

## Confidence in the ATTUNE® Knee is Driven by Real World Scientific Evidence: Response to Inaccuracies and Limitations in Bonutti, et al. Article<sup>1</sup>

Bonutti, PM, Khlopas, A, Chughtai, M, Cole, C, Gwam, CU, Harwin, SF, Whited, B, Omiyi, DE, Drumm, JE, Unusually High Rate of Early Failure of Tibial Component in ATTUNE Total Knee Arthroplasty System at Implant–Cement Interface. *J Knee Surg*, 2017;30:435–439.

### Article Assessment

In our assessment, there are several aspects of the Bonutti, et al.<sup>1</sup> article that we believe are inaccurate. There are also some limitations:

- The title of the article is misleading as it suggests there is a failure “rate” included in the article. However, a rate calculation is not provided. The number of revisions is stated as 15, but without the number of ATTUNE® Knee implants performed in total a rate cannot be determined.
- The authors state that aseptic loosening is an unusual presentation for early total knee revision. An abundance of literature demonstrates that infection is the most common cause of revision, followed by aseptic loosening as the second most common cause of revision in the first two years post-operatively.<sup>12,18</sup> After two years, aseptic loosening becomes the most frequent cause of revision for the rest of the implant life and is the most common cause overall.<sup>9</sup>
- The authors note that when the implant was extracted there was no bone cement attached to the tibial base at the time of revision surgery. This has been previously observed and reported for some other tibial base plates in other studies.<sup>5,7,8</sup> Some published studies have indicated that fixation strength as determined by pull off force has been shown to be independent of and not correlated to whether the fixation fails at the bone/cement or cement/interface junction.<sup>14</sup>
- The mean BMI reported in the article is 35 kg/m<sup>2</sup> (range 21–54). In the class of TKA, increased BMI over 35 has been associated with early aseptic loosening of the tibial component.<sup>2,13</sup>
- The article is a retrospective study with no control.
- No description of radiographic technique or positioning is included. Routine x-rays are not inherently accurate in diagnosing aseptic tibial loosening as it is dependent on the variability of radiographic technique.<sup>15</sup>
- The relationship between the grit blast and surface roughness is actually that the higher the grit number, the smoother the surface. The SIGMA® Knee Fixed Bearing Tibial Base has a 220-glass bead blasted finish, which is the smoothest in the SIGMA Knee portfolio. The SIGMA MBT Tibial Base is a 20 grit blast and the ATTUNE Knee is 60 grit blasted.
- The authors quote the MAUDE database information in the article. This use of the MAUDE database conflicts with the

intent of the database and FDA guidance. The FDA’s guidance is that, “MDR data alone cannot be used to establish rates of events, evaluate a change in event rates over time or compare event rates between devices. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices.”<sup>6</sup>

### ATTUNE® Knee Clinical and Registry Evidence

The data and evidence on the ATTUNE Knee indicates the following:

- An Implant Summary Report, which is an independent analysis obtained by DePuy Synthes from the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (NJR) of 10,605 ATTUNE Knee implantations, showed that the cumulative revision rate for the ATTUNE Knee is 1.3% at four years (98.7% implant survivorship at four years), comparing favorably to the 1.9% cumulative revision rate (98.1% implant survivorship at four years) for the overall class of total knee replacement.<sup>10</sup>
- Per the 2016 AOANJRR, in which 4,831 ATTUNE Knees are being tracked (N=3199 CR, N=1632 PS), the ATTUNE Knee estimated cumulative percent revision was 0.5% (ATTUNE Cruciate Retaining Knee), 0.4% (ATTUNE Posterior Stabilized Knee) at one year.<sup>4</sup> This compares favorably to the overall class of cemented total knee arthroplasty (TKA) at one year, which has an estimated cumulative percent revision of 1.0%.<sup>4</sup>
- One year results from two worldwide studies showed improved patient reported outcomes with the ATTUNE Knee compared to other leading knee systems examined in those studies.<sup>16</sup>
- At the 2017 Canadian Orthopedic Association Annual Meeting, Radiostereometric Analysis (RSA) data was presented by the Canadian RSA Network that displayed the ATTUNE Knee 2-year RSA results showing that the ATTUNE Knee tibial base achieved stable fixation by demonstrating average micromotion of 0.17 mm between one and two years.<sup>3</sup> This is consistent with implants that have acceptable revision rates due to aseptic loosening.<sup>11,17</sup>

