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Mid-term Safety and Efficacy Outcomes with UHMWPE Vitamin E Inserts in Total Knee Arthroplasty: Prospective Multicenter Trial

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Abstract

Abstract: Background: Ultra-High Molecular Weight Polyethylene (UHMWPE) vitamin E inserts are utilized in Total Knee Arthroplasty (TKA) due to their biocompatibility, high tensile strength, non-toxicity and anti-oxidative capacity [1]. Implants wear due to the release of microparticles, triggering osteolysis. Vitamin E UHMWPE implants have significantly reduced particle wear and osteolysis in hip replacements however, there is a scarcity of information in TKA [2, 3]. Method: This prospective multicenter study aims to evaluate the safety and efficacy of a vitamin E-blended UHMWPE knee tibial insert (3D Knee™, DJO). 171 patients were enrolled, with 122 and 54 attending their 2-year and 5-year follow-up visits, respectively. Range of Motion (ROM), knee stability, Knee Society Score (KSS), Western Ontario and McMaster Universities Osteoarthritis index (WOMAC), Oxford Knee Score (OKS), and independent radiographic analysis for lucency and alignment were reviewed during each visit. Five-year outcome data on the Stryker Triathlon knee system was utilized as a control cohort. Results: Statistically significant improvement ($p<0.0001$) in KSS, OKS, and WOMAC pain and functionality outcomes were observed at two-years and five-years, with no radiographic signs of early wear or osteolysis. Results demonstrate a high level of safety and efficacy associated with the vitamin E insert with 96% of patients satisfied at five-years and a survival rate of 97.9%. Conclusion: This is the longest prospective study that has reported both clinical and radiographic outcomes from a vitamin E-blended TKA. Given the recent shift towards vitamin E implants (up to 24%) [4] in TKA, it is important to monitor and report on the efficacy, safety, and potential value of these implants.

Keywords: Vitamin E polyethylene, total knee arthroplasty, tibial insert, 3D Knee System, 2-year follow-up and 5-year follow-up.

INTRODUCTION

Since the late 1960s, total knee arthroplasty (TKA) has become the standard of care for long term management of degenerative joint diseases. It improves quality of life, relieves pain, and restores function of the joint [5]. There is an increasing demand for long term success in TKA as younger and more active patient populations are opting for surgical management. Advancements in surgical technique, implant design, and material development have sought to improve the implants' longevity.

Throughout the development of knee implants, the incidence and reasons for failure have changed. Currently, infection is the primary cause of acute failure (within the first two-years) in TKA, while aseptic loosening and instability are the most significant reasons for failure [6]. Osteolysis has also been documented as a mechanism of early failure, with rates of 1-12% reported [7-12]. Data from extensive studies and joint replacement registries report a 2-20% incidence of revision due to polyethylene degradation or osteolysis [13-19].

The incidence of failure due to osteolysis is of concern, and recent advancements in polyethylene material and processing have aimed to mitigate this issue. Since its introduction, ultra-high molecular weight polyethylene (UHMWPE) has demonstrated great success as a low friction bearing surface in total joint replacement. First-generation implants underwent radiation cross-linking and thermal annealing to improve oxidative stability and reduce the overall incidence of osteolysis [20]. However, mechanical properties such as ductility and fracture toughness were reduced [21]. Second-generation implants have a variety of production methods that impact their mechanical properties such as temperature, method of vitamin E delivery, the concentration of vitamin E, radiation quantity and distribution, sterilization technique and

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annealing technique. The current generation of implants have sought to prevent polymer oxidation with the addition of vitamin E, while continuing cross-linking or sterilizing irradiation, and discontinuing post-irradiation thermal stabilization [22-24].

