What's Hot and Happening in the Cosmetics World

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TRANSFORMATIVE DERMATOLOGY BY Jill C. Fichtel MD

Conflicts of Interest / Disclosures

Viveve, Evolus, Prollenium, Alma, BTL, Omni, Prescribers Choice, Ortho, Aerolase, Strathspey Crown, Alphaeon

Neurotoxin Update

TRANSFORMATIVE DERMATOLOGY
BY Jill C. Fichtel MD

Jeuveau™

Just another botulinum toxin?

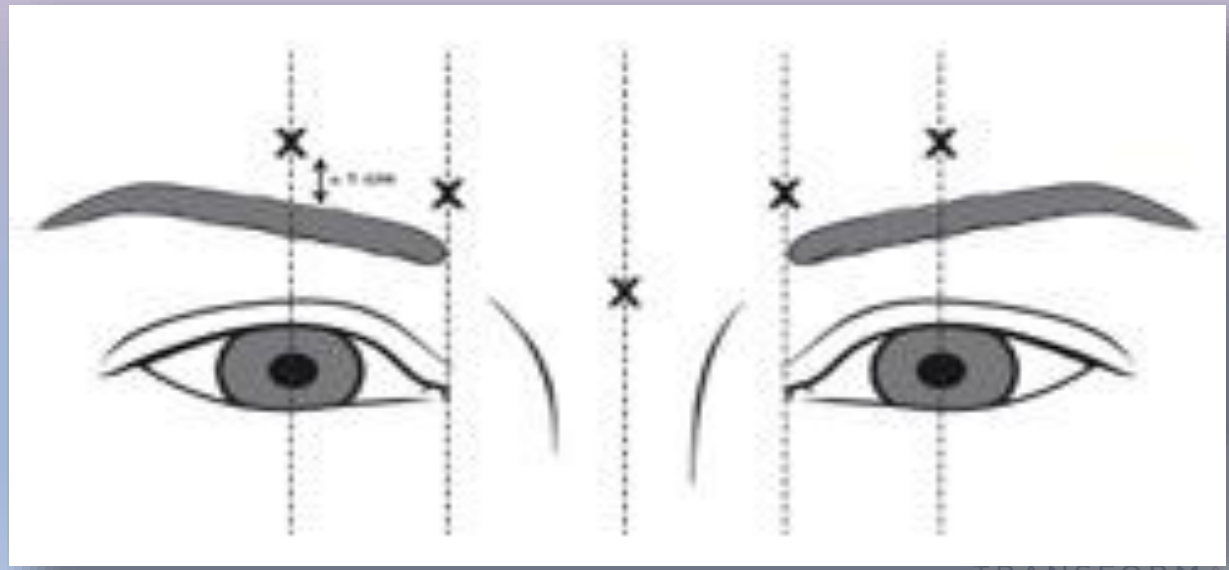
TRANSFORMATIVE DERMATOLOGY
BY Jill C. Fichtel MD

PrabotulinumtoxinA-xvfs for injection

INDICATIONS AND USAGE

- PrabotulinumtoxinA-xvfs is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for the **temporary improvement in the appearance of moderate to severe glabellar lines** associated with corrugator and/or procerus muscle activity in adult patients[1]

- 2.5 mL diluent added to 100U vial[2]
- 20 unit dose[2]
- 5 point injection pattern[2]



1. Jeuveau Package Insert Section 1.1
2. Jeuveau Package insert Section 2

PrabotulinumtoxinA-xvfs

Starting Ingredients[1,2]

Source Organism	*C. botulinum* producing A1 botulinum toxin
Active Ingredient	Botulinum toxin type A1 900kDa, full complex

Excipients

		Jeuveau™
Role	**Material**	**Content (per vial)**
Stabilizing Agent[1]	Human Serum Albumin, HSA	0.5 mg
Isotonic Agent[1]	Sodium Chloride, NaCl	0.9 mg
Active[1]	C. Botulinum Toxin Type A	100 units

1. Jeuveau Package Insert Section 2.2. Section 11
2. United States Patent : US 9,512,418 B2 Dec.6, 2016

PrabotulinumtoxinA-xvfs for injection

>2,100 Patients Across Five Clinical Trials

Phase III Studies
Single Treatment, 5 Month Studies

- US EV-001 and EV-002
  - Two identical Phase III studies
  - N= 330 EV-001, N= 324 EV-002
  - Superiority to placebo
  - Vacuum dried formulation
- Europe / Canada EVB-003
  - EVB-003
  - N=540
  - Non-Inferiority to onabotulinumtoxinA
  - Superiority to placebo
  - Vacuum dried formulation

Phase II Studies
Repeat Treatment, 1 Year Studies

- US EV-004
  - Open-label, repeat-tx, safety
  - N= 352
  - Freeze dried formulation
- US EV-006
  - Open-label, repeat-tx, safety
  - N=570 formulation
  - Vacuum dried formulation

Data on file CSR's EV-001, EV-002, EVB-003, EV-004 EV-006

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PrabotulinumtoxinA-xvfs
Europe and Canada Phase III Trial

AESTHETIC SURGERY JOURNAL

THE AMERICAN SOCIETY FOR AESTHETIC PLASTIC SURGERY

ACCEPTED MANUSCRIPT

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Single-Dose, Phase III, Non-Inferiority Study Comparing PrabotulinumtoxinA and OnabotulinumtoxinA for the Treatment of Moderate to Severe Glabellar Lines in Adult Subjects

Berthold-Josef Rzany, MD, ScM ✉, Benjamin Ascher, MD, Rui L Avelar, MD, Jesper Bergdahl, MD, Vince Bertucci, MD, Isaac Bodokh, MD, James Alastair Carruthers, MD, Hugues Cartier, MD, Henry Delmar, MD, Ralf Denfeld, MD, John E Gross, MD, FACS, Marc Heckmann, MD, Per Hedén, MD, Said Hilton, MD, Christopher Inglefield, MD, Patricia Ogilvie, MD, Gerhard Sattler, MD, Michael Sebastian, MD, Nowell Solish, MD, Arthur Swift, MD, Patrick Trévidic, MD

Aesthetic Surgery Journal, sjz110, https://doi.org/10.1093/asj/sjz110

Published: 05 April 2019 **Article history** ▾

Europe and Canada Phase III Trial

Glabellar Line Study Design

Study Design

Multi-center, blinded, randomized, single dose study
N = 540,
Randomized 5:5:1 (Prabot:Onabot:Placebo)

Study Population

Subjects ≥18 years of age
Moderate (GLS=2) to severe (GLS=3)
Glabellar lines had an important psychological impact (on mood, anxiety and/or depressive symptoms)

Primary Endpoint

GLS= 0 or 1 at Day 30 by Investigator Assessment
Non-inferiority

Rzany *et al*., (2019) *Aesthetic Surgery Journal*

Glabellar Line Scale Maximum Frown

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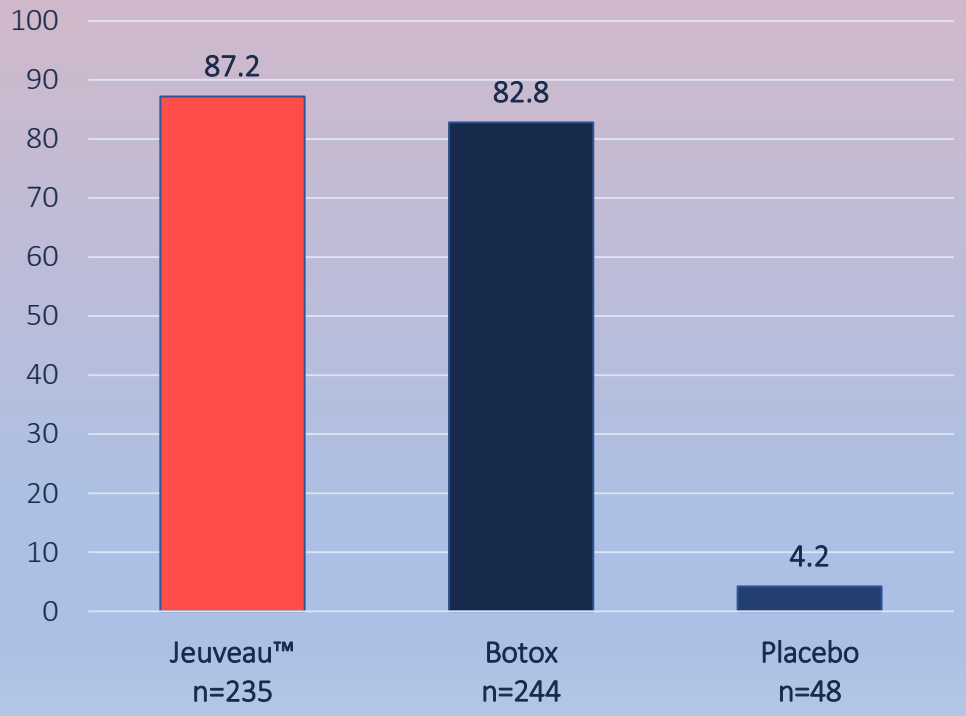
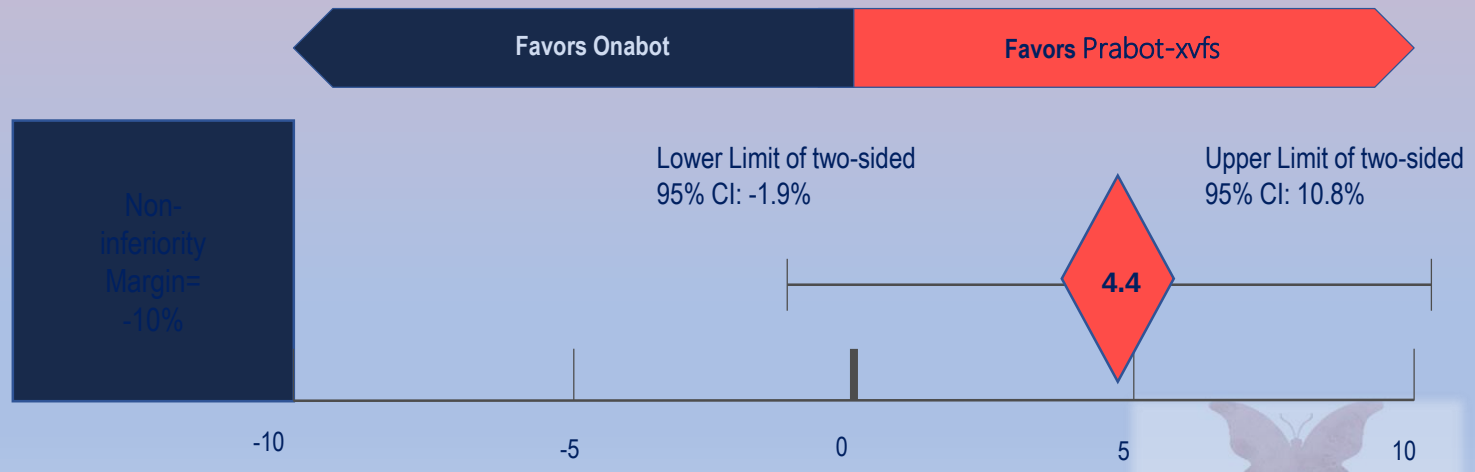
Europe and Canada Phase III Trial

Primary Endpoint: Non-inferiority Met

Primary Endpoint
Responder Rate Day 30
GLS = 0 or 1 at Maximum Frown Investigator Assessment



- Difference between groups: 4.4%
- Lower limit of one-sided 97.5% CI: -1.9%
- Non-inferiority margin: - 10%



Rzany *et al*., (2019) *Aesthetic Surgery Journal*

Europe and Canada Phase III Trial

Secondary Endpoints

≥1 Improvement GLS at Maximum Frown
Investigator Assessment

	Placebo	Onabot	Prabot-xvfs
Day 2	12.20%	57.00%	54.2%*

	Placebo	Onabot	Prabot-xvfs
Day 150	8.30%	34.40%	37.7%*

Subject Satisfaction
≥1 Improvement Subject Satisfaction

	Placebo	Onabot	Prabot-xvfs
Day 30	6.30%	86.60%	91.3%*

Source: Data on file (CSR EVB-003, pg 6)

*P-Value Placebo vs DWP-450 <0.001

Europe and Canada Phase III Trial

Secondary Endpoints

- HADS, Hospital Anxiety Depression Scale
  - Developed to detect states of depression, anxiety and emotional distress
    - Scale has 7 depression questions and 7 anxiety questions

Hospital Anxiety and Depression Scale DWP-450 vs Baseline Score at Day 90

	Anxiety			Depression		
HADS, All (Day 90)	Placebo	Onabot	Prabot	Placebo	Onabot	Prabot
Mean Change ±SD	–0.9	–0.9	–1.1	–0.5	–0.6	–0.6
P-Value vs baseline	<0.013	<0.001	<0.001	<0.071	<0.001	<0.001

