
Clinical Study of the Pixel CO₂ OMNIFIT™ Handpiece for Microscopic Fractional Ablative Skin Resurfacing

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ABSTRACT

Background/Objectives. Traditional CO₂ laser devices, though highly effective in skin resurfacing, are associated with prolonged recovery time and significant adverse effects. Nonablative modalities offer reduced downtime and fewer adverse effects but limited efficacy. The new fractional CO₂ laser handpiece (Pixel CO₂ OMNIFIT™, Alma Lasers Inc, Buffalo Grove, IL) produces arrays of microthermal wounds at customizable depths leaving the surrounding tissue unaffected. This prospective study describes the histological effects on human skin after a single treatment with the FDA-cleared Pixel CO₂ OMNIFIT handpiece when used on a commercially available laser CO₂ system (UltraPulse 5000C, Coherent). **Methods.** three patients received treatment with the Pixel CO₂ OMNIFIT™ Handpiece.. Three 3.5-mm punch biopsy specimens were obtained immediately after treatment from the treated areas of each subject. Additional specimens were obtained 3 days and 14 days after treatment in two subjects. Specimens were processed and examined microscopically by a board-certified dermatopathologist. **Results.** The slides of specimens taken immediately after treatment revealed arrays of small coagulative thermal lesions surrounded by undamaged epidermal tissue. The 3-day and 14-day specimens showed evidence of re-epithelialization and exfoliation of necrotic debris, respectively. No adverse effects or complications were detected during and after the treatment period. **Conclusion.** This *in vivo* study demonstrated that the Pixel CO₂ OMNIFIT™ energy delivery laser provides immediate post-treatment thermal damage zones that are similar to that observed following traditional CO₂ laser skin resurfacing procedures in that they are comprised of ablative and thermal damage zones. However, unlike traditional CO₂ laser skin resurfacing procedures, the damage zones rapidly re-epithelialize by 3-days post-treatment with the necrotic debris expelled as a “crust” over the newly formed epidermis with a completely normal epidermis (no overlying crust) by 14-days post-treatment. The histology examination suggests that the Pixel CO₂ OMNIFIT™ handpiece is an effective and safe modality for fractional ablative skin resurfacing.

INTRODUCTION

The goal of ablative laser resurfacing is to remove sun and age-damaged skin so it can be replaced with a new layer of skin. Clinical benefit is attributed to removal of epidermal tissue and subsequent dermal remodeling.

The clinical efficacy of conventional CO₂ and Er:YAG laser devices has been shown in numerous studies published in the past decade (Fitzpatrick 1996, Khatri 1999, Ross 1999, Fitzpatrick 2000, Bronz 2001, Hallock 2001, Goldman 2001, Koch 2002, Gold 2005, Kilmer 2006). The popularity of these ablative modalities has declined because of prolonged adverse effects (Bernstein 1997, Nanni 1998). Nonablative laser procedures with fewer complications have since become available (Bjerring 2000, Ross 2000, Trelles 2001, Lupton 2002). These newer modalities improve the appearance of skin with optical energy that penetrates much deeper - without epidermal damage - than the ablative CO₂ and Er:YAG laser energies that remove the entire epidermis. Nonablative devices, however, have only limited efficacy that does not and is not likely to equal that of their ablative counterparts.



Fig. 1 Pixel CO₂ OMNIFIT™ Handpiece connected into commercially available laser CO₂ system.

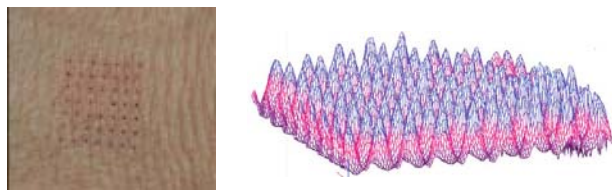
Recently, ablative fractionated laser technologies were introduced in procedural dermatology (Lapidoth 2008; Trelles 2008; Clementoni 2007). These systems overcame the limitations of both ablative and nonablative laser devices by producing arrays of

microthermal wounds at user-specified depths while sparing the tissue surrounding each wound. The result is faster healing of the epidermis and stimulation of new collagen development in the dermis.

