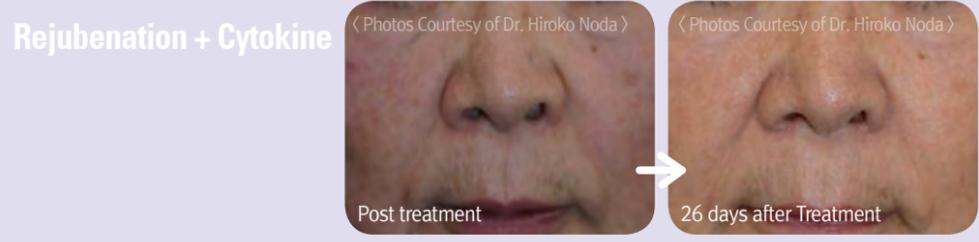


CONTENTS

1	Clinical Experience of INTRAcel	Dr. Hiroko Noda	2
2	Histologic Evaluation of Deep Dermal Heating by Fractional Radiofrequency According to Energy	Dr. Un-Cheol Yeo Dr. Doo-Rak Lee / Dr. So-Dug Lim	4
3	Combination Anti-Aging Tx including INTRAcel	Dr. Mi-Kyung Cho	10
4	The Clinical Efficacy and Statistical Evaluation of INTRAcel Treatment	Dr. Takashi Takahashi	14
5	Non-Surgical Facelift by INTRAcel : The Future of the Anti-Aging Technology	Dr. J.C Poon	18
6	Acne Treatment by Using INTRAcel	Dr. Joon Sung Yang	20
7	Open Label Study on The Safety and Efficacy of Fractional Radiofrequency with Microneedle™ (INTRAcel) on Mild to Severe Acne Scars in Asian Skin	Dr. Marie Socouer M. Oblepias	23
8	The Effectiveness of Selective Fractional RF Microneedle(INTRAcel) for the Treatment of Telangiectasia	Dr. Ayako Ito Dr. Kazuhiro Hayashi / Dr. Tomoyuki	27
9	INTRAcel Treatment Workshop Program	Dr. Mihara Toshiyuki	32
10	Microneedling Weiterentwickelt	Dr. Klaus Fritz	37
11	A Study on RF Impedance	Dr. Un-Cheol Yeo	40

CLINICAL EXPERIENCE OF INTRACEL

Dr. Hiroko Noda
M.D. Ph.D, JAPAN



Conclusion & Discussion

- Cases of good efficacy without treating less passes.
 - Scar for seborrhic skin type, Rhinophyma, Wrinkle for seborrhic skin type → two passes would be enough.
- Case of multi passes.
 - Higher energy would need for thicker skin.
- Meso Therapie
 - Before and after INTRAcel treatment, Meso Therapie would be helpful for decreasing number of emission, number of pass and level of energy.
- Case of using erbium laser and number of passes.
 - Check the depth and the area of scar first. Then, use erbium laser for the deep scar. For shallow scar and rough skin, INTRAcel is useful. It is recommendable to separate the treatment by the depth of scar.
- Skin thickness should be carefully considered before treat, this is the key which affects to power levels and number of passes.



Further Discussion

- Approaching dermis in regarding rejuvenation
 - Which layer would be more effective and how much it would approach in each layer will be considered to approve.
- Combining with other medicine
- Combining with other device

HISTOLOGIC EVALUATION OF DEEP DERMAL HEATING BY FRACTIONAL RADIOFREQUENCY ACCORDING TO ENERGY

Dr. Un-Cheol Yeo / Dr. Doo-Rak Lee / Dr. So-Dug Lim
S&U Dermatologic Clinic, Seoul, South Korea

LEVEL : A 10-WEEK FOLLOW UP STUDY

Background and Objectives

A new device, INTRACEL heating up deep dermis using microneedles of bipolar and monopolar RF in a minimally invasive way: Fractional Radiofrequency Microneedling ("FRM") technology was introduced lately. This study was conducted to see the wound healing response following FRM treatment for both human and porcine skin.

Study Design and Methods

A maximum power of 700W RF can be used on bipolar mode to deliver the thermal energy directly into the dermis. 49 microneedles are diffused to 1cm² areas on its tip, and those needles are insulated except its distal 0.3mm to avoid the thermal damage on the skin surface when it penetrates into skin. 10 healthy patients and aseptically processed a micro-pig were involved in this clinical trial. Healing responses were observed by the time after FRM treatment at various energy levels. Biopsy was conducted to see the wound healing process immediately after the treatment,

2days, 14days, 28days, and 10 weeks post the treatment. H&E stain and HSP47 stain were conducted to see the changes in inflammatory cell, collagen. Also, the study has conducted RT-PCR with the tissue biopsied from Micro-pig covering 10 weeks to see mRNA change of collagen, Heat Shock Proteins (HSPs), and matrix metalloproteinase (MMPs).

Results

No thermal damage was observed on the epidermis and upper dermis except the area the microneedle electrodes passed, but the collagen was damaged within the reticular dermis. Denatured collagen column was seen through H&E test. 10 weeks later, the observation clearly showed that the pattern of new collagen was granulated on the area of damaged collagen. The increases were observed in 70 days from the FRM treatment in various inflammatory cytokine, HSPs, procollagen 1, procollagen 3, tropoelastin, and fibrillin through RT-PCR test. Seeing the change due to the energy level used for the treatment, the tissue

treated with high level energy showed increase of the number of fibroblast, and the collagen reproduction as well as the replacement of damaged collagen.

Conclusion

FRM leaves minimal damage by its needle penetration on epidermis and upper dermis, and fractional deep dermal heating is possible in the lower dermis. Such damaged collagen is healed by new collagen being granulated as time passes, and fibroblast proliferation was seen. These conditions are well observed in RT-PCR results, as HSP expressions supporting the production of a new collagen in the tissue stained with HSP antibody. FRM treatment is expected to be good for a tightening, wrinkle reduction, and scar treatment, as it uses various needle depths with the different targets to induce the production of a new collagen and elastin.

Key words:

bipolar; fractional; micro-needle electrodes; neocollagenesis; neoelastogenesis; deep dermal heating; wound healing

Introduction

When ASR (Ablative Skin Resurfacing) was introduced to the aesthetic market, it was effective but it produced patients a lot of pain with a long down time. In contrast, NAR (Non-ablative Rejuvenation)'s side effects and pain was a lot less than ASR, but it provided insufficient efficacy to reach the patient's satisfactory level. Later, fractional laser technology was introduced, but epidermis was burnt and left pigmentation when it tried to deliver the strong energy to deep skin layer. It was obvious as it uses epidermis as the passage of the thermal energy. The new bipolar microneedles RF device was invented to satisfy such demands and needs. This machine has microneedles and it delivers fractional RF energy to induce the thermal damage

in the target area of the dermis. Fractional Radiofrequency Microneedling(FRMTM) makes thermally and partially injured columns in deep dermis. The dermis in between the thermally injured columns is not wounded. A histology, immunohistochemistry, and molecular biological studies are adopted to observe wound healing process on human body and micro-pig. As results, we found out the fact that FRM treatment induces a strong wound healing response to collagen draw out and elastin remodeling by expressing HSPs and cytokines.

Study Design and Methods

A study was carried out total of 70 days with 10 subjects and micro-pig. Patients and micro-pig were treated and observed immediately after, 2 days, 14 days, 28 days, and 10 weeks later. The treatment had done prior to their prescheduled biopsy to capture the temporal evolution of the in vivo wound healing response.

FRM delivers bipolar RF into dermis by 49 microneedles electrodes of 1.5mm or 0.8mm in their length. Microneedles are inserted into skin at 90 degrees. RF is emitted to dermis after 0.2 seconds post the insertion of microneedles. The delivery times of RF energy are different by the energy level, and the lengths of needles could be chosen among 0.5, 0.8, 1.5, and 2.0mm.

Histological wound healing response was measured to determine deep dermal heating of collagen, elastin, and inflammation. Incision treatments were done for 2 different 2mm biopsies at each time points. The biopsied tissue was set in 10% neutral buffered formalin and moved into paraffin. 10 paraffin or sections were stained with H&E and HSP47 through serial section. Semi-quantitative reverse transcription chain reaction, RT-PCR is used to measure the changes in molecules of remodeling within the dermis post FRM treatment. Electrophoresis was implemented after the RT-PCR. The densitometry analysis using AlphaEase software was used, and β -actin, β -globin glyceraldehyde-

3-phosphate dehydrogenase was used as housekeeping genes. Amplicon intensity ratio was estimated by dividing the intensity of housekeeping gene with the intensity value for the gene of interest by the intensity value of for β -actin. The study observed wound healing response in the human body and micro-pig by histology, immunohistochemistry, molecular biology technologies. Research findings indicate that FRM technology enables coagulation necrosis column to be developed in the dermis, and induced dramatic wound healing response, remarkable increase in HSP expression along with dynamical remodeling of collagen and elastin. Thus, this deep dermal fractional heating, FRM technology will be good for facial wrinkles, tightening and scar treatment.

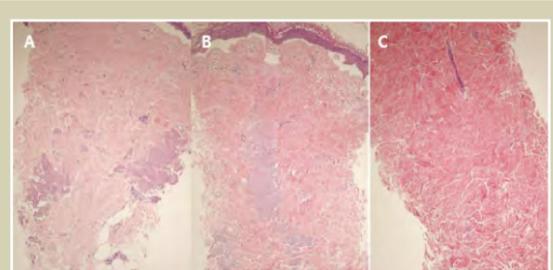


Fig.1. FRM lesions post-treatment. Study adopted in vivo test on human skin immediately, 14 days, 10 weeks post FRM treatment. Observation indicates remodeling in the dermis for 10 weeks. Immediate postoperative shown as “(A)”, “(B)” is postoperative 14days, and “(C)” is postoperative 10weeks. The immediate postoperative shows a clear approval of deep dermal fractional heating without damage on the epidermis, and the density of collagen postoperative 10 weeks more increased than immediate postoperative. Every approval shows dermis remodeling and the progress of new collagen was being created. All images are H&E stained and shown at 2X the original magnification.

Results and Conclusion

Deep dermal fractional heating

To see the change in the tissue after FRM treatment, biopsied tissue was stained by H&E immediate, 2days, 14days, 28 days, and 10 weeks post-treatments. Thermally

damaged area was detected in reticular dermis immediately after FRM treatment (Fig.1A). Coagulation necrosis part is formed in the deep dermis. Collagen denatured area is disappearing gradually 14 days post-treatment (Fig.1B), and then replaced with a new collagen completely in 70 days post-treatment (Fig.1C). A connection of two coagulation columns with needles tracts on the epidermis were observed in the tissue by serial section just after the treatment (Fig.2).

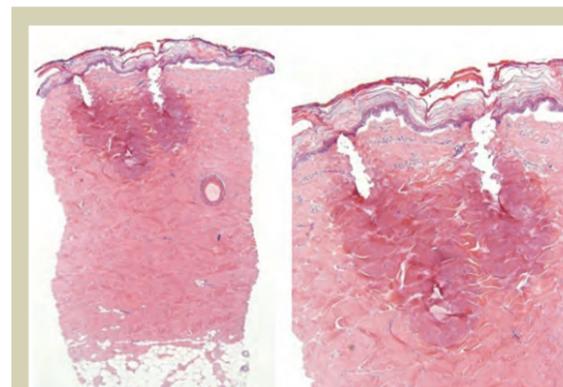


Fig.2. Immediate after FRM treatment. Coagulation columns were made that connected by the two electrodes of bipolar RF plus and minus being connected precisely

Collagen damage is repaired with time.

An infiltration of inflammatory cells was seen to the time points. From postoperative 2 days post treatment slight permeation of inflammatory cells is seen (Fig.3A), partially damaged collagen is absorbed in 14 days and new collagen is seen (Fig.3B). Postoperative 28days, the proliferation of young fibroblast is observed (Fig.3C). Lesion is being replaced with new collagen in 70 days.

HSP47 is expressed in the dermis between 28 days and 70days after the treatment unitedly with the response of inflammatory cells (Fig.4). The RT-PCR has been taken before the treatment and in the various time points to understand better on the results of molecule events

arousing by FRM treatment. Research found that cytokine expression increase for 4 weeks stably but MMPs increased gradually. HSP47 increased over 3 times until 70 days and the expression level of extracellular matrix protein also continued to increase up to 5, 3 times before treatment in tropoelastin and procollagen cases (Table.1)

Neo-collagenesis is correlated to degree of damage.