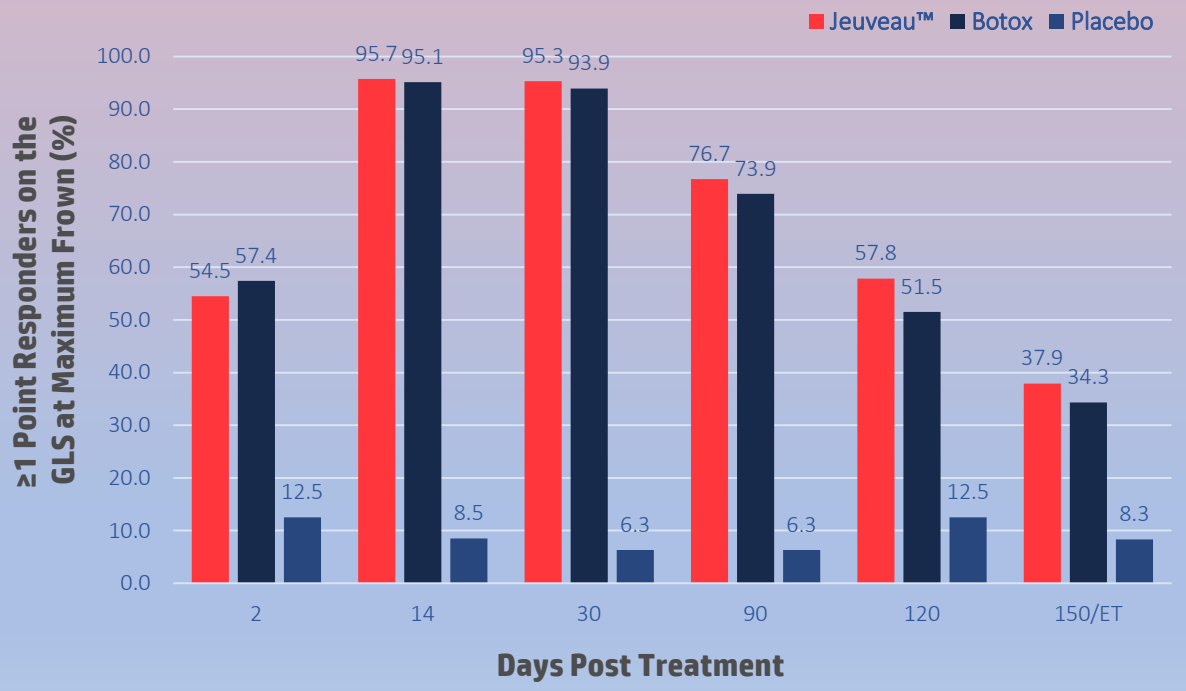
Europe and Canada Phase III Trial

Exploratory Endpoint

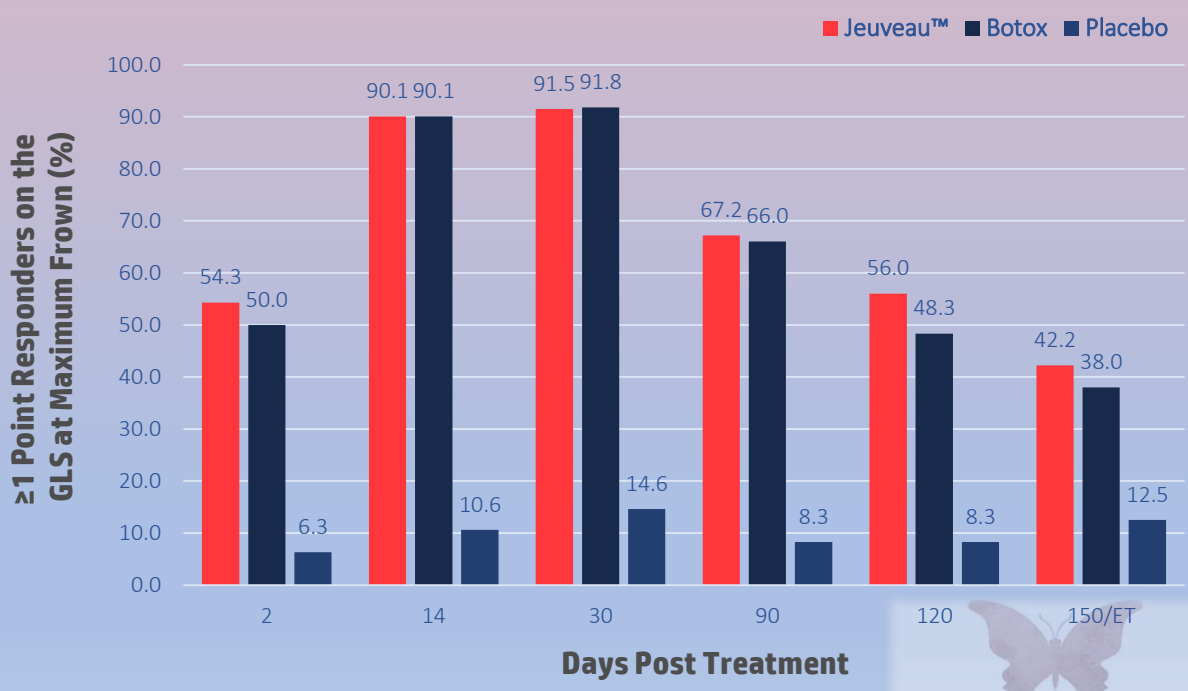
Prabot-xvfs **vs Onabot**

≥1 Pt Improvement of GLS at Maximum Frown

Investigator Assessment



Subject Assessment

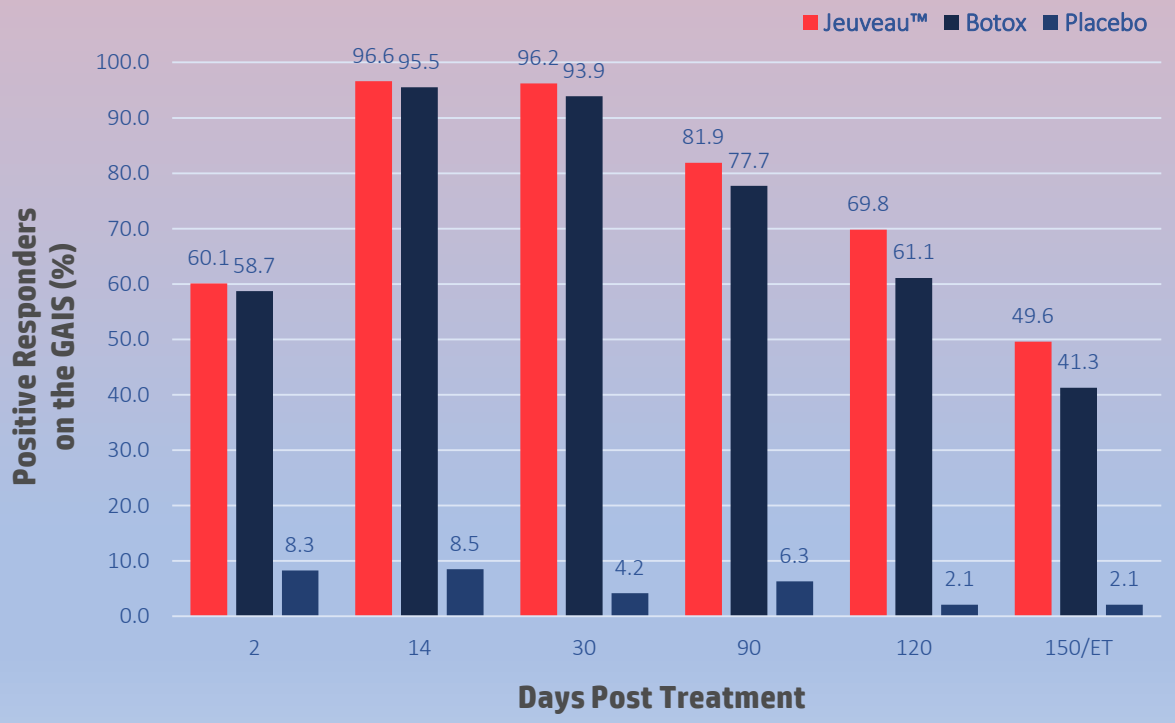


Europe and Canada Phase III Trial

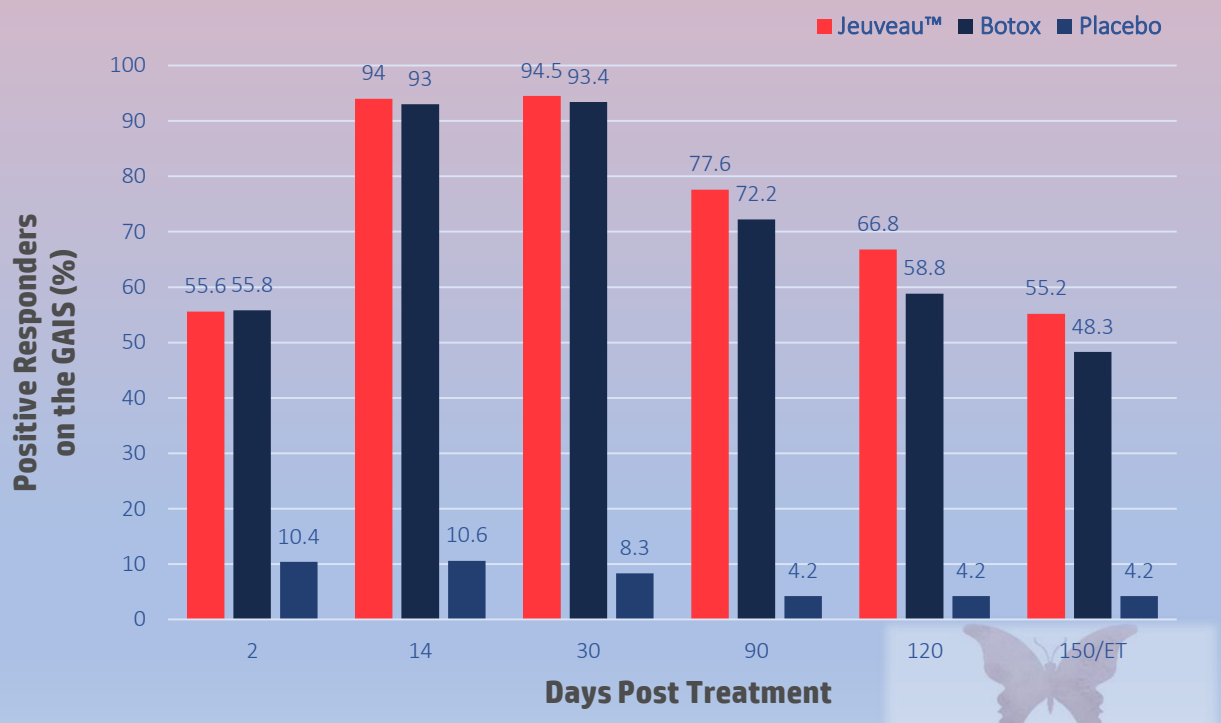
Exploratory Endpoint

Prabot-xvfs **vs Onabot**
Global Aesthetic Improvement Scale

Investigator Assessment



Subject Assessment

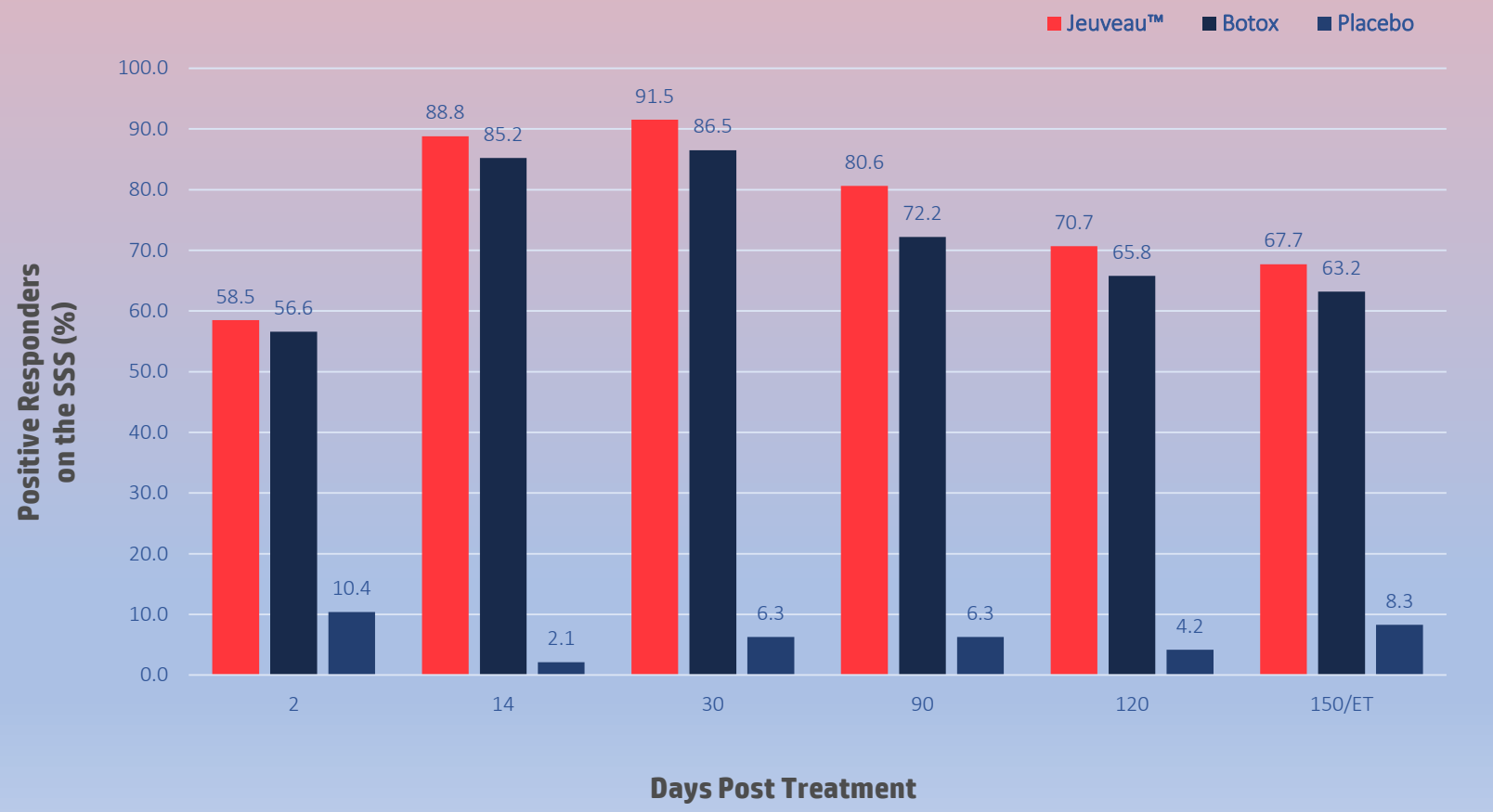


Europe and Canada Phase III Trial

Exploratory Endpoint

Prabot-xvfs **vs Onabot**

Subject Satisfaction



Source: Data on file (CSR EVB-003, pg 89)

PrabotulinumtoxinA EU/CA Phase III Trial

No Drug Related Serious Adverse Events

Adverse Event Parameter	Prabot (N=245)			Onabot (N=246)			Placebo (N=49)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events
Any AEs	92	(37.6)	152	103	(41.9)	165	16	(32.7)	27
Incidence diff., % (95% CI)		4.3 (-13.3, 4.4)							
Any serious AE	3	(1.2)	6	1	(0.4)	2	1	(2.0)	3
Any study drug-related AE	38	(15.5)	46	36	(14.6)	45	2	(4.1)	2
Any study drug-related AE of special interest	5	(2.0)	5	3	(1.2)	3	0	(0.0)	0
Any AE leading to study discontinuation	0	(0.0)	0	1	(0.4)	1	0	(0.0)	0
Any AE leading to death	0	(0.0)	0	0	(0.0)	0	0	(0.0)	0
Any AE with frequency ≥ 5%	52	(21.2)	59	48	(19.5)	54	9	(18.4)	12
Nervous system disorder, headache	34	(13.9)	38	25	(10.2)	26	7	(14.3)	10
Incidence diff., % (95% CI)		3.7 (-5.2, 12.5)							
Infections and infestations, nasopharyngitis	21	(8.6)	21	28	(11.4)	28	2	(4.1)	2
Incidence diff., % (95% CI)		-2.8 (-11.7, 6.0)							

Source: Data on file (CSR EVB-003 p 112, 114, 116)

PrabotulinumtoxinA EU/CA Phase III Trial

Summary of Adverse Events Occurring with a Frequency of ≥1% in Either the Prabot or Onabot Groups (Safety Population)

System organ class and preferred term	Prabot (N=245)		Onabot (N=246)		Placebo (N=49)	
	n	(%)	n	(%)	n	(%)
Nervous system disorders						
Headache	34	(13.9)	25	(10.2)	7	(14.3)
Muscle tone disorder	3	(1.2)	1	(0.4)	0	(0.0)
Infections and infestations						
Bronchitis	1	(0.4)	3	(1.2)	0	(0.0)
Influenza	3	(1.2)	5	(2.0)	0	(0.0)
Nasopharyngitis	21	(8.6)	28	(11.4)	2	(4.1)
Oral herpes	3	(1.2)	4	(1.6)	0	(0.0)
Sinusitis	3	(1.2)	1	(0.4)	1	(2.0)
Eye disorders						
Eyelid ptosis	4	(1.6)	0	(0.0)	0	(0.0)
Eyelid sensory disorder	0	(0.0)	4	(1.6)	0	(0.0)
General disorders and administration site conditions						
Pyrexia	1	(0.4)	3	(1.2)	0	(0.0)
Respiratory, thoracic, and mediastinal disorders						
Cough	1	(0.4)	3	(1.2)	0	(0.0)
Oropharyngeal pain	3	(1.2)	4	(1.6)	1	(2.0)
Injury, poisoning, and procedural complications						
Contusion	0	(0.0)	3	(1.2)	0	(0.0)
Procedural headache	3	(1.2)	2	(0.8)	0	(0.0)
Vascular disorders						
Hypertension	1	(0.4)	4	(1.6)	1	(2.0)

Source: Data on file (CSR EVB-003 p 112, 114, 116)

Europe and Canada Phase III Trial

Safety

Safety Profile: Adverse Events

EVB-003			
	Placebo	Onabot	Prabot-xvfs
All	32.7%	41.9%	37.6%
Related	4.1%	14.6%	15.5%

Serious Adverse Events (SAE's)

Drug Related

- None

Other AE's of Interest

Ptosis (related)

- Eyelid – Prabot-xvfs 1.6%, Onabot 0%
- Eyebrow – Prabot-xvfs 0%, Onabot 0.4%

Most Common **AEs (≥5%)**

- Headache
  (14.3% Placebo, 10.2% Onabot, 13.9% Prabot-xvfs)
- Nasopharyngitis
  (4.1% Placebo, 11.4% Onabot, 8.6% Prabot-xvfs)

Rzany *et al*., (2019) *Aesthetic Surgery Journal*

Early Experience with PrabotulinumtoxinA

- J.E.T. Program Survey
  - Over 28,000 consumers completing surveys after treatment:
    - Approximately 25% were toxin naïve
  - High rates of satisfaction at day 90
    - High willingness to recommend it to a friend

My Early Experience with Probat

- Treated my first patient approximately 4 months ago
- Have treated around 50 patients so far
- Initial Impressions:
  - “Kicks In” in around 48-72 hours
  - Seems to start working consistently in all areas
  - When near the minimum necessary dose for the frontalis, seems to be a “Peak, dip and plateau” (Sharon Stokes, FAAD – Orlando, Fl)

Frontalis Considerations

- NO ‘cookie cutter’ approach, regardless of which toxin used
  - Highly variable anatomy that changes over time, leading to changes in placement needs
  - Dose range can vary by 10x, from as little as 3 units to as much as 30
  - Patient may want some movement vs lots vs none
    - “Trade off” of softening line above brow vs more movement of brow
  - Recruiting frontalis to elevate eyelids
  - Thickening of dermis and depth of injection
  - Physical activity
  - Product variability from lot to lot
  - Wash out

Probat in Frontalis

- For a patient having frontalis treated with Probat for the first time:
  - Inject using same technique and dosing you would have used for Ona
  - Recheck/touch-up in two weeks
    - This is my standard protocol after any frontalis treatment
  - Recheck again in 4 weeks after that (6 weeks after initial injection)

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Off Label / Advanced Use of Neurotoxins

- Upper face
  - Correct ‘heavy’ brow
    - Whether natural or toxin induced
    - Whether medial brow or arches of brow
  - Widening of ocular aperture to equalize asymmetry or make the eyes appear larger
  - Bunny lines

Off Label / Advanced Use of Neurotoxins

- Lower face
  - Nasal sling
  - Gummy smile, uneven smile
  - Lip lines (lip flip)
  - DAO lines
  - Prominent mentalis (peau d’orange)
  - Trigeminal neuralgia
  - TMJ
  - Facial shaping, masseter hypertrophy

Off Label / Advanced Use of Neurotoxins

- Neck
  - Nefertiti neck lift
  - Neck bands (medial and lateral)

Filler Update

TRANSFORMATIVE DERMATOLOGY
BY Jill C. Fichtel MD

versa™

Just another cross-linked HA filler?

