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Tissue Micro-Coring Is a Safe and Effective Option for the Treatment of the Nasolabial Fold, Marionette, and Perioral Rhytids

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ABSTRACT

Background: Non-surgical treatment of the aging lower face remains a therapeutic challenge. Tissue Micro-Coring Technology (MCT) is a novel technology that permits the non-surgical removal of skin as micro-cores, tightening skin and inducing collagen and elastin.

Objective: To evaluate safety and efficacy of MCT for the treatment of the aging lower face.

Methods: This retrospective, single-site study assessed outcomes for subjects treated with MCT. Assessments included the change from baseline in Lemperle Wrinkle Severity Scale (LWSS) assessed for the nasolabial folds (NLF), marionette lines, lip lines, and global esthetic improvement scale (I-GAIS).

Results: A total of 10 patients met the study criteria. Mean (SD) I-GAIS was 1.7 (0.36), and mean (SD) change from baseline in LWSS for NLF, marionette lines, and lip lines were 1.1 (0.46), 1.3 (0.3), and 0.6 (0.35), respectively. Most subjects had some improvement in LWSS across all three treatment areas, with many experiencing > 1-point improvements.

Limitations: Limitations include the retrospective study design, small study population, and single-sex population.

Conclusion: In the real-world setting, MCT leads to improvements in global appearance and wrinkle severity. MCT is an effective alternative to injectable fillers for the treatment of nasolabial fold and marionette and perioral lines.

1 | Introduction

The aging lower face, in particular rhytids and lax skin, is a common reason for patients to seek esthetic care [1, 2]. Multiple cosmetic procedures, including surgical and nonsurgical treatment modalities, are available to improve the appearance of rhytids in the lower face and to tighten loose skin. Mechanical tissue Micro-Coring Technology (MCT; ellacor [Cytrellis Biosystems Inc., Woburn, MA]) removes micro-cores of skin to achieve tissue removal without surgery or thermal energy [3]. The MCT coring needles penetrate the epidermis and dermis, excising a full thickness column of skin with vacuum assistance. Excised cores are < 500 um in diameter, which minimizes the risk for scarring [3]. At each treatment, skin surface area is reduced, and the wound-healing response is initiated. MCT is approved by the US Food and Drug Administration (FDA) for the treatment of moderate to severe wrinkles in the mid to lower face for adults aged ≥ 22 years with Fitzpatrick skin types I-IV and is further indicated for fractional skin resurfacing [4].

The safety and efficacy of MCT have been established in clinical trials [3, 5]. A pivotal study with 51 subjects treated with MCT

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found that the treatment was safe and effective for the non-surgical removal of facial skin, a finding that was the basis for clearance of the device by the FDA [3]. Our early experience with the device in clinical practice led to the observation that many treated patients appeared to have injectable filler-like effects. The aim of this retrospective chart review was primarily to evaluate the efficacy of MCT for the treatment of the aging lower face.

2 | Materials and Methods

2.1 | Study Design

This study was a retrospective review of electronic medical record (EMR) data and photographic images collected over a study period from June 1, 2022 to March 31, 2023. All MCT procedures conducted during this period were identified and then all subjects who had a follow-up visit at least 30 days post-MCT treatment were included if before and after photographs were taken at those visits.

All subjects signed informed consent adhering to the guidelines outlined in the US Health Insurance Portability and Accountability Act of 1997 (HIPAA) and the International Conference on Harmonization E6 Good Clinical Practice. All criteria pursuant to 45 CFR 46.116(d) and 45 CFR 164.512(i)(1)(i) were met. The study was reviewed and approved by the Allendale IRB and was conducted in accordance with all applicable human subject research requirements as well as applicable federal regulations. All subjects provided written informed consent before undergoing any study-related procedures and provided written consent for the use of their photographs.

