard Burnett

### Publication

Knee Surgery, Sports Traumatology, Arthroscopy (2019) 27:1106–1115

### Goal of trial

To report the 10-year survival and patient-reported outcome of the Triathlon TKA

### Materials and methods

A prospective study evaluated 462 Triathlon TKAs (426 patients) performed by 7 surgeons from 2006 to 2007. Patellae were only resurfaced in 5.2% of the patients at the surgeon’s discretion. Kaplan–Meier survival analysis, radiographic review, SF-12, Oxford Knee Scores (OKS), and satisfaction were assessed preoperatively and at 1, 5 and 10 years. Forgotten Joint Scores (FJS) were collected at 10 years.

### Results

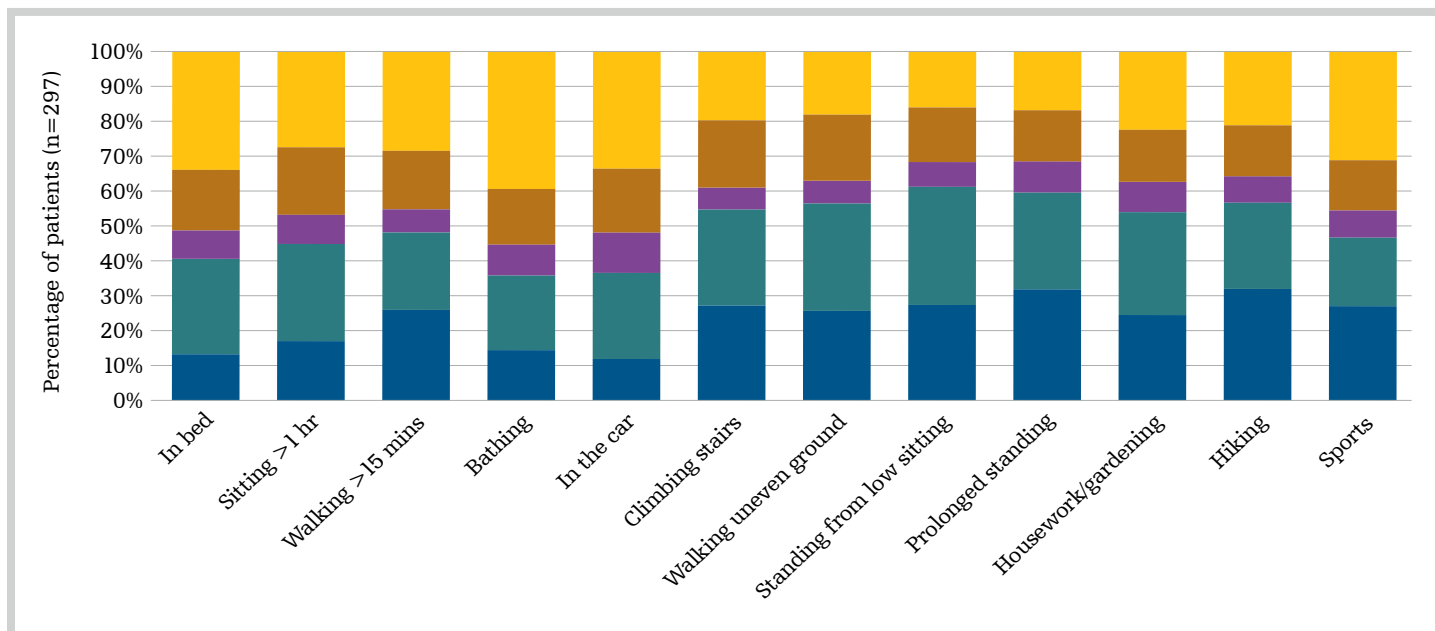
#### Survivorship at 10 years

All-cause survivorship	97.9%
Aseptic loosening survivorship	98.6%

#### Patient satisfaction

Patient satisfaction at 1 year	88.3%
Patient satisfaction at 5 years	88.0%
Patient satisfaction at 10 years	88.4%

**Forgotten Joint Score at 10 years: 48.2**



## Survivorship



In clinical studies (continued)

### Conclusion

“The Triathlon TKA continues to show favorable longer-term results with high implant survivorship, low rates of aseptic failure, consistently maintained PROMs and excellent patient satisfaction rates of 88% at 10 years.”

### Absolute PROMs at each timepoint with improvements in OKS for individuals

PROM	Timepoint	Median	Mean	P-value
SF-12 physical component scores	Preop	29.0	30.5	< 0.001
	0.5 year	42.1	41.5	
	1 year	43.4	43.4	
	5 years	39.3	41.7	
	10 years	39.6	39.2	
SF-12 Mental component scores	Preop	53.6	51.3	0.014
	0.5 year	55.4	52.3	
	1 year	55.9	52.6	
	5 years	54.4	51.7	
	10 years	50.9	48.6	
OKS	Preop	18	18.8	< 0.001
	0.5 year	37	34.3	
	1 year	39	36.3	
	5 years	41	37.3	
	10 years	38	34.7	
OKS improvement	Preop to 1 year	18	17.7	< 0.001
	1–5 years	1	1.2	
	5–10 years	– 1.5	– 3.0	

\*The decline in OKS between 5 and 10 years [ $37.3 \pm 10.3$  to  $34.7 \pm 10.$ ] is less than the minimal clinically important difference of 5.

## Survivorship



In clinical studies

### Study

Long-term survivorship and clinical outcomes of a single radius Total Knee Arthroplasty

### Authors

Jaydev B. Mistry, Randa K. Elmallah, Morad Chughtai, Melike Oktem, Steven F. Harwin, Michael A. Mont.

### Publication

Surgical Technology International 2016 Apr;28:247-51

### Goal of trial

To evaluate the long-term outcomes of patients who received a single radius knee prosthesis

### Materials and methods

54 patients (67 TKAs) were evaluated for implant survivorship, clinical outcomes, radiographic outcomes, and complications at a mean follow-up of 10 years. Kaplan-Meier analysis was performed to determine implant survivorship; Knee Society Score (KSS), University of California Los Angeles (UCLA) activity scale, and Short Form-36 (SF-36) mental and physical component scores were used to evaluate clinical and patient-reported outcomes. Anteroposterior and lateral radiographs were reviewed at final follow-up for evidence of component malpositioning or loosening.

### Results

All-cause survivorship of the femoral and tibial components	<b>99%</b>
Aseptic loosening survivorship	100%
Mean KSS score	64
UCLA activity scores	5
Mean SF-36 mental scores	53
Mean SF-36 physical component scores	39

### Conclusion

Continuous improvement in the techniques and designs of knee prostheses have led to the development of a knee prosthesis with a single radius, which has several potential advantages including flexion, rotation, flexibility, and excellent functional and radiographic outcomes. Single radius total knee arthroplasty demonstrated excellent long-term survivorship and functional outcomes.

