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VRIJE UNIVERSITEIT

GENITAL SURGERY IN TRANSGENDER MEN: TURNING CHALLENGES INTO OPPURTUNITIES

ACADEMISCH PROEFSCHRIFT

ter verkrijging van de graad Doctor aan de Vrije Universiteit Amsterdam, op gezag van de rector magnificus prof.dr. V. Subramaniam, in het openbaar te verdedigen ten overstaan van de promotiecommissie aan de Faculteit der Geneeskunde op donderdag 1 april 2021 om 11:45 in de aula van de universiteit, De Boelelaan 1105

door

Muhammed Al-tamimi

geboren te Al-Haroneya, Irak

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"I'M STILL LEARNING"

Michelangelo at age 87

Table of content:

• Introduction

Part 1: Historical overview

• Genital gender affirming surgery in transgender men in the Netherlands from 1989 to 2018: the evolution of surgical care.

Published in the Journal of Plastic and Reconstructive Surgery

Part 2: Reducing urological complications and improving surgical outcomes

- Colpectomy significantly reduces the risk of urethral fistula formation after urethral lengthening in transgender men undergoing genital Gender Affirming Surgery.
 Published in the Journal of Urology
- Genital Gender Affirming Surgery without urethral lengthening in transgender men. A clinical follow-up study on the surgical and urological outcomes and patient satisfaction *Published in the Journal of Sexual Medicine*
- Scrotal reconstruction in transgender men undergoing genital gender confirming surgery without urethral lenghtening: a stepwise approach.
 Published in Urology
- The surgical techniques and outcomes of secondary phalloplasty after metoidioplasty in transgender men: an international, multi-center case series.
 Published in the Journal of Sexual Medicine
- Surgical management of partial or total phalloplasty flap loss in transgender men.
 Submitted at Microsurgery

Part 3: Novel surgical technique

• The first experience of using the pedicled labia minora flap for urethral lengthening in transgender men undergoing anterolateral thigh and superficial circumflex iliac artery perforator flap phalloplasty: a multicenter study on clinical outcomes.

Published in Urology

CHAPTER 1

GENERAL INTRODUCTION

General introduction

Evolution of genital surgery in transgender men

'Transgender' is a term used to describe people whose gender identity differs from the assigned biological sex. Gender identity is an individual's internal, personal sense of being a male or female, a blend of both or neither.¹ However, gender identity involves something other than just anatomy, it also involves the inner sense of one's sex. Identities are usually subdivided in binary (e.g. male or female), non-binary (e.g. gender-fluid and queer) or ungendered (e.g. agender). Increasing numbers of people are being diagnosed with gender dysphoria.² This is likely related to the growing public awareness and social acceptance of transgender persons in recent years.³

Currently, it is estimated that about 355 individuals per 100.000 experience gender dysphoria in some degree. Within this group there are 9.8 individuals per 100.000 who wish to undergo hormonal gender affirmation therapy or gender affirming surgery (GAS).⁴ Various surgical procedures are available for transgender men who opt for GAS, which comprise procedures for top surgery (chest and breast tissue) and bottom surgery (genitalia and reproductive organs). Of these, penile reconstruction in transgender men is considered to be the most challenging procedure.

Genital gender affirming surgery (gGAS) has come a long way since the days when GAS was considered a taboo. Penile reconstruction techniques started to gain attention during the second world war. At that time, Dr. Harold Gillies, who is considered one of the founders of modern plastic surgery, gained experience with penile reconstruction by treating soldiers with genital injuries.⁵ But, genital injuries were rarely life-threatening and therefore received far less attention in comparison with injuries to other body regions and organ systems. Not to mention that 'plastic surgery' was a rare specialty during the second world war.

With his extensive knowledge about penile reconstruction, Gillies performed the first gender affirming penile reconstruction on Laurence Michael Dillon in 1946.^{6,7} Dillon was a transgender man, who was on oral testosterone treatment and previously underwent mastectomy. Back then, Dillon was one of the very few persons to openly admit to being transgender. As opposed to now, there were no peer support groups, nor were transgender people socially accepted, and studies on surgical treatment were nonexistent. Despite the lack of support, Dillon was determined to undergo the challenging surgery.

Until quite recently, transgender people were considered to have a mental disorder. In the eighties, gender identity disorder (GID) appeared as a distinct diagnosis in the American Psychiatric Association's third version of the Diagnostic And Statistical Manual of Mental Disorders(DSM) and this remained a category until the latest edition, the DSM-5.^{8,9} As GID was being considered a 'mental disorder', focus was mostly on providing psychological treatment rather than on physical gender

affirming (surgical) treatment.^{10,11} To give an example, in 1982, leading psychiatrist dr. Leslie Lothstein stated that "Sex reassignment surgery should only be considered as the last resort for a highly select group of diagnosed gender dysphoric patients. As physicians learn new ways to diagnose and treat transsexualism, either sex reassignment surgery will be abandoned as a routine treatment modality or new predictive variables for choosing suitable patients for sex reassignment surgery will be established".¹²

Despite the limited support for GAS, surgical techniques continued to being developed analogous to general reconstructive surgical innovations and the growing knowledge of genital anatomy. With the increase of knowledge on vascular anatomy, vascular territories and perforasomes, an expanding number of free and pedicled flaps were described within the reconstructive surgery field.¹³ With this, more variations for penile reconstruction became available as well. Also, more studies were published on the significant overall improvement in quality of life and psychological functioning after gGAS in transgender men.^{14,15} Gradually, a shift occurred in the treatment of transgender individuals from psychotherapy towards gender affirming treatment, including GAS. Nowadays, there is strong evidence that transgender people benefit primarily from gender affirming treatment of which GAS is an essential part.¹⁵

In 1946, Gillies used tissue from the abdominal wall for penile reconstruction. This technique became known as the Gillies technique and laid the foundation for modern genital gender affirming surgery in transgender men.⁷ For many years, this technique was the standard for penile reconstruction in this population. The introduction of microsurgery in plastic surgery enabled the discovery of new penile reconstruction techniques like the Radial Free Forearm Flap (RFFF) phalloplasty.¹⁶ In 1993, Hage et al. proposed requirements for the ideal penile reconstruction.¹⁷ They stated that the ideal phallus is reconstructed in a one-stage procedure, includes the creation of a neourethra to allow voiding while standing, has both tactile and erogenous sensibility, is bulky enough to tolerate the insertion of a penile prosthesis, produces an aesthetically acceptable result with minimal scarring and without functional loss in the donor area.

Gender affirming surgery in transgender men today

Reconstruction of the male genitalia in transgender men is a challenging procedure. Especially the urethra and the penile erectile tissue have a unique anatomy and function. Currently, there is no proper/likewise matching tissue replacement for these anatomical structures. Even in biological men, repair of damaged penile tissue is associated with a high complication risk.¹⁸ As the ideal reconstruction technique is yet to be discovered, transgender men are offered a wide range of procedures for penile reconstruction.

The genital gender affirming surgical techniques for transgender men can broadly be subcategorized into the 'metoidioplasty' and the 'phalloplasty' techniques.¹⁹ In metoidioplasty,

local tissue is used to construct a small neo-phallus. Preoperative hormonal treatment causes clitoral hypertrophy. The hypertrophied clitoris is released and stretched to reconstruct the neo-phallus and neo-glans. In those who opt for urethral lengthening, the native urethra is lengthened to reach the tip of the neo-penis, enabling some to void while standing.

Described advantages of this technique are the erectile capabilities, preservation of genital erogenous and tactile sensation, limited donor-site scar formation, low perioperative morbidity, a single-stage procedure and considerably lower costs compared to phalloplasty. Possible drawbacks are a relatively small neo-penis, that limits the possibility of having penetrative sexual intercourse. Also, most patients are unable to void from a standing position. ²⁰⁻²²

In phalloplasty, a penis of sufficient size is reconstructed that enables voiding from a standing position and penetrative sexual intercourse (after penile prosthesis implantation). The penis is reconstructed using a pedicled or free flap. Examples of pedicled flaps are: the superficial circumflex iliac artery perforator flap, anterolateral thigh flap or the abdominal flap. Examples of free flaps are the radial free forearm flap, latissimus dorsi flap or fibular flap.^{19,23,24}

As mentioned above, transgender men may have the wish to void from a standing position, which requires neo-urethral reconstruction. However, reconstruction of the neo-urethra has proven to be quite complicated. To give an idea, there are over 250 surgical procedures described for urethral reconstruction in biological men. ^{25,26}

In transgender men, the neo-urethra consists of three parts: the native urethra, the fixed part and the pendulant part.²⁷ Various tissues can be used to reconstruct the fixed and pendulant part. Different types of tissue can be used for reconstruction such as skin, buccal or bladder mucosa grafts, and vascularized skin flaps. This great diversity in surgical techniques and tissue options underlines the complexity of penile reconstruction and indicates the lack of one perfect surgical procedure. All of these tissues have their limitations when compared to autologous tissue, which can lead to specific flap related or urological complications that often require (multiple) secondary procedures.

