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Treating Striae Distensae Albae in Asians: Efficacy and Safety of Combined MFU-V and CaHA

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Background: This study evaluated the efficacy and safety of a single treatment combining microfocused ultrasound with visualization (MFU-V) and subdermal diluted calcium hydroxylapatite with lidocaine (CaHA+) for Striae Distensae Albae (SDA).

Methods: Ten prospectively enrolled women with abdominal, back or thigh SDA were treated with MFU-V at 3 focal depths (4.5, 3.0, and 1.5 mm), followed by 3–6 mL of diluted CaHA+ (1:1 ratio) in the same session. Outcomes were assessed at 1 month, 3 months, and 5 months postprocedure using a 5-point quartile grading scale, an SDA scoring scale, a 10-point visual analog score, and a global aesthetic improvement scale.

Results: All patients exhibited improvement in SDA at 3 months, with further improvement at 6 months. Physicians' assessment with the quartile grading scale showed that 8 patients improved moderately, whereas 2 had good improvement at 6 months. The mean overall SDA score was 11.6 at baseline, 11.1 (not significant) at 1 month, 7.9 ($P = 0.005$) at 3 months, and 6.2 ($P = 0.005$) at 6 months. All patients had improved global aesthetic improvement scale at 3 and 6 months, with 4 patients being much improved, and 3 patients being very much improved at 6 months. At the end of the study, all patients were less bothered with their SDA compared with baseline with a mean reduction of 2.7 in visual analog score, and all patients were satisfied or very satisfied with the treatment. No adverse events occurred.

Conclusion: A single combination treatment of MFU-V and diluted CaHA+ improves SDA without side effects and may be considered for patients seeking to minimize SDA. *(Plast Reconstr Surg Glob Open 2021;9:e3429; doi: 10.1097/GOX.0000000000003429; Published online 25 February 2021.)*

INTRODUCTION

Striae distensae (SD) are commonly observed in adolescents (with an incidence of 6%–86%),[1] in women during and after pregnancy (43%–88%), and in individuals with excessive weight gain (43%) or those with side effects after topical steroid usage. The condition begins as a pink or purple band (SD rubrae) which may be pruritic but eventually develops into a white, atrophic dermal scar (SD albae [SDA]).[2] The exact mechanism is unknown but is thought to be due to a combination of factors, among them hormonal, genetic, lateral stretching, chronic steroid use, and structural skin changes.[3] SD are often seen on the abdomen, buttocks, breasts, thighs, and the back.

Histologically, SD resemble dermal scars with epidermal atrophy, loss of rete ridges, and the absence of skin appendages.[4] There is altered dermal connective tissue framework involving components of extracellular matrix, namely fibrillin, elastin, fibronectin, and collagen.[5] Treatment should therefore be targeted to stimulate collagen and elastin production.

Many modalities have been attempted for the treatment of SDA but yielded varying results. These include topical creams,[6] chemical peels,[7] microdermabrasion,[8] pulse dye laser,[9] diode laser,[10] ablative and nonablative lasers,[11] intense pulse light,[12] microneedling,[13] fractionated microneedle radiofrequency,[14] and injections of dermal fillers and growth factors. A review of current treatment methods shows that, although therapeutic options are numerous, there is no single modality that has been far more consistent than the rest.[15,16] Fractional photothermolysis, despite the smaller number of preliminary

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studies, shows much promise in dermal remodeling and subsequent improvement of white and pigmented SD. However, a series of treatments are needed to obtain some level of improvement.[15,16]

The objective of this study was to evaluate the efficacy and safety of a single combination treatment of SDA using microfocused ultrasound with visualization (MFU-V; Ultherapy, Merz North America, Inc. Raleigh, N.C.) followed immediately by subdermal injections of diluted calcium hydroxylapatite with lidocaine (CaHA+, Radiesse (+), Merz North America, Inc.).