## Function



Gait

### Study

Quantitative, comparative assessment of gait between single radius and multi radius Total Knee Arthroplasty designs

### Authors

Bethany Larsen, MS, Marc C. Jacofsky, PhD, David J. Jacofsky, MD

### Publication

The Journal of Arthroplasty, June 2015, Volume 30, Issue 6, Pages 1062–1067

### Goal of trial

To use quantitative motion analysis techniques to evaluate the impact of a single radius versus multi radius knee design on the kinematics and kinetics of the knee during ground level walking as indicated within the paper at 1-year after surgery

### Materials and methods

Gait of 3 cohorts was compared, single radius (n = 16) knees, multi radius (n = 16) knees, and age-matched healthy control knees (n = 16). All TKAs were performed using posterior stabilized knee implants. Biomechanical data generated from a motion analysis laboratory during level walking, and patient reported Lower Extremity Activity Scale (LEAS) outcomes were analyzed at 1 year post-op

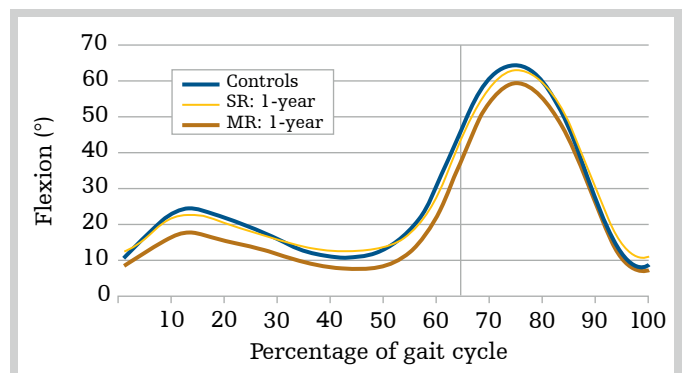
### Results

Post-operatively, single radius knees did not differ from healthy controls knees while multi radius knees continued to differ in important knee kinetic and kinematic properties. Multi radius knees remained more extended comparing to both single radius and healthy knees. Single radius results for power absorption during stance phase did not differ significantly from normal controls, which may provide greater control of knee flexion during weight acceptance than multi radius knees. The significant biomechanical differences are likely influenced by patella–femoral moment arm geometry and changing

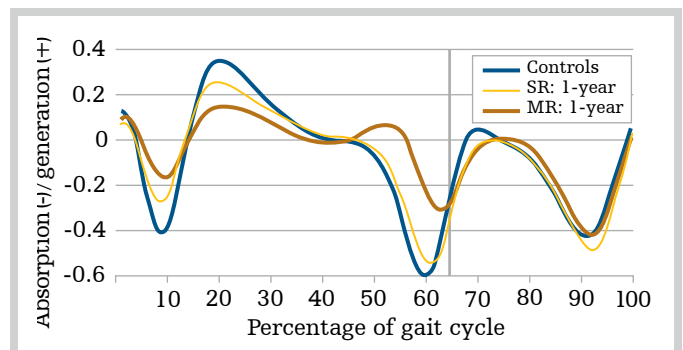
ligament laxity throughout the active range of motion. The single radius cohort had a significantly greater percentage of the stance phase where the rectus femoris and biceps femoris were firing independently when compared to the multi radius design.

### Conclusion

Single radius implant had no discernible gait abnormalities at one year post TKA while the multi radius implant exhibited several differences from control subjects, namely reduced knee flexion, reduced knee moments, and reduced knee power, likely due to the difference in implant design characteristics of rotation radius between single and multi radius knee design and/or adaptations to patient stimuli.



Knee flexion angle 1-year after TKA. The vertical line indicates toe off of the affected limb.



Knee power 1-year after TKA. The vertical line indicates toe off of the affected limb.

## Function

 Stability

### Study

In vivo movement of femoral flexion axis of a single radius Total Knee Arthroplasty

### Authors

Norimasa Shimizu, MD, Tetsuya Tomita, MD,  
Takaharu Yamazaki, PhD, Hideki Yoshikawa, MD,  
Kazuomi Sugamoto, MD

### Publication

The Journal of Arthroplasty. Volume 29, Issue 12,  
December 2014, Pages 2407–2411

### Goal of trial

To investigate in vivo femoro-tibial motion using the movement of femoral flexion axis of a single radius TKA with the hypothesis that a single femoral radius design TKA would offer a potential minimization of the paradoxical movement and provide joint stability.

### Materials and methods

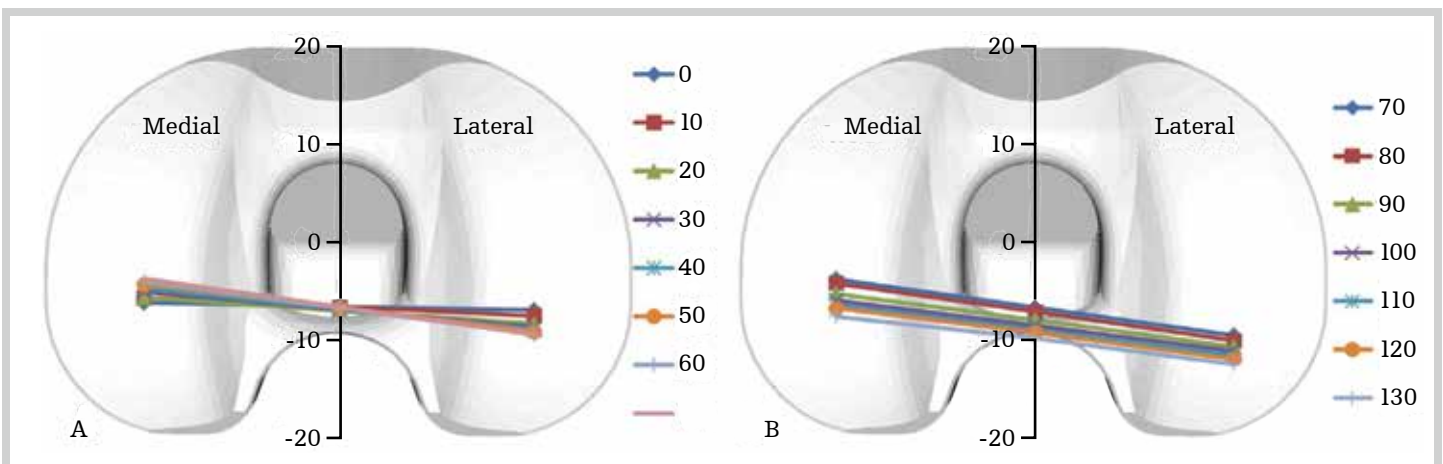
The motion of 20 Triathlon PS TKA from full extension to maximum flexion was examined under fluoroscopic surveillance in the sagittal plane by patients performing sequential deep knee flexion under weight-bearing condition at mean follow-up of 10.9 months

### Results

No paradoxical anterior femoral movement was shown until 70° flexion, afterward the femoral component rolled back with flexion. The initial post-cam engagement occurs relatively early at 55.2° of flexion. The early engagement could also contribute to reducing paradoxical motion and the kinematic stabilization.

### Conclusion

The femoral component was kinematically stabilized in mid-flexion ranges and posterior femoral rollback occurred in deeper knee flexion with this knee design. The data showed that the design of this prosthesis might reduce the paradoxical anterior femoral movement and provide stability in mid-flexion ranges.



The movement of femoral flexion axis during deep knee flexion (A: 0°–70° flexion, B: 70° to maximum flexion).

## Patient Reported Outcome Measurements (PROM)



Comparing outcomes of single radius vs. multi radius design

### Study

Functional outcomes used to compare single radius and multi radius of curvature designs in total knee arthroplasty.

### Authors

Laurence E. Cook, B.A., Alison K. Klika, M.S., Caleb R. Szubski, B.A., James Rosneck, M.D. Robert Molloy, M.D., Wael K. Barsoum, M.D.

### Publication

The Journal of Knee Surgery, 2012, Vol. 25 : Pages 249–254

### Goal of trial

To evaluate, using a modified KSS assessment, the functional advantages of a single radius implant design relative to a multi radius design at a minimum of 2 years follow-up.

