



# Clinical Evaluation of Autologous Micro-Fragmented Adipose Tissue as a Treatment Option for Meniscus Tears

Altamash Raja, DO, CSCS<sup>1</sup>, Brittany Wolf<sup>2</sup>, Gerard A. Malanga, MD<sup>2,3</sup>

1. Lincoln Memorial University-DeBusk College of Osteopathic Medicine 2. New Jersey Regenerative Institute 3. New Jersey Sports Medicine



## Background

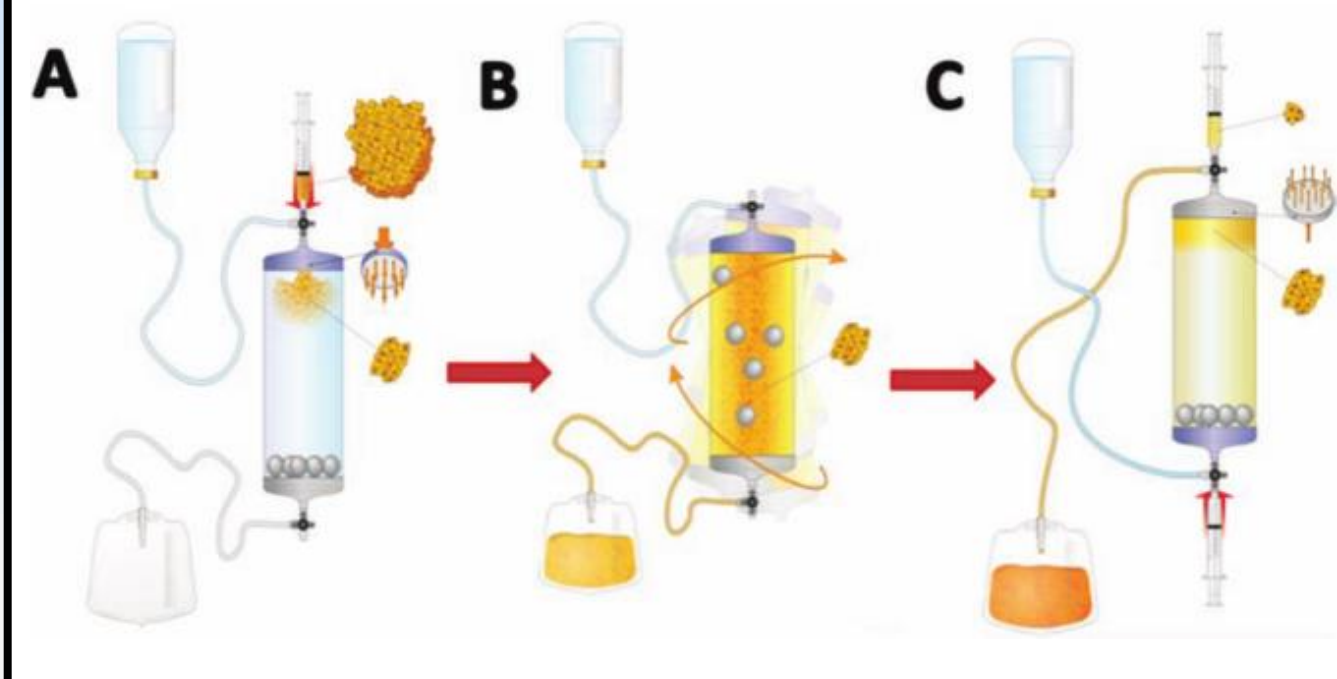
Meniscus tears are among the most commonly diagnosed causes of knee pain. They are also the most frequently performed surgical procedures. Historically it was believed that menisci served no functional purpose and therefore meniscectomies were the go-to procedure. However, we now know that meniscus integrity is essential for joint health and over the past decade there has been a shift in our approach to managing meniscus tears [1]. Surgical procedures now favor salvaging and restoring damaged meniscus whenever possible [2]. Yet still, majority of meniscus tears are treated with resection. This leads to premature joint degeneration. Increased knowledge of the long term consequences and altered biomechanics in the knee post meniscectomy has placed greater emphasis on meniscal preserving techniques [2, 3]. One minimally invasive technique that has developed growing interest over recent years is the use of mesenchymal stem cells (MSCs) for their regenerative and bioactive capabilities [4]. These mesenchymal stem cells play a dual role for musculoskeletal repair, due to their potential to differentiate into cartilage and muscle repair cells themselves and to produce special growth factors for its repair [5]. Several studies have used bone marrow and others have used adipose tissue that is harvested directly from the patient to produce the MSCs.

