Treatment of Osteochondral Lesions in the Ankle with a Particulated Juvenile Cartilage Allograft: Mid-Term Outcomes in a Challenging Clinical Population

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Introduction
Numerous treatment modalities are in use today to treat symptomatic osteochondral lesions in the ankle; however, there are ongoing challenges with the treatment of certain types of lesions and concern regarding the long-term effectiveness of current techniques.

Methods
The purpose of this study was to collect clinical outcomes of pain, function, and activity level in patients treated with DeNovo NT Natural Tissue Graft for symptomatic osteochondral lesions in the ankle. This single-arm, multi-center study collected outcomes prospectively in standard clinic patients who would be undergoing or who had previously undergone treatment with DeNovo NT Graft. Information was collected on reoperations and adverse events; no biopsies were collected for study purposes. The main exclusion criteria were high surgical risk, clinically diagnosed autoimmune diseases, or an active joint infection. The analysis presented here includes final follow-up to date for enrolled subjects who had reached at least the 12-month post-op visit.

Results
Eight males and eight females with an average age at surgery of 32.5 (range 17.5–69) years and an average BMI of 27.6±6.8 were included in this analysis. Nine subjects had failed at least one prior cartilage repair treatment including bone marrow stimulation (n=7), osteochondral autograft (n=1), and debridement (n=1) for the index lesion. All treated lesions were located either on the medial (n=13) or lateral (n=3) aspect of the talar dome and were accessed via an open (n=6), arthroscopic (n=3) or extended portal (n=7) procedure; half required osteotomies for lesion access. The average lesion size (n=14) was 128±78 (range 50–300) mm² with an average depth (n=11) of 6±5 (range 3-20) mm. Note that all lesions had at least one dimension ≥ 10 mm. In conjunction with the DeNovo NT Graft treatment, 25% of subjects had one concomitant procedure while 38% had more than one. Concomitant procedures included hardware removal and treatment for impingement, synovitis, instability, and malalignment. Clinical evaluations were performed with an average follow-up time of 16.4 (range 10.5-24.0) months. Available pre-operative scores showed an average (± SD)
AOFAS score of 59±24 (n=10). Average outcome scores at final follow-up (n=16) were AOFAS 82±20, SF12 PCS 49±11, SF12 MCS 55±5.7, FAAM ADL 83±16, FAAM Sports 65±28, and VAS pain (100mm) 19±23. An AOFAS score ≥ 80 was considered a good/excellent outcome in the combined assessment of ankle pain, function, and alignment; a SF12 score of 50 represents average health status. To date no graft failures have been reported; however, six re-operations at an average of 14.9 (range 2.5-21) months post-surgery have occurred. Five re-operations were performed to remove symptomatic or failed osteotomy hardware and one to correct anterior impingement. Two of the procedures included minimal debridement of the DeNovo NT Graft.

Conclusion
Preliminary data from a challenging clinical population with relatively large, symptomatic osteochondral lesions in the ankle suggests that treatment with a particulated juvenile cartilage allograft could provide an improvement in patient symptoms of pain and function. Longer follow-up and additional subjects are needed to evaluate improvement level and ideal patient indications.