Vitamin E is a fat-soluble vitamin that functions as a powerful antioxidant and harbors anti-inflammatory properties [25]. When blended in with UHMWPE, it aids in the prevention of oxidation of the polyethylene chains [26-29], and helps to decrease wear. As wear occurs, UHMWPE particles in the size of 0.1-1 micrometers, most biologically reactive at this size, trigger local inflammatory reactions leading to osteolysis [30, 31]. Cytokines that have been detected in the periprosthetic tissues include TNF-α (tumor necrosis factor-α), IL-1β (interleukin 1 β), IL-6, IL-8, IL-11, macrophage colony-stimulating factor (CSF), granulocyte-macrophage CSF, transforming growth factor (TGF) -α and -β, and prostaglandin E2. TNF- α is the most abundantly produced cytokine and has become a widely accepted marker for inflammation [32].

In vitro studies of radiation cross-linked UHMWPE blended with vitamin E have shown improved resistance to fatigue crack propagation, enhanced mechanical properties, and 73-86% reduction in wear versus conventional UHMWPE subject to post-irradiation melting [33-35]. Additionally, wear particles from vitamin E blended UHMWPE have exhibited decreased secretion of inflammatory cytokines (TNF alpha, IL-1beta, IL-6, IL-8) and reduced macrophage activity [36]; this local inflammatory cascade is essential for the development of osteolysis. The in vitro success of UHMWPE with vitamin E in both total hip arthroplasty (THA) and total knee arthroplasty is well documented [37]. To the best of our knowledge, the only in vivo evidence of UHMWPE with vitamin E is found in THA literature. Reduced wear and significantly lower femoral head penetration are the principal findings proving its efficacy [38-41]. We identified no studies evaluating the in vivo efficacy of vitamin E blended UHMWPE inserts for TKA. Differences in forces and loading across the knee joint make it difficult to infer the success seen in THA to be applicable to TKA patients.

The DJO 3D Knee™ System is a dual-pivot TKA design. We believe this is the first clinical study evaluating UHMWPE with vitamin E in a total knee replacement of up to 5-years post-operatively. The purpose of this study is to evaluate the clinical effectiveness, radiographic monitoring, and safety of a vitamin E blended UHMWPE insert. These parameters will be evaluated through knee society scores and radiographic analysis indicating osteolysis and notable wear via presence of lucencies. Results will elucidate the safety and effectiveness of vitamin E in improving outcome measures and determine whether their continued use is justified.

METHODS

This prospective non-randomized multicenter cohort study was initiated in 2012 at seven centers across the United States to demonstrate the clinical benefits associated with the improved polyethylene. Approval was obtained from the Institutional Review Board and informed consent was acquired from all patients prior to enrolment. Vitamin E blended UHMWPE tibial inserts (DJO 3D Knee™ System) are used exclusively in this study. The 3D Knee™ System is designed with a femoral component composed of cobalt chromium alloy and an ultra-high molecular weight cross-linked vitamin E impregnated polyethylene insert that is direct compression molded.

One hundred and seventy-one patients who underwent primary TKA with the DJO 3DKnee™ System and vitamin E insert were enrolled against the following inclusion and exclusion criteria. Inclusion criteria: patients diagnosed with a degenerative joint disease (osteoarthritis or traumatic arthritis); BMI less than or equal to 40 kg/m^2; aged between 40 and 75 years at the time of consent and were not pregnant. Exclusion criteria: prior total or uni-knee arthroplasty; avascular necrosis of femoral condyles; post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, patellar dysfunction or prior patellectomy, moderate valgus, varus or flexion deformities or rheumatoid arthritis; active cancer or cancer survivor of fewer than five years (except for squamous cell or basal cell skin cancer); chronic diseases the investigator determined may interfere with patients' ability to follow protocol; currently documented substance abuser; infection within the last three months; history of muscular/neurological/vascular deficiencies compromising affected extremity; BMI greater than 40 kg/m^2; loss of ligamentous structures; subject with high levels of physical activity and is unwilling to modify levels of physical activity to commensurate with recommendations; subject with mental condition that may interfere with the subject's ability to give an informed consent or willingness to fulfill the study requirements; prisoner; pregnant, known metal material sensitivities or aged less than 40 or greater than 75. The mean age of subjects was 64.4 years and 98.2% of subjects had a primary diagnosis of osteoarthritis followed by traumatic arthritis (1.2%). Further details can be found within Table 1.

