## Robot-assisted standardized laxity assessment during TKA does not affect clinical outcomes: preliminary 6-month results of a randomized controlled trial

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During the last decades, several surgical innovations have seen daylight in total knee arthroplasty (TKA). For example, surgical navigation has been introduced in the nineties to aid the surgeon to result in a more precise surgery compared to the conventional technique. While the early results were promising, computer-assisted total knee arthroplasty failed to gain traction due to the absence of clear superior clinical results. Similarly, patient specific instruments did not deliver a breakthrough to improved patient outcomes. Currently, robotic systems have been introduced into the surgical workflow to improve the procedures precision even further. While most of these robotic systems require the surgeon to perform a manual assessment of joint laxity, similar to the conventional procedure, one platform can be used to perform a standardized laxity assessment intra-operatively. Whether this technology can improve long term clinical outcomes is yet to be defined.

The aim of this study was to evaluate the effect of an integrated standardized laxity assessment during full range of motion with a robotic device in total knee arthroplasty on clinical outcomes. METHODS:

A randomized controlled trial was performed comparing conventional total knee arthroplasty with a manual tensioner versus robot-assisted total knee arthroplasty with a dedicated robotic platform including a standardized robotic tensioning device. All patients scheduled for primary total knee surgery were included in this study. Patients with previous fracture of femur or tibia, fixed flexion contracture > 10°, flexion < 110°, coronal deformity > 15°, history of infection, collateral ligament insufficiency, neurologic conditions limiting knee mobility and age > 80 years old were excluded from the study. In both groups, a posterior stabilized implant was used. Several patient reported outcome measures (Knee Osteoarthritis Outcome Score (KOOS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Pain Catastrophizing Scale (PCS), EQ5D5L, Quality of Life (QoL), Knee Society Score (KSS) and Forgotten Joint Score (FJS)) were obtained preoperatively, at 6 weeks and at 6 months postoperatively.

Coronal alignment and implant position were evaluated on full-leg weight bearing radiographs. The hip-knee-ankle axis was defined as the angle between the mechanical axis of the femur and the mechanical axis of the tibia. Femoral coronal alignment was measured as the mechanical lateral distal femoral angle (mLDFA), which is the angle between the mechanical axis of the femur and the line connecting the most distal points on the medial and lateral femoral condyle. Tibial coronal alignment was defined as the mechanical medial proximal tibial angle (mMPTA), which is the angle between the mechanical axis of the tibia and the line connecting the medial to lateral base of the tibial plateau. RESULTS:

A total of 60 patients currently have 6 month postoperative data (30 robot – 30 conventional) available in this study. There were no differences between both groups in baseline characteristics of age (63.5 years SD 11.9 vs 66.4 years SD 10.6), BMI (29.5 SD 5.1 vs 30.2 SD 4.8), side (Right/Left: 43%/57% for both robot-assisted and conventional TKA), gender (Female/Male: 80%/20% vs 71%/29% in robot-assisted and conventional TKA) and hip-knee-ankle axis (2.3° varus SD 5.4 vs 3.2° varus SD 4.7). Postoperatively, no statistically significant changes are seen of HKA (1.1° varus SD 2.5 vs 1.1° varus SD 2.3), mLDFA (90.1 SD 1.5 vs 89.7 SD 1.8) nor mMPTA (89.2 SD 1.7 vs 88.9 SD 1.3) between robot-assisted and conventional TKA. An overview of the reported clinical outcomes is presented in Table 1. The robot-assisted group demonstrated a lower score on the PCS (subscale magnification) compared to the conventional counterpart at 6 months postoperatively: 0.7 (SD 1.3) vs 3.2 (SD 4.1) (p = 0.04). No statistically significant differences were observed based on KOOS, WOMAC, EQ5D5L, QoL, KSS and FJS at all time intervals.

## **DISCUSSION AND CONCLUSION:**

Standardized balancing during full range of motion with a dedicated robotic device did not result in clear superior shortterm clinical outcomes after total knee arthroplasty compared to the conventional procedure. These findings should be interpreted with the knowledge that specific targets for ligamentous balance during full range of motion are currently still lacking. Long term studies will be necessary to confirm or disprove the current added value of robot-assistance during total knee arthroplasty.

