MERZ AESTHETICS

Ultherapy®

STUDIEN & PUBLIKATIONEN

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DAS **ULTRA**SCHALL-LIFTING

PUBLIKATIONSLISTE

1. Alam M, et al. Ultrasound tightening of facial and neck skin: a rater-blinded prospective cohort study. J Am Acad Dermatol. 2010 Feb;62(2):262-9. S. 5
2. Baumann L, et al. Evaluation of Micro-Focused Ultrasound for Lifting and Tightening Neck Laxity. J Drugs Dermatol. 2016 May;15(5):607-14. S. 5
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18. Minkis K, Alam M. Ultrasound skin tightening. Dermatol Clin. 2014 Jan;32(1):71-7. S. 12
19. Oni G, et al. Evaluation of a microfocused ultrasound system for improving skin laxity and tightening in the lower face. Aesthet Surg J. 2014 Sep;34(7):1099-110. S. 12
20. Pak CS, et al. Safety and efficacy of ulthera in the rejuvenation of aging lower eyelids: a pivotal clinical trial. Aesthetic Plast Surg. 2014 Oct;38(5):861-8. S. 12
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25. Weiss M. Commentary: noninvasive skin tightening: ultrasound and other technologies: where are we in 2011? Dermatol Surg. 2012 Jan;38(1):28-30. S. 14
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27. White WM, et al. Selective creation of thermal injury zones in the superficial musculoaponeurotic system using intense ultrasound therapy: a new target for noninvasive facial rejuvenation. Arch Facial Plast Surg. 2007 Jan-Feb;9(1):22-9. S. 15
28. White WM, et al. Selective transcutaneous delivery of energy to porcine soft tissues using Intense Ultrasound (IUS). Lasers Surg Med. 2008 Feb;40(2):67-75. S. 16
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Studien zum Wirkmechanismus, Histologien

Autor	Titel	Ziel der Studie
White et al, 2007; ARCH FACIAL PLAST SURG/VOL 9: 22ff	Selective Creation of Thermal Injury Zones in the SMAS Using Intense Ultrasound Therapy	Nachweis der gezielten Energieübertragung ins SMAS und Erzeugung von definierten Koagulationspunkten (TCP) in menschlicher Leichenhaut
Gliklichet al, 2007 ARCH FACIAL PLAST SURG/VOL 9: 88ff	Clinical Pilot Study of Intense Ultrasound Therapy to Deep Dermal Facial Skin and Subcutaneous Tissues	Prüfung der klinischen Sicherheit von Ultherapy® bei der Behandlung der Dermis und des subdermalen Gewebes im Gesichts- und Halsbereich (Entzündungsparameter, Schmerzempfinden, Nebenwirkungen und histologische Untersuchungen menschlicher Dermis und Subdermis)
Laubachet al, 2008 Dermatol Surg 34: 727ff	Intense Focused Ultrasound: Evaluation of a New Treatment Modality für Microcoagulation within the Skin	Untersuchung der thermalen und mechanischen Wirkung von Ultherapy® bei der punktuellen Erhitzung an menschlicher Leichenhaut
White et al, 2008 Lasers in Surgery and Medicine 40: 67ff	Selective Transcutaneous Delivery of Energy toporcine Soft Tissues Using Intense Ultrasound (IUS)	Untersuchung der Wirkung verschieden starker Ultraschallwellen (Ultherapy®) an Schweinehaut
Sue et al, 2011 Dermatol Surg 37: 1-8	Intense Focused Ultrasound Tightening in Asian Skin: Clinical and Pathologic Results	Untersuchung der Sicherheit und Wirksamkeit von Ultherapy® bei der Hautstraffung an 22 koreanischen Patienten (klinische Wirksamkeit und histologische Untersuchung)

Studien zum Thema Wirksamkeit und Sicherheit

Autor	Titel	Ziel der Studie
Alam et al, 2009 Dermatol Surg 62: 262ff	Ultrasound tightening of facial and neck skin: A rater-blinded prospective cohort study	Sicherheit und Wirksamkeit von Ultherapy® bei einer Behandlung des Gesichts-/Halsbereiches und Augenbrauenlift
Fabiet al. 2013 J Am Acad Dermato 69 (6): 965ff	Evaluation of microfocused ultrasound with visualization for lifting, tightening, and wrinkle reduction of the decolletage	Untersuchung der Wirksamkeit (anhand der Fabi/Bolton Chest Wrinkle Scale, FBCWS) und Sicherheit von Ultherapy® bei der Behandlung von Falten und Hauterschlaffung des Dekolletees
Oni et al, 2014 J Aesth Surg 34 (7): 1099ff	Evaluation of a Microfocused Ultrasound System for Improving Skin Laxity and Tightening in the Lower Face	Untersuchung des Liftingeffektes von Ultherapy® im Wangenbereich und Submentum (Sicherheit und Wirksamkeit)
Hitchcock and Marek K Dobke, 2014 J Cos Dermatol 13: 329ff	Review of the safety profile for mikrofocused ultrasound with visualisation	Sicherheitsprofil von Ultherapy® (Analyse von Daten aus Peer-Review/klinische Studien Ultherapy®/Anwendung im Markt und retrospektive Berichte von Behandlungsprotokollen)
Werschler et al, Clin Aesth Dermatol, 2016 (9); no21: 27ff	Long-term Efficacy of Micro-focused Ultrasound with Visualisation for Lifting and Tightening Lax Facial and Neck Skin Using a Customized Vectoring Treatment Method	Pilotstudie mit dem Ziel Wirksamkeit und Sicherheit einer Behandlung mittels individuell angepassten Behandlungsplan im Gesichts- und Halsbereich zu erfassen (kontrollierte Beobachtung bis 365 Tage)

1. Alam M, et al. Ultrasound tightening of facial and neck skin: a rater-blinded prospective cohort study. J Am Acad Dermatol. 2010 Feb;62(2):262-9.