Patients were assessed post-operatively at six months and annually thereafter up to ten- years. The two- and five-year results are presented below, and baseline demographics can be found within Table 2. Assessments include range of motion (ROM), knee stability, Knee Society Score (KSS), Western Ontario and McMaster Universities Osteoarthritis index (WOMAC), Oxford Knee Score (OKS), and independent radiographic analysis for lucency and alignment.

The KSS is a two-part assessment. The first part measures pain, flexion contracture, extension lag, total range of flexion, alignment, anteroposterior stability, and mediolateral stability. The second part assesses knee function and evaluates walking, the ability to use stairs, and how frequently walking aids are used. Each section is scored out of 100 and has the following grading scale: excellent (≥90), good (89–60), fair (59–35), or poor (<35) [42]. The WOMAC scale measures three dimensions: stiffness, pain, and physical function. Each section has a subscale of 8, 20, and 68, respectively [43]. On a scale of 0 to 96, higher scores represent more pain, while lower scores represent less pain. The OKS is an assessment of an individual's daily living and how affected they are by pain [44]. On a scale of 0 to 48, higher scores represent less pain, while lower scores represent more pain. Furthermore, radiograph assessments were performed to determine if there were any notable differences in device wear and osteolysis.

Statistical and Survival Analysis

Patient demographics, comorbidities, ROM, and knee function scores were compared via T-test or Chi-squared test. Survivorship was analyzed using the Kaplan-Meier method at two-years and five-years post-implantation. The following assumptions for the Kaplan-Meier method were closely adhered to. First, patients who are censored have the same survival prospects compared to those who continue to be followed. Second, the survival probabilities are the same for subjects recruited at any point during the study. Third, the event occurs at the specified time [45].

An outside independent reviewer analyzed post-operative follow-up radiographs for osteolysis and alignment (using the knee society total knee arthroplasty roentgenographic evaluation and scoring system). Any radiolucency greater than 1 mm was documented along with its location. A subject was considered a radiographic failure if there was a complete radiolucent line >2 mm wide at the bone/cement interface, a >3-degree migration (shift) of the component or a >3 mm migration (shift) of the component. Criteria for ROM deformity were as follows: a mild deformity is in the range of 0-10 degrees of alignment, neutral being 5-7 degrees, a moderate valgus deformity is 10-20 degrees, and a moderate varus is defined as 0 to -10 degrees.

Control cohort

Five-year outcome data on the Triathlon total knee system (Stryker Orthopedics, Mahwah, NJ, USA) was utilized as a control cohort [46]. Between 2006 and 2007, data were prospectively recorded for consecutive patients undergoing Triathlon TKAs performed or supervised by seven consultant surgeons at a single orthopedic teaching hospital. A total of 377 patients (462 procedures) were enrolled and returned for follow-up visits at six-months, one-year, and five-years post-implantation. Two hundred and eighty-nine (62.6%) patients were female. The mean age at the time of surgery was 68.7 years, the mean length of follow-up was 68.3 months (range 58-78) and 232 patients (50.2%) were right sided. Indications for surgery included osteoarthritis (97.9%), rheumatoid arthritis (5.8%), avascular necrosis (3.5%) and trauma/ previous high tibial osteotomy (2.8%). All patients received a Triathlon single-radius implant which contains X3, Stryker's highly cross-linked polyethylene insert. At five-years, patient reported outcome measures (PROMs) were available on 369 TKA's, with a response rate of 79%. The main outcomes under review were survivorship, adverse events and patient reported outcomes. Statistical analysis was performed using SPSS Software (T-Test and ANOVA) and Kaplan Meier for survivorship.

