



Impact of the initial experience in the penile inversion vaginoplasty technique on satisfaction levels: a pilot retrospective cohort study

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Background: There is a growing interest in reporting satisfaction levels of transgender women undergoing vaginoplasty surgery. The lack of information regarding satisfaction during the initial experience of the vaginoplasty technique, and the moderate morbidity related to the surgery, could discourage the immersion of new groups in initiating a program of this kind. Therefore, we aim to report patients' level of satisfaction during our initial experience in the penile inversion vaginoplasty technique.

Methods: Retrospective study of patients who underwent penile inversion vaginoplasty in our center between September 2019 and August 2021. Surgery technique, demographic data, preoperative clinical variables, and short and long-term follow-up are described. Six months after surgery, a survey elaborated by the research team was conducted by phone. The score goes from 1 to 5, and it evaluates satisfaction on esthetics, functional, psychosocial, and global aspects.

Results: Twenty patients underwent penile inversion vaginoplasty in our center during the described period. The average age was 35.6 years old, the mean body mass index (BMI) was 24.7 kg/m², and they presented low comorbidity. Half of the patients presented at least one complication, most of which were minor. One patient was urgently reoperated due to bleeding, and three patients were reoperated on a scheduled basis from minor surgeries. 90% of the patients answered the questionnaire. The most common answers to all four areas covered (esthetics, functional, psychosocial, and global) were satisfied or very satisfied, resulting in a mean over four points in each one of the sections. Lastly, 94.4% of the patients reported being satisfied with their choice of having undergone surgery.

Conclusions: Our initial experience in penile inversion vaginoplasty reveals good satisfaction results at short follow up.

Keywords: Learning curve; initial experience; vaginoplasty; satisfaction

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Introduction

Gender dysphoria, defined as the marked incongruence between one's experienced/expressed gender and the assigned one (1), has increased over the years. In this way, the demand for surgical procedures to obtain the genital appearance of the desired sex has also risen (2).

Vaginoplasty is the surgery performed on transgender women who desire to change the aspect of their external genitalia towards a feminine appearance. The most employed techniques are the inversion of the penis skin (with or without scrotal graft) and the creation of the neovagina out of the bowel (3). The aim is to create a functional vulva, a vagina that allows penetration, a sensible clitoris, a urethra enabling comfortable micturition and, esthetic major and minor labia.

The literature illustrates series describing esthetic, functional results, and complications with less interest from the scientific community towards the degree of satisfaction patients experience after surgery.

The percentage of complications varies among the different series, but it is not insignificant. The most severe complications (stenosis, fistulas, prolapses) may happen in 10% of cases (4), and rates of reoperation can get over 50% (5).

The moderate morbidity associated with the surgery and the low tolerance with suboptimal results could discourage the immersion of new workgroups on the procedure of vaginoplasties.

Levels of satisfaction described in the literature correspond mainly to groups with high casuistry, generally reporting remarkable results in quality life improvement (6,7). In this sense, cosmesis and functionality have been proposed as the main factors correlated to postoperative satisfaction (8). Remarkably, few groups have analyzed patients' satisfaction during the learning curve or at the initial experience of a program of this kind.

In order to develop the penile inversion vaginoplasty technique at our center, a multidisciplinary unit was created, joining urology and plastic surgery services.

This article aims to assess the impact that the initial experience in the penile inversion vaginoplasty technique may have on the patients' satisfaction levels. We present the following article in accordance with the STROBE reporting checklist (available at <https://tau.amegroups.com/article/view/10.21037/tau-22-108/rc>).

Methods

A retrospective cohort pilot study was conducted on a

prospectively collected database between September 2019 and August 2021 regarding the first consecutive cases of penile inversion vaginoplasties and scrotal graft performed in our hospital with a minimum follow-up of 6 months. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Research Ethics Committee of the Hospital Universitari of Bellvitge (Reference No. PR161/22) and individual consent for this retrospective study was waived.

Patients were referred from an attention center for transgender people. Inclusion criteria were as follows: Age over 18 years old, hormonal treatment for at least one year, body mass index (BMI) between 17 and 32 kg/m², American Society of Anesthesiologists (ASA) score below 3 and, non-active infection.

