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Metoidioplasty With Implantation of a Specific Semirigid Prosthesis

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ABSTRACT

Background: Metoidioplasty is a possibility for penis reconstruction in transmen that could be enhanced by a semi-rigid prosthesis support.

Aim: Describe the surgical technique of metoidioplasty with implantation of a specifically designed semi-rigid prosthesis -the ZSI100D4- and analyze preliminary results.

Methods: Implantation of semi-rigid prosthesis was proposed to transmen who chose metoidioplasty for genital gender affirming surgery in a specialized university hospital.

Outcomes: Surgical outcomes were collected from medical files. Functional outcomes and satisfaction were collected post-operatively with a questionnaire.

Results: A total of 15 patients were operated; the mean length of followup was 22 months (SD = 8.7). Median prosthesis size was 8.5 cm (range: 8.5-10). Seven (46.7%) minor complications (Clavien-Dindo grade 2; 5 wound dehiscence and 2 fistula, managed conservatively) and 1 severe (Clavien-Dindo grade 3b) complication (Hematoma that need surgical revision) occurred. Thirteen patients (86.6%) answered the questionnaire; 11 (84.6%) reported being either "very satisfied" or "satisfied" with the appearance of the new genitalia; 10 (76.9%) could void while standing; and 12 patients (92.3%) answered "not at all" to the question "do you have regrets about this surgery ?".

Conclusion: Implantation of a semi-rigid prosthesis in an enlarged clitoris seems to be a valuable option and can be proposed as another possibility

for the complex surgical answer to neophallus reconstruction in transmen. **Neuville P, Carnicelli D, Paparel P, et al. Metoidioplasty With Implantation of a Specific Semirigid Prosthesis. J Sex Med 2021;XX:XXX-XXX.**

Key Words: Genital Gender Affirming Surgery; Metoidioplasty; Penile Prosthesis; Gender Dysphoria

BACKGROUND

Surgical construction of a penis is a complex but achievable goal for transmen seeking genital gender affirming surgery (gGAS). The ideal technique would have both good surgical results (a low rate of complications, aesthetics of the new genitalia, low donor-site morbidity), and good functional results (urinary function and sexual function).[1] To answer these challenges, 2 main techniques have been developed: the phalloplasty (with many different possible flaps) and the metoidioplasty.[2] The latter consists in the creation of a small penis using a hormonally enlarged clitoris, associated with a complex urethroplasty bringing the urethral meatus to the tip of the preserved glans. Its advantages are a reduced number of surgeries and no donor-site morbidity, while preserving erogenous sensation and allowing voiding in a standing position; its main disadvantage is the small size of the reconstructed penis that does not permit penetrative intercourse and occasionally causes difficulties for voiding standing up.[3]

In order to limit this principal disadvantage, several improvements have been proposed. For example, complete releasing of the clitoral attachment and enhanced urethral reconstruction combined with vacuum therapy,[4] or extensive dissection of the clitoral crura combined with adapted traction device.[5] Another strategy is the use of a semirigid prosthesis that has recently been designed for implantation in small corpus cavernosum, the ZSI100D4 (Zephyr Surgical Implants, Geneva, Switzerland). Its theoretical advantages are to stake the metoidioplasty, avoiding retraction associated with scar tissue, and to permit better handing of the small penis for voiding in a standing position. The aim of the present paper is to describe the surgical technique of

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metoidioplasty with implantation of this specifically designed semi-rigid prosthesis, and to analyze preliminary results.

INDICATIONS FOR PROCEDURE

Trans people seeking medical treatment are provided care by our gender team composed of mental health professionals, endocrinologists, plastic surgeons, and urologists. Genital surgeries are discussed after assessment of the patient by two qualified mental health professionals, following the standards of care of the world professional association for transgender health (WPATH).[6]

For gGAS, the different techniques of phalloplasty and metoidioplasty are considered and a mutually agreed choice of one type of gGAS is made. When metoidioplasty was chosen, urethroplasty and implantation of a semi-rigid prosthesis is proposed after a presentation of its advantages and potential complications.

