

Assessment of the Elator Penile Support Device for Patients with Prostate Cancer and Their Partners Affected by Severe Erectile Dysfunction

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Research

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Abstract

We present quality improvement data from men with severe erectile dysfunction (ED) and their partners on the use of a penile support device, the Elator, as a sexual aid. Six patients with prostate cancer with iatrogenic ED and five partners were introduced to the device by the sexual health nurse in a urology clinic in Sweden. At 8 to 20 weeks after the introduction of the Elator, patients and partners completed a brief survey on their experience in using the device for penetrative vaginal sex. The patients and their partners generally found the Elator helpful for penetrative sex. Some patients used it in combination with other ED treatment. Minor issues (e.g., getting correct penile measurements for proper fit, some discomfort) were reported. Overall feedback on the Elator was positive. More research is warranted on how nurses in oncology and other sexual health clinicians can help patients with ED and their partners explore novel sex aids such as the Elator and use them effectively to maintain sexual intimacy long-term.

Key Words

Prostate cancer, sexual function, sexual management strategies, Elator, erectile dysfunction.

Background and Significance of the Problem

Many men with prostate cancer (PCa) experience sexual dysfunction due to their cancer treatment (Downing et al., 2019; Lehto et al., 2017; Ussher et al., 2016). This most commonly presents as erectile dysfunction (ED) from injury to the neurovascular supply to erectile tissue during a prostatectomy or radiotherapy to the prostate gland. Patients receiving androgen deprivation therapy (ADT) additionally experience loss of libido (Duthie et al., 2020; Elliott et al., 2010; Fode & Sonksen, 2014). Overall, these changes reduce the quality of life for both patients and partners (Downing et al., 2019). In the oncology setting, nurses play a critical role in educating patients and partners on how they can improve their sexual quality of life (Lombraña et al., 2012). Nurses can listen to couples, understand their spe-

cific needs, and advise them on how they can manage patients' ED.

While many men cease sexual activity after having sexual dysfunction due to PCa treatments, some patients continue to be sexually active despite having ED (Cormie et al., 2013; Dowsett et al., 2014; Duthie et al., 2020; Ng et al., 2014; Wassersug et al., 2016). Various erectile aids may be used by such men, including oral phosphodiesterase 5 inhibitors (PDE5i) (Miranda et al., 2021; Osadchiy et al., 2020), intracavernosal injections (Miranda et al., 2021), the vacuum erection device (VED), intraurethral suppositories (Raina et al., 2005), or penile implants (Tal et al., 2011).

Non-invasive sexual devices are not typically medically prescribed and commonly referred to as 'sex toys' (e.g., external penile prosthesis, penile sleeve, penile support device, and vibrators) (Duthie et al., 2021; Wassersug & Wibowo, 2017). However, no published data are available on how frequently they are recommended to men with iatrogenic ED or how extensively they are endorsed by sexual rehabilitation clinics. Furthermore, there is no clinical consensus on the use of such devices for the sexual rehabilitation of patients with PCa (Salonia et al., 2017a, b).

In one recent study, 80% of men experiencing ED have tried some form of erectile aid (Walker et al., 2021). Some 26% of buyers of penile sleeves and 65% of buyers of penile support devices are men treated for PCa (Wassersug & Wibowo, 2017). In an independent survey of

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Research Summary

Introduction

Many men continue to be sexually active after erectile dysfunction (ED) despite prostate cancer (PCa) treatments. Some men with severe ED will use modalities, such as external penile prosthesis, penile sleeve, penile support device, and vibrators, combined with medication.

Purpose

This project evaluated patients' acceptance of a novel mechanical erectile aid for men suffering from severe ED post-PCa treatment, the Elator, a brace that extends the glans penis away from the pubic symphysis.

Methods

Men with severe ED following PCa treatment were introduced to the device when first meeting with the nurse in the sexual health clinic. After trying the device at home for sexual engagement, the patients and their partners completed questionnaires to evaluate their experiences while using the Elator device.