Six months after surgery, measures of the neovagina and, at the same time, patients' satisfaction was registered. A telephonic survey was elaborated (Appendix 1), assessing the satisfaction of esthetic, functional, psychosocial, and global areas using a Likert scale (1 to 5). The person carrying out the interview was unrelated to the research team.

Preoperative evaluation

The patient's anatomy is explored at the first visit, and the procedure and postoperative care are explained. Pelvic floor exercises were recommended and encouraged to be carried out as soon as they entered the waiting list. Tobacco withdrawal at least four weeks before surgery was also recommended, and the cessation of hormonal treatment two weeks before. The patient had to follow a low-residue diet the three days before the surgery and apply an enema the night before.

Surgical intervention

For antibiotic prophylaxis, 1.5 grams of endovenous cefuroxime was used. The surgery starts designing the flap (Figure 1). Scrotum skin is dried out, and bilateral orchiectomy is performed (Figure 2A). The corpora cavernosa and both penile and bulbar urethra are identified and dissected. With the aid of Bresky valves, the neovaginal canal is made within the rectoprostatic space. Partial section of the levator muscles bilaterally allows the neovaginal diameter to become wider (Figure 2B). Dissection of the urethra from beneath the glans to the corpora cavernosa decussation is made (Figure 2C). Instillation of diluted adrenaline helps the creation of the neoclitoris by using

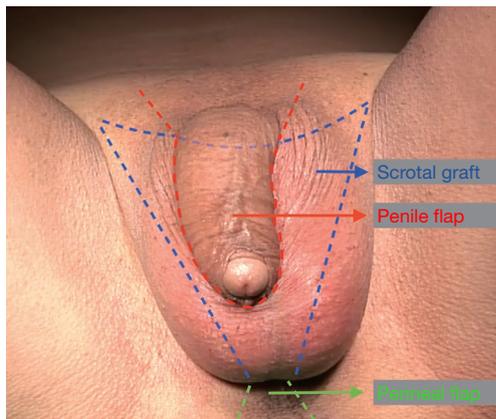


Figure 1 Design of the penile and perineal flaps and scrotal graft.

an ellipse from the glans and a foreskin flap (*Figure 2D*). Degloving of the penis skin and dartos and removal of the ventral aspect of both corpora cavernosa preserving the dorsal albuginea and the neurovascular bundle. Excision of the remaining sinusoidal muscle tissue is performed. Construction of the neoclitoris and fixation to the proximal cavernous remanent. The creation of labia minora is made either from the foreskin flap and the laterals of the glans or through a ventral and dorsal opening through the urethra, depending on the anatomic features of each patient (*Figure 3A*). Meticulous hemostasia over the neovaginal canal is made. Widening of the penile flap up to four centimeters of diameter and creation of the neovaginal proximal aspect with the scrotal skin graft placed over a gauze-filled double condom (*Figure 3B*). Electrocoagulation of hair follicles, insertion of the penile and scrotal skin and attachment to the neovaginal cavity. Placement of a 16Ch Foley catheter, confection of urethral neomeatus, and labia minora. Fixation and closure of the penile flap to the perineum's skin. Suture of labia majora and labia minora fixed to each cavernous ipsilateral body. Placement of the surgical drains, layers closure, and placement of the gauze package with a compressive dressing (*Figure 3C*).

Postoperative care

We recommend absolute bed rest during the first 72 hours after surgery; meanwhile, daily administration of low-molecular-weight heparin and intermittent pneumatic compression is mandatory. The external dressing is later removed and they start ambulation. On the sixth day after surgery, the internal dressing, the gauze pack, and the

urinary catheter are removed. Before hospital discharge, patients are reminded how to wash the neovagina and proceed with the dilatations.

Follow-up visits are scheduled weekly for the first month, monthly up to the sixth month, and annually after surgery. The frequency of dilatations decreases in time from the initial five recommended for the first three months to once or twice a week after the first year.

