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# Assessment of a Comprehensive Anti-Aging Neck Cream

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## INTRODUCTION

The purpose of this study was to determine the tested neck cream's effect on self-reported signs of aging including skin hydration, texture, wrinkles and laxity. This study further investigates key user characteristics of the product including absorption, application, scent and feel as these product attributes are highly impactful toward consistent use and resultant efficacy.

## METHODS

Subject screening was conducted via a virtual trial on 85 adult females ages 35-65 with Fitzpatrick skin types I through IV. Subjects applied the test neck cream (Marini Juveneck, Jan Marini Skin Research, San Jose, CA) and sunscreen (Antioxidant Daily Face Protectant SPF33, Jan Marini Skin Research, San Jose, CA) exclusively to the entire neck and jawline during the 3-month study period. Subjects rated satisfaction with skin using a 5 point scale from highly dissatisfied to highly satisfied in each of 4 categories including hydration, texture, wrinkles and laxity. Satisfaction with product attributes including application, feel and smell were also collected and assessed. Data collection was completed via online survey at Baseline, 2 days, 30 days, 60 days and 90 days.

## RESULTS

71 of the initial 85 participants (84%) completed the final 90-day assessment. Improvement in satisfaction with skin was statistically significant from baseline scores for all measured categories (hydration, texture, wrinkles and laxity) with 78%-80% of individuals noting improvement in each individual assessment and 94% of study subjects noting improvement in at least one of the four categories. The quantity of subjects scoring "Satisfied" and "Highly Satisfied" across measured categories increased 8x from baseline with a 94x increase in the quantity of highly satisfied assessments. Satisfaction with product attributes was also high with 94-100% of subjects responding favorably to the product scent, application, absorption and feel. Overall, satisfaction was high with 94% of subjects responding positively to overall product satisfaction.

## CONCLUSION

The results demonstrate that subject's belief that the neck cream product effectively improved the appearance of aging skin in the neck area. Based on subject assessment, it appears the neck cream product helped to significantly improve hydration and texture while significantly reducing the appearance of wrinkles and laxity along the jawline for more contoured skin. Results were rapid with continuing benefits over time. Future studies are recommended to determine the primary action mechanisms and to assess the degree of improvement by blinded physician assessment.

## INTRODUCTION

While frequently discussed and associated with aging of the face, photo-aging also affects the delicate skin of the neck yet, while there are many anti-aging solutions for the face, there are few clinically proven solutions to address the

range of photo-aging concerns to the neck. As such, there is significant growing media and consumer attention given to products and solutions for the neck. In the past three years there has been a significant increase in the number of devices and products indicated for or used on the neck yet

there are few to no published studies on topical anti-aging solutions for this region.

Photo-aging is characterized by sagging and thinning of the skin, discoloration, fine lines, and skin fragility. Clinical signs of photo-aging are caused by loss of elastin, hyaluronic acid (HA), and collagen. Loss of elastin contributes to skin lax / sagging skin which, combined with aging downward pull of the platysmal muscle results in horizontal wrinkles commonly referred to as necklace lines. Loss of collagen in skin leads to fine lines, thinness, vertical lines, fragility and textural change. Loss of hyaluronic acid in skin results in decreased skin plumpness and fine lines.

Photo-aging of the neck share many if not all of the physiologic changes associated with aging skin on the face, the neck requires several unique considerations from solutions designed for the face. Skin off the face is dryer than skin on the face where sebaceous gland density is the highest with 400-900 glands / cm<sup>2</sup>. Off face, by comparison, densities drop significantly with both smaller glands and lower densities of only 100 glands / cm<sup>2</sup> on the extremities.<sup>1</sup> Sebum naturally has a high content of Vitamin E and squalene. Because there are fewer sebaceous gland on the neck and other parts of the body as compared to the face, excretion of Vitamin E is 20x higher on the cheek and squalene is as much as 47X higher on the face than they are on the upper arm<sup>2</sup>. In addition, patients report that neck skin is more sensitive with an increased likelihood of redness and itching<sup>3</sup>, minimizing the range of ingredient options. Laxity, discoloration and textural changes on the neck are harder to address with complimentary solutions like fillers and botulinum toxin. Finally, fat loss in the cheeks, fat deposits under the jawline, and shortening of the platysma muscle can exacerbate the appearance of laxity on an aging neck line.

