

XF Microlens™ Optic and XD Microlens™ Compression Optic for Non-Ablative Fractional Skin Treatment with the Palomar Icon™ System

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Objective:

Advantages of fractional non-ablative treatment over full-surface ablative treatment procedures include reduced side effects, downtime, and patient discomfort. We describe two novel non-ablative fractional optics that expand upon these advantages by providing faster treatment coverage and deeper coagulation depths with minimized epidermal involvement as compared to previous-generation optics.

Conclusions:

The XF Microlens™ Optic provides fast high-coverage fractional treatment with coagulation depths that extend into the reticular dermis. The XD Microlens™ utilizes compression optics to deliver microbeam energy to deep portions of the dermis and the dermal/hypodermal (D/H) junction causing coagulated micro-columns over 1 mm in depth. Clinical experiences with both devices have demonstrated dermal remodeling and good results for the indications of striae, surgical scars, and acne scars.

Introduction

Fractional methods of non-ablative skin resurfacing generate micro-columns of thermal damage in the dermis resulting in controlled wound healing with minimal side effects and recovery time. Given the favorable safety profile of this technology, efforts are ongoing to further improve the efficacy and applicability of fractional resurfacing. From the practitioner's perspective, two areas with room for improvement are the speed and depth of resurfacing treatments. Addressing the former would enable more efficient treatment of larger anatomical areas while addressing the latter would provide better clinical outcomes for indications with deep dermal involvement such as scars and striae.

The goal of faster treatments can be met by delivering more energy per laser pulse. One of the optics described here, the XF Microlens™ Optic (Palomar Medical Technologies, Inc., Burlington, MA), contains a more efficient hexagonal array with an increase in microbeams per unit area and larger microbeam diameters than previous generation optics. Currently, available fractional technologies include either scanning or stamping devices. While scanning devices are associated with faster treatments, stamping devices enable parallel, contact cooling resulting in minimal epidermal involvement and reduced pain. The XF Microlens™, with its unique microbeam array, combines speed with the advantages of skin contact cooling.

For treatment of deeper dermal conditions, the XD Microlens™ combines cooling and tissue compression to overcome limitations inherent to wavelength selection, microbeam geometry, and energy. Briefly, wavelength absorption by the target chromophore (water) should be low enough to enable sufficient penetration of the tissue, yet high enough to permit selective photothermal coagulation. Attempts to increase depth of penetration by increasing microbeam energy also increases the diameters of the micro-columns causing greater epidermal injury and increased side effects. In addition, a saturation of column depth occurs that ultimately limits the maximum achievable depth. To improve the balance between maximal penetration with minimal epidermal involvement and side effects, the XD Microlens™ uses a contact mode of non-ablative treatment that combines cooling with tissue compression.

Description of Optics

XF Microlens™

The XF Microlens™ is a new optic designed for the 1540 Fractional Handpiece (Palomar Medical Technologies, Inc., Burlington, MA) that operates using the Palomar Icon™ Pulsed Light and Laser System. The optic is used in

a stamping mode while simultaneously delivering parallel cooling to the skin via a cooled sapphire window. The sapphire window houses a micro-lens array that separates a single large diameter beam from an Er:Glass laser into 175 micro-beams (Figure 1). Specifications for the optic are outlined in Table 1.

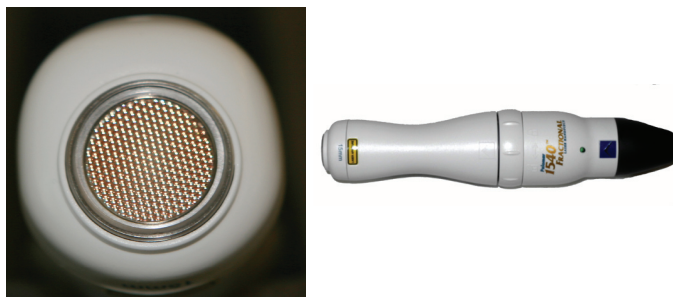


Figure 1. Palomar 1540 XF Microlens™

XD Microlens™

The XD Microlens™ attaches to the 1540 Fractional Handpiece on the Palomar Icon™ Pulsed Light and Laser System. The sapphire contact window consists of a square array with 49 micro-pins each co-aligned with a micro-beam and separated by 2 mm (Figure 2). Specifications for the optic are outlined in Table 1.

