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Autologous fat grafting does not improve burn scar appearance: A prospective, randomized, double-blinded, placebo-controlled, pilot study

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ARTICLE INFO

Article history:
Accepted 21 September 2016

Keywords:
Fat graft
Stem cells
Burn scar
Scar management

ABSTRACT

Objective: It has been proposed that fat grafts can improve the appearance of mature burn scars. The pluripotent progenitor cells contained within autologous adipose tissue grafts are believed to induce skin repair and improve scar appearance. We conducted a prospective, randomized, double-blinded, placebo-controlled study to evaluate the effects of fat grafts on the appearance of mature burn scars.

Methods: Pediatric burn survivors with mature scars were recruited for this study. A homogeneous scar measuring 10 × 5 cm was randomized into two halves: one was injected with autologous fat graft and the other with normal saline. Scar injection was performed using standard Coleman technique. Appearance of the two scar halves was assessed, six to twelve months later by the operating surgeon, by blinded observers and by the blinded patients.

Results: Eight patients completed the study pilot with 6-12 month follow-up. Assessment by the patients did not clearly favor fat grafts or saline injections; the operating surgeon did not identify any differences on any of the patients; the blinded observers measured all scars using Vancouver Scar Scale and noticed no differences in pigmentation, vascularity and height; differences in pliability showed similar changes in both the fat grafted and control arms. After the pilot was completed, decision was made to stop enrolling patients for this study since no benefit to fat grafting was observed.

Conclusions: Single treatment with autologous fat grafts did not improve mature pediatric burn scars when compared to normal saline injections.

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1. Introduction

Fat grafting has been utilized for over 100 years. It was first introduced by Neuber and Czerny in the 1890s. It was also used by Gillies, who noted that the quality of scars was improved after the subcutaneous application of fat grafts. It then soared into mainstream in the 1990s when Coleman popularized the technique of structured fat grafting [1].

Since then, autologous fat grafting has become a commonly used technique in the reconstructive as well as the esthetic arena, due to its wide availability and biocompatibility [1,2]. More recently, the discovery of adipose-derived stem cells in fat grafts has prompted the study of their role in tissue healing, regeneration and repair. It has been postulated that fat grafting can improve the qualitative and quantitative appearance of scars, including complicated scars such those caused by radiation and thermal injury [1,3,4,5]. To date, no prospective

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http://dx.doi.org/10.1016/j.burns.2016.09.019

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randomized blinded studies have been published to support the effectiveness of this technique for burn patients. In this study, we set out to elucidate whether autologous fat grafting actually does induce scar repair and improve the appearance of mature burn scars.

2. Materials and methods

Patients with mature burn scars who were scheduled to undergo unrelated surgical reconstruction at a pediatric burn unit were recruited to participate in this study. The Institutional Review Board approved the study with an enrollment goal of fifty patients and a provision to perform an initial evaluation of safety and efficacy after the first 10 patients were enrolled. Inclusion criteria included pediatric patients with late effects of burns requiring surgical reconstruction procedures who also had mature burn scars that were separate from the primary surgical site, age less than 21 years and with ability to assent to participate in the study. Patients with significant medical problems or American Society of Anesthesiologist Physical Status Classification System score>II indicating increased anesthesia risk were excluded from this study. Patient's age, ethnicity, gender, age of the scar, scar site, scar dimensions and fat graft donor site were recorded. Appearance of the two scar halves was assessed, six to twelve months later during their scheduled follow up visit, by a blinded independent evaluator using the Vancouver Scar Scale (VSS). Additionally, the scar halves were evaluated by the patient, who was also blinded to the treatment, using a subjective questionnaire asking the patient to compare the "look" and "feel" of the two sides.

During scheduled reconstructive surgery, a separate mature burn scar not in proximity to the area scheduled for surgery was selected for treatment in the study. The study required a homogeneous appearing scar measuring no less than 5×10 cm that could be divided into two similar appearing halves measuring 5×5 cm each. One half of the scar was injected with 5 mL of autologous fat grafts and the other half was injected with 5 mL of saline solution. Randomization was used to select the scar half to be injected with either fat or saline. The two scar halves were marked as side A and B and then a sealed envelope was opened in the operating room to see which side would be treated with fat and which with saline. Adipose tissue was harvested from the abdomen in all but one patient where it was harvested from the thigh because the abdomen had extensive scars and did not appear as a suitable donor site. The lipoaspirate was then centrifuged for 3 min at 3000 RPM and the cells were transferred into 1 mL syringes for grafting. Scar injection was performed using standard Coleman technique. Of note, a 1-mL syringe with an 18-gage needle was used for fat grafting, as opposed to a blunt tip cannula, in order to allow grafting into dense scar tissue. The amount of volume of fat or saline injected was 5 cc in each scar half and both sides were injected using an 18 gage needle. In order to prevent any differences on scar maturation that could be triggered by the trauma of the needle, the operating surgeon infiltrated both sides of the scar with an effort to make a similar amount of needle passes on each side.

3. Results

Ten patients, with age ranging between 5 to 20 years (mean 13 years), were enrolled into the first phase of the study. One patient opted out of the study on the day of the scheduled surgery. Complete data for analysis was available on eight of the nine remaining patients: one patient was lost to follow up. Postoperative follow-up ranged between 156–359 days (mean 240 days). The Scar injection sites were the forearm in 7 cases, the lower leg in one case and the chest in one case (see Table 1).

During follow-up evaluation, the senior author – who was the operating surgeon on all cases and the only person not blinded in the study – failed to identify any differences when comparing the sides of the scar treated with fat grafts to those treated with a saline injection (see Fig. 1). Similarly, all eight patients who completed the study failed to notice differences that would consistently favor either one of the two sides of the scar. When asked about the look of the scar, four patients preferred the fat grafted half, two patients saw no difference and two patients preferred the saline half. As far as the feel of the scar, two patients preferred the fat grafted half, two patients saw no difference and four patients thought the saline injected half was better (see Table 2). Of note: since none of the patients had experienced obvious changes on the scar or a clear improvement on one or the other side, most patients hesitated and often changed their mind when asked for answers during the patient qualitative assessment.

The blinded observers measured all scars using the Vancouver Scar Scale and noticed no differences in pigmentation, vascularity and height; differences in pliability showed similar changes in both the fat grafted and control arms: in

Table 1 – Patient demographics and follow-up.

Patient	Age at surgery	Gender	Site of scar	Follow-up (days)
1	11	F	Forearm	239
2	5	F	Lower leg	156
3	20	F	Forearm	185
4	17	M	Forearm	359
5	16	M	Chest	326
6	10	M	Forearm	312
7	12	F	Forearm	234
8	10	F	Forearm	340
9	16	F	Forearm	N/A

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