

THE IMPACT OF IMPLANT DESIGN ON HOSPITAL LENGTH OF STAY AND DISCHARGE DESTINATION EVIDENCE SUMMARY REPORT

INTRODUCTION

Total knee arthroplasty (TKA) is a successful and cost effective procedure that provides pain relief and improved function for patients with osteoarthritis of the knee.¹ Despite the globally reported success of the procedure, studies have shown that up to 20% of patients are dissatisfied with the results of TKA.²

The ATTUNE® Knee System is designed to reduce pain and improve patient satisfaction following TKA. Extensive research and science has gone into the design to address recognised industry challenges and help improve functional outcomes for patients.

Since the commercial launch in 2013, the ATTUNE Knee System has shown statistically significant improvements in multiple Patient Reported Outcome Measures (PROMs) compared to certain leading knee brands.³ Additional studies have demonstrated significant improvements in patellofemoral outcomes, including reduced anterior knee pain, compared to another leading knee brand.⁴⁻⁷ Results from several registries including the UK and Australia have also shown survivorship performance in line with the class of TKA.⁸⁻⁹

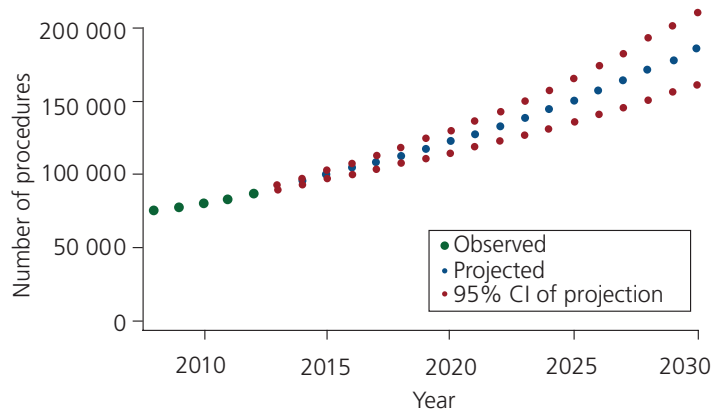


Figure 1. Projected TKA growth in the UK cited from Patel et al. 2015

Given the increasing incidence of osteoarthritis worldwide and the predicted growth of TKA procedures (figure 1), it is increasingly important for healthcare providers to demonstrate both improved clinical and economic outcomes to help minimise the total cost per procedure whilst maintaining quality of care.

Reducing length of stay (LOS) is recognised as a way to reduce the financial burden of elective orthopaedics.¹⁰ Emerging evidence suggests the ATTUNE Knee may facilitate earlier hospital discharge which could reduce resource utilisation and the cost of care.¹¹⁻¹⁶ In addition to reducing costs, decreasing LOS may positively impact a hospital's operational capacity.¹⁷

The purpose of the of this report is to summarise a series of studies that were designed to evaluate whether patients treated with the ATTUNE Knee had a shorter LOS versus a comparative device. The studies were conducted in several countries with differing healthcare systems. All the studies in this report defined LOS as the primary endpoint. An additional study by Clement et al., (2016) conducted in Scotland also observed a statistically significant 1.2 days reduction in LOS versus another leading knee system but is not included in this report as LOS was not the primary outcome.¹⁵

STATISTICAL REVIEW SUMMARY

There are several important aspects of this report that limit the comparability of results among the studies. Due to factors within each countries' healthcare systems, baseline mean LOS will vary, which limits direct comparison of the means and differences between studies. Statistical analyses also differ by study as they controlled for different factors because of the feasibility of data collection at each site, which further limits the comparability of the results. This review however, is not intended to aggregate the data, it is to report each study in isolation and highlight the reductions in LOS seen in multiple healthcare settings following the adoption of the ATTUNE Knee.

STUDY 1: COMPARATIVE ANALYSIS OF HOSPITAL LENGTH OF STAY AND DISCHARGE STATUS OF TWO CONTEMPORARY PRIMARY TOTAL KNEE SYSTEMS.¹¹

Sample size and comparator: ATTUNE Knee n=1,178; Triathlon™ (Stryker) Knee n=5,707.

Study period and design: January 2013 to December 2014. Retrospective analysis of the Premier Perspective™ Database.

Data Source: Premier Perspective™ Database. Based on data from 38 US hospitals.

