

Clinical Study on the Application of a Non-Invasive High-Intensity Focused Ultrasound with Visualization System for treatment of wrinkles Using Prolift HIFU

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Abstract

- Background and Objectives

High-intensity focused ultrasound (HIFU) is widely used for skin rejuvenation and tightening. The high-intensity focused ultrasound (HIFU) technology generates heat up to 65 degrees, which is delivered to different targeted depths into the dermis to create lifting, tightening and collagen stimulation. The objective of this study was to examine the application of a non-invasive high-intensity focused ultrasound with a visualization system for the treatment of wrinkles.

- Study Design/Material and Methods

The study was designed as a single group assignment, non-significant risk clinical trial, to evaluate HIFU procedure using the HIFU system for the treatment of wrinkles on the face and neck region.

Each subject is to receive a treatment, on a minimum of two planes of treatment using the 4-4.5mm, 7-3.0mm and the 7-1.5mm transducer depths.

The 4.5mm handpiece treats deep down to the Superficial Musculo Aponeurotic System (SMAS), which is the continuous fibrous network that envelops the muscles of facial expression and extends superficially to connect with the dermis of the skin. By treating the

SMAS, the HIFU treatment creates a lifting effect. The 3.0mm handpiece treats into the dermis where collagen and elastin are located and creates new collagen and tightens the elastin. The 1.5mm handpiece is used to target superficial facial lines. With the different depths used, it can be customized to your treatment needs.

The system is a table-top device, with High-Intensity Focus Ultrasound (HIFU) therapy device. The non-invasive HIFU handpiece operates using detachable cartridges for dermatological aesthetic treatments.

Using the HIFU medical device (Prolift HIFU), a non-invasive treatment to reduce wrinkles was performed for a maximum of 15 minutes per session. This treatment was conducted twice, once in the first week and again in the sixth week, with the final follow-up done in the 16th week.

- Inclusion Criteria

1. Willing to sign a written consent form
2. Willing to have facial skin and wrinkles assessed by the clinician
3. Male or female aged 35 to 65 years.
4. Willingness to comply with protocol requirements, including returning for follow-up visits and abstaining from exclusionary procedures for the duration of the study.
5. Willingness to cooperate with photography and adherence to photography procedures (i.e., removal of jewelry and makeup).
6. Must understand the ultrasound device (HIFU) treatment may have no therapeutic effect.
7. Willingness and ability to provide written informed consent and authorization prior to the performance of any study-related procedure.

- Exclusion Criteria:

1. Open wounds or lesions in the area(s) to be treated.
2. Severe or cystic acne on the area(s) to be treated.
3. Presence of an active systemic or local skin disease that may affect wound healing.
4. Active implants (e.g., pacemakers or defibrillators), or metallic implants in the treatment areas (dental implants not included.).
5. Subcutaneous fillers
6. Keloid scar
7. Patients with an anticoagulant treatment plan.
8. Children, pregnant women, and breastfeeding women.
9. Patients with the following disease conditions: bleeding disorders or coagulation disorder that may affect wound healing, active localized disease, herpes simplex, autoimmune diseases, diabetes, epilepsy bell-type paralysis (temporary facial palsy)

The clinical trial, upon examining ANTERA imaging data, showed an average reduction of 3.85mm in wrinkles among 45 subjects, with a wrinkle reduction rate of 14.32%. This confirms the effectiveness of HIFU (High-Intensity Focused Ultrasound) treatment. No serious side effects were reported following the treatment with the HIFU medical device (Prolift HIFU).

- Conclusion

In a clinical trial using the HIFU medical device (Prolift HIFU), the efficacy and safety of wrinkle improvement were confirmed. Among 45 subjects, a satisfaction survey revealed a high satisfaction rating with an average score of 92 points for wrinkle treatment, and all three specialists expressed 100% satisfaction with the device. Through this clinical trial, it was verified that the HIFU medical device (Prolift HIFU) provides continuous and effective wrinkle reduction non-invasively. There were no serious side effects during or after the procedure, and high satisfaction among the subjects was confirmed through the satisfaction survey.

Introduction

The public's interest in safely and effectively improving wrinkles through non-invasive procedures continues. The HIFU medical device (Prolift HIFU) stimulates the dermis layer of the skin non-invasively using high-intensity ultrasound. In this clinical trial, we aim to compare the treatment outcomes before and after using the HIFU medical device (Prolift HIFU) on facial skin prone to wrinkles and evaluate its effectiveness and safety in reducing wrinkles.

Materials and methods

The clinical trial involved 45 participants. The purpose of this clinical trial was to evaluate the degree of improvement through expert visual assessment (Figure 1) and Antera imaging (Figure 2), comparing before and after the application of the HIFU medical device (Prolift HIFU). Additionally, we aimed to assess satisfaction with the clinical trial medical device through a survey.

1st Measurement: 2023.05.09~2023.05.23 / 2nd Measurement: 2023.06.16~2023.07.06 / 3rd Measurement: 2023.08.21~2023.08.23

This clinical trial targeted patients who met the selection criteria, and the HIFU medical device (Prolift HIFU) for the clinical trial was used on individuals who voluntarily agreed to participate after receiving a verbal explanation of the purpose of the study. At this time, the participants signed the informed consent form and provided their handwritten signature and date. The researchers provided the participants with copies of the informed consent form. The application of the clinical trial medical device was conducted twice, for a maximum of 15 minutes per session, during the first and sixth weeks.

The application area of the medical device for clinical trials was set to the subject's face.

Before each patient's treatment or procedure, we meticulously cleaned the handpiece and transducer, as well as the body, using a gauze dampened with 70% alcohol. Additionally, we made sure to gather a comprehensive medical history from the patient, which included information about any previous treatment interventions. This step helped us assess the patient's suitability for treatment using the Prolift HIFU feature. Additionally, we informed the patient about potential side effects, which will be detailed on the following page. Finally, we inquired

about the patient's treatment goals and worked to gain a thorough understanding of their expectations, which allowed us to manage them effectively.

- Treatment Parameters

Type	Treatment Area	Energy (J)	Depth (mm)	Mhz
SD7-1.5	Face overall	0.2 – 0.25	1.5	7
	Eyebrow & periorbital			
	Forehead	0.1 – 0.25		
	cheek, chin line	0.2 -0.25		
	Neck	0.2 -0.25		
DD7-3.0	Face – cheek	0.25 – 0.45	3.0	
	Face – chin line	0.3 – 0.4		
	Face - forehead	0.2 – 0.35		
	Neck / Eyebrow & periorbital	0.25 – 0.35		
SM4-4.5	Face (except forehead)	0.8 - 1.2	4.5	4

- Side effects

- Erythema (redness): The treated area may exhibit erythema immediately following treatment. This typically resolves within 1-2 hours of treatment.
- Edema (swelling): The treated area may exhibit mild edema following treatment. This typically resolves within 48 hours of treatment.