METHODS

Patients

Ten healthy Asian women with SDA were enrolled into the study. None of the patients had any previous treatment or any new SDA in the prior 2 years. Six patients presented with SDA on the abdomen (from previous pregnancy), 1 had SDA on the back (from puberty), 2 had SDA on their thighs (from historical topical steroid), and 1 had SDA on her legs (from topical steroid use). All patients were informed of the risks, benefits, and possible complications of the treatment and follow-up schedule. All patients signed an informed consent form and agreed to follow the treatment and follow-up schedule. The study was performed in accordance with the principles of the Declaration of Helsinki. Patients were instructed to refrain from using any further clinical intervention in the study area for 6 months after the initial treatment.

Treatments

The area with the SDA was identified and photographed with the patient in standing and prone positions. A topical anesthetic mixture (20% benzocaine, 6% lidocaine, and 4% tetracaine) was applied to the area under occlusion for 20 minutes. The anesthetic mixture was cleaned off and the area was marked with treatment grids measuring 2.5 cm × 2.5 cm. The SDA were first treated with MFU-V using 3 transducers with a frequency of either 4, 7, or 10 MHz, and a focal depth of either 4.5, 3.0, and 1.5 mm, respectively. Depending on the surface area of the SDA, each patient was treated with a total of 480–880 lines, of which 200–400 lines were delivered at a depth of 4.5 mm, 200–400 lines were delivered at a depth of 3.0 mm, and 80 lines were delivered at a depth of 1.5 mm. CaHA+ was diluted with normal saline in a ratio of 1:1. Immediately after MFU-V treatment, the area was cleaned. Depending on the surface area of the SDA, a total of 3–6 mL of diluted CaHA+ were injected subdermally along the SDA and adjacent areas, using a fanning technique and a 25G, 48-mm-long cannula.

Evaluations

Standardized photographs were taken with a Sony A6400 camera and room lighting without camera flash. Photographs were taken at baseline and at the 1 month, 3 months, and 6 months postprocedure. Photographs at 3 and 6 months were evaluated by 3 independent reviewers using a grading scale to make qualitative comparisons and score the improvement of SDA. Grading was done with the patient in standing and prone positions at each follow-up visit compared with baseline. We employed a 5-point quartile grading scale, which has also been used to assess striae in published studies.[12,13] SDA were graded as 0 (no change), 1 (1%–25%; mild improvement), 2 (26%–50%; moderate improvement), 3 (51%–75%; good improvement), and 4 (76%–100%; excellent improvement). The improvement in SDA was further analyzed by the investigator at 0, 1, 3, and 6 months using an SDA scoring scale (Table 1) that was devised based on previously published scales.[11,17] Striae with the maximum width were identified and measured at each follow-up, and their appearance in terms of color mismatch, finish (matt or shiny), and contour were documented by the investigator at each follow-up. For each parameter, *P* values were calculated as the difference between the baseline value and the value at each follow-up timepoint (1, 3, or 6 months). Where *P* values could not be obtained (ie, not applicable or "n/a"), the values were assessed again using McNemar's chi-square test. The Wilcoxon Rank Sum test was used to determine if the change in the overall SDA score from baseline (month 0) to month 1, month 3, and month 6 was statistically significant for the cohort of 10 subjects at a 95% confidence level when compared with baseline.

Treatment efficacy was rated by each patient using the 10-point patient visual analog score (VAS) according to measures described in Table 2 and the patient global aesthetic improvement scale (GAIS; Table 3), whereas patient satisfaction was also evaluated at 1, 3, and 6 months (Table 4). The occurrence of side effects was recorded at each follow-up.

RESULTS

Ten healthy women presented with SDA and were recruited into the study (Table 5). Nine women were of Chinese ethnicity, and 1 was of Malay ethnicity, with a mean age of 36 years (range: 27–58 years). The duration of existence of the SDA was from 3 to 35 years (mean duration: 8 years). None of the patients had any previous treatment for SDA and none had developed any new SDA in the past 2 years. Six patients presented with SDA on the

Table 1. SDA Scoring Scale

Parameters	Score
Decrease in width of widest SDA	
Widest striae (baseline)	5
1 mm width	4
2 mm width	3
3 mm width	2
4 mm width	1
Color	
Skin color	1
Slight mismatch	2
Obvious mismatch	3
Finish	
Matte	1
Shiny	2
Contour	
Flush with surrounding skin	1
Slight indentation (atrophy)	2
Obvious indentation (atrophy)	3

Parameters assessed were the decrease in the widest width of the SDA, and the color, finish, and contour of the SDA.