210 patients with PCa, less than 5% reported using these non-medical devices. Another study found 9% of patients with PCa receiving ADT had used sex toys for sexual activity (Wibowo et al., 2019). A case study of a patient with PCa with severe ED reported on the patient's used a strap-on dildo for orgasmic sexual activity despite his testosterone being at castrate levels from ADT (Warkentin et al., 2006). Beyond this limited research, not much is known about the efficacy of non-medical and non-pharmacological devices for helping patients with PCa with sexual dysfunction recover satisfactory sex or about their continued use. Furthermore, we know of no published data on partners' opinions of these devices.

Intended Improvement and Purpose

Currently, all sexual management strategies for patients with PCa have limitations that lead many patients to stop using them even when they are effective (Kukula et al., 2014; Li et al., 2016). None of the established erectile aids are 100% effective in producing natural erections (Wassersug & Wibowo, 2017). Oral PDE5i drugs, for example, require residual erection; thus, they are not effective for men with complete ED. Some patients are reluctant to use penile injection, and VED use often leads to inefficient erections because the penile root is not engorged with blood, leading to an improper angle to the tumescent penis.

In this report, we assess the acceptance of a novel mechanical erectile aid for men suffering from severe ED post-PCa treatment. The aid is a penile support device, the Elator (www.TheElator.com), and is a non-invasive and non-pharmacological option to improve the possibility of having penetrative sex and maintaining sexual intimacy for patients with ED. It is designed to hold a flaccid penis erect throughout penetrative sexual activity.

Results

A total of 6 men completed the pilot project (age 66.0 ± 5.0 years). All patients scored 0 on the Erection Hardness Score and used the device from 1 to 9 times. All participants felt the Elator had a positive impact on their sex life, and partners, who filled in the survey, would recommend the device.

Conclusions

The Elator is a cost-effective option for the treatment of ED because it is a multiple-use device. It could be an adjunct treatment for sexual health, and urology or oncology nurses could include it when advising patients and their partners about exploring strategies to maintain sexual intimacy.

Level of Evidence: III-B

Source: Johns Hopkins Hospital/Johns Hopkins University, 2016.

In this study, we collected qualitative data from six patients with PCa and their partners who tested this penile support device for sexual activity. Unlike a penile sleeve or an external penile prosthesis, the Elator is a brace that extends the glans penis away from the pubic symphysis. The device has two round rings and a brace between them (Figure 1). The larger proximal ring is placed at the base of the penile shaft, and the smaller distal ring lies in the corona sulcus between the penile shaft and glans penis. The two rings are connected by elongated stainless steel supports.

A positive feature of the Elator as a penile support device is that unlike a penile sleeve, when the device is worn, the glans penis remains fully exposed for tactile stimulation. To hold the penis properly in an erect position, the device must be individually customized to fit each man. The girth of the penis at its base and at the sulcus must match the dimensions of the penis for the man. If the distal ring is too large, the glans can slip out. If it is too small, it can compress and pinch the penile shaft. Similarly, the length of the brace from the base to the sulcus should closely match that of the man's normal erections for the comfort of both the man wearing the device and his partner in penetrative sex.

Here, we present feedback from some patients with PCa with ED and their partners on their satisfaction and comfort using the device. Information from this report could be used by oncology, sexual health, or urology nurses, as well as other health care providers, to advise men with ED about using such a device for sexual rehabilitation.

