Research Article

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# High-Frequency Ultrasound for Skin Laxity of the Face and Neck: A Five-Year Review

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## 1. Introduction

As the largest and most external bodily organ, the skin is how we present ourselves to the world. The skin undergoes both intrinsic and extrinsic aging processes, exposed to daily stressors that ultimately contribute to laxity, rhytids, decreased elasticity, and texture changes, considered undesirable by many [1]. As such, large amounts of time and money are invested into pharmaceuticals and cosmetic procedures with the goal of reducing signs of cutaneous aging. Current noninvasive options include botulinum toxin, chemical peels, laser and light therapy, and soft-tissue fillers. Among newer noninvasive cutaneous rejuvenation treatments is high-intensity ultrasound. Prior to being used cosmetically, high-frequency ultrasound was shown to be effective in treating various solid tumors [2]. More recently, high-frequency ultrasound has shown utility in the cosmetic setting, with emerging technologies such as micro focused ultrasound (MFU) and parallel-beam ultrasound (PBU) being applied to the skin. Both MFU and PBU involve targeted application of high-frequency sound waves to specific depths within dermal and subcutaneous tissues. As the ultrasound waves penetrate tissue, resulting thermal energy creates coagulation zones at approximately 60-70 C°, which leads to contraction of denatured collagen as well as local inflammation. The targeted inflammatory response stimulates collagen remodeling and induces neo collagenesis [3-4].

While MFU and PBU have both been shown to effectively decrease skin laxity and improve cosmetic appearance through their effects on collagen, key features differentiate the two. Micro focused ultrasound was developed first, and used in conjunction with live-imaging techniques is termed micro focused ultrasound with visualization (MFU-V). MFU-V employs three separate ultrasound transducers to apply ultrasound waves of varying frequencies, each penetrating tissues perpendicularly to different depths. 1.5 mm (10.0 MHz), 3.0 mm (7.0 MHz), and 4.5 mm (4.0 MHz) are commonly targeted as these depths correspond to middle reticular dermis, deep reticular dermis, and subcutaneous tissue, respectively [3]. Through the 3.0 mm and 4.5 mm transducers, MFU-V is able to reach muscular layers, including the superficial musculoaponeurotic system (SMAS) and platysma [3]. This noninvasive technique is similar in mechanism to a traditional facelift involving the SMAS. Due to deeper penetration MFU-V is associated with side effects of tenderness, ecchymosis, edema, and injury to nerve structures [3]. Additionally, application of focused ultrasound waves to individual coagulation points generates a zone of elliptical thermal injury perpendicular to the surface of the skin [5]. When applied to the mid or superficial dermis, this perpendicular thermal damage can extend to the overlying epidermis. When applied more deeply, the thermal energy can penetrate underlying muscle, nerve, bone, and vessels.

Parallel-beam ultrasound utilizes seven high-frequency transducers on a single ultrasound probe placed in direct contact with the patient's skin. This design allows seven planes of ultrasound waves to be delivered simultaneously in a parallel orientation to the skin surface [5]. The low-divergence, high-frequency waves penetrate to a depth of 0.5-2.0 mm, primarily targeting the mid-dermis at 1.5 mm [5]. Parallel orientation of the applied ultrasound waves in relation to the skin surface theoretically confines thermal injury to the desired mid-dermal location and minimizes unintended damage to the overlying and underlying structures. Rather than applying targeted sound waves perpendicularly at different individual points along the skin, application of sound waves in parallel orientation induces neo-collagenation over greater surface area at any given time. Direct probe contact with the skin allows for temperature monitoring and cooling during the procedure, adding additional protection and improving patient comfort [5].

While each of these technologies has been well-received and successfully implemented into cosmetic practice, most existing studies investigate the clinical and histopathological effects of high-frequency ultrasound applied to depths of 3.0 mm and 4.5 mm. Additional independent studies assessing the effectiveness of synchronous ultrasound parallel beam technology and comparing it to micro focused ultrasound with visualization are needed. This review aims to consolidate and summarize most current literature pertaining to high-frequency ultrasound applied cosmetically to the face and neck.

## 2. Methods

A PubMed search was conducted using the algorithm: ((micro focused ultrasound) or (synchronous ultrasound parallel beam) or (HIFU) or (high intensity focused ultrasound) or (focused ultrasound) or (high-intensity ultrasound) or (parallel beam ultrasound)) and ((cutaneous) or (cosmetic) or (skin) or (dermatology)) and ((face) or (neck)) and ((collagen stimulation) or (histology) or (rhytids)) and ((depth) or (1.5 mm) or (3 mm) or (4.5 mm)). Inclusion criteria included full text clinical studies. Exclusion criteria included literature reviews, meta-analyses, retrospective studies, case reports, letters, studies not related to key words, studies conducted in a language other than English, studies investigating high-frequency ultrasound combined with other therapies, studies not pertaining to high-frequency ultrasound applied to the face and/or neck, cadaveric or animal studies, and studies published before 2018. Author names, study type, objectives, methods, and key findings were reported for each study included in this review.

