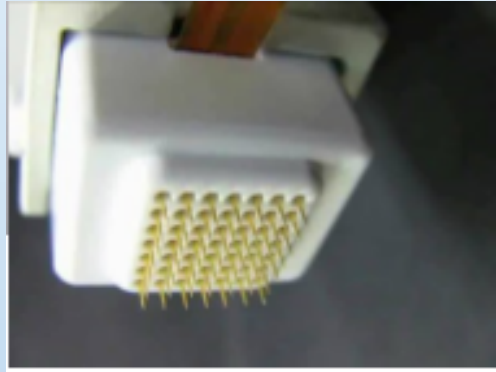
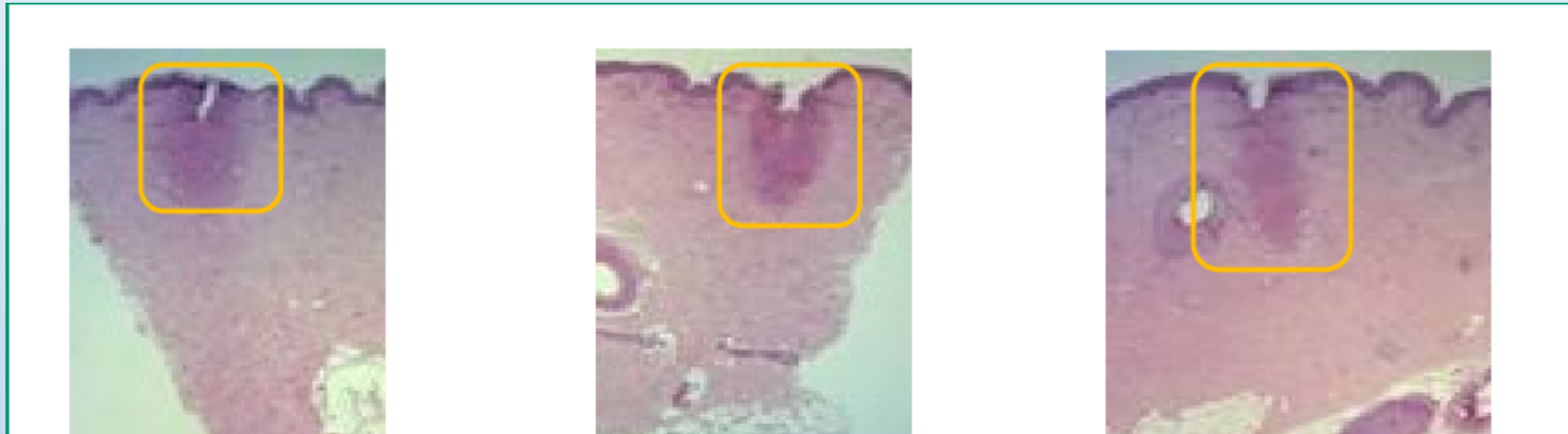


Radio-fréquences fractionnées 2016



Dr LE PILLOUER-PROST Anne
Groupe laser de la SFD
Trésorière de l'ESLD
doclepillouer@free.fr

Pénétration en profondeur fonction de la longueur des micro-aiguilles choisie



1.5 mm

2.5 mm

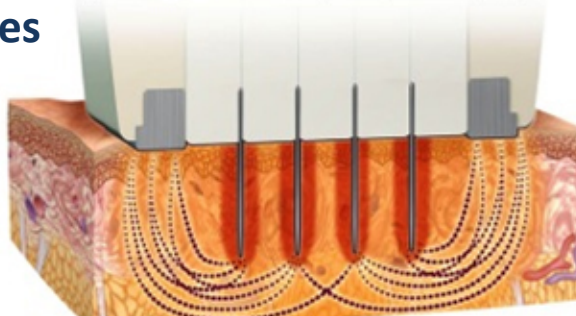
3.5 mm

SPECIFICATIONS EMBOUTS FRACTORA™

Embout 24 électrodes



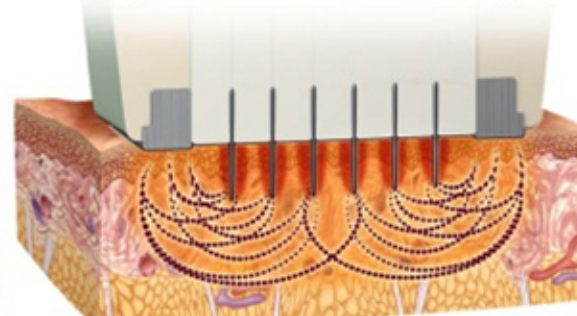
using the 2,500 micron, 24 pin array tip



