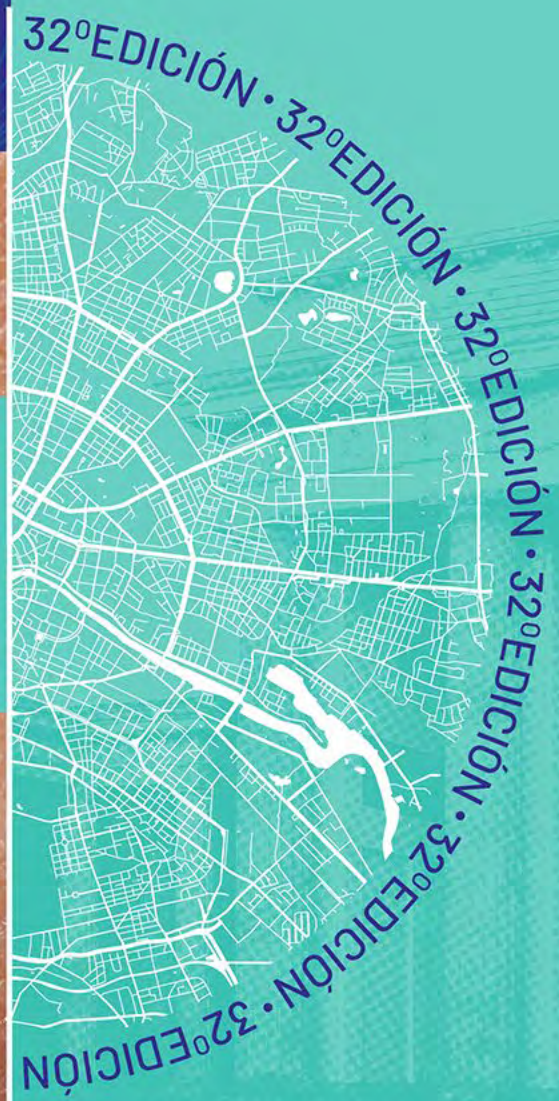
AEDV 2023 Highlights

Con el patrocinio de:

ucb



BERLÍN

11-14 OCTUBRE

Iniciativa científica de:

AEDV 1909

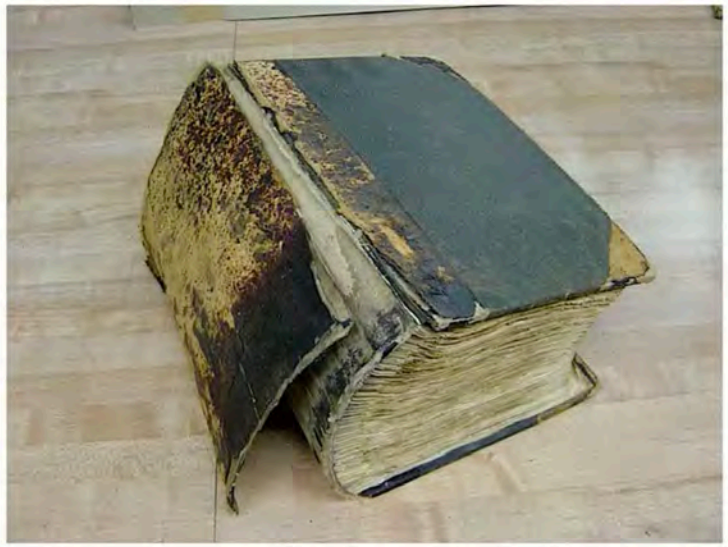
ACADEMIA ESPAÑOLA DE DERMATOLOGÍA Y VENEREOLOGÍA

WHAT IS REGENERATIVE MEDICINE?

- Replace tissues or organs damaged by:
  - Disease – congenital or acquired
  - Trauma
  - Age
- Treat the cause rather than the effects?
- "Replace like with like"

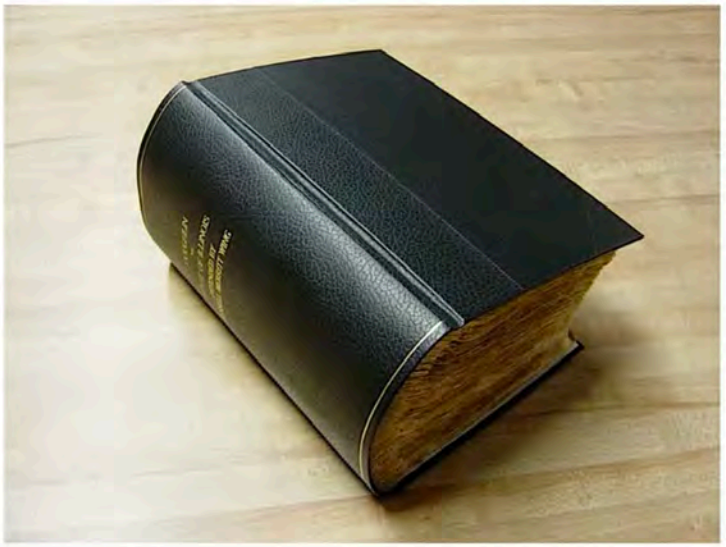
@drhemasundaram

THERAPEUTIC AESTHETICS...



AGING:

- DNA structure: loss + corruption
- DNA function: Deteriorating signaling and control



REGENERATION:

** RESTORE DNA STRUCTURE + FUNCTION

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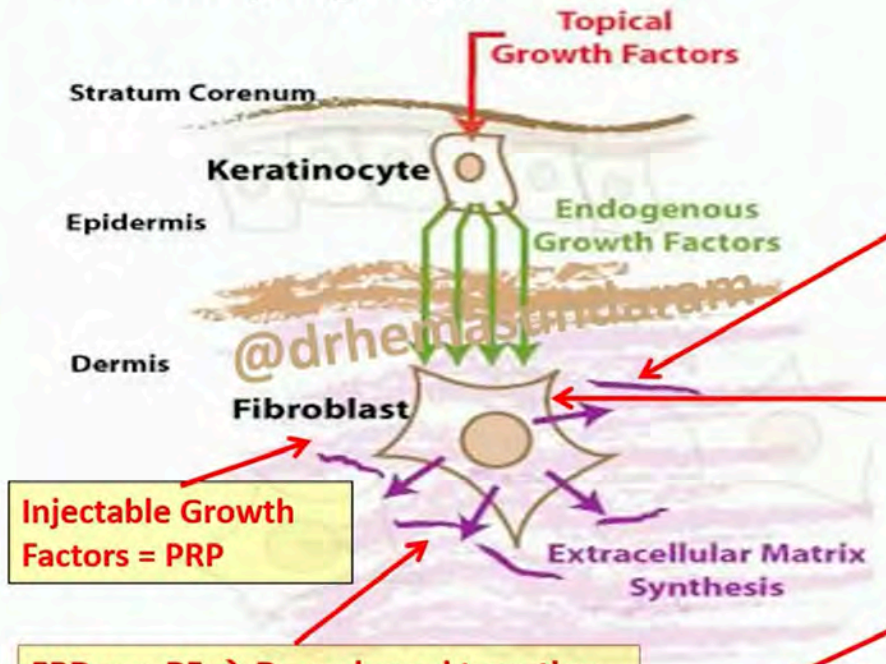
Combined treatments for Tissue Restoration: A Unifying Hypothesis



HA FILLER
interaction with CD44 receptors → GF cascade

BOTULINUM TOXIN

Injectable Growth Factors = PRP

THREADS?

EBD e.g. RF → Deep dermal targeting

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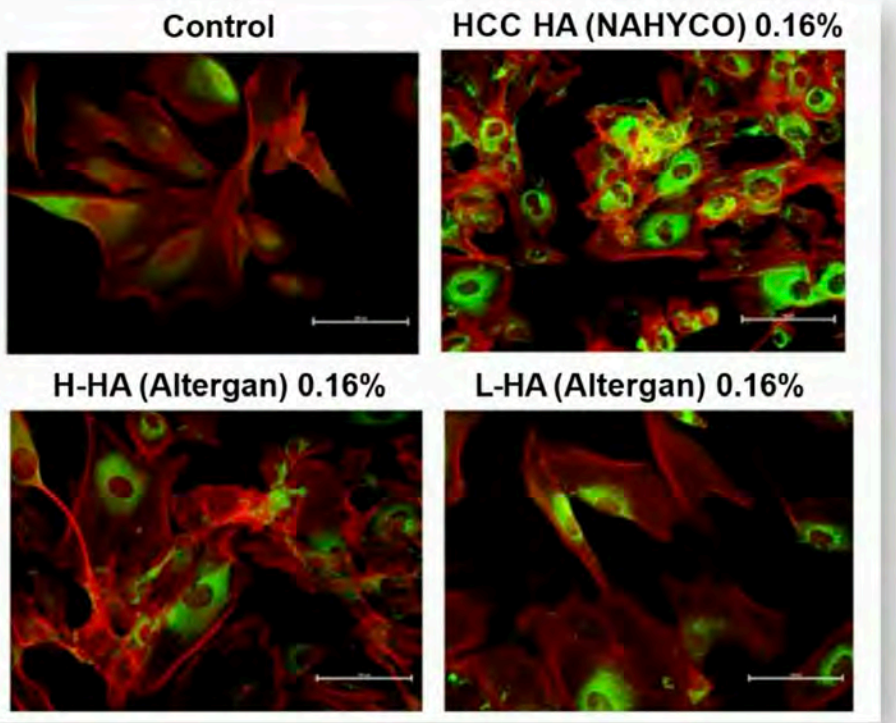
Increased Type I and III Collagen Synthesis in Fibroblasts



Hyaluronan Hybrid Cooperative Complexes as a Novel Frontier for Cellular Bioprocesses Re-Activation PLOSone (2016)

Antonietta Stellavato[1], Luisana Corsuto[1], Antonella D'Agostino[1], Annalisa La Gatta[1], Paola Diana[1], Patrizia Bernini[2], Mario De Rosa[1], Chiara Schiraldi[1]*

Significantly higher activation of **synthesis + different localization** of **Type I collagen** than with H-HA and L-HA

Immunofluorescence Staining of HDF cells

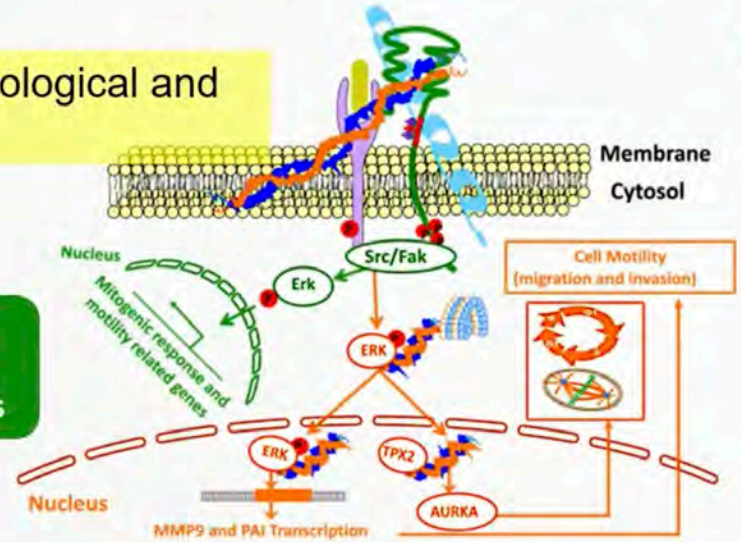
- Green **Type I collagen**
- Red **Cytoskeleton (Phalloidin)**
- Blue **Nuclei (DAPI)**