- Pain: Momentary discomfort may be experienced during the procedure while energy is being deposited.
- Bruising: Mild bruising, which is caused by damage to soft tissue blood vessels, may occur occasionally and typically resolves within 3-7 days of treatment.
- Nerve injury: Numbness, which may occur as a result of damage to a sensory nerve, is transient and resolves in a few days.
- Nerve Effects:
 - o Transient local muscle weakness may result after treatment due to inflammation of a motor nerve.
 - o Transient numbness may result after treatment due to inflammation of a sensory nerve.
 - o Transient pain, paresthesia, and/or tingling may be experienced. No permanent injuries to facial nerves have been reported. However, based on clinical evidence facial nerve injury can take months to be resolved
- Scarring: The possibility of scar formation may exist if an incorrect treatment technique is issued.

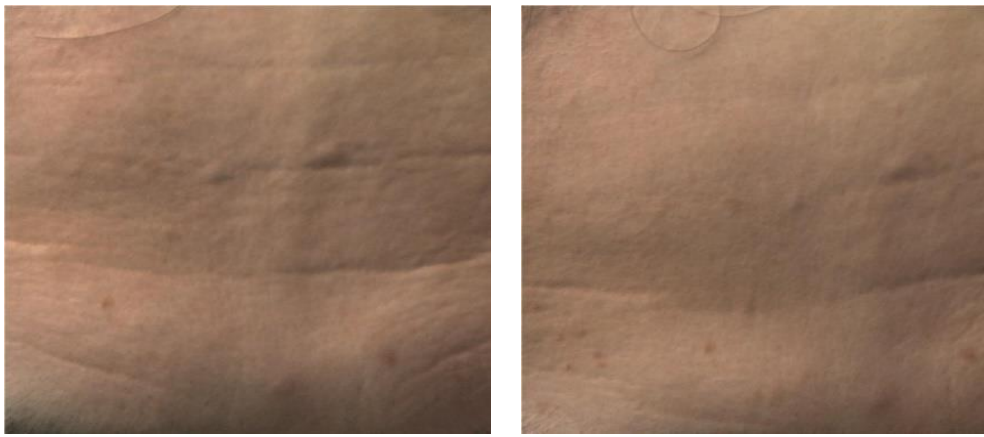
Results

Using the medical device HIFU (Prolift HIFU), we took photos before and after treating 45 subjects for wrinkles, as well as Antera images (Figure 1 and Figure 2). By quantifying the improvement in wrinkles based on the measurements before and after Antera imaging, we were able to confirm the degree of improvement. When comparing the measurements before the first treatment (A) and 5 weeks after the first treatment (B), the minimum improvement in wrinkles increased to 3.64mm from before the treatment, and the maximum improvement was -17.36mm. The average improvement was -3.73mm, with a standard deviation of 3.33mm. When comparing 5 weeks after the first treatment (B) to 15 weeks after the first treatment (C), the minimum improvement increased to 6.31mm from before the treatment, and the maximum improvement was -4.12mm. The average improvement was -0.12mm, with a standard deviation

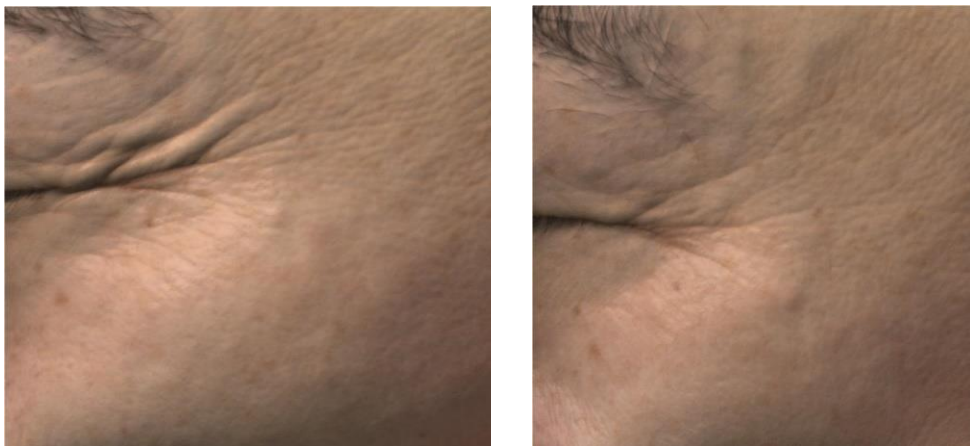
of 1.65mm. When comparing before the first treatment (A) and 15 weeks after the first treatment (C), the minimum improvement increased to 1.95mm from before the treatment, and the maximum improvement was -15.53mm. The average improvement was -3.85mm, with a standard deviation of 2.97mm (Table 1).

1. Comparison photos before and after the procedure

(1) Case-1



(2) Case-2



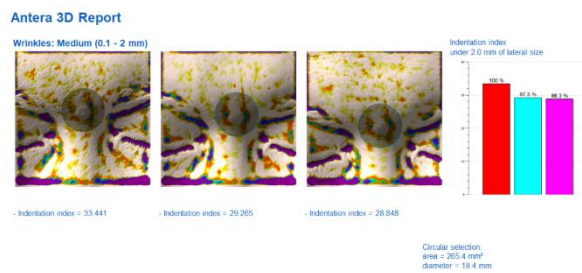
(3) case-3



Figure 1. Comparison photos before and after the procedure

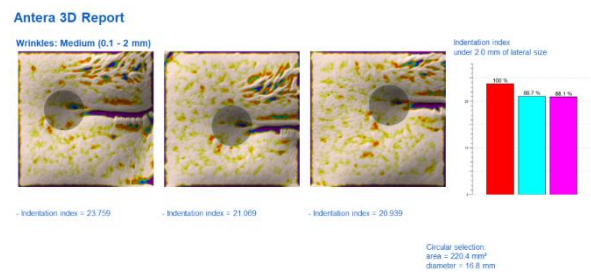
2. Comparison of ANTERA images

(1) KKM (-4.6mm)