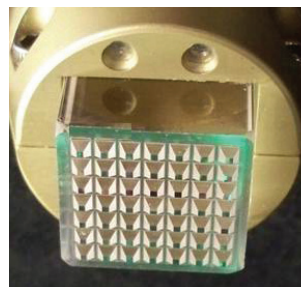


Figure 2. Palomar 1540 XD Microlens™

Table 1 lists specifications for the Palomar Icon™ System's three 1540 nm fractional non-ablative handpiece optics. The standard 15 mm tip can be used for indications where less coverage and low depth is required and/or when the risk of post-inflammatory hyperpigmentation (PIH) is elevated (e.g., in darker-skinned patients).

Specifications	1540 15mm XF Microlens™ 1 mm	1540 15mm Tip 0.6 mm	1540 XD Microlens™ 2 mm
Energy/Microbeam (Maximum)	60 mJ/mB	15 mJ/mB	70 mJ/mB
Pulsewidth(s)	10, 15 ms	10, 15 ms	15 ms
# of Microbeams	175	470	49
Microbeam Density	115 mB/cm ²	320 mB/cm ²	25 mB/cm ²
Average Column Depth of Coagulation	700 microns	550 microns	1150 microns
Average Column Width of Coagulation	260 microns	100 microns	300 microns
Percent Coverage per Pulse (Coagulation)	6%	2.5%	N/A
Approximate Treatment Time (30% Coagulation coverage 100 cm ²) 3% efficiency laser	6.5 minutes (0.8 Hz)	14 minutes (1 Hz)	(1.3 Hz)
Approximate Treatment Time (30% Coagulation coverage 100 cm ²) 2.6% efficiency laser	7.5 minutes (0.7 Hz)	16 minutes (0.85 Hz)	N/A

Table 1. Specifications for 1540 fractional handpiece optics.

Ex Vivo Histology

Material & Methods

Porcine skin was warmed to physiologic temperatures and treated either with the XF Microlens™ at 50 mJ/microbeam (mb), 15 ms or the XD Microlens™ at 70 mJ/mb, 20 ms. XF Microlens™ treatments consisted of applying the optic to the skin and firing the laser. Treatments with the XD Microlens™ were performed by applying the optic to the skin with firm pressure and firing the laser after a pre-determined compression time. Following both types of treatment, the tissue was biopsied and sectioned with a cryotome into 200 micron sections. Vertical tissue sections were stained with Nitroblue tetrazolium chloride (NBTC) and photographed to determine regions of cell viability loss. These regions were colocalized with regions of collagen coagulation (brighter regions). Horizontal sections were taken just below the epidermis and placed on a microscope slide with back lighting.

Damage Profiles

XF Microlens™

Figures 3A and 3B show the thermal injury profile in cross-sections perpendicular and parallel to the skin surface, respectively, following XF Microlens™ treatment. Viability staining (bluish-purple) of porcine dermis in Figure 3A shows a typical damage profile following treatment with the XF Microlens™ with the 1540 Fractional Handpiece at 50 mJ/mB. The unstained portion indicates the region of collagen coagulation at a depth of 687 microns and width of 297 microns. Figure 3B demonstrates that the XF Microlens™ provides 6% coverage per

laser firing. A typical treatment pass is laid out in horizontal rows and vertical columns with 50% overlap in the horizontal direction and 10% overlap (to avoid gaps) in the vertical direction. This means that the skin is treated twice in a single pass for approximately 12% coverage.

XD Microlens™

Figure 4 depicts a cross-section of tissue following 2 seconds of compression using the 1540 nm fractional handpiece with the XD Microlens™. The unstained, bright white region indicates the zone of coagulation. Compared to using the same handpiece and optic without compression, applying compression resulted in a nearly 50% increase in column depth and a simultaneous decrease in the diameter of the micro-column damage at the dermal/epidermal (D/E) junction. In addition, there was less separation of the D/E junction indicating less epidermal damage.

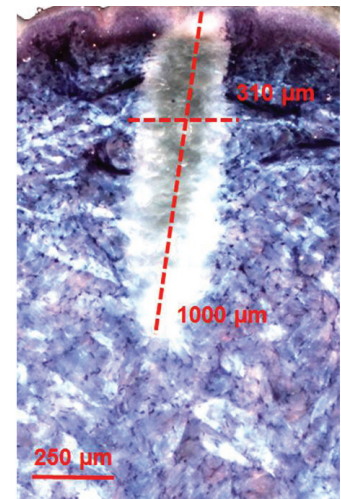


Figure 4. Histology showing typical damage profiles following treatment with the 1540 nm fractional handpiece with the XD Microlens™ using 2 seconds of compression at 70 mJ/mB.

