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## High-intensity focused ultrasound with surface cooling non-invasive abdominal subcutaneous adipose tissue reduction

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**Background** : High-intensity focused ultrasound (HIFU) quickly raises local temperature of subcutaneous adipose tissue, resulting in instantaneous cell death within the targeted area; higher temperatures can be safely applied using contact cooling.

**Objective** : Evaluate safety and performance efficacy of HIFU with surface cooling for Non-Invasive reduction of the subcutaneous adipose tissue (SAT) in the abdomen.

**Methods** : A new HIFU device (LIPOncel™, Jeisys Medical, Inc. Seoul, Republic of Korea) with contact cooling was used to reduce abdominal circumference adipose tissue in 3 treatment modalities.

**Results** : 30 subjects, mean age of 35.4 years underwent one or 2 HIFU treatments. Mean total energy dose was 509.4 J/cm<sup>2</sup>, 495 J/cm<sup>2</sup>, and 374 J/cm<sup>2</sup> for Groups A, B, and C respectively; whole study mean total fluence was 459.47 J/cm<sup>2</sup>. Mean waist circumference reduction was 2.95 cm, 2.4 cm, and 3.8 cm for Groups A, B, and C respectively. A significant mean waist circumference reduction of 3.05 cm from baseline was observed. Most subjects (63.3%) reported being satisfied or very satisfied with the results; 80% of the investigators reported satisfactory results. Conclusions: HIFU with surface cooling using high fluence, assessed by standardized waist circumference measurement, is safe and effective for abdominal SAT reduction and noninvasive body sculpting.

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## Evaluation of a novel device, high-intensity focused ultrasound with a contact cooling for subcutaneous fat reduction

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### Background

Non-invasive devices for fat reduction involving high-intensity focused ultrasound (HIFU) are attracting attention. HIFU can deliver energy to the desired depth and can ablate subcutaneous adipose tissue (SAT), but purpura and pain may still limit its use.

### Objectives

The aim of this study was to investigate the effects of a novel HIFU device for fat destruction with a contact cooling system compared to HIFU without contact cooling.

### Methods

A group of three pigs were administered a series of four HIFU treatments with or without contact cooling over a period of 12 weeks. Energy fluence parameters ranged from 60 to 300 J/cm<sup>2</sup>. Immediately after the treatment and at 1, 4, and 12 weeks, the tissue was studied by hematoxylin and eosin (H&E), Masson-trichrome, toluidine blue, CD68 staining, and transmission electron microscopy. Three human volunteers also received treatment with this HIFU device with cooling and were evaluated subjectively and objectively by computed tomography (CT).

### Results

HIFU treatment with a contact cooling decreased the skin surface temperature and prevented epidermal damage. Ecchymosis was observed on the non-cooled area immediately after HIFU treatment, but not on the cooled area. Histological analyses on both areas (cooled and non-cooled) revealed disrupted adipocytes in the treatment area immediately, at 1 and 4 weeks following treatment. Lipophagic histiocytic fat necrosis was evident at 4 weeks. Finally, at 12 weeks all inflammation subsided, and the lobules were markedly atrophied with reduced SAT thickness. The human volunteers experienced reduction of a few centimeter-range reduction in waist circumference after 4 weeks and pain was tolerable without bruising.

### Conclusions

HIFU treatment with a cooling system efficiently destroyed adipocytes. This novel HIFU device with an added contact cooling system may provide an effective, safe and less painful treatment as a non-invasive device for fat reduction.

\*Source : Evaluation of a novel device, high intensity focused ultrasound with a contact cooling for subcutaneous fat reduction - Lee - 2016 - Lasers in Surgery and Medicine - Wiley Online Library

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## Morphometric analysis of high-intensity focused ultrasound-induced lipolysis on cadaveric abdominal and thigh skin

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Non-focused ultrasound and high-intensity focused ultrasound (HIFU) devices induce lipolysis by generating acoustic cavitation and coagulation necrosis in targeted tissues. We aimed to investigate the morphometric characteristics of immediate tissue reactions induced by 2 MHz, 13-mm focused HIFU via two-dimensional ultrasound images and histologic evaluation of cadaveric skin from the abdomen and thigh. Acoustic fields of a 2 MHz, 38-mm HIFU transducer were characterized by reconstruction of the fields using acoustic intensity measurement.