### Materials and methods

559 primary total knee arthroplasty (TKA) procedures, which used either a Triathlon single radius knee (N= 426) or Duracon multi radius knee (N=133), were retrospectively analyzed at average follow-up of 3.9 years. All knees were cruciate retaining TKA prostheses. A modified KSS was compared and analyzed between 2 cohorts.

One limitation of the study was that the modified KSS score was conducted via the phone. The modified KSS has been shown to be similar to conventional KSS scoring data, but there is a possibility that comparing modified KSSs with office-administered preoperative KSSs could have resulted in biased data.

### Results

KSS knee and function subscores for the single radius design showed an advantage over the multi radius design in pain, stability, flexion, ability to completely straighten the knee, stairclimbing, walking, and the amount of support needed from an assistive device.

The single radius group's postoperative KSS knee and KSS function score was greater than the multi radius group's score. The patient population that received the single radius design was younger. The participating surgeons utilized the minimally invasive subvastus (MIS) approach for the majority of the procedures involving the single radius implant (87.6%) while they used the MIS and medial parapatellar approaches at very similar rates among the procedures involving the multi radius implant.

Preoperative KSS functional score was higher for single radius group. This possible bias was taken into consideration and the numerical advantage within the single radius group for postoperative function was much larger than the small advantage the single radius group had over the multi radius group for preoperative function.

### Conclusion

Patients who received a single radius TKA implant had better knee function and less knee pain postoperatively than a multi radius design. The study concludes that the advantages in stability, walking, stair climbing, and knee straightening stem from the improved design of the single radius system, particularly longer moment arm and improved ligament stability based on a maintained isometry throughout knee range of motion.

## Patient Reported Outcome Measurements (PROM)



Comparing outcomes of single radius vs. multi radius design

### Study

Implant design influences patient outcome after total knee arthroplasty. A prospective double-blind randomized controlled trial.

### Authors

D. F. Hamilton, PhD; R. Burnett, FRCS(Ed); J. T. Patton, FRCS (Ed); C. R. Howie, RCS (Ed); M. Moran, FRCS (Ed); A. H. R. W. Simpson, DPhil; P. Gaston, FRCS (Ed)

### Publication

The Bone & Joint Journal 2015; 97-B:64–70

### Goal of trial

To determine whether differences in TKA outcomes can be influenced by implant design.

### Materials and methods

Double-blind randomized control trial. Same surgical approach applied by 6 surgeons with experience using both implants in patients with comparable demographics. The study investigated outcomes of Triathlon Cruciate Retaining (CR) with Kinemax CR design as the control because Kinemax CR is an implant that has been used successfully for many years.

### Results

183 and 165 patients were available for outcome analysis at 1 and 3 years, respectively. Patient satisfaction, worst daily pain, ROM, and lower limb power output were significantly better with the Triathlon Knee System. Triathlon had greater improvement in Oxford Knee Score at 1 year follow-up ( $p = 0.05$ ). Triathlon also had greater improvement in Oxford Knee Score at 3 year follow-up, but the difference in improvement did not achieve statistical significance ( $p = 0.09$ ). Loss to patient follow-up during the additional analysis time points is likely to have substantially reduced the power of the study to detect a difference between groups.

### Conclusion

TKA design can influence patient outcome. Better patient function (lower limb power and knee flexion), pain levels and overall satisfaction with outcome were present in the patients treated with the newer Triathlon design.

## Constraint options



### Condylar-Stabilized (CS) insert in PCL sacrificed TKA

#### Study

Prospective randomized comparison of posterior-stabilized versus condylar-stabilized Total Knee Arthroplasty: final report of a five-year study

#### Publication

The Journal of Arthroplasty, 2018 May, 33(5):1384-1388

#### Author

David F. Scott, MD

#### Goal of trial

The prospective, randomized, Level I study evaluated and compared the clinical outcomes and radiographic results of patients undergoing posterior cruciate-sacrificing TKA receiving the CS insert with patients receiving the PS tibial insert at minimum 5-year follow-up. The study hypothesized that clinical outcomes would be equivalent, and that tourniquet time and intraoperative blood loss would differ.

#### Materials and methods

111 patients were randomized to either the CS or PS group. There were no significant differences in gender, age, and BMI. 56 patients with a PS insert were compared with 55 patients with a CS insert (Triathlon PS and Triathlon CS). All posterior cruciate ligaments (PCLs) were sacrificed and all patellae were resurfaced.

Clinical and radiographic assessments were performed preoperatively, 6 weeks and 6 months postoperatively, and annually. Clinical assessments included Knee Society pain, motion, and function scores, the lower extremity activity scale (LEAS), range of motion (ROM), and alignment. Additional data included hemovac drainage volume, tourniquet and operative time, as well as hemoglobin preoperatively and on postoperative days 1-3.

#### Results

Clinical and radiographic outcomes at 5-years were equivalent between the PS and CS cohorts. These results are comparable with the 2-year results of the same trial.

21% of the PS group reported painless mechanical sensations as compared to 9% of the CS participants at 1 year postoperatively. This difference in the incidence of mechanical sensations did not affect the patients' perception of the performance of their knee as evaluated by the outcome metrics used (KSS, LEAS, and SF-36)

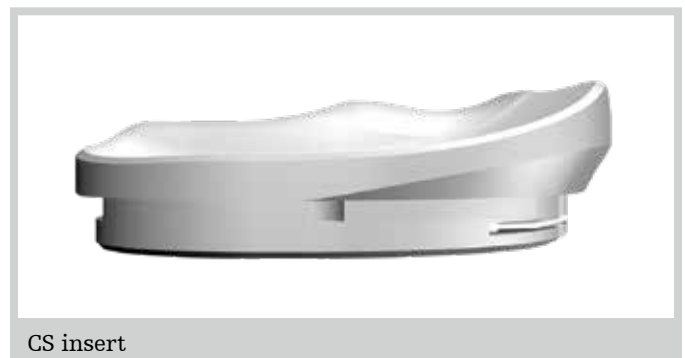
CS group had significantly shorter operative and tourniquet times than the PS group.

At a minimum 5 years of follow-up, both groups achieved 100% implant survivorship and 125° ROM.

#### Conclusion

With the PCL sacrificed, the CS knee demonstrated excellent clinical outcomes that are comparable to the results obtained with the PS knee. In this study, the CS knee also demonstrated shorter operative time with a lower incidence of painless mechanical sensations

The mid-term data comparing CS and PS type implants with PCL sacrificing in both cohorts provides support for the clinical use of the CS device as an alternative to the PS device.



## Constraint options



In complex primary patients

### Study

Coronal alignment predicts the use of semi-constrained implants in contemporary total knee arthroplasty

### Authors

Martin JR, Fehring KA, Watts CD, Levy DL, Springer BD, Kim RH

### Publication

Knee. Volume 24, Issue 4, 2017. Pages 863-868

### Goal of trial

To determine the preoperative radiographic characteristics for primary TKA patients to require a semi-constrained implant and compare the radiographic and clinical outcomes of semi-constrained implants to those of standard constraint implants

### Materials and methods

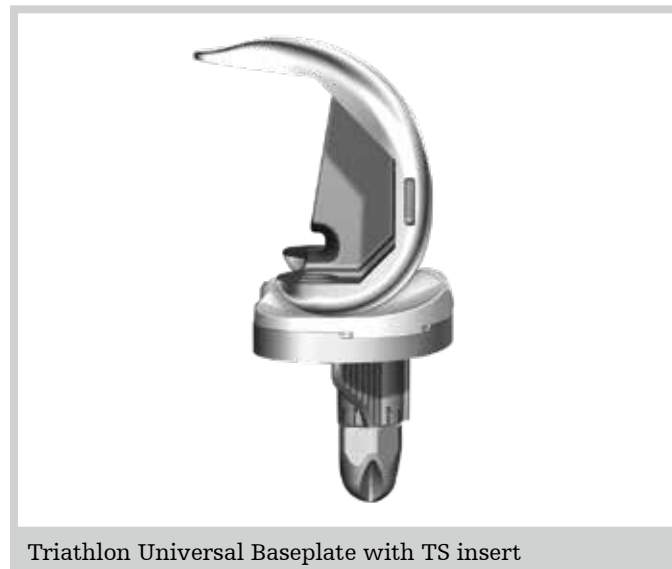
Each institution's joint registry was retrospectively reviewed to identify patients that underwent primary TKA with the use of a Triathlon PS TKA with a Total Stabilized (TS) tibial polyethylene insert (TS cohort, n = 75 TKA). TKAs in the TS group were matched with primary TKAs which utilized posterior stabilized components (PS group). Preoperative and postoperative radiographic and clinical data were reviewed at six-week post-operative and final follow-up. Matching was based on patient age, gender, and body mass index (BMI).