Embout 60 électrodes



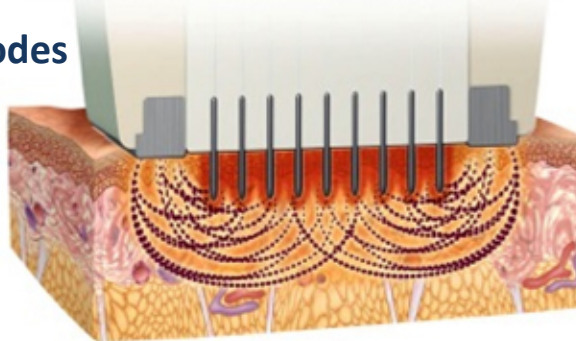
using the 600 micron, 60 pin array tip



Embout de 126 électrodes



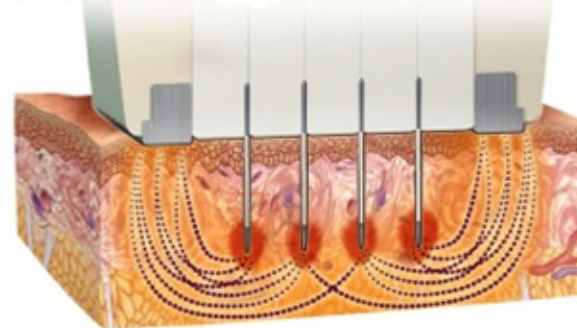
using the 600 micron, 120 pin array tip



Embout 24 électrodes
semi-isolées



silicone coated 2,500 micron, 24 pin tip

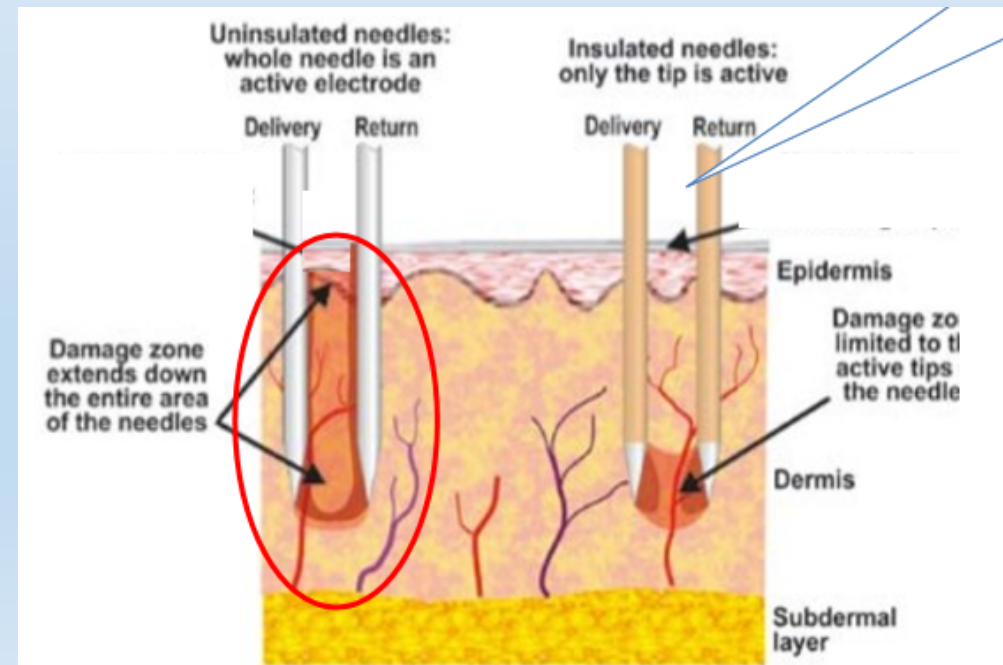
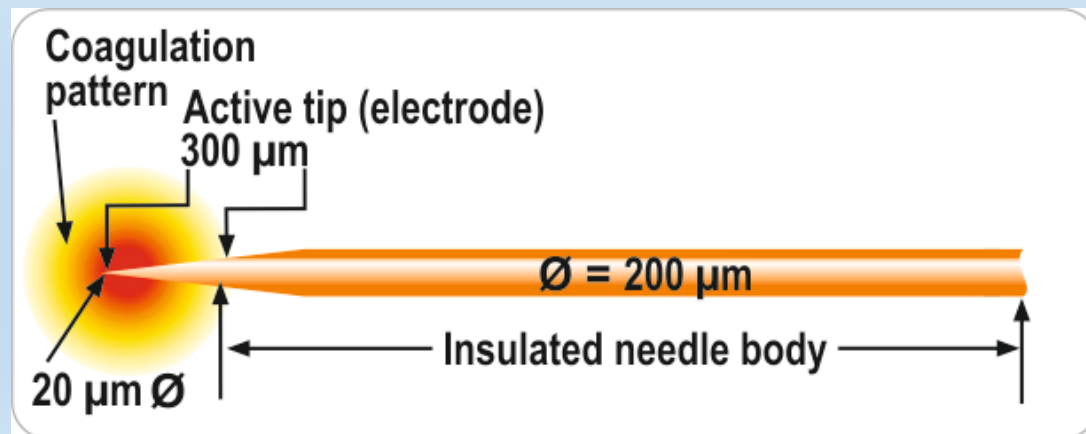


Embout 20 électrodes



Aiguilles isolées ou non isolées

- Une aiguille non isolée agit sur toute sa longueur
- Une aiguille isolée n'agit qu'en profondeur au niveau de la cible sans abimer la surface de la peau



Résultats cliniques

(Littérature - anglosaxonne...)

Cicatrices d'acné et acné active

Remise en tension

(amélioration laxité cou et ovale du visage)

Vergetures

Dos des mains

Transpiration excessive aisselles

Délivrance assistée de médicaments

FRF for the treatment of acne and acne scars

- Cochrane review « Interventions on acne scars » 2016 Apr

lack of high quality evidence...

Expert opinions, short series, data with bias...

24 trials included (789 patients)...

1 study on FRF: non inferiority vs fractional laser

(40 patients, very low quality evidence)



(Courtesy Dr Badawi A.)
ESLD Copenhagen 2015

FRF for the treatment of acne and acne scars

- J Cosmet Dermatol 2015 Nov, Park JY *et al.* : combined MN FRF and subablative FRF for acne scars in Asian skin
 - 20 patients, 3 sessions at 4 w interval
 - 4 grading scales assessed on subjective assessment: photos (blinded)
 - 20% grade 4 improvement (76-100%), 50% grade 3 (51-75%) and 30% grade 2 (26-50%)
 - Mean duration of crusting 5.2 days and erythema 2.5 days
 - Ccl: positive therapeutic effect...no serious complication...

