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Therapeutic efficacy and safety of a free-standing motorized ejaculation aid for patients with intravaginal ejaculatory dysfunction

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Abstract

Purpose: There are no approved drugs or devices for the treatment of intravaginal ejaculation disorders, and treatment is often difficult. This study aimed to evaluate the efficacy and safety of the A10 Cyclone SA + PLUS® ejaculation aid (Rends Co., Ltd., Chiba, Japan), which allows the user to adjust the intensity of stimulation, for intravaginal ejaculation disorders.

Methods: Each participant was instructed to perform practice masturbation with the A10 Cyclone SA + PLUS to simulate vaginal ejaculation. After 8 weeks of training, the participants were asked about their intravaginal ejaculation status. Sexual function was also evaluated before and after the training using several specific questionnaires, including the numerical rating scale for ejaculatory satisfaction.

Results: Among the 10 participants (41.5 ± 3.21 years) who completed the training and questionnaire evaluation, four (40%) became capable of intravaginal ejaculation. The questionnaire evaluation showed predominant improvement after training in the ejaculation-capable group according to the numerical rating scale, which expresses satisfaction with ejaculation. The participants experienced no significant adverse events.

Conclusion: As no effective treatment currently exists for intravaginal ejaculation disorders, we conclude that the A10 Cyclone SA + PLUS may be one treatment tool for intravaginal ejaculation disorders with good efficacy and no adverse events.

KEYWORDS
ejaculatory disorders, erectile dysfunction, intravaginal ejaculatory dysfunction, masturbation aid, sexual function

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1 | INTRODUCTION

While the world's population is increasing, that of Japan is decreasing, and the reduction in birthrate has become an urgent issue in Japan. The demand for infertility treatment is increasing as a part of fertility reduction strategies, and the importance of infertility treatment for both male and female infertility is growing. In Japan, large-scale surveys on male infertility, including causes and treatment, were conducted in 2007[1] and 2015.[2] Spermatogenesis dysfunction accounts for more than 80% of male infertility, but sexual dysfunction is also a major cause. In 2007, sexual dysfunction accounted for only 3.3% of cases, but in 2015, it accounted for as much as 13.5%. Erectile dysfunction (ED) is considered the most common type of sexual dysfunction, but when looking at the causes of infertility, ejaculation disorder (EjD) and ED accounted for 7.4% and 6.1% of the total, respectively. This may mean that EjD has been becoming more common than ED in young patients with sexual dysfunction who wish for a baby. For patients with ED, a phosphodiesterase type-5 (PDE5) inhibitor has been used as the first-line treatment, and its high efficacy is well known. However, the treatment strategy for EjD has not been fully established. In general, EjD as a cause of infertility mainly includes retrograde ejaculation and intravaginal EjD. From a global perspective, intravaginal EjD has not received nearly as much attention, and the treatment of premature ejaculation is the mainstay of EjD. Indeed, there have been several studies showing the effectiveness of training for premature ejaculation.[3] Furthermore, although there are also some effective drugs for retrograde EjD, such as tricyclic antidepressants,[4] there are no approved drugs or devices for the treatment of intravaginal EjD, and the treatment for this kind of EjD is often difficult for urologists and general physicians.

In Japan, the concept of intravaginal EjDs has gained increasing attention from the perspective of an aging society with declining birthrates. In particular, an increasing number of young male fertility patients, even though they have no erectile problems, feel strong pressure from their spouses or close relatives to have a baby and are unable to sustain an erection until ejaculation during sexual intercourse. In addition, intravaginal EjD is often the result of inadequate masturbation practices, which may include nonmanual masturbation or too strong a grip. Teaching adequate masturbation techniques is essential in the treatment of such patients. To improve inadequate masturbation, training with a hand-held cup-type ejaculation device may be an ideal and realistic tool because the patients were reported to be able to ejaculate vaginally after training with it.[5] Indeed, the number of patients treated with this device for intravaginal EjD has appeared to increase in Japan. However, no studies have been reported that scientifically analyze the efficacy or safety of treatment with this kind of device. In addition, more advanced devices are now available that are not manually operated. The A10 Cyclone SA+PLUS® (Rends Co., Ltd.) (Figure 1) masturbation aid is a motorized, free-standing device that allows the user to adjust the intensity of stimulation, movement, and lumen size. Thus, we speculated that training with this new device, which closely resembles the vaginal environment during sexual activity, could be a treatment option for EjD, for which no definitive treatment currently exists.