### Results

Patient demographic data	TS Cohort	PS Cohort	P-value
Age (years)	70.5	69.6	0.56
% Female	72	72	1
BMI	29.1	29.1	0.99
Pre-operative ROM (degrees)	108.2	111.8	0.0091
Medial joint space in valgus deformities (mm)	2.9 (3.4)	2.8	0.87
Lateral joint space in varus deformities (mm)	1.9	5.1	0.0001
Poly thickness (mm)	11.9	10.3	0.0001
Post-op ROM (degrees)	125	126.2	0.48

### Conclusion

Preoperative radiographic deformity may be utilized to predict patients who will require increased implant constraint during primary TKA. TS patients had greater preoperative varus and/or valgus deformities than the PS patients. Radiographic coronal deformity appears to be associated with ligamentous laxity, which is related to statistically significant increases in implant thickness and implant constraint to achieve stability. Utilizing a TS insert does not appear to increase the complexity of the surgery as inferred from similar operative times and intraoperative blood loss. Finally, the short-term results are promising for the use of the TS insert in a complex primary TKA.



Triathlon Universal Baseplate with TS insert

## Constraint options



In obese patients

### Study

Comparing the Efficacy of the Total Stabilizing and Posterior Stabilizing Knee Prostheses in Obese and Preobese Females: A Retrospective Cohort Study

### Authors

Kellen Worhacz, BS, Marc C. Jacofsky, PhD, David J. Jacofsky, MD, Sarim Ahmed, MD

### Publication

The Journal of Knee Surgery Vol. 31 No. 9, pages 884-888

### Goal of trial

This study retrospectively analyzed knee range of motion and stability of one TKA design with two different degrees of polyethylene conformity in the obese female population.

### Materials and methods

This retrospective cohort study compiled a list of all primary TKA patients between January 2011 and August 2013, further stratified to identify females with BMI >25. The patients in the cohort received either a PS insert (n=80) or a TS insert (n=93). The primary outcomes measures (2-week, 6-week, 3-month, > 3-month, 1-year visits) included: patient knee stability/laxity at 0° and 30° of flexion, active and passive knee flexion, and active and passive knee extension.



Anteroposterior and lateral views of left total knee arthroplasty in morbidly obese female with primary total stabilizing implant.

### Results

Preoperatively, the patients in the TS group were statistically significantly more obese when compared with the patients in the PS group and had statistically significantly increased preoperative valgus instability at both 0° and 30° of flexion. Despite the TS patients starting at a stability deficit, no statistically significant differences were detected between each group's stability measures.

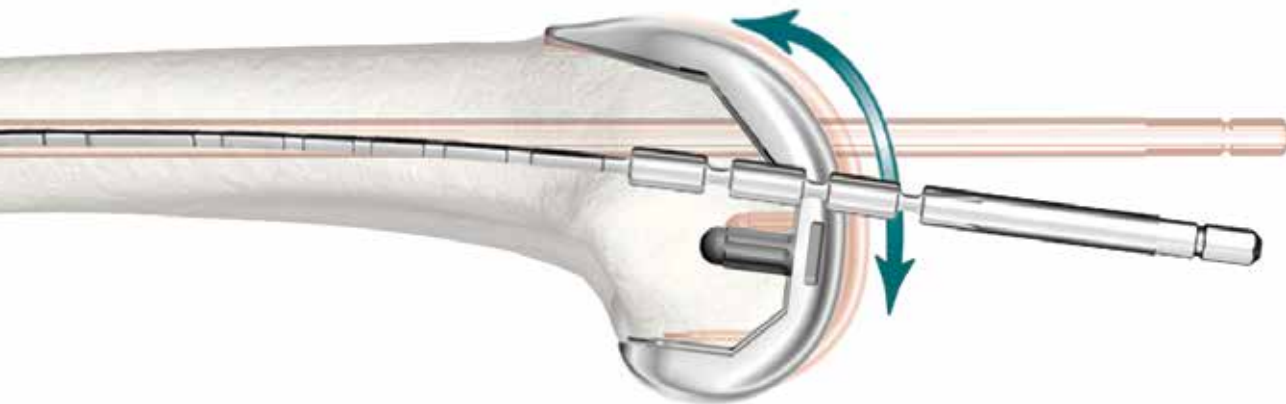
Patients in the TS group showed a better recovery of active extension range of motion than the patients in the PS group. The ability to achieve full passive extension was also significantly improved at 6 weeks postoperatively for the TS group. At 1 year, there were no longer any differences in ROM or stability measures between the groups. There was no difference in revision rate for PS and TS cohorts and no difference in reported complications.

### Conclusion

Since patients in the TS group were more obese and had less stable knee preoperatively, the TS group would be predicted to have been associated with poorer outcomes. However, these results show quicker restoration of both active and passive extension in the TS group over the PS group. The relative increase in constraint by the cam-post tolerances in the TS implant may have led to greater perceived stability and patient confidence, which could increase compliance, in turn leading to improved active terminal extension. Our results support the hypothesis that the TS implant results in better functional TKA outcomes in the obese female population.

## FlexRod

Traditionally, the distal femoral cuts in TKAs are determined by introducing a rigid intramedullary (IM) rod into the distal femur. The distal femur has the unique morphology of a single radius and an anterior bow. The position of the IM rod and the anterior bow can affect the size and orientation of the femoral component. Oversizing or undersizing has the potential to lead to suboptimal outcomes. A flexible IM rod (FlexRod) that can flex exclusively within the sagittal plane to accommodate the patient's unique anterior bow can be used to place the femoral component in a more anatomic position.



