INTERVENTIONS

Feasibility of an External Erectile Prosthesis for Transgender Men Who have Undergone Phalloplasty

Elizabeth R. Boskey, PhD,[1] Divya Jolly, MS,[1] Geetika Mehra, MD,[2] and Oren Ganor, MD[1]

ABSTRACT

Introduction: Transgender men interested in achieving penetration after phalloplasty are currently limited to internal devices and makeshift supports. More options are needed to support sexual penetration after phalloplasty.

Aim: This study was designed to assess the feasibility of an external erectile prosthesis (the Elator) for transgender men who have undergone phalloplasty and wish to use their neophallus for sexual penetration, assess how the device affected the sexual experiences of men and their partners, and identify any side effects and concerns.

Methods: Transgender men and their partners were provided with an erectile device to use for one month. They were surveyed at 4 time points: enrollment, measurement, receipt, and after using the device, using a combination of pre-existing and device-specific measures.

Main Outcome Measure: The primary outcome was whether men found it feasible to use an external penile prosthesis for sexual penetration after phalloplasty — defined as interest in, and willingness to, use the device more than once over the study period; intention to continue using the device on the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS); and no decrease in relationship satisfaction on the Gay and Lesbian Relationship Satisfaction Scale (GLRSS). The secondary outcome was an increase in sexual or relationship satisfaction with use of the device, defined as a statistically significant increase on either the Quality of Sexual Experience Scale (QSE) or the GLRSS.

Results: Fifteen couples enrolled in the pilot study. Of the 10 who completed the study, only 3 found device use feasible and endorsed strongly positive experiences, while the remaining 7 found it unusable. There were no changes in QSE or GLRSS scores. Most device issues were related to proper fit.

Conclusion: There is a great deal of interest in non-surgical options for achieving penetration after phalloplasty. The tested external erectile device can work well, but its utility is limited to individuals with very specific post-phalloplasty anatomy. Most individuals and couples found the device unsuitable for the neophallus and/or that it could not be used comfortably. **Boskey ER, Jolly D, Mehra G, et al. Feasibility of an External Erectile Prosthesis for Transgender Men Who have Undergone Phalloplasty. Sex Med 2022;XX:XXXXXX.**

Key Words: Transgender Men; Phalloplasty; Erectile Prosthesis; Gender-Affirming Surgery; Sexual Function; Erectile Function

INTRODUCTION

Among those individuals seeking gender-affirming phalloplasty, not all are interested in using their neophallus for sexual penetration. However, many of those who do have concerns about long-term use of internal erectile prostheses. The lack of reliable, durable, and desirable erectile devices has limited uptake of phalloplasty in the transgender community, where many individuals have chosen to wait for phalloplasty technology to improve before seeking out gender-affirming genital surgery.[1]

Received July 12, 2022. Accepted July 16, 2022.

[1]Center for Gender Surgery, Boston Children's Hospital, Boston, MA, USA;

[2]Internal Medicine, University of Chicago, Chicago, IL, USA

https://doi.org/10.1016/j.esxm.2022.100560

Transgender men may be justifiably concerned about device failure and the possible need for additional surgery with existing options for internal erectile prostheses, particularly given the higher complication rates seen for these devices in transgender men when compared to cisgender men experiencing erectile dysfunction in a natal phallus.[2–4]

As such, there is a need to develop alternative methods for helping transgender men achieve penetrative function after phalloplasty — through both surgical options[5] as well as non-surgical alternatives to assist with erectile function.[6,7] One such option may be the use of external erectile prostheses. These devices have several advantages: they are less expensive than internal prostheses, do not require surgical intervention, and are likely to have substantially fewer side effects in both the short- and long-term. However, unlike internal devices, which may be experienced by patients as a more natural and/or less intrusive intervention once implanted, external erectile devices remain apparent to both patient and partner during use, something that may be a source of discomfort or dysphoria.

There are currently two, apparently identical, external, multi-use erectile prostheses being marketed as consumer products for men experiencing erectile dysfunction. One of these devices, the Elator, was initially developed as a device that could be used by men experiencing erectile dysfunction after prostate cancer in order to more accurately simulate unassisted intercourse. The device consists of two silicone rings connected by a pair of plastic-coated rigid metal rods. One ring goes at the base of the phallus. The other ring is connected to the rods. This ring is placed behind the glans, and then the rods are connected to the base ring allowing it to stretch while providing rigidity to the phallus (Figure 1). Men can then penetrate their partners with their phallus, which is held rigid by the device until removal. The phallus remains mostly exposed to the sensations of penetration, and the device can be used with a condom or other barrier for protection.