- J Cosmet Dermatol 2015, Chae WS *et al.*: comparative study on 1550 nm Er:Glass and F MN RF for facial atrophic PAS
 - 20 patients, 3 sessions at 4 w interval
 - Group A Er:Glass : 15-20 mJ/MTZ, 500 MTZ/cm²
 - Group B F MN RF: 36 MN, 2 mm, 0,1 ms, 40-60 W
 - **Results**
Patients overall satisfaction: **similar**
Physician (ECCA grading scale) : **non inferiority**
-25% group A vs - 18,6% group B
Improvement > 50%: 80% group A, 65% group B
 - **After effects**
More pain : group A
Fewer adverse effects and shorter downtime: group B

- J Cosmet Dermatol 2015, Chae WS *et al.*
**Comparative study on 1550 nm Er:Glass
and F MN RF for facial atrophic PAS**

- 20 patients, 3 sessions at 4 w interval

Group A Er:Glass : 15-20 mJ/MTZ, 500 MTZ/cm²

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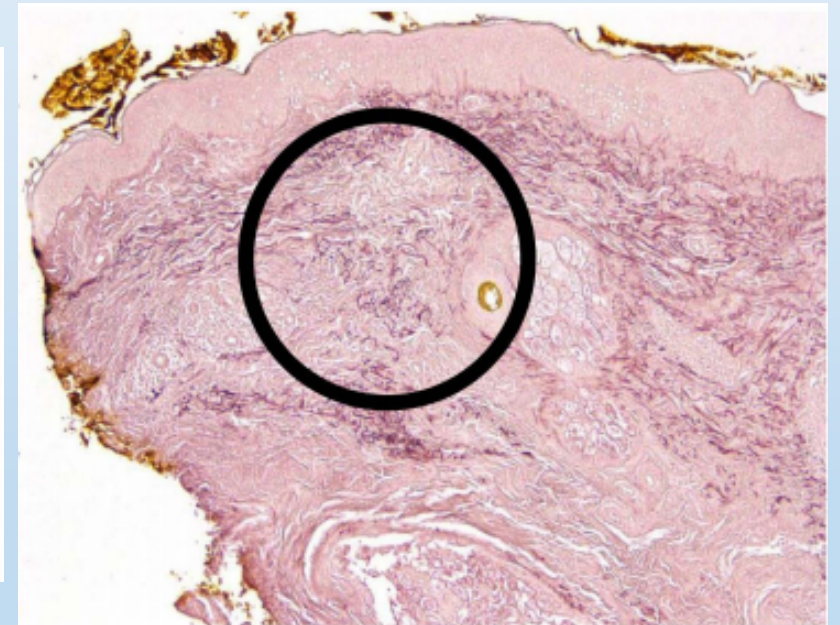
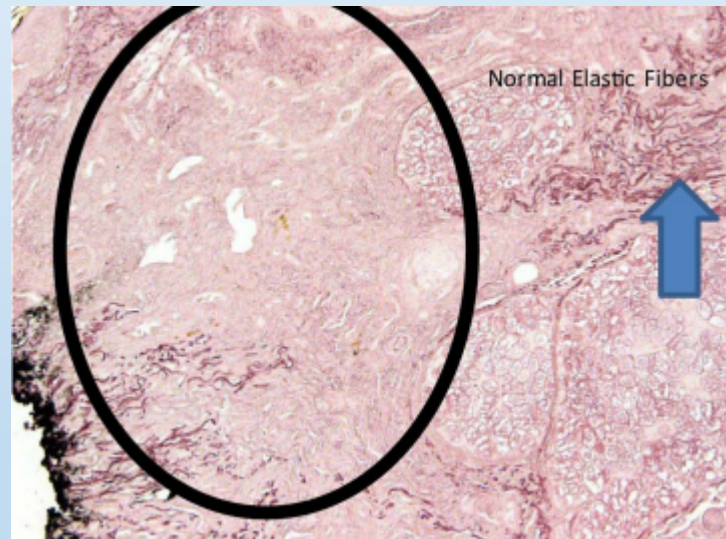
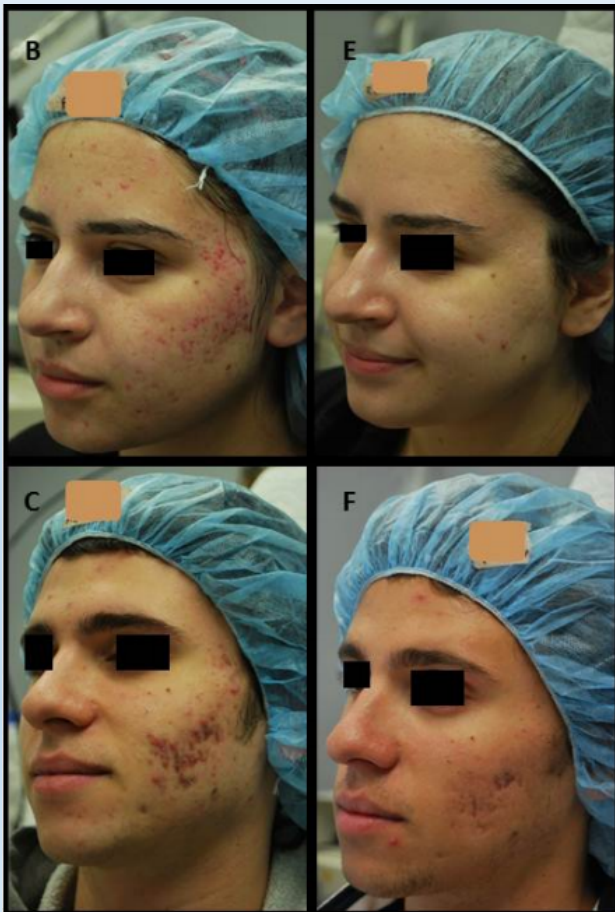


Group A
Er:Glass

Group B
F MN RF

FRF for the treatment of acne and acne scars

- J Cosmet Dermatol Sci 2015, 5:311-116, Hellman J.
Pilot study with, 8 patients, 2 patients with skin biopsies
4 sessions, **Fractora™** 24 RF needles, 2500 μ m insulated along 2000 μ m,
Significant improvement of acne lesions and acne scarring in all patients



(Courtesy Helman J.)