Table 2. Patient VAS

1	2	3	4	5	6	7	8	9	10

Example of patients' self-assessment of the appearance of their SDA from a scale of 1 (not bothered) to 10 (significantly bothered).
From a scale of 1 to 10, grade the appearance of your stretch marks.
1: I am not bothered by the appearance.
10: The appearance bothers me significantly.

Table 3. Patient GAIS

Please Tick Here	Rating	Description
4	Very much improved	Optimal cosmetic result from initial condition
3	Much improved	Marked improvement in appearance from initial condition, but not completely optimal
2	Improved	Obvious improvement in appearance from initial condition
1	No change	Appearance is essentially the same as the original condition
0	Worse	Appearance is worse than the original condition

Criteria and rating scale used for patients' self-assessment of the improvement of their SDA.

Table 4. Patient Satisfaction

Please Tick Here	Description
5	Very satisfied
4	Satisfied
3	Neither satisfied nor unsatisfied
2	Unsatisfied
1	Very unsatisfied

Example of patients' self-assessment of their treatment satisfaction on a 5-point scale.

Table 5. Mean Improvement in SDA with 5-point Grading Scale

		Improvement in SDA			
		At 3 mo		At 6 mo	
Patient	Location of SDA	Standing	Prone	Standing	Prone
1	Lower abdomen (R and L)	1	2	3	3
2	Right abdomen (u and l)	1	1	2	2
3	Upper abdomen (u and l)	1	1	2	2
4	Lower abdomen (R and L)	1	1	2	2
5	Lower abdomen (R and L)	1	1	2	2
6	Lower abdomen (R and L)	1	1	2	2
7	Back (R and L)	1	1	2	2
8	Thigh (R and L)	2	2	3	3
9	Thigh (R and L)	1	1	2	2
10	Leg (R and L)	1	1	2	2

SDA was graded as 0 for no improvement, 1 for mild improvement (1%–25%), 2 for moderate improvement (26%–50%), 3 for good improvement (51%–75%), and 4 for excellent improvement (76%–100%).
l, lower; L, left; R, right; u, upper.

abdomen (from the previous pregnancy), 1 had SDA on the back (from puberty), 2 had SDA on their thighs (from topical steroid use in the past), and one had SDA on the legs (from topical steroid use).

The 3 independent reviewers observed improvement in their SDA in all patients receiving a single session of combination MFU-V/CaHA treatment at 3 months and greater improvements at 6 months (Table 5). At 3 months, all patients had at least a mild improvement (1%–25%). At 6 months, 8 patients had a moderate to good improvement (25%–50%), whereas 2 had a good improvement (51%–75%). There is no difference in improvement whether the patients were photographed upright or prone. Patients in Figures 1 and 2 demonstrate good improvement in SDA, whereas patients in Figures 3 and 4 demonstrate a moderate improvement in SDA, although we note that the improvement at 6 months is superior to that at 3 months.

At 0, 1, 3, and 6 months, the investigator scored the decrease in width of the widest SDA, the color, the finish, the contour, and texture of the SDA (Table 1). The mean SDA score was 11.6 at baseline, decreasing to 11.1 at 1-month follow-up (not significant), 7.9 at the third month follow-up and 6.2 at the sixth month follow-up (both significant, $P = 0.05$; Table 6). Wilcoxon Rank Sum testing of the overall SDA scores at 0, 1, 3, and 6 months show that although the improvement in score was not significant at 1 month, it was significant at 3 and 6 months (both $P = 0.005$). Details on the individual SDA parameters used to evaluate the overall SDA Score are shown in **Table S1.** (See **Table S1, Supplemental Digital Content 1**, individual SDA parameters for evaluation of overall SDA score. Scores are assessed according to measures described in Table 1. **http://links.lww.com/PRSGO/B587**.)