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BY Jill C. Fichtel MD

PRODUCT CHARACTERISTICS

- Versa ™ is composed of BDDE-cross-linked HA gel, milled and combined with 10% unmodified HA, then dialyzed against PBS (phosphate buffered saline), filled in 1-ml syringes, and terminally-sterilized in an autoclave by moist heat
- The particles are uniquely spherical and uniform, providing a balance between smoothness and volume
- 25mg/mL of HA
- 7% cross linking (Juvederm® Ultra Plus 11%, Restylane® 1.2%)
- Versa™ is a homogenous filler due to an advanced wet milling technology and proprietary formula
- Revanesse® Versa™ is designed to be balanced with the water content of natural skin tissue
- The product doesn't release or absorb surrounding water

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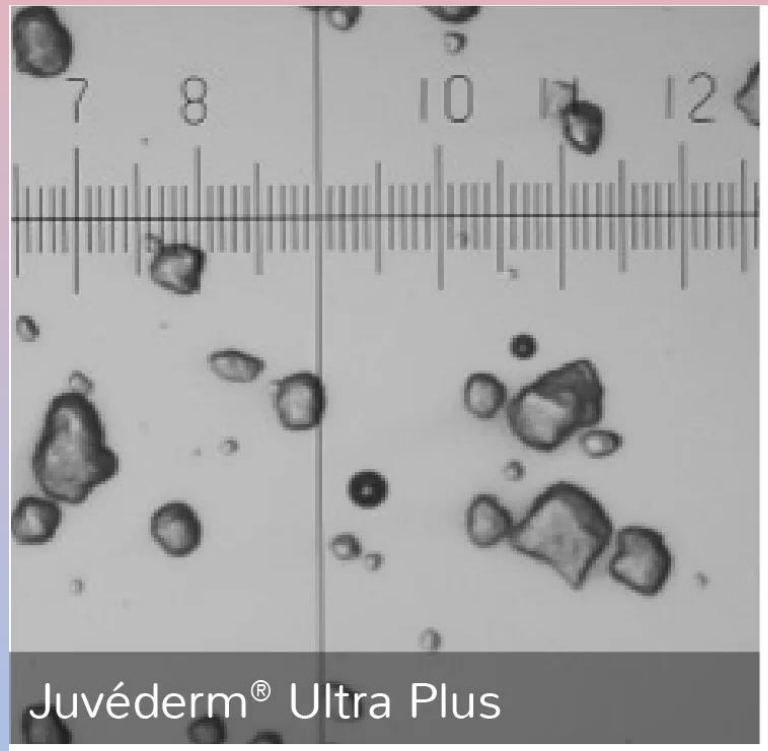
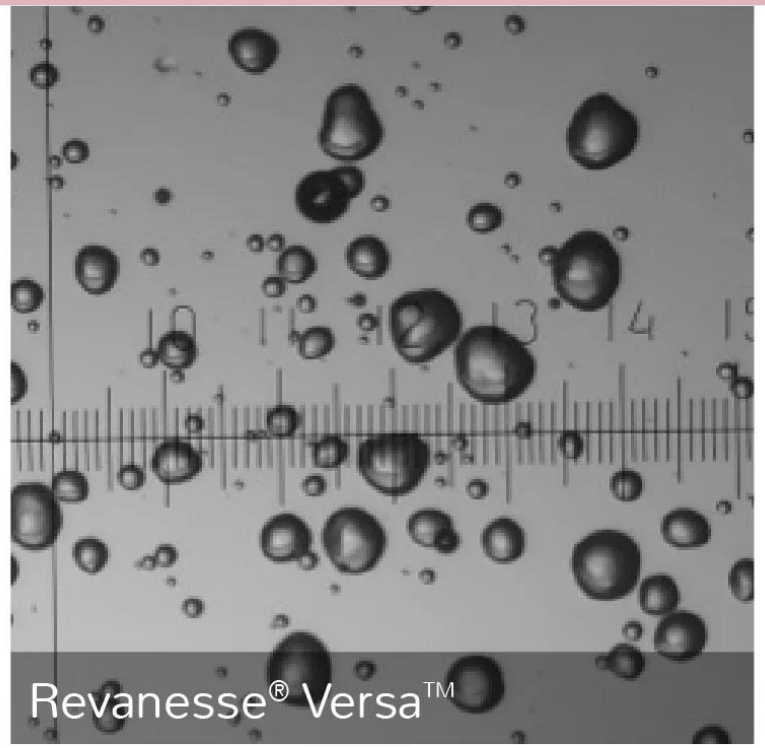
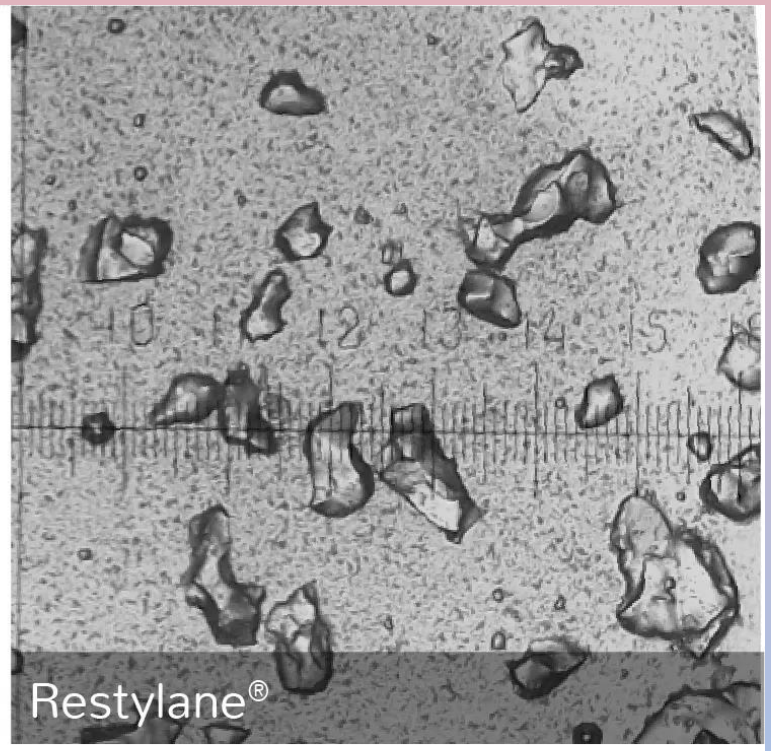
GEL PARTICLE SHAPE







Juvéderm® Ultra Plus is a registered trademark of Allergan. Revanesse® Versa™ is a registered trademark of Prollenium Medical Technologies Inc. Restylane® is a registered trademark of Galderma Laboratories, L.P.

RESTYLANE® PARTICLE

- The particles in Restylane® have a different character than those of Revanesse® Versa™ and Juvederm® Ultra Plus
- The particles are more irregular, and elongated, and appear 'harder' with sharper edges
- This may be a result of the proprietary 'double' cross-linking process used by Q-med, which is intended to produce a degree of 'physical' cross-linking
- This is supported by higher values of the storage modulus, G' seen with this filler

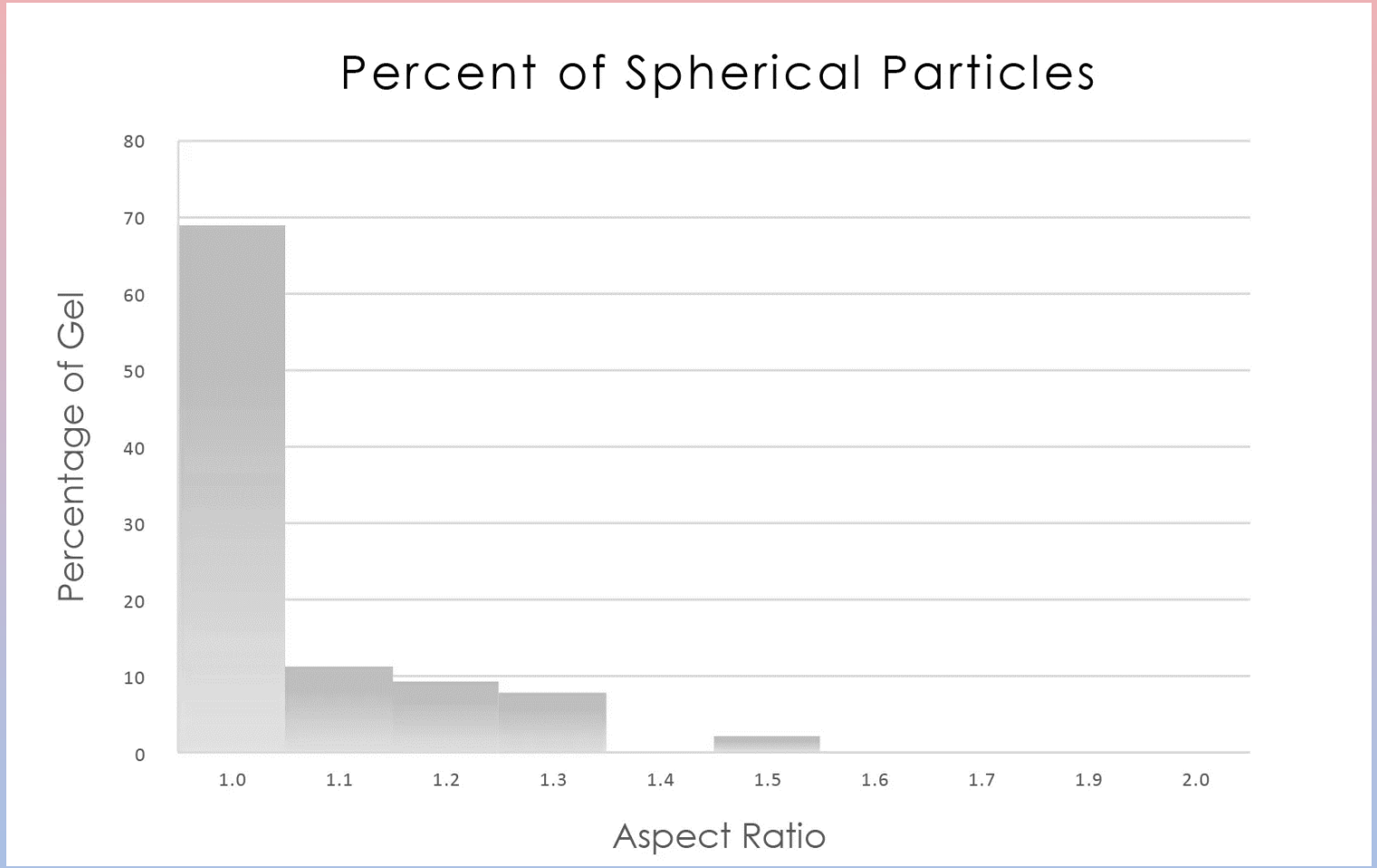
BDDE Cross-linked Hyaluronan Dermal Fillers Comparison of Commercial Products Update Report RD045

JUVEDERM® PARTICLE

- The particles in Revanesse® Versa™ and Juvederm® Ultra Plus are similar
- Approximately the same size
- Revanesse® particle is more round and spherical

BDDE Cross-linked Hyaluronan Dermal Fillers Comparison of Commercial Products Update Report RD045

SPHERICAL PARTICLE



The aspect ratio measures how spherical a particle is. To be a perfect sphere, the length and width of the particle should match. Following this method, the aspect ratio of a perfect sphere is 1.0. The batch of Revanesse® VersaTM tested for this study was composed of over 68% perfectly spherical particles.

BDDE Cross-linked Hyaluronan Dermal Fillers Comparison of Commercial Products Update Report RD045

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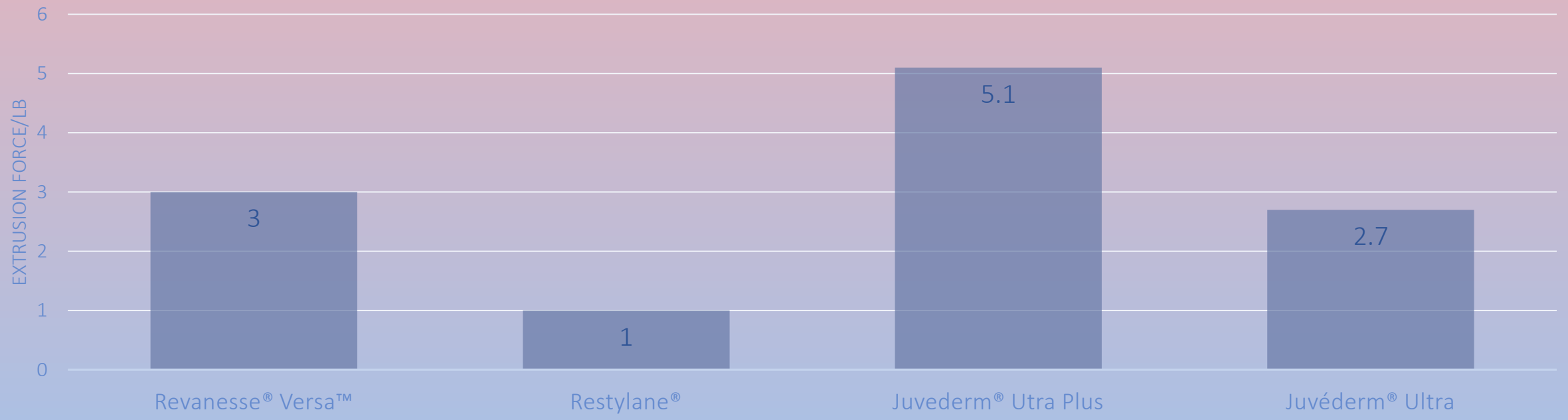
GEL PROPERTIES

EXTRUSION FORCE



BDDE Cross-linked Hyaluronan Dermal Fillers Comparison of Commercial Products Update Report RD045

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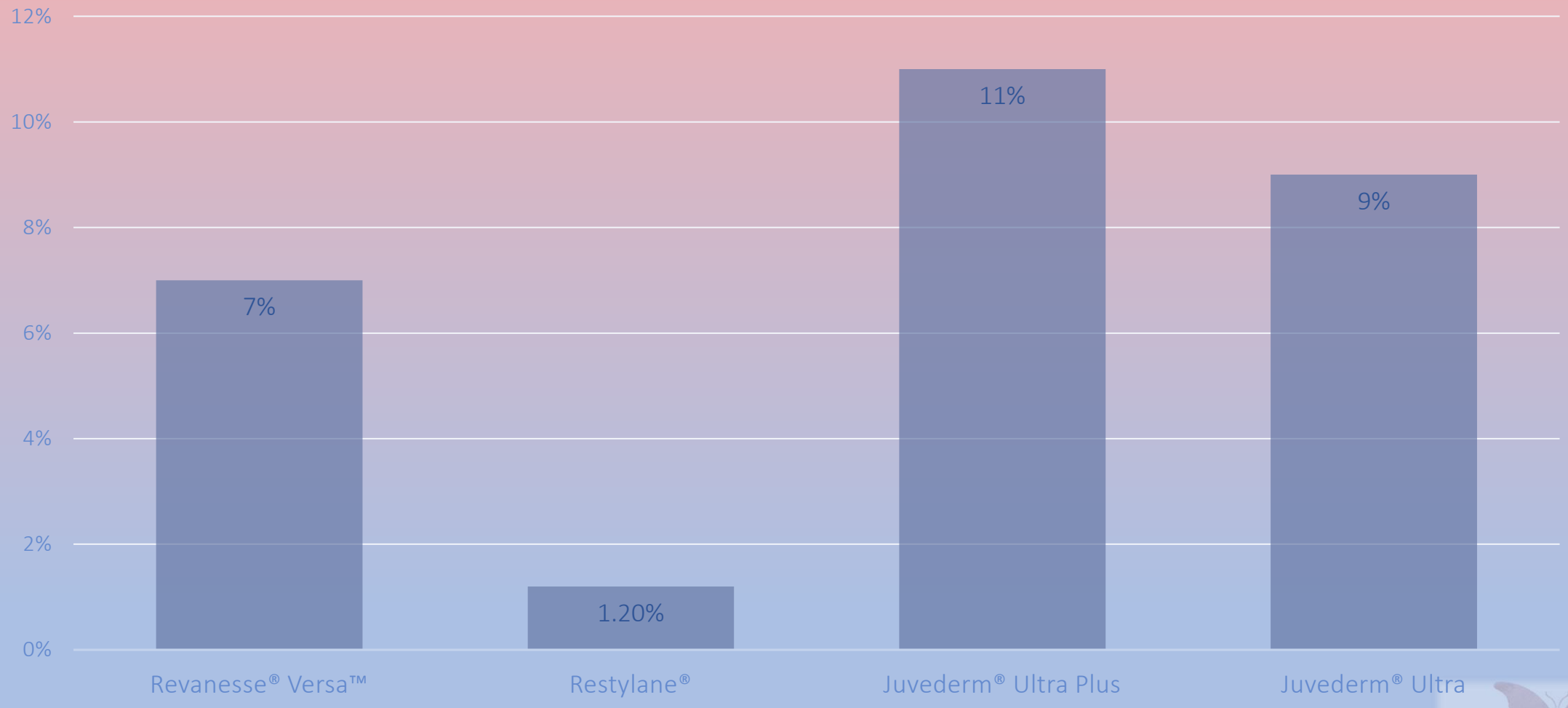
DEGREE OF CROSSLINKING

- The most important effect of cross-linking is to increase the durability of the filler
- It also has an effect on the degree to which the filler absorbs water after implantation
- Excessive cross-linking can lead to a hard implant with an unacceptable incidence of adverse reactions
- The most basic parameter describing the degree of cross-linking is the overall concentration of BDDE link molecules per disaccharide unit of HA in the gel
- The advanced crosslinking process is designed to promote links between different ha polymer chains and to minimize less effective links on parts of the same chain *