So, since the second world war an impressive progress has been made in genital gender affirming surgery in transgender men, with currently a great variation in surgical techniques.

Communicating these surgical options, associated risks and benefits, and the alternatives to a surgical intervention is perquisite to high-quality patient care. However, in gGAS in transgender men this is complicated by the fact that the increasing literature on gGAS has a common denominator: the lack of high-quality standardized data.

Although it is reported that most transgender men want to void from a standing position, limited evidence is available on this matter. First off, there is no consensus about the definition 'voiding from a standing position' in transgender men. For example, voiding while standing can be performed in various ways: by pulling the neo-phallus through the zipper hole or by dropping the pants to the ankles to urinate. It also remains unclear if transgender men, who initially were able to void while standing, are still able to achieve this multiple years after surgery. This unstandardized approach can explain the great difference regarding postoperative voiding outcomes in published literature that report on the same surgical technique.

Genital GAS, like all surgeries, comes with various risks, such as infection, bleeding, necrosis and/or postoperative pain. Unlike some other surgeries, however, there is a fairly high risk of complications associated with gGAS in transgender men. The most commonly occurring complications involve the urethra that impede the possibility to void. Especially strictures and fistulas are notorious complications, which may result in personal distress and the need for (multiple) surgical corrections^{28,29}. Reported rates of *urethral fistulas* after phalloplasty with urethral lengthening range from 21% up to as high as 68%.^{24,30-33} Fistulas can develop along the entire neourethra, but the urethral anastomoses are most at risk. The etiology of fistula formation is considered multifactorial (e.g., wound dehiscence, lack of sufficient tissue to cover the anastomosis and pre-stenotic dilatation in case of more distal urethral strictures).

Urethral strictures typically present 6-12 months after surgery with symptoms of a weak stream, straining with urination, and sometimes in combination with a fistula proximal from the stricture. Published numbers in the literature vary from 14 % to 74%.³⁴⁻³⁶ Strictures require surgical intervention with either dilation or urethroplasty. Correction of urethral strictures is considered complex, with a high recurrence rate.²⁸

As noticed, there is a great variance in urological complication rates as noted in current literature. This variation is due to multiple factors, including the various surgical techniques, various patient populations, lack of standardized definitions of complications, such as fistulas or strictures, and differences in clinical follow-up time and methods. Also, most studies report the outcomes of a single surgeon or single center. Available literature consists mostly of retrospective studies including a small number of patients.

Genital GAS can result in serious complications that require a specialized multidisciplinary approach. In contrast to the impressive progress regarding new surgical techniques, little is published on the management of these (less common) complications. For example, flap related complications are considered a serious complication that may cause significant patient morbidity and discomfort. Vascular compromise of the flap typically presents within the first 72 hours, and if recognized early (within hours) it can be salvaged by emergent return to the operating room for a revision of the vascular pedicle. In a later phase, complications of (partial) flap loss can be managed by performing salvage surgery. Providing high quality care includes having knowledge and practical skills of managing these complications. To conclude, an impressive progress has been made with the introduction of new gGAS techniques. Unfortunately, there is a lack of high quality data and standardization that makes is difficult to interpret the published literature and draw conclusions. These surgical techniques can give rise to serious complications of which the management is poorly described in the literature.

Aim

Given the increase in people seeking genital GAS and the paralleled increase of gender clinics worldwide, having insight into current surgical techniques and outcomes is essential. Such information could assist (surgical) healthcare providers in counseling and decision-making and to provide up-to-date information on technical options to transgender men applying for surgery and improve surgical care.

The aim of this thesis is to add to this body of knowledge in three ways by:

First, to present an historical overview of the advances made in the field of genital GAS in a leading high-volume gender surgical clinic.

Secondly, collecting high quality urological data in a standardized fashion and describe (new) surgical techniques to lower urological complications.

Finally, describing highly specialized secondary surgical corrections in genital GAS to increase the knowledge on complication management.

Thesis outline

Part 1. Historical overview

Chapter 1 gives an overview of the surgical revolution at the Amsterdam University Medical Center(AUMC), location VUMC. All surgical techniques from 1989 to 2018 are evaluated and put into perspective.

Part 2. Reducing urological complications and improving surgical outcomes

Chapter 2 describes the effects of a colpectomy on the incidence of urethral fistulas in transgender men undergoing gGAS with urethral lengthening. **Chapter 3** describes the surgical and patient reported outcomes after gGAS without urethral lengthening. The Amsterdam UMC is the first center worldwide to offer transgender men this surgical option. This surgical technique is subsequently described in detail in the form of a video article in **Chapter 4**. In **Chapter 5** the surgical techniques and outcomes in patients who were unsatisfied with their metoidioplasty and underwent a secondary phalloplasty is described. The study was conducted in collaboration with international gender affirming surgical clinics. **In Chapter 6** the surgical management and patients reported outcome measures after (partial) phalloplasty flap loss is presented.

Part 3. Novel surgical technique

Chapter 7 presents a novel surgical technique to lengthen the neo-urethra in collaboration with the Belgrade University Medical Center. The surgical and clinical outcomes were assessed one year postoperatively.

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PART 1

HISTORICAL OVERVIEW

CHAPTER 1

Genital gender affirming surgery in transgender men in the Netherlands from

1989 to 2018: the evolution of surgical care

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SUMMARY

Background: The number of individuals with gender identity incongruence seeking treatment, including genital Gender Affirming Surgery (gGAS), has increased over the last decade. Surgical techniques for gGAS in transgender men have evolved considerably. The aim of this study was to present an overview of the evolution of gGAS for transgender men in a single, high-volume center.

Methods: Retrospective analysis of medical records of all transgender men who underwent gGAS from January 1989 to January 2018 at our institution. Subject demographics, the type of surgery and surgical techniques were recorded.

Results: Over time, four hundred transgender men underwent gGAS. Metoidioplasty was performed in 222 (56%) patients and phalloplasty 178 (44%) patients. Before 2010 the majority of patients underwent metoidioplasty, while since 2010, phalloplasty is performed in most patients. Of 400 patients, 332 (83%) underwent urethral lengthening. The option to undergo genital surgery without urethral lengthening was offered from 2004. Since then, 68 (34%) patients chose to undergo gGAS without urethral lengthening. The choice of surgical options for gGAS in transgender men has grown from five in 1989 to 12 techniques currently. The variety and combination of flaps used for phalloplasty has increased over time. Conversely, the use of some flaps has been abandoned while other flaps re-emerge.

Conclusion: Genital GAS has developed over time in line with reconstructive surgical innovations. In spite of technical advancements, there is no one ideal technique and every technique has specific (dis)advantages. With the increase in surgical options, shared decision making and a shift from surgeon-centered towards more patient-centered care is required.

INTRODUCTION

The number of people with gender identity incongruence that consult specialized gender identity clinics has increased significantly in the past decade.¹ Of transgender men that seek gender affirming care, some express the wish to undergo genital Gender Affirming Surgery (GAS). Multiple studies have found that in general, transgender men report an improved quality of life and satisfactory sexual function after genital GAS, e.g., metoidioplasty and phalloplasty.^{2,3}

Reconstruction of the neo-phallus is considered one of the most challenging surgical procedures in transgender men.⁴ The ideal phallus is reconstructed in a one-stage procedure, includes the creation of a neourethra to allow voiding while standing, has both tactile and erogenous sensibility, is bulky enough to tolerate the insertion of a penile prosthesis, produces an aesthetically acceptable result with minimal scarring and without functional loss in the donor area.⁵

Over time, genital GAS at our center has developed in accordance with the reconstructive surgical innovations, improved knowledge of genital anatomy and the trend towards patient-centered decision making.

A wide variety of surgical techniques is currently offered to transgender men that wish to undergo genital GAS, to meet patients' individual needs. Each technique has its own advantages and disadvantages. The choice for a specific surgical technique depends on the patients' individual desires and expectations, psychological wellbeing as well as the surgical feasibility of the procedure.⁶ This underscores the importance thorough pre-operative counseling and knowledge about surgical options, their risks and benefits.

