INDEPENDENT CLINICAL STUDY

Performance of JAWZRSIZE®
Facial Fitness Device

DATES OF STUDY
December 4, 2020 - January 5, 2021

PSC Research Institute
Ethical Independent Clinical Studies

OFFICIAL CLINICAL RESEARCH FINAL REPORT

AUTHOR / INVESTIGATOR:	**Martin Giniger, MsD, PhD** Director of Clinical Dental and Dermatological Research PSC Research Institute, Inc.
COMMENCEMENT DATE: COMPLETION DATE:	December 4, 2020 January 5, 2021

SCIENTIFICALLY TESTED: **The following claims are tested in this study**

SURVEY INSTRUMENT
- Users feel they more handsome / beautiful after 1 month of use
- Users feel they have fewer facial lines and wrinkles after 1 month of use
- Users feel increases in confidence after 1 month of use
- Users feel healthier after 1 month of use
- The device is easy to use
- After using you feel less tension in face after 1 month of use
- Are you more likely to less likely to clinch your teeth after 1 month of use
- Do you feel an Increase in jaw strength after 1 month of use

OBJECTIVE MEASUREMENTS
- % Reduction in Facial Wrinkles
- Reduces Facial Wrinkles
- Increases Jaw Strength
- Photographic proof in change in jaw-line and facial muscular appearance

FOR PUBLICATION IN: INTERNAL CONFIDENTIAL DATA

STUDY METHODS: 20 Subjects / 30-day, twice-daily use as per manufacturer's directions using 20-pound, 25-pound, and 40-pound resistance balls.

Products Tested
Jawzrsize Device Bundle with 20-pound, 25-pound, and 40-pound resistance balls

Measurement Devices
VISIA Complexion Analysis System (Canfield Scientific, Inc., Fairfield, NJ).
Professional Photographer
Bite Force Recording Device (Dentoforce 2; ITL AB, Sollentuna, Sweden)

Subject Demographics
All subjects from South Florida
All subjects age 18+ with approximate mean age 45

OBJECTIVES   The objective of the study was to assess the efficacy of a facial exercise regimen using the commercially available Jawzrsize facial fitness device that included with 20-pound, 25-pound, and 40-pound resistance balls. A variety of scientific and clinical measurements were performed during the examination intervals, using a force meter, a digital facial skin analysis system, and clinical before and after photos were taken. All tests and measurements were performed using techniques well established in the dermatological and dental literature.

METHODS

This study was performed during December 2020 and January 2021 in South Florida using maximum COVID-19 precautins. The entire protocol was reviewed and approved by Jawzrsize corporate team, and an independent institutional review board prior to commencement of the study.

Before participating in the clinical study, each subject was required to sign a written informed consent, which explained the type of study, the procedures to be followed, the general nature of the materials being tested, and any known or anticipated adverse reactions that might result from participation. They also gave their consent to be photographed.

Subject Demographics and Inclusion / Exclusion Criteria
A total of 20 healthy male and female subjects were enrolled in the study. All subjects were deemed to have Fitzpatrick skin types II, III, or IV. Subjects were not pregnant, nursing, or undergoing any concurrent topical or surgical therapy on the face. Subjects with any chronic skin disease or disorder (e.g. Psoriasis, eczema, atopic dermatitis), visible skin cancers on the face, a known allergy to any component of the study formulations, or a proclivity to cutaneous hyper reactivity were excluded from the study. Additional exclusion criteria included use of oral isotretinoin 6 months or topical retinoic acid 2 months prior to the study, use of topical alpha-hydroxyl acids skin-care products, chemical peels, exfoliants or any abrasive substance on the face (all 1 month), or exposure of systemic (1 month) or topical (2 weeks) corticosteroids.

All study participants used the product for 30-days, twice daily minutes without interruption.

All manufacturers' directions for use were carefully followed. The product was always applied under the direct supervision of the study's clinical director. Modification of the facial skin-care instructions and concomitant use of any other skin-care products were not permitted during the study.

Jaw Strength Analysis
The Tekscan Novus (ITL AB, Sollentuna, Sweden) is a device which has a metal fork provided with strain gauge transducer. The fork is coated with a soft rubber which can be placed in the interocclusal region and on which the subjects can bite. The bite fork is connected to a recorder and the force (in Newtons) is displayed on a digital display device (Multimeter 4055. ITL AB, Solientuna. Sweden). The device can display the minimum and maximum values during the measurement as well as it can also display an instantaneous reading during biting. The device also consists of filters which increase the quality of the output signal. It can measure forces up to 1000 N which the American Dental Association recommends for these kinds of measurements. The thickness (vertical height) of the fork is 11 mm. After positioning, subjects are asked to bite as hard as possible for 3 to 4 seconds. This can be repeated with a relaxation period of 30 seconds intervals, and 3 readings =, before and after were taken during the study. The device has been successfully used for research purpose in the peer review literature
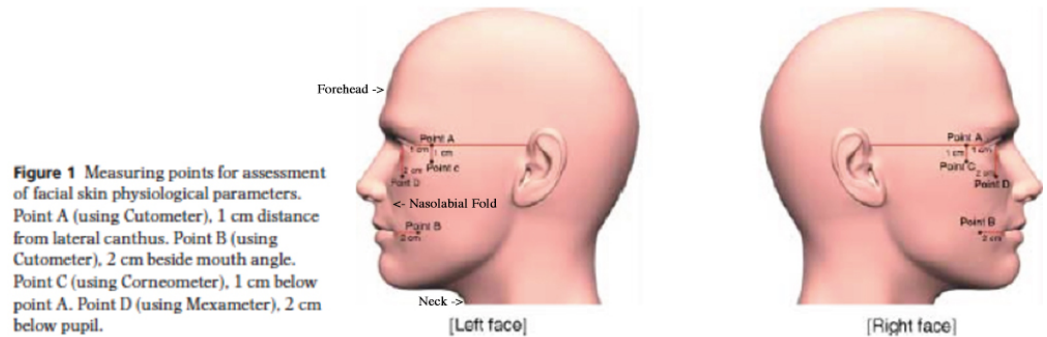

Facial Wrinkle Analysis
Digital complexion image analysis and measurement of physiological facial parameters on each side of the face were performed at baseline and 10 minutes after treatment. Skin measurements were made on untreated skin after washing with a standard dermatologist recommended facial cleanser (Cetaphil®). Temperature (20 ± 5° C) and relative humidity (50 ± 10%) were controlled, and subjects were required to acclimate to these conditions for 30 min prior to measurements. All

measurements were taken, real-time video and close-up images were captured under the same conditions (lighting, distance, head position, and measurement methods, etc.) at all time points.

Facial skin was analyzed using the VISIA Complexion Analysis System (Canfield Scientific, Inc., Fairfield, NJ). The system allows for the measurement of several facial feature parameters such as spots, pores, wrinkles and evenness (under-eye bags). Pores are the surface openings of follicles. Due to shadowing, pores appear darker than the surrounding skin and are identified on the basis of color and circular shape. Wrinkles are furrows, folds, or creases in the skin and are identified by their characteristic long, narrow shape. Smoothness (under-eye bags) measures were identified by looking at graduations in color from the surrounding skin tone as well as peaks and valleys on the skin surface. See Figure 1 (Point Facial Points A, C, D, Forehead, Nasolabial Fold and Neck) below to see sites where we plan to take measurements.