BACKGROUND: Nonablative skin tightening technologies offer the prospect of reduction of wrinkles and skin sagging with minimal downtime, discomfort, and risk of adverse events. The excellent safety profile is mitigated by the limited efficacy of such procedures.
OBJECTIVE: We sought to assess the efficacy of ultrasound skin tightening for brow-lift in the context of a procedure treating the full face and neck.
METHODS: This was a rater-blinded, prospective cohort study at a dermatology clinic in an urban academic medical center. Subjects were medicated with topical anesthetic and then treated with an investigational focused intense ultrasound tightening device to the forehead, temples, cheeks, submental region, and side of neck using the following probes: 4 MHz, 4.5-mm focal depth; 7 MHz, 4.5-mm focal depth; and 7 MHz, 3.0-mm focal depth. Standardized photographs of front and side views were obtained at 2, 7, 28, 60, and 90 days; rating scales of pain, adverse events, physical findings, and patient satisfaction were also completed.
Primary outcome measure was detection of improvement in paired comparison of pretreatment and posttreatment (day 90) photographs by 3 masked expert physician assessors, cosmetic and laser dermatologists, and plastic surgeons who were not authors. Second primary outcome measure was objective brow elevation as quantitated by a standard procedure using fixed landmarks. Secondary outcomes measure was patient satisfaction as measured by a questionnaire.
RESULTS: A total of 36 subjects (34 female) were enrolled, one subject dropped out, and 35 subjects were evaluated. Median age was 44 years (range 32–62). On the first primary outcome measure, 30 of 35 subjects (86%) were judged by the 3 masked experienced clinician raters to show clinically significant brow-lift 90 days after treatment (P = .00001). On the second primary outcome measure, mean value of average change in eyebrow height as assessed by measurement of photographs at 90 days was 1.7 mm.
LIMITATIONS: Limitations of this study include the inability to quantitatively measure lower face tightening because of the lack of fixed anatomic landmarks in this area.
CONCLUSION: Ultrasound appears to be a safe and effective modality for facial skin tightening. A single ultrasound treatment of the forehead produced on average brow height elevation of slightly less than 2 mm. Most treated individuals responded, commonly with accompanying transitory mild erythema and edema.

2. Baumann L, et al. Evaluation of Micro-Focused Ultrasound for Lifting and Tightening Neck Laxity. J Drugs Dermatol. 2016 May;15(5):607-14.

BACKGROUND: A novel device using micro-focused ultrasound with high-resolution ultrasound visualization (MFU-V) produces non-invasive lifting and tightening of lax skin on the face and neck when treatment is delivered at a single focal depth (Ulthera® System; Ulthera, Inc., Mesa, AZ).
OBJECTIVE: The following study was performed to test the hypothesis that customized application of MFU-V at two focal depths will produce clinical results that are superior to treatment at a single focal depth.
METHODS AND MATERIALS: Adult subjects (N=71) with skin laxity in the lower face and neck were enrolled; 64 met all entrance criteria and received treatment. On the basis of physical and anatomical characteristics, patients were assigned in nonrandomized fashion to one of three treatment groups to undergo treatment on the submental, submandibular, lower neck, and platysmal areas with MFU-V at single or dual depths.
RESULTS: Among evaluable subjects (N=64), investigator-assessment and subject-self-assessment demonstrated improved aesthetic changes at 60, 90, and 180 days after treatment. Overall, subjects that received MFU-V at two focal depths to the entire treatment area achieved slightly greater aesthetic improvement than subjects receiving MFU-V at single focal depths. There were no unexpected adverse events.
CONCLUSION: Applying treatment with MFU-V at two focal depths may provide improved aesthetic results in some subjects.

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3. Brobst RW, et al. Noninvasive treatment of the neck. Facial Plast Surg Clin North Am. 2014 May;22(2):191-202.

Emerging trends in neck rejuvenation include the incorporation of nonsurgical treatment modalities as an offering to those patients desiring minimal downtime and accepting of mild results. Intense focused ultrasound is a promising technology for treatment of the neck. It is rapidly growing in clinical use and undergoing further investigation to determine optimum treatment parameters and make its outcomes more predictable.

4. Carruthers J, et al. Consensus Recommendations for Combined Aesthetic Interventions in the Face Using Botulinum Toxin, Fillers, and Energy-Based Devices. Dermatol Surg. 2016 May;42(5):586-97.

BACKGROUND: The aging process is a complex interplay of intrinsic and extrinsic factors across multiple layers of the face. Accordingly, combining aesthetic interventions targeting different manifestations of aging often leads to better results than single modalities alone. However, no guidelines for a pan-facial approach using multiple interventions have been published to date.
OBJECTIVE: To develop consensus recommendations for the optimal combination and ideal sequence of botulinum toxin (BoNT), hyaluronic acid, calcium hydroxylapatite, and microfocused ultrasound with visualization (MFU-V) in persons of all Fitzpatrick skin types.
METHODS AND MATERIALS: Fifteen specialists convened under the guidance of a certified moderator. Consensus was defined as approval from 75% to 94% of all participants, whereas agreement of ≥95% denoted a strong consensus.
RESULTS: Optimal aesthetic treatment of the face begins with a thorough patient assessment and an individualized treatment plan. Spacing consecutive treatments 1 to 2 weeks apart allows for resolution of side effects and/or to assess results. For same-day treatments, BoNT and fillers may be performed together in either sequence, whereas MFU-V is recommended before injectable agents.
CONCLUSION: Expert consensus supports a combination approach using multiple modalities in specific sequence for the safe and effective treatment of the aging face.

5. Casabona G, Michalany N. Microfocused ultrasound with visualization and fillers for increased neocollagenesis: clinical and histological evaluation. Dermatol Surg. 2014 Dec; 40 Suppl 12:S194-8.

Microfocused ultrasound with visualization (MFU-V) is a technology that focuses ultrasound waves to precise well-defined areas in dermal and subcutaneous tissues, which creates distinct thermal coagulation points (TCPs). The heat generated by MFU-V generally reaches between 60°C and 70°C at the TCP and creates microcoagulation zones at 3 depths: 4.5, 3.0, and 1.5 mm. Normally, those depths target structures in fibromuscular, superficial subcutaneous, deep, and mid-dermal planes. Before treatment, a therapeutic ultrasound image is generated to verify the apposition of the transducer to the epidermis. Imaging permits ascertainment of the depths of the epidermis and dermis at the specific area of the anatomy being treated and also the location of the fascia and the bony interface.[1,2] The immediate response is the tightening of the collagen, as the intramolecular hydrogen bonds are broken, stimulating subsequent long-term neocollagenesis seen within at least 3 months after treatment. It has been shown to be a good nonsurgical modality for face-lifting and brow elevation.[2]
CONCLUSION: Clinicians have been concerned about combining MFU-V procedures with fillers because, theoretically, the heating process could start a dense inflammatory response and potentially lead to a foreign body reaction or the filler could change in appearance and characteristics after being heated. Through these findings, no granuloma or histologic changes in the filler appearance or efficacy was seen after the MFU-V treatment. On the contrary, MFU-V helps with the enhancement and quality of the new collagen and elastin fibers formed at least 6 months after the procedure, which can be a more natural and noninvasive way of 3-dimensional rejuvenation. The limitations of this study are that this was only a one-patient study, and larger prospective controlled studies need to be conducted.