To date, few studies have addressed the evolution of genital GAS in transgender men. Given the increase in people seeking genital GAS and the paralleled increase of gender clinics worldwide, having insight into this matter is essential.^{1,7,8} Such information could assist gender clinics in the field to provide up-to-date information on technical options to transgender men applying for surgery. The aim of this study was to present an overview of the evolution of genital surgical care over time for transgender men in a single, high-volume center. More than 95% of transgender men in the

Netherlands undergo genital GAS in our clinic; the Amsterdam University Medical Center, location VUmc, ideally placing it as a marker for trends.

PATIENTS AND METHODS

All transgender men, who underwent genital GAS between January 1989 and January 2018, were retrospectively identified form the hospital records of our institution. A systematic retrospective chart review was conducted, recording the following data: (1) date of surgery, (2) surgical team composition (plastic surgeon, urologist and/or gynecologist), (3) type of genital GAS (phalloplasty or metoidioplasty), (4) phalloplasty flap type (radial free forearm flap (RFFF)), anterolateral thigh (ALT) flap, superficial circumflex iliac artery perforator (SCIP) flap), abdominal flap (AF), lateral upper arm flap and fibula flap (FF), and (5) urethral reconstruction technique (perineostomy, buccal mucosa, full thickness skin grafts (FTG), tube-in-tube design (only in radial free forearm flap phalloplasty (RFFFP) pedicled labia minora flap (PLMF) or a second fasciocutaneous flap (RFFF, SCIP). Descriptive statistics were used to assess the data.

Pre-operative evaluation

Pre-operatively, patients are screened and counseled in accordance with the Standards of Care (SOC).⁹ The SOC is an International guideline published by 'The World Professional Association for Transgender Health (WPATH) to promote the highest standards of healthcare and to assist transgender people. The WPATH is a world leading professional organization devoted to the understanding and treatment of gender dysphoria. Assistance may include primary care, gynecologic and urologic care, mental health services and surgical treatments (e.g., top and/or bottom surgery). In our institution, patients attend a group-based educational program that address relevant knowledge concerning the peri-operative course, the clinical outcomes and complications, enhance group interactions and enable patients to learn from the experience of others. In addition, psychological and sexological evaluation is prerequisite for genital GAS to identify contraindications, better understand patients' motivation, readiness, behavioral challenges and emotional factors that may have an impact. Since 2018 an online decision aid is available to assist patients in making a well-informed decision about preferred the surgical procedure.

Main contraindications for surgery are a Body Mass Index(BMI) less than 18 or above 30, smoking (patients have to quit smoking for at least 3 months prior to surgery). The final decision to undergo a specific surgical technique is based on the patient preference, patient risk factors, psychological wellbeing, surgical feasibility and risk of the procedure. According to the Dutch Central Committee for Human Research, retrospective medical research is exempt from an institutional review board (IRB) approval.

RESULTS

General trends

From January 1989 to January 2018, a total of 400 transgender men underwent genital GAS. The number of performed genital GAS procedures has doubled over time from an average of 11 per year before 2011, to an average of 22 procedures per year since 2015 (Figure 1). The surgical choices offered to the transgender male at our institution have increased from five options, to a choice out of 12 surgical techniques (Figure 2) consisting of metoidioplasty and phalloplasty with or without urethral lengthening. The phalloplasty techniques consist of different (combinations) of fasciocutaneous free or pedicled flaps. Before 2007, a plastic surgeon was mainly involved in the surgical care of the transgender men. Since 2007, the gynecologist has played a more prominent role in the multidisciplinary surgical team by performing the primary colpectomy and the presurgical fertility counseling. Since 2013, the urologist performs the scrotoplasty, urethral lengthening, erectile and testicular prosthesis implantation and are therefore responsible for preservation of urinary and sexual function.

Metoidioplasty

Metoidioplasty was performed in 222 (55.5%) patients and was the most frequently performed genital GAS procedure between 1992 and 2010. Twenty-seven (12%) patients were unsatisfied with the metoidioplasty and underwent a secondary phalloplasty.

Phalloplasty

A total of 178 (44.5%) transgender men underwent free or pedicled flap phalloplasty. When comparing metoidioplasty and phalloplasty procedures, a shift was observed from 2010 onwards when phalloplasty became the most frequently performed genital GAS procedure. An overview of the used flaps is presented in Table 1. A historical overview of phalloplasty procedures is presented in Figure 3. Multiple trends were observed over the last decade. In general, the RFFFP was the most frequently performed phalloplasty procedure. The non-innervated AF was popular in the early nineties, but has not been performed since 2002. Striving for a sensate neophallus with less conspicuous donorsite the use of the innervated pedicled ALT flap was introduced in 2004 and its use has increased since then. The use of combination flaps (composite phalloplasty), using two free or pedicled flaps for shaft and neo-urethral construction were introduced in 2005 and the technique has been performed increasingly. The use of the non-innervated SCIP flap was abandoned in 2003, but this technique re-emerged in 2017 with the introduction of the innervated SCIP flap.

Urethral lenghtening

Out of 400 patients, 332(83%) underwent urethral lengthening. Anatomically the urethra after urethral lengthening in genital GAS in transgender men consists of 3 part: the native urethra, the pars fixa and the pars pendulans. Depending on the genital GAS technique the neourethra can be constructed using various techniques.

Pars fixa reconstruction in metoidioplasty is performed in much the same way as in phalloplasty. Currently, the infundibular tissue of the labia minora is tubularized around a Foley catheter to reconstruct the pars fixa. Additional coverage of the proximal urethral anastomosis (between the native urethra and pars fixa) with well-vascularized tissue is important to prevent urethral fistula formation. For this purpose, the anterior vaginal flap was introduced in 1993 by Hage et al.¹⁰ However, addition of the vaginal flap was associated with increased urethral complications (e.g. strictures and fistulas) and has not been used since the early 2000s. Since 2009, a colpectomy is performed in our center to obtain well vascularized tissue for urethral anastomosis coverage and successful reduction of the urethral fistula rate.^{11,12}

There are multiple surgical options available for pars pendulans reconstruction in metoidioplasty and phalloplasty. In metoidioplasty, the pars pendulans of the neo-urethra is constructed with the cranial part of the labia minora. Buccal mucosa may be added for additional lengthening.

In phalloplasty, pars pendulans reconstruction with FTG prelamination, a tube-in-tube design (only in RFFFP) or a second fasciocutaneous flap (tube-in-tube design) can be performed. An overview of the urethral lengthening techniques in phalloplasty is given in Figure 4. Between 1989 and 2002 prelamination with FTG was used in the AF, LUAF and the FF to lengthen the urethra. Since 2002, these flaps, including prelamination with FTG, have not been performed anymore. The use of a second fasciocutaneous flap for the reconstruction of the pendulant part of the neo urethra has increased since 2005 in accordance with the increase of combination flap phalloplasty. The option of genital GAS without urethral lengthening has been offered since 2004. From 2004 to 2018, 68 (33.6%) patients underwent genital GAS without urethral lengthening. Since 2017, a new technique for urethral lengthening in phalloplasty has been introduced: the PLMF.

Phalloplasty flap type	N(%)	
Total	178 (100%)	
RFFF	76 (43%)	
Combination flaps	42 (24%)	
ALT + RFFF	28 (16%)	
SCIP + SCIP	6 (4%)	
SCIP + PLMF	4 (2%)	
ALT + SCIP	2 (1%)	
ALT + PLMF	1 (1%)	
SCIP + RFFF	1 (1%)	
ALT	22 (12%)	
AF	17 (10%)	
SCIP	11 (6%)	
LUAF	8 (4%)	
FF	2 (1%)	
AF=abdominal flap, ALT= anterolateral thigh, FF= fibula flap, LUAF= lateral upper arm flap, PLMF=pedicled labia minora flap, RFFF=radial forearm free flap, SCIP= superficial circumflex iliac artery perforator		

Table 1: Overview of phalloplasty flap type



Figure 1. Overview of the performed metoidioplasty and phalloplasty over time.



Figure 2. Currently, metoidioplasty and phalloplasty options offered to transgender men at the Amsterdam UMC, location VUmc. ALT=anterolateral thigh, RFFF=radial forearm free flap, SCIP= superficial circumflex iliac artery perforator, PLMF= pedicled labia minora flap



Figure 3. Distribution of phalloplasty flap type. AF=abdominal flap, ALT= anterolateral thigh, RFFF=radial forearm free flap, FF= fibula flap, LUAF= lateral upper arm flap, PLMF=pedicled labia minora flap, SCIP= superficial circumflex iliac artery perforator



Figure 4. Overview urethral lengthening techniques in phalloplasty. FTG=Full Thickness graft, PLMF= pedicled labia minora flap.

