

IN-DEPTH REVIEWS

Noninvasive Body Contouring: Literature Review and Summary of Objective Data

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ABSTRACT

Background: There is increasing demand for noninvasive body contouring but objective data is difficult to compare between modalities. Currently, the most accepted forms of noninvasive body contouring are cryolipolysis (Cryo), focused ultrasound (FUS), radiofrequency (RF), and low level laser therapy (LLLT).

Objective: To summarize the objective data on noninvasive body contouring.

Methods: In October 2016, a pubmed search was performed with terms “noninvasive body contouring” or “non-invasive body contouring.” The search was limited to human studies in English on the four major modalities.

Results: 55 articles yielded data from 3649 patients. The most well studied modality was Cryo and the least was RF. Decreased abdominal/flank localized adiposity was most the most common endpoint reported. Both the minimum and maximum reported decreases in abdominal girth were from studies using RF (1.4cm and 7.4cm, respectively). Side effects were most common and significant with Cryo and absent with LLLT.

Conclusions: Noninvasive body contouring has a significant amount of objective data available in the literature to date. Reductions of localized adiposity are clinically and statistically significant but modest. To date, the best reported positive results have been obtained with RF and the lowest risk of side effects is with LLLT.

Capsule Summary:

- Noninvasive body contouring devices vary by efficacy, treatment schedule and safety profile.
- This review compares body contouring modalities, allowing for quick comparison between modalities.
- This review enables the selection of a body contouring modality that best suits each specific patient’s goals, availability and aversion to risk.

Abbreviations: Cryo: Cryolipolysis; FUS: Focused Ultrasound; RF: Radiofrequency; LLLT: Low Level Laser Therapy; HIFU: High Intensity Focused Ultrasound; LOFU: Low Intensity Focused Ultrasound

INTRODUCTION

Cosmetic procedures targeting excess fat have evolved over the past 30 years to be less invasive. Unfortunately, objective studies comparing modalities for noninvasive body contouring are limited, which hampers physicians and patients alike when choosing an appropriate treatment device. There are four major modalities for noninvasive body sculpting: cryolipolysis (Cryo), radiofrequency (RF), focused ultrasound (FUS) and low level laser therapy (LLLT)¹⁻⁷. FUS is subdivided into high intensity focused ultrasound (HIFU) and low intensity focused ultrasound (LOFU). Each modality varies by treatment schedule, onset of results, and side effect profile. Furthermore, results are reported in multiple ways, from circumference measurements to diagnostic ultrasound of fat thickness. This review of the published peer-reviewed literature presents and summarizes the objective data of the four major noninvasive modalities for comparison.

METHODS

In October of 2016, a pubmed search was performed with terms “noninvasive body contouring” and “non-invasive body contouring.” The search was limited to human studies in English. The scope was limited to objective data reported on Cryo, FUS, RF and LLLT. A total of 58 articles were found, the abstracts were screened, and all remaining articles were thoroughly read. Pertinent sources cited by these articles were also obtained and read.

RESULTS

55 articles were within scope and reported data from 3649 patients (Table 1). The modality with the least total study participants was RF (280 patients, 10 studies). The most

studied modality was Cryo (1407 patients, 15 studies).

Decreased localized abdominal/flank adiposity was the most consistently reported outcome across all studies, with minimum (1.4cm)⁸ and maximum (7.4cm)⁹ decreases both reported by RF studies (Figure 1). Cryo did not report results using girth as a metric but reported 19.6-25.5% decreased abdominal/flank fat thickness when measured by ultrasound¹⁰⁻¹¹. One RF study reported 29% decreased abdominal/flank fat thickness by ultrasound⁸. Two studies reported results that were not statistically significant, one using FUS¹² and the other using LLLT¹³. Almost all reported side effects were mild and transient. The most commonly reported side effect was pain (often reported as patient comfort). No pain was reported in all LLLT studies and 2 studies evaluating RF¹⁴⁻¹⁵ (Figure 2). Side effects were most common with Cryo, followed by RF and FUS. To avoid side effects, comparable results were often obtained via multiple, lower energy treatments. Reported patient satisfaction rates varied by modality (Figure 3) and body location.

The one non-transient side effect reported was paradoxical adipose hyperplasia (PAH) associated with Cryo. This rare adverse event was reported 4 times in the articles reviewed¹⁶⁻¹⁷. Some estimates of incidence are 1:20,000¹⁶ but may be as high as 1:200¹⁷.