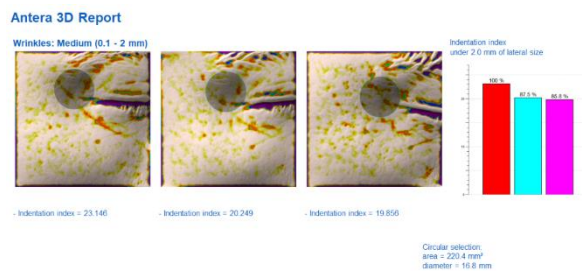
A. 33.4 B. 29.3 C. 28.8

(2) LJA (-2.8mm)



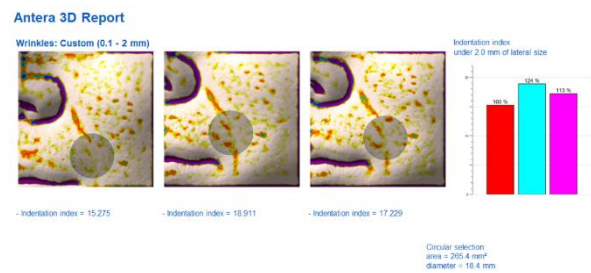
A. 23.8 B. 21.1 C. 20.9

(3) WJH (-3.3mm)



A. 23.1 B. 20.2 C. 19.9

(4) PJA (+2.0mm)

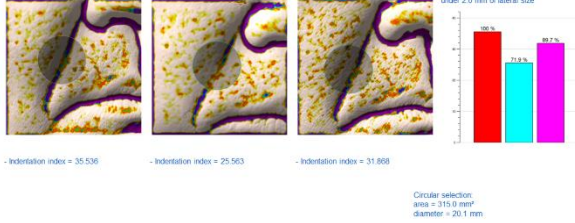


A. 15.3 B. 18.9 C. 17.2

(5) YTW(-3.7mm)

Antera 3D Report

Wrinkles: Medium (0.1 - 2 mm)

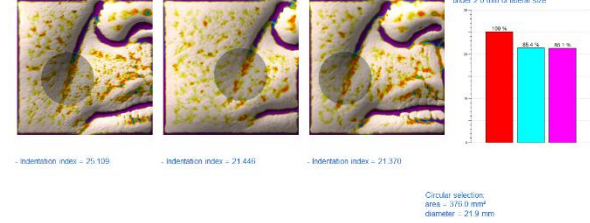


A. 35.5 B. 25.6 C. 31.9

(6) PJH(-3.7mm)

Antera 3D Report

Wrinkles: Medium (0.1 - 2 mm)

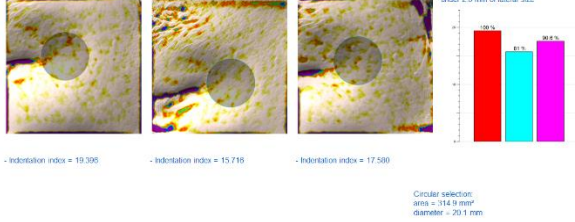


A. 25.1 B. 21.4 C. 21.4

(7) JHE(-1.8mm)

Antera 3D Report

Wrinkles: Medium (0.1 - 2 mm)



A. 19.4 B. 15.7 C. 17.6

(8) LSM(-2.4mm)

Antera 3D Report

Wrinkles: Medium (0.1 - 2 mm)

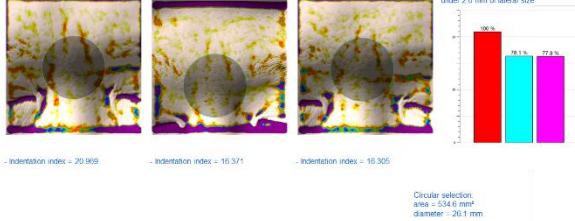


A. 20.0 B. 17.7 C. 17.6

(9) KJW(-4.7mm)

Antera 3D Report

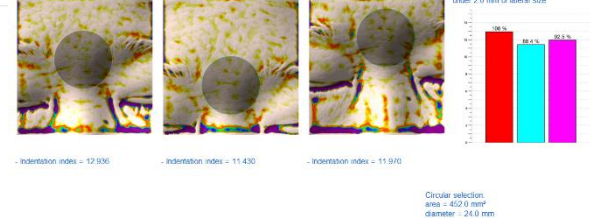
Wrinkles: Medium (0.1 - 2 mm)



A. 21.0 B. 16.4 C. 16.3

Antera 3D Report

Wrinkles: Medium (0.1 - 2 mm)

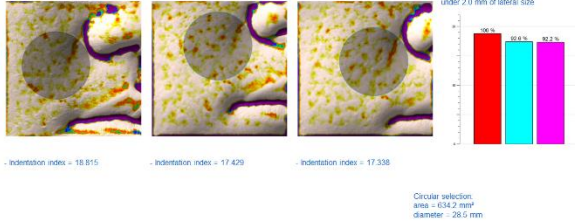


A. 12.9 B. 11.4 C. 12.0

(11) YTG(-1.5mm)

Antera 3D Report

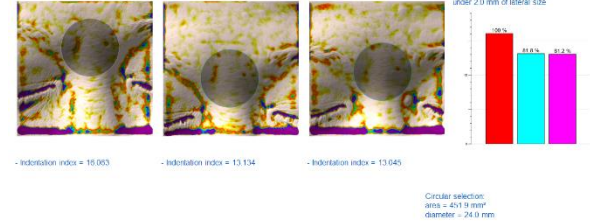
Wrinkles: Medium (0.1 - 2 mm)



A. 18.8 B. 17.4 C. 17.3

Antera 3D Report

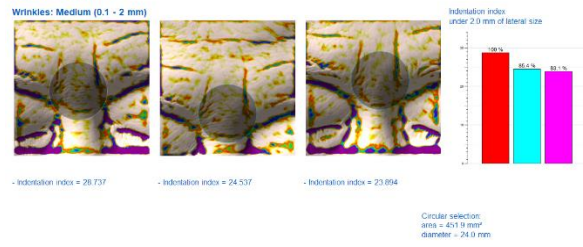
Wrinkles: Medium (0.1 - 2 mm)



A. 16.1 B. 13.1 C. 13.0

(13) KSB(-4.8mm)

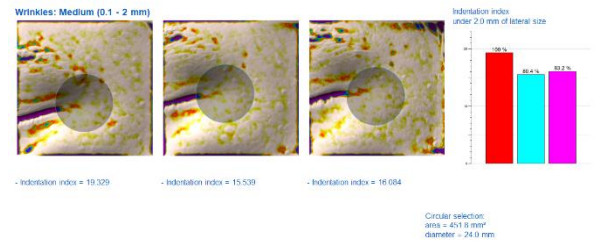
Antera 3D Report



A. 28.7 B. 24.5 C. 23.9

(14) LGH(-3.2mm)

