Clinical Evaluation of Erectile Dysfunction Treatment Using Low-Intensity Shock Wave Therapy MORENOVA®: A Study of 59 Cases

Jun Kato[1], Hajime Nakano[1], Akira Tsujimura[2]

Abstract:

This study investigates the efficacy of low-intensity shock wave therapy (MORENOVA®) for treating erectile dysfunction (ED) in 59 patients who presented with ED as their chief complaint at the East Ekimae Clinic Shinbashi in Tokyo, Japan.

Patient Background and Methods: The patients had an average age of 54.2 ± 13.26 years, ranging from their 20s to their 70s (maximum age of 78). The study included patients with no underlying health conditions prior to treatment, as well as those with various chronic conditions such as hypertension. MORENOVA® was conducted according to standard procedures, with evaluations of the patient's EHS (Erection Hardness Score) and SHIM (Sexual Health Inventory for Men) scores before treatment, and one and three months after treatment. EHS quantifies erection hardness, while SHIM is used to assess overall erectile function. In addition to these assessments, patients were asked to provide free-form feedback regarding their impressions and opinions after the therapy.

Results and Conclusion: One month after therapy, the average SHIM score improved from 11.4 to 16.7 ($p<0.01$), while the average EHS improved from 1.9 to 2.8 ($p<0.01$). After three months, the SHIM score improved from an average of 10.5 to 15.0 ($p<0.01$), and the EHS improved from 1.9 to 2.6 ($p<0.01$). The improvements in SHIM score and EHS were statistically significant at both one- and three-months post-treatment. Similar treatment effects were observed across different age groups and among patients with underlying health conditions. Of the 34 responses to the AI-analyzed post-treatment feedback, 70% were positive. This study strongly suggests that low-intensity shock wave therapy is a promising treatment option for ED across diverse age groups and patients with underlying health conditions. Future research should focus on exploring the relationship between patient background, underlying health conditions, and treatment efficacy, as well as evaluating the long-term sustainability of treatment effects over 6 months and 1 year.

Key Words: Erectile Dysfunction (ED), Low-Intensity Shock Wave Therapy for ED, MORENOVA®, Erection Hardness Score (EHS), Sexual Health Inventory for Men (SHIM)

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Introduction:

MORENOVA® is a cutting-edge medical device developed by DIREX, an Israeli company renowned for its advanced technology in the field of urology. It was designed specifically for the treatment of erectile dysfunction (ED) and is based on clinical results that suggest shock waves (pressure waves traveling faster than the speed of sound) can contribute to the improvement of ED. DIREX leveraged its expertise in shock wave therapy for kidney stone lithotripsy and adapted it for ED treatment, resulting in this groundbreaking medical device.

MORENOVA® is a compact version of the older RENOVA®, and while the fundamental principle remains the same, it utilizes low-intensity shock waves on the penis and perineum. Renova has been implemented in over 70 countries and boasts over 100,000 treatment cases. The therapy itself is relatively painless, takes about 20 minutes, and has not been associated with any side effects, making it a promising new strategy in ED treatment.

As shown in Figures 1-A & 1-B, the linear shock waves from MORENOVA® are a type of low-intensity shock wave therapy (ESWT = Extracorporeal Shockwave Therapy). The treatment involves delivering a total of 1,800 shock waves (900 from each of the two applicators) with an energy density of 1.8 mJ/mm² to the sides of the penis and the perineum. This stimulates endothelial cells within penile blood vessels, promoting angiogenesis[1)]. Improved blood flow to the penis leads to the delivery of adequate blood supply necessary for erection, thereby enhancing erectile function. It is also possible to combine MORENOVA® treatment with ED medication.

There is no standard protocol for the frequency of treatments[2)], however, this study followed the protocol recommended by DIREX, which entails five sessions conducted 2-3 times per week. Contraindications and exclusions for MORENOVA® are listed in Table 2.

Methods:

The study included 59 patients (average age: 54.1 ± 13.2 years) who presented with erectile dysfunction (ED) as their chief complaint at the East Ekimae Clinic Shinbashi from May 2022 to March 2024. Patients were included in the study if they met the eligibility criteria, did not have contraindications or exclusions to MORENOVA® treatment, and consented to participate in the clinical study. Participants received five treatment sessions over a period of two to five weeks.

Patient evaluation was based on age, underlying health conditions, duration of ED, and pre- and post-treatment SHIM (Sexual Health Inventory for Men) and EHS (Erection Hardness Score) scores (both in Japanese versions[3)]). This observational study did not restrict the use of ED medications during the study period. The study was conducted retrospectively, in compliance with the Helsinki Declaration and Good Clinical Practice (GCP) guidelines. It was approved by the local ethics committee (Ethics Committee of Juntendo University Urayasu Hospital, approval number E23-0445). Statistical significance was assessed using appropriate statistical methods (paired t-

test). Additionally, patients were asked to provide free-form feedback on their impressions and opinions about the therapy one month after the treatment.