The tested neck cream product contains multiple key ingredients designed to address hydration, improve texture, reduce wrinkles and improve skin tone and elasticity for a firmer, more lifted appearance. Key ingredients in the product include Rye Seed Extract, Oat Kernel Extract, Glucine, Aminophylline, Acetyl Decapeptide 3, Dimethylethanolamine, Oligopeptide-24, Dipotassium Glycyrrhizate, alpha-Bisabolol, Tocopherol, Biotin, Panthenol and Sodium Hyaluronate.

HA, composed of repeated units of sugars (saccharides), is a humectant. When applied to the surface of the skin, it draws water into itself, which can increase and maintain skin hydration. HA has been shown to increase the penetration of other ingredients.<sup>4</sup> Panthenol, a form of vitamin B5, is also a humectant and is highly absorbed by the skin, making it a

superior hydrating agent.<sup>5</sup> Studies have further shown that panthenol significantly reduces trans-epidermal water loss (TEWL) after 30 days of use.<sup>5</sup>

Biotin, another B vitamin and commonly referred to as vitamin H, is also shown to improve barrier function and reduce TEWL as well as reduce inflammation and sensitivity.

Alpha-bisabolol (bisabolol) is shown to have a broad range of benefits including anti-irritant and anti-inflammatory properties.<sup>6</sup> Bisabolol is also shown to possess anti-bacterial and anti-fungal properties as well as skin lightening characteristics associated with reduced inflammatory response.<sup>7</sup>

Vitamin E is one of the major naturally occurring antioxidants on the skin. The fact that there is less sebum production on the neck means that the neck has less natural protection to the sun and resulting free radicals. In addition to being a potent antioxidant, tocopherol (vitamin E) hydrates the skin and helps reduce inflammation, and inhibit UV-induced melanogenesis. Finally, dipotassium glycyrrhizate, the pure form of the active component in licorice root extract, is shown to inhibit tyrosinase (preventing the formation of melanin) resulting in evening of skin tone.

Anti-aging peptides and 2-dimethylaminoethanol (DMAE) are included to help reduce the appearance of wrinkles and help improve firming and contour. Although we do not know if these peptides are able to penetrate into the dermal layer of the skin, these advanced anti-aging peptides are engineered to encourage increased production of collagen and elastin by fibroblasts in the skin as well as increase hydration and cellular repair to minimize the appearance of fine lines and wrinkles. Their inclusion is based on in-vitro studies showing positive effect on these intended cells.<sup>8,9</sup> Dimethylaminoethanol (DMAE) is shown to help improve skin tensile strength and reduce forehead lines and periorbital fine wrinkles.<sup>10</sup> Glucine, Aminophylline, Rye Seed Extract and Oat Kernel extract are included in the formulation based on purported positive visible effects on skin tone, firmness contouring effect, though literature to prove these effects in-vivo is inconclusive or unavailable.

The intended combination of all these anti-aging, firming and hydrating technologies is to give the user the firmer, more contoured appearance. This prospective study investigates subject satisfaction using the neck cream product to determine its effect on self-reported signs of aging including skin hydration, texture, wrinkles and laxity. This study further investigates key user characteristics of the product including absorption, application, scent and feel as these product

attributes are highly impactful toward consistent use and resultant efficacy.

## METHODS

### Survey Subject Population

Subject screening was conducted via a virtual trial. Survey design consisted of an initial enrollment of 100 participants (of which 85 completed the baseline survey) to ensure a minimum of 25 participants at the three-month survey completion. All participants recruited for this online survey were females, Fitzpatrick skin types I through IV, between the ages of 35 and 65. All participants received 5 surveys at the following time points: Baseline, 2 days, 30 days, 60 days and 90 days.