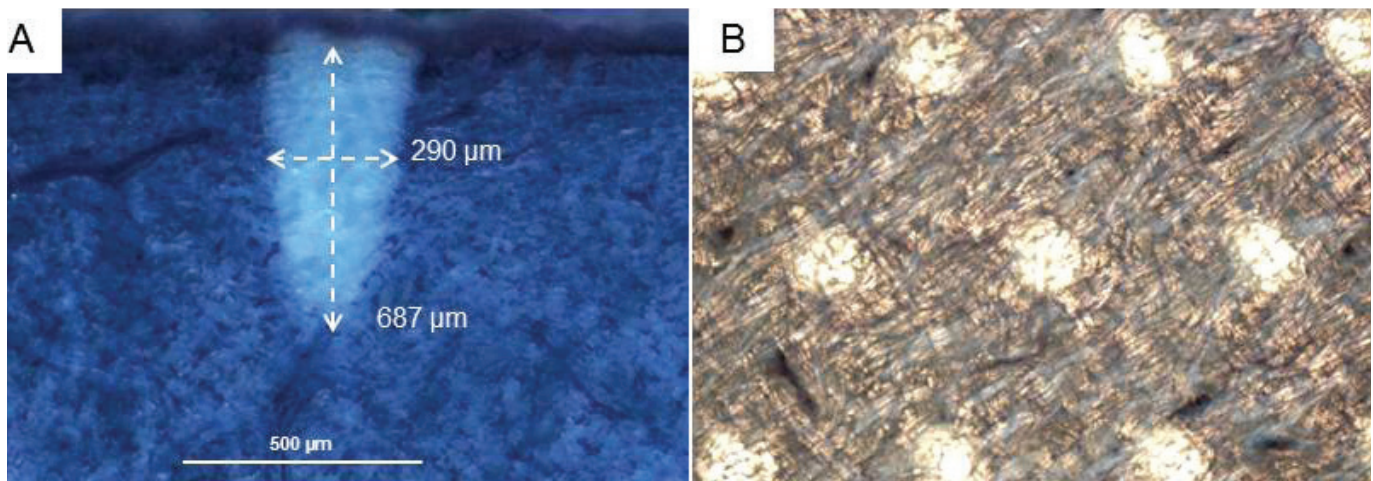


Figure 3. A) Histology showing typical damage profiles following treatment with the 1540 nm handpiece at 50 mJ/mB with the XF Microlens™. B) Typical damage profiles in a layer of dermis 200 microns thick located 200 microns beneath the epidermis. The image is back-illuminated such that bright regions represent regions of coagulated collagen caused by penetration of the micro-beams. The spacing between micro-beams is 1 mm and the coverage is approximately 6%. Treatment parameters were 50 mJ/mB at 15 ms.

Clinical Evaluations

Preliminary clinical evaluations for each optic were performed to assess how well they met their respective objectives of faster treatment (XF Microlens™) and deeper penetration with minimal epidermal involvement (XD Microlens™).

XF Microlens™

The speed of treatment is determined by the desired coverage of treatment, the area to be treated and the optic's coverage rate. For fractional treatments, coverage is defined as the surface area of treatment-damaged (coagulated collagen) skin to total area. Table 2 summarizes the treatment time for the clinical indications of striae and surgical scars. Compared to the prior optic's lower coverage of 2.5% per pulse and longer treatment time (see Table 1), this new optic offers key advantages for treating larger anatomical areas.

Indication	Total Coverage	# of Passes	Energy (coverage)	Overlap	Treatment Time (Size of Target Area)
Striae	10-20%	1-2	40 mJ (5%)	50:10	16 – 32 minutes for 1-2 passes (1000 cm ²)
Surgical scars	24-36%	2-3	50 mJ (6%)	50:10	14 – 21 minutes for 2-3 passes (300 cm ²)

Table 2. Approximate treatment times for striae and surgical scars using the XF Microlens™.

XD Microlens™

Histology shown in Figure 4 demonstrates the increased depth of penetration available with the XD Microlens™; however these depths must be carefully balanced against the optic's safety profile for realistic application. We investigated the relationship between compression time and the diameter of epidermal micro-injury zones to determine whether increased penetration resulted in increased epidermal injury zones.

