Triathlon Tritanium® Total Knee System
Clinical evidence
Executive summary

Cemented Total Knee Arthroplasty (TKA) has been the gold standard in knee arthroplasty for many years. Despite its long history, it is not the ideal solution for all TKA candidates.¹ In a current concepts review, Dalury stated the theoretical advantages of cementless TKA include the potential to preserve bone stock, avoid cement debris, and achieve lasting, biological fixation of the implant to the bone.² In this clinical and economic summary, we will review the clinical outcomes, implant fixation and cost effectiveness of the Triathlon Tritanium Total Knee System.

Clinical outcomes of the Triathlon Tritanium Knee System

Intra-op

- Similar blood loss
- Shorter OR time

Early post-op

- Similar pain reduction
- Faster return to function
- Improved early satisfaction

Short to mid-term outcomes

- Excellent 2-5 year implant survivorship

Figure 1. Favorable intra-operative, early post-operative and short to mid-term outcomes with Triathlon Tritanium Total Knee System
Triathlon Tritanium
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Introduction

The introduction of bone cement (polymethylmethacrylate, PMMA) in the 1960s played a significant role in the success of joint replacement procedures.\(^3\) Cemented stem fixation in Total Hip Arthroplasty (THA) became widely used in young and old patients and for both primary and revision procedures. Inconsistent results were seen with different implant designs and cement techniques that were more common than previously expected.\(^4\) Cementless THA has grown in popularity in many parts of the world.\(^7-9\) due to its relative ease and efficiency in implantation,\(^6\) and for meeting the need for biologic fixation to decrease aseptic loosening.\(^5\)

The need for TKA in younger, heavier and more active patients has been steadily increasing over the years.\(^10\) Due to a higher risk of revision seen in this challenging group of patients,\(^11\) An implant design that allows for initial biologic fixation to help avoid aseptic loosening and provide long term implant survivorship,\(^12\) as previously seen with cementless THA, may help address the changing TKA patient demographic.\(^13\)

The failure of early generations of cementless TKA implant designs, while all shown to be correctable, has led to the limited acceptance of this fixation method.\(^14,15\) However, there is a renewed interest in cementless TKA with improvements in cementless technology and the availability of new biomaterials to help promote biologic fixation for better implant longevity.\(^14\) Advantages of cementless TKA that have been shown in the literature include: shorter surgical times\(^21,22,25,26\), comparable blood loss\(^21,24\) and pain relief\(^27\), improved patient satisfaction and outcomes and potential long-term implant survivorship leading to potential cost-savings without the potential risks of hypersensitivity reactions.\(^16-18\)

Triathlon Tritanium TKA combines the kinematics of Triathlon with the latest in highly porous biologic fixation technology. The innovation behind Tritanium Tibial Baseplate and Metal-Backed Patella components are enabled by Stryker’s proprietary AMagine\(^{TM}\) Additive Manufacturing and SOMA- Stryker’s Orthopedic Modeling and Analytics technology. The Triathlon Tritanium cementless TKA implant was introduced with otherwise similar design features as its cemented counterpart, which has demonstrated over 10 years of good track record.\(^12\)

Clinical outcomes following TKA are critical in assessing an implant’s performance. The introduction of highly porous surfaces that promote biologic fixation has shown encouraging results and has led to a renewed interest in cementless fixation.\(^12\) But concerns of blood loss, prolonged or persistent pain, patient satisfaction and limited long-term survivorship and outcomes data with some cementless TKA implant designs persist.\(^12\)

Compared to the cemented Triathlon TKA system that has proven long-term survivorship and excellent clinical outcomes since it became available over a decade ago, the Triathlon Tritanium cementless TKA shows favorable intraoperative outcomes (significantly shorter tourniquet\(^{25}\) and OR time\(^{21,22,25,56}\), and similar blood loss\(^{21,24}\)), and early post-operative outcomes, (similar pain reduction\(^{27}\), faster return to function\(^{22}\) and improved patient satisfaction\(^{22}\)). Encouraging early and mid-term implant survivorship and good clinical and radiographic outcomes have also been reported in clinical studies.\(^{26-28}\)
Intra-operative and early post-operative clinical outcomes

