A Prospective, Within-Subject Controlled Study of the Safety of Allograft Adipose Tissue Injections into the Hypodermis of Healthy Adults

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INTRODUCTION: Autologous fat transfer (AFT) has been used for years as a permanent filling option for soft tissue defects. There are several challenges related to AFT such as overfilling, unpredictable resorption, and donor site morbidity. An allograft adipose-derived filler with native growth factors bound to the extracellular matrix to encourage angiogenesis and adipogenesis can be used as an alternative to AFT. In this study we evaluated the safety of allograft adipose tissue injections into the hypodermis of healthy adults who are scheduled for elective body reduction surgery.

MATERIALS AND METHODS: An ongoing prospective, within-subject controlled study of the safety of allograft adipose tissue injections into the hypodermis was conducted. All subjects planned to undergo elective body reduction surgery to areas such as the arms, legs, or abdomen in ≥ 30 to ≤180 days and received allograft adipose injections into an area of hypodermis intended for surgical excision. Similar tissue from the subject's contralateral side served as the control. The subjects rated pain on an 11-point scale and completed a 14-day safety diary beginning on the evening of treatment to report any injection site responses.

When the planned elective body reduction surgery was performed, the area treated with allograft adipose tissue injections was surgically excised and a biopsy of the treated area was sent for histopathology examination. Similar tissue on the contralateral control side which was not injected was also surgically excised and sent for histopathology examination. After the body reduction surgery the subjects returned for a 30-day post-op visit to assess adverse events that may have been related to the procedure.

RESULTS: To date no unanticipated adverse events related to the product were observed in this study and all treatment symptoms resolved within 11 days. Histological examination of the tissue showed no inflammation.

CONCLUSION: This study documents the safety of allograft adipose tissue injections in the hypodermis of healthy adults. The implants were derived from donated, cadaveric adipose tissue yielding an acellular, lipid-free, flowable implant composed mostly of ECM proteins in a physiological saline solution. Processing of this tissue included the retention of native growth factors known to promote host healing and remodeling of the matrix and de novo adipogenesis.