

A Study of a Novel Controlled Focal Septa Release Method for Improving Cellulite

Craig Layt, MBBS, FRACS (Plas)

Background: Cellulite is a common and often emotionally distressing condition among affected individuals. The dimpled appearance is caused by fibrous connective tissue, or septa, which tether the dermis to underlying fascia. A novel, minimally invasive, controlled focal septa release method was developed to selectively identify, target and manually release the tethers in a precise manner from a single insertion point (Revelle Aesthetics). The following pilot study evaluated the safety and feasibility of this method for treating subjects with moderate-to-severe cellulite.

Methods: Female subjects (N = 10), 21–55 years old underwent unilateral controlled, focal fibrous septa release on the buttocks and thighs. Local anesthesia was administered using standard techniques. Cellulite depressions were marked with the subject standing at rest. Target septa were identified in the marked areas by applying tension with the device to reproduce the dimple appearance on the skin. Once identified, the contributing septa were severed with the device. For eight subjects, access was achieved with one small incision in the gluteal crease. Study assessments occurred on posttreatment days 1, 3, 14, 30, and 90.

Results: All procedures were successfully completed with no serious or unexpected adverse events and the procedure was well tolerated. Mild adverse events were transient bruising and soreness. Target septa can be visualized on the skin by applying tension with the device. Multiple depressions can be treated from a single entry point.

Conclusion: These results confirm the safety and feasibility of the controlled focal fibrous septa release method to treat moderate and severe cellulite. Additional trials are ongoing. (*Plast Reconstr Surg Glob Open* 2022;10:e4237; doi: 10.1097/GOX.0000000000004237; Published online 8 April 2022.)

INTRODUCTION

Cellulite is a common condition estimated to affect 80%–90% of postpubertal women.¹ Although it is a generally benign condition, cellulite can be unattractive and emotionally distressing for affected individuals, having a significant impact on quality of life.^{2,3} Cellulite can occur in any anatomical area with subcutaneous adipose tissue but is most common in the outer and posterior thighs, hips and buttocks.⁴ Many individuals with cellulite seek treatment to improve their cosmetic appearance and emotional well-being.⁵ According to the American Society of Plastic Surgeons, there were 86,350 procedures to treat cellulite in 2020, an increase of 261% since 2000.⁶

The dimpled appearance of the skin is caused by columns or bands of fibrous connective tissue,⁷ usually referred to as septa,⁸ which tether the dermis to the underlying fascia, and fat herniation.⁹ Targeting these structures has been determined to be the strategy most likely to provide durable improvement in the appearance of cellulite.¹⁰ Although common in women, cellulite rarely occurs in men. This appears to be due to differences in the number, thickness, and orientation of septal connections in the superficial fascia and dermis in men.¹¹ The physiology and appearance of the skin in women are also significantly affected by the female sex hormones estrogens and progesterone. Estrogen deficiency decreases connective tissue production in the skin. The diminished type I and III collagen and elastin fiber content also contributes to cellulite formation.¹²

A new innovation for treating cellulite is a controlled mechanical method of focal fibrous septa release designed

From The Layt Clinic, Southport, Queensland, Australia.

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for in-office use. The locations of cellulite depressions are marked while the patient is in a relaxed, standing position. With the patient lying in the prone position and local anesthetic delivered, the device is inserted through the skin and advanced to a depression location. A light indicates the position of the end of the device beneath the skin. The device is opened and retracted proximally to engage the target septa. If pulling the septa recreates the appearance of a depression in the target area, the device is used to sever the septa. If pulling the septa does not recreate the depression, the device is repositioned, and another attempt is made to recreate the depression. The device can be advanced to numerous locations from a single insertion site. It is designed for single use only.

The objective of the following pilot study was to evaluate the safety and feasibility of the novel controlled focal fibrous septa release method to treat subjects with moderate or severe cellulite.

