



SKINPEN® + BIOJUVE™ CLINICAL STUDY SUMMARY





Topical application of skin biome care regimen containing live cultures and ferments of *Cutibacterium acnes* *defendens* strain XYCM42 and the impact on the clinical outcomes following microneedle induced skin remodeling

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INTRODUCTION

In aesthetic medicine, there are many examples of treatments where aesthetic improvements are mainly driven by the way in which the body heals. In real-world practice, many of these aesthetic procedures are paired with topical products or even a whole product regimen, often applied post-procedure, as a means to alleviate procedure-associated sequelae and discomfort as well as to reduce any social downtime by allowing for faster or more efficient superficial wound healing. However, as more is being discovered about the intricate relationship between the human skin and the skin's microflora, it has become essential to consider what effects both aesthetic treatments and any topicals applied pre- and/or post-procedure have on the skin microflora and what affect that dynamic can have on the overall success of the procedure's aesthetic outcome and overall skin health.

Given that many aesthetic treatments can disrupt, at least temporarily, the skin barrier, it is important to note that there is increasing evidence which points to the relationship of a healthy skin barrier and the commensal microbes on and in the skin.^{12,13} One way in which commensal microflora of the skin may potentially affect the outcomes of aesthetic procedures is via their metabolites, namely short-chain fatty acids (SCFA). These SCFAs, such as propionate and butyrate, have been shown extensively to contribute to reductions in systemic inflammation via the microflora of the gastrointestinal system and have become an indicator of human/microbiome symbiosis.^{19,20} Additionally, SCFA such as butyrate and propionate have been successfully used as treatments for inflammatory skin issues such as atopic dermatitis and psoriasis.²¹

Our previous research has described the benefits of daily topical application of live strains of the *C. acnes defendens* strain XYCM42.⁶ Given the observed benefits of having a healthy balance of commensal skin flora and their metabolites, especially during wound healing when transient dysbiosis may occur, we conducted a clinical study to ascertain whether we might obtain better clinical outcomes when performing skin microneedling in conjunction with pre- and post-procedure daily application of a regimen containing live cultures and ferments of the skin commensal *C. acnes defendens* strain XYCM42.

Study Design

- 36 subjects
- Treatment of acne scars
- 22-60 years old
- 4 SkinPen procedures, 3 weeks apart
- Follow-up 2 and 6 months post final procedure

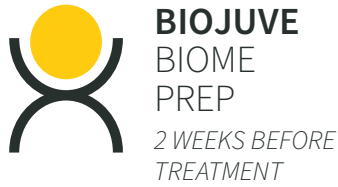
Subjects Randomly Assigned to Two Groups:

1. GROUP 1: Use BIOJUVE regimen 14 days prior to first SkinPen procedure through final post assessment. Daily diaries to track the usage of products.
2. GROUP 2: Use commercially available cleanser, moisturizer, and sheer sunscreen 14 days prior to first SkinPen procedure through final post assessment.



**Read the breakthrough study
published in the *Journal of Cosmetic
and Aesthetic Dermatology***

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THE DAILY REGIMEN CONSISTS OF:

PM Regimen

Meet Your Microbial Powerhouse.
with living Xycrobe™ Technology

Step 1: BIOJUVE™ Conditioning Cleanse



Cleanse & Prepare

Step 2: BIOJUVE™ Living Biome Essentials Serum



Deliver the living Xycrobe™ Technology

Step 3: BIOJUVE™ Activating Mist



The “On Switch” that activates the living microbes

AM Regimen

Nourishes and protects the skin and the living Xycrobes™ to allow for 24/7 skin biome care.