The Elator has also been marketed to transgender men, and their site contains anecdotal reports from men who have used and enjoyed the device after phalloplasty.[8] However, despite the existence of such anecdotal reports, there is no published data about the use of such devices after phalloplasty and only limited information about their use in cisgender men experiencing erectile dysfunction.[7] This is in part due to the United States Federal Drug Administration's exemption of external penile rigidity devices from pre-sale review.[9]

This pilot study was designed to test the feasibility of Elator use in transgender men who have undergone phalloplasty and wish to use their neophallus for sexual penetration,[10–12] assess how the device affects the sexual experiences of men and their partners, and to identify any side effects and concerns that patients and providers should be aware of before considering recommending the device to patients. We hypothesized that the device would be suitable for achieving enjoyable, satisfactory penetrative sex among transgender individuals who were not interested in, or ready for, an internal prosthesis.

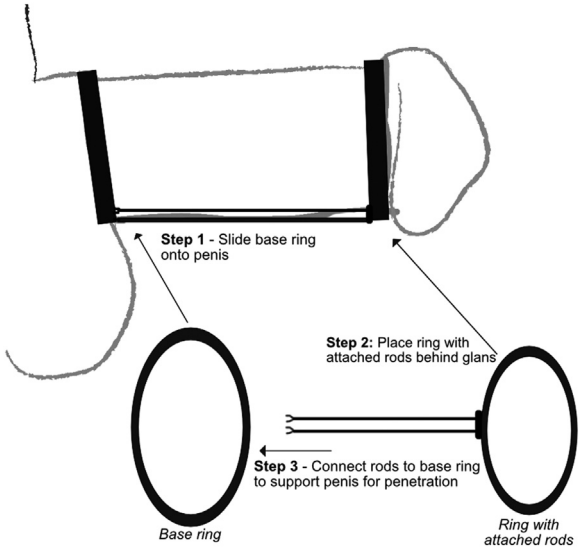

Figure 1. Diagram of the external penile prosthesis and its use.

MATERIALS AND METHODS

Transgender men who were between the ages of 18–65, had undergone a phalloplasty with glansplasty a minimum of 1 year before enrollment, had protective sensation to the tip of their neophallus, and were in a relationship in which they were either having sex with their partner or would like to be doing so were recruited using a combination of word-of-mouth and e-mail targeting of surgeons who perform gender-affirming phalloplasty. Partners were required to be between the ages of 18–65 and be interested in having penetrative sex. Both men and their partners needed to consent to enroll in the study. There were no restrictions on partners' genders for participation.

After consenting to the study, men and their partners completed an initial survey that assessed demographics, a brief sexual and relationship history, the Quality of Sexual Experiences Scale (QSE),[13] and the relationship satisfaction sub-scale of the Gay and Lesbian Relationship Satisfaction Scale (GLRSS).[14] These measures were chosen because they do not make explicit assumptions about individual or partner gender or anatomy, unlike many scales which include statements about binary gender and/or penile/vaginal intercourse. Once both partners had completed their initial assessment, they were sent a measuring kit for the external erectile device (The Elator[8]) and, upon receipt, were asked to fill out a brief survey about their experience measuring for their device. Participants were additionally asked qualitative, open-ended questions about their hopes for and experiences with the device. These surveys, and those at the remaining time-points, were collected online using the HIPAA compliant cloud-based survey platform REDCap.[15,16] Participants filled out the

surveys asynchronously, on their own. Patients and their partners were required to have separate e-mail addresses to which individual surveys were sent.

A device was then ordered and sent to each pair. Upon receipt of the device, both participants completed a short survey about their impressions of the device and then used the device for 1 month. At the end of that month, they completed another QSE and GLRSS, and answered the Interest in Sexual Activity Scale[17] and either the patient or partner version of the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS), as appropriate.[18] All participants were invited to keep the devices following completion of the study.

The primary outcome for this study was a determination of whether men found it feasible to use an external penile prosthesis for sexual penetration after phalloplasty. Feasibility was defined as interest in, and willingness to, use the device more than once over the study period, an answer of "wants to continue" on the EDITS, and no decrease in relationship satisfaction on the GLRSS. The secondary outcome was an increase in sexual or relationship satisfaction with use of the device. This was defined as a statistically significant increase on either the QSE or the GLRSS.

