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High-speed low-pain micro-focused ultrasound tightening of the lower face and neck

Introduction

There is strong demand for non-surgical tightening procedures, especially to the jowl and neck areas, for a more youthful mandibular and neck contour (jawline). Popular procedures such as filler and botulinum toxin injections mainly target the face leaving the jowl and neck areas increasingly lagging with time. Non-surgical jowl and neck lifting procedures include skin resurfacing and various skin heating devices such as infrared, radiofrequency and micro-focused ultrasound (MFU).[1-4] Ablative resurfacing can tighten the skin but is largely limited by the recovery time and potential complications such as pigmentary alteration and scarring. On the other hand, non-invasive skin tightening devices are limited by subtle and inconsistent results, long treatment times and significant procedural discomfort.[5] In 2016, the Australian Therapeutic Goods and Services (TGA) approved a new high-speed, low-pain MFU device (Ultraformer 3) for skin tightening. This study is an evaluation of the safety, efficacy and patient satisfaction rate of Ultraformer 3 on lower face and neck laxity.

Mechanism of action of Ultraformer 3

MFU can visibly tighten skin laxity in excess of 80% of cases.[6-8] MFU targets the SMAS (facelifting plane) for more natural and durable skin tightening. The delivery of the MFU is not associated with any epidermal injury and therefore does not require any recovery or down time. The focused and precise energy delivery is associated with significantly less side-effects such as burns, blisters, diffuse heating with collateral damage to adjacent epidermis or adipose tissue.

The Ultraformer 3 has a patented ultrasound focussing and delivery method that precisely targets tissue at adjustable depths of 4.5mm, 3mm and 1.5mm depending on the transducer cartridge selected, with corresponding frequencies of 4MHz, 7Mhz and 7 MHz respectively. In accordance to ultrasound physics, the higher frequency transducer cartridge corresponds to a more superficial focal depth. The Ultraformer 3 uses a proprietary mechanism enabling targeting a depth of 1.5mm without exceeding 7Mhz compared to conventional non-Ultraformer technology. The thermal injury zone (TIZ) is spaced between 1-2mm apart and the energy can be varied from 0.1J to 1.5J. The pulse duration for the 4.5mm cartridge range from 22ms (0.1J) to 33ms (1.5J) and the pulse duration for the 3mm cartridge range from 43ms (0.1J) to 65ms (1.5J). The relatively low pulse duration combined with adjustable energy allows precise and focussed energy delivery without excessive collateral damage beyond the TIZ. The patented technology also enables faster treatment times with less procedural discomfort.

The objective of this study is to prospectively evaluate the efficacy and safety of of the latest MFU (Ultraformer 3) for mandibular and neck contouring in patients with age-related laxity. We also undertook a patient satisfaction survey on the Ultraformer 3 procedure.

Methods

All 20 enrolled patients satisfied the inclusion/ exclusion criteria of: age 40 years or more, no previous skin tightening treatment in last 12 months, no neck or lower face botulinum injections for the last 6months and during the follow up period. Standardised face and neck photography was taken at baseline, immediately post-procedure and at subsequent follow-up at 6 weeks or more post-procedure. Patient satisfaction was assessed by a standardised survey performed at subsequent post-treatment follow-up visit (4 – 20 weeks). Procedural efficacy was rated by 2 blinded dermatologists examining baseline and post-procedural photos.

The skin tightening treatment was administered by 2 trained registered nurses using the Ultraformer 3 (Classys, Korea). All patients were pre-treated with 60 minutes of compound anaesthetic to the lower face and neck and intra-operative chilled air cooling (Cryojet) and the additional options of using inhaled nitrous oxide if required. The treatment areas were: (A) lower face and (B) upper neck: submental and submandibular regions (avoiding thyroid). The method of treatment is as follows: (A) lower face: 2 passes – 2 columns down and 2 columns across – first pass is parallel to the jawline and second pass is perpendicular (90 degrees) to the jawline, and (B) upper neck: 2 passes parallel to the mandibular jawline (bilateral) and submental region.

Results

The patient demographics were: 19 females and 1 male, age range: 49 to 69 years-old (mean 58.7 years-old). Almost all patients commented on some degree of skin contraction and improvement in facial and neck contours immediately post procedure. At follow-up (4 – 20 weeks), 75% of patients continue to report a high degree of satisfaction. 95% of patients found the procedure tolerable requiring only topical anaesthesia and chilled air (Cryojet) for pain control during treatment. None required oral or injectable anaesthesia and only one third of patients requested additional inhaled nitrous oxide. 85% of patients would consider having the Ultraformer 3 again in the future and 75% would recommend the procedure to a friend. The patient satisfaction survey is summarized in table 1.