FRF for the treatment of acne and acne scars

1 session, **Fractora™**

Significant improvement of acne scarring



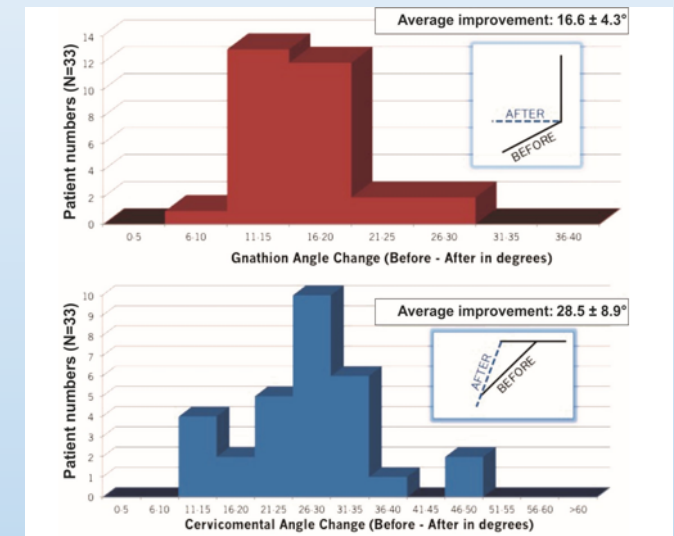
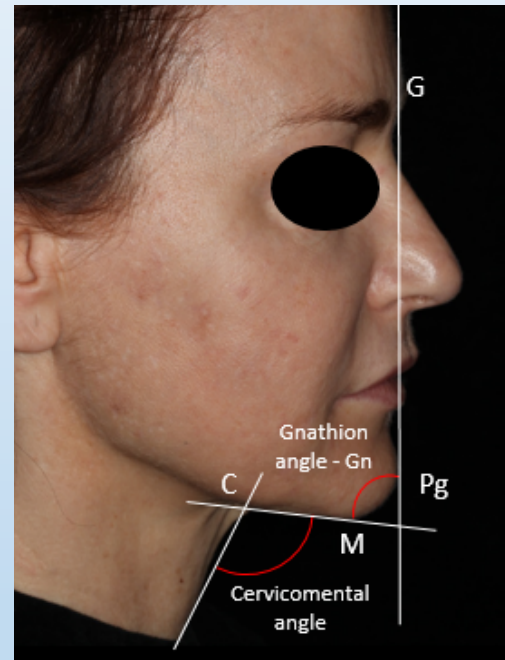
Fractora: Dr. C. Feibleman

Skin tightening - Face

- Well-recognized clinical application
- Study in high IF journal with objective **3-D volumetric assesment** on 20 Japanese patients (Lasers Surg Med 2015 Oct, Tanaka Y)
 - Only 1 session
 - Non-insulated MNRF device with a pulsed mode
 - 1MHz; 500-1000 pulses 80-110 ms in duration at 10-14W and 1.5-2.5 mm depth
 - **Long-lasting (6 months) high efficacy with minimal downtime (erythema 5 days) and no complication (no PIHP)**
- EBM ?
- All devices?

Skin tightening - laxity of the lower face and neck

- Lasers Surg Med 2016, Clementoni MT *et al.*
 - High intensity device, insulated MN
 - Infini™ - Lutronic**
 - Pilot study, 33 patients, 37-74 years, 3 sessions at monthly intervals, 3 passes per session
 - Evaluation 6 months after the final session : standardized computer measurement of improvement in the gnathion and cervicomental angles + global assessment
 - Significant decrease in the angles : 28.5° (cervicomental) and 16.6° (gnathion)**
 - 87% of patients very satisfied or better**
 - 3-4 days of downtime, no complication



Skin tightening - laxity of the lower face and neck



Lasers Surg Med 2016, Clementoni MT *et al.*

Skin tightening - Face and neck

- J Cosmet Las Ther 2015, Nelson AA *et al.*,
14 female patients, PT I-III, mean age : 62 years

Forma (InMode) : 7 pairs of positive electrodes with sensors

3/14 (21%) significant improvement

7/14 (50%): moderate improvement

4/14 (29%) mild improvement

No pain, no side-effects, no adverse events, no downtime....

« Lower temperatures over a longer exposure time period allows for the treatment to be painfree with no downtime »

Skin tightening - laxity of the lower face and neck

- Clin Plast Surg 2014, Mulholland RS

Nonexcisional, minimally invasive rejuvenation of the neck (Extensive review)

.... **Fractora™ 24 pin 3000μm silicon-coated tip**

« one of the more profound tightening fractional RF applications

New generation of bifractional stimulation, horizontal and vertical

D. Superficial mechanical fractional injury and deep, low density fractional RF injury, using the silicone coated 3,000 micron, 24 pin tip

