Determining Bias in Ankle Replacement Studies Conducted by Design versus Non-design Surgeons

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INTRODUCTION:
Total ankle arthroplasty (TAA) is an alternative to ankle arthrodesis for the treatment of end-stage arthritis while maintaining greater ankle motion and functionality. Early generation implants had unacceptably high complication rates. Increasing experience of foot and ankle surgeons with the procedure and newer third-generation designs have the potential to offer better outcomes; however, the literature has shown that articles written by design surgeons presents biased results. Therefore, the purpose of this study is to compare the reported outcomes between studies conducted by design and non-design surgeons.
METHODS:
A comprehensive search of MEDLINE for all articles published between 1996 and 2021 was conducted with a minimum two-year follow-up. Two reviewers evaluated each study to determine whether it was eligible for inclusion and abstracted the data of interest. Meta-analytic pooling of group results across studies was performed, including patient-reported outcome measures (PROMs) (i.e., AOFAS, FFI, SF-36). Fifty-two implant groups met inclusion criteria, of which eight were authored by a design surgeon. In total, 4,693 subjects were included with a mean age of 59.89 years and mean BMI of 27.77 kg/m^2. Statistical analysis between articles of design and non-design surgeons was performed using two-tailed Student *t*-test.
RESULTS:
Overall, at mean follow-up of 68.91 months, the reoperation rate was 25.2% (design=23.5%, non-design=25.5%; p=.843), revision rate was 9.3% (design=9.0%, non-design=9.4%; p=.935), and conversion to arthrodesis rate was 5.0% (design=2.5%, non-design=5.5%; p=.243). According to the COFAS Reoperations Coding System (CROCS), the majority of reoperations were not around the ankle (Code 1: 76.65%). Mean postoperative plantarflexion (p=.007) and mean preoperative dorsiflexion (p=.006) were significantly greater among non-design surgeons' reports. There was no difference in any pre- or postoperative PROM between groups. The implant survival rate at one, two, five, and ten years was 97.7% (design=98.5%, non-design=97.6%, p=.732), 96.5% (design=97.0%, non-design=96.4%, p=.865), 92.1% (design=96.4%, non-design=91.3%, p=.865), and 79.2% (design=87.9%, non-design=76.3%, p=.070), respectively.
DISCUSSION AND CONCLUSION: In the reporting of TAAs, design surgeons do not appear to be biased. Although reoperation, revision, and conversion to arthrodesis rates were worse among non-design surgeons, this was not significant. Similarly, implant survival was reportedly better for design surgeons, but this was not significant either. However, there was greater implant survival in the design surgeon group at ten years, as compared to non-design surgeons, with a *p*-value approaching statical significance. Overall, there was no obvious evidence of bias in TAA implant studies when comparing design vs non-design surgeons.