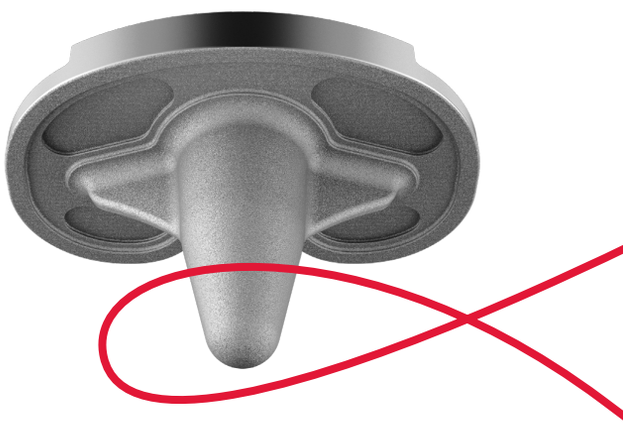
ATTUNE™ Knee System with ATTUNE S+™ Technology – Evidence Update



Two-year Survivorship and Clinical Outcomes of Total Knee Arthroplasty with a New Tibial Design from a Multi-Center Registry

Spitzer, Swank, Irving, Pomeroy, Croker, Fawley
Abstract presented at EFORT Congress, Lisbon, June 22-24th 2022

The authors present a retrospective review of data generated within a multi-center outcome registry. The standard of care follow-up varied between sites therefore standardized registry visit windows were established, which were back-to-back to include all follow-up data. Kaplan-Meier (KM) survivorship was performed with revision of the tibial component and revision of any component as endpoints. For each endpoint two survivorship analyses were performed with differing censoring assumptions. First, unrevised subjects were censored at the last clinical follow-up [clinical assumption (CA)], and second at the date of database extract [registry assumption (RA)].

- A total of 2,626 knees were implanted between September 2017 and November 2021.
- Primary diagnosis was osteoarthritis in 98.9% of cases. The mean age was 67.6 and 55% were female.
- Mean knee society total scores (SD; N) were 45.0 (17.9; 1870) pre-operatively and 90.9 (11.4; 645), 92.4 (9.6; 172), and 94.1 (5.3; 50) at 1-, 2-, and 3-years post-operative.
- The tibial component was revised in 10 cases
  - 3 – Instability
  - 2 – Loosening
  - 2 – Infection
  - 2 – Pain/stiffness
  - 1 – Implant fracture

98.6% (97.8--99.0%) survivorship at 3 years for revision of any component*
99.4% (98.9--99.7%) survivorship at 3 years for tibial revision*

Conclusions

ATTUNE™ Knee System with ATTUNE S+™ Technology is performing at or better than the TKA class, as reported within this multi-center outcome registry and two national registries[1,2]. When using ATTUNE S+ Technology, tibial loosening, an industry-wide challenge, is a low-risk with KM survivorship for the tibia ranging between 98.9% and 99.7% at 3 years post-operatively.

*Registry Assumption

References

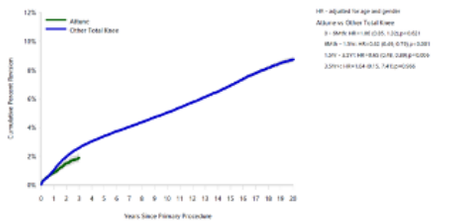
1. Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR), Automated Industry Report System (AIRS), ID No. 5901 for DePuy Synthes, ATTUNE Total Knee, (Procedures from 1 September 1999 – 4 February 2022), Generated 8 Feb 2022, AOA, Adelaide: 1-17.

   AOANJRR Disclaimer: AOANJRR is confident in the accuracy of the data included in this report, at the time it was provided. However, it was generated using an automated reporting system and has not been reviewed by the AOANJRR personnel.

2. National Joint Registry for England, Wales, Northern Ireland and the Isle of Man. Implant Summary Report for DePuy ATTUNE CR and ATTUNE PS (S+ tibial only). NJR Database extract 18 Nov 2021, page 12. Licensed for use until 24 Nov 2022.

   NJR Disclaimer: The data used for this analysis was obtained from the National Joint Registry ("NJR"). The Healthcare Quality Improvement Partnership ("HQIP"), the NJR and/or its contractor, Northgate Public Services (UK) Limited ("NPS") take no responsibility for the accuracy, currency, reliability and correctness of any data used or referred to in this report, nor for the accuracy, currency, reliability and correctness of links or references to other information sources and disclaims all warranties in relation to such data, links and references to the maximum extent permitted by legislation.