2.2 | Study Treatments

Subjects received treatment in the mid and lower facial areas, from the inferior border of zygoma to mandibular jawline, according to the protocol used in the pivotal clinical study and in concordance with device labeling. Briefly, the MCT cartridge is moved across the treatment area to treat one 10 mm × 10 mm square section at a time. A total of 5%–8% of skin (per 1 cm^2) may be removed in the targeted area; available settings are 1%, 3%, 5%, 7% and 8% density and treatment depth of 0–4 mm, adjustable in 0.5 mm increments. Subjects received up to two treatments at the discretion of the patient and treating physician.

2.3 | Assessments

Study variables extracted from patient EMRs included age, sex, number of treatments performed, time from last treatment to follow-up visit and final photographs. Treatment variables included core count and treatment depths used. Safety and adverse events reported by the study subjects or treating physician were also documented and identified on chart review.

The primary endpoint was the improvement in the treatment area using the Lemperle Wrinkle Severity Scale (LWSS), and investigator-assessed global esthetic improvement scale (I-GAIS) when comparing baseline to final post-treatment images (7-point scale ranging from +3 to −3, with +3 indicating "very much improved" and −3 indicating "very much worse") [6]. The LWSS grade was used to assess wrinkle severity in the nasolabial folds (NLF), marionette lines, and lip lines (6-point scale with 0 indicating no wrinkles and 5 indicating very deep wrinkles) [6]. Post-hoc LWSS grade and I-GAIS scores were assigned for each subject by three laser and energy-based device fellowship-trained board-certified dermatologists using digital photos from baseline and post-treatment time points. Expert evaluators, blinded to study treatments, were asked to sequence before and after images for each of the included subjects prior to assignment of I-GAIS. For LWSS, reviewers were shown one image at a time in a randomised fashion and asked to provide an LWSS score for each. Changes in LWSS grade and I-GAIS scores were calculated and are reported with standard deviation.

3 | Results

3.1 | Baseline Demographics and Subject Characteristics

A total of 10 subjects were included in the study. All subjects were female, and the average age (range) was 60.8 (52–77) years. Just over half (60%) of subjects received one MCT treatment, and the mean (range) number of cores collected was 5821 (4758–7401). The mean (range) time from treatment to follow-up evaluation was 89 (35–180) days.

3.2 | I-GAIS

Prior to assigning I-GAIS scores, blinded expert evaluators were shown pairs of images of each subject and asked to identify which image was from before and which image was from after MCT treatment. The expert evaluators were able to correctly sequence before and after images in 100% of cases.

I-GAIS was assessed for each subject based on the before and after images. All subjects had improvement from baseline as indicated by I-GAIS (Figure 1). The mean (SD) I-GAIS score across subjects was 1.7 (0.36), indicating patient improvement ("improved," "much improved," or "very much improved").

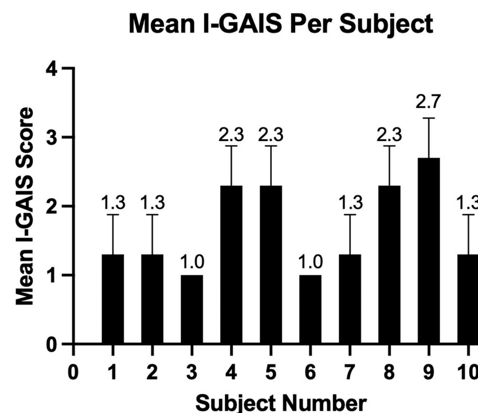

FIGURE 1 | Mean I-GAIS Per Subject. Mean scores were calculated from the average of I-GAIS scores from three expert evaluators. Error bars are the standard deviation. GAIS is a 7-point scale ranging from +3 to −3, with +3 indicating "very much improved" and −3 indicating "very much worse.".

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I-GAIS scores were as high as 2.7, with many subjects (40%) achieving scores above 2 ("much improved").

