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CLINICAL COMMENTARY

A clinical study to evaluate the safety and efficacy performance of the Morpheus8 applicator for the treatment of cellulite: A case series

Nkemjika Ugonabo MD, MPH[1] | Rachael Ward MD, MPH[2] | Anne Chapas MD[1]

[1]Unionderm, New York, New York, USA

[2]Division of Dermatology, University of Washington, New York, New York, USA

Correspondence
Nkemjika Ugonabo, MD MPH, UnionDerm, New York, NY, USA.
Email: n.ugonabo@gmail.com

1 | INTRODUCTION

Cellulite is a significant cosmetic concern for post-pubertal females and has been reported to affect 85% to 98% of post-pubertal females across all races.[1] The demand for treatment of cellulite has been on the rise in recent years. Recently, a multicenter clinical trial demonstrated improvement in cellulite of the upper thigh using microneedling with fractional radiofrequency (RF) to the dermal and subcutaneous area.[2] It is proposed that the microneedle RF induces a wound healing response at the level of the subcuticular junction or dermis, potentially disrupting the excessive tension placed by perpendicular fibrous septae. The microneedle RF is thought to induce new collagen, elastin, and HA at the subcuticular junction, further preventing fat herniation into the dermis.[2] Additionally, adding microneedling to radiofrequency enhances dermal heating by delivering energy through pins/needling that penetrate to a predetermined desired depth.[3]

Previously, the Morpheus8 (InMode Aesthetics, Lake Forest, CA) handpiece (24-pin tip up to 4 mm depth) received FDA clearance for use in dermatological and general surgical procedures for electrocoagulation and hemostasis. The Morpheus 40-body tip (InMode Aesthetics, Lake Forest, CA) with a depth of 6 mm was introduced to stimulate contraction and collagen formation while simultaneously affecting adipose tissue and fibro-septal network. However, this specific technology had not been previously published for the treatment of cellulite. Hence, our objective was to evaluate the safety and efficacy of the Morpheus8 Body 40-pin tip at a depth of up to 6 mm for treatment of the thighs to improve cellulite appearance, skin laxity, and subcutaneous fat deposits. Subjects self-assessed their outcome at each follow-up visit using 5-point Likert scales for Subject Satisfaction Scale (2: Very Satisfied, 1: Satisfied, 0: Neutral, −1: Dissatisfied, −2: Very Dissatisfied) and Subject Improvement Scale Global Aesthetic Improvement (GAI) scale (0: No change, 1: Slight Improvement, 2: Moderate Improvement, 3: Marked Improvement, 4: Significantly Marked Improvement). Similarly, investigators assessed improvement on a GAI scale (0: No Change, 1: 1%–24%, 2: 25%–49%, 3: 50%–74%, 4: 75%–100%), and a Skin Laxity/Tightening Improvement Scale (0: No tightening/firmness, 1: Slightly visible tightening/firmness, 2: Visible tightening/firmness, 3: Very visible tightening/firmness).

2 | CASE 1

Patient 1 was a 57-year-old female with a history of moderate-to-severe cellulite affecting posterior thighs and buttocks (Figure 1). The treatment area was marked by the investigator and measured approximately 20×20 cm in size on the posterior thighs only. For the first treatment, topical 30% lidocaine was applied to the treatment area in addition to the use of Pro-Nox™ for patient comfort. For the second treatment, a combination of topical 30% lidocaine as well as 12 ccs of injectable lidocaine 1% with epinephrine 1:100000 was used (i.e., 6 ccs per side) for anesthesia. The patient received two monthly treatments, 4 weeks apart with the following settings: First session: Energy 15 J, Treatment mode: Fixed, Depth 6 mm for 1 pass with 105 pulses on the right thigh and 185 pulsed on the left thigh followed by Depth 3 mm for 1 pass with 175 pulses on the left thigh. Second session: Energy 15 J, Treatment mode: Fixed, Depth 6 mm for 1 pass with 137 pulses on the right thigh and 135 pulses on the left thigh followed by 3 mm for 2 passes with 236 pulses on the right thigh and 253 pulses on the left thigh. The patient was seen at 4 follow-up visits at 1, 3, 6 and 9 months post treatment. At 9-month follow-up, the patient scored her satisfaction level as "satisfied" or 1 and improvement as "moderate improvement" or "2" on the Subject Improvement Scale

FIGURE 1 Patient 1 at initial visit and 9-month follow-up visit (lateral view)