## Objective

This study investigates the potential benefit of using autologous adipose tissue to help relieve pain and increase activities of daily living in patients with continuous symptoms of degenerative meniscus tears refractory to conservative management.

## Materials and Methods

This is a single-arm, prospective study which recruited 20 patients that presented to a private outpatient sports medicine practice with a medial and/or lateral meniscus tear. Eligible patients were treated with a minimally manipulated, non-digested, micro-fragmented adipose tissue (Lipogems) concentrate. Peri-abdominal region was the main harvest site. After injecting the anesthetic tumescence, needle tip was used to slightly expand the entry point to facilitate access for insertion of 13-gauge blunt end cannula. Fat aspiration was initiated 10-15 minutes later with an attempt to aspirate approximately 4:1 ratio of decanted fat for final injectate. Lipogems device was used to process fat aspirate and diagnostic ultrasound was used to identify target structures in coordination with imaging from MRI. Final injectate amount ranged from 4.5 mL to 11 mL depending on patient need. Direct ultrasound guidance was also used to ensure filling of soft tissue defects during injection of lipospirate. We collected data for factors potentially influencing the outcome, including age, sex, and body mass index (BMI). Follow-up outcome assessments were conducted by phone and functional questionnaires in addition to physical examination and functional measurements during office visits. Numeric Pain Scale (NPS), Knee Injury and Osteoarthritis Outcome Score (KOOS), Range of Motion (ROM) and strength were the main measures of clinical outcomes. Pain score and functional questionnaires were evaluated at baseline and then repeated at one, three, and six months. Range of motion and strength assessments were also repeated at every visit.



## Results

Eligible patients for the study met the following criteria: age  $\geq 35$ , mechanical symptoms, pain reproducible upon palpation, pain greater than three months in duration, MRI evidence of tear, failed standard, non-operative treatment. Patients with prior knee surgery, pathology other than meniscus tears, recent injections ( $< 6$  weeks), or any contraindications to lipospirate (bleeding disorder, malignancy etc.) were excluded. To date, 19 subjects (10 males, 9 females) have reported outcomes. KOOS and NPS were recorded at intervals of time zero, three, and six months following the procedure through a survey. NPS scores were also reported at an additional interval of one month. Moreover, at one month, patients were given an in-office follow up visit to evaluate their progress. Seven patients were reported to have full ROM, whereas nine went unreported pertaining to ROM. Their quadriceps strength was evaluated as well, and patients were recommended further physical therapy as needed. As illustrated in Figure 1, the KOOS increased exponentially and then plateaued over time. At the time of the procedure, the average KOOS score ( $n=19$ ) was  $56.05 \pm 16.49$ . At three months ( $n=13$ ), the average KOOS was  $77.36 \pm 18.09$ , and at six months ( $n=5$ ) was  $80.05 \pm 15.64$ . The closer to 100 the KOOS score is, the better the functionality. In reference to Figure 2, the NPS scores decreased dramatically from the time of the procedure to their one month follow up visit, and then continued to plateau. Lower NPS scores indicate lower pain, representing a better outcome. Mean NPS score at baseline was  $5.48 \pm 2.2$ , one month ( $n=13$ ) follow-up was  $1.04 \pm 1.13$ , three months ( $n=12$ ) was  $2.58 \pm 2.5$ , and six months ( $n=5$ ) was  $2 \pm 2.07$ . As seen from the data, the greatest exponential improvement occurred between one and three months. Only one patient had an adverse event of mild cellulitis at the harvest site.