Results:

Figure 2 shows the age distribution of the participants. The most common age group was the 50s, accounting for 32.2%, followed by the 60s at 30.5%, the 40s at 18.6%, the 20s and 30s at 10.2%, and the 70s (with a maximum age of 78) at 8.5%.

Figure 3 displays the duration of ED experienced by participants as part of the patient background. The majority of cases (71.0%, or 42 participants) had experienced ED for one to three years. Four cases (7%) had been experiencing ED for 10 to 14 years.

Figure 4 shows the breakdown of underlying health conditions among the participants. A total of 18 participants (30.5%) were receiving treatment for an underlying condition, with hypertension being the most common (33.3%), followed by dyslipidemia, diabetes, and hyperuricemia as the primary conditions.

Figures 5 shows the changes in SHIM score and EHS one month after treatment. The SHIM score improved significantly from 11.4 to 16.7 ($p<0.01$), and EHS also improved significantly from 1.9 to 2.8 ($p<0.01$).

Figures 6 shows the SHIM score and EHS three months after treatment. Although the number of cases decreased to 30 at three months, the SHIM score improved significantly from 10.5 to 15.0 ($p<0.01$), and EHS improved significantly from 1.9 to 2.6 ($p<0.01$). This demonstrates that the improvements were maintained even three months after treatment.

Furthermore, Figures 7 and Figure 8 display the changes in SHIM score and EHS by age group. While there was a trend of decline in the scores at three months across all age groups, the improvements achieved from before treatment were maintained.

Table 4a-4c contain free-form feedback and impressions about the treatment from participants. An AI analysis of the responses from 34 participants showed that 70% provided positive feedback (as shown in Figure 9).

Discussion:

The prevalence of erectile dysfunction (ED) has been rising worldwide[4)], including in Japan, where it has become a national health concern. The age distribution in this study (Figure 2) spanned from patients in their 20s to the oldest patient being 78 years old, with the majority of patients being in their 50s and 60s. Around 71% of patients had been suffering from ED for a relatively short duration of one to three years, while five patients were in their 70s, including one patient who had been receiving ED treatment for 10 to 14 years.

In terms of medication, 67.8% (40/59) of the patients were either currently using or had

previously used ED medications, while 18.6% (11/59) had never used ED medications (some had discontinued use due to side effects). Regarding underlying conditions (Figure 4), 30.5% (18/59) of the patients had comorbidities, with hypertension being the most common (33.3%). Although the use of antihypertensive medications was not thoroughly analyzed, a variety of medications were reported, with amlodipine being the most commonly used. The potential impact of medication-induced ED should be considered in future research.

Additionally, dyslipidemia and diabetes each accounted for 16.7% (2/18) of cases, and patients were typically prescribed statins or SGLT2 inhibitors. One case was managed with self-administered insulin injections. Other comorbidities included atrial fibrillation (post-ablation) and benign prostatic hyperplasia, indicating that some patients had multiple underlying conditions.

Future research should investigate the impact of various comorbidities (e.g., HbA1C levels) on the efficacy of MORENOVA® treatment. The improvements in SHIM score and EHS observed one month after treatment (Figures 5 and 6) were significant, with continued significant improvements observed three months post-treatment (Figures 7 and 8), despite the reduction in the number of respondents from 59 to 30.

The limited number of cases in this study may have affected the results, but the sustained improvement in EHS across almost all age groups is notable. It will be important to assess whether these improvements persist over longer periods, such as six months or a year.

Another study by Kurosawa et al.[5] assessed the efficacy of low-intensity shock wave therapy products (ED1000 and Renova) in 76 and 484 cases, respectively. A multivariate analysis identified age as the only factor influencing EHS (P=0.009), suggesting RENOVA® is recommended for patients under 70 years old.

In this study, improvements were observed even in patients over 70 years old (albeit only five patients), but a larger sample size might reveal similar trends to those of previous studies. Lastly, AI analysis of free-form feedback from 34 patients one-month post-treatment revealed that 70% of patients reported positive experiences (Figure 9).

Despite the limited sample size and observational period, the study suggests consistent efficacy of MORENOVA® treatment across age groups, ED duration, and the presence of comorbidities. The sustained improvements in EHS scores even three months post-treatment indicate the potential for long-term efficacy of this treatment method.