In a prospective, randomized controlled trial (RCT), Nam and colleagues compared groups that were implanted with a cemented Triathlon cruciate retaining (CR) TKA or a cementless peri-apatite (PA) beaded Triathlon femoral component and Tritanium tibial baseplate; the patella was not resurfaced in either cohort. All patients were permitted to be full weight bearing, start range of motion as tolerated and ambulated on the day of surgery. One hundred twenty (56 cemented and 64 cementless) were available for 2-year follow-up. No significant difference was noted in estimated blood loss despite pneumatic tourniquet used only in the cemented cohort. Total operative time was significantly shorter in the cementless compared to the cemented cohort (Table 1).

Table 1: Comparison of intra-op and perioperative variables between cemented and cementless cohorts

<table>
<thead>
<tr>
<th></th>
<th>Cemented (n=65)</th>
<th>Cementless (n=76)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operative time (min)</td>
<td>93.7 ± 16.7</td>
<td>82.1 ± 16.6</td>
<td>0.001</td>
</tr>
<tr>
<td>Estimated Blood Loss (mL)</td>
<td>185.2 + 134.9</td>
<td>183.3 + 146.7</td>
<td>0.9</td>
</tr>
<tr>
<td>Preoperative Hemoglobin (g/dL)</td>
<td>13.6 + 1.3</td>
<td>14.2 + 1.4</td>
<td>0.01</td>
</tr>
<tr>
<td>Postoperative Hemoglobin (g/dL)</td>
<td>11.1 + 1.2</td>
<td>11.6 + 1.4</td>
<td>0.03</td>
</tr>
<tr>
<td>Change in Hemoglobin (g/dL)</td>
<td>-2.5 ± 0.9</td>
<td>-2.6 ± 1.4</td>
<td>0.5</td>
</tr>
</tbody>
</table>

There was no difference in post-operative pain at 4 to 6-week follow-up and no difference in Oxford Knee Score (OKS), Knee Society Score (KSS - pain and function), Forgotten Joint Score (FJS) between both cohorts at all post-operative timepoints. One revision due to periprosthetic infection was reported in the cemented cohort and no revisions were reported in the cementless cohort. In addition, radiographic review showed no evidence of component loosening or subsidence in either group.

A faster return to function and improved early patient satisfaction was seen by Sharpe and colleagues (ISTA, 2018) when comparing cementless versus cemented TKA in a prospective, non-randomized, multicenter study. Patients on the cementless cohort (379 knees in 319 patients) received the Triathlon Tritanium Tibial Baseplate and Metal-Backed Patella with Triathlon PA femoral component while the comparator (146 knees in 133 patients) received the cemented Triathlon Total Knee System. OKS, new American Knee Society Score (KSS-2011), and Short Form 12 (SF-12) were collected through the 1-year postoperative follow-up. Their findings as presented on Figures 2 and 3 below, show that while cementless and cemented fixation provided similar positive outcomes at one year, cementless TKA may provide faster return to function, corresponding to increased patient satisfaction in the early postoperative period.

Figure 2. KSS-2011 Function Subscales
Improved early clinical outcomes, shorter tourniquet time with cementless TKA and similar blood loss between cementless and cemented TKA was reported by Miller, et al. in a retrospective matched case-control study of 400 primary TKAs where 200 patients implanted with a Triathlon PA beaded femoral component, posterior stabilized (PS) Triathlon Tritanium Tibial Baseplate and a cementless patellar component were compared to a matched cohort of 200 patients from a prospective total joint registry, implanted with a cemented TKA component of the same design.24 Cohorts were matched by age, BMI and pre-operative KSS. The mean follow-up in the cementless group was 2.4 years (range 2-3.5 years) and in the cemented group was 5.3 years (range 2-10.9 years). Blood loss was not significantly different between cohorts (355 ml, SD=276.1 versus 557 ml, SD=409.1, p=0.27).24 Patients in the cementless cohort showed better improvement in their clinical outcome scores at 2 years (Table 2).24 A single case of aseptic tibial loosening was reported in the cementless group while 5 cases of aseptic loosening were reported in the cemented group (0.5% vs 2.5% p=0.09).24

