

# Permanent Fillers for Treating Acne Scars

*Karol A Gutowski, MD, FACS*

*Hot Topics*

plastic  
surgery

THE MEETING

2015

BOSTON  
OCTOBER 16-20



AMERICAN SOCIETY OF  
PLASTIC SURGEONS®



THE PLASTIC SURGERY  
FOUNDATION®



# Disclosures

RTI Surgical - Advisor

Suneva Medical - Instructor

Angiotech/Surgical Specialties - Advisory Board

# Status of Product

**Bellafill (FKA Artefill, Articoll) Suneva Medical**

- PMMA + bovine collagen

## **FDA Status**

- Smooth moderate to severe smile lines
- Improve appearance of acne scars (2015)

# Presentation Level of Evidence

## Levels of Evidence and Qualifying Studies (Therapeutic Studies):

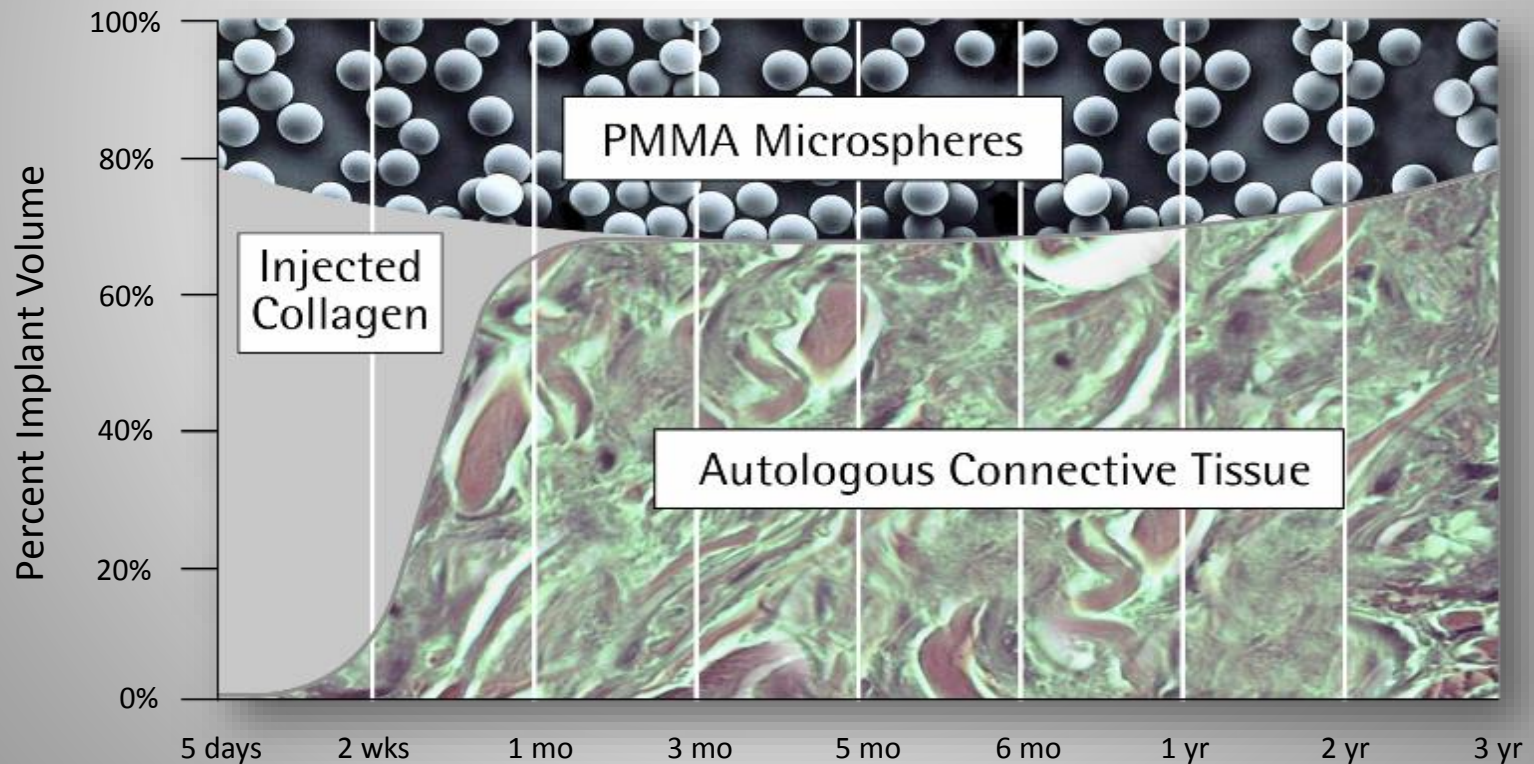
- I High-quality, multi-centered or single-centered, randomized controlled trial with adequate power ( $N \geq 100$ ); or a systematic review of these studies
- II Lesser-quality, randomized controlled trial; prospective cohort study; or systematic review of these studies
- III Retrospective comparative study; case-control study; or a systematic review of these studies
- IV Case series
- V Expert opinion; case report or clinical example; or evidence based on physiology, bench research or "first principles"