Figure 1 Measuring points for assessment of facial skin physiological parameters. Point A (using Cutometer), 1 cm distance from lateral canthus. Point B (using Cutometer), 2 cm beside mouth angle. Point C (using Corneometer), 1 cm below point A. Point D (using Mexameter), 2 cm below pupil.

Digitization
A standardized 1cm x 1cm patch of skin was digitized for each subject. Pores were visualized on a computer screen and a standard color marker was placed in the field of view. The difference between L* a* b* values of digitized pores and the L* a* b* values obtained photographing the color marker was used to measure changes in pore color. Then congestion index (C.I) was calculated subtracting black value to white one (L*) by averaging procedure of different pixels.

Qualitative Studies
Self-assessments were conducted at the end of the 10-minute treatment. Subjects were asked to provide an assessment of improvement relative to baseline for skin. texture, skin color, hyperpigmentation, fine lines, and overall improvement.

Statistics And Analysis
All statistical analyses were conducted using standard statistical software using a level of significance of $p < 0.05$. Data collected at each examination interval was compared between groups using a two-group Student's t-test for independent samples.

Subject Instructions
For the first week, the subjects were instructed to use the 20-pound resistance device for 3 reps of 30 bites into the device, twice daily. For subsequent weeks, the subjects we instructed to use in succession all three devices (20-pound, 25-pound and 40-pound resistance) for 30 reps, twice daily. The system was used for 30-days by each of the 30 subjects. It has been shown that 57 muscles in the jaw and face are affected by actively boting into the Jawrsize balls. It was hypothesized that over 30 days the subjects will have less facial wrinkles and a more defined jawline. It is also hypothesized that jaw strength will increase and people will feel an overall increase in self-esteem and wellness.

RESULTS OF STUDY

<u>Demographics</u>

All subjects were residents of South Florida and all major races were represented in the study groups. A total of 30 healthy male and female subjects (age: 50–89 years; 66.7% female / 33.3% male; mean age 67.3) were enrolled in the study.

Table 1 Summary Of The Demographic Data:

MEAN DEMOGRAPHICS	
PARAMETER	VALUE
Mean Age	56.32
S.D.	± 10.15
Number	25
M:F Ratio	8:17

<u>Facial Wrinkle Removal</u>

The table below shows the mean results of all of the measurements recorded in the study. The table below shows the results of the wrinkle depth improvement in the 25 subjects after using the Jawzrsize devices for 1 month. Facial skin was analyzed using the VISIA Complexion Analysis System (Canfield Scientific, Inc., Fairfield, NJ). Wrinkles are furrows, folds, or creases in the skin and are identified by their characteristic long, narrow shape. These furrows are digitized and depths are measured as described above. The mean wrinkle depth before Jawzrsize use was 149.25 μm. The table below shows that the average wrinkle reduction for all subjects was between 32.0% and 36.0%. This is highly different from baseline ($p < 0.05$) and thus we conclude through the most advanced scientific measurements possible, that Jawzrsize significantly reduces facial wrinkles by approximately 33% in all areas of the face and neck.

Table 2 Summary of Wrinkle Removal Data

MEAN REDUCTION IN WRINKLES				
GROUP NAME	UNDER EYE	CORNER OF EYE	NASOLABIAL FOLD	NECK WRINKLES
Men	32.5%	31.0%	34.0%	35.5%
Women	32.0%	31.5%	35.0%	36.0%

Increase in Jaw Strength Analysis

The Tekscan Novus (ITL AB, Sollentuna, Sweden) is a device which has a metal fork provided with strain gauge transducer. The fork is coated with a soft rubber which can be placed in the interocclusal region and on which the subjects can bite. The bite fork is connected to a recorder and the force (in Newtons) is displayed on a digital display device (Multimeter 4055. ITL AB, Solientuna. Sweden). The device can display the minimum and maximum values during the measurement as well as it can also display an instantaneous reading during biting. The device also consists of filters which increase the quality of the output signal. It can measure forces up to 1000 N which the American Dental Association recommends for these kinds of measurements. The thickness (vertical height) of the fork is 11 mm. After positioning, subjects are asked to bite as hard as possible for 3 to 4 seconds. This can be repeated with a relaxation period of 30 seconds intervals, and 3 readings =, before and after were taken during the study. The device has been successfully used for research purpose in the peer review literature.

The table below shows the mean results of all of the measurements recorded in the study. The table below shows the results of the wrinkle depth improvement in the 25 subjects after using the Jawzrsize devices for 1 month. Facial skin was analyzed using the VISIA Complexion Analysis System (Canfield Scientific, Inc., Fairfield, NJ). Wrinkles are furrows, folds, or creases in the skin and are identified by their characteristic long, narrow shape. These furrows are digitized and depths are measured as described above. The mean wrinkle depth before Jawzrsize use was 149.25 μm. The table below shows that the average wrinkle reduction for all subjects was between 32.0% and 36.0%. This is highly different from baseline ($p < 0.05$) and thus we conclude through the most advanced scientific measurements possible, that Jawzrsize significantly reduces facial wrinkles by approximately 33% in all areas of the face and neck.

**Table 3** Summary of Jaw Strength Data after 30 Days of Use

MEAN INCREASE IN JAW STRENGTH (in Newtons)				
GROUP NAME	BEFORE	AFTER	PERCENT INCREASE	STATISTICAL SIGGNIFICANT
Men	142 N	370 N	260.1%	YES (p<0.001)
Women	121 N	310 N	256.2%	YES (p<0.001)

SURVEY RESULTS

Surveys were distributed to the six (6) groups, and we performed six (6) different analyses. The reports are attached separately. The files containing the reports are listed here:
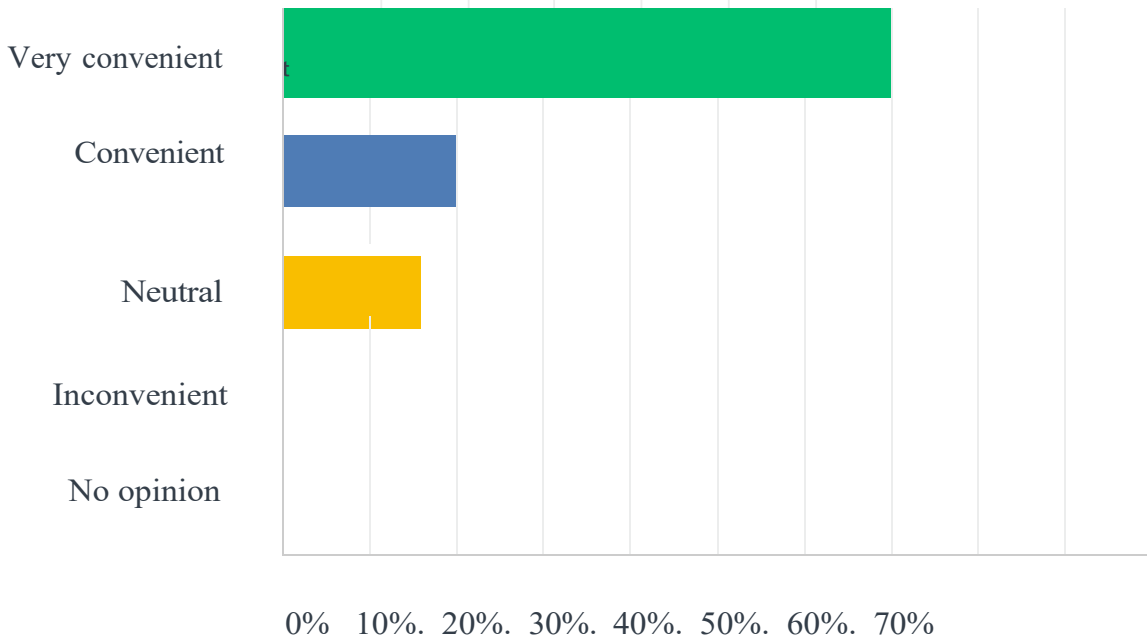
Q1: Gender:

Answered: 25   Skipped: 0
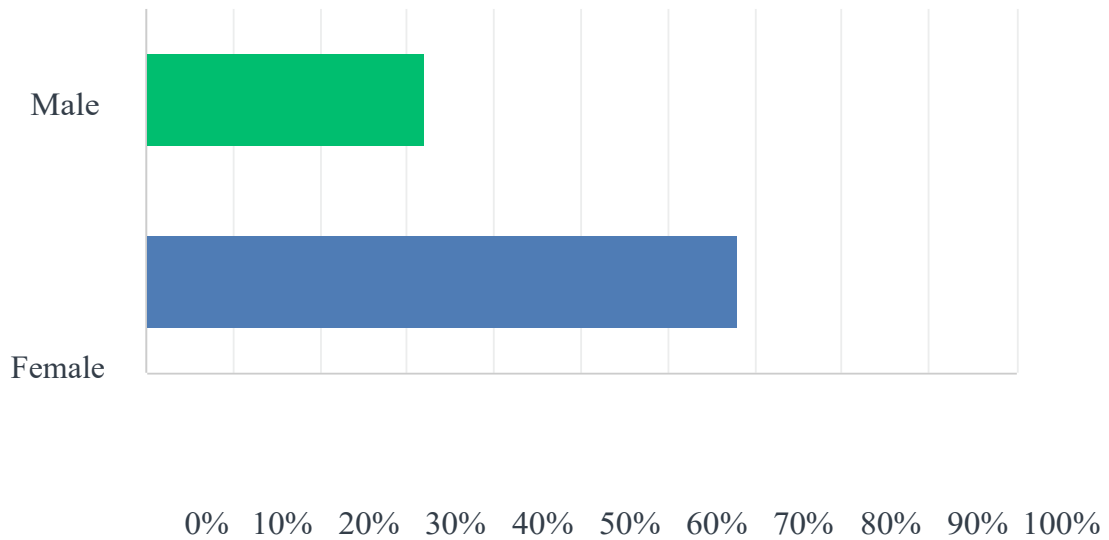
ANSWER CHOICES	RESPONSES	
Male	32.00%	8
Female	68.00%	17
TOTAL		25

Q2: How convenient is it to use the test product (please select one)?

Answered: 25   Skipped: 0

0%   10%. 20%. 30%. 40%. 50%. 60%. 70%

ANSWER CHOICES	RESPONSES	
Very convenient	64.00%	16
Convenient	20.00%	5
Neutral	16.00%	4
Inconvenient	0.00%	0
No opinion	0.00%	0
TOTAL		25

Q3: How easy is it to use the test product (please select one)?

Answered: 25   Skipped: 0
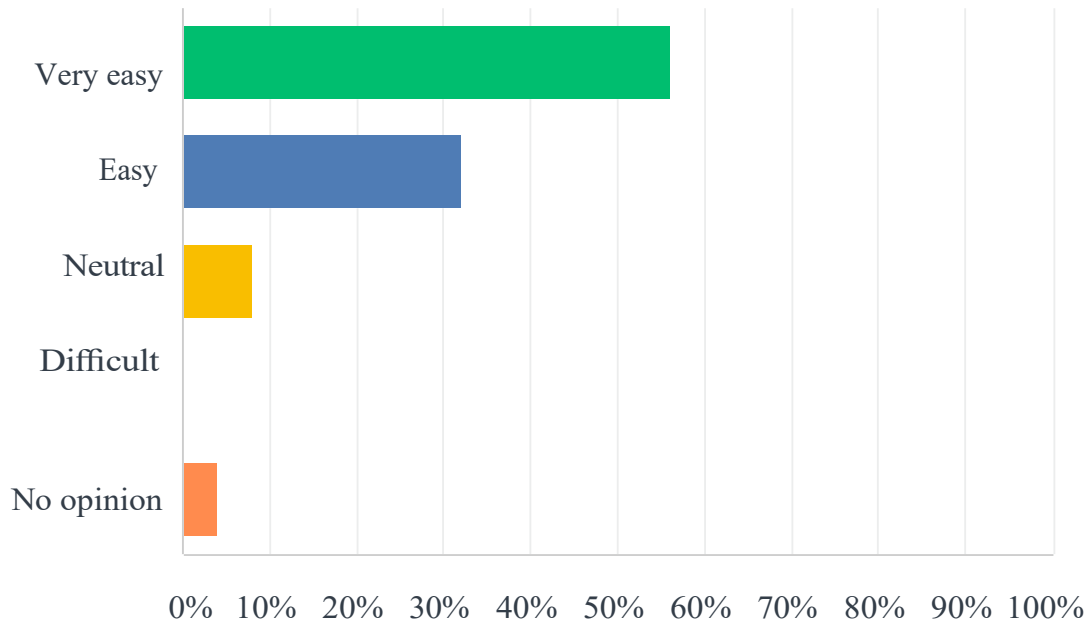
ANSWER CHOICES	RESPONSES	
Very easy	56.00%	14
Easy	32.00%	8
Neutral	8.00%	2
Difficult	0.00%	0
No opinion	4.00%	1
TOTAL		25

Q4: Do you feel more attractive after using the product for 4 weeks

Answered: 25   Skipped: 0
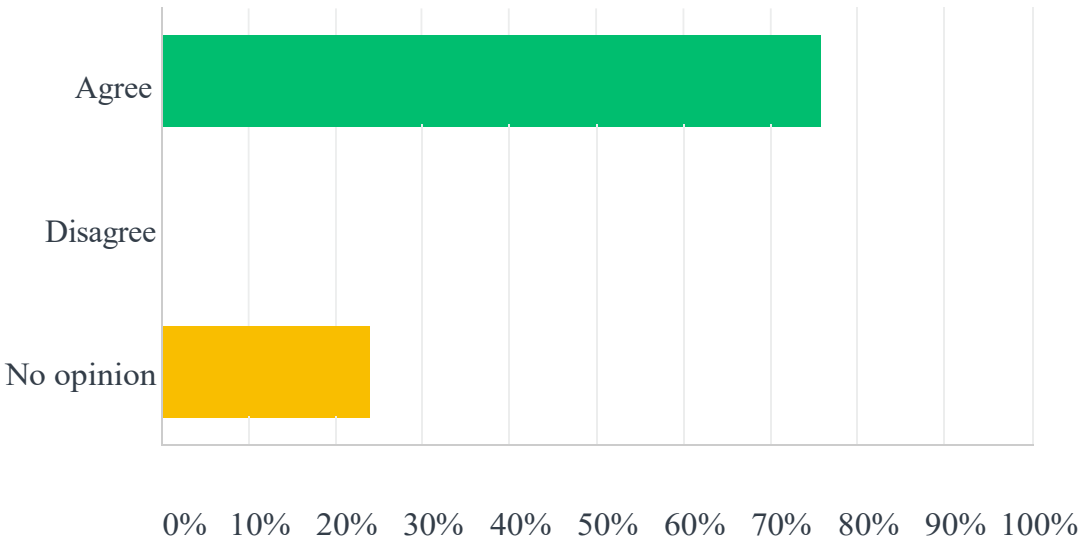
ANSWER CHOICES	RESPONSES	
Agree	76.00%	19
Disagree	0.00%	0
No opinion	24.00%	6
TOTAL		25