@drhemasundaram

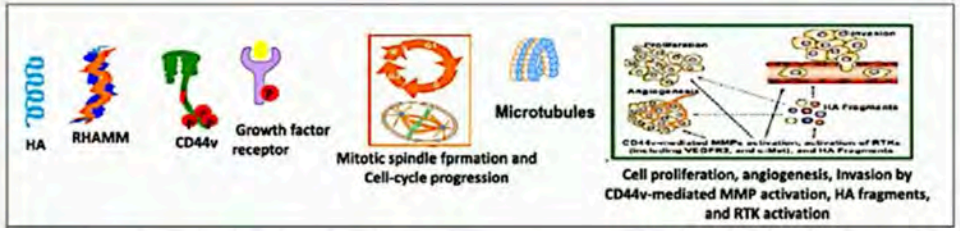
Cross-Talk between CD44 and RHAMM (CD68) interaction with HA

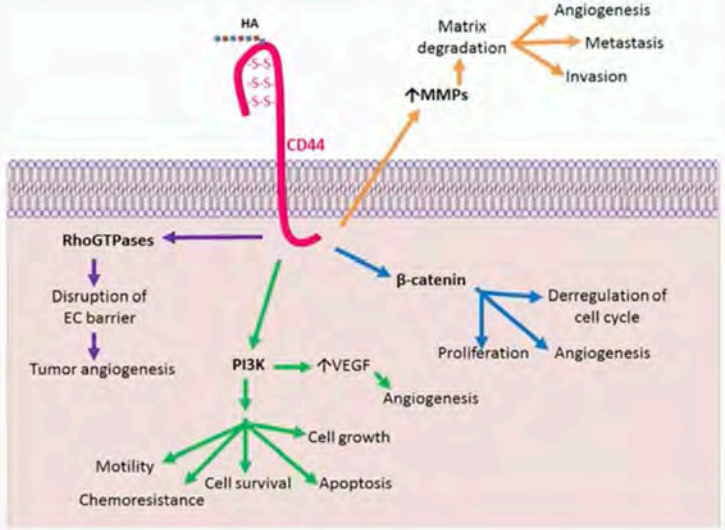
* Affects global physiological and cellular functions

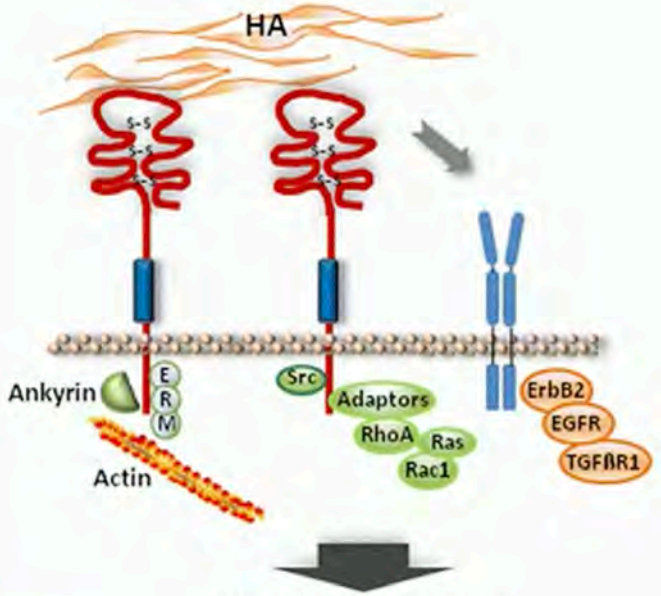
Extracellular RHAMM Signaling involving CD44-HA-mediated pathways



Intracellular RHAMM signaling







Cell surface RHAMM interacts with CD44, HA, and growth factor receptors (GFR)

→ protein tyrosine kinase signaling cascades

→ activate the ERK1/2 MAP **kinase cascade** in a c-Src/Raf-1/MEK-1/ERK1/2 dependent manner

Modulate signaling pathways
i.e. RAS-MAP kinase and PI3 AKT

↓

Cell proliferation, cell survival, cell motility and invasion, chemoresistance

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Terapéutica

Tranexamic Acid (TXA)

Evidence from prospective studies

- Wu, et al. evaluated use of oral TXA given in the dose of 250 mg BD for 6 months and follow-up was done for more than 6 months. The investigators evaluated the response in the form of improvement in pigmentation and decrease in melasma size. Good to excellent response was observed in about 65% patients.
- In moderate to severe melasma, oral TXA 250 mg BD provided 49% reduction in mMASI score versus 18% in the control group at 3 months.
- Padhi and Pradhan compared topical therapy versus oral TXA 250 mg given twice daily plus fluocinolone acetonide 0.01%, tretinoin 0.05%, and hydroquinone 2% combination cream given once daily for 8 weeks. In this study, there was significantly faster reduction in pigmentation with oral TXA plus triple combination therapy.

Reference –
Godse K, Sarkar R, Mysore V, Shenoy MM, Chatterjee M, Damisetty R, Shah S, Vedamurthy M, Aurangabadkar S, Srinivas C, Ganjoo A, Das S, Patil A. Oral tranexamic acid for the treatment of melasma: evidence and experience based consensus statement from Indian experts. Indian J Dermatol 2023;68:178-85

Tranexamic acid (TXA)

Adverse events and contraindications for use of oral TXA

- Gastrointestinal adverse events and hypomenorrhea are reported adverse events with TXA.
- Oral TXA should be stopped if patients receiving develops visual or ocular symptoms or severe allergic reaction.
- TXA should be avoided in patients with hypersensitivity reactions to it, women receiving combination hormonal contraception and those with history, risk, or active thromboembolic disease.
- TXA is not approved for the treatment of melasma by USFDA or Drug Controller General, India (DCGI). Clinicians should inform this to the patient and obtain informed consent before using it for melasma treatment.

Despite availability of several treatment options, outcomes of melasma are not satisfactory in many patients **and newer introductions are always welcome for better patient outcomes**

Tranexamic acid: Mechanism of action in melasma

Sun exposure

↓

Synthesis of plasmin activator

↓

Increased plasmin activity in keratinocytes

↓

Release of arachidonic acid (AA) via phospholipase A2

PG E2 synthesis promoted by AA stimulates melanogenesis

Increased α-melanocyte-stimulating hormone and fibroblast growth factor (potent melanocyte stimulators)

Plasmin: Role in angiogenesis by increasing the release of free VEGF

Tranexamic acid:

- Interferes with the plasminogen binding to the keratinocyte
- Prevents angiogenesis by blocking the action of plasmin
- Reduces VEGF and endothelin 1 (ET)-1

Indian J Drugs Dermatol 2017;3:61-3

Tranexamic acid for melasma: Dose and contraindications

- **Dose:** Low doses (250 mg BD)

Contraindications:

Defective color vision

- Coagulopathy
- Hypersensitivity
- Cardiovascular disease
- Stroke
- Anticoagulant medications

- **Adverse effects:** Gastrointestinal, reversible hypomenorrhea, deep vein thrombosis, myocardial infarction, pulmonary embolism

Indian J Drugs Dermatol 2017;3:61-3

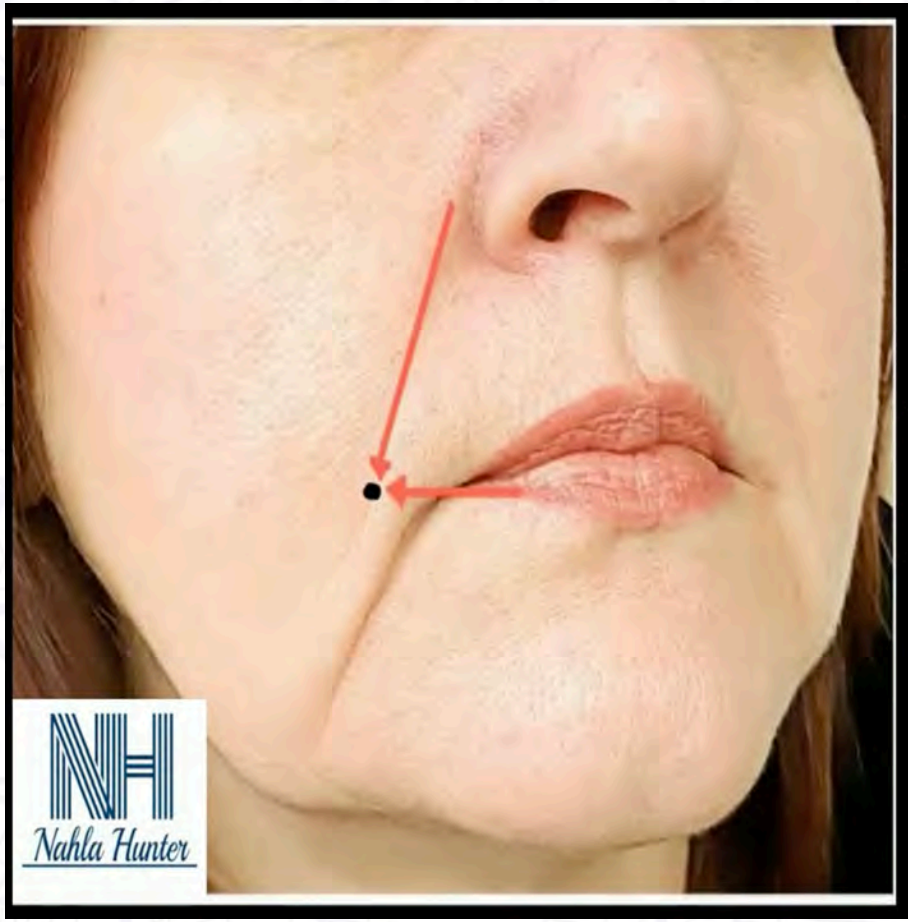
Materiales de relleno

MARKING

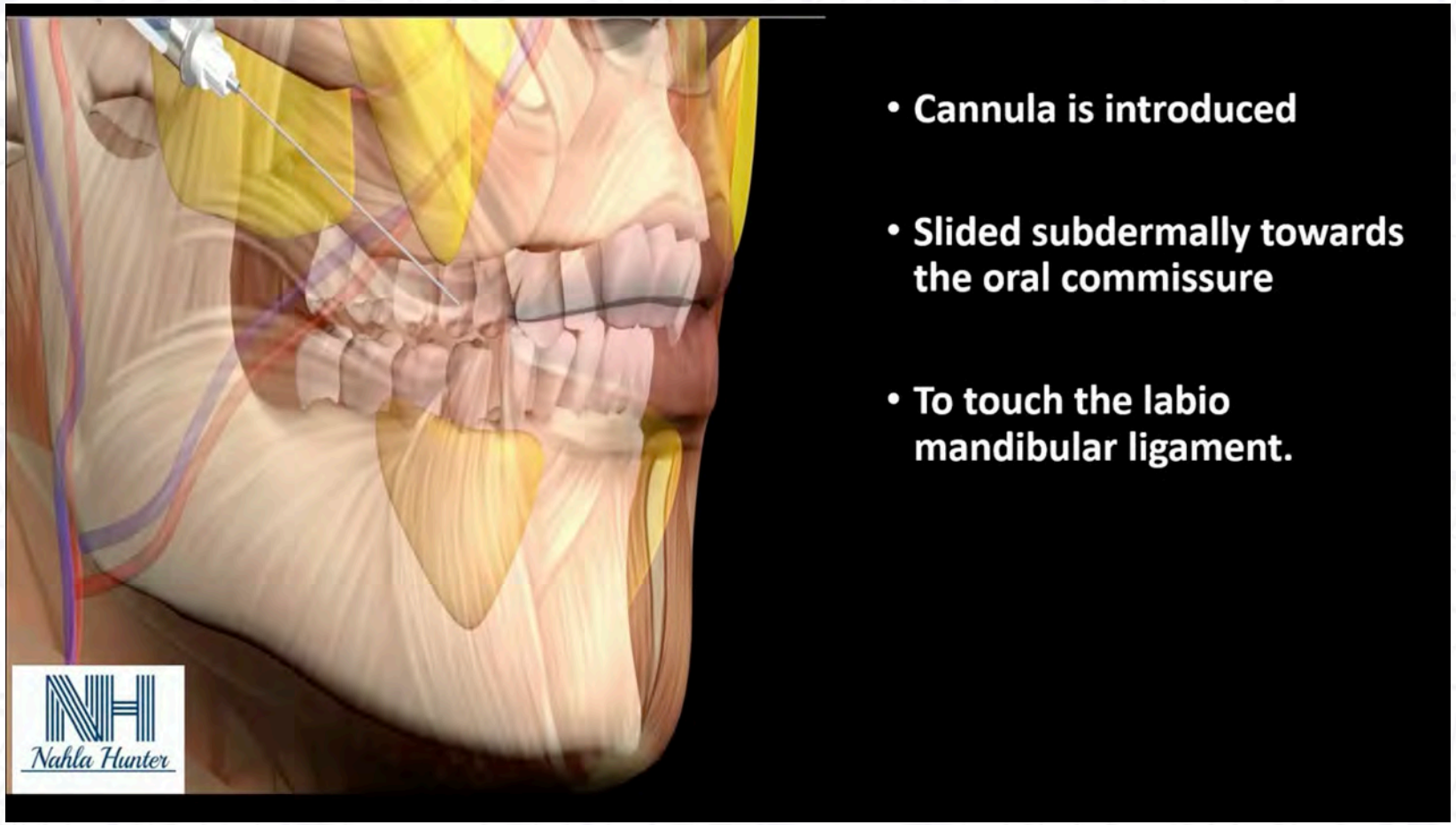
- The marionette line is marked.