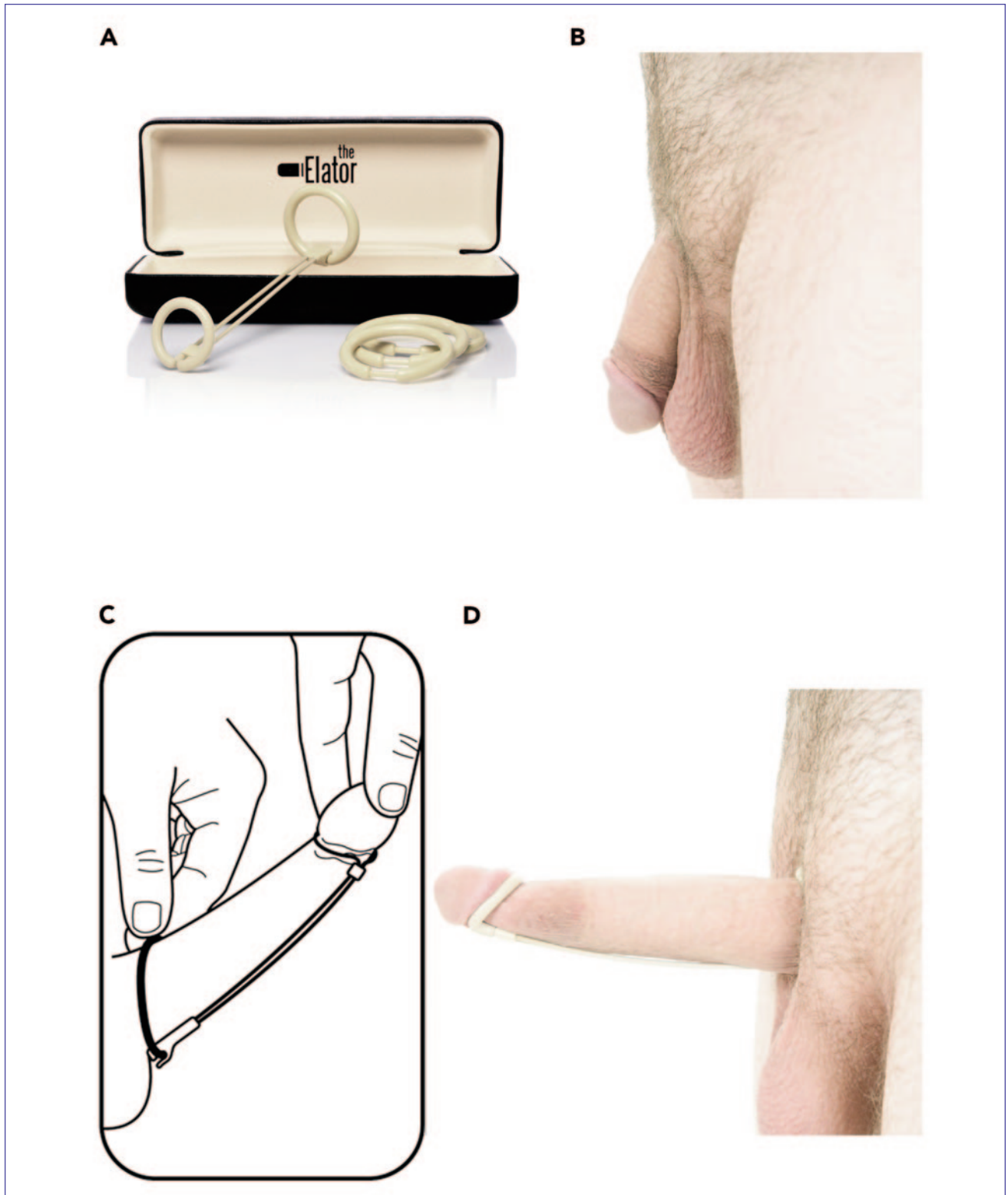
Methods

Participants and Setting

We present here quality assurance data from six

Figure 1.

Image of the Elator penile support device on its own (A), and a schematic diagram of the device when placed on a penis (C). Image (B) is showing a flaccid penis before using the Elator, and image (D) shows a penis with the Elator attached.



Source: Courtesy of Mark Schneider, CEO of the Elator. Used with permission.

patients with PCa referred to the sexual health clinician and nurse Carina Danemalm Jägervall (CDJ) at the Department of Surgery and Urology in Växjö, Sweden. Data collected fit under quality assurance, and as such, no Institutional Review Board approval was needed because such quality control data are required by law in Sweden according to the Swedish Health Care Law (Hälso- och sjukvårdslagen 2017:30, kap 5 § 4).

Recruitment took place between September 2020 to May 2021. Three men had mild ED prior to PCa treatment, though all six men had severe ED following their PCa treatment (either surgical prostatectomy or radiation therapy), as assessed by the Erection Hardness Scale (Parisot et al., 2014) at the time they first met with the nurse in the sexual health clinic. None of the men had Peyronie's disease or any other issues that would affect the penile tissue. All participants were asked for consent and approved.