Statistical analysis

A descriptive analysis was performed. Categorical variables were expressed as percentages. Chi-squared test was used to compare patient global satisfaction with the development of complications or the need for reintervention. Continuous data was presented as means \pm standard deviation (SD) or medians (interquartile range, IQR), depending on distributions. Values scoring $P < 0.05$ were considered statistically significant. The statistic study was carried out using Stata[®] 14 software.

Results

A total of 20 patients went through a penile inversion vaginoplasty with a follow-up of 9.5 months (SD 0.9, 95% CI: 7.6–11.4). The mean age was 35.6 years old (SD 2.6, 95% CI: 30.1–41.2), and the average BMI was 24.7 kg/m² (SD 0.97, 95% CI: 22.6–26.7). Two patients were lost during follow-up. *Table 1* shows the main basal characteristics of the patients.

Two intra-operative complications were registered: an urethral and a rectal injury. Both were identified and repaired intraoperatively with primary closure. The following evolution of both patients was satisfactory. See *Table 2* for data from the perioperative period.

Throughout the first month, 50% of patients developed at least one complication, most of them being minor. Three patients presented urinary retention, which was solved by temporary catheterization. Two patients required blood transfusion, and four febrile episodes were recorded. Antibiotic therapy was the only necessary measure in these cases.

One patient was readmitted to the hospital due to periurethral bleeding after a dilatation on day 13 after surgery. She required surgical revision because of the failure of conservative measures. No other visits to the emergency room were registered.

Up to the end of the follow-up, four patients were

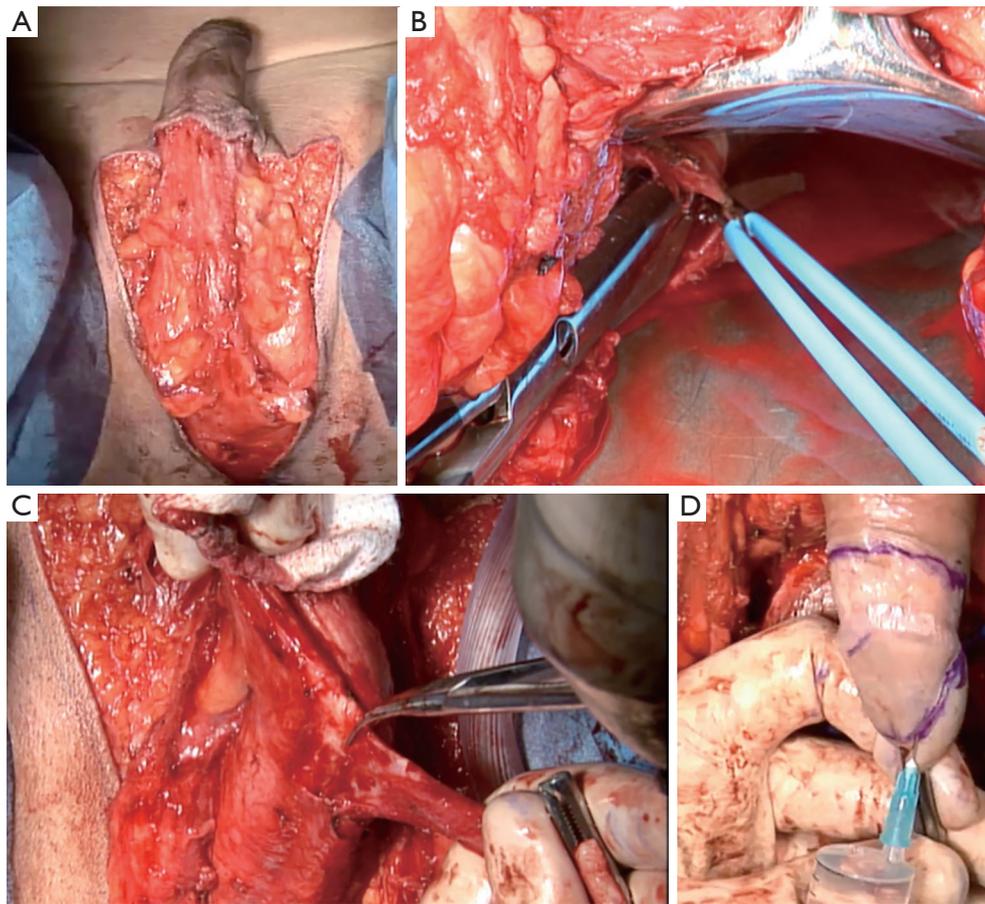


Figure 2 Initial surgical steps. (A) Skin is removed and bilateral orchiectomy performed, (B) section of the levator muscle, (C) proximal dissection of the penile urethra, (D) instillation of adrenaline prior to neoclitoris construction.