Thus, the purpose of this study was to evaluate the efficacy and safety of the A10 Cyclone SA+PLUS ejaculation aid for patients with intravaginal EjD.

2 | MATERIALS AND METHODS

After obtaining consent, each participant was instructed to perform practice masturbation with an A10 Cyclone SA+PLUS to simulate vaginal ejaculation. The machine is easily available through online shopping sites and can be purchased for around 300 US dollars. It is not disposable and requires a separate purchase of an attachment for the part to be inserted, but the attachment can be cleaned and used repeatedly.

The frequency of masturbation, with the goal being one to three times per week, and the duration and position of each masturbation practice were at the discretion of each individual participant. After 8 weeks of training, attending physician asked the participants about

FIGURE 1 The A10 Cyclone SA+PLUS® ejaculation aid.

their intravaginal ejaculation status and whether any adverse events had occurred. Patients were also evaluated by questionnaires to assess ejaculatory function, including intravaginal ejaculation and erectile function, before and after the training. For ejaculatory function, we used the numerical rating scale[6] (NRS) to assess ejaculatory satisfaction based on a rating system in which the best is 0 and the worst is 10, and the Male Sexual Health Questionnaire for assessing ejaculatory dysfunction[7] (MSHQ-EjD), which is a specific questionnaire for ejaculation. This questionnaire contains four questions related to EjD that the participants need to answer. Three of the four questions relate to assessing a participant's ejection function, including completion of ejaculation, intensity of ejaculation, and volume of semen at the time of ejaculation (MSHQ-EjD ejaculatory function). All questions are scored from 0 to 5 depending on the ejection function rating, with lower scores indicating more severe ejection function. Thus, the minimum score is 0, and the maximum score is 15. The fourth question on the MSHQ-EjD is related to bother or satisfaction with ejaculatory function: "If you have had ejaculation difficulties or have been unable to ejaculate, have you been bothered by this?" Bother/satisfaction was rated from 0 (no problem) to 5 (extremely bothered). Overall sexual function was assessed using the International Index of Erectile Function[8] (IIEF), and ED was especially assessed using the IIEF-5[9] and the Erection Hardness Score[10] (EHS). We further assessed sexual confidence with the Confidence in Performing Sexual Intercourse Questionnaire-12[11] (CPSIQ-12), which contains 12 questions on confidence in engaging in sexual activity. It is scored on a 7-point scale from "very unsure" to "very confident," especially for hardness and maintenance of erection, with the more confident participants scoring higher. Of the 15 men entered into this study, 10 (aged 41.5 ± 3.21 years) completed both the 8-week training and the pre- and post-training questionnaire assessments. We compared the pre-treatment condition of the group that became capable of intravaginal ejaculation (intravaginal ejaculation possible group; IVEjPG) and the group that did not (intravaginal ejaculation impossible group; IVEjIG) after the training and attempted to clarify the characteristics of the IVEjPG. We also evaluated the changes in the scores of the various questionnaires in each group.

2.1 | Ethical approval and informed consent

The study protocol complied with Good Clinical Practices and the Declaration of Helsinki (1996) and was performed in accordance with applicable institutional review board regulations. The protocol was approved by the institutional review board of Juntendo University Urayasu Hospital, Chiba, Japan (approval no. 2020-3-021). The study participants gave informed consent before the initiation of any study-related procedures and medications.