DISCUSSION

In this study, a historical overview of genital GAS in transgender men in a single high-volume center was presented, as a reflection of developments in patient care. Four hundred transgender men underwent genital GAS and were included in this retrospective analysis. Specific trends were observed over the last three decades.

In the Netherlands, the number of people who applied for transgender healthcare has increased drastically recently.¹ As our data show, this increase is accompanied by an increase in number of transgender men undergoing genital GAS (Figure 1). The exact reason for the increase in patient numbers remains unknown, but it is in part thought to be the result of growing social acceptance and recognition of gender-nonconformity in society.⁷

Reconstruction of the neo-phallus in transgender men involves unique technical challenges with regard to the aesthetical result, tactile and erogenous sensibility, urological functioning, erectile function, donor-site morbidity and complication risk. Surgical approaches have evolved considerably over time. Despite the significant progress made and the development of many surgical techniques, the creation of the ideal neo-phallus has yet to be achieved.^{4,13} Each of these technique has its own (dis)advantages. For example, performing an RFFFP will give an aesthetically pleasing result, but will also give obvious donor-site scars which can be bothersome and stigmatizing for patients.

Metoidioplasty consists of releasing the hypertrophied clitoris and reconstructing the neophallus using local tissue.^{4,14,15} Advantages are erectile capabilities, limited donor-site scar formation and preserved tactile sensation. Also, the procedure is considered less complex with shorter operative time, shorter hospitalization time, lower complication rates and lower costs compared to phalloplasty.^{16,17} Metoidioplasty is therefore a suitable option for transgender men that wish to have an external male genitalia including neo-phallus, urethra and scrotum. Disadvantages are a relatively small neophallus and the inability to have penetrative sex and in most cases to void standing out of the zipper . Therefore, some transgender men prefer to undergo a phalloplasty or a secondary phalloplasty at a later stage. Until 2009, metoidioplasty was the most performed surgical

procedure at our institution. Since then, phalloplasty has been performed more frequently. The exact reason for this shift is unclear. Possible explanation could be the improved phalloplasty surgical techniques, improved pre-operative counseling and/or a change in patients' expectations and desires. Currently, patients are free to choose between a metoidioplasty and phalloplasty.

Phalloplasty consists of creating a large neophallus. Pedicled flaps (e.g. SCIP flap, ALT flap or AF) or free flaps (e.g. RFFF, LD flap or fibular flap) may be used for phalloplasty.^{18,19} Phalloplasty techniques have evolved considerably as plastic reconstructive surgery has evolved over the years.⁴ The multistage pedicled tube phalloplasty (e.g. AF and SCIP flap) was considered the standard procedure to reconstruct the neo-phallus for multiple decades (until the 1980s).²⁰ The procedure was associated with high complication rates and poor neophallus sensation.²¹

However, this changed when microsurgery enabled the reconstruction of the neophallus using a tube-in-tube radial forearm free flap phalloplasty (RFFFP) in the 1980s.²² Since then, the RFFFP has been considered the golden standard for phalloplasty due to the reliability of the long vascular pedicle, pliability, flap thinness which gives an aesthetically pleasing result and being a one-stage procedure.²³ Subsequent introduction of the osteocutaneous version of the RFFF and the osteocutaneous fibula flap were expected to be the ideal phalloplasty technique that would enable voiding from a standing position while also including a neo-phallus stiffener to enable penetrative sexual intercourse.²⁴⁻²⁶ However, due to an increased flap failure rate, increase in urological complications (fistula and stricture rate up to 50%) and significant donorsite morbidity in osteocutaneous RFFFP, osteocutaneous flaps have not been performed anymore at our clinic since 2004. Major disadvantages of the RFFFP are the donor-site morbidity, penile color mismatch and the extensive donor-site scars which are considered stigmatizing by most patients.²⁷⁻²⁹ Therefore, pedicled phalloplasty remained quite popular until 2004.

With the introduction of sensate perforator flaps, the sensate ALT flap started to increasingly replace the RFFF as first choice flap since 2004 because of the hidden donor-site, better penile color match and no need for microvascular anastomosis.³⁰⁻³³ Disadvantages are that this flap is prone to be thicker than the RFFF, which makes it difficult to create a tube-in-tube flap for urethral

reconstruction and only suitable for patients with a low BMI. Also, there is still a considerable donorsite which has to be covered with split thickness skin grafts (STSG).

To overcome these disadvantages, combination flap phalloplasty was introduced in 2005. Combination of flaps may be used to reconstruct the neophallus (e.g. ALT or SCIP to reconstruct the shaft combined with RFFF, SCIP or PLMF for urethral reconstruction) and to limit extensive (conspicuous) scarring at one donor-site.²⁸ Also, combination flaps can be performed in patients who are not eligible for a tube-in-tube phalloplasty technique because of the thick subcutaneous layer. Surgical disadvantages comprise prolonged surgical time, use of multiple surgical teams and flap-related complications. Inner flap monitoring is difficult and increased urethral complications are reported, possibly because of flap swelling..¹⁹

To further improve the techniques, we recently (2017) developed a technique to perform an innervated pedicled SCIP phalloplasty. Originally, the flap is described as an insensate flap for phalloplasty. Erogenous sensation plays an important role in sexual arousal and protective sensibility is important to limit penile prosthesis protrusion. This was the main reason that in our clinic we stopped performing this phalloplasty technique in 2003. Advantages of this technique compromise that microvascular anastomosis is not needed, the donor-site can be closed primarily and gives a less conspicuous donor-site.³⁴⁻³⁶ The surgical and urological outcomes of this technique are set to be published in the near future.

Many transgender men who opt for GAS express the wish to be able to void while standing. To enable this, urethral lengthening and translocation of the urethral meatus more distally is required.. Urethral lengthening is considered a significant challenge in GAS; reflected by the high rates of urethral strictures and fistulas especially after phalloplasty.^{37,38} Reports on neourethral complications after phalloplasty are as high as 80%.³⁹ These urological complications can cause great discomfort for the individual patient and management of these complications is challenging.

Therefore, since 2004 the option to undergo genital GAS without urethral lengthening was offered to patients. Since then, 68 patients (33%) have opted for this procedure. This is deemed a good option for transgender men that want to minimize the risk of urological complications. The

surgical technique and outcomes of this technique is submitted and is set to be published in the near future.

Over time, the patient has become increasingly involved in health care decision-making. Currently, 12 surgical techniques are provided to choose from (Figure 2). Recently, we developed a decision aid for genital gender-affirming surgery in transgender men (DA-GST), so patients can carefully consider the pros and cons of surgery before making a decision.⁴⁰ The DA-GST does not render a "best choice, but helps transgender men to consider what is important for them as an individual. The great variety in surgical options also emphasizes the importance of having gender surgeons that are highly skilled in more than one particular genital gender-affirming surgical procedure working in a multidisciplinary fashion. Highly skilled gender surgeons can counsel patients to manage their expectations and identify contraindications for surgical procedures. Unfortunately, there is a lack of patient-reported outcome measures validated for transgender men to objectively evaluate and compare the influence of these surgical procedures.⁴¹

The practice of gGAS in the Netherlands has undergone significant evolution over the past 30 years in line with the advances made in plastic reconstructive surgery. With the ongoing advancements and innovations made in the field of plastic reconstructive surgery (e.g. biomaterials, tissue engineering and nanotechnology), we expect the that surgical options for transgender men will continue to expand in the future. This increase in options will require a more bespoke treatment to achieve the best possible result. In addition, with the increasing complexity and amount of procedures, a shift toward subspecialization in gGAS in transgender men may be inevitable.

There are some limitations to this study. The retrospective design is prone to confounding factors. Also, no reports have been made concerning the clinical outcomes and patient reported outcome measures. In addition, the data represents our unique experience at the Amsterdam UMC, location VUmc. However, this study is the first to give a comprehensive overview of genital GAS in transgender men over a period of 29 years in a high volume single-center. The trends observed in this study can be utilized by other (upcoming) clinics to gain insight in the development of genital surgical care in transgender men.

CONCLUSION

Genital gender affirming surgery at our institution has evolved over time in accordance with reconstructive surgical innovations. In spite of the technical advancements, there is no ideal technique to reconstruct the neo-phallus. Therefore, a wide variety of surgical techniques is offered and every technique has specific (dis)advantages. Having to choose between these multiple surgical options underlines the need for (1) shared decision making, (2) a shift from surgeon-centered towards more patient-centered care and (3) a multidisciplinary team that consist of highly qualified gender surgeons to offer these surgical options.

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PART 2

Reducing urological complications and improving surgical outcomes

CHAPTER 2

Colpectomy significantly reduces the risk of urethral fistula formation after urethral lengthening in transgender men undergoing genital Gender Affirming Surgery.