Q5: Do you feel more confident after using the product for 4 weeks

Answered: 25   Skipped: 0

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
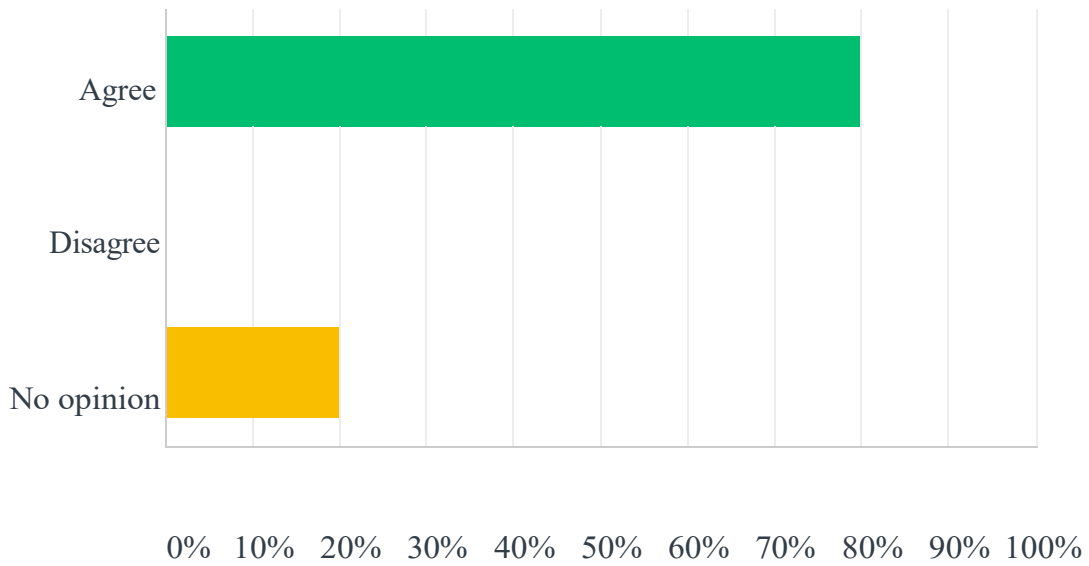
ANSWER CHOICES	RESPONSES	
Agree	80.00%	20
Disagree	0.00%	0
No opinion	20.00%	5
TOTAL		25

Q6 Do you feel healthier after using the product for 4 weeks

Answered: 25   Skipped: 0
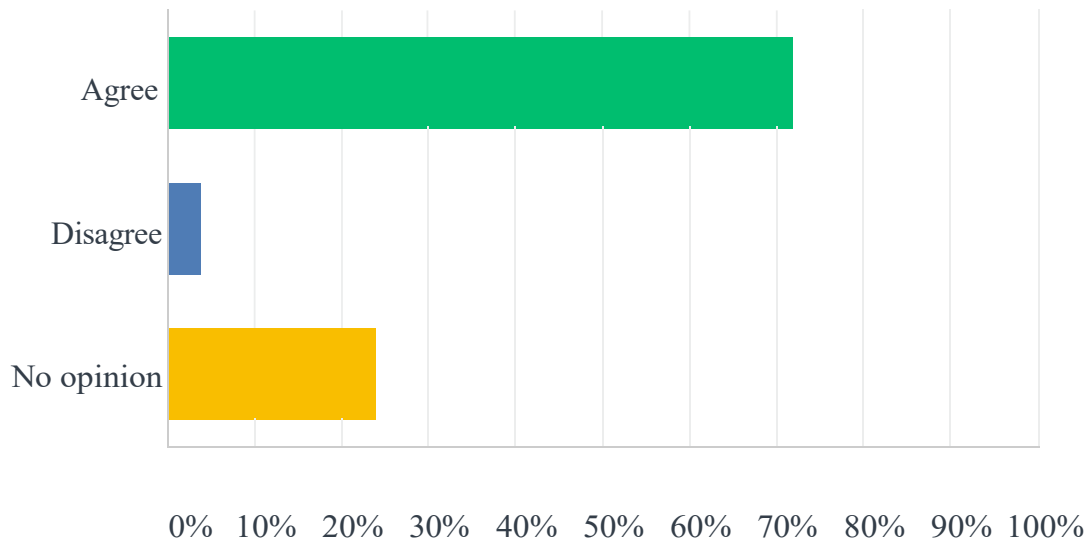
ANSWER CHOICES	RESPONSES	
Agree	72.00%	18
Disagree	4.00%	1
No opinion	24.00%	6
TOTAL		25

Q7 Do you feel more Jaw Strength using the product for 4 weeks

Answered: 25   Skipped: 0
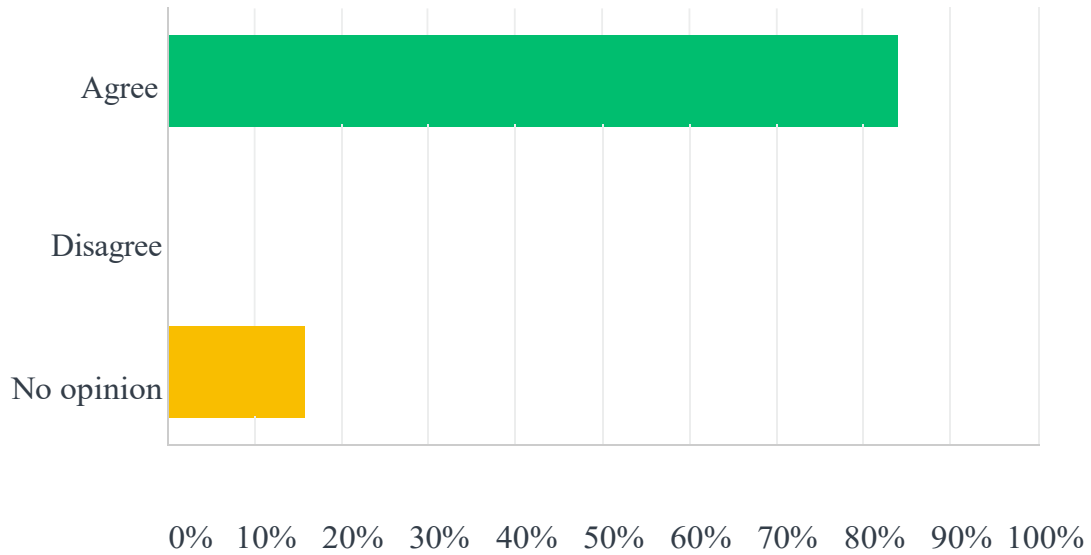
ANSWER CHOICES	RESPONSES	
Agree	84.00%	21
Disagree	0.00%	0
No opinion	16.00%	4
TOTAL		25

Q8: Do you feel like the product lessened (even in the smallest way) your facial wrinkles