Patient VAS scoring showed that at 1 month, 2 patients were less bothered with their SDA than they were at baseline. At 3 months, this increased to 7 patients while at 6 months, all patients recorded improvement in their VAS. At the end of the study, patient VAS was reduced by 1–6 points, with a mean reduction of 2.7 points from 7.0 at baseline to 4.3 at 6 months (Table 7).

Improvements in GAIS were recorded by 3 patients at 1 month and by all 10 patients at 3 months, 2 of whom recorded GAIS as much improved. At 6 months, 3 patients had improved GAIS, 4 had much improved GAIS, and 3 had very much improved GAIS (Table 7).

All patients noted improved SDA at 3 months and 8 were satisfied with the improvement. At 6 months, all patients were satisfied (5 patients) or very satisfied (5 patients) with the treatment (Table 7).

Both the investigator and the patients noted that improvement in the SDA was not obvious in some patients at 1 month. However, all patients had improvement in the SDA at 3 months and the improvement was better at 6 months, consistent with the statistical significance of the overall SDA scores at these timepoints. No side effects were observed during the follow-up sessions. Some bruises were seen immediately after the filler injection in 4 patients, all of which resolved without treatment.

DISCUSSION

SDA are atrophic dermal scars, and treatment should be targeted to stimulate collagen and elastin production to replace scar tissues. The rationale of combining MFU-V and diluted CaHA in treating SDA is in their ability to stimulate neocollagenesis and remodeling of dermal tissue. In the skin, MFU-V heats the tissue to approximately

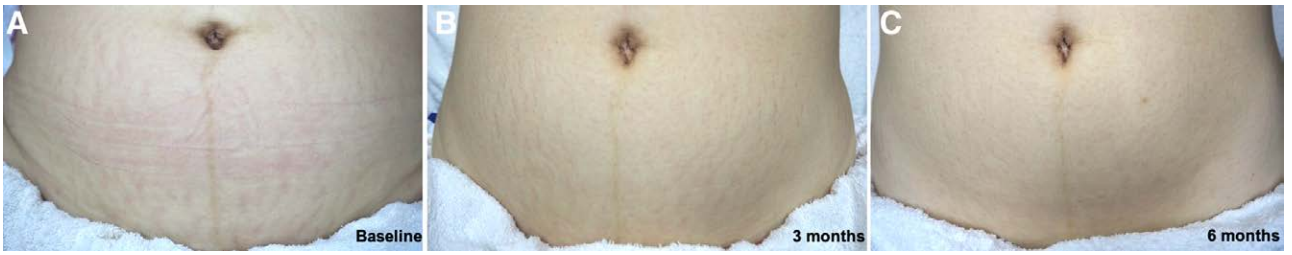

Fig. 1. Patient demonstrating good improvement of SDA on the lower abdomen following combination treatment. Patient was photographed at baseline (A), 3 months (B), and 6 months (C) posttreatment with a single session of MFU-V (400 lines with the 4-MHz transducer, 400 lines with the 7=MHz transducer, and 80 lines with the 10-MHz transducer) and 6 mL of CaHA (diluted 1:1).