## Component positioning and sizing

### SOMA data on fit<sup>13</sup>

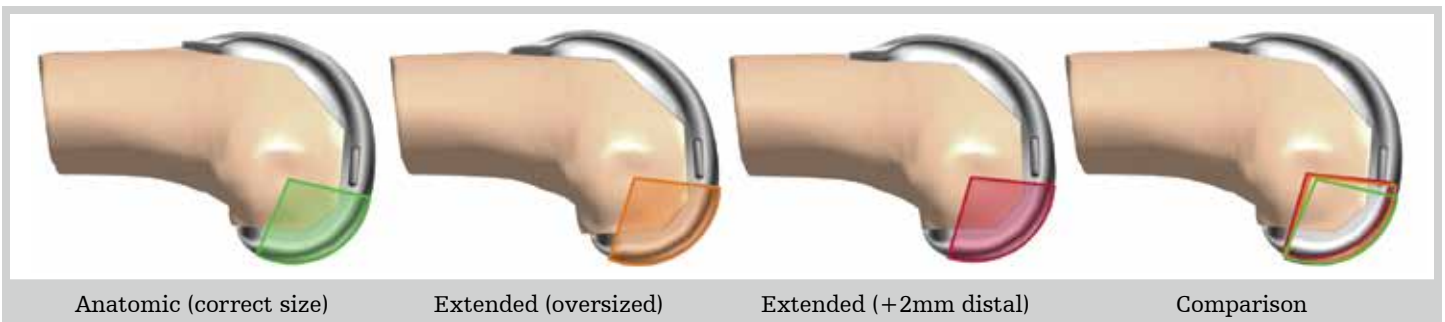
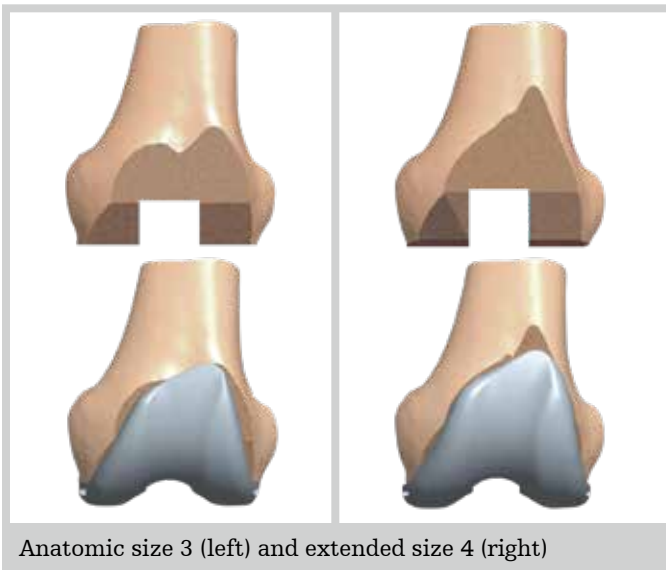
Oversizing of the femoral component may lead to ML overhang. While TKA procedures have demonstrated clinical success, mediolateral overhang of the femoral components  $\geq 3\text{mm}$  has been shown to be associated with increased knee pain.

Stryker's Orthopaedic Modeling and Analytics (SOMA) is a CT bone data and modeling tool with a diverse patient demographic from around the world. In a study that virtually implanted 981 TKAs with the FlexRod using SOMA, Triathlon femoral components were predicted to fit over 98.4% of the population across different ethnicities. Asian patients tend to have smaller distal femurs as compared to the Caucasian population. The same study also analyzed 267 Asian-identified bone data and predicted 98.3% femoral fit with  $< 3\text{mm}$  overhang in this patient subset. Images from SOMA demonstrated that accommodating for the femoral bow can reduce the incidence of overhang in bone types with anterior bow.

### Component positioning

Additionally, how the distal resection is made also influences component position. The patient's knee and the femoral component each have a center of rotation. The FlexRod is designed to bend to accommodate the bow of the patient's femur. This can help to position the single radius in the femoral component with the single radius of the patient's natural knee. Proper placement of the single radius may aid in balancing the knee. The impact can be observed in the illustration using the SOMA database below.

By taking the individualized bow of each patient into consideration, the FlexRod is designed to help the surgeon achieve proper fit and position of the femoral component. As reported by Hitt, et al., patients who received TKAs with the FlexRod showed a decreased risk of oversizing femoral components and better improvements in outcomes.<sup>14</sup>



## Component positioning and sizing



### Use of FlexRod and its influence on function

#### Study

Use of a flexible intramedullary rod and its influence on patient satisfaction and femoral size in total knee arthroplasty

#### Authors

Kirby D. Hitt, MD; Todd P. Pierce, MD; Julio J. Jauregui, MD; Jeffrey J. Cherian, MD; Randa DK Elmallah, MD; Evan Leibowitz, Scott Logan, & Michael A. Mont, MD

#### Publication

Journal of Long-Term Effects of Medical Implants, 25(3): 201–208 (2015)

#### Goal of trial

To assess the patient-reported functional outcomes, overall quality of life, and changes in implant sizing associated with TKAs performed with a FlexRod compared to a conventional, rigid rod.

#### Materials and methods

Femoral implant sizes of 277 patients using the rigid IM rod and 364 using the FlexRod were analyzed retrospectively to determine the tendency of each rod for selecting particular component sizes. 100 patients were prospectively randomized (1:1) to the FlexRod or the conventional rigid IM rod cohorts. Patient-reported outcomes were evaluated preoperatively and at 6 weeks, 3 months, 1 year, and 2 years postoperatively. Outcomes were assessed using KSSs and SF-36 scores.

#### Results

The FlexRod cohort showed greater improvement in clinical and functional KSSs, and in physical and mental SF-36 scores. With both clinical and functional KSSs, the FlexRod cohort had a higher score than the rigid IM rod cohort at all follow-up points. The FlexRod cohort had better ROM than the rigid IM rod cohort. Implant sizing tended to be smaller for the FlexRod cohort.

#### Conclusion

Femoral component orientation relative to anterior bow is an important variable when determining an appropriate resection plane. The FlexRod allows a distal femoral resection that mimics a patient's individualized anatomy, placing the femoral component in a more anatomic position. The FlexRod has the potential to aid in evaluating the ideal size of the femoral component, thus optimizing patient-reported outcomes, functional status, and overall quality of life. Patients who underwent TKA using a FlexRod demonstrated greater improvements in their patient reported outcomes and decreased risk of oversizing the femoral component.

## Wear resistance



X3 polyethylene clinical outcomes

### Study

Randomized clinical trial of conventional vs. highly cross-linked polyethylene in total knee arthroplasties

### Authors

Matthew P. Abdel, M.D., Anthony Viste, M.D., Ph.D., Cedric J. Ortiguera, M.D., Henry D. Clarke, Mark J. Spangehl, M.D., Mark W. Pagnano, M.D., Arlen D. Hanssen, M.D., Michael J. Stuart, M.D.

### Publication

Presented at AAHKS 26th Annual Meeting, Dallas TX, 2016

### Goal of trial

To compare the survivorship, clinical outcomes, and complications of highly cross-linked polyethylene (X3) vs. conventional polyethylene (N2Vac) of Triathlon PS at 5-year follow-up

### Materials and methods

A multi-center, randomized controlled trial compared survivorship, complication rate, KSS, SF-12 physical and mental scores of 396 patients receiving cemented, posterior-stabilized TKAs at mean follow up of 5-years. All patients' patellae were resurfaced.

### Results

5-year outcomes	X3	N2Vac
Pre-operative mean KSS	39	39
Post-operative mean KSS	89	89
Pre-operative physical SF-12 scores	33	33
Post-operative physical SF-12 scores	48	46
Pre-operative metal SF-12 scores	56	56
Post-operative metal SF-12 scores	57	55
Aseptic survivorship	100%	99%
All-cause survivorship	97%	97%

Complication rates similar between the two groups (p=0.2)

### Conclusion

Triathlon X3 highly cross-linked polyethylene and N2Vac demonstrated no significant differences in survivorship, clinical outcomes, or complications at 5-year follow-up

## Wear resistance



### X3 polyethylene clinical outcomes

#### Study

Multicenter study of highly cross-linked vs. conventional polyethylene in total knee arthroplasty

#### Authors

R. Michael Meneghini, MD, Philip H. Ireland, MD, Manoshi Bhowmik-Stoker, PhD

#### Publication

The Journal of Arthroplasty, 31 (2016) 809 - 814

#### Goal of trial

To compare the clinical and radiographic outcomes of highly cross-linked polyethylene (HXLPE) and conventional polyethylene of Triathlon PS TKA at 5-year follow-up.