METHODS

Subjects

Female subjects, 21–55 years old with a body mass index $<30\text{ kg/m}^2$ who were seeking treatment for moderate or severe cellulite were enrolled in the study ($N = 10$). Moderate cellulite was defined as the presence of depressions which appear spontaneously when standing but not when lying down. Severe cellulite was defined as the presence of depressions which appear spontaneously when standing and when lying down. Subjects of child-bearing potential provided a negative urine pregnancy test before study participation and all subjects agreed to abstain from any other cellulite treatments during the study. As this was a pilot study, only racially white subjects were enrolled to ensure visualization of the device below the superficial subdermal plane. Reasons for exclusion from study participation included prior liposuction of the thighs or buttocks at any time, or any cellulite procedure on the thighs or buttocks during the previous 90 days; greater than 10% change in body weight within the last 6 months or history of a greater than 60 kg weight loss; evidence of an active infection or body temperature higher than 38°C ; current or recent smoker (within 6 months); history of hypertension, diabetes or hypoglycemia; pregnancy or lactation; history of coagulopathy, pneumopathy or severe anemia; predisposition to atrophic or hypertrophic scarring or keloids; use of nonsteroidal antiinflammatory drugs, vitamin E, herbal teas or dietary supplements during the previous 14 days; or any other factor, condition or disease that might place the subject at risk or compromise the study objectives.

Procedure

With subjects in a relaxed standing position, a surgical marker was used to mark the planned treatment areas of moderate or severe cellulite on the thighs and buttocks before infiltration of local anesthesia. For this pilot study, subjects were treated unilaterally with the opposite side serving as a control. After treatment target marking,

Takeaways

Question: Is a novel focal fibrous septa release device safe for improving the appearance of moderate and severe cellulite?

Findings: All procedures were successfully completed with no serious or unexpected adverse events and the procedure was well tolerated.

Meaning: This device represents an advancement in the treatment of moderate and severe cellulite.

procedural planning was performed. In the case of more discrete dimples on the buttocks, single access was made from an entry on the gluteal crease. Longer linear depressions, typically located on the thigh were usually accessible from the same gluteal crease entry but occasionally approached from an additional entry on the thigh. The number of depressions and the choice of access sites were left to the discretion of the investigator. The treatment area was prepared using normal sterile technique. Examples of planning target areas for cellulite reduction are shown in [Figure 1A–C](#).

With subjects lying prone on the procedure table, local anesthesia was introduced into the planned treatment areas. Local anesthesia via infiltration was used without sedation. A 30-gauge needle was used to deliver anesthesia to the access sites. Then, a 20-gauge spinal needle, 6 inches long, was inserted through the superficial subdermal plane along the advancement pathway to the marked cellulite targets. Anesthetic was also delivered at least 1.5 inches past the marked targets to accommodate the distal tip of the device. Anesthetized areas were typically visualized by blanching of the skin after a few minutes dwell time.

The design of the distal end of the device is shown in [Figure 2](#). The device was introduced through the skin and advanced through the superficial subdermal plane to the site of a previously marked cellulite depression. With the light illuminated, the location of the distal end of the device was observed through the skin. The deployable links are stored coaxially in the device shaft for advancement and withdrawal from the target treatment area. An actuator on the handle was used to deploy the hook under the target area. The blunt link was used to pull on the septa to recreate a depression on the skin. Upon feeling resistance from engaged septa, the investigator visually confirmed the location of the created depression relative to the marked cellulite depression. The blunt link was then retracted, exposing the sharpened link which was used to sever the septa. The steps were repeated until the depression could no longer be recreated on the skin surface. If pulling the hooked septa did not recreate the previously marked depression, the hook was retracted into the shaft of the device and repositioned. The procedure was then repeated until all the depression locations were treated. The step-by-step cellulite reduction procedure is shown in [Figures 3 and 4](#).

Following the procedure, dressings are applied to skin access locations. Over-the-counter oral analgesics, such as acetaminophen, were used as needed during the first



Fig. 1. Marking target areas for cellulite reduction (A). Examples of planned device pathways to target areas on the buttock (B) and thigh (C).