3.3 | LWSS

The expert evaluators assessed the LWSS grade for the NLF, marionette lines, and lip lines of each subject before and after MCT treatment. At baseline, the mean (SD) LWSS-NLF grade was 3.13 (0.49), indicating moderately deep to deep wrinkles. The mean (SD) change from baseline in LWSS-NLF grade was 1.1 (0.46). All subjects had some degree of improvement in LWSS-NLF, and 60% of subjects experienced > 1 point improvement (Figure 2).

At baseline, the mean (SD) LWSS-Marionette grade was 3.4 (0.6), indicating moderately deep to deep wrinkles. The mean (SD) change from baseline in LWSS-Marionette grade was 1.3 (0.3). All subjects had improvement in LWSS-Marionette grade, and 80% of subjects experienced > 1-point improvement, with one subject achieving a mean improvement of 2.3 points (Figure 3).

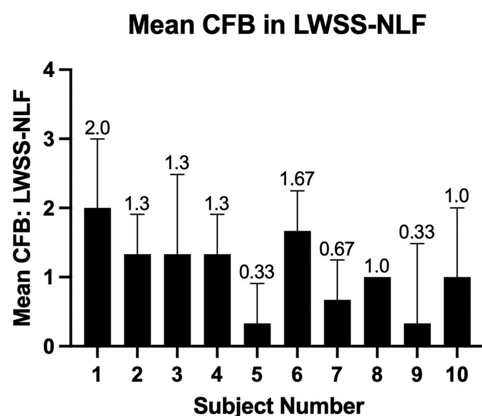

FIGURE 2 | Mean Change From Baseline in LWSS-NLF Grade Per Subject. Mean scores were calculated from the average of LWSS-NLF scores from three expert evaluators. Error bars are the standard deviation.

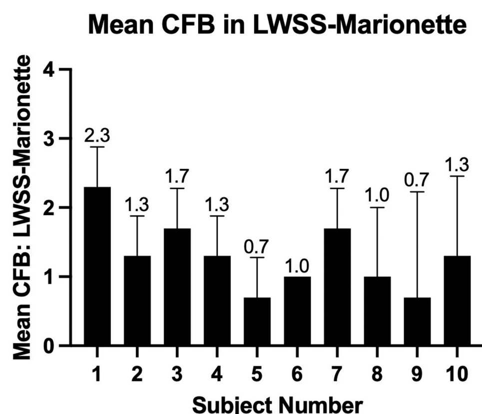

FIGURE 3 | Change From Baseline in LWSS-Marionette Grade Per Subject. Mean scores were calculated from the average of the LWSS-Marionette scores from three expert evaluators. Error bars are the standard deviation.

The mean (SD) LWSS-Lip Lines grade was 2.13 (0.51) at baseline, indicating shallow to moderately deep wrinkles in this area for most subjects. The mean (SD) change from baseline in the LWSS-Lip Lines grade was 0.6 (0.35). Most (90%) subjects had improvement in LWSS-Lip Lines grade, with 30% achieving > 1-point improvement (Figure 4).

3.4 | Subject and Clinical Reported Adverse Events

Thirty (30%) of study subjects reported post-treatment purpura at follow-up visits ranging from 1 to 5 days post-procedure, with all instances completely resolved within 2 weeks of treatment. Erythema, ranging from mild to moderate, was noted in 40 (60%) of study subjects at visits ranging from 1 to 7 days post procedure, and this number fell to 20 (20%) at follow-up visits ranging from 30 to 90 days post procedure. Importantly, no instances of infection or scarring were reported by study subjects or the treating clinician.