#### Materials and methods

A prospective multicenter study of 307 posterior-stabilized TKAs (168 conventional and 139 HXLPE) was performed. 224 TKAs (129 conventional and 99 HXLPE) were available for analysis at a minimum 4- to 5-year follow-up. Radiographs, KSS, Lower Extremity Activity Score (LEAS), Short-Form-6D health-related quality of life outcomes, and Short-Form 36 were collected preoperatively and evaluated postoperatively at 6 weeks, 3 months, 1 year, and annually out to 5 years. The Mental Composite Score and Physical Composite Score (PCS) of the Short-Form 36 are reported.

#### Results

No osteolysis, polyethylene failures, or progressive radiolucencies were observed in either group. One tibial component in the conventional polyethylene insert group was revised for aseptic loosening unrelated to the polyethylene. One conventional polyethylene insert was revised for treatment of arthrofibrosis. One inferior-pole patella fracture unrelated to the polyethylene was excised. Both conventional and HXLPE groups showed statistically significant improvements in all measures from preoperative baselines. Postoperative mean active range of motion was 130° in both cohorts. The HXLPE group showed statistically significant greater mean KSS and SF-36 physical function subset at latest follow-up, likely related to differences in age between patient cohorts. Despite being younger and intuitively more active on average than the conventional polyethylene group, no mechanical failures were reported in the HXLPE group. The HXLPE group had higher LEAS both preoperatively and at the latest follow up, so the amount of improvement was similar. All patients were able to ambulate in the community and participate in social and recreational activities at follow-up. The Short-Form-6D health-related quality of life outcomes index indicates positive patient perception of TKA results regardless of tibial insert polyethylene type.

#### Conclusion

No mechanical failure or radiographic osteolysis was observed with either conventional or HXLPE in this PS single radius TKA design at midterm follow-up. The study findings support comparative safety and outcomes of HXLPE in TKA.

## Triathlon Tritanium cementless TKA

Patient demographics for total knee arthroplasty (TKA) have become younger, more active, and heavier,<sup>22</sup> and these patients have demonstrated higher failure rates in TKAs.<sup>23</sup> The use of cementless TKA in obese patients, with the potential of durable long-term biologic fixation and increased survivorship, appears to be a promising alternative to cemented TKA.<sup>24</sup>

However, specific features of previous cementless TKA designs have led to low use of biologic fixation technique.<sup>25</sup> An understanding of previous modes of failure, along with new additive manufacturing techniques, has led to the development of a Triathlon Tritanium Tibial Baseplate and Metal-Backed Patella.

Since the introduction of Triathlon Tritanium TKA, clinical data from multiple centers have shown favorable early results.<sup>17,18</sup>



## Biologic fixation



In PS cementless TKA

### Study

Results of cemented vs. cementless primary total knee arthroplasty using the same implant design

### Authors

Adam J. Miller, BS, Jeffrey D. Stimac, MD, Langan S. Smith, BS, Anthony W. Feher, MD, Madhusudhan R. Yakkanti, MD, Arthur L. Malkani, MD

### Publication

The Journal of Arthroplasty, 2018 Nov 1;41(6):e765-e771

### Goal of trial

Compare the clinical and radiographic results of Triathlon Tritanium cementless TKA with the Triathlon cemented TKA

### Materials and methods

Clinical and radiographic outcomes of 200 Triathlon Tritanium TKAs were retrospectively matched and compared with 200 Triathlon cemented TKAs. There was no difference in age, BMI, and preoperative KSS between 2 cohorts. A Peri-Apatite (PA) posterior stabilized femur, a PA beaded patella, and a Tritanium baseplate were used in the Triathlon Tritanium TKAs cohorts; a cemented posterior stabilized or cruciate retaining femur, an all polyethylene patella component and a cemented baseplate were used in the cemented cohort. Patient selection between the cemented vs. cementless cohort was consistent and performed by the same surgeon. Patients with adequate bone quality at the periphery or rim of the tibial metaphysis were selected for cementless fixation. Both cohorts received the same anesthesia and postoperative protocol, which consisted of immediate weight bearing with passive and active motion exercises.

Demographic	Cementless (n=200)	Cemented (n=200)	P-value
Age, year	64,3±8,3	64,4±8,2	0.82
Gender			1
Male	74 (37.0%)	74 (37.0%)	
Female	126 (63.0%)	126 (63.0%)	
Side			.904
Left	103 (51.5%)	68 (49.2%)	
Right	96 (48.0%)	70 (51.8%)	
BMI, kg/m <sup>2</sup>	33.9 ± 7.5	33.1 ± 6.5	.22
Follow-up time, mo	27.6 ± 3.5	63.4 ± 23.0	<.00001

Patient demographics and outcome variables comparing matched cementless and cemented cohorts in total knee arthroplasty

## Biologic fixation

In PS cementless TKA (continued)

### Results

Outcome at 2.4 year follow-up	Triathlon Tritanium TKA	Triathlon cemented TKA	P-value
Total no. of revisions	7 (3.5%)	8 (4.0%)	0.069
Aseptic loosening	1 (0.5%)	5 (2.5%)	0.212
KSS functional score	76.0±20.4	70.2±22.3	.016
Change in function score	35.6(±19.8)	26.04 (±26.6)	.0014
KSS knee score	94.1±6.1	91.6±9.8	.0076
Change in knee score	53.8±13.8	52.4±16.7	.385

Radiographic analysis of the Triathlon Tritanium Baseplate demonstrated areas of spot welds primarily at the pegs similar to the areas of bone density noted at the screw sites with cementless THA.

### Conclusion

Triathlon Tritanium TKA demonstrated excellent short-term results and a 0.5% aseptic survivorship equivalent to the kinematically designed similar Triathlon cemented TKA. Additional data is required to determine if the benefits of biologic fixation can be realized over the long-term similar to the history and success of cementless THA.

## Biologic fixation



In CR cementless TKA

### Study

Early clinical outcomes of a new cementless total knee arthroplasty design

### Authors

Russell G. Cohen, MD; Nathan C. Sherman, MBA;  
Sheridan L. James, BS

### Publication

Orthopedics, 2018 Nov 1;41(6):e765-e771

### Goal of trial

To evaluate the efficacy and perioperative outcomes of Triathlon Tritanium cementless TKA

### Materials and methods

Radiographic and functional outcomes of 72 cementless TKAs using Triathlon CR PA beaded femurs, Triathlon Tritanium baseplates and metal-backed patellae were reviewed with mean follow up of 37 months. Intra-operatively assessment of bone quality excludes patients with osteoporotic bone from receiving cementless TKAs.

Surgical time, estimated blood loss, and post-operative range of motion were compared with those of a matched cohort of 70 Triathlon cemented knees performed by the same surgeon. Operative time was defined as the time from incision to placement of surgical dressing. Postoperative drain output during the first 24 hours was compared to assess if cementless TKAs lead to increased blood loss due to exposed porosity of the bone that is otherwise covered by cement. Early range of motion was compared between the 2 cohorts at 6 weeks to establish whether the cementless patients might have stiffer knees if they endured greater pain in the early postoperative time frame.

