# Treatment of Ankle Arthritis with Regenerative Medicine Injections: A Prospective Study of 22 Patients

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## Abstract

Ankle osteoarthritis, whether primary or secondary, is a pathological condition that many times requires aggressive surgical options including arthrodesis versus arthroplasty. Ankle arthroscopy is a common, more conservative, procedure that can be used as an alternative to conservative therapy as well. Regenerative medicine in the form of autogenous verse allogenic mesenchymal stem cells (MSCs) are arising as an alternative option. Twenty-two patients with primary and post-traumatic osteoarthritis were evaluated who received a regenerative medicine injection into the ankle. Of the 22 patients, 11 had a single injection in the office and 11 had an injection in the operating room after an arthroscopic debridement of the ankle joint. At the one-year follow-up VAS, AOFAS, and FFI scores were all found to demonstrate statistically significant improvement. This is the first report of the use of MSCs in the ankle showing satisfactory one-year results.

| | Pre-operative | | | 6 months post-operative | | | 1 year post-operative | | |
|---|---|---|---|---|---|---|---|---|---|
| | VAS | AOFAS | FFI | VAS | AOFAS | FFI | VAS | AOFAS | FFI |
| Average | 4.9 | 51.4 | 63.3 | 1.7 | 80.6 | 20.8 | 3.2 | 74 | 32.7 |
| STDEV | 3.1 | 18.5 | 14.5 | 2.5 | 18.1 | 17 | 1.5 | 16.7 | 17.8 |

Table 1.

## Methodology

A prospective, nonrandomized, consecutive enrollment cohort was established for any patient undergoing an injection with regenerative medicine. The pathologies leading to the procedure were limited to either primary or post-traumatic osteoarthritis. A single center was utilized for all procedures, and all procedures/injections were performed by the senior author from March 2016 through June 2018. A total of 22 patients were consecutively enrolled in the study. Injection substance was randomized into autogenous or allogenic. The authors and patients were not blinded to the product being used. Age, date of procedure, gender, BMI, history of tobacco or diabetes, and laterality are summarized in **Figure 1**. Kellgren-Lawrence grade (**Figure 2**), arthroscopic debridement of the ankle joint performed in the OR, sole injection in the office setting (**Figure 3**), and product used (**Figure 4**) were evaluated. Exclusion criteria included any patient who was unable to follow-up for the appropriate time frame, non-compliant with physical therapy or post-operative protocol. Injectable materials included a 1cc cryopreserved amniotic suspension allograft (Renu, Organogenesis, Canton, MA) or bone marrow aspirate (BMA) harvested from the patients ipsilateral calcaneus.

## Results

| Demographics | | STDEV |
|---|---|---|
| Mean Age | 68.8 | 16.49 |
| Males | 13 | x |
| Females | 9 | x |
| BMI | 27.6 | 9.02 |
| Tobacco | 3 | x |
| Diabetes | 0 | x |
| Left | 6 | x |
| Right | 16 | x |

Table 2.

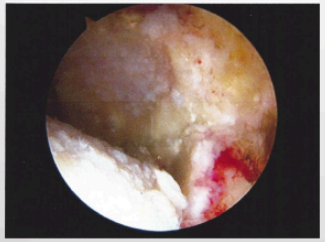


Image 1.

After application of the inclusion/exclusion criteria a total of 22 patients were included. The mean age was 68.8 years. There were 12 males (13/22, 59%) and 9 females (9/22, 41%). Of the 22 ankles, 11 (11/22, 50%) were performed in the office and 11 (11/22, 50%) were performed in the OR. The products utilized were a cryopreserved amniotic suspension allograft (15/22, 68%), and bone marrow aspirate (7/22, 32%). Pre-operative, 1 month, 2 months, 3 months, 6 months, and 1-year post-op VAS, AOFAS, FFI scores were obtained. The pre-operative VAS, AOFAS, FFI scores improved from a mean of 4.9(1-10), 51.4 (20-84), and 63.3 (35-100) to 1.7 (0-5), 80.6 (64-100), and 20.8 (0-41) at the 6-month mark. An unpaired student's t-test with significance set to $p<0.05$ was utilized to compare non-categorical variables and there was noted to be a statistically significant difference in the scoring for VAS ($p<0.03$), AOFAS ($p<0.001$), and FFI ($p<0.001$) at the 6-month follow-up.

The one-year VAS, AOFAS, and FFI scores were also evaluated and found to have improved at 3.2 (1-5), 74.0 (45-90), and 32.7 (8-55). Again, an unpaired t-test was used to compare the results and there remained statistical significance ($p<0.05$). A post-hoc analysis was then performed to evaluate if there was a difference in the outcomes between an in-office injection versus an injection in the OR following an adjunct arthroscopy. When the OR and in office procedures were separated there was noted to be no significant difference between the VAS, AOFAS, or FFI scores at 12 months.

| Product | |
|---|---|
| BMA | 7 |
| Amnion | 15 |
| Total | 22 |

Table 3.

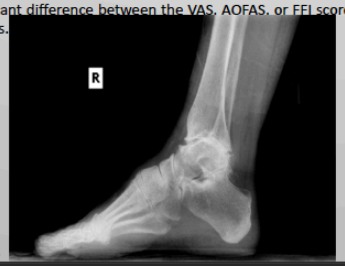
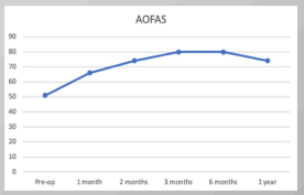



Image 2.

Image 3.

## Analysis & Discussion

The authors believe there is a role for regenerative medicine in ankle surgery. To the authors' knowledge this is the first report, to the authors' knowledge, that has a short-medium term nonbiased outlook for the use of regenerative medicine that shows promising results for primary and post-traumatic ankle osteoarthritis. Despite the results showing no statistical difference, the authors believe there is a benefit in performing an additional arthroscopic debridement. This gives the surgeon the ability to remove fibrosis, adhesions, synovitis, inflammatory cells within the joint fluid as well as the ability to evaluate for unexpected additional intra-operative findings (i.e osteochondral defects, osteophytes, loose bodies) that can be further addressed intra-operatively. We believe this debridement can achieve a more satisfactory result. However, we would advocate for limited debridement of osteophytes around the joint as this may recreate extra motion that could lead to increased pain within the joint.




Graph 1.


Graph 2.

## Figures & Tables

Table 1. VAS, AOFAS, and FFI scores summary.
Table 2. Demographics
Table 3. Products used indicated autograft vs allograft
Image 1. Severe ankle osteoarthritis as visualized arthroscopically.
Image 2. Lateral radiographs of severe osteoarthritis
Image 3. AP radiographs of severe ankle osteoarthritis.
Graph 1. Mean AOFAS scores (x-axis) vs time (x-axis)
Graph 2. Mean VAS scores (x-axis) vs time (x-axis)