

Research Studies Conducted by Blue Horizon International

Human Adipose Tissue Derived Stem Cell Therapy in Subjects with Musculoskeletal Disorders

Introduction

Musculoskeletal disorders are injuries or pain in the human musculoskeletal system with the consequent loss of mobility, pain and reduction in the quality of life.

Pain is a major healthcare problem affecting individuals with arthritis and musculoskeletal disorders. Pain reduction and mobility improvement are the main outcomes to determine the therapy efficacy of subjects with musculoskeletal disorders.

Stromal vascular fraction of adipose tissue contains mesenchymal stem cells that have the capacity to differentiate into cartilage, bone, muscle, and adipose tissue. Mesenchymal stem cells have been proposed as an optimal regenerative cellular therapeutic for musculoskeletal conditions like osteoarthritis and rheumatoid arthritis.

Adipose tissue can be easily obtained: almost without pain under local anesthesia; without risk of thrombosis or introduction of infection into the bone marrow resulting in sepsis or osteomyelitis.

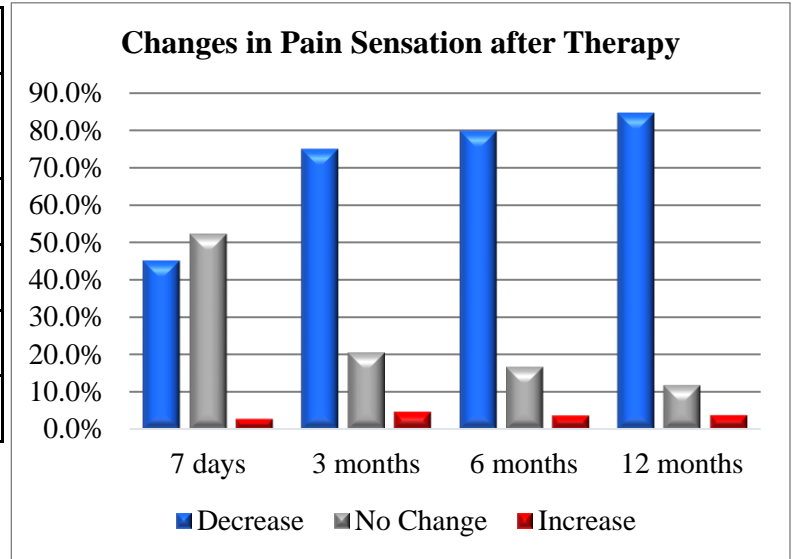
In the current study we analyzed changes in pain and mobility of research subjects with osteoarthritis and rheumatoid arthritis after adipose tissue-derived stem cell (ADSC) therapy.

Research Study Results

In the period from 2015 to 2018, 350 subjects underwent the therapy with their own stromal vascular fraction cells at the Malacky Hospital (Bratislava, Slovakia). Affected areas included knee and hip joints (right and left) with arthritis stage I-IV (1-minor, 4-severe). Analysis of subjects' pain and mobility changes was conducted seven days, three, six and 12 months after therapy. The study was approved by the Ministry of Health of the Slovak Republic. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000 (5).

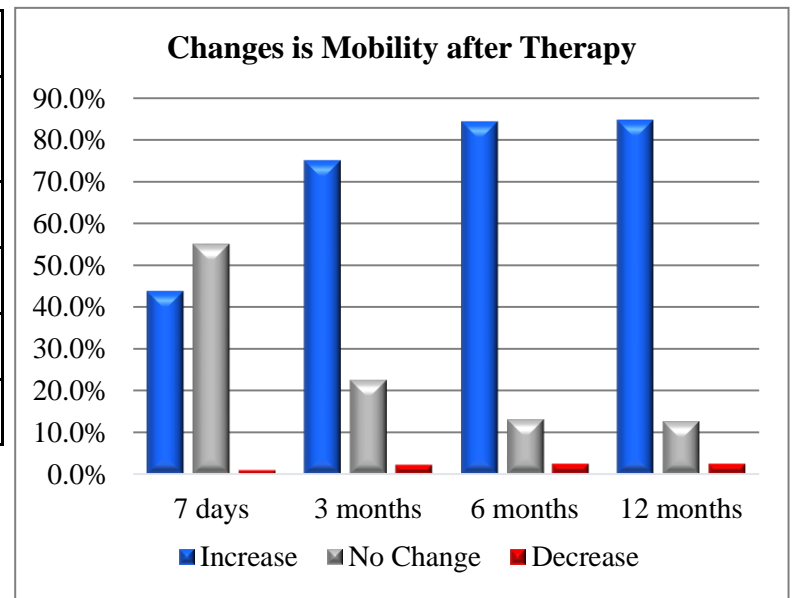
Statistically significant decrease in subjects' pain sensation was observed three, six and 12 months comparing to seven days after therapy (One Way Analysis of Variance).