Step 1: BIOJUVE™ Conditioning Cleanse



Cleanse & Prepare

Step 2: BIOJUVE™ Biome Support Complex



Boost

Step 3: BIOJUVE™ Hydrating Barrier Cream *Normal to Dry*



Hydrate

Step 4: BIOJUVE™ Sheer Finish SPF 50+ Sunscreen



Protect

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STUDY RESULTS

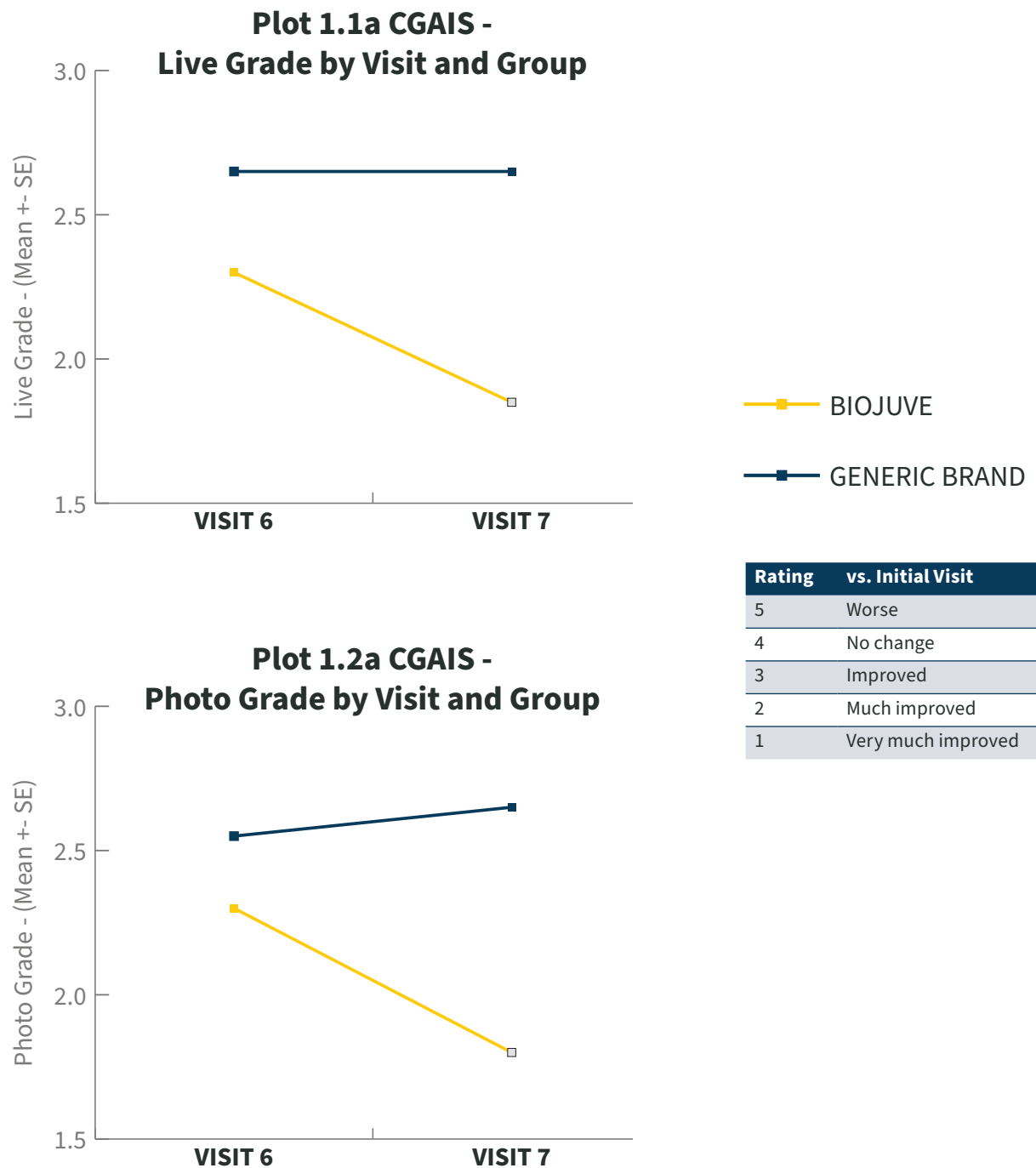
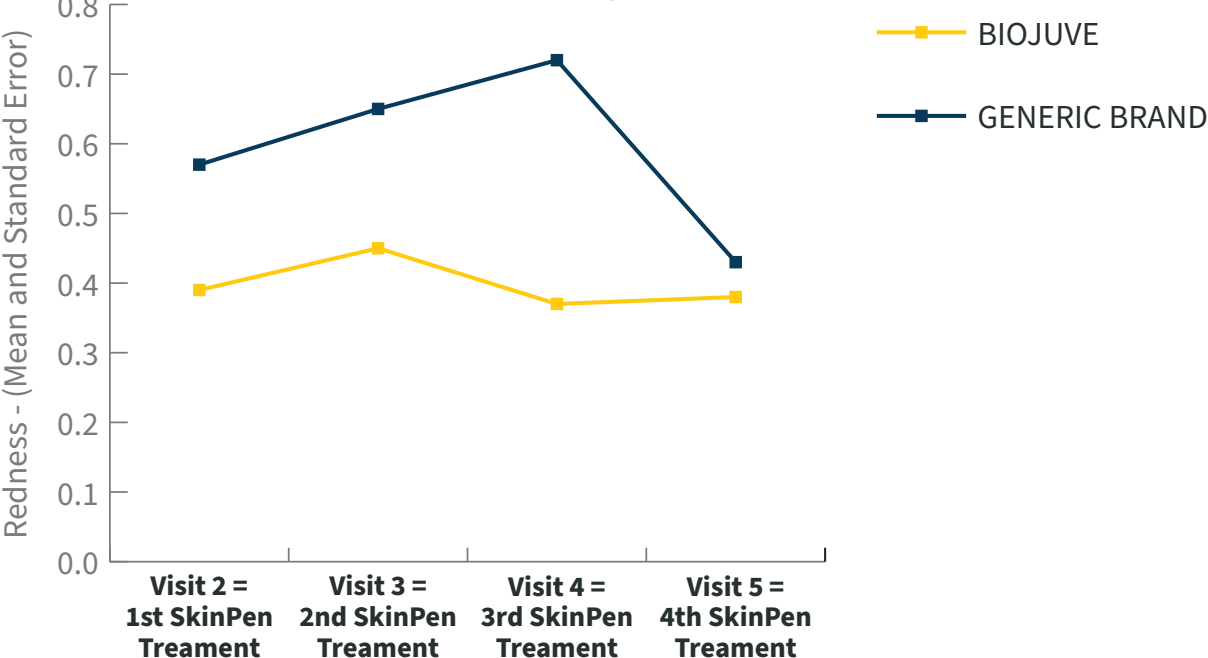