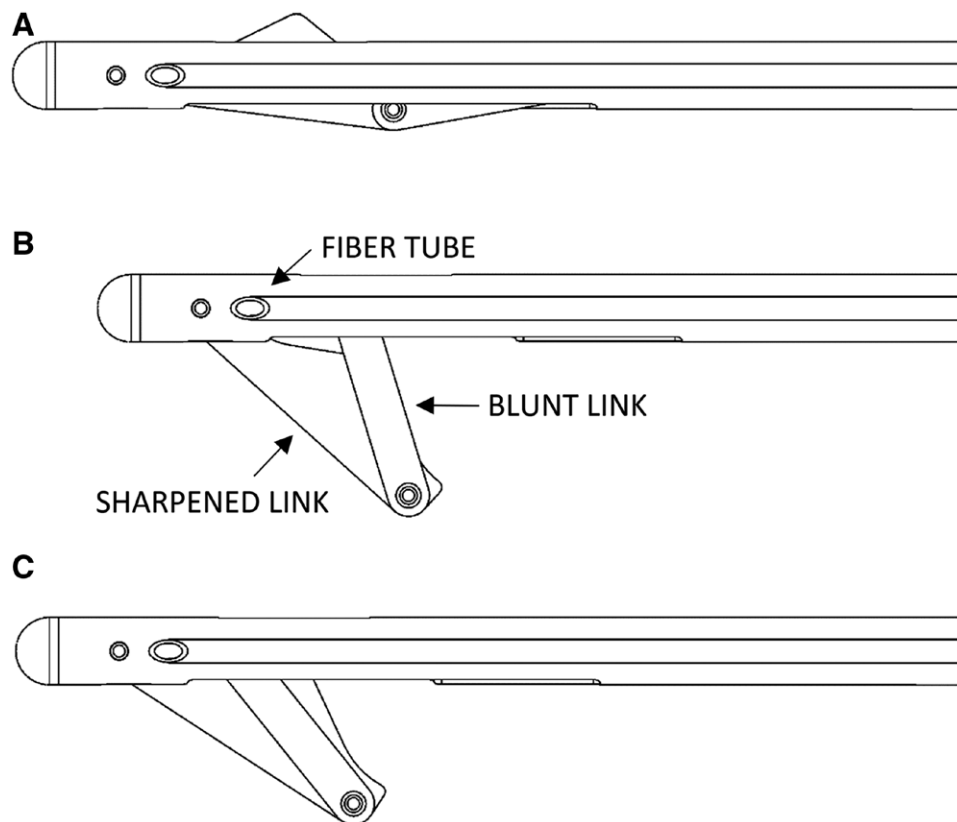


Fig. 2. Detail of distal end of device. The device in the closed position (A), open position (B) and cut position (C).

few days following the procedure at the discretion of the subject. Pre and posttreatment images with no identifiable features were obtained for each subject at baseline and each follow-up evaluation using a digital camera with standardized lighting in a relaxed standing pose and photographic garment.

Safety Assessments

Safety assessments were made on posttreatment days 1, 3, 14, 30, and 90. The day 1 assessment was a phone call

to check on possible adverse events and the need for any medications. At each subsequent evaluation, safety assessments included a physical examination for hematomas, ecchymosis, hemosiderosis, seromas, areas of firmness or softness, erythema, wound drainage, scarring, dyspigmentation, tissue atrophy, contour irregularities, concomitant medications, or other adverse events.

At each assessment, standardized digital imaging of each thigh and/or buttock was obtained. At day 30, height and weight measurements were obtained for BMI determination