6. Chan NP, et al. Safety study of transcutaneous focused ultrasound for non-invasive skin tightening in Asians. Lasers Surg Med. 2011 Jul;43(5):366-75.

BACKGROUND AND OBJECTIVES: Transcutaneous intense focused ultrasound has emerged as a novel technology for non-invasive skin tightening. The objective of this study was to evaluate the safety profile of a transcutaneous focused ultrasound device for the treatment of facial skin laxity in Asians.
MATERIALS AND METHODS: The patients received one to three full-face treatments with the transcutaneous focused ultrasound device. Three transducers (7.0 MHz, 3.0 mm focal depth; 7.0 MHz, 4.5 mm focal depth; 4.0 MHz, 4.5 mm focal depth) were used to deliver a single pass of microthermal coagulation zones without any topical anesthetics. Standardized photos were taken at baseline and at each follow-up with the Canfield Visia CR system® and were assessed by two independent physicians. Adverse effects were assessed up to 6 months post treatment. Subjective assessments in terms of pain and tolerability were also evaluated with patient questionnaires.
RESULTS: Forty nine Chinese patients (skin types III–IV, mean age 53.3) completed a total of 68 treatment sessions. Transient erythema and edema were seen in the majority of patients. Focal bruising was present in up to 25% of treatment sessions. Two cases of post-inflammatory hyperpigmentation were seen on the forehead at 1-month post-treatment. One patient experienced focal twitching over the lower eyelid at 1-month follow-up, which was clinically consistent with hemifacial spasm and was unrelated to the ultrasound device. The degree of pain during treatment was recorded as severe in 54.4% of treatment sessions.
CONCLUSIONS: Transcutaneous intense focused ultrasound appeared to be safe for non-invasive facial skin tightening in Asians. Adverse events were mild and transient. Pain control during treatment should be optimized. No serious permanent or delayed side effects were noted up to 6 months post treatment.

7. Dobke MK, et al. Tissue restructuring by energy-based surgical tools. Clin Plast Surg. 2012 Oct;39(4):399-408.

Energy-based noninvasive surgical tools can be used for ablative bio-stimulation (eg, collagen production) or tissue restructuring functions (eg, tightening or lifting) and are the subject of this review. The authors present the various methods and tools for noninvasive cosmetic surgery (ultrasound, radiofrequency, cryolipolysis, and lasers) and present the clinical outcomes of each. They summarize techniques and methods and their indications, physical parameters and tissue target, and consistency.

8. Fabi SG, et al. Evaluation of microfocused ultrasound with visualization for lifting, tightening, and wrinkle reduction of the décolletage. J Am Acad Dermatol. 2013 Dec;69(6):965-71.

BACKGROUND: Laxity and rhytides are manifestations of photodamage on the chest.
OBJECTIVE: We sought to evaluate efficacy and safety of microfocused ultrasound with visualization treatment of décolletage laxity and rhytides.
METHODS: In all, 24 subjects with moderate to severe rhytides, as measured by a validated 5-point photonumeric scale (Fabi/Bolton Chest Wrinkle Scale), received microfocused ultrasound with visualization treatment. Efficacy was measured at 90 and 180 days by the Fabi/Bolton Chest Wrinkle Scale, mid-clavicular to nipple distance, masked assessment, Physician and Subject Global Aesthetic Improvement Scales, and patient satisfaction. Adverse events were recorded.
RESULTS: Rhytides improved over time ($P < .0001$), with 46% and 62% of subjects showing a

[1] Murad A, White L, Martin N, Witherspoon J, et al. Ultrasound tightening of facial and neck skin: a rater-blinded prospective cohort study. J Am Acad Dermatol 2010; 62: 262–9.
[2] Kornstein A. Uthera for silicone lip correction. Plastic Reconstr Surg 2012; 129: 1014e–15e.

1- to 2-point improvement at days 90 and 180, respectively. Mean (SD) mid-clavicular to nipple distance decreased (P < .0001), from 20.9 (1.57) cm to 19.8 (1.50) cm and 19.5 (1.59) cm, at days 90 and 180, respectively. At day 90, 100% were improved by Subject Global Aesthetic Improvement Scale score (P < .0001) and 96% were improved by Physician Global Aesthetic Improvement Scale score (P < .0001), with similar findings at day 180. All subjects were satisfied or very satisfied at day 90, with similar results at day 180. Improvement by masked assessment at day 90 was 71%.
LIMITATIONS: Single-center study, small sample size, and only Fitzpatrick skin types I and II enrolled were limitations.
CONCLUSION: There was appreciable efficacy and patient satisfaction after a single microfocused ultrasound with visualization treatment in wrinkle reduction and lifting of the décolletage.

9. Fabi SG, Metelitsa AI. Future directions in cutaneous laser surgery. Dermatol Clin. 2014 Jan;32(1):61-9.

This article presents an overview of future trends in cutaneous laser therapy and technology. To enhance efficacy and specificity of treatment, new wavelengths directed at both old and new targets are on the horizon. New applications, including the use of lasers to aid in the detection of skin cancers and to enhance drug delivery, are being used and investigated. A trend toward combining different lasers and light sources to optimize results continues. Advancements in at-home devices have been made. Future applications will include waveforms beyond those in the visible light and infrared spectrum, such as microwaves, ultrasound waves, and radiofrequency.

10. Fabi SG, Goldman MP. Retrospective evaluation of micro-focused ultrasound for lifting and tightening the face and neck. Dermatol Surg. 2014 May;40(5):569-75.