## 3. Results

### • Literature Search

Literature search using the previously described algorithm yielded 81 articles. One article was not full text and thus was excluded. 80 articles underwent screening with inclusion and exclusion criteria. Eight articles meeting inclusion and exclusion criteria underwent in-depth review.

### • Patient Demographics

High-frequency ultrasound was tested in both males and females, aged 20-80, with mild to severe skin laxity of the face and neck [4-11]. Most subjects were female, and several studies exclusively studied high-frequency ultrasound in women [7-10]. Fitzpatrick types I-VI skin underwent treatment with MFU-V and SUPERB technology without differences in treatment efficacy noted between skin type.

### • Treatment Protocol

All studies tested the effectiveness of high-frequency ultrasound on skin tightening. Three studies (37.5%) tested treatment regimens with combined depths of 1.5 mm, 3.0 mm, and 4.5 mm [4,8,9]. Two studies (25%) assessed high-frequency ultrasound regimens with combined treatment depths of 3.0 mm and 4.5 mm [6,10]. Three studies (37.5%) assessed focused ultrasound solely at 1.5 mm, with two (25%) of those assessing parallel-beam ultrasound and one (12.5%) testing micro focused ultrasound with visualization [5,7,11]. Ultrasound frequencies targeting subcutaneous tissue at 4.5 mm included 4.0 MHz and 4.4 MHz [4,6,8-10]. Frequencies targeting deep dermis at 3.0 mm included 7.0 MHz and 7.5 MHz [4,6,8-10]. Frequencies used to target the middle dermis at 1.5 mm included 10 MHz, 11.5 MHz, and 19 MHz [7-9,11]. Applied frequency varied depending on clinician preference and patient skin characteristics. Six out of eight (75%) studies in this review exclusively evaluated micro focused ultrasound. Two (25%) evaluated parallel-beam ultrasound [5,11]. No studies compared the two forms of high-frequency ultrasound directly. The mean number of treatment lines applied to cosmetic treatment of the face and neck ranged from 100-1200 [4-11]. 100 lines were used for treatment of periorbital tissues including crow's feet and infraorbital tissues [7]. 1200 treatment lines were used to treat the lower lids, zygomas, cheeks, submental, mandibular lines [8]. The number of lines applied varied based on physician preference, specific region being treated, and total number of regions being treated.

### • Skin Laxity

Micro focused ultrasound was shown to induce significant improvement in rhytides and skin texture by three-dimensional analysis8. Blinded, physician-assessed improvement in skin laxity ranged from 53% to 100% of patients treated with micro focused ultrasound [6,7,10]. Self-assessed improvement in skin laxity ranged from 47% to 100% of patients treated with micro focused ultrasound [6,10]. Parallel-beam ultrasound induced significant decrease in mean depression volume of rhytides, as well as decrease in area of marionette lines and nasolabial folds through three-dimensional analysis [11]. Parallel-beam ultrasound also resulted in 88% improvement in rhytide appearance as assessed through blinded clinician reviewers, and 72% self-assessed patient improvement in rhytide appearance [5].

### • Histologic Changes

Micro focused ultrasound applied periorbitally at 1.5 mm resulted in histologic evidence of neocollagenesis and neoelastogenesis [7]. The greatest amount of collagen formation was observed in the upper dermis, while the greatest amount of elastin formation was observed in the lower dermis [7]. Three out of 10 patients in the study by Suh et al underwent biopsy and histologic analysis. No studies included in this review evaluated direct histological effects of parallel-beam ultrasound.

### • Adverse Effects

The greatest level of discomfort on a 1-10 pain scale was reported by patients with treatments targeting skin depth of 4.5 mm [4,10]. The next greatest pain level was experienced at treatment depth of 3.0 mm, and least pain was experienced at 1.5 mm. Shome et al reported moderate pain in 48% of patients treated with micro focused ultrasound [6]. Hongcharu et al reported an average pain scale rating of 6.64 for patients undergoing parallel-beam therapy, although no patients in the study received pretreatment pain medication [11]. Araco reported an average pain scale of 3.32 in patients receiving micro focused therapy, although patients received pretreatment oral and topical pain management [8]. Adverse effects of pain, welting, bruising, erythema, cramping, and gagging sensation were reported with high-frequency ultrasound therapy [4,7,10]. The adverse effects were largely self-limited and resolved within 3-14 days [4,7]. The two studies assessing parallel-beam ultrasound reported no adverse effects among patients [5,11].

### • Assessment Scales

The most common methods of assessing treatment efficacy were comparison of digital photographs before and after treatment and subjective patient satisfaction questionnaires. Scales employed to assess treatment effectiveness and change in skin appearance included the Investigator Global Aesthetic Improvement Scale (IGAIS), Visualized Analog Scale (VAS), Modified FACE-Objective Assessment Scale Scores (MFOAS), Subjective Global Improvement Assessment Scale (SGAIS), Physician Global Assessment Scale (PHh-GAS), Patient Global Assessment Scale, Clinician Global Aesthetic Improvement Scale (CGAIS), Merz Décolletage Wrinkle Scales, and Fitzpatrick Wrinkle and Elastosis scale. Two studies evaluated changes in skin laxity including using three-dimensional analysis [8,11]. Several studies did not use standardized assessment scales, but rated before and after treatment change using numerical scales.