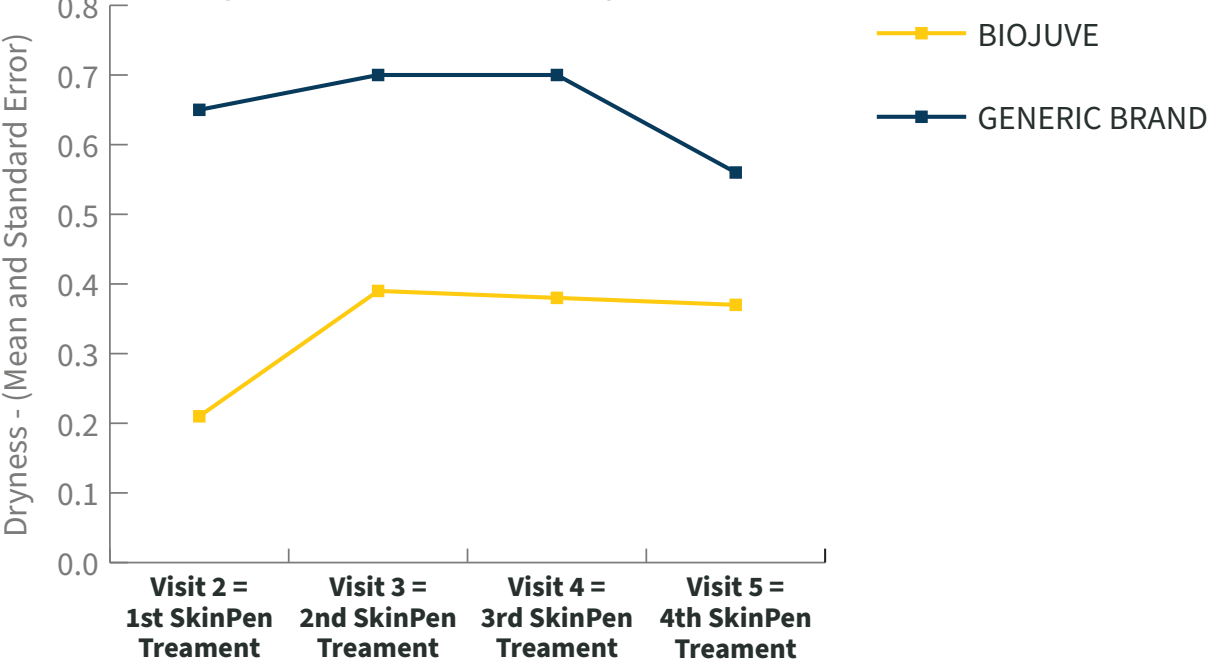
Figure 3 (A). Group 1 exhibited an average decrease of -0.47 in the live grading from visit 6 to visit 7. In contrast, Group 2 showed an average change of 0.00, indicating no substantial change between these visits. **(B).** The photo grading between the two visits for Group 1 had an average decrease of -0.37. In contrast, Group 2 displayed an average increase of 0.14. A similar trend was observed in both grading assessments, where significant improvement was observed in the group utilizing the topical probiotic.

