Promising results for early survivorship using the Persona[®] Knee with the ROSA[®] Knee System

An Automated Industry Report from the Australian Orthopaedic Association National Joint Replacement Registry

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Key Findings

The CPR for Persona Knee CR and PS bearings is 1.9 (95% CI, 1.6 - 2.2) at five years, compared to a CPR of 3.4 (95% CI, 3.4 - 3.5) for the same follow-up time with all other total knees. The revisions/100 observation years was 0.39 (95% CI, 0.14 - 0.86) for robotic assisted TKA using the Persona knee compared to 0.60 (95% CI, 0.52 - 0.68) without robotic assistance for the same implants. This demonstrates a relative reduction in revisions of 35% when robotic assistance was used.

Introduction

The robotic age of arthroplasty is upon us, and the utilization of these robotic systems in total knee arthroplasty (TKA) continues to rise¹. Compared to conventional instrumentation, multiple studies have confirmed improved accuracy and reliability with bone resections²⁻⁷ using a robotic surgical assistant, and some have demonstrated improved early outcomes and implant survivorship⁷⁻¹¹. A novel robotic orthopaedic surgical assistant (ROSA® Knee System, Zimmer Biomet, Warsaw, IN, USA) was recently introduced into the global market and little is known about its performance. As such, we reviewed an automated industry report¹² (AIRS) from the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) in order to evaluate the one-year survivorship following TKA using the Persona® Knee (Zimmer Biomet, Warsaw, IN, USA) with the ROSA Knee System.

Methods

The AOANJRR is a national registry of joint replacement procedures that was established with the intent to "perform routine data collection, analysis, and reporting" of arthroplasty procedures performed in Australia¹³. In the latest report, there are over 1.6 million arthroplasty procedures in the registry, with nearly 850,000 TKA procedures¹³. The Automated Industry Report System (AIRS) (#3845) was generated from the AOANJRR on 18 March 2021¹². Data provided was collected from 1 September 1999 to 16 March 2021 per the AOANJRR reporting process. The report provides survivorship information on the Persona Knee compared to all other TKA procedures in the registry. All robotic TKAs using the Persona Knee (n=2,179) were performed using the ROSA Knee System.

The first Persona Knee procedure was performed in Australia on 13 January 2013. Since then, 23,268 TKA procedures (20,024 patients) have been performed with either a Persona Cruciate Retaining (CR) or Posterior Stabilized (PS) implant. The mean follow-up time for the entire Persona Knee cohort was 1.77 ± 1.3 years (min 0.00, max 8.12).

Charts and data from the AIRS are provided; additional access to the remainder of the report is available upon request. Revisions of the implants systems (Persona Knee versus all others) are reported using the cumulative percent revision (CPR) rate¹³. Revisions per 100 observed component years for robotic and non-robotic cases are presented. This measure has been recommended by the European Federation of National Associations of Orthopaedics and Traumatology (EFORT) and introduced into the world of arthroplasty by the AOANJRR^{13,14}. The calculation of risk is based on the number of days from the index procedure until the date of revision, death, or end of study.

The distribution of age, gender, ASA grade, body mass index, and diagnosis between procedures performed using the Persona Knee and all other total knee cases appears consistent between the groups (Tables 1 - 5).

Table 1. Primary Total Knee Replacement by Model and Age (All Diagnoses) (Table 5, AOANJRR, 18/03/2021)

	Persona CR & Persona PS		Other Total Knee	
Age	N	Col%	Ν	Col%
<55	1489	6.4	50623	6.8
55-64	6665	28.6	197076	26.4
65-74	9626	41.4	295659	39.5
≥75	5488	23.6	204372	27.3
TOTAL	23268	100.0	747730	100.0

Table 2. Primary Total Knee Replacement by Model and Gender (All Diagnoses) (Table 6, AOANJRR, 18/03/2021)

	Persona CR & Persona PS		Other Total Knee	
Gender	N	Col%	Ν	Col%
Male	10447	44.9	327220	43.8
Female	12821	55.1	420510	56.2
TOTAL	23268	100.0	747730	100.0

