Clinical Efficacy of a Wearable Penile Constriction Device (Performance Ring) for Erectile Maintenance in Men with Incomplete Response to PDE5 Inhibitors and Intracavernous injection

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Conflict of Interest

Elliot Justin is affiliated with FirmTech Inc., the manufacturer of the

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Author Contributions

Yoshiichi Sato: Conceptualization, methodology, data analysis, manuscript drafting. Kazuki Takekawa et al.: Data collection and clinical investigation

Elliot Justin: Device-related technical input

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Abstract

Background: Phosphodiesterase type 5 inhibitors (PDE5-Is) are the first-line treatment for erectile dysfunction (ED); however, a subset of patients fail to achieve satisfactory sexual intercourse due to inadequate erection maintenance, even after second-line therapies such as intracavernosal injection (ICI). Noninvasive adjunctive options remain limited.

Aim: To evaluate the efficacy, safety, and usability of a wearable penile constriction device (Performance Ring) in men with erection maintenance failure despite pharmacologic therapy.

Methods: This retrospective study included 40 men (age 45–81 years; mean 67.8 years) with early detumescence during intercourse despite PDE5-I therapy with or without ICI. The Performance Ring was applied at the penile base after erection was achieved. Efficacy was defined as improvement in erectile rigidity and/or duration sufficient for satisfactory sexual intercourse. Outcomes were assessed using the Erectile Hardness Score (EHS) and a structured questionnaire.

Outcomes: Primary outcomes were improvement in erectile rigidity and maintenance sufficient for intercourse. Secondary outcomes included erection duration, ability to continue intercourse after ejaculation, device usability, and safety.

Results: Overall, 34 of 40 patients (85%) achieved satisfactory intercourse with adjunctive device use. Response rates were 92% (24/26) in the PDE5-I group and 71% (10/14) in the PDE5-I + ICI group. Efficacy was strongly associated with baseline erectile hardness: 100% response in patients with EHS 3, 50% in EHS 2, and 0% in EHS ≤1. Among responders, all showed improvement in rigidity and duration; 50% achieved 20–30 minutes of erection, and 5.9% exceeded 30 minutes. Additionally, 70.6% were able to continue intercourse after ejaculation (mean additional duration: 12 minutes, n=12). No discomfort was reported in 88.2%, and 91.2% reported easy application and removal. No significant adverse events were observed.

Clinical Implications: The Performance Ring may provide a practical, noninvasive adjunctive option for patients with erection maintenance failure, particularly those with preserved erection initiation.

Strengths & Limitations: This study highlights a clearly defined therapeutic window based on baseline erectile function. However, its retrospective design, small sample size, lack of a control group, and reliance on patient-reported outcomes limit generalizability.

Conclusion: The Performance Ring is a safe and effective adjunctive device for men who can achieve but not maintain erections. It addresses an important therapeutic gap by targeting erection maintenance and may enhance sexual

performance and satisfaction.

Introduction

Penile constriction devices are wearable medical devices designed to maintain penile rigidity by mechanically reducing venous outflow at the base of the penis.[1,2] These devices have long been used as noninvasive adjuncts to support erectile function, particularly in men who experience incomplete erections or early detumescence during sexual activity.

Phosphodiesterase type 5 inhibitors (PDE5-Is) are widely recommended as the first-line pharmacologic treatment for erectile dysfunction (ED).[3–5] However, a substantial proportion of patients fail to achieve satisfactory sexual intercourse due to insufficient erectile rigidity or duration, even with appropriate use of PDE5-Is. In such cases, second-line therapies, including intracavernosal injection (ICI), vacuum erectile devices and low-intensity extracorporeal shock wave therapy (Li-SWT) are commonly employed.[3–7] Although effective, these treatments are associated with complexity of use during sexual activity, disruption of sexual spontaneity, cost considerations, and psychological barriers, which may limit patient acceptance and long-term adherence.[3-7]

