Multi-Center Study for the Safety and Efficacy of Facial Procedures Using a Radiofrequency Device with Temperature Regulation

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Study Design:
• 25 subjects (Fitzpatrick skin type II-IV) with facial wrinkles and rhytides enrolled.
• 3-5 full face treatments 2 or 4 weeks apart.
• Individual zones were treated (forehead, periocular, upper cheek, lower cheek) using either a 20mm, 15mm or 10mm optics.
• The initial target temperature was set to 39° C and increased throughout the treatment.

Evaluation:
• High resolution 2D photographs were taken prior to each treatment and 30, 60 and 90 days post last treatment.
• Parameters recorded were; energy dosage, temperature, pain, and time.
• Subjects were assessed for adverse events immediately post treatment and 1 week post treatment.a continuous number of passes, creating a bulk heat which helps to resolve many skin problems.

Results:
• The target temperature of 43° C was achieved through multiple passes.
• Average pain score was 2.0/10 across all treatment zones.
• The infraorbital area and lower cheek area proved to be the most sensitive.
• All subjects were satisfied with their treatments. Subject noted their skin felt smooth, soft and firm.
• Only side effect was post procedural edema and erythema lasting less than 2 hours.

Conclusion:
• This new RF device with temperature regulation and an integrated thermistor tip visually improved wrinkles and rhytides determined through photographic analysis and subject evaluation by achieving and maintaining target temperature for neocollagenesis (42-43° C) with high patient tolerability and minimal downtime in both 2 and 4 week interval patients.