Additionally, abdominal and thigh tissues from a fresh cadaver were treated with a HIFU device for a single, two, and three pulses at the pulse energy of 130 J/cm<sup>2</sup> and a penetration depth of 13 mm. Acoustic intensity measurement revealed characteristic focal zones of significant thermal injury at the depth of 38 mm. In both the abdomen and thigh tissue, round to oval ablative thermal injury zones (TIZs) were visualized in subcutaneous fat layers upon treatment with a single pulse of HIFU treatment.

Two to three HIFU pulses generated larger and more remarkable ablative zones throughout subcutaneous fat layers. Finally, experimental treatment in a tumescent infiltration-like setting induced larger HIFU-induced TIZs of an oval or columnar shape, compared to non-tumescent settings. Although neither acoustic intensity measurement nor cadaveric tissue exactly reflects in vivo HIFU-induced reactions in human tissue, we believe that our data will help guide further in vivo studies in investigating the therapeutic efficacy and safety of HIFU-induced lipolysis.

\*Source : Morphometric analysis of high-intensity focused ultrasound-induced lipolysis on cadaveric abdominal and thigh skin | SpringerLink [VIEW ►](#)

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## The Innovative Skill for Fat Reduction Procedure Equipment (HIFU including Cooling system)

Akiko Tanaka M.D.

Akiko clinic, Japan

### Lipolysis by HIFU

HIFU (High Intensity Focused Ultrasound) medical device for partial fat reduction is the device to access fat from the surface of skin using the high intensity focused ultrasound. As this device irradiates ultrasound on one spot targeting the tissue of subcutaneous fat, it breaks down fats of the target area without any damage on the surface layer of skin. There are three kinds of lipolysis by HIFU: using thermal damage, without using thermal damage, and for last by only using cavitation. With HIFU, energy delivery is faster than heat loss therefore the temperature dramatically increases over 70 °C on the targeted area which results in instant heat increase of fat cells. On the contrary, for HIFU without using heat or cavitation, temperature increase on focused area is less than 0.5 °C which is immaterial increase that we cannot expect instant heat change on fat cells.

### HIFU with Cooling system

Using HIFU usually causes pain due to the thermal energy, and to solve this problem, HIFU with cooling system has been developed. LIPOnce is very first one on the market. This allowed pain level to be maintained as low as possible with Cooling system. This device uses 2 MHz frequency, irradiation energy of max. 150J/cm<sup>2</sup> and cooling function by contact cooling technology. This device is consisted of body, handpiece, and cartridge and produced relatively compact (Fig. 2). Set the cartridge on the skin surface of target area and press the button of handpiece and the dots irradiation will be generated on the 16 lines aligned every 2mm in range of 30mm x 30mm (Fig. 2). As the surface temperature of the contacts area, maintained at 5 °C during the procedure, pain to patient by heat is sharply reduced.

### Conclusion

Due to employment of the contact cooling technology, HIFU enabled accumulation of heat on the subcutaneous fat layer correctly without giving any effect to the outer layer of skin. This allowed reduction of pain and irradiation with high power and also brought the instant effect and middle-long term effect together. The HIFU with contact cooling is expected as an innovative fat reduction device that gives the comfort and high effect of fat reduction at the same time.

\*Source : [LIPOnce] 2016 JSAPS Seminar Report by Akiko Tanaka(v1.0)\_Eng.pdf (jeisysms.com)

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## Advanced Cooling System Gives LIPOncel an Edge Over Competition

**Ungku Shahrin, M.D.**

Mediceutical Clinic Johor Bahru, Malaysia

Patient safety is at the forefront of Jeisys Medical Inc.'s (Seoul, South Korea) LIPOncel™ device. This noninvasive body contouring system employs high-intensity focused ultrasound (HIFU) to destroy fat cells without damaging peripheral tissues resulting in circumferential reduction.

LIPOncel's high temperature targets subcutaneous fat cells at over 70° C, up to a maximum power of 150 J/cm<sup>2</sup>. The HIFU energy's direct focal zone is formed only on fat layers below 1.3 cm, thus built-in contact cooling reduces pain to the epidermis.