# Treatment & Costs

- Product                    \$300 per 0.8cc syringe
- Disposables            None (injection cannula \$5)
- Treatment                1-2 syringes per side of face
- Sessions                 1-2
- Patient cost             \$700 to \$900 per syringe
- Skin test                 Required but reaction is rare

# Mechanism of Action

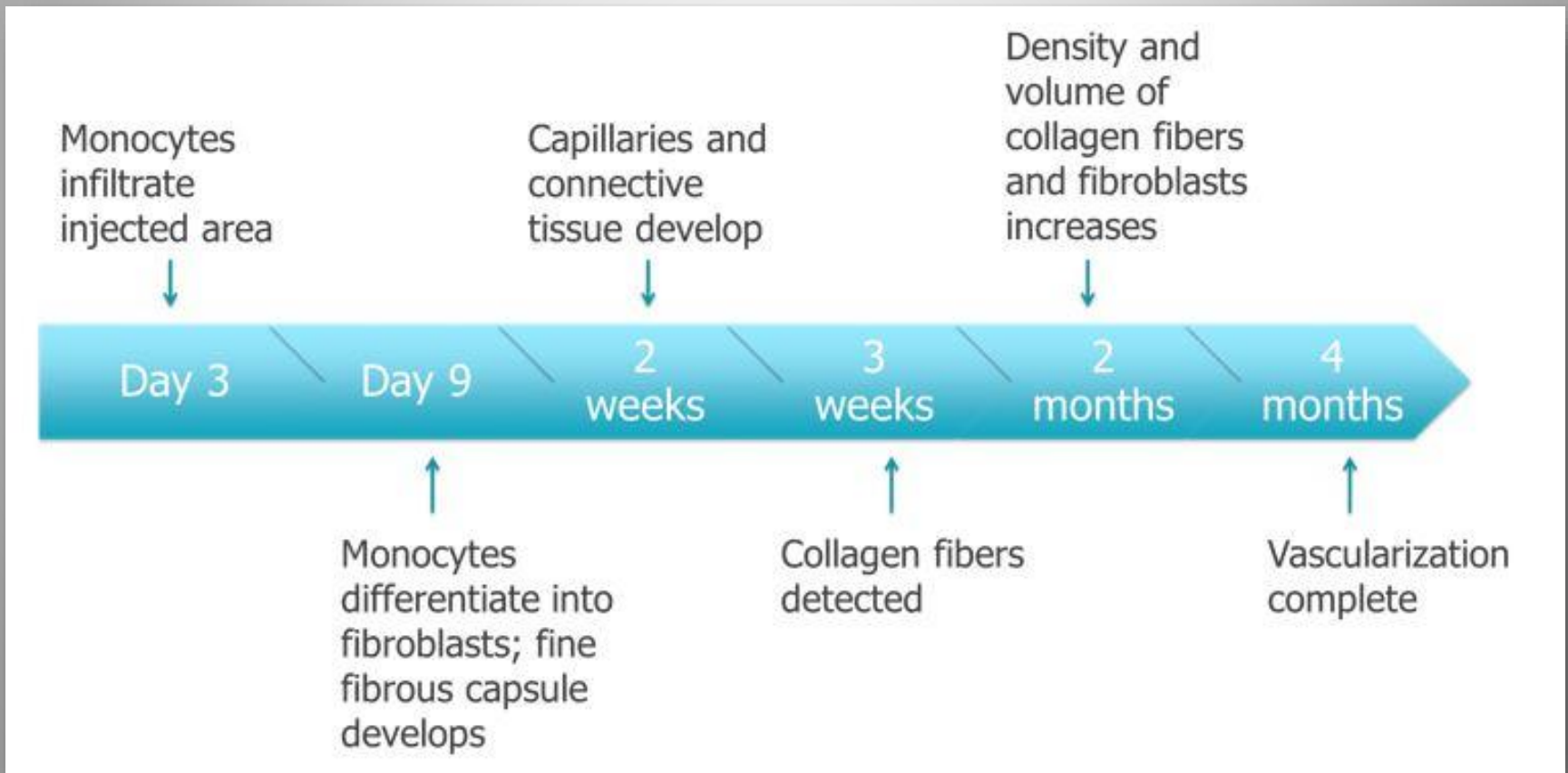
- Initial volumization (bovine collagen)
- Secondary autologous collagen stimulation (PMMA)