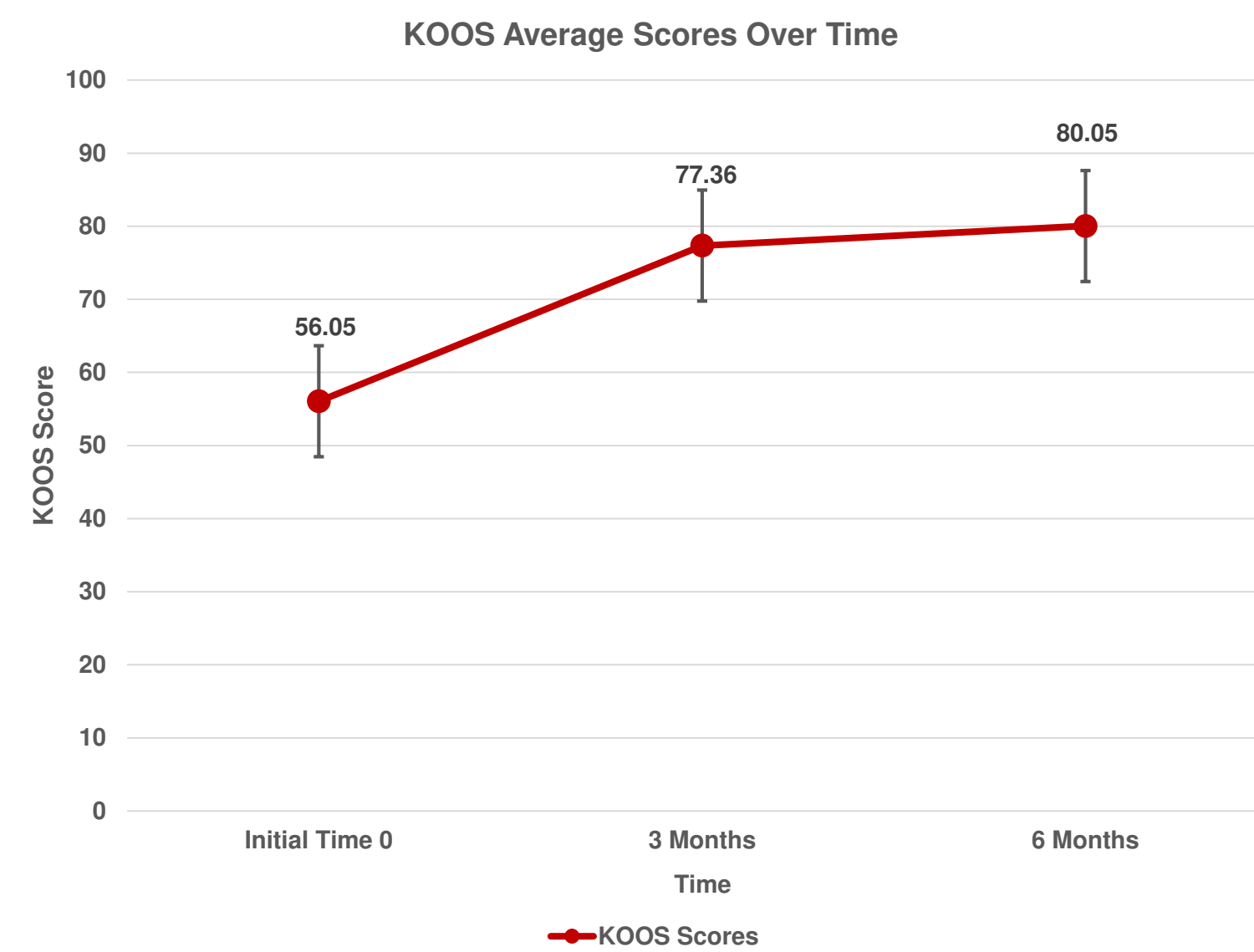


Figure 1: Knee Injury and Osteoarthritis Outcome Score (KOOS) averages over time in patients with meniscus tears treated with micro-fragmented adipose tissue injections. The best KOOS score achievable for functionality is 100. Lines on data points indicate standard error.

