EPITHESIS VERSUS PROSTHESIS IN POST-PHALLOPLASTY TRANSGENDER PEOPLE

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1. To generate initial data on whether a penile epithesis (ElatorTM) is a potential alternative to a penile prosthesis (ZSITM 475 FtM) in post-phalloplasty transgender individuals. 2. To assess participcant and partner expectations and experiences...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56636

Source
ToetsingOnline

Brief title
EROS

Condition

- Other condition

Synonym
Erectile dysfunction, sexual problems

Health condition

Erectiele functie, seksuele functioneren

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Ziekenhuis Gent
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Epithesis, Phalloplasty, Prothesis

Outcome measures

Primary outcome

- Percentage of participants choosing either for the prosthesis or the epithesis at the start of study.

o At baseline, participants will get information on both the prosthesis and the epithesis and will be free to choose between them. This difference in percentage and the reasons for choosing between either will be noted.

- Capability of vaginal and/or anal penetration of the participant*s partner at 1 and 4 months.

o Capability will be defined as full repetitive anal and/or vaginal penetration of the partner while using the epithesis or prosthesis, which was not possible before use or implantation, without pain to participant and/or partner, until the end of the intended sexual intercourse.

o If penetration is not possible, the reasons for this incapacity will be noted

o These measures will be evaluated at 1 and 4 months after start of use and compared between epithesis and prosthesis groups

Secondary outcome

- Feasibility of epithesis use by the participants.

o Feasibility will be defined as the proportion of participants in the

epithesis arm with interest in and willingness to continue use of the external penile epithesis after the study period by both participant and partner.

- Quality of sexual experience (QSE) + specific questions added on experience during diary entry.

o Quality of Sexual Experience questionnaire (15)

o The QSE provides a summative score between 7 and 49. A higher score indicates a better sexual experience.

o At 1, 2, 3 and 4 months the difference between respectively 1m-, 2m-, 3m- and 4m-scores and the baseline score will be calculated. The changes in QEQ-scores will be compared between epithesis and prosthesis groups in both participants and their partners.

- Treatment satisfaction (EDITS) at 1 and 4 months.

o Erectile Dysfunction Inventory of Treatment Satisfaction (16)

o The EDITS provides two summative scores of 0-44 and 0-20 for participant and partner scores respectively. A higher score indicates a better treatment satisfaction. Higher scores indicate better outcome.

o At 4 months the differences in QEQ-scores will be compared between epithesis and prosthesis groups in both participants and their partners.

- Relationship satisfaction, sexual satisfaction, and quality of life (MMQ) at 1 and 4 months.

o The Maudsley Marital Questionnaire (17)

o The MMQ provides three summative scores of 0-80, 0-40 and 0-40 on relationship satisfaction, sexual satisfaction, and overall quality of life. Lower scores indicate better outcome.

o At 1 and 4 months the difference between respectively 1m- and 4m-scores and the baseline score will be calculated. The changes in MMQ-scores will be compared between epithesis and prosthesis groups in both participants and their partners.

- Lower urinary tract symptoms (ICIQ-MLUTS) at 1 and 4 months.

o International Consultation on Incontinence Questionnaire - Male Lower Urinary Tract Symptoms module (18)

o The ICIQ-MLUTS module, consisting of 7 questions, provides a summative score between 0 (asymptomatic) and 24 (most symptomatic) (question 1 - 6) and a bother score between 0 (not bothersome) and 3 (very bothersome) (question 7).

o At 4 months, the difference between 4m-scores and the baseline score will be calculated. The changes in ICIQ-MLUTS-scores will be compared between epithesis and prothesis groups.

- Maximum flow rate (Qmax) at 1 and 4 months.

o The Qmax may only be interpreted is the voided volume exceeds 150ml. Flow rated based on smaller volumes will be considered invalid and will the excluded from further analysis.

o At 1 and 4 months the difference between 1m and 4m Qmax measurements and the baseline Qmax measurement will be calculated. The changes in Qmax will be

compared between epithesis and prosthesis groups.

- Post-void residue (PVR) at 4 months

o The PVR will be evaluated by a trained physician or nurse using sonography. The evaluation will be performed within 10 minutes after adequate uroflowmetry.

o At 1 and 4 months the difference between 1m and 4m PVR measurements and the baseline PVR measurement will be calculated. The changes in PVR will be compared between epithesis and prosthesis groups.