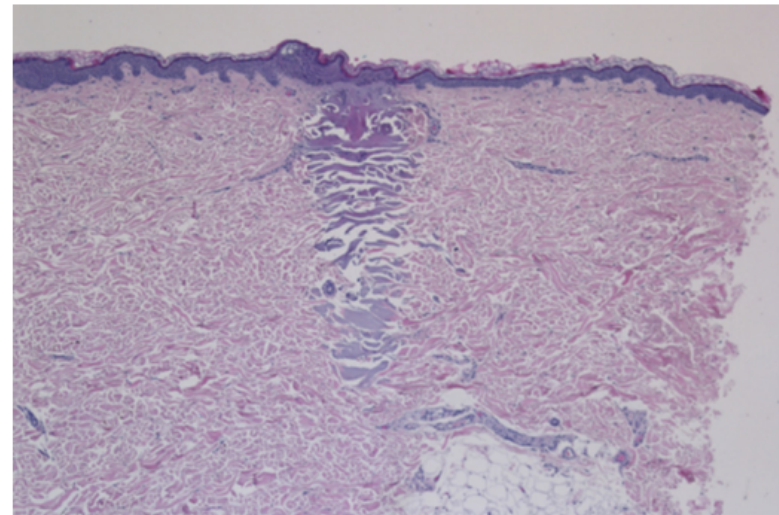
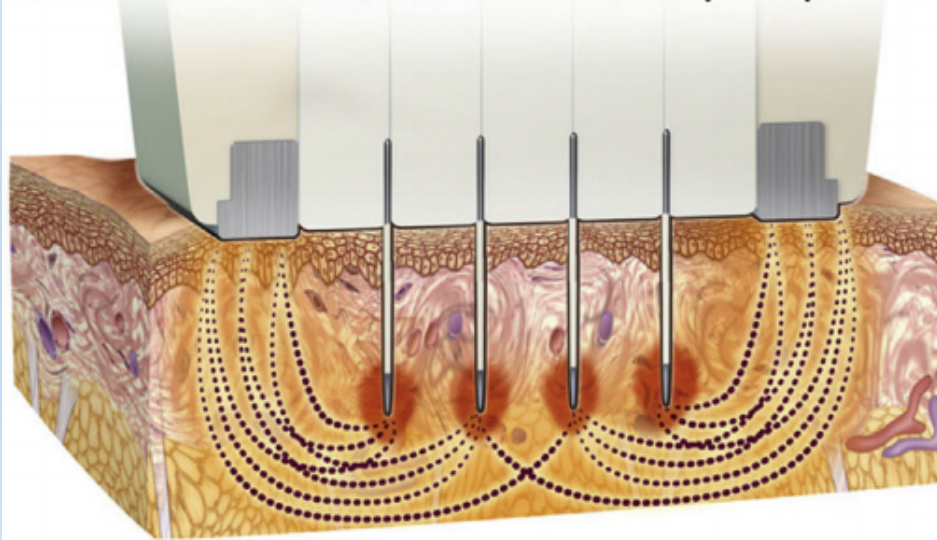


Fig. 11. High power histology showing the Fractora silicon-coated needle tissue effect with a non-ablative penetrating trauma superficially and a deep dermal thermal fractional injury with a superficial thermal sparing effect.

Skin tightening - laxity of the lower face and neck

- Clin Plast Surg 2014, Mulholland RS

Nonexcisional, minimally invasive rejuvenation of the neck

Fractora™ 24 RF needles, 2500 μ m insulated along 2000 μ m



Skin tightening - laxity of the lower face and neck

- Clin Plast Surg 2014, Mulholland RS

Nonexcisional, minimally invasive rejuvenation of the neck

Fractora™ 24 RF needles, 2500 μ m insulated along 2000 μ m



Fig. 7. Cervical rejuvenation with combined sub-dermal heating with Facetite for tightening, IPL for color correction, fractional RF ablative resurfacing for texture and CO2 shave excision of raised dermal and epidermal lesions.

Skin tightening - laxity of the lower face and neck

- Loeb T.

Nonexcisional, minimally invasive rejuvenation of the neck

Fractora™



Stretch marks

J Drugs Dermatol 2015 Nov; Ross EV et al.

The use of fractional ablative micro-plasma RF device

- 5 female patients, PT II-IV, abdominal striae alba and rubra
- **F RF (AccentXL, Alma Lasers)**, 4 sessions every 2 weeks, settings based on test spots
- Assessment on a 1-4 clinical scale (4 being the most severe)
- Results at 3 months
 - **Mean improvement of 20% (mean severity score from 2,9 to 2,5)**
 - Patient questionnaire : good to very good improvement (mean score of 2,4/4)
- After effects
 - Small gray dots lasting about 2 weeks
 - Mean pain: 2/10, erythema and edema 1 day
 - No pigmentation abnormalities

Stretch marks

Lasers Surg Med 2016 Mar, Passeron T *et al.*

Fractionated bipolar RF and bipolar RF potentiated by infrared light for treating striae: a prospective, randomized, comparative trial with objective evaluation

- 14 patients, mature and immature abdominal striae
- 4 quadrants, 3 monthly sessions

eTwo device (Syneron)

- Bipolar RF potentiated with IR light: Sublime applicator 5 passes 100J/cm²; 20-30% overlap
 - Fractional bipolar RF : Sublative applicator 2 passes, 50-65 mJ/pin; 50% overlap
 - **Combined approach Sublime + Sublative applicators**
 - ctl
 - **Objective assessment** of the depth 3D camera Antera, Miravex*
 - **21,64% at 6 months follow-up** with the combined approach
- statistically greater compared to control areas