From the patient's point of view, the main argument for a metoidioplasty is that he wants a small penis because it feels right for him; other arguments include the use of genital tissue for reconstruction, preservation of erogenous sensation, a less heavy operation than the phalloplasty with no donor-site morbidity and a smaller wound area, and the strong possibility of voiding standing up.[7] Arguments against include the desire to engage in penetrative intercourse,[7] which is very rarely reported as possible.[8] Additional arguments against, and more from the physician's point of view, include the presence of a significant quantity of supra-pubic fat that can hide the metoidioplasty. More generally, the hormonally enlarged clitoris should be of sufficient size to propose this technique. The choice between phalloplasty and metoidioplasty is integrated in an individualized approach to best meet a patient's need.

However, according to one of the rare studies reporting the distribution of genital surgeries (in the Netherlands), it seems that before 2010 the majority of patients underwent metoidioplasty whereas since 2010 phalloplasty is the most frequently performed.[9]

ETHICS STATEMENT

This study is part of a larger study evaluating phallus construction in our service specialized in genito-urinary reconstruction (ClinicalTrials.gov Identifier: NCT04314141), which has received financial support from the French association of urology (*Association Française d'Urologie*). All subjects were counseled that there was no safety data available concerning the ZSI100D4 implant and potential complications were detailed. The use of the ZSI100D4 (EC certificate no.15749) received approval from the pharmacological and medical device departments of our institution. All individuals gave informed consent, and a written consent of the patient concerned was given for publication of images.

PREOPERATIVE PREPARATION

According to the WPATH standards of care, genital surgery is possible for transmen after 12 continuous months of appropriate