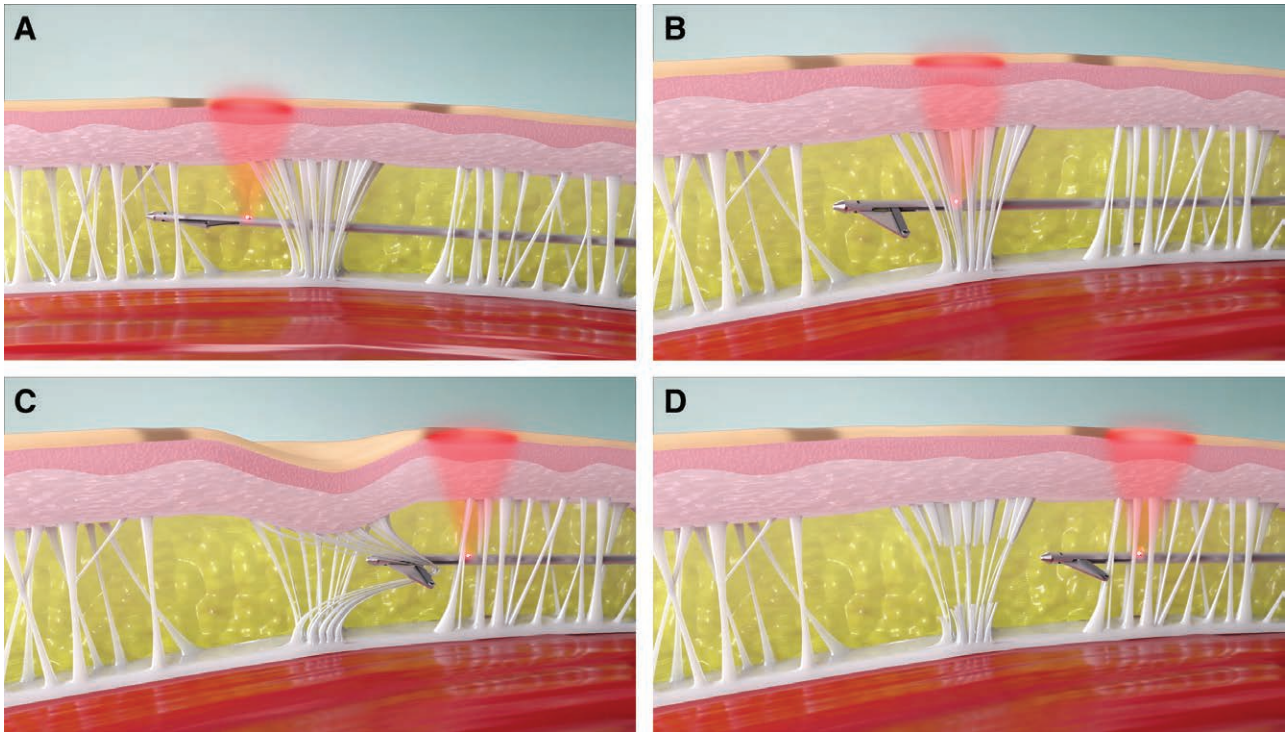


Fig. 3. Controlled focal fibrous septa release method. The light enables correct positioning of the distal end of the device (A). After advancing to the target septa (B), pulling with the deployed blunt hook will confirm its correct location (C). The blunt link is then retracted, and the sharpened link is used to sever the septa (D).



Fig. 4. Cellulite reduction procedure. The device is advanced in the closed position to the previously marked cellulite depression location (A). Pulling on the fibrous septa in the open position recreates the appearance of the cellulite depression (B). The captured fibrous septa is severed by pulling with the device in the cut position (C).

and a physical examination of the thighs and buttocks and circumferential measurements were obtained.

Five subjects were initially enrolled and treated. Upon completion of their day 1 phone follow-up, an interim safety analysis was performed consisting of all data collected up to that point. This interim safety analysis was reviewed by a data safety monitoring board which unanimously agreed the study could continue enrolling the remaining five subjects per the approved clinical investigational plan.

Feasibility Assessments

The feasibility endpoint was assessed by an independent blinded physician assessor. Using digital images, the blinded physician rated the regional change in baseline

cellulite appearance on posttreatment day 30 and day 90 using the five-point Global Aesthetic Improvement Scale (GAIS) (Table 1). The method for performing the blinded evaluations is shown in Figure 5. The GAIS has been previously used to assess the efficacy of cellulite treatments.^{13,14}

Study Endpoints

This study was not adequately powered to make statistically valid comparisons; however, a 10-subject sample size is considered typical of first-in-human pilot studies. The primary safety endpoint would be established by the absence of serious adverse device events.

The primary feasibility endpoint was the proportion of subjects who achieved an improvement of one point or more in GAIS scores at day 90. The secondary feasibility

Table 1. Global Aesthetic Improvement Scale

Score	Description
-1	Worse
0	No/minimal (0%–19%) improvement
1	Slight (20%–49%) improvement
2	Moderate (50%–79%) improvement
3	Significant (80%–100%) improvement

endpoint was reached if more than 50% of subjects had a noticeable improvement in GAIS scores at day 90.