In conclusion, MORENOVA® shows promise as a new option in the treatment of erectile dysfunction (ED). It may offer an alternative for patients who experience a reduction in efficacy with ED medications, as well as for those who cannot continue ED medication due to side effects or contraindications. Long-term clinical trials and comparative studies with other ED treatment methods are crucial and are expected to clarify MORENOVA®'s positioning in the treatment of ED.

References:

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Fig 1 -A

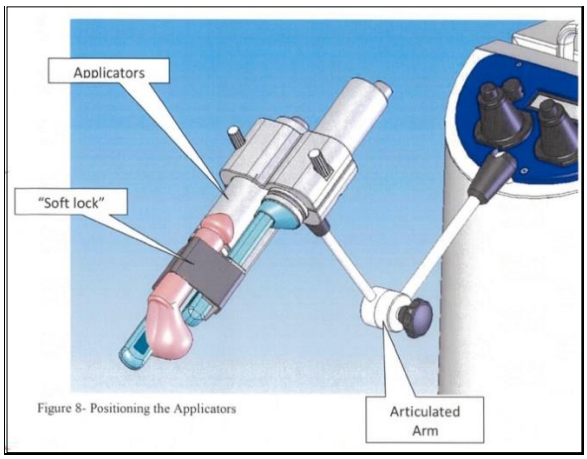

Fig 1 -B

1. Individuals with a history of radical prostatectomy or extensive pelvic surgery. 2. Patients with venous leak erectile dysfunction. 3. Those with abnormal bleeding tendencies or coagulation disorders, such as an international normalized ratio (INR) greater than 3. 4. Patients with hemophilia (A and B). 5. Individuals experiencing localized bleeding. 6. Those who have undergone pelvic area surgery or radiation therapy within the last 12 months. 7. Patients with a history of cancer treatment within the last 12 months or those in the recovery phase. 8. Those with neurological or psychiatric conditions that impact erection. 9. Individuals with penile deformities or abnormalities (e.g., Peyronie's disease) during erection. 10. Patients with local wounds, dermatitis, infections, or tumors in the penile, scrotal, or inguinal regions. 11. Those with implants within the penis (including penile prostheses). 12. Other medical history or conditions that the physician deems necessary for exclusion.