**Table 2: Comparison of Outcome Scores in Matched Cementless vs Cemented TKA.**

<table>
<thead>
<tr>
<th>Outcome Score</th>
<th>Cemented TKA</th>
<th>Cementless TKA</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>KSS function score</td>
<td>70.2 ± 22.3</td>
<td>76.0 ± 20.4</td>
<td>.016</td>
</tr>
<tr>
<td>Change in function score</td>
<td>26.04 ± 26.6</td>
<td>35.6 (±19.8)</td>
<td>.0014</td>
</tr>
<tr>
<td>KSS knee score</td>
<td>91.6 ± 9.8</td>
<td>94.1 ± 6.1</td>
<td>.0076</td>
</tr>
<tr>
<td>Change in knee score</td>
<td>52.4 ± 16.7</td>
<td>53.8 ± 13.8</td>
<td>.385</td>
</tr>
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</table>
Favorable early to mid-term clinical outcomes and survivorship

Since Triathlon Tritanium Tibial Baseplate was launched in 2013, favorable early to mid-term performance of this device is starting to be generated and published from multiple centers.

Cohen, et al. published results of their prospective study of 72 cementless TKA cases (Triathlon cementless cruciate-retaining (CR) and all patellae were resurfaced using the Tritanium Metal-Backed Patella) compared to an age and gender matched cohort of 70 cemented TKA cases performed by a single surgeon. They reported “biologic fixation achieved in 100% of patients” with improved OKS, KSS functional and objective scores at 3-year follow-up. After a mean follow-up of 37 months, no aseptic loosening or implant migration was reported.

Buzhardt et al. (2017) reported similar findings of good fixation and short-term clinical results with the Triathlon Tritanium Tibial Baseplate including PS femoral component and PA beaded patella in 100 patients. All patients achieved good radiographic fixation and stability of the tibial baseplate. Knee flexion improved from a mean of 105.8 degrees at pre-op to 117.9 degrees at latest follow-up. KSS was also reported to have significantly improved in all patients. At a mean follow-up of 24.8 months (range 15 to 33) with no cases of aseptic loosening reported.

In a large series comparing 2 cementless implants: PA beaded (805 patients) and highly porous titanium-tibia and patella (219 patients), Harwin, et al., compared survivorship, KSS, range of motion (ROM), complications and radiographic findings between the two groups and found that at a mean follow-up of 4.4 years (range 2-9 years), all cause implant survivorship was 99.5% for both groups. No significant differences noted in pain, function and range of motion for either group. Complication rate and number of revisions were also similar in both cohorts.

Bhowmik-Stoker and colleagues (WAC, 2018) shared the results of their study looking at 2-4 year clinical performance of the Triathlon Tritanium Tibial Baseplate in a large retrospectively reviewed cohort of 708 TKAs to assess survivorship, functional and radiographic outcomes. Their findings show that at latest follow-up, the cementless Tritanium Tibial Baseplatedemonstrated 99% survivorship (CI: 0.997 to 0.983) and excellent post-operative functional outcomes. Radiographic review did not show any progressive radioluencies, loosening or component subsidence.