# Time Line

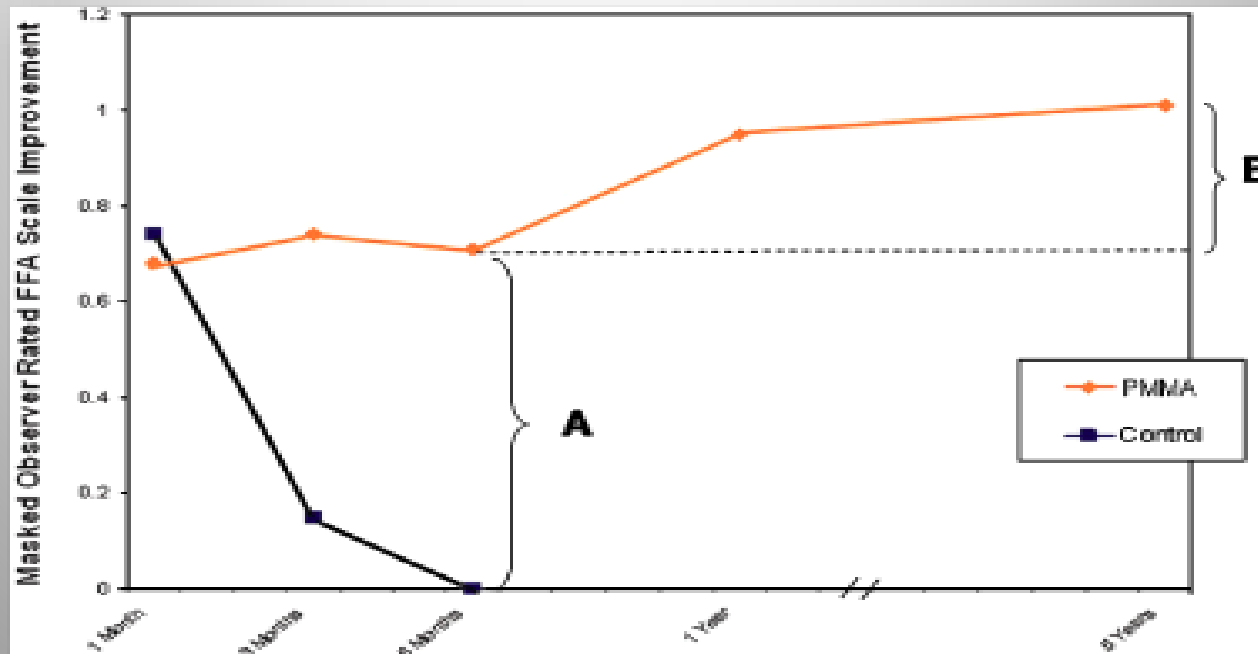
6 to 8 weeks to final result



# Update on Duration of Effect

## Post Marketing Study

- 145 patients followed for 5 years
- 5 year 90% patient & investigator satisfaction





