Doublo; “Clinical study of non-invasive face-lifting treatment in application of HIFU”

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[Abstract]

Doublo: Clinical study of non-invasive face-lifting treatment in application of HIFU

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(Face Lifting & Rejuvenation)
**Face Lifting & Rejuvenation**

1. **Introduction**

As human gets older, skin and its under structure tissues constantly get ageing process. Typically, number of fibroblast on the skin decreases and collagen synthesis also decreases. And functions and numbers of many skin appendage are also dropped. For under tissues of the skin that maintain the face contour also form laxity due to the aging process. Before learning more about face lifting using HIFU (High Intensity Focused Ultrasound), it is necessary to understand the face anatomy. Face and scalp are composed of several layers and these can be specifically composed into five standard layers(Figure 1).

![Figure 1. 5 Layers to compose face and scalp](image)

1) Skin  
2) Subcutaneous layer  
3) Musculoaponeurotic layer (SMAS: Superficial MusculoAponeurotic System)  
4) Loose areolar tissue (ie, spaces and retaining ligaments)  
5) Fixed periosteum and deep fascia

So far in the laser treatment area of dermatology, the epidermis and dermis were the main interested therapeutic areas for the skin treatment. However, collagen remodelling on deep dermis slightly helps to regain some degree of skin elasticity but it is difficult to improve its own fundamental face contour.

2. **History of Face Lifting & Tightening**

The Latin word ‘Rejuvenation’ is the compound word of ‘Re’ and ‘Juvenile’ which can be interpreted ‘as a kid again’ or ‘be young again’. The proposition of ‘becoming young again’ is a human desire of all time. Also such development of the laser was developed to meet the wishes of human, and ‘rejuvenation’ is still somewhat a question to dermatologists.
The development of laser and other medical equipment for rejuvenation can be classified in many different ways but can be largely categorized in five (Table 1, Figure 2).

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When the laser technology was not developed in old days, ablative laser or chemical peeling was used for face lifting. It was the time when we had to face all side effects through laser treatment. All these experiences and trials affect in the later days the development of next generation lasers. Due to serious side effects and downtime, these are narrowly treated nowadays. Along with development of IPL, interests were focused on 'photorejuvenation' but the effect was insignificant and it soon was dismissed in the market. But IPL has several advantages that it is still widely used in pigmentation, vascular, and hair removal.

The item that has been used for longest time in Rejuvenation is the ‘Radiofreqency’ of using electrical energy. It is either divided into MONOPOLAR or BIPOLAR. Only the RF was applied for the treatment or it was developed into a ‘hybrid form’ of adding other lasers like diode laser, IR, and IPL. In domestics, RF needle is now widely used as method of transferring electrical current fractionally. Most of Korean laser companies are manufacturing this ‘needling RF’.

Fractional laser is also the ‘rejuvenation item’ that has long run. There are many factional lasers with different wavelengths, such as 1,550nm(Er:glass fiber), 10,600nm(CO2), 2,940nm(Er:YAG) that are developed and applied for treatments.
‘HIFU’ is a new spotlight concept in these days. Without damaging the skin or the subcutaneous layer and its surrounding tissues, it makes ‘selective thermal coagulative zone’ on the subcutaneous layer and SMAS layer improving the skin aging. HIFU is a high intensity focused ultrasound that is transferred into deep structures, such as deep dermis, boundary layer of deep dermis and subcutaneous fat, fibrous tissues of subcutaneous fat, SMAS layer and fascia. And over the wound healing process for several months, a gradual face lifting effect can be achieved.

3. Conditions to the Ideal Rejuvenation Equipments

The most important condition to the rejuvenation equipment is ‘to minimize the side effect and to maximize the effect’. But so far, those of equipments showing dramatic results had relatively high risk of side effect (Figure 3).

So far, those of equipments having higher risk of side effects showed dramatic result. The development target of rejuvenation equipment is to minimize the side effect while maximizing the effect.

For the full face resurfacing using laser or chemical peeling, effect is positive in case of successful treatment but there were risk of nearly 100% side effects. As a result, high risk is high return. Thus, far the most important matter in developing rejuvenation equipment is to minimize the side effect while maximizing the effect. And the closest equipment of this can be said as HIFU.

Concepts of HIFU

1. Ultrasound
‘HIFU (High Intensity Focused Ultrasound)’ is not using the ‘light’ like other standard lasers but is using ‘sound waves’ and is a new method in medical device. Frequency of the sound that human ear can hear is generally in the range of 16Hz~20kHz. If frequency exceeds 20kHz, it is called ultrasonic wave (Figure 4).