- Complication rate

o Complications in the epithesis group will be assessed over the study period using the Common Terminology Criteria for Adverse Events-(CTCAE) criteria (19).

o Complications in the prosthesis group will be assessed using the Clavien-Dindo (CD) scoring system (20).

o Both CTCAE and CD systems will be dichotomized into non-severe (CTCAE 1-2 or CD 1-2) and severe (CTCAE 3-5 or CD 3-5) events.

o Complication rate will be compared between epithesis and prosthesis groups at 1 and 4 months.

- Cross over rate

o If a participant is not satisfied with the epithesis during the study period, he will be free to opt for an erection prosthesis and will then cross over to the epithesis arm.

o If a participant has had an explantation of the erection prosthesis for any

reason during the study period, he will be free to opt for an epithesis and

will then cross over to the epithesis arm.

Study description

Background summary

Gender dysphoria refers to an inner mental unrest resulting from an incongruity between the assigned biological sex and the mentally experienced sex (1). The generally accepted treatment for gender dysphoria aims to bring a person's physical characteristics in line with his or her perceived gender identity. This gender-affirming treatment consists of a combination of psychological counselling, hormonal therapy and, if desired, genital gender-affirming surgery (GGAS), which involves the removal of the biological reproductive organs and in some cases (part of) the biological sex organs. These can be replaced by surrogate sex organs of the desired sex while maintaining urological and sexual function. In transgender men, metoidioplasty or phalloplasty are performed. In order to be able to proceed to penetrative sexual intercourse, one option can be the implantation an internal erectile prosthesis or the use of an external device or epithesis. Internal protheses form at this point the main method of attaining penile rigidity after phalloplasty. Both malleable and inflatable options are available today. However, these devices, just as the primary GGAS procedures, carry a high risk of complications. Previous research with prostheses originally designed for cisgender men has shown that up to 22% of prostheses was explanted for various reasons including infection, erosion and malfunction within 20 months (5). Another study showed that only 62% of people still had their prosthesis in place after 4 years (6). More recent publications with a prosthesis specifically designed for phalloplasty people (ZSITM 475 FtM, Zephyr Surgical Implants, Switzerland, Europe) have shown explantation rates of 19% and 23% at 9 and 18 months respectively (7,8). The lack of reliable, and durable erectile devices leads to the fact that a large proportion of people either chooses for phalloplasty but never goes on the placement of an erectile prothesis or completely abandons the idea of GGAS under the form of phalloplasty at this point in time (9). As underlined in a recent qualitative study, transgender men may very well be concerned about the complication rates and likely need for additional surgeries associated with the surgical treatments they seek to diminish their gender dysphoria, specifically in penile implant surgery (10). This is further aggravated by the fact that penile implant surgery is associated with higher complication in a transgender population than in a cisgender population (11). Penile prostheses were originally designed for an older cisgender male population with treatment resistant erectile disfunction wishing to regain the capacity of penetrative sexual intercourse. No data exists on what the durability of penile implants

are in a younger and more sexually active population. Furthermore, the placement of a prosthesis is particularly more difficult after phalloplasty as there are no cavernosal bodies with surrounding tunica albuginea that can be used as scaffold for anchoring of the prosthesis to the pubic bone and preventing it from erosion through the skin. Therefore, alternative options for transgender and gender non-conforming people after phalloplasty are needed. Although some may be surgical, it may be interesting for some individuals to have non-surgical options as well (12).
When considering penile epitheses, multiple types are commercially available. One of such devices is a penile lifter or splint and is marketed as the ElatorTM or the ErektorTM for cisgender people with erectile dysfunction after prostate cancer. These devices consist of two rigid rings connected by rigid metal rods. The biggest of two rings is placed around the base of the phallus. The second ring is connected to the metal rods and is placed behind the coronal ridge. By connecting the rods to the ring at the base of the penis, tension and therefore rigidity between the two rings is created. With the device in place, men can then penetrate their partner and remove it again after intercourse. Penile splints were originally designed in the beginning of the 20th century for various reasons of erectile disfunction. Loewenstein was the first to produce a study on his personal re-interpretation of this device in 1941 (13). Originally, these devices have been designed for cisgender men with erectile dysfunction, but social media and patient conversations suggest that post-phalloplasty people have been experimenting with them. Feedback from transgender people using this device can be found on the website of the product manufacturers, but also on social media sites sucht as Tumblr, Youtube, and private Facebook channels. They may form a potential alternative to internal prostheses in transgender people not wishing to undergo further surgery after phalloplasty or in people that have experienced problems after implantation.