# Update on Duration of Effect

## 5 Year Safety Trial

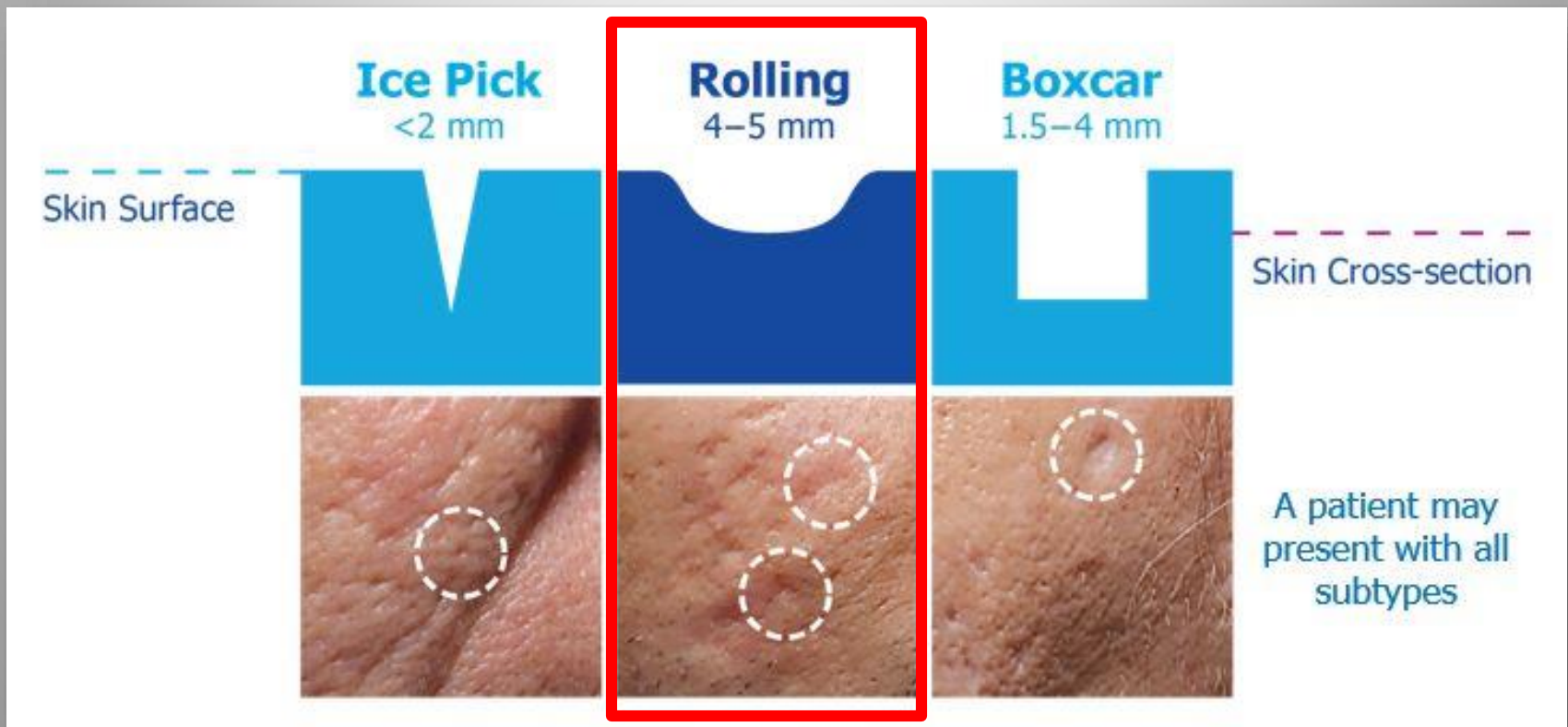
- 1008 patients followed for 5 years
- 87% retention
- 94% “somewhat” to “very satisfied”