The target population was selected from a self-reported set of individuals who met the following inclusion and exclusion criteria:

### Inclusion Criteria

- Females between the ages of 35 to 65 with a loss of youthful elasticity, mild to moderate wrinkles and laxity on the neck. These include visible textural changes, mild laxity (up to 5mm under the chin) and fine to medium depth wrinkles.
- Participants who agree to limit their exposure to the sun and be willing to wear a sunscreen on their face and neck for the duration of the study.
- Females who are not pregnant, planning a pregnancy, or breast-feeding and are willing to use a consistent, medically effective method of birth control throughout the course of the study.
- Participants able to read, understand, and agree to participate in the online survey for three months

### Exclusion Criteria

- Participants with excessive laxity, including deep lines and wrinkles along neck
- Use of any dedicated neck cream during the past 3 months
- Use of retinoids on the face or neck in the past 3 months (prescription or non-prescription)
- Use of topical medications on the neck for any skin condition (including acne)
- Any anti-aging resurfacing procedure (ablative or non-ablative laser or medium depth chemical) peel in the past 3 months that extended beyond the jawline
- Use of oral isotretinoin in the last 6 months
- Anyone who is pregnant, nursing, or planning a pregnancy
- Enrollment in any other clinical research study in the past

30 days (prior to enrollment)

- Anyone unwilling or unable to follow protocol and use products for the full study duration
- Anyone with known allergies /sensitivities to ingredients in either product
- Participants who smoke (more than an occasional cigarette at any time - past or present)

### Survey Materials

Participants were instructed to apply the neck cream product, Marini Juvenileck, (Jan Marini Skin Research, San Jose, CA), to the entire neck including under the chin, from the collarbone to the jawline and around both sides of the neck including behind the ears, twice daily in the morning and afternoon. Participants were also required to wear a broad spectrum SPF (Antioxidant Daily Face Protectant SPF 33, Jan Marini Skin Research, San Jose, CA). Study subjects received the neck cream products with home instructions to use throughout the three-month online survey period. The study was open-label, non-placebo controlled, with a generic product name "Neck Cream" given to the product.

Email notifications and reminders were provided to give instructions on how to fill out the 5 online surveys to determine the effectiveness and consumer preference of each of the products. Our detailed questionnaire allowed us to assess the participants' responses regarding the improvement of the neck skin's appearance at each time point as compared to baseline assessments. It also allows us to show the importance of their perception regarding the efficacy of the neck cream product.

### Data Collection

Data was collected via online surveys at 5 time points – Day 0 (baseline) and days 2, 30, 60 and 90. Surveys were designed not to capture personal identifiable information. Online surveys were provided to all enrolled participants, ensuring confidentiality of their individual responses. All five surveys asked participants to assess their overall satisfaction with 4 categories of concern on their neck: a) hydration, b) texture, c) wrinkles, and d) laxity, along the neck and jowls. Follow-up surveys on days 2, 30, 60 and 90 also asked participants to assess their overall opinion of the neck cream, usage characteristics including feel, smell and texture, as well as overall perceived improvement in hydration, texture, quantity of wrinkles, depth of wrinkles, elasticity, jawline definition and tightening / lifting.

Statistical significance was determined using paired t-test comparing results at each time interval to baseline or prior time intervals.

**RESULTS**

Online survey participation was highly successful, with 85 participants completing the baseline questionnaire and 71 participants (84%) completing the final 90-day assessment. Of the 71 final online survey participants, 65 completed both the baseline and 90-day questionnaires. For averages, the full data set of participant’s responses was used. For statistical significance, only the 65 participants with paired baseline and 90-day assessments were included.