Table 3. Primary Total Knee Replacement by Model and ASA Grade (All Diagnoses) (Table 7, AOANJRR, 18/03/2021)

	Persona CR & Persona PS		Other Total Knee	
ASA Grade	N	Col%	Ν	Col%
1	1169	5.0	22343	5.9
2	12413	53.6	208474	54.9
3	9378	40.5	144985	38.2
4	212	0.9	4169	1.1
5	1	0.0	10	0.0
TOTAL	23173	100.0	379981	100.0

Note: The AOANJRR commenced collection of ASA data in 2013. 95 Persona CR & Persona PS procedures with no ASA Grade recorded are excluded from this table

Table 4. Primary Total Knee Replacement by Model and BMI (All Diagnoses) (Table 8, AOANJRR, 18/03/2021)

	Persona CR & Persona PS		Other Total Knee	
BMI	N	Col%	Ν	Col%
Underweight (<18.50)	43	0.2	593	0.2
Normal (18.50-24.99)	2155	9.5	30218	10.6
Pre Obese (25.00-29.99)	6862	30.3	89447	31.2
Obese Class 1 (30.00-34.99)	7102	31.4	87976	30.7
Obese Class 2 (35.00-39.99)	3966	17.5	48403	16.9
Obese Class 3 (≥40.00)	2498	11.0	29639	10.4
TOTAL	22626	100.0	286276	100.0

Note: The AOANJRR commenced collection of BMI data in 2015. 642 Persona CR & Persona PS procedures with no BMI recorded are excluded from this table

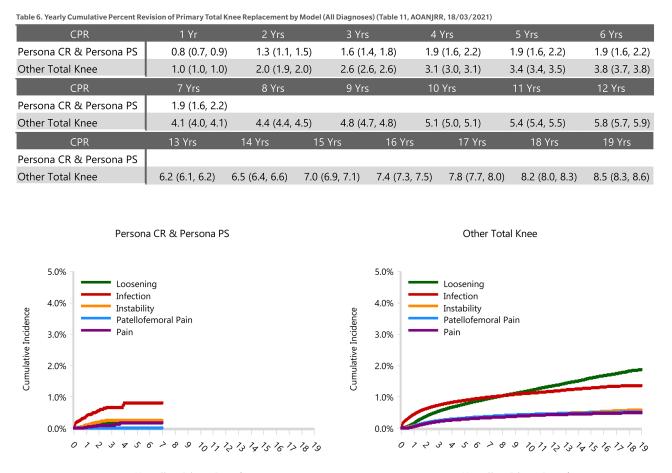
Table 5. Primary Total Knee Replacement by Model and Primary Diagnosis (Table 9, AOANJRR, 18/03/2021)

	Persona CR & Persona PS		Other Total Knee	
Primary Diagnosis	N	Col%	Ν	Col%
Osteoarthritis	22877	98.3	730650	97.7
Rheumatoid Arthritis	189	0.8	9227	1.2
Other Inflammatory Arthritis	122	0.5	3749	0.5
Osteonecrosis	72	0.3	2298	0.3
Tumour	1	0.0	938	0.1
Fracture	3	0.0	618	0.1
Chondrocalcinosis			18	0.0
Osteochondritis Dissecans			2	0.0
Other	4	0.0	230	0.0
TOTAL	23268	100.0	747730	100.0

Results

The cumulative percent revision (CPR) for Persona Knee CR and PS bearings is less than those reported for all other total knee implants (Table 6). For example, the CPR for Persona Knee CR and PS bearings is 1.9 (95% CI, 1.6 – 2.2) at five years, compared to a CPR of 3.4 (95% CI, 3.4-3.5) for the same follow-up time with all other total knees.

The primary reasons for revision included loosening, infection, instability, and pain (Figure 1). Interestingly, loosening appears to be less frequent (graphically) when the Persona knee was used. These indications for revision are consistent with those reported in the AOANJRR 2020 Annual report¹³.