Prior to LIPOncel, HIFU-based systems had not really shown their worth in aesthetic applications, according to Ungku Shahrin, M.D., managing director of the Mediceutical Clinic in Johor Bahru, Malaysia. "While this technology has proven to be useful in some medical fields, such as urology, clinical studies of other brands of HIFU devices for fat reduction have demonstrated a low level of evidence and small numbers of subjects," he said.

To test the system's clinical efficacy, Dr. Shahrin conducted his own trial utilizing the LIPOncel procedure. "Astonishingly, it changed my views on non-surgical fat reduction," he expressed. "The HIFU wave is concave, therefore any biological and/or mechanical changes only take effect at a single concentrated point thus making it safe to use higher energy levels. In contrast, radiofrequency (RF)-based technology will heat up every layer it passes through, so the higher the energy the bigger risk it poses to the skin layers."

The LIPOncel is indicated for fat reduction on the human body and is safe to use on any skin type, Dr. Shahrin added. "Especially when treating the abdomen, the device's depth and frequency parameters are kept constant, so that the operator only needs to adjust the energy output and cater the threshold of pain for the patient," he said. "Not much preparation is needed before the treatment except for marking of the patient."

Dr. Shahrin objectively reported reduced measurements in all of his LIPOncel subjects. "My patients were seeing results within one month and up to six months after a single treatment. Some of them show an almost similar outcome as the tumescent liposuction procedures that I used to perform, but LIPOncel does not have any downtime or risk of complications. It has become my first line of treatment for non-surgical fat reduction," he said.

"As a best case example, one of my patients, a 58-year-old female, saw abdominal circumference reduction of 3.5 cm in four weeks," Dr. Shahrin reported. "After 12 weeks it was 5.5 cm."

LIPOncel's advanced contact cooling system can reduce the unit's handpiece surface temperature down to 5° C, which reduces patient pain in epidermal and nerve areas while delivering very high energy. "This feature allows practitioners to deliver total energy output up to 300 J/cm<sup>2</sup> without the patient feeling much pain, as compared to other brands without contact cooling (up to 180 J/cm<sup>2</sup> only)," said Dr. Shahrin.

Patients have been very satisfied with the outcomes, Dr. Shahrin added. "Based on my clinical trial and a patient satisfaction scale of disappointed to very satisfied, all but one of the subjects claimed that they were satisfied to very satisfied with the procedure."

\*Source : [LIPOncel] 2016 The Asian Aesthetic Guide by Ungku\_Eng\_2016.pdf (jeisysms.com)

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## Here Comes a Painless Obesity Treatment Device We Want to Recommend to Patients : [LIPOncel™] Loaded with Latest HIFU Technology

**Dr. Hideaki Teramachi.**

Seishin Plastic and Aesthetic Surgery Osaka Clinic, Osaka, Japan

A lot of patients hesitate about reducing size by using an obesity treatment device because of "pain". Addressing such concern, [LIPOncel™] is born as a "less painful" obesity treatment device.

Finally, we've got a non-invasive obesity treatment device that delivers great satisfaction to patients, as it inflicts no pain and yields immediate effects by implementing a procedure with great power.

### **The less painful and highly effective obesity treatment device that adopts contact cooling method to strike the patient's "fat around the abdominal area"**

Medical devices for treating obesity are available in various types that adopt Cryolipolysis or Radiofrequency methods. One catch is that they inflict irresistible pain or do not deliver visible instant size reduction as it absorbs the fat layer over an extended period of time, thus making patients who have undergone the procedure hesitate to return to receive the treatment.

So, people have hope to see an obesity treatment device that "can be easily recommended to patients" for its immediately felt reduction effects and little pain.

Then I came to know [LIPOncel™], which destroys fat cells with HIFU technology. More than anything else, what made me choose the equipment is the cooling technology loaded on it.

It adopts contact cooling which protect the surface simultaneously HIFU energy heating.

HIFU with contact cooling developed for surface cooling is expected to mitigate pain and protect the epidermis from thermal damage. So, the patient can undergo procedures feeling almost no pain.

Furthermore, as it causes no pain, it enables a powerful scan (maximum 150J/cm<sup>2</sup>, reference from Jeisys) on the targeted device that "can be easily recommended" to patients.