Ethics

Each subject provided informed written consent before undergoing the study procedure. This protocol and related materials were approved by a commercial institutional review board (Bellberry Ltd., Adelaide, Australia) and conducted according to principles that have their origin in the Declaration of Helsinki.¹⁵

RESULTS

Ten subjects were enrolled and completed the study. Subjects had a mean (SD) age of 37.2 (8.8) years (range, 25–48 years) and mean BMI of 22.9 (2.7) kg/m² (range, 19.7–29.1 kg/m²). Baseline cellulite severity assessments were rated as moderate (n = 8), severe (n = 1), or missing (n = 1). Seven of the 10 subjects had treatment on both the buttocks and the thighs, two had treatment on the buttocks only and one had treatment on the posterior thigh only. For eight subjects, access was made from a single small incision on the gluteal crease. For two subjects, a second small entry site was used to facilitate treatment. Regions of the buttock and thigh were outlined on

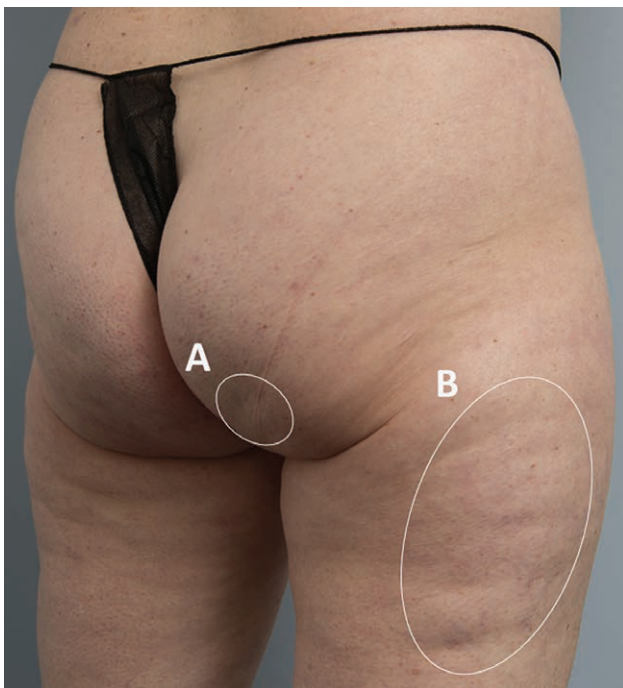


Fig. 5. Blinded assessments. This figure demonstrates the technique for performing the blinded evaluations.

the photographs to group the treated cellulite depressions that were near each other in a region to facilitate the independent, blinded reviewer assessment (Fig. 5). Among the 10 subjects, a total of 26 regions (range, 1–5 per subject) were assessed by the blinded reviewer. Reported safety findings were transient soreness and mild bruising (n = 8) which persisted at day 14 (n = 4) but had resolved by day 30. There were no serious or unexpected adverse events.

As early as 14 days after treatment, there was a visible reduction in the appearance of cellulite in the treated areas as compared to baseline photographs. These improvements were confirmed at 90 days by independent blinded physician assessment. At day 90, most regional treatment areas (n = 22, 84.6%) achieved an improvement of one point or more in GAIS scores and 90% of subjects achieved an improvement of two point or more in appearance of their cellulite compared to the untreated side (Table 2). Therefore, the study results achieved the feasibility endpoints. Pre and posttreatment images of one subject are shown in Figure 6.

DISCUSSION

One of the technical questions when initiating the study was whether hooking and pulling on septa in the superficial space would recreate a depression on the skin when the patient was prone. The procedural experience and postprocedure results indicate that it does. The study demonstrated that the controlled focal fibrous septa release method is able to address moderate and severe cellulite depressions by identifying and severing the specific fibrous septa responsible for causing cellulite depressions. As a result, most treated areas achieved aesthetic improvements in cellulite severity.

This method also permitted treatment of multiple cellulite depressions from a single insertion site. From a single point at the gluteal fold, cellulite depressions in both the thighs and buttocks were treated, reducing the risk of scarring and hyperpigmentation. Using the controlled focal fibrous septa release method, reported adverse events consisted of mild and transient bruising and soreness.