	Strongly disagree (-2)	**Disagree (-1)**	**Uncertain (0)**	**Agree (1)**	**Strongly agree (2)**	**Weighted mean (-2 to 2)**	**Median score**
Q1. **I am satisfied with the outcome of the procedure**							
	0 respondent	1 respondent	4 respondents	7 respondents	8 respondents	1.1	Strongly agree
Q2. **I would consider having the procedure again in the future**							
	0 respondent	0 respondent	3 respondents	7 respondents	10 respondents	1.35	Strongly agree
Q3. **I would recommend this procedure to a friend**							
	0 respondent	0 respondent	5 respondents	6 respondents	9 respondents	1.2	Strongly agree
Q4. **I find the comfort level of the procedure to be:**							
	'very uncomfortable' 1 respondent	*'uncomfortable but bearable'* 7 respondents	*slightly uncomfortable'* 7 respondents	*'comfortable'* 4 respondents	*'very comfortable'* 1 respondent	-0.15	Slightly uncomfortable but bearable
Q5. **I find the duration of treatment:**							
	'much longer than expected' 0 respondent	*'longer than expected'* 1 respondent	*'about right'* 14 respondents	*'shorter than expected'* 3 respondents	*'much shorter than expected'* 2 respondents	0.3	About right

Table 1. Ultraformer patient satisfaction survey.

Two blinded dermatologists were asked to study a series of subject images consisting of baseline images, immediately post-procedure images and one or more follow-up images ranging from 4- to 20- weeks post-procedure (figures 1-4). The blinded dermatologists were then asked to pick out the 'best' (most improved) image, which correlated with the follow-up images in 71.4% of cases (5 out of 7 patients). The blinded dermatologists (D1 and D2) were also asked to pick out the 'worse' image, which correlated with the pre-procedure baseline images in 72.5% of cases. The blinded dermatologists' survey is summarised in table 2.