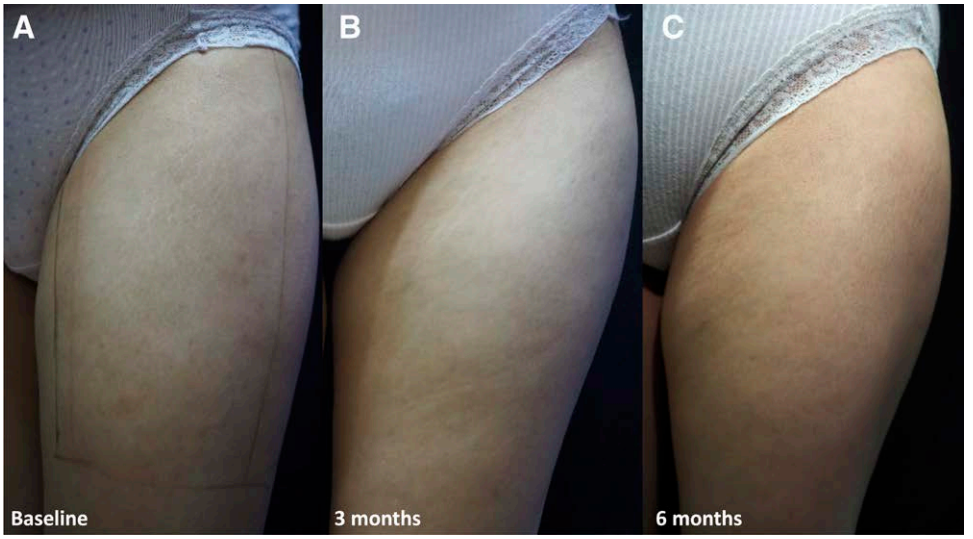

Fig. 2. Patient demonstrating good improvement of SDA on the upper thighs following combination treatment. Patient was photographed at baseline (A), 3 months (B) and 6 months (C) posttreatment with a single session of MFU-V (200 lines with the 4-MHz transducer, 200 lines with the 7-MHz transducer, and 80 lines with the 10-MHz transducer) and 3 mL of CaHA (diluted 1:1).

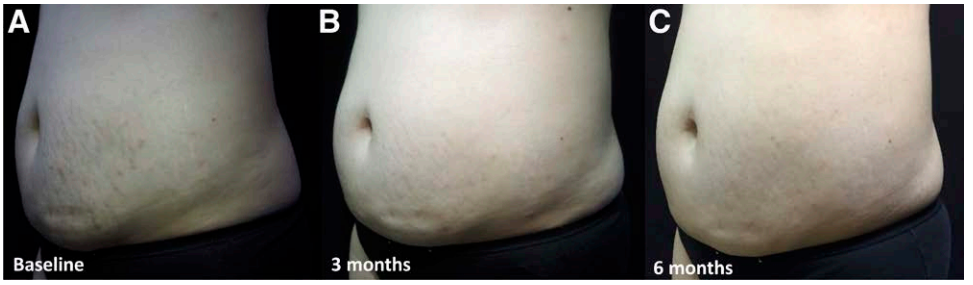

Fig. 3. Patient demonstrating moderate improvement of SDA on the lower abdomen following combination treatment. Patient was photographed at baseline (A), 3 months (B) and 6 months (C) posttreatment with a single session of MFU-V (200 lines with the 4-MHz transducer, 200 lines with the 7-MHz transducer, and 80 lines with the 10-MHz transducer) and 3 mL of CaHA (diluted 1:1).

60°C–70°C, producing small (<1 mm^3) zones of thermal coagulation within the dermis and subdermis. This fractional heating initiates a wound healing response and stimulates neocollagenesis and collagen remodeling.[16] Real-time visualization of the delivered ultrasound energy ensures that there is good coupling of the ultrasound transducer, gel, and skin surface, and that thermal coagulation points are created at the correct tissue depths, which contributes to the safety and efficacy of the treatment. CaHA and diluted CaHA are biostimulatory fillers consisting of microspheres of CaHA (30%) suspended in an aqueous gel of carboxymethylcellulose (70%). When injected, CaHA behaves as a filler and induces neocollagenesis (and gradually replaces collagen type III with collagen type I), neoelastogenesis, and angiogenesis.[18–21] Combining these 2 treatments produces a synergistic effect. Histologic analysis