Results summary: The ATTUNE Knee patients had a 0.19 day shorter LOS (2.94 vs 3.13 days p<0.001) and a 39% lower adjusted odds of discharge to a skilled nursing facility compared to patients who received a Triathlon™ TKA. Sensitivity analyses suggest that the effect on LOS could not be explained by patient factors including age, insurance and marital status.

Conclusion: Patients who received the ATTUNE Knee had a slightly shorter LOS compared to patients who received the Triathlon™ Knee.

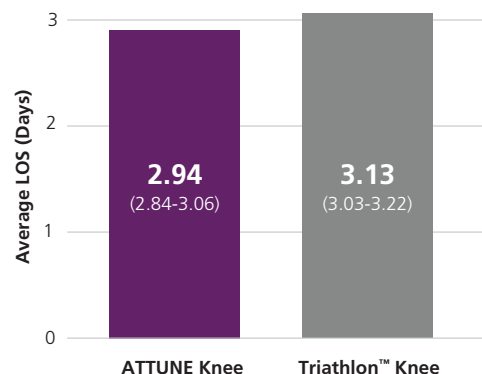


Figure 2. Adjusted Hospital Length of Stay, Mean Days (95% CI)

STUDY 2: ECONOMIC EFFECTIVENESS OF THE ATTUNE® KNEE SYSTEM. ANALYSIS OF REAL WORLD HOSPITAL LENGTH OF STAY AND INCIDENCE OF EARLY COMPLICATIONS.¹²

Sample size and comparator: ATTUNE Knee n=238; SIGMA® Knee (Depuy Synthes) n=238; Columbus® (bBraun) Knee n=149.

Study period and design: April 2014 to April 2015. Single centre retrospective cohort study.

Data Source: University Teaching Hospital, England, UK.

Results summary: Patients implanted with the ATTUNE Knee reported a 0.8 day (95% CI 0.1-1.9, p=0.0197) reduction in mean LOS compared patients receiving the SIGMA Knee and a 1 day (95% CI 0.1-1.5, p=0.0212) reduction in mean LOS compared to patients receiving the Columbus® knee (shown in Figure 3). No statistically significant differences in patient or surgical characteristics were reported between the groups; with the exception of age between the ATTUNE Knee and the Columbus® Knee cohorts.

Conclusion: Patients treated with an ATTUNE Knee experienced significantly shorter LOS compared to the patients implanted with either a SIGMA Knee or Columbus® knee.

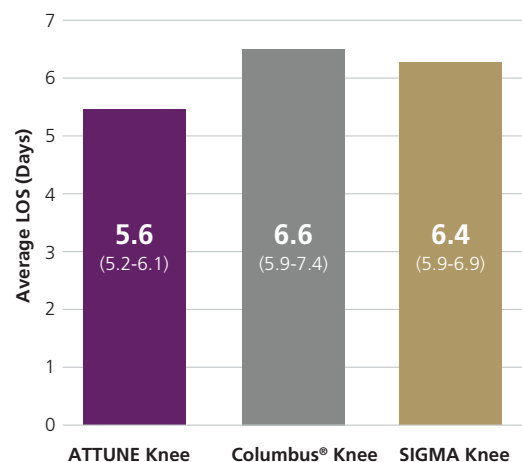


Figure 3. Adjusted Hospital Length of Stay, Mean Days (95% CI)

STUDY 3: ECONOMIC EFFECTIVENESS OF THE ATTUNE® KNEE SYSTEM: ANALYSIS OF REAL WORLD HOSPITAL LENGTH OF STAY IN THE GERMAN HEALTHCARE SYSTEM.¹³

Sample size and comparator: ATTUNE Knee n=85; LCS™ Knee (Depuy Synthes) n=85.

Study period and design: July 2008 to October 2016. Single centre, single surgeon retrospective chart review.

Data source: Private German Hospital.

Results: The unadjusted mean LOS for patients implanted with the ATTUNE Knee was 2.1 days (95% CI 1.6-2.7, p < 0.001) shorter than patients implanted with the LCS Knee (shown in Figure 4). Due to the duration of data extraction and the possible impact of longitudinal change on LOS, a sensitivity analysis was performed to understand its impact on the reported LOS reduction. The adjusted LOS reduction in patients implanted with the ATTUNE Knee was 0.8 days (p<0.01) which is still statistically significant.