## 4. Discussion

Although both micro focused ultrasound with visualization and synchronous, parallel-beam ultrasound are both FDA approved for tightening and lifting skin, additional independent studies analyzing high-frequency ultrasound for cosmetic procedures are needed. Most existing data pertains to micro focused ultrasound with visualization at three distinct depths, while few independent clinical studies have evaluated synchronous ultrasound parallel beam technology confined to the mid-dermis. To our knowledge, there are currently no existing clinical trials evaluating head-to-head effectiveness of MFU-V and PBU. The overwhelming majority of current literature discusses MFU-V, with significantly less data existing for PBU. Although the existing MFU-V treatment protocol includes targeted ultrasound energy applied to superficial layers of the dermis at 1.5 mm, in addition to deeper dermis and subcutaneous tissue at 3.0 mm and 4.5 mm, the delivery of parallel energy and subsequent thermal injury zones created at 1.5 mm by PBU needs to be further evaluated. While developer-sponsored studies speculate at differences in treatment effectiveness, histologic effect, and adverse effect profile between the two technologies, studies directly comparing MFU-V and PBU would provide useful insight to guide future advances.

Despite the proposed differences between micro focused ultrasound and parallel-beam ultrasound, both appear to be highly effective at improving skin laxity and decreasing the appearance of fine lines and wrinkles of the face and neck, through both subjective and objective measures. In almost all studies, improvement detected by objective measures correlates to a similar level of improved patient satisfaction. Both technologies aim to induce formation of new collagen and elastin at treatment sites, and appear to do so as measured by improved facial texture and decreased rhytide depth on three-dimensional analysis and a variety of improvement scales [8,11]. There is limited clinical data assessing the histologic effects of high-intensity ultrasound technologies. Notably, the only studies assessing histological changes induced in-vivo by MFU-V have been conducted by Suh et al. There are no current clinical studies specifically measuring histologic effects of PBU in human subjects. Interestingly, the histologic analysis by Suh et al involved MFU-V applied only to 1.5 mm, raising the question of how different the histological effect of each technology would be at similar depths [7]. While Suh et al did perform punch biopsy analysis before and after MFU-V treatment, the number of subjects participating in this aspect of the study was limited [7]. This is likely due to the inherently cosmetic nature of these procedures; biopsy analysis at a site treated for cosmetic purposes directly threatens the aesthetic improvement attained from treatment. A previous study by Kim et al did assess the effect of micro focused ultrasound on cadaveric tissues, and this may prove to be a viable alternative when in vivo tissue analysis is not possible or realistic [12]. Although histopathological insight into these technologies would certainly prove useful, alternative methods of assessing neocollagenesis and tissue response that do not threaten aesthetic appearance of treated sites will undoubtedly be more effective. The current large and diverse number of scales used to rate both objective and subjective improvement skin laxity makes side-by-side comparison of existing data somewhat challenging. As high-intensity ultrasound becomes commonplace in cosmetic settings, development of uniform objective and subjective analysis tools will allow for better understanding of the subtle differences between MFU-V and PBU. Another important aspect to consider with any cosmetic procedure is treatment logistics, including patient comfort, treatment time, and adverse effects. In the existing literature, increased treatment depth is clearly correlated to increased patient discomfort [4,10]. This is logical; treatment targeting the deep dermis and subcutaneous tissue is inherently closer with nerves and other structures that contribute to the sensation of pain. Based on clinical data and these logical principles, high-frequency ultrasound applied at more superficial depths inherently leads to a more comfortable treatment experience. In this review, only two studies explicitly reported treatment time [8,11]. Based on proposed mechanism and clinical experience outside this review, parallel-beam ultrasound is associated with less overall treatment time, which benefits both patient and provider. While similar pain and adverse effect profiles exist for MFU-V and PBU, treatment tolerance without pain medication and recovery time appear to be superior for parallel-beam ultrasound [6,11]. High-frequency ultrasound technology has also been well-tolerated with additional noninvasive cutaneous rejuvenation strategies, including hyaluronic acid filler, Botox and radiofrequency treatments [13], although the combination of additional noninvasive strategies with high-frequency ultrasound is beyond the scope of this review. As micro focused ultrasound and parallel-beam ultrasound become better understood, assessing their effectiveness when combined with synergistic treatment modalities will provide additional insights.

## 5. Conclusion

High-frequency ultrasound is becoming increasingly popular as a cosmetic treatment for the face and neck. As the demand for noninvasive skin rejuvenation continues to rise, so will the use of high-frequency ultrasound. Further study of the underlying mechanisms and long-term implications of synchronous parallel beam ultrasound technology and micro focused ultrasound will facilitate improved outcomes for both patients and providers.

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