Figure 1: Cumulative Percent Revision of Primary Total Knee Replacement by Model (All Diagnoses)



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs	9 Yrs
Attune	14573	10090	6631	2161	0	0	0	0	0	0
Other Total Knee	811186	750700	687392	623612	559859	495740	434044	376848	323419	274209
Number at Risk	**10 Yrs**	**11 Yrs**	**12 Yrs**	**13 Yrs**	**14 Yrs**	**15 Yrs**	**16 Yrs**	**17 Yrs**	**18 Yrs**	**19 Yrs**	**20 Yrs**
Attune	0	0	0	0	0	0	0	0	0	0	0
Other Total Knee	229282	187931	151473	120316	93076	70191	51255	35391	22816	13023	5588

Table 13: Yearly Cumulative Incidence Revision Diagnosis of Primary Total Knee Replacement by Model (All Diagnoses)

Model	Event	N Events	1 Yr	2 Yrs	3 Yrs	5 Yrs	10 Yrs	15 Yrs
Attune	Infection	82	0.4 (0.3, 0.5)	0.6 (0.5, 0.8)	0.7 (0.6, 0.9)			
	Loosening	27	0.1 (0.0, 0.1)	0.2 (0.1, 0.2)	0.3 (0.2, 0.5)			
	Instability	22	0.1 (0.0, 0.1)	0.2 (0.1, 0.3)	0.2 (0.1, 0.3)			
	Patellofemoral Pain	4	0.0 (0.0, 0.1)	0.0 (0.0, 0.1)	0.0 (0.0, 0.1)			
	Pain	14	0.0 (0.0, 0.1)	0.1 (0.1, 0.2)	0.1 (0.1, 0.2)			
	Other	41	0.2 (0.1, 0.3)	0.3 (0.2, 0.5)	0.4 (0.3, 0.5)			
	Deceased	135	0.4 (0.3, 0.5)	0.9 (0.7, 1.1)	1.6 (1.3, 1.9)			
	All Revision	190	0.8 (0.7, 1.0)	1.5 (1.3, 1.7)	1.9 (1.6, 2.2)			
Other Total Knee	Infection	8061	0.4 (0.4, 0.5)	0.6 (0.6, 0.6)	0.7 (0.7, 0.8)	0.9 (0.9, 0.9)	1.1 (1.1, 1.1)	1.3 (1.3, 1.3)
	Loosening	8057	0.2 (0.1, 0.2)	0.4 (0.4, 0.4)	0.5 (0.5, 0.6)	0.8 (0.7, 0.8)	1.2 (1.1, 1.2)	1.6 (1.5, 1.6)
	Instability	2948	0.1 (0.1, 0.1)	0.2 (0.2, 0.2)	0.2 (0.2, 0.2)	0.3 (0.3, 0.3)	0.4 (0.4, 0.4)	0.5 (0.5, 0.5)
	Patellofemoral Pain	2740	0.1 (0.1, 0.1)	0.2 (0.2, 0.2)	0.2 (0.2, 0.2)	0.3 (0.3, 0.3)	0.4 (0.4, 0.4)	0.5 (0.4, 0.5)
	Pain	2635	0.0 (0.0, 0.0)	0.1 (0.1, 0.2)	0.2 (0.2, 0.2)	0.3 (0.3, 0.3)	0.4 (0.4, 0.4)	0.5 (0.4, 0.5)
	Other	8901	0.2 (0.2, 0.2)	0.4 (0.4, 0.5)	0.6 (0.6, 0.6)	0.8 (0.8, 0.8)	1.2 (1.2, 1.3)	1.8 (1.7, 1.8)
	Deceased	14549	0.7 (0.7, 0.7)	1.7 (1.7, 1.7)	3.0 (2.9, 3.0)	6.4 (6.3, 6.4)	15.7 (15.6, 15.8)	37.7 (37.5, 37.9)
	All Revision	33342	1.0 (1.0, 1.0)	1.9 (1.9, 2.0)	2.5 (2.5, 2.6)	3.3 (3.3, 3.4)	4.7 (4.7, 4.8)	6.1 (6.0, 6.1)

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Two-year Survivorship and Clinical Outcomes of Total Knee Arthroplasty with a New Tibial Design from a Multi-Center Registry

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BACKGROUND

In 2011, the ATTUNE™ Knee System (DePuy Synthes, Warsaw, IN) was released and since that time has performed well according to numerous registry reports and peer-reviewed publications. A new tibial tray design (ATTUNE S+™ Technology) was released in 2017, which included a microblast finish to increase surface roughness, cement-implant interdigitation, and reduce fluid infiltration at the cement-implant interface. In addition, four cement pockets with 45° undercut pockets provide a “macrolock” between the implant and cement.

OBJECTIVES

To assess survivorship of this knee system, including the new tibia, utilizing a multi-center, retrospective case review from a company sponsored registry.

DESIGN AND METHODS

Clinical assessments were summarized at standardized registry visit windows, which were back-to-back and included all follow-up data. Kaplan-Meier (KM) survivorship was performed with revision of the tibial component and revision of any component as endpoints, with two separate censoring assumptions. First, unrevised subjects were censored at the last clinical follow-up [clinical assumption (CA)], and second at the date of database extract [registry assumption (RA)]. Survivorship was not calculated at timepoints where <40 knees were available for follow up. Tibial component survivorship was censored at the time of revision of other components.

