The efficacy of combined treatment using pressure garments and silicone sheets in treating limb scars, compared to treatment with pressure garments treatment.

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Statistical Analysis Plan

Scar characteristics will be evaluated using both objective and subjective outcome measures. Objective measurements will include scar height and area assessed using the EinScan HX® scanner, scar elasticity measured using the Cutometer®, and scar color evaluated using the Skin Colorimeter®. Subjective scar assessment will be performed using the Patient and Observer Scar Assessment Scale (POSAS 3.0). Measurements will be collected at baseline and during monthly follow-up assessments throughout the three-month study period.

Statistical analyses will be performed using IBM SPSS Statistics software, version 3.0 . Descriptive statistics will be used for data analysis. The Shapiro-Wilk test will be performed to assess the distribution of all variables. For normally distributed variables, data will be presented as mean and standard deviation. For non-normally distributed variables, data will be presented as median and interquartile range.

For inferential statistics and evaluation of the research hypotheses, objective and subjective outcome measures will be analyzed using a Two-Way Repeated Measures ANOVA in cases of normal distribution. In cases of non-normal distribution, the Friedman test will be performed, with appropriate post-hoc analyses.

Additional statistical analyses will be conducted to evaluate differences in adherence and cooperation between the two groups using an independent samples t-test or Mann-Whitney U test according to data distribution. Correlations between treatment usage duration and outcome measures will also be examined.

Statistical significance will be set at $p < 0.05$.

Study Protocol

This study is designed as a prospective, non-randomized, parallel-group interventional study with repeated measurements and monthly follow-ups over a period of three months. Sixty participants with pathological scars of the extremities will be recruited from Sheba Medical Center. Participants will be aged 18-65 years and will include individuals with scars located on the extremities, with a minimum scar length of 5 cm and a scar age of 1-6 months. Exclusion criteria will include scars crossing joints, medical conditions affecting wound healing, skin diseases, active infections, silicone sensitivity, and neurological disorders affecting the involved extremity.

Participants will be allocated into two groups using a matching method according to age, sex, scar location, and skin tone to minimize potential confounding variables. The intervention group will receive combined scar treatment using pressure garments and silicone sheets, while the control group will receive treatment using pressure garments alone.

Each participant will undergo an initial evaluation session documenting demographic information, scar characteristics, and baseline scar assessment. Scar evaluation will include objective and subjective outcome measures. Objective measurements will include scar height and area assessment using the EinScan HX® scanner, scar elasticity evaluation using the Cutometer® and scar color assessment using the Skin Colorimeter®. Subjective scar evaluation will be performed using the Patient and Observer Scar Assessment Scale (POSAS 3.0), including both patient-reported and observer-rated assessments.

Participants will receive instructions regarding scar management and appropriate use of the prescribed treatment. Both groups will be followed monthly throughout the three-month study period, and repeated scar assessments will be performed to evaluate changes in scar characteristics over time.

The primary aim of this study is to examine the efficacy of combined pressure garment and silicone sheet therapy compared with pressure garment therapy alone for the treatment of pathological scars of the extremities. In addition, the study aims to establish a comprehensive scar assessment framework integrating objective and subjective evaluation tools.