This research shows the relationship between a new collagen production and energy level on damage, as the observation shows the increase of the fibroblast proliferation and HSP47 expression at the various energy levels. As the energy level increased, collagen production also increased along with the number of fibroblast (Fig.5). HSP47 also was expressed more in the higher level (Fig.6).

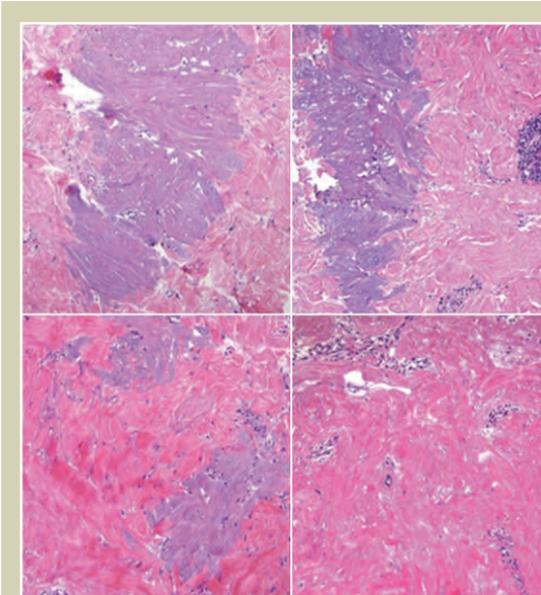


Fig.3. The amorphous degeneration. There is a minimal inflammation in the lesion in 2 days post-treatment (A). Mild infiltrate of chronic inflammatory cells are present in the lesion and adjacent perivascular spaces 14 days post treatment (B). The lesion got absorbed and appeared edematous. The irregular collagen tissue partially replaced to the degenerated lesion in 28 days post treatment (C). The lesion is almost replaced by collagen and was remarkably raised cell density in 70days post treatment (D). The image is seen at the 4X original magnification.

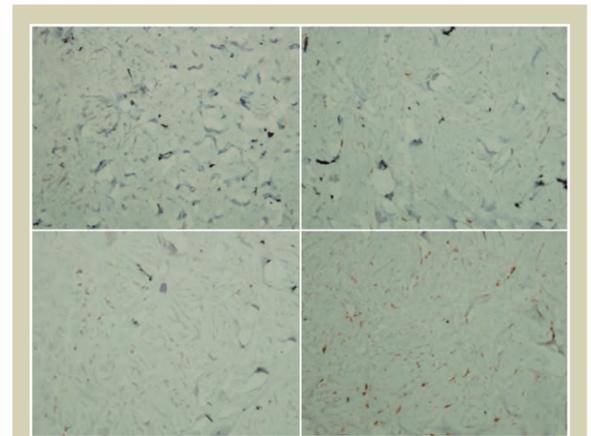


Fig.4. HSP47 responses to FRM treatment. The tissue of micro-pig was stained with HSP47 antibody post FRM treatment. (A) is immediately post treatment, (B) is 14 days post treatment, a minimum of HSP47 expression was detected in the dermis immediately post FRM treatment. HSP47 increases gradually (B), expressed between 28 days (C) and 10 weeks (D), and diffused causing the coagulation necrosis column to be well recovered.

Biopsy showed that the number of the fibroblast didn't increase in the low energy level, and only the hypertrophic response which can get fibers thicker. While fibroblast number increased in the higher energy showing hyperplastic response, an increase in cellularity. The number of cells increases during the wound healing, the effect continued a long time, in general.

No change beyond the treatment depth.

HSP47 expression area was observed to see the influence on the extension of collagen remodeling which can be caused by FRM treatment. The comparison of H&E and HSP47 stained tissue shows the occurrences of the strongest expression at the area of collagen denaturation. However, it wasn't expressed any energy level in the deeper area (Fig.7). Therefore, it is better to try FRM to treat the target area when the lesion is in the deep area

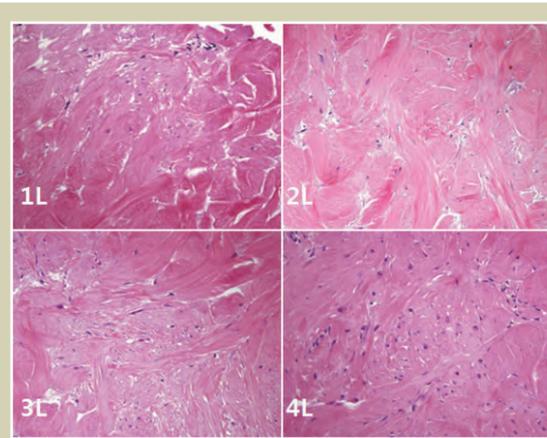


Fig.5. Fig of micro-pig tissue 70 days post FRM treatment. Nucleus and fibers are increased more as energy level get higher.

effect and doesn't make down time long as it produced more collagen. Through the study, fractional deep dermal heating system on a selected target area is expected to provide good and positive efficacy for a skin tightening, wrinkle reduction, scars and pore treatment.

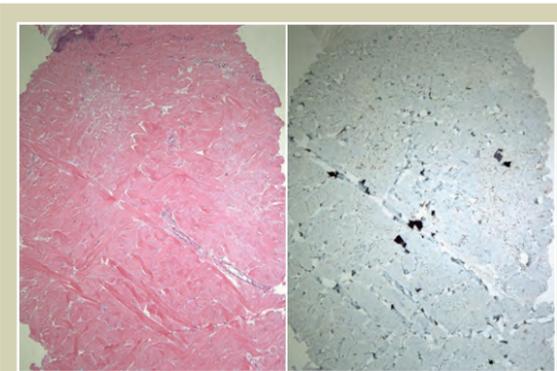


Fig.7. Responses of HSP47 to FRM treatment. HSP47 is expressed between denatured areas, but never expressed in the deep dermis deeper than the area treated before.

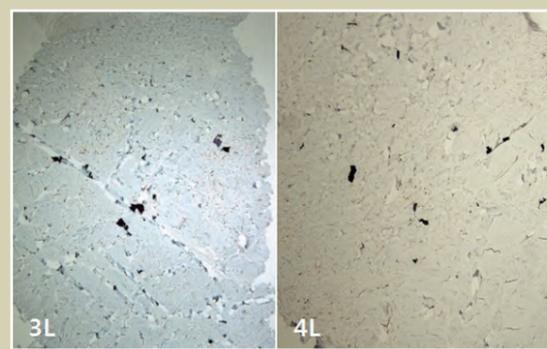


Fig.6. HSP47 response 70 days post FRM treatment. In fact, HSP47 expression is more than doubled in the higher energy level, which means high energy level causes the greater collagen composition.

Discussion

The 10 weeks observation post FRM treatment has shown dermis remodeling process such as increased production of HSP47 and procollagen, and a full replacement of turning denatured collagen into a new collagen. The study proved the actual volume effect by showing increased production of procollagen and new elastin in the immunohistochemistry and RT-PCR. The result of FRM treatment is better when it operated with a high energy level if it doesn't cause side

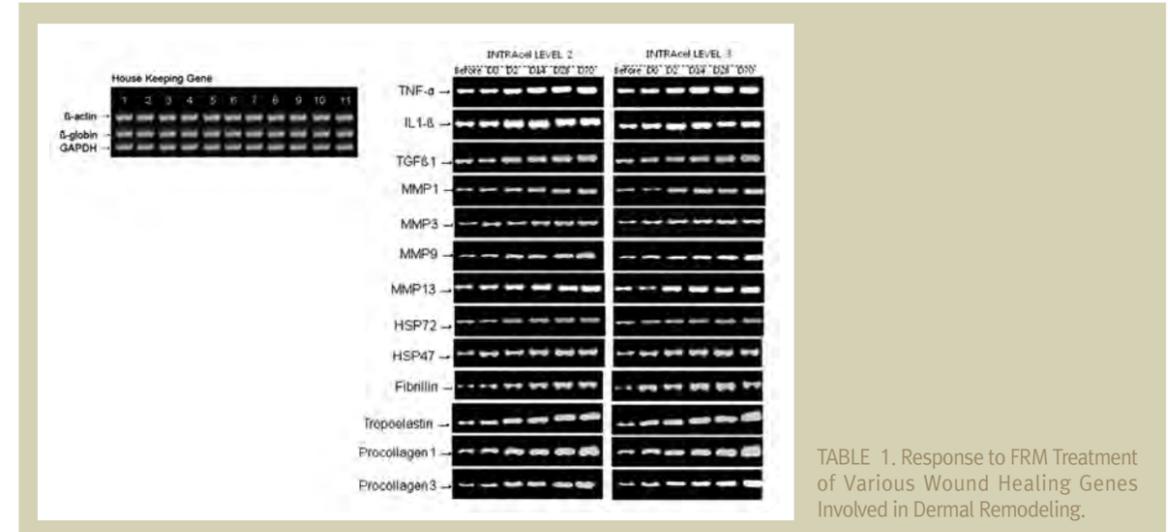


TABLE 1. Response to FRM Treatment of Various Wound Healing Genes Involved in Dermal Remodeling.

	Baseline	1.5 3L D0	1.5 3L D2	1.5 3L D14	1.5 3L D28	1.5 3L D70
TNF-α	0.32	0.38	0.4	0.4	0.45	0.58
IL-1β	0.26	0.33	0.35	0.35	0.4	0.42
TGF-β1	0.39	0.38	0.42	0.42	0.46	0.58
MMP-1	0.26	0.42	0.36	0.36	0.38	0.37
MMP-3	0.31	0.22	0.39	0.39	0.35	0.46
MMP-9	0.43	0.49	0.87	0.87	1.01	1.13
MMP-13	0.41	0.46	0.67	0.67	0.89	0.81
HSP72	0.62	0.78	0.52	0.52	1.65	1.62
HSP47	0.51	0.62	1.15	1.15	1.42	1.81
Fibrillin	0.84	0.98	1.21	1.21	1.2	1.54
Tropoelastin	0.27	0.36	0.82	0.82	1.12	1.36
Procollagen1	0.67	1.08	1.18	1.18	2.07	2.67
Procollagen 3	0.74	0.92	1.02	1.02	1.32	1.62

Relative expression was calculated as the ratio of the expression level of the gene of interest/expression level of β-actin at each particular time point.

COMBINATION ANTI-AGING TX INCLUDING INTRACEL



Dr. Mi-Kyung Cho
S&U Dermatologic Clinic, Seoul, South Korea

Combination Antiaging Tx including INTRAcel

Antiaging Treatment

Aging は皮膚の老化により現れる現象として、弾力がなくなり、毛根が開き、しわが深くなり、皮膚の色がくすみ、色素、そばかすが増えます。またボリュームが減るに従い、ホウレイ線、インディアンフォールド (Indian fold) がひどくなり、くぼむ部分が出て、それがたるむとマリオネットライン (marionette line) ができ、あごが垂れるという症状が挙げられます。

一つの治療ですべての老化現象が改善するといいますが、症状別に効果的な治療があるので、より効果的なアンチエイジング (Anti ageing) のためには、様々な治療を並行するのがいいと考えます。我々は全般的な老化改善には、フレクショナル治療 (Fractional) を、しわにはボツリヌス菌 (botulinum) を、くぼみや深いしわの治療には Filler (フィラー) 注射、弾力がなく垂れ下がって膨れた輪郭にはアキュリフト (Acu lift) を、また、全般的な皮膚改善にはハイドロトキシソリフト (Hydrotoxin lift) を薦めています。

Antiaging Treatment

Aging is the phenomenon that occurs as the skin ages. Elasticity drops, pore widens, wrinkles deepen, skin tone becomes dark, blemish gets thicker, volume declines, making 8-shaped wrinkle and Indian fold gets intensified and falls in, resulting in sagging and marionette line as well as drooping of chin.

While it must be good to treat all aging symptoms with one type of treatment, there are different effective treatment for each symptom. In this regard, it is good to receive several treatment at the same time for effective anti-aging.

It is recommended to receive fractional treatment for overall aging improvement, get shot of botulinum toxin for wrinkles, filler shot for fallen or deep wrinkle treatment, to receive Acu lift for non-elastic, drooped or bulging contour, and Hydrotoxin for overall skin improvement.