Study objective

1. To generate initial data on whether a penile epithesis (ElatorTM) is a potential alternative to a penile prosthesis (ZSITM 475 FtM) in post-phalloplasty transgender individuals.
2. To assess participcant and partner expectations and experiences with the usability of the penile epithesis compared to the penile prosthesis.
3. To assess participant and partner quality of life and before, during and after penile epithesis compared to penile prosthesis use.
4. To assess participant and partner sexual and relationship satisfaction before, during and after penile epithesis compared to penile prosthesis use.

Study design

All post-phalloplasty transgender patients in follow-up at the participating centers who indicate a desire to pursue penetrative sexual contact will be informed of the existence of the study. Furthermore, the study will be

announced on the Ghent University Hospital as well as the Amsterdam University Medical Center website. The investigators will reach out to the transgender health psychologists all over Belgium and the Netherlands to inform them of the existence of the study, and the study recruitment information will be made publicly available on the national transgender information website (Transgenderinfo.be) and their social media channels. Interested participants can contact the researchers in they are willing to participate and will be invited for a study consultation. Recruitment will be done by all principal and sub-investigators of the study in each of the participating centers. Central screening for eligibility will be done by the sub-investigator of the principal center (WiCl) who is a urologic resident experienced in transgender health. All eligible participants will be included upon written and signed informed consent form of both the main participant and their partner.

Upon inclusion, participants and their partners will receive an initial pre-use assessment. Herein, a thorough history taking, and medical file evaluation will take place (See further). Furthermore, both participant and partner will be asked to complete an MMQ and a QSE questionnaire. They will also receive specific questions on the device or prosthesis and sexual experience expectations and concerns. Specific questions on previous sexual experience and interest in penetrative sexual intercourse will be asked.

Study Cohort

After completion of the initial assessment the couples will be invited to perform a penile measurement themselves using the company provided tools and information first. These sizes will be recorded, and a second measurement is performed together with the investigators using the same tools. With the combination of these two, an actual device will be fitted. Only in case of correct fit according to the investigators, the participant can use this device for the rest of the study. In case of a discordant fit, further measurement will take place using devices until the fit is deemed appropriate.

Comparison cohort

Participants will then undergo penile prosthesis implantation of the ZSITM 475 FTM prosthesis with a technique at the discretion of the performing surgeon. In case prosthesis implantation is for any reason deemed impossible to perform, those people will be excluded from the study. The participants are free to have testicular prostheses placed at the same time of surgery if they wish so as this is the general turn of events. After implantation. The participants must refrain at least six weeks from using the prosthesis of having any sexual intercourse using their own genitals so that the implantation site can properly heal. After this healing period, the participants are seen in the urology clinic. Upon discretion of the treating surgeon, the participants will be deemed healed enough for prosthesis use and will receive practical information on how to handle the mechanics of the prosthesis.

Participants and their partners in both groups will be asked to use the epithesis or prosthesis over the course of one month hereafter and record usage in an online diary for every attempt on intercourse. This diary will contain a QSE questionnaire and open-ended questions on device experience for every sexual encounter. During the study period, participants will be free to use a