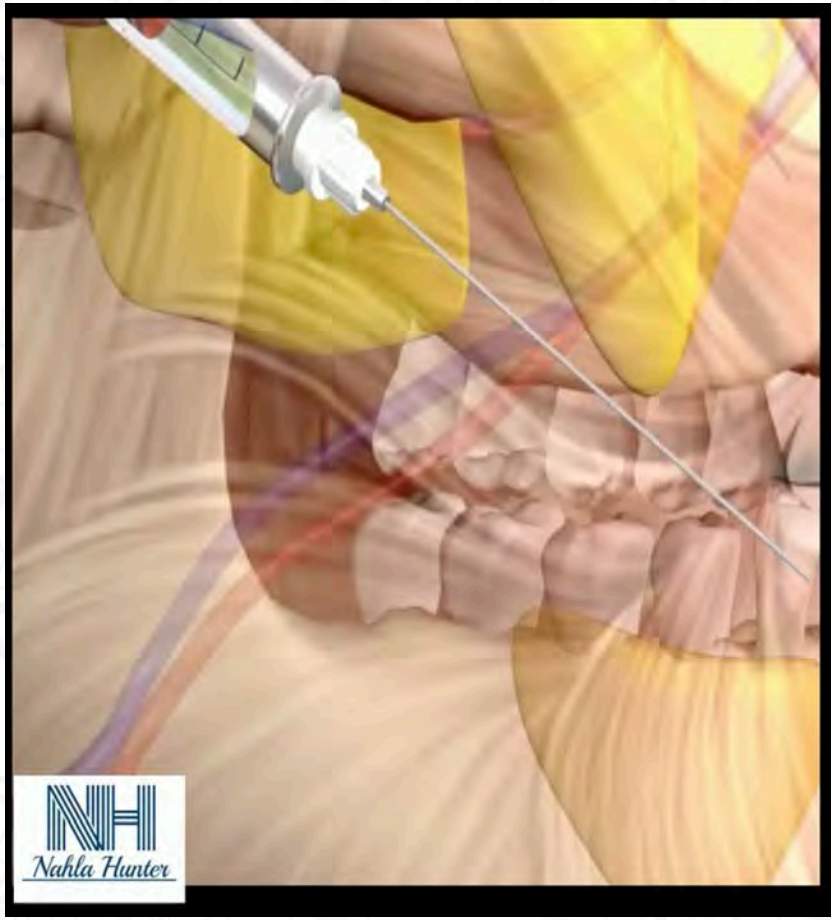
Subcommissural triangle is drawn

Labiomental area that need to be subcised is marked

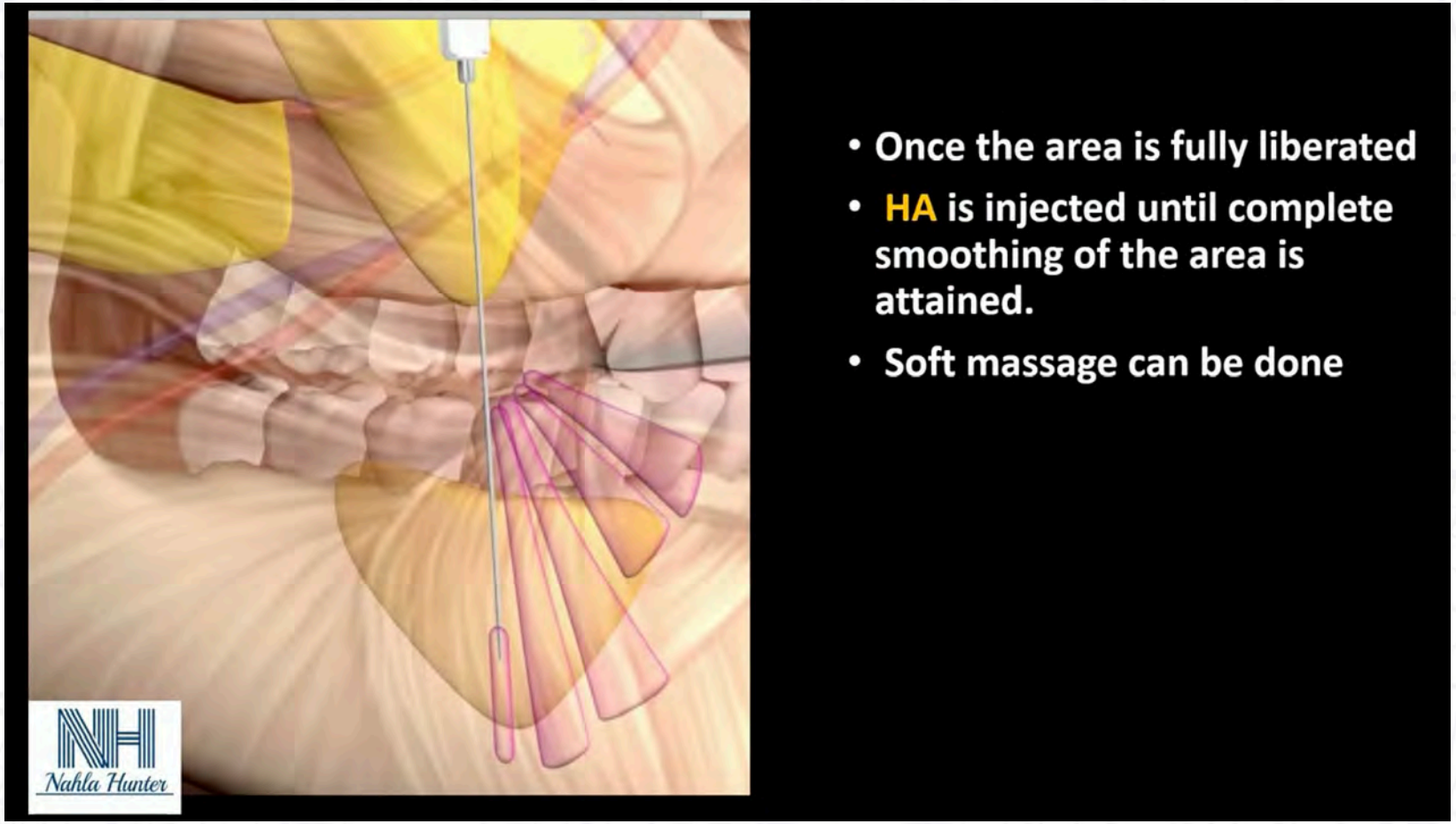


- Crossing of a line extending laterally from the lower vermillion and the nasolabial fold .
- At this location no important underlying vascular structures
- There is a good superficial fat compartment facilitating sliding the cannula subdermally.
- Directing the cannula superiorly can treat the nasolabial fold if desired from the same insertion point.

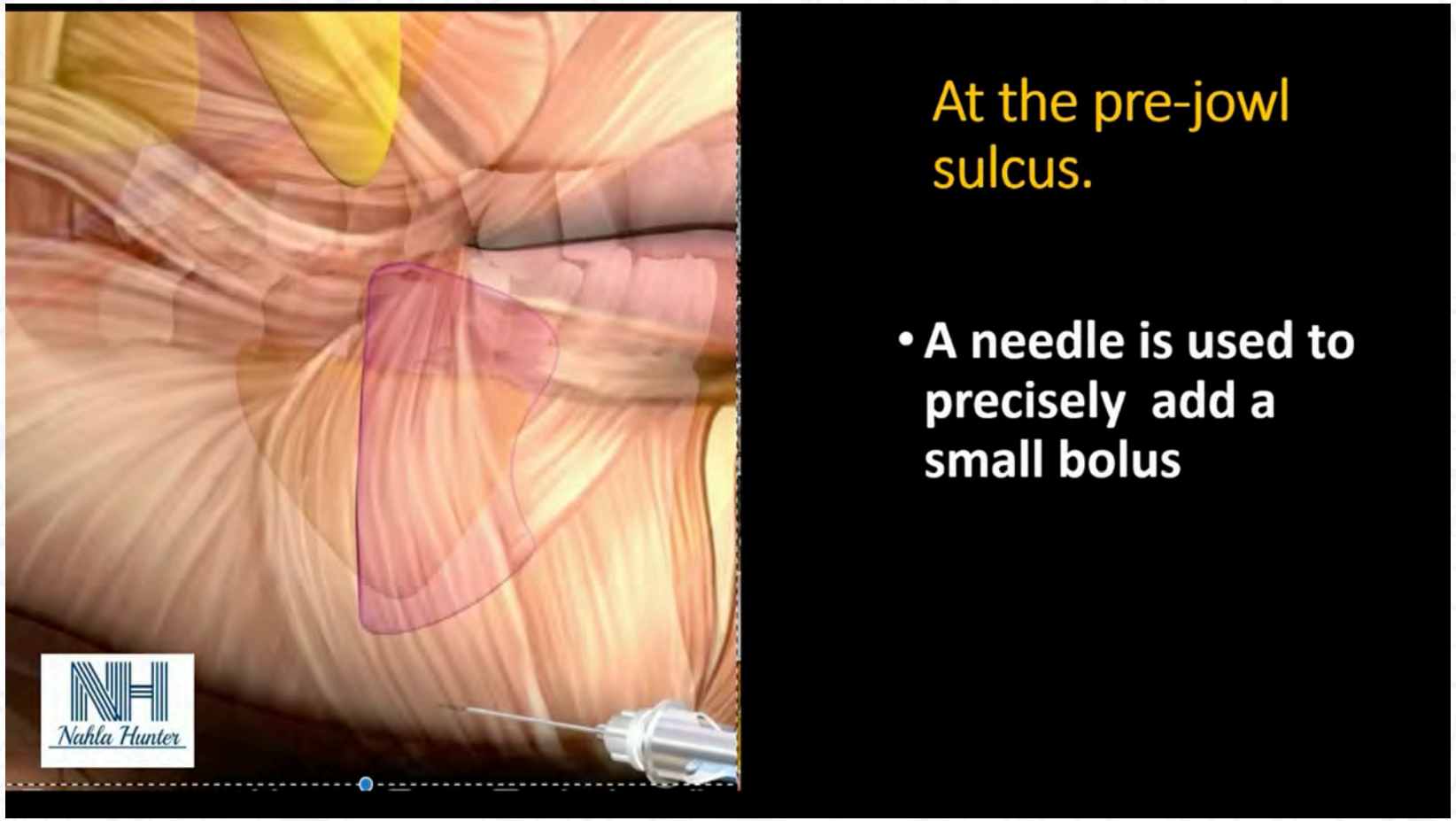

• Cannula is introduced
• Slided subdermally towards the oral commissure
• To touch the labio mandibular ligament.
NH
Nahla Hunter



- The cannula is softly pushed through the ligament back and forth until a subcision is made.
- Subcision of the **labiomandibular** ligament starting from the oral commissure for a length of 5-10 mm inferiorly
- The pre-jowl sulcus is not subcised.