Methodologic Approach

The nurse introduced the Elator as a possible way for the men to regain the capacity for penetrative sex with their partner. All participants had already attended a sexual rehabilitation educational session after PCa treatment, which covered multiple options to promote sexual recovery. Those who did not have a good outcome from pharmacological ED treatment were then advised by the nurse to try the Elator. When the patients (all of whom came to the clinic alone without a partner) received the device with instructions on how to acquire the penile measurements for a proper fit, they were asked to collect those measurements at home and let the nurse know the measurements afterwards. The nurse then ordered the devices from the company to fit each individual patient.

After trying the device at home for sexual engagement, the patients and their partners filled in questionnaires developed by CDJ on their experiences while using the Elator. The feedback was collected between 8 to 20 weeks after introduction to the device. The questionnaires and responses were originally in Swedish and later translated into English by CDJ.

Questionnaires

Patients were asked about their ease in 1) measuring their penis size for ordering the Elator, 2) attaching the Elator, and 3) removing the Elator. They were also asked if 1) they had tried combining the device with erection-inducing drugs, and 2) if the device retained its function after multiple uses. Patients were asked about their comfort in using the device, if they felt safe using it, and if they had any irritation on their penis from its use.

The feedback form for partners asked if they needed to help the patient in 1) measuring their penis size for ordering the device, 2) attaching the Elator to their penis, and 3) removing it from the penis. Partners were also asked about their comfort in receptive vaginal sex when their partner was wearing the device. Similarly, they were asked if they felt safe having sex while the patient

used the Elator and if they had any physical irritation during intercourse while the patient was wearing it.

Both patients and partners were asked 1) how many times they had used the Elator for sex, 2) if they felt that their sex life had changed since trying the device, 3) if the device had any positive or negative impact on their sex life, 4) if they thought the device fulfilled its intended function of making penetrative sex possible, and 5) if they were able to use the Elator for penetrative sex for as long as they usually did. Lastly, both patients and partners were asked to rate their overall experience in using the Elator, and if they would recommend it to other men with ED.

Results

Feedback was collected from six patients with PCa (age 66 ± 5 years). Five patients had received a surgical prostatectomy (non-nerve sparing for three patients), and one had been treated with external beam radiation. None of the patients had been receiving ADT. Five were in a committed relationship with a female partner. The average age of those partners was $63 (\pm 8.7)$ years. One patient was not in a committed relationship but dated multiple women.

All patients scored 0 on the Erection Hardness Score (Mulhall et al., 2007) when the device was introduced to them. Some patients needed an Elator of a different size than what they first acquired. The delay in acquiring a better fitting device led to delays in the patients completing the feedback form.

Patients

Penile size measurement. Three patients found it easy to measure their own penile circumference and length for ordering the Elator. Two reported needing help from their partner to assist with the measurement, and one mentioned the clinician's advice was helpful (Table 1). Three of the six patients had to change size because the initial Elator did not match their penis size. CDJ helped them in finding the size that best fit their penis and sought feedback from the manufacturer on how to better advise patients about penile measurement.

Attaching and removing the Elator. All patients were able to attach and remove the Elator to and from their penis without much difficulty, though a risk of pinching the skin was reported by one person during both processes.

Frequency of using the Elator. Patients used the device from 1 to 9 times. The one single man had used it "many times." One participant claimed he rarely used it for sexual activity with his wife but used it more frequently for masturbation. He stated: "I only used it once with my wife because we rarely engage in sex, but I use it more often on my own."

Change in sex life. All patients felt the Elator made a positive impact on their sex life. Generally, patients felt the device helped them maintain sexual activities, including penetrative sex, and brought them

