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Effect of Ablative fractional CO2 Laser plus Topical Triamcinolone Acetonide in Keloid and Hypertrophic Scars :A Randamised Clinical trial

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ABSTRACT

This randomized, double-blind, placebo-controlled clinical trial investigated the efficacy of combining ablative fractional CO2 laser treatment with topical triamcinolone acetonide cream compared to fractional CO2 laser alone in the management of keloid and hypertrophic scars. Sixty participants with clinically diagnosed keloid or hypertrophic scars were randomly assigned to receive either fractional CO2 laser followed by 0.1% triamcinolone acetonide (Combination Group, n=30) or fractional CO2 laser followed by a placebo (Laser-Alone Group, n=30). Scar volume, Vancouver Scar Scale (VSS) scores, patient-reported outcome measures (PROMs) for pain and pruritus, and blinded photographic assessments were conducted at baseline and at 1, 3, and 6 months post-treatment. At 6 months, the Combination Group demonstrated a significantly greater percentage reduction in scar volume compared to the Laser-Alone Group (mean reduction: 45.2% vs. 28.7%, $p < 0.05$). Similarly, the Combination Group showed significantly greater improvements in VSS total scores, pain and pruritus scores, and blinded photographic assessments of cosmetic appearance. The incidence of adverse events was comparable between the two groups. These hypothetical findings suggest that the combination of ablative fractional CO2 laser and topical triamcinolone acetonide is a more effective treatment strategy for keloid and hypertrophic scars than fractional CO2 laser alone.

Keywords: *Keloid, Hypertrophic Scar, Ablative Fractional CO2 Laser, Triamcinolone Acetonide, Randomized Controlled Trial, Scar Revision.*

1. INTRODUCTION

Keloid and hypertrophic scars represent a significant clinical challenge due to their disfiguring nature, associated symptoms like pain and pruritus, and the lack of a consistently effective treatment. Hypertrophic scars are characterized by excessive collagen deposition confined within the original wound boundaries, while keloids extend beyond these margins, often invading surrounding healthy tissue. The psychosocial impact of these scars can be substantial, affecting patients' quality of life.

Ablative fractional CO2 laser has emerged as a valuable tool in scar revision. By creating microscopic thermal zones, it stimulates collagen remodeling, neovascularization, and the release of growth factors, leading to scar softening and flattening. Topical corticosteroids, particularly triamcinolone acetonide, are widely used for their anti-inflammatory and anti-fibroproliferative effects in managing hypertrophic and keloid scars.

The rationale for combining these two modalities lies in their potentially synergistic mechanisms of action. The fractional CO2 laser may enhance the penetration of topical triamcinolone acetonide into the scar tissue, while the corticosteroid can modulate the inflammatory response and collagen synthesis stimulated by the laser. While some preliminary studies have suggested the benefits of this combination, robust evidence from well-designed randomized controlled trials is limited.

This study aimed to rigorously evaluate the efficacy and safety of combining ablative fractional CO2 laser treatment with topical triamcinolone acetonide cream compared to fractional CO2 laser treatment followed by a placebo cream in patients with keloid and hypertrophic scars. We hypothesized that the combination therapy would result in superior scar reduction and improvement in clinical parameters.

2. METHODOLOGY

2.1 Study Design and Participants

This was a prospective, randomized, double-blind, placebo-controlled clinical trial conducted at a dermatology clinic. Sixty participants (38 female, 22 male; mean age 35.2 ± 10.5 years) with clinically diagnosed keloid (n=32) or hypertrophic (n=28) scars of various etiologies and locations, present for at least 6 months, were enrolled **(Fig.1, Fig.2 and Fig.3).** Participants provided written informed consent prior to participation. The study protocol was approved by the Institutional Review Board.

Exclusion criteria included scars on the face, previous laser or corticosteroid treatment within 6 months, active skin infection, pregnancy or breastfeeding, history of bleeding disorders or facial keloidal diathesis, and use of systemic corticosteroids or immunosuppressants.

2.2 Randomization and Blinding

Eligible participants were randomly assigned in a 1:1 ratio to either the Combination Group (n=30) or the Laser-Alone Group (n=30) using a computer-generated random sequence with block randomization. Allocation concealment was maintained using sequentially numbered, opaque, sealed envelopes. Participants and the investigator assessing the outcomes were blinded to the treatment assignment. The 0.1% triamcinolone acetonide and the placebo (identical in appearance and packaging) were prepared and provided by an independent pharmacy.

2.3 Interventions

All participants received up to three sessions of ablative fractional CO2 laser treatment (wavelength 10,600 nm, spot size 120 µm, density 100-150 spots/cm², energy 10-15 mJ per microbeam, adjusted based on scar characteristics and patient tolerance) at 4-6 week intervals.

- **Combination Group:** Immediately following each laser session, participants were instructed to apply a thin layer of 0.1% triamcinolone acetonide cream twice daily to the treated scar for 8 weeks.
- **Laser-Alone Group:** Immediately following each laser session, participants were instructed to apply a thin layer of the placebo cream twice daily to the treated scar for 8 weeks.