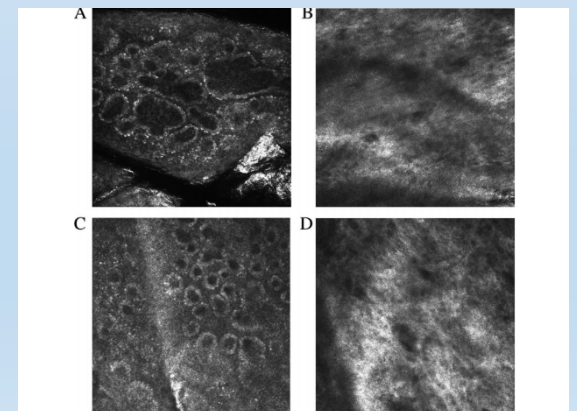
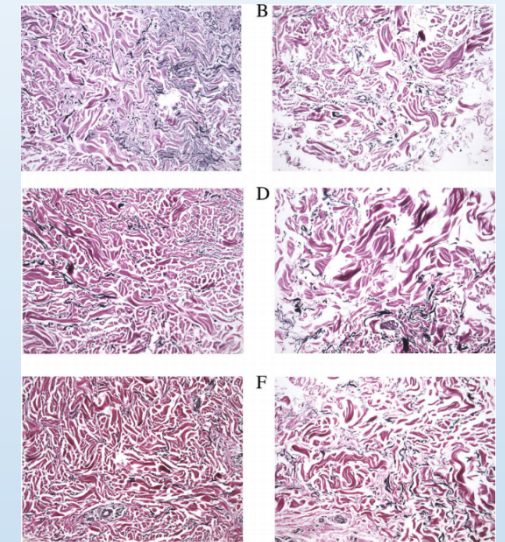
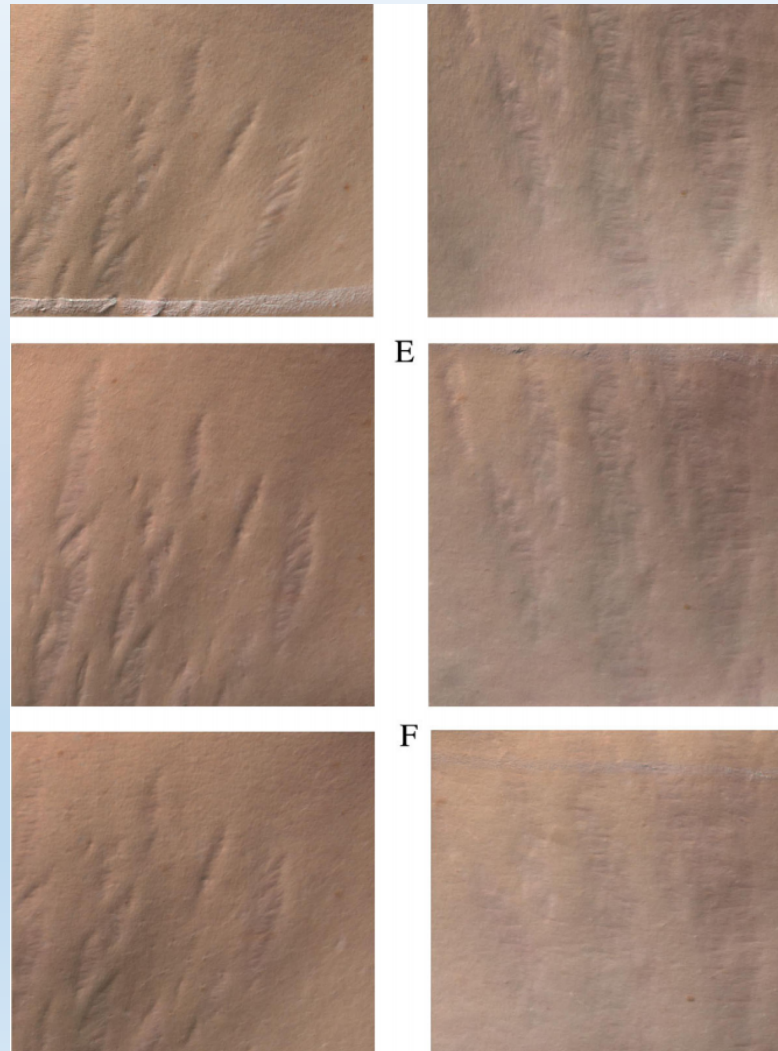


Fig. 4. Laser confocal microscopy of striae treated with fractionated bipolar radiofrequency + bipolar radiofrequency potentiated by infrared light. (A) Elongated dermal papilla before treatment; (B) collagen fibers with parallel disposition before treatment; (C) dermal papilla with a rounder shape after treatment; (D) collagen fibers with a more reticulated disposition after treatment.