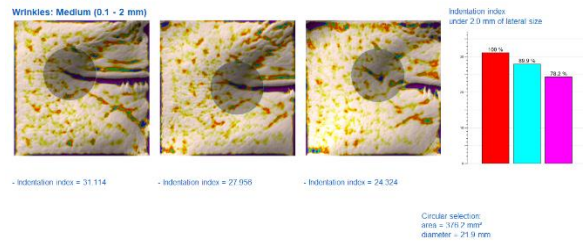
Antera 3D Report



A. 19.3 B. 15.5 C. 16.1

(15) HSH(6.8mm)

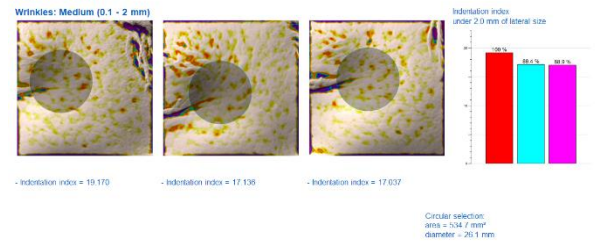
Antera 3D Report



A. 31.1 B. 28.0 C. 24.3

(16) JKC(2.1mm)

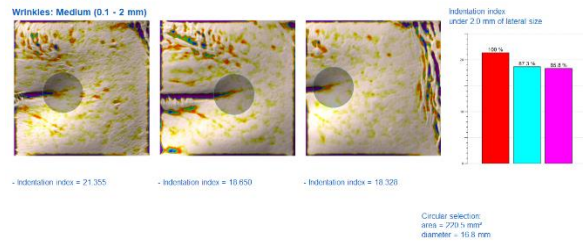
Antera 3D Report



A. 19.2 B. 17.1 C. 17.0

(17) LYS(3.0mm)

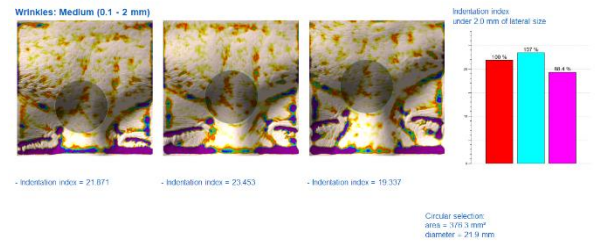
Antera 3D Report



A. 21.4 B. 18.7 C. 18.3

(18) JKJ(2.5mm)

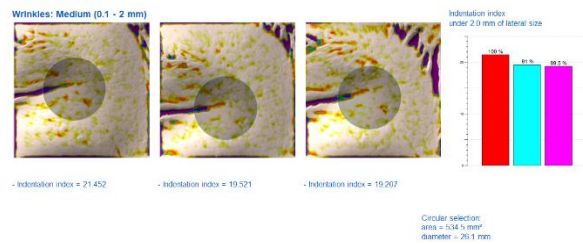
Antera 3D Report



A. 21.9 B. 23.5 C. 19.3

(19) HIS(2.2mm)

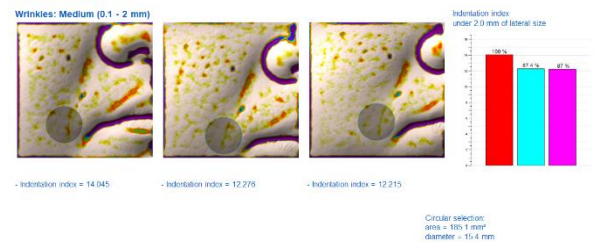
Antera 3D Report



A. 21.5 B. 19.5 C. 19.2

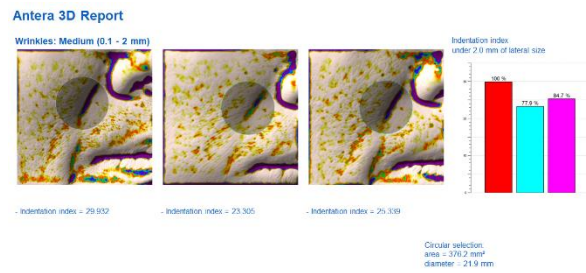
(20) PJB(1.8mm)

Antera 3D Report



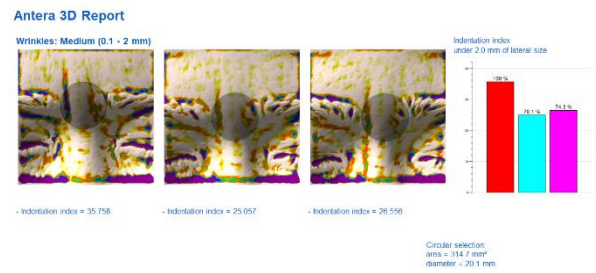
A. 14.0 B. 12.3 C. 12.2

(21) KYS(4.6mm)



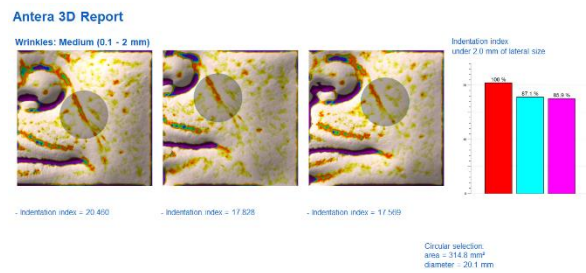
A. 29.9 B. 23.3 C. 25.3

(22) CSW(9.2mm)



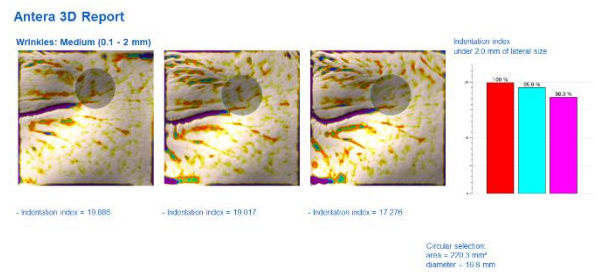
A. 35.8 B. 25.1 C. 26.6

(23) KSA(2.9mm)



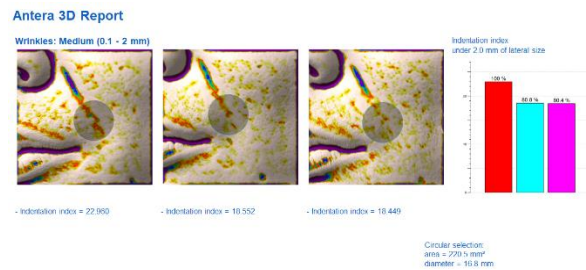
A. 20.5 B. 17.8 C. 17.6

(24) SMJ(2.6mm)



