

Clinical Summary

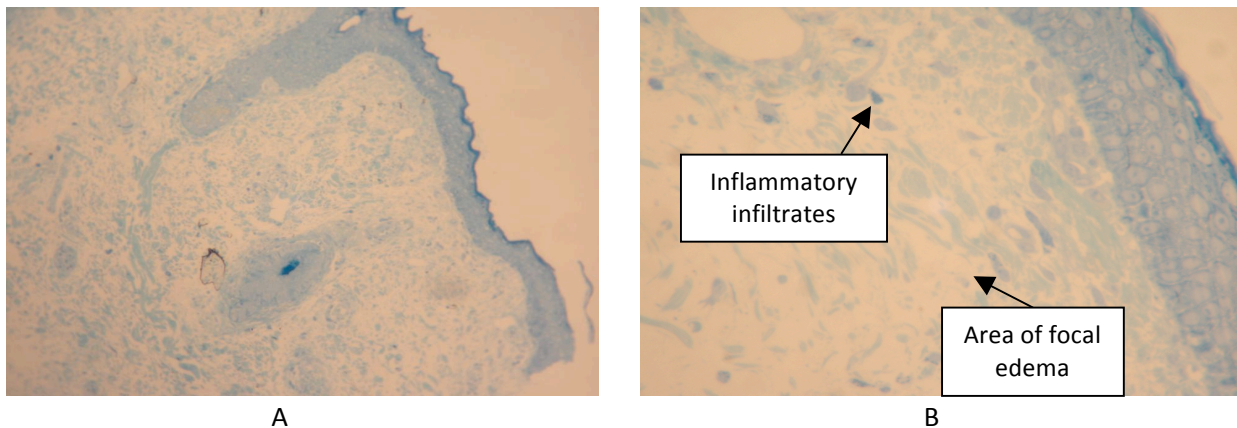
Histopathological Analysis of Tissue Before and After Pellevé Treatment

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As part of a study assessing the improvement in periorbital rhytides and midface laxity with the Pellevé™ Wrinkle Reduction System (Ellman® International, Oceanside, NY), 2 volunteer patients had their right upper eyelid treated with Pellevé while leaving the left upper eyelid untreated (control)¹. Each patient received two Pellevé treatments spaced seven weeks apart with biopsy specimens taken one week after the second treatment. Histopathologic analysis of the biopsy specimens from the treated and control eyelids was performed utilizing both Transmission Electron Microscopy (TEM) and Light Microscopy (LM).

As depicted in Figure 1, the comparison between the untreated control and the treated specimens under light microscopy demonstrates a change with dermal cellular infiltration and edema in the treated specimen. This is reflective of the desired inflammatory response that facilitates collagen formation and remodeling of tissue.

Figure 1

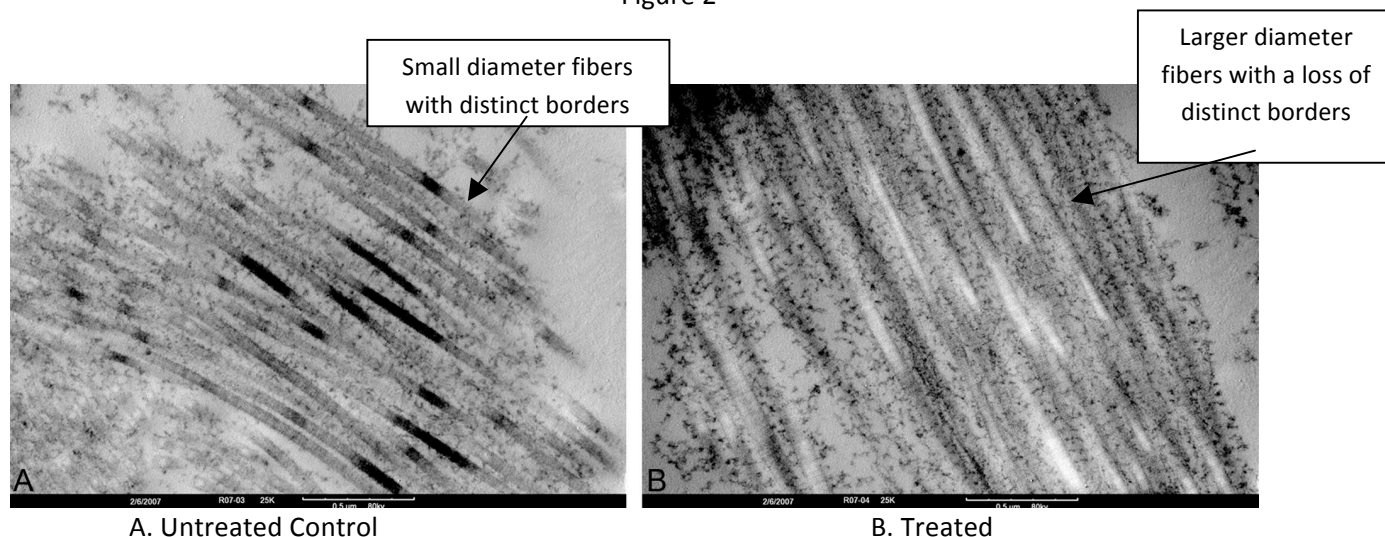


A. Untreated Control - Section of the skin illustrated using light microscopy shows a typically normal pattern.

B. Treated - Epidermis and dermis shows focal edema and inflammatory infiltrates in the deeper dermis. The inflammatory infiltrates found in the treated specimen indicate a wound healing response from thermal injury to the dermis which leads to an increase in collagen production.

Analysis by transmission electron microscopy of the 2 untreated control and 2 treated skin biopsy samples revealed collagen remodeling in the treated specimens as a result of radiofrequency generated heat delivered to the tissue. This collagen formation was most likely from the initial Pelleve treatment 8 weeks prior as the process occurs over a period of time.

Figure 2



Transmission electron microscopy (25,000x) shows scattered diffuse changes in collagen fibril architecture with a shift from smaller diameter collagen fibers in the untreated samples (A) to larger diameter and a loss of distinct borders fibers in the treated samples (B) compared with normal fibrils. This is consistent with the collagen denaturation described by Zelickson, et al² following skin tightening with a radiofrequency dermal remodeling device. This denaturation of collagen following radiofrequency treatment is what would be expected one week following treatment.

1. Javate, R, Cruz, R. Khan, J., Trakos, N., Gordon, R. Nonablative 4-MHz Dual Radiofrequency Wand Rejuvenation Treatment for Periorbital Rhytides and Midface Laxity, *Ophthal Plast Reconstr Surg*, Vol. 0, No. 0, 2011
2. Zelickson, B, Kist D., et al. Histological and Ultrastructural Evaluation of the Effects of a Radiofrequency-Based Nonablative Dermal Remodeling Device, *Archives of Dermatology*, Vol. 140, Feb. 2004