



RESEARCH ARTICLE

A REVOLUTIONARY MINI-INVASIVE TREATMENT FOR CELLULITE BLEMISHES:
15 MONTHS OF INITIAL EXPERIENCE

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ABSTRACT

Introduction: In October 2016 I started, as one of the first in Europe, my experience with a new procedure that represents the only FDA-cleared minimally invasive treatment clinically proven to improve the cellulite blemishes for nearly four years in only one session.

Materials and Methods: We report our experience after 15 months in 50 patients (48F; 2M) with cellulite treated in a single session. Follow-up were scheduled after 7 days (T7), 14 days (T14), 30 days (T30), 90 days (T90) and 180 days (T150) for all the 50 patients; 13 patients (1M) had a medical check at 12 months and 3 patients (1M) at 15 months. Outcome measures included subject photographs, Cellulite Severity Scale (CSS) and Global Aesthetic Improvement Scale (GAIS) assessment. Patient satisfaction and pain rating were also recorded. The treatment takes 45-60 minutes. Cellulite dimples are marked and the device is applied to stretch and stabilize tissue in a vacuum chamber, while local anesthesia is delivered. Then, a precise minimally-invasive subcutaneous release of the connective bands (TS-GS: stabilized-guided subcision) is performed with a micro-blade, without cuts or incisions. We have safely treated 6 to 45 sites in one session. After treatment, a light compression is applied and patients are able to return promptly to their daily life.

Results: The procedure treated successfully the primary structural cause of cellulite blemishes in all the 50 patients. Patient satisfaction was 87% at T90 in 50 patients (48F; 2M), 95% at T180 in 50 patients, 97% at 12 months in 13 patients (1M) and 100% at 15 months in 3 patients (1M). Transient treatment-related adverse events were mild in severity and the most common side effects reported were soreness and bruising. Among 50 patients, 95% had bruising at T7, 23% at T14 and no patient had bruising at T30. Soreness is reported in 100% of patients at T7, 19% at T14, 4% at T30 and 0% at T90. Global Aesthetic Improvement Scale (GAIS) and Visual Analog Scale (VAS) are also reported.

Conclusions: This revolutionary FDA-cleared procedure for the cellulite puckering, combines a proven approach with an innovative technology to treat the primary structural cause of cellulite blemishes in posterior thighs and buttocks. This study confirms his safety, and efficacy with vacuum-assisted precise tissue release for the treatment of cellulite, which is also strengthened by patients satisfaction.

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INTRODUCTION

I've been one of the first physician selected in Italy from Merz Italia in October 2016 and one of the first in Europe to offer Cellfina (Ulthera, Inc, Mesa, Arizona) for the treatment of cellulite (Dell'Avanzato, 2016; 2017). Cellfina represent the only FDA-cleared minimally invasive treatment clinically proven to improve the cellulite blemishes in posterior thighs and buttocks for nearly four years in only one session (Kaminer, 2015; Green, 2015; Kaminer, 2016; Kaminer 2014; Christman, 2017). Cellulite refers to the dimpled appearance of

skin, which is estimated to affect approximately 85% of post-pubertal women of all races (Kaminer, 2015; Sainio, 2000; <https://www.census.gov/programs-surveys/international-programs.html>). This means that 1.4 billion of female worldwide have cellulite (Avram, 2004) and 80% of them (1.1 billion) are concerned with their cellulite; 98% of them are motivated to do something; therefore, over 1 billion women worldwide who have cellulite want to do something (Harris Poll, 2015). The appearance of cellulite has been associated with behavioral changes and can negatively affect self-esteem (Hexel, 2010). Although the etiology of cellulite is not completely understood, the anatomical structures associated with cellulite have been studied: fibrous septa connect the skin to underlying tissue at select points, are oriented perpendicular to the skin surface and pull down on the dermis and this results

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in dimpled, bumpy skin (Green, 2015; Omi 2013). In a previous study, results of the MRI analysis showed that cellulite depressions on the buttocks were significantly associated with the presence of underlying fibrous septa; fibrous septa were visualized in 96.7% of the area with cellulite depressions and all the fibrous septa found in the examined areas were perpendicular to the skin surface (Hexel, 2009). Current treatments for cellulite include non-invasive procedures that generally target the fat cells instead of the septa. Treatments directed specifically at the fibrous septa includes subcision (Orentreich, 1995; Alam 2005; Hexsel, 2000; Hexsel, 2010) laser liposuction (Dell'Avanzato, 2016; Dell'Avanzato, 2017; Toledo, 1991) and other laser treatments where the most effective procedure is represented by Endolift (Dell'Avanzato technique) (Dell'Avanzato, 2017) performed with a 200-300 micron fiber connected to a 1470nm diode laser instead of the application of a 1440-nm Nd:YAG laser cannula (DiBernardo, 2013) too aggressive in comparison with the Endolift procedure. Subcision, a tissue release technique, has been utilized for many years with discontinuous results worldwide (Hexsel, 2000; Hexsel, 2010; Orentreich, 1995). Cellfina has refined subcision with both depth and area control providing reproducible, safe and certified results with little downtime due to an external system with excellent safety profile and effectiveness, that allows to complete the procedure in a medical setting, in local anesthesia. The optimal candidate is a patient in the 20/50 year range classified with mild or moderate cellulite dimples at rest and in dynamic, with mild skin laxity at rest, with stable weight. Although cellulite is uncommon in men, we have successfully treated two male patient with the Cellfina procedure.