2.2 | Statistical analysis

Data are presented as the mean ± standard error. Statistical significance was determined by a paired and unpaired *t*-test. A p value <0.05 was considered statistically significant. We used IBM SPSS Statistics for Windows, Japanese version 20 (IBM Japan) for the statistical analysis.

3 | RESULTS

Of the 15 entrants, 10 completed both the 8-week training and the pre- and post-training questionnaire assessments. Of these 10 participants, four (40%) became capable of intravaginal ejaculation after training, and these four comprised the IVEjPG. Table 1 shows the overall scores of the questionnaires. The Mean participant age was 41.5 ± 3.21 years, and the mean score of the IIEF-5 was 13.5 ± 2.15, which indicated mild-to-moderate ED. Table 2 shows the age and score before the training between the IVEjPG and IVEjIG. Although the participants in the IVEjPG were relatively older (46.5 years) than those in the IVEjIG (37.5 years), this difference did not reach statistical significance. The NRS score was significantly higher in the IVEjPG than the IVEjIG. As higher NRS scores indicate lower ejaculation satisfaction, ejaculation satisfaction even before training was lower in the IVEjPG. Although other factors, including the score of MSHQ-EjD ejaculatory function and bother/satisfaction, IIEF, IIEF-5, EHS, and CPSIQ12, were all lower in the IVEjPG than in the IVEjIG, they did not differ significantly. When changes in scores due to training were evaluated in each group (Table 3), only the NRS of IVEjPG was found to improve significantly. For MSHQ-EjD ejaculatory function, although the scores of the IVEjPG tended to increase after the training (from 3.5 ± 1.54 to 9.0 ± 0.65), this change did not reach statistical significance ($p = 0.08$). No adverse events of bleeding, pain, persistent erection, or other events were observed throughout the training.

4 | DISCUSSION

In this study using the A10 Cyclone SA + PLUS, 40% of the participants who completed the treatment were able to ejaculate vaginally.

TABLE 1 Overall questionnaire scores of the 10 patients with intravaginal ejaculatory dysfunction.

Age, years	41.5 ± 3.21
NRS	4.5 ± 1.06
MSHQ-EjD ejaculatory function	8.0 ± 1.49
MSHQ-EjD bother/satisfaction	1.5 ± 0.66
IIEF	41.0 ± 3.22
IIEF-5	13.5 ± 2.15
EHS	3.0 ± 0.51
CPSIQ-12	2.0 ± 0.36

Abbreviations: CPSIQ-12, Confidence in Performing Sexual Intercourse Questionnaire-12; EHS, Erection Hardness Score; IIEF, International Index of Erectile Function; MSHQ-EjD, Male Sexual Health Questionnaire for assessing Ejaculatory Dysfunction; NRS, numerical rating scale.

In the absence of effective treatments for intravaginal EjD, the fact that as many as 40% of the participants could ejaculate vaginally is a breakthrough, and it is expected that the treatment reported herein will be applied for intravaginal EjD in the future.

There are several ways of classifying EjD around the world. The 2015 4th International Consultation on Sexual Medicine Classification[12] classifies EjDs into the following 9 types: premature ejaculation, delayed ejaculation, retrograde ejaculation, anejaculation, anhedonic ejaculation (nonenjoyable ejaculation), anorgasmia, hypohedonic orgasm (low enjoyable orgasm), painful ejaculation, and postorgasmic illness syndrome. According to the 2018 International Classification of Diseases,[13] ejaculatory disorders are classified into five types: early ejaculation, delayed ejaculation, retrograde ejaculation, and two other specified ejaculatory dysfunctions. The 2022 American Urological Association/Sexual Medicine Society of North America guideline,[14] which is the most recent guideline, describes two forms: premature and delayed ejaculation. The concept of intravaginal EjD does not exist in any of these classifications. While intravaginal EjD may be perceived as a disease unique to Japan, in fact, there must be similar patients in other countries, but they may be placed in the "delayed ejaculation" category. Various treatments for delayed ejaculation have been suggested to be effective.[15] In drug therapy, cabergoline[16] and bupropion[17] are commonly used in the United States, albeit off label. Psychological approaches[18] and penile vibratory stimulation[19] are also used. Although there are many reports of efficacy, there is a lack of solid evidence, and more research is needed. Even though the concept of intravaginal EjD itself may not be global and there is no term for it in the Western literature, Japanese institutions have reported the presence of many patients with intravaginal EjD.[20] As patients with intravaginal EjD can achieve erections and ejaculate normally during masturbation, it is unlikely that their EjD is caused by physical dysfunction. Rather, it is assumed that in most cases, psychogenic factors are strongly involved, which is why EjD is more likely to occur during high-pressure pregnancy activities such as timing therapy.

