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Knee Osteoarthritis Treatment

Cryopreserved Amniotic Suspension for the Treatment of Knee Osteoarthritis

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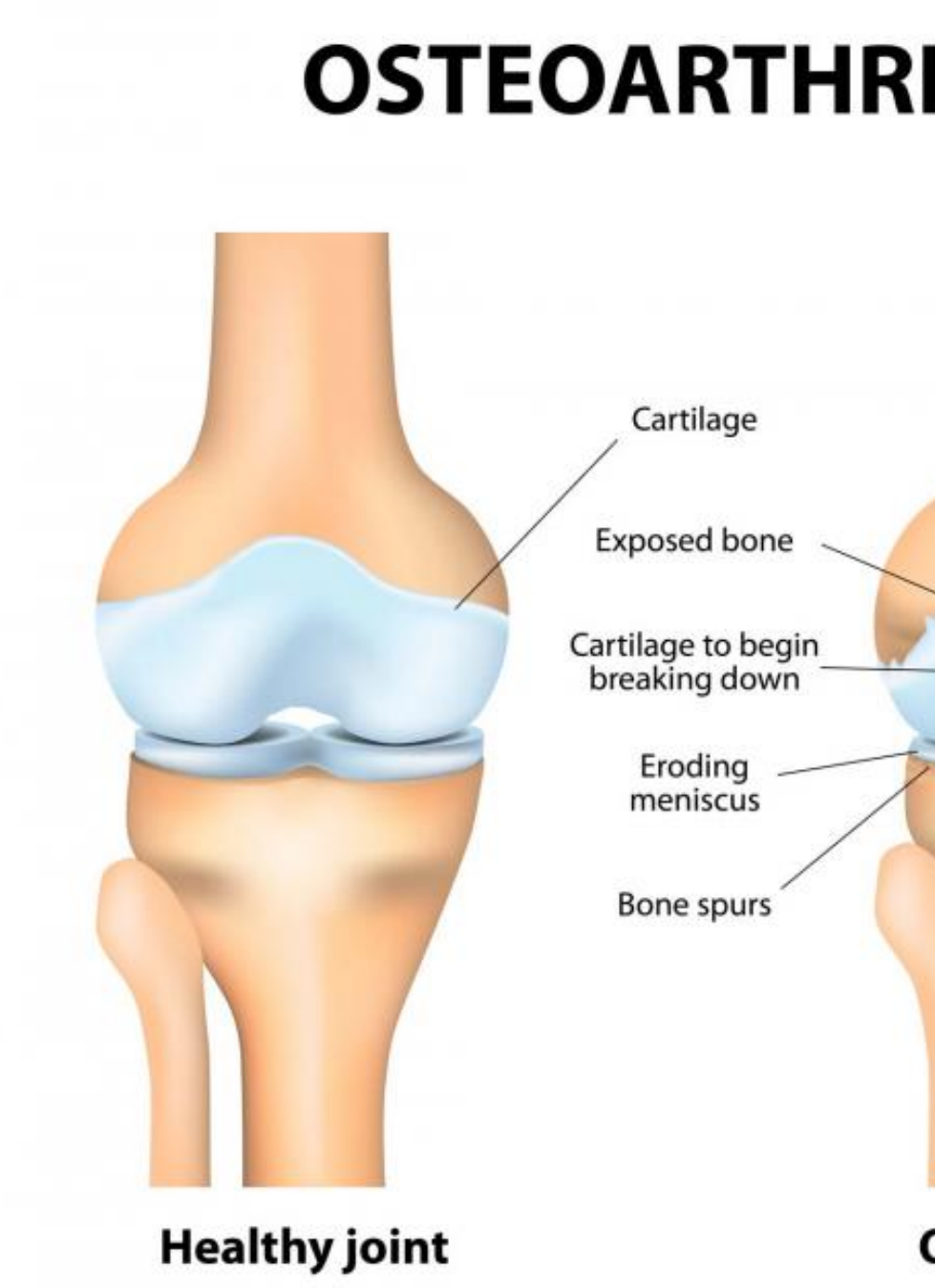

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This preliminary study lacks the "power of numbers", but begins to address the use of amniotic/placental allograft stem cells in patients, a treatment with great but unproven potential. Hopefully, much larger and more detailed studies will follow. -Kelly Cunningham MD

Abstract

There are few treatment options for symptomatic knee osteoarthritis (OA).Human amniotic suspension allografts (ASA) have anti-inflammatory and chondroregenerative potential and thus represent a promising treatment strategy. In anticipation of a large, placebo-controlled trial of intra-articular ASA for symptomatic knee OA, an open-label prospective feasibility study was performed. Six patients with Kellgren-Lawrence grades 3 and 4 tibiofemoral knee OA were administered a single intra-articular ASA injection containing cryopreserved particulated human amnion and amniotic fluid cells. Patients were followed for 12 months after treatment. No significant injection reactions were noted. Compared with baseline there were (1) no significant effect of the ASA injection on blood cell counts, lymphocyte subsets, or inflammatory markers and (2) a small, but statistically significant increase in serum IgG and IgE levels. Patient-reported outcomes including International Knee Documentation Committee, Knee Injury and Osteoarthritis Outcome, and Single Assessment Numeric Evaluation scores were collected throughout the study and evaluated for up to 12 months. Overall, this study demonstrates the feasibility of a single intra-articular injection of ASA for the treatment of knee OA and provides the foundation for a large placebo-controlled trial of intra-articular ASA for symptomatic knee OA.

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The KOOS5 outcome score increased from a baseline of43.35 to 70.23 by the 1-year time point. The IKDC assessment increased from an average score of 41.7 at baseline to 63.4 at 6 months. This improvement was maintained at the 1-year time point with an average of 64.4. SANE scores30 increased from an average of 51.25 at baseline to 87.3 at 6 months. This improvement was maintained at the 1-year time point, with an average score of 85.8. Due to the small patient population assessed, it was determined that statistical testing would not be appropriate for PRO data.

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