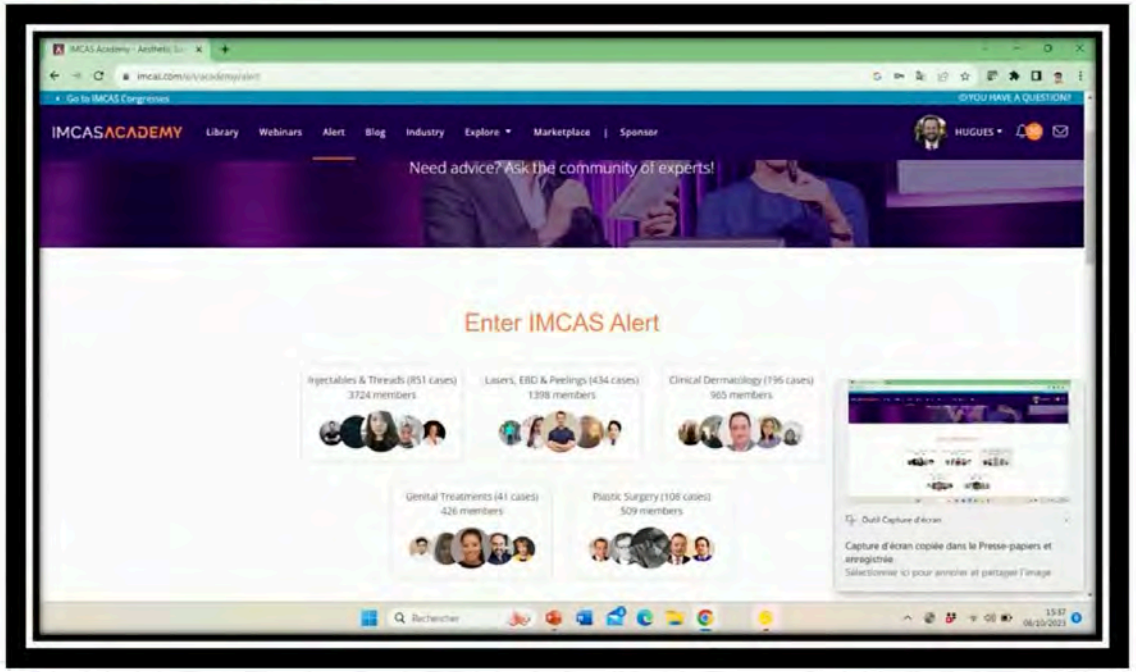


- Once the area is fully liberated
- HA is injected until complete smoothing of the area is attained.
- Soft massage can be done


At the pre-jowl sulcus.
• A needle is used to precisely add a small bolus
NH
Nahla Hunter

EADV CONGRESS

A tool for MD



Ultrasound imaging & ultrasound guided treatment

1. Place probe on bruise, put on duplex mode and detect flow pattern of deep artery. Register also flow patterns in subcutaneous space.
2. Mark outline of probe (for reference after H-ase injection)
3. Inject under ultrasound guidance H-ase (50-75 units) at deepest level of the superficial fatty layer (just above SMAS or fascia)
4. Place probe on bruise again according to the outline in (2). If after 10 minutes no increased flow and/or clinical improvement is detected, repeat step (3) and (4).
5. If not successful repeat procedure the next day

Dr. Peter Belthius

Allergan

abbvie

Long-term Safety With a Hyaluronic Acid and Calcium Hydroxyapatite Combination Filler in Facial Aesthetic Rejuvenation

Fernando Urdiales-Gálvez[1], Lea Elmaleh[2], Liat Goldshaid-Zmiri[2], Malka Salomon[2]

[1]Aesthetic Medicine, Málaga, Spain; [2]Allergan Aesthetics, an AbbVie Company, Ltd, Israel

OBJECTIVE

Assess late-onset adverse events (AEs) ≥18 months after injection of combination hyaluronic acid and calcium hydroxyapatite (HA+CaHA) soft-tissue filler with lidocaine.

Assess the presence of HA+CaHA in facial tissues ≥18 months after injection.

CONCLUSIONS

These results support the long-term safety of HA+CaHA soft-tissue filler

No long-term AEs were reported by the subjects, and no treatment-related skin abnormalities, AEs, allergic reactions, granulomas, or infections were detected by dermatoscope or ultrasound

HA+CaHA filler was not detected in any subjects who were assessed by ultrasound

For additional information or to obtain a PDF of this poster

References

Presented at the European Academy of Dermatology and Venereology (EADV) October 11-14 2023, Berlin, Germany

Allergan Aesthetics

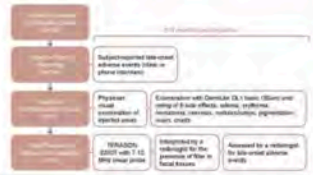
INTRODUCTION

- HA+CaHA soft-tissue filler with lidocaine combines crosslinked HA gel (20 mg/mL) matrix with embedded CaHA (55.7% w/w) microspheres
- The complementary dual mode of action includes soft-tissue filling from the HA (leading to an immediate visible aesthetic outcome) and neocollagenesis from CaHA (resulting in sustained dermal thickening and improved skin architecture that increase skin firmness and improve overall skin quality)
- While the safety of each of the individual components of HA+CaHA in facial aesthetic procedures is well established,[1,2] the long-term safety of this combination product is of interest

METHODS

- Retrospective postmarketing study of adults who received HA+CaHA injections ≥18 months before evaluation
- 104 clinical trial subjects received subdermal or deep-dermal injections of HA+CaHA
- Subsets of the 104 subjects were assessed via visual and dermatoscopic examinations and ultrasound evaluation

Study Assessments



RESULTS

Subject Demographic and Treatment Characteristics

Characteristics	Total Subjects (N=104)
Age (years), mean (SD)	51.8 (9.6)
Range	29-73
Sex, n (%)	
Female	101 (97)
Male	3 (3)
Time from treatment, n (%)	
13-17 months	2 (2)
18-23 months	37 (36)
24-30 months	56 (54)
>30 months	9 (9)
Injection site, no. of sites*	
Cheek bones	85
Nasolabial folds	53
Marionette lines	50
Jaw line	13
Chin	5
Eyebrows	5
Nose	2
Injected volume, total mL per subject, mean (SD)	2.99 (1.91)

*Subjects were treated at multiple sites

Injection Sites Included Cheeks, Nasolabial Folds, Marionette Lines, Jaw Line, Chin, Eyebrows, and Nose

Safety

- No adverse events were reported by subjects (N=104)

No Skin Abnormalities or Noticeable Adverse Events Were Identified by Visual and Dermatoscopic Evaluations

Evaluation	Total Subjects (N=87) Yes	No
Visual examination, n (%)		
Are there any wounds/cracks in the skin?	0	87 (100)
Are there any visible lumps?	0	87 (100)
Is there swelling accompanied by redness?	0	87 (100)
Is an active skin inflammation evident?	0	87 (100)
Is there a problem with the color/appearance/texture of the skin?	0	87 (100)
Does the subject feel pain from touch?	0	87 (100)
Dermatoscopic evaluation, n (%)	**Yes**	**No**
Is the following effect noticeable?	0	87 (100)
Edema	0	87 (100)
Erythema	0	87 (100)
Hematoma	0	87 (100)
Necrosis	0	87 (100)
Nodules/lumps	0	87 (100)
Pigmentation	0	87 (100)
Scars	0	87 (100)
Crusts	0	87 (100)

No Allergic Reactions, Granulomas, or Infections Were Found by Dermatoscopic Evaluation

Dermatoscopic Evaluation, n (%)	Total Subjects (N=87) Yes	No
Allergic reaction	0	87 (100)
Granuloma	0	87 (100)
Infection	0	87 (100)

No Treatment-Related Inflammation, Granulomas, or Other Adverse Events Were Detected by Ultrasound

Ultrasound Evaluation, n (%)	Total Subjects (N=64) Yes	No
Inflammation	1[a]	63 (98.4)
Adverse reaction	2[b]	62 (96.9)
Granuloma	0	64 (100)

[a]Result of ongoing surgical dental care
[b]These 2 cases (fibrosis and cyst) were classified by the radiologist as random findings, with no relation to previous material injection.

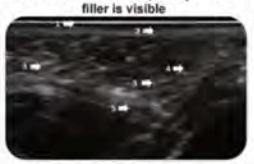
Filler Detected by Ultrasound Was Present Only in Recently Injected Controls and Subjects Who Had Received Repeat Injections Within 18 Months

Subject Type	Subject	Time Since Last HA+CaHA Injection	Filler Detection	No. of Calcifications
Controls (not injected and recently injected)	1	Not injected	No	NA
	2	4 months	Moderate	NA[a]
	3	11 months	Slight	2
Re-treated study subjects	1	11 months	Slight	2
	2	16 months	Slight	2
	3	7 months	Slight	5-6

[a]Filler presence was observed "moderately"; calcifications could not be determined; NA, not applicable.

HA+CaHA Filler Ultrasound Patterns Vary at Different Times After Injection

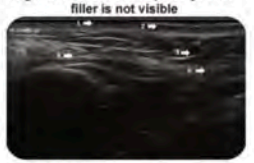
Left cheek 11 months postinjection: filler is visible



There is a heterogeneous pattern with diffuse anechoic and hypoechoic images that demonstrates the total integration of HA. A coarse grain snow pattern due to the presence of CaHA is observed with a high level of fibrosis (hyperechoic images).

1. Epidermis. 2. Dermis. 3. Coarse snow grain pattern. 4. Anechoic area. 5. Heterogeneous and more fibrous pattern (ie, normal skin with HA/CaHA integration). CaHA, calcium hydroxyapatite; HA, hyaluronic acid.

Right cheek 30 months postinjection: filler is not visible



There is a heterogeneous pattern with anechoic and hypoechoic images that indicates the absence of HA. A coarse grain snow pattern expected with the presence of CaHA is not detectable and there is a low level of fibrosis (ie, hyperechoic images).

1. Epidermis. 2. Dermis. 3. Anechoic area. 4. Heterogeneous and less fibrous pattern (ie, normal skin). CaHA, calcium hydroxyapatite; HA, hyaluronic acid.

