Evaluation of the Safety and Efficacy of Ultherapy® for the Treatment of Signs and Symptoms of Erythematotelangiectatic Rosacea

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BACKGROUND AND OBJECTIVE

- It is hypothesized that creation of focal lesions in the dermis and sub-dermis may affect the symptoms of erythematotelangiectatic rosacea by inducing coagulation in superficial blood vessels and reducing blood flow in the skin

METHODS

- The study enrolled 88 subjects (79 female and 9 male) with a mean age of 49.8 (range, 21-65 years). Fitzpatrick Skin Types were I (5.7%, II (40.9%) and III (53.4%).
- Pre-treatment medication was limited to 800mg Ibuprofen taken at least 60 minutes prior to treatment.
- Treatment groups are summarized in **Table 1**.
- Assessments (baseline & follow-up visits):
  - Standardized photographs
  - 5-point Clinical Erythema Assessment (CEA) Scale
  - Colorimeter assessment
- **Figures 1-3** illustrate the treatment maps used for each transducer depth and density.

Table 1. Treatment groups. All subjects were to receive 2 treatments.

Group	Subjects, n	Treatments, n	Treatment Density
A	20	1	Low (15 lines/square)
B*	22	2	Low (15 lines/square)
C	24	1	High (30 lines/square)
D*	22	2	High (30 lines/square)

**Due to a treatment protocol modification, only subjects in Groups B & D recieved 2 treatments (14 +/- 4 days apart).

Figure 1. Treatment map for 4 MHz/4.5 mm transducer.

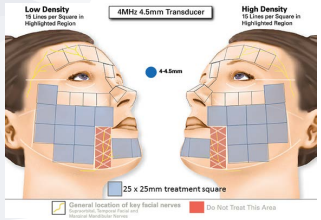


Figure 2. Treatment map for 7 MHz/3.0 mm transducer.

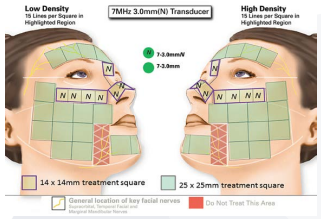
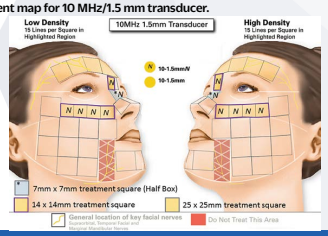


Figure 3. Treatment map for 10 MHz/1.5 mm transducer.



RESULTS

Figure 4. Treatment Success Based on CEA Scores. CEA improvement (≥1-grade improvement) was greatest in Group C at Day 90 (91%) and at Day 365 (96%), Group A at Day 180 (95%).

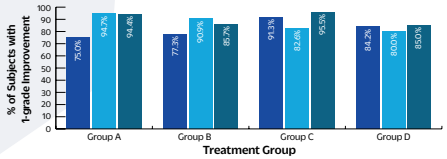


Figure 5. Treatment Success Based on PSA Scores. PSA improvement (≥1-grade improvement) was greatest in Group D at Day 90 (74%), Group D at Day 180 (75%), and Group B at Day 365 (76%).

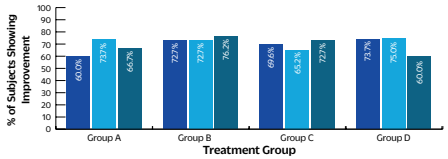


Table 1. Adverse Events. No serious adverse events were reported.

Adverse Event	# Subjects		Average Duration of Resolved AEs (Days)
	N=88	(%)	
Bruising	39	44%	10.2
Soreness/Tenderness	38	43%	12.9
Parasthesia (numbness)	9	10%	12.5
Raised Area of Edema/Welts	15	17%	9.0
Erythema (redness)	33	35%	4.8
Other (oily skin, worsening of rosacea, aphthous ulcer)	4	4.5%	2.0/31.0/10

Figure 6. Improved Colorimeter Readings. Colorimeter improvement (reduction in red-green spectrum vs baseline only) was greatest in Group A at Day 90 (75%), Group A at Day 180 (74%), and Group C at Day 365 (86%).

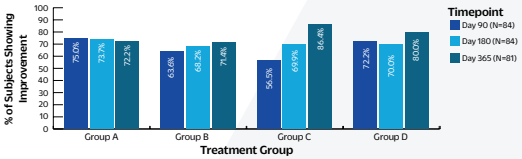


Figure 7: Mean Pain Scores, First Treatment. Mean pain scores were generally consistent between treatment groups; for subjects in Group B &D, the second treatment pain scores were similar to the first treatment.

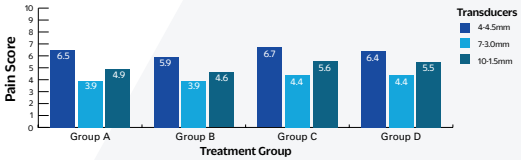


Figure 8. Sample Patient Before (Left) and At Day 90 (Right)

CONCLUSIONS

- **Results suggest Ultherapy may be efficacious for treatment of signs and symptoms of erythematotelangiectatic rosacea.**
- **Study data suggest that high density Ultherapy treatment is superior to low density treatments or to superficial treatments.**

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