Clinical, functional, and radiographic outcomes of TKA performed with customized instrumentation

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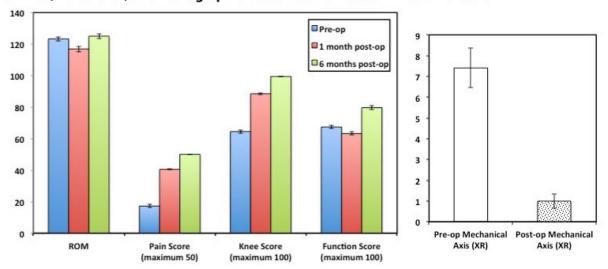
Introduction: Customized instrumentation (CI) is an innovative technology that utilizes preoperative MR imaging to create a customized guide for cutting block placement in TKA. We have previously established that CI is capable of accurately establishing femoral and tibial component alignment and femoral component rotation and sizing that is in accordance with the surgeon's preoperative plan. Although this technique is increasingly gaining acceptance, very little data exists regarding the clinical, functional, and radiographic outcomes associated with this technology. The purpose of this study was to evaluate preoperative, one, and six-month postoperative clinical, functional, and radiographic outcomes following a single surgeon's initial clinical experience with CI TKA. Our hypothesis was that the accuracy with which TKA is performed using CI would be reflected in early consistent high quality clinical and functional outcomes.

Methods: The first 44 CI TKA (14 male, 30 female) performed by a single surgeon were evaluated. The Knee Society Scoring System was used to translate patient pain level, ROM, stability, and ambulatory status to generate clinical and functional outcome scores. Long-standing AP mechanical axis radiographs were obtained pre and postoperative to evaluate anatomic alignment.

Results: CI produced favorable short-term clinical and functional outcomes. Preoperative, 1 month postoperative, and 6 month postoperative knee scores were 64, 88, and 98, respectively. Preoperative, 1 month postoperative, and 6 month postoperative ROM was 123°, 116°, and 125°. Preoperative, 1 month postoperative, and 6 month postoperative Pain scores were 17, 40, and 50, respectively. Pre and postoperative mechanical axis measurements averaged 7.4° of varus and 0.9° varus, respectively.

	Mean	Std. Deviation	Minimum	Maximum	Range
Preop Mechanical Axis (XR)	7.4	6.2	-9.07	14.55	23.62
Postop Mechanical Axis (XR)	1.0	2.3	-3.9	5.87	9.77
Preop ROM	123.3	9.3	98	138	40
Preop Pain Score (max = 50)	17.2	7.0	0	20	20
Preop Knee Score(Max=100)	64.5	7.1	45	70	25
Preop Functional Score (Max=100)	67.4	22.7	17	97	80
Postop ROM (1 month)	116.9	11.7	65	135	70
Postop Pain Score (1 month)	40.5	2.2	40	50	10
Postop Knee Score (1 month)	88.5	3.9	79	100	21
Postop Function Score (1 month)	63.2	18.6	32	97	65
Postop ROM (6 month)	125.0	8.0	105	140	35
Postop Pain Score (6 month)	50.0	0.0	50	50	0
Postop Knee Score (6 month)	99.4	1.1	96	100	4
Postop Function Score (6 month)	79.6	16.7	40	94	54

Clinical, Functional, and Radiographic Outcomes with Custom Instrumentation in TKA



Discussion: Customized instrumentation is an innovative technology that utilizes preoperative 3D MRI reconstructions to generate customized guides for TKA cutting block placement. Our experience with CI suggests that this technology is capable of accurately establishing femoral and tibial component alignment, femoral component rotation, and femoral component sizing that is in accordance with the surgeon's preoperative plan. We hypothesized that the accuracy of each step of the TKA procedure made possible by CI may help to improve postoperative mid-flexion stability, reduce the risk of component misalignment and malrotation, and potentially translate to improved early, as well as late, clinical and functional outcomes following TKA.

The present study suggests that the accuracy associated with the use of customized instrumentation produces favorable and consistent short-term clinical, functional and radiographic outcomes following TKA

Conclusion: CI is capable of not only being performed intraoperatively in accordance with the surgeon's preoperative plan, but also producing favorable short-term clinical, functional, and radiographic outcomes. Long-term follow-up studies are required to determine if the potential advantages of working with CI can translate to improved clinical, functional and radiographic outcomes. Case-controlled studies, which we are currently performing, and randomized studies comparing CI with manual and CAS techniques, will help clarify whether CI provides significant clinical benefit relative to these more established TKA technologies.