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SUMMARY

Purpose: To assess the effect of performing a colpectomy before (primary) or after (secondary) gender affirming surgery (GAS) with single-stage urethral lengthening on the incidence of urethral fistulas in transgender men.

Materials and Methods: Retrospective chart review of all transgender men who underwent GAS with urethral lengthening between January 1989 and November 2016 at VU University Medical Center. Patient demographics, surgical characteristics, fistulas and their management, primary and secondary performed colpectomy were recorded. Descriptive statistics were calculated and incidence rates were compared.

Results : Two hundred ninety-four transgender men underwent GAS with urethral lengthening. Of 232 patients without colpectomy, 111 (48%) developed an urethral fistula. Of 62 patients who underwent primary colpectomy, 13 (21%) developed a urethral fistula (p<0.01). Secondary colpectomy was performed in 17 patients with recurrent urethral fistula at the proximal urethral anastomosis (PUA) and the fixed part of the neo-urethra, which resulted in 100% fistula closure.

Conclusions: Performing a primary colpectomy decreases the incidence rate of urethral fistulas. Also, performing a secondary colpectomy is an effective treatment for fistulas at the PUA and the fixed part of the neo-urethra.

INTRODUCTION

Transgender men generally report an improved quality of life and satisfactory sexual function after genital gender affirming surgery (GAS), e.g., phalloplasty and metoidioplasty.^{1,2} Many transgender men who opt for GAS express the wish to be able to void while standing.³ To enable this, urethral lengthening and translocation of the urethral meatus more distally is required. After GAS with urethral lengthening, the urethra consists of three parts: the native urethra, the fixed part and the pendulant part. Two anastomotic sites exist in the reconstructed urethra: the proximal urethral anastomosis (PUA) between the native urethra and the fixed part, and the distal urethral anastomosis (DUA) between the fixed part and the pendulant part (Figure 1).

Urethral lengthening is considered a significant challenge in GAS; reflected by the high rates of urethral strictures, obstructions or fistulas especially after phalloplasty.³ Compared to biological men undergoing phalloplasty, transgender men have a higher rate of urological complications which may result in personal distress, correction surgery and impede the ability to void while standing. ^{4,5}

Reported rates of urethral fistulas after free radial forearm (FRFF) phalloplasty range from 10% up to as high as 68%.⁶⁻¹¹ Fistulas occur most frequently at the PUA and DUA.¹² The etiology of fistula formation is multifactorial (e.g., wound dehiscence, lack of sufficient tissue to cover the anastomosis and pre-stenotic dilatation caused by urethral strictures).¹²⁻¹⁶ Additionally, the female urethral meatus is pointed downwards and to reconstruct the fixed part of the neo-urethra, a 90 degrees angle has to be made (Figure 1). This results in a high tension pressure at the PUA, contributing to the development of fistulas.¹⁴

To obtain well vascularized tissue for PUA coverage and reduce the urethral fistula rate we perform a colpectomy before (primary) or after (secondary) GAS with urethral lengthening.

To date, there is little evidence to confirm the hypothesis that colpectomy reduces the risk of fistula formation, especially at PUA and the fixed neo-urethra. We describe the effect of colpectomy on the occurrence rate of urethral fistulas after single-stage urethral lengthening in transgender men and describe the treatment of these fistulas.



Figure 1. Overview of the corresponding urethral parts in transgender men after urethral lengthening. DUA=Distal Urethral Anastomosis, PUA=Proximal Urethral Anastomosis.

MATERIALS AND METHODS

Patient selection and data collection

All transgender men who underwent GAS with urethral lengthening between January 1989 and November 2016 were retrospectively identified form the hospital records of the VU University Medical Center, Amsterdam, The Netherlands. Patient demographics, surgical characteristics, fistula occurrence and their management, primary and secondary performed colpectomy were recorded. According to the Dutch Central Committee for Human Research, retrospective medical research is exempt from an institutional review board (IRB) approval.

Proximal and distal urethral fistula

Fistulas at the PUA and the fixed part of the neo-urethra are clinically observed as urethrovaginal fistula and urethrocutaneous fistula with drainage in the perineal area (behind the scrotum), which we refer to as proximal urethral fistula (PUF). Fistulas at the DUA and the pendulant part of the neo-urethra are clinically observed as urethrocutaneous fistula with drainage in the penoscrotal angle and the penile shaft (in front of the scrotum), which we refer to as distal urethral fistula (DUF), see Figure 2.


Figure 2. Illustration of urethral fistula localization. DUF= Distal Urethral Fistula, PUF= Proximal Urethral Fistula

Colpectomy

Before 2009 indications for colpectomy were mainly based on the patients' desire. From 2009, the policy changed and all transgender men were required to undergo a primary colpectomy before undergoing phalloplasty or metoidioplasty. The time interval between primary colpectomy and GAS was at least 3 months. Colpectomy is performed by a gynecologist and can be performed laparoscopically or vaginally as a stand-alone procedure. ¹⁷⁻¹⁹ Since 2011, robot-assisted laparoscopic colpectomy (RaLC) is an alternative for the vaginal approach if the procedure is combined with robot-assisted total laparoscopic hysterectomy and bilateral salpingo-oophorectomy (TLH-BSO).¹⁸ A detailed description of the RaLC technique can be found elsewhere.¹⁸ Vaginal colpectomy was performed by sharp dissection of the vaginal tissue. The vaginal wall muscle tissue is left intact. Two levator ani stitches were placed to narrow the vaginal introitus and stabilize the neo-perineum, followed by closure of the skin.

Urethral lengthening

In essence, the technique to lengthen the first part of the urethra(fixed part) is similar in all patients regardless of the metoidioplasty or phalloplasty technique.

In urethral lengthening without colpectomy, the pars fixa is mainly reconstructed using the inner lining of the labia minora and an additional pedicled flap from the anterior vaginal wall. In patients who underwent primary colpectomy (Figure 3a), lengthening of the proximal part of the urethra (fixed part) is performed by tubularizing the infundibular tissue and the inner lining of the

labia minora around a Foley catheter (Figure 3b). Additionally, multiple layers of surrounding tissue, including bulbospongiosus muscle, are used to cover the PUA and the fixed urethra (Figure 3c). Lastly, fat was mobilized from the labia majora to further cover the anastomosis and fixed part of the neo-urethra (Figure 3d).

Lengthening of the distal part of the urethra (pendulant part) is performed depending on the metoidioplasty or phalloplasty technique: possible use of buccal mucosa in metoidioplasty, tube-in-tube shape in a FRFF or a second fasciocutaneous flap in double flap phalloplasty. Prefabrication using a full thickness graft (FTG) was performed in a small number (<5%) of patients who underwent phalloplasty in the early 90's.



Figure 3. Lengthening of the first part of the urethra (fixed part) after primary colpectomy. A. Incision outlining. Approximately one centimeter of vaginal mucosa is preserved after primary colpectomy. The lateral aspects of the labia minora will be excised. **B**. Tabularization of infundibular tissue and labia minora inner lining. Remaining vaginal mucosa is excised and the vaginal opening is closed. **C**. Additional bulbospongiosus muscle to cover the proximal urethral anastomosis and fixed part of the urethra. In patients without colpectomy the remaining vaginal opening prevents mobilization of the bulbospongiosus muscle. **D**. Coverage of the proximal urethral anastomosis and fixed part of the urethra using fat from the labia majora.

Fistula management

Conservative measures

In our clinic, conservative treatment is usually the first step in newly-formed neo-urethral fistulas. In case of extreme discomfort a suprapubic catheter is placed to relieve discomfort and give fistulas the chance to heal spontaneously. If the fistula does not close within six months, then a surgical intervention is performed.

Surgical correction

Given the heterogeneity in fistula locations and characteristics, there is no uniform approach to fistula localization and correction. If necessary, methylene blue dye is pre-operatively injected into the neourethra to identify neourethral fistulas. The visualized fistula is excised (fistulectomy), and the urethral defect is closed in multiple layers over a catheter. Depending on the size of the remaining defect, a graft may be needed to close the urethra. In case of a prestenotic fistula, the surgical correction is combined with treatment of the stricture.

When multiple surgical efforts fail or the urethral damage is too extensive to correct on the short term, a temporary perineal urethrostomy can be performed.

Secondary colpectomy, fistulectomy and closure of perineum

Fistula at the PUA mainly drain in the vagina. In our experience, these fistulas show little tendency to heal spontaneously and often recur after surgical closure. In such cases, we combine fistula correction with a secondary colpectomy and closure of the perineum.

Main outcome measures

We investigated the effect of primary colpectomy on the occurrence of urethral fistulas and the effect of secondary colpectomy on the recurrence of PUF.