# Acne Scar Treatment Options

- Fillers (HA, PLLA)
- Laser resurfacing
- Chemical peels
- Topical treatments
- Dermabrasion
- Subcision
- Excision

# Atrophic Acne Scar Treatment

Rolling scars improved with skin traction



FDA panel approval for Bellafill 2015

# Scars Improved with Traction



# Acne Scar Assessment

Category	Score	Description
Minimal	1	Depth up to .5 mm
		Visibility = Perceptible with tangential lighting
Mild	2	Depth >.5 mm to <1.5 mm
		Visibility = Moderately detectable with tangential lighting
Moderate	3	Depth $\geq$ 1.5 mm to <2.5 mm
		Visibility = Easily seen with tangential lighting
Severe	4	Depth $\geq$ 2.5 mm
		Visibility = Substantial shadowing with tangential lighting

Study: Grade 3 & 4 rolling acne scars



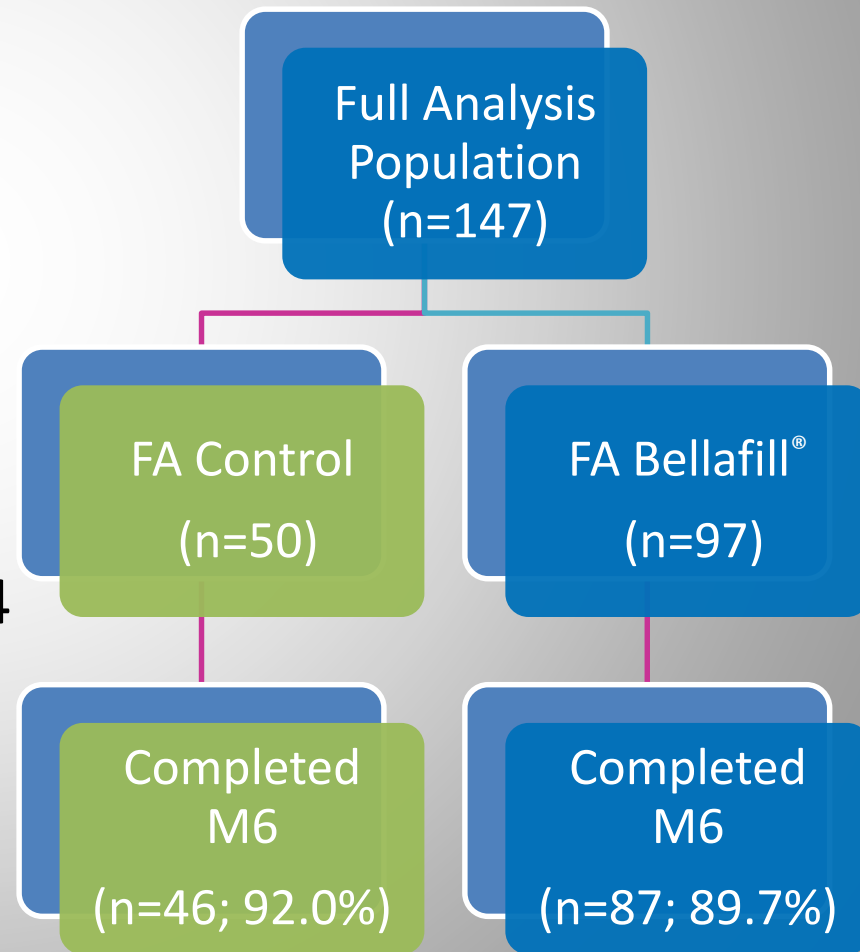
# Patient Selection



Study: Grade 3 & 4 rolling acne scars

# ERAS Trial

- Double blinded RCT at 10 sites
- Mean age 45 yo, 2/3 female
- Average 0.1 cc per scar
  - 1.0 cc first treatment
  - 0.7 cc touch up treatment
- 80% touch up treatment
- Effectiveness: At least 50% of scars improved by  $\geq 2$  points (4 point scale) at 1 year





