Permanent Fillers for Treating Acne Scars

Karol A Gutowski, MD, FACS

Hot Topics
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)
Levels of Evidence and Qualifying Studies (Therapeutic Studies):

I  High-quality, multi-centered or single-centered, randomized controlled trial with adequate power (N ≥ 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
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

<table>
<thead>
<tr>
<th>Category</th>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimal</td>
<td>1</td>
<td>Depth up to .5 mm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Visibility = Perceptible with tangential lighting</td>
</tr>
<tr>
<td>Mild</td>
<td>2</td>
<td>Depth &gt;.5 mm to &lt;1.5 mm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Visibility = Moderately detectable with tangential lighting</td>
</tr>
<tr>
<td>Moderate</td>
<td>3</td>
<td>Depth ≥ 1.5 mm to &lt;2.5 mm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Visibility = Easily seen with tangential lighting</td>
</tr>
<tr>
<td>Severe</td>
<td>4</td>
<td>Depth ≥ 2.5 mm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Visibility = Substantial shadowing with tangential lighting</td>
</tr>
</tbody>
</table>

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 ≥2 points (4 point scale) at 1 year

**Full Analysis Population (n=147)**

- **FA Control** (n=50)
  - Completed M6 (n=46; 92.0%)

- **FA Bellafill®** (n=97)
  - Completed M6 (n=87; 89.7%)
ERAS Trial: Investigator Evaluation

Evaluated by Blinded Investigator

Responders, %

<table>
<thead>
<tr>
<th>Time</th>
<th>Bellafill®</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>W4</td>
<td>26.9</td>
<td>18.8</td>
</tr>
<tr>
<td>W8</td>
<td>40.9</td>
<td></td>
</tr>
<tr>
<td>M3</td>
<td>66.7</td>
<td>35.7</td>
</tr>
<tr>
<td>M6</td>
<td>64.4</td>
<td>32.6</td>
</tr>
<tr>
<td>M9</td>
<td>61.5</td>
<td></td>
</tr>
<tr>
<td>M12</td>
<td>70.7</td>
<td></td>
</tr>
</tbody>
</table>

P =
| Time | 0.3082 | 0.0078 | 0.0077 | 0.0005 | 0.0005 |

Responder = ≥ 2-point improvement in ≥ 50% of treated scars
## ERAS Trial: Adverse Events

Reported in > 1% of subjects

<table>
<thead>
<tr>
<th>Adverse Events, n (%)</th>
<th>PMMA-collagen n = 143*</th>
<th>Control n = 50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection site reaction—lumpiness and papule (3 mild, 1 moderate)</td>
<td>4 (2.8%)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Injection site bruising (2 mild, 1 severe)</td>
<td>3 (2.1%)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Injection site pain (mild)</td>
<td>3 (2.1%)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>
2 syringes over 2 treatment sessions total for both cheeks

Only circled scars were treated
2 syringes over 2 treatment sessions total for both cheeks

Only circled scars were treated
Results

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

Only circled scars were treated
Only circled scars were treated
Results

Only circled scars were treated

0.4 cc for these 3 sites
Only circled scars were treated

0.4 cc for these 3 sites
Independent Study

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

Jwala Karnik, MD,¹ Leslie Baumann, MD,¹ Suzanne Bruce, MD,¹ Valerie Callender, MD,¹,²,³
Steven Cohen, MD,¹,²,³ Pearl Grimes, MD,¹,² John Joseph, MD,¹ Ava Shamban, MD,¹ James Spencer, MD,¹
Ruth Tedaldi, MD,¹ William Philip Werschler, MD,¹ and Stacy R. Smith, MD¹
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

Blinded Physician Evaluation

Patient GAIS Evaluation
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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Permanent Fillers for Treating Acne Scars

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Hot Topics
Acne Scar Treatment Results

Before              6 Months           12 months

Before              6 Months           12 months
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

- Worth it (8)
- Not worth it (1)
- Not sure (4)