New strategy and possibility for using ADRCs for treating Scleroderma

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■Profile

1964 to 1970 Educated at Medical Doctor
1990 to 2014 Chief of the Department of Plastic, Aesthetic, Reconstructive and Burn surgery, Dept gathering more than 40 surgeons, Dept of Plastic, Aesthetic, Reconstructive and Burn surgery, Hôpital de la Conception - AP-HM, MARSEILLE, France
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■Abstract

Scleroderma is an autoimmune/auto-inflammatory disease associated with progressive fibrosis of the skin and other organs. Almost all patients with this disease exhibit Raynaud's Phenomenon and many exhibit substantially impaired hand function leading to reduced ability or inability to perform everyday tasks. Many patients also exhibit digital ulceration. Aesthetic and functional impairment on the face, particularly perioral fibrosis, are also a significant issue for many patients.

We have now treated completed two year follow-up on a clinical trial, SCLERADEC I, in which autologous adipose-derived stromal vascular fraction cells (obtained using the Celution System; Cytori Therapeutics Inc. San Diego, CA, USA) were used to treat hand dysfunction. This trial enrolled 12 patients in a single arm, open label prospective clinical trial performed following approval from the French National Agency of Medicine and Health Products Safety (ANSM). The 12 patients (24 hands) were treated with Stromal Vascular Fraction, aiming at an angiogenic and anti-fibrotic effects. Cells were prepared from 135-270 g of fat collected by manual aspiration and processed using the Celution system. This approach prepared 5cc of SVF containing, on average, 50x106 cells. This product was diluted into 10 doses of 1cc; 1cc per digit delivered by subcutaneous injection into each finger with a 25 gauge or 0.5mm cannula under local anesthesia.

■Results

We observed spectacular results, with a very rapid improvement of the vascularisation of the fingers and later of trophic disorders with significant functional enhancement and improved quality of life. Results persist to at least the second year. Hand dysfunction assessed using a validated tool (the Cochin Hand Function core) was reduced by an average of more than 50% at two years. Similar improvements in other endpoints (pain, Raynaud's Condition Score, and the Scleroderma Health Assessment Questionnaire) were also observed. No significant complications were observed.

■Conclusions

We conclude that the injection of stromal vascular fraction in fingers triggers an obvious functional improvement in every day life activities. Two randomized clinical trials are underway in France and USA. Overall, this safe and minimally invasive technique provides an important benefit in terms of functional improvements.