RESULTS

Patient Reported Outcome Measures

Patients demonstrated post-operative improvement at both two- and five-year time intervals. Patients had improved scores for knee pain and functionality, demonstrated by the utilization of the Knee Society Score, Oxford Knee Score, and WOMAC endpoint metrics. The baseline scores were 48.8 and 21.0 for the KSS and OKS, respectively. Two-year follow-up results revealed an average increase of 36.0 from baseline for the KSS and 19.4 for OKS. With regards to WOMAC, the score decreased from 49.1 to 11.9. All scores were statically significant with $p<0.0001$ (Table 3). The same pattern was found at 5-years, with an average increase of 18.8 for OKS and 40.3 for KSS. A decrease from 49.1 to 8.7 was observed for the WOMAC Score. All scores were statistically significant with $p<0.0001$ (Table 4). Patient scores increased significantly by the two-year follow up and retained improvement at the five-year evaluation demonstrating considerable improvement in knee quality and function following TKA with the 3D Knee™ system and vitamin E insert.

For the Triathlon knee system, the Oxford Knee score improved by a mean of 17.4 by one-year post-implantation from baseline (41.3), giving a score of 23.9; this was maintained through five-years. It should be highlighted that the design of the OKS survey has altered since introduction. Originally, it was charactered as a score between 12 and 60 with lower scores representing better knee pain and function. Subsequently, although the questions remain consistent, the score representation has adjusted to be between 0 and 48, with higher scores representing better function. The 3D Knee™ cohort utilized the latter method while the control cohort used the original format. This alteration justifies the significant difference in values.

For the 3D Knee™, patients' ROM was evaluated at two-years and demonstrated marked improvement in anteroposterior (AP), mediolateral (ML), alignment, flexion, flexion contracture, and extension lag with at least $p<0.05$ for all parameters (Table 5). At five-years, patients' ROM displayed statistically significant improvements compared to baseline ($p<0.05$) for ML, flexion, and flexion contracture (Table 6). Unfortunately, ROM data is not available for the Triathlon cohort and thus, a comparison cannot be provided for this outcome.

High patient satisfaction scores at both two- and five-years (Table 7) complement the standardized scores in Tables 3 and 4. Interestingly, patient satisfaction increased slightly from 95.1% at two-years to 96.0% at five-years. The control group reported a slightly lower patient satisfaction level of 88.0% at five-years.

Surgical or Post-Operative Complications

At five-years, there were 48 operative site events recorded. A breakdown of the events and their respective percentages out of 48 operative events is provided in Table 8. Out of 171 patients, three subjects (1.8%) underwent revision surgery during their study participation. One subject's initial revision surgery was due to pain, which occurred nine months after the primary surgery, leading to the tibial insert being revised. A second revision surgery in the same subject was required due to instability and occurred twelve months after the first revision surgery. During the second re-operation, the femoral component, baseplate, insert, and patella were removed. The second subject underwent revision surgery due to failed patellar fixation at three years post primary surgery, and the third, due to instability at two years post primary surgery. There have been no reported cases of catastrophic polyethylene wear or radiographic evidence of osteolysis.

During implantation of the Triathlon Knee, tibial tray repositioning was required when the cement was still wet due to internal rotation and lateralization of the tibial component for two patients (0.4%). Furthermore, early complications occurring less than 6-weeks post-implantation included 19 (4.1%) wounds with prolonged leaking, nine (1.9%) confirmed thromboembolic events, three (0.6%) cardiac events, two (0.4%) reports of cellulitis and one (0.2%) deep infection. The following late complications were reported: 12 (2.9%) cases of stiffness; 10 (2.9%) anterior knee pain; five (1.1%) deep infections and two (0.5%) periprosthetic fractures. Re-operation was required for 17 knees (3.7%), this included 12 (2.9%) manipulations under anesthetic, three (0.7%) secondary patella resurfacings, one (0.5%) open reduction and internal fixation tibia and one (0.5%) arthrolysis. At 5-years, there were eight reported failures due to infection, aseptic loosening of the tibia and instability