Table 1

Number of Subjects by Age Group

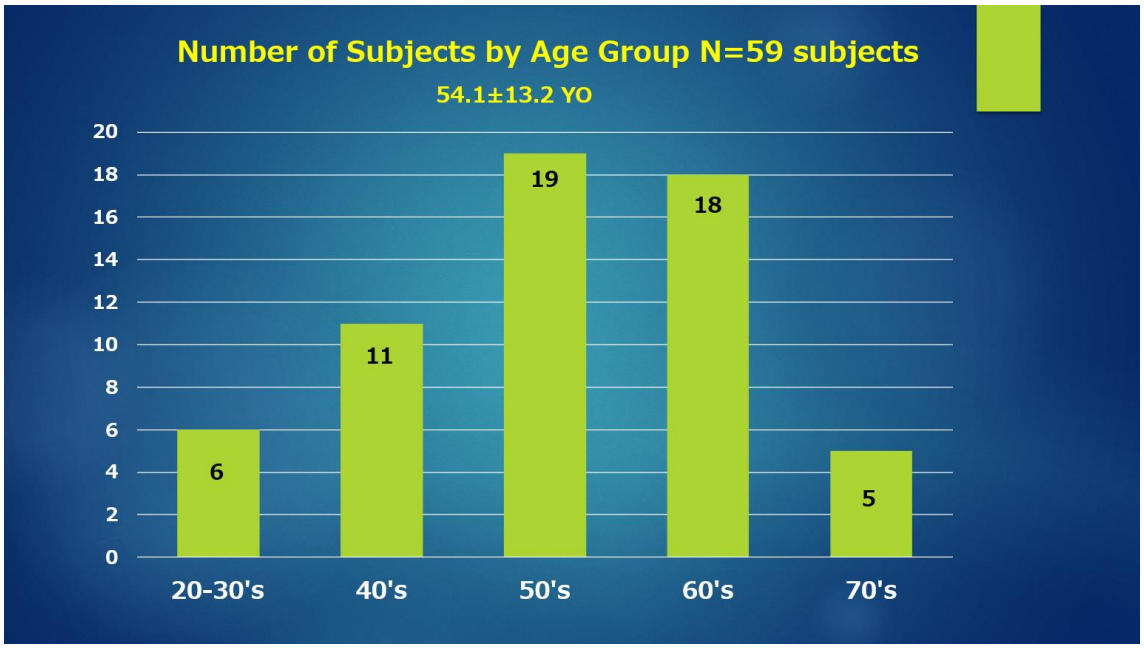

Fig.2

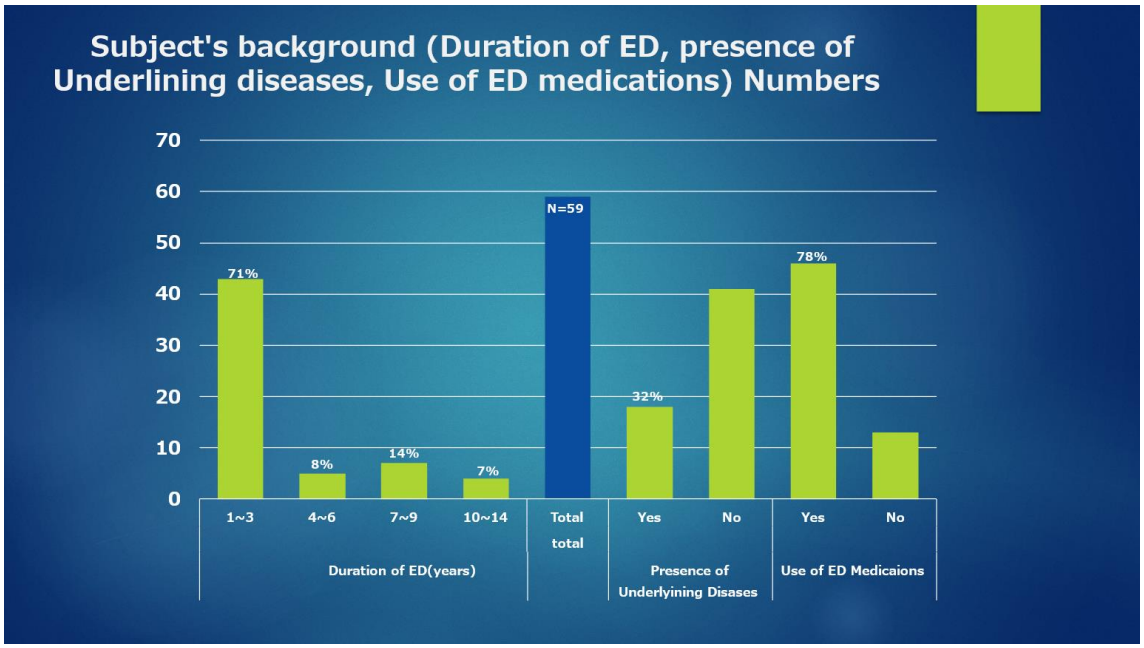
Subject's background (Duration of ED, presence of Underlining diseases, Use of ED medications) Numbers
70
60
50
40
30
20
10
0
71%
8%
14%
7%
N=59
32%
78%
1~3
4~6
7~9
10~14
Total
total
Yes
No
Yes
No
Duration of ED(years)
Presence of Underlyining Disases
Use of ED Medicaions

Fig. 3

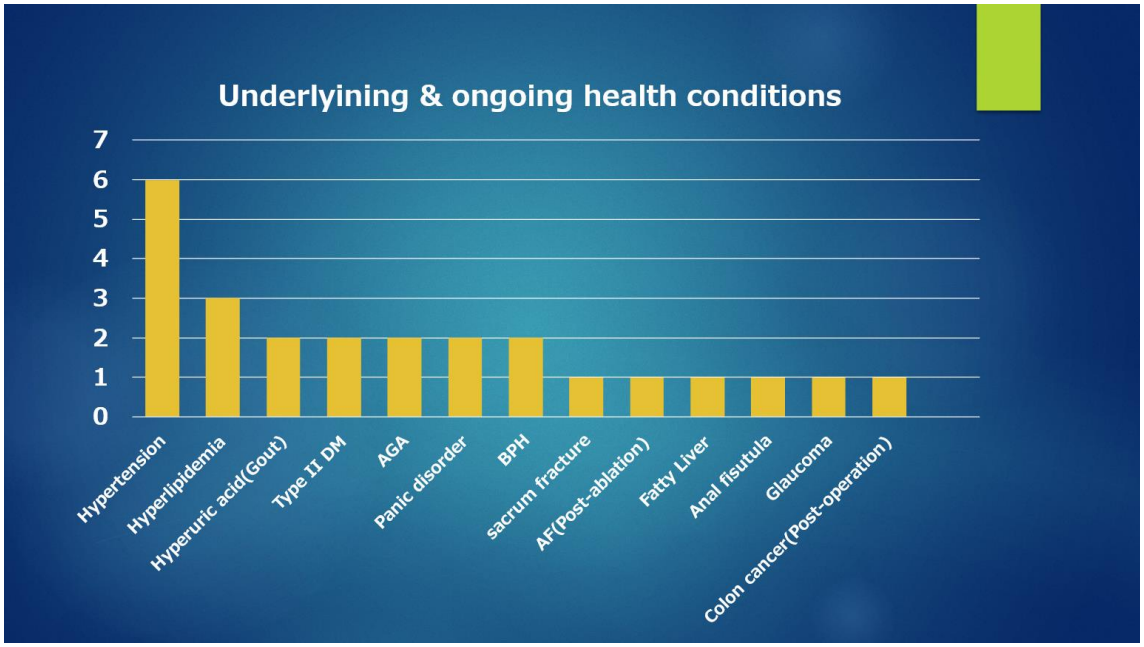
Underlyining & ongoing health conditions
7
6
5
4
3
2
1
0
Hypertension
Hyperlipidemia
Hyperuric acid(Gout)
Type II DM
AGA
Panic disorder
BPH
sacrum fracture
AF(Post-ablation)
Fatty Liver
Anal fisutula
Glaucoma
Colon cancer(Post-operation)