- HA+CaHA filler was not detected by ultrasound in subjects treated ≥18 months before evaluation

0868

Delayed-Onset Nodules Following Vycross Hyaluronic Acid Filler Treatment: Reported Rates From Global Post-marketing Surveillance

Robert S. Walsh, MD, MBA, FCCP, FAHA[1]; Maureen Newman, RN, BSN[1]; Saran J. Cross, PhD[1]; Joseph M. Purpura, MD, MS[1]

[1]AbbVie Inc, North Chicago, IL, USA

CONCLUSIONS

This analysis of 15 years of post-marketing surveillance data demonstrate that the global reported rate of delayed-onset nodules associated with Vycross dermal fillers is low (0.016%)

Inflammatory nodules, which typically require intervention/treatment,[1] were reported less frequently than non-inflammatory nodules

Event rates have been noted to increase with early adoption of individual products, then decrease as utilization with the specific products increases

For additional information or to obtain a PDF of this poster

Allergan Aesthetics

INTRODUCTION

Objectives

- Dermal filler treatments can be associated with adverse events that can occur at various time points following injection (eg, bruising, edema, nodules)
  - Literature show that these late-onset events are associated with all hyaluronic acid fillers, suggesting a class effect[1]
- This analysis examined global post-marketing surveillance (PMS) data on the reported rates of delayed-onset nodules presenting ≥4-weeks after injection of hyaluronic acid fillers based on the Vycross technology platform

METHODS

Design

- Post-marketing surveillance data on delayed-onset nodules reported to Allergan Aesthetics 2007-2021 for Vycross fillers:
  - VYC-15L (Volbella)
  - VYC-17.5L (Volift/Vollure)
  - VYC-20L (Voluma/Voluma XC)
  - VYC-25L (Volux)
- Delayed-onset nodules were defined as having onset ≥4-weeks post-treatment and classified as *non-inflammatory nodules* or *inflammatory nodules* (including granulomas confirmed by biopsy)
- Reported rates were calculated as the number of nodules divided by the total number of syringes sold globally

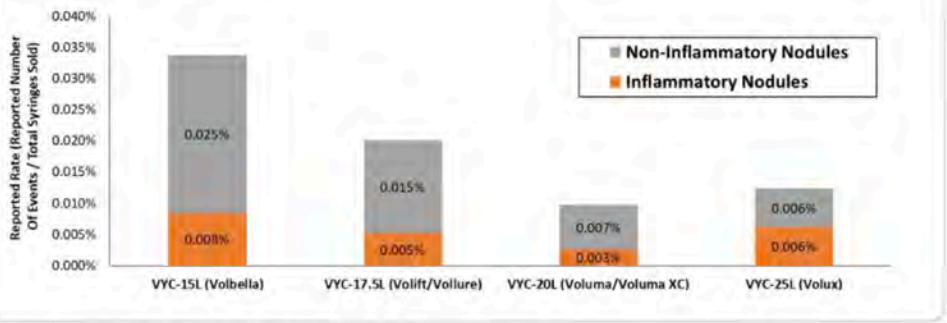
RESULTS

Global Reported Rates of Delayed-Onset Nodules by Product and Nodule Type

- A total of 5,333 delayed-onset nodules were reported, corresponding to an overall reported rate of 0.016%
- Non-inflammatory nodules were reported more frequently (n=3,913) than inflammatory nodules (n=1,420, including n=233 granulomas)

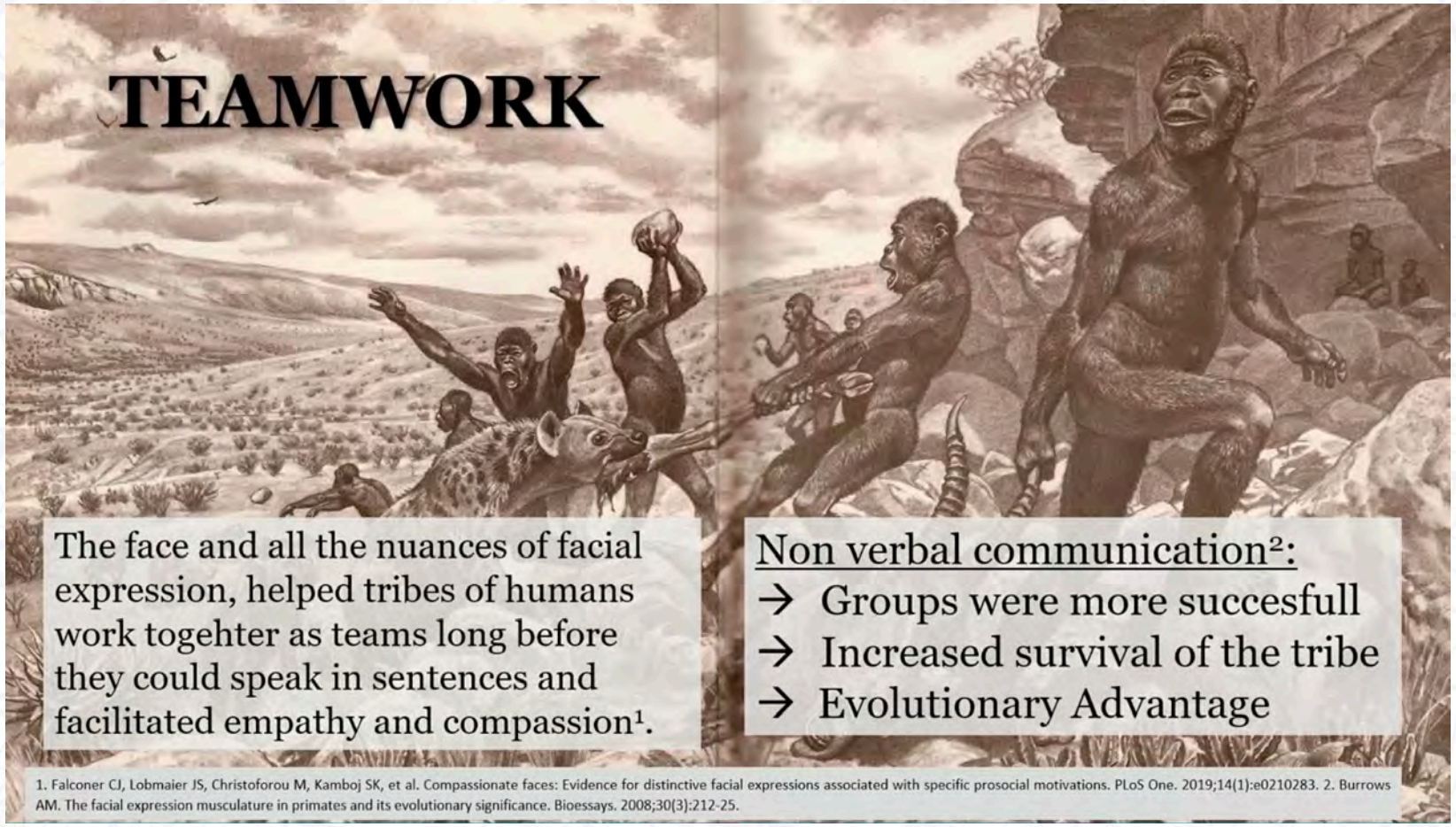
Important Considerations

- As a passive surveillance system, PMS has limitations (eg, incomplete, inaccurate, untimely, unverifiable, or biased data)
- The incidence or prevalence of an event cannot be determined from PMS alone due to potential under-reporting, duplicate reporting of events, and lack of verification that the device caused the event



First product launches in any market worldwide: 2007 (VYC-35L); 2012 (VYC-15L and VYC-17.5L); 2019 (VYC-25L)

Toxina botulínica



Dr. Doomstord

Functions of Facial Expressions[1,2]

Counterpart´s Emotions (positive/negative) ⟷ affect/amplify ⟷ Facial Expressions (muscular movement) ⟷ affect/amplify ⟷ Our Own Emotions (well-being, health)

- Tell others what we think and feel (non-verbal communication)[2]
- Provide commentary to those around (non-verbal communication)[2]
- Contribute and enhance to our emotions (facial feedback theory)[2,3]

1. Dong Z, Wang G, Lu S, Li J, et al. Spontaneous Facial Expressions and Micro-expressions Coding: From Brain to Face. Front Psychol. 2022;12:784834.
2. Xu Q, Yang Y, Tan Q, Zhang L. Facial Expressions in Context: Electrophysiological Correlates of the Emotional Congruency of Facial Expressions and Background Scenes. Front Psychol. 2017;8.
3. Söderkvist S, Ohlén K, Dimberg U. How the Experience of Emotion is Modulated by Facial Feedback. J Nonverbal Behav. 2018;42(1):129-151.

„Facial Over-Expressiveness“

"WITH AGING WE TRY TO COMPENSATE THE LOSS OF SKIN INTEGRITY DUE TO ELASTOSIS, VOLUME LOSS AND GRAVITY LEADING TO SAGGINESS, BY OVERACTIVITY OF FACIAL MUSCLE CONTRACTIONS. THEREFORE OVER THE YEARS WE ARE INCREASINGLY GRIMACING AND BECOME CARICATURES OF OURSELVES."

OPINIÓN DEL PONENTE EN BASE A SU EXPERIENCIA CLÍNICA

Proprietary Name	Manufacturer	Trade Names (or Alternative names)	US FDA Approved	Advantages	Disadvantages
PrabotulinumtoxinA	Evolus, Inc. (USA)	Nuceiva	Europa	Equivalent to botox Lower cost	
DaxibotulinumtoxinA	Revence Therapeutics (USA)	Daxxify	EEUU	No HSA Long duration (24 weeks)	
LetibotulinumtoxinA	Hugel Pharma (Korea)	Letybo	Europa		Lower potency than Xeomin
BotulinumtoxinE	BoNTi. Inc. (USA)	EB-001	No	Onset of action—24 h	Duration—2–4 weeks
Liquid Toxins	1. Medytox (Korea) 2. Galderma (Switzerland) 3. Allergan (USA)	Alluzience	Europa	Lower risk of error in preparation	Costly

Take home message:

Botulinum toxin type A reconstituted in 1 % lidocaine hydrochloride with epinephrine 1:100,000 :
results not confirmed, potential side effects

New formulations of botulinumtoxin have been approved , that claim to offer longer durations .
Studies show slightly improved results but differ from marketing messages, older studies did not include results > 5 months

higher doses of botulinumtoxin
All types of BonTA show longer effects with dose increase of up to 5 times, but also cost and side effects increase

FTP-501/mu-conotoxin CnIIIc coinjected with BoNT/A
The only way to achieve up tpo 50 % longer effect without an increase in side effects or costs

Klaus Fritz (Germany)

Fastox FTP-501 boosts significantly BoNT/A onset & duration

Co-injecting
BoNT/A and **FTP-501**
- a specific blocker of muscular Nav 1.4 voltage-gated sodium channels –
significantly enhances BoNT/A duration of action

Fastox technology works on all BoNT/A tested; proven in2 validated animal models
Preclinical work has validated the use of FTP-501 with the key BoNT products marketed worldwide.It follows a completely different mechanism of action and has
Potential to be more effective than high dose and DaxibotulinumtoxinA

Klaus Fritz (Germany)

Scars and primary prevention

- There is some evidence that pretreatment with BoNT-A in facial areas might reduce scar formation


Fastox | Pharma
Unlocking botulinum toxin potential

About us

Fastox is a Swiss biotechnology start-up c
experts in biotech and botulinum neurotox

Millions of treatments with botulinum neur
performed in both therapeutics and aesth
there are 2 limitations with this very efficie
action, it indeed takes a few days for the t
importantly, its duration, limited to 3 to 4 m
come back regularly to get re-treated and
symptoms reappearance impacts their qu

