

SAFETY AND EFFICACY OF PERCUTANEOUS INJECTION OF LIPOGEMS MICRO-FRACTURED ADIPOSE TISSUE FOR OSTEOARTHRITIC KNEES

Jay Panchal, MD^{1,2}, Gerard Malanga, MD^{1,2}, Mitchell Sheinkop, MD³

¹Rutgers New Jersey Medical School, Department of Physical Medicine and Rehabilitation, Newark, NJ

²Kessler Institute for Rehabilitation, West Orange, NJ

³Weil Foot Ankle and Orthopedic Institute, Des Plaines, IL



Select Medical

Introduction

- Knee pain affects a large portion of the population with significant impairment in the quality of life.
- Current treatment options do not address the destructive inflammatory micro-environment within the joint that lead to age-related degeneration, or disease-induced deterioration.
- New therapeutic approaches, such as the use of mesenchymal stem cells, show promising results.
- Adipose tissue is an ideal source of bioactive and regenerative cellular elements due to its abundance easy access.
- In addition, adipose tissue graft can be used to provide cushion, volume, and filling of soft tissue defects.

Methods

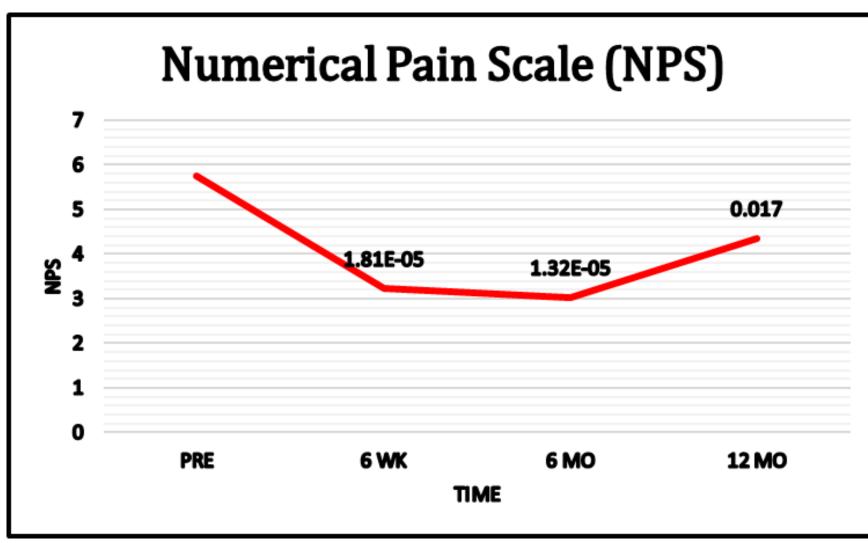
- 17 subjects (26 knees) with a median age of 70 years with a history of knee osteoarthritis (Kellgren-Lawrence grade of 3 to 4) underwent treatment with ultrasound-guided injection of micro-fractured adipose tissue.
- Micro-fractured fat was obtained by using a minimal manipulation technique in a closed system (Lipogems®), without the addition of enzymes or any other additives.