Data from closed-ended questions were primarily reported using descriptive statistics due to the small sample size. QSE and GLRSS scores were compared pre- and post- intervention using one-way repeated measures ANOVA. Open-ended questions were analyzed using a form of conceptual content analysis where we coded for frequency of a concept related to concerns about external erectile prostheses, where all codes were generated using an interactive set of concepts and categories (positive/negative/neutral) rather than sticking to a rigid set of pre-defined concepts. This allowed us to incorporate new, important information into the coding process that allowed us to better comprehend the topic.[19]

All coding was completed by two coders with training and experience in qualitative analysis. Codebook generation was done independently by both coders and then discussed to resolve any discrepancies. Coders were blinded to participant demographics other than study arm (i.e., patient/partner) and coded all data independently before coming together to discuss results and resolve any discrepancies in coding. All discrepancies in codebook generation and coding were minor and related to specific phrasing of themes rather than thematic groupings or valence.

Positionality

The research team was comprised of a mix of transgender and cisgender individuals. All of the research team has extensive experience, either lived or clinical, with the transgender community. The research team consists of a mix of researchers and clinicians, with combined experience in gender-affirming plastic surgery, microsurgery, internal medicine, public health, medical anthropology, social work, sex-positive sexuality education, and sex therapy. The surgeon on this team performs phalloplasty but does not insert erectile prostheses. Both of the qualitative coders identify as queer, and one is transgender. Neither of the qualitative coders have undergone phalloplasty.

RESULTS

Fifteen couples living in the United States and Canada enrolled in this pilot study. Most men and their partners were between the ages of 25−34, and the vast majority were White. Of the partners, 13 were assigned female at birth, one was assigned male, and one did not provide this information. Eleven of the men gave their gender as transgender male and 4 as male, while 11 of the partners identified as female and 3 as non-binary. Most men (12/15) had undergone radial forearm phalloplasty and one had a history of previous internal device explanation. Couples had been together for an average of 7 years with a range of 3 months to almost 20 years. Most couples stated that, at baseline, they were having sex less than once a week and would prefer to be having sex more or much more often (Table 1). Only one study participant had undergone phalloplasty with the authorship team.

There was substantial loss to follow-up over the course of the study. Ten couples completed the study. One couple dropped out after having a bad experience with the device and did not complete the final study assessment. Three couples dropped out after receiving the device with no further communication.

After using the device, individuals endorsed a range of feelings about interest in sexual activity. Men and their partners reported mixed feelings about looking forward to sex, having sex more frequently, sex being enjoyable, sex being more stressful, and worries about whether sex was desired. However, all couples reported that either they felt closer to their partner and had a stronger relationship or that those factors had not changed (Table 2). There was a similar diversity of experiences reported by both men and their partners (Table 3) on the EDITS. Interestingly, as individuals, both men and their partners tended to report moderate increases in relationship satisfaction (RSS) and quality of sexual experience (QSE) scores at the end of the study, although there were a wide range of both positive and negative experiences such that, at the study level, the mean scores across both scales modestly decreased, although the changes were not significant (Figure 2).

Qualitative Themes

At the time of enrollment into the study, individuals primarily reported being hopeful about sex and hopeful that they might be able to avoid surgery to get an internal prosthesis. At this time point, concerns about the device were rarely reported (Table 4). One man stated, "I've been wanting to try the Elator or something similar for some time. I have some dysphoria about

Table 1. Demographics and baseline data

	Patient (N = 15)	Partner (N = 15)
Age		
18–24	1	0
25–34	8	10
35–44	5	1
45–54	0	1
55–64	1	1
Race*		
White	14	14
Black	1	1
Asian	0	0
Native American/Alaskan Native	0	1
Native Hawaiian/Other Pacific Islander	0	0
Other	1	0
Ethnicity		
Not Hispanic or Latino/a/x	14	14
Hispanic or Latino/a/x	1	0
Assigned Sex at Birth		
Male	0	1
Female	15	13
Gender Identity		
Male	4	0
Transgender Male	11	0
Female	0	11
Transgender Female	0	0
Non-Binary	0	3
Type of Phalloplasty		
Radial Forearm	12	N/A
Anterolateral Thigh (ALT)	1	
Abdominal	1	
Abdominal + Thigh	1	
Length of relationship (months)	M 90, SD 65, R [3,233]	
Baseline		
In the past 4 wk, my partner and I have been sexually intimate:		
Not at all	1	1
1–2x over the course of the month	7	6
Once a week or less. . .	2	4
2–4 times a wk	4	4
Every day	1	0
In an ideal world, we would be having sex:		
Much less often	0	0
Less often	0	0
As often as now (no change)	2	1
More often	10	12
Much more often	3	2

*Participants could choose more than one race.Not all participants answered all questions, so numbers may add up to <15.

needing to use coban and a condom to have sex and I think this device will help with my comfort and excitement to have sex again."