FIGURES

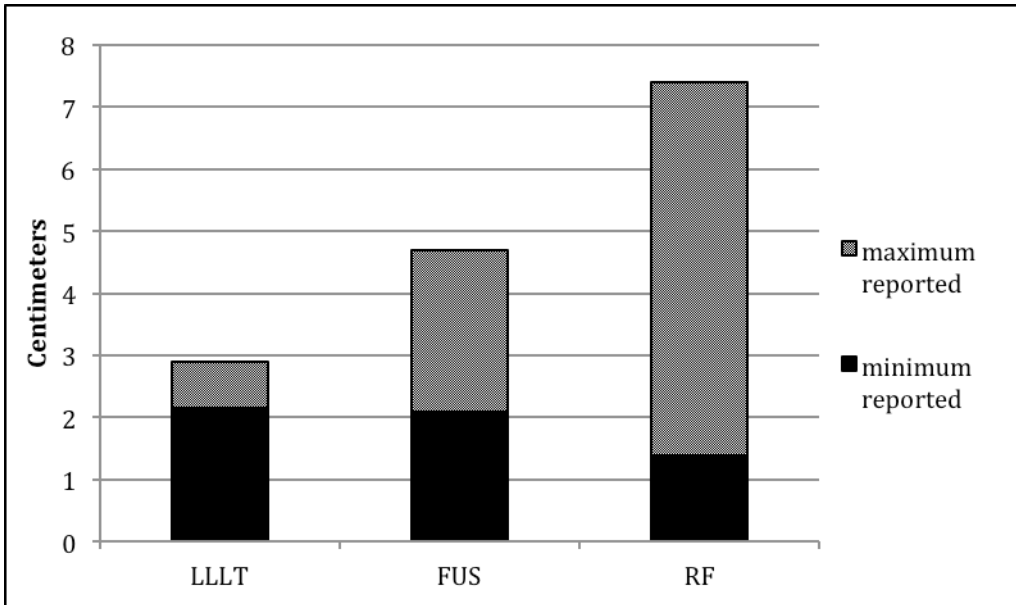


Figure 1: Average Decreased Abdominal Circumference. Data pooled from all studies. Cryo did not report girth measurements.

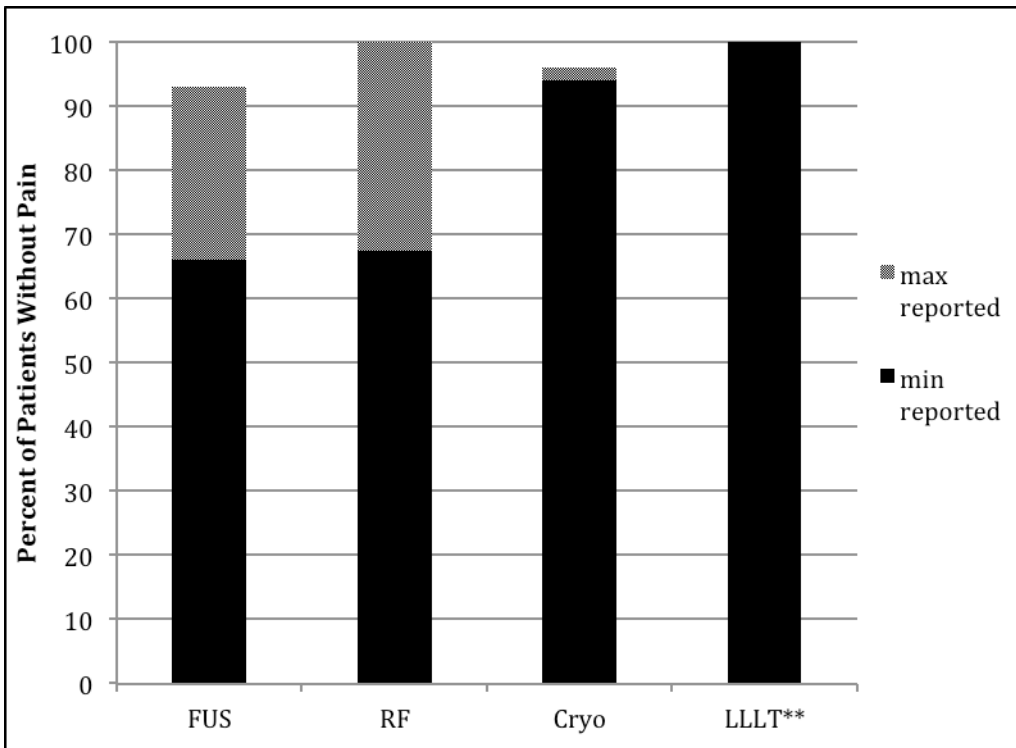


Figure 2: Patient Comfort/Lack of Pain. Data pooled from all studies. ** All studies using LLLT had no pain.