single layer of condom during penetrative sexual intercourse as this may also be used to prevent sexually transmitted diseases.
At the end of this first month, participants and partners will receive an MMQ questionnaire and EDITS questionnaire to fill out. The participant only will be asked to fill out an ICIQ-MLUTS questionnaire. The couple will also be contacted and invited for study consultation for voiding function evaluation, medical assessment and overall experience. If possible, tips on usage will be provided. Then, participants and partners will be asked to continue usage for another 3 months, during which at least 1 diary completion of both participant and partner (of the same sexual encounter) per month is aimed for.
At the end of these additional 3 months, an overall evaluation will be made by MMQ questionnaire, EDITS questionnaire, accompanied by specific questions on penetrative intercourse and open-ended questions on overall sexual experience and specific device or prosthesis experience. These measures will be taken in both participants and their partners. The participant only will be asked to fill out an ICIQ-MLUTS questionnaire. The couple will also be contacted and invited for study consultation for voiding function evaluation. After the study, the couples in the epithesis group will be free to keep using the epithesis they received.
If a participant is not satisfied with the epithesis during the study period, he will be free to opt for an erection prosthesis and will then cross over to the epithesis arm. The same accounts for prosthesis arm participants. If, for any reason, an explantation of the erection prosthesis was performed during the study period, he will be free to opt for an epithesis and will then cross over to the epithesis arm.
All study data will be collected and stored in REDCap for the duration of the study and stored on a secured hospital-owned server after (24).

Intervention

The intervention group in this study will recieve a penile epithesis (penile attachment) to enable penetration during sexual intercourse instead of an internal erection prosthesis.

Study burden and risks

The main burden to participants receiving treatment within the context of the study compared to those receiving the same treatment outside of it lies mainly in the questionnaires that are required to be filled in at three different moments. This could be considered time consuming.
Furthermore there are no additional risks or burdens associated with participation in the study. Participants are freely able to choose which treatment arm they would like to enter and are therefore not subject to randomization.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Participant and partner age >= 18 years.
- Transgender or gender non-conforming individuals diagnosed according to the DSM-5 diagnostic criteria for gender dysphoria.
- Participants have undergone phalloplasty as a form of genital gender affirming surgery.
- >= 1 year after phalloplasty (any type of flap combination is allowed), performed at the Ghent University Hospital or Amsterdam UMC.
- >= 3 months after coronaplasty and having reasonably pronounced coronal ridge, as defined by the surgeons* expert opinion (This criterion is only obligatory in the eptithesis group, not in the prosthesis group).
- Absence of urethral stricture or other structural problem resulting in voiding dysfunction.
- Established (primary) sexual relationship with partner who is willing to take

part in the study.
- Participant is unable to penetrate the partner (anal or vaginal) adequately sexually without the aid of supportive measures (condom, taping, penile sleeve, penile epithesis or any other measure defined as supportive by the investigators).
- Fit and eligible for erection prosthesis surgery, based on the surgeons* expert opinion.
- No history of erection prosthesis surgery.
- Treatment naïve in the use of the Elatortm or Erektortm epithesis.

Exclusion criteria

- Participant age < 18 years. - Absence of coronaplasty or coronaplasty performed < 3 months ago or coronaplasty did not leave sufficiently pronounced coronal ridge as defined by the surgeons* expert opinion (This criterion is only obligatory in the epithesis group, not in the prosthesis group) - Penile dimensions are not anatomic (e.g. too small or too large). - Underlying LUTDs requiring further investigation and/or treatment. - Participant does not have sufficent sensations in the phallus - No established (sexual) partner and/or partner is not willing to take part in the study. - Participant and/or partner have no interest in penetrative sexual intercourse.

Warnings as provided by the manufacturer, adjust and summarised according to the needs of the target study population:
1. Always apply a water or silicone based lubricant to all areas of the phallus in contact with the epithesis.
2. To make penetration easier at the beginning of intercourse, always prepare with adequate foreplay.
3. Should any painful or uncomfortable physical sensations arise during intercourse cease the activity. Apply more lubricant or change positions if needed. If this does not alleviate the discomfort then stop use of the epithesis immediately to prevent injury.
4. Do not use the epithesis while you or your partner are under the influence of alcohol or drugs that may impair judgement or alter skin sensations or awareness.
5. Do not fall asleep while wearing the epithesis, since prolonged inactivity while wearing the epithesis may cause permanent injury to the phallus.
6. Use of the eptithesis does not prevent transmittion of sexually transmissible diseases. Always wear a condom over the phallus and epithesis in order to prevent this.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2023
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Generic name:	The Elator;The Erektor
Registration:	No

Ethics review

Approved WMO

Date:	06-03-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	B6702023000188
CCMO	NL84339.018.23