Regeneration Booster
by Jan Marini Skin Research

PRODUCT SUMMARY
Regeneration Booster is a cutting-edge anti-aging powerhouse proven through independent studies to significantly improve the appearance of aging skin. Maximum results are delivered through a concentrated combination of advanced ingredients including cycloastragenol, TGF Beta-1, CoEnzyme Q10, multiple beneficial growth factors and peptides and antioxidants.

KEY INGREDIENTS
- Cycloastragenol
- TGF Beta-1 (rh-Polypeptide-22)
- Epidermal Growth Factor (sh-Oligopeptide-1)
- Keratinocyte Growth Factor (sh-Polypeptide-3)
- Peptides: Palmitoyl Pentapeptide-4, Myristoyl Pentapeptide-8, Myristoyl Pentapeptide-11, Myristoyl Tetrapeptide-12
- Green Tea Extract
- CoEnzyme Q10
- Hyaluronic Acid
- Essential Fatty Acids

STUDY TESTIMONIAL
"We were very impressed by the results of our Regeneration Booster study. Subject satisfaction was very high with improvement visible after just 2 weeks of use and 100% of subjects noting improvement in multiple categories of aging skin. These results support Regeneration Booster's use as an advanced anti-aging skincare solution."
– Robert Weiss, MD

Evaluation of a Novel Anti-aging Topical Formulation Containing Cycloastragenol, Growth Factors, Peptides and Antioxidants

Robert Weiss, MD, Baltimore MD

INTRODUCTION
This study investigates the efficacy, tolerance and usability of a single product containing cycloastragenol, growth factors, peptides and antioxidants to decrease the visible signs of aging, including fine lines and wrinkles, texture, pore size, elasticity, skin color / clarity, redness, hydration and overall skin quality.

METHODS
Twenty subjects were enrolled in a 90-day, open-label, patient-assessment study. Subjects used a gentle cleanser, Regeneration Booster and a broad spectrum SPF for the duration of the 90-day study. Assessments were taken at baseline, 14, 30, 60 and 90 days. All assessments were compared against baseline for statistical significance.

RESULTS
18 of the 20 subjects completed the study. Improvement was significant after just 2 weeks of use for all measured categories except erythema and significant for all categories at 90 days. 100% of study subjects noted improvement in at least 3 or more of the 8 assessed categories with an average improvement in 6.7 categories. Improvement response rate for individual categories ranged from 67% to 100% of study subjects. There were zero cases of sensitivity or irritation and product smell, feel and ease of application were rated "positive" by 100% of study subjects. Photographic improvement was most notable in texture and lines on the cheeks and eye area.

CONCLUSION
Regeneration Booster when used as a stand–alone anti-aging solution delivers rapid and significant reduction in the visible signs of aging. Subject satisfaction was extremely high and there were zero reported cases of sensitivity or irritation. Based on these observations, Regeneration Booster is a safe and effective topical product for individuals seeking significant improvement in the appearance of aging skin.

INTRODUCTION
The professionally dispensed topical anti-aging market continues to grow and evolve driven by new ingredients, advancements in formulations and new utilizations of synergistic combinations of proven ingredients. It is estimated that from 2011 to 2015 global sales of physician-dispensed topicals will increase by 12.2% per year (Medical Insights Inc., June 2011).

The tested product, Regeneration Booster (Jan Marini Skin Research), is an advanced, patented, anti-aging formulation consisting of multiple anti-aging technologies.

A key ingredient in Regeneration Booster's patented formulation is a new topical compound cycloastragenol. Cycloastragenol, is a purified extract from the astragalus plant. Cycloastragenol, a strong antioxidant, is also shown to significantly reduce many of the visible signs of aging. (Baumann, July 2011) (Valenzuela H, 2009)

In addition to cycloastragenol, Regeneration Booster contains high concentrations of three growth factors: Transforming Growth Factor Beta 1 (rh-polypeptide-22),

Keratinocyte Growth Factor (sh-Polypeptide-3), Epidermal Growth Factor (sh-Oligopeptide-1) and four anti-aging / skin-conditioning peptides Myristoyl Tetrapeptide-12, Myristoyl Pentapeptide-11, Palmitoyl Pentapeptide-4 and Myristoyl Pentapeptide-8.

Finally, Regeneration Booster contains a broad range of topical antioxidants, hydrators and skin-protectants including Coenzyme Q10, Green Tea Extract, Hyaluronic Acid, Ceramides 2 and multiple essential fatty acids.