\*Source : lipocel\_clinical\_170126.indd (jeisysms.com)

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## LIPOcel™ Non-Invasive Fat Reduction HIFU System

### Dr. Hwan-ik Kim

Cube Aesthetic Clinic, Seoul, Korea

#### Equipment Introduction and Features

LIPOcel™ is a product using HIFU for cosmetic purposes of body contouring approved by the Food and Drug Administration as an equipment for waist size reduction. LIPOcel™ uses high intensity focused ultrasound energy, and precisely focuses the energy on the subcutaneous fat layer using non-surgical and non-invasive ways without damaging any surrounding tissues. Thus it is equipped with safe medical procedures. In addition, it breaks down fat cells with high temperature. Its advantage lies in creating excellent results with a small number of treatments.

#### Recommended Target Patients

This treatment method is optimized for the patients who cannot receive surgery or wish to avoid surgical methods. The treatment of abdomen and flanks using HIFU enables the reduction of waist size by a minimum 2cm after a single treatment. When consulting with a patient, a doctor must notify that the procedure using LIPOcel™ is a body contouring treatment, which is not an ultimate solution for reducing weight or curing obesity.

The patient group that LIPOcel™ can be ideally applied is a contemporary man who has abdomen and flanks resistant to the effects of exercise or diet control, or who has a hard time doing exercise or diet control due to his/her vigorous social activities such as school or work. Among these patients, a patient who has a BMI of 30 or lower, good skin tone and elasticity, at least 2.5cm or more of subcutaneous fat, no scars in the treatment area, and who has realistic expectations about the treatment is the ideal patient. When it comes to evaluating a patient, their subcutaneous fat volume can be checked by using calipers or a pinch test. If you wish to measure more accurately, the ultrasonic instrument can be used to measure the thickness of the subcutaneous fat.

There are patients that should not receive HIFU treatment. Such patients include those with ruptures around the treatment area, pregnant women or those with the possibility of pregnancy, and those with less than 1cm of subcutaneous fat thickness. Like all other medical treatments, checking the medical history of a patient and the status of his/her body must be done under any circumstances.

#### Reasons for Recommendation

LIPOcel™ is equipped with a contact cooling system, which keeps the pain to a tolerable level even when high energy is applied. This reduces the discomfort that most patients experience after treatment procedure conducted without pretreatment.

\*Source : lipocel\_clinical\_170126.indd (jeisysms.com)

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## LIPOcel Boasts Powerful Fat Removal for the Entire Body

### Akiko Tanaka, M.D.

Akiko clinic, Japan

The LIPOcel is an innovative body shaping device from Jeisys Medical (Seoul, Korea) that uses high intensity focused ultrasound (HIFU) to thermally destroy fat cells. Thanks to the recent release of 8 mm and 11 mm cartridges, treatment indications have expanded to include areas that were traditionally unfit for the procedure due to the low fat content, such as the arms, waist, hips and thighs.

While the original 13 mm cartridge only allowed for treatment on body parts with adipose tissue thicker than 2.5 cm (measured by caliper); the new, shorter focal length cartridges make it possible to treat areas with 2 cm of fat tissue, or even as little as 1 cm thick.

In addition, the LIPOcel includes a contact cooling function that reduces the magnitude of pain compared with devices from other manufacturers. Also, it can exert a high output of 90 J to 100 J per stack. With minimal discomfort, yet high-power, the device definitely appeals to many patients. Immediately after treatment, a patient can enjoy visible fat reduction results within two weeks. This effect is further accelerated as the surrounding fat cells – if not immediately destroyed – are gradually discharged through apoptosis and macrophage digestion within a period of 8 to 12 weeks. Thus, patients continue to be highly satisfied with results as fat further decreases.

Another benefit for busy practices is that the device is compact so it does not take up a lot of space. Whereas large-size equipment cannot be easily relocated once installed, and often occupies an entire room, LIPOcel's small size and light weight enable it to be easily moved by virtually any staff member, and once plugged in it can be used instantly.

In my experience, a practitioner does not need any special skills in order to operate the LIPOcel, as the system boasts excellent quality. One only has to mark the body parts to be treated, place the handpiece against the target area, activate the switch and then LIPOcel does the rest. One application delivers three stacks, making it very easy to use. Treatment on 40 sites takes approximately one hour, including the marking process. With its cooling function maintaining a handpiece surface temperature of 5° C and a high-power output, LIPOcel offers a painless and safe treatment with excellent results.