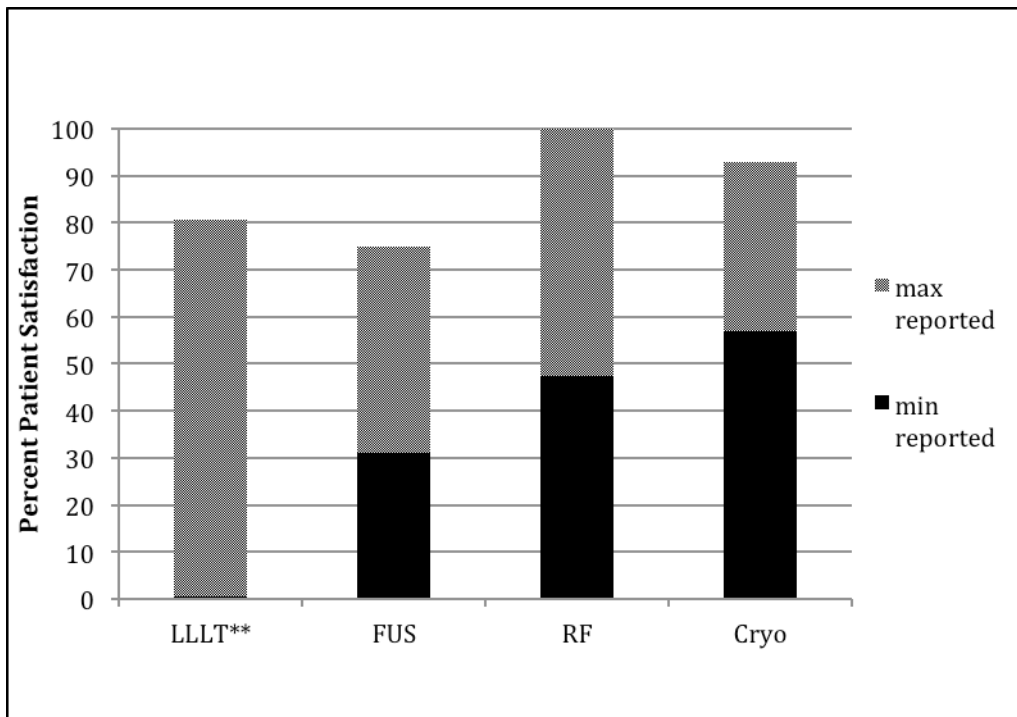


Figure 3: Patient Satisfaction. Data pooled from all studies. **Results from Elm et al not statistically significant, 0% patient satisfaction.

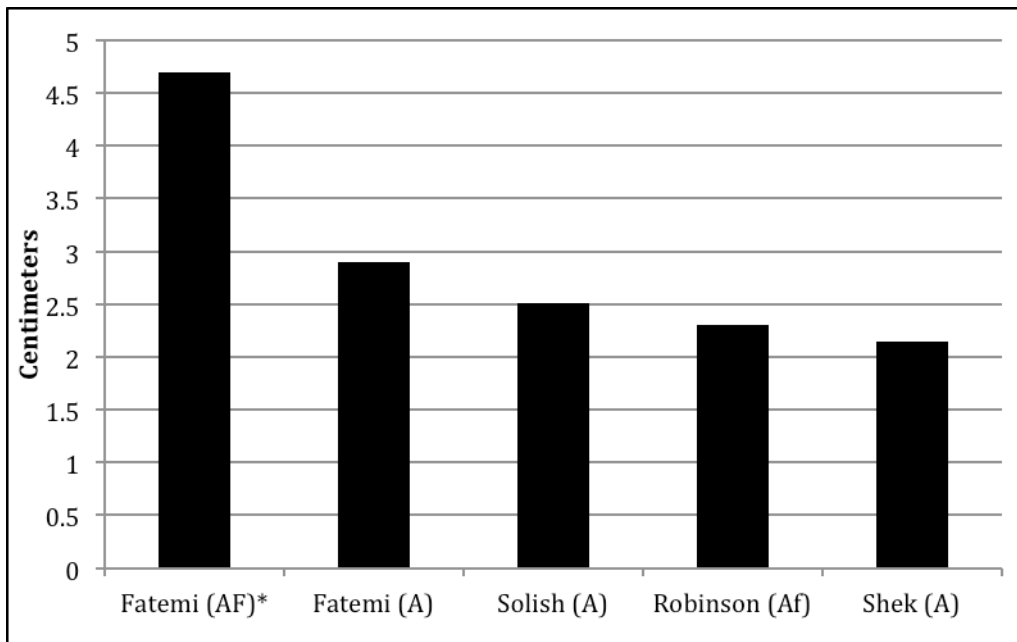


Figure 4: HIFU: Average Decreased Waist Circumference²¹⁻²⁴. (A)Abdomen only, (Af)Abdomen +/- flanks, (AF)Abdomen and flanks. *All studies had Oxford CEBM level of evidence 2b except Fatemi et al (level 4).