The purpose of this study is to determine Regeneration Booster's ability to decrease the visible signs of aging, including fine lines and wrinkles, texture, pore size, elasticity, skin color / clarity, redness, hydration and overall skin quality. In addition, this study also seeks to assess the product's user experience including smell, feel, ease of use, acclimation and irritation.

METHODS
Twenty subjects were enrolled in a 90-day, open-label patient assessment study to determine the efficacy of Regeneration Booster. The study was conducted by the office of Robert Weiss, MD of the Maryland Laser, Skin and Vein Institute.

Study protocol specified enrollment of subjects aged 35-75 with a moderate degree of photo-aging, defined by a starting Glogau score of II or III. Of these, a minimum of 70% of subjects were required to have a starting Glogau wrinkle score of III. Exclusion criteria included anyone with known allergies to product ingredients, anyone with recent hormonal changes including pregnant or nursing, a history of smoking, and use of any professional skin care products, retinoids or prescription topical medications in the past 90 days.

To control the environment, all subjects were required to use only the test product, (Regeneration Booster by Jan Marini Skin Research), Age Intervention Gentle Cleanser (Jan Marini Skin Research) and Antioxidant Daily Face Protectant SPF33 (Jan Marini Skin Research). Products were applied AM and PM, with the SPF being applied only in the AM or prior to outdoor activity. No other topical skin care products were allowed over the study period. Subjects were allowed to wear daily makeup per individual preference.

Results were determined through subject self-assessment surveys. Surveys were administered at study initiation and follow up visits at 14, 30, 60 and 90 days. Assessments graded 8 categories: the appearance of fine lines and wrinkles, texture, pore

size, and skin color clarity / uniformity, skin elasticity, erythema, hydration and overall skin quality. Each assessment was performed using a 5-point scale: -2=Significantly Dissatisfied, -1=Dissatisfied, 0=Neutral, 1=Satisfied and 2=Significantly Satisfied. Subjects were also asked at each follow-up visit to rate their perceived change in each of the above categories as worsened, none, mild, moderate and significant.

To determine product usability, subjects rated the product as negative, neutral or positive for each of the following categories: ease of application, texture / feel, smell, and overall usage. Finally, subjects recorded adverse events to determine acclimation including sensitivity, tingling / burning or other.

Table 1: Assessment Scores by Category at Time Intervals

Days	0	14	30	60	90
Wrinkles	-1.06	-0.41	0.00	0.29	0.33
Texture	-0.78	0.06	0.35	0.71	0.78
Pore Size	-0.78	-0.06	0.29	0.47	0.44
Elasticity	-1.00	-0.29	0.00	0.29	0.67
Skin Clarity / Uniformity	-1.06	-0.12	0.12	0.35	0.44
Erythema	-0.33	0.12	0.24	0.29	0.39
Hydration	-0.94	-0.18	0.41	0.47	0.72
Overall Skin Satisfaction	-0.89	-0.18	0.24	0.29	0.83

Table 2: Improvement and Significance at 14 and 90 Days

	14 Days		90 Days	
	Delta	Signif.	Delta	Signif.
Wrinkles	0.64	p=0.017	1.39	p<0.001
Texture	0.84	p=0.004	1.56	p<0.001
Pore Size	0.72	p=0.018	1.22	p<0.001
Elasticity	0.71	p=0.014	1.67	p<0.001
Skin Clarity / Uniformity	0.94	p=0.010	1.50	p<0.001
Erythema	0.45	p=0.104	0.72	p=0.014
Hydration	0.77	p=0.014	1.67	p<0.001
Overall Skin Satisfaction	0.71	p=0.003	1.72	p<0.001

improvement for smoother, more uniform looking skin with marked reduction in the appearance of fine lines and wrinkles, erythema, skin color / clarity and pore size. 100% of subjects responded favorably with improvement in multiple areas of measurement. There were zero cases of even mild tingling or irritation with use allowing for immediate use with no acclimation period. Additionally, subjects noted improved elasticity and hydration with use. Finally, while this study is limited to a 90-day period, the rates of improvement indicate subjects should continue to notice further improvement in the visible signs of aging with continued use.

The benefits of rapid improvement with zero irritation lead to high subject satisfaction and compliance placing Regeneration Booster as a premier stand-alone topical product to address the visible signs of aging.

REFERENCES
Baumann, D. L. (July 2011). Cosmeceutical Critique - Astragalus. *Aesthetic Dermatology*, 22.

Medical Insights Inc. (June 2011). *Physician Dispensed Topicals: Product Innovations Drive Growth*. Medical Insights Inc.

