The FIRST published, multicenter randomized clinical trial evaluating the efficacy of an amniotic injection for the treatment of symptomatic knee osteoarthritis.[1]

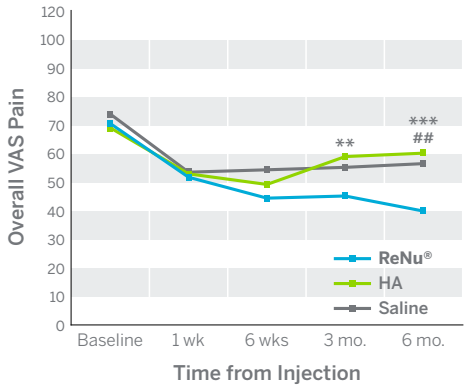
Study Design

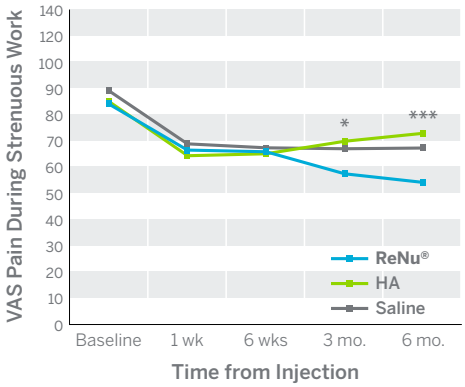
A multicenter randomized controlled clinical trial was designed to evaluate the efficacy of ReNu®, an amniotic suspension allograft (ASA), compared to hyaluronic acid (HA) and saline in patients with symptomatic knee osteoarthritis. A total of 200 patients enrolled over 12 sites were blinded to their allocation and were randomized 1:1:1 to one of three treatment arms: a single injection of ReNu, a single injection of a commercially available hyaluronic acid (HA), or a single injection of saline. Changes from baseline of patient-reported outcomes (PROs) were compared between groups. Statistical analysis was completed by comparing changes in PROs from baseline to 3 and 6 months for all groups.[1]

Results

Visual Analog Score (VAS)

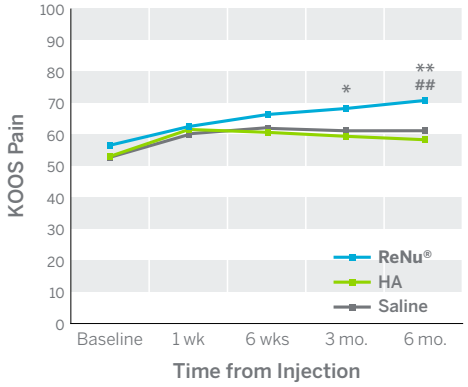
The ReNu treatment group had **significantly greater improvements** in overall pain (decreased pain scores), strenuous work scores, and normal daily living score compared with the HA group at 3 months. At 6 months, ReNu treatment resulted in **significantly greater improvements** in pain scores compared with both HA and saline, and improved strenuous work and normal daily living scores compared with the HA group.[1]

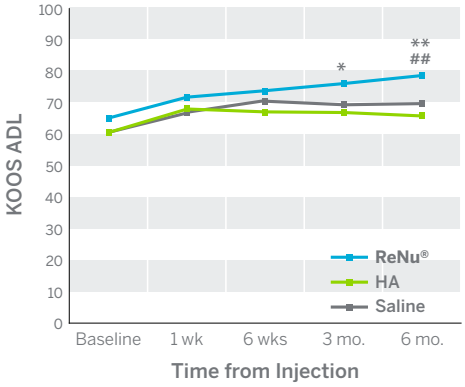




Knee Osteoarthritis Outcome Score (KOOS)

At 3 months, the ReNu treatment group showed **significantly greater improvements** in pain and activities of daily living (ADL) scores compared with the HA group, and **significantly greater improvements** in the symptoms score compared with both HA and saline groups. At 6 months, the ReNu group showed **significantly greater improvement** compared with HA in the sports and recreation and quality of life subsets, and **significantly greater improvement** compared with both HA and saline groups in the pain, symptoms, and ADL subsets.