BACKGROUND: Microfocused ultrasound (MFU) is an effective means for tightening and lifting lax facial and neck skin.
OBJECTIVE:To evaluate the safety and efficacy of MFU with visualization (MFU-V) for noninvasive treatment of facial and neck skin laxity 180 days after treatment and determine what lifestyle factors affect treatment outcomes.
MATERIALS AND METHODS: Healthy women (N = 48) previously treated with MFU-V on the face and upper neck were enrolled. Depending on when MFU-V treatment occurred, subjects completed 90- or 180-day follow-up visits or both. Digital images of each subject were obtained before treatment and at follow-up visits.
RESULTS: Data were obtained at 90 (N = 16) and 180 days (N = 45), and physician Global Aesthetic Improvement Scale (GAIS) scores demonstrated that 81.3% and 77.7% patients achieved improvement, respectively. At 90 and 180 days, subject GAIS scores showed 75% and 77.8% of subjects perceived improvement, respectively. At 180 days, blinded reviewer assessments indicated that 67% of subjects showed improvement in appearance. There was no association between improvement and age, Fitzpatrick skin type, alcohol intake, or major illness. One minor adverse event was reported.
DISCUSSION: Although the data obtained at 90 days must be interpreted cautiously because of the smaller number of patients, subjects achieved significant lifting and tightening of facial and neck skin up to 180 days after one MFU treatment.

11. Fabi SG, et al. Combining Microfocused Ultrasound With Botulinum Toxin and Temporary and Semi-Permanet Dermal Fillers: Safety and Current Use. Am Soc Dermatol Surg. 2016 May;42:168-76.

BACKGROUND: A microfocused ultrasound system with visualization (MFU-V) is currently indicated for use as a noninvasive dermatological aesthetic treatment to lift the eyebrows, lax submental and neck tissue, and improve lines and wrinkles of the décolleté.
OBJECTIVE: To determine the existence of any safety signals when combining MFU-V with botulinum toxin-A and/or semipermanent and temporary dermal fillers.
MATERIALS AND METHODS: A retrospective chart review was performed using subjects who received aesthetic treatments including incobotulinumtoxinA injection, cohesive polydensified matrix hyaluronic acid (CPM HA) dermal fillers, and calcium hydroxylapatite (CaHA) dermal fillers within 6 months of treatment with MFU-V in the same or different anatomic areas.
RESULTS: All subjects (N = 101; 96 female; 25–70 year old) received MFU-V, 18% received incobotulinumtoxinA injections, and 81% were treated with CPM HA and/or CaHA fillers. Seven adverse events (7%) were reported: bruising/purpura (n = 4), swelling (n = 1), paresthesia (n = 1), and herpes simplex virus (HSV) outbreak (n = 1). Only the HSV outbreak was considered to be related to combined treatments.
CONCLUSION: Although limited by relatively few subjects, the results of the present study suggest that the safety profile of MFU-V combined with other aesthetic products is consistent with the safety profiles of the individual treatments.

12. Gliklich RE, et al. Clinical pilot study of intense ultrasound therapy to deep dermal facial skin and subcutaneous tissues. Arch Facial Plast Surg. 2007 Mar-Apr;9(2):88-95.

OBJECTIVE: To evaluate the clinical safety of intense ultrasound in the treatment of the dermis and subcutaneous tissues of the face and neck in terms of skin inflammation, pain, adverse events, and histologic features.
DESIGN: In an open-label, phase 1 study, patients scheduled to undergo a rhytidectomy were enrolled into immediate (face-lift surgery within 24 hours of intense ultrasound treatment) and delayed (face-lift surgery 4–12 weeks after treatment) treatment groups. Intense ultrasound treatments were performed as a series of several linear exposures delivered 1.5 to 2.0 mm apart with the use of 1 of 3 available handpieces with different focal depths. Subject pain ratings and standardized digital photographs were obtained at uniform points. Photographs were blindly rated for inflammation. Histologic evaluation of treated tissues was performed with nitroblue tetrazolium chloride viability stain.
RESULTS: Fifteen subjects with a mean +/- SD age of 53 +/- 7 years were enrolled. Seven subjects were nonrandomly assigned to the immediate group and 8 were in the delayed group. On histologic examination, thermal injury zones were consistently identified in the dermis at exposure levels greater than 0.5 J as focal areas of denatured collagen. At this threshold level or above, most patient exposures were associated with transient superficial skin erythema and slight to mild discomfort on a standardized pain scale. No other adverse effects were noted in any case. Thermal injury zones were produced in the expected linear pattern and were consistent in size and depth from zone to zone. Increasing source power did not increase the depth of the epicenter of the thermal injury zone. Epidermis was spared in all cases.
CONCLUSION: In this first clinical study of intense ultrasound therapy to facial tissues, the intense ultrasound system allowed for the safe and well-tolerated placement of targeted, precise, and consistent thermal injury zones in the dermis and subcutaneous tissues with sparing of the epidermis.

13. Hitchcock TM, Dobke MK. Review of the safety profile for microfocused ultrasound with visualization. J Cosmet Dermatol. 2014 Dec;13(4):329-35.

The Safety of Microfocused Ultrasound with Visualization (MFU-V) has been well established in both controlled clinical studies and in clinical use, showing only mild and transient anticipated side effects and only rare unanticipated adverse events (AEs).
This publication discusses the safety profile of MFU-V based on data from a variety of sources. Reports of side effects and AEs were obtained from published peer-reviewed medical literature, clinical studies, in-market use reports (AEs reported to the manufacturer), and retrospective chart reviews of patient treatments. Events that were typical included tenderness, redness, and slight edema. Rare events included bruising, welting, and nerve-related effects (paresthesia and paresis). Rare incidence of surface thermal effects was seen in some cases where improper technique was used. In all cases where the device was uses properly, the safety events reported tended to be transient, mild in nature, and resolved without sequelae. In general, unexpected and rare AEs could be attributed to incorrect treatment technique or classified as unrelated to MFU-V treatment. Side effects that do occur are generally mild and transient in nature. MFU-V consistently allows for safe treatment when correct treatment technique is used.

14. Laubach HJ, et al. Intense focused ultrasound: evaluation of a new treatment modality for precise microcoagulation within the skin. Dermatol Surg. 2008 May;34(5):727-34.

