Early Outcomes with a New Primary TKA System vs. Contemporary TKA: Interim Results of Two Worldwide, Multi-Center Prospective Studies

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Introduction

While advances in implant design have the potential to improve patient outcomes, orthopaedic stakeholders need evidence to assist in decision making when adopting new products. This is particularly important given that the literature has shown that up to 20% of TKA patients are not satisfied.

Using a comprehensive set of patient reported outcomes (PROMs), the purpose of this study was to evaluate whether a new primary, cemented multi-radius TKA system (NEW-TKA) demonstrated improvement versus currently available TKAs (CA-TKA).

Methods

- Two, worldwide, prospective multi-center studies
- Same surgeons in both studies in US, UK, Australia and New Zealand
- Patients completed questionnaires in both studies, including KOOS[1], OKS[2], PKIP[3,4], EQ5D-3L[5]
- Demographics were similar between groups (mean±SD or % for CA-TKA; NEW-TKA): Age (65.6±8.2; 65.1±7.7), BMI (31.9±6.4; 31.3±5.7), Gender (58.5% Women; 58.9% Women), Diagnosis (98.2% OA; 99.5% OA)

Table 1. Study Details

	CA-TKA	NEW-TKA
Implants used	**SIGMA® Knee** - DePuy Synthes (89%) **NexGen®** - Zimmer (3%) **Triathlon®** - Stryker (7%) **Other** (1%)	**ATTUNE® Knee** - DePuy Synthes
Number of Sites	22 sites	23 sites (19 sites same as CA-TKA)
Number of Knees	845 Knees	862 Knees†
Configurations	Cruciate Retaining Fixed Bearing (CR FB) Cruciate Retaining Rotating Platform (CR RP) Posterior Stabilized Fixed Bearing (PS FB) Posterior Stabilized Rotating Platform (PS RP)	Same as CA-TKA
Study Visits	Pre-Op, Post-op to 10-months, 1-year, 2-years	Same as CA-TKA
Enrollment Period	October 2011 - March 2015	November 2012 - May 2015
ClinicalTrials.gov NCT#	NCT# 01497730	NCT# 01746524
Data Extracted	Data through January 2017	

†A total of 1138 knees enrolled, 276 excluded as learning curve cases for analysis in this poster.

Regulatory Status: All products used in these investigations have the appropriate regulatory clearance/approval for use in the countries in which these studies were conducted.

References

1. Roos et al, J. Orthop Sports Phys Ther. 1998 Aug;28(2):88-96. **2.** Murray, JBJS-Br, 2007;89:1010-4. 3. Coles et al, Value Health 2014;17:A568. **4.** Lewis et al, Value Health 2014;17:350-9. **5.** Brooks et al, EuroQol: Health Policy 1996;37:53-72.

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Results

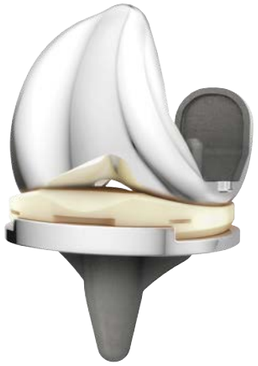
Table 2. 1 & 2 Year PROMs

		1 Year (Unadjusted) Mean ± SD			2 Year (Unadjusted) Mean ± SD			
			CA-TKA	NEW-TKA	p-value for Means* (Covariate Adjusted)**		CA-TKA	NEW-TKA	p-value for Means* (Covariate Adjusted)**
		Scale	N= 737	N= 713		Scale	N= 667	N= 479	
KOOS	Activities of Daily Living	0-100	85.1 ± 15.7	88.5 ± 12.8	**<0.0001**	0-100	87.5 ± 15.0	89.9 ± 13.5	0.0265
	Pain	0-100	84.6 ± 16.9	87.4 ± 14.3	**<0.0001**	0-100	87.6 ± 15.6	89.4 ± 14.4	0.0576
	Symptoms	0-100	78.5 ± 16.9	81.3 ± 14.3	**0.0002**	0-100	82.4 ± 15.5	84.3 ± 14.4	0.0445
	Function in Sport & Recreation	0-100	55.5 ± 30.4	59.9 ± 28.0	**0.0019**	0-100	61.1 ± 29.3	63.1 ± 29.3	0.2215
	Quality of Life	0-100	70.0 ± 23.3	73.3 ± 21.4	**0.0029**	0-100	74.9 ± 22.4	78.1 ± 21.1	0.0297
OKS		0-48	40.2 ± 7.4	41.5 ± 6.2	**<0.0001**	0-48	41.4 ± 6.9	42.3 ± 6.3	0.0779
PKIP (Patient Knee Implant Performance)	Overall	0-100	71.3 ± 19.1	74.7 ± 17.7	**0.0037**	0-100	74.2 ± 19.3	77.1 ± 18.5	0.0434
	Confidence	0-10	8.0 ± 1.9	8.3 ± 1.7	**0.0003**	0-10	8.1 ± 2.0	8.4 ± 1.8	0.0506
	Stability	0-10	8.2 ± 2.0	8.5 ± 1.8	**0.0018**	0-10	8.3 ± 2.0	8.7 ± 1.8	0.0371
	Satisfaction	0-10	7.9 ± 2.1	8.2 ± 2.0	0.0106	0-10	8.1 ± 2.0	8.4 ± 1.9	0.1462
	Modifying Activities	0-10	6.2 ± 3.3	6.5 ± 3.4	0.4053	0-10	6.6 ± 3.3	6.7 ± 3.5	0.8363
EQ5D-3L		-1 - 1	0.8 ± 0.2	0.9 ± 0.2	**0.0006**	-1 - 1	0.9 ± 0.2	0.9 ± 0.2	0.7200

Note: p-values <0.01 are shown in bold
*Since pre-op assessment was included as a covariate, the p-value for the comparison of means is identical to the p-value for the comparison of change from pre-op baseline
**Covariate Adjusted for: Age, Gender, BMI, Configuration, Pre-op Assessment, and Days Post-op

Discussion

- This PROMs comparison, which represents a comprehensive evaluation of the performance of a new device to that of currently available products, confirmed that outcomes with NEW-TKA were at least equivalent to, if not better than the CA-TKA devices. NEW-TKA showed statistically significant improvement in several of these PROMs.
- The clinical significance of the observed PROM improvements is currently unclear; however, many point estimates were statistically significant and should be interpreted within the context of the large sample size of these 2 cohorts.
- More comprehensive data collection (survivorship, radiographic outcomes, etc.) and longer follow-up is ongoing.
- Since up to 20% of TKA patients are not satisfied, the focus on the PROMs included in this comparison is important to the orthopaedic community when considering the adoption of new devices.



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