This prospective study describes the histological effects on human skin after a single treatment with the FDA-cleared Pixel CO₂ OMNIFIT handpiece (Alma Lasers Inc., Buffalo Grove, Ill), that was fitted into an existing CO₂ laser system (UltraPulse 5000, Coherent) and which can be fitted and easily attach onto most existing CO₂ laser devices (Figure 1).

TECHNOLOGY

The Pixel CO₂ OMNIFIT Handpiece intended use is in the surgical application requiring the ablation, vaporization, and coagulation of soft tissue. The handpiece contains special (laser) fractionated lens beam technology. This special lens divides the laser beam into 7 x 7 (49) or 9 x 9 (81) small beams (pixels) that produce an array of 150-250-µm wounds (lesions) in the epidermis and dermis. The pixilated array comprised of 12.2% (0.250 x 49/100) of the treated area. The remaining 87.8% is intact. The single pixel spot diameter is 0.12 mm, the spot density is 400 micro-treatment zones/cm², and the distance between wounds was approximately 0.5 mm. Figure 2(a) shows the Pixel CO₂ OMNIFIT skin imprinting matrix with microscopic lesions/wounds. Figure 2(b) depicts 9 x 9 Gaussian shape beam profile of Pixelated CO₂ OMNIFIT laser at the focal point.



(a) Fig. 2 (b)

METHODS

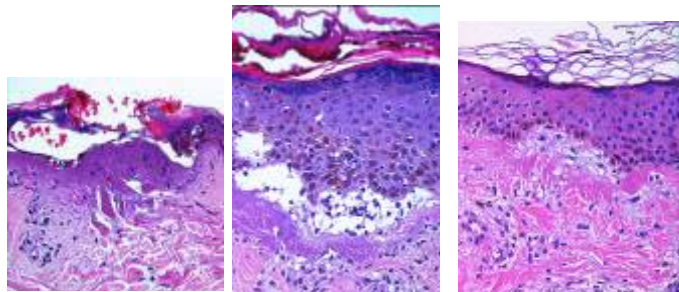
Three patients meeting the inclusion/exclusion criteria enrolled in this open-label, prospective, single-center study. Areas to be treated were prepped thoroughly and dried before treatment. Subjects received a single pass in their postauricular areas with the Pixel CO₂ OMNIFIT Handpiece. Fractionated energy was delivered in both the continuous wave and ultra-pulsed modes at 10 to 20 watts. Three 3.5-mm punch biopsy specimens (day 0) were obtained immediately after treatment from the treated areas of each subject. Additional 3.5-mm specimens were obtained 3 days and 14 days after

treatment in two subjects. Specimens were fixed in formalin solution (10%), stained (H&E), imbedded in paraffin, sliced into thin sections with a microtome, affixed to a slide, and examined by a board-certified dermatopathologist.

RESULTS

Figure 3 depicts histology (H&E) photographs at day 0 (immediately after), day 3, and day 14 post treatment using 30 Watts, 0.1 sec 1-stack. Re-epithelialization and exfoliation of necrotic debris are shown in the 3-day and 14-day specimens, respectively. In both subjects, invaginating epidermal cells replaced the vaporized cells within 48 hours and necrotic debris was exfoliated at 7 days. By day 14, replacement of the debris by normal stratum corneum was complete. The space resulting from treatment was filled by newly synthesized collagen on day 14. Three months post treatment demonstrated tissue replacement with no evidence of scar formation

Fig. 3



Day 0 Day 3 Day 14

The depth and width of the ablated area varied with the Pixel energy used and is depicted in Figure 4. The evaporative component increased gradually as the energy was increased from 40.8 mJ/P to 244 mJ/P, whereas the thermal component increased to 350 microns at 61.2 mJ/P and remained at that level as the fluence was increased to 244 mJ/P. At 244 mJ, the depth and width of the wound were equal.