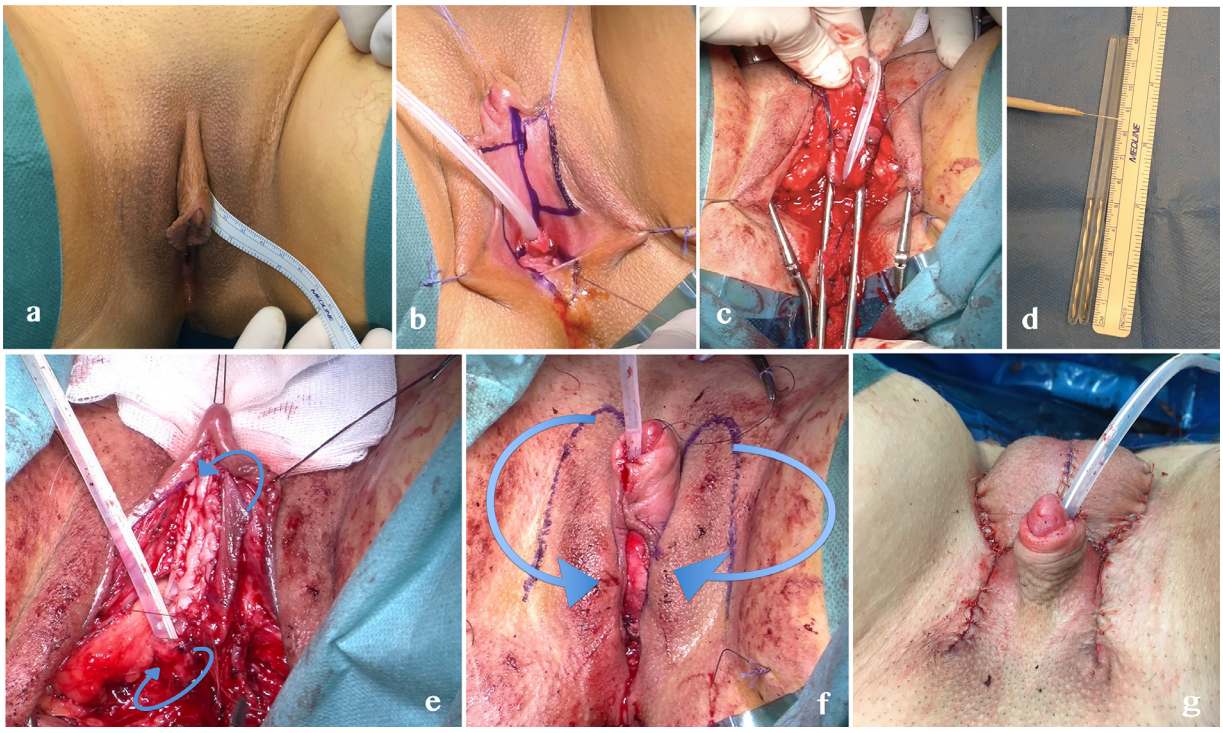

Fig. 1. Surgical proceedings: (a) Measurement of the clitoris; (b) Urethral flaps design; (c) Testing of the proximal dilatation; (d) Prostheses cut at the desire length; (e) Urethral construction; (f) Scrotoplasty; (g) Final outcome.

hormone therapy.[6] This period is indicated to provide a reversible step in experiencing desired gender role before irreversible surgery. This is also required for a metoidioplasty reconstruction, since the maximum expected effect of clitoral enlargement is obtained 1−2 years after masculinizing hormone.[10]

Patients treated in our urology department are, preoperatively, recommended to undergo vacuum-therapy; local transdermal androgen therapy is not proposed because of poor drug product availability. Patients undergo a presurgery urine analysis, and the preoperative aseptic technique follows our institution recommendations for prothesis implantation (shower with antiseptic solution, and two 5-minute washes in the operating room).

INTRAOPERATIVE CONSIDERATIONS

The metoidioplasty technique consists of creating a neophallus using the components of a hormonally enlarged clitoris (Figure 1a). The main objectives are removal of the vaginal tissue − the most frequently, but not always, chosen surgical option, releasing of the clitoris from its urethral plate, and performing an advanced urethroplasty to bring the meatus to the tip of the glans.

Step 1: We start with the removal of the vaginal tissue by picking a vaginal graft that will be used for urethral reconstruction. The graft is harvested from the posterior vaginal wall and reserved. The rest of the vaginal mucosa is then vaporized with a cautery knife after adrenaline serum injection. All mucosa must be carefully removed before closure of the vagina. Circular closure is then performed and must be rigorous in order to prevent formation of emptied space that will be at risk to fill with urine and lead to fistulae or diverticulum formation.

Step 2: In all cases the proximal part of the urethra is constructed using the inner part of the right labia minora and the mucosal part of the urethral plate. Then available tissue is evaluated in order to plan urethral reconstruction. When the left labia minora is sufficiently developed, reconstruction of the distal and ventral part of the urethra can be performed with the inner part of the left labia minora (Figure 1b). If not, an inner labia majora flap can be prepared for this reconstruction. The clitoris is then dissected and released from its urethral plate. Dissection of the corpus cavernosum is performed along the external part of the ischio-cavernous muscle.

Step 3: The prosthesis is inserted before placement of the vaginal mucosa graft in order to prevent local contamination. With the same intention, cavernotomy are performed on the proximal part of the corpus cavernosum after dissecting the ischio-cavernous muscle laterally in order to move away the cavernotomy sutures from the urethroplasty area. In order to prevent damage to the urethral reconstruction, dilatation of the corpus cavernosum must be performed before finalizing the neo-urethra.

Implantation then follows usual steps of semi-rigid penile prosthesis implantation. Each clitoral corpus cavernosa is carefully dilated, proximally and distally, with Mayo scissors and 8 Hegar dilatators. Proximal dilatation is then tested by insertion of 2 Hegar dilatators, as for penile prosthesis implantation (Figure 1c).