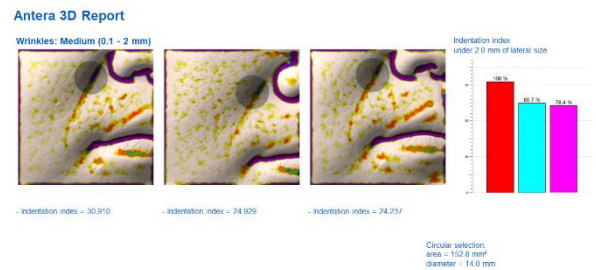
A. 19.9 B. 19.0 C. 17.3

(25) LJB(4.5mm)



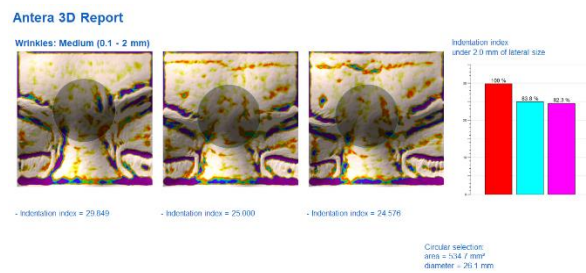
A. 23.0 B. 18.6 C. 18.4

(26) KSC(6.7mm)



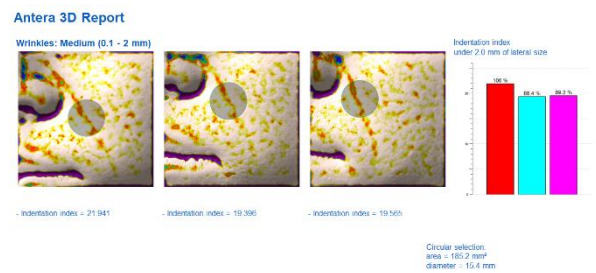
A. 30.9 B. 24.9 C. 24.2

(27) KWG(5.3mm)



A. 29.8 B. 25.0 C. 24.6

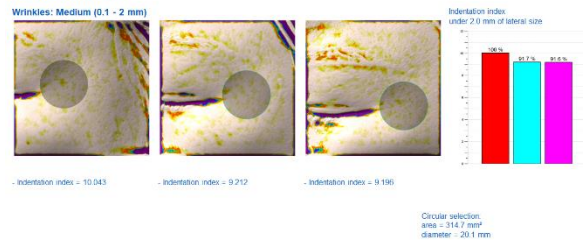
(28) HGN(2.4mm)



A. 21.9 B. 19.4 C. 19.6

(29) KCS(0.8mm)

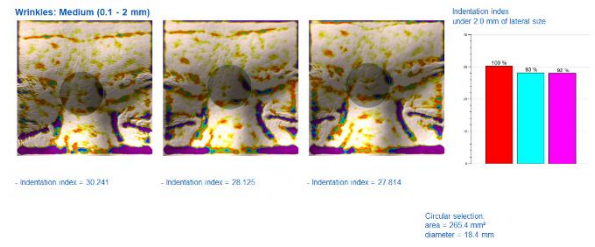
Antera 3D Report



A. 10.0 B. 9.2 C. 9.2

(30) KJH(2.4mm)

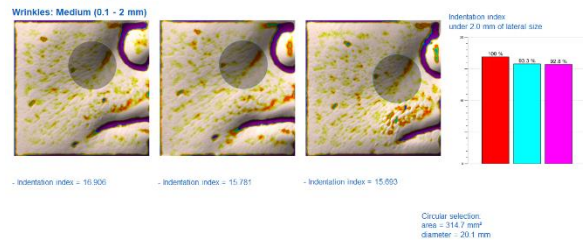
Antera 3D Report



A. 30.2 B. 28.1 C. 27.8

(31) PWS(1.2mm)

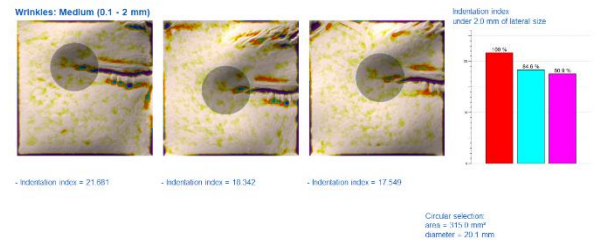
Antera 3D Report



A. 16.9 B. 15.8 C. 15.7

(32) KMJ(4.1mm)

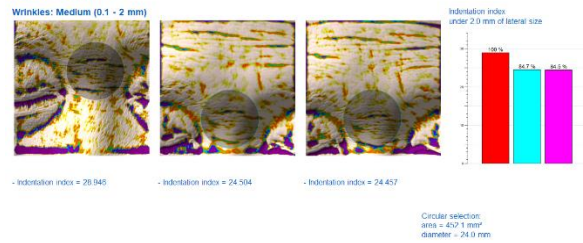
Antera 3D Report



A. 21.7 B. 18.3 C. 17.5

(33) KYY(4.5mm)

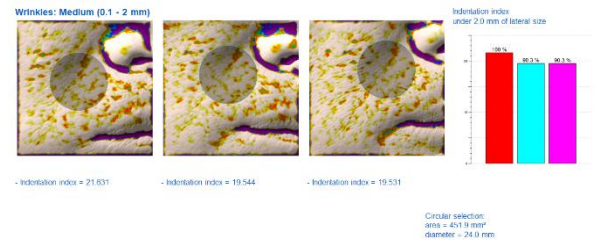
Antera 3D Report



A. 28.9 B. 24.5 C. 24.5

(34) LYH(2.1mm)

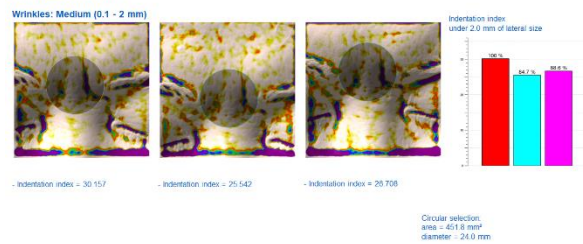
Antera 3D Report



A. 21.6 B. 19.5 C. 19.5

(35) JHW(3.4mm)

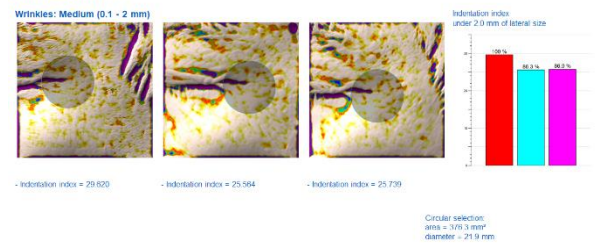
Antera 3D Report



A. 30.2 B. 25.5 C. 26.7

(36) LHM(3.9mm)