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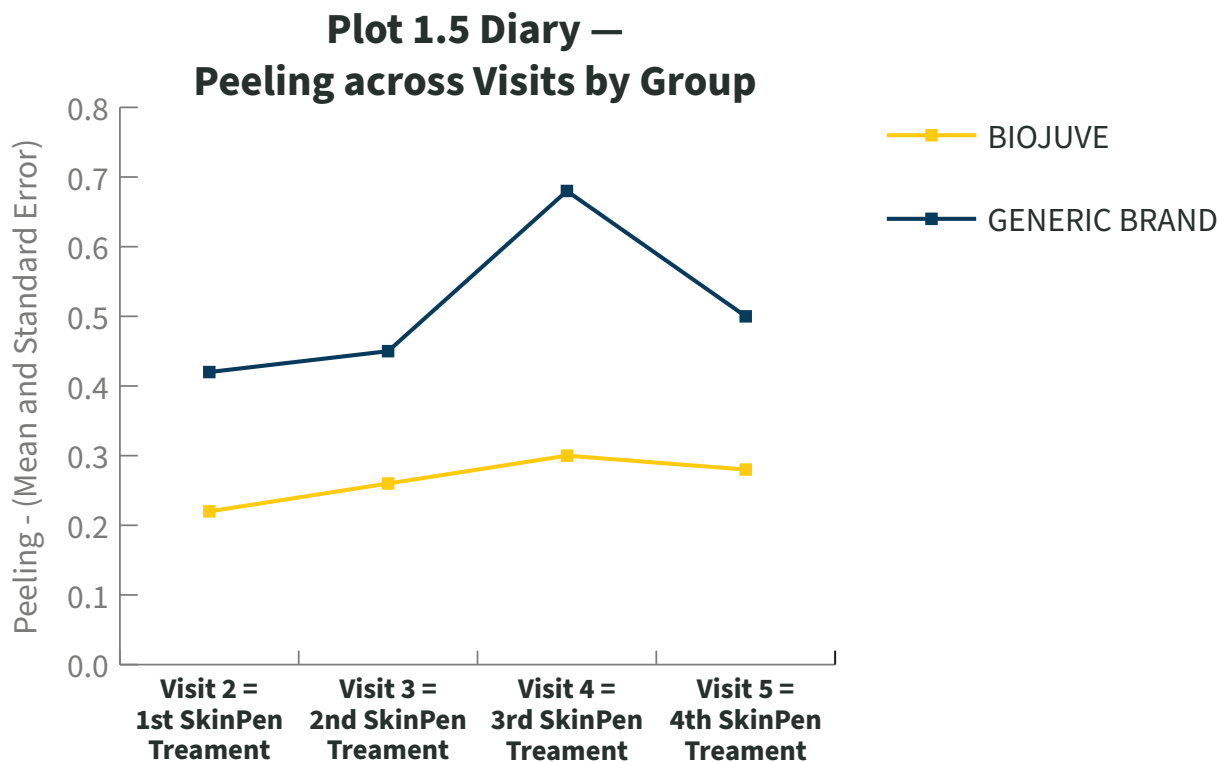
**Plot 1.1 Diary —
Redness across Visits by Group**