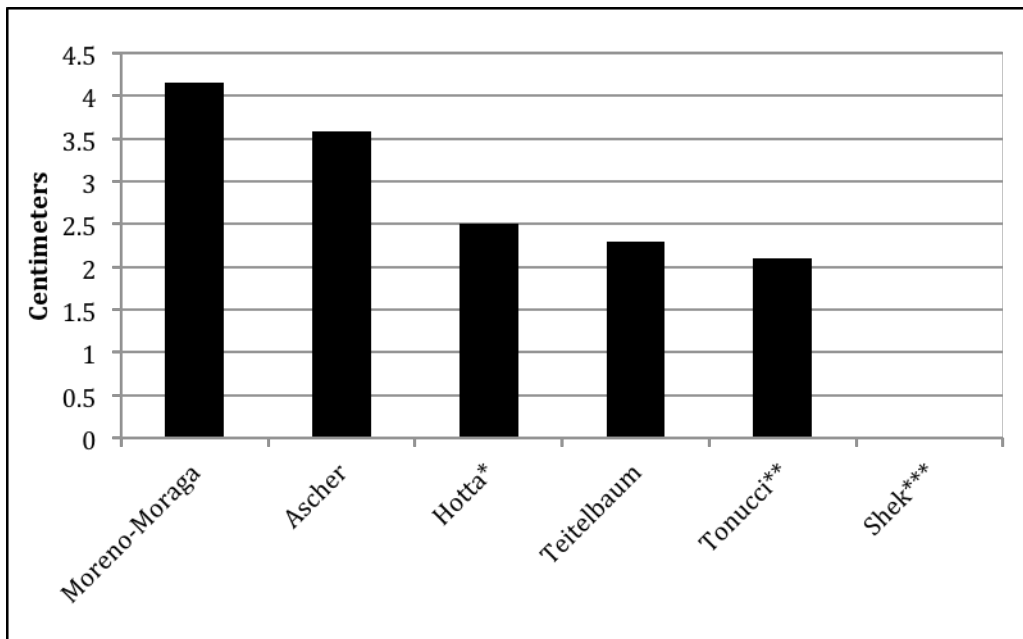


Figure 5: LOFU: Average Decreased Waist Circumference^{12, 26-30}. (*)Average of multiple treatment areas, (**)Unique LOFU device, (***)Results not statistically significant. All studies had Oxford CEBM level of evidence 2b.

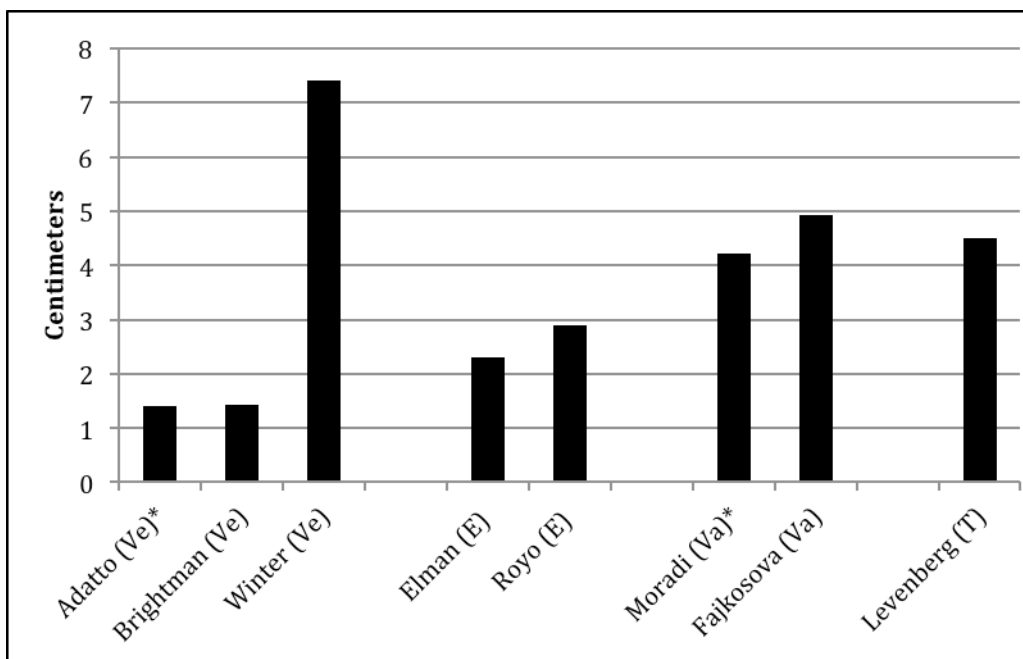


Figure 6: RF: Average Decreased Abdominal Circumference^{8-9, 14-15, 35-37, 40}. (Ve)Velashape, (E)Endymed, (Va)Vanquish, (T)TriPollar. (*)Treatment included abdomen and flanks. All studies had Oxford CEBM level of evidence 2b.