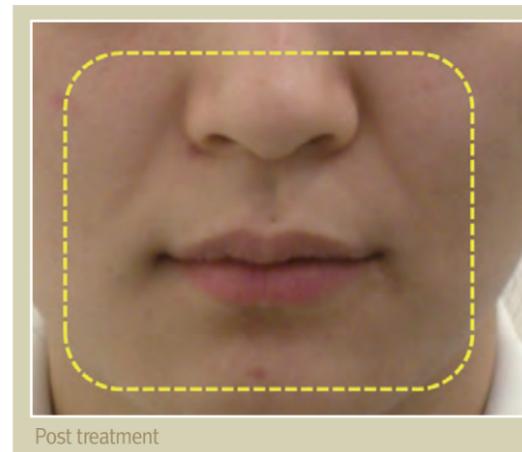
<イントラセル (Intracel) の単独治療>



Post treatment

INTRAcel + Plasma gel

続いては、イントラセルとプラズマジェル注射治療 (PPP Gel) を併行したケースです。プラズマジェルは、患者の全血 (ぜんけつ) を遠心分離して得られた血漿 (けっしょう) を、ALSAを利用してジェル状に固めた後注射する治療で、くぼんだ部分をふっくらさせる目的に利用しています。



Post treatment

INTRAcel + Hydrotoxin lifting

次に、イントラセルと、ハイドロトキシソリフト注射 (Hydrotoxin lifting) を併行したケースです。ハイドロトキシソリフト注射は、ヒアルロン酸 (hyaluronic acid) と、ボツリヌス菌 (botulinum) を1対1で混ぜ、1cm間隔で顔全体に注射する治療で、皮膚が明るくなり、しっとりし、張りが出る効果があります。一般的に1ヶ月間隔で3回の治療の後、3から6ヶ月間隔を維持する治療を薦めています。

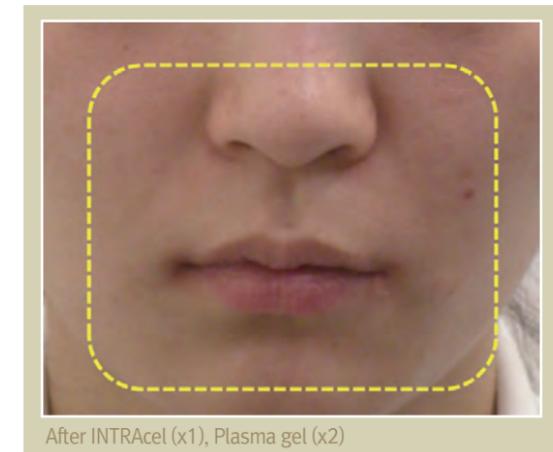
<Case of INTRAcel Treatment only>



After INTRAcel (x4)

INTRAcel + Plasma gel

Following figure shows the case of receiving INTRAcel and PPP gel at the same time. PPP gel is the treatment of injecting the plasma that was obtained with centrifugation of whole blood of patient, after hardening it to gel status using ALSA. It is used for filling up the fallen parts.



After INTRAcel (x1), Plasma gel (x2)

INTRAcel + Hydrotoxin lifting

Both INTRAcel and Hydrotoxin lifting can be administered at the same time. Hydrotoxin lifting is the treatment of mixing hyaluronic acid and botulinum at the ratio of 1:1 and injecting at overall faces at the interval of 1 cm. Skin gets brighter and more moist, and resilient. In general, it is recommended to receive treatment 3 times at the interval of 1 month, and to receive maintenance treatment at the interval of 3-6 months.

INTRAcel + Dermotoxin + Filler

イントラセル (Intracel)とDermotoxin (ダーマトキシン)、Filler (フィラー)を並行したケースです。ダーマトキシンはボツリヌス菌 (botulinum) を筋肉層にも入れますが、主に上部真皮、真皮内注射する方法でしわを自然に改善し、皮膚の色やきめ、毛根、えらの張りを改善する効果があります。



Post treatment

INTRAcel + Dermotoxin + Filler

It is the case of receiving INTRAcel, Dermotoxin and Feeler at the same time. Dermotoxin is the method of injecting inside or upper part of corium, while Botulinum can be injected to muscle layer. It makes wrinkle naturally improved, and has effects of improving skin tone, texture, pore and square chin.



After INTRAcel (x4), Dermotoxin, Filler

INTRAcel + Dermotoxin + Plasma gel + Acculift

イントラセル、ダーマトキシン (Dermotoxin)、プラズマジェル (PPP Gel)、アキュリフト (Aculift)を平行したケースです。アキュリフトは波長1444nmのレーザー (Laser)で脂肪を溶かし、輪郭を改善し、リフティング (Lifting)を誘導する効果があります。



Post treatment

INTRAcel + Dermotoxin + Plasma gel + Acculift

It is the case of receiving INTRAcel, Dermotoxin, PPP Gel and Aculift at the same time. Acculift makes the contour by melting the fat with 1444nm wavelength and has effects of inducing lifting.



After INTRAcel (x3), Dermotoxin(x1), P.gel(x1), Acculift(Cheek)

結論として

イントラセル (Intracel)は維持費が抑えられ、他のフレイクショナル治療 (Fractional)に比べ、施術後目立ちにくく、リフティング (Lifting)効果がはっきり現れ、にきび予防効果まで期待することができるという長所があります。イントラセル単独でも皮膚の色、きめ、しわ、弾力、毛根など、全般的な皮膚老化の症状が改善されますが、様々な治療を複合して並行すると、さらに効果的です。

Conclusion

INTRAcel requires low maintenance cost and shows less mark than Fractional treatment. It has advantage of expecting acne prevention effects in addition to clear lifting effects. While INTRAcel only treatment can improve overall skin aging symptoms such as skin tone, texture, fine wrinkles and pore, several kinds of treatment are more effective.

THE CLINICAL EFFICACY AND STATISTICAL EVALUATION OF INTRACEL TREATMENT



Dr. Takashi Takahashi
Dermatologist Takahashi Clinic
Shibuya, Tokyo, Japan

INTRAcel Treatment

Background

Minimally invasive Fractional Radiofrequency Microneedles(FRM) device is recently introduced. The device gives selective heating in the dermis using bipolar RF (or monopolar RF) through microneedles. This study is to demonstrate clinical improvement following FRM.

Methods

60 subjects with scar, facial laxity and large pore were enrolled. 60 patients were treated with a minimally-invasive FRM device (INTRAcel). Bipolar RF energy was delivered through 49 micro-needle electrodes deployed into the reticular dermis from the papillary dermis vertically to the skin surface. Only subjects consenting to longitudinal follow-up during the study were enrolled to observe the improvement as time went by.

Results

As the result of 3 months follow-up, all patients did not

have any problems during the period and any adverse events or complications weren't observed. Patient satisfaction was high with 83.3%. Self-assessment of clinical outcome showed moderate to significant improvement in skin laxity, scar and pore.

Conclusion

Bipolar RF treatment makes deep dermal fractional heating in targeted deeper dermis. Clinical improvement by FRM treatment is related to collagen and elastin fiber which are generated by wound healing process.

These results suggest Fractional Radiofrequency Microneedles treatment may become an important option for the treatment of facial skin laxity and scars.

Introduction

Previous generation ASR(Ablative Skin Resurfacing) laser devices were effective, but many of them could not avoid the problems of long down time and patient pain. On the contrary, NAR (Non-ablative Skin

Rejuvenation) laser devices reduced pain and adverse effects, but these devices could not make dramatic effects. In the middle of 2000s, fractional technology opened new generation overcoming previous problems. But the fractional treatment was limitedly used because it could not control penetration depth and it gave damage on the epidermis. Recently introduced FRM opens new generation in aesthetic market by meeting the market demand. We observed wound healing process after the FRM treatment in the human body using histological and molecular biology technology. As the result, we found out the fact that FRM treatment induced a strong wound healing response drawing out collagen and elastin remodeling by Heat Shock Protein (HSPs) expression and various cytokines. Clinical improvement in skin laxity and acne scar is achieved by volume effects produced by neocollagenesis and ne elastogenesis.

Study Design and Method

All subjects consented prior to participation. Patient consent for digital photography and adding the photos in article was also organized prior to treatment. Exclusion criteria consisted of history of injection with silicone, botox, filler, fat or a synthetic material placed in the intended treatment area, hypertrophic scar or bleeding disorder, lidocaine hypersensitivity, photosensitivity or anaphylaxis. Patients with a compromised immune system impaired wound healing, collagen vascular disease, implantable electronic device, or active infection were disqualified from participation. Only subjects consenting to longitudinal follow-up during the study were enrolled.

Clinical Procedure

Patients were treated with a minimally-invasive FRM device. Bipolar RF energy was delivered through 49 micro-needle electrodes deployed into the reticular dermis vertically to the skin surface. The epidermis and superficial dermis were protected securely from RF heating at the insertion location by insulating the rest of each electrodes except its

distal 0.3mm. Standardized photographs were taken at the baseline and at 3-month follow-up. Follow-up patients were asked to rate their overall satisfaction, the impression of scars and laxity improvement using a five-point scale.

Treatment Results

60 subjects with mild to significant scar and rhytids were enrolled. All patients received one FRM full face treatment. All subjects were managed for 3 month follow-up. Mean age was 41.2 +/-23.5 years.

All patients experienced transient edema and erythema, but it resolved within 48 hours. 13.3% of the patients experienced dry skin. However it was gone away within 2 weeks. Patient satisfaction was high with 1.6% dissatisfied, 15% neutral, 0% satisfied and 83.3% very satisfied (Fig 1). FRM treatment self assessment of clinical outcome showed significant improvement in acne scar and moderate to significant improvement in skin laxity.

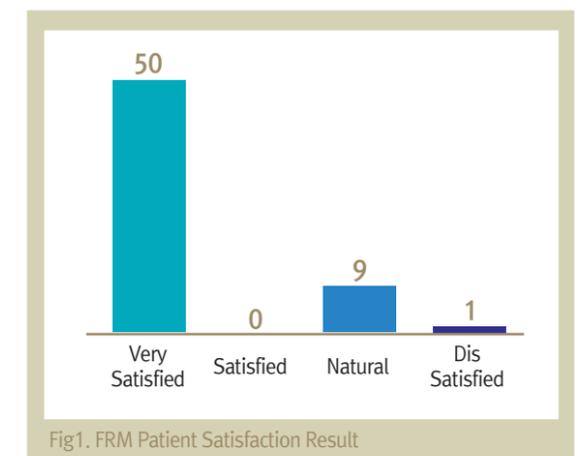
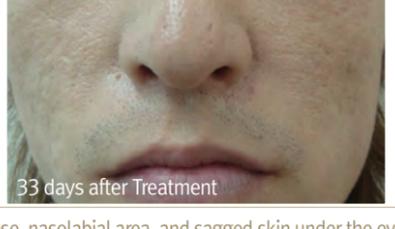
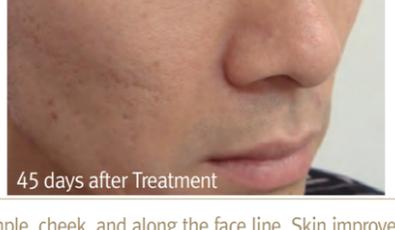


Fig1. FRM Patient Satisfaction Result

Conclusion

FRM treatment has been shown to provide consistent and meaningful improvement in facial scar and laxity without complications and adverse effects. In this study, the average improvement seen following a single FRM treatment was approximately 93.3%. The result of this study may become an important option for scar and facial laxity treatment.

No.	Before	After Treatment
1		 35 days after Treatment
This is a 24 years old female case. After 35 days, rugged area and red keloid of the right face line improved.		
2		 35 days after Treatment
19 years old male patient after 33 days. Red and uneven acne areas improved. Patient testified he did not get acnes.		
3		 35 days after Treatment
30 years old male patient. Major symptom was acne and rough uneven face. This is after 1 month. It shows the certain improvement.		
4		 35 days after Treatment
Keloid kind of scar had improved.		
5		 1 Month after Treatment
30 years old female patient. Pretty much improved on uneven dented acne scars.		

No.	Before	After Treatment
6		 26 days after Treatment
20 years old male patient. Patient testified that his acne and pore had decreased.		
7		 33 days after Treatment
66 years old female patient. Sagged skin and Nasolabial fold had much improved.		
8		 33 days after Treatment
26 years old male patient. After INTRAcE treatment, skin improved as shown in the picture and he was satisfied.		
9		 33 days after Treatment
26 years old male patient. We can see the improvement on his nose, nasolabial area, and sagged skin under the eyes.		
10		 45 days after Treatment
28 years old male patient. Dramatic result has shown on his temple, cheek, and along the face line. Skin improvement had continued after 45 days from the treatment.		

