Cairo University

KASR ALAINY

Faculty of Medicine, Cairo University Postgraduate Research Program Template

Last edit: 20-Novemeber-2021

1- Study

Proposed Study Title: ***Evaluation of complex dermal layer repair in treatment of facial cut wounds***

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2.Invistigator:

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3. Promoters Contact Information

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Background and Rationale:

Widening of scars is a frustrating event that most if not all plastic surgeons have encountered.

A scar generally forms as the body attempts to heal a wound. It is the natural endpoint of inflammation and subsequent fibrosis. Scars can result from trauma, infection, and certain diseases as well as from iatrogenic causes.

Delayed epithelialization beyond 10 to 14 days is well known to increase the incidence of hypertrophic scarring. Wounds subjected to high tension due to motion, body location, or tissue loss are at increased risk of excessive scarring and spreading of scars. Scar widening usually results from tension perpendicular to wound edges during healing process. Thus, the risk of widened scars and hypertrophic scars increases in body areas where tension across skin is relatively high(KRAKOWSKI et al., 2017).

The modern understanding of wound healing is based on the knowledge of restoring skin anatomy and function, and a thoughtful selection of suture materials and closure techniques. Surgical approaches should precisely coapt the tissue layers and margins. This is necessary to minimize new tissue formation within the wound. Suitable surgical closing techniques will also eliminate a potential cavity by approximating the subcutaneous tissue. If misalignment and dead space is minimized adjacent to the opposed wound edges, new tissue has limited room to grow. Atraumatic handling of tissue in combination with avoiding tight closures result in better aesthetic outcomes(KRAKOWSKI et al., 2017).

In their unique articles “Scar repair by the double-breasted vest principle” and “Widening of scars: foe coaxed into a friend?” Dr RALPH MILLARD, MD and Dr ADEL M. WILSON, MD, FRCS respectively demonstrated how to revise a widened scar by minimizing tension on the edges and render most of the tension on the deep strong scar tissue. The results obtained by both methods were very promising as width and visibility of scars were both reduced shortly after(MILLARD,1970;WILSON,2000).

1. **Objectives:**
   The aim of this study is to prevent scar widening and reduce its visibility in facial wounds by reducing tension on deep dermis.

2. **Study Design:** (Please fill in the appropriate study design, see attached PDF guide)

- Descriptive: - Survey (cross sectional) ☐
  - Qualitative ☐
- Analytic: - Observational: - Case-control study ☐
  - Cross sectional analytic study ☐
  - Cohort (Longitudinal) study ☐
- Experimental: - Randomized Clinical Trial ☐ Phase:
  - Non-randomized clinical trial ☐
  - Animal study ☐
  - Cellular study ☐
- Others: Please describe:

3. **Scientific committee approval**
(Was it scientifically approved by the department?)

Date of approval:

4. **Study Methods**

- **Population of study & disease condition**
Patients with facial wounds
- **Study setting:**
- **Inclusion criteria:**

❖ Patients between 16 and 60 years old
❖ Patients with acute facial cut wounds

- Patients candidate for facial scar revision

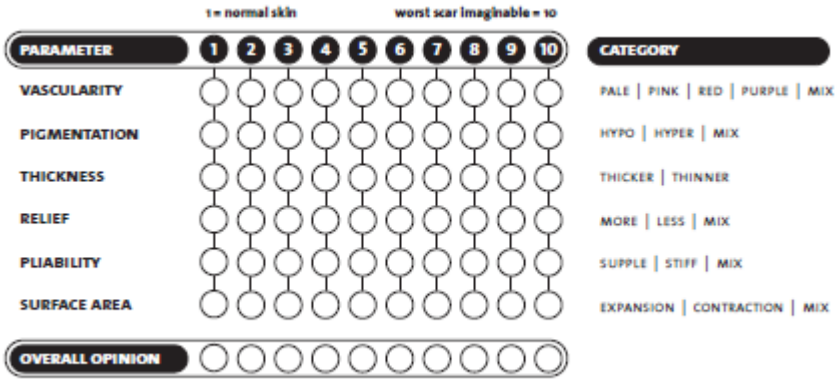
- **Exclusion criteria:**

- Patients with connective tissue disease
- Patients refusing to participate in the study
- Patients with grossly contaminated wounds
- Patients with wounds of significant skin loss