**Plot 1.4 Diary —
Dryness across Visits by Group**



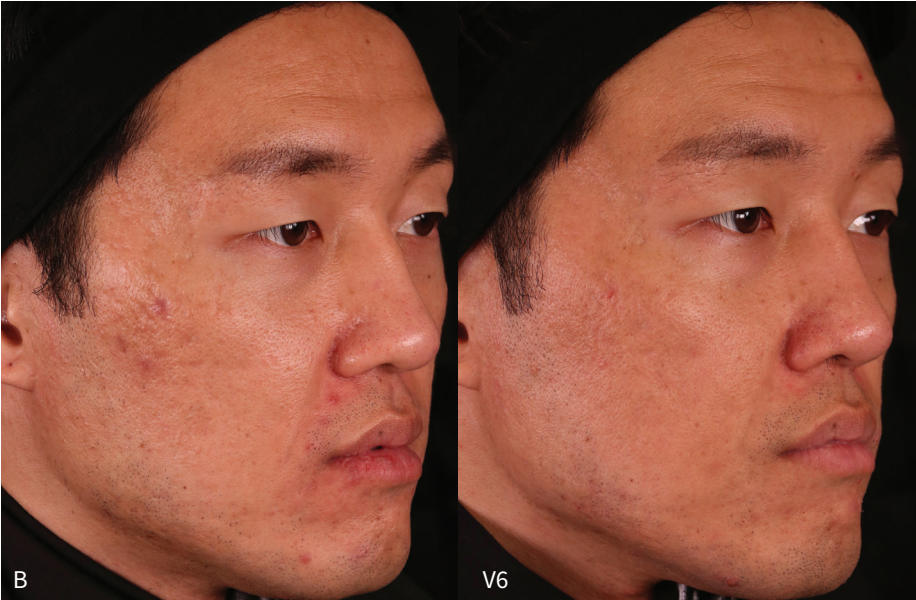
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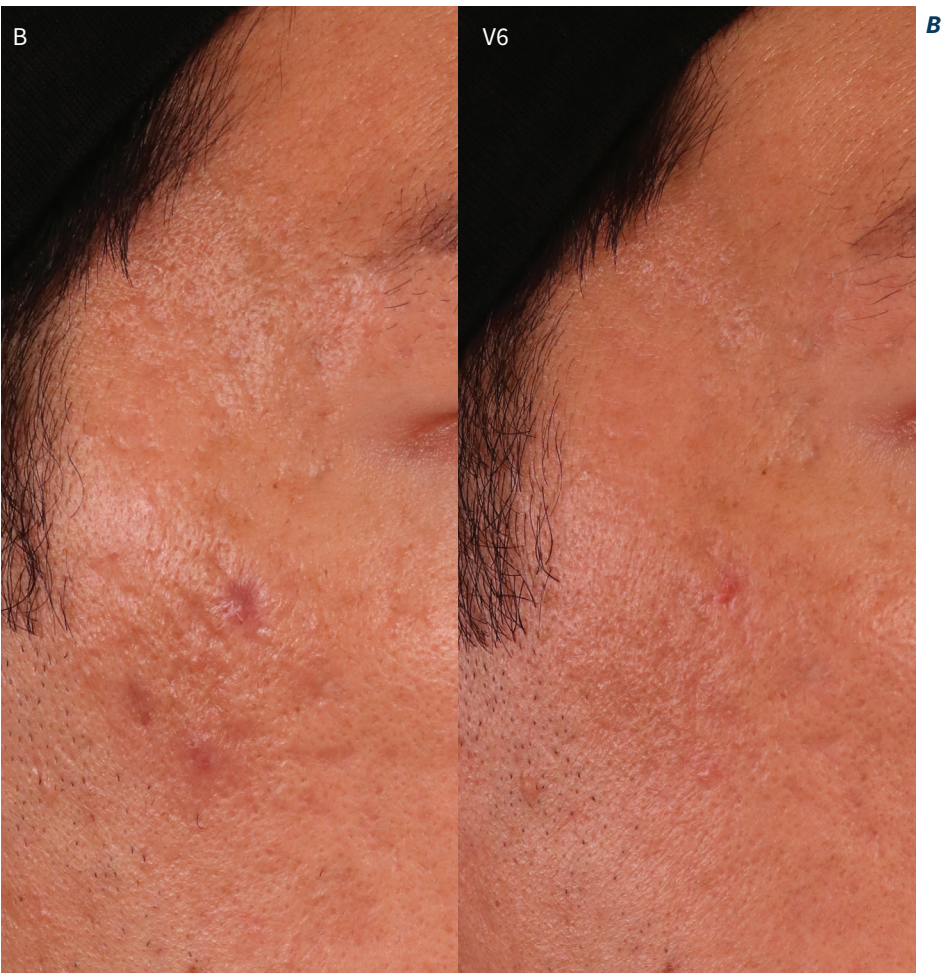
CONCLUSION

