

## Efficacy of a *Morinda citrifolia* Based Skin Care Regimen

Brett J. West and Rachel A. Sabin

Research and Development Department, Morinda, Inc., American Fork, Utah, USA

**Abstract:** A six week clinical trial of a *Morinda citrifolia* (noni) based skin care regimen was conducted with 49 women, ages 38 to 55 years. Daily application of three product formulations to the face and neck resulted in significant reductions in lateral canthal fine lines and wrinkles (crow's feet), as measured by technician scoring and digital image analysis. Use of the regimen also improved skin elasticity and firmness Cutometer® measurements. No evidence of skin irritation was present in any participant at any time during the trial. A study questionnaire revealed that the measured improvements were visibly perceptible to more than 90% of the participants. The trial results substantiate traditional uses of the noni plant to improve skin health.

**Key words:** Clinical trial, *Morinda citrifolia*, noni, skin care

### INTRODUCTION

*Morinda citrifolia*, commonly known as noni, is a widely distributed tropical tree. It grows on the islands of the South Pacific, Southeast Asia, Central America, Indian subcontinent, and in the Caribbean. The fruit and leaves of this tree have a history of use both as food and for the promotion of health (Morton, 1992). The leaves were found by indigenous people to be particularly useful in treating various types of inflammation and poisonous fish and insect stings (Camb and Ash, 1994; Dittmar, 1993). The leaves are reported to have been one of the leading plants used in the Marquesas Islands to treat topical inflammation, as well as in Rotuma for burns (Brown, 1935; McClatchey, 1993). In a clinical trial, noni leaf extracts have been shown to provide protection to the skin against ultraviolet light induced erythema (West *et al.*, 2009). Such anti-inflammatory activity could help prevent premature aging of the skin. Noni fruits were also used by Pacific Islanders to treat skin conditions, such as boils and ulcerated sores (Whistler, 1992; Weiner, 1970). The fruit was also used to treat a condition described as "spreading dark spots on the skin" and as an emollient (Dittmar, 1993).

All of the aforementioned properties indicate potential utility of noni fruit and leaf derived ingredients in skin care products. Potential benefits may include prevention or reduction of the appearance of facial wrinkles and improvement in skin elasticity. However, such skin care properties, as constituted in a format that is useful to consumers, have not been adequately evaluated in a human trial. The purpose of our investigation was to

evaluate both the safety and efficacy of a skin care regimen involving the use of three noni based products formulated to improve the appearance of facial fine lines and wrinkles, as well as improve skin elasticity.

### MATERIALS AND METHODS

Noni fruits were harvested in French Polynesia and allowed to fully ripen. The fruit was then processed into a puree by mechanical removal of the seeds and skin, followed by pasteurization at a good manufacturing certified fruit processing facility in Mataiea, Tahiti. Noni seeds were collected from discarded material from the noni fruit finishing process on the island of Tahiti. Seeds were washed and dried. Following drying the seeds were cracked and ground to 2-20 mm particle size. The flaked seeds were then pressed in a screw press to expel the oil, followed by an additional oil extraction. Fresh noni leaves were collected from the Society Islands of French Polynesia and shipped to the main island of Tahiti. There, the leaves were pressed in a cloth copra press to extract the juice. These ingredients were incorporated into three investigational products to be used as a skin care regimen. These included a cream for the skin surrounding the eyes (referred to as an eye treatment), an emulsion (referred to as a serum) to apply to cleansed facial skin, and a cream to be applied to the face at night (referred to as a night cream). The eye area treatment included (in order of predominance) noni fruit juice, noni seed oil, and noni leaf juice. The facial serum included noni leaf juice and noni seed oil. The night cream contained noni fruit juice and noni seed oil. All products contained

other functional ingredients in addition to the noni based ingredients.

Forty-nine women, ages 38 to 55 years, were enrolled in and completed the clinical trial. Two of the participants were Hispanic. The remaining women were Caucasian. Inclusion criteria were: a fine line and wrinkle score of five (noticeable) or greater in the lateral canthi (crow's feet areas), ability to give written informed consent, and ability to complete the study. Exclusion criteria were visible skin disease, sunburn or suntan during the study, participation in concurrent research trial involving the face, use of medication which may interfere with the study, dermabrasion or laser resurfacing on the face within the previous 2 years, chemical face peel within the previous year, superficial peel in the past two months, or surgical cosmetic procedures within the previous 10 years. Exclusion criteria also included the presence of acne, psoriasis, or active eczema, history of cancer, current treatment for asthma or diabetes, and known sensitivities to cosmetics or personal care products.