RESULTS

A total of 2626 knees were implanted between September 2017 and November 2021. Primary diagnosis was osteoarthritis in 98.9% of cases. Mean age was 67.6 years (range 36-94), 55% were female and BMI averaged 30.3 (range 15 to 54). There were 26 revisions; reasons for revision (N; %) are shown in Table 1. The tibial component was revised in 10 of these cases, for a diagnosis (N) of instability (3), loosening (2), infection (2), pain/stiffness (2), and implant fracture (1). KM estimates for revision of any component and revision of the tibial component (95% CI; N with further follow-up) are presented in Table 2. Plots of the KM survivorship of the TKA construct with 95% confidence interval (shaded) is provided in Figure 1, and for the tibial component in Figure 2. Mean American Knee Society (pre-2011) total scores (SD; N) are shown in Table 3.

CONCLUSION

In an observational registry data setting it is believed that RA tends to overestimate survivorship estimates, whereas CA has the potential to underestimate survivorship; this report included both analysis methods to improve transparency. This knee system with the new tibia component is performing at least equivalently to other knee systems in registries. Tibial loosening is low risk with KM survivorship for the tibia ranging between 98.8% and 99.6% at 2 years postoperatively for both assumptions. Further study is planned to evaluate whether this early success persists with longer follow up.

Table 1: Revisions

Revision Reason	N	% of Revisions
Instability	16	61.5
Pain/Stiffness	4	15.4
Tibial Loosening	2	7.7
Infection	2	7.7
Patellar Fracture	1	3.8
Dislocation/Subluxation	1	3.8
TOTAL	26	

Table 2: Kaplan-Meier Survivorship Estimates

All Knees (N=2626)	1 Year KM Survivorship	2 Year KM Survivorship	3 Year KM Survivorship
	KM Estimate (95% CI) N with Later Follow-up		
All Cause Revision – CA	98.4% (97.2%, 99.1%) N= 577	95.1% (92.0%, 97.0%) N= 150	N<40 knees
All Cause Revision – RA	99.4% (99.0%, 99.7%) N= 2041	98.9% (98.4%, 99.3%) N= 1294	98.6% (97.8%, 99.0%) N= 506
Tibial Revision – CA	99.2% (98.3%, 99.6%) N= 577	98.8% (97.1%, 99.5%) N= 150	N<40 Knees
Tibial Revision – RA	99.7% (99.4%, 99.9%) N= 2041	99.6% (99.3%, 99.8%) N= 1294	99.4% (98.9%, 99.7%) N= 506

Table 3: Knee Society Scores (KSS)

	Mean Pre-op KSS (SD; N)	Mean 1 Year KSS (SD; N)	Mean 2 Year KSS (SD; N)	Mean 3 Year KSS (SD; N)
All Knees	45.0	90.9	92.4	94.1
(N=2626)	(17.9; 1870)	(11.4; 645)	(9.6; 172)	(5.3; 50)

Figure 1: Any Component Kaplan-Meier Suvivorship and 95% CI

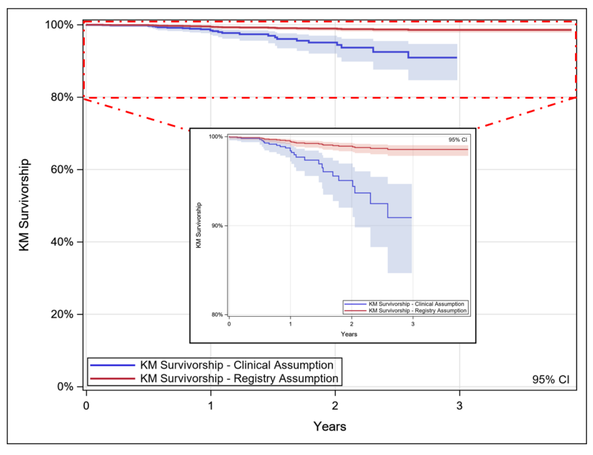
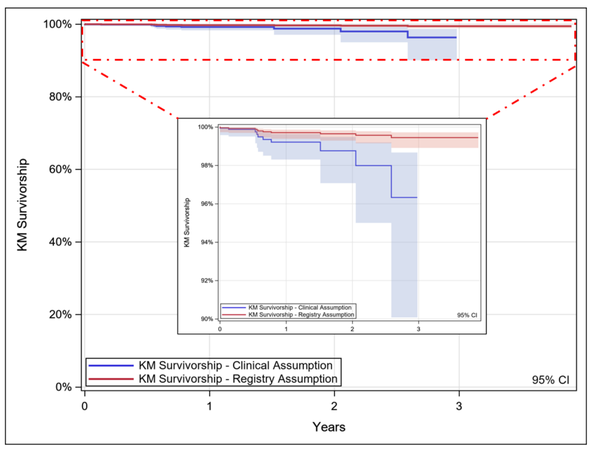


Figure 2: Tibial Component Kaplan-Meier Survivorship and 95% CI



Information presented here reflect data through 13OCT2021

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