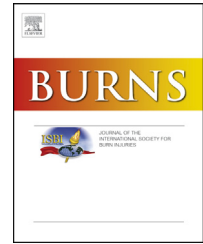


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# Combination of medical needling and non-cultured autologous skin cell transplantation (ReNovaCell) for repigmentation of hypopigmented burn scars

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## ABSTRACT

Burn scars remain a serious physical and psychological problem for the affected people. Clinical studies as well as basic scientific research have shown that medical needling can significantly increase the quality of burn scars with comparatively low risk and stress for the patient with regards to skin elasticity, moisture, erythema and transepidermal water loss. However, medical needling has no influence on repigmentation of large hypopigmented scars.

The goal of this study is to evaluate whether two established methods – needling (for improvement of scar quality) and non-cultured autologous skin cell suspension (for repigmentation) – can be successfully combined.

Twenty subjects with mean age of 33 years (6–60 years) with scars from deep second and third degree burns have been treated. The average treated surface area was 94 cm<sup>2</sup> (15–250 cm<sup>2</sup>) and was focused on prominent areas such as the face, neck, chest and arm.

Percutaneous collagen induction or “medical needling” was performed using a roller covered with 3 mm long needles. The roller is vertically, horizontally and diagonally rolled over the scar, inducing microtrauma. Then, non-cultured autologous skin cell suspension (NCASCS) was produced and applied using the ReNovaCell Autologous Cell Harvesting Device (Avita Medical), according to the manufacturer’s instructions.

The patients were followed 12 months postoperatively. Pigmentation changes were measured objectively, as well as with patient and observer ratings. Patient satisfaction/preference was also obtained.

Taken together, the pigmentation ratings and objective measures indicate individual improvement in 17 of the study participants. The melanin increases seen 12 months after NCASCS treatment are statistically significant.

Medical needling in combination with NCASCS shows promise for repigmentation of burn scars.

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## 1. Introduction

Approximately 11 million people worldwide each year suffer from burns receiving medical treatment [1]. Due to improvements in medical practice and research, the mortality rate after burns has decreased significantly over the last decades [2]. More people with deep and extensive burns survive their injury. There is a corresponding increase of long term consequences like scarring, and patients frequently request treatment to improve scar quality, such as textural problems or pigmentation.

Melanocyte death, melanogenesis disruption, weakened paracrine signaling between melanocytes and other skin cells all have been shown to affect skin pigmentation [3]. Dyspigmentation of burn scars is therefore a common consequence after partial and full thickness burns [4]. Additionally, the scar tissue itself may present a barrier for melanin transfer and melanocyte migration [5]. Physical changes like higher sensitivity for sunburns [6] and psychological impairments also affect the patients, as conspicuous scars are a frequent reminder of traumatic situations [7].

Currently, numerous methods are available to treat hypopigmented skin, such as split skin grafting [8], lasers [9] and cultured skin cell transplantation [10]. In recent years, research focused additionally on the use of non-cultured skin cell suspension (NCASCS). Although the primary objective when using NCASCS was to achieve reepithelization in acute and chronic wounds [11], repigmentation has also been observed. Hence, the method has also been used to treat hypopigmentation associated with vitiligo and burn scars [12,13]. The Autologous Cell Harvesting Device is used to create a spray suspension of viable autologous skin cells. These cells are harvested intraoperatively and applied directly, in suspension, to the prepared wound.

Wounds are prepared for application of NCASCS using dermabrasion or laser, which are both ablative methods. By nature, ablative treatments remove skin structures and cells, including the basement membrane, which are then replaced by a thinner epidermis with flatter rete ridges [14]. The associated inflammatory response stimulates fibroblasts to produce parallel oriented scar collagen instead of physiological lattice pattern collagen [15]. Additionally, the risk of dyspigmentation increases after ablative treatments due to associated damage to the melanocytes [16].

Medical needling as non-ablative treatment overcomes the shortcoming of ablative treatments by not destroying structures of the epidermis, but rather promoting the formation of physiological collagen instead of scar collagen and initiating the expression of growth factors. In recent years, it has been shown that it is possible to achieve these ideal treatment goals with percutaneous collagen induction or “medical needling” [17,18]. It has been shown that medical needling does not have the risks of hyper- or hypopigmentation. However, repigmentation of large hypopigmented scars is not achieved after medical needling [19].

Therefore, the aim of this study is to evaluate if it is possible to achieve repigmentation of large ( $>10\text{ cm}^2$ ) hypopigmented burn scars by combining non-ablative medical needling and NCASCS. The hypothesis is that the melanocytes of the cell

suspension link through the parenchymal canals onto the basal membrane. They may be successfully transplanted after 24 h, when all needling channels are closed [18].

## 2. Methods

### 2.1. Study design

This study is a prospective randomized controlled within-subject comparison. Subject's hypopigmented scar areas were divided into 3 subareas for which treatment was randomly allocated as (1) the combination of medical needling and NCASCS, (2) medical needling alone (positive control) and (3) no treatment (negative control). The subjects were assessed at baseline (pre-treatment) and after 3, 6, 9 and 12 months pigmentation was objectively measured for each of the subareas at each study visit. Scar outcomes for the area treated with the combination of medical needling and NCASCS were assessed by both the patient and an observer using the Patient and Observer Scar Assessment Scale (POSAS). POSAS outcomes of scars treated with Medical Needling only are already published [17,20]. Hence, we focused on the scars treated by medical needling and NCASCS to clarify the difference regarding repigmentation.

### 2.2. Subject selection

In order to be included, patients were required to have hypopigmented burn scars that had healed by secondary intent, and were at least both  $10\text{ cm}^2$  in size and 1 year in age.

Exclusion criteria were pregnancy and severe underlying diseases or skin lesions like cancer or infections.

### 2.3. Procedure

We received approval from the local ethical committee for this study. All subjects signed an informed consent. Informed consent was obtained from parents of subjects younger than 18 years of age. The treatment, including general anesthesia, medical needling, skin sample harvesting and preparation and application of the cell suspension was performed in a surgical suite.

### 2.4. Medical Needling and NCASCS

Medical needling is repetitive puncturing of the scar with a roller equipped with 3 mm long needles (Figs. 1 and 2).

The needling device is repeatedly rolled over the scar in three directions, longitudinally, diagonally and horizontally. According to the extent of the scar, this procedure can last 30 min or longer. It is important to use the device with constant pressure and in a straight way to prevent shear forces. The needles disrupt the old collagen structures that connect the scar with the upper dermis. The needles do not have a lumen. Hence, they temporarily displace the skin cells rather than destroy them. They penetrate the dermis 2.5–3.0 mm and lead to thousands of microwounds and intradermal bleedings. A scar is sufficiently prepared for NCASCS when multiple and confluent hematoma develop; the skin is swollen and has a livid appearance.

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