* M.H. Gold, Stafford Baumann, C.P. Clark III, J. Schlessinger

PERCENTAGE CROSS-LINKING



M.H. Gold, Stafford Baumann, C.P. Clark III, J. Schlessinger

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US PIVOTAL STUDY

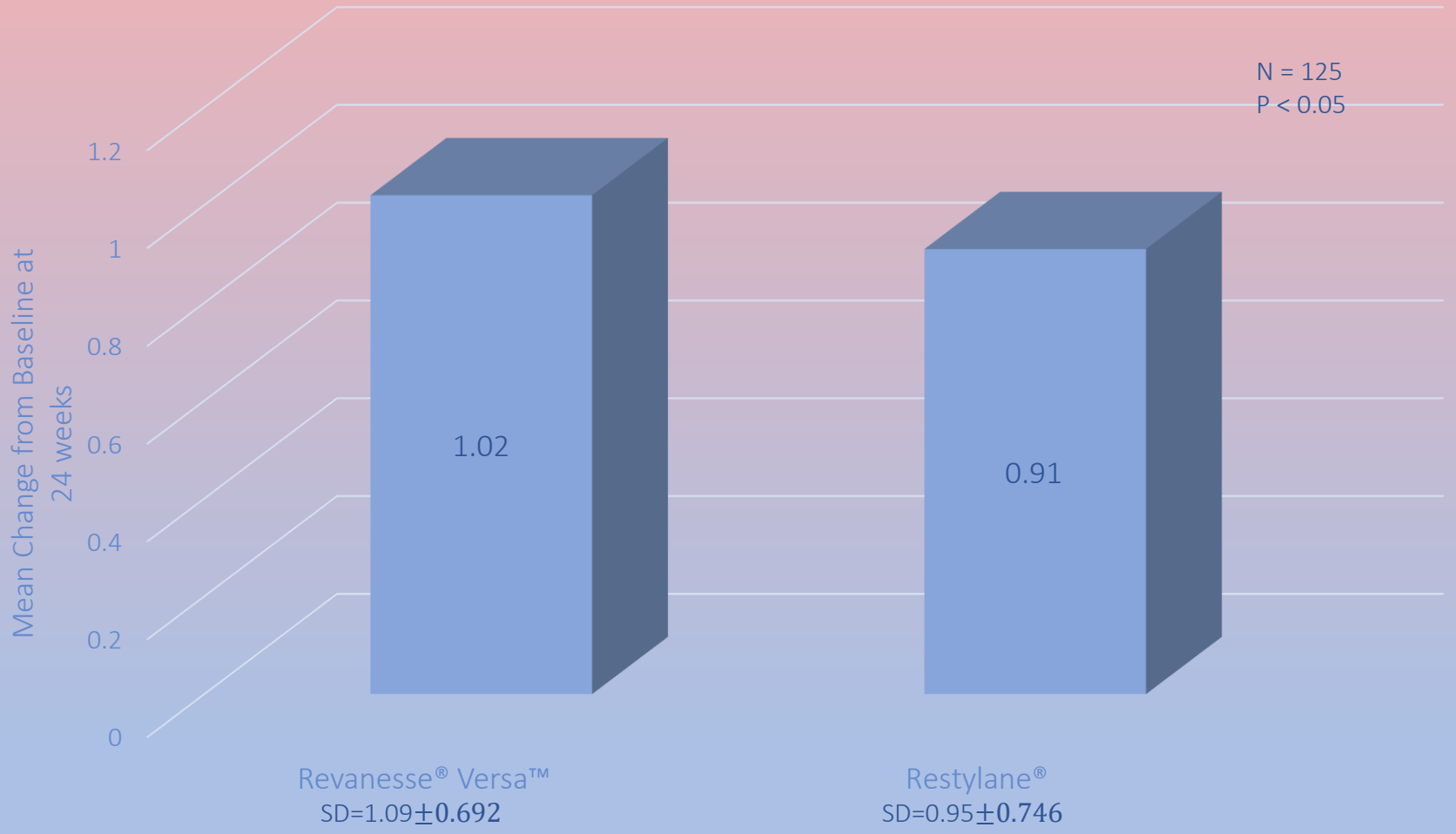
background

- Designed as a non-inferiority study vs Restylane®
- Set up to reveal the safety profile of Revanesse® Versa™
- The FDA defined the primary endpoint of 24 weeks

STUDY DESIGN

- Qualified subjects had NLFs with a wrinkle severity rating scale (WSRS) score of 3 or 4 (moderate or severe)
- NLFs were treated with Versa™ on one side of the face and Restylane® on the other side
- Side of the face for each product was randomly assigned
- Evaluating investigator and subject were blinded and injections were performed by unblinded physician
- Maximum of 2mL per fold
- All initial treatments were administered at baseline in addition to WSRS, evaluations included the global aesthetic improvement scale (GAI) of the investigator and the patients as well as adverse events recorded in a diary of each subject
- Based on use of photographs, the WSRS is designed to quantify facial folds by visual assessment of the length and apparent depth of the fold without referring to baseline
- In contrast, the GAI scale is used to grade overall improvement in each fold by comparing its appearance at follow up against a high magnification photograph taken before treatment
- For subjects not requiring retreatment, the study period ended at week 24

PRIMARY EFFICACY ENDPOINT



Gold, M. A Multicenter, Double-Blinded, Randomized, Split-Face Study of the Safety and Efficacy of a Novel Hyaluronic Acid Gel For the Correction of Nasolabial Folds. Data on File.

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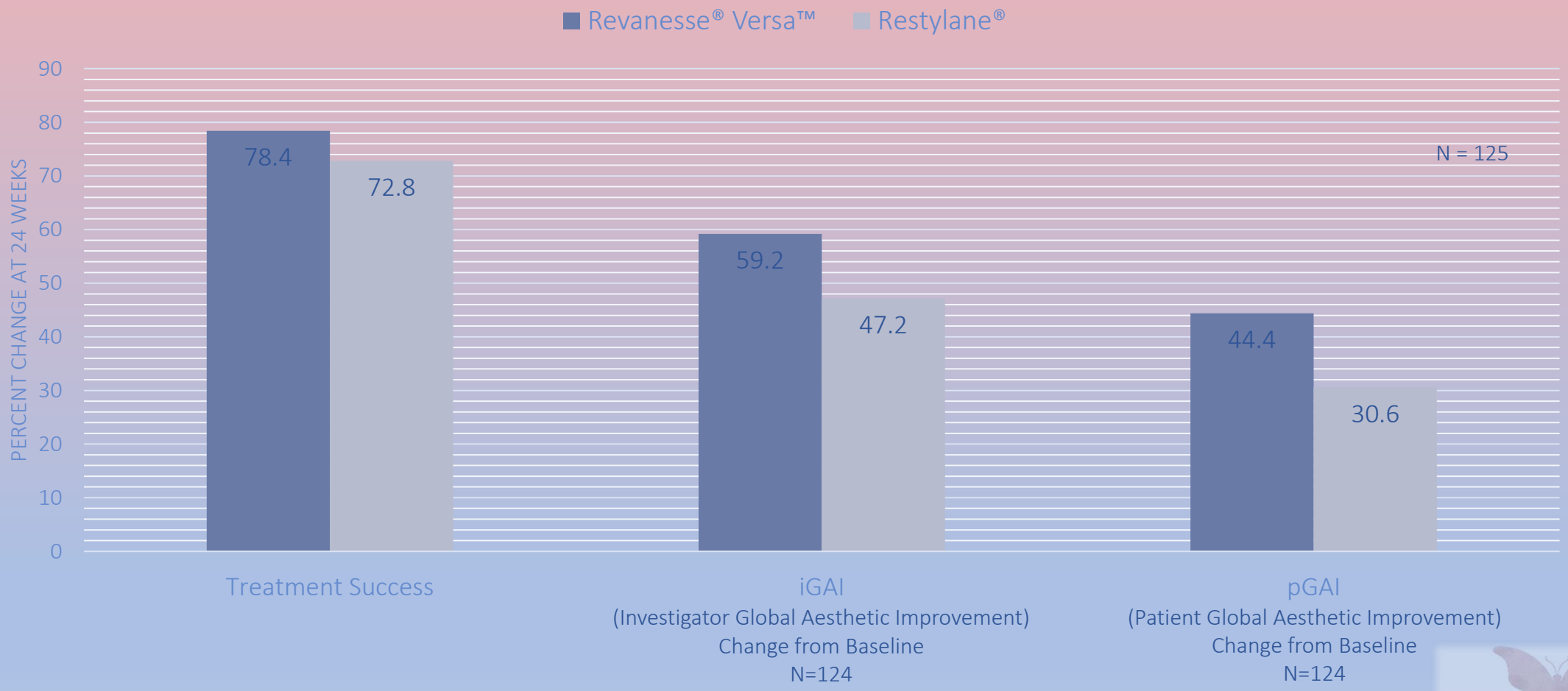
SECONDARY EFFICACY VARIABLES OF TREATMENT SUCCESS



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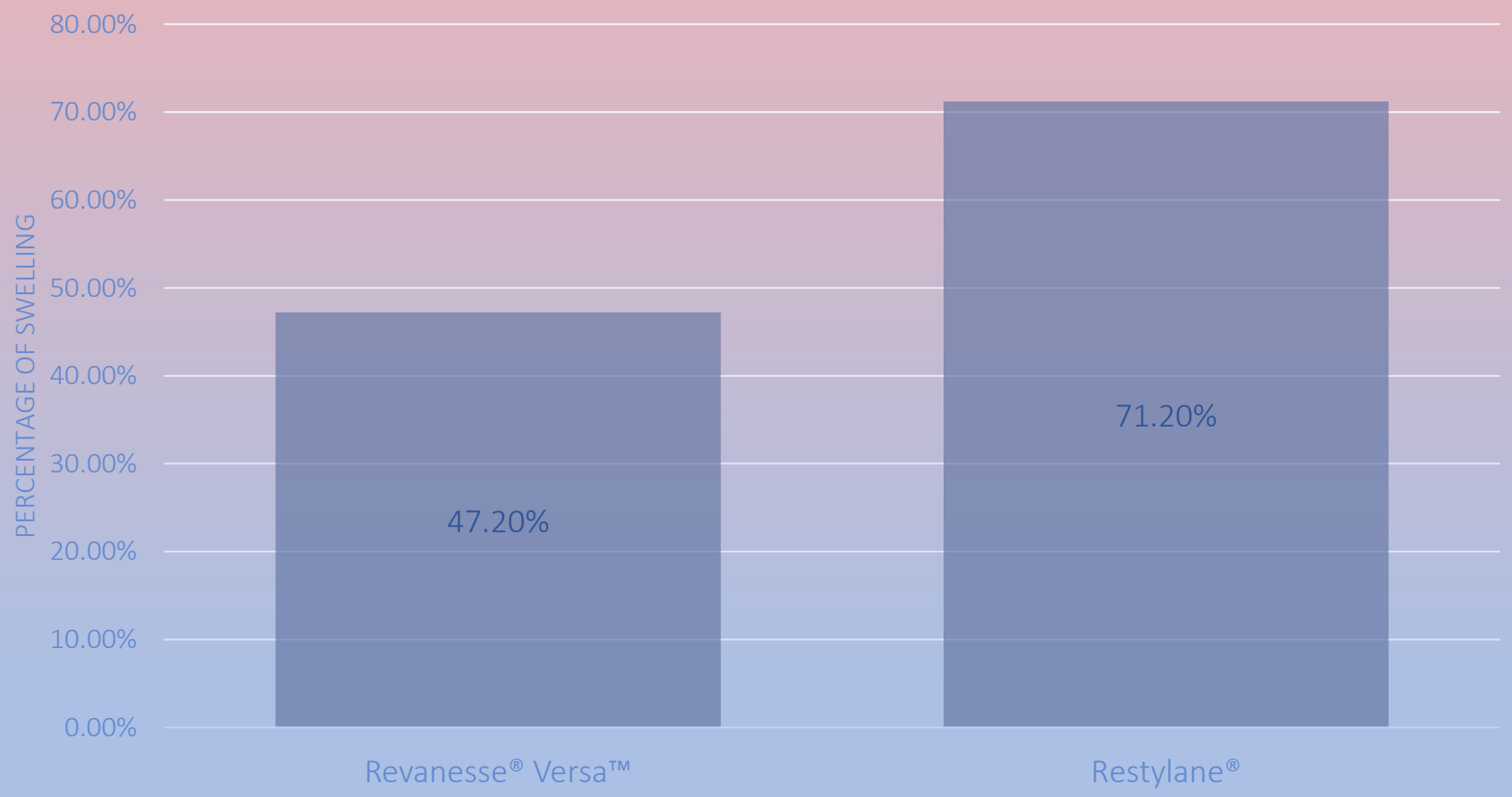
PERCENTAGE OF TEST PATIENTS REPORTED SWELLING



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SAFETY

Treatment-emergent adverse events

- No subjects discontinued the study due to AE
- TEAEs were reported for 69.9% of Revanesse® Versa ™ subjects vs. 84% of Restylane ® subjects
- Most common injection site TEAEs were:
  - Hematoma (50.3% versa ™ /47.2% Restylane ®)
  - Swelling (47.2% versa ™ /71.2% Restylane ®)
  - Pain (38% versa ™ /66.3% Restylane ®)
- Only 2 subjects reported non-injection site TEAEs (headache 3.1%, arthralgia 1.85)

Gold, M. A Multicenter, Double-Blinded, Randomized, Split-Face Study of the Safety and Efficacy of a Novel Hyaluronic Acid Gel For the Correction of Nasolabial Folds. Data on File.

Advanced Filler areas

- Forehead
- Ocular area
- Oral area
- Nose
- Jawline
- Chin

Body Sculpting Update

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BY Jill C. Fichtel MD

Muscle Sculpting Market Opportunity

1. Global Wellness Institute; 2. Zion market research, 2018; 3. IHS Market, 2017; 4. Ecovia Intelligence, 2019; 5. Center for automotive research, 2019; 6. Global Wellness Institute; 7. IPSOS, 2018; 8. FHE Health; 9. IHRSA, 2017; 10. American Journal of Preventive Medicine, 2018; 11. One Poll, 2019; 12. American College of Sports Medicine

TRANSFORMATIVE DERMATOLOGY
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- Trusculpt Flex
  - Electrical stimulation of muscle
- EmSculpt
  - Magnetic stimulation of muscle
- BeautyFill
  - Integrated Liposuction/Fat Transfer System

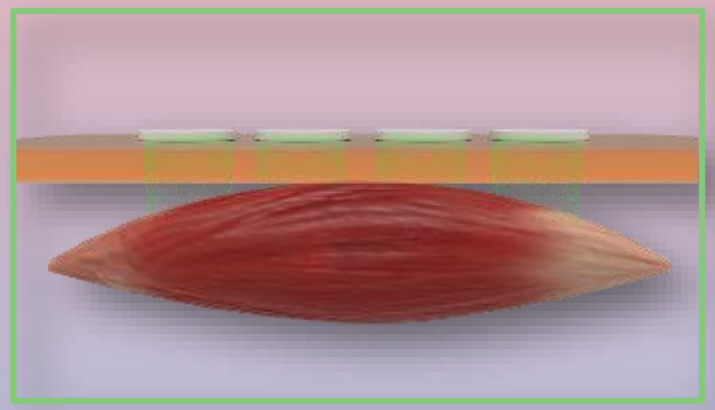
ELECTRICAL MUSCLE STIMULATION

Electrical muscle stimulation (EMS)

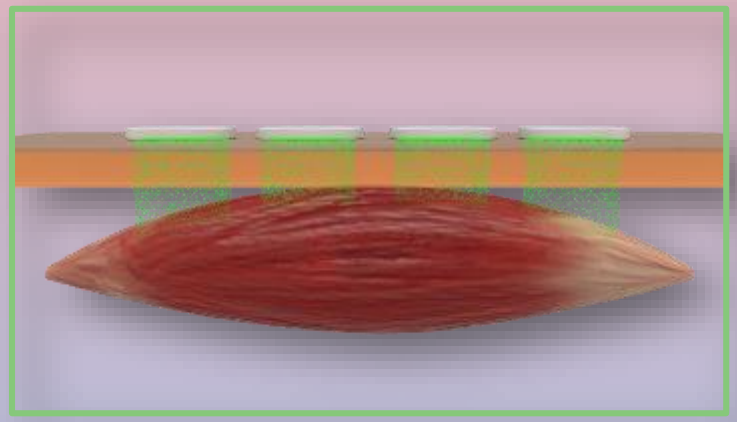
- Used for muscle strengthening in physiotherapy and sport science

- Limitations:
  - Electrical current finds the shortest path between the electrodes. Most of the energy concentrates in superficial layers, only part of it reaches the muscle.
  - Intensity is limited due to pain and risk of burns.