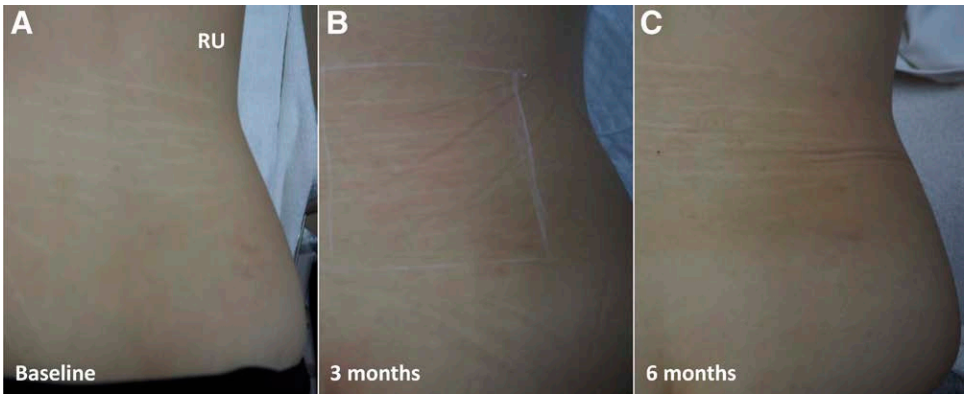

Fig. 4. Patient demonstrating moderate improvement of SDA on the back following combination treatment. Patient was photographed at baseline (A), 3 months (B) and 6 months (C) posttreatment with a single session of MFU-V (200 lines with the 4-MHz transducer, 200 lines with the 7-MHz transducer, and 80 lines with the 10-MHz transducer) and 3 mL of CaHA (diluted 1:1).

Table 6. Overall SDA Score

	Individual SDA Scores			
Months	**Baseline (0)**	**1**	**3**	**6**
Patient 1	13	12	7	4
Patient 2	12	12	9	7
Patient 3	12	12	8	7
Patient 4	13	13	11	7
Patient 5	12	12	9	7
Patient 6	11	11	7	7
Patient 7	12	12	6	5
Patient 8	10	10	7	5
Patient 9	10	10	7	6
Patient 10	13	10	8	7
Wilcoxon ranked-sum test for SDA score				
Mean SDA score	11.6	11.1	7.9	6.2
P	—	0.084	0.005	0.005

Overall SDA score was analyzed for significance according to the Wilcoxon ranked-sum test. Line plots were constructed to demonstrate the decreasing trend in mean overall SDA score for the entire study cohort. Parameters assessed to obtain the overall SDA score at 1, 3, and 6 months included the decrease in the width of the widest SDA, and the color, finish, and contours of the SDA (See **Table S1, Supplemental Digital Content 1**, individual SDA parameters for evaluation of overall SDA score. Scores are assessed according to measures described in Table 1 **http://links.lww.com/PRSGO/B587**).

Table 7. Individual Patients' Evaluations

	VAS				GAIS			Patient Satisfaction		
Location of SDA	**0 mo**	**1 mo**	**3 mo**	**6 mo**	**1 mo**	**3 mo**	**6 mo**	**1 mo**	**3 mo**	**6 mo**
Lower abdomen (R and L)	7	3	4	1	I	MI	VMI	S	S	VS
Right abdomen (U and L)	5	4	4	3	I	I	MI	S	S	S
Upper abdomen (U and L)	6	6	4	3	NC	I	VMI	N	S	VS
Lower abdomen (R and L)	10	10	10	9	NC	I	I	N	S	S
Lower abdomen (R and L)	8	8	7	5	NC	I	I	N	N	S
Lower abdomen (R and L)	4	4	4	3	NC	I	I	N	N	S
Back (R and L)	10	10	10	5	NC	I	MI	N	S	S
Thigh (R and L)	6	6	5	4	NC	MI	VMI	N	S	VS
Thigh (R and L)	8	8	7	6	I	I	MI	S	S	VS
Leg (R and L)	6	6	5	4	NC	I	MI	N	S	VS
Overall trend of parameter										