The mode of action of the controlled focal fibrous septa release method is directly controlled by the physician and fundamentally different from motorized or energy-based therapies and thus warrants some discussion. The procedure distinguishes between two types of connective tissue between the superficial fascia; fibrous septa that form a connection from the dermis to the superficial fascia in the area underlying cellulite depressions and septa forming connections between the dermis and the superficial fascia that do not cause cellulite depressions. The device used in this study can be used to test the septa to determine which ones are responsible for the depressions before the

Table 2. 90-day Study Assessments

Improved Cellulite Appearance	
No. treated subjects	10
No. treated cellulite regions	26
Regions with ≥ 1 -point improvement in GAIS scores	22 (84.6%)
Subjects with $>50\%$ improvement in cellulite appearance	9 (90.0%)

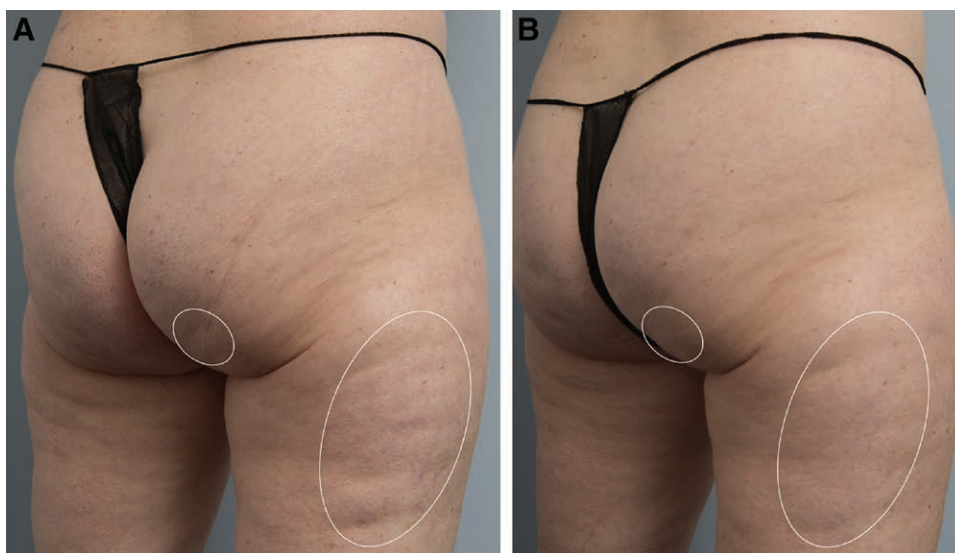


Fig. 6. Pre-and posttreatment photographs. These images show the subject before treatment (A) and 90 days posttreatment (B). Note that all subject images are from the same subject.

physician severs the septa, thereby allowing the physician to let go of septa that are not causing the depression.

Subcision is a minor surgical procedure that has been used to treat cellulite for many years.¹⁴ Subcision can also improve the appearance of cellulite by releasing the dermis from underlying fibrous septa¹⁵ and is usually performed by advancing a triangular needle into the subcutaneous adipose tissue layer to disrupt the fibrous septa; however, this method does not permit targeting the specific septa causing cellulite depressions. Another disadvantage of existing subcision techniques include the need for multiple needle insertions for treating multiple depressions, increasing the likelihood of adverse events, such as pain, numbness, nodules, hyperpigmentation, seroma, and skin irregularities.⁸

Limitations to this study included an open-label design, a modest number of enrolled subjects and the limited racial demographics of the study population.

This study demonstrated that the controlled focal fibrous septa release method is a safe and feasible treatment for moderate-to-severe cellulite. Based on the promising results of this pilot study, additional trials for treating moderate and severe cellulite with the controlled focal fibrous septa release method are underway.

CONCLUSIONS

The controlled focal fibrous septa release method is a new approach to the treatment of moderate-to-severe cellulite based on the concept of mechanically testing first then precisely releasing fibrous septa. The results of the safety and feasibility study suggest a novel controlled focal fibrous septa release method can treat moderate and severe cellulite by identifying the specific fibrous septa responsible for causing cellulite depressions. Most patients experienced a reduction in the appearance of their cellulite by 2 weeks and a sustained response to at least 90 days with no patients experiencing serious or unexpected adverse events. These

initial results indicate the method has a favorable safety profile and may ultimately deliver rapid improvement with minimal short-term morbidity. Additional trials are ongoing.

Craig Layt, MBBS, FRACS (Plas)

The Layt Clinic
16 Harvest Court
Southport, QLD 4215, Australia
E-mail: craig@thelaytclinic.com

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