

One-Stage versus Two-Stage Treatment for Prosthetic Joint Infection: A Prospective, Randomized Clinical Trial

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INTRODUCTION: A two-stage approach is most commonly used to treat prosthetic joint infection (PJI). Successful one-stage studies are underpowered, lack a two-stage comparative group, and exclude patients with comorbidities or resistant organisms. Given the morbidity and expense of two-stage treatment, we conducted a multicenter, randomized trial to compare the results of one- and two-stage treatment for chronic PJI, specifically including patients with comorbidities and resistant organisms.

METHODS: Chronically infected primary hip and knee arthroplasties defined by MSIS criteria with a known organism were included. Exclusions were revision patients, fungal infections, immunosuppressed patients, or soft tissue involvement precluding wound closure. Patients were classified according to MSIS host staging system. Success at one-year was defined as no reoperation for PJI. All patients underwent a double surgical setup, similar irrigation protocols, six weeks of IV antibiotics initially, and six months of oral antibiotics post reimplantation. A total of 321 patients (n=164 one stage; n=157 two stage) were randomized. Groups were similar with respect to demographics and host classification. To date, 50 of 321 (16%) patients are lost to follow up, and 26 (8%) patients have not completed the study. For this interim, one-year analysis, 245 patients (n=128 one-stage; n=117 two-stage) were included in the comparison of success rates.

RESULTS: Overall, the one-year success rate of one-stage treatment was 98% (125/128) while the success of two-stage treatment was 94% (110/117) (p=.15). Compared to the two-stage group, the one-stage group had a 61% reduced relative risk of failure (RR .39; 95% CI.10, 1.4). After adjusting for age and MSIS host classification, relative risk of failure was 1.02 (95% CI .99, 1.04). Adverse event rates were also similar between groups [one-stage 32% (53/164) vs. two-stage 38% (60/157); p=.27].

DISCUSSION AND CONCLUSION: Interim results of this randomized-controlled clinical trial indicate that the success rate of one- and two-stage treatment for PJI is similar.