Fig.4

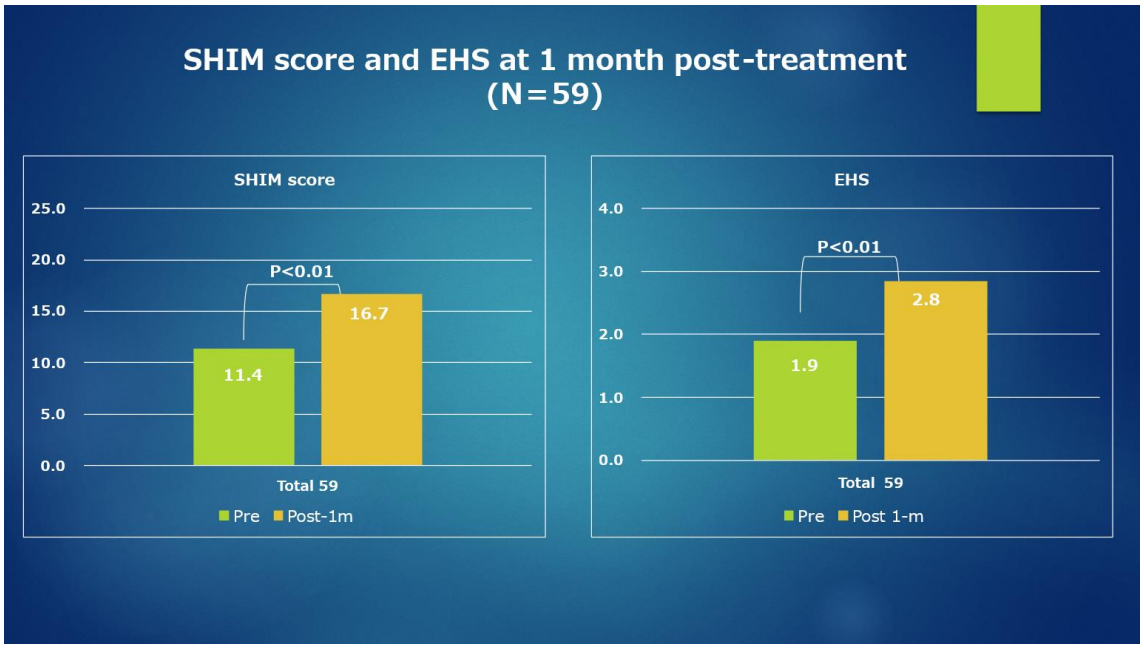
SHIM score and EHS at 1 month post-treatment
(N=59)
SHIM score
25.0
20.0
15.0
10.0
5.0
0.0
P<0.01
11.4
16.7
Total 59
Pre
Post-1m
EHS
4.0
3.0
2.0
1.0
0.0
P<0.01
1.9
2.8
Total 59
Pre
Post 1-m