MATERIALS AND METHODS

We report our experience after 15 months in 50 patients (48F; 2M) between 18 to 71 year range (mean 37.3), with body mass index (BMI) <35 (mean 23.7). Ethnicity was the following: 34 white, 10 black (1M), 4 asian, 2 hispanic (1M). Patients were divided in 6 classes according to the Fitzpatrick skin type: class I and II (13), class III (26), class IV (9), class V and VI (2M). Regarding the two male patient treated, the first was a 45 years-old male with a gonadotropin-releasing hormone deficiency and low testosterone levels; the second was a 34 years-old male with BMI <35. All the patients received a single session of treatment. Outcome measures included patient photographs with an appropriate overhead lighting to accentuate contour irregularities, control of the weight, Cellulite Severity Scale (CSS) and Global Aesthetic Improvement Scale assessment. Patient satisfaction and pain rating were also recorded. None of the 50 patients change the weight by more than 10%, otherwise they would be excluded from the present study. Follow-up assessments were scheduled after 7 days (T7), 14 days (T14), 30 days (T30), 90 days (T90) and 180 days (T150) for all the 50 patients; 13 patients (1M) had a medical check at 12 months and 3 patients (1M) at 15 months. The treatment takes between 45 to 60 minutes. The procedure starts marking the cellulite while standing, with a pre-marked photos printed in my hand. It's always better that the patient has seen the marked photos in order to be able to understand and confirm the plan. Once the patient is in a prone position, we disinfect the skin with a solution not to remove the preoperative markings. Following the marking, the device is applied to stretch and stabilize the tissue in a vacuum chamber, than the anesthetic solution is infiltrated using the Cellfina System's 22-gauge multi-hole needle at a depth of 6

mm or 10 mm. Once all the areas have been infiltrated with anesthesia, a precise minimally-invasive subcutaneous release of the connective bands (TS-GS: stabilized-guided subcision) is performed with a micro-blade, without cuts or incisions, to release the tissue underneath the marked areas. We have safely treated 6 to 45 sites in one session with a range of 15-30 sites in 73% of cases, 6-14 sites in 20% and 31-45 in 7%. After treatment, a light compression is applied during the one-two weeks following the procedure and patients are able to return promptly to their daily life. Immediately after the procedure, patients are dressed with absorbent bandages until the next day, underneath a compressive garments, because of the leakage of anesthesia fluid. It's better to limit the exercise for 3-4 days after the procedure in order to reduce swelling and bruising. Transient treatment-related adverse events were mild in severity and the most common side effects reported were soreness and bruising. No seromas has been reported in all the 50 patients.

RESULTS

Patient satisfaction was 87% at T90 in 50 patients (48F; 2M), 95% at T180 in 50 patients, 97% at 12 months in 13 patients (1M) and 100% at 15 months in 3 patients (1M). Bruising was the only relevant side effect. Nevertheless among 50 patients, 95% had bruising at T7, 23% at T14 and no patient had bruising at T30. In our series, soreness is reported in 100% of patients at T7 and usually can last for several days: 19% at T14, 4% at T30 and 0% at T90. The default depth of choice is 6 mm, but if there is a site too close is better to perform the adjacent release at 10 mm of depth to avoid the connection of sites at the same depth. This avoids problems encountered during the early development of the device where aggressive connection of sites at a single depth led to larger contiguous areas of release, which took longer time to heal and more seromas that were common with the old subcision. Dr. Hexel referred that in the postoperative period after subcision all the patients had pain, bruises and hemosiderosis. The Hexsel Cellulite Severity Scale (CSS) (Green, 2015; Hexsel, 2009) is a current evaluation tool to measure cellulite severity. The Hexsel CSS rates each of 5 domains of cellulite (number of evident depressions, depression depth, morphologic skin surface alterations, skin laxity, flaccidity, or sagging, and Nürnberger and Müller classification) from "0" (no alteration) to "3" (most severe). The simplified Cellulite Severity Scale (CSS) assessment used in this study is the one developed and validated in the Kraminer et al. Multicenter Pivotal Study (Kaminer, 2015) in which the two key clinical morphologic features of cellulite were quantified: (A) number of evident depressions in the treatment area and (B) average depth of the depressions. Regarding the Global Aesthetic Improvement Scale (GAIS), which assesses the improvement in cellulite, showed that the mean baseline CSS score of 3.6 decreased to 1.2 at T90 ($p < 0.001$) and 1.1 at T180 ($p < 0.001$); in the 13 patients controlled after 12 months the score remained 1.1 ($p < 0.001$); in the 3 patients controlled at 15 months, it decrease to 1.0 ($p < 0.001$). Visual Analog Scale (VAS) from 0 to 10, is used to check the level of pain during the anesthetic infiltration (a mean score of 3.8 similar with other cosmetic procedures), it was 2.2 at T7, 1.8 at T14 and 0 from T90 onwards.

Conclusion

This revolutionary FDA-cleared procedure for the cellulite puckering, combines a proven approach with an innovative technology to treat the primary structural cause of cellulite

blemishes. The results of this study showed that a single treatment with a novel controlled tissue release system improved the appearance of cellulite on posterior thighs and buttocks. This study confirmed the safety, efficacy and patient satisfaction with vacuum-assisted precise tissue release in the treatment of cellulite and showed that with a proper patient selection and technique, the Cellfina procedure delivers outstanding results and patient satisfaction.

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