BACKGROUND AND OBJECTIVE: Focused ultrasound can produce thermal and/or mechanical effects deep within tissue. We investigated the capability of intense focused ultrasound to induce precise and predictable subepidermal thermal damage in human skin.
MATERIALS AND METHODS: Postmortem human skin samples were exposed to a range of focused ultrasound pulses, using a prototype device (Ulthera Inc.) emitting up to 45 W at 7.5 MHz with a nominal focal distance of 4.2 mm from the transducer membrane. Exposure pulse duration ranged from 50 to 200 ms. Thermal damage was confirmed by light microscopy using a nitroblue tetrazolium chloride assay, as well as by loss of collagen birefringence in frozen sections. Results were compared with a computational model of intense ultrasound propagation and heating in tissue.
RESULTS: Depth and extent of thermal damage were determined by treatment exposure parameters (source power, exposure time, and focal depth). It was possible to create individual and highly confined lesions or thermal damage up to a depth of 4 mm within the dermis. Thermal lesions typically had an inverted cone shape. A precise pattern of individual lesions was achieved in the deep dermis by applying the probe sequentially at different exposure locations.
DISCUSSION AND CONCLUSION: Intense focused ultrasound can be used as a noninvasive method for spatially confined heating and coagulation within the skin or its underlying structures. These findings have a significant potential for the development of novel, noninvasive treatment devices in dermatology.

15. Lee HS, et al. Multiple pass ultrasound tightening of skin laxity of the lower face and neck. Dermatol Surg. 2012 Jan;38(1):20-7.

BACKGROUND: Skin laxity is a common complaint of patients who request skin rejuvenation. Radiofrequency and infrared light are widely used for nonablative treatment of skin laxity. Intense focused ultrasound (IFUS) has been investigated as a tool for the treatment of solid benign and malignant tumors for many decades but is only now beginning to emerge as a potential noninvasive alternative to conventional nonablative therapy.
OBJECTIVES: To evaluate the efficacy of IFUS for the treatment of face and neck laxity.
METHODS: Twelve female volunteers were enrolled in the study, and 10 were ultimately evaluated. The device under investigation was an IFUS. Areas treated included the face and neck. For treatment, the 4-MHz, 4.5-mm probe was used first, followed by the 7-MHz, 3.0-mm probe. Two blinded, experienced clinicians evaluated paired pretreatment and post-treatment (day 90) photographs. Patient self-assessments were also obtained.
RESULTS: On the first primary outcome measure, two blinded clinicians felt that 8 of 10 subjects (80%) showed clinical improvement 90 days after treatment. Nine of 10 subjects (90%) reported subjective improvement.
CONCLUSIONS: IFUS has many advantages for skin tightening.

16. Lee HJ, et al. The efficacy and safety of intense focused ultrasound in the treatment of enlarged facial pores in Asian skin. J Dermatolog Treat. 2015 Feb;26(1):73-7.

BACKGROUND: Intense focused ultrasound (IFUS) has been used successfully for skin tightening.
OBJECTIVE: To investigate the efficacy of IFUS in treating enlarged pores and to evaluate changes in skin elasticity and sebum production following IFUS. Materials and methods: Twenty-two subjects with enlarged pores were randomized to receive a single treatment with IFUS using 1.5-mm transducer on one side of the face, and 3.0-mm transducer on the other. Objective clinical assessments were made by blinded photographic evaluation. Subjective satisfaction and adverse effects were evaluated. Measurements of elasticity and sebum were performed at baseline, 3 and 6 weeks post-treatment. Results: Physicians' evaluation showed clinical pore improvements in 86% and 91% of the IFUS-treated sites using 1.5-mm and 3.0-mm
transducer, respectively. The mean improvement scores were 1.7 and 1.9 for 1.5-mm and 3.0-mm transducer, respectively, with no statistical differences. Cutometer measurement demonstrated a significant improvement in skin elasticity. Sebum level showed a reduction without statistical significance. There was a positive correlation between improvement in elasticity and pore improvement grades. All treatments were well tolerated without significant side effects.
CONCLUSION: IFUS using 1.5-mm or 3.0-mm transducer was safe and effective for reducing enlarged pores in Asian skin with an improvement in skin elasticity.

17. MacGregor JL, Tanzi EL. Microfocused ultrasound for skin tightening. Semin Cutan Med Surg. 2013 Mar;32(1):18-25.

The demand for noninvasive skin tightening procedures is increasing as patients seek safe and effective alternatives to aesthetic surgical procedures of the face, neck, and body. Over the past decade, radiofrequency and infrared laser devices have been popularized owing to their ability to deliver controlled heat to the dermis, stimulate neocollagenesis, and effect modest tissue tightening with minimal recovery. However, these less invasive approaches are historically associated with inferior efficacy so that surgery still remains the treatment of choice to address moderate to severe tissue laxity. Microfocused ultrasound was recently introduced as a novel energy modality for transcutaneous heat delivery that reaches the deeper subdermal connective tissue in tightly focused zones at consistent programmed depths. The goal is to produce a deeper wound healing response at multiple levels with robust collagen remodeling and a more durable clinical response. The Ulthera device (Ulthera, Inc, Meza, AZ), with refined microfocused ultrasound technology, has been adapted specifically for skin tightening and lifting with little recovery or risk of complications since its introduction in 2009. As clinical parameters are studied and optimized, enhanced efficacy and consistency of clinical improvement is expected.

18. Minkis K, Alam M. Ultrasound skin tightening. Dermatol Clin. 2014 Jan;32(1):71-7.

Ultrasound skin tightening is a noninvasive, nonablative method that allows for energy deposition into the deep dermal and subcutaneous tissue while avoiding epidermal heating. Ultrasound coagulation is confined to arrays of 1-mm(3) zones that include the superficial musculoaponeurotic system and connective tissue. This technology gained approval from the Food and Drug Administration as the first energy-based skin "lifting" device, specifically for lifting lax tissue on the neck, submentum, and eyebrows. Ultrasound has the unique advantage of direct visualization of treated structures during treatment. Ultrasound is a safe and efficacious treatment for mild skin tightening and lifting.

19. Oni G, et al. Evaluation of a microfocused ultrasound system for improving skin laxity and tightening in the lower face. Aesthet Surg J. 2014 Sep;34(7):1099-110.