4 | Discussion

Treatment of the lower face, in particular rhytids and laxity, requires the challenging balance of efficacy, safety and natural-looking results. While a surgical facelift is the gold standard for reducing lax tissue, it often fails to improve the appearance of the perioral area and deep rhytids such as the NLF and marionette lines. Additionally, traditional facial surgery is invasive, carries unique risks like complications and/or scarring, and can require significant healing time [7–9]. Lastly, many subjects, even those open to surgery, prefer and seek out less invasive procedures. The use of fillers to treat deep rhytids and volume loss has increased significantly more recently as part of the demand for minimally invasive procedures, eclipsing the demand for surgical interventions. However, injectable fillers can also come with serious side effects, including vascular occlusion, blindness, infections and filler reactions. Additionally, the use of these products requires a high level of expertise, the lack of which can lead to unnatural-looking outcomes. Current nonsurgical treatment options, including energy-based devices (ablative and non-ablative lasers, radiofrequency,

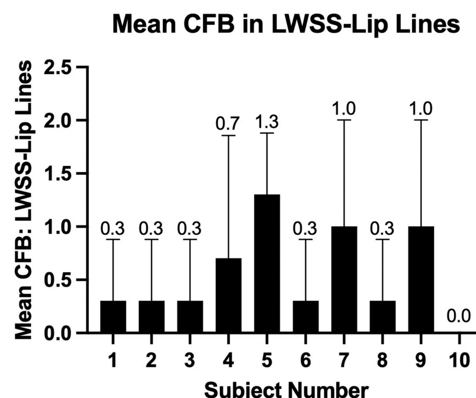

FIGURE 4 | Change From Baseline in LWSS-Lip Lines Grade Per Subject. Mean scores were calculated from the average of the LWSS-Lip Lines scores from three expert evaluators. Error bars are the standard deviation.

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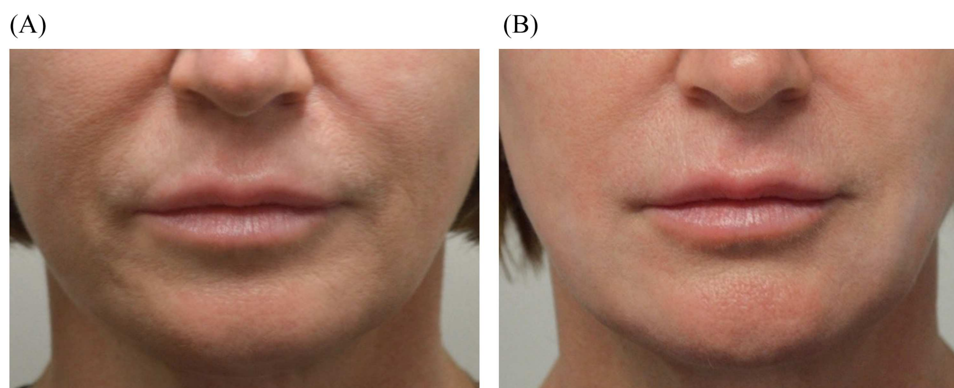

FIGURE 5 | A 57-year-old female subject before (A) and 180 days after (B) 2 treatments, spaced 6 weeks apart, of mechanical dermal Micro-Coring technology in the lower face. Treatment included from 5% to 7% skin removal and a coring depth of 4 mm. Treatment one removed 5004 cores and treatment 2 removed 6002 cores.

microfocused ultrasound), and microneedling, have also been used to rejuvenate the lower face but have yielded inconsistent results in treating rhytids and laxity, especially in the lower face and perioral area.

The MCT device for non-surgical skin removal can remove and tighten lax skin and minimize the appearance of wrinkles. The device's novel mechanism for microexcision of full-thickness skin columns is complemented by the wound-healing response, which induces both collagen and elastin [10]. This retrospective study indicates that MCT treatment results in improvements in both wrinkle severity and global appearance in a real-world setting. Subjects treated with MCT showed consistent improvement across the facial treatment areas (NLF, marionette lines, and lip lines) with the various assessment scales used in this study (I-GAIS and LWSS, including many achieving greater than 1 point improvement in LWSS scores. Because the original pivotal studies that led to FDA clearance of MCT only measured improvement of wrinkles on the cheek, our initial clinical observations that subjects treated with MCT also had tightened, injectable filler-like effects on the nasolabial and marionette folds, as well as perioral rhytids were of interest, especially given how difficult these areas can be to manage with fillers. For example, nasolabial fold effacement often results in excessive volume in the midface and an unnatural esthetic. MCT, on the other hand, is able to address this concern consistently in a wide range of subjects without adding volume, a feature of treatment that appeals to many subjects. A representative image of treatment results is shown in Figure 5.