The prosthesis is then cut to the desired length and implanted (Figure 1d). The ZSI100D4 is 12 cm long (the distal part is composed of a 5 cm-silver rod, and the 7 cm proximal part is made only of silicone) and 4 mm in diameter, and can be cut in its proximal part to adjust the length of the prosthesis (from 5 to 12 cm). The prosthesis is fixed with one stitch of nonabsorbable wire in order to prevent migration, considering the lower density of the albuginea of clitoral corpus cavernosum.

Step 4: After implantation of the prosthesis and closing of corpus cavernosum, the urethra is finally reconstructed from 3 different segments (Figure 1e). The very proximal part is made of a 1 cm-long rotational vaginal flap harvested from the anterior part of the vagina and sutured to the first cm of the mucosa of the urethral plate. The medial part is formed by a tubularized flap of labia minora detached in continuity with the mucosal part of the urethral plate between the glans and the native urinary meatus. Particular attention is given to recover the bulbar part with the bulbo-cavernosus muscle in order to prevent fistula formation at the native urethra where urinary flow is important. The distal urethra is formed by a dorsal part made from an onlay graft of defatted vaginal mucosa, and a ventral part from the contralateral labia-minora flap (or the inner part of the labia majora if the labia minora is too short). The glans wings are finally detached to shape the meatus of the prolonged urethra.

Step 5: The neo-penis shaft is then formed with an appropriate amount of the external part of the labia majora.

Step 6: A scrotoplasty is performed with two labia majora flaps (Figure 1f), detached with maximum of fat tissue in order to provide enough volume.

A video of the surgical technique is available at https://youtu.be/1PgL1b70gp0.

POSTOPERATIVE MANAGEMENT AND FOLLOW-UP

The length of hospitalization is generally from 2 to 4 nights. The patient leaves the hospital with two urinary diversions: a suprapubic catheter and a clamped urethral catheter. A 5-day postoperative antibiotic therapy (amoxicillin and clavulanic acid) and daily dressings are prescribed. The urethral catheter is removed at home on the 7th day after the operation.

A postoperative consultation is conducted on the 15th day after surgery, when an antegrade urethrogram is performed (Figure 2). If the procedure is satisfactory (in particular no fistula nor diverticulum are found) the suprapubic catheter is removed. Another systematic consultation is conducted at the 3rd postoperative month.

For the description of patients herein, surgical data were collected from the patient electronic medical files. Complications are reported according to the Clavien-Dindo classification: complications ≤Clavien-Dindo2 are minor complications; complications