Valenzuela H, F. T. (2009). Cycloastragenol extends T cell proliferation by increasing telomerase activity. *The Journal of Immunology,* 182:90.30.

The four subjects who did not indicate positive intent to recommend the product indicated a neutral or undecided intent to recommend. There were zero cases of dissatisfaction or intent not to recommend.

DISCUSSION

Anti-aging is the primary driver for the cosmetic industry and, now more than ever, adults in all age categories are seeking solutions to address the visible signs of aging.

The tested sample provided rapid and significant improvement in the appearance of multiple common signs of aging with no sensitivity, irritation or acclimation. Subjects were able to use the product as directed from day one for optimal results. Improvement was rapid with individuals noting significant change at the initial 2 week visit in all categories except erythema, which was also significant at 90 days.

One notable point was the rapid response and broad degree of improvement in skin satisfaction. 100% of subjects improved by self-assessment from baseline to study completion in 3 or more categories. On average, subjects improved in 6.7 of the 8 categories with 100% noting improvement in overall skin quality (Figure 3). Further across all 144 individual assessments (18 subjects by 8 individual measured categories each), 117 (81%) of all assessments noted increased satisfaction from baseline while only 4 (0.03%) noted decreased satisfaction. Additionally, improvement in the visible signs of aging was not limited to those who completed the study. The two subjects lost to follow-up (not included in data) completed the study through the 60 day follow-up and showed improvement in 4 and 8 categories, respectively, with no decreased categories or adverse events.

While erythema reduction was not significant at 2 weeks, existence of erythema was not a criterion for enrollment so many individuals rated their satisfaction with erythema as Neutral to Significantly Satisfied at study baseline, leaving little room for improvement. For the subset of individuals (6 in total) that rated erythema as Significantly Dissatisfied or Dissatisfied, erythema decreased rapidly in the first 2 weeks of use from an average starting score of -1.3 (between significantly dissatisfied and dissatisfied) to +0.13 (between Neutral and Satisfied).

A good indicator of overall subject satisfaction is the increase in the number of subjects indicating satisfaction with skin post vs. pre study (Figure 4). The number of subjects indicating Satisfied to Significantly Satisfied per category increased significantly over the duration

Figure 3: Percent of Subjects With Perceived Improvement

Figure 4: Subjects Rating Satisfied to Significantly Satisfied
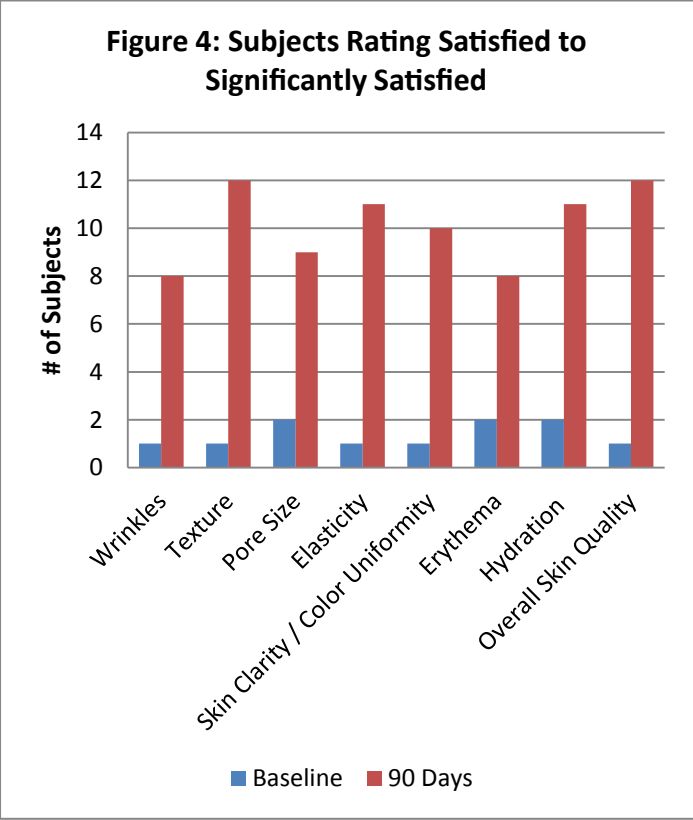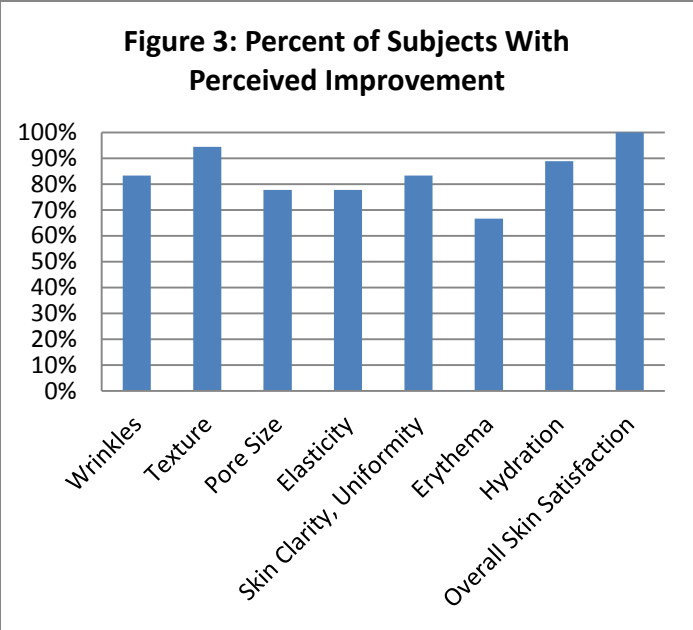
of the study with an average increase of 8.75 individuals per category, ranging from a minimum increase of 6 individuals for erythema to a maximum increase of 11 individuals for texture and overall skin quality.