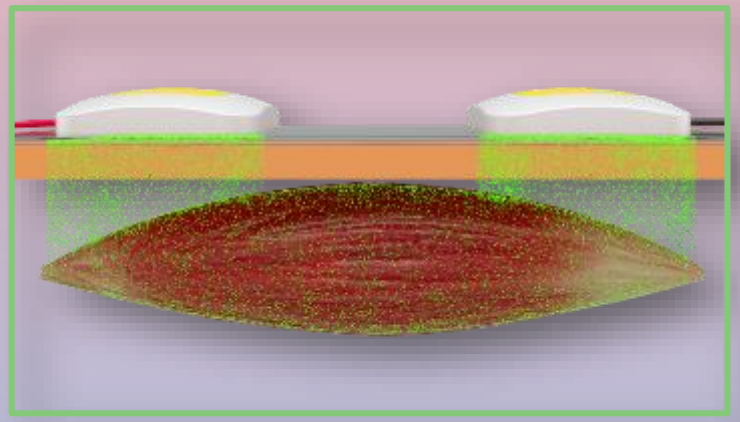
3 Main Categories of Bio-Electrical Muscle Stimulation



Transcutaneous Electrical Nerve Stimulation (TENS)



Traditional Electrical Muscle Stimulation (EMS)



truSculpt flex Multi-Directional Stimulation (MDS)

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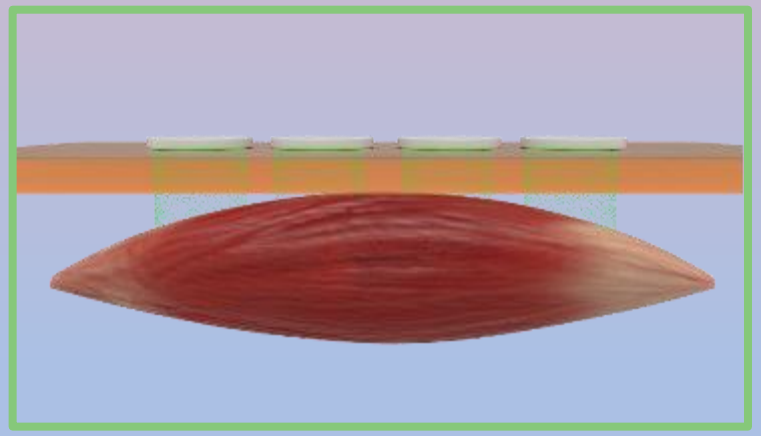
TENS Mechanism Of Action

Transcutaneous Electrical Nerve Stimulation

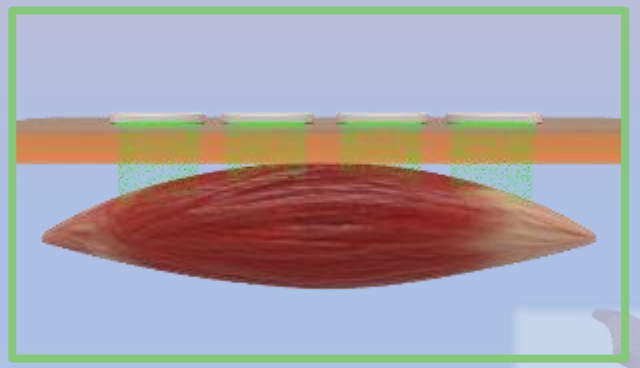
- Stimulation of superficial nerves with <1 mA
- Induces a “flicking” effect on the muscles
- Appropriate for management of pain and inflammation



Traditional EMS Mechanism Of Action

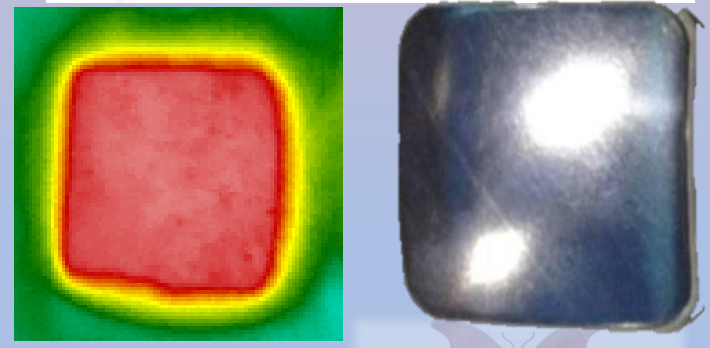
Electrical Muscle Stimulation

- Stimulation of the superficial muscle with <10 mA
- Induces a single direction slight muscle contractions
- Generally used for muscle rehabilitation to reduce atrophy from injury



The truSculpt flex Improvement

- truSculpt flex differs from previously existing EMS systems via:
  - Updated treatment modes & protocols
  - Enhanced power supply
  - Channels operate independently and simultaneously
  - Increased power delivery to muscle with truSculpt handpieces and truGel
  - Even energy delivery allowed delivery of 2-3 X more current to the muscle
  - Intuitive user interface
  - Retractable cables



Proprietary 3D Machined Solid Electrode

truSculpt flex

Bio-Electrical Muscle Stimulation

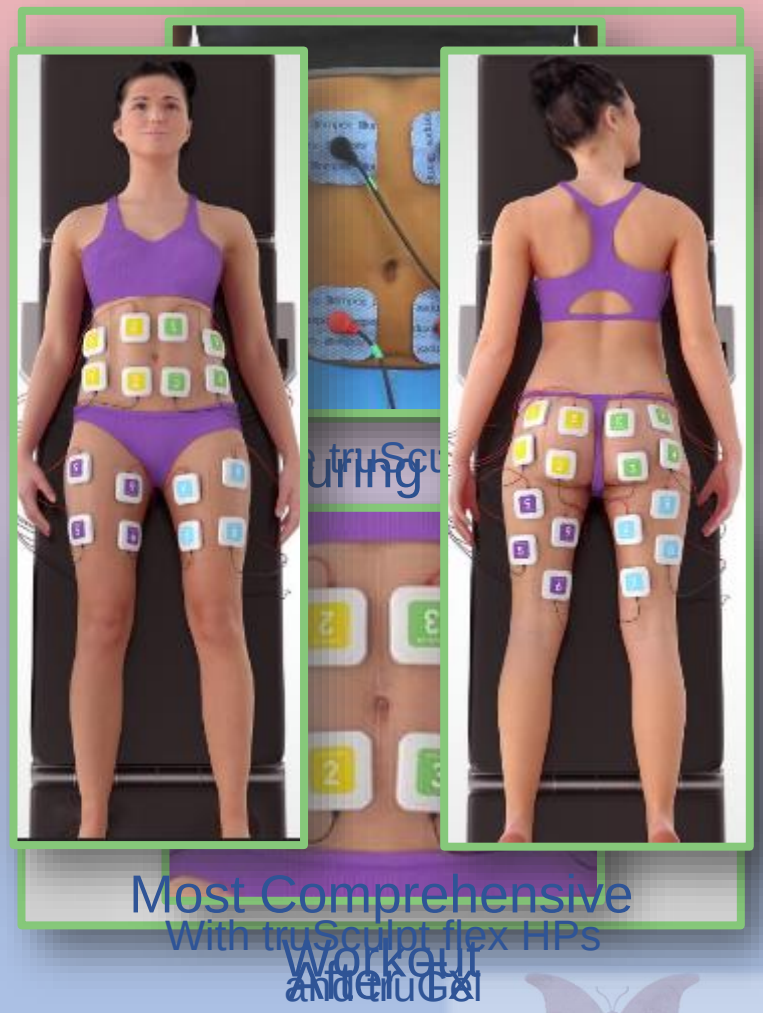
- Direct vs indirect stimulation for high intensity and specificity with 30 mA
- Changes polarity or direction

truControl™

- Targets selective muscles, customize current delivery (intensity and direction)

Multi-Directional Stimulation (MDS)

- Offers three treatment mode options
- Creates multiple types of muscle contractions
- Treats up to 8 areas per session



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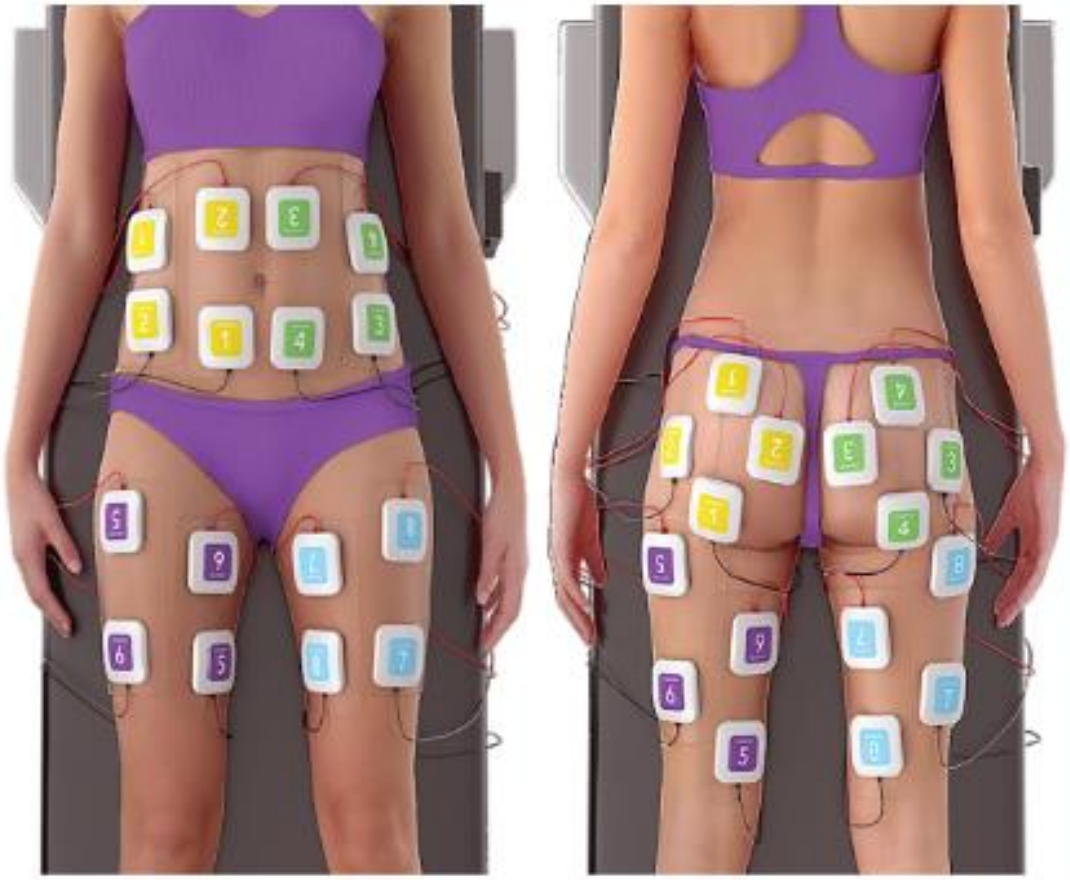
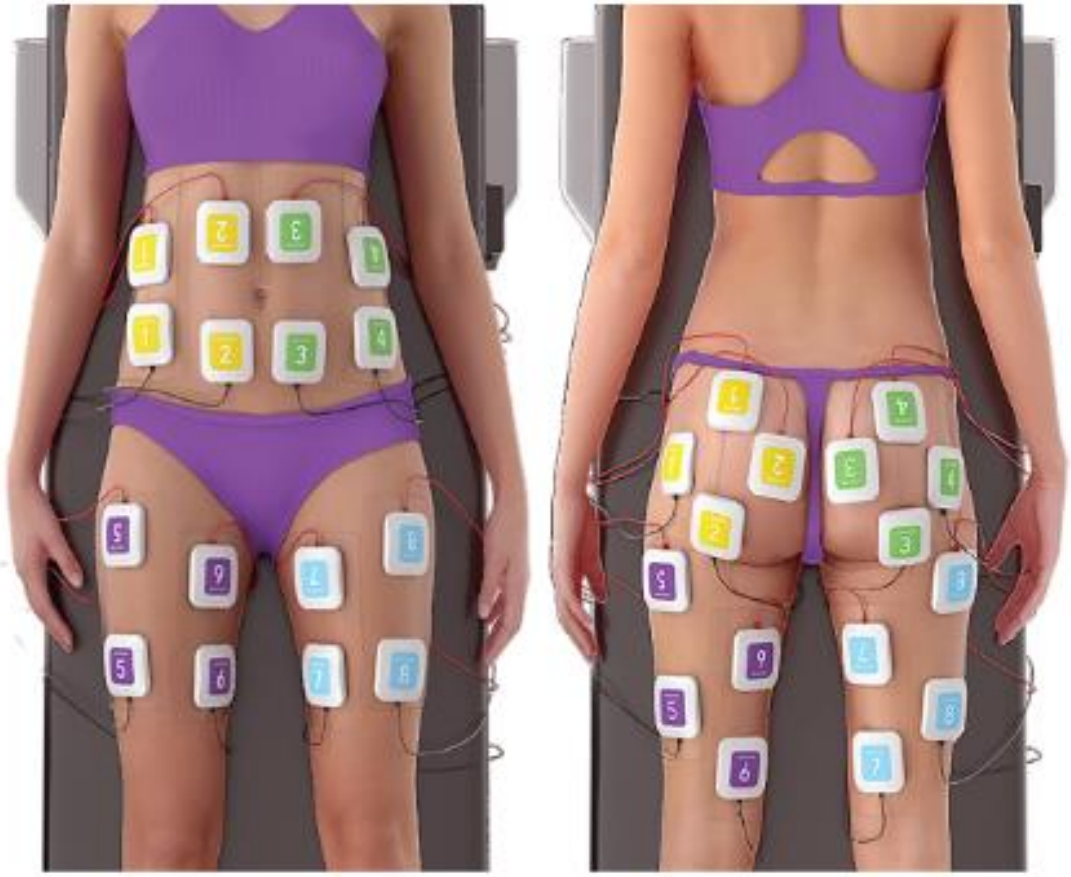
Prep
Treatment Mode



Tone/Sculpt
Treatment Mode



Clinical Data

***All patients maintained weight within +/- 5%**

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truSculpt flex Results

truSculpt® flex

Photos courtesy of Somenek+Pittman

FACE + BODY AESTHETIC SOLUTIONS by CUTERA®

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truSculpt flex Results

Photos courtesy of S. Ronan, M.D.

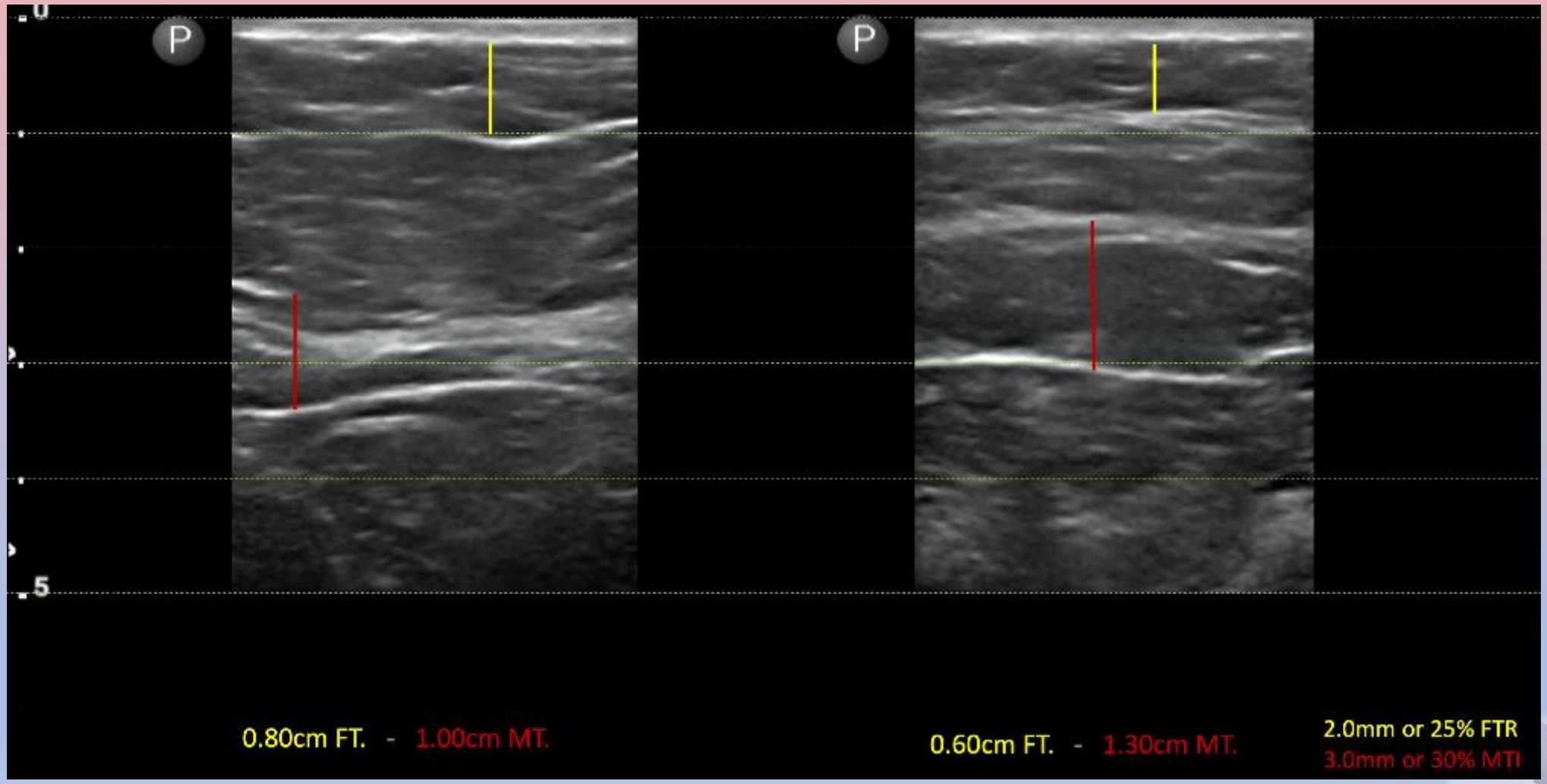
FACE + BODY AESTHETIC SOLUTIONS by CUTERA®

truSculpt flex Results

Photos courtesy of S. Ronan, M.D.