Because patients with intravaginal EjD can still insert their penis into a vagina, they are not often seen when they are unmarried, but they often visit a specialist when the goal is to become pregnant. Otani[20] reported that 40%–58% of patients with EjD who visited a male infertility clinic at a high-volume center in Japan had intravaginal EjD. The inability to ejaculate intravaginally is a problem when trying to conceive. There are two main causes of intravaginal EjD: inappropriate stimulation during masturbation and psychogenic disorders. Psychogenic causes include those who cannot concentrate on ejaculation unless they are alone, those who develop the condition

TABLE 2 Baseline scores in the intravaginal ejaculation possible group and intravaginal ejaculation impossible group.

	IVEjPG	IVEjIG	
	N = 4	*N* = 6	*p*
Age, years	46.5 ± 5.15	37.5 ± 4.08	0.81
NRS	9.5 ± 1.03	3.0 ± 1.04	0.02
MSHQ-EjD ejaculatory function	3.5 ± 1.54	9.5 ± 1.79	0.1
MSHQ-EjD bother/satisfaction	1.0 ± 1.02	2.5 ± 0.84	0.55
IIEF	33.5 ± 3.34	46.5 ± 4.25	0.19
IIEF-5	12.5 ± 2.77	18.0 ± 2.95	0.51
EHS	2.5 ± 0.41	4.0 ± 0.45	0.17
CPSIQ12	1.0 ± 0.22	2.0 ± 0.51	0.17

Abbreviations: CPSIQ-12, Confidence in Performing Sexual Intercourse Questionnaire-12; EHS, Erection Hardness Score; IIEF, International Index of Erectile Function; IVEjIG, intravaginal ejaculation impossible group; IVEjPG, intravaginal ejaculation possible group; MSHQ-EjD, Male Sexual Health Questionnaire for assessing Ejaculatory Dysfunction; NRS, numerical rating scale.

TABLE 3 Change of questionnaire scores of the intravaginal ejaculation possible group and intravaginal ejaculation impossible group.

	IVEjPG			IVEjIG		
	N = 4			*N* = 6		
	Before	After	*p*	Before	After	*p*
NRS	9.5 ± 1.03	6.0 ± 1.09	0.02	3.0 ± 1.04	8.0 ± 1.26	0.08
MSHQ-EjD ejaculatory function	3.5 ± 1.54	9.0 ± 0.65	0.08	9.5 ± 1.79	9.0 ± 2.37	0.54
MSHQ-EjD bother/satisfaction	1.0 ± 1.02	3.5 ± 0.41	0.3	2.5 ± 0.84	4.0 ± 0.91	0.84
IIEF	33.5 ± 3.34	42.0 ± 5.63	0.33	46.5 ± 4.25	52.5 ± 5.41	0.88
IIEF-5	12.5 ± 2.77	19.0 ± 2.90	0.33	18.0 ± 2.95	23.0 ± 3.20	0.81
EHS	2.5 ± 0.41	2.5 ± 0.25	0.71	4.0 ± 0.45	3.0 ± 0.43	0.08
CPSIQ12	1.0 ± 0.22	2.0 ± 0.54	0.25	2.0 ± 0.51	2.5 ± 0.45	0.68