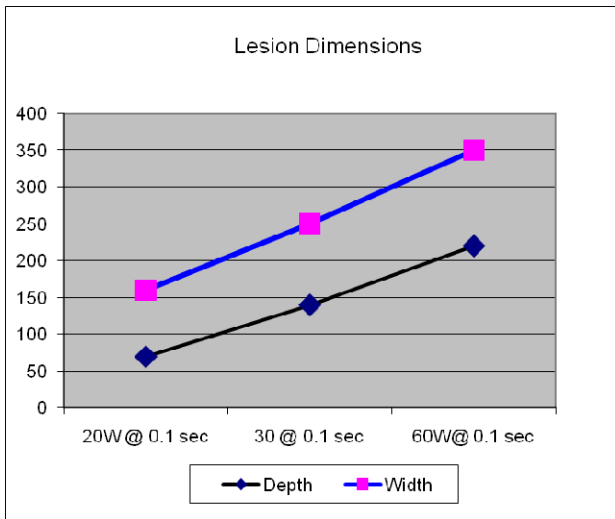


Fig. 4. The relationship between the Pixel CO₂ OMNIFIT™ energy delivered from UltraPulse 5000C, laser system (Coherent) and skin lesion dimensions (depth and width)

DISCUSSION

Successful laser surgery relies on controlling the anatomic distribution of photothermal injury; that is, controlling (1) the sites where laser will be absorbed and (2) the amount of light absorbed at those sites. Outcomes depend on the depth of injury which, in turn, depends on fluence per pass and the number of passes. For example, the traditional CO₂ and Er:YAG laser devices are the modalities of choice for skin resurfacing. Each pass of pulsed or focused energy vaporizes a thin layer of the skin surface, leaving a layer of residual thermal coagulation caused by heat conduction during the vaporization process. The thickness of the residual thermal injury is critical (Ross 1999), both for homeostasis and wound healing. After dermal wound healing, the subject's skin appears smoother and tighter as a result of heat-induced collagen shrinkage.

Unlike conventional ablative lasers, the Pixel CO₂ OMNIFIT handpiece produces wounds in which tissue ablation and coagulation are limited to only to 12.2% at 30W 0.1sec. of the target area. Since each small wound is surrounded by undamaged skin, re-epithelialization and exfoliation of necrotic tissue occur more rapidly. In addition to skin resurfacing, the Pixel CO₂ OMNIFIT handpiece has been used for the treatment of acne scars, rhytids, seborrheic and skin texture of the face, neck, chest, and hands (data on file, Alma Lasers, Inc.).

This *in vivo* human study demonstrated that this fractionated CO₂-based handpiece can achieve microscopic fractionated ablative and thermal skin injury and therefore can convert a standard CO₂ laser to a fractionated laser delivery system. The fractionated CO₂-based handpiece provides immediate post-treatment thermal damage zones that are similar to that observed following traditional CO₂ laser skin resurfacing procedures in that they are comprised of ablative and thermal damage zones. However, unlike traditional CO₂ laser skin resurfacing procedures, the damage zones rapidly re-epithelialize by 3-days post-treatment with the necrotic debris expelled as a "crust" over the newly formed epidermis with a completely normal epidermis (no overlying crust) by 14-days post-treatment. Treatment with the passive fractionated CO₂ laser handpiece leaves large areas of intact skin around each of the small injury zones in the treatment area resulting in quicker healing than with traditional laser skin resurfacing. This unique fractionated CO₂-based handpiece is simple to operate, less expensive and a valuable add-on for existing CO₂ laser armamentarium in dermatology or plastic surgery. The rapid re-epithelialization and exfoliation of the "crust" by 3-days post-treatment and normal epidermis by 14-days post-treatment is more similar to "fractional" laser treatment procedures that penetrate more deeply into the tissue

CONCLUSION

This *in vivo* study demonstrated that the Pixel CO₂ OMNIFIT™ energy delivery laser provides immediate post-treatment thermal damage zones that are similar to that observed following traditional CO₂ laser skin resurfacing procedures in that they are comprised of ablative and thermal damage zones. However, unlike traditional CO₂ laser skin resurfacing procedures, the damage zones rapidly re-epithelialize by 3-days post-treatment with the necrotic debris expelled as a "crust" over the newly formed epidermis with a completely normal epidermis (no overlying crust) by 14-days post-treatment.

The histology evidence of this study suggests that the Pixel CO₂ OMNIFIT handpiece is an affective and safe modality for fractional ablative skin resurfacing with no complications.

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