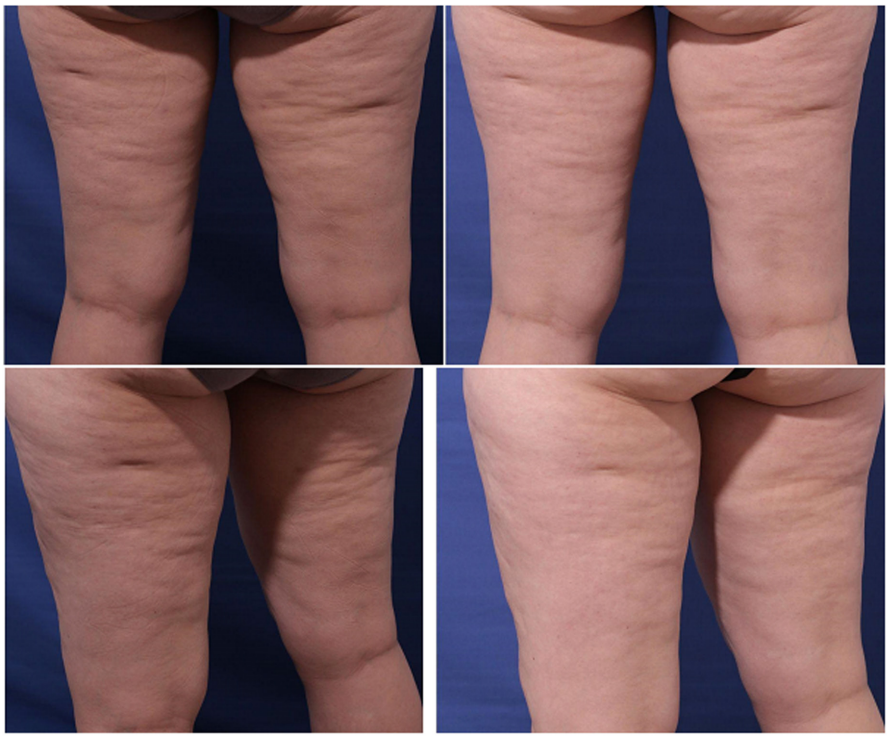

FIGURE 2 Patient 2 at initial and 3-month follow-up visit

GAI Scale. At 9-month follow-up, the physician rated the improvement as 25%–49% or "2" on the GAI scale and "visible tightening/firmness" or "2" on the Skin Laxity/Tightening Improvement Scale.

3 | CASE 2

Patient 2 was a 50-year-old female with a history of moderate-to-severe cellulite affecting posterior thighs and buttocks (Figure 2). The treatment area was marked by the investigator and measured approximately 16×16 cm in size on the posterior thighs only. For patient's comfort, local infiltration of tumescent solution consisting of 250 ml of normal saline, 25 ml of 1% lidocaine with epinephrine, and 3 cc of 8.4% sodium bicarbonate was used for anesthesia, with a total of 125 cc injected to each posterior thigh using a Klein pump prior to treatment. The patient received two monthly treatments, 4 weeks apart with the following settings: Energy 15 J, Treatment Mode: Fixed, Depth 6 mm for 2 passes followed by Depth of 3 mm for

3 passes. At the first session, a total of 304 pulses were applied at the 3 mm depth of the right thigh and 245 pulses at the depth of 6 mm. A total of 316 pulses were applied on the left thigh at the depth of 3 mm and 245 pulses at the depth of 6 mm. At the second session, a total of 317 pulses were applied at the 3 mm depth of the right thigh and 201 pulses at the depth of 6 mm. A total of 306 pulses were applied on the left thigh at the depth of 3 mm and 179 pulses at the depth of 6 mm. The patient was seen at two follow up visits at 1 and 3 months post treatment and is scheduled for additional follow up at 6 and 9 months. A 3-month follow-up, the patient scored her satisfaction level as "very satisfied" or "2" and improvement as "marked improvement" or "3" on the Subject Improvement Scale GAI Scale. Similarly, at 3-month follow-up, the physician rated the improvement as 50%–74% or "3" on the GAI scale and "very visible tightening/firmness" or "3" on the Skin Laxity/Tightening Improvement Scale.