NON-SURGICAL FACELIFT BY INTRACEL : THE FUTRE OF THE ANTI-AGING TECHNOLOGY



Dr. J.C Poon / MD / F.C.F.P. / D.A.B.A.A.R.M

Cosmetic Physician & Anti-Aging Specialist
Beautiful One Lipodissolve & Laser Centres, Toronto, Canada

INTRAcel Treatment

INTRAcel can be applied not just face but body as well. Because with laser technology, we also concern about the damage, down time and damaging epidermis. With INTRAcel technology, we are able to bypass epidermis. Therefore you don't have to worry about complication. Patients worried about micro needles, but within an hour, it is all seals off. They can wash their faces or whatever they want. The only thing to avoid is the sun. And These are my clinical result of INTRAcel treatment. Comparing before and 2 month after photos(Fig.1), the texture and wrinkles were greatly improved.



Fig.1. INTRAcel Result –Skin Type II

He had 2 treatments and those pictures(Fig.2) are taken before treatment, 1 week after 1st treatment, before 2nd treatment and 1 week after 2nd treatment. Line and scar are improved. Skin texture is also improved. The face is nice and shiny.



Fig.2. INTRAcel Results –Skin Type IV

And This is for darker skin type(Fig.3), it immediately got whitening. The picture(Fig.4) is clinical result of eye treatment. The line is greatly improved after two months.

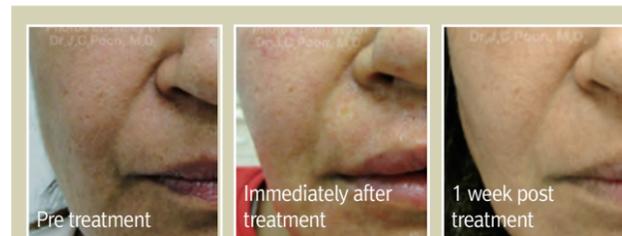


Fig.3. INTRAcel Results –Skin Type V

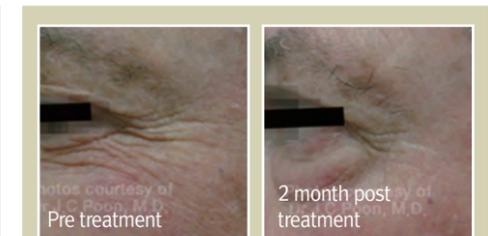


Fig.4. INTRAcel Results

This is the case of neck(Fig.5). It is actually first treatment for me to the neck and I was very surprised to see the improvement. Amazing result. The possibilities are really beginning to explore what we can apply for this technology to.



Fig.5. INTRAcel Results –Skin Type IV

ACNE TREATMENT BY USING INTRACEL



Dr. Joon-Sung Yang

Aroomdawoon Dermatologic Clinic, Jeju Island, Korea

INTRAcet Treatment

Previous treatment

ACNE usually appears in teenage period, but some people begin to have acne in the age of 20s or 30s, and sometimes ACNE is a disease that stays long time. There are several reasons for the ACNE. Reasons are increases the production of sebum from sebaceous glands, abnormal increase of cornification in follicle, proliferation of P.acne bacteria, genetic reason and inflammatory reaction.

For these ACNE, there were a lot of drug treatments like using antibiotics, retinoid, benzoyl peroxide. These drug treatments are good for the light symptom, but active ACNE, repeatable ACNE and chronic patient would have resistance of antibiotics. Patient could have distrust or feel anxious about long term treatment. Also, drug treatment is difficult to use for women who are in period of pregnancy.

There is also the case of chemical skin peeling. This treatment removes wastes on skin and has anti-

inflammatory reaction. This also effects temporally decreasing production of sebum. However, effecting period is too short and it needs to have often treatment.

Recently, there is ACNE treatment by using photodynamic therapy. Even though photodynamic therapy gives better result of lesion and stay longer time than old type of peeling, there are also weakness of long downtime, higher possibility of pigmentation and unsatisfied result for anti-inflammatory lesion. These methods are mostly giving temporally result and has weakness of recurrence depend on treatment.

Kobayashi needle

Next one is ACNE treatment by Kobayashi needle. Insert insulated needles inside dermis and flowing current. Then, destroy sebaceous glands with any epidermal damage. This treatment is not temporally suppressing sebum, but known as semi-permanent

ACNE treatment since production of sebum decrease by destroying sebaceous glands. My hospital also uses this treatment. I use this treatment for patient who is not able to have drug treatment or who continuously returns ACNE at the same place. The result is satisfied. However, since this treatment needs to operate in every pore, it takes long time and it is difficult to have operation when ACNE is all over the face. Instead of teenage patients who have ACNE all over the face, partial or repeatable treatment for adults would be good. Please make sure that this treatment needs a lot of experience and high technique.

New treatment : INTRAcet

I was hoping that Kobayashi needle develops in several ways which are shorter operation time, Possibility of treating the whole face and treating for anyone. What I found is INTRAcet is similar treatment as Kobayashi needle that uses insulated needle. Basic theory for INTRAcet is that insulated needle gets into the dermis and put RF energy in.

This RF energy destroys aging skin and replace with new connective tissue (Fig. 1). So, I used this for patients who want to have face lifting and who want to remove wrinkles or scars. Later on, I could see that there were several cases of having dry skin from my patient, and could figure that change of dermis can possibly make production of sebum less due to destroying sebaceous glands at the same time. Then, I start using INTRAcet for ACNE treatment.

One of the key point for INTRAcet is adjustable needle length, so that doctors can use in different power levels and it can apply to various depth of dermis. In other word, doctors are able to use in different depth of dermis and in wide distribution depending on face area.

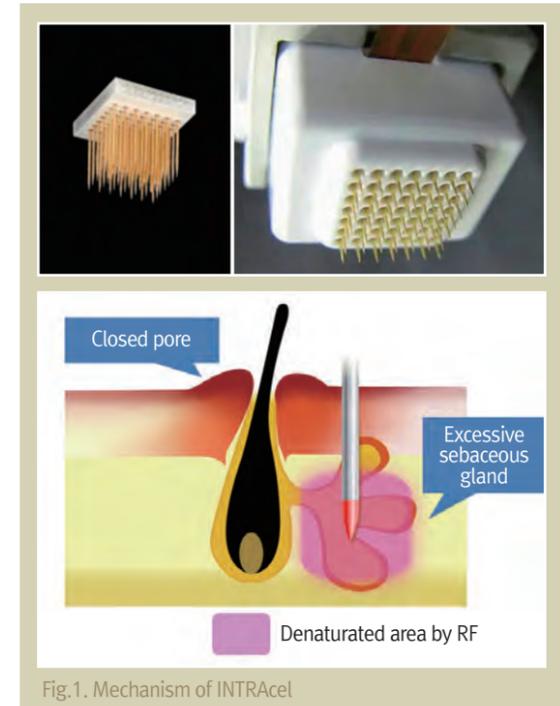


Fig.1. Mechanism of INTRAcet

Since most of sebaceous glands are distributing in 1mm depth area, doctors can start the first pass with 0.8mm needle in level 2 or 3, then do the second pass with 1.5mm needle in level 3 or 4. This will bring the result of destroying sebaceous glands in around 0.5mm based on 1mm depth (Fig. 2).

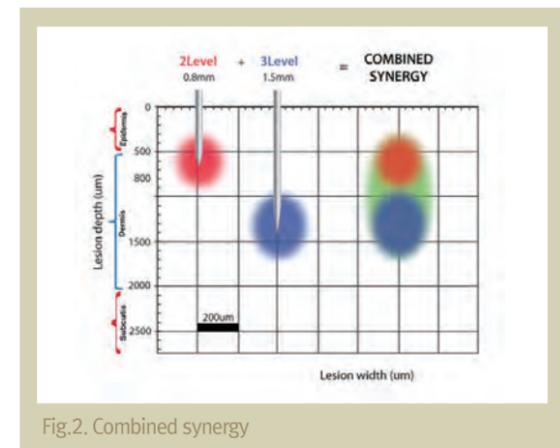


Fig.2. Combined synergy

I started to treat patients with this theory and had a successful result. In overall, occurrence of ACNE was decreased and pores have been tightened by decreasing the production of sebum. Also, ACNE scar was getting better as well because regeneration of collagen was expediting by given stimulation. Comparing with Kobayashi needle, Kobayashi might have a little bit stronger result. However, INTRAcel has more advanced treatment because INTRAcel can be used in all over the face .It is possible to treat in any ages. Faster operation time due to using many needles (49). Possible to have preventive effects because treatment can apply not only for infected area, but also for other area.

Treatment was done 3~5 times in monthly period. Since sebum is emitting from sebaceous glands, I asked patients to visit hospital a day after treatment and removed sebum. Patients can be seen some red parts on the face, but it is ok. Actual result will be shown about a week after the treatment and they will have a lot better result from the second operation.



Fig.3 INTRAcel Results – Skin Type I

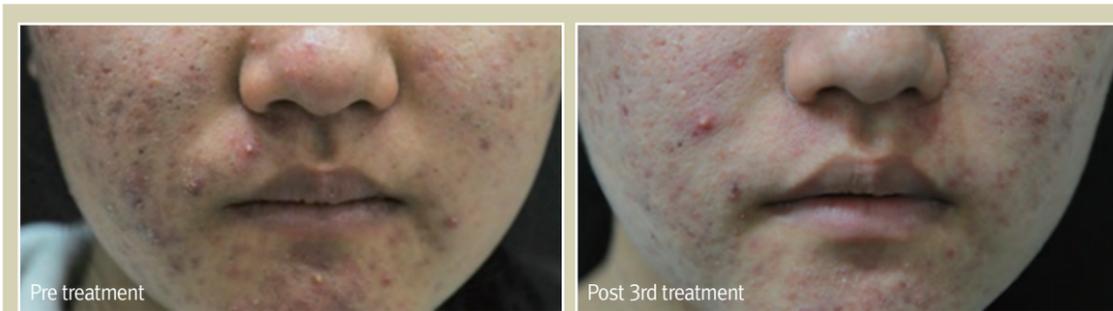


Fig.4 INTRAcel Results – Skin Type II

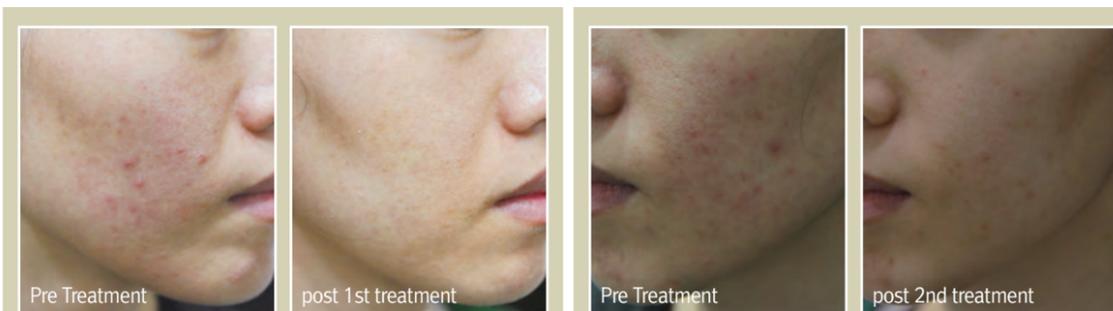


Fig.5. INTRAcel Results – Skin Type III

Fig.6. INTRAcel Results – Skin Type IV

OPEN LABEL STUDY ON THE SAFETY AND EFFICACY OF FRACTIONAL RADIOFREQUENCY WITH MICRONEEDLE™ (INTRACEL) ON MILD TO SEVERE ACNE SCARS IN ASIAN SKIN



Dr. Marie Socouer M. Oblepias / FPDS
Consultant Dermatologist Acnecure Center, Manila, Philippines

INTRAcel Treatment

Introduction

Acne scars are one of the dreaded complications of acne . These can be classified into the hypertrophic and keloid scars resulting from excess collagen deposition and decrease collagenase activity and the atrophic scars due to loss of tissue. Atrophic scars can be subdivided further into icepick, rolling and boxscar. With management of acne scars, you can either do dermal fillers, surgical techniques like punch excision or subcision. You can do nonsurgical resurfacing method like dermabrasion, medium-depth chemical peels or a lot of lasers. These procedures can pose no problem on skin type 1–3 or coacation skin. With darker skin individual like asian or patients with Fitzpatrick IV–VI, the danger of post inflammatory hyper-pigmentation after the laser poses problem.

Study design and methods

A new modality called fractionalized radiofrequency

micro-needling. INTRAcel is a device using micro-needles that are insulated except at 0.3mm of the needle end where the radiofrequency comes out. This new technology gives deep thermal heating without damage to the epidermis. Thus, it could minimize the occurrence of hyper-pigmentation after treatment.