Another stated, "I am very excited to see how well external prostheses can work and feel physically and mentally. Due to its minimalist design, I do not worry much about feeling dysphoric using it in the moment."

Partners were also hopeful about the device with one stating, "I'm hopeful it will help us find a spark again. We haven't really had a sex life in years. When he told me he didn't want an erectile device I lost hope it would improve." Another stated, "I'm hoping it could improve our sex life, making it easier/more seamless for my partner and I to have sex."

After learning about the device, but before seeing it, people reported a more even balance of positive and negative themes. Many were hopeful that using the external prosthesis would cause less interference with sex and that they would feel more confident, and smaller numbers reported hope that the external device would be easier to use than their current method, positive expectations for sensation, and excitement about sex. Things men stated they were looking forward to included "Having intercourse without so much manual assistance," "penetrative sex with a device that is easy to use," "finally being able to use my penis for sex the way I have imagined," and "hopefully being more confident about my ability to perform sexually." Things partners stated they were looking forward to included, "seeing how my partner reacts and making him happy," "being intimate with my partner in a way that is not currently possible," and "more enjoyable experiences" At the same time, people reported substantial concerns about measurement issues, device failure, and discomfort. Things men stated they were worried about included "the comfort level for both me and my partner," "that it may slip off," and that "the device will not fit me as I am a trans male and the product is designed for cis males." Similar themes were reported after individuals had seen the device but not yet used it, with one additional, neutral theme arising of people wondering how the device would work (Table 4). Statements about device function included worries that "the tip of my partner's penis will slide out of the device," "it will hurt my partner or not feel good for her," and about it "slipping off during sex."

After using the device, positive themes were less common, although several people reported that they appreciated getting to try the device and having more sexual options, and a few reported increased interests in sex and that the device was easy to use. More people reported negative themes including being unable to use the device at all, general issues with measurement and fit, and specific measurement and fit issues related to being trans. As one person stated,

"The measurement instructions were confusing and did not seem to take into account differences between a post-surgical penis of a trans person vs a cis person with erectile dysfunction who is struggling to become engorged." However, it is important to note that even several of the people who reported negative experiences with the device had (neutral) hopes that it might be possible to make the device work with some improvements.

Table 2. Interest in sexual activity at follow-up

	Strongly disagree N	Disagree N	Neither agree nor disagree N	Agree N	Strongly agree N
I find myself looking forward to sex with my partner					
Patient (n = 10)	2	0	1	3	4
Partner (n = 8)	1	0	4	1	2
My partner and I have had sex more frequently					
Patient	3	0	5	1	1
Partner	2	0	3	0	3
Sex with my partner has become more enjoyable					
Patient	1	2	3	3	1
Partner	1	1	3	0	3
Sex with my partner has become more stressful					
Patient	2	1	3	3	1
Partner	2	1	2	1	2
I am worried that my partner will want to have sex					
Patient	9	0	1	0	0
Partner	3	1	3	0	1
I am worried that my partner will NOT want to have sex					
Patient	2	1	2	2	3
Partner	3	0	2	1	2
I feel closer to my partner					
Patient	0	1	3	5	1
Partner	0	0	4	2	2
My relationship with my partner feels stronger					
Patient	0	1	4	3	2
Partner	0	0	4	2	2

Table 3. Evaluation of experience with the Elator on the Erectile Dysfunction Index of Treatment Satisfaction (EDITS)

	Patient (n = 10) M (SD) [Range]	Partner (n = 8) M (SD) [Range]
Overall Satisfaction (1 Very Satisfied — 5 Very Dissatisfied)	3.8 (1.5) [1,5]	3.75 (1.6) [1,5]
Likely to Continue Using (1 Completely — 5 Not at All)	3.6 (1.8) [1,5]	N/A
Degree Met Expectations (1 Completely — 5 Not at All)	4 (1.3) [2,5]	4.12 (1.4) [2,5]
Ease of Use (1 Very Easy — 5 Very Difficult)	3.6 (1.7) [1,5]	N/A
Satisfied with Speed of Use (1 Very Satisfied — 5 Very Dissatisfied)	2.9 (1.9) [1,5]	N/A
Satisfied With How it Lasts (1 Very Satisfied — 5 Very Dissatisfied)	3.1 (1.8) [1,5]	3.25 (1.7) [1,5]
Affected Your Sense of Being Desirable (1 Much More Desirable — 5 Less Desirable)	N/A	3.38 (0.74) [3,5]
Made You Feel Sexually Confident (1 Very Confident — 5 Very Much Less Confident)	3.6 (1.5) [1,5]	N/A
Use Felt Natural (1 Very Natural — 5 Very Unnatural)	3.9 (1.1) [2,5]	N/A

Note: Wording on the EDITS differs slightly for the patient and partner scales, and different 5- point Likert scales are used for each question. Where one half of the couple is not asked the question, the person who was not asked the question is recorded as N/A. EDITS items around perceptions of partner satisfaction were asked but are not reported in this table.