Answered: 25   Skipped: 0
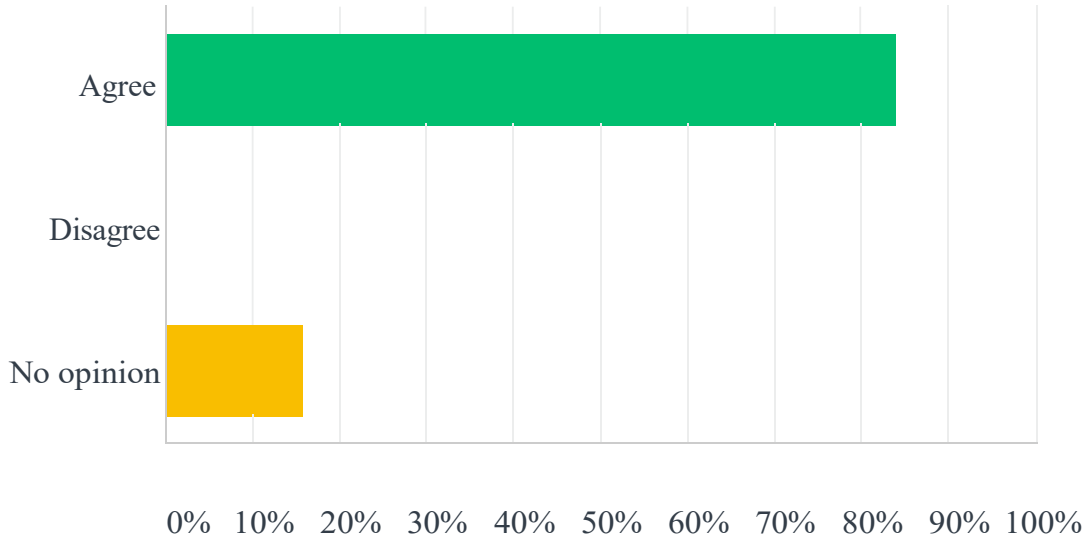
ANSWER CHOICES	RESPONSES	
Agree	84.00%	21
Disagree	0.00%	0
No opinion	16.00%	4
TOTAL		25

Q9: I have not experienced any jaw pain during the use of the product?
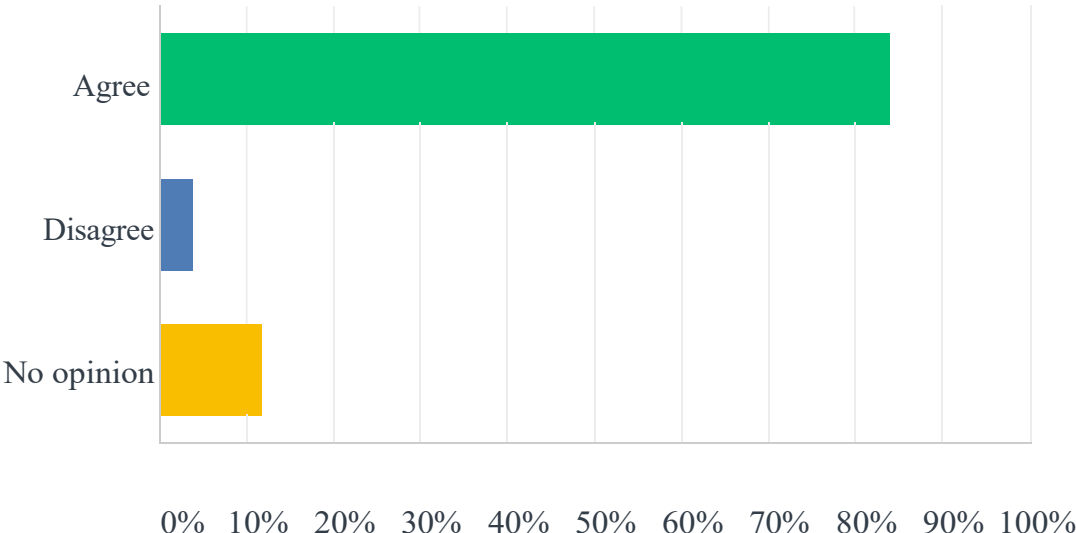
ANSWER CHOICES	RESPONSES	
Agree	84.00%	21
Disagree	4.00%	1
No opinion	12.00%	3
TOTAL		25

Q10: On what week after you started using te product did you first notice results?

Answered: 25   Skipped: 0
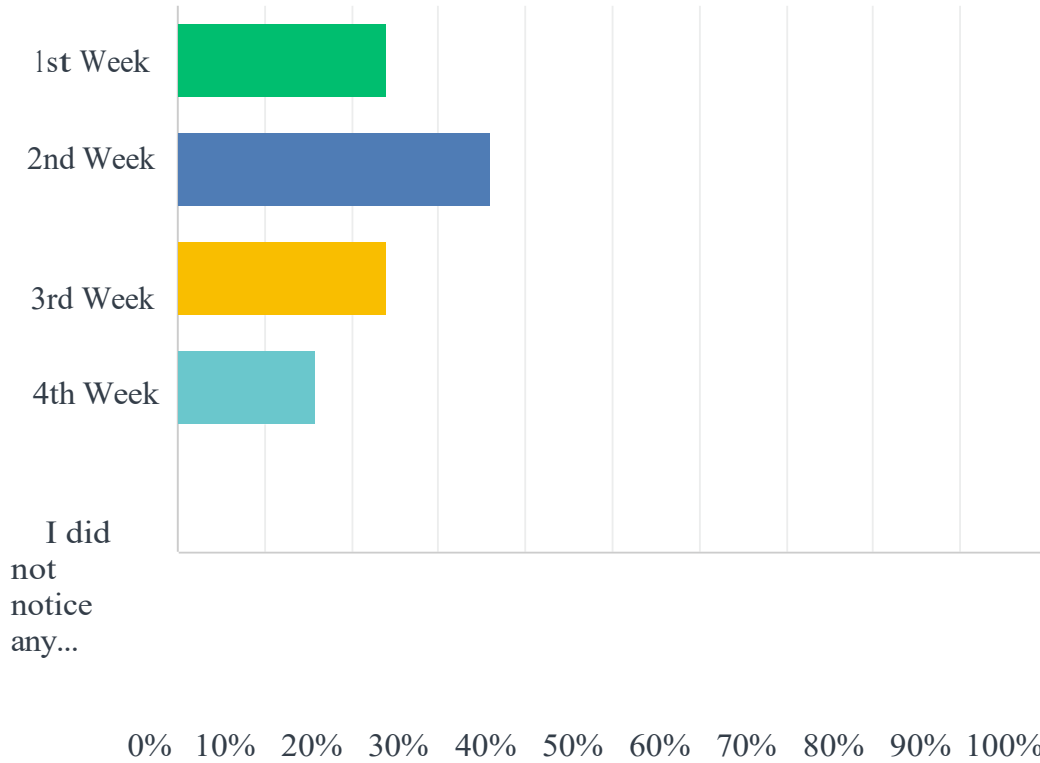
ANSWER CHOICES	RESPONSES	
1st Week	24.00%	6
2nd Week	36.00%	9
3rd Week	24.00%	6
4th Week	16.00%	4

I did not notice any res

ults

	0.00%	0
TOTA		25

Q11: I would recommend the test product to a friend?