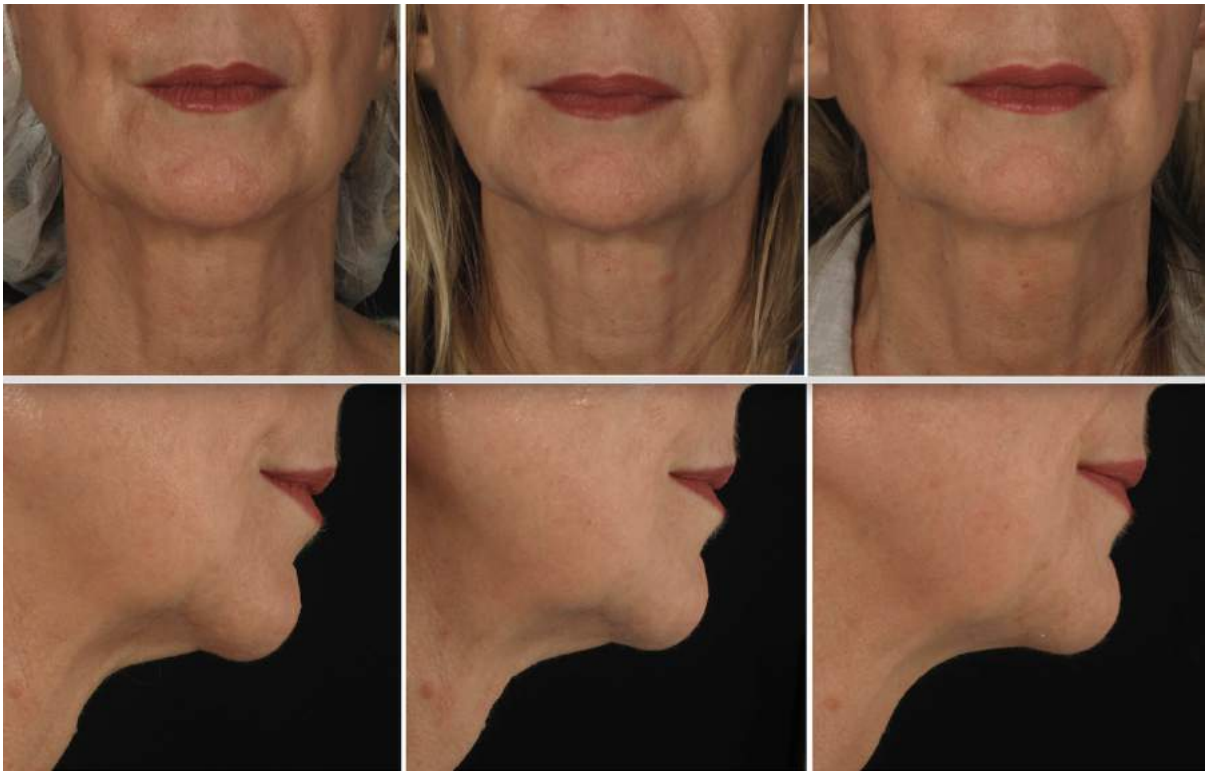

Figure 1: 59 year-old female at baseline, 1-month, 2-months post-procedure (left to right).

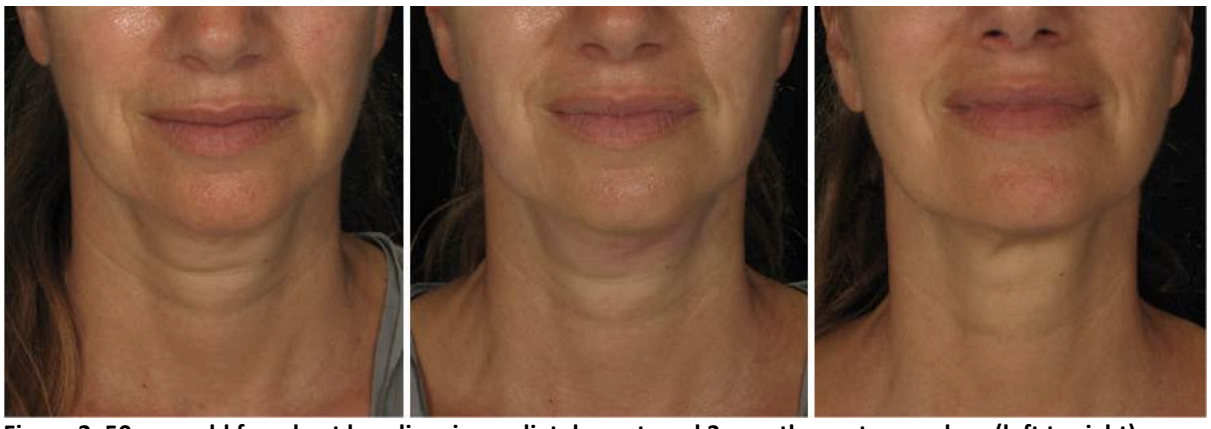

Figure 2. 50 year-old female at baseline, immediately post, and 3-months post procedure (left to right).

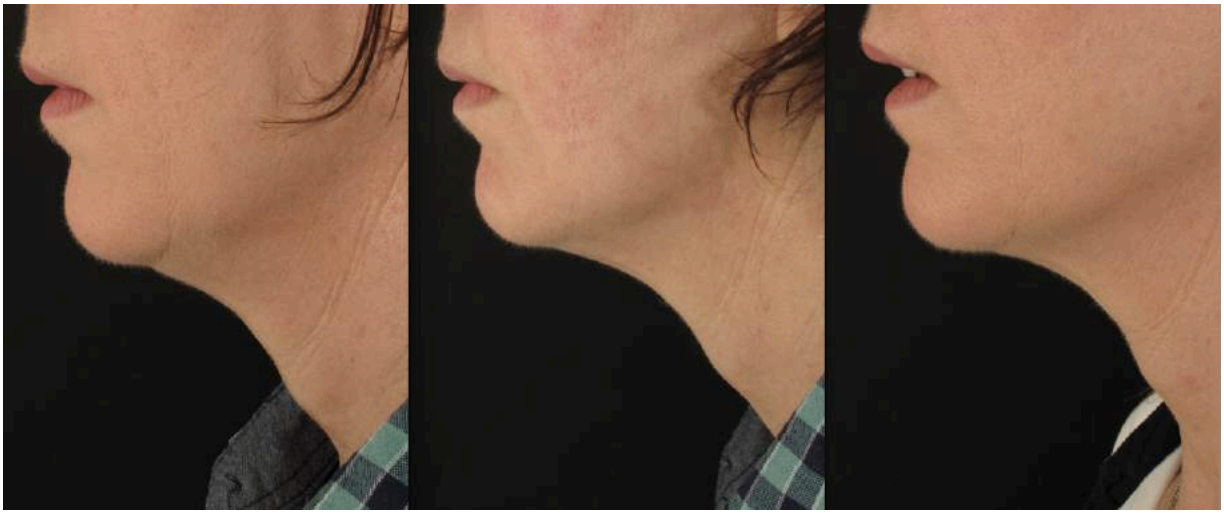

Figure 3. 50-year old female at baseline, immediately post, and 3-months post-procedure (left to right).

