

ANALYSIS OF TOTAL KNEE REPLACEMENT USING THE ATTUNE® KNEE SYSTEM IN THE NATIONAL JOINT REGISTRY FOR ENGLAND, WALES, NORTHERN IRELAND AND THE ISLE OF MAN

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Introduction

National joint registries provide valuable information on the revision rates and survivorship of orthopaedic implants. Typically they include large cohorts with data from all surgeons and from all centres, irrespective of surgeon experience level. The National Joint Registry for England, Wales, Northern Ireland, and the Isle of Man (NJR) has been in operation since 2003 and in that time has collected data on over 770,000 primary total knee replacements (TKR).¹

The cemented ATTUNE® Knee System was introduced to the UK in 2012 and builds upon the successful clinical heritage of the SIGMA® Total Knee System² to provide an improved biomechanical solution for patients undergoing TKR. The ATTUNE Knee System is part of the Beyond Compliance initiative and has been awarded a Pre-Entry A* ODEP benchmark. Beyond Compliance is an optional service in the UK to support the safe and stepwise introduction of new or modified implants such as joint replacements.³ The purpose of this analysis is to examine the early results of the ATTUNE Knee System in the context of the overall class of TKR in the NJR. Analysis was conducted by a DePuy Synthes Companies biostatistician on data made available from the NJR Supplier Feedback system, downloaded on 11th April 2016.⁴

Results

In total the dataset records 5,388 ATTUNE Knee System implantations in primary TKR.⁴ The mean age of the cohort was 68.2 years (range 24-94), 56% were female and 44% were male. 98% of patients had a primary diagnosis of osteoarthritis. Eighteen revision procedures have been recorded, which equates to a crude revision rate of 0.33%. The system allows for multiple reasons for revision to be entered and these are supplied in Table 1. It can be noted that only two cases of Aseptic Loosening were reported, giving a crude aseptic loosening rate of 0.04% at this early follow up.

| Reason and timing post-op in days | N | Overall Incidence |
|--|---|-------------------|
| Infection (42, 46, 47, 132, 135, 693, 887) | 7 | 0.13% |
| Instability (143, 210*, 944) | 3 | 0.06% |
| Peri-Prosthetic Fracture (98, 455) | 2 | 0.04% |
| Progressive Arthritis (541, 651) | 2 | 0.04% |
| Pain (210*, 385) | 2 | 0.04% |
| Aseptic Loosening – Tibia (248) | 1 | 0.02% |
| Aseptic Loosening – Femur (389) | 1 | 0.02% |
| Other (485) | 1 | 0.02% |

Table 1. ATTUNE Knee System: Reasons for Revision. (2016 NJR)

*Single revision procedure with two reasons for revision provided

An unadjusted Kaplan-Meier survival analysis was undertaken with an end point of revision of any component for any cause and the annual estimates are provided in Figure 1 and Table 2 with results truncated when fewer than 40 implants remained at risk.⁵ The 3 year cumulative revision rate estimate for the ATTUNE Knee System is 1.30% (95% Confidence Interval 0.63, 2.70%). The 3 year cumulative revision rate estimate for the class of cemented TKR is 1.49% (95% CI 1.46, 1.53%).⁶ The published 3 year cumulative revision rate estimate for the SIGMA® Total Knee System is 1.35% (95% CI 1.30, 1.40%).⁷ Based on analysis of the point estimates and confidence intervals the ATTUNE Knee System demonstrates a similar 3 year cumulative revision rate to the established SIGMA Total Knee System and the class of cemented TKR.

| Group | 1 yr | 2 yrs | 3 yrs |
|---------------------------------|-----------------------------------|---------------------------------|---------------------------------|
| ATTUNE Knee System N=5,388 | 0.21% (0.11, 0.41%) n=2,379 | 0.68% (0.38, 1.23%) n=761 | 1.30% (0.63, 2.70%) n=157 |
| SIGMA Knee System N=241,679 | 0.37% (0.35, 0.40%) | not reported | 1.35% (1.30, 1.40%) |
| Class of Cemented TKR N=651,680 | 0.39% (0.37, 0.41%) | 1.00% (0.97, 1.02%) | 1.49% (1.46, 1.53%) |

Table 2. ATTUNE Knee System, SIGMA Knee System and Cemented TKR Class: Cumulative Revision Rate Estimates. (2016 NJR) (95% CI), n with Later Follow-up.