Figure 5 shows the appearance of the skin following application of the XD Microlens™ using firm pressure.

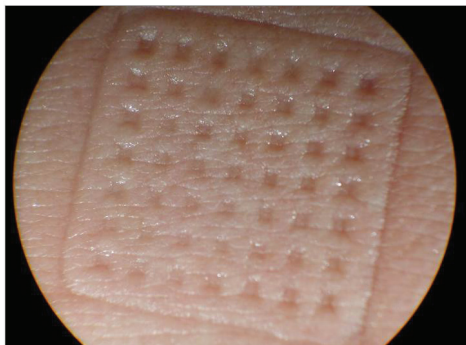


Figure 5. Human forearm skin showing impression of the XD Microlens™.

Figure 6 shows the appearance of the epidermal micro-injury zones generated following treatment of the volar forearm in a Fitzpatrick Skin Type III subject. Three single pulses from the XD Microlens™ were delivered at 70 mJ/mb using 0, 2, or 5 seconds of firm compression. Two days after treatment, the treated sites were photographed to measure the size of the epidermal micro-injury zones coincident with the micro-columns. These darkened zones, previously defined as micro-necrotic debris (MENDs), were also seen in histology at this time point and were defined by a contiguous basal cell layer above which lies necrotic cellular debris and pigment presumed to be melanin or oxidized by-products. The epidermal injury zones were co-aligned with the underlying coagulated micro-columns in the papillary dermis. The effects of compression time on the diameter of the epidermal zones are shown in Figure 7. As compression time was increased from no compression time to 2 and 5 seconds, there was a 15% and 20% reduction, respectively, in the epidermal area involvement.

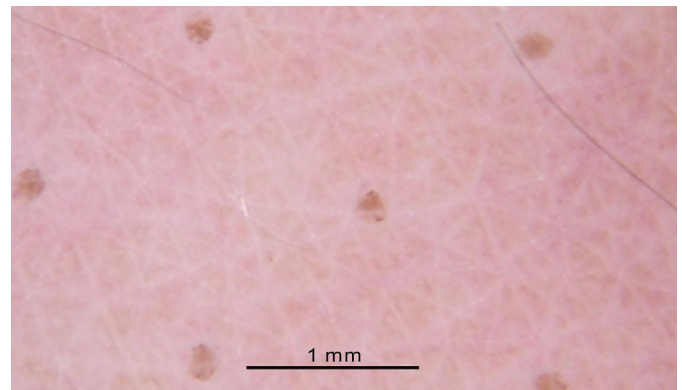


Figure 6. Epidermal micro-zones following treatment with the 1540 nm fractional handpiece and XD Microlens™.

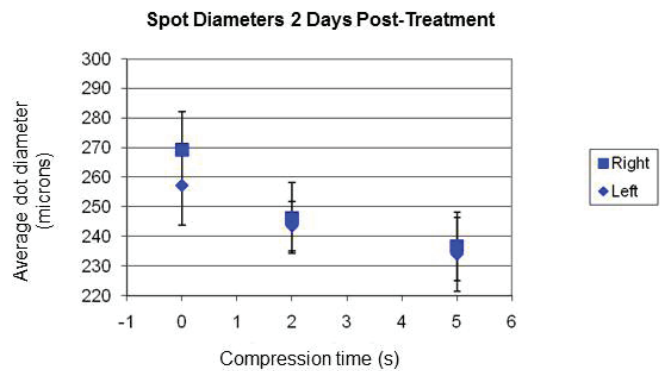


Figure 7. Differences in the diameters of the epidermal injury zone following various compression times. A 10% reduction in spot diameter translates to a 20% decrease in area of epidermal injury. Errors bars indicate \pm standard deviation.

Conclusion

Histology and preliminary clinical evaluations demonstrate the efficacy of the new XF Microlens™ and the XD Microlens™ in meeting the respective objectives of faster treatment coverage and deeper penetration with minimized epidermal involvement. The XF Microlens™ enables 6% treatment coverage per laser firing, with depths of coagulation of up to 700 microns in a single pulse. The fractional non-ablative XD Microlens™ delivers deeper penetration, up to 1.1 mm in a single pulse, and reduced involvement at the dermal/epidermal junction. Together, these optics provide flexibility for practitioners desiring fast treatment coverage, treatment of deeper indications such as surgical scars, acne scars, and striae and tailoring of treatment across a wide range of skin types.