Polymethylmethacrylate-Collagen for the Correction of Moderate to Severe Atrophic Acne Scars: Results of a Randomized Double-Blind Multicenter Study with 12 Month Follow-Up.

Background

Polymethylmethacrylate (PMMA)-collagen [Bellafill] consists of PMMA microspheres suspended in a carrier of bovine collagen gel.[1] A Randomized Double-Blind study demonstrated the safety and effectiveness of this product in correcting atrophic acne scars. Results of the 6-month endpoint was previously described in Karnik et al.[2] To determine the continued benefit of PMMA-collagen for atrophic acne scars, and confirm the original findings over a longer time period, the study was continued through 12 months follow up.

Objectives

Demonstrate PMMA-collagen is safe and effective in correcting moderate to severe atrophic acne scars using the validated acne scar rating scale (ASRS).

Methods

A Phase III, multicenter, randomized, double-blind, controlled study was conducted in subjects with ≥ 4 acne scars in the facial area. Eligible scars were distensible, rolling scars that were considered moderate to severe (3 or 4) on a validated 4-point (1-4) ASRS.

Subjects were randomized in a 2:1 ratio to PMMA-collagen or saline (control). Subjects received up to 2 injections per scar and followed for 12 months. Evaluations were performed by treating and blinded investigators and subject self-assessments. Success was determined by an improvement of 2 points on the ASRS by at least 50% of treated scars. At month 6, the blind was removed and control subjects were given the option to receive treatment with PMMA-collagen. All subjects were followed for 12 months following last PMMA-collagen injection.

Results

147 subjects enrolled and underwent treatment. At 6 months 64.4% of PMMA-treated subjects were graded as responders compared to 32.6% of the control subjects ($p = 0.0005$). Improvement with PMMA-collagen was durable over time as noted by the ASRS response rates of 61.5% and 70.7% at Month 9 and 12 respectively. High scores were observed for subjective endpoints on GAIS with 97.6% and 83.1% of physicians and subjects respectively noting improvement. Subjects expressed a high degree of satisfaction (90.4%) with the amount of scar correction. PMMA-collagen showed excellent safety with generally mild, reversible adverse events. No significant differences in efficacy or safety were noted between genders, for darker skin types, or in older age groups. PMMA-treated subjects followed for 12 months continued to show an excellent safety profile.

Discussion

PMMA-collagen demonstrates substantial effectiveness in the treatment of atrophic acne scars while maintaining an excellent safety profile.

References

1. Bellafill [Instructions for Use]. San Diego, Ca: Suneva Medical, Inc.; 2015
2. Karnik J, Baumann L, Bruce S, et al. A double-blind, randomized, multicenter, controlled trial of suspended polymethylmethacrylate microspheres for the correction of atrophic facial acne scars. J Am Acad Dermatol. 2014;71:77-83.