Answered: 25   Skipped: 0
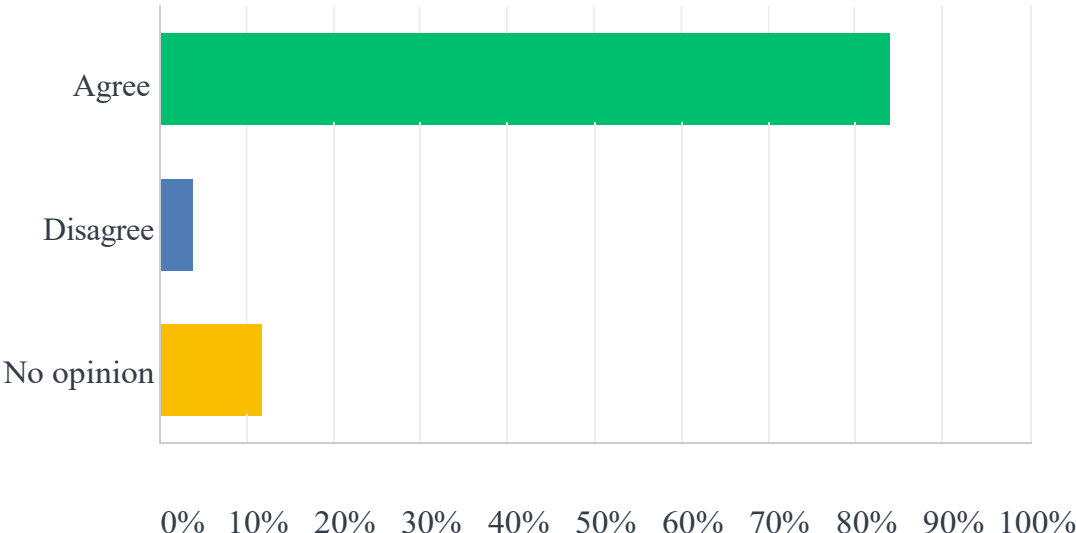
ANSWER CHOICES	RESPONSES	
Agree	84.00%	21
Disagree	4.00%	1
No opinion	12.00%	3
TOTAL		25

# Q12: The results I achieved from using the test product :

Answered: 24   Skipped: 1
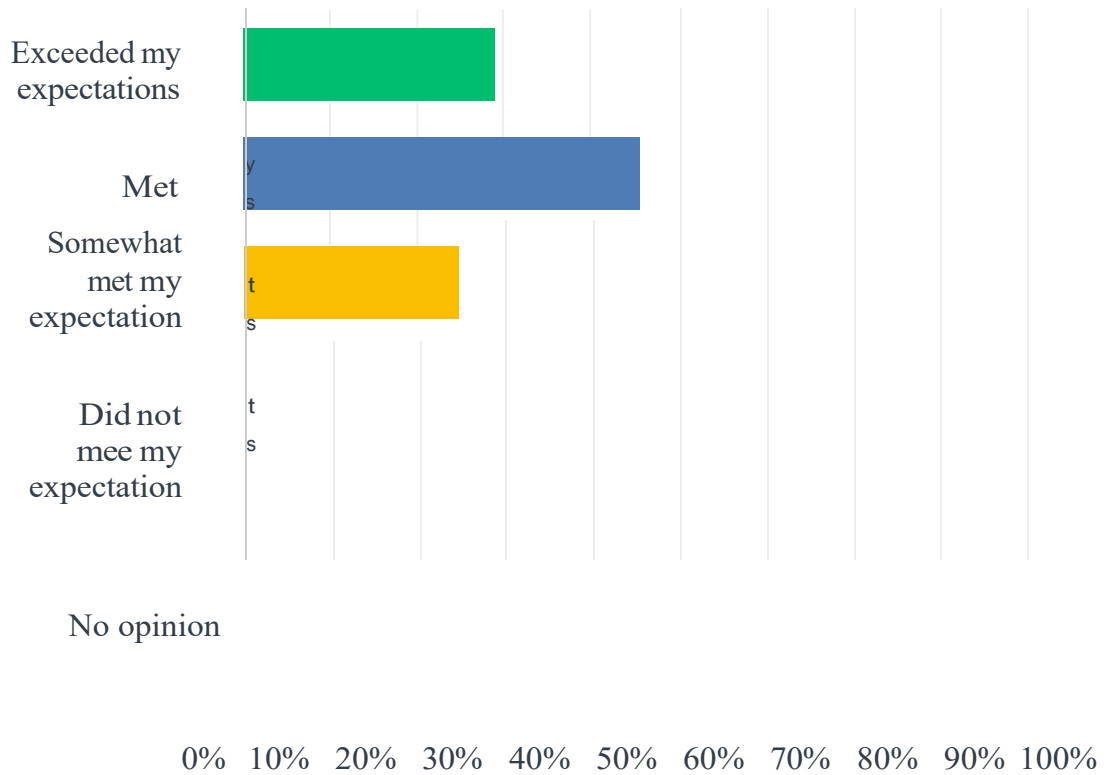
ANSWER CHOICES	RESPONSES	
Exceeded my expectations	29.17%	7
Met my expectations	45.83%	11
Somewhat met my expectations	25.00%	6
Did not meet my expectations	0.00%	0
No opinion	0.00%	0
TOTA		24

Q13: How satisfied are you with the results you have achieved after using the test product for 4 weeks?