Fitzpatrick skin types III–V (25% –III; 70%–IV; 5% –V). There were 20 patients, 35% males and 65% females, with a mean age of 33 (± 9.39) years old. Each subjects received two full face FRM treatment at 35 days interval. The parameters used were 2mm–1.5mm needles for the cheeks , level T,2 for the RF level and only 2 passes were done. Each investigator graded the acne scars as mild, moderate or severe based on photograph of patients with mild, moderate and severe scars before each treatment and 4 weeks after each treatment. Investigators and subject were also ask to do a global assessment that was done at baseline and 4 weeks after every treatment using the global assessment scale

Results

For global assessment scale

1. no improvement : 0–25% decrease in scar depth
2. minimally improved : 26–50% decrease in scar depth
3. much improved : 51–75% decrease in scar depth
4. very much improved : >75% decrease in scar depth

Baseline acne scar data showed that more than half of the patients had moderate acne scars, 25% had mild scars while 20% had severe scars. Four weeks after first treatment, the fraction of patients with severe acne scars declined to zero.

However, the proportion of patients with moderate acne scars increased to 63% and those with mild scars rose to 37%. Four weeks after the second treatment, 87% of patients had mild acne scars and 13% had moderate scars. The rise in the number/percentage of patients with moderate acne scars from 55% to 63% can be explained by the fact that the patients with severe acne scars from the start improved to become moderate scars one month after treatment(Fig. 1).

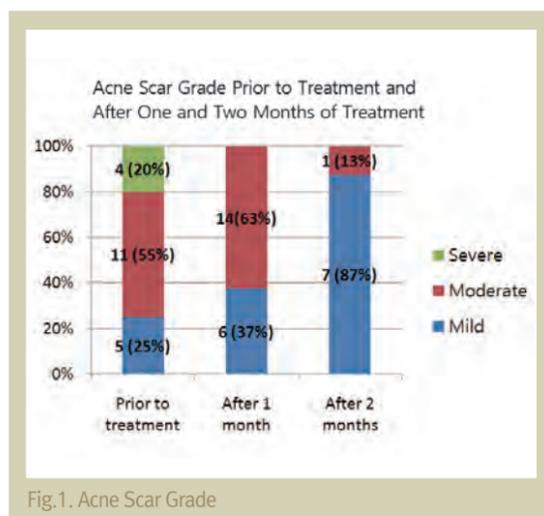


Fig.1. Acne Scar Grade

On the other hand, patient’s global assessment showed that 75% had minimal improvement and 5% of them noted much improvement on their acne scars.

Four weeks after second treatment, 11% had very much improvement , 61% of the subjects reported much improvement on their acne scars, 22% had minimal improvement and 6% felt no improvement(Fig. 2).

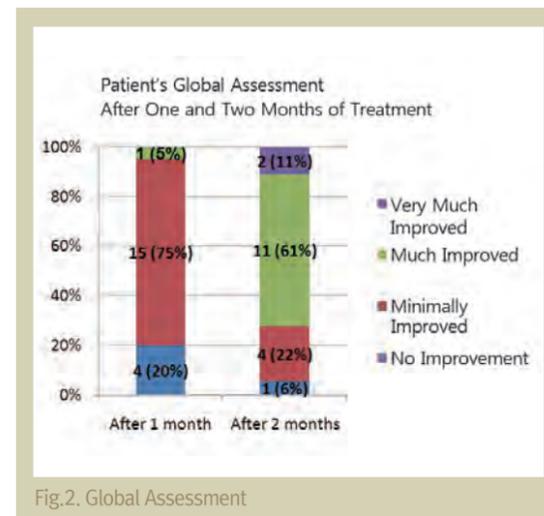


Fig.2. Global Assessment

The continued improvements observed may suggest that there maybe continued long-term dermal remodeling. Since new collagen synthesis occurs, the results are expected to be long lasting, compared with short term improvements that are seen with filler substances. Post-treatment complications included erythema which lasted for 1 to 3 days. Swelling was noted in 60% of the subject population which lasted from a few hours to a day. One patient experienced “square” indentations identical in size to the treatment tips which lasted for a month and eventually disappeared. And on the second treatment there were no other adverse events were reported(Fig. 3).

Complications like burn or PIH were not noted in our investigation and there were no other adverse events.

Conclusion

Fractional radiofrequency microneedling (INTRAcet) device is an effective and safe method for the treatment of mild to severe facial acne scars in Fitzpatrick III–V (asian skin). It is ideally suited for those patients seeking a minimally invasive, reduced downtime procedure.

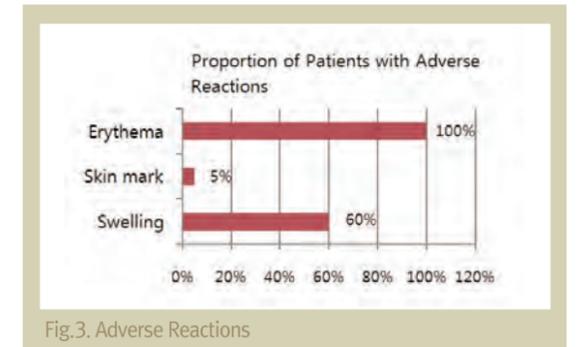


Fig.3. Adverse Reactions



Fig.4. Clinical Data

Recommendations

However since we were using very low parameter, we are recommending as following.

1. a higher level of RF
2. increase the number of passes
3. increase the number of treatments
4. other studies be conducted on the other indications like skin laxity, stretch marks, etc.



Fig.5. Clinical Data

Summary

Fractionalized radiofrequency with microneedling (INTRAcel) which gives deep thermal heating without damage to the epidermis. Histological studies have also shown new collagen and elastic fiber formation.

Clinical studies done have shown improvement of scars and skin laxity. Minimal downtime of around 2–3 days with no occurrence PIH after treatment. Adverse events like erythema, swelling and pain are transient and are well tolerated by the patients. FRM offers an effective and safe method for the treatment of mild to severe facial acne scars, telangiectasia, skin texture and laxity in all types of skin including Fitzpatrick III–V (asian skin).

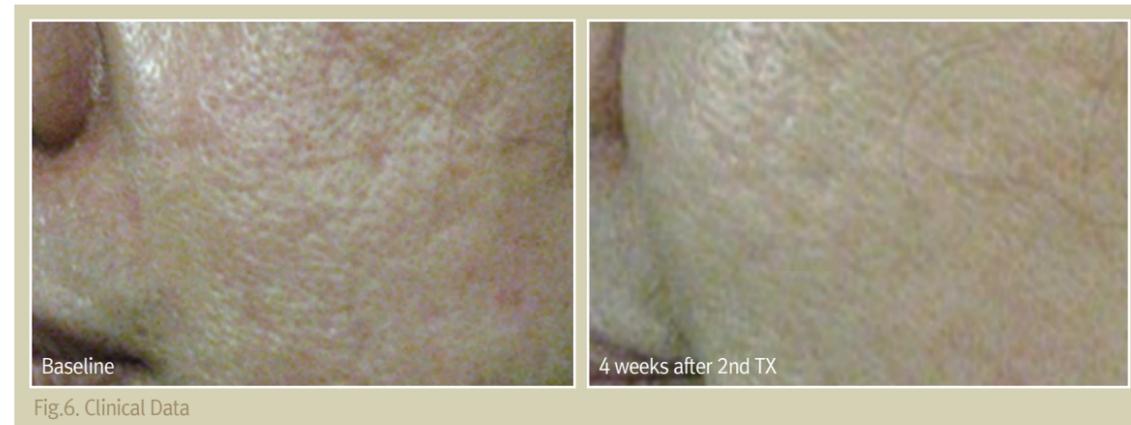


Fig.6. Clinical Data

THE EFFECTIVENESS OF SELECTIVE FRACTIONAL RF MICRONEEDLE (INTRACEL) FOR THE TREATMENT OF TELANGIECTASIA

Dr. Ayako Ito / Dr. Kazuhiro Hayashi / Dr. Tomoyuki Matsukura
Matsukura Clinic, Tokyo, Japan

INTRAcel Treatment

INTRAcel burst on our industry as the machine that put the bipolar RF and the fractional Laser together in 2009. We have started to treat this machine since Oct 2009. We have treated 80 patients by now. 9 patients are male and 71 patients are female. Usually, we use INTRAcel for acne or acne scar. We had to use some lidocaine cream as local anesthesia. During the treatment, patient had a little bit of bleeding, and there was some downtime for a few days. As the photos (Fig.1), we could see the improvement in acne and acne scar by only one INTRAcel session. Refer to the graph(Fig.2), the different result can be shown by each level and needle depth. Therefore, we thought we could use the INTRAcel for the treatment of telangiectasia in dermis.



Fig.1. Acne and Acne scar treatment

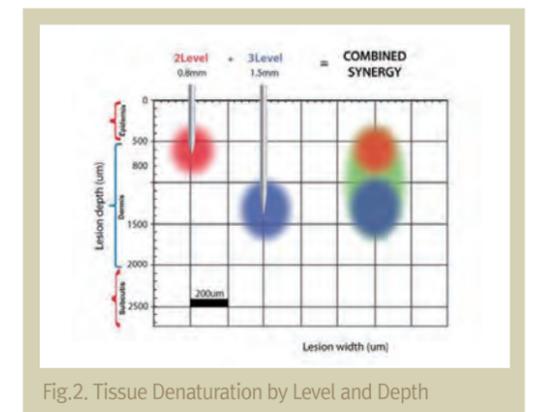


Fig.2. Tissue Denaturation by Level and Depth

Treatment of Earlobe Telangiectasia

As you can see the photos(Fig.3), there is difference immediately after first treatment, but we were already sure that it is effecting one week after. And we had second treatment with longer needle length. 11 weeks later, we and this patient were satisfied for good result.



Fig.3. Treatment of Earlobe Tenlangiectasia

Telangiectasia Treatment for Face

We referred to this examination, we made the plan like this. We took close-up pictures of patients and silicon rubber mold before the 1st treatment, at 6 weeks and 3 months after the follow up. In a few cases, we added to take pictures with microscope and movies before and immediately after the 1st treatment. After all, we compared and considered about the effectiveness for the telangiectasia with them. Below photos(Fig.4) are the case of telangiectasia for left cheek. The result is clear. And the Micro pictures of another patient(Fig.5). He needed a second treatment. But we could get there that the result has last. Neither of us need to say that he was satisfied with the result.



Fig.4. The case of telangiectasia for left cheek

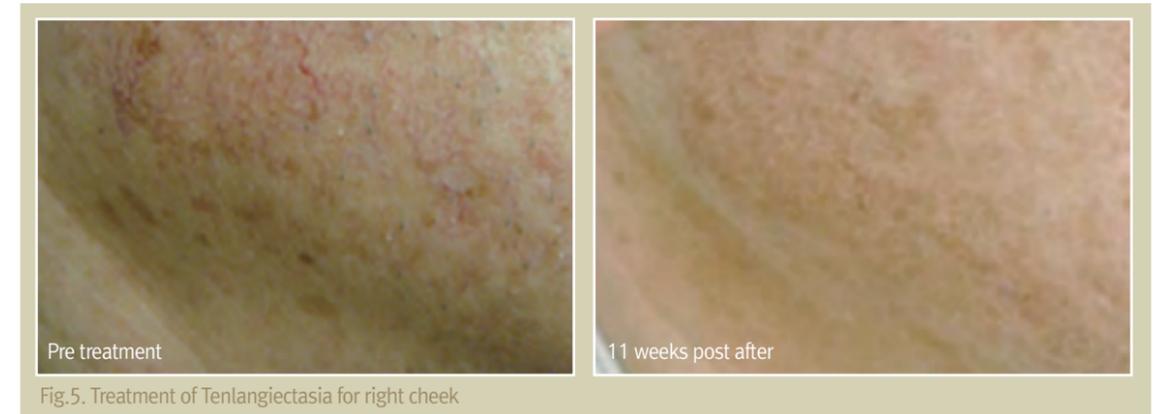


Fig.5. Treatment of Tenlangiectasia for right cheek

Conclusion

INTRAcel is effective treatment for not only scars, acne scars, tightening, and rejuvenation, but also telangiectasia. In addition, as even the skin texture gets better, most of the patients obtain satisfactory results with this treatment. However we should pay attention to PIH when we try INTRAcel with high power multiple treatments.

The Effect for Acne

INTRAcel is showing great clinical efficacy for acne since RF heating of INTRAcel can kill acne germs in dermis(Fig.6). The pictures are taken by UV camera. It shows the change of Porphyrin(Fig.7).