Antera 3D Report

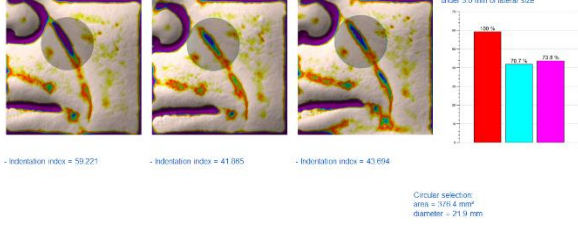


A. 29.6 B. 25.6 C. 25.7

(37) CHJ(15.5mm)

Antera 3D Report

Wrinkles: Large (0.1 - 3 mm)



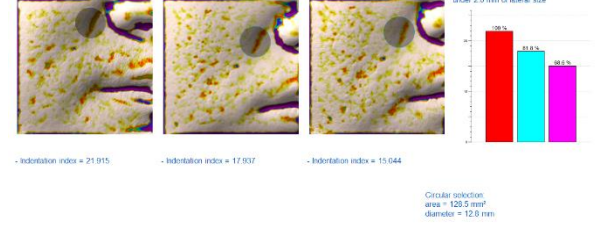
A. 59.2 B. 41.9 C. 43.7

(38) HSW(6.9mm)

Antera 3D Report

현상판

Wrinkles: Medium (0.1 - 2 mm)

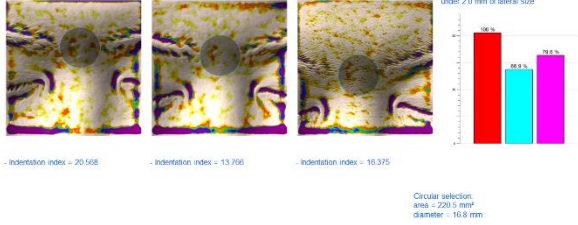


A. 21.9 B. 17.9 C. 15.0

(39) LSS(4.2mm)

Antera 3D Report

Wrinkles: Medium (0.1 - 2 mm)

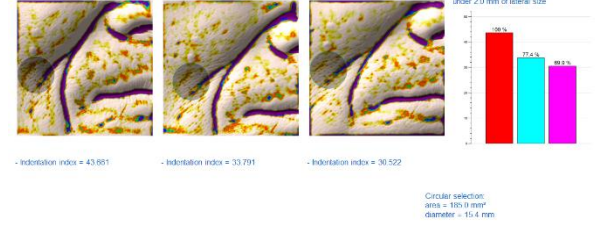


A. 20.6 B. 13.8 C. 16.4

(40) LCH(13.1mm)

Antera 3D Report

Wrinkles: Medium (0.1 - 2 mm)

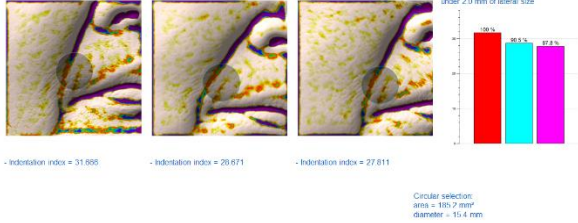


A. 43.7 B. 33.8 C. 30.5

(41) LMY(3.9mm)

Antera 3D Report

Wrinkles: Medium (0.1 - 2 mm)

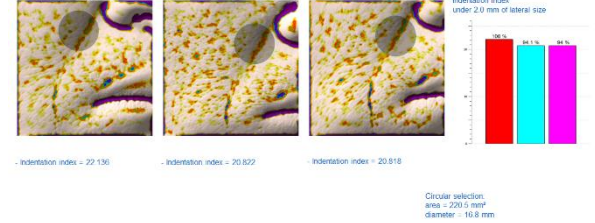


A. 31.7 B. 28.7 C. 27.8

(42) WMS(1.3mm)

Antera 3D Report

Wrinkles: Medium (0.1 - 2 mm)

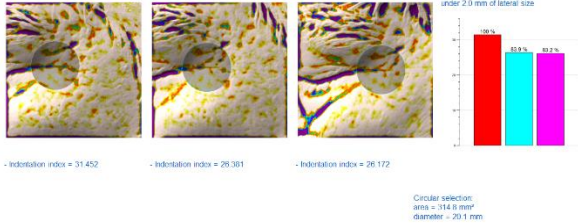


A. 22.1 B. 20.8 C. 20.8

(43) KBH(5.3mm)

Antera 3D Report

Wrinkles: Medium (0.1 - 2 mm)

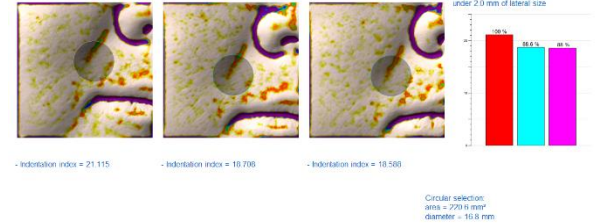


A. 31.5 B. 26.4 C. 26.2

(44) JJP(2.5mm)

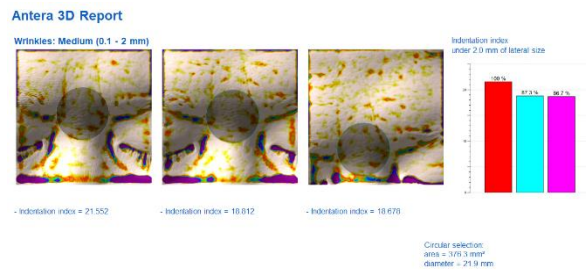
Antera 3D Report

Wrinkles: Medium (0.1 - 2 mm)



A. 21.1 B. 18.7 C. 18.6

(45) KKY(2.9mm)



A. 21.6 B. 18.8 C. 18.7

Figure 2. Comparison of ANTERA images Week1(A. Before), Week7(B. 5 weeks later) and Week17(C.15 weeks later) Prolift HIFU test for Improvement of wrinkles.

3. ANTERA data

	Indentation index(mm)			Decline rate (%)		
	B-A	C-B	C-A	B-A	C-B	C-A
Minimum value	3.64	6.31	Minimum value	3.64	6.31	Minimum value
Maximum value	-17.36	-4.12	Maximum value	-17.36	-4.12	Maximum value
Average	-3.73	-0.12	Average	-3.73	-0.12	Average
Standard Deviation	3.33	1.65	Standard Deviation	3.33	1.65	Standard Deviation

Table 1. . Antera data Analysis (A : Before, B : Before the second treatment, C: 10 weeks after the second treatment)

Discussion

The wrinkle improvement effect of HIFU (High-Intensity Focused Ultrasound) has the effect of increasing confidence and leads to positive changes in attitude toward life. Through this clinical trial, we were able to confirm positive changes in the subjects.