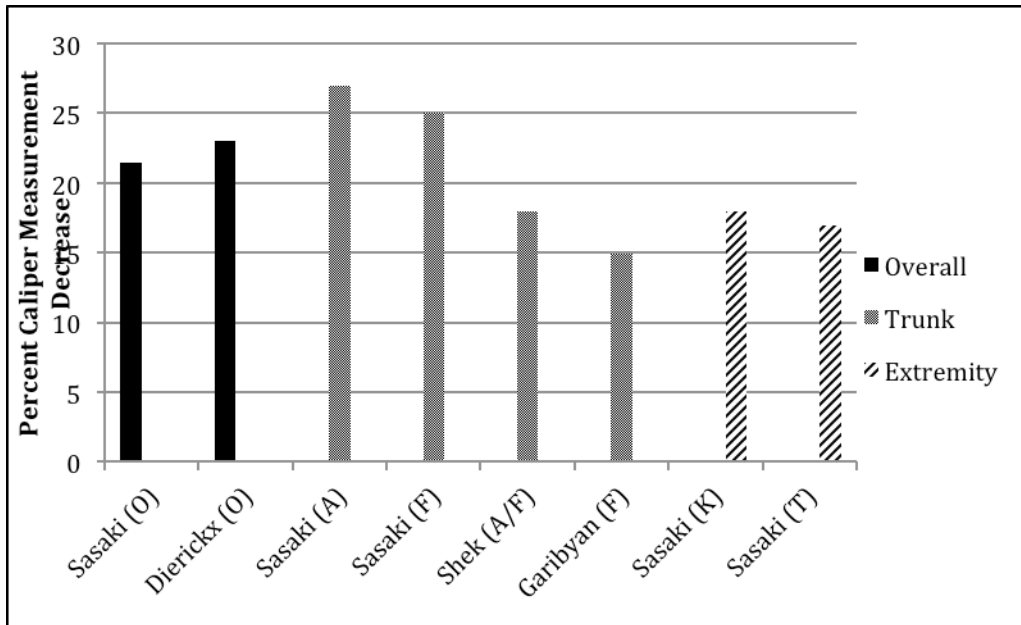


Figure 7: Cryo: Average Caliper Decrease By Location^{10, 18, 44-45}. (O)Average of multiple areas, (A)Abdomen only, (F)Flanks only, (A/F)Abdomen and/or Flanks only, (K)Knees, (T)Thigh. *All studies had Oxford CEBM level of evidence 2b except Garibyan et al (level 1b).

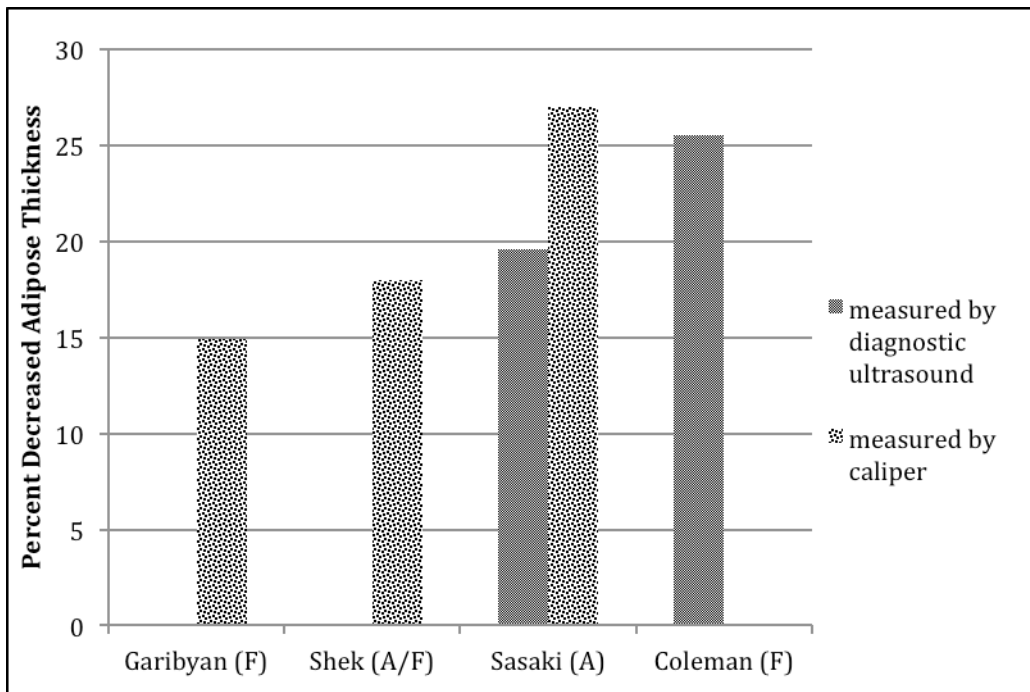


Figure 8: Cryo: Average Decreased Trunk Adipose Thickness^{10-11, 18, 44}. (A)Abdomen only, (F)Flanks only, (A/F)Abdomen and/or Flanks only, (F/B)Flanks or Back. *All studies had Oxford CEBM level of evidence 2b except Garibyan et al (level 1b).