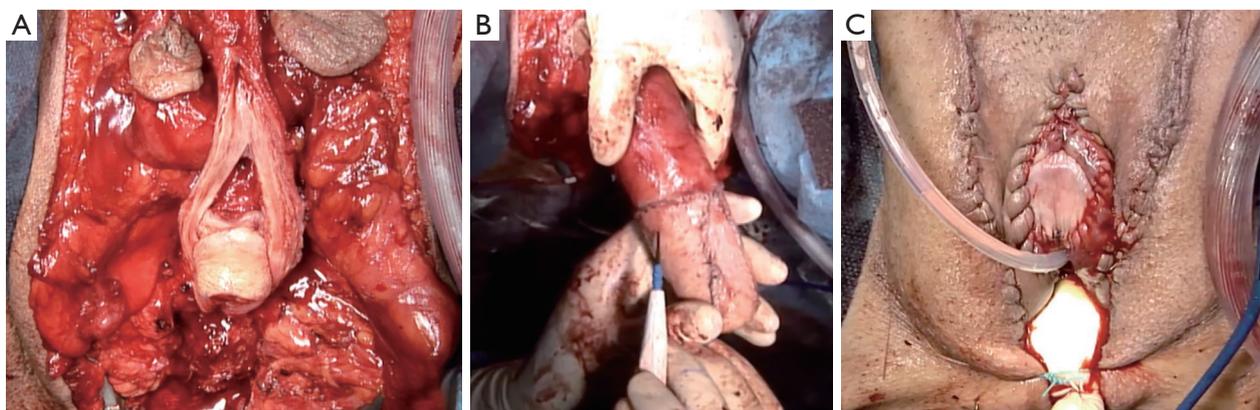


Figure 3 Reconstruction process and result. (A) Creation of the labia minora, (B) coagulation of hair follicles, (C) esthetic result before the dressing placement.

Table 1 Preoperative variables

Variable	Number	Percentage
Total of patients	20	100
Active smoking	10	50
ASA I-II	19	95
Comorbidities		
Hypertension	1	5
Diabetes mellitus	1	5
HIV	3	15
HCV	1	5
Tuberculosis	2	10
Depression	1	5
Asthma	1	5
Charcot-Marie-Tooth disease	1	5

ASA, American Society of Anesthesiologists score; HIV, human immunodeficiency virus; HCV, hepatitis C virus.

reoperated. The aforementioned urgent intervention and three minor outpatient surgeries: a periurethral granuloma excision, a labiaplasty of labia majora, and the insertion of skin grafts upon the vaginal introitus due to partial necrosis of the penile skin flap. Finally, a patient developed distal stenosis of the neovagina with minimal functional impact, so she has decided not to be reoperated.

Eighteen out of the 20 patients (90%) accepted to participate in the satisfaction survey. The results are shown in *Table 3*.

Globally, the most frequent answers in esthetics, functional, psychosocial, and global sections are satisfied (4/5) or very satisfied (5/5), obtaining an average higher than four in every question.

Thirteen out of the eighteen patients are very satisfied with the vaginal dimensions (width and depth) and the clitoris appearance, resulting in the best scores within the esthetics section. Regarding the sexual area, around 30% of patients did not answer their satisfaction with sexual intercourse or a change with their sexual life because they had not had sexual relations yet.

Two patients manifested to be very unsatisfied regarding their orgasms. One of them explained to feel “mentally blockade”, so she believes it is a mental issue rather than an anatomical problem. The second patient presents a harmful sensitivity during clitoral stimulation, which makes it impossible to achieve orgasms. Other than this,

88.9% of patients claim to be very satisfied with their clitoris sensitivity, being one of the items with the highest satisfaction degree.