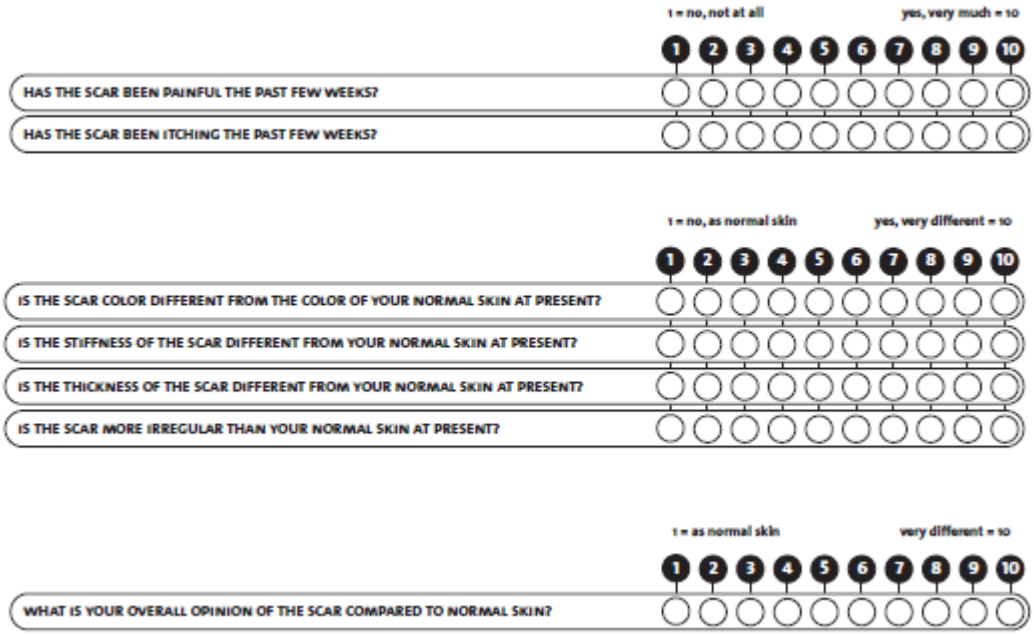
Methodology in details:

- Verbal consents will be taken from patients with facial cut wounds seeking wound closure or scar revision.
- Wound will be thoroughly cleansed and sterilized
- Adrenaline with local anaesthetic will be injected through wound edges (not to exceed maximum doses).
- One edge will be de-epithelialized (about 2 mm wide), while the other edge's deep dermis will be reduced to match the original dermal layer. Both edges may be undermined at the level of SMAS to about double the width of the de-epithelialization.
- Deep layers will be approximated using absorbable suture.
- The de-epithelialized edge is to be anchored under the dermis of the other edge using absorbable suture (pds 6/0).
- The most superficial skin layer will be stitched using non-absorbable suture (polypropylene 6/0).
- Flexible adhesive skin bandages (Steristrips) then will be applied to act as backup for sutures.
- Polypropylene sutures are to be removed within 5 to 7 days.
- Scar is examined in 6 month and given score (from 6 to 60) according to POSAS observer and patient scale (2) (tables below):

POSAS observer scale:



POSAS patient scale:



- **Intervention:**

☐ Diagnostic intervention (please describe):

■ Therapeutic intervention (please describe):

Described above.

☐ No intervention

- **Potential risks:**

❖ Wound infection
❖ Wound dehiscence
❖ Seroma formation

9- Study outcomes:

- **Primary outcome**

❖ Prevention of scar widening and reducing the visibility of facial cut wounds.

- **Secondary outcome parameters**

10- Sample size & statistical methods

40 patients with facial wounds:

-20 patients with acute facial cut wounds

-20 patients seeking scar revision in the face

11- Source of funding: (is there any source of funding or not?)

- No ■
- Yes □
- Source of funding if yes:

12- Time plan:

- When to start? December 2021

- When expected to finish? 6 months following the date of last case

13- Statistical Methods:

Data were collected, coded, revised and entered to the Statistical Package for Social Science (IBM SPSS) version 20. The data were presented as number and percentages for the qualitative data, mean, standard deviations and ranges for the quantitative data with parametric distribution and median with inter quartile range (IQR) for the quantitative data with non-parametric distribution.

***Paired t-test* was used in the comparison between two groups with quantitative data for before and after and parametric distribution and *Wilxon Rank test* was used in the comparison between two groups with quantitative data for before and after and non-parametric distribution.**

The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered significant as the following:

- **P > 0.05: Non-significant (NS)**
- **P < 0.05: Significant (S)**
- **P < 0.01: Highly significant (HS)**

13- Most relevant References:

1. Carswell L, Borger J. Hypertrophic Scarring Keloids. StatPearls. 2019 Jan.
2. Draaijers LJ, Tempelman FR, Botman YA, et al. The patient and observer scar assessment scale: a reliable and feasible tool for scar evaluation. Plast Reconstr Surg. 2004;113(7):1960-1967.

3. Ogawa R, Akaishi S, Kuribayashi S, Miyashita T. Keloids and Hypertrophic Scars Can Now Be Cured Completely: Recent Progress in Our Understanding of the Pathogenesis of Keloids and Hypertrophic Scars and the Most Promising Current Therapeutic Strategy. J Nippon Med Sch. 2016. 83 (2):46-53.
4. MILLARD, RALPH. SCAR REPAIR BY THE DOUBLE-BREASTED VEST PRINCIPLE. PLASTIC AND RECONSTRICTIVE SURGERY. 1970 JUNE; 45 (6):616-619
5. WILSON, ADEL. WIDENING OF SCARS: FOE COAXED INTO A FRIEND?. PLASTIC AND RECONSTRICTIVE SURGERY. 2000 DECEMBER; 106 (7):1488-1493
6. KRAKOWSKI, ANDREW AND SHUMAKER, PETER (2017). THE SCAR BOOK FORMATION, MITIGATION, REHABILITATION AND PREVENTION. PHILADELPHIA: WOLTERS KLUWER