BACKGROUND: The Ulthera System (Ulthera, Inc, Mesa, Arizona) employs microfocused ultrasound to cause discrete focal heating of the dermis and stimulate neocollagenesis and elastin remodeling.
OBJECTIVES: The authors investigated tightening and lifting of cheek tissue, improvement in jawline definition, and reduction in submental skin laxity in patients treated with the Ulthera System.
METHODS: A total of 103 adults were enrolled in this prospective nonrandomized clinical trial. Three-dimensional photographs obtained at baseline and 3 months posttreatment were assessed qualitatively by 3 blinded reviewers and quantitatively with AutoCAD software (Informer Technologies, Redwood City, California). The relationship between outcomes and body mass index (BMI) was examined as well. Patients rated pain during the procedure and provided subjective assessment of their outcome at 90 days. Adverse events were documented.
RESULTS:Ninety-three patients were evaluated. Blinded reviewers observed improvement in skin laxity in 58.1% of patients. During quantitative assessments, overall improvement in skin laxity was noted in 63.6% of evaluated patients. No change was detected in 54.5% of patients whose BMI exceeded 30 kg/m2 or in 12.2% of patients whose BMI was ≤30 kg/m2. At day 90, 65.6% of patients perceived improvement in the skin laxity of the lower half of their face/neck. The average procedural pain scores for the cheek, submental, and submandibular regions were 5.68, 6.09, and 6.53, respectively. Wheals, which resolved without intervention or long-term sequelae, were reported for 3 patients.
CONCLUSIONS: To the authors' knowledge, this is the largest clinical study of the effectiveness of the Ulthera System for rejuvenation of the lower face. At day 90, improvements were reported by two-thirds of patients and by nearly 60% of blinded reviewers. Outcomes were better in patients with BMI ≤30 kg/m2.

20. Pak CS, et al.Safety and efficacy of ulthera in the rejuvenation of aging lower eyelids: a pivotal clinical trial. Aesthetic Plast Surg. 2014 Oct;38(5):861-8.

BACKGROUND: The changes in the periorbital region are among the most prominent features of the aging process in the lower eyelids. Intense focused ultrasound (IFUS), known as the Ulthera System, was designed to correct this process. The current study assessed the safety and efficacy of the Ulthera System.
METHODS: This study enrolled seven adult patients who presented from March 2011 to May 2012 for correction of lower eyelid aging by Ulthera. The subjects were treated using Ulthera 1.5 and 3.0 mm probes. The 1.5 mm probe is used to tighten of loose eyelid skin and the deep dermis, whereas the 3.0 mm probe is used to tighten the orbicularis oculi muscle and the orbital septum. The patients were evaluated for allergic reactions and other side effects. The subjects' satisfaction with clinical photographs and the degree of pain were evaluated. Moreover, orbital computed tomography (CT) and ophthalmologic examinations were performed. The study used CT both as a research tool and as a clinical score system for evaluating aging lower eyelids and performed statistical analysis.

RESULTS: Based on the CT images, the difference between the pre- and postoperative distances from the baseline (line between the most inferior point of the supraorbital rim and the most superior point of the infraorbital rim) to the most protruding point of the orbital septum was 0.51 ± 0.23 for the right eye (p\0.001) and 0.54 ± 0.17 for the left eye (p\0.001). The subjective score for patient satisfaction was 3.85 ± 0.69. The objective satisfaction scores reported by two blinded researchers were respectively 3.45 ± 1.69 and 3.25 ± 1.43. During the study period, no adverse events and no suspected serious adverse reactions were noted.
CONCLUSIONS: Tightening of infraorbital laxity and skin can be achieved using the Ulthera System. Patients showed a minimal pain level during treatment, and topical analgesic cream was able to manage pain during the procedure.

21. Pritzker RN, et al. Comparison of different technologies for noninvasive skin tightening. J Cosmet Dermatol. 2014 Dec;13(4):315-23.

Facial skin laxity is a bothersome sign of aging. In the past, the only option for treating laxity was surgery. While surgical lifting remains the gold standard, there has been a growing demand among patients for less invasive techniques. Patients are increasingly seeking procedures with little to no downtime, lower risk profiles, and a more natural appearance. The industry has responded to these demands with an emergence of noninvasive skin tightening devices. The rate of development and marketing of these devices has increased exponentially within the last decade. Whereas we previously had no options, now we are faced with many choices. How do we choose which technology is best for our patients? While there is a paucity of comparative trials to date, a critical exploration of these technologies is worthwhile. The underlying mechanism of action of all these treatments is essentially the same: heating of the dermis and subdermal areas while minimizing injury to the epidermis. In this article, we outline the different technologies and highlight the differences to help guide us in selecting the right treatment.

22. Suh DH, et al. Intense focused ultrasound tightening in Asian skin: clinical and pathologic results. Dermatol Surg. 2011 Nov;37(11):1595-602.

BACKGROUND: Laxity and wrinkles of the aging face are common cosmetic concerns. Intense focused ultrasound (IFUS), a novel treatment modality for skin laxity, produces thermal effects at various depths while sparing overlying epidermis.
OBJECTIVE: To evaluate the safety and efficacy of IFUS in facial skin tightening.
METHODS AND MATERIALS: Twenty-two Korean patients with facial laxity were analyzed after a single IFUS treatment. Patient assessments were recorded, and two blinded, experienced clinicians who assessed improvement of nasolabial folds and jaw tightening evaluated photographs of patients and rated skin laxity. Skin biopsies were taken from 11 patients before and 2 months after treatment.
RESULTS: Objectively, nasolabial folds and jaw lines were improved in all patients. Subjectively, 77% of patients reported much improvement of nasolabial folds, and 73% of patients reported much improvement at the jaw line. Histologic evaluation of skin biopsy samples using hematoxylin and eosin and Victoria blue stains showed greater dermal collagen with thickening of the dermis and straightening of elastic fibers in the reticular dermis after treatment.
CONCLUSION IFUS: is a safe, effective, noninvasive procedure to tighten the facial skin of Asian patients. Improvement is associated with greater production of dermal collagen and straightening of dermal elastic fibers. The authors have indicated no significant interest with commercial supporters.

23. Suh DH, et al. A intense-focused ultrasound tightening for the treatment of infraorbital laxity. J Cosmet Laser Ther. 2012 Dec;14(6):290-5.

BACKGROUND: Infraorbital laxity is a common problem that increases with age. Blepharoplasty with lipectomy is a very commonly performed surgical procedure to treat this problem; however, it is invasive and is associated with the potential for re-emergence. Therefore, young patients may prefer a non-surgical procedure rather than to a surgical procedure. Intense-focused ultrasound (IFUS) has emerged as an effective, non-surgical, tissue-tightening procedure.
OBJECTIVE: This study assessed the safety and efficacy of IFUS (Ulthera system, Ulthera Inc, Mesa, AZ, U.S.A.) for facial tightening in Asian patients with infraorbital laxity.
METHODS: We studied 15 patients who were treated with an IFUS device applied to both lower eyelids. The primary outcome measure was an objective improvement in a paired comparison of pre-treatment and post treatment (6 months) photographs. A secondary outcome measure was patient satisfaction as measured by a questionnaire.
RESULTS: The mean patient age was 50 years (range, 27–69). All patients received one to two treatments with intense-focused ultrasound. All patients in the study experienced both subjective and objective improvement.
CONCLUSION: IFUS can be used as a non-invasive, skin-tightening procedure for infraorbital laxity. No serious, permanent, or delayed side effects were noted up to 6 months post treatment. Thus, this procedure can be effective and safe in the treatment of decreased laxity of the lower eyelids.

