Ankle function is sustained between 4- and 8 years in a long-term prospective cohort study of ankle arthroplasty versus arthrodesis

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INTRODUCTION:

End stage ankle arthritis (ESAA) is a debilitating condition associated with pain, dysfunction, and reduced quality of life equivalent to those reported by patients with end stage hip osteoarthritis (OA), congestive heart failure, or end stage kidney disease. Patients who have failed conservative management seeking surgical treatment have two primary treatment options: ankle arthrodesis (AA) and total ankle arthroplasty (TAA). Early studies showed higher adverse event rates with ankle replacement, and comparable outcomes. More recent studies have shown better functional outcomes with TAA. The increasing volumes of TAA has led to calls that directly compare TAA with AA.

METHODS:

This IRB approved prospective cohort study included 6 sites with enrollment from May 2012 to May 2015. Adult patients seeking surgery for ESAA who were candidates for either AA or TAA were recruited to participate. Subjects were excluded if they had systemic disease such as inflammatory arthritis or had other disorders that impacted gait. Surgeons were recruited who had experience with both procedures. Prior to surgery and at 12-month intervals, the following patient reported measures were collected: The *Foot and Ankle Ability Measure* (FAAM) Scales (ADL and Sports)and the SF-36 physical and mental health capacity (PCS and MCS) measures. Pain was assessed using numeric rating scales for worst and average ankle pain. And three validated patient satisfaction questions were assessed. Age, sex, and BMI and other factors unequally distributed between groups and associated with the outcomes were included as covariates in all multivariable analyses.. Linear mixed effects regression was used to estimate the trajectory of postoperative improvement in outcomes up to eight years. All models included main effect variables by study visit interactions to estimate the difference in postoperative improvement by surgical procedure adjusting for potential confounders. Hypothesis testing focused on testing for improvement in outcome at eight years from pre-op or four years for all patients and how these improvements differed by surgery group.. Sensitivity analyses to address confounding by indication employed inverse probability of treatment weighting (IPTW) in a propensity score analysis. In addition, multiple imputation of missing follow-up outcomes was carried out to test robustness of findings due to potential informative loss to follow-up using the MICE algorithm which was particularly important for later follow-up time points.

RESULTS:

Among those who consented, 419 underwent TAA and 103 underwent AA. Follow up scores were available in 426 (82%), 346 (67%), and 269 (52%) of patients at four, six, and eight-years follow-up with approximately equivalent percentages of follow-up in each surgery group. The attrition reflects those who have either withdrawn, missed (but still engaged), died, or not reached the corresponding follow-up window. Pre-treatment, the two groups were not substantially different by sex, race, marital status, education, severity of OA, alignment, osteoporosis, degenerative disc disease, or alcohol use and there was no difference in the baseline function and pain measures by group. TAA patients were older and lighter, less likely to be employed full-time, higher income, less likely to have post-traumatic ESAA, previous ankle surgery, an anxiety or depression disorder, had lower functional comorbidity index scores, and were less likely to smoke and had higher Kellgren-Lawrence grades.

At eight years of follow-up, all outcomes in both groups maintained strong improvement compared to pre-op ($p<.0.0001$[NDC(S1)]). Overall mean eight-year improvement from pre-op for the FAAM ADL and Sports scores was 27 (95% CI, 25-29) and 28 (95% CI, 25-31) points, respectively, far exceeding the MCID for both groups and both outcomes. Mean eight-year improvement in the SF-36 PCS was 8.6 (95% CI, 7.5-9.7) points and mean improvement in the worst and average pain scales was 5.3 (95% CI, 5.0-5.6) and 4.0 (95% CI, 3.8-4.3) points, respectively. Those undergoing TAA maintained an 11 point (95% CI, 6-15) greater mean improvement in the FAAM ADL score at eight years than those undergoing AA ($p<.0001$). While there were declines in mean improvement from four to eight years post-op in the two FAAM measures and the SF-36 PCS, in patients overall, these were relatively small in magnitude compared to the overall improvement from pre-op. Significant Improvement from baseline in both pain measures was maintained from four to eight years within in both treatment groups with no significant difference. Satisfaction outcomes were high in both groups but slightly higher in the TAA group.

DISCUSSION AND CONCLUSION: In conclusion, both treatments for ESAA are effective maintaining pain relief and improving patient-reported functional outcomes. These gains are sustained over an eight-year period. While there is some attenuation in functional outcomes between four and eight years in both groups, this same attenuation is not observed in

pain reduction. Despite both surgical approaches being effective, TAA maintains a slight edge in improvement over AA in up to eight years after surgery.