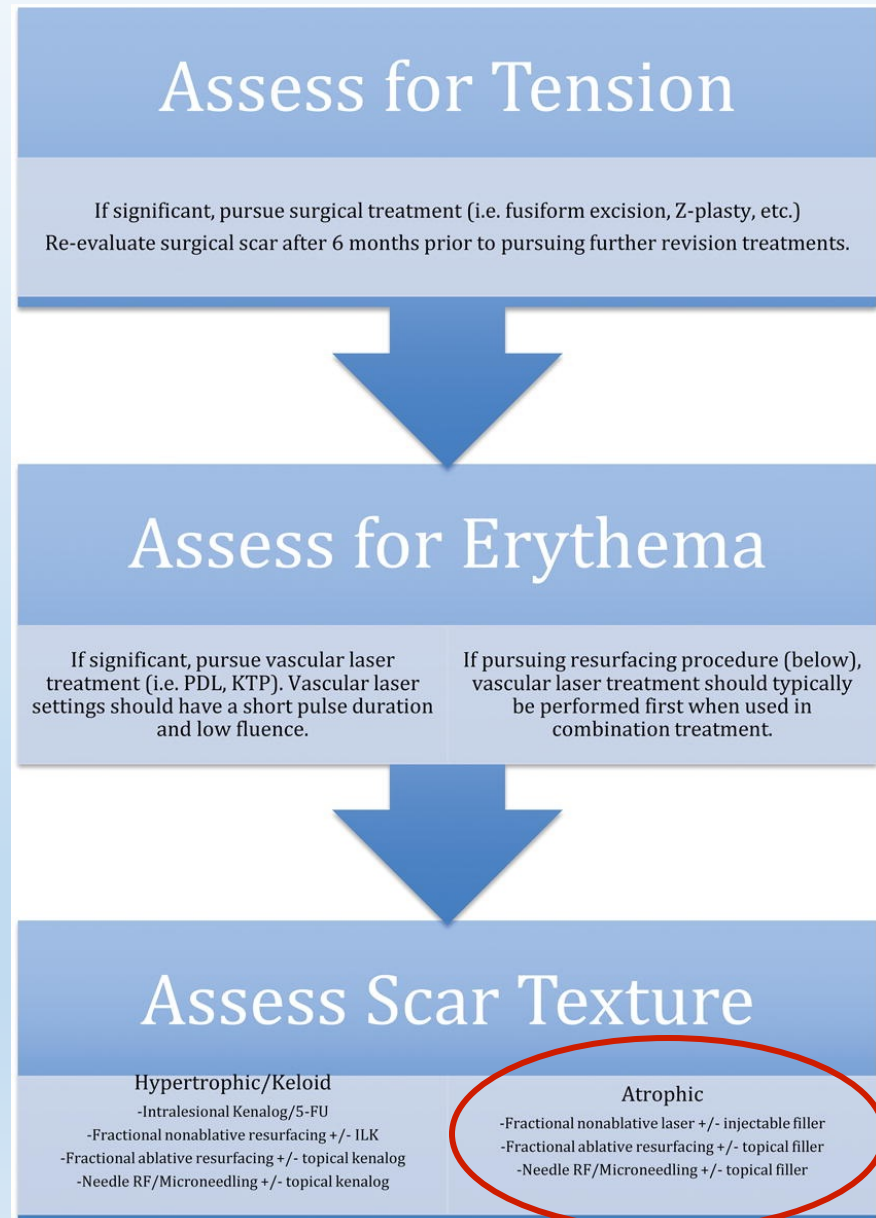
Expanding clinical applications: Hands

- Dr Willis N.
- Fractora™



Expanding clinical applications: post-surgical scars

- Dermatol Surg 2016 May, Eilers RE *et al.*: a combination approach to surgical scars

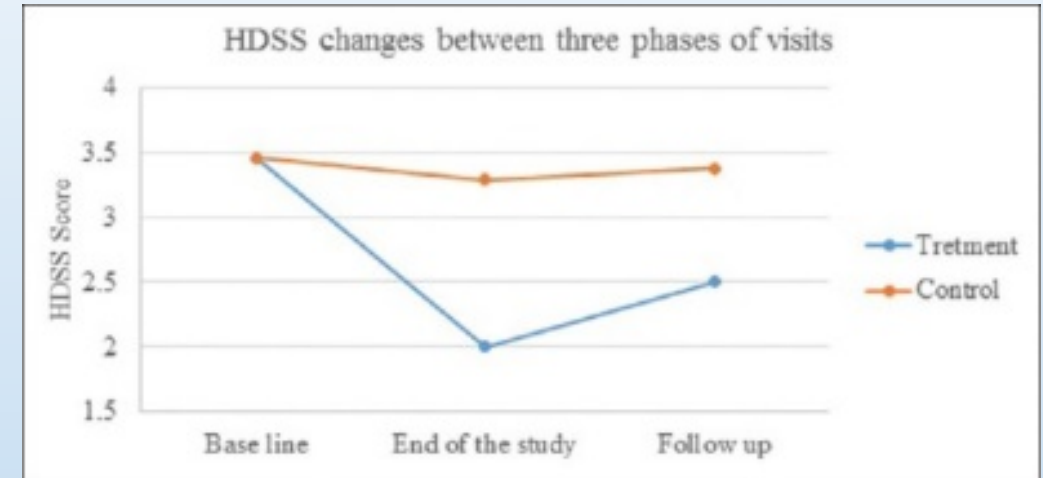


Hyperhidrosis

Treatment of PAH by F MN RF: is it still effective after long-term follow-up?
Indian J Dermatol 2016 Mar-Apr

- Sham-controlled study, 25 patients
- **Infini™-Lutronic**: 49 insulated MN, 1 MHz
 - 3 sessions at 3 weeks intervals
 - 3 passes: 2-3 mm, 120-180 ms, level 6-10
 - Under topical Emla, per and post-op ice pack, vaseline gauze, topical zinc oxyde
 - 1 patient lost: arm dysesthesia
- **Results** : Table 1 (photo documentation of starch-iodine test) **88% at 3 months - at 1 year follow-up**:
 - 10 patients (42%) no relapse
 - 11 patients (46%) with relapse
 - Significant correlation between relapse and high BMIs
- **Temporary side-effects**: erythema, swelling and redness transient 2 months

*1 case of numbness and 2 cases of compensatory HH in another study Kim *et al.* Dermatology 2013: 20 patients, 2 sessions 95% efficacy starch iodine test



FMR 2-3 mm insulated MN

88% at 3 months and 42 % at 1 year

- BTxA : Non-inferiority (85-90% 3-6 months)

- Miradry™:

Hong *et al.*, DS 2014:31 patients, 93,3% D30, 100% Y1-2

Glaser *et al.*, DS 2012:120 patients, 89% D30, 69% Y1

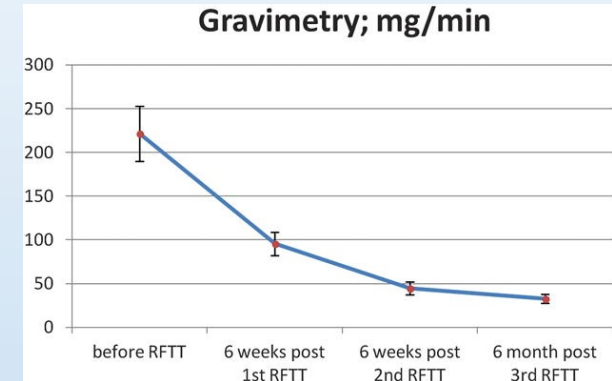
Lee *et al.*, JCLT 2013: 12 patients, 83,3% M7