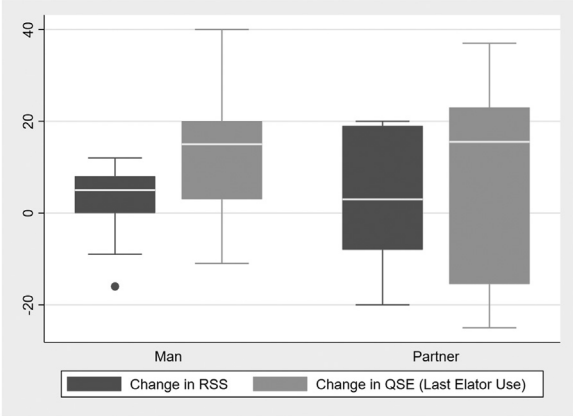

Figure 2. Distribution of individual changes in the relationship satisfaction subscale of the gay and lesbian relationship satisfaction scale (RSS) and the quality of sexual experiences scale (QSE). Numbers greater than zero represent an improvement from baseline scores.

Several individuals also offered technique suggestions and suggestions to improve the device (Table 5). Factors that individuals reported as affecting their ability to use the device included: penile girth and length consistent with device options, the need for testicular implants to support the penis upright, and the importance of having a pronounced glans to keep the device in place. Suggestions for improving the device included having a wider range of sizes, telling people to measure to the glans rather than the tip of the penis, and encouraging people to use a condom with the device to help keep it in place(Table 5).

DISCUSSION

There is substantial interest in alternatives to internal erectile prostheses for individuals who have undergone phalloplasty and are interested in using the neophallus for sexual penetration.[4] This reflects, in part, the fact that current internal devices have high failure rates and may require multiple surgeries for implantation and removal,[10,20,21] as well as pose a risk of causing damage to the neophallus.[22,23] As phalloplasty is, inherently, a complex surgery with a high risk of complications,[24] the idea of undergoing additional surgeries to attain sufficient rigidity for penetration may be untenable for some individuals. This may be particularly true for individuals whose primary goals for undergoing gender-affirming phalloplasty do not involve sexual penetration, even if they still have an interest in using their phallus for sexual activity.[25]

Prior to receiving the external prosthesis, couples in this study expressed enthusiasm for the possibility of a device that would be easy to use, allow them to maintain sensation, and enable sexual penetration without undergoing additional surgeries. However, upon learning more about the device, both men and their partners expressed what turned out to be justifiable concerns about the suitability of the external prosthesis for transgender men. While some couples did indeed find that the device was easy to use and made sexual penetration more feasible, many individuals experienced issues with device fit and comfort that rendered it unsuitable for ongoing use. Our results suggest that current external erectile device choices are not suitable for many transgender men and their partners.

Device Improvement Suggestions and Clinical Implications

The process of identifying an appropriate option for attaining penile rigidity can be both difficult and expensive. Several study participants expressed appreciation at being able to try out a device that they would otherwise be unable to afford. It may be worthwhile for providers to lobby for insurance coverage, or reimbursement for, penile supports such as the Elator and other external devices that seem suitable for their phalloplasty patients. External penile supports, if functional and appropriate for a given individual, have the potential to be substantially less expensive for insurance companies than surgical options; however, they may still be out of reach as out-of-pocket expenses for transgender individuals with limited financial resources. Companies manufacturing such devices primarily for the cisgender erectile dysfunction market may also wish to engage transgender and/or surgical consultants to improve product function for post-phalloplasty patients.

Although some individuals only expressed frustration and disappointment that the external prosthesis was unsuitable for their needs, several made suggestions about how such a device could be made functional for the transgender population and expressed hope that a different external device, or a different version of the existing device, could meet their needs. In particular, participants believed that a wider size range that addresses the variable dimensions of the neophallus and measurement instructions specific to the post-phalloplasty population would increase the utility of a similar device. Specifically, participants noted that expanded sizes for the silicone rings would improve the usability of the device. Participants did, however, note that different types of surgery, surgical choices, and surgical techniques, as well as individual healing variation, could limit the utility of any splint that requires a specific anatomical arrangement, such as a glans of sufficient prominence that the ring will not slip past it. Our clinical experience additionally suggests that the glans may flatten over time during the healing process in gender-affirming phalloplasty, which may contribute to transgender men's difficulty with using the device.

