Collecting Long-Term (5 to 10 Years) Patient-Reported Outcome Measures May Be Unnecessary for Total Knee Arthroplasties

Pedro Javier Rullan, Ignacio Pasqualini, Jianhua Shen[1], Manoshi Bhowmik-Stoker[2], Emily Hampp[3], Robert M Molloy, Viktor Erik Krebs, Matthew Edward Deren[4], Nicolas Santiago Piuzzi
[1]Stryker Orthopaedics, [2]Stryker Orthopaedic, [3]Stryker, [4]Cleveland Clinic

INTRODUCTION:

The clinical relevance ratio (CRR) was developed to account for the loss of follow up in clinical studies reporting patient-reported outcomes measures (PROMs). However, no study has tested its use with original outcome data for total knee arthroplasties (TKA). Therefore, this study aimed to 1) determine the proportion of patients that had a clinically significant improvement in PROMs at each follow-up visit following TKA; and 2) calculate the CRR over time for PROMs following TKA.

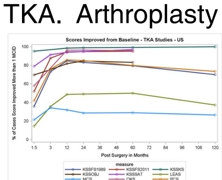
METHODS:

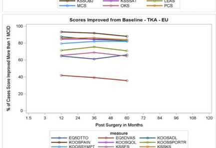
Four independent studies reporting PROMs at baseline to 10 years for 1,416 patients who underwent primary TKA in Europe or the United States were aggregated. A total of 1,587 TKAs performed from 2005 to 2017 were included (**Table 1**). A distribution-based minimal clinically important difference (MCID) threshold was used to determine which patients had a clinically significant improvement in PROMs. The CRR was calculated by dividing the number of cases that met the MCID threshold by the number of cases at the beginning of the study. The maximum follow-up time was ten years.

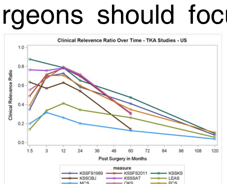
RESULTS:

The proportion of TKA patients that had a clinically significant improvement in PROMs at each follow-up visit is summarized separately for US and EU studies (**Tables 2-3**). For US studies, MCID attainment was higher for KSS-KS, KSS-SAT, OKS, compared to other PROMs (**Table 2**). Similarly, for EU studies, MCID attainment was greatest for KOOS-Pain, KOOS-ADL, KOOS-QOL, and KSS-KS (**Table 3**). General health PROMs, such as the EQ5D-VAS, MCS, and LEAS score had the lowest percentages of score improvements. Improvements in PROM scores were relatively similar between 1- and 5-year follow-up visits, with few PROMs decreasing in trend between 5- and 10-years of follow up (**Figure 1**). However, the CRR decreased over time for all PROMs reported in the TKA studies (**Figure 2**). The tipping point where the CRR began decreasing for TKA studies was at the 1-year follow-up timepoint.

DISCUSSION AND CONCLUSION: The clinical relevance ratio for PROMs decreases significantly after short-term follow-up periods for TKA patients. Long-term PROM collection at 5 to 10 years and analysis may be unnecessary following TKA. Arthroplasty surgeons should focus on 1-year PROMs to assess clinically significant improvements after TKA.







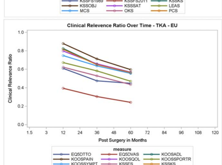


Table 1. Demographic characteristics of the study cohorts

Characteristic		Knee
Region		US & EU
Number of cases		1587
Number of patients		1416
Age in years	Mean (SD) [range]	64.8 (8.3) [30-90]
Gender, n (%)	Male	606 (42.8%)
	Female	810 (57.2%)
BMI [kg/m²]	Mean (SD) [range]	30.9 (4.7) [17.7-55.2)
Ethnicity, n (%)	Hispanic or Latino	41(3.5%)
	Not Hispanic or Latino	1134 (96.5%)
	Unspecified	241
Race, n (%)	American Indian or Alaskan	3 (0.3%)
	Asian	7 (0.6%)
	Black or African	72 (6.0%)
	Native Hawaiian or other Pacific	0 (0%)
	White	1103 (92.5%)
	Unspecified/NA	231
Cigarette use, n (%)	Non-smoker	961(60.8%)
	Current cigarette smoker	82 (5.2%)
	Ex-cigarette smoker	539 (34.1%)
	Unspecified	5
Alcohol use, n (%)	Never	222 (14.0%)
	Not in last year	337 (21.3%)
	< 3 Drinks/Week	615 (38.8%)
	3-7 Drinks/Week	274 (17.3%)
	8-14 Drinks/Week	109 (6.9%)
	15+ Drinks/Week	28 (1.8%)
	Unspecified	2
Primary diagnosis, n (%)	Osteoarthritis	1554 (97.9%)
	Traumatic Arthritis	22 (1.4%)
	Avascular Necrosis	3 (0.2%)
	Other	8(0.5%)
	Unspecified	0
Medical condition, n (%)	None	76 (4.8%)
	Cancer	141(8.9%)
	Cardiovascular	1120 (70.6%)
	Dermatologic	84 (5.3%)
	Digestive	515 (32.5%)
	Endocrine/Metabolic	566 (35.7%)
	Immunologic/Lymphatic	44 (2.8%)
	Musculoskeletal	897 (56.5%)
	Neurologic	188 (11.9%)
	Psychologic	257 (16.2%)
	Respiratory	296 (18.7%)
	Substance dependence	9 (0.6%)
	Urogenital	304 (19.2%)
	Other	698 (44.0%)