Analysis

Continuous variables were presented as means with standard deviations or as medians with ranges. The chi-square goodness of fit test was used to compare the fistula rates after GAS with

urethral lengthening in patients that underwent primary colpectomy and patients without colpectomy. The Mann-Whitney U test was used to compare continuous variables.

RESULTS

A total of 294 transgender men underwent GAS with urethral lengthening. Of these patients 62 (21%) patients underwent a primary colpectomy and 232 (79%) did not undergo colpectomy. Patient demographics are presented in Table 1.

The effect of primary colpectomy on fistula formation

In patients who did not undergo colpectomy 111 of 232 (48%) patients developed an urethral fistula. Significantly less patients (13 (21%), p<0.01) who underwent primary colpectomy developed a urethral fistula (Table 2). In the first group 49 of 111 (44%) patients with a fistula had an urethral stricture, in the second group 7 of 13 (54%) patients had an urethral stricture. Overview of the urethral fistulas within the time frame is depicted in Figure 4.

Of 111 patients that developed fistula and did not undergo colpectomy, 32 (29%) patients developed PUF only, 52 (47%) DUF only, and 27 (22%) both a PUF and a DUF. Of 13 patients that developed fistula after primary colpectomy, no (0%) patients PUF only, 11 (85%) developed DUF only and 2 (15%) both a PUF and a DUF. Table 2 shows the occurrence of urethral fistulas.

Secondary colpectomy as treatment of proximal urethral fistula

From the 65 patients that developed PUF after undergoing GAS and urethral lengthening without colpectomy, 17 (26%) patients had recurrent PUF. In these patients correction of the PUF was combined with a secondary colpectomy. Successful closure of the PUF was achieved in all patients.

	Total	Without	Primary	P-value	
		colpectomy	colpectomy		
Number of patients	294	232	62		
Age at GCS, y (minimum-maximum)		33(19-62)	33(19-57)		
Phalloplasty, n (%)	128(44%)	78(34%)	50(80%)		
FRFF, n (%)		37(47%)	30(60%)		
ALT, n (%)		6(8%)	20(40%)		
Abdominal flap, n (%)		18(23%)	-		
Groin flap , n (%)		8(10%)	-		
Free lateral arm flap, n (%)		6(8%)	-		
Free osteocutaneous fibula, n (%)		3(4%)	-		
Metoidioplasty, n (%)	170(56%)	154(66%)	12(20%)	<0.001 [±]	
BMI, kg/m² ± SD		24 ± 3^	25 ± 3°	0.36*	
Number of active smokers		52*	9*		
Clinical follow-up time (years) ± SD		9±7	2 ± 1.3	<0.001*	
[±] Chi-square goodness of fit test, * Mann-Whitney U Test, ^ N=136, ° N=42, * N=150, * N=62; FRFF=Free Radial Forearm Flap, ALT=Anterolateral Thigh					

Table 1: Patient Demographics

Table 2: Occurrence rate of urethral fistula in patients with primary colpectomy and without colpectomy.

Treatment	n	Fistula		DUF			PUF			
		n	(%)	p-value	n	(%)	p-value	n	(%)	p-value
Phalloplasty										
All	128	58			45			23		
Without colpectomy	78	46	(59%)	<0.001	35	(45%)	<0.05	22	(28%)	<0.05
Primary colpectomy	50	12	(24%)	<0.001	11	(22%)	<0.05	1	(2%)	<0.05
Metoidioplasty										
All	166	66								
Without colpectomy	154	65	(42%)	<0.05	38	(25%)	0.2	43	(28%)	0.14
Primary colpectomy	12	1	(8%)	<0.05	1	(8%)	0.2	1	(8%)	0.14
Total P+M										
All	294	124								
Without colpectomy	232	111	(48%)	<0.001	73	(31%)	<0.0E	65	(28%)	<0.001
Primary colpectomy	62	13	(21%)	<0.001	12	(19%)	<0.05	2	(3%)	<0.001
Chi-square goodness of fit test is used to calculate the P-value, DUF= Distal Urethral Fistula, PUF= Proximal Urethral Fistula, P=Phalloplasty, M=Metoidioplasty, P-value describes the difference in occurrence rate of urethral fistula in patients with primary colpectomy and without colpectomy										



Figure 4. Historical overview of the performed urethral lengthening, accompanying urethral fistula and the performed secondary colpectomy. Primary colpectomy has been performed since 2009. DUF=Distal Urethral Fistula, PUF=Proximal Urethral Fistula

DISCUSSION

In this study, we described the occurrence and treatment of fistulas following GAS with urethral lengthening in 294 transgender men. Fistulas occurred significantly less in patients who underwent primary colpectomy (111/232 (48%) vs 13/62 (21%), p<0.01). Combining fistulectomy with a secondary colpectomy can be performed as successful treatment for PUF.

In GAS with suprapubic abdominal flaps a fistula rate of 55% is reported.²⁰ Small studies with pedicled flaps like the anterolateral thigh (ALT) and groin flaps for phalloplasty showed a lower fistula rate (10%).^{21,22} In contrast, a recent study reported a higher fistula rate (22%) after a pedicled ALT in 64 patients.¹¹ The small number of studies, possible differences in surgical experience, different

techniques/indications and interinstitutional variations in postoperative follow-up make it difficult to draw generalizable conclusions on this.

Pressurized urine follows the path of least resistance, and may flow through the ventral sutures of the PUA. This often results in urethrovaginal fistula originating from the PUA. Performing a total colpectomy and closing the cavity and perineum is likely to resolve this. If a cavity persists after the total colpectomy, the neo-urethra will be susceptible for new PUF formation.¹² This was the case in two of our patients. In both instances fistulas were resolved by excision and closure of the persistent vaginal cavity.

Coverage of the PUA and the fixed part of the neo-urethra with well-vascularized tissue is important to prevent urethral fistulas. Transgender men use androgens, which often, results in notable atrophy of the urethra, vagina, vulva and thus reduces the usability for coverage.²³ After primary colpectomy, a sufficient amount of vascularized vestibular tissue including the bulbospongiosus muscle, exists to cover the anastomosis using multiple layers (Figure 2).²⁴

Little is published concerning the effect of colpectomy on fistulas originating from the PUA. Colpectomies were only performed in case of increased vaginal discharge or a low male selfesteem. ^{17,18} In 1996, Chesson et al. firstly described the effect of colpocleisis (partial removal of vaginal epithelium from the anterior and posterior wall followed by vaginal cavity obliteration) on urethral lengthening and fistula occurrence in transgender men.²⁵ The perineum was not closed, to allow vaginal discharge from the remaining vaginal epithelium. The colpocleisis significantly decreased fistula formation. The sample size of 20 patients was small and the observed fistula rates after colpocleisis were still higher (35%) than in our colpectomy group. Possible explanations could be the required surgical experience and a completely different technique to remove the vagina and lengthen the urethra.

Massie et al described the effect of vaginectomy on urethral complications in transgender men.²⁴ Two hundred and fifteen patients underwent vaginectomy and urethral lengthening and nine patients had vaginal preservation. Performing a vaginectomy was associated with a significant

decrease in urethral fistula (30/215 (14%) vs 5/9 (56%). The reported fistulas were not additionally divided based on their level in the urethra and thus making it difficult to determine if the colpectomy reduced PUF and/or DUF. Also the vaginal preservation group was small (9) and no information was given concerning treatment of the fistula with a secondary colpectomy.

Fistula rates are likely to drop while gaining surgical experience.^{19,26,27} However, in our series, the highly significant drop in fistula rate since 2009, especially PUF, cannot be explained merely by a learning curve. The surgical team consisting of plastic gender surgeons and a reconstructive urologist remained the same since 2007.

Furthermore, we noticed a less significant decrease in DUF in the colpectomy group. Hypothetically, the colpectomy does not have an effect on the DUA and the mobile part of the urethra. These fistulas may be more related to the urethral reconstruction technique (e.g., FTG, fasciocutaneous flaps, roll-in-roll) of the pars pendulans. Also, having a long non-compliant urethra makes the phalloplasty more prone to develop pre-stenotic DUF in comparison to a metoidioplasty.

Urethral strictures are another common urethral complication after GAS that contribute to a higher voiding urinary pressure which cause prestenotic dilation and possible fistula formation. Reports on urethral strictures rates after GAS vary from 14% up to 58%.^{11,13,28,29} High urethral strictures rates were reported in older papers and have decreased over time. Urethral strictures occur mainly at urethral anastomosis sites or distal from the urethral anastomosis.³⁰ Solving these strictures increases the chance of successful fistula treatment.¹²

Limitations

The retrospective design of the study is prone to bias and availability when collecting data. Furthermore, different surgeons with different surgical experience have operated in the past years while using different techniques for urethral reconstruction and colpectomy. Strengths of our study comprise that the presented series of 294 transgender men, is the largest series published to date. Another strength is the major follow-up time.