These participant-provided solutions have important clinical counseling implications for clinicians offering phalloplasty (Figure 3). Our clinical and lived experience suggests that surgeons offering these procedures may be less familiar with nonsurgical alternatives to achieve a neophallus that is capable of penetrating a partner. Providers offering phalloplasty should be aware that for post-phalloplasty transgender individuals who have a neophallus with a prominently ridged glans and slim to

Table 4. Themes endorsed by participants at different study timepoints

Positive:	*Negative:*
At the start of the study. . .	
Hopeful about sex (7)	Worried about discomfort (1)
Hopeful about confidence (1)	
Hopeful about avoiding surgery/internal device (5)	
After learning about the device, but not yet having seen it. . .	
Less interference with sex (7)	Worries about measurement/sizing (10)
Increased Confidence (8)	Worries about device slipping/failure (6)
Easier to use than current method (4)	Worries about safety (1)
More sensation than current method (4)	Worries about discomfort (9)
Excited about sex with the device (5)	
After seeing the device, but not yet having used it. . .	
Positive:	*Negative:*
Not needing to use more cumbersome options (9)	Not enjoyable/painful for the penetrated partner (12)
Being able to enjoy sex (5)	Device won't work (10)
Improved penetration (6)	Might not work for trans (3)
More spontaneity (2)	Might cause pain or damage (4)
	Might interrupt sex (1)
Neutral:	
How will it work? (4)	
After using the device. . .	
Positive:	*Negative:*
Easy to use (1)	Nothing enjoyable/Couldn't Use (10)
Increased interest in sex (2)	Painful (2)
More sexual options (3)	Slipping (5)
Appreciating getting to try something new (4)	Didn't work well (4)
Improved confidence/sex life (2)	Measurement/Fit issues — General (5)
	Fit issues — Specific to being trans (7)
Neutral:	
Hopeful it could work with some improvements/size changes (3)	
Technique suggestions (5)	
There's a learning curve (1)	
Suggestions for a better device (4)	

The number of participants addressing the theme is in parentheses.

moderate girth and wish to use their neophallus to penetrate a partner, the Elator may be a viable surgical alternative to internal prostheses. For those who with large girth or a flattened glans (ie, the majority of transgender men who had phalloplasty), the device does not appear to be an ideal solution. However, even for those whom the device was not an ideal solution, participants expressed that adding lubrication and using condoms improved their ability to use the device. Providers should inform all patients who wish to use their neophallus for penetrative sex about the device, as well as how the patient's specific anatomy may or may not be compatible with the device. Patient counseling should include information about the risk that device may not work for all individuals and may be physically uncomfortable for partners receiving penetration (Table 2). Alongside improved insurance coverage, this would allow patients to determine whether the Elator, or a similar device, would suit their needs. In turn, this has the potential to improve patients' decision-making ability around whether they wish to pursue an internal prosthetic device. Additionally, our data suggests that experimentation with sexual options has the potential to make men and their partners feel closer to one another, which may improve overall relationship satisfaction.

Table 5. Selected participant quotes around factors affecting their ability to use the Elator, and suggestions for improvement

Factors affecting device use:
"It may have been the lack of testicular implant, but it didn't hold the penis upward like in the video."
"Device was not large enough girth even for my RFF phallo result, would not properly fit"
Suggestions related to device suitability:
"If you have any glans flattening at all, it will probably slip off during sex."
"You cannot have a lot of girth"
Suggestions related to measurement:
"The sizing guide that Elator gives is completely wrong for trans guys. Only measure from pelvic bone to start of glans (not to tip of penis)"
"Ensure to [sic] measure both the top and bottom of your penis when finding the length. The measuring instructions say to measure from the top but I found out that the length on my penis is shorter underneath due to scar tissue. I only measured the top and ordered the length based on that number which caused the Elator to be too long and not fit."
Suggestions related to use during sex:
"Lubrication really helped me"
"Lubricant makes the penis more likely to fall out of the rings."
"It's possible to use with a condom without any pinching of your partner if you can't slide the device all the way to the top."
"The condom is a game changer! Use one!"
Suggestions for device improvement:
"I would like a device where the bar can be adjusted by sliding out to be longer or shorter and then locked into place. This would have made the device fit for sure."
"I think that if this device is to be marketed to trans people then it is necessary to do a little more research on phalloplasty and trans bodies"