FACE + BODY AESTHETIC SOLUTIONS by CUTERA®

truSculpt flex Ultrasound Results



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Emsculpt

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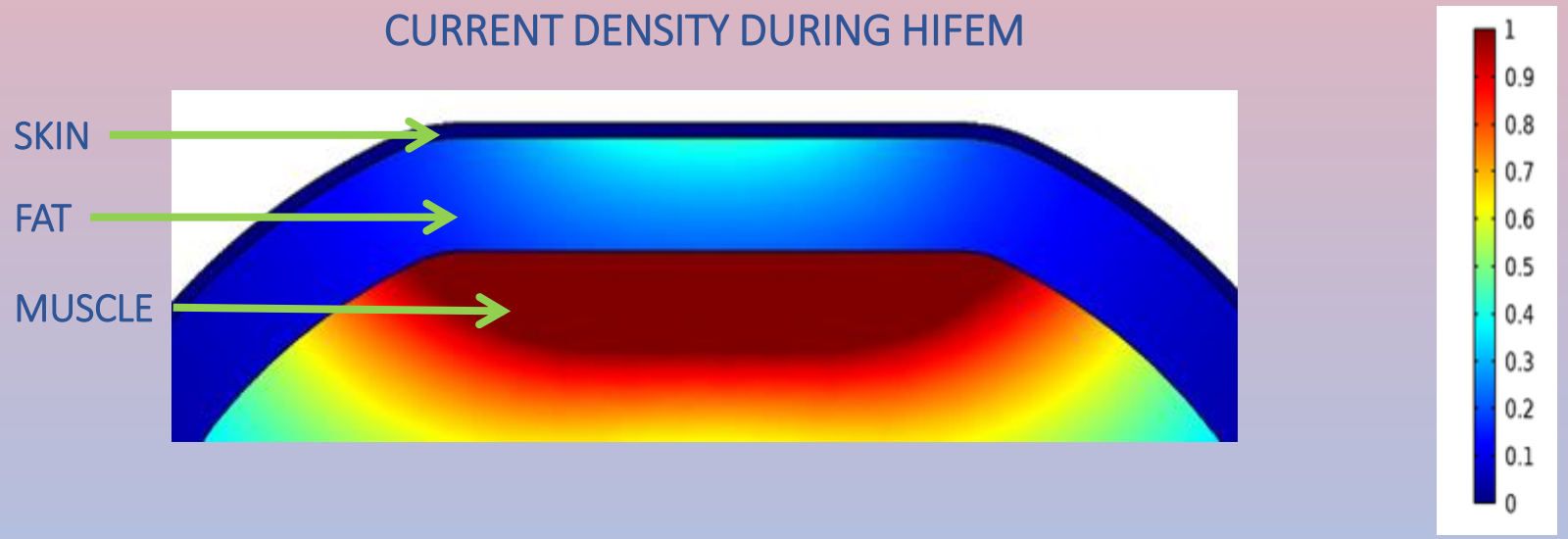
HIFEM TECHNOLOGY

High-Intensity Focused Electromagnetic Energy

- Rapidly changing magnetic fields induce currents in the tissue.
- This leads to **depolarization of motor neurons** in the treated area-> muscle contraction
- The focused energy induces **20,000 muscle contractions in 30 min**
- This results in so-called **supramaximal contractions** that can never be achieved through normal voluntary muscle action

HIFEM MUSCLE STIMULATION



- HIFEM uses secondary current induced by magnetic fields. Current density peaks in the muscle, not skin. This allows extremely intense stimulation.

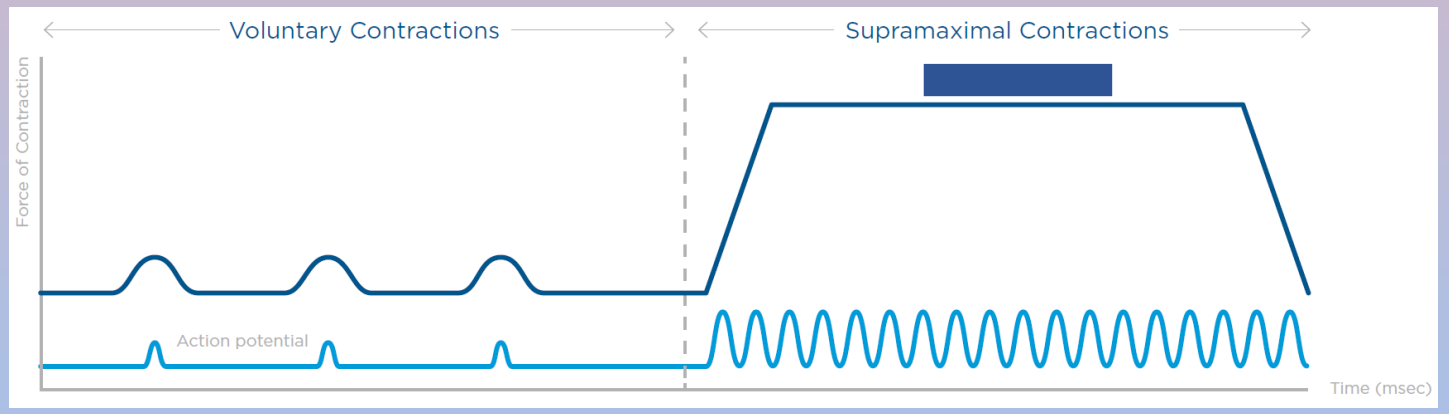
- EMS/TENS systems use direct superficial electricity which limits their intensity.

“SUPRAMAXIMAL CONTRACTIONS“

Autonomous brain reserve
Untrained individual can only activate 40-60% of muscle potential.

CNS pathways limitations
The intensity of electrical signaling from the brain has certain limits.

Complete tetanic state
Voluntary exercise doesn‘t allow such high frequency of contractions which is needed to achieve maximum tension in the muscle.



HIFEM is independent of the brain function and so bypasses these limitations.

PEER-REVIEWED RESEARCH
9 MONTHS AFTER INTRODUCTION TO THE MARKET

AUTHOR	TYPE	TITLE	SAMPLE	PUBLISHED
Jacob et al	Tummy; Tape measure	Safety and efficacy of a novel HIFEM technology device for noninvasive abdominal body shaping	22	JCD 2018
Kinney et al	Tummy; MRI	HIFEM Therapy Evaluated by Magnetic Resonance Imaging: Safety and Efficacy Study of a Dual Tissue Effect Based Non-Invasive Abdominal Body Shaping	22	LSM 2018
Weiss et al	Pigs; Histology	Induction of Fat Apoptosis by a Non-Thermal Device: Mechanism of Action of Non-Invasive HIFEM Technology in a Porcine Model	3	LSM 2018
Multicenter (7)	Butt; BA & Satisfaction	HIFEM Technology for Non-Invasive Buttock Lifting and Toning of Gluteal Muscles: A Multi-Center Efficacy and Safety Study	75	JDD 2018
Kent et al	Tummy; CT	Computed Tomography (CT) Based Evidence of Simultaneous Changes in Human Adipose and Muscle Tissues Following a HIFEM Application: A New Method for Noninvasive Body Sculpting	25	ASLMS 2018
Busso et al	Butt; Tx feasibility	Efficacy of HIFEM Field Therapy when Used for Non-Invasive Buttocks Augmentation and Lifting: A Clinical Study	22	ASLMS 2018
Katz et al	Tummy; Ultrasound	Ultrasound Assessment of Subcutaneous Abdominal Fat Thickness Following Treatments with HIFEM Field Device: A Multi-Center Study	33	DS 2019 (accepted)
Duncan et al	Leg; Histology	Non-Invasive Induction of Muscle Fiber Hypertrophy and Hyperplasia: Effects of HIFEM Field Evaluated in an In Vivo Porcine Model	4	ASLMS 2019
Kent et al	Tummy; CT&MRI	Long-Term Follow-Up on Patients with HIFEM-Induced Abdominal Tissue Changes: MRI and CT Assisted Quantification of Muscle Growth and Fat Reduction	21	ASLMS 2019
Katz et al	Tummy; Ultrasound	Ultrasonography Evaluation of Changes in Subcutaneous Abdominal Fat Thickness Following HIFEM Treatments: Results of 6-Month Follow-Up	18	ASLMS 2019
Palm et al	Butt; MRI	MRI Evaluation of Changes in Gluteal Muscles Following Treatments with the HIFEM Technology	25	ASLMS 2019
Halaas et al	Tummy; Histology	Biochemical Perspective of Fat Physiology after Application of HIFEM: Field Technology: Additional Investigation of Fat Disruption Effects in a Porcine Study	3	ASLMS 2019
A. Fatemi	Tummy; Ultrasound	An ultrasound evaluation of HIFEM technology for fat reduction: case study	7	IMCAS PARIS 2019
R. Rakus	Literature; Efficacy	Thermal vs. non-thermal technologies in non-invasive body contouring	n/a	IMCAS PARIS 2019

PRIMARY EFFECTS ON THE MUSCLES

Supramaximal contractions induce microinjury & trigger muscle growth.

RESEARCH SO FAR

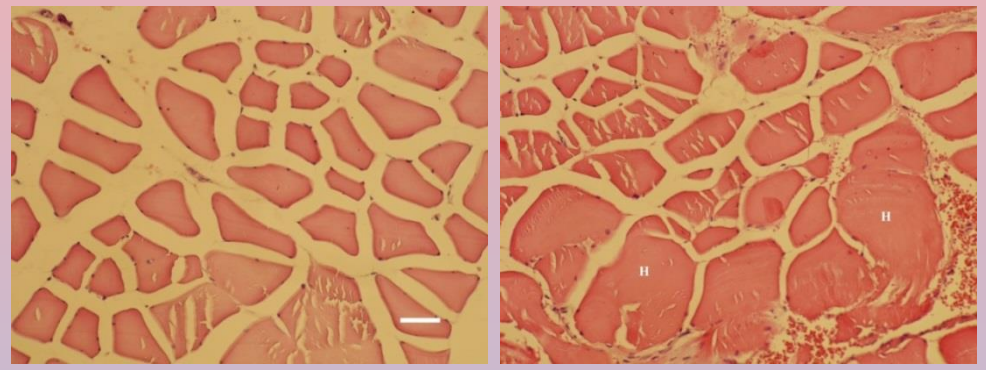
23% increase in muscle mass density
- 16% hypertrophy
- 7% hyperplasia

19-23% abdominal muscle thickening

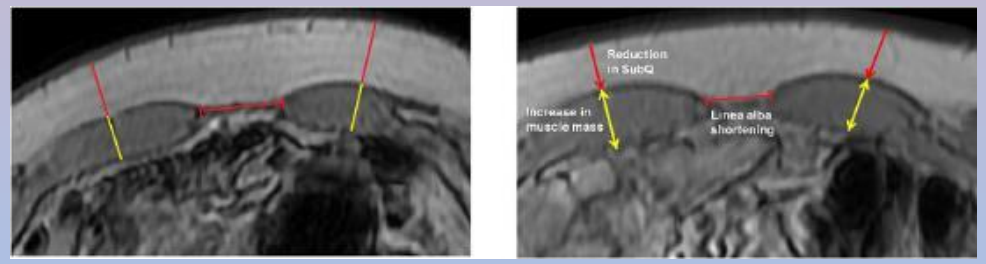
11% increase in total volume of
all three gluteal muscles

10-11% reduction in
abdominal separation / diastasis recti

Measureable improvement
preserved 6-12 months post treatments



Histology of porcine femoris biceps m. before and 2 weeks after 4 HIFEM treatments. Visible hypertrophic effects can be observed post application.



MRI assisted documentation of rectus abdominis growth and reduction in diastasis recti 2 months after 4 treatments.

Effects of HIFEM on myo-satellite cells is still subject of investigation

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SECONDARY EFFECTS HAPPEN IN ADIPOSE TISSUE

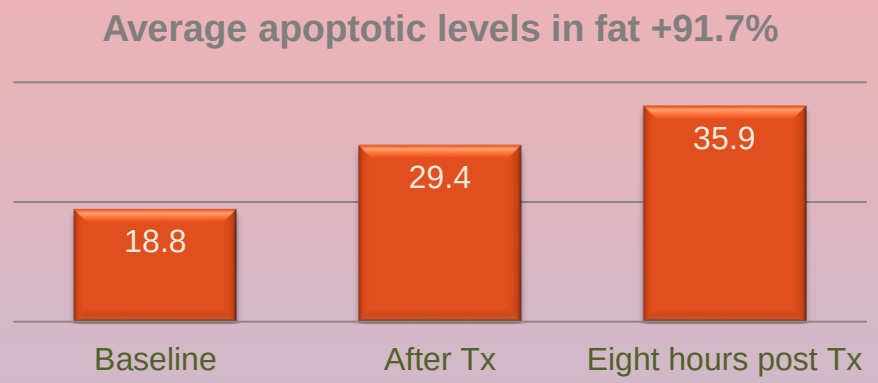
In certain concentrations, **free fatty acids** (FFA) were proven to **have apoptosis inducing effects** (*Hardy et al 2013; Zhang 2012; Gunduz et al 2012; Guo et al 2007*)

HIFEM induced contractions **lead to** a hypermetabolic state with a rapid **release of FFA** in fat tissue (*Weiss 2018*)

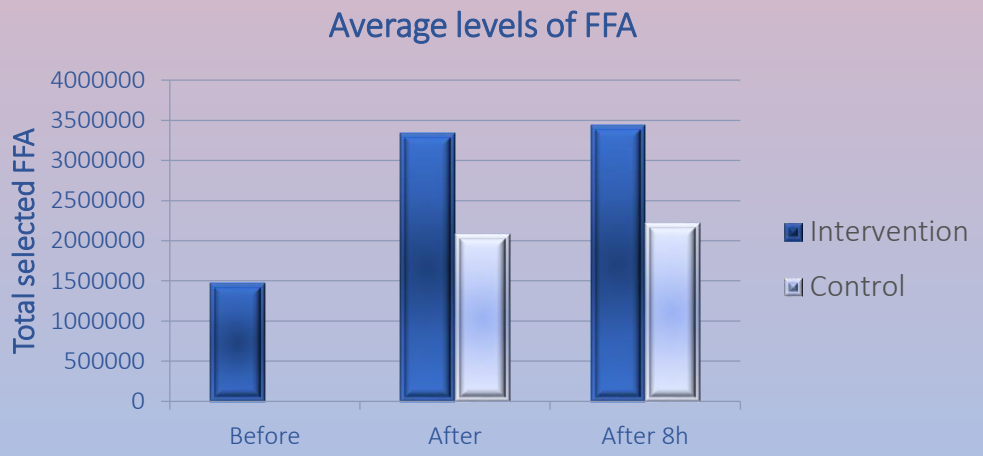
A statistically significant **increase in fat apoptotic levels was measured** (*Weiss 2018*) as well as an **increase in mRNA apoptotic markers** (*Weiss 2018*)

Reduction in subcutaneous fat thickness was successfully observed in patients (*Kent 2018; Kinney 2018; Katz 2018; Jacob 2018*).

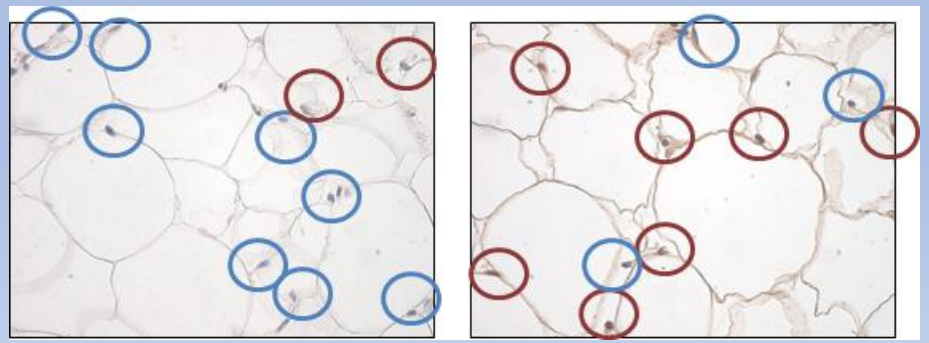
CASCADED EFFECT IN ADIPOSE TISSUE



The average apoptotic index increased from 18.8% before application to 35.9% after application.



In the treated area, the concentration of FFA in fat tissue rapidly increased immediately after the treatment.



Brown marked are cells with initiated DNA breakdown. The # apoptotic cells increased post application.

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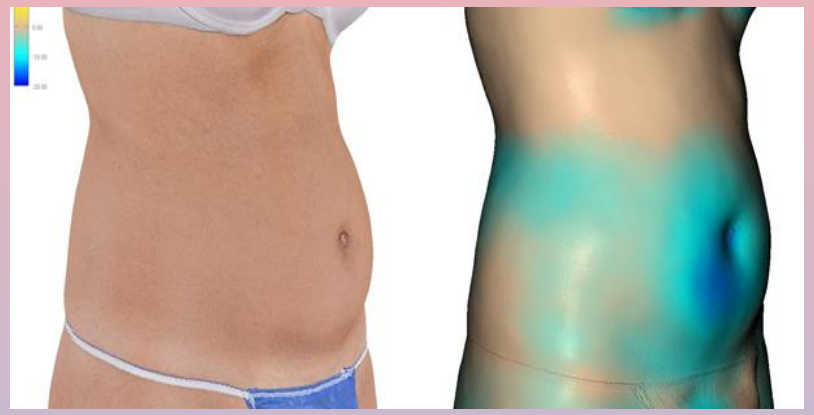
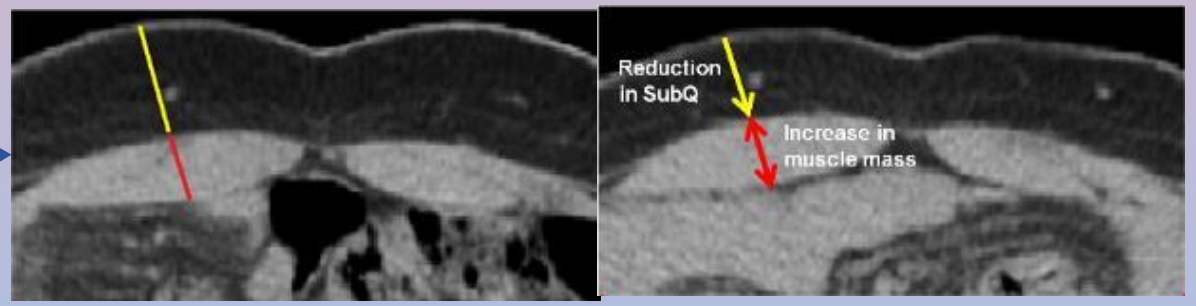
AVERAGE 19-27% REDUCTION IN FAT MEASURED IN PATIENTS

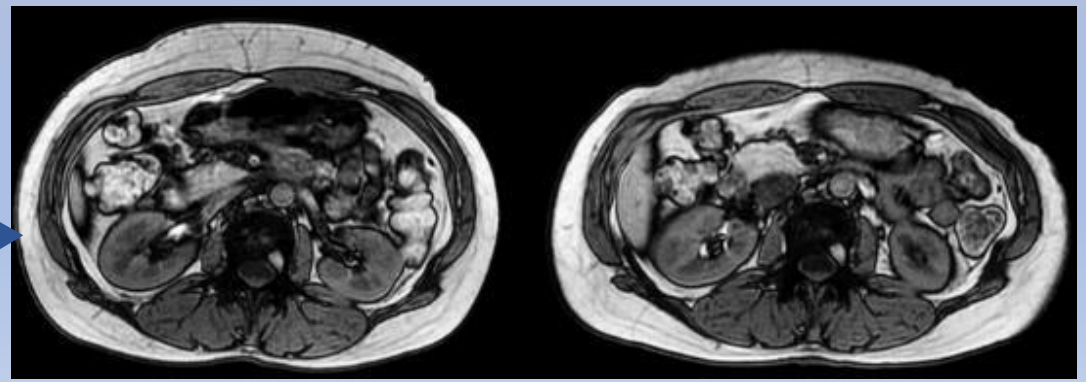


Reduction in subcutaneous fat following a series of HIFEM treatments. 3D photography shows consistent reduction of fat across the abdomen.