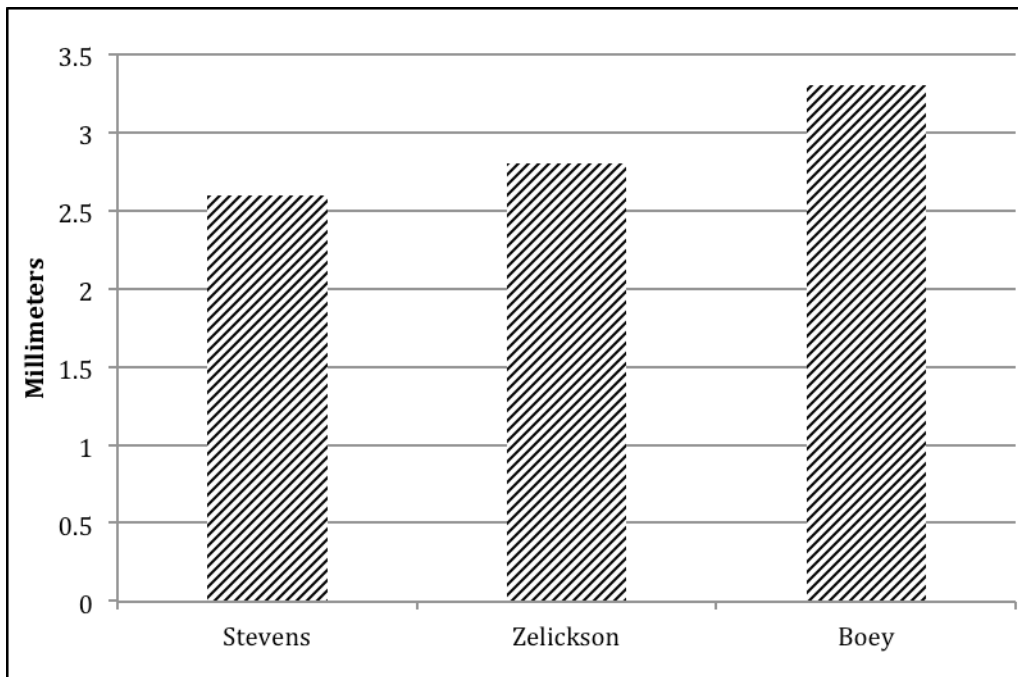


Figure 9: Cryo: Average Decreased Thigh Adipose Thickness⁵¹⁻⁵³ Measured By Ultrasound. All studies had Oxford CEBM level of evidence 2b.

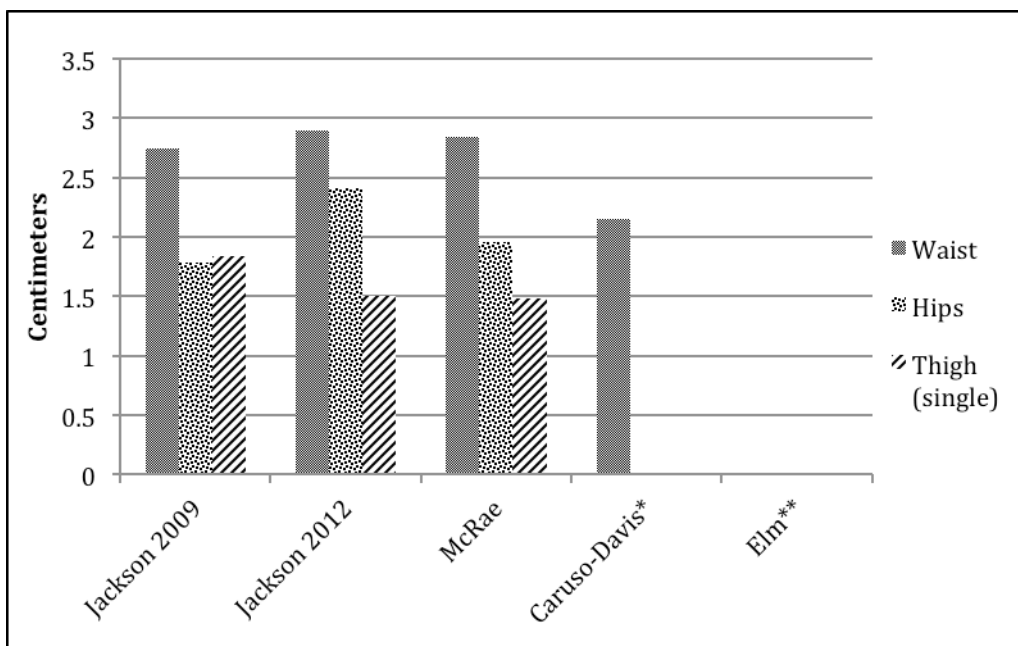


Figure 10: LLLT: Average Decreased Girth By Location^{55-56, 58-59, 62}. (*)Results not statistically significant. Oxford CEBM level of evidence 1b for Jackson et al 2009, Elm et al and Caruso-Davis et al. Oxford CEBM level of evidence 2b for Jackson et al 2012 and McRae et al.

