



CO₂RE[®]

Summary of Peer-Reviewed Articles

June 2020

CE Indications

Surgical procedures in the area of dermatology, plastic surgery and treatment of vaginal atrophy and rejuvenation.



Fractional CO₂ Laser Treatment of the Vulva and Vagina and the Effect of Postmenopausal Duration on Efficacy*

Alexiades MR. Lasers Surg Med. 2020 Apr 23. Online ahead of print.

STUDY DETAILS

- 18 postmenopausal women (mean age 53±7 years) with atrophic vaginitis* received 3 monthly CO₂RE laser treatments, with Intima handpieces and Deep Mode, to the vulva and vaginal canal
- 10 subjects were postmenopausal >3 years (range 3–16 years) and 8 subjects postmenopausal <3 years
- Investigator assessment of treatment outcome using the vaginal health index (VHI) at each study visit
- Subjects reported on sexual function using the validated Female Sexual Function Index (FSFI)

RESULTS AT 12 MONTHS AFTER TREATMENT

- Significant improvement of VHI and FSFI at all study treatments and follow-ups to 12 months (p<0.001)
- Restoration of normal or near-normal (23–25) VHI following treatment in the recently menopausal (1–3 years) cohort was significantly greater (p<0.05) than that of the >3 years postmenopausal population
- Transient erythema and edema, with no adverse events associated with treatment

* Not FDA-cleared indication. The CO₂RE device has Health Canada clearance for GSM and SUI. The CO₂RE device has CE Mark for the treatment of vaginal atrophy and rejuvenation. CE Marking of Conformity is applicable to the European Economic Area (28 member countries of the European Union (i.e. France, Italy, Germany, etc.) and member states of the European Free Trade Association).



Efficacy of the Use of Fractional CO₂RE Intima Laser Treatment in Stress and Mixed Urinary Incontinence*

Palacios S, Ramirez M. Eur J Obstet Gynecol Reprod Biol 2020 Jan;244:95-100.

STUDY DETAILS

- 25 women aged 35–68 years who presented with moderate, severe and very severe symptoms of SUI* or MUI*, based on Sandvik index and ICIQ-UI scores were treated
- 3 monthly CO₂ treatments with 2 laser passes: first to the vaginal canal with an energy of 70 mJ and a fluence of 396 J/cm², followed by a second pass covering an angle of 120° of the anterior area (from 10 to 2 o'clock) to reinforce the bladder region
- Validated ICIQ questionnaire and Female Sexual Function Index (FSFI) scores evaluated after each treatment

RESULTS AFTER TREATMENT SERIES

- Statistically significant improvement in ICIQ-UI scores and Sandvik index after the 1st treatment (p = 0.025); increasing to (p< 0.001) after the 2nd and 3rd treatments
- Total FSFI score demonstrated a statistically significant increase (p<0.05) with the highest score in the desire domain
- Side effects limited to 2 cases of vaginal candidiasis

* Not FDA-cleared indication. The CO₂RE device has Health Canada clearance for GSM and SUI.



Efficacy of the Carbon Dioxide Fractional Laser in the Treatment of Compound and Dermal Facial Nevi Using With Dermatoscopic Follow-Up

Köse O. J Dermatolog Treat 2019 Aug;30(5):498-502.

STUDY DETAILS

- 330 patients (210 females, 120 males) with 684 facial nevi – pigmented, elevated, with brown or skin color, papular or nodular shape and 2–10 mm in diameter
- CO₂ laser treatments performed at 2-month intervals until complete clearance observed dermatoscopically: at each session, nevi were irritated with laser energy 4–6 mJ and fluences of 20–35 J/cm²; between 3–10 ablative passes were done in 50 µm ablation mode and 100 µm thermal ablation for each application with a 0.9/2.0/2.9 (mm) square spot size and 30% overlap
- Global Assessment Scale (GAS) scores used to assess the overall results
- Dermatoscopic changes were evaluated at the 1-year follow-up period with respect to structures of nevus cell remnant, scars, hypo/hyperpigmentation, and fibrosis