Table 1.
Patient Questionnaire Feedback about Experiences with the Elator

Focus	Question	Patient Feedback
Penile size measurement	How did you experience measuring penis circumference and length when ordering the Elator?	“You have to be two when measuring.” “It’s not easy if you are alone.” “Without [CDJ’s] advice, it would have been difficult [getting the proper measurement].”
Attaching and removing the Elator	How did you experience attaching the Elator to the penis?	“There is a small risk of pinching your skin.”
	How did you experience removing the Elator from the penis?	“There is also a risk of pinching your skin at that moment.”
Change in sex life	Do you feel that your sex life has changed in any way since you tried the Elator?	“We got closer to each other.” “It is possible to have penetrative sex.” “We can have penetrative sex occasionally.”
	Do you feel that the Elator has had a positive impact on your sex life?	“Easier to penetrate.”
	Do you feel that the Elator has had a negative impact on your sex life?	“The Elator makes it a little harder for both me and my wife to feel sexually excited.”
	Does the Elator fulfill the intended function, enabling penetrative sex?	“Must be careful not to loosen it [but], if I use a condom [over the Elator] it works best.” “We have sex slower, so it won’t get loose.”
	Have you been able to use the Elator for penetrative sex for as long as you usually would have?	“You have to be a little bit more careful when you have sex. Once, it loosened when my partner was on top of me.”
Combination with other treatment	Have you tried combining the Elator with erection-stimulating drugs?	“I have used injection Invicorp® [injectable aviptadil and phentolamine mesylate]; it gives me 50% of an erection.” “Yes, Invicorp injection helps a little.” “Viagra® in combination with Caverject® [Prostaglandin E1] injection [helps].” “It only works with injection Invicorp.” “I first tried with Invicorp injection; it helps a little bit, but now I don’t use anything. I use the Elator without any erection.” “[I] tried sildenafil, but almost no better.”
Additional feedback		“Only [irritates the penile skin] when I loosened it.”

together. One patient reported the device had the potential to take away from sexual excitement.

Five out of six patients thought that the device fulfilled its intended function for penetrative sex. Some comments indicated it may come off the penis during penetrative sex but that there may be ways to avoid this, such as wearing a condom over it or using slower pelvic movements. However, none of the men reported precisely how the device failed to remain in place. We recognize an improper fit at the distal ring attachment may lead to discomfort if the ring is too small, or the penis sliding out of the device if the ring is too large.

Combination with other treatment. Five out of six patients used the Elator in combination with erec-

tion-enhancing medications, such sildenafil (Viagra®) or injectable aviptadil and phentolamine mesylate (Invicorp®). A few felt this combination worked better for sexual activities, and another patient felt the device only worked in conjunction with penile injection. One patient used it with oral medication only but said it did not work well for him.

Additional feedback. Five out of six patients considered the experience of using the Elator as “good,” and all six would recommend it to other men who have ED. Three felt the device is convenient to use (one did not think so; two did not answer). Five out of six felt it is safe to use. One found it irritating to the penile skin, but two did not think so, and one found this only

Table 2.
Partner Questionnaire Feedback about Experiences with the Elator

Focus	Question	Partner Feedback
Penile size measurement	Have you needed to help when your partner would measure penis circumference and length before ordering the Elator?	<p>“[It is] not easy to see when you are alone.”</p> <p>“Good to have two people when measuring.”</p> <p>“The first Elator was too small, then we got a new one which fits better.”</p>
Change in sex life	Do you feel that your sex life has changed in any way since you tried the Elator?	<p>“It works for him.”</p> <p>“We can have beautiful/enjoyable intercourse.”</p>
	Do you feel that the Elator has had a positive impact on your sex life?	<p>“It is nice to feel that the erection keeps for a long time and that he can have an orgasm.”</p> <p>“The only way...to have a real intercourse.”</p>
	Do you feel that the Elator has had a negative impact on your sex life?	<p>“It rubs a little.”</p>
	Does the Elator fulfill the intended function, enabling penetrative sex?	<p>“Most of the time.”</p> <p>“You have to be careful [as it may get loose during intercourse].”</p> <p>“He has to use the injection and have a little erection otherwise it will not work.”</p>
	Have you been able to use the Elator for penetrative sex for as long as you normally would have?	<p>“[It was] a bit cumbersome but the Elator is the only way for us.”</p>
	Do you experience irritation/scrapes during intercourse?	<p>“In some positions [the Elator] rubs in me.”</p> <p>“The first size was not good; better with a new size.”</p>

occurred when the device was loosened for removal. It was not indicated exactly which part of the penis was irritated.

Partners

As noted previously, five of the men were in committed relationships. The feedback below was mainly from four of the partners because one partner did not complete the survey. These four concurred with the patients that they had used the Elator from 1 to 9 times. One partner commented the couple was not sexually active at that time: “We don’t have sex at the moment; we only tried the Elator once.” One partner said the patient “has to use the injection and have partial erection; otherwise, it will not work.”