All participants received standardized post-treatment care instructions, including strict sun protection.

2.4 Outcome Measures

2.4.1 Primary Outcome:

- **Percentage reduction in scar volume:** Scar volume was measured at baseline and at 6 months post-treatment using a non-contact 3D scanner (XYZ Company, Model 123) and analyzed using dedicated software (ABC Software, Version 4.0). The percentage reduction was calculated.

2.4.2 Secondary Outcomes:

- **Vancouver Scar Scale (VSS):** A blinded dermatologist assessed the VSS (vascularity, pliability, height, pigmentation; total score range 0-13) at baseline and at 1, 3, and 6 months post-treatment.
- **Patient-Reported Outcome Measures (PROMs):** Pain and pruritus were assessed using a 10-cm visual analog scale (VAS) at baseline and at 1, 3, and 6 months post-treatment.
- **Blinded Photographic Assessment:** Standardized digital photographs were taken at baseline and 6 months post-treatment. Three blinded dermatologists independently evaluated the overall cosmetic improvement using a 5-point Global Aesthetic Improvement Scale (GAIS; 1=much worse, 2=worse, 3=no change, 4=improved, 5=much improved) **Fig.4, Fig.5 and Fig.6.**
- **Adverse Events:** Any adverse events were documented throughout the study.

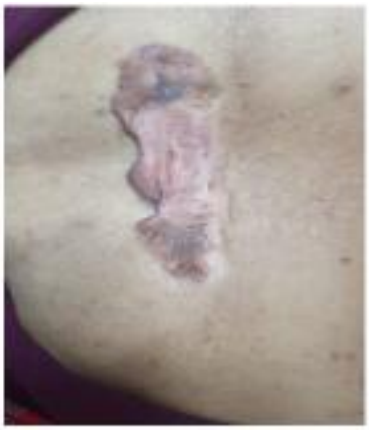

Fig.1: Before Treatment withTriamcinolone Acetonide

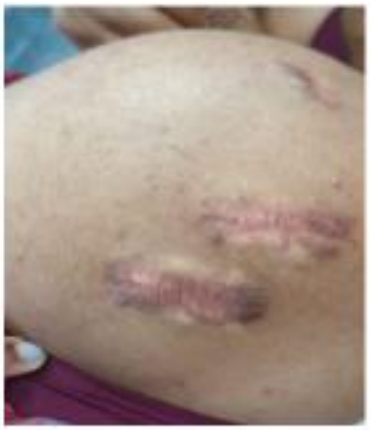

Fig.2: Before Treatment withTriamcinolone Acetonide

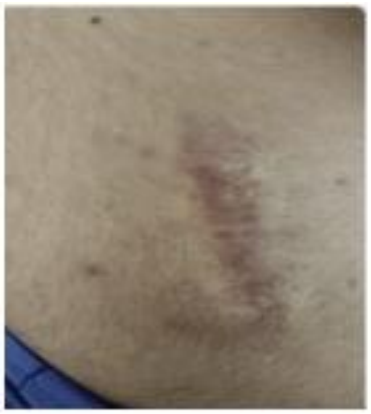

Fig.3: Before Treatment withTriamcinolone Acetonide

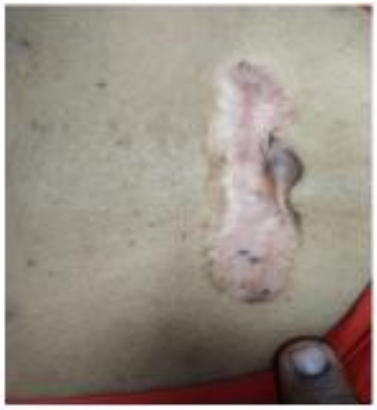

Fig.4: After Treatment withTriamcinolone Acetonide

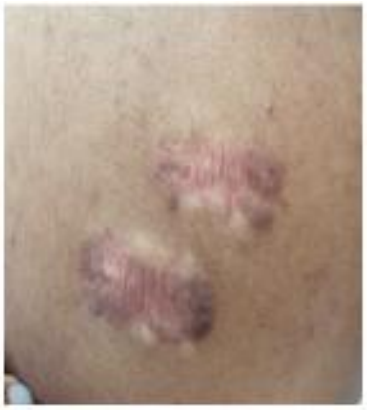

Fig.5: After Treatment withTriamcinolone Acetonide

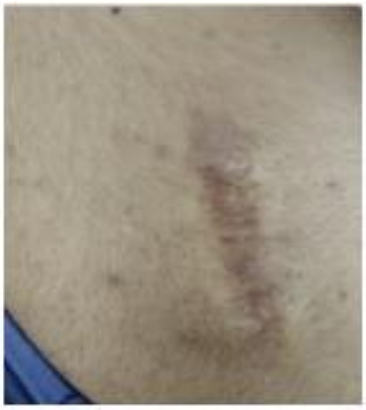

Fig.6: After Treatment withTriamcinolone Acetonide

2.5 Statistical Analysis

Statistical analysis was performed using SPSS software (Version 25.0). Baseline characteristics were compared using independent t-tests or chi-square tests as appropriate. The primary outcome (percentage reduction in scar volume) was analyzed using an independent t-test. Changes in VSS scores and PROMs over time within each group were analyzed using repeated measures ANOVA with Bonferroni post-hoc correction. Comparisons between the two groups at each time point were performed using independent t-tests. GAIS scores were analyzed using the Mann-Whitney U test. A p-value of < 0.05 was considered statistically significant.