Despite the availability of these therapeutic options, there remains a significant unmet clinical need for simple, noninvasive strategies that improve erectile

performance without imposing substantial financial or time-related burden. This need is particularly relevant in patients who are able to achieve an erection but are unable to sustain it long enough for satisfactory intercourse—a condition commonly referred to as erection maintenance failure or early detumescence. In such cases, penile constriction devices offer a physiologically rational solution by mechanically restricting venous outflow and thereby enhancing erection maintenance. [1,2] Although conventional constriction devices have been available for decades, their clinical adoption has been limited due to concerns regarding discomfort, uncertain efficacy, and poor usability.[1,2]

Recently, a novel wearable constriction device, the Performance Ring (FirmTech, USA), has been introduced.[8] This device has been designed to improve usability, comfort, and overall patient experience compared with traditional constriction devices. Prior studies have suggested that FirmTech devices are preferred by patients because of their ease of use and high satisfaction.[9] Although these data were primarily derived from studies using the company's Tech Ring device, [9, 10,11] the underlying structural concept is similar, and the Performance Ring is specifically optimized for therapeutic use.[8] The clinical value of such devices may be particularly pronounced in patients who retain the ability to achieve partial erections but are unable to maintain sufficient rigidity. However, clinical data evaluating the effectiveness of

wearable constriction devices in this specific patient population remain limited.

In the present study, we evaluated the clinical efficacy, safety, and tolerability of the Performance Ring as an adjunctive treatment in men with erectile dysfunction who experienced inadequate erection maintenance despite treatment with PDE5-Is with or without intracavernosal injection therapy. We also investigated the relationship between baseline erectile hardness and treatment response to better define the patient population most likely to benefit from this approach.

Materials and Methods

Study Design and Treatment Algorithm

This retrospective observational study was conducted in accordance with the Declaration of Helsinki and approved by the institutional review board (SUH-EC 2025-1). Written informed consent was obtained from all patients.

This study evaluated the clinical utility of a wearable penile constriction device, the Performance Ring (FirmTech Inc., USA), in men with erectile dysfunction (ED) who experienced inadequate erection maintenance during sexual intercourse despite pharmacologic therapy. A total of 40 patients were included. The mean age was 68.1 years (range, 45–81 years).

All patients had persistent difficulty maintaining an erection sufficient for

satisfactory sexual intercourse despite standard ED treatment. All patients had persistent difficulty maintaining an erection sufficient for satisfactory sexual intercourse despite standard ED treatment. The treatment algorithm is illustrated in Figure 1. Patients were initially treated with phosphodiesterase type 5 inhibitors (PDE5-Is) at the maximum tolerated dose. Those who achieved erection but remained dissatisfied due to inadequate maintenance were offered adjunctive use of the Performance Ring (Group 1) or escalation to intracavernosal injection (ICI) therapy. Patients who remained dissatisfied despite ICI, with or without PDE5-Is, were subsequently offered the Performance Ring and classified as Group 2.

The clinical efficacy, usability, and safety of the device were evaluated after at least three uses. Patients who achieved satisfactory intercourse with prior therapy alone, as well as those who declined further treatment, were excluded. Additional exclusion criteria included penile prosthesis implantation, concealed or buried penis, psychiatric conditions precluding participation, and coagulopathy or other hematologic disorders.

Patient Characteristics (Table 1)

The study population was divided into two groups based on prior treatment: Group 1 (n = 26), consisting of patients dissatisfied with PDE5-Is alone, and Group 2 (n = 14), consisting of patients who remained dissatisfied despite ICI

therapy with or without PDE5-Is.

Baseline erectile function, assessed using the Erectile Hardness Score (EHS), was predominantly EHS 3 in both groups (Group 1: 23/26; Group 2: 9/14), with smaller proportions of patients presenting with EHS 2 or EHS 0–1.

Comorbidities included hypertension (n = 7), diabetes mellitus (n = 2), and dyslipidemia (n = 2). A history of prostate cancer treatment was observed in 8 patients, including radical prostatectomy (n = 6) and radiation therapy (n = 2), with a higher proportion in Group 2.Detailed baseline characteristics are summarized in Table 1.

