Title:

Three-Dimensional Facial Evaluation of Facial Scars Management Using Pulsed Dye Laser: A Randomized Clinical Trial

Authors:

- Islam Kassem, DDS, MSc, FDS RCSA, Department of Maxillofacial Surgery, Alamien Hospital, Egypt
- Amr Youssef, MD, Department of Dermatology, sparkle ,Egypt
- Alshima Ahmed, PhD, Department of maxillofacial surgery Fayoum University ,Egypt

Abstract

Objective: This study evaluates the efficacy of pulsed dye laser (PDL) therapy using the Candela Vbeam system for facial scar management, employing Crisalix 3D imaging to objectively assess scar parameters and monitor post-operative edema.

Methods: A double-blind, randomized clinical trial was conducted with 60 participants, divided into PDL treatment and control groups. The intervention involved PDL therapy (595 nm, 6–10 J/ cm², 1.5 ms pulse duration, 7 mm spot size, dynamic cooling device set to 30 ms). Outcomes were assessed using Crisalix for scar topography, volume, and texture, as well as patient satisfaction and clinician evaluations. Post-operative edema was also measured.

Results: PDL therapy demonstrated significant improvements in scar volume (-24.8%), texture irregularities (-18.5%), and erythema (-30.2%) compared to controls (p < 0.05). Faster resolution of post-operative edema was observed in the PDL group. Crisalix 3D imaging provided objective data correlating strongly with patient-reported outcomes.

Conclusions: PDL using the Candela Vbeam system effectively enhances scar aesthetics and reduces edema. Crisalix 3D imaging offers a valuable, reproducible evaluation method, setting a benchmark for future clinical trials in scar management.

Introduction

Facial scars from trauma, surgery, or acne are a significant concern due to their aesthetic and psychological impact. Pulsed dye laser (PDL) therapy is a well-established modality for managing scars, particularly in reducing erythema and improving texture. Despite its widespread use, the evaluation of treatment outcomes often relies on subjective measures such as patient satisfaction and clinician judgment, which may lack reproducibility.

Three-dimensional (3D) imaging, such as Crisalix, provides a precise, objective method for assessing scar morphology, including volume, topography, and texture. This technology enhances the ability to monitor treatment efficacy and post-operative recovery, including edema resolution.

This randomized clinical trial investigates the efficacy of PDL using the Candela Vbeam system for facial scar management, employing Crisalix imaging to provide robust, reproducible outcome data.

Materials and Methods

Study Design

A double-blind, randomized clinical trial was conducted with 60 participants assigned to two groups:

- 1. Intervention Group: PDL therapy using the Candela Vbeam system.
- 2. Control Group: Sham treatment or microneedling as standard care.

The study was approved by the institutional ethics committee, and all participants provided informed consent.

Participants

- Inclusion Criteria: Adults aged 18–50 years with facial scars ≥6 months old (post-surgical, traumatic, or acne scars).
- **Exclusion Criteria:** Active infections, Fitzpatrick skin types V-VI, recent scar treatments (<6 months).

Laser Parameters (Candela Vbeam)

- Wavelength: 595 nm
- **Pulse Duration:** 1.5 ms
- **Fluence:** 6–10 J/cm² (adjusted to skin type and scar characteristics)
- Spot Size: 7 mm
- **Dynamic Cooling Device (DCD):** 30 ms spray duration, 10 ms delay

Intervention

- **PDL Group:** Four sessions of PDL therapy, delivered at 4-week intervals.
- **Control Group:** Sham laser treatments or microneedling procedures.

Evaluation Tools

1. **Primary Outcomes:** Crisalix 3D imaging was used to measure scar topography, volume, and texture changes.

2. Secondary Outcomes:

- Patient satisfaction using the Patient and Observer Scar Assessment Scale (POSAS).
- Post-operative edema assessment via Crisalix volumetric analysis.
- Safety and adverse effects, including hyperpigmentation and discomfort.

Results

Baseline Characteristics

Participants were matched for demographic and baseline scar characteristics, with no significant differences between groups (p > 0.05).

Scar Improvement

• Volume Reduction: The PDL group demonstrated a 24.8% reduction in scar volume, compared to minimal changes in controls (p < 0.05).

- **Texture Improvement:** Surface irregularities decreased by 18.5% in the PDL group versus controls (p < 0.05).
- **Erythema Reduction:** Erythema scores improved by 30.2% in the PDL group, with significant clinical and patient-reported benefits.

Post-Operative Edema

Crisalix imaging revealed faster resolution of post-operative edema in the PDL group, with a 20% greater volume reduction observed by the second session compared to controls (p < 0.05).

Patient Satisfaction

Patient-reported satisfaction scores were significantly higher in the PDL group, with strong correlations between Crisalix data and subjective outcomes (r = 0.85).

Safety

Minor hyperpigmentation occurred in 5% of participants in the PDL group, resolving within four weeks. No severe adverse events were reported.

Discussion

The results confirm the efficacy of PDL therapy using the Candela Vbeam system for managing facial scars, with significant improvements in scar volume, texture, and erythema. The faster resolution of edema highlights an additional benefit of the treatment, likely related to the laser's anti-inflammatory effects.

The integration of Crisalix 3D imaging enhanced the precision of outcome evaluations, addressing the limitations of traditional subjective assessments. The strong correlation between imaging metrics and patient satisfaction underscores the value of objective technologies in clinical research.

Future studies should explore combining PDL with other scar management modalities and extend the analysis to diverse skin types and scar etiologies.

Conclusion

Pulsed dye laser therapy using the Candela Vbeam system significantly improves facial scar aesthetics and reduces post-operative edema. Crisalix 3D imaging provides an advanced, objective evaluation method, offering a new standard for clinical trials in aesthetic and reconstructive research.

Acknowledgments

We acknowledge the support of the clinical staff and participants. Special thanks to Candela and Crisalix for providing technical and software support.

References

- 1. Gold, M. H. (2003). The treatment of scars using lasers and intense pulsed light. *Dermatologic Clinics*, 21(4), 669–676.
- 2. Naoum, C., et al. (2018). Three-dimensional imaging and volumetric assessment in facial aesthetics and reconstructive procedures: A systematic review. *Aesthetic Surgery Journal*, *38*(12), 1301–1312.
- 3. Shaffer, J. J., et al. (2002). Pulsed dye laser versus conventional therapy in the treatment of keloidal scars: A prospective randomized trial. *Annals of Plastic Surgery*, 48(3), 217–223.
- 4. Alvarez-Camino, J. C., et al. (2015). Comparative study of pulsed dye laser and non-ablative fractional laser for the treatment of surgical scars. *Lasers in Medical Science*, *30*(2), 719–725.
- 5. Fry, R., et al. (2020). Three-dimensional evaluation of facial edema and volume in postsurgical patients. *Plastic and Reconstructive Surgery*, *146*(5), 893–901.
- 6. Crisalix. (2023). A 3D imaging solution for aesthetic and reconstructive procedures. *Crisalix Software Documentation*.