All women were provided with investigational products, were given instructions on the use of the products, and were provided with a daily diary. Participants were instructed to record in the diary the dates and times the products were used, as well as any comments they had while using the products. They were also instructed to abstain from using any new skin care or cosmetic products. They were also asked to refrain from using any other anti-aging treatments, serums, eye treatments, or eye creams during the trial. For six weeks, the participants were to follow a daily skin care regimen. This regimen involved applying the eye treatment, every morning and night, to the cleansed skin surrounding the eyes. It also involved applying the serum, every morning and night, over the cleansed face and neck, with an upward and outward motion. This step was to be completed prior to applying moisturizer. The final step in the daily regimen was to massage the night cream onto the cleansed face and neck, with an upward and outward motion, every evening.

Baseline evaluations of the participants were made just prior to the in-use phase of the trial. Evaluations were made with participants having freshly washed faces, with no cosmetic or skin care products applied to the eye and facial areas. The same evaluation procedures were followed after two, four, and six weeks of following the skin care regimen. A trained technician scored lateral canthal wrinkles according to a semi-quantitative scale, as follows: 0 = none; 1 to 3 = slight; 4 to 6 = noticeable; and 7 to 9 = very noticeable. Digital images of the face from the front, right and left side views were also taken of each participant during each visit. Parallel and cross-polarized lighting were used to obtain digital images. Images were also obtained with fluorescent lighting. To standardize the

evaluation of the images, each participant was draped in black cloth around the shoulders and wore a black headband to cover and pull hair away from the face. Digital images were analyzed with Image-Pro® software (Media Cybernetics, Bethesda, MD, USA) to determine changes in lateral canthal mean wrinkle score. This was done by calculating the mean wrinkle width, in pixels, for each image obtained at baseline and weeks two, four, and six. Percent changes from baseline of both the semi-quantitative and digital image derived wrinkle scores were compared with Student's *t*-test and the Wilcoxon signed-rank test.

The elasticity and firmness of the skin, in mm vertical deformation under controlled partial vacuum, was measured on the face of each participant with a Cutometer® (Courage+Khazaka, Cologne, Germany), a device that is widely used in skin health research (Dobrev, 2002). Percent increases from baseline in skin elasticity and firmness were compared with Student's *t*-test and the Wilcoxon signed-rank test. Irritation of the facial skin was also evaluated visually at each visit by a trained technician. Visible evidence of irritation was scored accordingly: 0 = no irritation; + = irritation barely perceptible; 1 = mild irritation; 2 = moderated irritation; 3 = marked irritation; 4 = severe irritation. At the end of six weeks, each participant completed a questionnaire, summarized in Table 1, concerning the perceived efficacy of the skin care regimen.

All statistical analyses were conducted with JMP® statistical software (SAS Institute, Cary, NC, USA). The study complied with the regulations governing good clinical practices, as described in the U.S. Code of Federal Regulations, Title 21, Part 50. Written informed consent was obtained from each participant in the study.

## **RESULTS AND DISCUSSION**

The methods used to assess fine lines and wrinkles are typical of those reported in previous publications (Callaghan and Wilhelm, 2008). Technician scored lateral canthal lines (crow's feet) were significantly reduced with use of the skin care regimen, Table 2. This decrease appeared to occur within the first two weeks of product use, as mean scores remained constant through the remainder of the trial. The more sensitive digital image analysis also revealed significant wrinkle reductions due to the skin care regimen, Table 2. But unlike the technician scored values, mean lateral canthal line widths continued to decrease throughout the entire trial period. By the sixth week, participants experienced a 7.4% average decrease in crow's feet lines and wrinkle widths. The percentage of participants experiencing a reduction in fine lines and wrinkles, based on the image analysis, increased throughout the trial to 96% by the end of six weeks.

Table 1: Participant questionnaire prompts, statements and possible answers

Graded prompts	Possible responses to graded prompts
Lessening of the appearance of crow's feet fine lines/wrinkles	Extremely noticeable change
Improved skin firmness -- skin has become more firm.	Very noticeable change
Improved skin elasticity.	Noticeable change
Lessening of the appearance of age spots/skin discolorations.	Slight change
Skin tone appears more "even".	No change
Skin appears "healthier" since applying the product.	
Skin appears "younger" since applying the product.	
Statements of agreement	Possible responses to statements
After using the product, the overall quality of my skin improved.	Agree
After using the product, I would purchase it if it were available on the market.	Disagree
After using the product, I would recommend it to a friend.	