CT scan shows reduction in subQ fat approximately 6 weeks after a series of treatments.



MRI scan of a patient with visible fat pad reduction 2 months after the last treatment.



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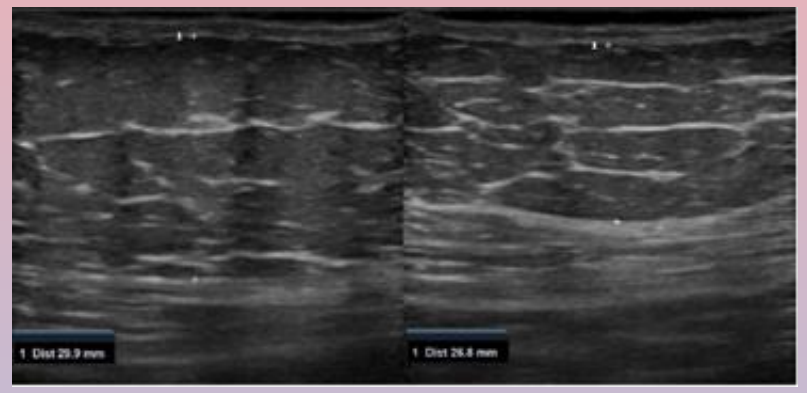
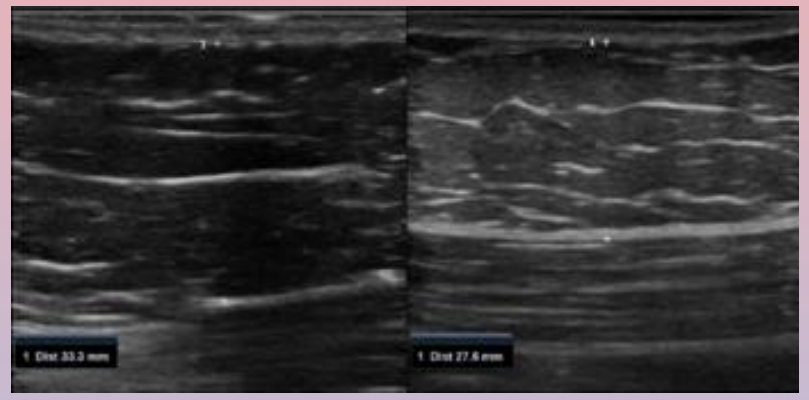
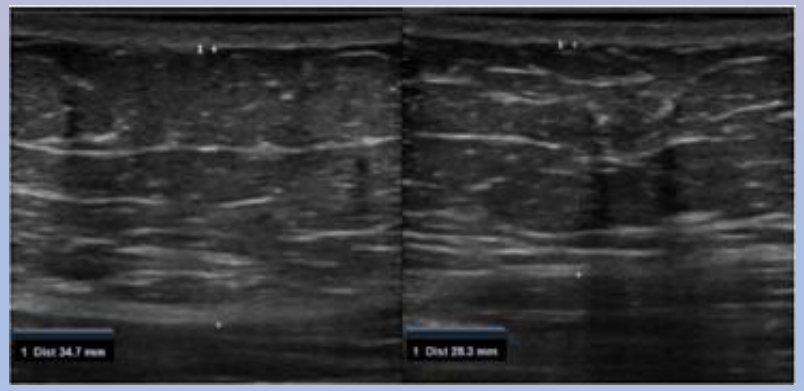
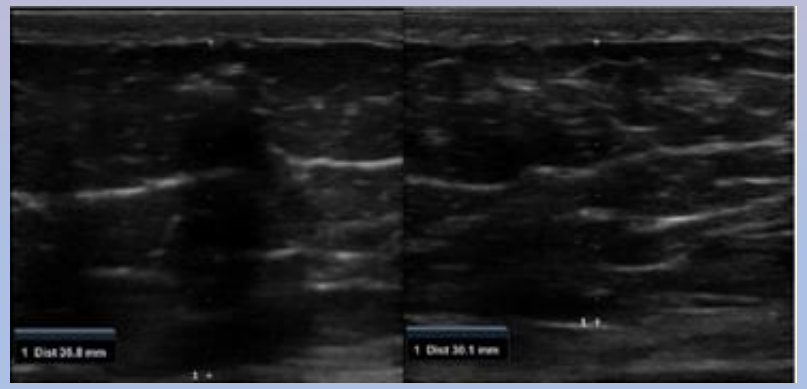
AVERAGE 19-27% REDUCTION IN FAT:

AN ULTRASOUND EVIDENCE









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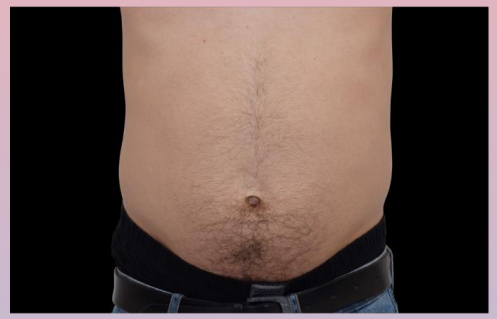
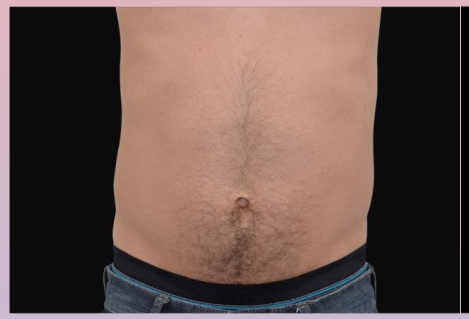
PATIENTS SEEKING IMPROVEMENT IN BOTH MUSCLE & FAT

BEFORE

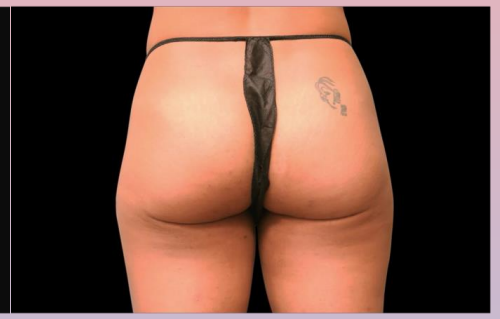


12 WEEKS AFTER 4th TREATMENT

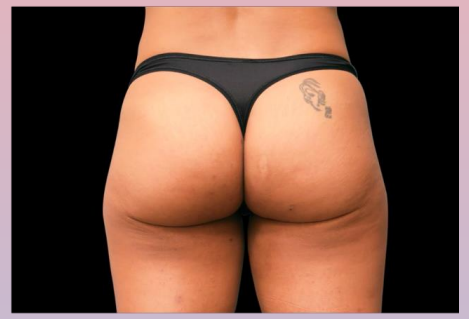


COURTESY OF: CAROLYN JACOB, M.D.

BEFORE

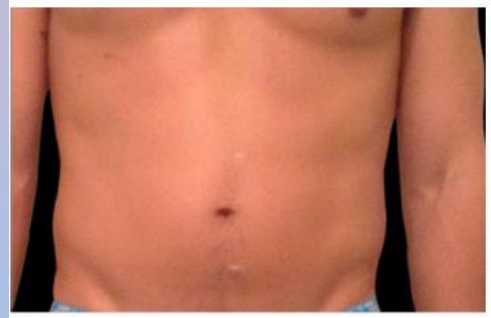


AFTER 4th TREATMENT

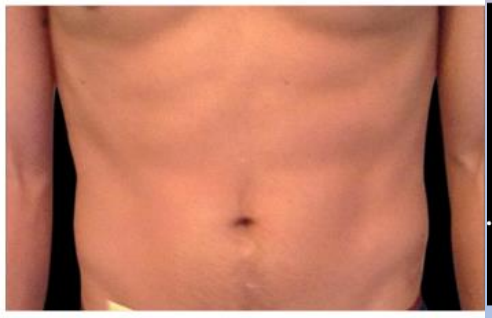


COURTESY OF: BRIAN KINNEY, M.D.

BEFORE

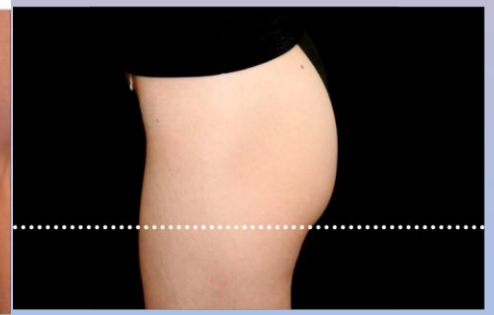


AFTER 4th TREATMENT



COURTESY OF: ANITA STURNHAM, M.D.

BEFORE



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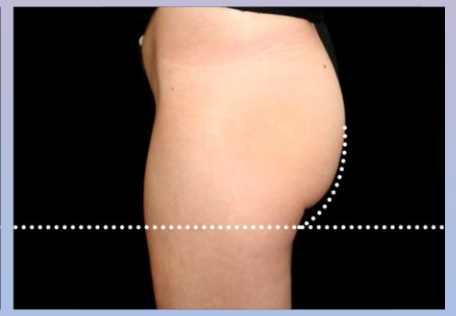

COURTESY OF: SUNEEL CHILUKURI, M.D.

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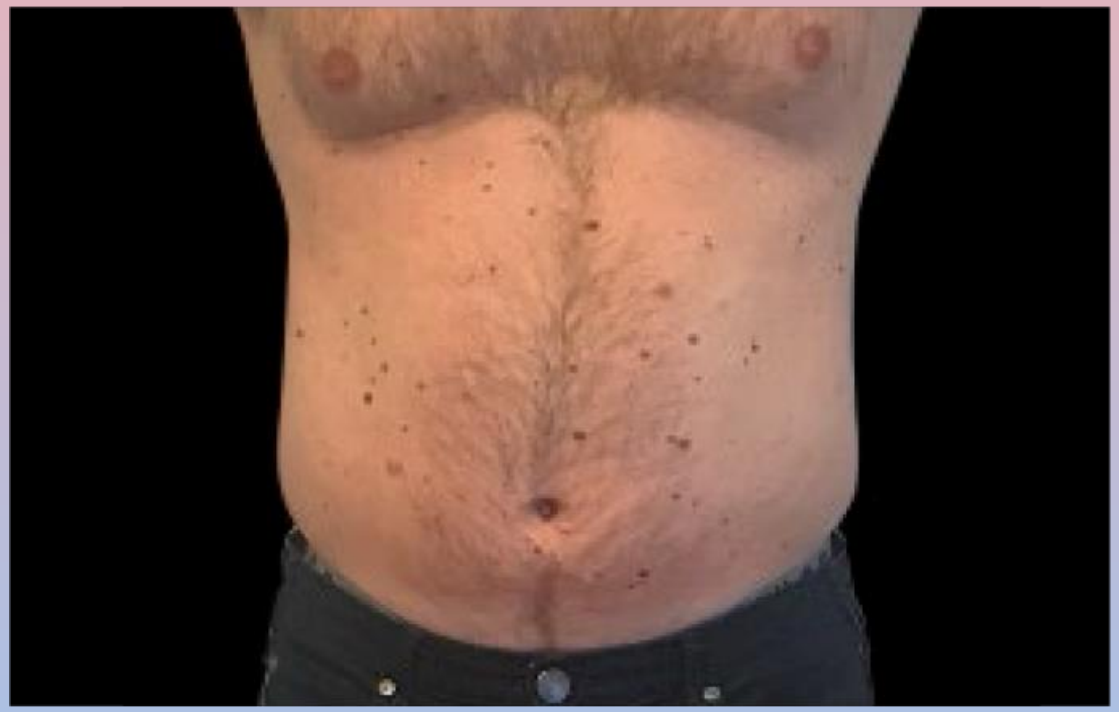
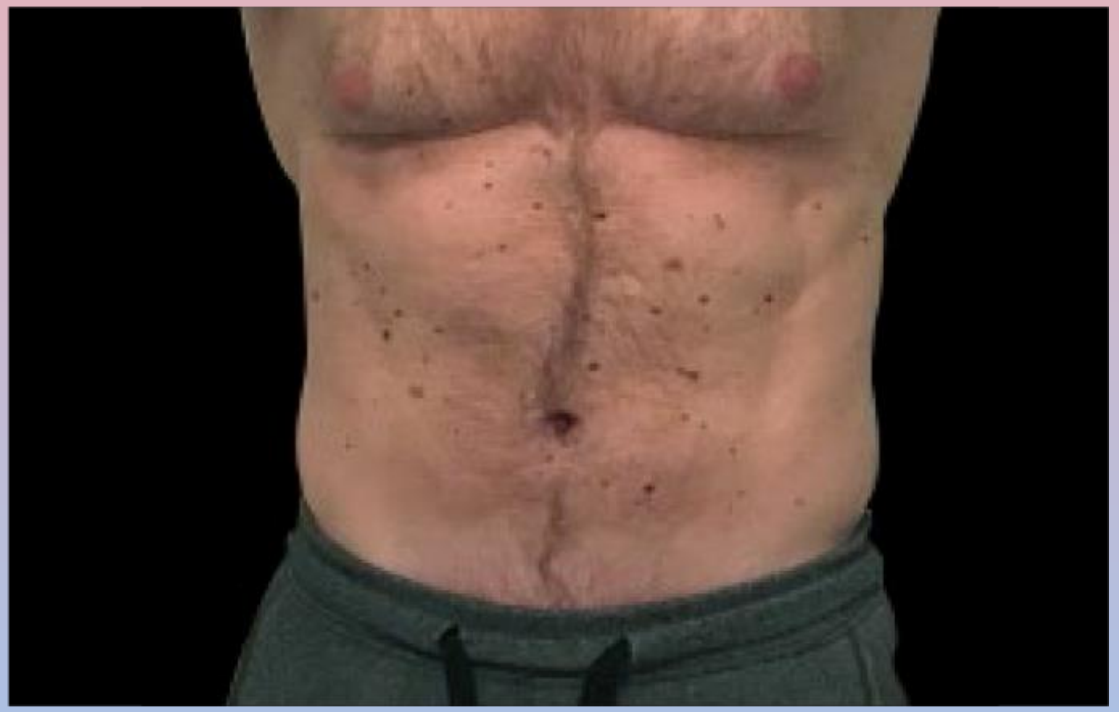
Body Sculpting with HIFEM technology (FAT AND MUSCLE)

BEFORE



AFTER 4th TREATMENT



COURTESY OF: ANITA STURNHAM, M.D.