Radiographic Outcomes

The UHMWPE tibial insert crosslinked with vitamin E displayed positive preservation of bone with radiolucency <1 mm. Radiolucency's greater than 1 mm during postoperative follow up were reported for only two patients of the 171 enrolled (1.2%). The first patient's radiolucency was discovered at the three-year follow up, identified on the lateral femoral view in zone 4, and did not meet the criteria for a radiologic failure. The second patient's radiolucency was discovered at the two-year follow up, identified on the lateral tibial view in zone 3, and did not meet the criteria for a radiologic failure. This radiolucency was not identified on the subsequent three year follow up radiographs, and the patient was later lost to follow up at the four-year period. Neither of these patients demonstrated clinical signs of implant loosening or pain. The radiographic data suggests the vitamin E component maintained the structural integrity of the tibia and femur.

Three-hundred and thirty-six Triathlon Knee radiographs at a mean of 4.1 years were reviewed. Radiolucent lines were observed in 31 tibial components and 67 femoral components giving an actual rate of 29.2%; none of these were symptomatic, and all were believed to be associated with primary cement defects.

Survival Analysis

The Kaplan-Meier survivorship is presented within Figure 1. Implant survivorship with a 95% confidence interval was determined to be 98.7% and 97.9% at two-years and five-years, respectively. The Triathlon Kaplan-Meier analysis reported a five-year survival of 97.6%.

DISCUSSION

Osteolysis is amongst the common causes of knee implant failure [47]. Multiple efforts have been made to address osteolysis, such as optimization of surgical methods, techniques, and implant designs. Among implant designs, the incorporation of vitamin E is widely used and well-documented in hip replacements. The use of vitamin E as an antioxidant in TKA tibial inserts has gained popularity since 2012. A recent report citing 24% of tibial inserts implanted in the US in 2017 contained an antioxidant component [4]. Despite the practice of incorporating vitamin E in THA and TKA, there is a large knowledge gap in documented efficacy and outcome measures of vitamin E implants in TKAs. This case series is the first of its kind to report on the use of vitamin E impregnated tibial inserts in a unique, in-vivo setting.

There are several key strengths to this study. First, this is a novel and ongoing case series report that analyzed in vivo patient results with a UHMWPE cross linked vitamin E implant. Patient information was meticulously documented and presented through a variety of outcome scores which illustrated virtually no early evidence of osteolysis in radiographic data. The growing body of patients with a vitamin E tibial insert lends itself to in vivo studies and long-term reports on their progress, which have otherwise been sparse in the current literature. Second, although there is a theoretical advantage of vitamin E use in TKA implants, there has been a paucity of clinical data to support its widespread adoption. Finally, seven surgeons participated in this study, which reduces physician bias, creates a balanced patient base, and fortifies data reliability. A weakness of the study is the small number of patients observed at five years (54 patients) due to patient attrition. Furthermore, a disadvantage of utilizing a multi-surgeon model is the lack of quality control variables to ensure homogeneity in patient care. Finally, the inclusion of a control cohort would have been advantageous to incorporate into the initial study design to allow for an accurate and reliable comparison. Due to the lack of this attribute, results from a similar prospective clinical investigation on the Triathlon knee implant was utilized.

Although our study on the 3DKnee with UHMWPE vitamin E tibial insert occurred a few years after the Stryker Triathlon Knee study, both prospectively collected outcome data on the implant and tibial insert and the patient populations were similar with the main indication for surgery being osteoarthritis and mean age of patients falling within a similar range. Due to the differences in design, it is of paramount importance DJO continue to monitor the UHMWPE with vitamin E tibial insert to generate data on the lifetime of the device. Furthermore, in the future, we hope to adopt and incorporate national joint registries in tracking patient implants and survivorship better.

