A Prospective, Double-Blinded, Randomized Controlled Trial of an Acellular Amnion-Derived Allograft Injection Comparing Two Doses (1cc and 2cc injection) and a Placebo in the Treatment of Osteoarthritis of the Knee.

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INTRODUCTION: The purpose of this study is to determine the dose effect of a single acellular amnion-derived allograft allograft (AADA) injection for the treatment of symptomatic knee osteoarthritis (OA). Three treatment arms, including a placebo, are utilized to determine whether the use of 2cc AADA offers a statistically significant advantage over 1cc AADA in the treatment of knee osteoarthritis.

METHODS: Sixty-one (N = 61) patients with unilateral primary knee OA, defined as Grade 1 through 3 on the Kellgren Lawrence grading scale, were randomized into three treatment arms: 1cc AADA, 2cc AADA, or a sterile saline placebo injection. The patients, the clinician performing the injection, and research staff were blinded to the dosage. Patients were contacted 24 hours after their injection to document any adverse events. Patient-reported outcome measures (KOOS, WOMAC, and VAS Pain) as well as any adverse events were recorded at baseline and at 1, 3, and 6 month post-injection intervals.

RESULTS: Seventeen (N = 17) patients received a 1cc AADA injection, 28 patients received a 2cc AADA injection, and 16 patients received a placebo injection. No adverse events were reported throughout the follow-up period. Standard t-tests and Wilcoxon t-tests were performed and revealed no statistically significant differences in pain VAS scores between all three groups and no difference in outcome scores between the 1cc and 2cc AADA groups. There were significant differences in mean outcome scores between the 1cc and placebo groups at 6 months post-injection for KOOS Daily Living (P = 0.005, 1cc = 88.06, Placebo = 72.98), KOOS Pain (P = 0.01, 1cc = 80.23, Placebo = 65.8), KOOS PS (P = 0.006, 1cc = 21.12, Placebo = 32.88), KOOS Quality of Life (P = 0.02, 1cc = 64.34, Placebo = 45.7), KOOS Symptoms (P = 0.044, 1cc = 77.31, Placebo = 66.07), KOOS JR (P = 0.009) (Mean 1cc = 75.49) (Mean Placebo = 62.66), Total WOMAC (P = 0.009, 1cc = 17.91, Placebo = 31.49), WOMAC Function (P = 0.005, 1cc = 11.94, Placebo = 27.02), WOMAC Pain (P = 0.019, 1cc = 15.59, Placebo = 29.69), and WOMAC Stiffness (P = 0.005, 1cc = 23.53, Placebo = 43.75). There were significant differences in mean outcome scores between the 2cc and placebo groups at 6 months post-injection for KOOS Daily Living (P = 0.045, 2cc = 81.25, Placebo = 72.98), KOOS Pain (P = 0.016, 2cc = 77.48, Placebo = 65.8), KOOS JR (P = 0.02, 2cc = 72.04, Placebo = 62.66), WOMAC (P = 0.009, 2cc = 22.59, Placebo = 31.49), WOMAC Pain (P = 0.017, 2cc = 17.5, Placebo = 29.69), and WOMAC Stiffness (P = 0.023, 2cc = 29.02, Placebo = 43.75).

DISCUSSION AND CONCLUSION: Acellular Amnion-Derived Allograft (AADA) injections appear to be effective and well tolerated in the treatment for knee OA. No dose-related effect was observed between the 1cc and 2cc groups; moreover, both groups had improved outcomes compared to the placebo.