

Artificial Cartilage Replacement – Early Clinical Results

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Statement of Purpose: Management of chondral and osteochondral damage utilizes techniques that repair or regenerate the articular surface. Of the available methods for treating articular cartilage defects of the knee, osteochondral allograft transplantation, autologous chondrocyte implantation (ACI) and osteochondral autograft transfer surgery are frequently utilized. Non-biologic or synthetic solutions, if successful, may offer several advantages.

An implant made from a synthetic hydrogel has been developed that has the strength and biphasic viscoelasticity of normal articular cartilage. This implant, called SaluCartilage-TM, has mechanical properties that are similar to the articular cartilage and is capable of withstanding repetitive loading typical of normal walking conditions. The purpose of this study is to determine the feasibility and early-term efficacy of the SaluCartilage implant for the treatment of painful focal chondral and osteochondral lesions.

Methods: This study is a multi-center short-term feasibility and efficacy study that includes a non-randomized prospectively evaluated cohort of patients with knee pain due to articular cartilage damage. Indications for treatment include the existence of a known symptomatic focal chondral or osteochondral defect including osteochondritis dissecans or localized arthritic change of the knee articular surface. Exclusion criteria included infection, pregnancy, generalized osteoarthritis, uncorrected ligamentous instability, and previous joint replacement in the contralateral knee.

The IKDC (International Knee Documentation Committee) score was used to assess improvement in individual components (e.g., pain, function, range of motion) and overall score. Irrgang et al. have shown that the IKDC is a reliable and valid knee-specific measure of symptoms, function and sports activity and is appropriate for any age group, sex or knee diagnosis. A paired Students' t test was used to evaluate changes that were statistically significant at the $p < 0.05$ level.

Results: The pre-operative survey of activity level and range of motion was captured using the validated IKDC score system. In general, the severity of disease in these first patients was high. For the forty-eight patients who provided both baseline and 3-month data, the mean IKDC score before surgery was 41 (range 22-86). The IKDC score was then compared to surveys taken 3 months after the operation. The scores were compared in a t-test for statistical significance.

Safety of treatment with this device can be deduced from complication rates. Surgeons performing the first 137 implantations were polled to reveal any complications. This survey revealed 8 adverse events. The surgeons who operated on the patients with adverse events were interviewed, and, where possible, retrieved devices were analyzed. In the 8 adverse events, one or

more implants were removed in a second operation. Six cases involved first time use of the implant and the other two cases involved second time use of the implant by the surgeon. Seven cases involved an implant dislocation. In these cases patients complained of effusion (five), of pain (five), decreased range of motion (four), joint locking (one), and a foreign body feeling in the knee (one). One patient was noted to have a bone cyst below the implant. The source of these dislocations has been traced to the drill size and has since been corrected. The 8 complications occurred in the first 137 patients implanted with a SaluCartilage device; therefore, the complication rate is 8/137 or 5.8%.

The first surgeries demonstrated a learning curve where improvement was noted after the surgeon had performed two or more implants. Including initial surgeries, the success rate overall was 62% ($n=48$). In this group, the average improvement in IKDC score was 14 points ($p < 0.001$). However, excluding the initial two surgeries performed by surgeon gave a subsequent success rate of 87% ($n=15$). The IKDC scores also improved by 21 points in this second group.

Of the forty-eight patients with 3-month data, fourteen failed to meet the inclusion/exclusion criteria listed in the product Instructions for Use. Specifically, these patients had either a varus/valgus knee or uncorrected ligamentous instability, which are both contraindicated for SaluCartilage implantation. Additionally, previous ACL surgery had a negative impact on overall success. Excluding these patients from the group where two or more surgeries were performed yielded a **success rate of 92%** ($p < 0.001$, $n=13$) with an average **improvement in score of 24 points**, highly clinically significant.

Discussion: The use of SaluCartilage implants for pain relief and maintenance of joint function is supported by the clinical evidence presented in this study. The efficacy of the device is demonstrated by the statistically and clinically significant improvement in IKDC scores in all patient groups after 3 months. By following inclusion and exclusion criteria and considering additional patient selection criteria, the level of clinical improvement increases. The best indication for clinical success was in patients with a painful focal chondral or osteochondral defect with decreased knee function, a relatively stable knee, and no previous ACL reconstruction. SaluCartilage may be used to treat painful focal chondral or osteochondral articular cartilage defects. The device provides clinically significant improvement with few complications.

References: Irrgang J, Anderson A, Boland A, et al.: Development and validation of the international knee documentation committee subjective knee form. The American Journal of Sports Medicine 29(5):600-613, 2001.