Table 3: Triathlon Tritanium TKA 2-4-year survivorship

<table>
<thead>
<tr>
<th>Survivorship</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>100% at 2 years</td>
<td>Buzhardt et al.</td>
</tr>
<tr>
<td>100% at 3 years</td>
<td>Cohen et al.</td>
</tr>
<tr>
<td>99.5% at 4 years</td>
<td>Harwin et al.</td>
</tr>
<tr>
<td>99% at 4 years</td>
<td>Bhowmic-Stoker, et al.</td>
</tr>
</tbody>
</table>

These studies provide encouraging intra-operative, early post-operative, early to mid-term performance of the Triathlon Tritanium TKA system. In addition, these encouraging clinical outcomes are seen in CR, PS components, regardless of whether patella resurfacing was performed or not.
Young and active patients

Age can be a major factor that affects the outcome of primary TKA. Various national joint replacement registries have shown that the revision rate increases with decreasing age.\textsuperscript{7,8,30} Aseptic loosening and instability were identified as reasons for revision in younger patients due to their higher activity level leading to greater stress on the implant.\textsuperscript{32} One study reported 4.7x higher risk of aseptic revision within one year of TKA in patients less than 50 years of age.\textsuperscript{33}

Mont and colleagues reported 100% survivorship in patients <50 years of age undergoing cementless primary TKA at a single high-volume institution. 29 patients (31 knees), with a mean age of 45 years (range, 34-49 years) received a PA beaded femoral component (PS) and cobalt chrome tibial baseplate or a Triathlon Tritanium Tibial Baseplate when it became available; patellae were resurfaced.\textsuperscript{34} At a mean 4-year follow-up (range, 2 to 6 years), no failures or revision surgeries were performed, no radiographic evidence of component loosening or progressive radiolucency was reported.\textsuperscript{34} Patients also demonstrated excellent functional outcomes scores and ROM.\textsuperscript{34}

Triathlon Tritanium TKA has demonstrated excellent survivorship, functional outcomes and satisfaction in both young\textsuperscript{34} and elderly\textsuperscript{35} patients alike. This versatility should help the orthopedic surgeon address some of the challenges that have been identified with both age groups.

Patients with BMI 30-40

Obesity affects about 35% of the US population and has been steadily increasing over the years.\textsuperscript{36} The increased prevalence of obesity has been linked to the rapidly increasing demand for joint arthroplasty procedures, especially TKA.\textsuperscript{37} In 1995, forty-two percent of patients who underwent TKA were considered obese and in 2005, this number increased to 60%. This presents a challenge as TKA in the morbidly obese has been associated with greater peri-operative complications.\textsuperscript{36}

In a study of over 5000 primary TKAs implanted using cemented components, patients with BMI ≥35 kg/m\textsuperscript{2} were found to have an almost two times greater risk for aseptic tibial component failure.\textsuperscript{38} Cemented TKAs also showed an increase in failure rates due to aseptic loosening in obese patients despite well-aligned knees.\textsuperscript{36} The following studies offer data that demonstrate that cementless TKA may be a good option in the obese patient.

Sharpe and colleagues compared outcomes and implant survivorship of cementless TKA between two groups of patients stratified by BMI in a multicenter, prospective study. Cementless TKA patients were stratified based on body mass index (BMI): < 30 kg/m\textsuperscript{2} (non-obese) or BMI 30 to < 40 kg/m\textsuperscript{2} (obese). OKS, KSS-2011, SF-12 and SF-6D transformed health utility scores were collected through 2 years.\textsuperscript{39} An interesting finding was that in the obese cohort,

![Figure 4. Cementless Cohort KSS-2011 Functional Score by BMI](image-url)
patients reported higher satisfaction scores at the 6th post-operative week, experienced a significant improvement in function as early as six weeks postop which was sustained through two years of follow-up. No statistically significant difference in adverse events or implant survivorship were seen between the cemented and cementless groups.39

In a retrospective study comparing cemented versus cementless primary TKA with a PS design in morbidly obese (BMI ≥40) patients, Sinicrope, and colleagues extracted demographic, clinical, surgical, radiographic, post-operative complications and survivorship in 193 patients. At a minimum follow-up of 5-years, five failures requiring revisions were reported in the cementless group including one for aseptic tibial loosening (0.9%), while 22 failures requiring revisions were reported in the cemented group, including 16 cases of aseptic loosening (18.8%).40 A statistically significant difference in survivorship (p=0.02) was noted with aseptic loosening as the endpoint; 99.1% implant survivorship in the cementless group versus 88.2% in the cemented cohort at 8 years (Figure 6). These results led the authors to conclude that “the use of cementless TKA in morbidly obese patients with the potential of durable long-term biologic fixation and improved survivorship appears to be a promising alternative to mechanical cement fixation.”44