4 | DISCUSSION

Microneedle radiofrequency (RF) creates thermal and mechanical effects of the skin to increase collagen, elastin, and hyaluronic acid (HA), leading to improvements in skin laxity and rhytids. This technology provides direct and controlled delivery of thermal injury at controlled penetration depth to the junction of the deep reticular dermis and superficial subcutis.[3,4] Multiple microneedle electrodes enter the tissue to deploy bipolar radiofrequency energy to the assigned treatment depth. Heat in this technique is generated from the resistance of tissue components to the movement of charged molecules within the radiofrequency field.[3]

More recently, the indication of microneedling with radiofrequency has been broadened to include the treatment of cellulite. Cellulite is a localized disorder of subcutaneous tissue that is characterized by the protrusion of adipose within fibrous connective tissue septae into the dermis, causing a modification of skin topography.[1] Microscopically, differences in septae orientation are noted with women having perpendicularly oriented septae compared to men.[1] Fat protrusion into the dermis is a result of continuous and progressive tension placed on these septa, which are located in the hypodermis of the skin.[1] The Morpheus8 device can potentially lead to tension disruption of the fibrous septae at the subcuticular junction with higher depth use. Additionally, its use at deeper settings is known to deliver direct heat which disrupts adipocytes.[5] Its use may promote new collagen, elastin, and HA induction aimed at prevention of dermal fat herniation at medium depth use.

The literature on the use of microneedling in the treatment of cellulite is relatively scarce. Alexiades et al.[2] performed a multicenter clinical trial of subcutaneous microneedle RF for the treatment of cellulite. Patients with cellulite were enrolled and received one subcutaneous microneedle RF treatment of the posterolateral thighs. Efficacy of treatment was assessed based on blinded dermatologists and investigators by grading photos at baseline, 1, 3, and 6 month follow ups. Number of dimples present on each photograph and the severity of undulation irregularities were assessed using a 5-point scale and Nurnberg–Muller scale. Subjects also rated their treatment results using the same 5-point scale and additionally, satisfaction was assessed using the 5-point Likert scale. Overall, the study found an average reduction of at least one dimple at both 3- and 6-month follow-up visits by both blinded and treating physicians. The reduction in undulation severity was also similar for blinded and treating physicians at 3 months (0.83 vs. 0.86) and better for treating physicians at 6 months (0.60 vs. 1.02). Investigator improvement assessment distribution revealed that most subjects at 3- and 6-month follow-up obtained a score in the moderate-to-good improvement categories. Satisfaction results at 3 and 6 months were slightly higher for the investigators (85% and 89% chose "satisfied") than for the subjects (70% and 75% chose "satisfied").[2]

In a case study performed by Yu et al. in 2018, the use of RF microneedling to improve skin laxity and cellulite in a 39-year-old woman was evaluated.[6] Two sessions of RF microneedling were performed 5 months apart on the bilateral medial thighs. The study was conducted using the Profound device and was administered in two passes at a depth of 5.8 mm. The study reported a five-point improvement on the Hexsel and Dal'Forno Cellulite Scale score, and the patient reported satisfaction with the results. In the Alexiades et al. study, treatments were also conducted using Profound Sub-Q device, which delivers microneedles into the dermis with an exposed portion extending from 3.9 to 5.8 mm beneath the skin surface. In both studies, each patient was treated at one treatment depth. Treatments in our study were conducted using the Morpheus8 Body 40-pin tip. This particular device is the first to be FDA-approved to provide treatment to penetrate subdermal tissue up to 7 mm. Importantly, both patients in our study were treated at a depth of 6 mm followed by a depth of 3 mm for a total of 2 sessions. Treatment at both medium and deeper depths in our study may have led to better targeting of the reticular dermis and subcutaneous tissue and subsequently more effective heating and remodeling of the dermis in addition to the disruption of adipocytes and fibrous septae tension. Side effects in both patients were limited to minimal transient bruising.

It should also be noted that in our study, local infiltration of tumescent solution was used for anesthesia in patient 2 due to severe pain experienced by the first patient. This ultimately enabled the treating physician to complete more treatment passes; nonetheless, the patient still reported pain rated as "none." Contrarily, patient 1 received topical lidocaine 30% and Pro-Nox™ for comfort and rated her pain level as "severe." This suggests that use of tumescent anesthesia can result in more treatment pulses, which could potentially lead to better treatment outcomes and improved patient and provider satisfaction as was the case with our patient.

Limitations of this case series include lack of assessment by blinded investigators and lack of a validated scale to assess the improvement in cellulite. Regardless, our study further adds to the growing body of literature that supports the safety and effectiveness of RF microneedling for the treatment of cellulite. We further highlight the increase in benefit that can be attained with use of the Morpheus8 Body 40-pin tip, which can achieve an increased depth and therefore deeper subdermal adipose tissue remodeling as

compared to other devices. Additional controlled studies are needed to further support these findings.

DATA AVAILABILITY STATEMENT

Data sharing not applicable to this article as no datasets were generated or analysed during the current study.

ETHICAL APPROVAL

This material has not been previously published elsewhere and represents the original work of the authors. It is not currently being considered for publication elsewhere and credits the meaningful contributions of all co-authors.

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