Conclusion: Comparing two cohorts with similar demographic factors the patients implanted with the ATTUNE Knee demonstrated a shorter LOS compared to patients treated with the LCS Knee.

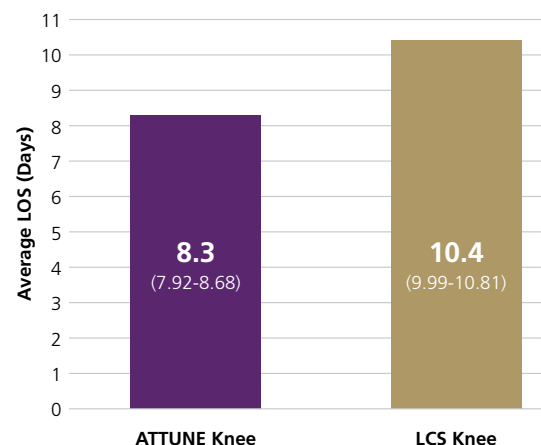


Figure 4. Unadjusted Hospital Length of Stay Mean Days (95% CI)

STUDY 4: ECONOMIC EFFECTIVENESS OF THE ATTUNE® KNEE SYSTEM: ANALYSIS OF REAL WORLD HOSPITAL LENGTH OF STAY IN AN ITALIAN HOSPITAL.¹⁴

Sample size and comparator: ATTUNE Knee n=100; SIGMA Knee n=100.

Study period and design: April 2013 to April 2015. Single centre, single surgeon retrospective chart review.

Data source: Private Italian Hospital.

Results summary: Patients treated with the ATTUNE Knee reported a 4.4 day (CI 3.5-4.5, $p < 0.0001$) reduction in mean LOS compared to SIGMA Knee patients. ATTUNE Knee mean LOS was 9.7 days versus the SIGMA mean of 13.7 as shown in Figure 5. There were no significant differences in reported patient characteristics between the groups.

Conclusion: Statistically significant differences were noted in the LOS between the two groups with ATTUNE Knee patients demonstrating a reduced LOS compared to patients treated with SIGMA Knee.

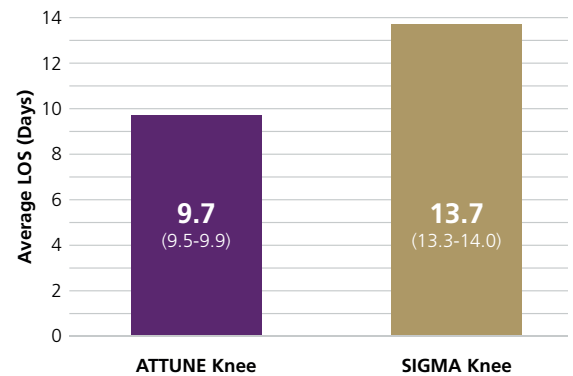


Figure 5. Adjusted Hospital Length of Stay Mean Days (95% CI)

STUDY 5: COMPARATIVE ANALYSIS INVESTIGATING THE IMPACT OF IMPLANT DESIGN ON HOSPITAL LENGTH OF STAY AND DISCHARGE DESTINATION IN A DUTCH HOSPITAL WITH AN ESTABLISHED ENHANCED RECOVERY PROGRAM.¹⁶

Sample size and comparator: ATTUNE Knee n=100; SIGMA Knee n=100.

Study period and design: January 2015 to October 2017. Single centre, single surgeon retrospective chart review.

Data source: Public Netherlands Hospital.

Results summary: The study found patients treated with the ATTUNE Knee reported reductions in adjusted mean LOS ($p < 0.01$). The adjusted means in the ATTUNE Knee and SIGMA Knee groups were 2.76 days (95% CI 2.45-3.10) and 3.43 days (95% CI 3.08-3.81) respectively. Patients discharged to a rehabilitation centre was also lower in the ATTUNE Knee group: 4.4% vs 11.4%. No statistical differences in patient demographics were found between the two treatment groups.

Conclusions: ATTUNE Knee patients in this study demonstrated a 0.67 day adjusted mean LOS reduction compared to patients treated with the SIGMA Knee. These improvements were achieved in a hospital environment with an established enhanced recovery program and a low baseline LOS.