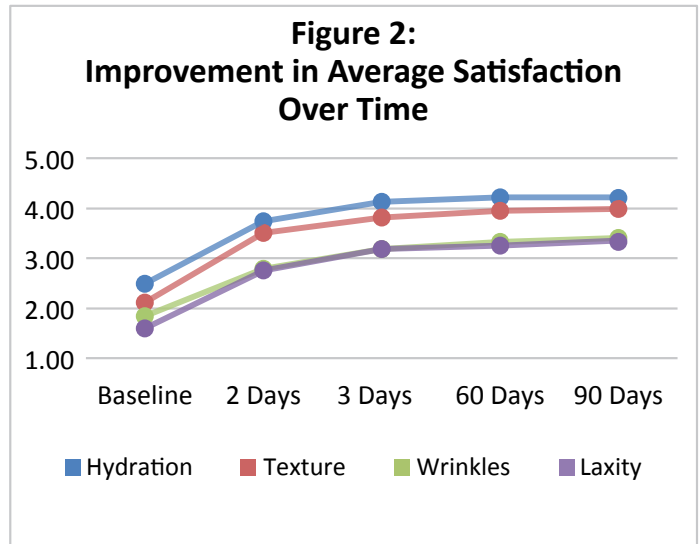
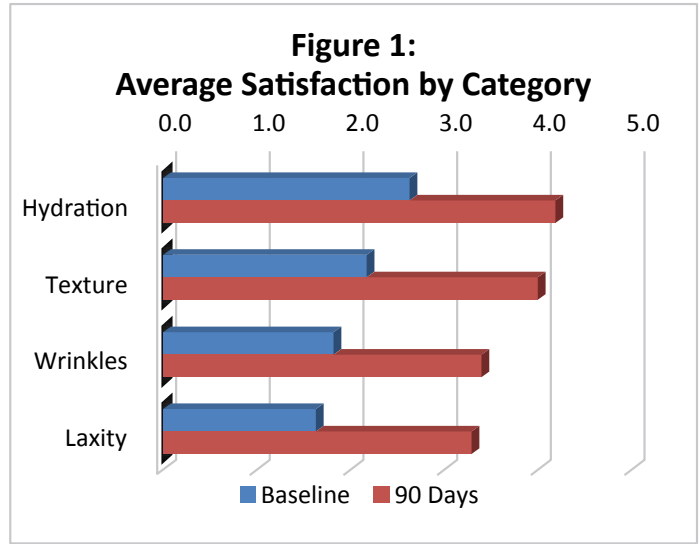
	AVERAGE SATISFACTION (TABLE 1)						
	Day 0	Day 2	Day 30	Day 60	Day 90	Delta	p value
Hydration	2.49	3.74	4.13	4.22	4.2	1.55	3.14E-13
Texture	2.11	3.52	3.81	3.95	3.99	1.83	5.68E-15
Wrinkles	1.84	2.78	3.17	3.32	3.41	1.58	1.42E-12
Laxity	1.6	2.76	3.19	3.25	3.32	1.66	5.09E-14

Improvement in satisfaction by category was determined by measuring satisfaction at baseline and comparing it against satisfaction at each follow-up visit. Subjects rated satisfaction in four key categories (Hydration, texture, wrinkles and laxity) using a 5-point grading scale: 1=Significantly Dissatisfied, 2=Dissatisfied, 3=Neutral, 4=Satisfied and 5=Very Satisfied. Participants noted significant improvement in satisfaction at all post-visits. Average satisfaction scores as well as statistical significance at day 90 are shown in Table 1.

Figure 1 also shows change in improvement from baseline to the 90-day visit. Figure 2 shows improvement changes at each follow-up visit.

PERCENT OF PARTICIPANTS WITH IMPROVEMENT FROM BASELINE (TABLE 2)	
Hydration	80%
Texture	78%
Wrinkles	77%
Laxity	78%
One or More Categories	94%

The online surveys indicated that rate of improvement was high with 94% of participants noting improvement in one or more categories vs. baseline – indicating that only 6% of respondents failed to note improvement. Table 2 shows improvement response rates by each individual category. Table 3 shows the total number of participants who rated



themselves as “Satisfied” or “Highly Satisfied” with each of the categories on the baseline and 90-day surveys. The quantity of “Satisfied” and “Highly Satisfied” responses increased significantly with an 8x increase in overall satisfied assessments and a 94x increase in highly satisfied assessments.

NUMBER OF SATISFIED ASSESSMENTS PRE AND POST USE (TABLE 3)						
Concern	Baseline (n=85)			90 Days (n=71)		
	Satisfied	Highly Satisfied	Sum	Satisfied	Highly Satisfied	Sum
Hydration	10	1	11	18	40	58
Texture	9	0	9	27	28	55
Wrinkles	2	0	2	22	13	35
Laxity	0	0	0	20	13	33
% of Total	6.5%	0.3%	6.8%	31%	33%	64%