Demographic	Cement group	Cementless group
Patients, no.	66	70
Total knee arthroplasty, no.	70	72
Bilateral total knee arthroplasty, no.	4	2
Age*, mean (SD) [range], year	63.5 (7.1) [41-74]	66.1 (6.7) [48-75]
Body mass index, mean (SD) [range], kg/m <sup>2</sup>	30.1 (4.9) [19.3-38.4]	30.1 (3.8) [22.6-39.1]
Dates of operation, start and end	1/30/2013 and 7/1/2013	11/3/2014 and 5/6/2015
Demographics of the two patient groups		

\*P=.02

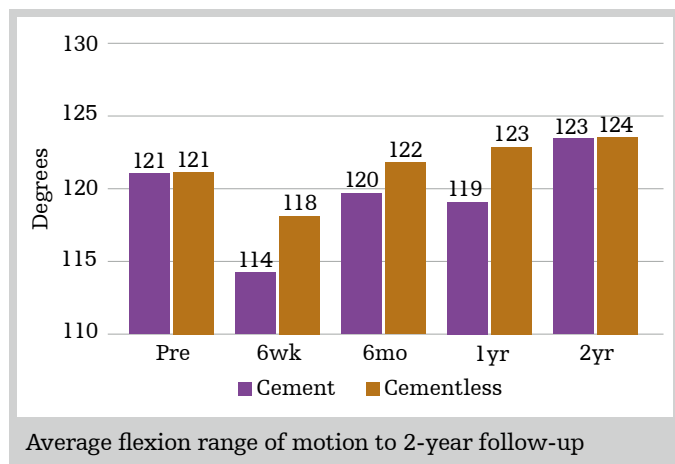
## Biologic fixation

In CR cementless TKA (continued)

### Results

At an average of 37 months follow up, no implants aseptically loosened or migrated in the cementless cohort. All patellar implants appeared well fixated along each of the 3 pegs on most recent radiographs. The KSS functional scores and OKS showed significant improvement in functional outcomes with Triathlon Tritanium cementless TKA.

Mean operating time was significantly shortened for cementless TKA from 45.6 to 40.8 minutes. There was no difference in estimated postoperative blood loss between the cemented and cementless cohort. The cementless cohort showed slightly increased but statistically insignificant early range of motion at 6 weeks comparing to the of cemented cohort. Range of motion of both groups continued to improve to 2-year follow up, with both achieving a mean of greater than 120° of flexion.



### Conclusion

Triathlon Tritanium cementless TKA revealed excellent clinical results at 3-year follow-up and resulted in shortened operative times. Biologic fixation was achieved in 100% of patients with improved functional and objective scores. Given the excellent long-term results of the Triathlon design on which the joint biomechanics of this implant are based, the short-term result of Triathlon Tritanium cementless is encouraging and shows the potential for enhanced long-term outcomes for Triathlon Tritanium cementless TKA.

### Knee Society scores and Oxford knee scores\*

Outcome measure	Mean (SD)			P	
	Preoperative	6 weeks	Most recent	Preoperative to 6 weeks	6 weeks to most recent
Knee Society score functional (maximum score, 100)	43.9 (16.1)	59.2 (15.4)	83.0 (13.6)	<.0005	<.0005
Knee Society score objective (maximum score, 100)	53.9 (21.9)	85.0 (6.8)	91.6 (4.5)	<.0005	<.0005
Oxford knee score (maximum score, 50)	23.9 (1.2)	31.7 (6.9)	43.4 (4.7)	<.0005	<.0005

\*Forty-five patients

## Triathlon TS Revision Knee System

The goals of revision TKA include reconstructing bony defects to restore the anatomical joint line and achieving a well-fixed, stable joint that improves the patient's quality of life.<sup>26</sup>

The Triathlon Revision system provides patented implants and instrumentation designed to properly locate the joint line and balance the knee consistently,<sup>27</sup> as well as reaming instrumentation to allow for accurate preparation of metaphyseal fixation.<sup>28-31</sup> The system features a single radius design, which has been shown to maintain ligament stability throughout the active range of motion<sup>32-35</sup>; and the Triathlon Tritanium Cone Augments, which allow for metaphyseal fixation while maintaining desired alignment.<sup>28</sup>

Triathlon Revision has clinically demonstrated favorable survivorship and functional outcomes at short- and mid-term.<sup>19, 20, 36</sup>



## Survivorship



In clinical study

### Study

Short-to-midterm outcomes of revision total knee arthroplasty patients with a total stabilizer knee system.

### Authors

Chukwuweike U. Gwam, MD, Morad Chughtai, MD, Anton Khlopas, MD, Nequesha Mohamed, MD, Randa K. Elmallah, MD, Arthur L. Malkani, MD, Michael A. Mont, MD

### Publication

Journal of Arthroplasty, Vol 32 (8), pages 2480-2483.

### Goal of trial

To evaluate device survivorship, patient reported outcomes, postoperative complications, and radiographic outcomes of patients who underwent revision TKA using Triathlon TS revision knee system

### Materials and methods

Ninety-three patients from 2 hospitals underwent rTKA with Triathlon TS; mean age of 65 and a mean follow-up of 4 years. Survivorship was assessed using Kaplan-Meier survival curves, KSS were collected pre- and post-operatively, and radiographic review was performed using the Knee Society Roentgenographic Evaluation and Scoring System.

### Results

At 2-7 year follow-up (mean 4 years), aseptic survivorship was 96%; all-cause survivorship was 94%. The KSS was 86 points and the functional KSS was 52 points. Postoperative extension was 2 degrees and postoperative flexion was 106 degrees. Excluding the aseptic and all-cause failures, there were no progressive radiolucencies or osteolysis noted on radiographic evaluation.

### Conclusion

This study demonstrated favorable survivorship, improvements in range-of-motion and clinical outcomes, a low rate of complications, and no further radiographic failures (at a mean 4 years follow-up) in revision TKA patients who used this revision system.

This study demonstrates better survivorship results on revision TKAs than multiple other studies and large joint registries.

## Function



### Clinical outcomes

#### Study

Aseptic revision knee arthroplasty with total stabilizer prostheses achieves similar functional outcomes to primary total knee arthroplasty at 2 years: a longitudinal cohort study

#### Authors

Hamilton DE, Simpson PM, Patton JT, Howie CR, Burnett R

#### Publication

Journal of Arthroplasty, Volume 32 (4), pages 1234-1240

#### Goal of trial

To chart patient reported and functional outcomes in the initial 2 years following aseptic revision TKA using total stabilizer implants and compare to published data for primary TKA.

#### Materials and methods

53 consecutive aseptic revision total knee replacements performed over a 2 year period.

All procedures were revision of a primary implant to a Triathlon TS device.

Patients were assessed preop, then at outpatient clinical review at 6 weeks, 6 months, 1 year and 2 years postop.

Patients were evaluated using OKS, global knee pain severity, ROM, aggregated function score, and patient satisfaction (assessed at 2 years only).

Secondary analysis compared result of revision cohort to a previously reported cohort of 212 primary total knee patients.