Fig.6. Treatment for Acne



Fig.7. Porphyrin change *Porphyrin -여드름균이 만들어내는 물질로 포피린의 감소는 여드름균의 감소를 의미

The Effect for Acne Scar

Comparing pre treatment and the result of treatment, I used silicon plate to confirm the improvement of the skin(Fig.8). After taking the picture and imitating treatment area of the skin with silicon, INTRAcel treatment was started. A month later, I took another picture and imitated silicon on the treated area. Then, I compared the pre treatment.

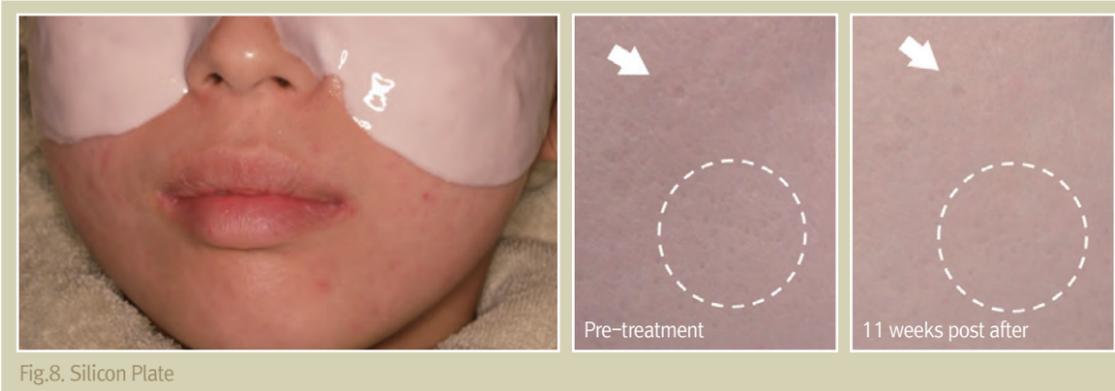


Fig.8. Silicon Plate

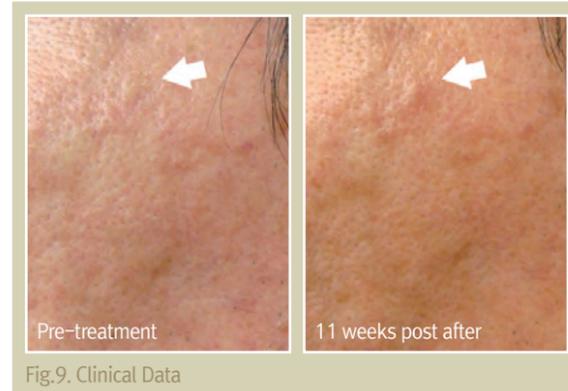


Fig.9. Clinical Data



Fig.10. Clinical Data



Fig.11. Clinical Data

The Effect for Stretch Mark

This is case of stretch marks(Fig.12). He was weighted over 130 kg. He was succeed in diet but he had stretch mark on epidermis. He was over joining for the result of the first treatment. He wanted for his second treatment. In fact, we did third treatment soon after two days.



Fig.12. Clinical Data

INTRACEL TREATMENT WORKSHOP PROGRAM

Dr. Mihara Toshiyuki
Seishin Beauty Clinic

INTRAcel Treatment

はじめに

聖心美容外科では2009年12月よりイントラセルを導入し、今日まで全7院（札幌、東京、横浜、名古屋、大阪、広島、福岡）にて1265例の患者様に処置を行ってまいりました。若干の考察と検討を加え報告させていただきます。

処置の実際（ペインコントロール）

主にペインブロック（塗る麻酔）を使用する。皮膚の薄い所や骨に当たる所は痛みを感じやすい。体の処置などは比較的痛みを感じにくい。痛みに耐えない患者や希望があれば静脈麻酔を使用する。

ペインブロックの塗り方

皮脂を拭き取る。何度も塗り込む。ラッピングする。体などはアルコールを混ぜて行う。時間は30分程度だが、痛みのチェックをしてから行う。

処置の実際（ダウンタイム）

処置後赤みは3~4日程度。もちろん個人差はあるので長引く場合は1週間程度の場合もある。肌の乾燥は1週間程度。メイクは翌日から行って頂いてもトラブルの経験はありません。

Starting

Seishin Beauty Clinics introduced INTRAcel in Dec. 2009 and performed 1265 cases of patient treatment at 7 hospitals (Sapporo, Tokyo, Yokohama, Nagoya, Hiroshima, Fukuoka). I'd like to present some matters for considerations and reviews additionally.

Actual Treatment(Pain Control)

Mainly pain block(applying narcosis). The area with thin skin or corresponding to bone is easy to feel pain. Physical treatment is hard to feel pain relatively. Use intravenous narcosis to patients who cannot endure pain or want to receive such narcosis.

How to Apply Pain Block

Wipe out sebum. Apply several times and wrap. Perform this on the body by mixing with alcohol. It takes about 30 minutes, but perform it after checking pains.

Actual Treatment (Downtime)

Redness after treatment remains for about 3~4 days. Depending on persons, it takes as long as 1 week, but skin dryness lasts for about 1 week. Patients were allowed to apply makeup the day after treatment, but no experience of trouble reported.

処置後

処置直後の赤み・つっぱり感を抑えるために当院では成長因子入りの薬剤を塗布しております。成長因子入りの化粧水などもありますのでホームケアとしておすすめしております。

To restrict redness right after treatment, our hospital applies the agent added with growth factor. It is recommended as home care since there is a beauty watch added with growth

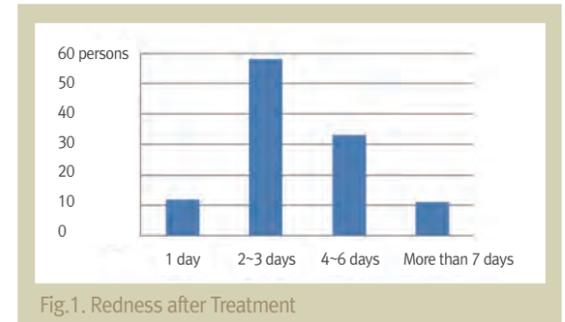
ワンポイントアドバイス①

基本的には強く照射する方が効果を期待できるが、痛みや赤みを伴うことが多い。痛みや赤みがリピートの阻害要因になることもあるため、「痛くてもしっかり照射して欲しい」や「痛いのは嫌だ。」などの患者様のニーズを読み取ることが大切。

経過

- 直後~3日 赤み
- 4日~10日 乾燥
- 2週~1ヶ月 効果の実感
- 3ヶ月 ベストの状態

当院ではモニター患者様に6週間後チェックと3ヶ月後チェックを行っておりますが、3割程度の方が6週後より3ヶ月後の状態の方を良いと感じておられます。現在の所、効果が無くなったなどという訴えはありません。



One Point Advice ①

Effects can be expected from strong irradiation in principle, but pain and redness may be accompanied. Since pain and redness serve as an obstacle factor for repeated treatment by patient, it is important to find out the request of patients such as 「I want strong irradiation even if it hurts」 or 「I don't like pain.」.

Progress

- Immediately~3 days : Redness
- 4~10 days : Dryness
- 2 week~1 month : Realization of effects
- 3 months : Best conditions

Our hospital performs post 6 week check and post 3 week check on the monitor patients. About 30 percent feel the improvement of status in 6 week to 3 months. No effect was felt at that moment. There was no complains about pain.



Fig.2. INTRAcel Results



Fig.3. INTRAcel 腹部たるみ

経過の観察とその後の案内

たるみやニキビの凹凸に関しては、複数回処置を行うことでさらに効果を実感できる。アンチエイジングに関しては、半年から1年に1回をおすすめしています。

Observation of progress and instruction after that

Drooping and bump of acne can be improved with several times of treatment. 1 time a half year or 1 year is recommended for anti-aging.



Fig.4. INTRAcel 腹部タルミ

ワンポイントアドバイス②

日々変化していく状態は、患者様自身での効果の判定が難しくなることが多いのでしっかりbeforeの写真をとっておく事が大切。写真で見比べていくと、患者様が気付いていない変化もわかります。複数回かけて改善していくことをお伝えするためにも経過の写真を撮っておくと、少しずつ良くなっていることを喜んで頂けます。基本的には、患者様が感じているより変化が大きい事がほとんどです。

One Point Advice ②

Since status of changes everyday cannot be easily determined by patient himself, it is important to take photos. Comparison of photo enables them to realize changes they could not notice. To show the improvement through several times, photo of progress clearly indicate progress, making patients happy. Basically, changes were bigger than patient may feel in most cases.

合併症、後遺症、トラブルとその対策

処置後の赤い斑点（針の跡）が残ることはあるが基本的には経過観察で改善。
色素沈着は高いLVを短い針や、また長い針であっても複数回照射すると起こりうる。
針が浮かないようにしっかりとハンドピースを肌に密着させることも大切。金の糸やペースメーカーの使用は禁忌となる。チタンプレートなどは問題ない。
高齢者の首やフェイスラインでは内出血しやすいので注意が必要。

Complication, Aftereffect, Trouble and Measures

Red spot(mark of needle) remains after treatment in some cases, but it was found to be improved at the progress observation. Pigmentary deposit may occur if high LV is irradiated several times with short needle or long needle. It is important to attach hand-piece to the skin surely so that the needle will not float. User of gold thread or pacemaker) are prohibited from using. Titan plate causes no problem. It requires cautions since internal hemorrhage may occur at the neck or face line of the aged.



Fig.5. INTRAcel ニキビ跡 炎症あり

効果・適応

ニキビの凹凸に関しては、繰り返し行うことで少しずつ凹凸が目立たなくなる。ニキビの炎症（赤み）、脂症に関しては、RFで発生する熱により皮脂腺が弱まるため皮脂の産生が弱り改善が期待できる。
熱刺激により、タイトニング効果とコラーゲンの産生が促されるため弛み・小じわ・妊娠線・毛穴の引き締め効果が期待できる。
肌のくすみがとれて透明感が出てくる。

Effects・Application

With regard to bump of acne, repeated treatment helps bump not stand out little by little.
With regard to infection(redness) of acne, adiposis, sebaceous may weaken by the heat from RF so that production of sebum may be weakened. Tightening effects and creation of collagen are activated by heat stimulation, so that tightening of drooping, fine wrinkle, stretch marks and pores are expected.



Fig.6. INTRAcel 臀部肉割れ

MICRONEEDLING WEITERENTWICKELT

Dr. Klaus Fritz

Landau - Germany

Director of Dermatology and lasercenters Landau and Kandel
President of ESLD (European Society for Laser Dermatology)

Associate Univ.-Professor at the University of medicine and pharmacy “Carol Davila” - Bukarest
Lecturer and Consultant Dermatologist at the university Osnabrueck (D) and University clinic Bern (Switzerland)

Secretary General of the Association of German dermatologists (BVDD)
EADV (European Academy of Dermatology) – Chair website committee



Fig.7. INTRAcel リフトアップ



As yet, ablative lasers are used for skin tightening and resurfacing. But even when used in a fractional operation mode, i.e. only punctual removal of a part of the epidermis, their disadvantages such as pain, delayed wound healing or risk of infection, scarring and

persisting erythema cannot be avoided completely.

In contrast, treatment with non-ablative lasers leaves the epidermis intact as the development of heat is restricted to the dermis where it is supposed to lead to fibroblast stimulation and a tightening effect. The above-mentioned side effects can be avoided completely or almost completely with such treatments, but unfortunately their results are also less impressive. Up to now, an alternative to laser treatments has been the micro needling. This treatment method uses needles with a length of 1–2mm which are pressed into the previously anaesthetized skin either by a roller or in stamp form. According to the respective approach, this leads to up to 200 micro injuries per square centimeter which, due to tissue pressure and the superficial penetration depth which only reaches the upper dermis, will immediately close again and thus also avoids the disadvantages of ablative treatments.

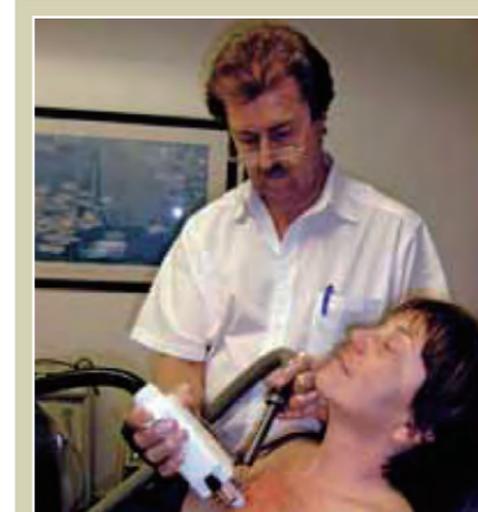


Fig.1. Dr. med. Klaus Fritz bei der minimalinvasiven fraktionalen Frequenzmikroneedling-Behandlung

Koagulation in der oberen oder mittleren Dermis

For scars and rejuvenation the results with micro needling systems have been good, but they have to be repeated several times because the stimulus in the upper dermis consists merely of the mechanical injury and the repair mechanism hereby induced. Only lately a new, advanced method has been introduced to the aesthetic market: The minimal invasive fractional frequency micro needling treatment (FRM).