Case	Post (week)	D1* 'worse'	D2* 'worse'	D1** 'best'	D2** 'best'
1	0, 6, 20	0	0	1	0
2	0, 10	1	1	1	1
3	0, 4	0	1	0	1
4	0, 4	1	1	0	1
5	0, 6	1	0	1	0
6	0, 4, 8	1	0	1	1
19	0, 8	1	1	1	1
7	0	0	1		
8	0	1	1		
9	0	1	1		
10	0	1	1		
11	0	0	0		
12	0	0	0		
13	0	1	1		
14	0	1	1		
15	0	1	1		
16	0	0	1		
17	0	1	1		
18	0	1	1		
20	0	1	1		
		14/20 *	15/20*	5/7**	5/7**

*correctly identifies the baseline ('worse') picture. D1, D2 mean = 72.5%
** correctly identifies the best ('latest') picture. Di, D2 mean = 71.4%

Table 2: Blinded physician (dermatologists D1 and D2) survey.

There were no long term adverse events noted. Mild to moderate transient erythema is commonly seen post-procedure lasting approximately 30 minuets. One patient on fish oil developed mild bruising that resolved fully after a few days. There were 2 transient but

notable post-treatment effects: one patient had transient mild linear erythematous plaques for 24 hours after treatment and another patient had subtle asymmetry of smile for a few days after treatment, which fully resolved after one week.

Discussion

MFU has been used for skin tightening in facial and non-facial sites.[5,6,9,10] Upper face tightening for brow and eyelid laxity are easier to objectively measure using fixed landmarks such as pupils and eyebrows and have been subjected to studies with various skin tightening procedures including MIFU.[6] The jowl and neck areas are more difficult to consistently measure in the absence of an objective grading scale or readily identifiable landmark and studies have to rely on photographic changes and subjective patient self-assessment. We elected to study jowl and neck tightening because this is an area that is not easily treatable by other non-invasive techniques such as cosmetic injectables and non-MIFU skin tightening procedures. The aging jowl and neck is therefore of great concern to all cosmetic patients, with progressive lagging in these areas with the passage of time, relative to the mid- to upper- face, resulting in strong patient demand in our practice for jowl and neck tightening procedures.

The limitations of skin tightening devices include inconsistent results, need for multiple treatments, procedural discomfort, durability of results and costs.[5] Patient satisfaction rate for skin tightening procedures range from 31% for monopolar radiofrequency to 80% for MFU.[8,11] In our study, 75% of patients are satisfied with the treatment outcome and this high patient satisfaction rate in part translates to a desire for repeat procedures (85%) and referring the procedure to others (75%). Procedural tolerability is another important patient consideration for return visits. In this regard, Ultraformer 3 is notably different from non-Ultraformer MFU in that it is well tolerated - 95% reported the experience as either ‘very comfortable’, ‘comfortable’ or ‘slightly uncomfortable but bearable’. The average treatment time is less than 20 minutes and 70% of patients rated the treatment time to be ‘about right’ while another 25% rated the treatment time to be ‘shorter’ or ‘much shorter’ than expected. Pre-Ultraformer devices tend to be associated with a significant discomfort requiring oral anxiolytics and oral / intramuscular narcotic analgesics and is clearly a significant barrier to the uptake of pre-Ultraformer MFU treatments.[4]

The safety of MFU is well established with a very low reported incidence of adverse events. Overheating of the skin with inappropriately high energy settings can result in blisters and reticulate scars but the associated pain will usually prevent this from happening and indeed there are no reports of MFU related scarring.[4] In our study, there were 2 transient post-treatment effects that deserve further comment: firstly, transient mild linear erythematous plaques can occur but these generally last for less than 24 hours although there has been report of these lasting for days with subsequent full resolution with topical steroids. When linear plaques become noticeable during treatment, a decrease in fluence is recommended. Another patient had transient thermal neuropraxia from inadvertent MFU targeting of the left marginal mandibular nerve resulting in subtle transient lip weakness. The temporal nerve and marginal mandibular nerve are vulnerable to MFU effects at the temple and lateral chin respectively, and are ‘caution areas’ during MFU therapy. Transient sensory thermal neuropraxia presenting as tingling and numbness can also uncommonly occur.