TABLES

Noninvasive Modality	Human Studies	Total Patients	Prospective Patients
Cryo	13	1407	394
FUS	11	973	831
RF	10	280	266
LLLT	7	989	209

Table 1: Overall breakdown of studies and patients included in this review.

	Cryo	FUS:HIFU	FUS:LOFU	RF	LLLT
Device(s) Studied	CoolSculpting	Liposonix	UltraShape	VelaShape, 3DEEP, Vanquish, ThermiSmooth, TriPollar	Zerona, Lapex
Mechanism	Freezing	Thermal	Non-thermal	Thermal	Non-thermal
Treatment Schedules	Once	Once	every 4 weeks	every 1-2 weeks	3 times per week
Treatments	1	1	3	4-6	6
Visit Duration (minutes)	60	45-60	30-90	35-45	40
Onset (weeks)	8	4	2	1	1
Expected Results (weeks)	24	12	12	4-16	2
Decreased Abdominal Girth (centimeters)	N/A	2.1-4.15	2.15-4.7	1.4-7.4	2.15-2.89

Table 2: Data summarized from all four major modalities of noninvasive body contouring.

DISCUSSION

Table 2 summarizes treatment schedules and results by modality. Patient goals should guide appropriate selection of modality. Some patients may request a single treatment while others may prefer minimal downtime, etc. Of note, Cryo is reported to have diminishing returns with successive treatments¹⁸, while other modalities are associated with progressive, cumulative results. To further guide appropriate modality selection, each modality will be assessed below.

FUS

Subdivisions of FUS are HIFU (thermal lipolysis) and LOFU (mechanical cavitation)¹⁹⁻²⁰.

HIFU was studied via Liposonix (Solta)²¹⁻²⁵, with reported results within 4 weeks of a single treatment²³⁻²⁴. Each treatment took under an hour and multiple passes were delivered over a localized area. The HIFU device was studied on the abdomen and flank only (Figure 4). Redness, pain, swelling, and bruising were common side effects with treatment. Altered sensation and formation of subcutaneous nodules were found in some patients, but all reported side effects were transient.

LOFU was studied primarily via UltraShape Contour I (Syneron/Candela)²⁶⁻²⁹. Results were seen as early as 2 weeks^{26, 29} but 3 treatments were typically performed. Each treatment session took 30-90 minutes, depending on the area(s) targeted. The device was studied on the abdomen^{26, 28-29}, flanks^{26, 28-29}, thighs²⁸⁻²⁹, knees²⁸ and chest/breast²⁸. Figure 5 summarizes LOFU results on the waist. The most common side effects were redness and pain. Rarely, blisters and bruising occurred. In particular, LOFU penetrates deeper than HIFU and superficial bones (iliac crest) may reflect

energy and cause blisters¹². For this reason, caution should be used over areas with superficial bony structures. In addition, one study with a high dropout rate (only 11/53 subjects returned for follow-up evaluation) failed to find statistically significant results. The lack of follow-up may have significantly decreased the study's power¹².

RF

Many RF devices have been studied to date and review articles specific to RF have been published³¹⁻³⁴. The VelaShape (Syneron/Candela)^{8-9, 35}, 3DEEP (Endymed)^{14, 15}, Vanquish (BTL)³⁶⁻³⁷, ThermiSmooth 250 (Thermi/Almirall)³⁸ and TriPollar (Pollogen/Lumenis)³⁹⁻⁴⁰ systems all had objective, clinical data on humans. Treatment regimens were similar amongst them but results were variable, which may be due to the small sample of patients studied. Onset was appreciable within a week¹⁴ but multiple treatments were often performed. The abdomen^{8-9, 14-15, 35-37, 40}, flanks^{8-9, 14-15, 35-37, 40}, buttocks^{8-9, 40}, thighs^{8-9, 14, 39-40}, arms³⁵ and face³² were all studied with RF for body contouring. Reported RF results on abdominal girth are presented in Figure 6. Transient redness and swelling were expected side effects, with most studies reporting both in 100% of patients. VelaShape had some reports of bruising and burns as well^{8-9, 35}.

Cryo

The main Cryo device investigated was CoolSculpting (Zeltiq)^{10-11, 18, 41-54}, which has also had review articles published specific to the modality⁴¹⁻⁴³. Only one treatment was usually necessary but diminishing returns with additional treatments were reported¹⁸ and onset took about 8 weeks^{11, 44}. In addition to the abdomen^{10, 18, 45-46}, flank^{10-11, 18, 44-48}, buttocks⁴⁵ and back^{10, 45-46}, specific applicators exist for the arms⁵⁰, knees^{10, 45} and thighs^{10, 45-46, 49-52}. Despite these adaptations, reported results on the trunk

tended to exceed those of the extremities^{10, 45}(Figures 7, 8, 9). Redness, swelling, tissue infiltration and mild pain were expected transient side effects, while bruising was much less common. Almost all patients experienced some degree of altered sensation after treatment. Most were limited to numbness but the effects lingered up to 6 weeks¹¹. Unfortunately, there were some reports of PAH, which is thought to be permanent and occurred 2-12 months after treatment¹⁶⁻¹⁷. The incidence of PAH is estimated to be 1:20,000 treated patients¹⁶ but may be as high as 1:200¹⁷ and may occur in higher proportions of men¹⁶. Over 30 cases have been reported to date.