RESULTS AT 1 YEAR AFTER TREATMENT

- 554 nevi (81%) successfully treated in 1 session, 89 (13%) in 2 sessions, 34 (5%) in 3 sessions and 7 (1%) in >3 sessions
- The majority of side effects were mild and transitory. No serious side effects observed
- At the 1-year follow-up, patients' (87%) and physicians' (85%) GAS scores were rated as good-excellent



Combination of Fractional Resurfacing and Dermabrasion Techniques to Improve Aesthetic Outcomes of Facial Grafts

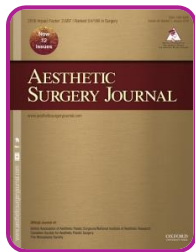
Worley B, Cohen JL. J Drugs Dermatol. 2019 Mar 1;18(3):274-275.

CASE STUDY DETAILS

- 2 patients with full-thickness skin grafts (FTSG) for MOHRs surgical defects, one below the eye and one on the nasal tip, underwent CO₂ fractional resurfacing and manual dermabrasion to blend the skin graft with surrounding tissue
- At 2 months after the initial surgery, CO₂RE laser treatment with 2 passes in Fusion Mode (30% fractional coverage, ring 116mJ, Core energy of 70mJ) were applied to the surface of the skin graft with 50% overlap onto native skin
- Light to medium manual dermabrasion, using a sterilized diamond fraise, was applied in 3 passes to the edges and skin graft

RESULTS AT 4 MONTHS AFTER TREATMENT

- Color and texture of the skin grafts improved after treatment
- Softening of the transition between the skin grafts and native skin was apparent
- No pulsed dye laser was used for either patient as most of the redness resolved spontaneously
- No additional treatment sessions were needed for camouflaging with surrounding skin



Treatment to External Labia and Vaginal Canal with CO₂ Laser for Symptoms of Vulvovaginal Atrophy* in Postmenopausal Women

Samuels JB, Garcia MA. Aesthet Surg J. 2019 Jan; 39(1): 83–93.

STUDY DETAILS

- 40 postmenopausal women (mean age 56±8 years) underwent 3 CO₂RE laser treatments, with Intima handpieces and Deep Mode, to the vulva and vaginal canal
- Investigators assessed treatment outcome using the vaginal health index (VHI) at each study visit
- Subjects reported on symptoms of dryness, itching and dyspareunia, using an 11-point Likert Scale
- Subjects reported on sexual function using the validated Female Sexual Function Index (FSFI)

RESULTS AT 6 AND 12 MONTHS AFTER TREATMENT

- Significant improvement of 9.6 and 9.5 points on the vaginal health index (VHI) at 6 and 12 months after the treatment series
- Dryness, itching and dyspareunia improved significantly ($p < 0.05$) at all evaluations.
- 83% of subjects reported improvement on the FSFI at 12 months
- Histology findings: Increased collagen and elastin staining, as well as a thicker epithelium and better degree of surface maturation

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Effects of Early Combinatorial Treatment of Autologous Split-Thickness Skin Grafts in Red Duroc Pig Model Using Pulsed Dye Laser and Fractional CO₂ Laser

Bailey JK, Blackstone BB, DeBruler DM, et al. Lasers Surg Med 2018 Jan;50(1):78-87.

STUDY DETAILS

- 8 female red Duroc pigs (FRDP) received 4 standardized, 1 in. x 1 in. third degree burns that were excised and autografted
- Wound sites were treated as follows: fractional CO₂ (CO₂RE) at 70mJ setting and 396J/cm² fluence, 150 μm spot diameter, 5% fractional coverage; PDL (Vbeam®) at 5-6J/cm², 10 mm spot size, 0.45ms pulse duration, and DCD 30/20ms or both (PDL followed by fractional CO₂)
- 3 treatments at 4, 8, and 12 weeks post grafting. Grafts receiving no laser therapy served as controls
- Scar appearance, morphology, size, and erythema were assessed, and punch biopsies collected at weeks 4, 8, 12, and 16

RESULTS AT WEEK 16 AFTER 3 TREATMENTS

- Treatment with PDL, FX CO₂, or PDL + FX CO₂ resulted in significantly less contraction versus skin graft only controls. No statistically significant difference among laser therapy groups
- Scars treated with the CO₂RE system were visually smoother and contained significantly fewer wrinkles
- Hyperpigmentation was significantly reduced in scars treated with the CO₂RE system