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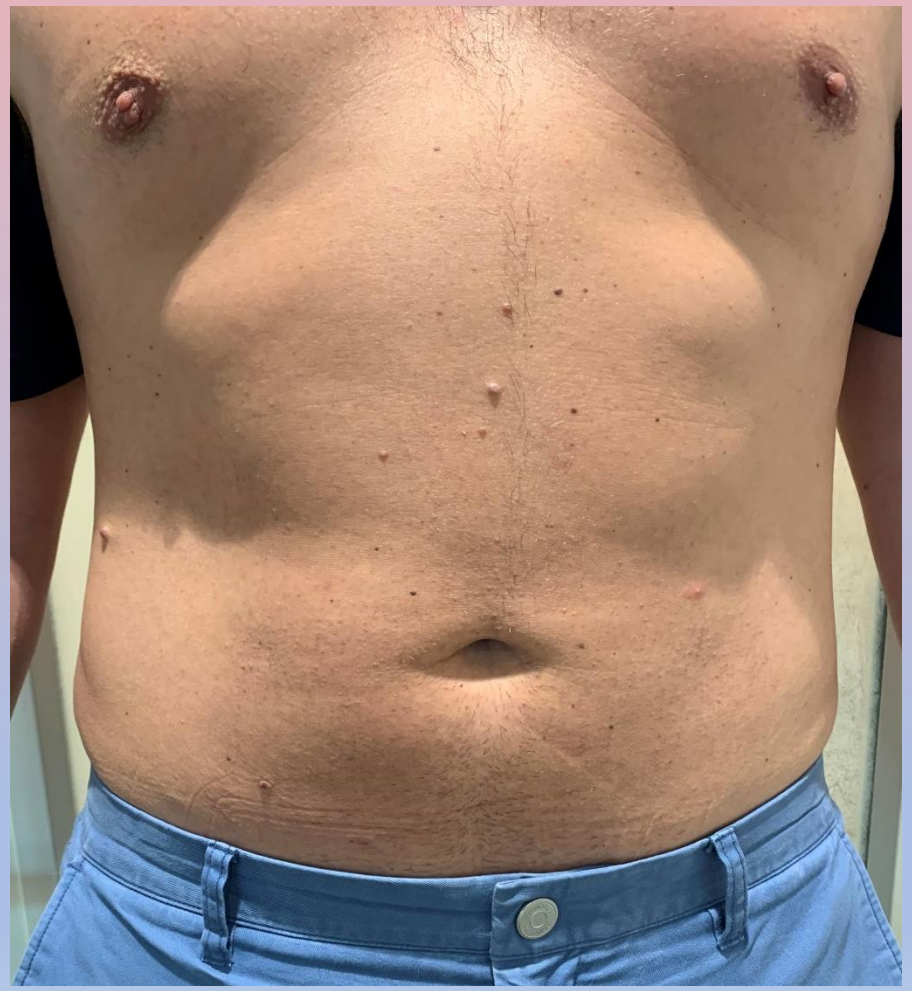
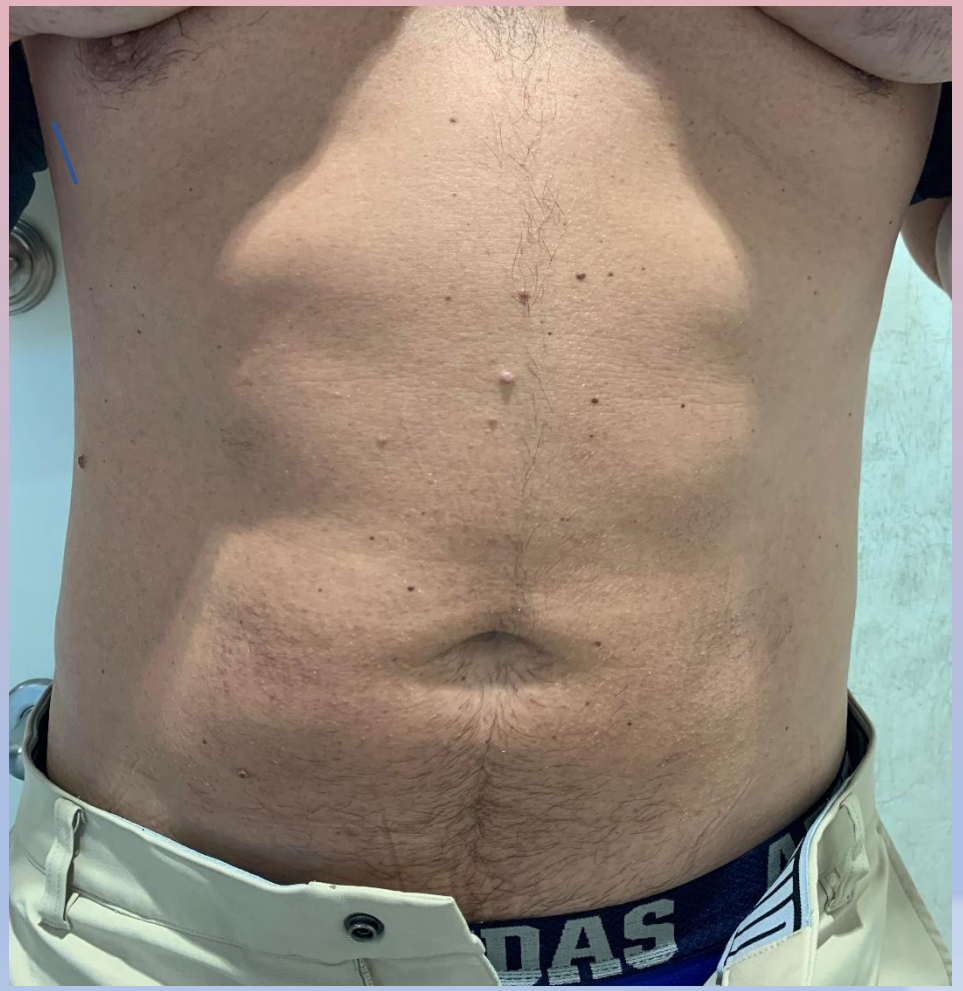
First patient we treated,
3 treatments over 4 weeks





TRANSFORMATIVE
DERMATOLOGY
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QUANTITATIVE CLINICAL DATA (PEER-REVIEWED STUDIES)

92%	Increase in FAT APOPTOSIS after 1 treatment	11%	Reduction in DIASTASIS RECTI
16%	Increase in MUSCLE THICKNESS	~4cm	WAIST CIRCUMFERENCE reduction
19%	Reduction in ABDOMINAL FAT	11%	VOLUMETRIC GROWTH of all three gluteal muscles

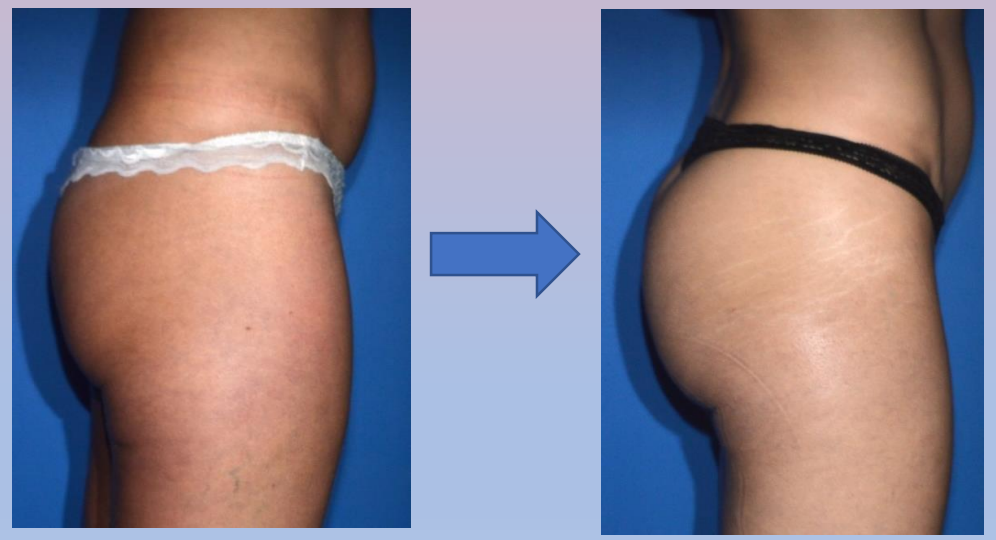
TRANSFORMATIVE DERMATOLOGY BY Jill C. Fichtel MD

HIFEM – ALTERNATIVE TO CURRENT BUTTOCK PROCEDURES

- The shape of buttocks is predominantly defined by gluteal muscles (g. Maximus, Medius and Minimus)
- By volume, gluteus maximus is one of the largest muscles in the human body

➡ Large potential for firming and toning by HIFEM stimulation

BEFORE **3M POST-TREATMENT**



Courtesy of Mariano Busso MD

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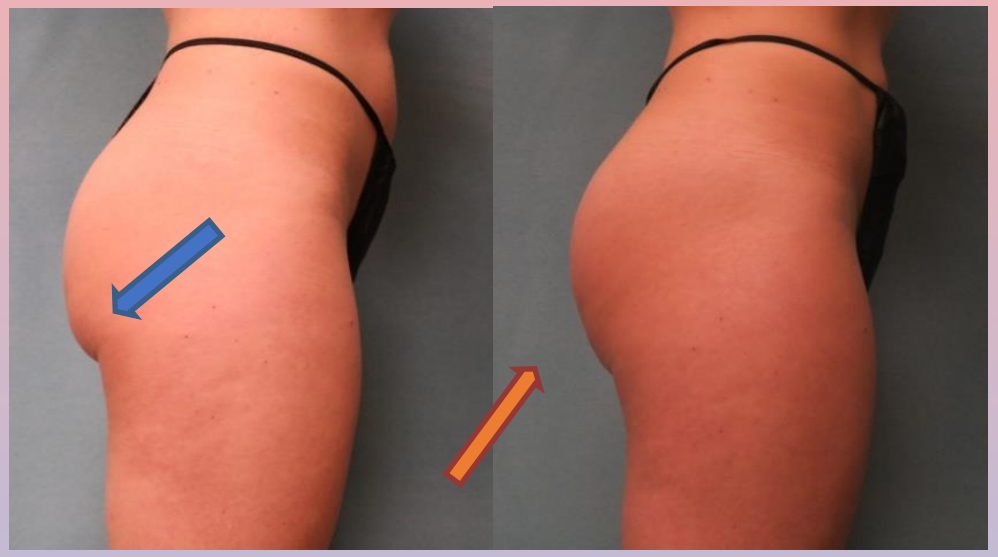
EXAMPLE OF PATIENT RESULTS



Courtesy of Brian Kinney MD

TRANSFORMATIVE DERMATOLOGY
BY Jill C. Fichtel MD

BeautyFill

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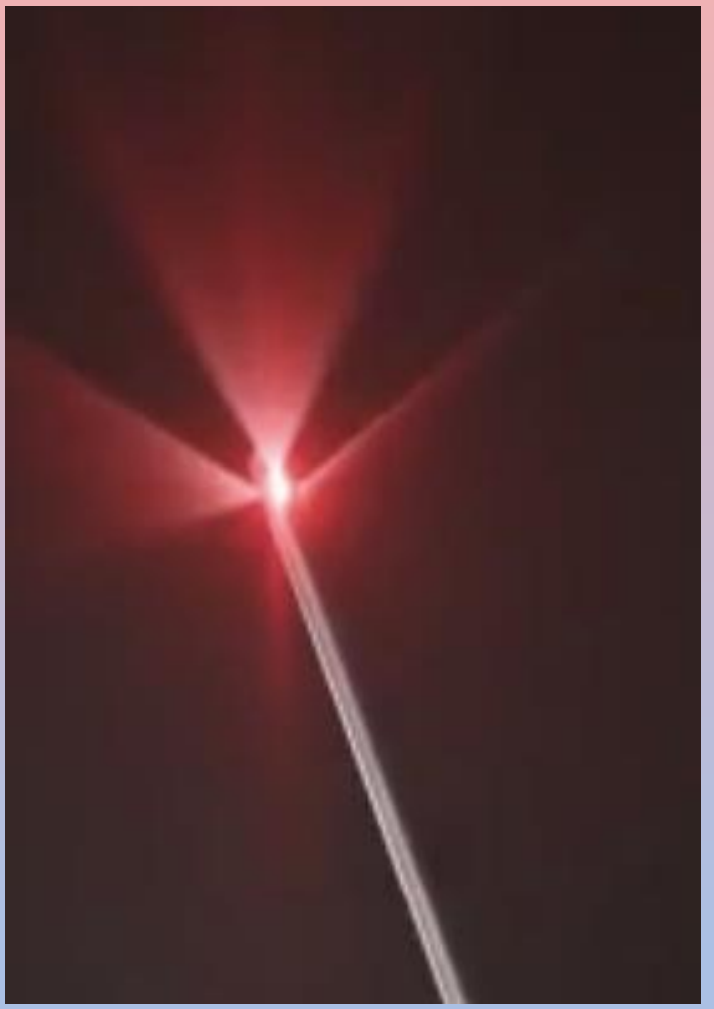
First closed loop autologous fat transfer system

- System simultaneously combines:
  - Laser to assist in fat cell harvest
  - Aspiration to collect fat cells
  - Initial processing of fat cells to optimize viability



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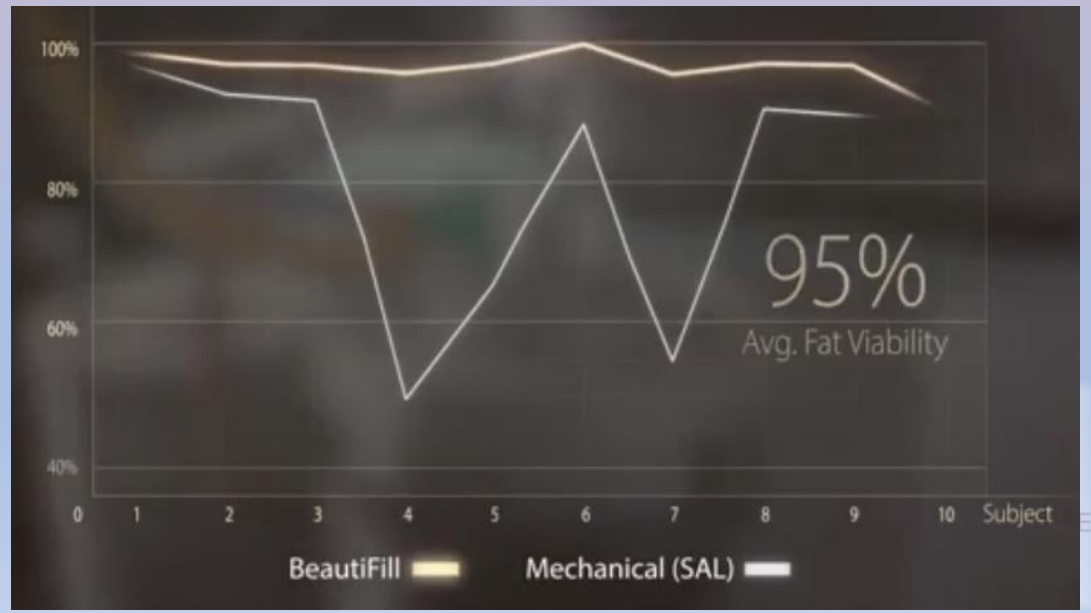
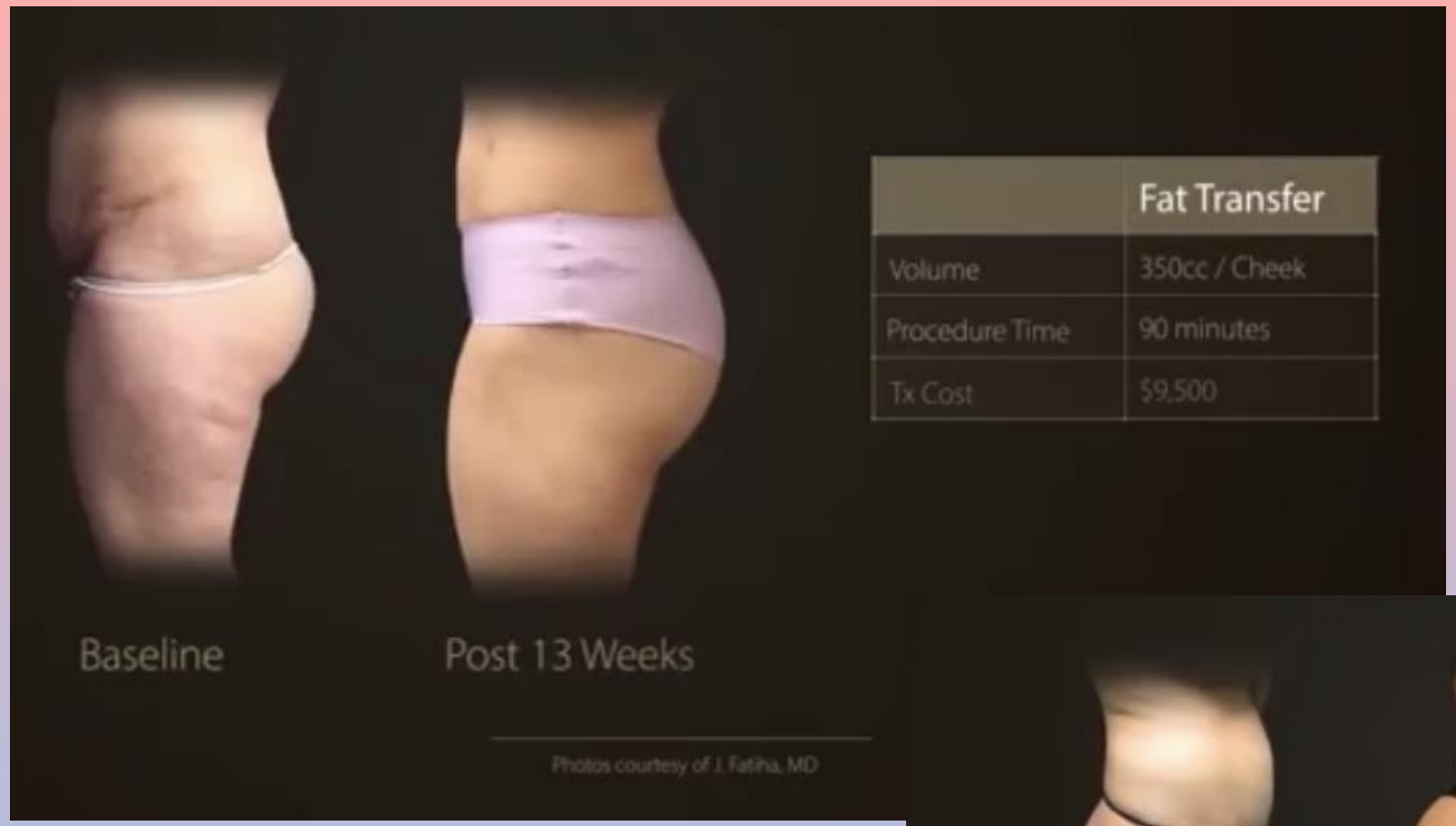
- Compared to traditional liposuction, the Beautyfill system resulted in:
  - 38.9% more fat in a given collection volume
    - 40% of the volume collected in traditional ultrasound consists of oil and blood
    - Likely derived from damaged lipocytes
  - Much higher consistency of lipocyte viability compared to mechanical liposuction





	Fat Transfer
Volume	350cc / Cheek
Procedure Time	90 minutes
Tx Cost	$9,500

	Fat Transfer
Volume	350cc / Cheek
Procedure Time	90 minutes
Tx Cost	$6,500

Thank You!!!!!! jillf5013@yahoo.com

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