LLLT

LLLT has been separately reviewed as a modality⁵³ and was investigated via Zerona (Erchonia)⁵⁴⁻⁶⁰ and Lapex 2000 (Meridian)⁶¹. Treatments were studied on the abdomen^{54-55, 57-58}, flanks^{54-55, 57, 58}, buttocks^{54, 57-58}, thighs^{54-55, 57-58} and arms^{56, 59-60}. Six of the seven studies published on LLLT for body contouring used the Zerona device, with treatments 3 times per week for 2 weeks and results first noted at 1 week⁵⁹. The Lapex 2000 was used twice a week for 4 weeks and yielded results at 2 weeks⁶¹. While the results were modest compared to other modalities (Figure 10), there were absolutely no side effects reported. However, one study⁵⁵ failed to report significant results. It was noted that the study was very small (only 5 patients) and was only applied to partial body sites. Since LLLT may involve mobilizing released fat for systemic metabolism, broader application of the laser light may be relevant. Furthermore, Jackson et al⁵⁷ reported decreases in girth at untreated sites, supporting a systemic mechanism. Still, the study was retrospective and those patients that volunteered to share their experience are may be those with superior results.

Combinations

Combination devices are available, two of which were investigated. UltraShape RFVac (Syneron/Candela)⁶² combined HIFU and RF technology while Proshockice (Promoitalia)⁶³ combined acoustic shock wave therapy and Cryo. Chang et al⁶² studied UltraShape RFVac on 32 patients with treatments every 2 weeks for 3 treatments. Average results yielded 3.91cm decreased abdominal circumference at 1 month follow-up and the results were durable up to 1 year later⁶⁴.

Ferraro et al⁶³ studied 50 patients using Proshockice every 15 days for 3-4 treatments and reported 6.86cm average decreased abdominal circumference.

While it is possible that the diminishing returns of Cryo could be mitigated by additional, simultaneously applied modalities, the small sample size must be taken into account and further studies should be completed for confirmation.

Limitations

Variability of reported endpoints was the main limitation. Comparing circumference measurements to ultrasound or caliper measurements was not straight forward⁶⁵. Some endpoints combined multiple treatment areas into a single large measurement, which may include bilateral areas or the summation of multiple, distinct treatment areas. Flank results were grouped with the abdomen or back, depending on the study. The waist or hips represented any combination of the abdomen, back and/or flanks.

Additional problems existed with variability in study protocols. Not all studies required patients to abstain from diet and exercise and those that did tracked weight changes as a marker of compliance. Unfortunately, small fluctuations in weight could correspond to unpredictable changes in body contour.

Another limitation was the high percentage of retrospective study patients (53%). Retrospective studies tended to report better results and may underestimate complications due to selection bias.

This study is also limited by scope and search terms. There are more devices than those described in this review that have been studied by other means.

Nevertheless, patients and physicians don't necessarily need to be precise and accurate when it comes to body contouring. Ultimately, patients and physicians are looking for improvement in body contour without significant risk. As such, patient satisfaction and paucity of side effects may be more important than clear cut, drastic results. If such results are desired, abdominoplasty and liposuction are options.

Future Studies/Devices

A formal meta-analysis is needed for each modality so results can be combined and compared.

The field of noninvasive body contouring is growing and many new devices are on the horizon. One recently introduced device is SculpSure (Cynosure). SculpSure is a new type of laser, which reportedly causes lipolysis rather than inducing transient micropores in adipocytes. Well-designed multi-center studies will be required to evaluate this (and other) new technology, so that patients and clinicians can optimize results.

CONCLUSIONS

Noninvasive body contouring is a growing field, projected to accrue more objective, peer-reviewed data with each passing year. While modalities vary by mechanism and side effects, reductions of localized adiposity are

generally mild but clinically and statistically significant. Not unsurprisingly, the modalities with the least risky side effect profiles were associated with the most modest reductions in localized fat. While it is unlikely that noninvasive devices will ever rival their surgically invasive counterparts, it is equally apparent that the side effect profiles of noninvasive procedures are likely to remain superior to invasive surgery. Most importantly, patients and physicians must discuss specific goals, both long term and short term, when deciding the best course of treatment for body contouring. To date, reported positive results for noninvasive body contouring have been most noticeable via RF while LLLT has reported the lowest risk of side effects.

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