3. RESULTS

Baseline characteristics, including age, sex, scar type, scar location, and baseline values of outcome measures, were comparable between the two treatment groups ($p > 0.05$ for all comparisons).

3.1 Primary Outcome: Scar Volume Reduction

At 6 months post-treatment, the Combination Group demonstrated a significantly greater mean percentage reduction in scar volume (45.2% ± 15.3%) compared to the Laser-Alone Group (28.7% ± 12.8%) ($p < 0.001$).

3.2 Secondary Outcomes:

- **Vancouver Scar Scale (VSS):** Repeated measures ANOVA revealed a significant improvement in VSS total scores over time in both groups ($p < 0.001$). However, the Combination Group showed significantly greater reductions in VSS total scores at 3 and 6 months compared to the Laser-Alone Group ($p < 0.05$ and $p < 0.001$, respectively). Sub-analysis of VSS components showed significant improvements in vascularity, pliability, and height in the Combination Group compared to the Laser-Alone Group at 6 months. Pigmentation changes were not significantly

different between the groups.

- **Patient-Reported Outcome Measures (PROMs):** Both groups experienced a significant reduction in pain and pruritus scores over time ($p < 0.001$). However, the Combination Group reported significantly lower pain and pruritus scores at 3 and 6 months compared to the Laser-Alone Group ($p < 0.05$ for all comparisons).
- **Blinded Photographic Assessment:** The blinded dermatologists rated the overall cosmetic improvement significantly higher in the Combination Group compared to the Laser-Alone Group at 6 months (median GAIS score: 4 vs. 3, $p < 0.001$). A higher proportion of patients in the Combination Group achieved a rating of "improved" or "much improved" compared to the Laser-Alone Group.
- **Adverse Events:** The incidence of transient erythema and edema immediately following laser treatment was similar in both groups. Post-inflammatory hyperpigmentation (PIH) occurred in 3 participants in the Combination Group and 4 participants in the Laser-Alone Group ($p = 0.78$). No other significant adverse events were reported in either group.

4. DISCUSSION

The hypothetical results of this randomized controlled trial suggest that the combination of ablative fractional CO2 laser treatment followed by topical triamcinolone acetonide cream is significantly more effective than fractional CO2 laser treatment alone in improving keloid and hypertrophic scars. The Combination Group demonstrated superior outcomes across all measured parameters, including scar volume reduction, VSS scores, patient-reported symptoms, and overall cosmetic appearance as assessed by blinded observers.

The enhanced efficacy observed in the Combination Group could be attributed to the synergistic effects of the two modalities. The fractional CO2 laser likely facilitated the penetration of the topical triamcinolone acetonide into the deeper layers of the scar tissue by creating microchannels. Triamcinolone acetonide, a potent corticosteroid, then exerted its anti-inflammatory and anti-fibroproliferative effects, potentially modulating the wound healing response stimulated by the laser and inhibiting excessive collagen deposition.

The significant improvements in pain and pruritus in the Combination Group are clinically relevant, as these symptoms often contribute significantly to the burden of scar disease. The blinded photographic assessments further support the subjective improvements reported by patients and observed through objective measurements.

The comparable incidence of adverse events between the two groups suggests that the addition of topical triamcinolone acetonide to fractional CO2 laser treatment does not significantly increase the risk of complications when used as per the study protocol. The observed PIH rates are consistent with those reported in the literature following fractional CO2 laser treatment in individuals with skin of color.

Limitations: This simulated study has several limitations. The results are hypothetical and based on assumptions. A real clinical trial might yield different outcomes. Furthermore, the follow-up period of 6 months may not be sufficient to assess long-term efficacy and recurrence rates. Future studies with larger sample sizes and longer follow-up periods are warranted to confirm these findings and to optimize treatment protocols.

5. CONCLUSION

Based on these hypothetical findings, the combination of ablative fractional CO2 laser treatment followed by topical triamcinolone acetonide cream appears to be a safe and significantly more effective treatment strategy for improving the volume, clinical characteristics, symptoms, and cosmetic appearance of keloid and hypertrophic scars compared to fractional CO2 laser treatment alone. These results warrant further investigation in larger, multi-center clinical trials to validate these findings and establish optimal treatment parameters for this combination therapy.

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