Table 1: *Participant Demographic and Baseline Characteristics*

Characteristic	**N = 171**
Race	
White	(155, 90.6%)
Black or African American	(3, 1.8%)
Asian	(0, 0%)
Puerto Rican Indian Mexican Other Declined Missing	(0, 0%) (1, 0.6%) (3, 1.8%) (6, 3.5%) (2, 1.2%) (1, 0.6%)
Sex	
Female	(101, 59.1%)
Male	(70, 40.9%)
Age (n=169)	(64.4, 7.1±SD)
Operative side	
Left	(88, 51.5%%)
Right	(83, 48.5%)
Primary Diagnosis	
Osteoarthritis Traumatic Arthritis Missing	(168, 98.2%) (2, 1.2%) (1, 0.6%)
Smoking Status	
Yes No Missing	(19, 11.1%) (151, 88.3%) (1, 0.6%)
Body Mass Index (kg/m^2; ±SD) (n=170)	(30.0 kg/m2, 4.5±SD)
Retention or sacrifice of the posterior cruciate ligament (PCL) Retained Sacrificed/Non-functional	 (133, 77.8%) (38, 22.2%)

Table 2: *Participant Demographic and Baseline Characteristics*

Characteristic	**2-years N = 122**	**5-years N = 54**
Race		
White	(115, 94.3%)	(52, 96.3%)
Black or African American	(1, 0.8%)	(2, 3.7%)
Other	(6, 4.9%)	
Sex		
Female	(73, 59.8%)	(32, 59.3%)
Male	(49, 40.2%)	(22, 40.7%)
Age (n=122)	(64.4, 8.3±SD)	(62.9, 7.5±SD)
Operative side		
Left	(61, 50.0%%)	(24, 44.4%)
Right	(61, 50.0%)	(30, 55.6%)
Primary Diagnosis		
Osteoarthritis	(122, 100%)	(54, 100%)
Smoking Status		
Yes No	(16, 13.1%) (106, 86.9%)	(3, 5.6%) (51, 94.4%)
Body Mass Index (kg/m^2; ±SD) (n=122)	(29.8 kg/m2, 4.6±SD)	(29.9 kg/m2, 4.1±SD)
Retention or sacrifice of the posterior cruciate ligament (PCL) Retained Sacrificed/Non-functional	 (90, 73.8%) (32, 26.2%)	 (35, 64.8%) (19, 35.2%)

Table 3: Baseline, 2-years Post-Op Knee Arthroplasty and Change from Baseline Scores for Primary Endpoints

Endpoint	**Pre-op Baseline**	**Score 2-years Post-Op**	**Change from Pre-Op Baseline**	**P-Value**
Knee Society Score	48.8, ±16.3 SD N=169	85.0, ±13.5 SD N=122	36.0, ±18.6 SD [95% CI 32.6 to 39.4] N=120	<0.0001
Knee Society Score (Function)	53.4, ±21.5 SD N=171	83.0, ±18.6 SD N=122	28.2, ±23.0 SD [95% CI 24.1 to 32.4] N=122	<0.0001

Oxford	21.0, ±8.0 SD N=170	41.3, ±7.5 SD N=122	19.4, ±9.3 SD [95% CI 17.7 to 21.0] N=121	<0.0001
WOMAC	49.1, ±17.3 SD N=170	11.9± 14.1 SD N=122	-35.9 ± 17.7 [95% CI -39.1 to -32.7] N=121	<0.0001

Table 4: *Baseline, 5-years Post-Op Knee Arthroplasty and Change from Baseline Scores for Primary Endpoints*