Device Description and Application (Fig.2)

The Performance Ring (FirmTech Inc., USA)[9] is an external penile rigidity device registered with the U.S. Food and Drug Administration (FDA) and categorized as a low-risk device under general controls. The device is composed of medical-grade elastomer, allowing flexibility and adaptation to body contours, thereby enhancing comfort during use (Fig.2). Its patented loop-and-hook design enables easy application and removal, contributing to user safety. The device was applied at the base of the penis after erection had been achieved through pharmacologic therapy and/or sexual stimulation. Prior to use, patients received standardized instructions regarding proper placement, recommended duration of use, and safe removal. Patients were advised to limit continuous use

to approximately 30 minutes and to remove the device promptly after completion of sexual activity.

Outcome Measures

The primary endpoint was improvement in erectile rigidity and maintenance sufficient to achieve satisfactory sexual intercourse. The effectiveness of the Performance Ring was defined as achieving or maintaining an erection sufficient for vaginal penetration (EHS ≥3) and/or a clinically meaningful increase in erection duration compared with baseline. These outcomes were assessed during sexual activity using the Performance Ring, based on the Erectile Hardness Score (EHS) and a structured ad hoc questionnaire evaluating erectile function and device usability (see Supplementary Data).

Secondary endpoints included:

- Improvement in penile rigidity (EHS)
- Prolongation of erection duration
- Erection duration (patients recorded duration using a clock and selected from predefined time categories)
- Ability to achieve ejaculation
- Ability to continue intercourse after ejaculation
- Device comfort and ease of use
- Presence of discomfort or adverse events

Statistical Analysis

Descriptive statistics were used to clinical outcomes. The association between baseline erectile hardness score (EHS) after prior therapy (PDE5 inhibitors with or without intracavernosal injection) and treatment response to the Performance Ring was evaluated using Fisher's exact test. In addition, the Cochran–Armitage trend test was performed to assess for a linear trend in response rates across ordered EHS categories. All statistical analyses were performed using EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), a graphical user interface for R. A two-sided p value < 0.05 was considered statistically significant.

Results

Patients′ characteristics (Table1)

PDE5-I group (n = 26): Patients treated with PDE5 inhibitors alone who were unable to maintain satisfactory erections. This group included one patient with a history of radical prostatectomy and one patient who had undergone proton beam therapy for prostate cancer. PDE5-I + ICI group (n = 14): Patients requiring intracavernosal injection therapy in addition to PDE5-Is due to inadequate response. This group included five patients with a history of radical prostatectomy and one patient who had received radiation therapy for prostate cancer.

Overall Treatment Efficacy (Fig. 3)

A total of 34 of 40 patients (85%) achieved satisfactory sexual intercourse with the adjunctive use of the Performance Ring. In the PDE5-I group, 24 of 26 patients (92%) demonstrated improvement in erectile rigidity and/or duration sufficient for intercourse. In the PDE5-I + ICI group, 10 of 14 patients (71%) achieved satisfactory outcomes.

Response According to Baseline Erectile Hardness (Fig. 4)

Treatment efficacy was strongly associated with baseline erectile hardness achieved with prior therapy (Fig. 2). The response rates were as follows: EHS 3 (n = 32), 100%; EHS 2 (n = 4), 50%; and EHS 0–1 (n = 4), 0%.

Response rates increased significantly with higher baseline EHS, demonstrating a clear positive association between pre-treatment erectile hardness and the efficacy of the Performance Ring ($p < 0.001$, Cochran–Armitage trend test).

Patients who were able to achieve EHS 3, even transiently, but were unable to maintain a sufficient erection responded uniformly to the Performance Ring. Notably, among patients with EHS 2 who were unable to achieve vaginal penetration with pharmacologic therapy alone, 50% achieved satisfactory intercourse with the addition of the device. In contrast, no clinically meaningful improvement was observed in patients with EHS ≤1.

Improvement in Erectile Function Among Responders (Table 2)

Among responders (n = 34), adjunctive use of the Performance Ring resulted in consistent improvements in both penile rigidity and erection duration compared with prior pharmacologic therapy alone.

Post-treatment erectile hardness improved to EHS 3 or 4 in all responders, with an equal distribution between the two categories (50% each).

Erection duration was substantially prolonged. The majority of patients achieved durations of 20–30 minutes (50.0%), followed by 10–20 minutes (26.5%), <10 minutes (17.6%), and >30 minutes (5.9%).