This treatment method uses a radio frequency device with a handpiece that holds a stamp with 49 micro needles which are completely coated with the exception of their tips. At their tips they emit a bipolar radio frequency between the rows of needles.

The penetration depth of these needles can be set between 0.5 / 0.8 / 1.5 and 2.0 mm. Depending on the objective of the treatment this enables a modification of the penetration depth from a deep epidermal effect to a superficial dermal effect. An automatic mechanism shoots the needles into the skin within milliseconds and immediately pulls them back, just like a stamp. The device emits bipolar radio frequency through the tips at the exact moment when the tip of the needle has penetrated the epidermis.

This leads to coagulation in the upper and central dermis which is comparable to the effects on tissue of fractional CO2 lasers or fractional unipolar radio frequency methods.

Epidermis bleibt vollständig erhalten

Naturally, such coagulation will lead to a tightening of the dermis and thus of the whole tissue in the course of the wound healing process and will stimulate the wound healing mechanism much stronger than a purely mechanical micro needling treatment, with the result of new collagen formation and activation of fibroblasts.

But other than with fractional ablative methods, the epidermis will remain completely intact because of the fact that the micro injuries at the entrance ports of the needles will close up immediately after the needles have been pulled back in order to leave the barrier of the skin unharmed as a safety shield.

This means a very low risk of side effects for the patient, but nevertheless enables a dermal effect which as yet could only be reached with ablative CO2 and Er:YAG lasers. Moreover, depending on the aim of the treatment, intensity und fluency of the radio frequency may be varied in watt.

When aiming for a superficial and a deep effect, even two to four passes are possible which of course enable more tissue reaction. As a result the patient only notices reddening and, depending on the intensity, minor edema which will last for 1 to 4 days.

The treatment can be repeated 3–6 times every 2–4 weeks. Young skin often needs only 1–2 treatments.

The studies of Takahachi and others have proved that a significant clinical and photographic improvement with regard to rejuvenation and acne scars could be achieved and that patient satisfaction was at 83.3%. Moreover, a distinct improvement of skin slackening can be reached.



Fig.2. Die Nadeln werden stempelförmig in die Haut eingeschossen

Thus, the indications for this method are the same as for fractional CO2 lasers – if not even more widespread because of the pronounced tightening effect: scar treatment, rejuvenation, skin slackening also at the neck, at the arms or after liposuction and, above all, treatment of problem areas at the lips, periorbital and in the d – collet – area.

The heat development also induces a reduction of fine telangiectasia in said areas (Study: Ayakoito). Acne scars have been improved by up to 90% after only one session (Study: OBLEPIAS).

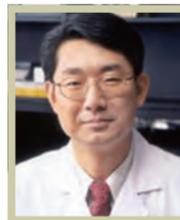
Histological examinations showed a significant increase of collagen which started after 28 days and could be definitely proven histologically after 70 days.

The dermis contained thickened and newly produced collagen. Laboratory tests could also prove that a regenerative process started in the treated areas: Tropoelastin, Procollagen 1 and 3 as well as MMP 9 increased significantly.

With this we now have a method at our disposal which has been histologically and biochemically proven and which achieves results that as yet have only been reached with fractional ablative lasers, but which does not entail any of the disadvantages and side effects of ablative lasers any more.

This method is particularly well suited for the everyday treatment, especially in the dermatology practice, and it follows the patients' trend: achieve a good result with the least invasive treatment.

A STUDY ON RF IMPEDANCE



Dr. Un-Cheol Yeo
S&U Dermatologic Clinic, Seoul, South Korea

RF IMPEDANCE

Correction of impedance in RF equipment is really important. Since Radio Frequency is an alternating current and 60MHz, electrode changes 6 million times in 1 second as shown in [Fig. 1]. Heat is generated as the electron comes and goes 6 million times per

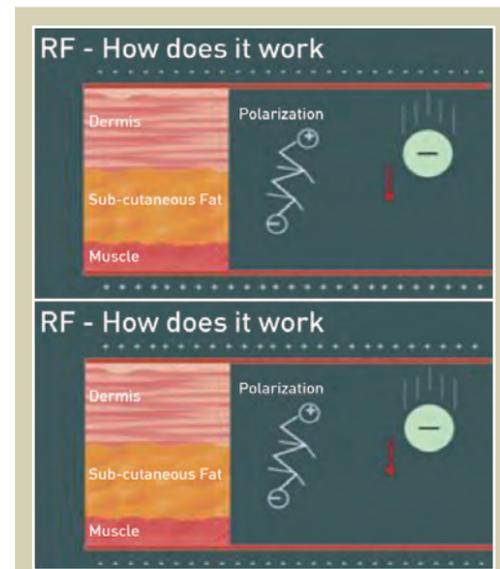


Fig.1.

second inside. Originally, the number of photon generated reduces as the depth of laser gets deeper. Less heat is generated since there is no photon for working in the deeper place. That is why laser is hotter in the shallow place and less heat is generated in the deeper place. So that heat is not less generated in the deeper place than epidermis. When the cooling is given to the epidermis, the temperature is low at the epidermis and heat is less generated at the deeper place. Thermage is also the same type. This type is

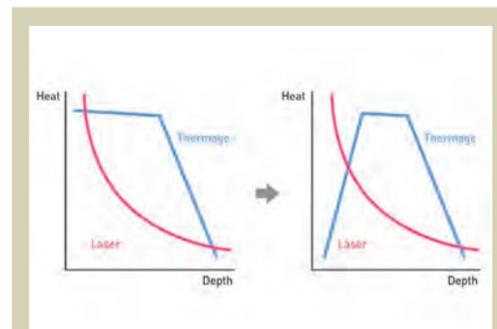


Fig.2.

called reverse thermal gradient. Reverse thermal gradient is the effective method of safely treating the people with dark skin color. Electricity(RF) treats the deep area and basic difference is that it generates less heat on the epidermis than the laser. This is the advantage of using electricity(RF). Impedance is also called resistance. Impedance differs much depending on tissue. Impedance and conductivity are the opposite meaning. If Conductivity is high, the impedance is low, and if the impedance is high, the conductivity is high. In general, the conductivity of epidermis is 0.25. If it is dry, the resistance is high.

In general, the moist skin has low resistance, while the dry skin has very high resistance. Skin also has higher resistance than blood. There are many cases requiring comparison of skin and fat layer. It is difficult for the electricity to pass through the fat layer? Or it is more difficult for the electricity to pass through the skin? When comparing normal skin with fat layer, it is difficult for the electricity to pass through the fat. Since the conductivity of fat is 0.03 and that of skin is 0.25, skin has about 10 times higher conductivity. Accordingly, skin carries electricity easier than the skin.

Fig.3. Electrical Conductivity of Different Types of Tissue at 1MHz

Tissue	Conductivity (S m m ⁻¹)
Blood	0.7
Bone	0.02
Fat	0.03
Dry Skin	0.03
Wet Skin	0.25

Aurora, made by Cineron is the RF equipment used by dermatologists for the first time. There are bipolar electrode on two sides and IPL for emitting lights between electrode. If there are 2 electrodes, the electricity flows as shown in [Fig.4].

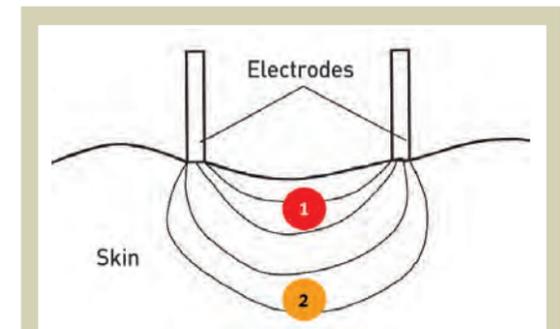


Fig.4. Schematic representation of the flow of electrical current through the epidermis using a bipolar system

Density of electricity is higher in area 1 and becomes lower as it closes to area 2. Since the resistance gets bigger as the distance between electrodes gets longer, electricity is highest near the needle. In general, there is a suggestion that maximum current flows at the depth half of the distance between needles with bipolar of 2 electrodes in general.

Cineron made the equipment which radiates RF on the surface of e-matrix and emits the RF with penetration of e-Prime Needle in diagonal line. e-Prime measured the temperature for the first time and measured impedance to keep the temperature constant. 5 patients were treated. As a result of continuous tracking for 6 seconds of impedance treatment, impedance was high at first and then lowered next. Needle was not moved, but remained at the same place, and as the temperature rose, impedance lowered. More heat is generated without some change since the impedance dropped. Temperature of 5 people were made constant by changing the flow of electricity while measuring

the temperature.

Tissue damage is calculated with temperature x time. It should be considered that tissue damage would be same if 5 patients are exposed to same temperature for the same time. It is the most idealistic method. However, different temperature doesn't mean there will be no damage. If the temperature is high, set the time shorter. If the temperature is low, set the time longer.

[Fig. 5] shows that tissue temperature rose when the laser started to irradiate, and that it began to drop upon completion of irradiation. Most doctors thought that temperature might rise little more. Temperature at the first graph in [Fig. 5] expresses the active mass of molecule, movement degree of covalent bond and movement of electron, and the heat began to cool down upon completion of laser irradiation.

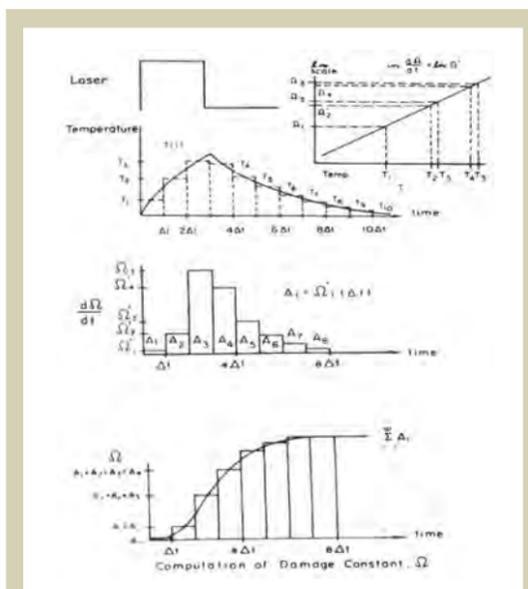


Fig.5. Computation of The Damage Constant Ω

This temperature refers to the temperature of target and if it reacts with laser and blood vessel, it becomes the

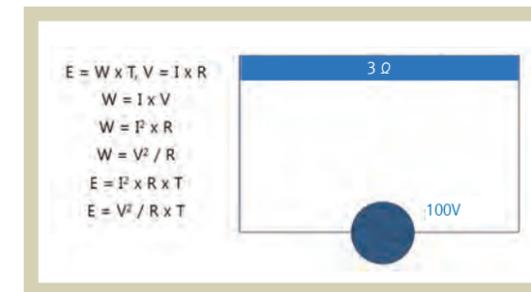
temperature of blood vessel. When we treat nevus of ota or have INTRAcel, it is regarded as medical procedure. The target receives energy and high temperature, it conducts heat around it upon finishing irradiation. It can become skin or the place under the place where the target is located. Therefore, the temperature gets little higher when the treatment is over.

The degree of heat transmission through solid means conduction, and the transmission of heat through air is called convection. Heat is more transferred through solid than through air. When the Target became hot, heat moves to the skin to lower the temperature of target and the skin gets hotter over the time.

Many people thought that the effects of treatment dropped with cold pack after treatment. The place where we want to cool down is the epidermis. It is not the area with target. When the temperature of target is carried to the epidermis and is exposed to high temperature for long period of time, PIH and erythema may be generated. While the convection is performed with the heat carried to the epidermis, air is not carried and the time exposed to high temperature gets longer. If the cold gauze is attached on the solid, heat is transferred fast there and the temperature of epidermis lowers. It is better to attach cold gauze for a long period of time until the temperature of epidermis is cooled down.