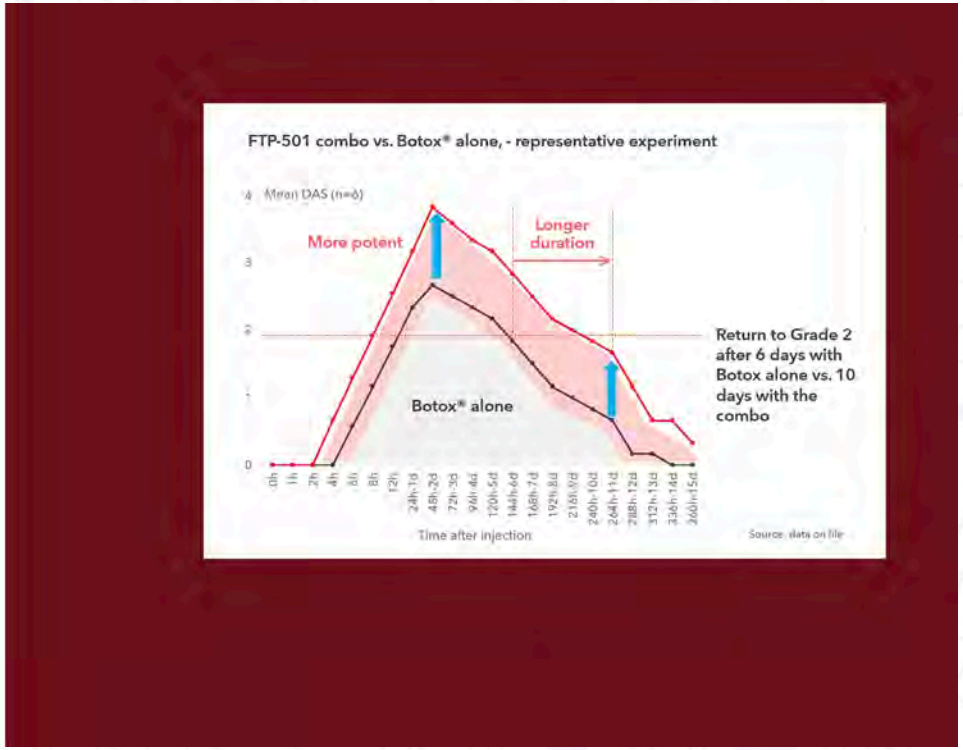
Fastox was created for accelerating the o
(hence its name…) by combining it with a
a marine shell. While testing this hypothes
discovered that this mini-toxin could also
duration of action of BoNT-A.

Pipeline

FTP-501: Fastox lead candidate will be entering clinical stage in 2023.

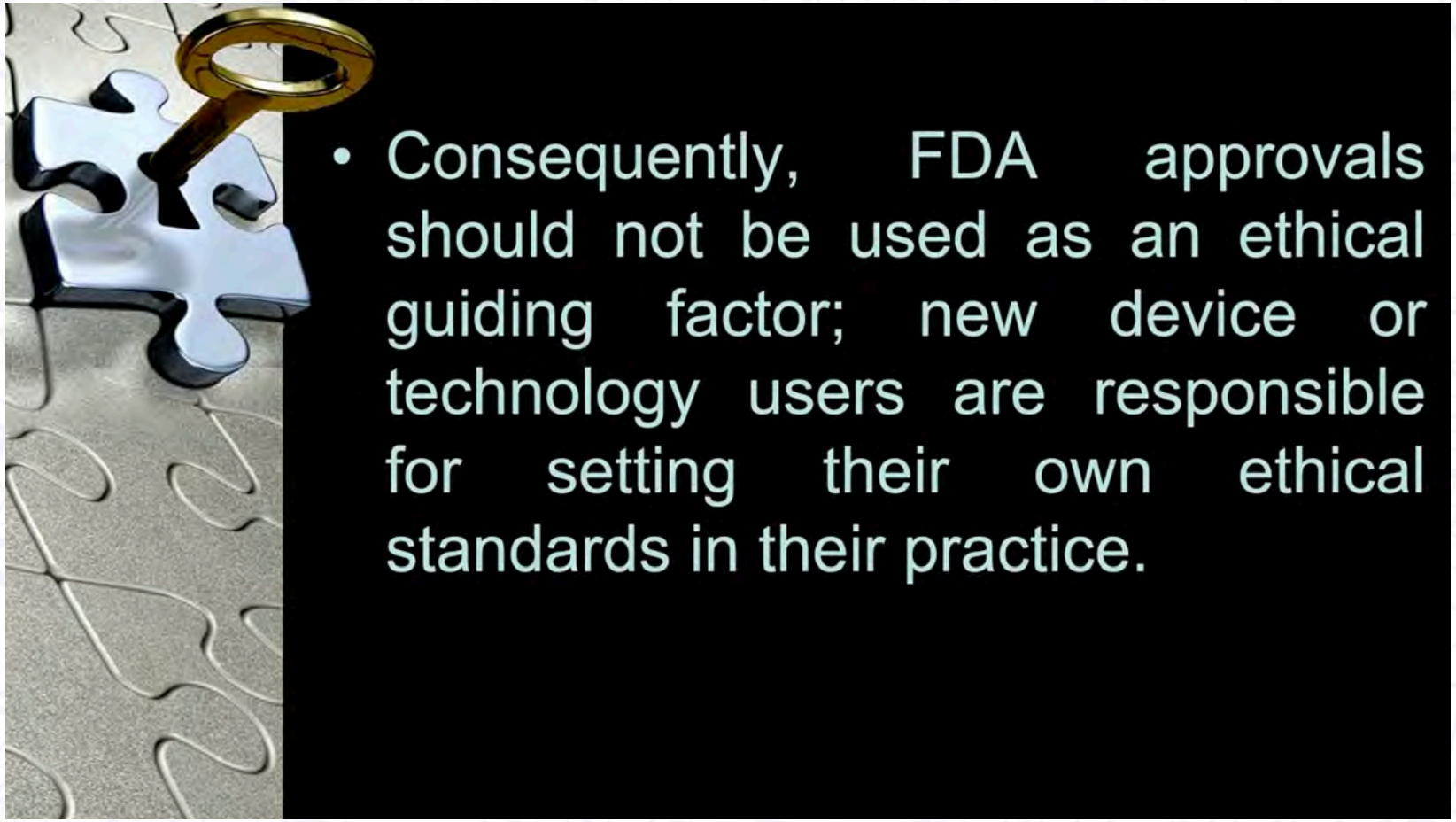
The graph on the right represents a typical outcome of the DAS (digit abducting score) in rats showing an improvement of the FTP-501 combination with botulinum toxin A compared to the toxin alone. This improvement is consistent across all time points, from peak effect to return to baseline: we gain, on average, at each timepoint, one point on the DAS score (5-point scale).
These results are reproducible across experiments, labs and botulinum toxin doses and brands.

Fastox first patent "composition of matter" has been published in 2020: WO2020/254690

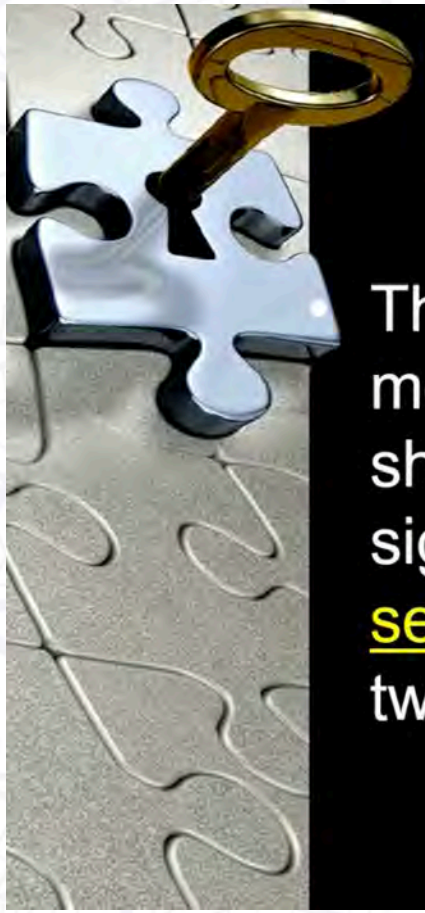


After screening approximately 200 molecules with similar activities, we selected our lead product FTP-501, the most potent BoNT-A duration enhancer with a very good safety profile.

Láser

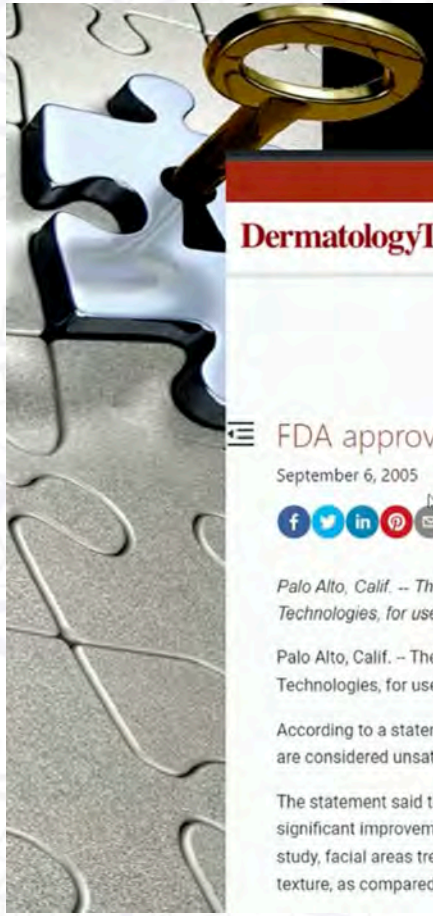


Dr. Peter Belthius



FDA approves Fraxel for melasma treatment

The FDA's approval of Fraxel to treat melasma was based in part on a study showing that use of the device resulted in significant improvement of melasma in seven of 10 female patients assessed by two independent investigators.



Example

Aesthetic AUTHORITY DermatologyTimes

DermatologyTimes NEWS MEDIA CONFERENCES PUBLICATION CME/CE RESOURCES EDITORIAL BOARD SUBSCRIBE

FDA approves Fraxel for melasma treatment

September 6, 2005

Palo Alto, Calif. -- The Food and Drug Administration (FDA) has approved Fraxel, a skin-resurfacing laser device manufactured by Reliant Technologies, for use in the treatment of melasma associated with pregnancy, female hormonal activity and certain drugs.

Palo Alto, Calif. -- The Food and Drug Administration (FDA) has approved Fraxel, a skin-resurfacing laser device manufactured by Reliant Technologies, for use in the treatment of melasma associated with pregnancy, female hormonal activity and certain drugs.

According to a statement issued by Reliant, melasma is resistant to traditional therapies and traditional laser and pulsed-light treatments are considered unsatisfactory because of poor results, significant downtime or the risk of adverse events.

The statement said the FDA's approval of Fraxel to treat melasma was based in part on a study showing that use of the device resulted in significant improvement of melasma in seven of 10 female patients assessed by two independent investigators. In a second 10-patient study, facial areas treated with the device showed statistically significant improvements in the appearance of melasma and quality of skin texture, as compared with use of topical therapy alone. No serious adverse events were observed in any of the studies.