Abbreviations: CPSIQ-12, Confidence in Performing Sexual Intercourse Questionnaire-12; EHS, Erection Hardness Score; IIEF, International Index of Erectile Function; IVEjIG, intravaginal ejaculation impossible group; IVEjPG, intravaginal ejaculation possible group; MSHQ-EjD, Male Sexual Health Questionnaire for assessing ejaculatory dysfunction; NRS, numerical rating scale.

following instruction in the timing method, and those who have a particular object of sexual stimulation. In our clinical practice, we often encounter patients with intravaginal EjD due to inappropriate stimulation or masturbation methods. If the patient is masturbating inadequately, he should be guided to masturbation using thrusting movements with a soft grip. However, in many patients, there are problems with long-term masturbation methods that have continued since puberty, so guidance is difficult in many cases. There have been case reports in Japan using ejaculation aids as a training method, and some effectiveness has been reported. If masturbation instruction is not successful, masturbation can be performed in the supine position, and when the patient is about to ejaculate, the penis is inserted for intravaginal ejaculation with the woman in the supine position.

Although there are no guidelines for EjD in Japan, in the most well-known classification by Otani,[20] EjD was classified into (1) both masturbation and intravaginal EjD (retrograde ejaculation, inability to ejaculate either forwardly or retrogradely), (2) intravaginal EjD, (3) abnormal time to ejaculation (premature or delayed ejaculation), (4) lack of orgasm, and (5) headache or ejaculation pain during ejaculation. As mentioned above, intravaginal EjD is a major problem in Japan, so the use of intravaginal EjD as a classification method is considered very useful in clinical practice, especially in the treatment of EjD in male infertility clinics. As intravaginal EjD appears to be a concept unique to Japan, there is, to our knowledge, no literature in Europe or the United States that examines intravaginal EjD. In the era of assisted reproductive technology, it is possible to have a baby with intrauterine (artificial) insemination, in vitro fertilization, and intracytoplasmic sperm injection, even for patients with intravaginal EjD. However, if intravaginal EjD can be overcome, a natural pregnancy will be possible. We believe that a natural pregnancy should be vastly preferable and will be of great benefit to couples who wish to have a child. In the present study, ejaculation satisfaction increased significantly in the IVEjPG. This suggests that intravaginal EjD treatment may be useful from the viewpoint of improving quality of life. The IVEjIG showed a worsening of the NRS (from 3.0 ± 1.04 to 8.0 ± 1.26) after the training, but this may be due to the fact that the participants' expectations were not met and suggests that the availability of intravaginal ejaculation affects satisfaction.

There are several limitations to this study. The number of participants is small, so a larger survey is desirable. Due to the small number of cases, we have not been able to examine which patients are more likely to be able to ejaculate vaginally. We would like to increase the number of cases in the future to examine the use of PDE5 inhibitors, age, frequency of training, and other factors.

The evaluation is based on self-reporting from patients and responses to a questionnaire and thus lacks objectivity. However, we believe that it is extremely difficult to scientifically evaluate whether ejaculation is possible during sexual intercourse. In addition, there is no literature on the effectiveness of treatment of intravaginal EjD in Europe or the United States, so the results cannot be compared with those of previous studies. In this study, we used a free-standing, motorized ejaculation aid that can also be used for simulated sexual intercourse practice, but we have not been able to examine its superiority over manual ejaculation aids already reported, as there are no more comprehensive reports than those of past case reports.

5 | CONCLUSION

Free-standing motorized ejaculation aids have shown good results in the treatment of intravaginal EjDs, for which no effective treatment exists. The present study participants experienced no significant side effects from use of the A10 Cyclone SA+PLUS, and the ability to ejaculate vaginally improved ejaculation satisfaction, indicating that a self-supporting electric ejaculation aid may be a useful tool in the treatment of intravaginal EjD.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

HUMAN RIGHTS STATEMENTS AND INFORMED CONSENT

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1964 and its later amendments. Informed consent was obtained from all participants included in the study.

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