CONCLUSION

Primary colpectomy significantly reduces the risk of urethral fistula formation after GAS with urethral lengthening in transgender men. In addition, patients who already developed proximal urethral fistula can be treated effectively by combining a fistulectomy with a secondary colpectomy.

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CHAPTER 3

Genital Gender Affirming Surgery without urethral lengthening in transgender men. A clinical follow-up study on the surgical and urological outcomes and patient satisfaction

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SUMMARY

Background

Genital gender affirming surgery (gGAS) with urethral lengthening (UL) in transgender men is associated with high urological complication

and re-operation rates. Since 2009 we offer gGAS without urethral lengthening (UL) to avoid these complications.

Aim

The aim of this study was to assess what portion of the transgender men opted for gGAS without UL and to assess functional, surgical

outcomes and patient satisfaction after gGAS without UL.

Material and methods

Retrospective data was collected from patients charts. The International Prostate Symptom Score

(IPSS), uroflowmetry and 24 hour frequency

voiding chart (FVC) were used to assess voiding and a self-constructed semi-structured

questionnaire was used to assess patient

reported outcomes. Transgender men who underwent gGAS without UL between January 2009 and

January 2018 were included and 56

transgender men were approached to complete the PROM. Simple statistical analysis combined with the Mann-Whitney U test and the Wilcoxon Signed Rank test were used.

Outcomes

68 transgender men were included. Median follow-up time was 24 (6-129) months.

Uroflowmetry and the IPSS were completed by 44 transgender men while 13 completed the FVC pre and post operatively respectively. The

PROM was completed by 71% (40/56).

Result

Postoperative surgical and urological complications occurred in 13% (9/68) and 12%(8/68) patients, respectively. Storage and voiding function remained unchanged. The median quality of life (QoL) due to urinary symptoms was scored as "pleased". Sexual functioning and voiding were scored

satisfactory and very satisfactory in respectively 45% (18/40) and 53% (21/40) of the patients. The number of patients satisfied with the penis and neo-scrotum were 63% (25/40) and 65% (26/40). Increased self-esteem was reported by 80% (32/40), 68% (32/40) would undergo the surgery again and 70% (28/40) would recommend it to others respectively.

Clinical Implications

GGAS without UL should be part of the surgical armamentarium in centers performing GAS. Strength and limitations

Strengths of this study comprise the number of patients, the completeness of data, incorporation of patient-reported outcomes and description of a relatively new surgical approach that may be well-suitable for a subgroup of transgender men. Limitations are the retrospective study design and the lack of validated questionnaires.

Conclusion

GGAS without UL, shows good surgical and urological outcomes. After extensive counseling the majority of this selective group of patients show favorable patient reported outcomes.

INTRODUCTION

Genital gender affirming surgery (gGAS) in transgender men in general consist of the reconstruction of a neo-scrotum and phallus with urethral lengthening (UL). In case of phalloplasty a penile stiffener may be inserted to enable sexual intercourse. Urological complications e.g. urethral strictures and urethral fistulae, are common after gGAS with UL (range between 50-70 %), are associated with psychological distress and have socioeconomic consequences (9,10). Treatment of these complications often require restorative surgical procedures, or sometimes long-lasting intermittent neo-urethral dilatation (9,10). The requirements for masculinizing surgery are outlined by the Standards of Care (SOC) of the World Professional Association for Transgender Health (WPATH) (2). According to those standards, transgender men are considered eligible to proceed with the surgical phase of the transition when gender dysphoria is documented and diagnosed by a psychologist mental health professional, when having the capacity to provide fully informed consent, being of age of majority, having well-controlled medical or mental health concerns if present, having undergone 12 continuous months of hormone therapy in accordance with their medical transition goal and having lived continuously for at least 12 months in the gender role that is congruent with ones gender identity. Different gGAS techniques are described with the aim of creating a male genital in which the maintenance of urologic functions (micturition and sexual function) are important. In general, favorable results of satisfaction and sexual function are reported after gGAS (0,5,5). In the Centre of Expertise on Gender Dysphoria at the Amsterdam UMC, VUMC a multidisciplinary team including the psychology, psychiatry, endocrinology, plastic surgery, urology and gynecology is involved in the (surgical) care. A surgical plan is made based on shared decision making and is supported by a decision aid (8), taking into account individuals preferences, the surgical possibilities (BMI, clitoral and labia minora hypertrophy, upper leg or flank thickness of subcutaneous tissue layer), outcomes of voiding assessment, realistic expectations and the psychological ability to cope with potential post-operative complications. The gynaecologist, plastic surgeon, urologist and psychologist are involved in the pre-operative counselling process for the gGAS. In the VUMC, gGAS in transgender men was performed in two stages, with UL and the construction of a neo-scrotum first, followed by a secondary phalloplasty (6,7). Nowadays, gGAS in

transgender men is a one stage procedure. The surgical options have traditionally been the metoidioplasty or the phalloplasty with UL. Since 2009, gGAS without UL has been offered at our center. We hypothesized that gGAS without UL would reduce post-operative urological complications and secondary procedures. In addition, we expected that extensive preoperative counseling would increase post-operative satisfaction of surgical outcome and function. The aim of this study was to assess what portion of the transgender men chose gGAS without UL and to assess the urological and surgical outcomes and satisfaction after gGAS in this group of transgender men.

METHODS

Patient selection

In this follow-up clinical study, transgender men who underwent gGAS without UL between 2009 and 2018 with a post-operative follow-up time of at least 1 year were eligible to participate. Eligible participants were invited to complete a questionnaire assessing post-operative satisfaction.

Demographics and surgical and urological outcomes

Age at gGAS, body mass index (BMI), follow up time, surgical characteristics: phalloplasty or metoidioplasty, phalloplasty flap type, intraoperative complications, postoperative complications (hematoma, skin necrosis and phalloplasty flap loss), urological complications (urethral fistula/stenosis and perineal orifice stenosis) were collected from the patients files.

Urinary function (storage and voiding) assessment

All transgender men had storage and voiding function assessment which consisted of completion of the International Prostate Symptom Score (IPSS) questionnaire and a 24 hour frequency voiding chart (FVC) combined with performing a uroflowmetry. Scores of the IPSS between 1-7, 8-19 and 20-35 are indicative of respectively mild, moderate and severe symptoms. Scores of the quality of life (QoL) question range from 0 = delighted to 6 = terrible. There are no standards for a normal FVC, but a frequency around 6 times a day with voided volumes between 200 and 500 are regarded as normal storage function (11). With concern to the uroflowmetry, maximal voided velocity (Qmax) above 15 ml/s is indicative for absence of Bladder Outlet Obstruction (BOO) although consensus on the definition of BOO is lacking (12).

Uroflowmetry with voided volumes above 150 ml were regarded as representative for the assessment of voiding. Patients with severe preoperative pelvic floor dysfunction (established by IPSS, 24 hour FVC and the uroflowmetry) and accompanying dysfunctional voiding aren advised to undergo gGAS without UL. For the assessment of voiding the IPSS, functional bladder capacity and uroflowmetry were collected before and after the gGAS. Postoperative outpatient visits were scheduled after 3 weeks, 3 and 12 months, unless indicated otherwise.

Patient Reported Outcome Measurement (PROM)

Data was collected using a non-validated self-compiled questionnaire with close-ended questions. A comprehensive concept questionnaire was compiled and the inputs of other medical specialties (e.g. psychologist, plastic surgeon and psychiatrist) was obtained. In accordance with their input, changes were made to the questionnaire. This resulted in the PROM used in this study which comprised questions with concern to satisfaction of surgical outcome and function, feeling of masculinity and sexuality and was completed at least one year after the gGAS. Questions concerning satisfaction were ordinally scaled with 5 options ranging from 1 (the most favorable result) to 5 (the most unfavorable result). For the question concerning masculinity a ladder was used ranging from 0 not at all to 10 totally (see attachment). The questionnaire was digitally entered at a moment chosen by the patient in a private setting. In line with comments from the medical ethic committee a part of the study group was not approached to complete the PROM because they had already completed the more comprehensive questionnaire for another study.