# ERAS Trial: Investigator Evaluation

## Evaluated by Blinded Investigator



Responder =  $\geq 2$ -point improvement in  $\geq 50\%$  of treated scars

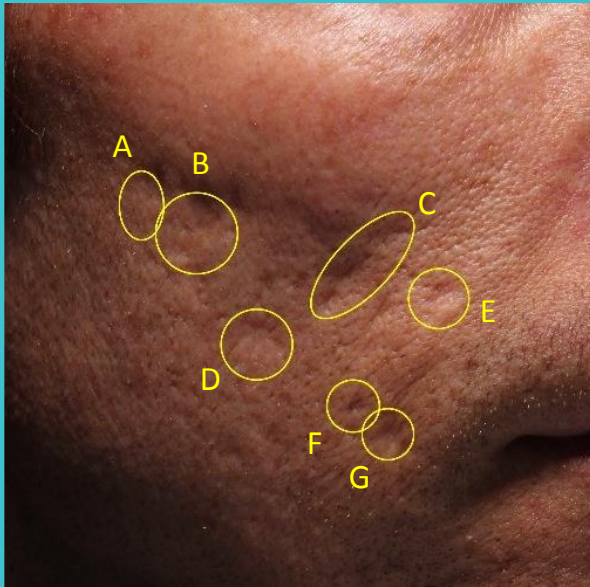
# ERAS Trial: Adverse Events

Reported in > 1% of subjects

Adverse Events, n (%)	PMMA-collagen n = 143*	Control n = 50
• Injection site reaction—lumpiness and papule (3 mild, 1 moderate)	4 (2.8%)	0 (0)
• Injection site bruising (2 mild, 1 severe)	3 (2.1%)	0 (0)
• Injection site pain (mild)	3 (2.1%)	0 (0)

