CYNOSURE

Multi-Phase Study for the Validation and Usability of a Novel Radiofrequency Device

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Study Design:

- Phase 1- Animal tissue was used to perform a comparison of the thermally affected zones (TAZ) between the novel RF device and the predicate RF device at different power settings.
- Phase 2- two subjects were treated, and temperature readings from both the device and a thermal camera were compared to ensure accurate temperature sensing capabilities. 10 subjects were treated with the two different devices and the adverse event profile was compared.
- Phase 3- Two Abdominoplasty patients were treated to study the effects of the RF device both in-vivo and ex-vivo post excision.

Evaluation:

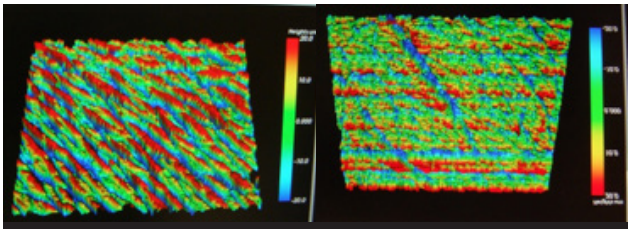
- P Advanced photography was taken at each treatment and follow-up visit in order to grade clinical usability and safety.
- **Optical Coherence Tomography (OCT)**
- A immediate post Tx OCT image was taken of the treated tissue after being treated with the 10mm probe, 30 minutes. Compared to baseline OCT, it showed:
    1) increased blood flow
    2) smoother surface contour

Results:

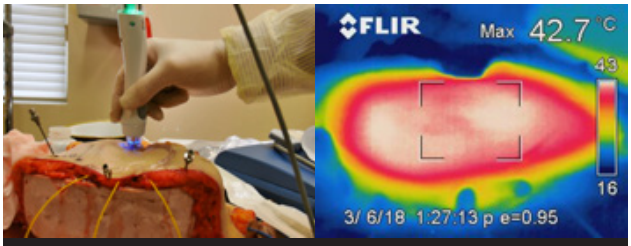
- Across the three types of animal tissue, the affected tissue was considered substantially equivalent for both devices and it was observed that the TAZ overlapped in each of the tissue areas with at least 2 of the 3 power settings.
- Across eighteen treatments performed on two subjects, the average temperature difference between the device and the thermal camera was within ± 1.5°C.
- Adverse events in the 10 subjects assessed were minimal and included erythema and edema lasting an hour on average.

Conclusion:

- This novel RF device for heating tissue has been shown to be equivalent to a previously approved electrosurgical device in terms of affected tissue.
- It was proven to be capable of reporting accurate tissue temperature readings providing safety and comfort during treatment.



Before & Immediately Post Treatment



TempSure RF exposures to *ex-vivo* abdominoplasty tissue using embedded temperature sensors at various depths - 10mm probe, energy = 45, temp setting = 42° C

Before & After 3 Months, 2 Treatments