Satisfaction surveys conducted on the subjects at the completion of the procedure can be found in graphs from Table 2 to Table 6. The satisfaction survey consisted of a total of 7 questions, including whether the subjects felt a reduction in wrinkles (Table 2) and their satisfaction with the wrinkle treatment using the device (Table 3 to 5), as well as any side effects (Table 6). 98% of the subjects were satisfied with the treatment results (Table 5).

Upon completion of the procedure, a satisfaction survey was administered to three specialists, as indicated by the graphs presented in Tables 7 through 10. This satisfaction survey encompassed four questions, which inquired about the reduction in wrinkles (Table 7), their satisfaction with the device (Tables 8 to 9), and the ease of use (Table 10). Notably, all three specialists reported being completely satisfied with the device.

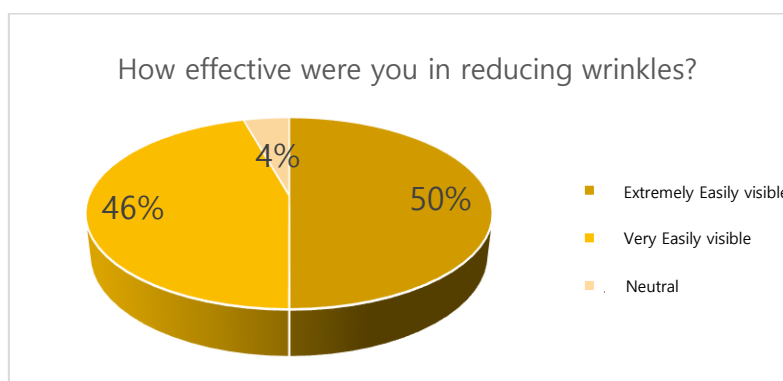


Table 2. The question was asked about how much of an effect in reducing wrinkles the subjects could see. The results were as follows: A very significant change (Extremely Easily visible) of 50%, a somewhat significant change (Very Easily visible) of 46%, neutral (Neutral) at 4%, almost none (Slightly change) at 0%, and none at all (No Reduction at all) at 0%.

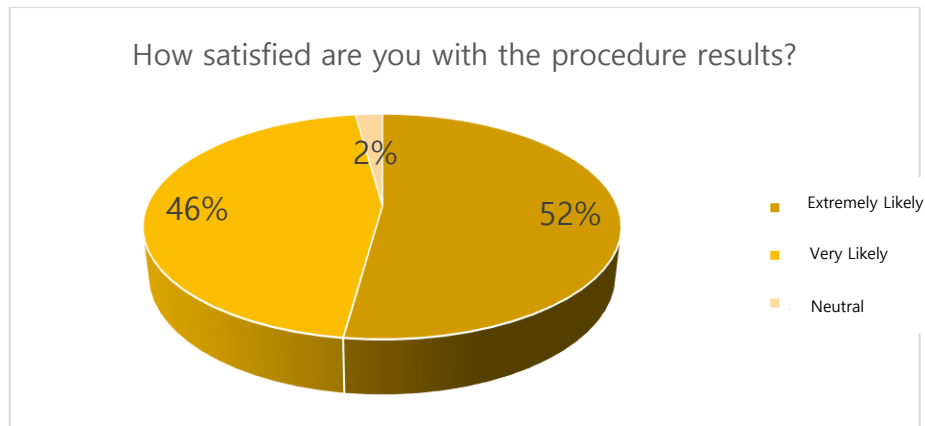


Table 3. The subjects were asked how satisfied they were with the results of the procedure. Very satisfied (Extremely Likely) 52%, Satisfied (Very Likely) 46%, Neutral (2%), Slightly Dissatisfied (0%), and Dissatisfied (Not at all Likely) 0%.



Table 4. The subjects were asked how satisfied they were with their wrinkle treatment. Extremely Satisfy 61%, Very Satisfy 37%, Neutral 2%, Slightly Satisfy 0%, and Dissatisfaction (Not at all Satisfy) 0%.

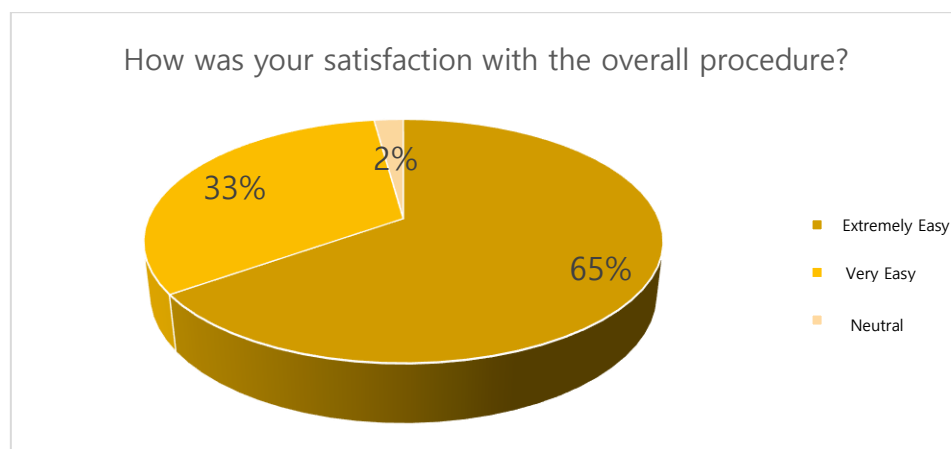


Table 5. The subjects were asked how satisfied they were with the overall procedure. Extremely Satisfied (Extremely Easy) 65%, Satisfied (Very Easy) 33%, Neutral (2%), Slightly Dissatisfied (0%), and Dissatisfied (Not at all Easy) 0%.