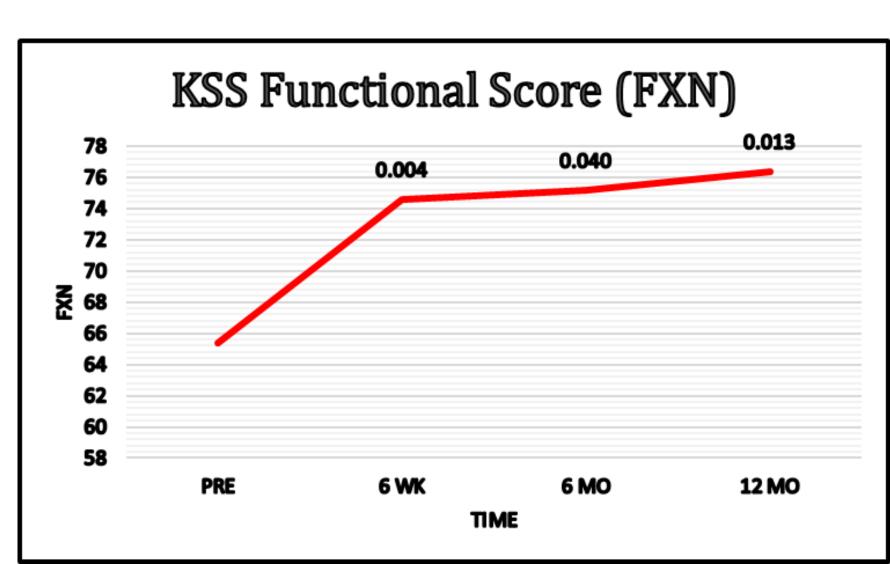


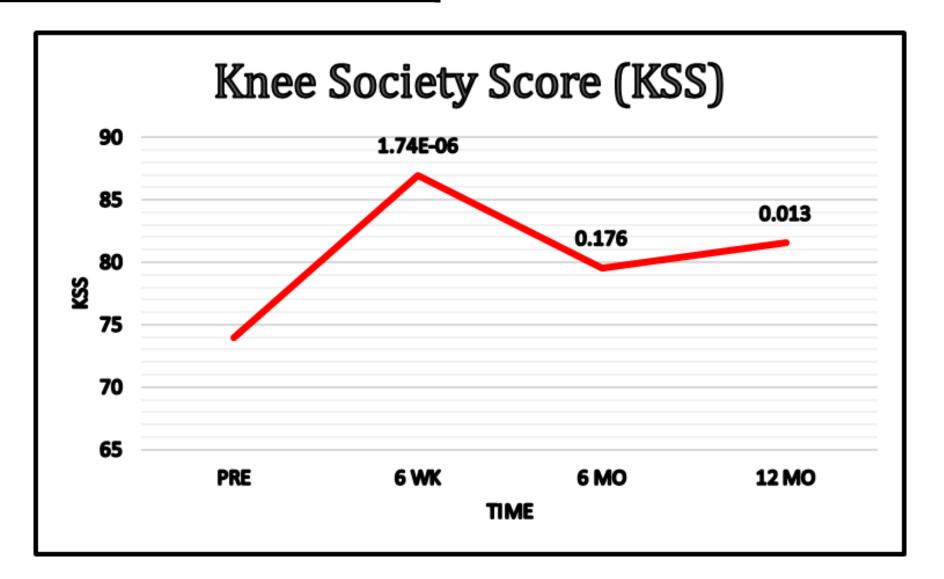
Results and Analysis

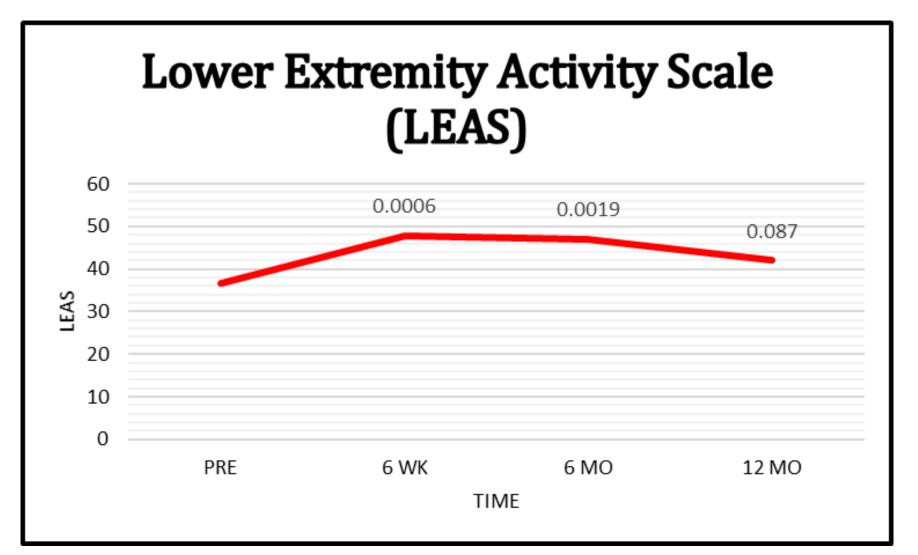
- Study subjects were clinically evaluated using Numerical Pain Scale (NPS), 100 point Knee Society Score (KSS) with its functional component (FXN), and Lower extremity activity scale (LEAS) at 6 weeks, 6 months, and 12 months following this procedure.
- When compared to baseline, significant improvements were noted in the mean values of NPS, FXN, and LEAS at 6 weeks, 6 months, and 12 months.
- The mean KSS significantly improved at 6 weeks and 12 months.
- No serious adverse events were reported.

Patient Demographics	
Male n (%)	15 (57.7)
Age mean+- SD (range)	68.27 +- 7.43 (54-78)
BMI mean+- SD (range)	28.98 +- 4.50 (21.41-34.9)
Kellgren Lawrence Grade 3 (n)	(7)
Kellgren Lawrence Grade 4 (n)	(19)









Discussion

- Currently, nonoperative treatment options for knee osteoarthritis are limited and fail to address the progressively inflammatory and degenerative environment of the joint. Although basic science and animal models have demonstrated the potential benefits of bone marrow and adipose derived stem cell therapies, ongoing clinical studies are needed to support whether this treatment option may be a viable alternative to patients who have failed the current nonoperative treatments.
- Adipose tissue has been noted to have multiple positive effects on tissue healing via a cascade of events including signaling, trophic, immunomodulatory, mitogenic, anti-microbial, antiscarring, and anti-apoptotic properties that contribute to potential regenerative mechanisms.
- The results of this study demonstrate significant improvements in pain, and functional outcome measures.
 In particular, average NPS improved from 5.74 to 4.35, average KSS improved from 74 to 82, FXN from 65 to 76, and LEAS from 36 to 47 from 0 to 12 months.
- There are several weaknesses of this study. This is a case series and not a randomized, controlled study and therefore, placebo effects cannot be excluded.
- More investigation is needed regarding products of regenerative medicine, as they may ultimately have profound implications in the way knee osteoarthritis is managed.

Conclusions

- The injection of autologous, micro-fractured, and minimally manipulated adipose tissue appears to be a safe and effective treatment option in patients with refractory knee osteoarthritis.
- This intervention may represent a nonsurgical treatment option to avoid knee joint replacement in this population; however, further investigation is needed.

References

- 1.Tremolada, C., et al. "Adipose Mesenchymal Stem Cells And "Regenerative Adipose Tissue Graft"(lipogems™) For Musculoskeletal Regeneration." *Eur J Musc Dis* 3 (2015).

 2.Insall JN, Dorr LD, Scott RD, Scott WN. Rationale of the Knee Society clinical rating system. Clin Orthop Relat Res 1989:13-4.
- 3.Saleh KJ, Mulhall KJ, Bershadsky B, et al. Development and validation of a lower-extremity activity scale. Use for patients treated with revision total knee arthroplasty. J Bone Joint Surg Am 2005;87:1985-94.
- 4. Salaffi F, Stancati A, et al. Minimal clinically important changes in chronic musculoskeletal pain intensity measured on a numerical rating scale. European Journal of Pain 2004; 283–291.