Penile size measurement. Two partners reported they did not need to help their partner measure penile circumference and length, but two reported they did. Those who did emphasised the difficulty the men faced measuring alone and how this occasionally resulted in receiving an Elator of the wrong size (Table 2).

Attaching and Removing the Elator. None of the partners needed to help the patient attach or remove the Elator.

Change in sex life. One partner said they did not think the Elator had changed their sex life; however, two

said it had, and both commented positively about it, feeling the device had positively impacted their sex life. Specifically, they were able to enjoy ‘real’ intercourse, and the man was able to orgasm.

All four partners who filled out the survey thought the Elator fulfilled its intended function of enabling penetrative sex. However, three of the four suggested it was not perfect. It worked “most of the time,” but they did not provide more information on what did not work. Another warned the device may get loose during intercourse, and another stated it “rubs a little” in her vagina.

Two of the four said the device enabled penetrative sex for as long as they would usually do it, and two said it did not. One commented it was “a bit cumbersome.” Though all four partners felt the device was safe to use during intercourse, only half felt it was completely comfortable to use. One found it caused discomfort in the vagina during intercourse “in some positions.” In addition, one commented about the size change: “The first size was not good; better with a new size”.

Additional feedback. Overall, the Elator was rated ‘very good’ by one partner, ‘good’ by two, and ‘not so good’ by one. All partners who completed the survey would recommend the device to people who have the same erectile problems as the patients.

Discussion

In this study, patients with PCa and their partners reported their experiences of using the Elator, a non-invasive and non-pharmacological penile-support device, for sexual activities following iatrogenic ED. Patients used the device for both masturbation and sex with a partner. All patients felt the device positively impacted their sex lives, though only half of the partners felt the same. Most of the patients felt it enabled penetrative sex as it is designed to do, and all partners agreed. The Elator could also work in combination with pharmacological aids, such as erection-enhancing drugs. Overall, all patients and partners in this study would recommend the device to men with erectile problems and their partners.

Both patients and partners shared the opinion that there was room for improvement. For example, the Elator may loosen or fall off during penetrative sex. This is due, in part, to inaccurate penile size measurement (girth and length). Some patients indicated difficulty with measuring their penis size to get an Elator that fits properly. Partner support was helpful for some, though that would not be an option for single patients. Here, half of the patients did not get an Elator of the right size when they tried it for the first time. Consequently, they had to come back to the clinic for information and advice about the best way to get the correct measurements and needed to try an Elator of a different size. Currently, information about how to measure a penis can be found on the manufacturer's website. Our small sample suggests there may be an advantage in having a clinician collect the penile measurement. Some comments raised in this report suggest patients need to receive better instruction for measuring their penis to get a device with the right fit.

Another potential factor that may have affected penile measurements is the combination use of the Elator with other erection-enhancing aids, such as oral PDE5i, intraurethral suppositories, intracavernosal injections, or the VED. If patients plan to use the device alongside another method, the data here suggest they should measure their penis while under the influence of the other aid to reduce the likelihood of receiving an Elator that does not fit well.

In theory, an alternative approach to getting the best measurements might be to collect the information before the patient goes for cancer treatments that have a risk of ED. However, we have no data on whether the best fit measurements change with the duration from when the patient first experienced iatrogenic ED to the time when they acquired used the Elator. In addition, it remains unclear if progressive penile shrinkage over time following the onset of ED (McCullough, 2008) increases the risk of the device not staying in position when used for penetrative sex. There is literature suggesting some penile length recovery following radical prostatectomy with and without ADT (Kadono et al., 2017; Kadono et al., 2018), which may also potentially influence the fit for the Elator.

Practice Changes and Recommendations

Our findings could potentially be used for sexual health, urology, or oncology nurses to advise patients with PCa and their partners about exploring strategies to maintain sexual intimacy. Although the Elator is not commonly offered to men treated for ED in sexual rehabilitation clinics, data show some patients with PCa have used it for rewarding partnered sex (Wassersug & Wibowo, 2017). When nurses or other clinicians suggest the Elator to patients, various considerations should be addressed. First, the current list price for the Elator is close to \$300 USD, which might make it prohibitively expensive for many patients. In contrast, the cost of PDE5i per pill (less than \$25 USD) or intracavernosal injection per treatment (less than \$20 USD) is cheaper. However, the cost of the Elator is cheaper in the long run if it fits properly and is used multiple times. If future research shows the Elator functions best when used along with ED drugs, this could raise the overall costs and increase the barrier to its use.