Finally, almost 95% of the patients are very satisfied with the choice of having undergone surgery. Notably, no association was found between global satisfaction and the development of complications ($P=0.137$) or the need for reoperation ($P=0.197$).

Discussion

Our initial experience in the penile inversion vaginoplasty is associated with good results of global, esthetic, functional, and psychosocial satisfaction at short follow up. A suitable formation prior to the immersion in this project enabled us to reach global satisfaction levels higher than 90%. These results match with the high rates of satisfaction described by more experienced groups (6,7).

Since the publication of the first vaginoplasty in 1930 (9), different surgical approaches have emerged seeking improvement of transgender women's quality of life. An adequate feminine genitalia appearance was initially the primary goal, and then, functionality overcame as a new purpose.

In this sense, subjects of interest reported in the literature have also evolved. Indeed, the focus has moved from the description of the surgical technique, the esthetic/functional results, or the possible complications towards highlighting the importance of the results patients perceive after surgery (10).

Due to the absence of validated questionnaires addressed to transgender women's satisfaction after the vaginoplasty, we elaborated a survey (*Appendix 1*) collecting esthetic, functional, psychosocial, and global satisfaction related to the operation. A Likert scale was designed to score from 1 to 5 the answers, where one equals “Very unsatisfied” and five means “Very satisfied”.

It is traditionally assumed that any surgical technique initiation implies higher complications and, as a result, undesirable dissatisfaction. Vaginoplasty may be a highly exigent technique and is associated with a large proportion of complications (4) and reoperations (11). Training on cadavers under expert supervision has been proposed as a tool for optimizing the learning curve (12).

The learning curve is the initial development period of an individual's abilities on a procedure, essential to the patient's safety and surgical training (13). Falcone (14) and Whynott *et al.* (15) analyze their learning curves retrospectively, obtaining different results.

Table 2 Data from the intraoperative and postoperative period

Variable	Mean (SD; 95% CI)/median (IQR)	Range
Operative time, minutes, mean (SD; 95% CI)	253.4 (9.7; 232.9–273.8)	170–335
Intraoperative bleeding, mL, median (IQR)	430 (350–600)	300–1,500
Hemoglobin decrease, g/dL, mean (SD; 95% CI)	3.9 (0.3; 3.2–4.7)	2.1–7.3
Hospital stay, days, median (IQR)	8 (8–9)	6 - 15
Follow-up, months, mean (SD; 95% CI)	9.5 (0.9; 7.6–11.4)	180–685
Neovaginal depth, cm, mean (SD; 95% CI)	14.6 (0.2; 14.1–15.1)	120–160
Neovaginal width, mm, median (IQR)	30 (30–34.5)	30–37

SD, standard deviation; CI, confidence interval; IQR, interquartile range; mL, milliliters; g, grams; dL, deciliters; cm, centimeters, mm, millimeters.