Endpoint	Baseline Scores	Score 5-years Post-Op	Change from Baseline	P-Value
Knee Society Score	48.8, ±16.3 SD N=169	87.1, ±13.7 SD N=49	40.3, ±21.8 SD [95% CI 33.9 to 46.7] N=47	<0.0001
Knee Society Score (Function)	53.4, ±21.5 SD N=171	88.7, ±18.9 SD N=49	30.9, ±24.4 SD [95% CI 23.9 to 37.9] N=49	<0.0001
Oxford	21.0, ±8.0 SD N=170	42.1, ±7.4 SD N=54	18.8, ±10.3 SD [95% CI 16.0 to 21.6] N=54	<0.0001
WOMAC	49.1, ±17.3 SD N=170	8.7, ±12.5 SD N=54	-34.7±18.4 SD [95% CI -29.7 to -39.7] N=54	<0.0001

Table 5: *Baseline, 2-years Post-Op Knee Arthroplasty and Change from Baseline ROM Metrics*

Endpoint	Baseline Scores	Score 2-years Post-Op	Change from Baseline	P-Value
ROM – AP	1.75, ±1.82 SD N=170	1.20, ±1.28 SD N=124	-0.51, ±1.47 SD [95% CI -0.78 to -0.25] N=123	0.0002
ROM – ML	2.46, ±2.69 SD N=170	1.02, ±1.14 SD N=124	-1.59, ±2.95 SD [95% CI -2.11 to -1.06] N=123	<0.0001
ROM – Alignment	6.03, ±8.30 SD N=170	2.61, ±2.55 SD N=124	-3.95, ±9.38 SD [95% CI 5.63 to -2.28] N=123	<0.0001
ROM – Flexion	108, ±19.7 SD N=170	121, ±9.13 SD N=124	12.7, ±23.4 SD [95% CI 8.53 to 16.90] N=123	<0.0001
ROM – Flexion Contracture	4.89, ±5.07 SD N=170	0.177, ±0.766 SD N=124	-4.81, ±5.17 SD [95% CI -5.74 to -3.89] N=123	<0.0001
ROM – Extension Lag	1.40, ±5.34 SD N=169	0.097, ±0.547 SD N=124	-1.17, ±5.70 SD [95% CI -2.19 to -0.15] N=122	0.0250

Table 6: *Baseline, 5-years Post-Op Knee Arthroplasty and Change from Baseline ROM Metrics*

Endpoint	Baseline Scores	Score 5-years Post-Op	Change from Baseline	P-Value
ROM – AP	1.75, ±1.82 SD N=170	1.65, ±1.61 SD N=51	-0.28, ±1.83 SD [95% CI -0.80 to 0.24] N=50	0.2846
ROM – ML	2.46, ±2.69 SD N=170	1.39, ±1.18 SD N=51	-1.52, ±3.14 SD [95% CI -2.41 to -0.63] N=50	0.0013
ROM – Alignment	6.03, ±8.30 SD N=170	2.82, ±2.51 SD N=51	-3.95, ±9.38 SD [95% CI 5.63 to -2.28] N=50	0.0870
ROM – Flexion	108, ±19.7 SD N=170	122, ±9.42 SD N=51	13.0, ±21.1 SD [95% CI 6.97 to 18.95] N=50	<0.0001
ROM – Flexion Contracture	4.89, ±5.07 SD N=170	0.196, ±0.849 SD N=51	-5.86, ±5.75 SD [95% CI -7.49 to -4.23] N=50	<0.0001
ROM – Extension Lag	1.40, ±5.34 SD N=169	0.196, ±0.849 SD N=51	-1.20, ±4.94 SD [95% CI -2.62 to -0.22] N=49	0.0945