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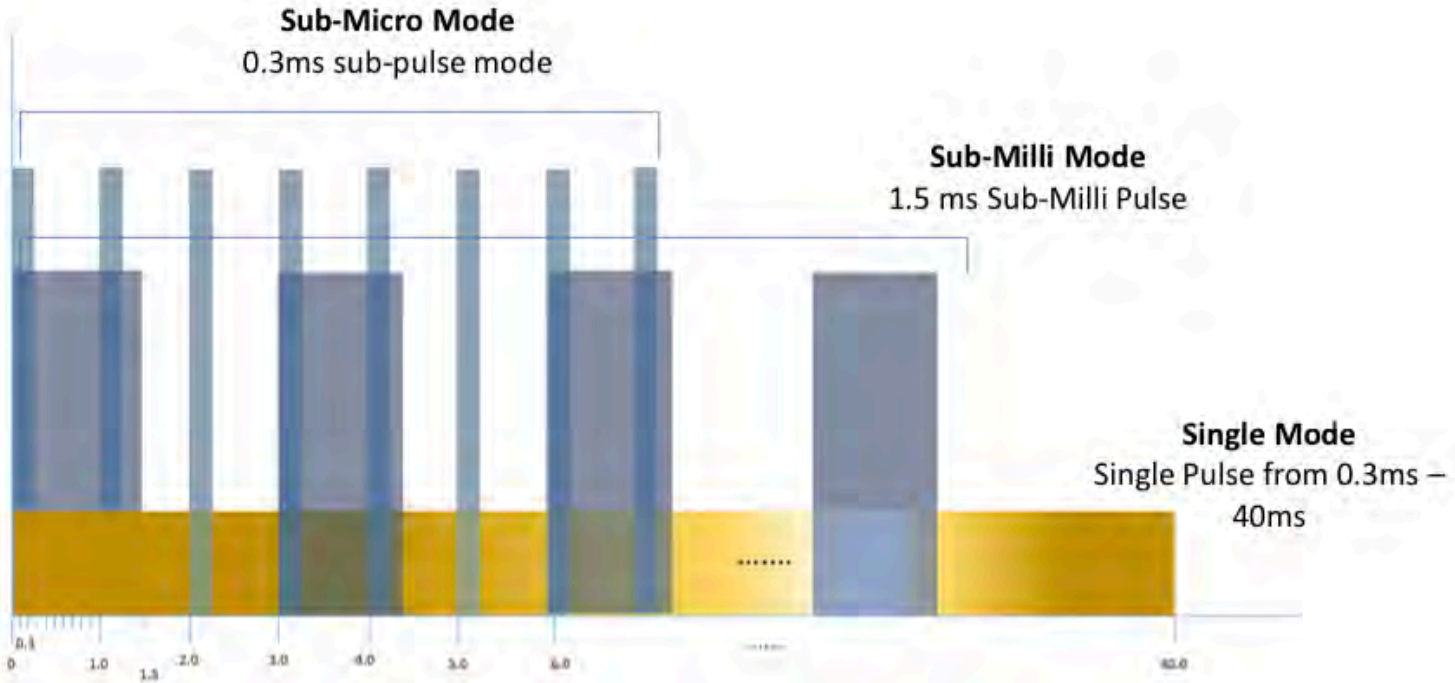
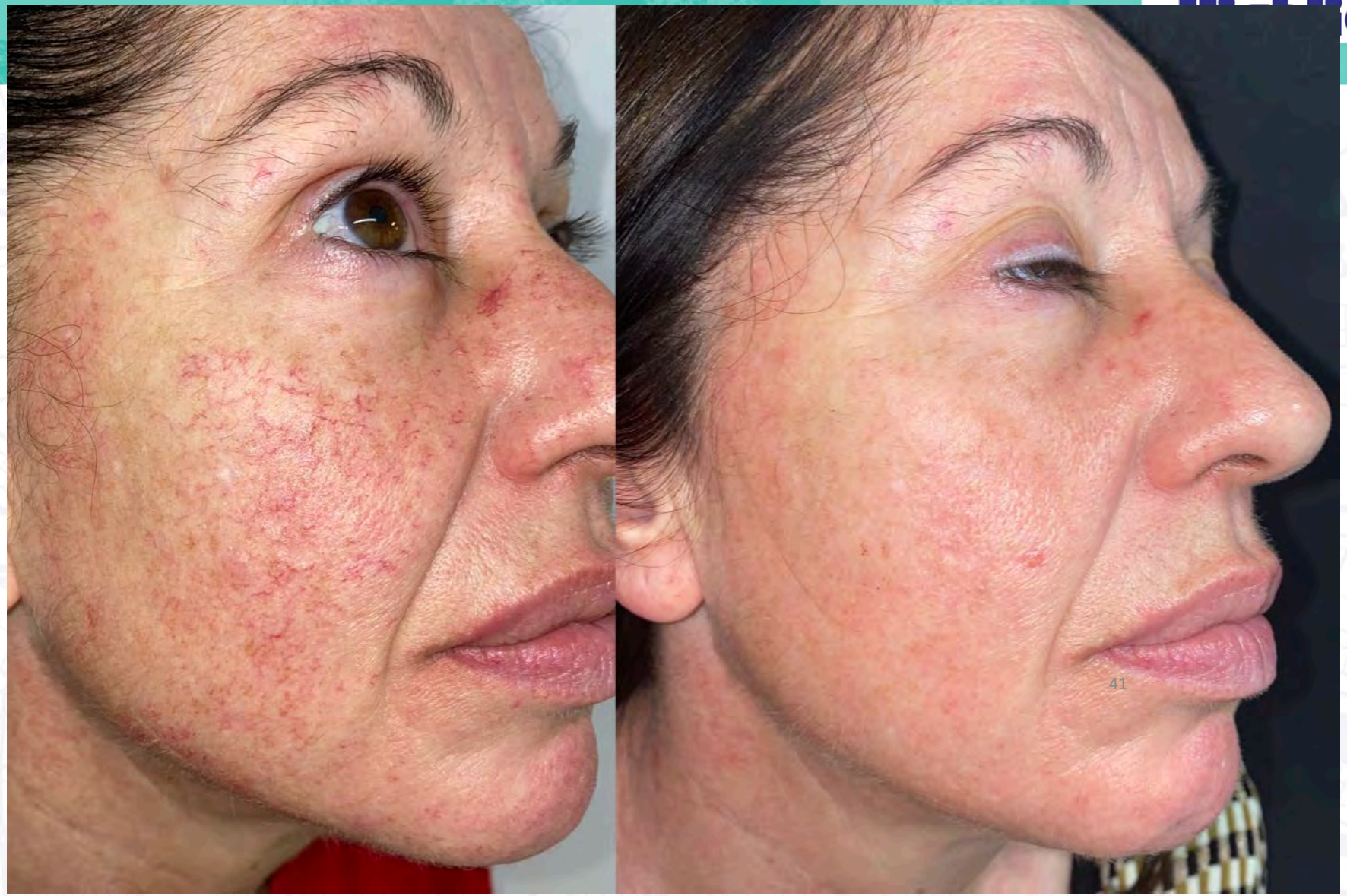
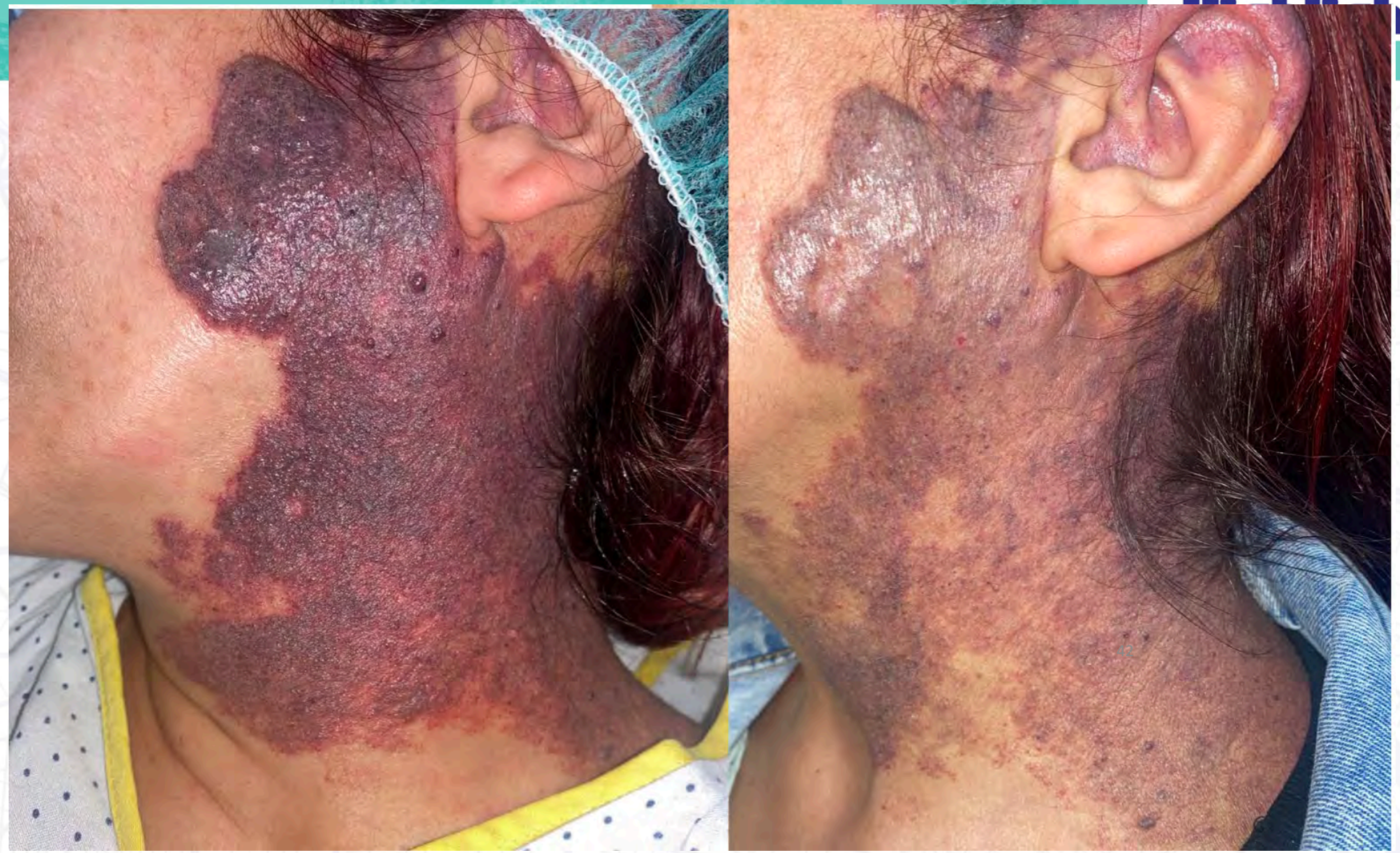


*Cortesía Dr. Pablo Boixeda





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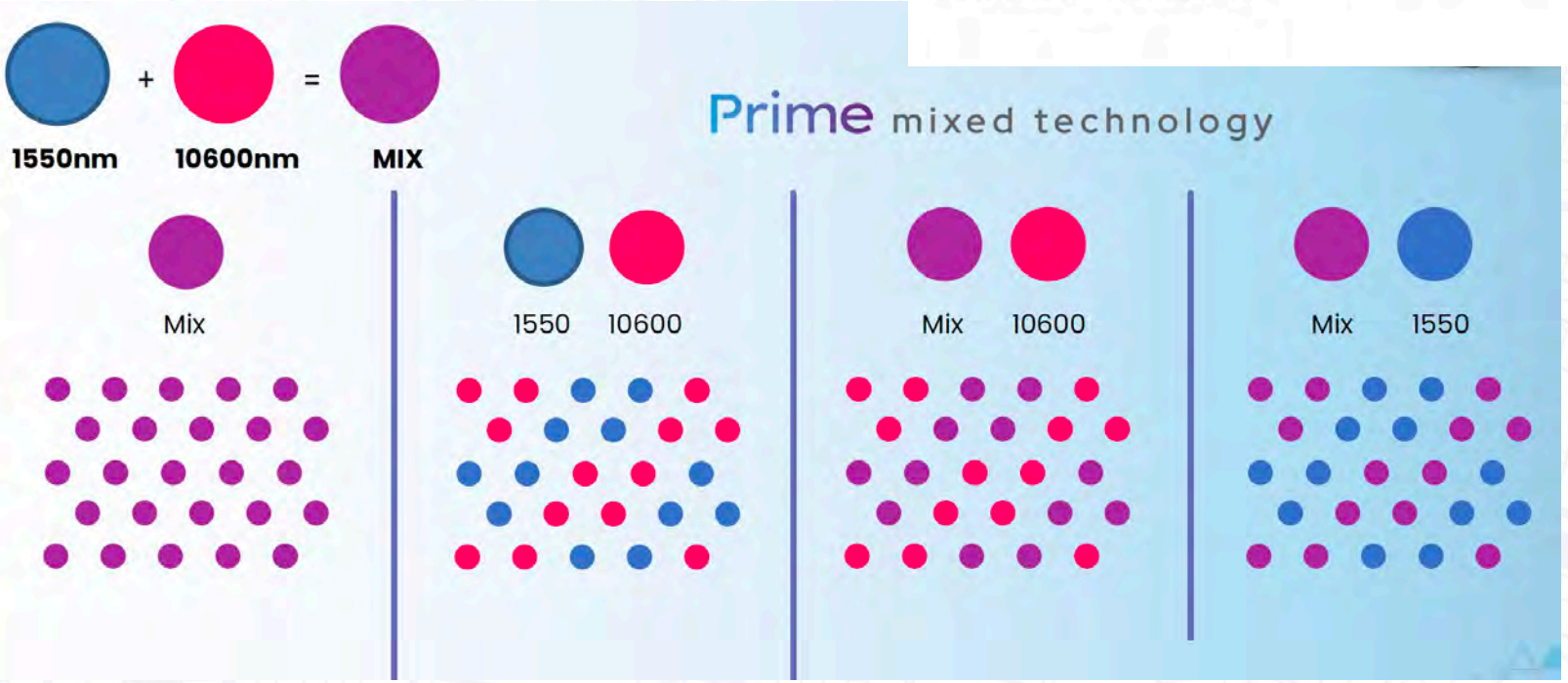