Fig. 1: Reduction in lateral canthal fine lines and wrinkles (crow's feet) of a 52 year old female

Table 2: Lateral canthal wrinkle scores (mean±standard deviation)

Week	Mean score	Mean % decrease from baseline
Technician evaluation		
0 (baseline)	6.2±1.2	-
2	5.7±0.7*	4.9
4	5.7±0.7*	5.3
6	5.7±1.2*	5.3
Digital image analysis		
0 (baseline)	7.0±0.5	-
2	6.8±0.4**	3.7
4	6.7±0.5**	5.3
6	6.5±0.4**	7.4

\*: Statistically significant difference from baseline (p<0.05); \*\*: Statistically significant difference from baseline (p<0.001)

Table 3: Cutometer® measurements, in mm of vertical deformation (mean±standard deviation), of facial skin elasticity/firmness

Week	Mean score	No. of individuals improved from baseline
0 (baseline)	0.559±0.145	-
2	0.651±0.128*	32
4	0.624±0.182*	30
6	0.613±0.142	27

\*: Statistically significant difference from baseline (p<0.05)

An example of the reduction in fine lines and wrinkles of one of the participants, a 52 year old female, is presented in Fig. 1. Skin elasticity and firmness improved throughout the trial period, Table 3. Mean Cutometer® measurements were significantly greater by the second week of following the skin regimen. Week two and four average elasticity/firmness readings were, respectively, 42.4 and 33.8% greater than baseline values. At the end of the trial, mean facial skin elasticity/firmness was

greater than prior to the start of the study, but not as great as during the previous two visits. However, 55% of participants had measureable increases in elasticity and firmness by the end of the trial. The data suggest that the greatest improvement occurs within the first two weeks of product use.

The skin care regimen was found to be non-irritating. In fact, no signs of facial irritation were observed in any participant and any time during the trial. This finding is consistent with a previously reported repeat insult patch test of extracts made from noni leaves (West *et al.*, 2009), as well as the traditional uses of the plant to sooth inflamed skin.

Responses to the questionnaire provide some insight into the perceived efficacy of the products in the skin care regimen, Table 4. Consistent with the results of the technician scored and digital image analyses, at least 92% of the participants reported some degree of change in the reduction of the appearance of fine lines and wrinkles, while 96% reported increased skin firmness and elasticity. The questionnaire also revealed that 92% of the participants felt that a decrease in the appearance of age spots/skin discolorations had occurred. The perceived reduction in skin discoloration is of particular interest, as bioactive constituents of noni have been reported to inhibit the process of melanogenesis (Masuda *et al.*, 2012). The percentage of subjects who felt that some improvement had occurred in skin tone, appearance of healthy skin, and appearance of younger skin was 84,

Table 4: Questionnaire responses at completion of skin care regimen trial. Results are expressed as percentages of the total responses for each prompt or statement

	Percentage of responses				
	Extremely noticeable change	Very noticeable change	Noticeable change	Slight change	No change
Lessening of the appearance of crow's feet fine lines/wrinkles	10.2	18.4	38.8	24.5	8.2
Improved skin firmness -- skin has become more firm	12.2	22.4	36.7	24.5	4.1
Improved skin elasticity	14.3	18.4	38.8	20.4	8.2
Lessening of the appearance of age spots/skin discolorations	6.1	16.3	32.7	36.7	8.2
Skin tone appears more "even"	2.0	34.7	30.6	16.3	16.3
Skin appears "healthier" since applying the product	16.3	28.6	34.7	16.3	4.1
Skin appears "younger" since applying the product	8.2	22.4	30.6	30.6	8.2
	Agree	Disagree			
After using the product, the overall quality of my skin improved.	87.8	12.2			
After using the product, I would purchase it if it were available on the market.	87.8	12.2			
After using the product, I would recommend it to a friend.	87.8	12.2			

96 and 92, respectively. Generally, the largest group of participants felt that these changes were “noticeable”, with a smaller number reporting “very noticeable” or “extremely noticeable” changes. All but a small fraction of study participants felt that the skin care regimen improved the overall quality of the skin and indicated that they would use the product, or recommend it to a friend, if available on the market.

### CONCLUSION

The results of the six week clinical trial of the safety and efficacy of a noni based skin care regimen appear to substantiate the traditional uses of the noni plant for the improvement of skin health. Significant improvements in the appearance of fine lines and wrinkles and skin elasticity and firmness were evident. These benefits appeared within two weeks of product use. Consistent with traditional use and previous safety tests of noni leaf extract, the products of the regimen were nonirritating. The current trial has demonstrated the safety and potential utility of noni derived ingredients for the improvement of skin health and appearance.

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