Early Outcomes With A New Primary Total Knee Arthroplasty (TKA) System vs. Contemporary TKA: Interim Results of Two Worldwide, Multi-Center Prospective Studies

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PURPOSE

To evaluate whether a new TKA (NEW-TKA) improved patient reported outcomes (PROMs) vs. currently available products (CA-TKA).

MATERIALS & METHODS

- 2 Worldwide, Prospective, Multi-Center, Non-Randomized Studies: same surgeons
- PROMS: KOOS (includes WOMAC), PKIP, OKS, & EQ5D

Data through Jan 2016	CA-TKA	NEW-TKA
Implants used:	**Sigma®- DePuy Synthes (89%) NexGen® - Zimmer (3%) Triathlon® - Stryker (7%) Other (1%)**	**ATTUNE® - DePuy Synthes**
Number of Sites Participating:	**22 sites**	**23 sites (19 sites same as CA-TKA)**
Number of Participants:	**845 Knees**	**1137 Knees** Learning Curve: 1st 10 cases/site excluded
Configurations:	CR FB, CR RP, PS FB, 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
Demographics	Similar in 2 cohorts: 58% women, Ave age= 65, 98%OA, Ave BMI= 31.9	
ClinicalTrials.gov NCT#	NCT# 01497730	NCT# 01746524

RESULTS

Min 1-year PROMs

		Scale	(Unadjusted) Mean ± SD *Change from Pre-op Baseline* CA-TKA	NEW-TKA	*Covariate adjusted* *p-value*
KOOS	Activities of Daily Living	0-100	85.3 ± 15.7 *34.9 ± 20.2*	88.1 ± 13.3 *37.4 ± 19.2*	0.001
	Pain	0-100	84.9 ± 16.5 *38.6 ± 20.7*	87.2 ± 14.6 *42.3 ± 19.3*	0.003
	Symptoms	0-100	78.4 ± 17.0 *30.0 ± 23.0*	80.9 ± 14.7 *32.8 ± 21.0*	0.005
	Function in Sport & Recreation	0-100	55.3 ± 30.4 *37.0 ± 31.8*	59.9 ± 27.9 *42.1 ± 29.0*	0.002
	Quality of Life	0-100	70.2 ± 23.2 *44.9 ± 26.0*	72.8 ± 22.1 *48.0 ± 25.8*	0.039*
OKS		0-48	40.3 ± 7.3 *17.1 ± 8.9*	41.5 ± 6.4 *17.9 ± 8.5*	0.002
PKIP	**Overall**	0-100	71.6 ± 19.0 *43.8 ± 22.1*	74.2 ± 18.1 *45.3 ± 21.6*	0.026*
	Confidence	0-10	8.0 ± 1.9 *4.3 ± 2.4*	8.3 ± 1.8 *4.4 ± 2.2*	0.010
	Stability	0-10	8.2 ± 2.0 *4.8± 2.5*	8.5 ± 1.8 *4.9 ± 2.4*	0.057*
	Satisfaction	0-10	7.9 ± 2.1 *5.8 ± 2.5*	8.1 ± 2.0 *6.0 ± 2.5*	0.132*
	Modifying Activities	0-10	6.2 ± 3.3 *2.5 ± 4.3*	6.5 ± 3.4 *2.6 ± 4.3*	0.229*
EQ5D-3L		-1-1	0.85 ± 0.19 *0.26 ± 0.26*	0.86 ± 0.18 *0.28 ± 0.25*	0.136*

- **At a p-value threshold of 0.01, Min 1-year comparisons of covariate adjusted PROMS were statistically significant favoring the NEW-TKA, except where noted (*);** covariates were: pre-op evaluation, demographics, site, configuration & time post-op.
- **At <1-year PKIP Satisfaction favored NEW-TKA (p<0.001).**

CONCLUSIONS

NEW-TKA exhibited a trend toward improved outcomes across a broad range of PROMs compared to currently available TKA implant designs.

Longer follow-up is ongoing.

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