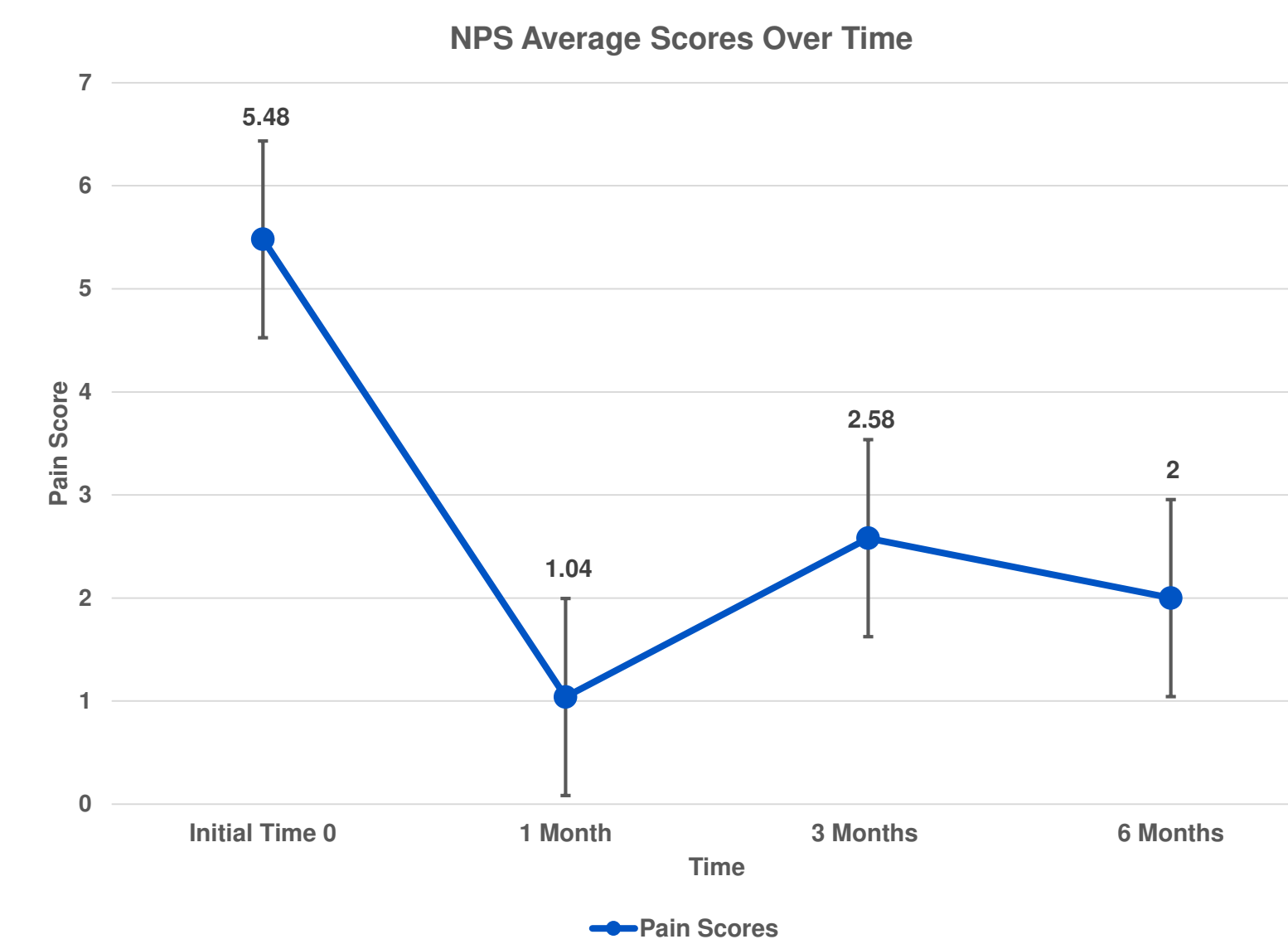


Figure 2: Numeric Pain Scale (NPS) score averages over time in patients with meniscus tears treated with micro-fragmented adipose tissue injections. The lower the pain score the better. The best achievable is a pain score of zero. Lines on data points indicate standard error.