24. Suh DH, et al. Comparative histometric analysis of the effects of high intensity focused ultrasound (HIFU) and radiofrequency (RF) on skin. J Cosmet Laser Ther. 2015 Aug;17(5):230-6.

INTRODUCTION: High-intensity focused ultrasound (HIFU) and radiofrequency (RF) are used for non-invasive skin tightening. Neocollagenesis and neoelastogenesis have been reported to have a mechanism of controlled thermal injury.
OBJECTIVE: To compare neocollagenesis and neoelastogenesis in each layer of the dermis after each session of HIFU and monopolar RF.
METHODS: We analyzed the area fraction of collagen and elastic fibers using the Masson's Trichrome and Victoria blue special stains, respectively, before and after 2 months of treatments. Histometric analyses were performed in each layer of the dermis, including the papillary dermis, and upper, mid, and deep reticular dermis.
RESULTS: Monopolar RF led to neocollagenesis in the papillary dermis, and upper, mid, and deep reticular dermis, and neoelastogenesis in the papillary dermis, and upper and mid reticular dermis. HIFU led to neocollagenesis in the mid and deep reticular dermis and neoelastogenesis in the deep reticular dermis. Among these treatment methods, HIFU showed the highest level of neocollagenesis and neoelastogenesis in the deep reticular dermis.
CONCLUSIONS: HIFU affects deep tissues and impacts focal regions. Monopolar RF also affects deep tissues, but impacts diffuse regions. We believe these data provide further insight into effective skin tightening.

25. Weiss M. Commentary: noninvasive skin tightening: ultrasound and other technologies: where are we in 2011? Dermatol Surg. 2012 Jan;38(1):28-30.

Commentary/review of skin tightening advances in 2011 including MFU and RF. No abstract.

26. Werschler WP, Werschler SP. Long-term Efficacy of Micro-focused Ultrasound with Visualisation for Lifting and Tightening Lax Facial and Neck Skin Using a Customized Vectoring Treatment Method. J Clin Aesth Dermatol. 2016 Feb;9(2): 27-33.

BACKGROUND: Micro-focused ultrasound with visualization has been cleared by the United States Food and Drug Administration to noninvasively lift the eyebrow, lift submental and neck tissue, and improve lines and wrinkles of the décolleté.
OBJECTIVE: The objective of this prospective, open-label pilot study was to evaluate the efficacy and safety of patient-specific, customized micro-focused ultrasound with visualization treatment with vertical vectoring to lift and tighten facial and neck tissue.
METHODS AND MATERIALS: Subjects 25 to 60 years of age (N=20) with areas of skin laxity on the face and neck were enrolled and treated. A dual depth treatment was administered using a vectored pattern. Subjects were evaluated after 90 days, 180 days, and one year.
RESULTS: Overall improvements in Subject Global Aesthetic Improvement Scale and Physician Global Aesthetic Improvement Scale scores were reported by 90 and 100 percent of subjects at 90 and 180 days, respectively, and 95 percent for both measures at one year. Six of 14 evaluable subjects were rated as improved by blinded assessment at one year. Self-reported improvements maintained for up to one year included less sagging (79%), fewer lines and wrinkles (58%), and smoother skin texture (47%).
CONCLUSION: Based on these results, treatment with micro-focused ultrasound with visualization with vertical vectoring demonstrated appreciable lifting and tightening of facial and neck tissue resulting in improved Global Aesthetic Improvement Scale scores and a high degree of patient satisfaction for up to one year.

27. White WM, et al. Selective creation of thermal injury zones in the superficial musculoaponeurotic system using intense ultrasound therapy: a new target for noninvasive facial rejuvenation. Arch Facial Plast Surg. 2007 Jan-Feb;9(1):22-9.

OBJECTIVES: To transcutaneously deliver intense ultrasound (IUS) energy to target the facial superficial musculoaponeurotic system (SMAS), to produce discrete thermal injury zones (TIZs) in the SMAS, and to demonstrate the relative sparing of adjacent nontargeted layers superficial and deep to the SMAS layer.
METHODS: In 6 unfixed human cadaveric specimens, the SMAS layer was visualized and targeted using the ultrasound imaging component of the IUS device. Using 2 IUS handpieces, 202 exposure lines were delivered bilaterally in multiple facial regions by varying combinations of power and exposure time (0.5–8.0 J). Tissue was then excised and examined grossly and histologically for evidence of thermal injury using nitroblue tetrazolium chloride viability stain.
RESULTS: Reproducible TIZs were produced selectively in the SMAS at depths of up to 7.8 mm, and sparing of surrounding tissue including the epidermis. Higher energy settings and high-density exposure line pattern produced a greater degree of tissue shrinkage.
CONCLUSIONS: In human cadaveric facial tissue, IUS can noninvasively target and selectively produce TIZs of reproducible location, size, and geometry in the SMAS layer. The ability to produce focused thermal collagen denaturation in the SMAS to induce shrinkage and tissue tightening has not been previously reported and has significant implications for aesthetic facial rejuvenation.

28. White WM, et al. Selective transcutaneous delivery of energy to porcine soft tissues using Intense Ultrasound (IUS). Lasers Surg Med. 2008 Feb;40(2):67-75.