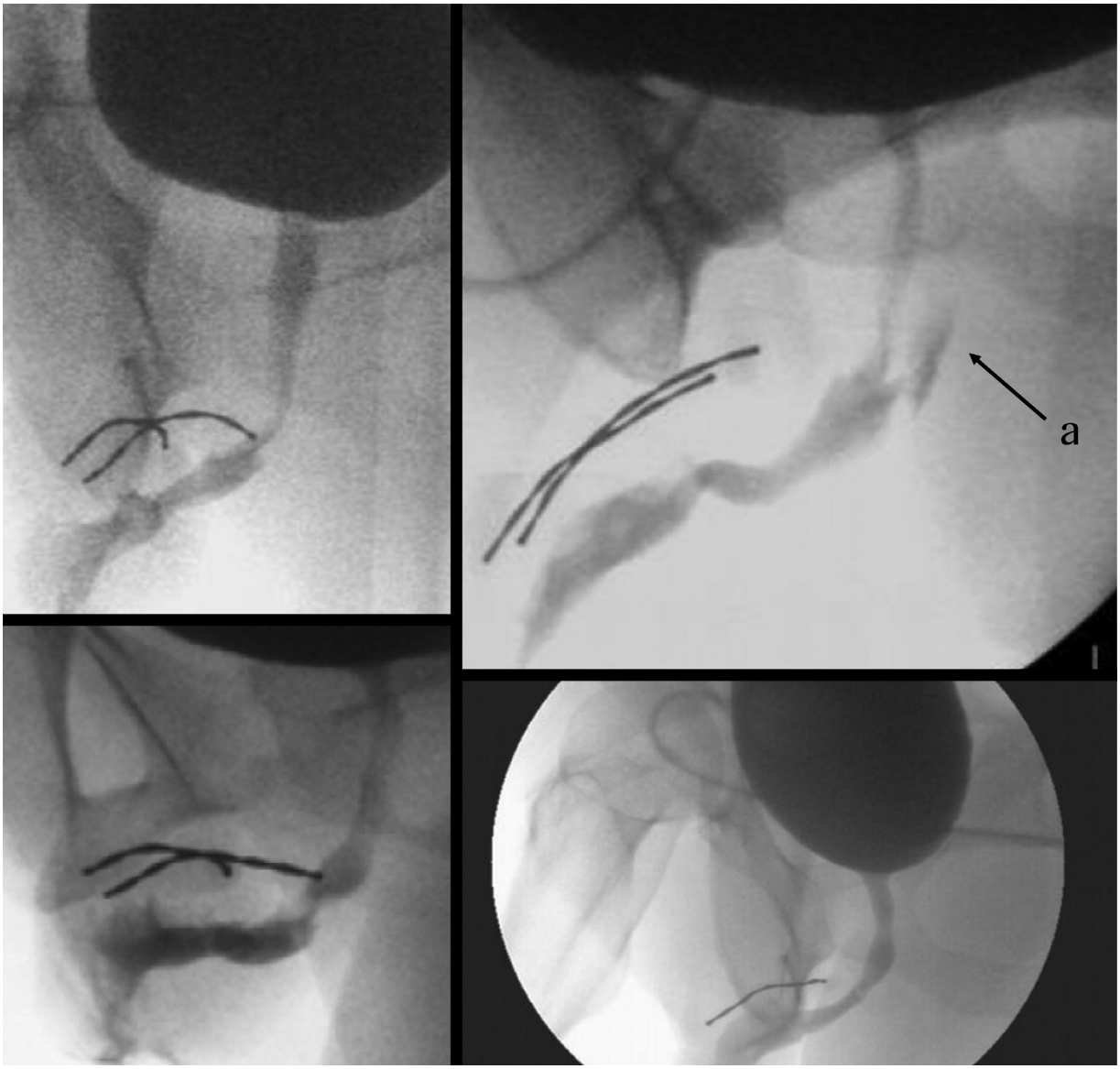

Fig. 2. Post-operative urethrogram ("a" indicates a fistula).

Clavien-Dindo3 require surgical, endoscopic or radiological intervention (under general anesthesia for Clavien-Dindo3b); and complications Clavien-Dindo4 result from organ dysfunction.[11]

A specific interview was conducted, either face-to-face or telephone, in order to collect functional results with a post-operative questionnaire designed for the evaluation of phallus construction. This non-validated questionnaire included queries about post-operative satisfaction, regrets about the surgery (both evaluated with a 5-point Likert scale), and urinary position.

OUTCOMES

A total of 15 patients were operated on from August 2017 to September 2019 by 2 specialized reconstructive urology surgeons. Their general characteristics are summarized in Table 1. Mean length of follow-up was 22 months (SD = 8.7). One patient had only 1 cylinder of the ZSI100D4 implanted. There were 11 patients whose labia minora was sufficiently developed to reconstruct the urethra, by combination with vaginal free graft (Figure 1b). For the other 4 patients, an additional labia majora flap was necessary to build the neo-urethra. Scrotoplasty was performed in 13 patients, of whom 3 in a second procedure. No testicular prosthesis was implanted. Complications are summarized according to the Clavien-Dindo classification[11] in Table 2. The median time of supra-pubic diversion was 16 days (range: 14–44). Two patients had a fistula (Figure 2a) managed with prolonged suprapubic urinary diversion (respectively 40 and 44 days).