Fig. 5

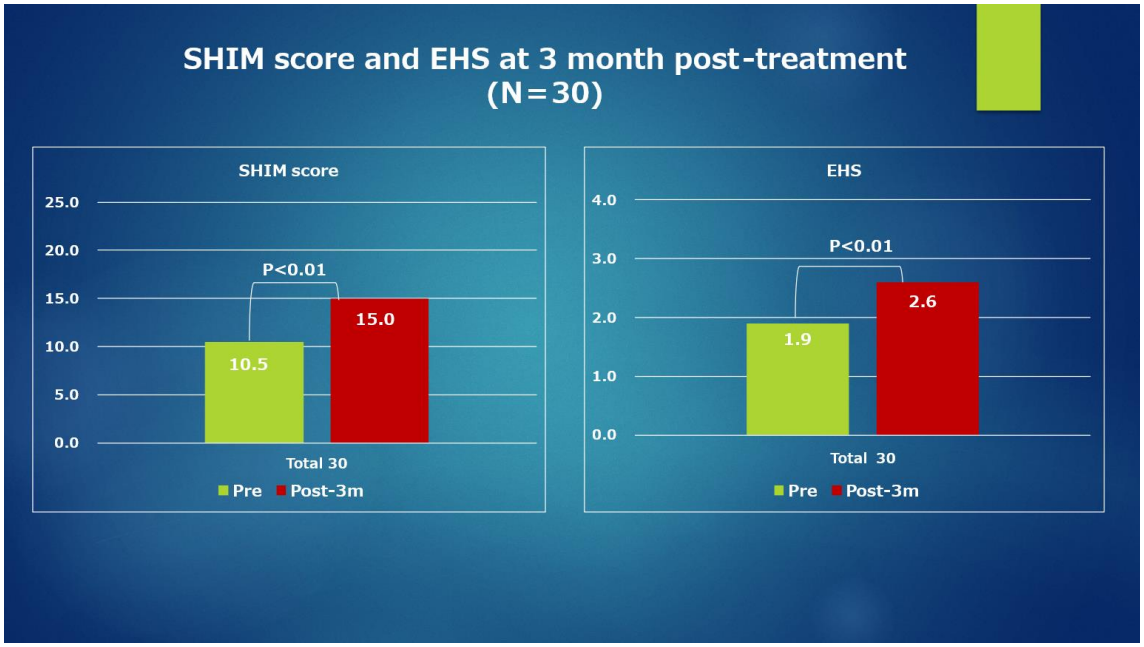
SHIM score and EHS at 3 month post-treatment
(N=30)
SHIM score
25.0
20.0
15.0
10.0
5.0
0.0
P<0.01
10.5
15.0
Total 30
Pre
Post-3m
EHS
4.0
3.0
2.0
1.0
0.0
P<0.01
1.9
2.6
Total 30
Pre
Post-3m

Fig.6

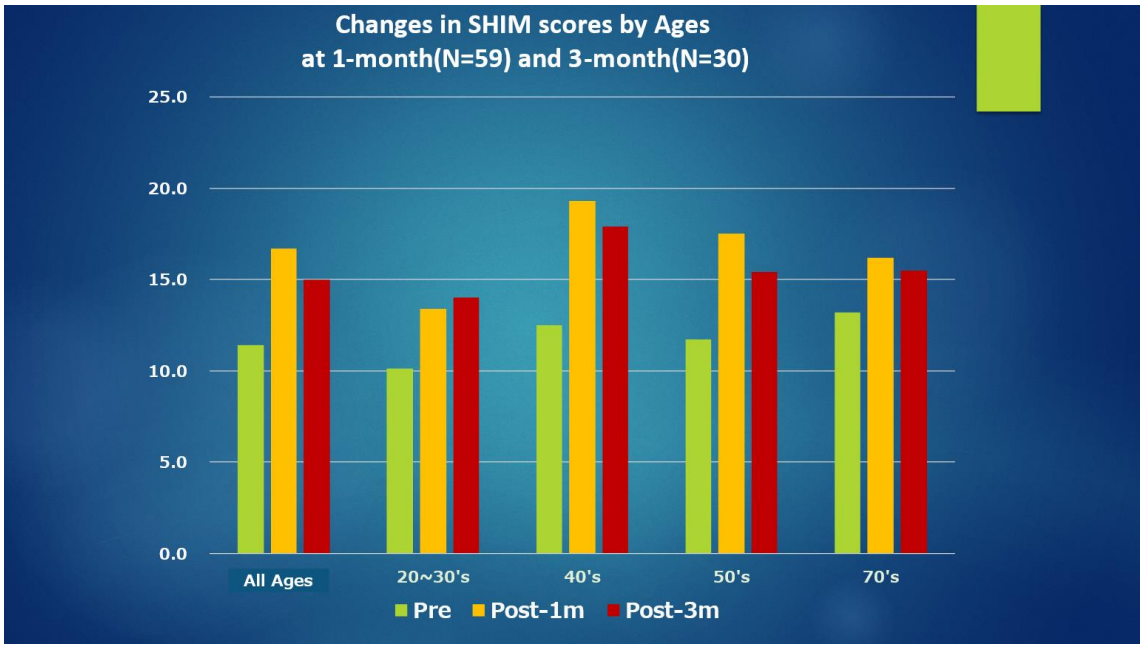
Changes in SHIM scores by Ages
at 1-month(N=59) and 3-month(N=30)
25.0
20.0
15.0
10.0
5.0
0.0
All Ages
20~30's
40's
50's
70's
Pre
Post-1m
Post-3m