OBJECTIVE: Various energy delivery systems have been utilized to treat superficial rhytids in the aging face. The Intense Ultrasound System (IUS) is a novel modality capable of transcutaneously delivering controlled thermal energy at various depths while sparing the overlying tissues. The purpose of this feasibility study was to evaluate the response of porcine tissues to various IUS energy source conditions. Further evaluation was performed of the built-in imaging capabilities of the device.
MATERIALS AND METHODS: Simulations were performed on ex vivo porcine tissues to estimate the thermal dose distribution in tissues after IUS exposures to determine the unique source settings that would produce thermal injury zones (TIZs) at given depths. Exposures were performed at escalating power settings and different exposure times (in the range of 1–7.6 J) using three IUS handpieces with unique frequencies and focal depths. Ultrasound imaging was performed before and after IUS exposures to detect changes in tissue consistency. Porcine tissues were examined using nitro-blue tetrazolium chloride (NBTC) staining sensitive for thermal lesions, both grossly and histologically. The dimensions and depth of the TIZs were measured from digital photographs and compared.
RESULTS: IUS can reliably achieve discrete, TIZ at various depths within tissue without surface disruption. Changes in the TIZ dimensions and shape were observed as source settings were varied. As the source energy was increased, the thermal lesions became larger by growing proximally towards the tissue surface. Maximum lesion depth closely approximated the pre-set focal depth of a given handpiece. Ultrasound imaging detected well-demarcated TIZ at depths within the porcine muscle tissue.
CONCLUSION: This study demonstrates the response of porcine tissue to various energy dose levels of Intense Ultrasound. Further study, especially on human facial tissue, is necessary in order to understand the utility of this modality in treating the aging face and potentially, other cosmetic applications.

29. Wulkan AJ, et al. Microfocused Ultrasound for Facial Photorejuvenation: A Review. Facial Plast Surg. 2016 Jun;32(3):269-75.

Microfocused ultrasound is a unique technology to treat skin laxity of the brow, lower face, and the rhytides of the décolletage. Over the past several years, the efficacy and safety of this device has been well documented and its adoption widespread. By delivering focused acoustic energy, which is converted to heat, this device creates predictable and reproducible microcoagulative zones that initiate a concentrated inflammatory wound response. By targeting the deep reticular dermis and superficial muscle and fascial planes, such as the superficial musculoaponeurotic system, platysma, and pectoralis muscle fascia, this nonablative technology increases neocollagenesis and neoelastogenesis in a novel fashion, while avoiding many of the complications related to epidermal heating observed in several other nonablative devices. Although the results are not equivalent to those of a rhytidectomy, microfocused ultrasound provides an excellent noninvasive means to achieve a regenerative effect on the face, neck, and décolletage when performed in the appropriate patient population.

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https://www.merz-aesthetics.de/produkte/ultherapy/science-briefe/

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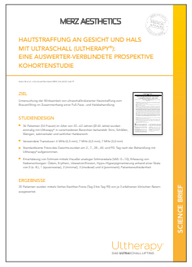
Science Brief Ultherapy® – Wirkmechanismus

Präzise Wirkung des mikrofokussierten Ultraschalls in definierten, bis zu 4,5 mm tiefen, Gewebeschichten und gleichzeitige Bildgebung. Lifting-Effekt durch Kollagen-Remodelling

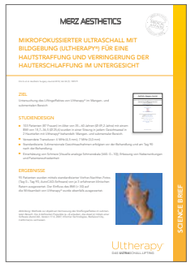


Science Brief Ultherapy® – Augenbrauenlifting im Zusammenhang mit Full-face-Behandlung

Alam M, et al. J Am Acad Dermatol. 2010 Feb;62(2):262-9.

Erhöhung der Augenbrauen und Hautstraffung im Gesichtsbereich

Gute Verträglichkeit während und nach der Behandlung



Science Brief Ultherapy® – Hautstraffung und Verringerung der Hauterschlaffung im Untergesicht

Oni G. et al. Aesthet Surg J. 2014 Sep;34(7):1099-110.

Lifting durch mikrofokussierten Ultraschall im Wangen- und submentalen Bereich

Gute Verträglichkeit während und nach der Behandlung

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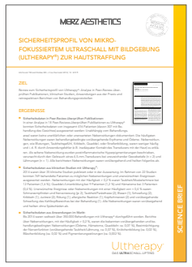
Science Brief Ultherapy® – Hautstraffung, Straffung und Faltenreduktion des Dekolleté

Fabi SG, et al. J Am Acad Dermatol. 2013 Dec;69(6):965-71.

Verbesserungen von Falten und Linien sowie von Hauterschlaffung und Hauttextur

Hohe Patientenzufriedenheit und gute Verträglichkeit



Science Brief Ultherapy® – Sicherheitsprofil von mikrofokussiertem Ultraschall mit Bildgebung

Hitchcock TM, Dobke MK. J Cosmet Dermatol. 2014 Dec;13(4):329-35.

Umfassende Datenlage aus Studien und Praxis

Science Brief Ultherapy® – Langzeitwirksamkeit von mikrofokussiertem Ultraschall mit Visualisierung (MFU-V) zur Behandlung von Hauterschlaffung im Gesichts- und halsbereich

Werschler WP, Werschler SP. J Clin Aesthet Dermatol. 2016 Feb;9(2):27-33.

Pilotstudie mit dem Ziel, Wirksamkeit und Sicherheit einer individuell angepassten Ultherapy® im Gesichts- und Halsbereich zu erfassen

Science Brief Ultherapy® – Histometrische Vergleichsuntersuchung der hautstraffenden Wirkung von hochintensiv-fokussiertem Ultraschall mit Visulisierung (HIFU-V) versus Radiofrequenz (RF)

Suh DH, et al. J Cosmet Laser Ther. 2015;17(5):230-6.

Vergleich der Wirkung von HIFU (Ultherapy®) und monopolarer RF auf die Kollagen- und Elastinneubildung in verschiedenen Dermisschichten

Science Brief Ultherapy® – Kombinierte Anwendung von mikrofokussiertem Ultraschall mit Visualisierung (MFU-V), Botulinumtoxin und Dermalfillern: Sicherheit und Einsatz und Einsatz in Praxi

Fabi SG, et al. Dermatol Surg. 2016 May;42 Suppl 2:S168-76.

Erfassung von Sicherheitsdaten bei der Kombination von MFU-V (Ultherapy®) mit BoNT und/oder Dermalfiller

Science Brief Ultherapy® – mikrofokussierter Ultraschall mit Visualisierung (MFU-V) zur Behandlung von erschlaffter Haut im Halsbereich

Baumann L, et al. J Drugs Dermatol. 2016 May 1;15(5):607-14.

Individualisierte Behandlungsprotokolle für den submentalen Bereich und Halsbereich: Wirkungen einer Behandlung in 2 verschiedenen Tiefen im Vergleich zu einer einlagigen Behandlung

NOTIZEN

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