Answered: 25   Skipped: 0
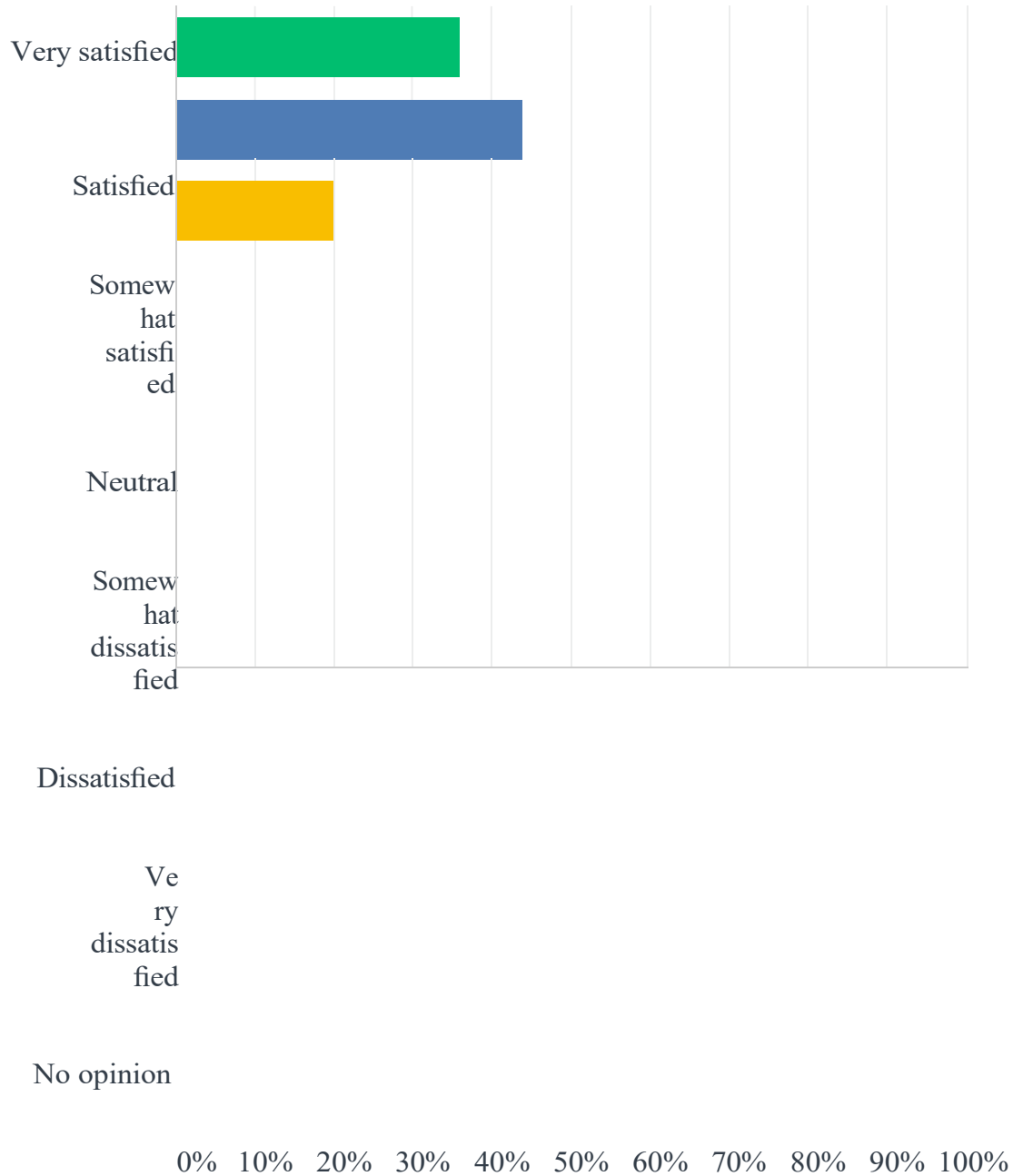
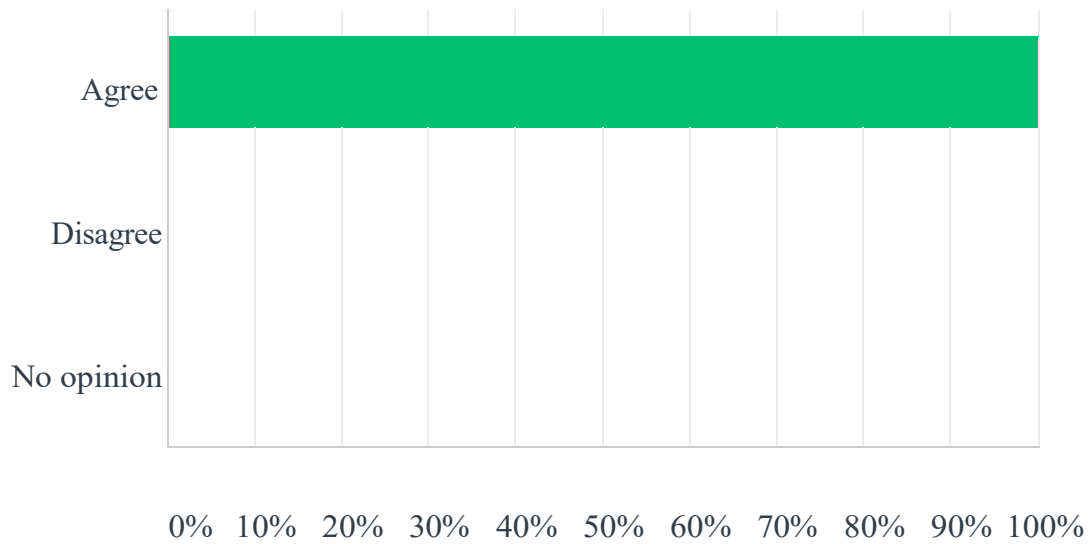| ANSWER CHOICES	RESPONSES	
Very satisfied	36.00%	9
Satisfied	44.00%	11
Somewhat satisfied	20.00%	5
Neutral	0.00%	0

Somewhat dissatisfied	0.00%	0
Dissatisfied	0.00%	0
Very dissatisfied	0.00%	0
No opinion	0.00%	0
TOTAL		25

Q14: Using the test product is a pleasant experience?

Answered: 25   Skipped: 0

ANSWER CHOICES	RESPONSES	
Agree	100.00%	25
Disagree	0.00%	0
No opinion	0.00%	0
TOTAL		25

Q15: I would use the test product again?

Answered: 25   Skipped: 0
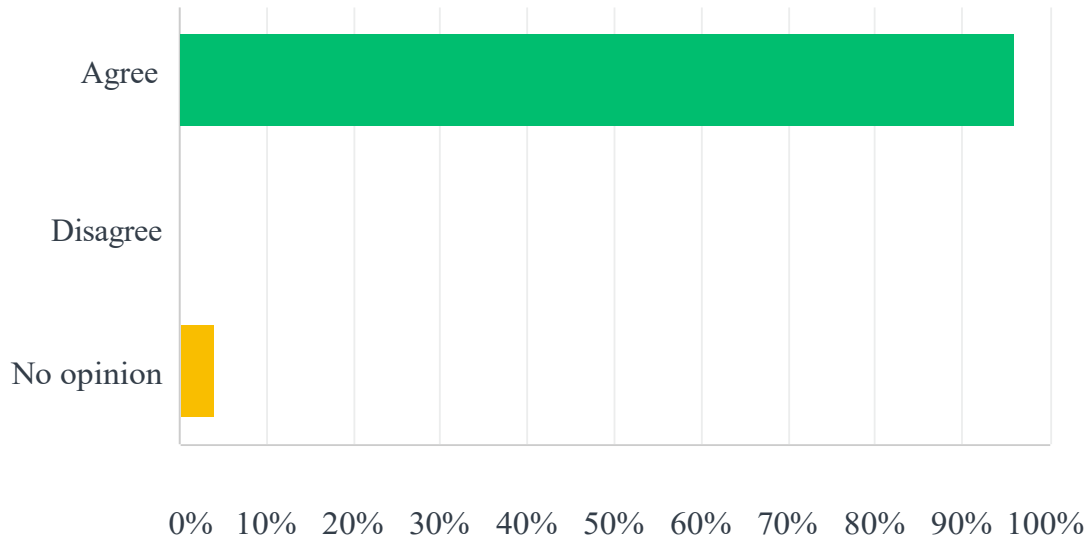
ANSWER CHOICES	RESPONSES	
Agree	96.00%	24
Disagree	0.00%	0
No opinion	4.00%	1
TOTAL		25