Years Since Primary Procedure Years Since Primary Procedure

Figure 1. Cumulative Incidence Revision Diagnosis of Primary Total Knee Replacement by Model (All Diagnoses) (Figure 2, AOANJRR, 18/03/2021)

The CPR for Persona Knee CR and PS bearings is 1.9 (95% CI, 1.6 - 2.2) at five years, compared to a CPR of 3.4 (95% CI, 3.4 - 3.5) for the same follow-up time with all other total knees. The revisions/100 observation years was 0.39 (95% CI, 0.14 - 0.86) for robotic assisted TKA using the Persona knee compared to 0.60 (95% CI, 0.52 - 0.68) without robotic assistance for the same implants (Table 7). This demonstrates a relative reduction in revisions of 35% when robotic assistance was used.

Table 7. Revision Rates of Persona CR & Persona PS Primary Total Knee Replacement by Robotic Assistance (All Diagnoses) (Table 22, AOANJRR, 18/0	3/2021)
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Robotic Assistance	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Robotically Assisted	6	2179	1521	0.39 (0.14, 0.86)
Non-Robotic	237	21089	39650	0.60 (0.52, 0.68)
TOTAL	243	23268	41171	0.59 (0.52, 0.67)

Discussion & Conclusion

The Persona Knee was reported to have lower CPR rates compared to all other knee implant systems. Further, even though the ROSA Knee System has only been available in the Australian Market since 2019, the early revision rates are promising with a relative reduction of 35% compared to conventional instrumentation using the same implants. Thus, the combination of the Persona Knee with the ROSA Knee System may provide improved survivorship in patients undergoing primary TKA.

However, these results should be considered with some limitations. First, this is a novel robotic system in the Australian market and though early evaluations are promising, substantial follow-up is still needed to evaluate the differences in long-term survivorship between robotic and conventional TKA. Second, the data is limited to the Australian healthcare system and may not be generalizable to other populations.

A recent report by Macri¹⁵ noted the benefits of medical technology in the Australian population, yet emphasized the challenges facing new technologies as they must "not only improve the health and well-being of citizens," but that they must also be cost effective. This is important when considering the high cost of robotic assistants. When using "cost per revision avoided" as a primary outcome, Yeroushalmi et al.¹⁶ noted reduced costs in higher volume centers performing unicompartmental knee arthroplasty

(UKA) given the reduced number of revisions in robotic cases compared to conventional UKA. Cool et al.¹⁷ reported significantly lower costs in the 90-day episode of care following robotic TKA compared to conventional TKA in a US Medicare population. The reduction in the episode of care costs included lower index facility costs, fewer patients discharged to skilled nursing facilities, fewer post-acute care services, and a reduction in readmissions by 33%. The data presented in the current report corroborate these findings with a lower overall risk of revision in the robotic procedures, and though early, it should be noted that the cost benefits reported in the other studies were seen in the early phases by reducing immediate postoperative complications and healthcare utilization.

The survivorship reported within the AOANJRR of Persona Knee implants combined with early data from the ROSA Knee System is promising. Improved component positioning², personalized implant sizing¹⁸, and the potential for fewer soft-tissue releases¹⁹ should result in fewer early revisions associated with surgical errors, and may underlie the observed reduction in revision procedures. Further analysis of mid- and long-term survivorship is needed to evaluate the intra- and post-operative outcomes of this novel robotic orthopaedic surgical assistant.

