Reliability and photographic equivalency of the SCAR scale, an outcome measure for postoperative scars
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PRÉCIS

Study Title
Reliability and photographic equivalency of the SCAR scale, an outcome measure for postoperative scars

Objectives
To assess the reliability of utilizing photographs in lieu of live patient scar rating assessments, and to determine the inter- and intra-rater reliability of the SCAR scale.

Design and Outcomes
Reliability study to assess clinicians’ inter- and intra-rater reliability, as well as the reliability of using high-quality macro photographs of postoperative scars.

Population
Non-identifying macro photographs of scars derived from a private practice dermatology clinic, with assessed scar photographs representing a range of surgical procedures including those performed by dermatologists, plastic surgeons, and general surgeons.

IMPORTANT NOTE:
This study involves the analysis of existing data, and subjects cannot be identified directly or through identifiers linked to the subjects; this study therefore does not involve “human subjects” and would be exempt from Institutional Review Board approval per 45 CFR §46.101 (b)(4).
STUDY TEAM ROSTER

Principal Investigator: Jonathan Kantor, MD, MSCE, MA

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1 STUDY OBJECTIVES

1.1 Primary Objective

To assess both the inter- and intra-rater reliability of the SCAR scale on a range of postoperative scars.

2 BACKGROUND AND RATIONALE

2.1 Background

Assessing the merits of various surgical approaches and outcomes is predicated on the existence of clinically valid and statistically reliable measurement scales. Many scales, of varying length and complexity, have been described for assessing scars.\textsuperscript{1-4} Historically, the Vancouver Scar Scale (VSS)\textsuperscript{5} was used to assess scarring, though this four-item scale was initially developed to assess burn scars, rather than postoperative linear scars, which have a very different set of clinical considerations. More recently, the patient and observer scar assessment scale (POSAS) was developed for burn scars,\textsuperscript{6} though several years after initial scale development it was reliability tested for linear scars as well.\textsuperscript{7} Other scar scales in use include the Hamilton Scale,\textsuperscript{8} the Seattle Scale,\textsuperscript{9} the Manchester Scar Scale,\textsuperscript{10} the Stony Brook Scar Evaluation Scale,\textsuperscript{11} the University of North Carolina 4P Scar Scale,\textsuperscript{12} and their variants.

2.2 Study Rationale

The Scar Cosmesis Assessment and Rating (SCAR) scale, whose initial development and validation has been described separately,\textsuperscript{14} was developed as a rating scale for postoperative linear scars that could be utilized on both live patients and photographs, while capturing change in a particular scar component over time. This scale was built upon prior work, including the development of a patient rating scale that highlighted the need to differentially weight scar hypertrophy, spread, and erythema when assessing scar quality.\textsuperscript{15} The SCAR scale is thus unique in that the items are weighted based on the degree of clinical importance assigned by the multi-specialty validity committee, as well as patients.

3 STUDY DESIGN

Inter-rater reliability will be assessed by a group of five clinicians scoring a set of 60 non-identifying high-quality scar photographs. All patients will be rated using the SCAR scale and an overall visual analogue scale (VAS) for scar quality. A subset of ten patients will also be evaluated using the OSAS and VSS.

To assess for intra-rater reliability, ten patients will be assessed twice by each rater. To minimize the chance of recall, raters were not informed beforehand that selected scars would be rated twice, which will be randomly inserted into the photographic set.

A secondary analysis of internal consistency will be performed on both the full data set as well as the subset of 10 scars assessed by all three scales to assess whether the overall SCAR scale, as well as the OSAS and VSS, predicted the presence of a desirable scar.
4 SELECTION AND ENROLLMENT OF PARTICIPANTS

Scar photographs will be selected from a preexisting set of non-identifying macro photographs.

This study involves the analysis of existing data, and subjects cannot be identified directly or through identifiers linked to the subjects; this study therefore does not involve “human subjects” and would be exempt from Institutional Review Board approval per 45 CFR §46.101 (b)(4).

4.1 Inclusion Criteria

De-identified macro photographs of scars on patients aged over 18 years of age.

4.2 Exclusion Criteria

Photographs that do not demonstrate a clear scar image.

4.3 Study Enrollment Procedures

No “human subjects” will be enrolled in this study. The study only utilizes non-identifying photographs.

5 STUDY INTERVENTIONS

5.1 Interventions, Administration, and Duration

None.

5.2 Handling of Study Interventions

N/A.

5.3 Concomitant Interventions

N/A.

5.4 Adherence Assessment

N/A.

6 STUDY PROCEDURES

None