Furthermore, 70.6% of responders reported the ability to continue sexual intercourse after ejaculation. Among the 12 patients who provided evaluable

data, the mean additional duration of intercourse after ejaculation was 12 minutes. This functional extension was associated with improved sexual performance and overall satisfaction.

Device Usability, Safety, and Satisfaction

Regarding device tolerability, 88.2% of patients reported no discomfort during use, while 11.8% experienced only mild discomfort.

Ease of application and removal was rated as "easy" by 91.2% of responders and "slightly difficult" by 8.8%, with no patients reporting difficulty.

No significant adverse events were observed.

Patient-reported satisfaction was high, with 73.5% of patients reporting being satisfied and the remaining 26.5% reporting being somewhat satisfied; no patients reported dissatisfaction. Partner-reported outcomes (available in a subset of 15 patients) showed a similarly favorable trend, with 66.7% reporting satisfaction.

Overall, the device demonstrated a favorable safety profile, high tolerability, and strong patient acceptability.

Discussion

The present study evaluated the clinical utility of the Performance Ring, a wearable penile constriction device registered with the U.S. Food and Drug

Administration,[8] in men with erectile dysfunction who experienced insufficient erection maintenance despite pharmacologic therapy. Our findings demonstrate that this device represents a practical and effective adjunctive option for patients who are able to achieve an erection but are unable to maintain adequate rigidity during sexual intercourse.

A key finding of this study is that the therapeutic efficacy of the Performance Ring is strongly dependent on baseline erectile hardness achieved with prior therapy. Patients who were able to reach Erectile Hardness Score (EHS) 3, even transiently, demonstrated a 100% response rate, whereas those with EHS 2 showed a 50% response rate. In contrast, patients with EHS ≤1 did not experience clinically meaningful improvement. These results define a clear therapeutic window for constriction device use, indicating that the device is most effective in patients with preserved erection initiation but impaired maintenance. Clinically, a large proportion of men with erectile dysfunction are able to achieve erections sufficient for vaginal penetration but are unable to sustain them.13,14,15 The Performance Ring effectively addresses this common phenotype by maintaining EHS 3-level rigidity once achieved. Notably, even among patients with EHS 2 who were unable to achieve penetration with pharmacologic therapy alone, 50% were able to achieve satisfactory intercourse with the addition of the device. This effect is likely explained by mechanical

reduction of venous outflow, combined with continued sexual stimulation, which facilitates additional cavernosal blood inflow and enables attainment of penetrative rigidity.

In contrast, patients with EHS ≤1 are less likely to benefit from this approach. In such cases, insufficient arterial inflow due to corporal fibrosis, reduced compliance, or neurovascular impairment may limit the ability to achieve adequate intracavernosal pressure, rendering venous occlusion strategies ineffective. In our cohort, these patients frequently included those with a history of radical prostatectomy (particularly non–nerve-sparing procedures), radiation therapy, or advanced age, suggesting more severe structural and vascular impairment.[4,5]

This clinical phenotype is consistent with a pathophysiological mechanism of veno-occlusive dysfunction or early detumescence, in which erection cannot be maintained despite relatively preserved arterial inflow. Therefore, mechanical restriction of venous outflow using a constriction device represents a physiologically rational adjunctive strategy.

Among responders, the device not only improved erectile rigidity but also substantially prolonged erection duration, with 50% of patients achieving durations of 20–30 minutes. In addition, 70.6% of patients were able to continue intercourse after ejaculation. These findings indicate that the device extends the

functional window of sexual activity and may enhance both patient and partner satisfaction.