Fig.7

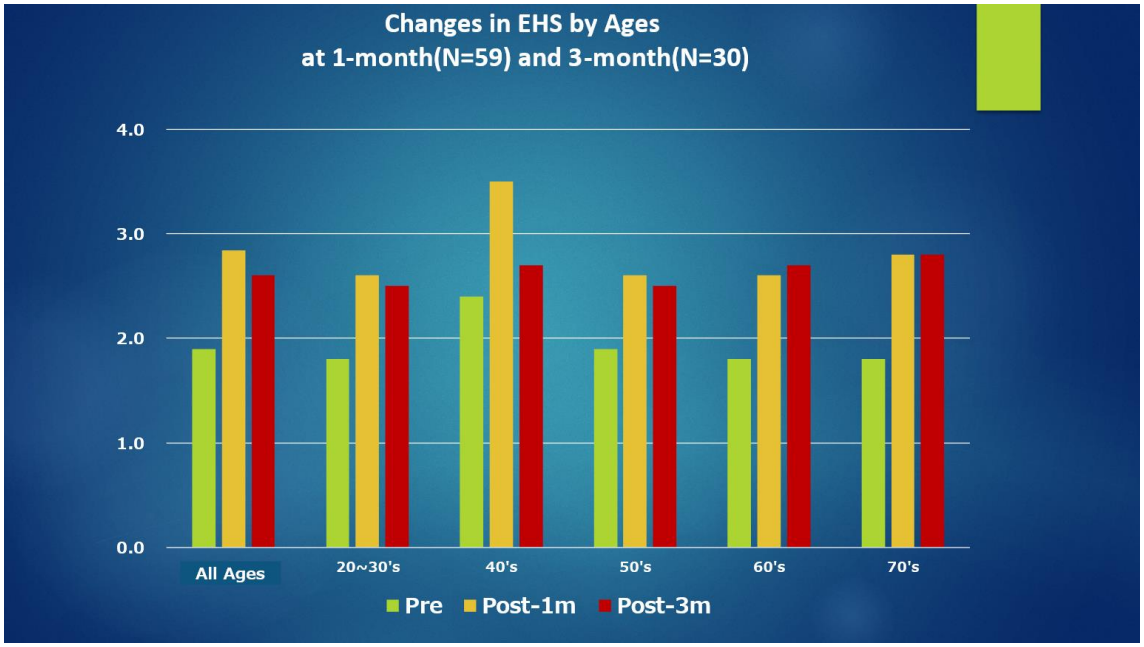
Changes in EHS by Ages
at 1-month(N=59) and 3-month(N=30)
4.0
3.0
2.0
1.0
0.0
All Ages
20~30's
40's
50's
60's
70's
Pre
Post-1m
Post-3m

