STATIONARY PULSED THERAPEUTIC ULTRASOUND POST LIPOSUCTION

Conducted by:

| Charles Mok, D.O. | Shelby, Michigan |

BACKGROUND: Therapeutic Ultrasound after surgery and injury is often used to reduce swelling, relieve pain, and promote healing. After liposuction surgery, pain and swelling dampen the excitement of the results of this otherwise very satisfying and popular cosmetic procedure. Liposuction remains the most common cosmetic surgical procedure in the US, and with advances that promote safety, rapid recovery, and minimal downtime, it is likely to remain so for the foreseeable future.

OBJECTIVE: This study was designed to investigate the relative safety and effectiveness associated with the Hands Free Ultrasound manufactured by Hill Laboratories immediately following liposuction.

METHODS: This was a one treatment group, single-center, randomized, non-blinded, matched-sides, prospective study. The 11 subjects with no previous liposuction treatments in the target area(s) were all 35 years of age or older. Eleven (11) female patients with 11 matched sites were treated. The sites were matched in that each treatment site was partitioned into two equal sides. One side was treated with the ultrasound unit and the other side received no ultrasound treatment following liposuction. Using a survey format to collect data following treatment, the patients were asked to describe their skin/tissue response as well as skin appearance.

RESULTS: In contrast to the side not treated with the ultrasound, the majority of the patients reported reduced swelling (91%), improved-to-no pain (100%), and improved appearance (91%) on the side treated with the ultrasound. There were no side effects reported with the use of the ultrasound.

CONCLUSIONS: Stationary therapeutic ultrasound post-liposuction is preferred by the patient in contrast to liposuction without any ultrasound treatment. The treating clinician should consider...

Relatively modern techniques for body contouring and removal of fat date back to French surgeon, Charles Dujarier. A tragic case that resulted in gangrene in the leg of a French model in a procedure performed by Dr. Dujarier in 1926 set back interest in body contouring for decades to follow. However, with recent advances, liposuction, also known as lipoplasty ("fat modeling"), liposculpture or suction lipectomy ("suction-assisted fat removal") has become a routinely performed cosmetic surgery operation that removes fat from many different sites on the human body.

After liposuction, the most common complaints are spots of discomfort and swelling, as well as temporary surface irregularities that are due to swelling. It has been long felt that ultrasound will accelerate healing, but limited studies have shown benefit or lack thereof. A big limitation to ultrasound after liposuction is the time it takes for the technician to administer it, as well as the difficulty of having someone continuously move a soundhead over an affected area.

Stationary low intensity pulsed ultrasound has repeatedly shown to be effective in accelerating and enhancing a number of soft tissue and bone injuries. Stationary low intensity pulsed ultrasound has significant beneficial effects on tissues displaying acute inflammatory reactions. This form of ultrasound can also enhance soft tissue repair, accelerate ligament healing, accelerate fracture healing, decrease the loss of reduction during fracture-healing, accelerate bone-to-tendon junction repair, improve cartilage repair, accelerate bone-to-tendon junction repair, enhancing the early healing of medial collateral ligament injuries, and new research suggests it can repair intervertebral disc degeneration.

Hill Laboratories (Frazer, PA) has developed the HF54 Ultrasound Unit that has a large (65cm2) treatment surface area. The soundhead can safely be left stationary for extended periods of time without operator involvement. If a large coverage area is needed, the patient can be trained to move the soundhead to multiple locations.

This study was conducted to demonstrate that stationary therapeutic ultrasound post-liposuction (ultrasound immediately following the liposuction...
procedure and at time intervals following the liposuction procedure) offers the patient relief from detrimental skin/tissue responses commonly associated with liposuction procedures as well as improvement in appearance.

Materials and Methods

Not everybody is a good candidate for liposuction. It is not a good alternative to dieting or exercising. The ideal candidate for liposuction is over 18 years of age, in good general health, has tried a diet and exercise regime, and has persistent fat retention in certain pockets on the body which could not be eliminated through exercise and diet. Diabetes, any infection, or heart or circulation problems usually nullify one's eligibility for the procedure.

In older people, the skin is usually less elastic, so it does not tighten so readily around the new shape. In this case, other procedures can be added to the liposuction, such as an abdominoplasty.

The study objectives for this clinical trial were to determine the effect: 1) tissue response, 2) skin appearance, and 3) patient perception of pain as they relate to the use of the HF54 Hands Free Ultrasound Unit immediately following each liposuction treatment.

This study embodied one study center with an annual caseload of approximately 15,000 patient visits and an annual liposuction volume of 400 patients. A total of 11 female patients met the inclusion/exclusion criteria and were enrolled in the study. Among those 11 patients, 11 matched sites were treated. The sites were matched in that each treatment site was partitioned into two equal sides. One side was treated with the ultrasound unit and the other side received no treatment following liposuction. Treatment site sides were randomized as to treatment assignment. Seven of the eleven treatments (64%) were to the neck (sub mental area). The remaining four treatments were to either the hips or back. The average age was 50.7 ± 11.1 years. The youngest patient was 35 and the oldest 65. The average patient height and weight was 65.5 inches and 182 lbs, respectively.

Ultrasound treatments were administered to all 11 patients with a stationary soundhead from the HF54 Hands Free Ultrasound Unit manufactured by Hill Laboratories. This ultrasonic device consists of 3 piezoelectric crystals in a large 65cm² (3 5/8" diameter) soundhead. The Hands Free Ultrasound was ideal for this study because of its low BNR and large coverage area. Patients were treated with a frequency of 1Mhz-60 cycles pulsed at 50% at an energy setting of 0.20 watts/cm² for a range of 5-15 minutes per treatment area. All patients were treated over a 9-month period.