![Figure 4] Classification of Sound wave For Each frequency area:

If frequency exceeds 20kHz it is classified as ‘ultrasound’, and ultrasound over 250kHz is classified as ‘high frequency ultrasound’. Ultrasound has a tendency to transmit water and that allowed to use in ultrasound diagnostic units for long period of time in medical field. Recently ultrasound is widely used in not only the diagnostic unit but in therapy equipment.

The principles of ultrasonic applied in the treatment area is the physical effects of its ultrasound (Table 2).

[Table 2. Three Types of Physical Effects of Ultrasound]

1) Mechanical Effect
2) Cavitational Effect
3) Thermal Effect

2. History of HIFU

HIFU is to treat various cancers like liver cancer, uterine cancer, and breast cancer through thermal energy which is created in the focal point of supersonic wave, collected from the ultrasound transducer. At first it is developed to treat solid tumor but in later days it could get attention as non invasive treatment modality (Foster RS et al. High-intensity focused ultrasound in the treatment of prostatic disease. *Eur Urol* 1993;23:29–33).

3. Apply to the Skin Rejuvenation
HIFU makes ‘selective thermal coagulative change’ on subcutaneous layer and SMAS layer without damaging surrounding tissues. For other light based devices or RF devices, it was unavoidable to damage the epidermis and upper dermis to stimulate the deep dermis. However, HIFU does not effect the skin and subcutaneous layer at all but forms ‘thermal coagulative zone’ on only the deep dermis. The first time of applying HIFU to skin rejuvenation was in 2007 by Gliklich(Gliklich RE et al. Clinical pilot study of intense ultrasound therapy to deep dermal facial skin and subcutaneous tissues. *Arch Facial Plast Surg* 2007; 9(2): 88–95). It begins to attract attention in detail when research data using body tissues was released in 2008 at Harvard Wellman Center(Laubach HJ et al. Intense focused ultrasound: evaluation of a new treatment modality for precise microcoagulation within the skin. *Dermatol Surg* 2008; 34(5): 727–34). Research on facial skin tightening was announced but it was a limited research mainly on eyebrow-lifting (Alam et al. Ultrasound tightening of facial and neck skin. *J Am Acad Dermatol* 2010; 62(2): 262–9).

4. Principle of ‘Face Lifting’ using HIFU

When electrical energy is transferred to the ceramic of HIFU transducer, electrical energy transforms into ultrasound. And when this created ultrasound is focused, it generates thermal energy at ‘maximum focusing point’. (Figure 5).

![Figure 5. Diagram of thermal energy emitted by HIFU](image)

A. Diagram of thermal effect of HIFU

B. Diagram of forming thermal coagulation zone on SMAS layer when HIFU is emitted

Such thermal effect of the ultrasound within the tissues is observed as the following(Figure 6).

In other words, it only generate thermal energy on the ‘maximum focusing point’ and create ‘selective thermal coagulative zone’ on SMAS layer without damaging epidermis and subcutaneous tissues. These thermal coagulation zones react to high energy of over 60°C. This causes the sagging skin tissues to contract and give skin tightening and lifting effects.
A. Image of 7.5MHz concentrated ultrasound using Schlieren method
B. Histology of energy deposited in human skin tissue

The actual coagulation zone after HIFU applied to real tissues
cf) Schlieren method: A way of making the light visible pattern of wave which is reflected by the change of density based on sound wave

To prove this, a test was carried out on a micro pig (female) having the most similar skin to human by emitting HIFU (Figure 7). Even in this animal experiment, selective coagulation zones from thermal damage were found.

A. Before Emitting HIFU
B. After Emitting HIFU: There is no damage on epidermis and tissues above dermis, and there is coagulation zone formed on subcutaneous layer where HIFU was emitted.

HIFU is high intensity focused ultrasound energy which is transferred fractionally to depth of skin that creates thermal damage on the deep structures like deep dermis, subcutaneous layer, fascia and
SMAS layer. And it will gradually lead to face lifting effect through few months of wound healing process.

Unlike the general HIFU of treating solid tumor, the HIFU that is used on the skin for rejuvenation purpose has very short exposure duration (in mili second). So the energy delivered to the target is also low(below 15J per pulse). As the ultrasonic is emitted in short time, it does not damage on epidermis and upper dermis but able to target the SMAS layer and deep dermis.

If exposure time(same as pulse duration) gets longer, thermal zone will be created on the skin surface in axial direction. Therefore, when it becomes longer, damages on skin surface is unavoidable. And so short exposure time is very important to treat the target more effectively by not hurting epidermis and upper dermis.