Taken together, the findings here confirm that MCT is an effective non-surgical treatment approach for wrinkles and laxity in the mid to lower face, suggesting that it could also be a potential alternative to treatment with dermal fillers. Furthermore, significant outcomes can be achieved with 1–2 treatments. Though prior studies of MCT have evaluated changes in wrinkle severity after a series of three treatments, in this study, the majority (60%) of subjects underwent only one treatment, suggesting that subjects can achieve substantial, clinically meaningful results after a single treatment. The most commonly reported adverse events were noted to be bruising and lingering erythema which are minor and common adverse events with laser and energy-based device treatments of the skin. The use of a vascular laser can help mitigate these minor side effects.

While all subjects experienced positive outcomes from MCT, the degree of response varied from subject to subject. Some variability in the degree of improvement observed may be due, in part, to the severity of the rated area at baseline. For example, a subject without substantial lip lines is unlikely to see an improvement, and for subjects who are severe at baseline and have some improvement may be satisfied and have an improved global appearance without substantial improvement on the rating scale. In addition, variability could be influenced by differences in rater scores. These factors aside, however, clinically there is some variability in subject response to treatment, with some subjects having modest improvement and others near surgical results. Thus far, outcome does not appear to be related to age or baseline severity. Potential considerations include wound healing dynamics, inflammatory profile, skin quality and thickness, or previous subject exposure to injectable treatment. Further research into subject characteristics will help inform subject selection and management of subject expectations.

This study has limitations. The small sample size limits the conclusions that can be drawn from the data, though it is encouraging that all subjects had positive outcomes, especially given the rigorous methodology used for blinded grading. All included subjects were female, which may limit the applicability of these findings to male subjects. Future research should focus on recruiting male subjects as well as seeking to understand the key drivers of response and if it is possible to predict the number of treatments needed for optimal effect. Finally, this study is subject to the limitations inherent to a real-world, retrospective study, including the potential for selection bias.

5 | Conclusions

MCT is a novel and effective method for non-surgical skin removal. Data from this retrospective study indicate that subjects treated using MCT experienced positive measurable outcomes, and that MCT may serve as an additional treatment option to consider when contemplating injectable filler.

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Basset, PhD, Principal Medvantage LLC, Atlanta, Georgia, under the direction of the authors. Funding for this support was provided by Cytrellis Biosystems Inc.

Consent

All subjects provided written informed consent before undergoing any study-related procedures and provided written consent for the use of their photographs. No animal subjects were involved in this research.

Ethics Statement

All subjects signed informed consent adhering to the guidelines outlined US Health Insurance Portability and Accountability Act of 1997 (HIPAA) and International Conference on Harmonization E6 Good Clinical Practice. All criteria pursuant to 45 CFR 46.116(d) and 45 CFR 164.512(i)(1)(i) were met. The study was reviewed and approved by the Allendale IRB and was conducted in accordance with all applicable human subject research requirements as well as applicable federal regulations.

Conflicts of Interest

OA is a consultant and Advisory Board member for Cytrellis Biosystems Inc. Consultant for Galderma and Allergan; MA receives royalties from Cytrellis Biosystems Inc. and holds intellectual property with Cytrellis Biosystems Inc. HRJ is a consultant and Advisory Board member for Cytrellis Biosystems Inc. and is a consultant and investigator for Galderma and Allergan.

Data Availability Statement

Research data are not shared.

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