



Safety Evaluation and Clinical Testing of an Extended Life Lens Array for Picosecond Laser on The Abdomen, Back, and Thighs

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BACKGROUND

- Picosecond lasers are effective in treating various indications, including pigmented lesions, tattoo removal and facial revitalization.
- Rejuvenation is commonly treated with specialized lens arrays that allow for energy to be focused into smaller beams which deliver higher density energy.
- This study evaluates the safety of an updated version of the lens array that delivers more pulses than the traditional lens arrays.

METHODS

- 14 subjects (FST I-IV) were enrolled and treated with a picosecond laser and three lenses on either the back, abdomen, or thigh.
- Each of the three lenses were used during treatment until they reached a total of 80,000 pulses. Lenses were then brought to an engineering lab to confirm they were working as intended. Once confirmed, the remaining 112,000 total pulses were used.
- Photographic evaluation, pain rating and adverse events were assessed.

RESULTS

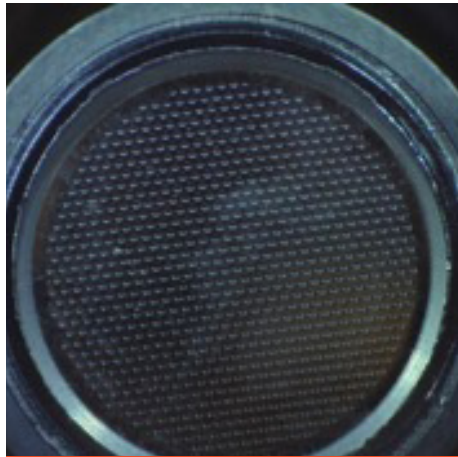
- 25 treatment sessions were performed: a total of 91 different treatment areas.
- Subjects found the treatments to be comfortable with an average pain score of 2/10.
- The most common adverse events were edema and erythema, which are typical with picosecond lasers.
- There was no difference in the lens array performance at any evaluation point.

CONCLUSION

- Extended use of a diffractive lens array showed no changes in the optical output and thus increasing the shot count of the lens from 80,000 to 112,000 pulses did not sacrifice the safety of the lens.



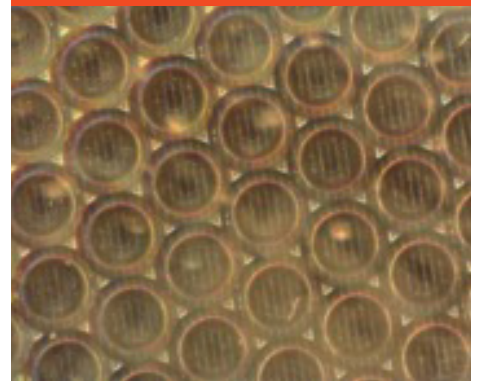
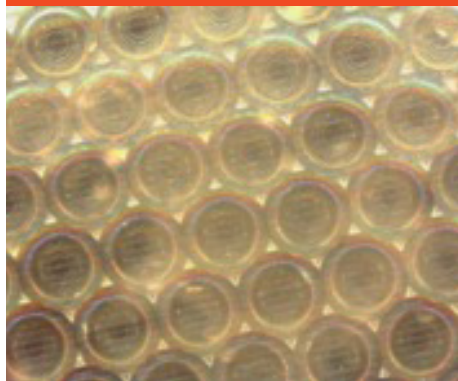
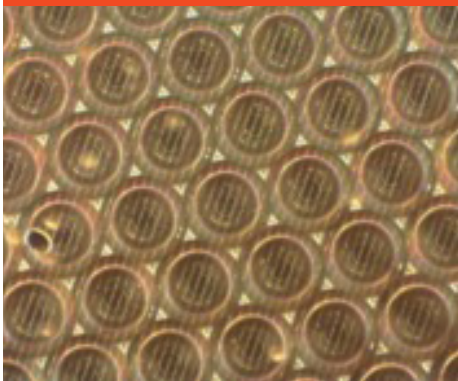
0 Pulses Delivered



80k Pulses Delivered



112k Pulses Delivered



The change in image brightness for 80K shots is due to debris from the patient treatments and following cleaning process on the array after usage which is expected. The debris did not significantly impact throughput of the optical system nor the energy in the 100 micron spot and thus the effectiveness of the lens was not affected by the standard use and cleaning procedures.