Attribute	PERCENT OF RESPONDENTS (TABLE 4)			
	Day 2 (89 Subjects)	Day 30 (86 Subjects)	Day 60 (79 Subjects)	Day 90 (71 Subjects)
Like the feel of the product	99%	99%	99%	100%
Like the application of the product	99%	99%	100%	100%
Like the absorption of the product	99%	100%	100%	99%
Like the scent of the product	91%	94%	97%	94%
Notice improved hydration	44%	67%	78%	72%
Notice improved texture	96%	99%	99%	94%
Notice reduced quantity of wrinkles	9%	42%	52%	46%
Notice reduced depth of wrinkles	16%	56%	59%	59%
Notice increased elasticity	19%	44%	46%	49%
Notice improved jawline definition	19%	56%	65%	59%
Notice tightening / lifting	21%	51%	63%	59%
Would recommend the product	72%	65%	78%	72%
Would use the product	97%	90%	85%	77%
Like the overall product	98%	99%	94%	94%

Wearability and overall perception of change was assessed at each interval (Table 4). Participants were asked to agree or disagree with a statement pertaining to product feel, application, absorption and scent. Example statement “I like the feel of the neck cream product” with two choices “Agree” or “Disagree”. The average satisfaction exceeded 90% for product attribute measurements at all follow-up surveys.

Subjects were also asked to assess their perception of improvement from the start of the study for a variety of attributes. Subjects were asked questions with 3 options – improved, remained the same, worsened i.e. “Compared to the start of the study, the number of wrinkles on my neck: “Reduced in Quantity”, “Remains the same” or “Increased in Quantity”. Of note, 0 respondents (0%) noted an increase in quantity of wrinkles, depth of wrinkles and laxity at 90 days.

Overall satisfaction with the neck cream product was high (Table 4) at each time interval with 94% - 99% of respondents reporting that they liked the overall results

and feel of the product. Further, the majority of participants would both choose to use the product and recommend it to a friend or colleague.

## DISCUSSION

This study was designed to target a representative sample of female subjects seeking improvement in their neckline. To assess improvement, the study enrolled subjects with self-reported mild-to-moderate aging of the neck. Self-reported aging is more representative of retail product usage in a practice setting but presents a greater challenge to showing statistical significance as outside cases with either greater or less significant aging may be enrolled in the study.

To ensure greater success, studies frequently narrow the inclusion criteria to those subjects most probable to show measurable results. As online surveys tend to have a higher drop-out rate than in-office procedure-based studies, an initial enrollment of approximately 100 subjects was deemed necessary to ensure a final population of 30 or more subjects.

Compliance was far higher than expected with a dropout rate of only 16% of subjects (71 of 85 baseline assessments completed the study) vs. the near 60-70% expected dropout rate. This high retention rate indicates the demand for and satisfaction with the neck cream product.

The results of the study were notable with significant improvement in all measured categories at every time interval and continued average improvement over time.

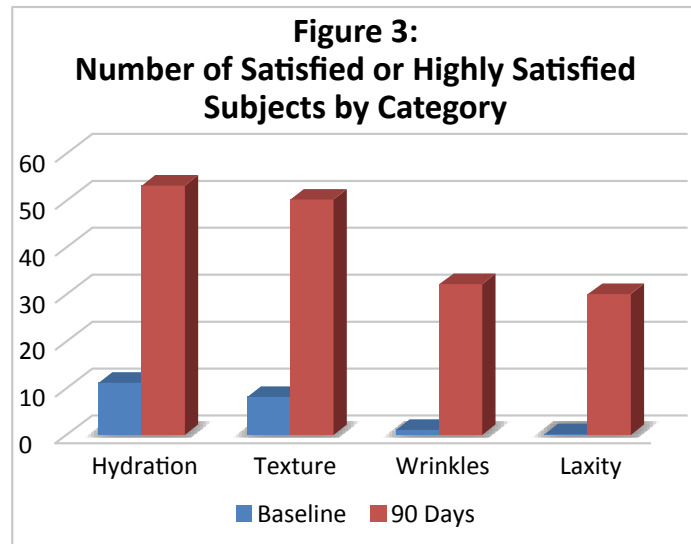
The observed improvement over time is particularly visible when comparing subject-perceived improvement for wrinkle depth, wrinkle quantity, elasticity, jawline definition and lifting / contouring from baseline to day 2 with the change from day 2 to day 30. As expected, the change from day 2 to day 30 was much more significant than the change from baseline to day 2.