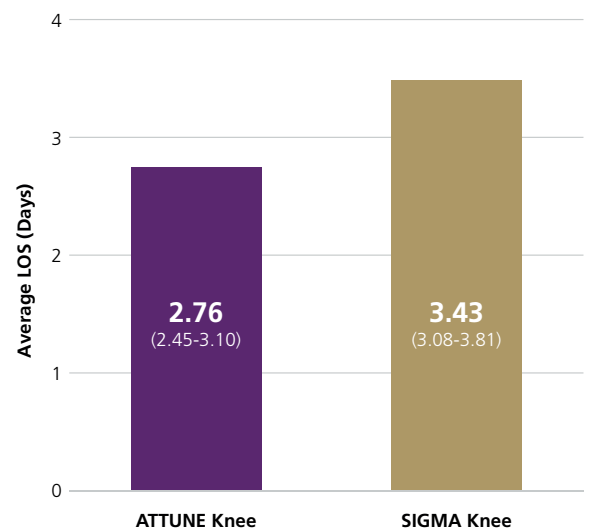


Figure 6: Adjusted Hospital Length of Stay Mean Days (95% CI)

SUMMARY

The results of these studies, demonstrate that the ATTUNE Knee may positively impact patient LOS following TKA. Whilst it is important to acknowledge that there are many factors that can contribute to differences in LOS, the data summarised above suggests that implant design could be an important factor to consider. This evidence supports a potential association between implant design and earlier hospital discharge, which could translate into cost reductions and bed capacity gains.

The individual study summaries presented in this document report key results and conclusions. Please see the referenced article or poster for full study details.

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Table KT22 Cumulative Percent Revision of Minimally Stabilised Primary Total Knee Replacement by Revision (Primary Diagnosis OA)

Revision	N	1 Yr	3 Yr	5 Yr	10 Yr	15 Yr	18 Yr	
Controlled	4712	16.96%	0.8 (0.6, 0.9)	2.2 (2.1, 2.3)	2.9 (2.9, 3.0)	4.5 (4.4, 4.6)	6.3 (6.2, 6.9)	6.9 (6.5, 7.3)
Concurrent	4791	16.92%	1.2 (1.1, 1.3)	3.2 (3.1, 3.3)	4.2 (4.1, 4.4)	6.1 (6.0, 6.3)	8.3 (8.1, 8.9)	9.8 (9.3, 10.3)
Hybrid	3864	18.87%	0.8 (0.6, 0.9)	2.3 (2.2, 2.4)	3.1 (3.0, 3.2)	4.6 (4.4, 4.7)	6.4 (6.2, 6.7)	7.9 (7.4, 8.2)
TOTAL	13511	17.95%						

Table KT23 Cumulative Percent Revision of Posterior Stabilised Primary Total Knee Replacement by Revision (Primary Diagnosis OA)

Revision	N	1 Yr	3 Yr	5 Yr	10 Yr	15 Yr	18 Yr	
Controlled	4714	14.07%	1.1 (1.1, 1.2)	2.9 (2.8, 3.0)	3.9 (3.8, 4.0)	5.9 (5.8, 6.1)	7.9 (7.8, 8.2)	8.2 (7.7, 8.6)
Concurrent	137	19.47%	1.9 (1.2, 2.2)	4.0 (3.4, 4.8)	5.0 (4.5, 5.6)	6.3 (6.4, 7.1)		
Hybrid	675	11.65%	1.8 (1.4, 1.8)	4.2 (3.8, 4.6)	5.0 (4.6, 5.4)	7.3 (6.7, 7.9)	10.3 (9.5, 11.8)	10.9 (9.3, 12.6)
TOTAL	5526	14.97%						

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Australian Orthopaedic Association National Joint Replacement Registry 2017 Annual Report
 Extracted from Table KT7 Cumulative Percent Revision of Cemented Primary Total Knee Replacement by Prosthesis Combination