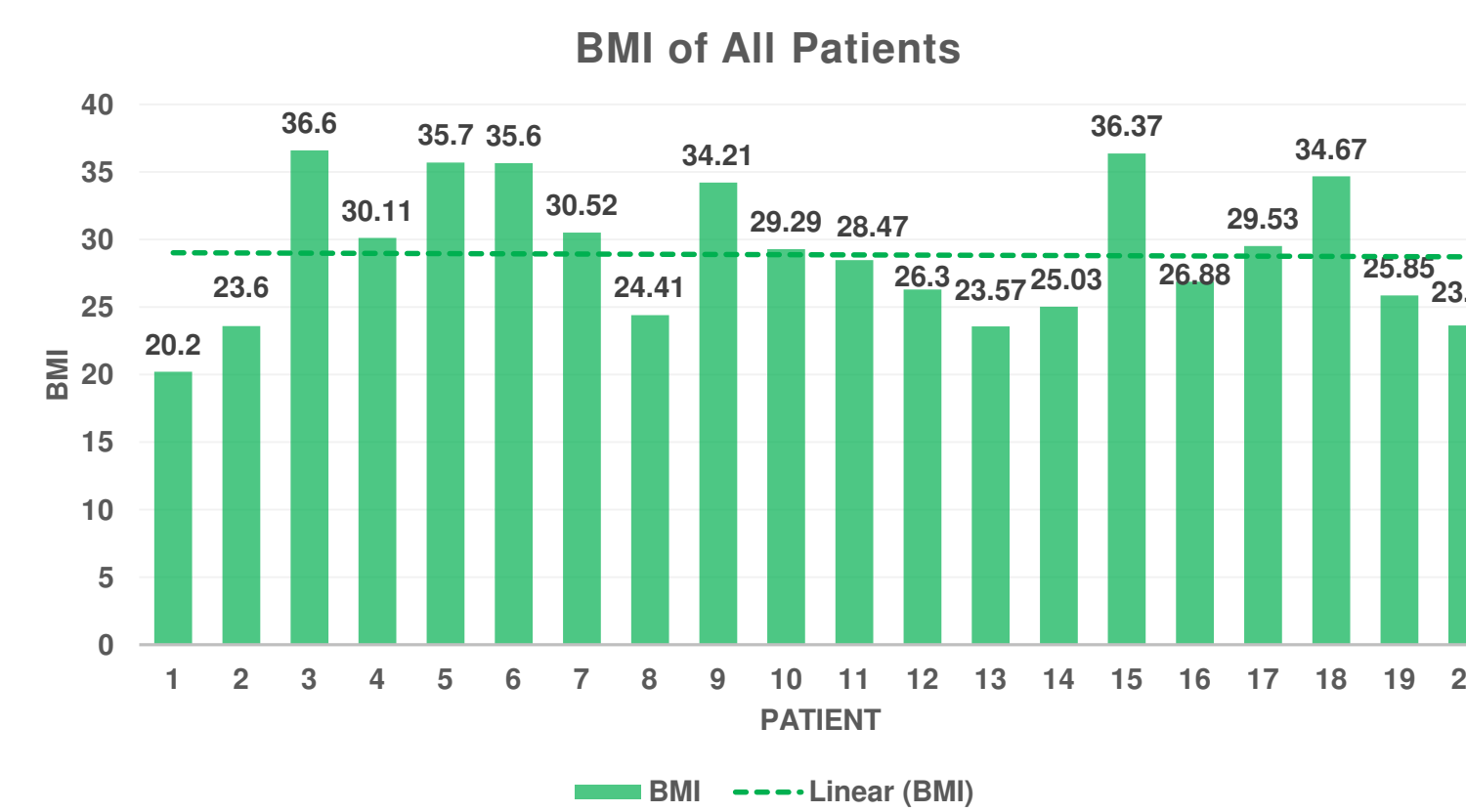


Figure 3: BMI values of all participating patients in the study. Average BMI is 29.03,  $n=20$ . Line of best fit shows average BMI graphically.