Overall improvement in satisfaction with skin on the neck was highly significant. 94% of total study subjects at Day 90 noted improvement in at least one category.

Further, out of the 65 paired baseline and 90-day assessments, there was an 8x increase in the number of subjects rating satisfied or significantly satisfied with any of the 4 measured attributes on the neck and a 94X increase in the number of highly satisfied assessments. Out of a total of 260 individual assessments (4 assessments by 65 paired subjects), there were only 21 total “satisfied” assessments and only 1 “highly satisfied” assessment at

baseline. By contrast, at day 90 there were 87 satisfied assessments and 94 highly satisfied assessments or 36.2% of total assessments were highly satisfied and 69.6% of assessments were satisfied or highly satisfied. Figure 3 and Table 3 show the total number of subjects rating satisfied or highly satisfied by category. The significant change from ratings of “Dissatisfied” to “Satisfied” shows the impact of the product on overall satisfaction with skin on the neck.

Equally significant to the observed increase in satisfaction was the decrease in dissatisfied assessments. 76% of all assessments were dissatisfied at baseline with 29% of total assessments rated as “highly dissatisfied”.



By day 90, only 5% of assessments were rated as highly dissatisfied and only 19% of assessments were rated as dissatisfied. This indicates that the product worked across all individuals with varying degrees of aging skin and satisfaction at baseline.

In addition to creating a firmer, more contoured, less wrinkled appearance, subjects reported consistently high satisfaction with user attributes including product feel, application, absorption and scent. This is an important factor when assessing the probability of long-term use to achieve maximum efficacy and satisfaction. Our data show that, based on participant’s satisfaction with the product attributes, perception of improvement and comparison to baseline assessments, the neck cream product creates an improved skin appearance in the neck area.

The overall participant’s satisfaction, results and significant improvement compared to baseline assessments, high overall satisfaction and observed rate of improvement indicate indicates that the neck cream improves the

appearance neck skin appearance. The high satisfaction ratings with product aesthetics including feel, application absorption, and scent indicate a high probable willingness for subjects to use the product long-term where they will observe best results.

It is important to remember that this is an open-label survey with the likelihood of a placebo effect. The placebo effect is enhanced by the fact that the data gathered was subjective. However, the high satisfaction rates and low drop-out rates suggest that the subjects were pleased with the effects and aesthetics of the product. This suggests that they would be compliant with the product and repurchase it - which would increase long term efficacy.

### CONCLUSION

In conclusion, results from the participant’s online survey assessments demonstrate that subjects believe that the neck cream product effectively improved the appearance of aging skin in the neck area. It appears that the neck cream product helped to significantly improve hydration and texture, while significantly reducing the appearance of wrinkles and laxity along the jawline for more contoured skin. Results were rapid with continuing benefits over time. Future studies are recommended to determine the primary action mechanisms and to assess the degree of improvement by blinded physician assessment.