## Function

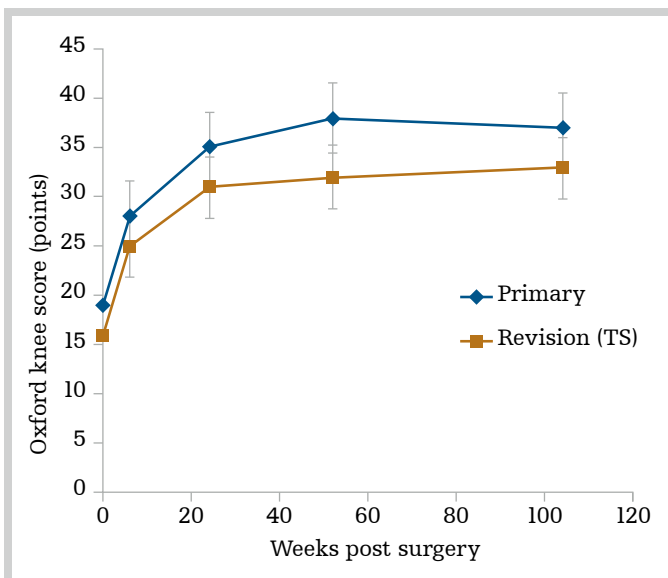
### Clinical outcomes (continued)

#### Results

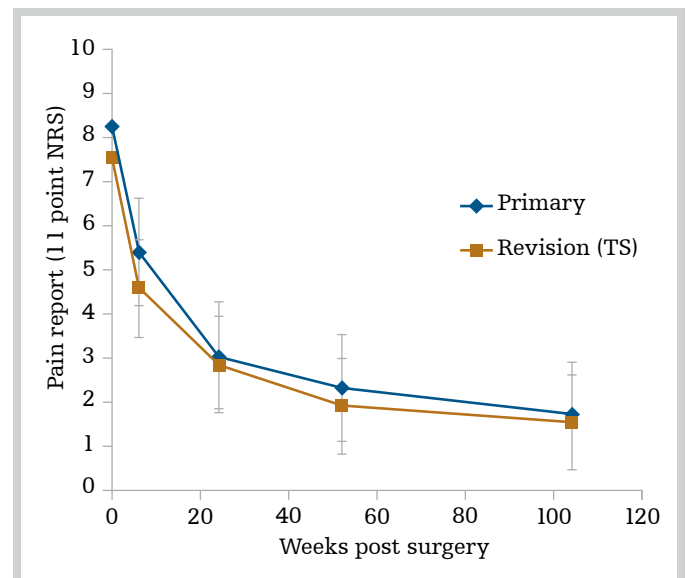
Between preop and 2 years, 15 point increase in OKS, 21 degree improvement in knee flexion, 60% reduction in pain report and 15 second improvement in timed performance; all were statistically significant. 84% of patients were satisfied at 2 years.

#### Conclusion

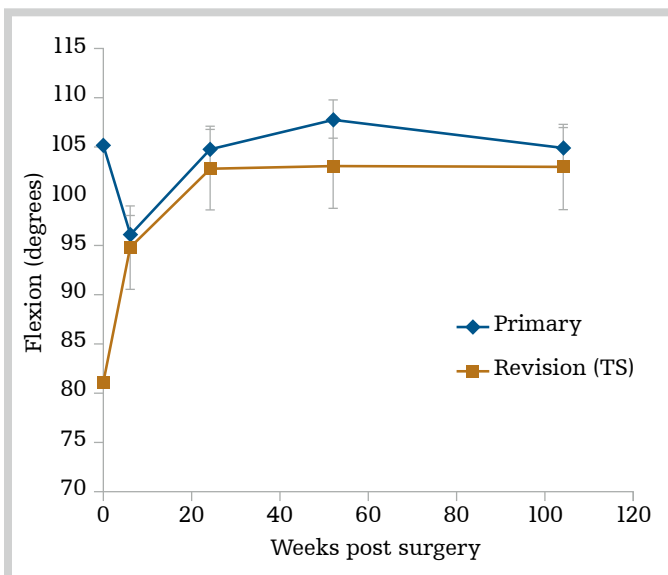
Patients undergoing revision TKA with Triathlon TS made substantial improvements in OKS, pain score, knee flexion, and timed functional performance in the initial 2 years after surgery. The early results achieved are remarkably similar to those reported for primary arthroplasty, suggesting that high levels of function can be achieved.



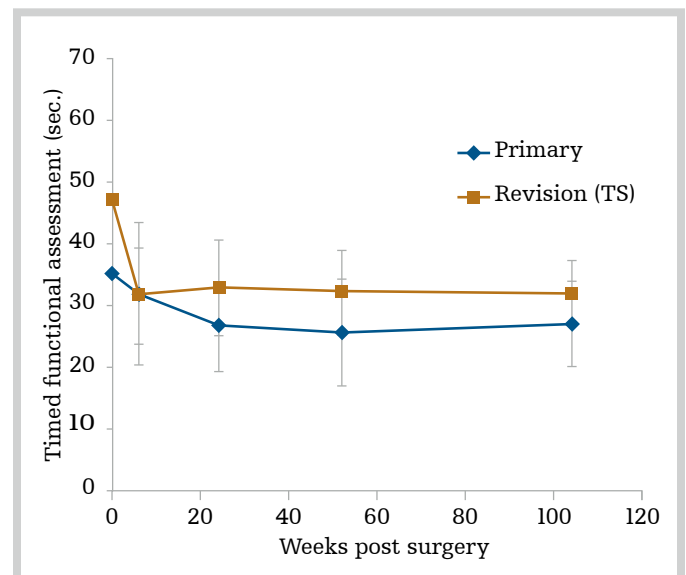
Change in Oxford knee score



Change in pain report



Change in range of motion



Change in timed functional assessment

## Accurate component positioning



Restoration of Posterior Condylar Offset (PCO) and Joint Line (JL) in revision TKA

### Study

Optimizing Posterior Condylar Offset and Joint Line Restoration in Revision Total Knee Arthroplasty Using a Contemporary Implant System

### Authors

Samson, Anthony, J., FRACS, FAOrthoA ; Hamilton, David, F., PhD; Loh, Brian, FRACS, FAOrthA; MacPherson, Gavin, FRCS (Ed); Burnett, Richard, FRCS (Ed)

### Publication

Techniques in Orthopaedics, May 2018, page 1-4

### Goal of trial

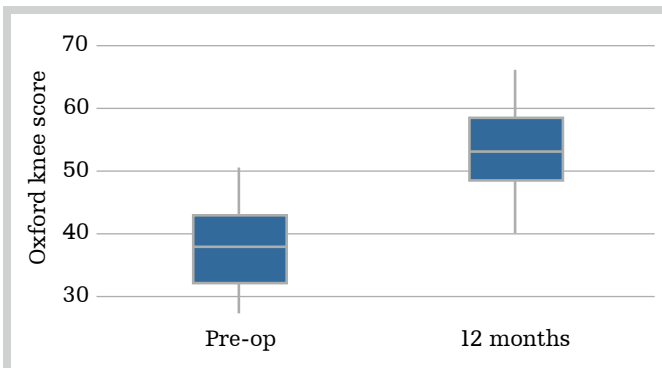
To present the surgical technique for the Triathlon TS system that has been developed and utilized at Edinburgh Royal Infirmary and to describe their focus on JL restoration and PCO through evaluation in Triathlon TS procedures performed with this philosophy.

### Materials and methods

Prospective data were collected for rTKA to Triathlon TS implant from 2011 to 2015 using the described operative technique. Pre- and postoperative radiographs were reviewed to evaluate JL and PCO ratio. Functional outcomes and satisfaction reported preoperatively and 12 months postoperatively.

### Results

Twenty-nine patients with an average age of 72.9. JL ratio reflected a statistically significant change preoperative to postoperative of 0.06. PCO ratio reflecting a statistically significant change of 0.15.



Oxford knee score pre- and post-surgery:  
Difference in pre-operative and 12 months post-operative Oxford knee scores.

### Conclusion

The technique of short cemented stems allows femoral flexion and posterior translation thereby increasing the PCO while maintaining JL. The data demonstrates a significant improvement in OKS and very high patient satisfaction scores at 1 year.

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## Joint Replacement

Prior to 2018, any X3 data published included product manufactured using compression molding consolidation and gas plasma sterilization. In 2018, Stryker added ram extrusion consolidation and EtO sterilization capabilities to the X3 manufacturing process.

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

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