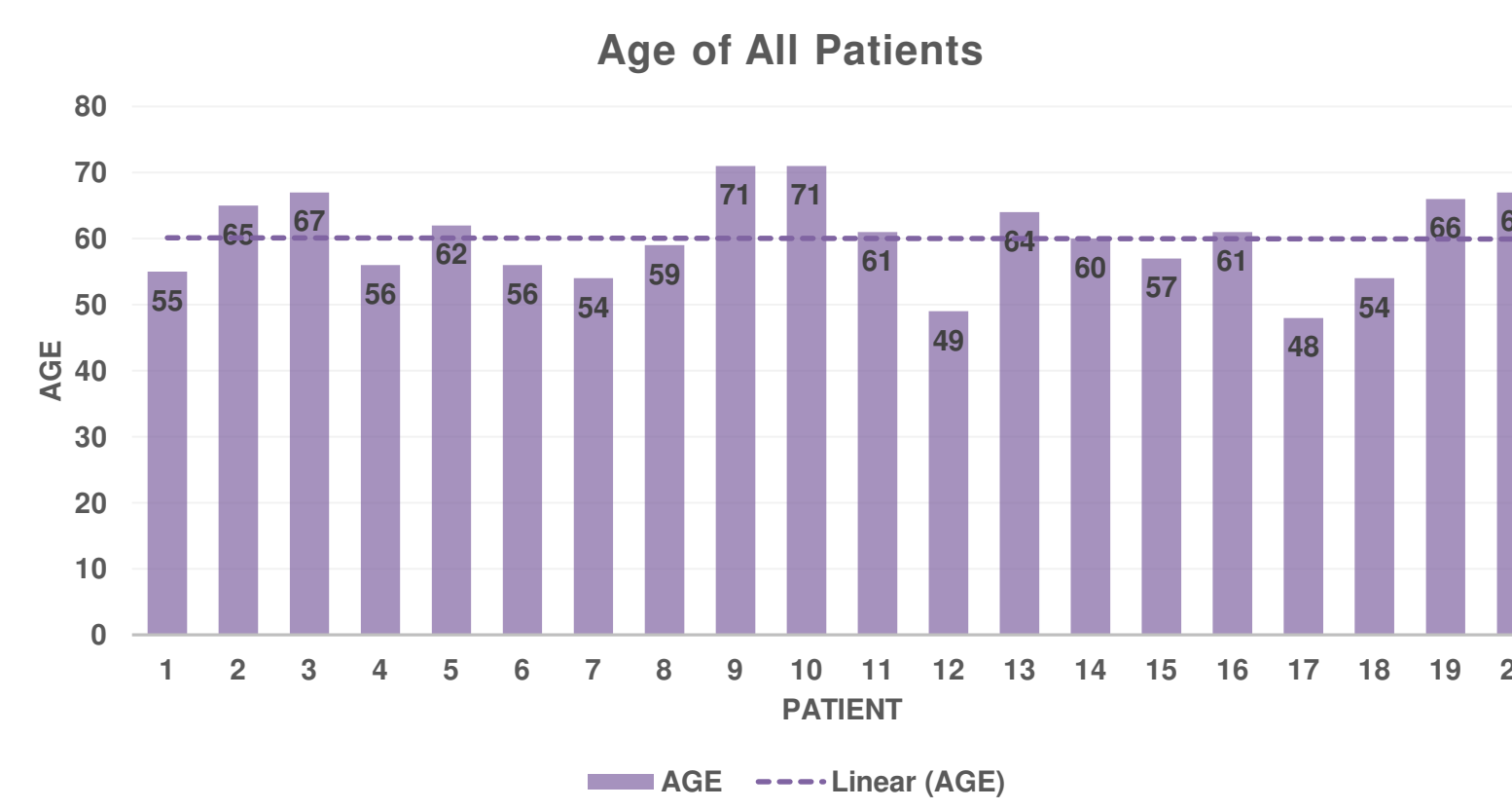


Figure 4: Ages of all participating patients in the study. Average age is 60.15,  $n=20$ . Line of best fit shows average age graphically.

## Conclusion

Preliminary results of this case series indicate that autologous adipose-derived stem cells may be a promising treatment for degenerative meniscus tears. Subjects who reported outcomes in this study improved in their activities of daily living while experiencing a substantial decrease in knee pain. Meniscal tissue is crucial for providing knee stability, force dissipation, and nutrition for the articular cartilages of the knee. Once damaged, however, few conservative options have shown to help with recovery. If conservative management fails, the current standard of meniscectomy leads to early joint degeneration. This in turn leads to more pain, poor quality of life, and an increase in the number of knee replacements. The regenerative capabilities of mesenchymal stem cells may help preserve meniscus integrity and promote longevity of injured knees. Incorporation of this novel treatment within the algorithm of management for meniscus tears may help delay or even prevent unnecessary arthroscopies, decrease financial burden, and improve long term outcomes of health. The current literature supporting minimally invasive applications of stem cell based therapies consist largely of case reports, yet utilization of these therapies continues to grow as patients seek novel treatments to treat conditions with few alternatives. Therefore, further investigation with randomized controlled trials involving a comparison group is necessary.

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## Further Information

Altamash Raja: altamash.raja@lmunet.edu  
Gerard Malanga: gmalangamd@hotmail.com  
Brittany Wolf: Brittany@njsportsmedicine.com  
njregenerativeinstitute.com