The biggest difference of HIFU from other lasers or light is that it is not related to skin color or chromophore(color blind). It is an advantage that it can do effective rejuvenation even on the dark skin, which was difficult to treat with light based treatment.

HIFU is the new concept therapy equipment for a truly 'non invasive rejuvenation'.

About Hironic Co.

Hironic Co., Ltd is the new global name of BSP Medical which is well known as New MIDAS. It is a total laser company of selling various laser equipments and it is procuring users in domestics but also as globally in more than 30 countries worldwide. Currently their main products are Greenxel, New MIDAS, Doublo, MIDEPI, MIXEL.

In 2011, awarded 3million export tower from the Kyunggi Province and is selected as Small-Gient Enterprise in 2012.
Advantages of doublo

(1) More precise and safe
Unlike the existing HIFU equipment using single transducer to generate ultrasonic, doublo is equipped with two ‘multi transducer’. This allows to have precise focusing and reduce damage of surrounding tissue, and also can reduce the consumables cost due to long lifespan of the transducer.

(2) Real-time high resolution: High resolution image probe
Existing HIFU equipment has 16CH image probe. Innovatively, doublo improved the imaging. Using 128CH allows to provide clear and high resolution allowing precise and safe treatment.

(3) Double control system
The existing HIFU equipment has image probe and transducer as one inside the cartridge. But doublo separated these image probe and transducer. So HIFU energy from the cartridge is independent from the skin imaging area.
Actually consumed part is only the HIFU generating device and image probe can be used semi-permanent. When exchanging the cartridge, there is no need of changing the image probe but only need changing the HIFU generating device. It can lower the manufacturing cost on cartridge and leads to more effective device operation. Also it is possible to continue the treatment when image is not monitored.
(4) Three types of optimum cartridges for different treatment area
Different cartridges like M7, D4 and D7 are offered depending on the treatment area.

(5) Optimized parameters offered for each treatment area
Parameters saved in the memory setting allow easy and fast treatment. It is also possible to change the values in detail upon the user’s decision. Energy setting and spacing are easy to adjust and treatment time is fast.

(6) User-friendly interface
It provides GUI (Grahpic User Interface) that is maximized the convenience for practitioners. This is the biggest merit of Korean lasers. Everyone can easily do the treatment after listening 10 minutes of explanation. Also, there is a foot switch which allow to reduce the practitioner’s tiredness.

(7) More resonable comsumables cost
They paid efforts to lower the equipment cost and to meet reasonable cartridge (consumables) cost. This allows to have relatively low treatment cost and so it also allows to offer retouch comfortably if there’s dissatisfaction.

**Clinical Applications of doublo**

Doublo can be applied for tissue tightening and lifting in various ways(Table 3). This will be a good solution to patients who are interested in face lifting but are worried and feel uncomfortable with ‘interstitial laser’ that needs insertion of cannula into skin hole.

Table 3. Clinical Indications of doublo

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<td>Nasolabial fold reduction</td>
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<td>Malar augmentation</td>
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<tr>
<td>Eyebrow lifting</td>
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Treatment is very easy and simple, but need to think about several variables(Figure 9).
The three variables on the parameter to think of during the treatment are 1) cartridge type, 2) spacing, 3) energy. Spacing means the distance (gap) between the dots. If the spacing is narrow, danger of side effect will increase and the wider spacing can offer the safer treatment. Energy means the intensity of HIFU. The most important thing to consider during treatment is the selection of cartridge(Figure 10A). It is most common to carry out two modes among three types(Figure 10B).

M7 and D4 cartridges are most commonly used. M7 (7.0 MHz) cartridge targets the relatively superficial area like deep dermis and subcutaneous layer, and D4 (4.0 MHz) cartridge targets SMAS layer. M7 targets 3.0mm from the probe. It targets deep dermis which is 3.0mm depth from the
surface of the skin and it leads to strong collagen regeneration. Through the 2-4 weeks of face lifting, collagen and elastine are generated continuously over 3-6 months and is predicted to create tissue tightening.

Destroying subcutaneous fat which is about 3-4mm depth from the surface of the skin can be similar to liposculping concept which can improve the face outline.

D4 targets 4.5mm from the probe. It targets around SMAS layer that is 3.0~4.5mm depth from the surface of the skin. And it generate less than 1mm size of thermal coagulation zone which becomes contraction and relaxation after some time affecting face outline lifting effect.

It is even more effective to use M7 and D4 cartridges as a combination treatment since they tighten specific areas. Below you can find ‘Ratio of D4:M7 for each treatment area’ when doing combination treatment of D4 and M7.