Table 2. PROM Data for the U.S. TKA Studies

Measure	Visit	MCID Attainment (%)	Clinical Relevance Ratio	Visit Month for Graph
KSSFS1989	Baseline to 6 Week	35.7	0.35	1.5
	Baseline to 3 Month	73.1	0.70	3
	Baseline to 1 Year	84.8	0.73	12
	Baseline to 2 Year	83.1	0.58	24
	Baseline to 5 Year	79.5	0.41	60
	Baseline to 10 Year	70.0	0.08	120
KSSFS2011	Baseline to 6 Week	51.8	0.49	1.5
	Baseline to 3 Month	87.7	0.72	3
	Baseline to 1 Year	94.4	0.78	12
	Baseline to 2 Year	94.8	0.70	24
	Baseline to 5 Year	95.2	0.30	60
KSSKS	Baseline to 6 Week	95.2	0.88	1.5
	Baseline to 1 Year	98.5	0.79	12
	Baseline to 2 Year	98.9	0.65	24
	Baseline to 5 Year	99.3	0.48	60
	Baseline to 10 Year	100	0.10	120
KSSOBJ	Baseline to 6 Week	69.7	0.64	1.5
	Baseline to 3 Month	75.4	0.57	3
	Baseline to 1 Year	81.8	0.63	12
	Baseline to 2 Year	84.7	0.54	24
	Baseline to 5 Year	83.1	0.14	60
KSSSAT	Baseline to 6 Week	79.0	0.77	1.5
	Baseline to 3 Month	91.4	0.76	3
	Baseline to 1 Year	94.0	0.78	12
	Baseline to 2 Year	94.8	0.71	24
	Baseline to 5 Year	97.0	0.31	60
LEAS	Baseline to 6 Week	14.5	0.14	1.5
	Baseline to 3 Month	35.7	0.34	3
	Baseline to 1 Year	48.7	0.41	12
	Baseline to 2 Year	49.1	0.34	24
	Baseline to 5 Year	50.0	0.26	60
	Baseline to 10 Year	37.3	0.06	120
MCS	Baseline to 6 Week	21.4	0.20	1.5
	Baseline to 3 Month	34.3	0.32	3
	Baseline to 1 Year	32.0	0.26	12
	Baseline to 2 Year	28.7	0.20	24
	Baseline to 5 Year	29.0	0.13	60
	Baseline to 10 Year	26.6	0.04	120
OKS	Baseline to 6 Week	57.9	0.55	1.5
	Baseline to 1 Year	96.3	0.80	12
	Baseline to 2 Year	96.4	0.72	24
	Baseline to 5 Year	95.8	0.31	60
PCS	Baseline to 6 Week	41.9	0.39	1.5
	Baseline to 3 Month	76.1	0.70	3
	Baseline to 1 Year	85.8	0.71	12
	Baseline to 2 Year	85.1	0.60	24
	Baseline to 5 Year	79.9	0.35	60
	Baseline to 10 Year	73.4	0.11	120

Table 3. PROM Data for the E.U. TKA Studies

Measure	Visit	MCID Attainment (%)	Clinical Relevance Ratio	Visit Month for Graph
EQ5DTTO	Baseline to 1 Year	64.8	0.61	12
	Baseline to 3 Year	61.3	0.48	36
	Baseline to 5 Year	66.2	0.45	60
EQ5DVAS	Baseline to 1 Year	41.9	0.39	12
	Baseline to 3 Year	39.3	0.30	36
	Baseline to 5 Year	35.8	0.24	60
KOOSADL	Baseline to 1 Year	87.6	0.83	12
	Baseline to 3 Year	84.4	0.65	36
	Baseline to 5 Year	82.8	0.56	60
KOOSPAIN	Baseline to 1 Year	93.3	0.88	12
	Baseline to 3 Year	91.9	0.71	36
	Baseline to 5 Year	88.1	0.60	60
KOOSQOL	Baseline to 1 Year	84.8	0.80	12
	Baseline to 3 Year	85.0	0.66	36
	Baseline to 5 Year	84.1	0.57	60
KOOSSPORTR	Baseline to 1 Year	71.4	0.67	12
	Baseline to 3 Year	75.6	0.58	36
	Baseline to 5 Year	71.0	0.47	60
KOOSSYMPT	Baseline to 1 Year	79.5	0.75	12
	Baseline to 3 Year	82.1	0.64	36
	Baseline to 5 Year	82.1	0.56	60
KSSKS	Baseline to 1 Year	85.9	0.82	12
	Baseline to 3 Year	86.3	0.65	36
	Baseline to 5 Year	84.0	0.57	60
KSSFS	Baseline to 1 Year	65.6	0.62	12
	Baseline to 3 Year	69.0	0.53	36
	Baseline to 5 Year	64.7	0.43	60