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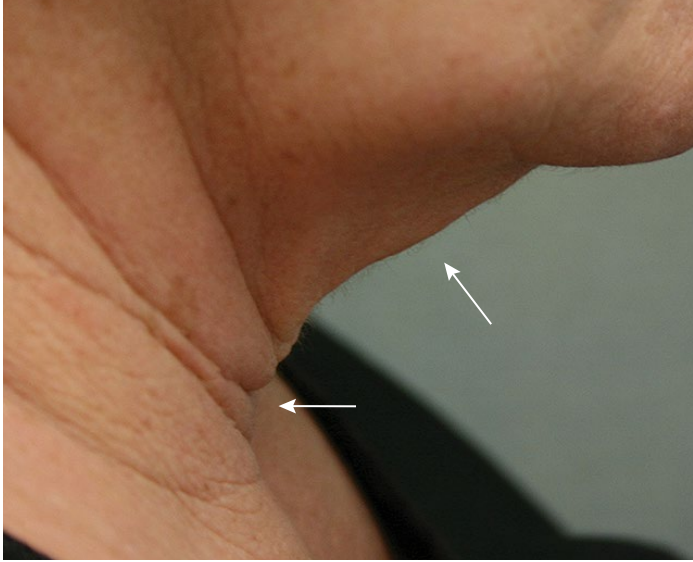
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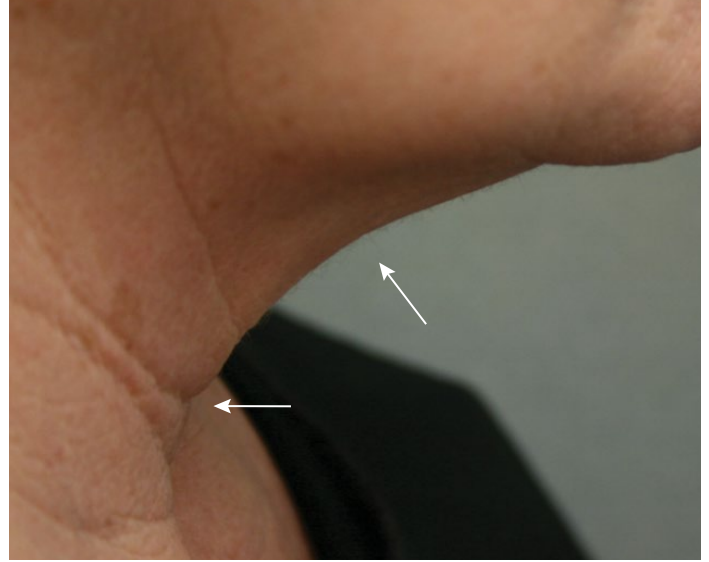
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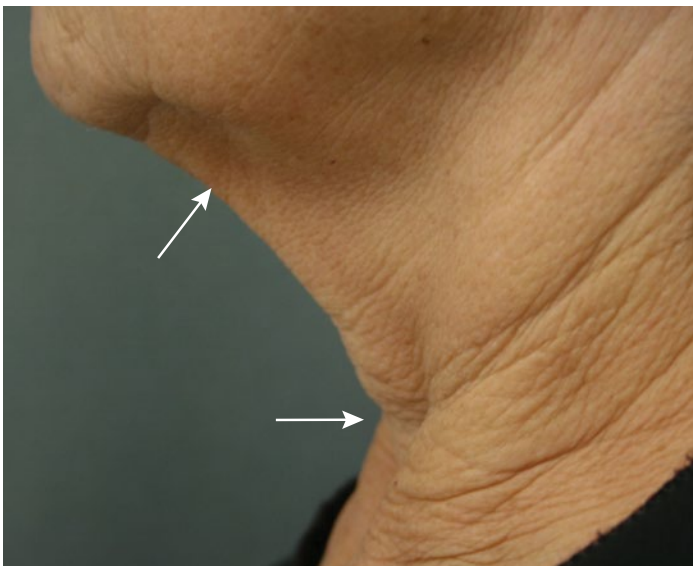
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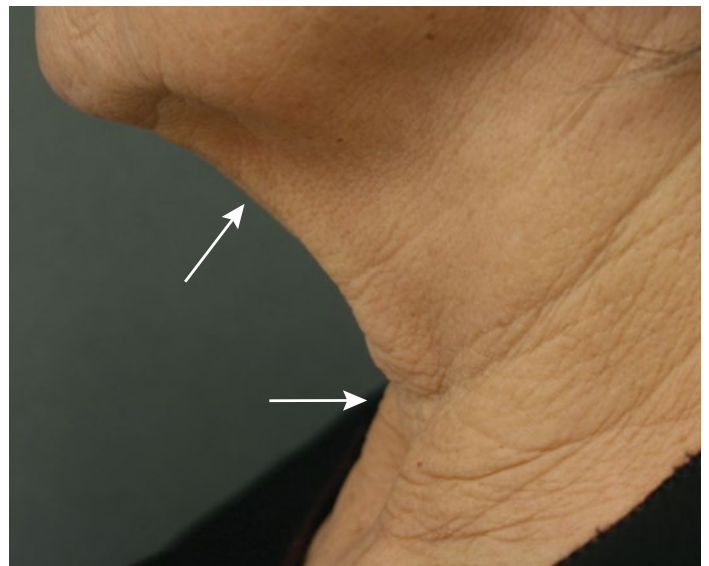
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5 MONTHS



BASELINE



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