(1) low face (including jowl)
For lifting, this area is the most important and important factor for lifting is the SMAS. So to tighten the SMAS, D4 should be used as the main cartridge. For low face lifting, D4:M7 ratio should be 6:4 or 7:3. But when it is bottom of the neck, subcutaneous tissues becomes less and SMAS is joined to platysma muscle, so it is recommended to lower the energy to avoid side effect when doing the neck area treatment.

(2) mid face
The mid face structure gets laxity and runs down and becomes the reason for forming nasolabial folds. For this case of skin tightening, it is important to tighten the structure in deep dermis. So for mid face, ratio D4:M7=5:5 should be enough. Eye surroundings are easy to get bruised. Therefore, for around the forehead and eye surroundings, D4 and D7 are not used but recommended to use only M7.

(3) upper face
HIFU got certified for eyebrow lifting but it requires a careful treatment of this area. For forehead treatment, there is danger of side effect so it is better to use M7 or lower the energy. Ratio of D4:M7 should be 3:7 so that it does not induce side effect. Forehead has almost no subcutaneous fat. So actually using D4 would mean to applying energy not to the SMAS layer / fascia but to the muscle or periosteum. And in some cases, patients complain of ‘headache’ after treatment.

Complications & Managements

(1) Pain
HIFU is a sense of ‘shockwave’ created by ‘soundwaves’ but it generates heat through secondary action.
Since generating heat might create pain, it is required to use anesthesia. There are topical anesthesia and nerve block for facial anesthesia. Commonly topical anesthesia is recommended. During treatment, important thing to remember is the bony prominence which is same as using RF. Areas where bones are protruded have relatively thinner soft tissue, so HIFU can target periosteum or deeper portion. In this case, there is a possibility of accompanying nerve damage, so it requires special attention.

This kind of area on the face is the cheekbone, mandibula surroundings and forehead area. Forehead often carries pain, and as in many cases, this pain is related to side effect. Therefore, it is good to lower the power to 1.2J.

In rare cases, patients complain about toothache. If patients are equipped with prosthetics or tooth braces, reduce the intensity and make enough air space inside the cheek and do the treatment. Then it will reduce the side effect. Also, for the areas nearby mouth and teeth, it is better to use M7 than D4. Specially forehead has bigger pain. This is because the subcutaneous tissue is relatively thinner and so D4 hits the fascia or periosteum.

(2) Nerve injury
Since HIFU targets relatively deep layers like SMAS layer, the possibility of nerve injury should be kept in mind. Even if the nerves are damaged, partial damages such as neurapraxia or axonotmesis can be recovered after a period of time. But in case of neurotmesis, it can lead to permanent disability, so be careful of selecting energy and treatment area.

And also in this case, patients’ subjective responses to the pain or the facial nerve response are important indicators for the treatment. Therefore, as mentioned in earlier sentences, nerve block is not recommended.

Important thing to think about for nerve damage is the superficial line coming from the facial nerve branch to the skin. And should take attention on the eye and mouth areas. Around the mouth, pay attention on the mouth branch of infraorbital n. and mental n.. Nerves around the mouth are superficially ascended in many cases. And especially, those bony prominence compared to other areas will need a special attention. Therefore, do not treat too much on the mouth surrounding wrinkles and will need to turn down the level of patient satisfaction.

Around the eyes, pay attention on the supratrochler n. and infraorbital n..

(3) Thermal injury (Burn)
In case of skin burn is very rare compared to the frequency of burns from IPL, fractional laser or the RF devices. There are two big possibilities of skin burn during the HIFU treatment.

First, when energy is too high, thermal damage area becomes wider and that also burns the skin surface. If energy is high, it is the symptom of thermal coagulation zone being increased to skin
surface in axial direction. Main causes are that 1) energy is too strong 2) energy is applied to the same area continuously or 3) setting for the spacing is too narrow compared to the energy.
Second, due to the improper contact between the skin and the cartridge, ultrasound emitting surface of the cartridge generates thermal and burns the skin.
The thermal is occurred on the boundary surface due to the improper emission of ultrasound, and this kind of cause and condition is same as the general skin burn from existing devices. In case of using not enough ultrasound gel or making not full contact to the skin, there are chances to get burn but the frequency is very low.