Strengths and Limitations

To our knowledge, this is the first study to test the use of an external erectile device for transgender individuals interested in exploring non-surgical options for sexual penetration. However, enrollment was limited, and the device size range limited its usability. In addition, there was substantial loss to follow-up, and the study had difficulty enrolling transgender men with male sexual partners who were interested in testing the device. Further research is needed to understand the use of external erectile prostheses in larger and more diverse cohorts. It is unclear how the experiences of couples in this study may translate to other forms of penetrative sex, such as penetrative anal sex, as the majority of our participants engaged in penile-vaginal sex.

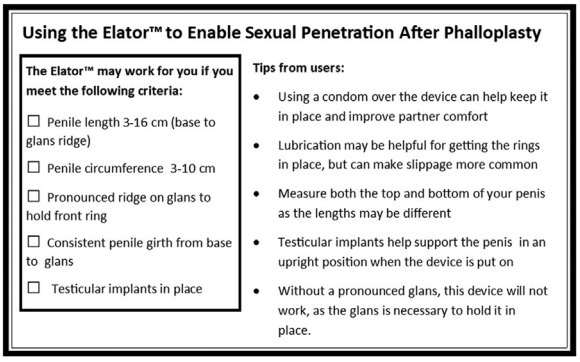

Figure 3. Patient counseling guide.

CONCLUSIONS

While the tested external erectile device was feasible for only a subset of men who have undergone gender-affirming phalloplasty, even some participants who could not use the device felt that it would be possible to create an external penile support that would be functional for a broader range of individuals. Factors affecting feasibility of the current device included presence of testicular prostheses (to hold device and phallus upright), neophallus size, neophallus shape, and the presence of a pronounced glans. Individuals whose neophalluses have a coronal ridge of sufficient depth that the ring will stay in place behind it and are of a circumference (3−10 cm) and length (3−16 cm) that are consistent with available options may find that this external erectile prosthesis is an effective tool for engaging in sexual penetration. However, it can be difficult to measure appropriately for the device, and some sexual partners endorse discomfort with use, which may make the process of getting an appropriately sized device untenable in the absence of sufficient financial resources. There remains a need for additional surgical and non-surgical options that transgender men can use to attain penile rigidity after gender-affirming phalloplasty as well as insurance coverage for these supports.

Corresponding Author: Elizabeth R. Boskey, PhD, Center for Gender Surgery, Boston Children's Hospital, 300 Longwood Ave, Boston, MA, 02115, USA. Tel: 617-919-6525; Fax: 617-730-7637; E-mail: elizabeth.boskey@childrens.harvard.edu

Conflict of Interest: The authors report no conflicts of interest.

Funding: This research was supported by a pilot grant from the Sexual Medicine Society of North America. The sponsor did not play a role in study design or the collection, analysis, or interpretation of data.

STATEMENT OF AUTHORSHIP

Conceptualization, ERB and OG; Formal Analysis, ERB and DJ; Funding acquisition, ERB and OG; Investigation, ERB, DJ and GM; Methodology, ERB and DJ; Resources, OG; Writing − original draft, ERB, DJ, GM, and OG; Writing − review & editing, ERB, DJ, GM, and OG.