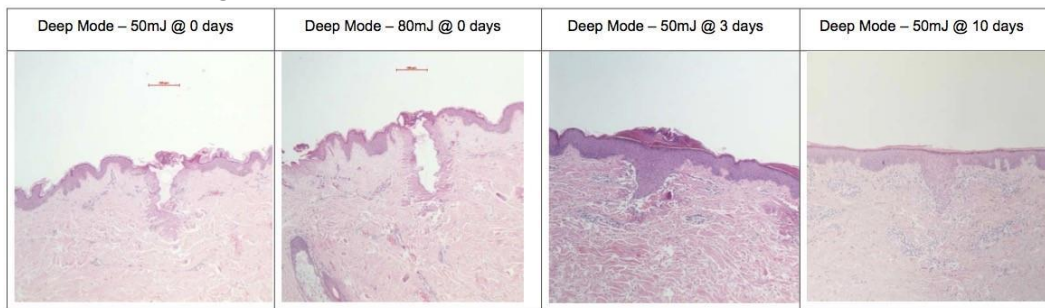


In-Vivo Histological Analysis of a Fractional CO₂ Laser System Intended for Treatment of Soft Tissue

Hurliman E, Zelickson B, Kenkel J. J Drugs Dermatol. 2017 Nov 1;16(11):1085-1090.

HISTOLOGY STUDY DETAILS & FINDINGS

- 9 healthy females (mean age 39 years) with Fitzpatrick Skin Types I-IV underwent CO₂RE laser treatment, with different modes and energy, to abdomen prior to abdominoplasty at different time points
- Histologic evaluation showed ablation to levels of up to 900 microns in depth using the Deep Mode (see Figure). Healing process of up to 10 days with Deep Mode
- The higher the energy used with the CO₂RE system, the greater the degree of ablation and coagulation in tissue, which can lead to a greater tissue response in terms of fibroblast activity, collagen remodeling, and new collagen formation





Fractional CO₂ laser treatment for vulvovaginal atrophy symptoms* and vaginal rejuvenation* in perimenopausal women

Arroyo C. Int J Womens Health. 2017; 9: 591–595. Published online 2017 Aug 28.

STUDY DETAILS

- 21 peri-menopausal women (mean age 45±7 years) underwent 3 CO₂RE laser treatments, with Intima handpieces and Deep Mode, to the vulva and vaginal canal
- Investigator assessment of treatment outcome using the vaginal health index (VHI) at each study visit
- Subjects reported on improvement in sexual gratification and vaginal rejuvenation and subject satisfaction at the 12-week follow-up

RESULTS AT 12 AND 24 WEEKS AFTER TREATMENT

- Significant improvement on the vaginal health index (VHI) at 12 and 24 weeks after the treatment series
- 81% of subjects reported improvement in sexual gratification, 94% in vaginal rejuvenation, and 100% satisfaction with treatment at the 12-week follow-up
- Immediate treatment responses were mild and transient. No treatment complications

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Safety and Efficacy Evaluation of Pulsed Dye Laser Treatment, CO₂ Ablative Fractional Resurfacing, and Combined Treatment for Surgical Scar Clearance

Cohen JL, Geronemus R. J Drugs Dermatol. 2016 Nov 1;15(11):1315-1319.

STUDY DETAILS

- 25 healthy subjects (15 males, 10 females; mean age 61 years) with Mohs surgical scarring
- Randomized to treatment arms: 3-4 CO2RE laser treatments, Vbeam pulsed dye laser treatments or combined treatments following suture removal
- Investigator assessments of Vancouver Scar Scale (VSS)

RESULTS AFTER TREATMENT

- 83% significant improvement response rate on VSS with CO2RE treatments
- 100% response rate on VSS with combined treatments
- CO2RE treatments showed greater improvement with pigmentation, while Vbeam treatments improved vascularity
- Combined treatments potentially have a synergistic effect and an accelerated outcome on the cosmesis of recent surgical scars



Thank you

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