CONCLUSION

The tested product is a revolutionary new topical anti-aging product. It provides rapid and clinically proven

Finally, to assess overall satisfaction, subjects were asked on their 90-day assessment if they would recommend the product to a friend or family member.

Images were taken using a Visia camera at each visit to observe photographic changes. Statistical significance was determined based on pre and post assessment values. Significance was determined using a two-tailed paired t-test with a p value of <0.05 being considered significant.

RESULTS

Of the twenty enrolled subjects, eighteen completed the study. The two subjects lost to follow-up were lost after the 60-day follow-up, prior to the final 90-day follow-up. Results were significant in all measured categories with 100% of subjects experiencing improvement in 3 or more categories.

Self assessed satisfaction scores by category at each visit are shown in Table 1 and Figure 1. Figure 2 shows the percent of subjects with improvement in each category over the duration of the study.

Scores are based on a 5-point scale. -2=Significantly Dissatisfied, -1=Dissatisfied, 0=Neutral, 1=Satisfied and 2=Significantly Satisfied.

Improvement was rapid with significant improvement noted in all categories but erythema by week two. Results improved over the duration of the study with significant improvement in all categories at study completion (Table 2, Figure 1).

100% of individuals improved in 3 or more categories with an average improvement in 6.5 of the 8 measured categories. The average satisfaction score (range from -2 to 2) across all categories increased by 1.43 points from -0.85 pre to 0.58 post (Figure 1).

Figure 2 shows the percent of individuals with improvement vs. baseline by category across the duration of the study. 100% of subjects also improved by perceived change in skin in 3 or more categories each with 100% noting an improvement in overall skin quality and an average improvement in 6.7 of the eight categories (Figure 3). There were 0 cases of perceived reduction in skin quality in any recorded category.

Product attributes including smell, texture, feel and application were all rated as positive by 100% of study subjects. Further, there were 0 cases of subjects experiencing acclimation, tingling or burning reported in any follow-up assessment. Across all subjects and