Each patient's satisfaction is shown based on the location of their SDA and their follow-up at either 3 or 6 months post MFU-V/CaHA treatment. Graphical representations of tabulated data show improvements in their GAIS, satisfaction, and VAS by 6 months posttreatment.
I, improved; L, left; MI, much improved; N, neither satisfied nor unsatisfied; NC, no change (0); R, right; S, satisfied; VMI, very much improved; VS, very satisfied.

of skin samples from combined MFU-V/CaHA treatment sites at 6 months demonstrated increased dermal thickening and more dense collagen fibers than sites treated with CaHA alone or MFU-V alone.[22]

A review of current treatment methods for SDA show that combining MFU-V and diluted CaHA as a single treatment for SDA has not been reported. Among the various therapeutic options, the more popular treatments include laser, both ablative and nonablative, fractionated microneedle radiofrequency, and microneedling.[14,15] All of these options require multiple treatment sessions to improve SDA. Fractional lasers, both ablative and nonablative, typically require 3–5 sessions at 2–4 weekly intervals to improve SDA.[14,15]

An advantage of using MFU-V is that the skin color and chromophores have no influence on the treatment, as the absorption of ultrasound energy is independent of the melanin content of the skin, or on the epidermis, where melanocytes are found. The incidence of postinflammatory hyperpigmentation (PIH) is high when treating SDA with fractional lasers or fractionated microneedle radiofrequency in patients with Fitzpatrick skin type IV and above. The 450-nm diode laser has a 65% incidence of PIH, whereas the pulse dye laser has 100% incidence of PIH when treating SDA in skin type IV and V, making both lasers unsuitable for such patients. In this study, the only side effect observed was a temporary bruising that self-resolved.[8,9] The MFU-V/CaHA combination treatment did not cause PIH and is thus safe for Asian patients.

Casabona and Marchese[17] have treated SDA with either MFU-V or CaHA as individual treatments at separate time points. In one study,[17] up to 3 mL of lidocaine-diluted CaHA (1:1) was injected into stria in the buttocks, thighs, knees, abdomen, and breasts of 25 patients, followed by microneedling and topical ascorbic acid. Striae were improved at 1-month follow-up based on a reduction in Manchester Scar Scale scoring, with most patients being very satisfied with their results. In another study, 20 patients with persisting skin atrophy following previous CaHA, ascorbic acid, and microneedling treatments were treated at 3.0 and 1.5 mm

with 7 and 10 MHz transducers, respectively.[23] At 90 days, these patients experienced further reduction in Manchester Scar Scale scores and an increase in patient satisfaction, with 70% of patients being very satisfied with their treatment outcomes. Taken together, these modalities demonstrated efficacy at improving striae when used separately and on different days of treatments. The same author also used the same combination of modalities within a single treatment session on the same day to improve skin laxity and cellulite appearance.[24] The MFU-V/CaHA combination produced statistically significant improvements in cellulite severity and appearance of skin dimples after only a single procedure. Histology of skin samples taken at day 90 showed a 251% increase in collagen type III fibers compared with the control. Although no histology was done in the present study, we assume a significant increase in collagen type III fibers in the SDA at 3 months as well. Based on wound healing studies, the tissue remodeling process is ongoing and may take up to a year for collagen type III fibers to be gradually replaced by type I fibers, potentially explaining why the improvement in SDA at 6 months exceeds that at 3 months.

This study was limited by its small sample size and the lack of an objective instrument to standardize the evaluation of outcomes. Therefore, we devised an SDA scoring scale by integrating key elements of the Manchester Scar Scale with the change in width of the widest SDA.[11,17] Further studies are thus needed to validate our scale and objectively analyze histological changes, as well as to determine the optimal number of treatment lines for MFU-V and the optimal volume of CaHA used.

CONCLUSIONS

Many treatment modalities have been used to treat SDA but produced varying results. We now show that it is possible to combine MFU-V and diluted CaHA+ within a single treatment session in 1 day, to safely and effectively improve SDA for up to 6 months and without the risk of PIH. It can thus be considered for the treatment of SDA in Asian patients.

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