While treatment of laser on the bone is considered dangerous due to the fact that heat is well conducted to solid, heat is not transmitted in the bone. If IPL is given on the cheek and forehead, it gives heat to the epidermis but delivers heat to the place deeper than target and disappears. Since the heat is not conducted to the bone, heat emitted from the target is transmitted to the epidermis, giving more heat. While the derma may be cooled down when cold gauze is attached to the epidermis, it already

gave sufficient heat damage to the target so that cold pack after treatment may not drop effects. If cold pack can reduce side effects such as PIH and erythema, it is better to cool down heat of epidermis.



Using current (I) X resistance(Ω) formula, voltage (V) is 100V. If the current is 1A, the resistance becomes 100 Ω.

$$100V = 1A \times ?$$

$$? = 100V / 1A = 100\Omega$$

This is the basic. Then, create this formula next, that is,

$$W = I^2 \times R \quad \text{①}$$

$$V = I \times R \quad \text{②}$$

$$W = I \times V$$

Applying No. 1 formula (I²R) instead of No. 2 formula, it becomes

$$W = I \times I \times R$$

$$= I^2 \times R$$

In the same type, leave the voltage as it is, and substitute I = V/R, and it becomes W = V²/R.

Since E = W x T, substitute I² x R or V² / R instead of W, and it becomes E = I² x R x T or E = V² / R x T.

Approve the voltage of 100V to electric circuit, and resistance of 10Ω is given. Then, the current becomes 10A. Then, what is the watt in the circuit?

Use W = V²/R formula, and

$$(100)^2 / 10 = 1000W$$

If current is given for 1 second?

Then, 1000W * 1T = 1000 Joule is approved.

Q1. It was changed to Monopolar in treatment of INTRAcel. Then, tissue has never changed with the same time and voltage as bipolar. Why is it so?

Reaction looks different when the energy is applied for same time and with the same voltage as Monopolar. With Monopolar, does the resistance of electric circuit increase from the time of Bipolar?

Since Bipolar has low electric resistance at the smallest distance between 2 poles, and electricity comes from the electrode and should move to the place attached with return pad, Monopolar has longer distance than Bipolar. The longer the distance between 2 electrodes, the higher the resistance gets. Difference between resistance gets severer.

Let's examine which situation occurs in case of Monopolar and bipolar.

The resistance value increases over the distance while the voltage remains the same.

When 100V is approved, the resistance is 10 Ω in case of bipolar, and it is 20Ω in case of Monopolar,

Using W = V²/R formula,

$$\text{Bipolar : } (100V)^2 / 10\Omega = 1000W$$

$$\text{Monopolar : } (100V)^2 / 20\Omega = 500W$$

When the same voltage and same time are given, reactions are only half at Monopolar than bipolar. Actually, the resistance value is bigger than 20Ω. It's not sure whether the resistance increases in proportion to distance, but ohm

is displayed in Thermage every time. The resistance value is reduced when the distance gets shorter. Given this, it is known that it should not be done with the same bolt and time. Since electricity gets longer in case of Monopolar, the resistance gets bigger and watt drops, so that it is realized later that more energy will be delivered with the higher voltage.

While many machines display [W x T], such watt is displayed by measuring volt at the given resistance value. If actually approved watt is displayed, the volt dropped according to impedance, meaning that treatment was weak. But many companies made the machine which raises the watt with the increase of volt by changing the volt with easy operation after checking that several watt comes when the several volts are approved with the same resistance at the certain bipolar tip.

Since INTRAcel Monopolar first followed the impedance measurement method of bipolar, volt was approved constantly but impedance was high compared to bipolar, so that the watt actually applied to the skin was low. When the volt value was raised to increase watt value, similar tissue reaction was identified same as the bipolar. In the end, INTRAcel measured impedance with Monopolar and what is good for this is that different voltage value can be given depending on measured impedance so that difference of resistance per entity and part can be corrected. Then, constant watt can be approved with correction of voltage value.

Lower the voltage if the impedance rises, and raise the voltage if the impedance drops to make watt constant. If Watt x T is joule, and it becomes the energy actually applied. Impedance correction means that constant damage can be given by measuring different impedance at each area, and adjusting the voltage, and that same watt can

be applied by measuring impedance and adjusting the volt while they react different with the same bolt, ignoring the different impedance measured with different persons. In INTRAcel, there is no such problem that carbonization occurs at one patient with level 3, while no mark is found at other person with level 5.

The biggest advantage of impedance correction is that same clinical effects can be given in the degree that we feel as level 1 ~7 by correcting the difference of resistance value per system and part.

Q2. High heat generated at the area with high electric resistance.

While it became problem as heat was not generated at the area with high electric resistance, there was suggestions opposite to this. Such suggestions argue that heating is more easier with the structure that has high impedance. So that there are many wound and damage. It is totally opposite to the story up to now. Why does it happen?

Given that there is [Fig. 6] circuit, 3Ω(fat) and 7Ω (skin) are serially connected. When 100v is given, it becomes a total of 10Ω.

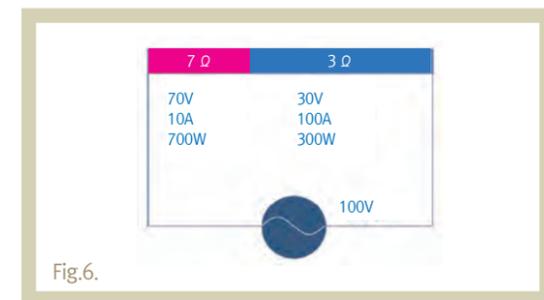


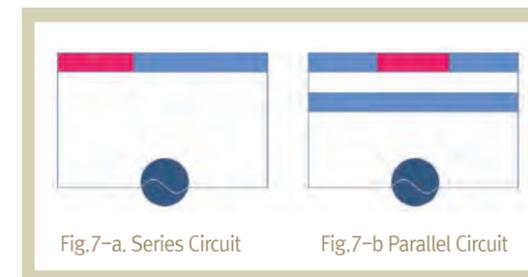
Fig.6.

This means that 10Ω of 100V makes 10A current flows. From the whole circuit, the current is 10A but the voltage on each resistance differs.

Using $V = I R$,
 At 7Ω, $V = 10A \times 7Ω = 70V$
 At 3Ω, $V = 10A \times 3Ω = 30V$

Above voltage generate. While current flows for 1 second, an energy of 700J occurs at 7Ω and 300J occurs at 3Ω.

So that, much heat occur at the place with high resistance in series circuit. Since bipolar is series circuit, much heats are generated at the area with high resistance. If one of 2 electrode does not completely contact the skin, the resistance gets higher so that much heats are generated at epidermis, resulting in necrosis of the skin. Thermage does not emit RF if 4 tips do not contact.



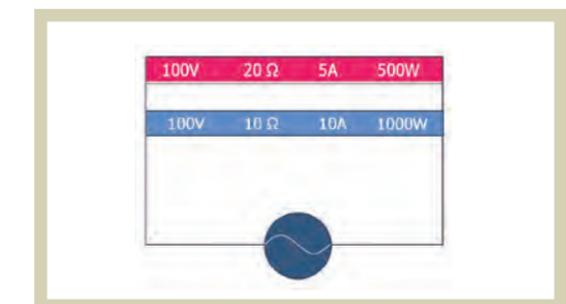
[Fig.7-b] At the parallel circuit, if the red one is high resistance and blue one is low resistance. Which one generates more heat?

Parallel circuit gives same voltage for each resistance and the current is inverse proportion to the resistance. Since the current of the area with high voltage decreases, Watt($W = V \times I$) also dropped and less heat is generated. In addition, Watt is proportionate to the square of current and to resistance. ($W = I^2 \times R$) If resistance increases and the value of current

becomes half, it becomes 1/4 since it is proportionate to the square of current, so that the watt decreases by half when the resistance increases at the whole circuit. At the parallel circuit, the increase of resistance has lower effects than decrease of current. In conclusion, the current does not flow to the area with high resistance and heat is not generated if the current does not flow. While heat is not generated since the current does not flow to the area with high resistance at the parallel circuit, only one path of current is allowed at serial circuit so that high heat is generated at the area with high resistance.

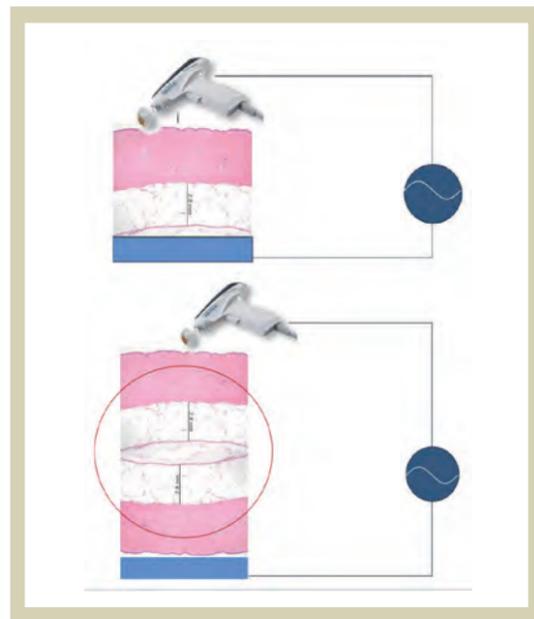
Q3. Can high frequency dissolve visceral fat?

If return pad is attached on the back, and high frequency is given, high frequency(current) may penetrate the skin and fat or may not go to the fat but go to the return pad along the skin. If we assume that red line is the circuit passing the fat, while the blue line is the circuit that does not pass through fat, the resistance value differs by 2 times and watt reduces by half. To approve same watt, 2 times higher voltage should be applied to the area with high resistance. In fact, 10 times higher voltage should be applied in order for high frequency to penetrate the skin and dissolve the fat. Skin may melt before melting of fat.



At Thermage, it was suggested that heat occurred at the area with thick skin. Considering the depth that actually energy penetrates into, fibrous septae fat at the fat layer is not full of fat only, but fibrous tissues are between them so that current flows there. In conclusion, when RF current flows at fat tissue, fibrous septae area has higher heats about 1.4 times of fat cell area. Collagen remodeling by this heat is the principle of tightening. It was explained this way.

Q4. From experiment video showing the treatment of skin with Monopolar electrode after placing pork fat on the return, fat layer melts down. What happened?



When high frequency is given to the pork fat, the fat melts down. RF was irradiated after attaching return pad on the pork fat with skin attached. Fat melts down profusely. That is why it is said that even visceral fat melts down when high frequency is irradiated to abdomen fat, attaching return pad on the back. Fat has high resistance and the skin

has relatively low resistance. In this status, current passes through the skin and fat, and comes to the return pad. High resistance and low resistance are connected serially as shown earlier and therefore, much heats are generated at the fat with high resistance and melted down.

In fact, however, the fat is surrounded by skin. There is a method that current flows through the skin and goes to return pad, that is, from skin – fat – skin again. It is connected in parallel circuit. It was explained earlier that current flows to the area with low resistance at parallel circuit, and much heats are generated here. However, since the current flows to the skin with low resistance and moves to the return pad, no heat is generated at the fat.

Q5. At bipolar treatment, heat damage occurs around the electrode? Or evenly around the area of connecting electrodes?

When the INTRAcel was studied for the first time, it was expected that coagulation would not be generated near electrode, but coagulation evenly occurs between electrode. But, it was coagulated around the end of needle.

Why is that so? The distance between the end of needle between 2 electrodes is narrow (No. 1 area), and the interval of line is longer as it becomes distant (No. 2 area). (See Fig. 4) Degeneration occurs much at the end of needle with narrow interval of lines.

Q6. During Monopolar treatment, thermal damage will be generated around needle or evenly throughout the electric circuit? Why it has weak heat damage compared to Bipolar?

At Monopolar, distance from the end of needle to return pad is distance so that heat damage occurs with spread. If same conditions are set in Bipolar and Monopolar, coagulation zone is big at Monopolar, and coagulation zone is small at Bipolar. Since thermal spread occurs from the end of needle, coagulation occurs weak than Bipolar.

Since Monopolar occurs this way, it is safe with shallow setting. There is a concern that there will be a problem if strong irradiation is given to the shallow area with Bipolar, but it is regarded safer with treatment of shallow area.

Since it is weaker than Bipolar, it is safe with higher energy and may cause no problem with 2 pass and 3 pass. Effects can be obtained faster right after treatment if shallow area is treated rather than deep area for pore. In general, while Mosaic is known to have later effects in the pore than INTRAcel, superficial rejuvenation will occur fast with several passes safely with Monopolar. Pore, fine wrinkles and overall textures will get better. All these were the assignment that could be solved with study of impedance.