A total of 13 patients (86.6%) answered the post-operative questionnaire; two patients were unreachable. Among those who replied, 11 (84.6%) reported being either "very satisfied" or "satisfied" with the appearance of the new genitalia; one patient was "neither satisfied nor unsatisfied"; one patient was

Table 1. General and surgical characteristics

General characteristics (n = 15)	
Mean age at surgery, years (SD)	33.8 (7.1)
Mean duration of general hormonotherapy before surgery, years (SD)	6.2 (3.6)
Mean BMI kg/m^2 (SD)	25.5 (5.5)
Surgical characteristics (n=15)	
Mean operative time, minutes (SD)	288 (46)
Median hospital stay, nights (range)	3.3 (3 - 4)
Median prosthesis length, cm (range)	8.5 (8.5 - 10)
Mean metoidioplasty length, cm (SD) [n=13]	4.1 (0.9)

SD = Standard Deviation
BMI = Body Mass Index

Table 2. Complications

Surgical complications	Classification
Wound dehiscence n = 5	Clavien-Dindo 2
Fistula n = 2	Clavien-Dindo 2
Hematoma n = 1	Clavien-Dindo 3b
Total, n (%)	
7 (46.7%)	Clavien-Dindo 2
1 (6.7%)	Clavien-Dindo 3b

"unsatisfied" after facing unsightly scar retraction. Ten patients (76.9%) could void while standing, and 12 (92.3%) answered "not at all" to the question "do you have regrets about this surgery?". The patient who was unsatisfied reported having regrets about the surgery.

In the largest series to date of a well described metoidioplasty technique,[12] Bizic et al. reported a median length of a neophallus of 5.6 cm (range: 4–10 cm), 46.8% had at least 1 complication (1.4% urethral stricture, 8.8% of urethral fistula), 29.1% surgical revisions (mainly for vaginal remnant followed by complications due testicular prostheses); 94.7% of patient were satisfied with appearance of their new genitalia and all could void while standing. In the four other noticeable series reported,[13–16] the length of the neophallus is not always reported (Vukadinovic et al. report a mean length of 7 cm); the frequency of fistulas ranged from 6.1%[15] to 37.1%.[14] Stenosis is reported in 3 studies, and ranged from 2%[15] to 35.7%.[14] Other complications are those caused by testicular prosthesis (up to 80%,[14]), hematoma, and 1 compartment syndrome of leg.[16]

COMPLICATIONS

The main complications of metoidioplasty are due to the complex urethral reconstruction.[3] Fistulas are frequent and may