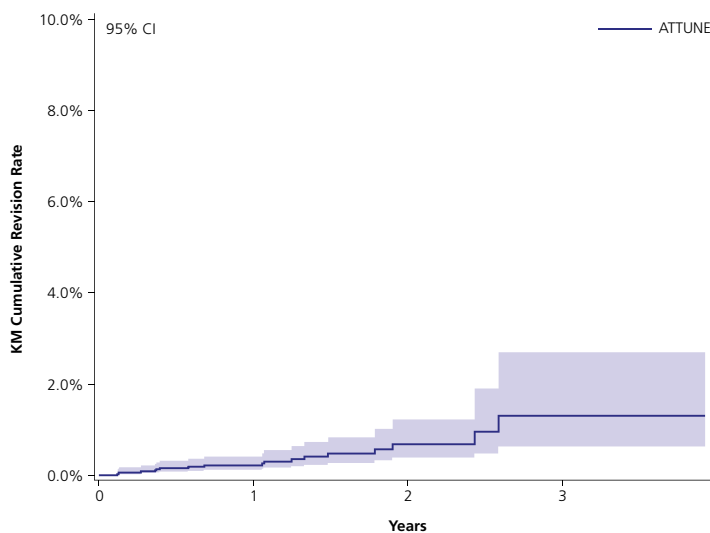


Figure 1. ATTUNE Knee System: Cumulative Revision Rate Estimates. (2016 NJR)

The Kaplan-Meier survival analysis has also been conducted for the different configurations within the ATTUNE Knee System (Table 3), including cruciate-retaining and posterior-stabilised femoral components, along with the fixed and mobile tibial components.³ Based on analysis of the point estimates and confidence intervals, all variants within the ATTUNE Knee System are performing at least in line with the relevant class from the NJR.⁶

In addition to survivorship data, the NJR now provides Patient Reported Outcome Measures (PROMs). Although this dataset remains limited (N=34), the data for the ATTUNE Knee System shows that 97% of those patients who reported PROMs data via the Oxford Knee Score confirmed an improvement in their quality of life at 6 months.⁴

Summary

The National Joint Registry results detailed for the ATTUNE Knee System demonstrate low cumulative revision rates out to 3 years that compare favourably to the class of cemented TKR. This performance is maintained across all four variants of the system, where the revision rates are again in line with the relevant class. These early results need to be confirmed by further analysis and the ATTUNE Knee System will continue to be assessed within the Beyond Compliance system.

| Group | 1 yr | 2 yrs | 3 yrs |
|--------------------------------------|---------------------------------|---------------------------------|--------------------------------|
| ATTUNE Knee System CR FB N=2,780 | 0.18% (0.06, 0.58%) n=950 | 0.47% (0.18, 1.26%) n=242 | n/a |
| Class of Cemented CR FB N=426,844 | 0.34% (0.33, 0.36%) | 0.91% (0.88, 0.94%) | 1.37% (1.33, 1.41%) |
| ATTUNE Knee System CR RP N=539 | 0.19% (0.03, 1.35%) n=276 | 0.19% (0.03, 1.35%) n=135 | 0.19% (0.03, 1.35%) n=94 |
| Class of Cemented CR RP N=30,641 | 0.51% (0.43, 0.59%) | 1.22% (1.10, 1.36%) | 1.86% (1.70, 2.03%) |
| ATTUNE Knee System PS FB N=1,502 | 0.31% (0.11, 0.82%) N=781 | 0.90% (0.30, 2.67%) N=177 | n/a |
| Class of Cemented PS FB N=161,508 | 0.44% (0.40, 0.47%) | 1.08% (1.03, 1.14%) | 1.62% (1.55, 1.69%) |
| ATTUNE Knee System PS RP N=555 | 0.20% (0.03, 1.41%) N=362 | 1.32% (0.48, 3.61%) N=202 | 1.32% (0.48, 3.61%) n=40 |
| Class of Cemented PS RP N=10,258 | 0.71% (0.56, 0.90%) | 1.53% (1.30, 1.81%) | 2.14% (1.86, 2.47%) |

Table 3. ATTUNE Knee System and Cemented TKR Class: Cumulative Revision Rate Estimates Split by design. (2016 NJR) (95% CI), n with Later Follow-up, n/a applies when fewer than 40 patients.

References

1. National Joint Registry for England, Wales, Northern Ireland and the Isle of Man, 12th Annual Report. (2015). Table 3.1. Available from: www.njrreports.org.uk
2. Hopley, C., Dalury, D. (2014). A systematic review of clinical outcomes and survivorship after total knee arthroplasty with a contemporary modular knee system. *Journal of Arthroplasty* 29(7), 1398-1411.
3. Beyond Compliance, <http://www.beyondcompliance.org.uk/home.aspx>, date accessed
4. National Joint Registry for England, Wales, Northern Ireland and the Isle of Man, (2015). NJR data from 1st April 2003 -11th April 2016 on DePuy products supplied for post-marketing surveillance, NJR Centre, Note: NJR-NJR PMS data do not include Hospital Episode Statistics (HES) data linkage. Revisions may therefore be underreported. Available from: www.njrreports.org.uk
5. Lettin, A.,W.,F., Ware, H.,S., Morris, R.,W. (1991). Survival analysis and Confidence Intervals. An assessment with reference to the Stanmore total knee replacement. *Journal of Bone and Joint Surgery Br*.73B(5), 729-731.
6. National Joint Registry for England, Wales, Northern Ireland and the Isle of Man, 12th Annual Report. (2015). Table 3.27 (a). Available from: www.njrreports.org.uk
7. National Joint Registry for England, Wales, Northern Ireland and the Isle of Man, 12th Annual Report. (2015). Table 3.31. Available from: www.njrreports.org.uk

All analysis was carried out by DePuy Synthes, the NJR do not vouch for the accuracy of the interpretation.

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