Q16: I feel relaxation and / or relief from pain in my jaw joints after use of the products
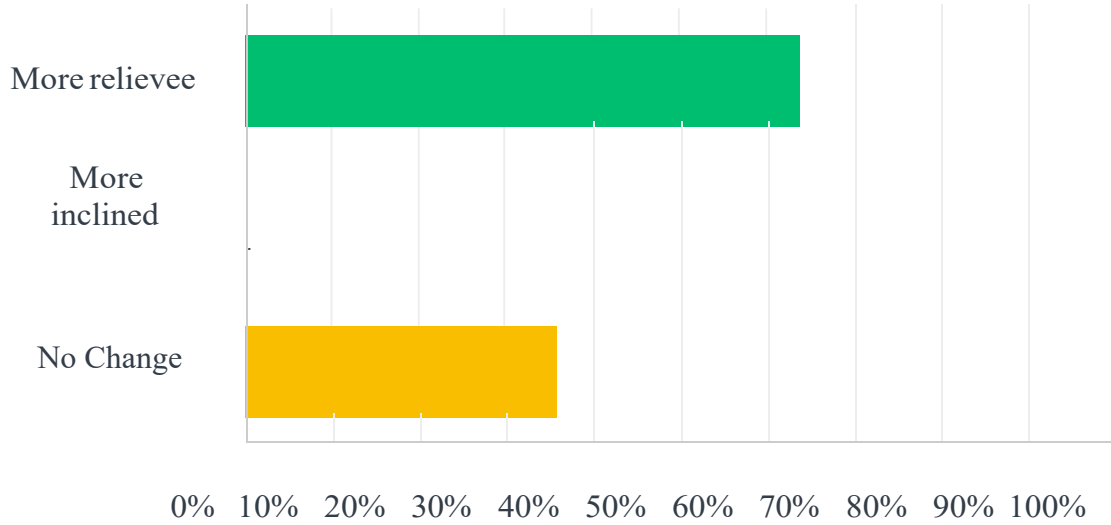
Answered: 25   Skipped: 0
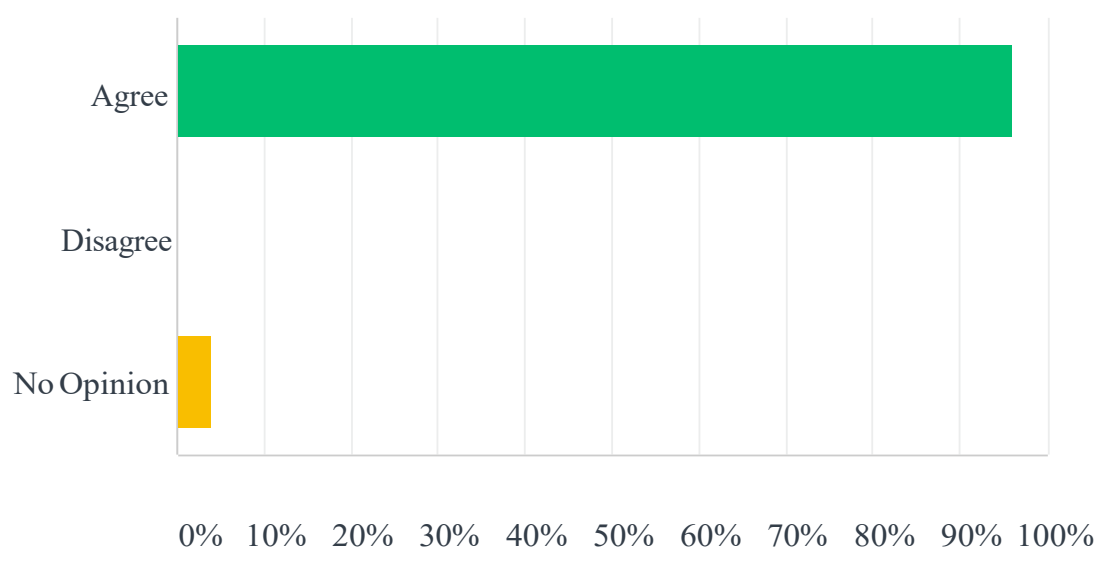
ANSWER CHOICES	RESPONSES	
Agree	96.00%	24
Disagree	0.00%	0
No Opinion	4.00%	1
TOTAL		25

Q17: When exercising with your Jawzersize do you feel relieved afterwards? Or do you feel more inclined to clench and grind your teeth?
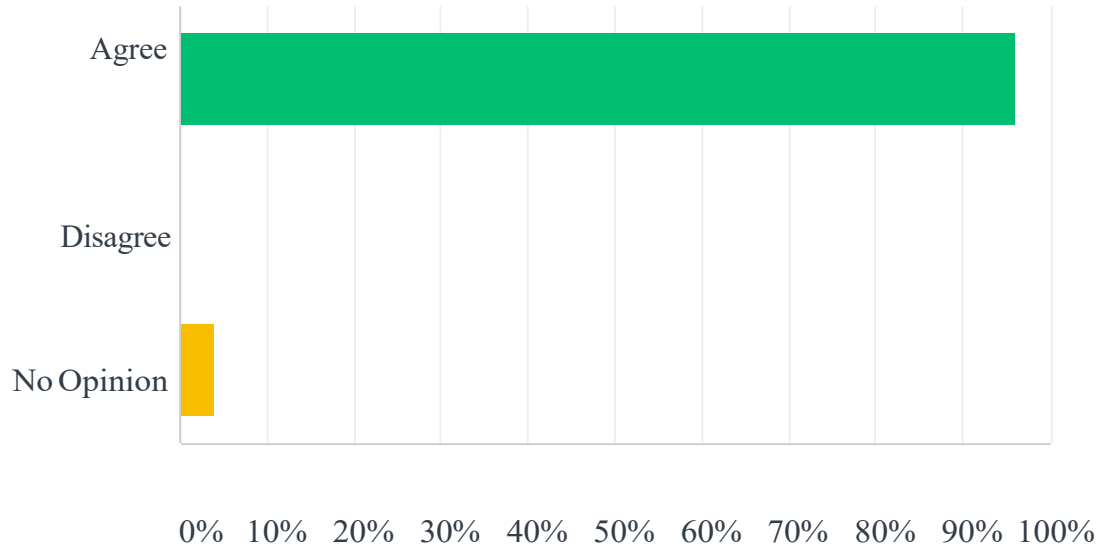
Answered: 25   Skipped: 0

ANSWER CHOICES		RESPONSES	
More relieved		64.00%	16
More inclined to clench and grind		0.00%	0
	No Change	36.00%	9
TOTA			25

Q18: Have you noticed less tension in your face, neck and jaw joints?

Answered: 25   Skipped: 0

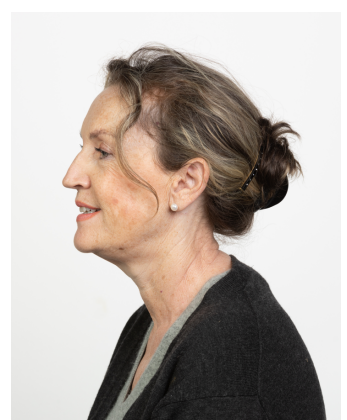| ANSWER CHOICES	RESPONSES	
Agree	96.00%	24
Disagree	0.00%	0
No Opinion	4.00%	1
Total Respondents		25

Example Before and After Pictures

BEFORE AFTER BEFORE AFTER

CONCLUSIONS:

THE FOLLOWING CLAIMS ARE VERIFIED BY INDEPENDENT INVESTIGATIN TO BE TRUE

- Users feel they more handsome / beautiful after 1 month of use (76% Agree, 0% disagree)
- Users feel they have fewer facial lines and wrinkles after 1 month of use (84% Agree, 0% disagree)
- Users feel increases in confidence after 1 month of use (80% Agree, 0% disagree)
- Users feel healthier after 1 month of use (72% Agree, 0% disagree)
- The device is easy to use (100% Agree)
- After using you feel less tension in face after 1 month of use (96% Agree, 0% disagree)
- Are you more likely to less likely to clinch your teeth after 1 month of use (64% Agree, 0% disagree)
- Do you feel an Increase in jaw strength after 1 month of use (84% Agree, 0% disagree)

  OBJECTIVE MEASUREMENTS
- 33% Reduction in Facial Wrinkles after 1 month of use
- Reduces Facial Wrinkles Yes, statistically significant ($p < 0.001$)
- 255% Increases Jaw Strength
- Photographic proof in change in jaw line and facial muscular appearance (Yes, See Photos)

TESTIMONIAL:

ALL of the claims that were requested to be tested by Jawzrsize LLC were "verified to be true" by our clinical scientists and we stand behind these findings under the testing conditions described above.

VERIFIED:

X _Martin S. Giniger_

Date: February 17, 2021
Martin Giniger, DMD, PhD
Principal Investigator