The outcomes of Treating Shoulder Degenerative Joint Disease (DJD) and Related Rotator Cuff Tears with Autologous Micro Fragmented Adipose Tissue (MFAT) Processed by Washing/Fragmentation

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OBJECTIVES

A prospective, non-randomized, single-arm, clinical study examining the safety and efficacy of autologous MFAT generated by a MiniTC® device for the management of pain and function in the shoulder joints of osteoarthritic subjects with an associated diagnosis of rotator cuff partial thickness tear.

MATERIAL AND METHOD

The cohort selection criteria included Grade III or Grade IV osteoarthritis using the Kellgren Lawrence grading scale (K-L Grade) as diagnosed using physical examination, X-ray, and MRI. Study Subjects must have failed a minimum of two conservative therapies, spanning at least 4 months, including (i) oral pain medications, (ii) corticosteroid injection of the shoulder, (iii) viscosupplementation injection of the shoulder, and (iv) formal physical therapy. 21 patient cases were assessed for 12 months. The age range of patients was 58-80 years with a BMI average of 29.6. Gender split: 8 male, 13 female (Fig 1)

Subjects with unilateral disease had a minimum shoulder pain score of 5/10 using the Numeric Pain Score. Excluded were subjects whose shoulder pain was attributed to (1) displaced labrum tear, (2) biceps tendon dislocation, or (3) avascular necrosis. In addition, subjects who had surgery on either shoulder within 6 months before the screening visit and those who had a major injury to the targeted/treatment shoulder within 12 months before enrollment were excluded. Also, those who received an injection in either shoulder within the prior 3 months, including corticosteroids, viscosupplementation, or platelet-rich plasma (PRP) were excluded. Patients with gout, inflammatory arthritis, severe bone deformity, infection of the shoulder joint, or fibromyalgia were not part of the cohort. Also excluded were subjects who had symptomatic OA of the cervical spine that would potentially interfere with the evaluation of the problematic shoulder.

Fig1. ALL CASES SUMMARY

Case Count	21
Providers Count	3
Treatments per case	1
Age range	58-80
Avg BMI	29.6
Male	8
Female	13

INTERVENTION

Adipose tissue was harvested under local anesthesia by Tumescent infiltration.

Treatment consisted of 10ml of MiniTC processed MFAT injected under ultrasound guidance. The average total nucleated cell (TNC) dose delivered was 8.9x10v6 generated at the point of care.

CONCLUSION

All 4 assessed parameters reflected a statistically significant improvement in the first post-treatment month. The improvement has continued and increased one year after the treatment. At 18 months in a small number of patients, there was observed regress in QD and Pain Score, despite preserving the desired functionality score at the normal range.

RESULTS

The average baseline pain score pretreatment was 6/10 (range 5-7); at 12 mos., 1.08/10. There was no correlation between the pain score and DJD grade. QuickDASH (QD) score in which no disability is graded at 0 and inability to use at 100% was calculated at 60.2 on average (range 40.9 – 79.5) pretreatment diminishing to a statistically significant 18.8% at one year ($p < 0.05$) (Fig 2). The Functional Shoulder Score average was calculated at 47.4 (range 30-75) pretreatment; the functional score had improved by 32% in the first month and reached 81.8% improvement at 12 months ($p < 0.05$) and 88% at 18 months (partial data, n=4) (Fig.3). Pain rating has been improving steadily over 12 months from 6 points down to 1.5 ($p < 0.05$) while reverting to 4 points at 18 (based on 4 patients evaluation) (Fig 4). The combination WOOS score (%) has improved by 40% in the first month and demonstrated a statistically significant 75% improvement at 12 months. The total nucleated cell (TNC) dose delivered was 8.9x10v6 generated at the point of care his situation might give a demand for income and people statement negatively to our services.

Fig 2. QUICK DASH

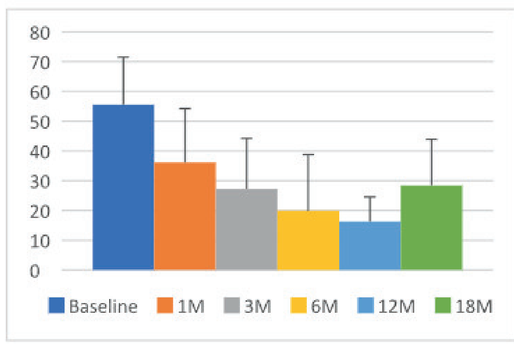


Fig 3. DESIRED FUNCTIONALITY

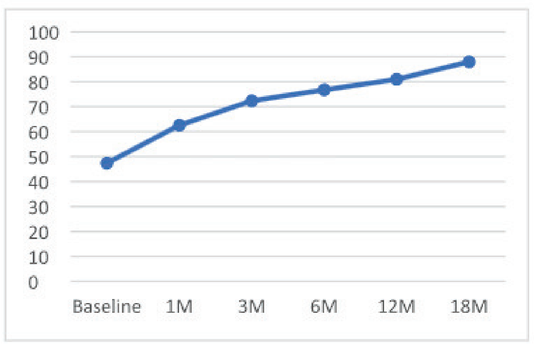


Fig 4. NUMERIC-PAIN-RATING

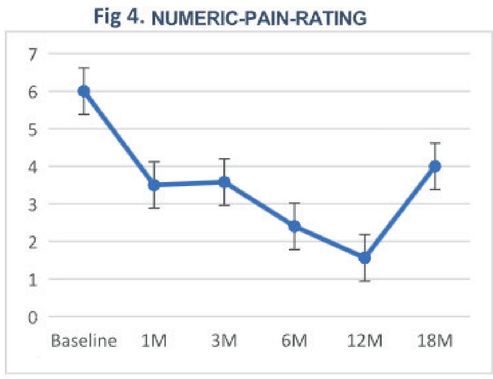
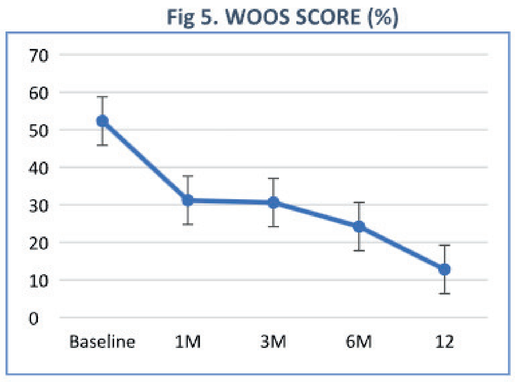


Fig 5. WOOS SCORE (%)



SUMMARY

MiniTC-generated MFAT is a safe and effective treatment for shoulder degenerative joint disease and rotator cuff pathology. The protocol is conveniently integrated into practice workflow, and well tolerated by patients. Clinically MiniTC MFAT produces clinically effective dose that delivers sustainable pain relief and functional improvement of the shoulder joint. This is an ongoing study and long-term evaluation will be reported.