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**Table KT9 Cumulative Percent Revision of Primary Total Knee Replacement with Cemented Fixation**

Femoral Component	Tibial Component	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	7 Yrs	10 Yrs	15 Yrs
Attune CR	Attune	17	3199	0.5 (0.3, 0.9)					
Attune PS	Attune	7	1632	0.4 (0.2, 0.9)					
Genesis II CR	Genesis II	421	13019	0.9 (0.8, 1.1)	2.4 (2.2, 2.7)	3.1 (2.8, 3.5)	4.0 (3.6, 4.4)	4.3 (3.9, 4.7)	5.6 (4.7, 6.7)
Genesis II PS	Genesis II	518	14812	1.2 (1.1, 1.4)	2.8 (2.6, 3.1)	3.7 (3.4, 4.1)	4.3 (3.9, 4.7)	5.0 (4.5, 5.5)	
Journey Oxinium	Journey	220	3032	1.4 (1.0, 1.9)	4.5 (3.8, 5.3)	6.4 (5.5, 7.4)	8.8 (7.6, 10.0)		
Nexgen CR Flex	Nexgen	254	16286	0.7 (0.6, 0.8)	1.5 (1.3, 1.7)	2.0 (1.8, 2.3)	2.3 (2.0, 2.6)	2.7 (2.2, 3.2)	
Nexgen LPS Flex	Nexgen	838	27014	0.9 (0.8, 1.0)	2.3 (2.1, 2.5)	3.2 (3.0, 3.4)	3.9 (3.6, 4.2)	5.0 (4.7, 5.5)	
PFC Sigma CR	PFC Sigma	277	11461	0.8 (0.7, 1.0)	1.9 (1.6, 2.2)	2.4 (2.1, 2.7)	2.9 (2.5, 3.3)	3.4 (3.0, 3.9)	
PFC Sigma PS	PFC Sigma	241	7167	1.2 (1.0, 1.5)	2.6 (2.2, 3.0)	3.2 (2.7, 3.6)	3.5 (3.1, 4.0)	4.5 (3.9, 5.3)	
Triathlon CR	Triathlon	497	25632	0.8 (0.7, 0.9)	2.1 (1.9, 2.3)	2.6 (2.4, 2.8)	3.0 (2.7, 3.4)	3.8 (3.2, 4.5)	
Triathlon PS	Triathlon	185	5886	1.5 (1.2, 1.8)	3.2 (2.7, 3.7)	4.0 (3.4, 4.6)	4.6 (3.9, 5.3)		
Vanguard CR	Maxim	133	6778	0.6 (0.4, 0.8)	2.2 (1.8, 2.7)	2.8 (2.4, 3.4)	3.3 (2.7, 4.0)		
Vanguard PS	Maxim	166	3500	1.9 (1.5, 2.4)	4.6 (3.9, 5.4)	5.7 (4.9, 6.7)	6.8 (5.7, 8.0)		

**Table KT22 Cumulative Percent Revision of Primary Total Knee Replacement by Fixation (Primary Diagnosis OA)**

Fixation	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	7 Yrs	10 Yrs	15 Yrs
Cemented	8439	258789	1.0 (0.9, 1.0)	2.6 (2.5, 2.6)	3.4 (3.4, 3.5)	4.2 (4.1, 4.3)	5.1 (5.0, 5.3)	7.3 (6.9, 7.7)
Cementless	4612	103903	1.2 (1.1, 1.3)	3.2 (3.1, 3.3)	4.3 (4.2, 4.4)	5.0 (4.9, 5.2)	6.1 (5.9, 6.3)	8.1 (7.7, 8.6)
Hybrid	3964	119262	0.9 (0.9, 1.0)	2.5 (2.4, 2.6)	3.3 (3.2, 3.5)	3.9 (3.8, 4.1)	4.8 (4.7, 5.0)	6.6 (6.2, 7.0)
TOTAL	17015	481954						

Note: Excluding cementless Genesis Oxinium and Profix Oxinium femoral prostheses

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