Importantly, the Performance Ring demonstrated a favorable safety and tolerability profile. No serious adverse events were observed. The majority of patients (88.2%) reported no discomfort during use, and only mild discomfort was reported in 11.8% of cases. Ease of application and removal was high, with 91.2% of patients reporting the device as easy to use. These characteristics are clinically relevant when compared with second-line therapies, such as intracavernosal injections or surgical interventions, which are often associated with greater physical and psychological burden.3,6,7

Our findings also support the long-standing concept that constriction devices can enhance the veno-occlusive mechanism and improve erection maintenance.[1,2] However, conventional devices have been underutilized due to issues related to discomfort, complexity, and poor patient acceptance.[2] The Performance Ring, with its flexible loop-and-hook design, appears to overcome many of these limitations by offering improved usability and safety. Severe complications associated with constriction devices, such as penile necrosis or skin injury, have been reported in the literature; however, these are typically related to rigid, non-medical ring-shaped objects causing penile strangulation.[16,17,18] In contrast, the flexible design of the Performance Ring allows for easy removal and is

unlikely to result in device-related incarceration. Furthermore, similar loop-based devices (e.g., TechRing) have been used for prolonged wear, suggesting favorable tolerability over extended periods.

From a clinical perspective, our results highlight the importance of phenotype-based treatment selection in erectile dysfunction. Patients with erection maintenance failure—particularly those achieving EHS 3 or selected EHS 2—appear to derive the greatest benefit from constriction device therapy. This subgroup remains under-recognized in current treatment algorithms, which tend to focus primarily on erection initiation rather than maintenance.

Several limitations should be acknowledged. First, this study was retrospective, conducted at a single institution, and involved a relatively small sample size with a short observation period. In addition, the absence of a control group limits the ability to precisely quantify the magnitude of the treatment effect. However, in the context of penile constriction devices, direct comparisons can be challenging due to substantial differences in device design and structure, which may confound interpretation. Future multicenter studies with larger cohorts, including comparative evaluations of different devices, are warranted. Furthermore, long-term safety remains an important consideration, and extended follow-up will be necessary to confirm the durability and safety of this approach. Second, outcomes were based primarily on patient-reported

measures rather than validated instruments or objective assessments, particularly with respect to the measurement of erection duration. More objective and precise methods for assessing duration would strengthen the validity of these findings Third, in the present study, factors influencing the efficacy of the Performance Ring were assessed primarily according to baseline erectile hardness (EHS) achieved with prior therapy. A more comprehensive analysis incorporating additional clinical variables in a larger cohort may help to further refine patient selection and clarify the optimal indications for this device. Although six patients with a history of radical prostatectomy were included in this study, further accumulation of such cases is needed. The Performance Ring may represent a valuable adjunctive option for improving erectile dysfunction, climacturia,[19] and stress urinary incontinence in this population; however, additional investigation is required. Fourth, this study evaluated the Performance Ring primarily as a second- or third-line treatment option. However, penile constriction devices may have broader clinical applications. Future studies should explore their potential role as a first-line or earlier adjunctive therapy in the management of erectile dysfunction.

In conclusion, the Performance Ring is a safe and effective adjunctive device for men with erectile dysfunction who experience early detumescence despite pharmacologic therapy. By targeting erection maintenance rather than

initiation, this device fills an important therapeutic gap and provides a practical, noninvasive treatment option within a clearly defined clinical window.

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Figure Legend

Figure 1. Treatment algorithm and study group classification
Schematic overview of the treatment algorithm and study group classification. Patients who were dissatisfied with phosphodiesterase type 5 inhibitors (PDE5-Is) despite achieving erections were assigned to Group 1 (PDE5-Is + Performance Ring). Patients who remained dissatisfied despite intracavernosal injection (ICI), with or without PDE5-Is, were assigned to Group 2 (ICI ± PDE5-Is + Performance Ring).

Figure 2. Performance Ring
Representative image of the Performance Ring used in this study. The device was applied at the base of the penis after erection to enhance rigidity by reducing venous outflow.

Figure 3. Treatment efficacy of the Performance Ring in the overall cohort and by treatment group
Efficacy rates of the Performance Ring in the overall cohort (n = 40) and stratified by treatment group: Group 1 (n = 26) and Group 2 (n = 14). Efficacy was defined as achievement of erection sufficient for satisfactory sexual intercourse.

Figure 4. Treatment efficacy of the Performance Ring according to baseline Erectile Hardness Score (EHS)
Efficacy rates stratified by baseline Erectile Hardness Score (EHS). A significant positive trend in efficacy was observed with increasing baseline EHS (Cochran–Armitage trend test, $p < 0.001$).