

Statistical analysis plan for study: 1550-nm Non-Ablative Laser (Fraxel) Versus Ablative 10,600-nm Carbon Dioxide (CO₂) Fractional Laser in the Treatment of Surgical and Traumatic Scars: A Comparison Study on Efficacy and Treatment Regimen.

Background

The main objective of this study is to compare the effectiveness of 10,600-nm carbon dioxide (C02) fractional laser and 1550-nm non-ablative laser (Fraxel) in the treatment of surgical and traumatic scars as well as identify the minimum number of treatments required to achieve the highest benefit at the lowest cost. This was a split-scar study, so each laser was randomly assigned to half of the scar and then each half of the scar was evaluated separately. Patients assessed scars prior to the first treatment (baseline) and 6 months after the last treatment using the Patient and Observer Scar Assessment Scale (POSAS). At both visits, photographs were taken using identical camera settings, lighting and patient positioning. Four blinded examiners then evaluated these photographs using the Manchester scar scale. There were 100 patients enrolled in the study and of those 83 have POSAS scores for the 6-month follow-up and 84 have photo evaluator scores for the 6-month follow-up (ID LSS108.2 was missing in the patient scores). The data was analyzed using SAS v9.4 software.

Hypotheses

- 1) The ablative 10,600-nm carbon dioxide (C02) fractional laser and the 1550-nm non ablative laser (Fraxel) will both lead to improvement in the appearance of a surgical or traumatic scar as well as reduction of symptoms such as pain and itch.
- 2) The ablative 10,600-nm carbon dioxide (C02) fractional will lead to a superior cosmetic outcome compared to the 1550-nm non-ablative laser (Fraxel) over the same number of treatments, thereby proving a more cost effective treatment.

Analysis Approach

First, we looked at the scoring distributions for each photo evaluator to check for differences in scoring patterns. Six paired t-tests were conducted to compare the total scores for all possible combinations of observers for each laser at both time points. Next, to assess the effectiveness of the C02 and Fraxel lasers, five paired t-tests were performed on both the patient self-scores and the photo evaluator scores from the 6-month follow-up:

- 1) C02 laser vs. Fraxel laser at baseline.
- 2) C02 laser vs. Fraxel laser at 6-month follow-up.
- 3) C02 laser at 6-month follow-up vs. C02 laser at baseline.
- 4) Fraxel laser at 6-month follow-up vs. Fraxel laser at baseline.
- 5) Difference in C02 laser after 6 months vs. difference in Fraxel laser after 6 months.

Paired t-tests compare whether the mean of the differences in two paired samples differs from 0. A statistically significant difference would indicate that the average scores are not the same for either the C02/Fraxel lasers or for each laser at different time periods.

We also used McNemar's test to investigate the agreement between the C02 and Fraxel lasers for both the POSAS and photo examiner scores, as well as the agreement between the POSAS and photo examiner scores for the C02 and Fraxel lasers separately.