Table 3 Results from the satisfaction survey

Patient-reported outcome	Mean (SD)	Very unsatisfied, n (%)	Unsatisfied, n (%)	Neither satisfied nor unsatisfied, n (%)	Satisfied, n (%)	Very satisfied, n (%)	No reply, n (%)
Esthetics							
I'm ... with the depth of my vagina	4.7 (0.14)	–	–	1 (5.6)	4 (22.2)	13 (72.2)	–
I'm ... with the width of my vagina	4.7 (0.14)	–	–	1 (5.6)	4 (22.2)	13 (72.2)	–
I'm ... with the appearance of my genitalia	4.5 (0.16)	–	–	2 (11.1)	5 (27.8)	11 (61.1)	–
I'm ... with the appearance of my labia majora and menora	4.4 (0.2)	–	1 (5.6)	1 (5.6)	6 (33.3)	10 (55.6)	–
I'm ... the appearance of my clitoris	4.6 (0.18)	–	1 (5.6)	–	4 (22.2)	13 (72.2)	–
Functional							
I'm ... with urination	4.2 (0.2)	–	1 (5.6)	2 (11.1)	7 (39.0)	8 (44.4)	–
I'm ... with the urinary stream's direction	4.1 (0.29)	1 (5.6)	1 (5.6)	3 (16.7)	3 (16.7)	10 (55.6)	–
I'm ... with the urinary stream's force	4.9 (0.08)	–	–	–	2 (11.1)	16 (88.9)	–
I'm ... with the urinary continence	4.4 (0.2)	–	–	4 (22.2)	3 (16.7)	11 (61.1)	–
I'm ... with the defecation	4.8 (0.13)	–	–	1 (5.6)	2 (11.1)	15 (83.3)	–
I'm ... with bowel continence	5	–	–	–	–	18 (100.0)	–
I'm ... with sexual intercourse	4.3 (0.24)	–	–	3 (16.7)	3 (16.7)	7 (38.9)	5 (27.8)
I'm ... with orgasms	4.2 (0.42)	2 (11.1)	–	1 (5.6)	1 (5.6)	13 (72.2)	1 (5.6)
I'm ... with my clitoris sensitivity	4.8 (0.23)	–	1 (5.6)	1 (5.6)	–	16 (88.9)	–
Psychosocial							
After the vaginoplasty I'm ... with myself	4.8 (0.17)	–	–	1 (5.6)	1 (5.6)	16 (88.9)	–
After the vaginoplasty I'm ... with others	4.3 (0.28)	–	–	5 (27.8)	2 (11.1)	11 (61.1)	–
After the vaginoplasty I'm ...with my sexual life	4.5 (0.19)	–	–	1 (5.6)	4 (22.2)	7 (38.9)	6 (33.3)
Global							
Generally speaking, I'm ... with the whole process	4.8 (0.13)	1 (5.6)	–	–	3 (16.7)	14 (77.7)	–
I'm ... about having undergone surgery	4.9 (0.08)	–	–	–	1 (5.6)	17 (94.4)	–

Table 4 Comparison of surgery results among different learning curves

Variable	Falcone	Whynott	Bellvitge Hospital
Number of patients	69	43	20
Follow up, months	5	17	16
Operative time, minutes	245	225	253
Intraoperative complications, %	1.45	0	10
Transfusions, %	1.45	6.98	10
Hospital stay, days	8	2.9	8
Reoperation, %	>26	20	20
Vaginal depth, cm	12	Not available	14.6

Falcone (14) registered improvement on surgical time, vaginal depth, hospital stay, and percentage of intraoperative complications as they gained experience. However, these variables did not change over Whynott *et al.* learning curve (15). They did identify a shorter surgical time and a faster achievement of clitoris sensitivity. Both authors believe that the stability of results is obtained with a minimum of 30 interventions. These results are summarized in *Table 4*, along with our results. Neither Falcone nor Whynott analyzed patients' satisfaction.

Literature provides only two studies that evaluate patient satisfaction after an initial program of vaginoplasties (16,17). The current problem of collecting and comparing satisfaction results lies in the absence of validated questionnaires aimed at this population. For this reason, initial and established series use either questionnaires validated for non-transgender population or self-developed questionnaires (18,19); the latter being the case of the present study.

Loree *et al.* (16) report a self-elaborated questionnaire aimed at 24 patients from their initial experience. They describe 92% satisfaction (22/24) on esthetic results, orgasms during penetration, and general satisfaction.

Bernal Riquelme *et al.* (17) show their satisfaction results combining validated surveys (Female Sexual Function Index (FSFI), Female Genital Self-Image Scale (FGSIS), International Prostate Symptoms Score (IPSS), American Urological Association-Quality of life (AUA-QoL) with independent self-develop questions. 9 out of 10 patients answered these questionnaires obtaining the following scores: 16.5 on FSFI, 25.4 on FGSIS, 6.7 on IPSS and 0.8 on AUA-QoL. When asked on a scale from 0 to 10 about their satisfaction regarding esthetic results, an 8.8 score is

described, and a 9.0 in the positive impact on their quality of life. The lowest satisfaction outcomes correspond to sexual intercourse, their partner's satisfaction, and the neovaginal depth, having obtained an average depth of 13.7 cm. This result contrasts with the minimum of 11 cm depth described as optimal by the literature (20). In this way, it becomes crucial to clarify patients' expectations and possibilities of achieving them before surgery to obtain satisfactory results.

