BACKGROUND AND OBJECTIVE

- Cellulite refers to the dimpled appearance of skin which is estimated to affect approximately 95% of post-pubertal women of all races
- The appearance of cellulite has been associated with significant social stigma and can adversely affect self-esteem
- Tissue stabilized-guided subcision (TS-GS, Cellfina® System, Ulthera, Inc.) builds on the proven approach of dermal undermining, or subcision; the system is designed to provide vacuum-assisted control of both the depth and area of tissue release to allow for precise, reproducible and consistently effective treatment results (Figure 1)

REGISTRY DESIGN

- Prospective, multi-center, non-randomized, standard of care, observational registry study
- 53 female subjects were enrolled at 8 sites and treated using a TS-GS device by investigator or sub-investigator according to the sites’ standard of care

Registries Endpoints and Analyses

- Primary: Subject-observed Global Aesthetic Improvement Score (GAIS) at day 180
- Secondary:
  - Physician Global Aesthetic Improvement Score (GAIS) at Day 180 post-treatment
  - Quality of life questionnaire at the treatment visit, 30, 90, and 180 day follow-up visits
determine effect of cellulite on clothing (0=no effects at all; 10=very much affects)
- Subjects were asked to rate their level of pain from 0 -10 (0 = no pain and 10 = worst possible pain)

31 Treatment details.

- The most frequently used concomitant medication was dicloxacillin; however 16% of patients received no additional medications at the time of the procedure
- Average time for anesthesia delivery: 25 minutes
- Pain rated on average as a 4/10
- Average time for vacuum release: 21 minutes
- Pain rated on average as a 1.7/10

CONCLUSIONS

- Information gathered within the registry aligns with the pivotal study conducted previously
- All patients experienced mild to moderate treatment effects, but no further treatment was required for any patient
- Quantitative image analysis directly supports the subject- and physician assessed efficacy data by demonstrating objective improvements in dimple depth and volume
- Results indicate this FDA-cleared long-lasting cellulite treatment that takes an average of under one hour is safe and effective in real-life clinical practice