Revision	Sub-Component	N	1 Yr	3 Yr	5 Yr	10 Yr	15 Yr	18 Yr
Attune CR	Attune	443	20.5%	0.6 (0.4, 0.6)	2.1 (1.4, 3.1)			
Attune PS	Attune	18	20.5%	0.4 (0.2, 0.8)	1.1 (0.6, 1.9)			
Genesis II CR	Genesis II	466	19.6%	0.9 (0.8, 1.1)	2.4 (2.1, 2.7)	3.1 (2.8, 3.4)	4.3 (3.9, 4.7)	5.6 (4.9, 6.5)
Genesis II CR	Profile/Mobility	35	4.0%	1.7 (0.8, 3.0)	3.4 (2.1, 5.4)	5.4 (3.9, 7.5)	8.0 (6.1, 10.2)	
Genesis II	Genesis II	347	7.4%	1.0 (0.8, 1.3)	2.8 (2.4, 3.3)	3.7 (3.2, 4.2)	6.1 (5.5, 6.8)	10.9 (9.3, 14.2)
Genesis II	Genesis II	765	15.2%	1.5 (1.3, 1.7)	3.8 (3.4, 4.1)	5.2 (4.8, 5.6)	7.5 (6.9, 8.1)	
Genesis II PS	Genesis II	571	19.1%	1.2 (1.1, 1.4)	2.8 (2.6, 3.1)	3.7 (3.4, 4.0)	5.0 (4.5, 5.5)	6.2 (5.7, 7.0)
Navigon PS	Navigon	119	3.8%	0.6 (0.4, 0.8)	1.4 (1.1, 1.9)	1.9 (1.5, 2.4)	2.9 (2.4, 3.6)	5.1 (4.2, 6.4)
Navigon CR	Navigon	8	3.0%	0.2 (0.1, 0.3)	0.7 (0.3, 1.8)			
Navigon CR	Navigon	315	10.1%	0.7 (0.4, 0.8)	1.5 (1.3, 1.7)	2.1 (1.8, 2.3)	2.8 (2.4, 3.3)	
Navigon LOCX	Navigon	29	7.6%	2.0 (1.1, 3.4)	3.6 (2.4, 5.5)	5.2 (3.9, 7.0)	8.2 (5.9, 7.9)	
Navigon LPS	Navigon	239	9.7%	1.0 (0.8, 1.3)	2.9 (2.6, 3.3)	4.0 (3.6, 4.5)	6.0 (5.5, 7.0)	6.0 (5.2, 7.0)
Navigon LPS	Navigon	156	20.1%	0.9 (0.6, 1.0)	2.3 (2.1, 2.5)	3.1 (2.8, 3.4)	5.0 (4.7, 5.4)	
PFC Sigma CR	MST	28	11.3%	0.9 (0.5, 1.6)	1.7 (1.0, 2.6)	2.1 (1.4, 3.2)	3.0 (2.0, 4.3)	
PFC Sigma CR	PFC Sigma	318	12.2%	0.8 (0.7, 1.0)	2.0 (1.7, 2.3)	2.4 (2.1, 2.7)	3.4 (3.0, 3.9)	5.7 (4.6, 7.1)
PFC Sigma PS	MST	231	9.9%	0.9 (0.7, 1.2)	2.7 (2.3, 3.1)	3.3 (3.0, 4.0)	4.8 (4.2, 5.5)	
PFC Sigma PS	PFC Sigma	234	7.6%	1.2 (0.9, 1.6)	3.0 (2.6, 3.5)	3.9 (3.5, 4.4)	4.7 (4.1, 5.4)	7.2 (5.8, 8.8)
Persona	Persona	6	3.1%	0.5 (0.2, 1.5)	1.5 (0.6, 3.5)			
Triathlon CR	Triathlon	107	31.6%	0.8 (0.7, 0.9)	2.0 (1.8, 2.2)	2.3 (2.1, 2.5)	3.9 (3.4, 4.5)	
Triathlon PS	Triathlon	219	6.0%	1.4 (1.2, 1.7)	3.1 (2.8, 3.6)	4.0 (3.4, 4.5)	5.1 (4.5, 6.0)	
Vanguard CR	Mainline	178	7.1%	0.6 (0.5, 0.8)	2.1 (1.9, 2.3)	2.9 (2.5, 3.4)	4.3 (3.5, 5.3)	
Vanguard CR	Vanguard	16	3.8%	0.5 (0.2, 1.0)	1.2 (0.7, 2.0)	1.4 (0.8, 2.6)		
Vanguard PS	Mainline	188	3.7%	1.9 (1.5, 2.4)	4.5 (3.8, 5.3)	5.7 (4.9, 6.6)	7.5 (6.1, 9.3)	

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