The study was originally designed to be a split body study (1/2 with ultrasound and 1/2 with no ultrasound). The problem was that the patients lost interest in study participation, as the side treated with ultrasound was soft, pliant, and non tender. The side untreated was hard, woody, and tender. Consequently, the patients requested to be withdrawn from the study and further requested that both sides be treated with the ultrasound. Because of the clear high acceptance of this post operative procedure, the study center routinely benefits from therapeutic ultrasound after liposuction.

The first patient who declined to continue with single side ultrasound treatments was asked to write down the reasons she was opting out. “By giving me the treatment on only one side of my body to begin with, I was able to notice a distinct difference the moment I stood up and more of a difference when I started to walk. The ultrasound treatments made me feel lighter, less swollen in those areas, and minimized the feeling of pressure and pulling in my skin.” Several of the subsequent liposuction patients reported the same experience. As a result, all of the patients were eventually treated on both sides.

Results

All 11 patients were treated between July 2006 and April 2007. Following the therapeutic ultrasound treatment, the patients were asked to complete surveys in which they provided descriptions of their skin/tissue response and overall treatment area appearance. The median number of ultrasound treatments per liposuction site was 7.5 with one patient having as few as one ultrasound treatment and another having as many as 32 ultrasound treatments.

The majority of the patients self-reported reduced swelling (91%), improved-to-no pain (100%), and improved appearance (91%) on the side treated with the ultrasound. In contrasted to the side not treated with the ultrasound, 10 patients (91%) attributed the results directly to the use of the ultrasound following liposuction treatment. There were no reported side effects with the use of the ultrasound. Figure 1 summarizes the patients’ responses following the use of the ultrasound.
Some of the observations self-reported by the patients included the following: “Directly after US, skin was softer.”, “Less lumpy, softer, less hard tissues.”, “Less swelling, softer skin.”, “Pain relief and decrease in swelling.”, and “Softer skin, less swelling; healed faster.” One patient wrote in a letter to the attending physician, “The ultrasound treatments that you prescribed for me weeks ago has made a remarkable difference in my comfort.” She went on to say., “By giving me the treatment on only one side of my body to begin with, I was able to notice a distinct difference the moment I stood up and even more of a difference when I started to walk.” She concluded the letter to her doctor by saying, “It has also been at least three weeks since my last ultrasound treatment, so I am hopeful that my treatment this week will make me feel better as they have done in the past.”

**Summary and Conclusions**

As emphasized previously, this study provides additional evidence that stationary low intensity pulsed ultrasound can be effective in accelerating and enhancing the recovery of soft tissue injuries. This study was conducted to ascertain patient perception of skin/tissue response and skin appearance associated with the use of ultrasound following liposuction. One study center contributed 11 patients with 11 split side treatment areas. All of the patients were female with an average age of 51 years. The majority of the treatment sites were to the chin/jowl area of the anatomy. On the average, the patients received approximately 7.5 ultrasound treatments following liposuction. All of the sites were treated with the HF54 Hands Free Ultrasound Unit manufactured by Hill Laboratories.

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**Discussion**

The study was designed to be a split body study. The patients initially agreed to participate, with one side being the control, and the other side being the treated side. However, all of the patients ultimately requested...
Given the inflammation, pain, and swelling often associated with liposuction, the HF54 Ultrasound provides clinically significant beneficial effects to alternative tissues in acute conditions. We believe that the primary feature contributing to this beneficial effect is the consistent application of ultrasound across the entire liposuction treated area with the HF54 Ultrasound unit.

Although these findings are restricted to the practice of one dermatological clinic, there seems to be evidence to suggest that stationary therapeutic ultrasound post-liposuction using the HF54 Ultrasound unit may result in less pain/discomfort and improved appearance to the treatment site liposuction than without the HF54 Ultrasound.

Future research, as with this investigation, will entail careful pre- and post-treatment selection of therapy and sites when treating patients who are good candidates for liposuction. We would like to explore the effect of varying the duration and length of treatments. Moreover, it is well known that, “When ultrasound interacts with matter, part of the energy of the beam will be absorbed and converted into heat.” For non-thermal effects, it is also well known to use “the lowest intensity possible to get the desired physiological effect.”

Our future research will include attempting to establish lower tolerance limits for non-thermal effects. Finally, future investigations will be devoted to estimating optimum treatment area while obtaining optimum ultrasound benefits. We are dedicated to providing the clinician with evidence-based information which will facilitate the incorporation of ultrasound technology into his/her healthcare practices.

As this was the clear trend, the study center now routinely performs ultrasound treatments after liposuction when the firmness, discomfort or swelling is a cause of concern to the patient. Typically, patients receive 1-2 treatments per week for 1-3 weeks. Being hands free, the device uses very little staff resources, and is very popular and well accepted by the patients.

These observations support the safe and effective use of HF54 Hands Free Ultrasound Unit post liposuction as an approach for enhancement of subdermal tissue response and appearance. These observations were seen on the treatment sites where ultrasound post liposuction was administered.
Therapeutic Ultrasound Post Liposuction

References


Hill Laboratories

Corporate Headquarters:
Hill Laboratories
3 N. Bacton Hill Road,
PO Box 2028
Frazer, PA 19355