Figure 1 Average Score By Concern

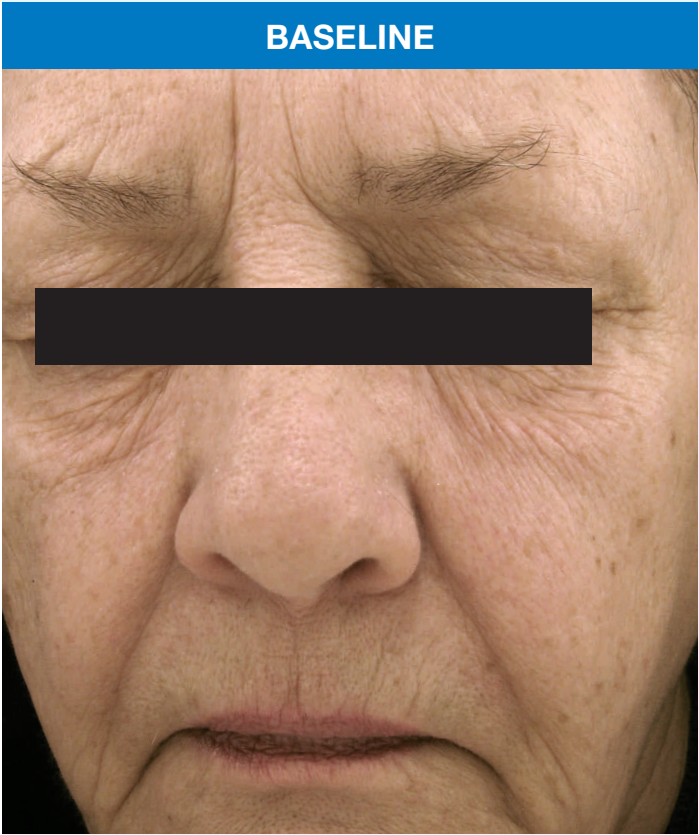**Figure 2: Percent of Subjects with Improvement vs. Baseline**
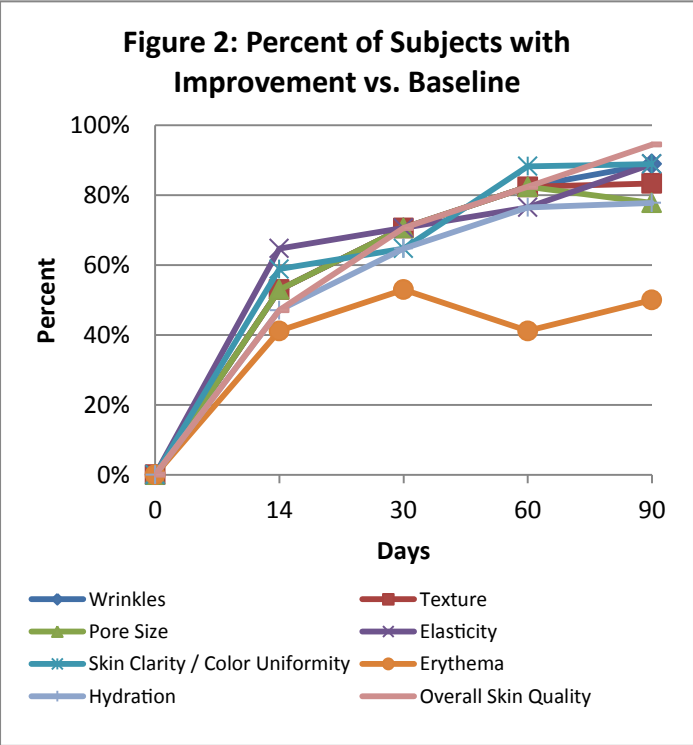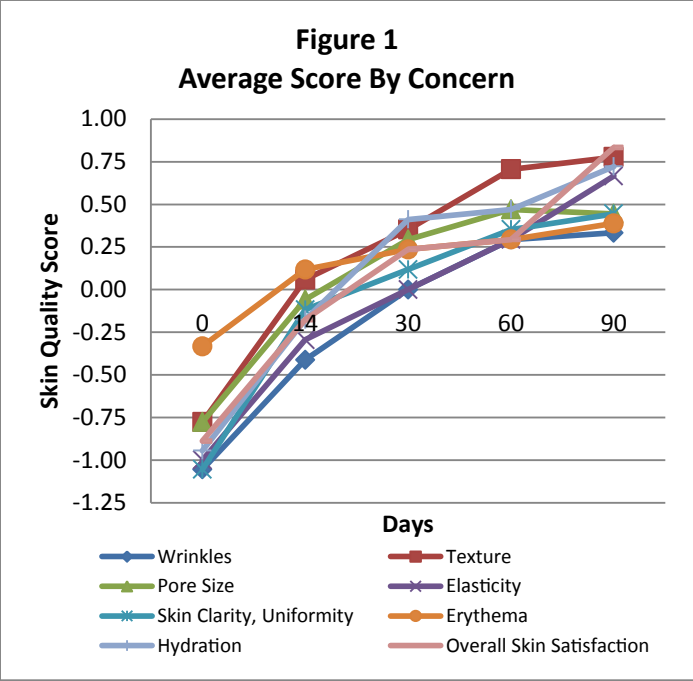
follow-up assessments there were a total of 4 reports of transient mild itching following application. No individual noted this for more than 2 of the 4 follow-up visits.

Satisfaction with the product was high with 100% of subjects indicating overall satisfaction with the product. Fourteen subjects indicated moderate to high satisfaction and 13 indicated that they would recommend the product to a family member or friend.

BASELINE

90 DAYS

Images courtesy of Robert Weiss, MD.

BASELINE

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