Blinded physician assessment of the before-and-after photos show a noticeable change post-procedure (1- to 4.5- months, mean: 8.6 weeks). Although there is an initial non-response rate of up to 27.5%, based on on blinded 2-dimensional photo-ratings, these 'non-responders' may subsequently show a noticeable tightening response at a later time-point (figure 4), consistent with delayed collagen remodelling effects. The durability of results has not been well studied and there is no data on the effects of regular MFU treatment on skin ageing. Although MFU is generally considered a single session treatment, others have anecdotally observed better patient results with up to 3 treatment sessions at 4-6 month intervals, followed by annual maintenance sessions (personal communication, Korea). We hypothesize that regular maintenance MFU treatments may slow down skin laxity and aging and we will examine this with longitudinal data on the effect of regular MFU on skin laxity over time.

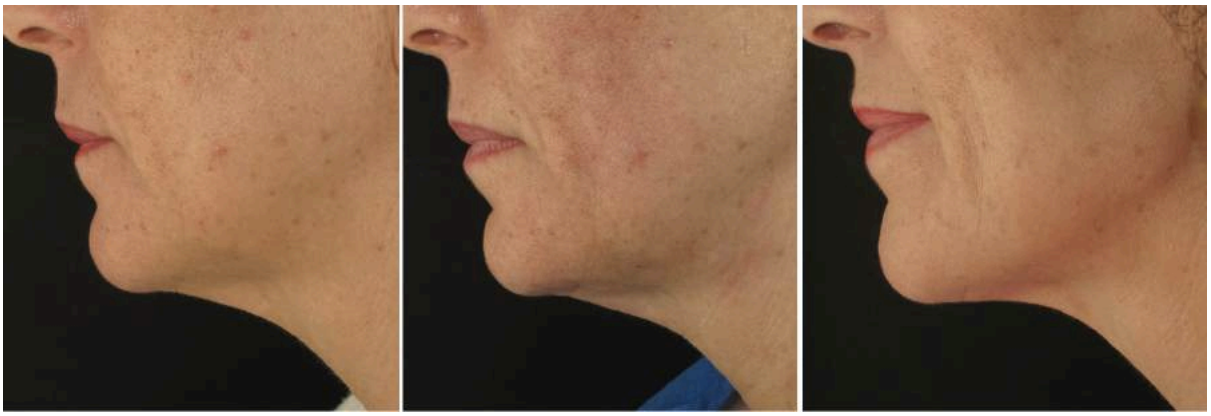

Figure 4. 50 year-old female at baseline, immediately post- and 1-month post-procedure (left to right) highlighting gradual neck and jawline tightening even though there was no observable change immediately post-procedure (centre image).

Our commercial experience with Ultraformer 3 has been very favourable. There is a market gap for a non-surgical lower face and neck tightening procedure that delivers consistent results without being too uncomfortable or protracted. Patients are often very receptive to procedural recommendation for jowls and facial sagging and will be prepared to have repeat treatments and recommend the procedure to others if the procedure meets their expectation in efficacy and tolerability. From the practitioner's perspective, the Ultraformer 3 is easy to handle and drive and can be performed by doctors, nurses, dermal therapists and other trained allied health practitioners. Ultraformer 3 can be delegated to suitably trained staff because of its dependable, non-laser technology coupled with a low incidence of adverse events. The device affordability and low running cost makes it an attractive business and commercial proposition, which adds value for the patient.

The limitations of this study are a relatively small sample size, a relatively short follow-up period of less than 6-months and potential investigator bias from using an industry-sponsored device (Cryomed Australia).

Conclusion

MFU therapy with the Ultraformer 3 is a safe, effective high-speed, low-pain procedure that meets a clear need amongst patients seeking skin tightening. The procedure induces noticeable skin tightening post-procedure with a 75% patient satisfaction rate that is

independently and objectively verifiable. Patients tolerated the procedure well with only topical anaesthesia and chilled air cooling. The favourable procedural experience and results convert to an 85% reported desire for repeat procedures and 75% referral rate to others.

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