\*Source : [LIPOcel] The Asian Aesthetic Guide\_Article\_Dr.Akiko\_Eng.pdf (jeisysms.com)

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## A True Beauty Should Have Vivid Healthy Lines!

### Hyung Moon Kim M.D.

Miaero Clinic, Ilsan, Korea

LIPOcel™ treatment lightens the time burden for patients, more than anything else.

To be more specific, a patient may get partial treatment during lunch hour, and back to normal life. Thus, it is a procedure that revives the healthy lines for people, who are heavily tied up with frequent overtime work, tight schedule, child rearing, or family care.

LIPOcel™ employs HIFU (High-Intensity Focused Ultrasound). LIPOcel™ completes the beautiful body lines semi-permanently by naturally annihilating fat cells, which are storages of body fats. The Contact Cooling of LIPOcel™ system ensures that all the procedures are completed in a short span of time, without surgery or anesthesia. An ideal procedure delivers a cold feel on the skin at treatment area and a warm, heat sensation underneath of the treatment area.

When LIPOcel™ treatment combined together with other fat management procedures, there will be synergy. LIPOcel™ will make even more upscale composite procedures. For example, a method also uses tumescent injection therapy, in order to induce more powerful partial annihilation of fat cells. The procedure enjoys great popularity and is recommended to people who want partial fat removal.

It effectively manages not only abdomen, muffin top, flanks, love handles, thighs, and upper arms, but also flabby lines after child birth or a diet. Continuous care through partial procedures can bring greater effects.

There are more methods that help maximize the effects of procedures. And they can be done in daily life. Reduce your daily intake of carbohydrate by 50% for a week after a procedure, fast walking for 30 minutes a day, reducing coffee and other soft drinks and having more water instead, using stairs, and walking one bus stop distance on your way back home from work. If your food and daily exercise are managed well, your body lines will revive more effectively two weeks from your procedure.

\*Source : lipocel\_TESTIMONIAL\_170816.indd (jeisysms.com)

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## Faster, Comfortable, Effective Body Shaping

### Hyun Jun Park M.D.

Maylin Clinic, Apgujeong branch, Seoul, Korea

LIPOcel™ is a non-surgical fat dissolving device that uses HIFU (high intensity focused ultrasound) for body contouring by concentrating dense energy on the layer below 1.3cm under the skin to coagulate necrosis using the heat.

"3 staking" method which is consecutively performing three times in one spot is used to increase the effect. However, this conventional method involves pain as it destroys fat cells by using heat energy.

Unlike other thermal focused ultrasound devices, LIPOcel™ is equipped with contact cooling system that allows the temperature able to be remained 5°C and it protects the epidermis, reduces pain and side effects such as bruising.

With the use of this cooling system, the amount of ultrasonic wave energy is increased up to 2.5 times higher than the energy of other devices. It took about 30 minutes for a treatment based on treating the abdomen area, and the patients willingly booked the next treatment as its procedure is simple and easy with less pain.

Moreover, since the 3cm<sup>2</sup> size of the transducer is relatively small in comparison to ones from other companies, it is ideal for Asian body and I can precisely and fully treat the flank area.

According to the published article that I participated in as a co-author, when applying LIPOcel™ treatment after injecting tumescent solution to the treatment area, the area of fat dissolving became broader due to the characteristics of ultrasound (ultrasound becomes more conductive with water). Collagen regeneration was also increased around the fat and dermis. Furthermore, with adding lidocaine into tumescent solution, the pain could be reduced while the effect is increased, consequently improved patient's compliance during the treatment.

The pain level was significantly low in comparison to the other HIFU devices. The recently developed grid type of transducer shortened the treatment time in half, making the treatment more convenient.

I recommended patients to have 2 sessions of treatment with 8 weeks interval. I used monopolar RF treatment with interval of one week between the two LIPOcel™ sessions. This protocol helps increasing the circulation to remove damaged fat cells and at the same time enhances patients' satisfaction by improving skin elasticity.

\*Source : lipocel\_TESTIMONIAL\_190502.indd (jeisysms.com)

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