# Results

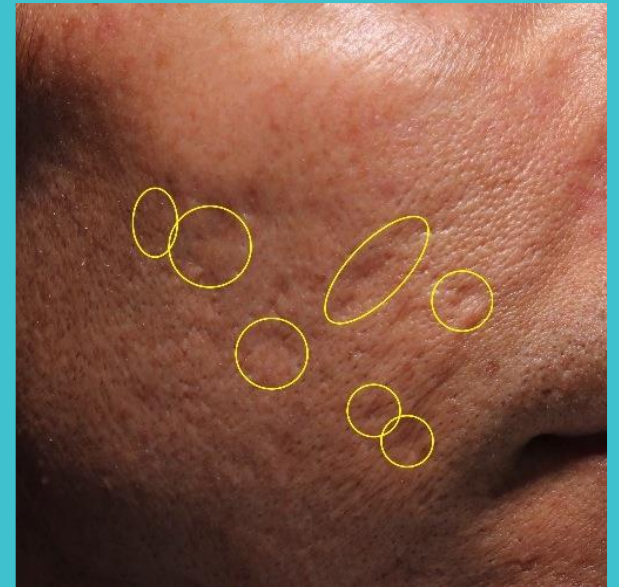
Baseline



Month 6



Month 12



**2 syringes over 2 treatment sessions total for both cheeks**

Only circled scars were treated

# Results

Baseline

Month 6

Month 12



**2 syringes over 2 treatment sessions total for both cheeks**

Only circled scars were treated



# Results

Baseline

Month 6

Month 12



**2.5 syringes for each cheek**

Only circled scars were treated

# Results

Baseline

Month 6

Month 12



**2.5 syringes for each cheek**

Only circled scars were treated

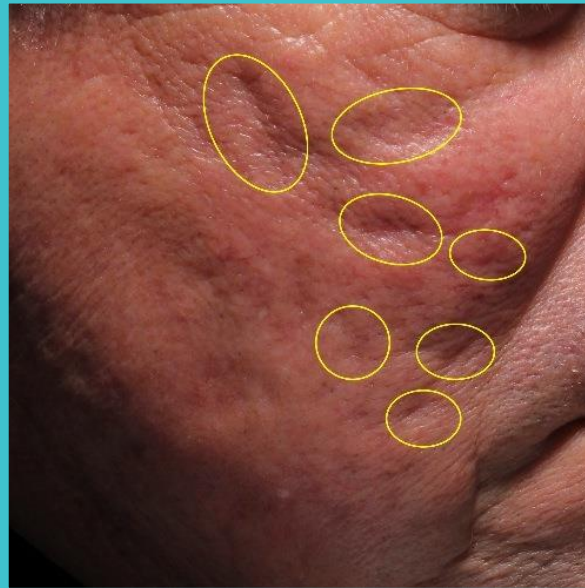


# Results

Baseline



Month 6



Month 12

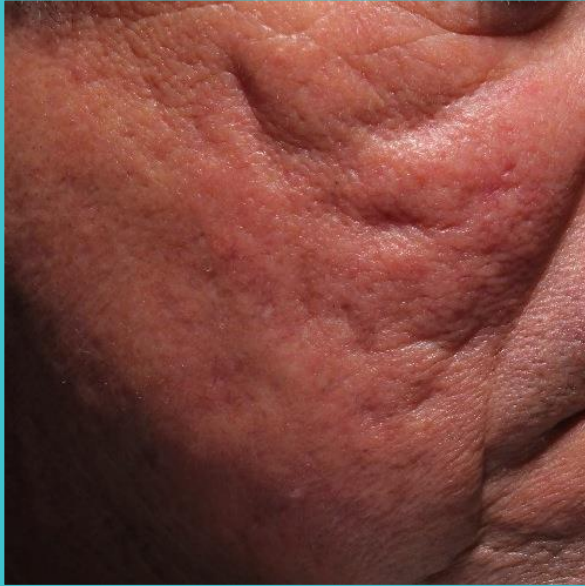


Only circled scars were treated



# Results

Baseline



Month 6



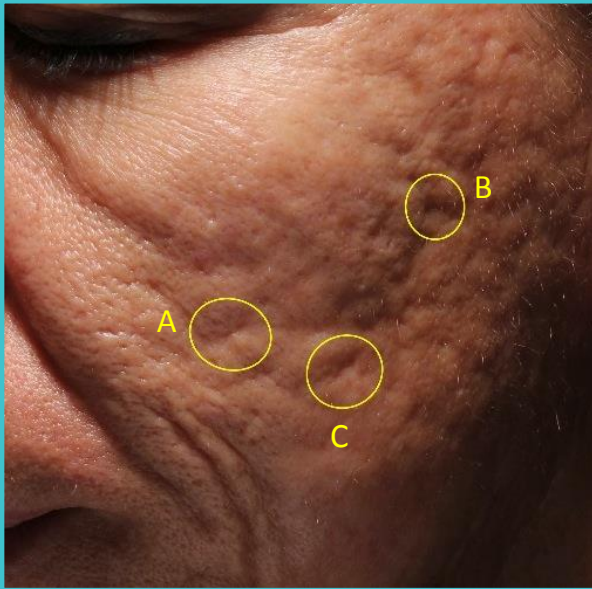
Month 12



Only circled scars were treated

# Results

Baseline



Month 6



Month 12



**0.4 cc for these 3 sites**

Only circled scars were treated



# Results

Baseline



Month 6



Month 12



**0.4 cc for these 3 sites**

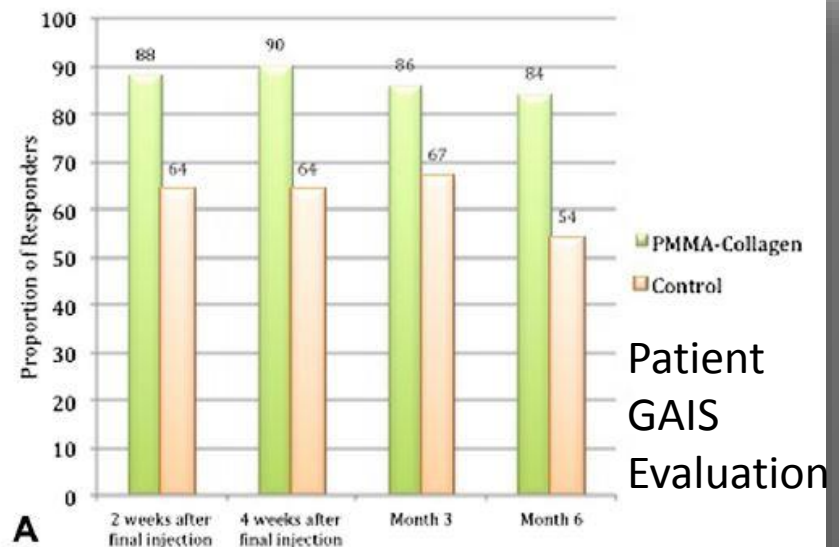
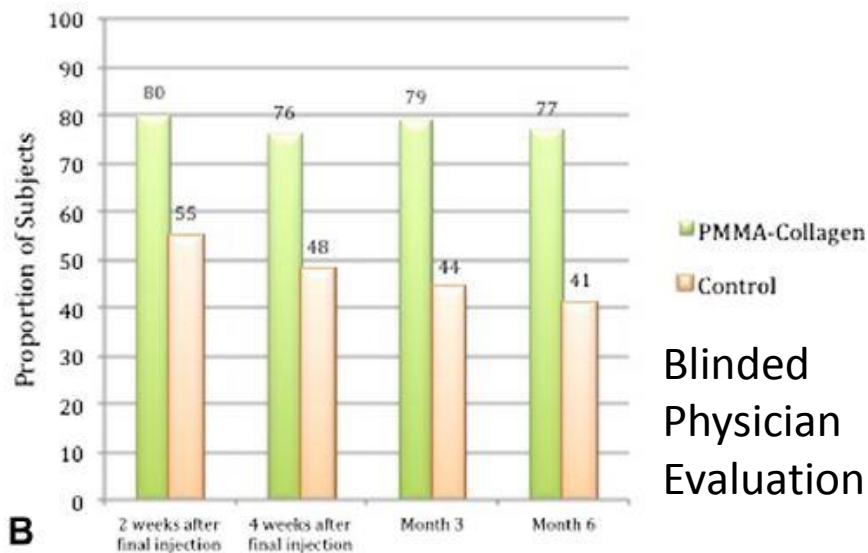
Only circled scars were treated