		Robot-assisted TKA			Conventional		
		Preoperative	6 weeks	6 months	Preoperative	6 weeks	6 months
KOOS	Pain	40.9 ± 15.5	63.9 ± 14.0	71.1 ± 18.3	48.5 ± 16.0	62.8 ± 11.7	67.2 ± 17.7
	Symptoms	44.1 ± 21.4	70 ± 19.8	80.2 ± 19.4	47.3 ± 17.9	75.4 ± 21.1	72.1 ± 23.1
	ADL	41.2 ± 20.7	71.3 ± 16.5	80.5 ± 20.5	43.1 ± 14.2	79.2 ± 11.6	70.9 ± 24.3
	Sports	12.6 ± 19.4	34.2 ± 32.6	50.3 ± 36.9	14.6 ± 18.9	48.1 ± 39.3	39.3 ± 32.1
	QoL	19.0 ± 19.0	51.2 ± 23.9	63.4 ± 25.3	19.7 ± 12.2	53.5 ± 23.4	58.8 ± 26.1
WOMAC	Pain	13.1 ± 3.4	7.5 ± 3.4	6.0 ± 4.0	12.4 ± 3.1	8.9 ± 3.8	6.2 ± 3.4
	Stiffness	4.0 ± 2.0	2.0 ± 1.6	1.3 ± 1.5	4.1 ± 1.9	1.9 ± 1.4	2.2 ± 1.9
	Function	57.0 ± 14.0	36.5 ± 11.2	30.3 ± 13.9	55.7 ± 9.7	31.2 ± 7.9	36.8 ± 16.5
PCS	Rumination	12.4 ± 5.1	6.7 ± 4.5	5.7 ± 4.6	11.6 ± 5.2	4.6 ± 4.1	7.8 ± 7.2
	Magnification	4.2 ± 3.1	1.2 ± 1.5	0.7 ± 1.3*	4.6 ± 3.5	1.2 ± 2.0	3.2 ± 4.1*
	Helplessness	12.4 ± 6.7	4.9 ± 5.0	3.1 ± 5.1	13.4 ± 6.3	2.9 ± 3.1	7.4 ± 8.9
	Total	29.0 ± 13.8	12.8 ± 10	9.5 ± 10.4	29.6 ± 13.4	8.7 ± 8.7	18.4 ± 20.1
EQ5D5L		0.4 ± 0.3	0.8 ± 0.2	0.8 ± 0.2	0.4 ± 0.4	0.8 ± 0.2	0.7 ± 0.5
QoL		64.2 ± 23.2	69.0 ± 21.3	70.6 ± 21.7	59.2 ± 26.1	75.7 ± 12.0	71.0 ± 26.1
kss	Symptoms	6.9 ± 5.7	17.2 ± 6.5	18.7 ± 6.4	6.2 ± 3.1	18.9 ± 3.5	16.0 ± 8.4
	Satisfaction	15.1 ± 8.0	27.3 ± 7.5	30.0 ± 8.9	15.4 ± 8.5	27.8 ± 9.3	26.4 ± 13.8
	Expectations	13.9 ± 1.6	10.1 ± 2.8	9.7 ± 2.7	$14.1 \pm 1.1$	10.1 ± 2.5	9.0 ± 3.2
	Function	37.1 ± 17.3	55.8 ± 16.5	70.5 ± 22.3	36.2 ± 13.3	55.0 ± 25.3	61.8 ± 17.9
Forgotten Joint Score		NA	41.0 ± 28.6	66.1 ± 37.1	NA	41.2 ± 32.8	34.2 ± 35.2

 Table 1. Overview of clinical outcomes in robot-assisted versus conventional total knee arthroplasty

 based on KOOS, WOMAC, PCS, EQ5D5L, QoL, KSS and FJS both preoperatively and postoperatively at

 6 weeks and 6 months. \* Statistically significant with p = 0.04.