Summary: Symptoms and Lasers

Colour

- Hyperpigmentation
- Hypopigmentation
- Redness
- Pain, itch

- Qs 1064 nm, 532, IPL, Pico
- Excimer 308 nm
- Pulsed dye
- Pulsed dye+ Nd Yag

Tissue surface

- Proliferation-hypertrophic
- atrophic

- LLLT
- Fractional ablative and non ablative, Pico (LIOB)

Efficacy and safety of microneedling radiofrequency with an advanced cooling system in treatment on rosacea

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Introduction & Objectives

Rosacea is a chronic inflammatory disorder characterized by telangiectasia, erythema, papules, and pustules on the central face. Rosacea has been classified into the following four subtypes by the National Rosacea Society Expert Committee : erythematotelangiectatic rosacea (ETR), papulopustular rosacea (PPR), phymatous rosacea, and ocular rosacea. There are many treatment options for rosacea, including systemic antibiotics, topical agents, and laser-based therapies. The aim of this study was to investigate the impact of microneedling radiofrequency (MRF) with an advanced cooling system, an emerging treatment modality in dermatology, on the clinical improvement and safety in rosacea patients.

Materials & Methods

This study was performed as a 12-week, prospective clinical trial. Subjects with Fitzpatrick skin Types III or IV and who had mild to moderate rosacea were recruited. In total, 13 patients with ETR or PPR were enrolled in this study. The exclusion criteria were as follows: any previous treatment with topical ointment, oral medications, or laser treatment in the previous 2 months; history of inserting filler into the face or a metal device into the body; and pregnancy or lactation in women. All of the subjects provided written informed consent before participating in the study.

A topical anesthetic cream was applied under occlusion for 15 minutes before treatment and then infrared light was delivered to the face to increase blood flow. The FMR device (Virtue RF, ShenB, Korea) delivered radiofrequency energy to the skin with the applicator tip comprising 36 insulated microneedles that interating an advanced cooling system. The energy level (1–7) and conduction time (100–7,000 milliseconds) are adjustable. The treatment in this study was done at energy levels 3 to 4 for 1000 miliseconds, 0.5Hz, 10 pulses. The deep was set at 1.5-2mm. FMR treatment was performed with 30% overlap in 2 passes. Each patient received 3 sessions of treatment with a 4-week interval between treatments. Immediately after each treatment, postoperative care was managed with frozen gauze for 5 minutes before covering with a nonadherent topical dressing.

Outcome assessment was performed at baseline and Weeks 4, 8 and 12. Response to treatment was assessed by the rosacea severity score, physician's assessment, and subjective satisfaction evaluation. Standardized photographs were obtained at each visit using VISIA system. The response to treatment was objectively compared of clinical photographs taken before and after treatment.

1. Patients were asked to report any treatment side effects and pain scores using 10 visual analog scales (VASs) ranging from 0 (no pain) to 10 (extremely painful).
2. The rosacea severity score was evaluated by the physician based on the Investigator Global Assessment (IGA) Grading Scale. Scores from 0 to 4 (0, absent; 1, almost clear; 2, mild; 3, moderate and 4, severe) was calculated. Severity scores were measured before and after the 3 treatment sessions at week 0, 4, 8, 12.
3. Therapeutic improvement was graded as follows: "poor" (0%–25% improvement), "fair" (26%–50% improvement), "good" (51%–75% improvement), or "excellent" (76%–100% improvement).
4. The patients were surveyed at Weeks 4, 8, and 12 on their degree of satisfaction as very satisfied, satisfied, slightly satisfied, or dissatisfied.

Results

- Thirteen patients (1 man and 12 women) were enrolled, and there was no dropout. The mean age of the subjects was 32.5 $\pm$ 10.3 years. All patients had Fitzpatrick skin Type IV. Five patients had ETR, and 8 had PPR. The duration of rosacea was 20.7 $\pm$ 14.2 months. Baseline severity of rosacea was mild in 7 patients and moderate in 6 patients.
- There was no serious adverse effect which caused discontinuation of the study. The treatments were extremely well tolerated by all patients; the mean VAS scores for pain were 2.1 $\pm$ 0.6; 1.6 $\pm$ 0.3; 1.5 $\pm$ 0.3 in the first, second and third treatment sessions. 13 (100%) patients had mild pain during the procedure. All patients experienced transient erythema and edema immediately after each treatment, which resolved within a few hours without special management. There were no noticeable adverse events such as pigmentation or scarring in either of the treated areas.
- Clinical improvement of rosacea was observed in 13 (100.0%) at week 4, 8, 12. The mean IGA scores were 2.3$\pm$1.16 at the baseline and 1.6 $\pm$0.97, 0.9 $\pm$0.8, and 0.6 $\pm$0.2 at Weeks 4, 8, and 12, respectively ($p = 0.001$, $p = 0.01$, $p = 0.02$).
- Erythematotelangiectatic lesions showed a significantly greater decrease after MRF treatment than papulopustular lesions during follow-up visits.
- 7/13, 9/13, 12/13 patients reported "satisfied" and "very satisfied" after 1, 2 and 3 sessions, respectively, showing that patients had high satisfaction to the MRF treatment.

Discussion

The underlying inflammation is regarded as an important factor in the pathogenesis of rosacea. It is expected that MFR could have effects on rosacea treatment by reducing inflammation and there were come reports evaluating the efficacy of MFR for the treatment of rosacea until now[2]. The facial symptom in patients with rosacea is a burning sensation on the skin. In this study, the temperature and complaints of patients with rosacea decreased after every RF irradiation. [2] The histologic and immunohistochemistry staining analysis showed a reduction of inflammation and angiogenesis after MFR[1,3]. Kim et al. found no significant difference between RF and PDL treatment in ETR and RF treatment had a significantly greater decrease in papulopustular lesion count and rosacea severity score in PPR compared with PDL treatment.[4] In our study, MRF with an advanced cooling system is an emerging treatment modality in dermatology that helps to optimize the outcomes by controlling and maintaining the temperature of the cooling plate to protect the epidermis and reduce the pain but also enables safer and more powerful energy delivery.

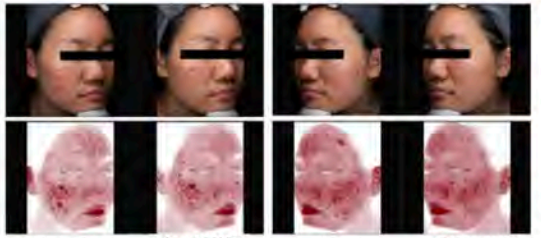

Figure 1: Clinical photographs showing improvement of papulopustular rosacea with significant decreased papules, pustules, telangiectasia and burning sensation.

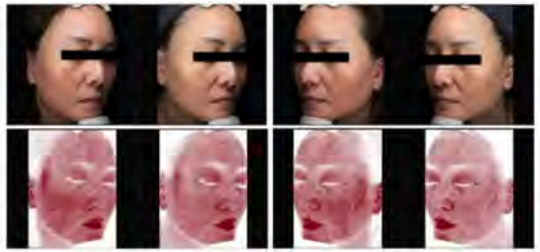

Figure 2: Clinical photographs showing improvement of erythematotelangiectatic rosacea with significant decreased telangiectasia.

Conclusion

MRF with an advanced cooling system resulted in good clinical improvement of rosacea with minimal side effects. Therefore, we suggest that MRF with an advanced cooling system may be a good alternative therapeutic option in mild to moderate rosacea.

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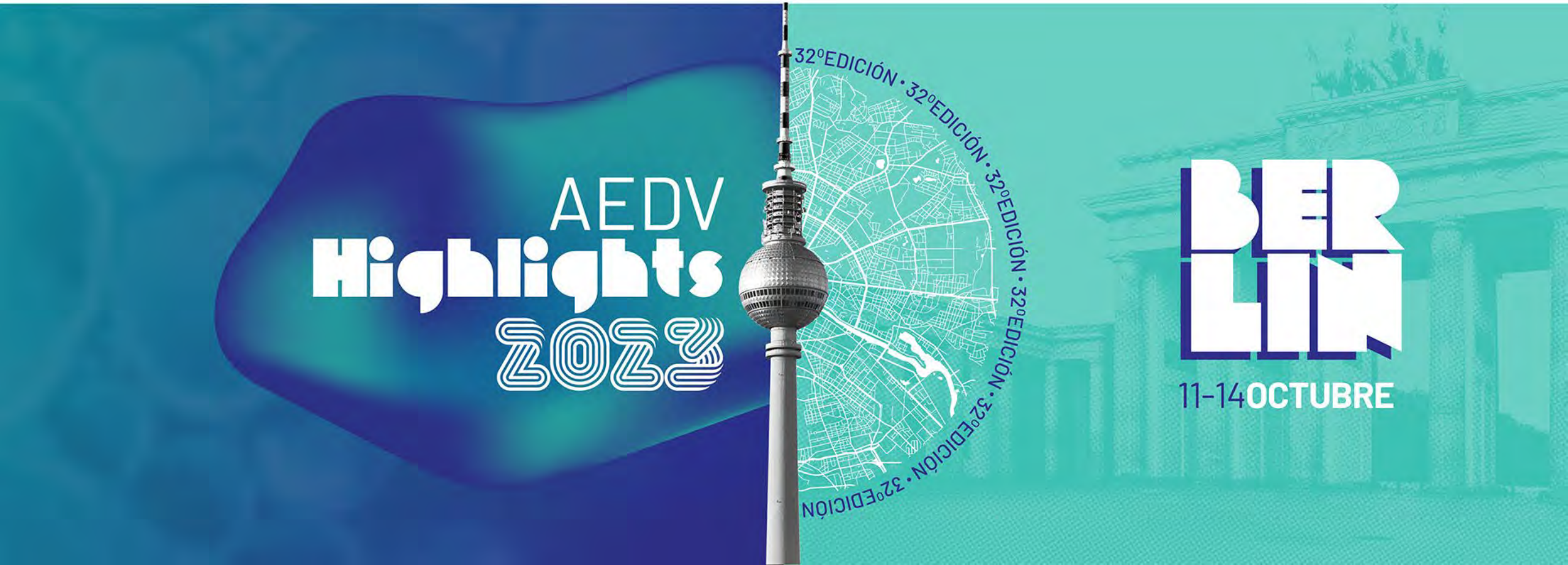

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