Pain Sensation			
Follow up	Decrease	No Change	Increase
7 days	45.2 %	52.2 %	2.6 %
3 months	75.0 %	20.6 %	4.4 %
6 months	79.8 %	16.8 %	3.5 %
12 months	84.6 %	11.8 %	3.6 %



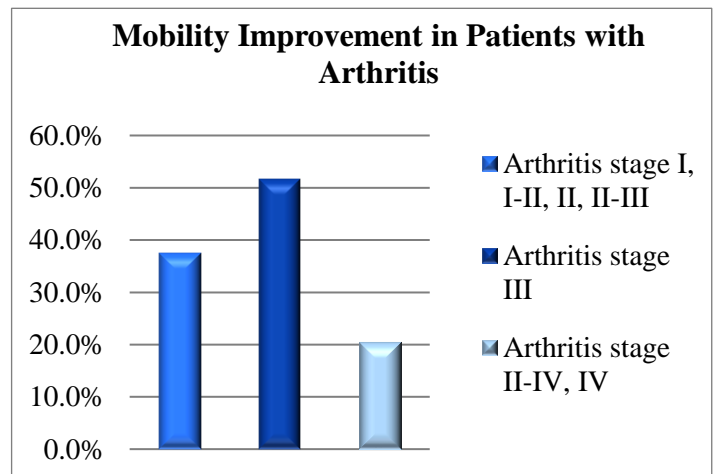
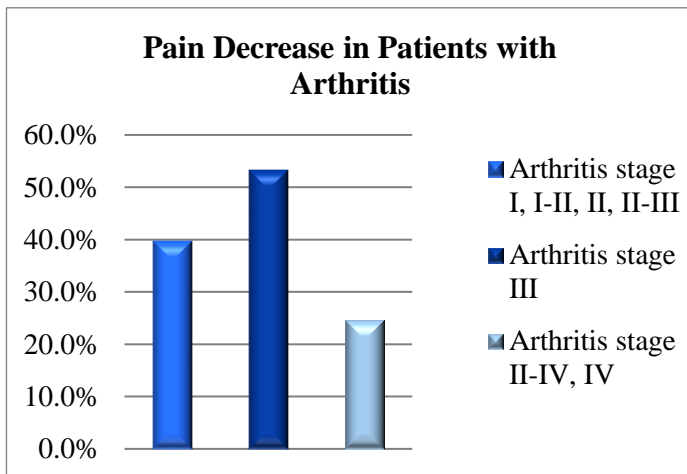
Statistically significant improvement in subjects' mobility was observed three, six and 12 months comparing to seven days after therapy (One Way Analysis of Variance).

Mobility			
Follow up	Increase	No Change	Decrease
7 days	44.0 %	55.0 %	0.9 %
3 months	75.2 %	22.6 %	2.1 %
6 months	84.4 %	13.2 %	2.4 %
12 months	84.8 %	12.7 %	2.4 %



Depending on arthritis stage, subjects were divided into 3 groups. First group included subjects with arthritis stages I, II, and II-III; second group included arthritis stage III; third group included arthritis stage III-IV and IV. Analysis indicated that the therapy was most effective in subjects with arthritis stage III.

Arthritis classification	I, I-II, II, II-III	III	III-IV, IV
Pain Decrease	39.6%	53.3%	24.5%
Mobility Improvement	37.5%	51.7%	20.4%



Intra-articular injection of ADSCs was effective in the improvement of some symptoms related to musculoskeletal conditions. Significant decrease in pain sensation and mobility improvement were observed three, six and 12 months after ADSC therapy. In order to further analyze the safety and efficacy of ADSC therapy, further prospective studies are warranted.