SCAN TO ACCESS THE FULL STUDY

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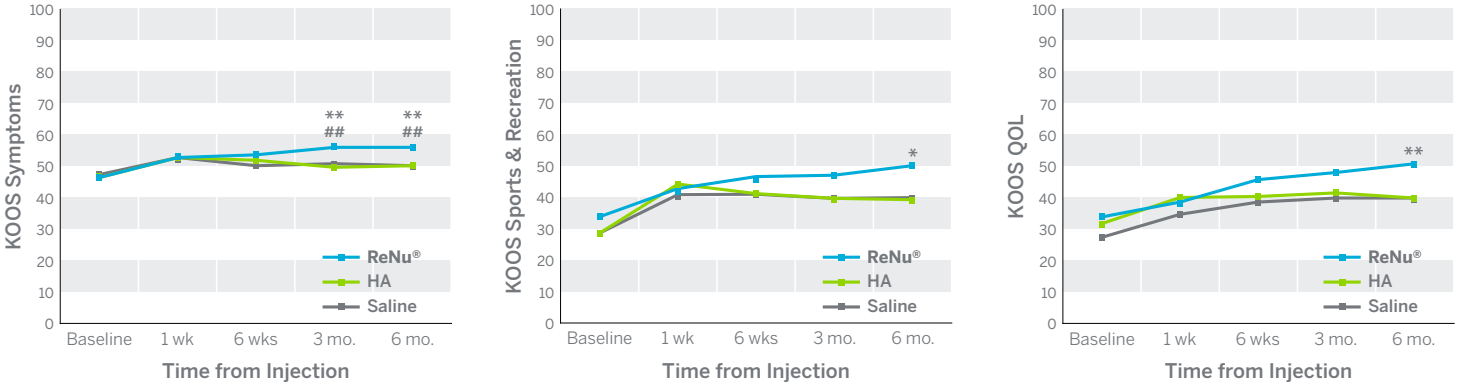
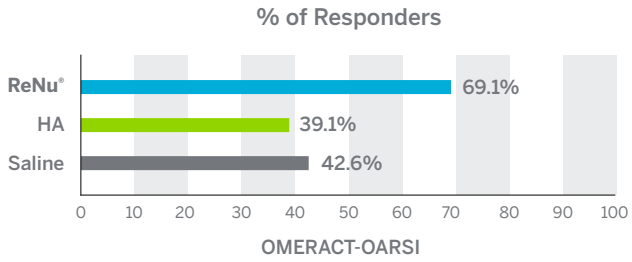
Results (cont'd)

Knee Osteoarthritis Outcome Score (KOOS) (cont'd)



OMERACT-OARSI Responder Analysis

At 6 months, ReNu, HA, and saline responder rates for the OMERACT-OARSI simplified criteria were 69.1, 39.1, and 42.6%, respectively.[1]



Summary

- This multicenter randomized controlled trial was designed to evaluate the efficacy of symptom modulation with ReNu, an amniotic suspension allograft (ASA), compared with saline and hyaluronic acid (HA) in subjects with knee osteoarthritis. The study found that the results of treatment with ReNu were superior to HA and saline.[1]
- Comparison of demographics between treatment groups showed no significant differences between groups.[1]
- Patients reporting unacceptable pain at 3 months in each group were ReNu (13.2%), HA (68.8%), and saline (75%).[1]
- Patients receiving ReNu treatment demonstrated significantly greater improvements from baseline for overall pain (VAS), KOOS pain, and KOOS-adjusted daily living scores compared with those in the HA group at 3 months and both groups at 6 months. ReNu patients had significantly greater improvements in KOOS symptoms scores compared with HA and saline at 3 and 6 months, respectively.[1]
- OMERACT-OARSI responder rates for ASA, HA, and saline groups were 69.1, 39.1, and 42.6%, respectively.[1]

To access the full study, scan the QR code on the previous page or visit https://www.thieme-connect.com/products/ejournals/pdf/10.1055/s-0039-1696672.pdf

2641 Rocky Ridge Lane | Birmingham, AL 35216
(800) 824-9194 Toll Free | (877) 402-8598 Fax | **www.organogenesis.com**

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References: 1. Farr J, Gomoll AH, Yanke AB, Strauss EJ, Mowry KC, ASA Study Group. A Randomized Controlled Single-Blind Study Demonstrating Superiority of Amniotic Suspension Allograft Injection Over Hyaluronic Acid and Saline Control for Modification of Knee Osteoarthritis Symptoms.. J Knee Surg. 2019;32(11):1143-1154.

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