A Prospective Evaluation of a 3-D printed 4th Generation Total Ankle Prosthesis with Patient Specific Instrumentation with 1-year Follow-Up

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INTRODUCTION: Fourth-generation ankle replacements is evolving to account for the continued high rate of complications and revision following implantation. Previous studies have highlighted the importance of adequate positioning of total ankle implants for achieving favorable outcomes. Additionally, poor alignment has been associated with premature component wear. Moreover, literature in total joint arthroplasty has indicated that increased operative time is associated with increased postoperative complications. Patient specific instrumentation (PSI) has been proposed as a tool with implications to increase the accuracy of implant placement and reduce operative time. The purpose of this study is report on and compare prospectively collected patient reported outcome measures (PROMs) in a multi-institutional study of a 3D printed fourth-generation total ankle implanted with PSI.

METHODS: Patients presenting for a total ankle replacement at 12 institutions were prospectively enrolled and implanted in both academic and private settings. A total of 129 of 199 subjects enrolled have reached one year in follow-up currently, 124 (96.1%) of which were implanted using PSI. Patients had demographics and PROMs recorded preoperatively and at 6 month and 12-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 1-year of follow-up were analyzed.

RESULTS: From the 199 enrolled (51.0% male) with an average age of 63.2 ± 9.91 years old with an average BMI of 31.0 ± 6.3. The most common preoperative diagnosis was post-traumatic arthritis (69.8%), followed by degenerative arthritis (28.6%) and rheumatoid arthritis (1.6%). One patient experienced an intra-operative complication and at 1-year, there were 5 (4.0%) device related adverse events. The patients improved in all PROMs domains at one year, including: Mean Total AOS (PSI= -35.8 ± 22.6, p=?); PROMIS Global Physical Health (PSI= 1.7 ± 12.7, p=?); Total FAOS Symptom Scores (PSI= 33.2 ± 23.3, p=?). At 1 year 89.4% of PSI patients rated excellent or good in satisfaction with their surgery. DISCUSSION AND CONCLUSION: At the one-year post-implantation follow-up, the fourth-generation 3D printed total

ankle replacement utilizing Patient-Specific Instrumentation (PSI) demonstrated a low revision rate and exhibited safety and effectiveness. Patients who received implants with PSI reported experienced statistically significant clinical improvements across all domains of their PROMs as well as overwhelming patient satisfaction.