REFERENCES

1. Yerke AF, Mitchell V. Am I Man Enough Yet? A comparison of the body transition, self-labeling, and sexual orientation of two cohorts of female-to-male transsexuals. **Int J Transgenderism 2011;13:64–76. doi:** 10.1080/15532739.2011.622125.
2. Kocjancic E, Iacovelli V. Penile prostheses. **Clin Plast Surg 2018;45:407–414. doi:** 10.1016/j.cps.2018.03.012.
3. Ko OS, Bennett NE. Ambicor two-piece inflatable penile prosthesis: Background and contemporary outcomes. **Sex Med Rev 2018;6:319–327. doi:** 10.1016/j.sxmr.2017.07.010.
4. Boskey ER, Mehra G, Jolly D, et al. Concerns about internal erectile prostheses among transgender men who have undergone phalloplasty. **J Sex Med 2022;0. doi:** 10.1016/j.jsxm.2022.03.604.
5. Yin Z, Liu L, Xue B, et al. Dynamic penile corpora cavernosa reconstruction using bilateral innervated gracilis muscles: A preclinical investigation. **Sex Med 2018;6:162–170. doi:** 10.1016/j.esxm.2018.01.002.
6. Gray RE, Klotz LH. Restoring sexual function in prostate cancer patients: an innovative approach. **Can J Urol 2004;11:2285–2289.**
7. Wassersug R, Wibowo E. Non-pharmacological and non-surgical strategies to promote sexual recovery for men with erectile dysfunction. **Translational Androl Urol 2017;6:S776–S794. doi:** 10.21037/tau.2017.04.09.
8. The elator - the revolutionary natural solution for erectile dysfunction - an external penile support device for men suffering from any form of erectile dysfunction. Phalloplasty n.d. Available at: https://www.theelator.com/phalloplasty. Accessed September 10, 2018.
9. Food and Drug Administration. Class II special controls guidance document: external penile rigidity devices 2004.
10. Falcone M, Garaffa G, Gillo A, et al. Outcomes of inflatable penile prosthesis insertion in 247 patients completing female to male gender reassignment surgery. **BJU Int 2018;121:139–144. doi:** 10.1111/bju.14027.
11. Frey JD, Poudrier G, Chiodo MV, et al. A systematic review of metoidioplasty and radial forearm flap phalloplasty in female-to-male transgender genital reconstruction: Is the "Ideal" Neophallus an achievable goal? **Plast Reconstr Surg Glob Open 2016;4:e1131. doi:** 10.1097/GOX.0000000000001131.
12. van de Grift TC, Pigot GLS, Boudhan S, et al. A longitudinal study of motivations before and psychosexual outcomes after genital gender-confirming surgery in transmen. **J Sex Med 2017;14:1621–1628. doi:** 10.1016/j.jsxm.2017.10.064.
13. Sanders SA, Herbenick D, Reece M, et al. The development and validation of a brief Quality of Sexual Experience (QSE) scale: results from a nationally representative sample of men and women in the United States. **J Sex Med 2013;10:2409–2417. doi:** 10.1111/jsm.12198.
14. Belous CK, Wampler RS. Development of the gay and lesbian relationship satisfaction scale. **J Marital Fam Ther 2016;42:451–465. doi:** 10.1111/jmft.12158.
15. Harris PA, Taylor R, Thielke R, et al. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. **J Biomed Inform 2009;42:377–381. doi:** 10.1016/j.jbi.2008.08.010.
16. Harris PA, Taylor R, Minor BL, et al. The REDCap consortium: Building an international community of software platform partners. **J Biomed Inform 2019;95:103208. doi:** 10.1016/j.jbi.2019.103208.
17. Flynn KE, Lin L, Cyranowski JM, et al. Development of the NIH PROMIS® sexual function and satisfaction measures in patients with cancer. **J Sex Med 2013;10:43–52. doi:** 10.1111/j.1743-6109.2012.02995.x.
18. Althof SE, Corty EW, Levine SB, et al. EDITS: development of questionnaires for evaluating satisfaction with treatments for erectile dysfunction. **Urology 1999;53:793–799.**
19. Carley K, Palmquist M. Extracting, representing and analyzing mental models. **Soc Forces 1992;70:601–636.**
20. Scherzer ND, Dick B, Gabrielson AT, et al. Penile prosthesis complications: Planning, prevention, and decision making. **Sex Med Rev 2018. doi:** 10.1016/j.sxmr.2018.04.002.
21. Briles BL, Middleton RY, Celtik KE, et al. Penile prosthesis placement by a dedicated transgender surgery unit: A retrospective analysis of complications. **J Sex Med 2022;19:641–649. doi:** 10.1016/j.jsxm.2022.01.518.
22. Hoebeke P, de Cuypere G, Ceulemans P, et al. Obtaining rigidity in total phalloplasty: experience with 35 patients. **J Urol 2003;169:221–223. doi:** 10.1097/01.ju.000004221268181..25.
23. Kocjancic E, Jaunarena JH, Schechter L, et al. Inflatable penile prosthesis implantation after gender affirming phalloplasty with radial forearm free flap. **Int J Impot Res 2020;32:99–106. doi:** 10.1038/s41443-019-0153-8.
24. Wu S-H, Shen B-H, Perng C-K, et al. Complications of free-flap procedures for phalloplasty in female-to-male transgender surgery: 25-year experience a single medical center. **J Chin Med Assoc 2022;85:341–345. doi:** 10.1097/JCMA.0000000000000677.
25. Ganor O, Taghinia AH, Diamond DA, et al. Piloting a genital affirmation surgical priorities scale for trans masculine patients. **Transgend Health 2019;4:270–276. doi:** 10.1089/trgh.2019.0038.