Hyperhidrosis

Radiofrequency thermotherapy for treating axillary hyperhidrosis

Dermatol Surg 2016 May,

- 30 patients, grade III PAH
- F MN RF **Secret MN RF System (Ilooda)**, 5x5 non insulated MN, 2 passes
 - 1st : 3 mm, 250 ms, intensity: 70
 - 2nd : 2 mm, 200 ms, intensity: 60
- Results
 - HDSS:
 - QLQI
 - Gravimetric measurements



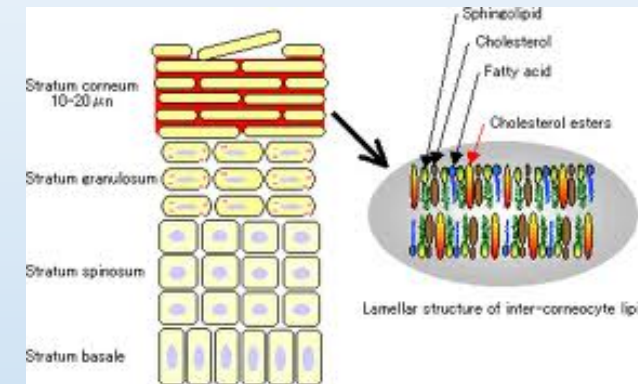
Assisted Topical Drug Delivery

Skin : largest organ

Major barrier : Stratum corneum

"brick and mortar" structure

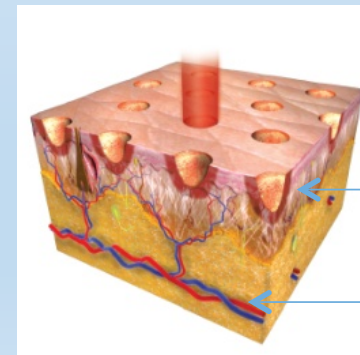
- 20 cell layers of hydrophilic corneocyte (10-20 μm thick layer)
- **Highly hydrophobic lipid matrix** organized into lamellar membranes
- **Penetration: only for lipophilic molecules with molecular weight under 500 Da**



Laser and EBD microporation is one of the physical strategies recently advocated to enhance intradermal drug delivery

of hydrophilic and macro- molecule drugs

and intense research efforts are in progress...



Intradermal DD

(Transdermal DD:
Systemic delivery)

Laser Assisted Drug Delivery

An Evolving and Promising Technique

Clinical existing applications

- *Except dermatology*
 - *Hormons - Infertility, anticancer drugs, vaccine...*
- **Dermatology**
 - NMSC : ALA & MAL and others (IMQ, 5-FU, IMB, Solaraze)
 - Scars: TAC
 - Psoriasis (MTX), deep infantile hemangioma (Timolol)
 - Lidocaine (anesthesia)
- **Anti-aging & esthetic**
 - **Autologous PRP** +++
 - **Allogenic mesenchymal cutaneous stem cells**: CO2AFL, mice, engraftment
 - **Autologous cell suspensions**: melanocytes, adipocytes
 - **Botulinum toxin**: Crow's feet, CO2 AFL, statistically significant wrinkle reduction
 - PLLA (Newfill): atrophic scar
 - **Anti-oxidants**: vit C (3 studies on porcine or human skin)
 - Specific unknown preparations : antiscar antiaging (Alma laser)

Many devices...

- Lasers and EBD
 - Ablative Lasers
 - Er:Yag 2940 nm
 - Conventional / Fractional
 - **CO2**
 - Fractional
 - **Radio-frequency (+/- acoustic pressure US)**
 - Fractional non ablative lasers
 - Q switch Nd-YAG
- Others...: Microneedling, Sandpaper...

FMR- Assisted Topical Drug Delivery literature

- 5-aminolevulinic acid (Lasers Med Sci 2016 Jan)
- Triamcinolone for hypertrophic scar treatment (Int J Dermatol 2013)
- Retinoic acid for stretch marks treatment (Lasers Surg Med 2013)
- Platelet-rich plasma for stretch marks (Int J Dermatol 2012)
-

Lasers Surg Med. 2013 Feb;45(2):81-8. doi: 10.1002/lsm.22105. Epub 2012 Dec 31.

Transepidermal retinoic acid delivery using ablative fractional radiofrequency associated with acoustic pressure ultrasound for stretch marks treatment.

Issa MC¹, de Britto Pereira Kassuga LE, Chevrand NS, do Nascimento Barbosa L, Luiz RR, Pantaleão L, Vilar EG, Rochael MC.

Conclusion

New RF "world " is all the rage in 2015-2016

- Good ratio efficacy-cost-downtime EBD
 - Ability to by-pass the epidermis (and the concomitant pronounced downtime)
 - Ability to cause thermal damage to dermal collagen and appendages
- Broad applicability
 - From skin tightening to fat reduction via numerous emerging applications: stretch marks, acne vulgaris, hyperhidrosis, different type of scarring... and assisted drug delivery
- Confusing terminology
 - Needle electrodes, MN arrays....
 - Sheathed/insulated/coated vs unsheathed/non insulated/uncoated
 - Monopolar, bi, tri...
 - Ablative, non ablative, subablative, high vs low RF...
 - Refractive, dual layer...
- EBM: no/low level of proof... necessity of further randomized controlled trials....