

Infiltration with Microfragmented Adipose Tissue in the Treatment of Ankle Osteoarthritis: A Pilot Study

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INTRODUCTION:

Ankle osteoarthritis affects approximately 2% of the world population and it is a debilitating and progressive condition. This seems like a small percentage but it is a considerable number if we think that we are about 8 billion people in the world. Unlike the hip and knee joint, ankle osteoarthritis is secondary to previous trauma in 90% of cases.

To limit the progression of osteoarthritis, various therapeutic approaches, surgical and nonsurgical, have been studied and attempted over the years. The goal is to maximize therapeutic efficacy and, at the same time, minimize the incidence of side effects. For these reasons, new therapeutic approaches have been developed, such as regenerative medicine that uses mesenchymal stromal cells. Cells can be isolated from various tissues such as bone marrow, blood, and adipose tissue through mechanical or enzymatic processes.

In this sense, the use of mesenchymal stem cells harvested from adipose tissue has numerous advantages as usable fat is generally well represented in patients of all ages, the collection procedure is minimally invasive and the infiltration can be performed in a single surgical procedure.

METHODS:

The aim of this prospective study is to show the effect of the infiltration of microfragmented adipose tissue, in terms of clinical scores in 30 patients affected by moderate-severe grade ankle arthrosis (grade 1-3 according to Giannini's classification).

After the enrollment of the patients, a baseline clinic visit and a questionnaire was performed for each patient. An MRI of the affected ankle has been requested to each patient to rule out the presence of osteochondral lesions which excluded the patient from the study.

The surgical procedure consisted of three steps: collection of the adipose tissue, micro fragmentation and purification of the adipose tissue, and infiltration. The patient was light sedated. Before harvesting adipose tissue from the abdominal area through liposuction, a injection of a solution composed of 250 mL saline, 20 mL lidocaine 2%, and 0.5 mL adrenaline 1mg/mL was performed in the donor site.

About 10 minutes after the injection it was possible to proceed with adipose tissue aspiration. The fat was then microfragmented and purified with a dedicated instrument set. The device used for the collection of adipose tissue and its purification was a single-use closed-circuit device to collect, microfragment, and purify the lipoaspirate without using enzymes or centrifuge. Finally, 5 cc of the product obtained was infiltrated into the ankle affected by osteoarthritis.

The evaluation in clinical terms was carried out by a clinic visit and a questionnaire 1-3-6-12 months after surgery.

RESULTS:

The study showed an improvement in primary outcome measure, the AOS (Ankle Osteoarthritis Scale).

Secondary outcome indicators including AOFAS (the American Orthopedic Foot and Ankle score), VAS pain, SF-12, EQ-5D current health assessment, EQ-VAS, Patient acceptable symptom state (PASS), final judgment on treatment also have showed improving results over the months. Twenty-five patients of the total were very satisfied, 3 satisfied, and only 2 had not experienced any improvement.

DISCUSSION AND CONCLUSION:

In selected patients with moderate-to-severe ankle osteoarthritis, when conservative treatment is no longer effective, infiltration with mesenchymal cells harvested from abdominal fat could be a definitive therapy or a "bridge" to a more invasive surgery such as ankle prosthesis or arthrodesis. Despite a limited case series and a short-time follow up, the results obtained in this pilot study show the safety and potential benefit of the use of autologous microfragmented adipose tissue on people who are affected by moderate-severe ankle osteoarthritis.

Ankle osteoarthritis classification system (as suggested by Giannini and colleagues⁷¹)

Stage	Radiographic Osteoarthritis Signs
Stage 0	Normal joint or subchondral sclerosis
Stage 1	Presence of osteophytes without joint-space narrowing
Stage 2	Joint-space narrowing with or without osteophytes
Stage 3	Subtotal or total disappearance or deformation of joint space

Adapted from Giannini S, Buda R, Faldini C, et al. The treatment of severe posttraumatic arthritis of the ankle joint. *J Bone Joint Surg Am* 2007;89 Suppl 3:15.