The present study revealed an average above four points in all four areas analyzed (esthetics, functional, psychosocial, and global). We observed a lower satisfaction on the urinary stream's direction (4.1), labia appearance (4.4), the satisfaction with sexual intercourse (4.3), and with the orgasms (4.2).

Most importantly, 95% of patients rated five on the choice of having undergone surgery. This score is consistent with the percentage of regret described in the literature. A recent systematic review (20) shows less than 1% of total regret and 5.5% of some regret.

Massie *et al.* (6) report the largest series of satisfaction results at one single center (117 patients, 66 participants). A non-validated questionnaire with binary answer (yes/no) is employed, which describes a satisfaction of 94% regarding the surgery. Low satisfaction (60%) with vaginal depth is once more present; however, measures of the neovagina are not described, so few conclusions can be drawn. In the present study, with a vaginal depth of 14.6 cm, this item represents one of the highest rates of the survey (4.7). We believe that our multidisciplinary team of urologists and plastic surgeons has been critical to reaching a good balance between esthetic and functional results. Although an association between complications and satisfaction

results was not established in our experience, Massie found that minor complications correlate the most with patient dissatisfaction. Intravaginal and excessive external scarring, prolonged pain, hematoma/bleeding, and loss of sensation were the top predictors of negative patient satisfaction.”

In conclusion, the analysis of our initial experience in the first vaginoplasties performed at our center reveals high satisfaction levels at six months of follow-up.

Limitations

The absence of validated questionnaires for this population hinders the comparison of satisfaction levels. The GENDER-Q, which is on a validation stage, might allow us to standardize results (21).

The patients from this study were mainly of normal weight, and they barely presented comorbidity. A population of higher surgical risk and, consequently, higher risk of complications may negatively affect satisfaction results. However, this association was not found in the present study.

Finally, this study was carried out within a public health system, and likely, the absence of economic impact on the patients might positively influence their satisfaction.

Conclusions

Our initial experience of penile inversion vaginoplasty is associated with good satisfaction results regarding global, esthetic, functional, and psychosocial aspects at short follow-up. The arrangement of a multidisciplinary team with previous training on the surgical procedure and management of complications is essential to attain adequate satisfaction levels.

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Footnote

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Data Sharing Statement: Available at <https://tau.amegroups.com/article/view/10.21037/tau-22-108/dss>

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at <https://tau.amegroups.com/article/view/10.21037/tau-22-108/coif>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Research Ethics Committee of the Hospital Universitari of Bellvitge (Reference No. PR161/22) and individual consent for this retrospective study was waived.

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Appendix 1 Satisfaction survey elaborated by the research team

ESTHETICS	SCORE
I'm ... with the depth of my vagina	1-5
I'm ... with the width of my vagina	1-5
I'm ... with the appearance of my genitalia	1-5
I'm ... with the appearance of my labia majora and menora	1-5
I'm ... the appearance of my clitoris	1-5
FUNCTIONAL	
I'm ... with urination	1-5
I'm ... with the urinary stream's direction	1-5
I'm ... with the urinary stream's force	1-5
I'm ... with the urinary continence	1-5
I'm ... with the defecation	1-5
I'm ... with bowel continence	1-5
I'm ... with sexual intercourse	1-5
I'm ... with orgasms	1-5
I'm ... with my clitoris sensitivity	1-5
PSYCHOSOCIAL	
After the vaginoplasty I'm ... with myself	1-5
After the vaginoplasty I'm ... with others	1-5
After the vaginoplasty I'm ...with my sexual life	1-5
GLOBAL	
Generally speaking, I'm ... with the whole process	1-5
I'm ... about having undergone surgery	1-5

1: Very unsatisfied; 2: Unsatisfied; 3: Neither satisfied nor unsatisfied; 4. Satisfied; 5. Very satisfied.