Table 7: *Patient Satisfaction 2-years and 5-years After Knee Arthroplasty*

2-Year Patient Satisfaction (n=121)					
Question	**Mostly True**	**TRUE**	**Mostly False**	**FALSE**	
I can do most things I thought I would be able to do after the surgery	54 (44.6%)	61 (50.4%)	5 (4.1%)	1 (0.8%)	
My pain relief is as good as I expected following surgery	29 (24.0%)	80 (66.1%)	12 (9.9%)	0 (0%)	
I am happy with the results of my knee surgery	31 (25.6%)	84 (69.4%)	4 (3.3%)	2 (1.7%)	
I would have the same surgery again for the same problem	24 (19.8%)	90 (74.4%)	3 (2.5%)	4 (3.3%)	
Question	**Excellent**	**Very Good**	**Good**	**Fair**	**Poor**
Overall satisfaction with the surgery	79 (65.3%)	26 (21.5%)	10 (8.3%)	3 (2.5%)	3 (2.5%)
Overall pain relief after the surgery	71 (58.7%)	30 (24.8%)	11 (9.1%)	4 (3.3%)	5 (4.1%)
5-Year Patient Satisfaction (n=50)					
Question	**Mostly True**	**TRUE**	**Mostly False**	**FALSE**	
I can do most things I thought I would be able to do after the surgery	27 (54.0%)	21 (42.0%)	1 (2.0%)	1 (2.0%)	

My pain relief is as good as I expected following surgery	19 (38.0%)	30 (60.0%)	0 (0%)	1 (2.0%)	
I am happy with the results of my knee surgery	15 (30.0%)	32 (64.0%)	1 (2.0%)	2 (4.0%)	
I would have the same surgery again for the same problem	16 (32.0%)	31 (62.0%)	2 (4.0%)	1 (2.0%)	
Question	**Excellent**	**Very Good**	**Good**	**Fair**	**Poor**
Overall satisfaction with the surgery	33 (66.0%)	12 (24.0%)	3 (6.0%)	1 (2.0%)	1 (2.0%)
Overall pain relief after the surgery	29 (58.0%)	14 (28.0%)	3 (6.0%)	3 (6.0%)	1 (2.0%)

Table 8: Post-Operative Complications

Category	No. of Events (% of Total - 48)
Pain, Operative Joint	18 (37.5%)
Arthrofibrosis	5 (10.4%)
Edema	3 (6.3%)
Numbness	3 (6.3%)
Joint Stiffness	3 (6.3%)
Manipulation	3 (6.3%)
Fall, With or Without Injury	2 (4.2%)
Flexion Contracture	2 (4.2%)
Joint Instability	2 (4.2%)
Limited Range of Motion	2 (4.2%)
Synovitis	2 (4.2%)
Neurologic, unrelated (weakness, numbness, sciatica, paralysis, dizziness)	1 (2.1%)
Hemarthrosis	1 (2.1%)
Post-Operative Bleeding	1 (2.1%)

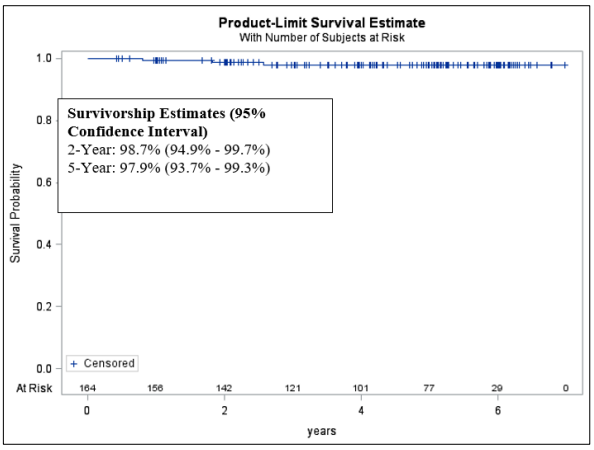

Figure 1: Kaplan Meier Survivorship with Event = Revision of Knee Implant

CONCLUSION

In conclusion, patients were successfully tracked over two- and five-years, and results were both excellent and consistent across these timepoints. The aim of the study was to demonstrate the safety and performance of the vitamin E insert which was successfully shown through five-years, with no significant findings of osteolysis and good implant survivorship. To our knowledge this is the first and longest longitudinal in vivo report on UHMWPE tibial inserts crosslinked with vitamin E. It is important to continue to monitor this patient population to obtain long-term outcomes to ensure continued efficacy of the tibial insert.

Conflict of Interest

None declared.

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