Harwin, et al. were able to show no significant difference in component survivorship when comparing patients of varying BMI (less than 30 kg, 30-40 kg/m2, 40-50 kg/m2). They reported 99% survivorship (CI:0.997 to 0.983) at mean 27 months follow-up in 708 cementless TKAs using Triathlon Tritanium.41

**Patients with rheumatoid arthritis**

Rheumatoid arthritis (RA) is a systemic inflammatory disease that is characterized by chronic inflammation and progressive deterioration of joint function resulting in pain and disability.42 In 2005, RA was estimated to affect 1.3 million adults in the US.43 TKA is a treatment option in patients with RA but can be challenging due higher incidence of poor bone quality, synovitis and disuse muscular atrophy. In this sub-set of patients, cemented TKA is the usual recommended approach but only a limited number of studies that have evaluated the safety and efficacy of cementless TKA in patients with RA.

One hundred twenty-two patients (126 TKAs) diagnosed with RA were enrolled by Patel, et al. in a study to investigate implant survivorship and clinical outcomes. Patients were not excluded because of subjective view of poor bone stock. All patients were implanted with a cementless, beaded, PA beaded femoral component and CoCr tibial baseplate. Patella resurfacing was done on all patients using PA-coated patella. From June 2013 and onwards, a Triathlon Tritanium Tibial Baseplate was used, and patellae were resurfaced with a highly porous, coated, metal-backed prosthesis.44 At a mean follow-up of 4 years (range: 2-8 years), excellent implant survivorship was reported (99.2%) in patients with RA. Clinical and patient reported outcomes at final follow-up were excellent with no surgical complications reported. Radiographic review revealed no radiolucency or loosening, although one patient was revised due to tibial baseplate subsidence. This study has demonstrated that cementless TKA may be an option for patients with RA.44

![Figure 5. Kaplan-Meier survival curve of primary TKA in morbidly obese patients with aseptic loosening as the endpoint.](image-url)
Radiostereometric analysis (RSA)

Radiostereometric analysis (RSA) is an accurate 3D imaging technique that uses two simultaneous calibrated radiographs to precisely monitor changes in implant position over time. Implant migration over the first two post-operative years has been shown to be predictive of aseptic loosening and migration that is less than 0.2 mm in the second-year post-operative period indicates stable fixation. RSA allows prediction of loosening with small sample sizes and is being advocated as an important tool for introducing new and innovative implants to the orthopedic market.

Initial stability

Given the importance of stable primary fixation the keel and four bullet cruciform pegs on the Tritanium baseplate were designed to reduce micromotion and lift off. The SOMA database of bone morphology was used to optimize the depth and placement of the pegs. Using RSA technology, Sporer and colleagues sought to investigate the press fit fixation of Triathlon Tritanium Tibial Baseplates and Metal-Backed Patella to the underlying bone. Twenty-seven patients were prospectively enrolled and RSA images collected at the immediate post-op, 6 weeks, 3, 6, 12 and 24-month follow-up visits. Most component migration was observed over the first six post-operative weeks, after which no significant migration between the 12 and 24-month timepoints was observed. This demonstrates the biphasic migration pattern in cementless components, characterized by a high initial migration followed by stabilization, characterized by a plateau of migration. This early migration pattern suggests the patella and tibia achieve fixation through highly porous metal.

This pattern is consistent with other longer-term RSA studies showing that stabilization of uncemented tibial components can be achieved after high initial migration.
Value of cementless TKA

As the volume of total joint replacement procedures continue to increase, the costs associated with this surgical procedure continue to be an important topic of discussion and research. While implant cost has long been a focus of the expense associated with joint arthroplasty procedures, other factors such as hospital length of stay and operating room costs have been identified to contribute significantly to the total cost of these procedures. As data continue to be generated, available evidence demonstrates that cementless TKA can be a potential cost beneficial alternative to cemented TKA.