References

- 1. Antonios JK, Korber S, Sivasundaram L, et al. Trends in computer navigation and robotic assistance for total knee arthroplasty in the United States: an analysis of patient and hospital factors. Arthroplast Today. 2019;5(1):88-95.
- Seidenstein A, Birmingham M, Foran J, Ogden S. Better accuracy and reproducibility of a new robotically-assisted system for total knee arthroplasty compared to conventional instrumentation: a cadaveric study. Knee Surg Sports Traumatol Arthrosc. 2020. Cadaveric studies are not necessarily indicative of clinical performance.
- 3. Liow MH, Xia Z, Wong MK, Tay KJ, Yeo SJ, Chin PL. Robot-assisted total knee arthroplasty accurately restores the joint line and mechanical axis. A prospective randomised study. J Arthroplasty. 2014;29(12):2373-2377.
- 4. Mannan A, Vun J, Lodge C, Eyre-Brook A, Jones S. Increased precision of coronal plane outcomes in robotic-assisted total knee arthroplasty: A systematic review and meta-analysis. Surgeon. 2018;16(4):237-244.
- 5. Scholl LY, Hampp EL, de Souza KM, et al. How Does Robotic-Arm Assisted Technology Influence Total Knee Arthroplasty Implant Placement for Surgeons in Fellowship Training? J Knee Surg. 2020.
- 6. Ren Y, Cao S, Wu J, Weng X, Feng B. Efficacy and reliability of active robotic-assisted total knee arthroplasty compared with conventional total knee arthroplasty: a systematic review and meta-analysis. Postgrad Med J. 2019;95(1121):125-133.
- 7. Kayani B, Konan S, Ayuob A, Onochie E, Al-Jabri T, Haddad FS. Robotic technology in total knee arthroplasty: a systematic review. EFORT Open Rev. 2019;4(10):611-617.
- 8. Wakelin EA, Shalhoub S, Lawrence JM, et al. Improved total knee arthroplasty pain outcome when joint gap targets are achieved throughout flexion. Knee Surg Sports Traumatol Arthrosc. 2021.
- 9. Hamilton DA, Ononuju U, Nowak C, Chen C, Darwiche H. Differences in Immediate Postoperative Outcomes Between Robotic-Assisted TKA and Conventional TKA. Arthroplasty Today. 2021;8:57-62.
- 10. King CA, Jordan M, Bradley AT, Wlodarski C, Tauchen A, Puri L. Transitioning a Practice to Robotic Total Knee Arthroplasty Is Correlated with Favorable Short-Term Clinical Outcomes-A Single Surgeon Experience. J Knee Surg. 2020.
- 11. Marchand RC, Sodhi N, Anis HK, et al. One-Year Patient Outcomes for Robotic-Arm-Assisted versus Manual Total Knee Arthroplasty. J Knee Surg. 2019;32(11):1063-1068.
- Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR), Automated Industry Report System (AIRS) ID No. 3845 for Zimmer Biomet Australia Persona CR & Persona PS Total Knee, procedures from 1 September 1999 - 18 March 2021.
- 13. Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). Hip, Knee, & Shoulder Arthroplasty: 2020 Annual Report. In: 2020.
- 14. Labek G, Group QS. Quality of Publications regarding the Outcome of Revision Rate after Arthroplasty. Medical University of Innsbruck, Dept. of Orthopaedic Surgery;2010.
- 15. Macri J. Australia's Health System: Some Issues and Challenges. J Health Med Econ. 2016;2(2).
- 16. Yeroushalmi D, Feng J, Nherera L, Trueman P, Schwarzkopf R. Early Economic Analysis of Robotic-Assisted Unicondylar Knee Arthroplasty May Be Cost Effective in Patients with End-Stage Osteoarthritis. J Knee Surg. 2020.
- 17. Cool CL, Jacofsky DJ, Seeger KA, Sodhi N, Mont MA. A 90-day episode-of-care cost analysis of robotic-arm assisted total knee arthroplasty. J Comp Eff Res. 2019;8(5):327-336.
- 18. Massé V, Ghate RS. Using standard X-ray images to create 3D digital bone models and patient-matched guides for aiding implant positioning and sizing in total knee arthroplasty. Computer Assisted Surgery. 2021;26(1):31-40.
- 19. Alessi A, Fitzcharles E, Weber IC, Cafferky NL. The Functionality of a Novel Robotic Surgical Assistant for Total Knee Arthroplasty: A Case Series. Case Reports in Orthopedics. 2021;2021:6659707.

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