A Prospective Evaluation of a 4th Generation Total Ankle Prosthesis with Flat Cut Versus Chamfer Cut Talar Component

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INTRODUCTION:

Fourth-generation total ankle prostheses are evolving to address common complications following total ankle replacement, one of which is aseptic talar component loosening. A chamfered cut talar dome component, requiring less bone resection than flat cut components, is commonly used. Alternatively, A flat cut talar dome component with a larger talar "peg" has been suggested to increase bone-implant interface and stability. To date, there is limited reported data concerning survivorship and clinical improvement following the use of these two interchangeable talar dome components with the same tibial replacement component. The purpose of this study is report on prospectively collected patient reported outcome measures (PROMs) and clinical outcomes in a multi-institutional study of a fourth-generation total ankle with either flat or chamfer cut talar implant.

METHODS:

Patients presenting for a total ankle replacement at 12 institutions were prospectively enrolled and implanted in both academic and private settings. Patients were implanted with a single low profile tibial implant and one of two interchangeable talar components, either a flat cut component with a talar stem and anterior fixation pegs or chamfered cut with anterior fixation pegs. A total of 132 subjects were enrolled, 89 (67.4%) were implanted with a chamfered cut talar component and 43 (32.5%) with flat cut component. Patients had demographics, adverse events, and PROMs recorded pre-operatively and at 6, 12, and 24-month intervals. The following PROMs were collected: Ankle Osteoarthritis Score (AOS), PROMIS Global Physical Health, Foot and Ankle Outcome Score (FAOS), and satisfaction scores. The preoperative and latest follow-up scores for patients with minimum two years of follow-up were analyzed.

RESULTS:

The overall cohort (54.7% male) had an average age of 64.2 ± 9.39 years old with an average BMI of 31.0 ± 5.17. Regardless of talar component, patients improved significantly in all PROMs domains at two years, including: Mean Total AOS (Chamfered: 19.1 ± 20.0, p<.0001; Flat: 16.8 ± 14.9, *p*<.001); PROMIS Global Physical Health (Chamfered: 8.83 ± 7.63, p<.0001; Flat: 8.56 ± 8.21, *p*<.001); Total FAOS Score (Chamfered: 38.1 ± 20.7, p<.0001; Flat: 40.2 ± 20.8, *p*<.001). There was no significant difference in the change in PROMs between talar components. At 2-years, 5 (4.9%) patients who received the chamfer cut component experienced device-related adverse events. None of the patients who received the flat cut talar component experienced such events or required revision surgery.

DISCUSSION AND CONCLUSION:

At two-years post-implantation follow-up, the fourth-generation total ankle replacement with flat cut component had a low revision rate and proved to be safe and effective compared to historical ankle replacement outcomes. Patients had statistically significant clinical improvements in each domain of their PROMs, with there being no difference between the two talar components.

Table 1. Improvement in Patient Reported Outcome Measures from Baseline to 2-years Post-implantation.

	Overall		Chamfer Cut		Flat Cut		Between Cohorts
	Improvement (Mean ± SD)	*p* Value	Improvement (Mean ± SD)	*p* Value	Improvement (Mean ± SD)	*p* Value	*p* Value
Total AOS	-39 ± 21.2	**<.0001**	-37 ± 20.1	**<.0001**	-43 ± 23.4	**<.0001**	.4406
PROMIS Global Physical Health	8.74 ± 7.79	**<.0001**	8.83 ± 7.63	**<.0001**	8.56 ± 8.21	**<.0001**	.9666
Total FAOS Symptom	38.7 ± 20.7	**<.0001**	38.1 ± 20.7	**<.0001**	40.2 ± 20.8	**<.0001**	.5807