Significantly shorter operating room (OR) time consistently seen with cementless TKA (Table 4) may be a factor affecting the cost of the procedure, considering that each minute of OR time in the US is estimated to be worth $62 (excludes surgeon and anesthesia time) and a median of £16 per minute (range, £12-£20 per minute) in the UK.

Differences in OR time between cemented and cementless TKA was used for cost comparison of these procedures by Lawrie and colleagues. When looking at cost variables including, OR time, cement, cement accessories and implants benchmarked against data from Nam et al. JOA 2017 for OR time, using institutional and market data for costs of cement, accessories and implants, they found that the actual cost of cementless and cemented TKA are similar.

The use of antibiotic impregnated bone cement is not approved for prophylactic use in primary total joint procedures. Literature suggests that “an increasing number of orthopedic surgeons in the United States have adopted the practice of routine addition of low-dose antibiotic to cement for use in primary knee arthroplasty.” The use of antibiotic bone cement potentially increases the cost of cemented TKA.

Although the cost of a cementless prosthesis is traditionally greater than that of a cemented implant, other perioperative factors such as the cost of cement, other equipment/accessories (vacuum mixer, cement injection kit), and OR times as well as short term and longer-term outcomes, should be considered when evaluating cementless TKA prostheses.

Table 4: OR time significantly shorter in cementless compared to cemented TKA

<table>
<thead>
<tr>
<th>Study</th>
<th>Cemented TKA (minutes)</th>
<th>Cementless TKA (minutes)</th>
<th>P value</th>
</tr>
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<tbody>
<tr>
<td>Nam, et al.21</td>
<td>93.7 ± 16.7</td>
<td>82.1 ± 16.6</td>
<td>0.001</td>
</tr>
<tr>
<td>Cohen, et al.25</td>
<td>45.6 ± 7.2</td>
<td>40.8 ± 6.0</td>
<td>0.0006</td>
</tr>
<tr>
<td>Chen, et al.56</td>
<td>80.0 ± 34.3</td>
<td>62.3 ± 17.4</td>
<td>NR</td>
</tr>
<tr>
<td>Sharpe, et al.22</td>
<td>83.4 ± 24.5</td>
<td>60.5 ± 19.4</td>
<td>&lt;0.0001</td>
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NR – Not Reported
Triathlon Tritanium clinical evidence

Summary

The optimal fixation method in TKA continues to be debated. The collection of studies presented here on the additive manufactured Triathlon Tritanium Knee System using new biomaterials that can help promote initial biologic fixation, that demonstrate encouraging peri-operative outcomes (comparable pain score\textsuperscript{27} and blood loss\textsuperscript{21,24}, shorter OR\textsuperscript{21,22,25,56} and tourniquet time\textsuperscript{12,24}), favorable short to mid-term implant survivorship\textsuperscript{25-28} and functional and patient reported outcomes\textsuperscript{25-28} similar to its cemented counterpart may be a good option for patients requiring TKA, especially in younger, heavier and more active patients.

The cost of cementless TKA implants continues to be an important consideration, but data from various studies are starting to show the value of shorter operating room times, fewer supplies and equipment needed and better patient outcomes.

Available publications are showing the clinical and economic benefits Triathlon Tritanium TKA system. It offers surgeons the versatility to address the needs of a challenging sub-set of patients including young\textsuperscript{34}, active and the obese.\textsuperscript{39-41}

Long-term data on implant survivorship is not yet available but encouraging RSA data on the Triathlon Tritanium baseplate and patella shows stable migration at 2 years consistent with biologic fixation of the uncemented components.\textsuperscript{50}
References


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References


49. Stryker Test Protocol 92911.


57. Lawrie, C. et al. The Cost of Implanting a Cemented vs. Cementless Total Knee Arthroplasty. Poster #72. AAHKS 2018. Dallas, TX


Joint replacement

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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