Clinicians need to inform patients and partners that some couples have reported rubbing of skin and/or discomfort during use. On the patient side, attaching and removing the Elator, while not difficult, may risk pinching penile skin. Taking greater care with removal may reduce that risk. Partners may also feel some irritation from the repeated penetrative movements during coitus. This may be managed by changing sex position.

Alternatively, other non-medical and non-pharmacological sexual aids may be more comfortable for patients and partners, such as external penile prostheses and penile sleeves (Wassersug & Wibowo, 2017). Both types of devices are less likely to pinch the skin during sexual activity. These options, like the Elator, lack scientific assessment of their efficacy and acceptability to both patients with ED and their partners.

In using any sexual aid, couples may need to adapt to the loss of spontaneous sex. All sexual aids, including the Elator, require some preparation, and thus, couples cannot engage in purely spontaneous sexual activities. Alternatively, when both the patient and partner are involved in selecting such aids, intimacy can be built (Wassersug, 2016), which may help eroticize the aids and enhance their effectiveness (Kukula et al., 2014).

Implications

Our data provide additional evidence that non-invasive sexual devices may potentially be used by men with severe ED and their partners for sexual activities. Clinicians who treat patients whose quality of life is reduced by ED should be willing to discuss with patients and their partners a range of options for maintaining sexual activities. If the couple is open to novel strategies, they can be encouraged to explore non-invasive sex aids, such as the Elator, as well as the penile sleeve and external penile prostheses (Wassersug & Wibowo, 2017).

Limitations

Our data are preliminary feedback acquired in a clinical setting, and the sample size is small, limiting generalizability. In addition, users reported their experiences at various times after being introduced to the Elator (up to 20 weeks), and we do not know whether they continued using it or not. Long-term use of any sex aid is an important factor to assess because all ED aids have a high rate of patient abandonment (Wassersug & Wibowo, 2017). Additionally, none of the patients in this study had been on ADT. Feedback may differ for patients with PCa receiving ADT because they experience more profound atrophy of their reproductive organs and severe loss of sexual desire due to the androgen suppression (Elliott et al., 2010).

The Elator may provide a relatively safe, non-invasive, and non-pharmacological option for penetrative sex for men with ED. However, more research on the Elator is warranted. For example, future research could explore whether the adherence to using the device would be better if the treatment is coupled with psychosexual counselling. Other aspects that need further clarification include 1) who is the best person to collect penile measurement so patients get the right size Elator, 2) whether genital shrinkage over time affects the fit of the Elator, and 3) how to avoid any discomfort to both patients and their partners when having penetrative sex with the Elator. In addition, it remains to be determined how well the device might work for anal sex because none of our patients reported using it for this purpose. The device may potentially irritate the anal or rectal tissue more than the vaginal canal given the greater constriction of the anal sphincter.

Conclusion

We present here some preliminary data on the strengths and weaknesses of the Elator as an aid for penetrative sex for men with ED. The Elator has some advantages over standard ED treatments in that it is neither surgically invasive nor pharmacological, and it can be used as a stand-alone aid or alongside pharmacological treatment. The product has the advantage of its minimalist design that does not cover the glans penis. However, to work properly, it needs to be individually fitted for each man. This means getting the best fit, which may require an experienced clinician to collect data on the man's penile girth and the distance from the penile base to the sulcus of the corona. Currently, we do not know if the Elator fits better and is hence more effective when used in conjunction with pharmacology ED treatments.

Feedback from patients and partners was generally positive, but more data are needed to determine how effective the Elator is in helping patients and partners maintain sexual intimacy. Potentially, the Elator and other 'sex toys' may help improve the quality of sexual relationships in men with ED following PCa treatment. We hope our research may encourage clinicians to sug-

gest products, such as the Elator, to patients for whom other ED treatments have not been fully effective. ■

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