Clinical Results at Four Years after a Single Injection of SVF in Patients with End-Stage Knee OA

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INTRODUCTION: A variety of clinical studies evaluated the safety and efficacy of injective treatments based on mesenchymal stem cells in knee OA (KOA). Nevertheless, clinical studies mainly focus on initial stages of KOA and, to our knowledge, there are no studies evaluating the safety and efficacy of adipose-derived products exclusively in patients with severe KOA. A particular focus are young patients with end-stage knee OA already requiring total knee replacement (TKR) surgery. Indeed, recent studies have reported that patients under 60 and 65 years old have higher incidences of TKR failure when compared to older patients and therefore need an alternative treatment to postpone, if possible, the replacement surgery. Hence, a prospective clinical trial evaluating the safety and clinical efficacy of a single intra-articular injection of autologous adipose tissue enriched in stromal vascular fraction (SVF) in patients with severe knee osteoarthritis (Kellgren-Lawrence IV) was designed.

METHODS: A prospective, monocentric, single arm, clinical trial has been designed to evaluate the clinical efficacy and safety of a single injection of autologous adipose tissue enriched in SVF in 42 patients with severe knee osteoarthritis (Kellgren-Lawrence IV). Patients will be followed for up to 5 years after the treatment monitoring the variations of clinical (KOOS subscales, EQ-5D-5L, NRS) and radiological (WORMS score for MRI, Joint Space Width on X-rays) scores in addition to adverse effects. The incidence rate and timing of any required total knee replacement (TKR) surgery will be monitored to investigate the potential capacity of delaying a TKR.

RESULTS:

42 patients have been treated and, so far, 35 patients have been evaluated at 4 years of follow up after the injective treatment while 7 have been lost to follow up. The analysis of the clinical results obtained at 6 months highlights an average statistically significant clinical and functional improvement for all KOOS subscales and NRS. The average clinical results appear substantially stable up to 24 months of follow up and then begin to worsen slightly, although remaining statistically better than baseline even 4 years after the treatment. To date, eleven patients have undergone TKR due to lack of clinical response, at an average of 30 months after the injective treatment. On the other hand, 24 patients still benefit from the injective treatment 4 years after the treatment.

DISCUSSION AND CONCLUSION:

Those presented are the results of the first clinical trial evaluating the use of a single injection of Autologous Adipose Tissue enriched in SVF exclusively in patients with end-stage KOA (Kellgren Lawrence IV). Our preliminary clinical results suggest that a single injection of autologous adipose tissue enriched in SVF is a safe and effective treatment in terms of pain reduction and joint functionality improvement also in patients presenting severe knee osteoarthritis. Statistically significant improvement of all KOOS subscales and NRS were reported at 6 months after the treatment and clinical results remained stable up to 24 months of follow up. At three years after the injection, mean clinical score start to worsen but still remain better than baseline scores. A similar treatment could be useful to delay total knee replacement for at least 2 years while providing clinical improvements in more than half the inital cohort at 4 years after the injection.