Figure 11. Clinical results of side effects on different treatment area

A. It is edema after treatment using D4 1.7J. It is a temporary phenomenon that it gets better with no scars within 1 week without any extra treatment.
B. It is crust occurred from tiny vesicle on the neck area, which gets better with no scars within 1 week by applying topical steroid.
Cheek has less frequency of side effect during treatment, but neck or the forehead have relatively higher chances of side effect. On the cheek using D4 as standard, there is no problem of using power upto 1.7J except leading temporary edema(Figure 11A). But on the neck, there are higher chances of having blister or crust even when high energy is not used(Figure 11B). The neck comparing to face has higher possibility of side effect because 1) epidermis has little capillary bloodstream that is difficult to thermo diffusion 2) subcutaneous layer is thin. On the bony prominence like forehead or jaw, it is hard to make full contact between cartridge and skin surface, which makes coagulation zone on shallow area than the targeted area. So it is required to pay attention making full contact using M7 cartridge than D4/D7.

**Combination Treatment**

1.Completion of Rejuvenation: Triple Tightening Rejuvenation (TTR)

Each rejuvenation has all different advantages and disadvantages. As a result in clinical trials, it is the best method to take advantages of various rejuvenation modality and apply to the treatment.
For my case, I would recommend the best treatment method is to combine three methods like fractional laser (1,550 nm Er:glass fiber laser), RF and HIFU. Reasons of using these three devices can be described by following principle of tying up the shoestring.

Figure 12. Rejuvenation principle comparing to a way of tying shoestring

A. Fractional laser or RF
B. HIFU
C. Triple Tightening Rejuvenation

This is a comparison picture of using only the fractional laser or RF (Figure 12A). It is the case to make surface change on only the epidermis and upper dermis. It makes surface change and improves fine wrinkles on the surface, but it does not correct below the deep dermis even after a long time. Many treatments are required in order to correct the aging of deep dermis and therefore it has disadvantage of long downtime period. Even after many times of treatment, it is hard to do the basic lifting as it does not correct SMAS layer.

This is a comparison picture of lifting deep dermis and SMAS layer by using HIFU (Figure 12B). It can be felt as if face was lifted up with surgical procedure. It is not to lift the SMAS layer physically but is to create thermal coagulation zones fractionally on SMAS layer which results natural face lifting. But, since it takes some time for lifting result to come out, there are cases with less satisfaction with patients. Then carrying fractional laser or RF at same time might help to increase the patient satisfaction.

The real completion of rejuvenation is to hold and tighten every part of 1) epidermis & upper dermis, 2) deep dermis & subcutaneous layer, 3) SMAS (Figure 12C, Figure 13).
In the past when laser technology was not developed, it was difficult to transfer energy to SMAS layer without damaging the epidermis. However, this has been solved by the development of HIFU. Thus, the method of tightening all areas from epidermis to SMAS is proposed as ‘Triple Tightening Rejuvenation’.

2. Package Composition of Triple Tightening Rejuvenation (TTR)

It is good to carry HIFU on the first day. Since it does not have downtime during treatment, it is possible to safely treat. And since the results come out in a month or two, it is more effective for package composition to do this treatment in the beginning. Following is my actual package composition, and this program can be changed as per patient’s need, skin condition or based on the types of devices in the hospital (Table 4).

[Table 4. Example of package composition on Triple Tightening Rejuvenation (TTR)]

| 1) HIFU + RF | (HIFU 1 session, RF 3 sessions, SC 7 sessions) |
| HIFU --> SC --> RF --> SC 2 sessions --> RF --> SC 2 sessions --> RF --> SC 2 sessions |

| 2) HIFU + RF + FL | (HIFU 1 session, RF 3 sessions, FL 2 sessions, SC 6 sessions) |
| HIFU --> SC --> RF --> SC --> FL --> SC --> RF --> SC --> FL --> SC --> RF --> SC |
| cf) Treatment Interval: 1 week |
| SC: skin care (Regeneration or whitening programs) |
| RF: needling, conventional, hybrid (new Midas, Arneb, Polaris, Aurora) |
| FL: 1,550 nm Er:glass fiber laser |

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Conclusion

HIFU is noninvasive and advanced face lifting technology. Various rejuvenation devices like IPL, RF, and Fractional laser were introduced in the past, but HIFU is a new concept different from existing rejuvenation equipments by tightening SMAS layer for face lifting.

doublo is a safe equipment using high intensity focused ultrasound(HIFU) and obtained the first Korea FDA as eyebrow lifting. It is the second generation as worldwide and is developed in Korean laser manufacturer Hironic.

doublo is targeting on the deep dermis, subcutaneous layer and SMAS layer which are the cause of skin lagging and wrinkles and lead to face lifting and collagen regeneration without any surgical procedure. It is possible to do effective treatment, and is safe from the danger of side effects such as burns and hyperpigmentation.