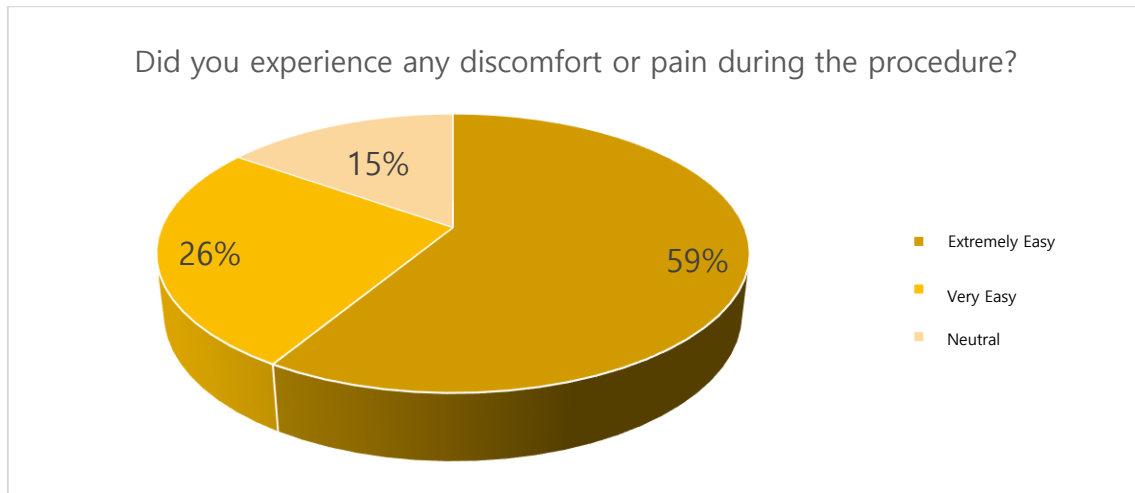


Table 6. The subjects were asked whether they experienced discomfort and pain during the procedure. No discomfort at all (Extremely Easy) 59%, Very Easy (26%), Neutral (15%), Inconvenience (Slightly Easy) 0%, Very inconvenient (Not at all Easy) 0%.

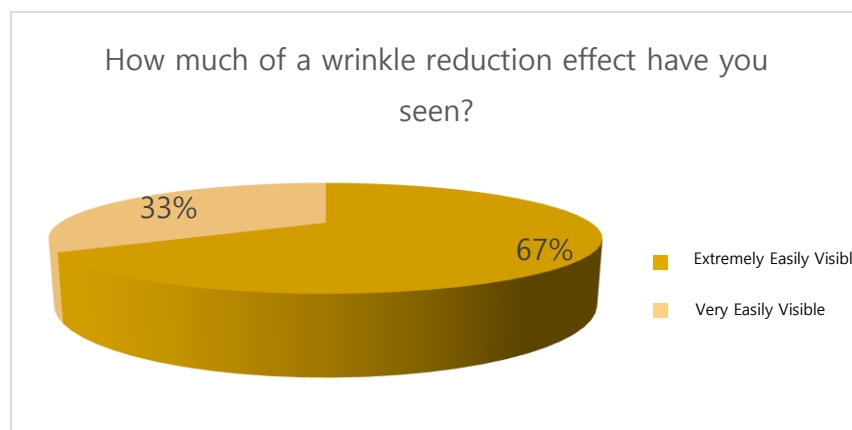


Table 7. We asked three specialists about how effective they felt in reducing wrinkles. Extremely Easily visible 67%, Very Easily visible 33%, Neutral 0%, Slightly Change 0%, and No Reduction at all 0%.

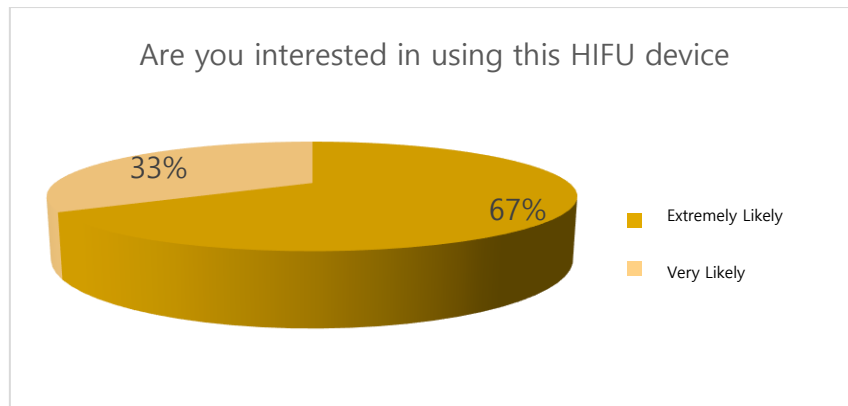


Table 8. Three specialists were asked whether they would be willing to use this HIFU device. Extremely Likely 67%, Very Likely 33%, Neutral 0%, Slightly Likely 0%, and Not at all Likely 0%.



Table 9. We asked three specialists how satisfied they were with this device for treating wrinkles. Extremely Satisfy was 100%, Very Satisfy was 0%, Neutral was 0%, Slightly Satisfy was 0%, and Dissatisfied was 0%.

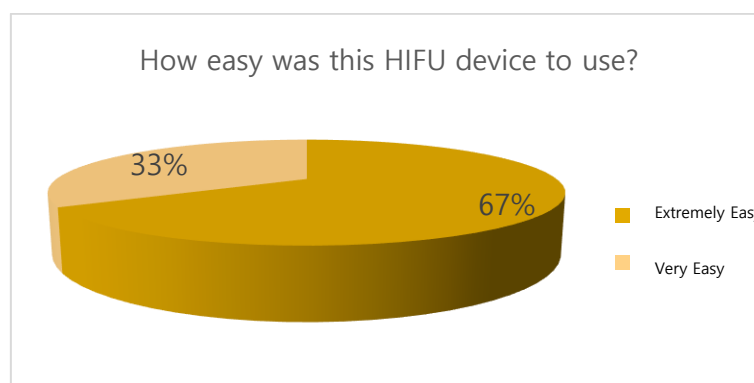


Table 10. We asked three experts about how easy it was to use the device. Extremely Easy 67%, Very Easy 33%, Neutral 0%, Slightly Easy 0%, and Hard (Not at all Easy) 0%.

Conclusion

In a clinical trial involving a total of 45 adults and elderly individuals aged 35 to 65 years, the HIFU medical device (Prolift HIFU) confirmed its efficacy and safety for wrinkle improvement. The 45 subjects were able to observe a reduction in the depth of wrinkles through before-and-after photos, ANTERA images, and analysis data during the clinical trial. These results demonstrate the effectiveness of HIFU (High-Intensity Focused Ultrasound) in wrinkle improvement. While there were minor side effects such as a slight tingling sensation, tolerable pain, and a feeling of stiffness after the procedure, no serious side effects occurred during the clinical trial, thus confirming its safety. The 45 subjects expressed a high level of satisfaction with wrinkle treatment, averaging a score of 92 in a satisfaction survey, and all three specialists were 100% satisfied with the device.

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