Fig. 8

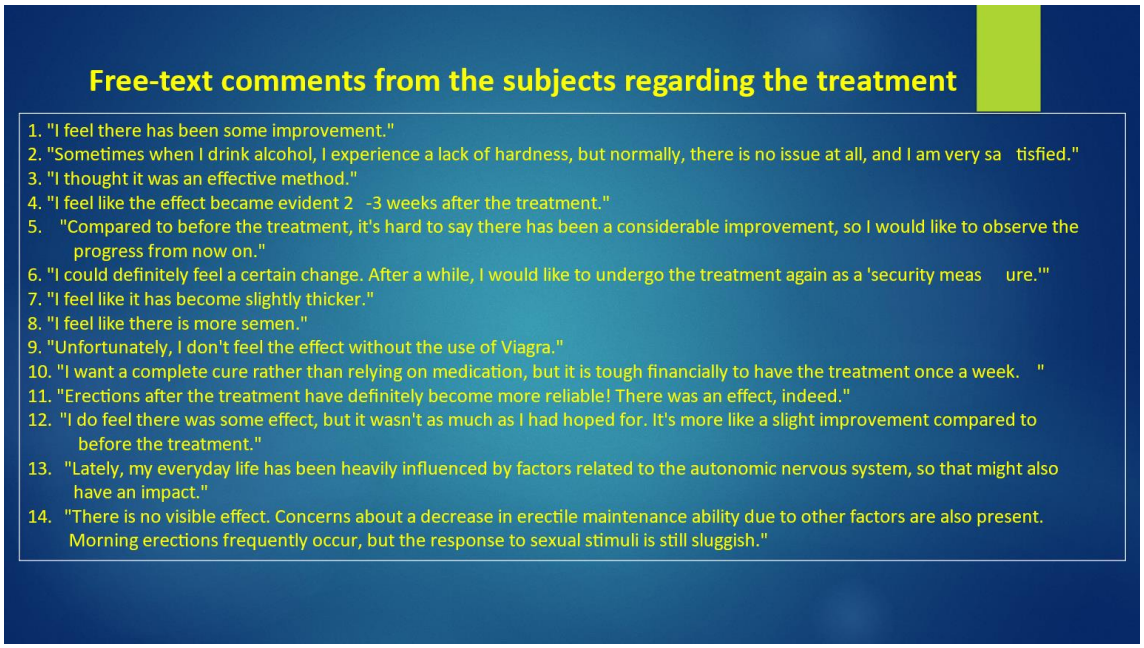

Table-4a

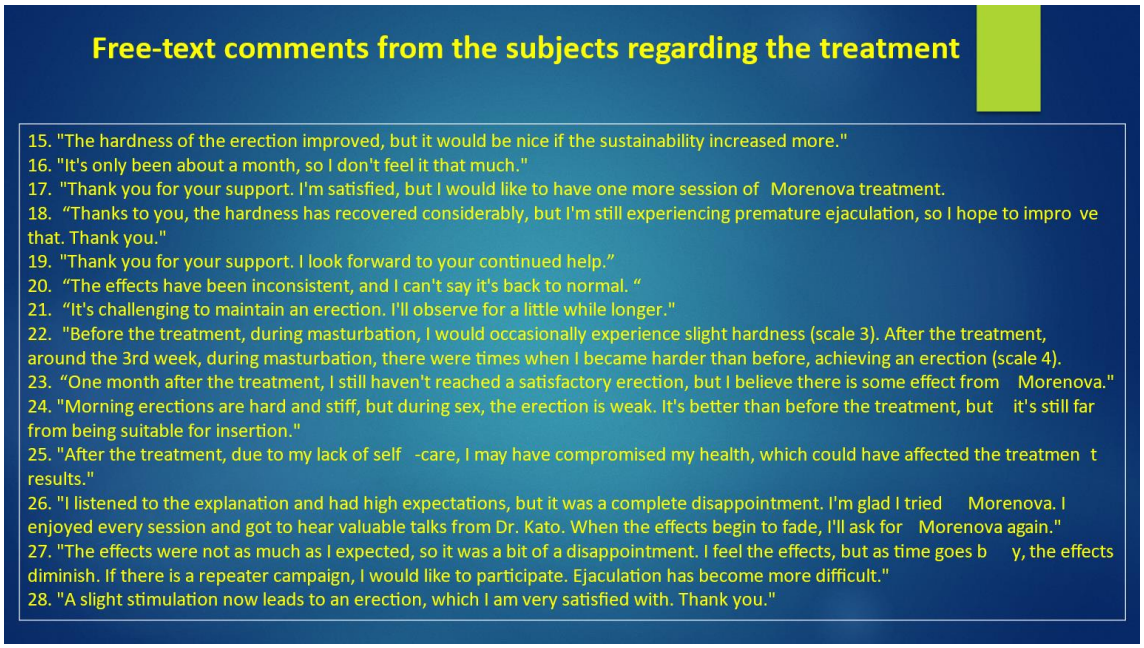

Table-4b

Free-text comments from the subjects regarding the treatment

29. "Due to various reasons, I haven't been able to practice until September, which is unfortunate, but my condition has imp roved considerably."
30. "There was a certain effect, but it doesn't feel like one session was enough."
31. "I didn't really feel much of an effect."
32. "No particular change."
33. "The process has been satisfactory, and I would consider another treatment if it's reasonably priced.
34. "Before the treatment, I felt quite old, but now I feel somewhat better. I'm curious about how much more improvement a repeat treatment might bring."

Table-4c

Based on AI analysis (ChatGPT) of the feedback from 34 participants, 70% of the responses were positive.

Positive:
Individuals reported feeling the effects of the treatment and expressed satisfaction. Some mentioned improvements in their condition and believed the treatment was effective. Many were interested in receiving additional treatments and repeated sessions.

Neutral:
Some individuals noted that there was some effect, but they were not fully satisfied. Others mentioned feeling somewhat disappointed or having no particular change in their condition.

Negative:
A few individuals expressed that they did not feel any effect from the treatment and felt disappointed. Some mentioned financial concerns, making it difficult for them to pursue additional treatments. Others still struggled with maintaining erections and found the treatment did not fully address their issues.

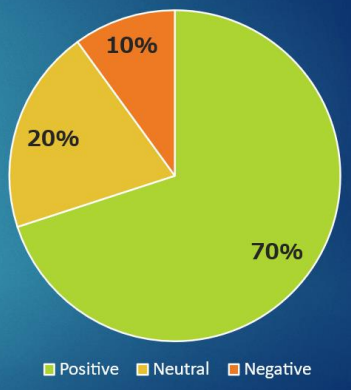

Fig.9