An Observational Study of the Safety and Efficacy of Tissue Stabilized-Guided Subcision to Improve the Appearance of Cellulite

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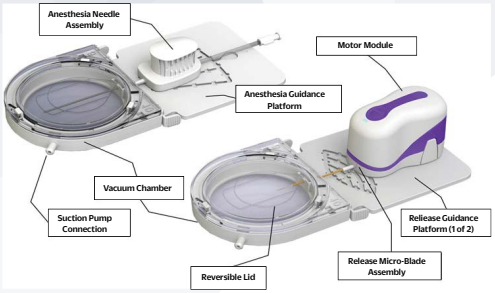
BACKGROUND AND OBJECTIVE

- 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(R) 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**)[1]

Figure 1. TS-GS schematic[1]



- TS-GS is FDA cleared for the long-term improvement in the appearance of cellulite on the buttocks and thighs, with no loss of benefit for up to 3 years (**Tables 1 and 2**)[1-3]
- The purpose of this observational study was to collect data on TS-GS treatment administration, safety, and effectiveness in real-life clinical practice

Table 1. Pivotal Trial Efficacy. The mean improvement on the Cellulite Severity Scale remained constant through 3 years of follow-up.

Primary Endpoint	3M	1 Year	2 Year	3 Year
Average Improvement (0-5 scale)	2.1 points	2.0 points	2.0 points	2.0 points
% of ≥ 1 grade improvement (none, mild, moderate, severe)	93%	94%	88.5%	91%

Table 2. Pivotal Trial Subject Satisfaction. Most subjects (≥93%) remained satisfied or very satisfied with the results of their treatment through 3-years.

Satisfaction	Baseline (N=55)	3D (n=55)	14D (n=54)	1M (n=54)	3M (n=55)	6M (n=52)	1Y (n=50)	2Y (n=54)	3Y (n=45)
Very Unsatisfied	28	1	0	0	0	0	0	0	0
Unsatisfied	27	10	1	2	1	2	0	0	0
Neutral	0	22	16	9	7	4	3	2	3
Satisfied	0	18	25	29	26	25	24	26	23
Very Satisfied	0	4	12	14	21	21	23	24	19
% Satisfied	0%	33%	69%	80%	85%	88%	94%	96%	93%

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

Registry Endpoints and Analyses

- Primary:
  - Subject-assessed 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 to determine effect of celllulite 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)
- Adverse events and expected treatment effects (effects more than moderate in severity were considered adverse events)

REGISTRY RESULTS

Table 3. Patient demographics

Characteristic	Subjects (N=53)
Mean age, y (range)	44.1 (23-61)
Mean baseline BMI (range)	22.3 (17.4-28.6)
Fitzpatrick skin type, n (%)	
I	0 (0)
II	18 (33.9)
III	23 (43.4)
IV	10 (18.8)
V	0 (0)
VI	2 (3.8)
Ethnicity, n (%)	
Caucasian	48 (90.5)
Aafrican American/Black	1 (1.9)
Hispanic/Latino	0 (0)
Asian	1 (1.9)
Native American/ Alaskan Native	3 (5.7)

Treatment Details

- The most frequently used concomitant medication was dicloxicillin; however 38% 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 4.5/10.
- Average time for vacuum release: 21 minutes
  - Pain rated on average as a 1.7/10

Clinician and Subject GAIS at Day 180

Figure 2. Subject and Physician GAIS Scores at 180 days. Mean physician rating was 2.05, corresponding to "Much Improved."

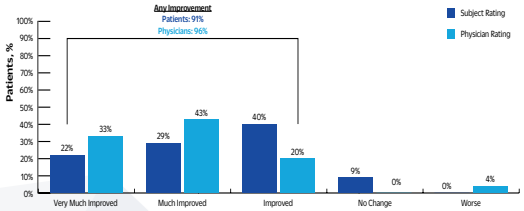


Table 4. Treatment areas. Most patients were treated on both the thighs and buttocks.

	Subjects, n (%)	Average # of sites treated
Both	43 (81.1%)	11.9
Buttocks	7 (13.2%)	16.4
Thighs	3 (5.7%)	20.6

Table 5. Treatment depth. The majority of releases were performed at the 6 mm depth.

	6mm	10mm	Both
Buttocks (n=50)	30 (60%)	0 (0%)	20 (40%)
Thighs (n=46)	41 (89.1%)	1 (2.2%)	4 (8.7%)

Adverse Events and Expected Treatment Side Effects

- All subjects experienced some mild treatment effects, but no further treatment was required for any subject.
- The majority of procedure-related adverse events resolved by 90 days
- The most common effects were petechiae, bleeding and blanching, red spots from needle punctures, and fluid accumulation
- Mild to moderate
- Only 1 adverse event (induration) was reported
- There were no serious adverse events reported

3D ANALYSIS

Single Site Analyses

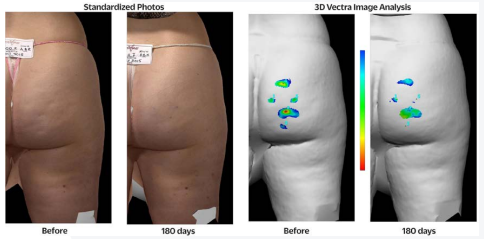
- One of the registry sites conducted additional pilot analyses of efficacy including:
  - 3D Vectra imaging of the treatment areas to quantitatively assess changes in dimple depth and volume
  - Blinded investigator assessment of 2D photography
- A total of 13 patients at this site were included in the 3D image analyses and the blinded investigator assessment of 2D photography

3D ANALYSIS RESULTS

Single Site Analysis: 3D Analysis of Dimple Depth and Volume

- 145 dimples treated with TS-GS in 13 subjects; 3D Vectra image analyses were conducted using standardized photos
- Mean improvement in volume was 67.4%
- Mean improvement in height of the dimple was 58.4%

Figure 3. Example Before & After Photos from 3D Image Analysis. Show Quantitative Improvements in Dimple Depth and Volume at 180 Days



Single Site Analysis: Blinded Physician Assessment of Improvement

- At 180 days, the majority of patients, the majority of patients were rated >50% improved by blinded physicians (both dimple depth and overall improvement; **Table 7**)

Table 7. Blinded physician assessment at 180 days. The majority of patients were rated >50% improved in terms of dimple depth and overall improvement.

Degree of Improvement	Improvement Overall, n (%) (N=13)	Improvement in Dimple Depth, n (%) (N=13)
4 (76-100%)	4 (30.8%)	4 (30.8%)
3 (51-75%)	4 (30.8%)	5 (38.4%)
2 (26-50%)	5 (38.4%)	4 (30.8%)
1 (0-25%)	–	–
Mean	2.8	2.9

CONCLUSIONS

- **Information gathered within the registry aligns with the pivotal study conducted previously[2,3]**
- **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**
- **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**

References: 1. Cellfina System [instructions for use]. Mesa, AZ: Ulthera, Inc.; 2016; 2. Kaminer MS, et al. *Dermatol Surg.* 2015;41(3):336-347; 3. Kaminer MS, et al. *Dermatol Surg.* 2017;43(10):1249-1262.

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