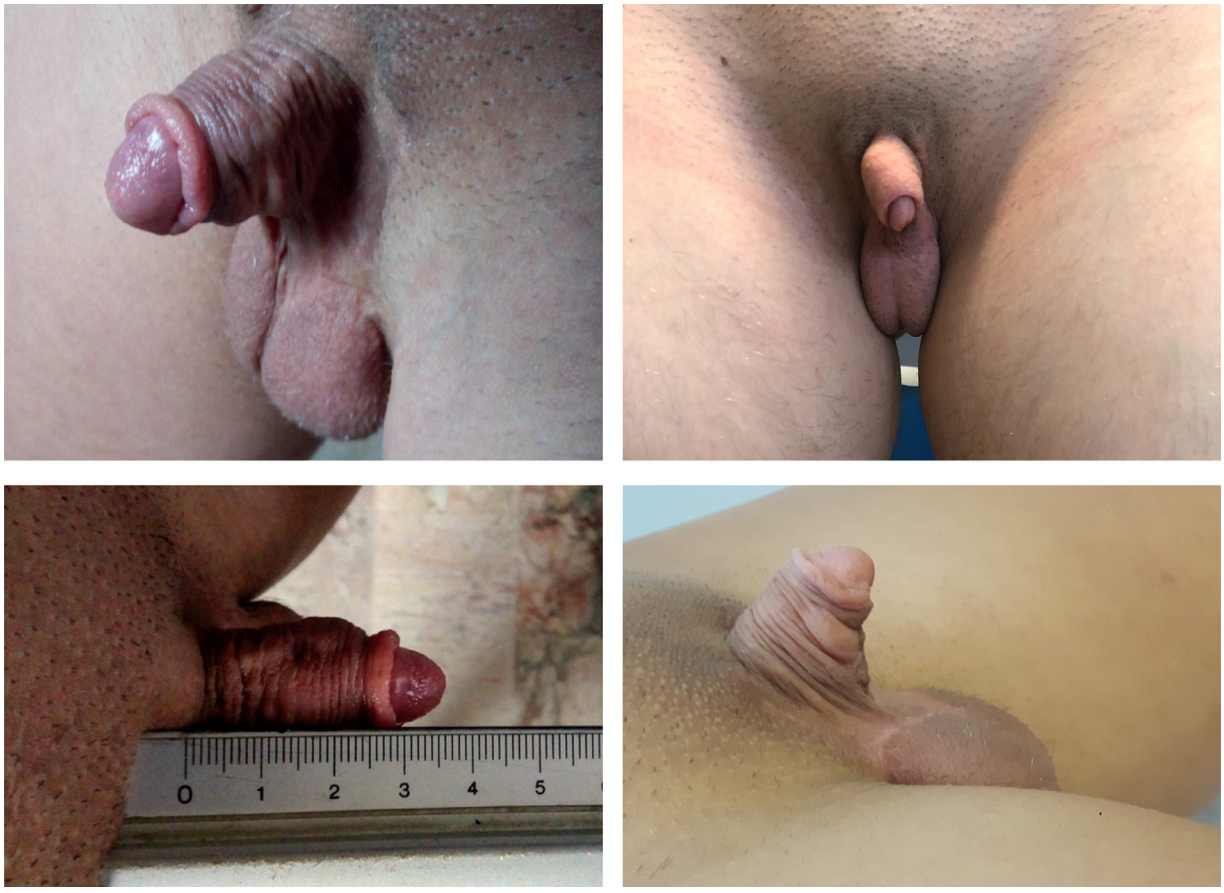

Fig. 3. Post-operative appearance (from 3 to 9 months post-operatively). The two left-side pictures are the same person.

lead to stenosis. Some fistulas can be managed nonoperatively with prolonged urinary diversion but may need surgical repair in case of persistence.

In our experience, the rate of urethral complication; 13.3% fistula — managed conservatively — herein does not seem increased by implantation of a semirigid penile prosthesis, while also considering the limitations inherent to the small sample size of these preliminary results. The most common complication we had to face was wound dehiscence (33.3%), always managed with daily dressings (Clavien 2). Wound dehiscence is very often situated at the junction of the 2 scrotoplasty flap where vascularity is littler.

We report no complication of the semi-rigid ZSI100D4 prosthesis. In particular, there was no infection nor erosion during a mean follow-up of 22 months, which are the complications dreaded considering the possibly less solid albuginea and the proximity of the urethral reconstruction. While the absence of complication is encouraging, these must evidently be confirmed with longer follow-up.

TAKE-HOME MESSAGE

Metoidioplasty with implantation of the ZSI100D4 seems a safe technique allowing to stake the metoidioplasty and may present interesting results. Implantation of a semirigid prosthesis in an enlarged clitoris seems to be a valuable option and can be proposed as another possibility for the complex surgical answer to neophallus construction in transmen (Figure 3)

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Conflicts of Interest: D. Carnicelli is a consultant for Boston Scientific and Coloplast. N. Morel-Journel is a consultant for ZSI, Boston Scientific, and Coloplast. A. Ruffion is a consultant for Boston Scientific. P. Neuville and P. Paparel report no conflicts of interest.

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