We believe that this is the first study of its kind to combine a living skin biome care regimen with an aesthetic procedure such as microneedling. This study supports the safety of a skin biome care regimen utilizing a specific living bacterium *XYCM42*, based on *C. acnes defendens*, applied throughout the course of microneedling treatments. Additionally, it also demonstrates an improved recovery of patients after microneedling treatments, compared to a general cleanser and moisturizer routine. Any concern regarding potential for opportunistic infection of a barrier-impaired microneedled skin by the bacteria was not substantiated. No infections were seen in any patient after any of the microneedling procedures or during the use of the probiotic product line. We conclude that the use of a probiotic skin biome care regimen addresses the needs of the skin before and after microneedling and provides significant, early demonstratable benefits to the patient. Additional studies should be undertaken to assess if these study findings, seen with this regimen and microneedling, translate to other aesthetic treatments such as laser skin resurfacing, laser hair removal, Intense Pulse light (IPL) photorejuvenation, microdermabrasion, chemical peels, and facial “cleansing” procedures. The evidence generated here suggests an important role of pre-procedural skin biome optimization in the optimization of the clinical outcomes of aesthetic interventions.

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A *Figure 4(A). A side view of a 32 year old male, Fitzpatrick type III in Group 1 (SkinPen + BIOJUVE) that presented boxcar and rolling acne scars at baseline. (B) A close-up image of the same subject's temple.*



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A *Figure 5(A). Side view of a Fitzpatrick type IV, 29 year old male in Group 1 (SkinPen + BIOJUVE). (B). Side view of a Fitzpatrick type III, 25 year old female in Group 1 (SkinPen + BIOJUVE) who had noticeable improvement at their 2-month follow-up visits.*



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Figure 9. Side view of a Fitzpatrick type III, 25 year old female in Group 1 (SkinPen + BIOJUVE).



Figure 10. A close-up image of subject's temple who is a 30 year old male with Fitzpatrick type III skin in Group 1 (SkinPen + BIOJUVE).

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A *Figure 13. Frontal and side views of a Fitzpatrick type VI, 29 year old female in Group 1 (SkinPen + BIOJUVE).*



B

**For more information please contact Crown Medical Affairs at
medinfo@crownaesthetics.com**

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