# Independent Study

## A double-blind, randomized, multicenter, controlled trial of suspended polymethylmethacrylate microspheres for the correction of atrophic facial acne scars

Jwala Karnik, MD,<sup>a</sup> Leslie Baumann, MD,<sup>l</sup> Suzanne Bruce, MD,<sup>b</sup> Valerie Callender, MD,<sup>c,d</sup> Steven Cohen, MD,<sup>e,f</sup> Pearl Grimes, MD,<sup>m</sup> John Joseph, MD,<sup>h</sup> Ava Shamban, MD,<sup>i</sup> James Spencer, MD,<sup>j</sup> Ruth Tedaldi, MD,<sup>n</sup> William Philip Werschler, MD,<sup>k</sup> and Stacy R. Smith, MD<sup>g</sup>  
*Santa Barbara, San Diego, Beverly Hills, and Los Angeles, California; Miami, Florida; Houston, Texas; Glenn Dale, Maryland; Washington, District of Columbia; New York, New York; Wellesley, Massachusetts; and Seattle, Washington*

2014



# Personal Experience

- Challenges with photo documentation
  - VISIA not useful
- Patient expectations
  - Moderate to severe rolling scars
- Multimodality approach
  - Micro-needling
  - Chemical peels
  - Fractional CO2 laser

# Questions?

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# Acne Scar Treatment Results



# RealSelf Rating

## BELLAFILL WORTH IT RATING DETAILS

 89%

BASED ON 13 REVIEWS  
IN THE LAST 24 MONTHS

 89%

BASED ON 13 REVIEWS  
IN THE LAST 12 MONTHS

 89%

BASED ON 13 REVIEWS  
OVER ALL TIME