Preoperative work up

Transgender men were fully informed about all types of gGAS with and without UL. Expectations with concern to voiding, complications, aesthetic result and the possible need for additional surgical procedures were extensively discussed. All transgender men were consulted by a psychologist about their wishes and expectations of the surgery and an inventory is made about their psychological capacity and self-reliance in case of complications. Prerequisites for gGAS were having a BMI between 17 and 30 and refraining from smoking for at least 6 weeks. Flap choice is based on individuals preference, taking into account subcutaneous fat thickness. A maximum thickness of 1 cm of the donor site determined by ultrasound or pinch is mandatory to prevent too

large phallic girth. For metoidioplasty, clitoral hypertrophy was a prerequisite for creating a micropenis. The type of genital surgery is determined by the patients desire, psychological capabilities, surgical feasibility and the outcomes of the urological assessment. Pre-operative voiding assessment was performed as mentioned above. A colpectomy is mandatory in case of gGAS with UL as it has shown to reduce post-operative urethral strictures and fistulae (14). The colpectomy is performed during a separate surgical session and prior to the gGAS. In case of gGAS without UL, the colpectomy is optional and dependents of the individuals desire.

Surgical technique

The scrotoplasty is based on the scrotoplasty as developed by Hoebeke and Monstrey (13). The labia minora and a large part of its inner lining are resected leaving about one centimeter mucosa surrounding the urethral meatus. As a result, a wide urogenital opening at the perineal scrotal junction is created. The anatomical position of the urethral meatus remains unchanged. If the vaginal canal is preserved, the perineal orifice is referred to as the urogenital opening which allows voiding and drainage of vaginal discharge. In case the vaginal canal is removed, the orifice is referred to as a perineal urethrostomy which allows voiding. The clitoral skin is incorporated in the ventral part of the neo-scrotum. The perineum is lengthened by closing part of the perineal skin, making it more masculine. A 16 French trans urethral catheter is placed. The flaps used for the phalloplasty were the anterolateral thigh flap (ALT) from the upper leg or the superficial circumflex iliac perforator flap (SCIP) from the groin. Both are pedicled flaps with an easy to conceal and less conspicuous donor site. Because the flap sensory nerves must be spared, these flaps cannot be thinned out too rigorously. Appropriate thickness of these fasciocutaneous flaps is therefore important because this determines the final girth of the neo-phallus. The transurethral catheter is removed at day 4 or 5 (during hospital stay) so the transgender men leave the hospital without catheter. In comparison, our transgender men who undergo gGAS with UL have a hospital stay of approximately 7 days, and both a suprapubic and transurethral catheter for at least three weeks postoperatively. Postoperative outpatient visits are scheduled after 3 weeks, 3 and 12 months. Urinary storage and voiding assessment using the IPSS, 24 hour FVC and uroflowmetry is performed at 12 months postoperatively unless otherwise indicated.

Figure 1 to 4 shows different end results of phalloplasty's and metoidioplasty.

Figure 1 Per operative end result of scrotoplasty without urethral lengthening Ventral apart perineal urethrostomy



Figure 2 SCIP phalloplasty, scrotoplasty and testicular implants



Fidure 3 ALT phalloplasty 2 days post operative and other transgender men > 3 months



Metoidioplasty without urethral lengthening



Data analyses

Continuous variables were presented as means with standard deviations or as medians with ranges. Descriptive analyses were performed using IBM SPSS Statistics Version 22 data analysis software (IBM Corp., Armonk, NY USA). The Mann-Whitney U test was used to compare the non-parametric continuous variables. The Wilcoxon Signed Rank test was used to compare the non-parametric paired continuous variables.

Ethical statement

Approval was granted by the Medical Ethics Review Committee of VU University Medical Center under FWA number FWA00017598. Informed consent was obtained in all transgender men participating in this study before the start of surgical phase.

RESULTS

Out of the 202 transgender men who had gGAS, 134 (66%) underwent gGAS with UL and 68 (34%) gGAS without UL and were included in the study. A metoidioplasty without UL and a phalloplasty without UL was performed in respectively 35 (52%) and 33 (48%) cases. An overview of the individuals characteristics is given in Table 1. Of 68 transgender men, 66 consciously choose to undergo gGAS without UL. For this group, having no complications after surgery outweighed the urge to void while standing. Two (3%) transgender men who primarily preferred to have gGAS with UL where advised to refrain from this after pre-operative urological consultation with urinary function assessment. One was wheelchair bound because of a spinal cord injury and the second had severe pre-operative dysfunctional voiding due to pelvic floor dysfunction. Both indicated that they were satisfied with esthetical and functional result after the operation and both were content with the pre-operative counseling with concern to the decision to perform this procedure. There were no patients who indicated regret of gGAS without UL.

Surgical complications

An overview of the surgical characteristics and complications is given in Table 2. No intraoperative complications occurred. Early postoperative surgical complications occurred in 9 out of 68 (13%) transgender men. Post-operative hematoma (three at the pubic area and one in the neo-scrotum)

in 4 out of 68 (6%) which required surgical drainage. Necrosis of the phallus (all at the top of the phallus) occurred in 3 out of 68 transgender men (4%). All were treated with debridement and coverage with split skin graft. Complete phalloplasty flap loss (both ALT) was seen in 2 out of 68 (6%) transgender men for which a salvage phalloplasty (secondary phalloplasty) was performed at a

later time.

Surgical duration, minutes (range)	
Metoidioplasty	106 <mark>(</mark> 60-199)
ALT	306 (210-433)
SCIP	200 (180-307)
Mean length of in-hospital stay, days ± SD	
Metoidioplasty	4.51 ± 1.12
ALT	6.5 ± 1.18
SCIP	6.18 ± 1.07
Intraoperative complications	0 (0%)
Postoperative complications*	9 (13,23%)
Hematoma	4 (5,8%)
Skin necrosis	3 (4,4%)
Phalloplasty flap loss	2 (5,7%)
Urethral fistula	0 (0%)
Urethral stenosis	0 (0%)
Perineostomy stenosis	8 (11,7%)

ALT=anterolateral thigh, SCIP= superficial circumflex iliac artery perforator, *= within three weeks which required surgical correction

Urinary complications and storage and voiding outcomes

Urinary complications occurred in 8 out of 68 (12%) transgender men and consisted of stenosis of the urogenital opening (n=5) and perineal urethrostomy stenosis (n=3). No urethral stricture or urethral fistula occurred. These stenosis were caused by contraction of the skin of the orifices and not by stenosis of the meatus of the urethra. A stenosis of the perineal urethrostomy caused obstructive voiding. In case of a stenosis of the urogenital opening, obstructive voiding, persistent fluid discharge and the feeling of voiding in the vaginal cavity were recorded. Transgender men who had not undergone a colpectomy were treated by releasing the circular scar (episiotomy), mobilization of vaginal mucosa and suturing of the vaginal mucosa to the perineal skin in an interdigitated way to create a wider urogenital opening. In case a colpectomy was performed, the circular scar was released and the meatus mobilized and spatulated. Hospital stay after this corrective surgery was two days and the transurethral catheter could be removed the day after surgery. No recurrence of urogenital opening or perineal urethrostomy stenosis occurred.

An overview of the storage and voiding function assessment pre-and postoperatively is presented in Table 3. The Uroflowmetry was performed by 44 transgender before and after the

gGAS. The IPSS was completed by 44 of them before and after the gGAS. The transgender men were poorly motivated to complete the FVC post gGAS and in only 13 transgender men it was completed before and after the surgery. No changes were seen in pre- versus postoperative voiding and storage functions. This also accounts for the transgender men who underwent a colpectomy. No significant changes occurred in uroflowmetry (e.g., max flow rate, voided volume, time to max flow) pre-and post-operatively and no changes occurred in post residual volume. Furthermore, no significant changes occurred in IPSS score. There was however, a statistically significant decline of the QoL score of the IPSS (p=0.037) going from 0 (delighted) to 1 (pleased) (n=44). With concern to the FVC there was no difference in day frequency, night frequency and functional bladder capacity when comparing the group of patients who completed the FVC before and after the gGAS (n=11).

Table 3: Urinary voiding assessment pre-and postoperatively	/. The data is from the transgender men who completed the assessment.
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	Pre-operative	n	Post-operative	n	P-value
Uroflowmetry ^{mwu}				·	
Max flow rate, ml/s (range)	26 (6,2-84)	44	28.3(10-80)	44	0.526
Average flow rate, ml/s (range)	14 (2-49)	35	13 (2-49)	26	0.671
Flow time, s (range)	22 (6.9-54.3)	35	19 (4.9-125)	26	0.699
Time to flow max, s (range)	5.7 (0.8-25.1)	35	6.3 (1.5-20)	26	0.274
Voided volume, ml (range)	263 <mark>(</mark> 19.7-896)	44	311 (27-792)	44	0.381
Post residual volume, ml (range)	0 (0-90)	44	0 (0-250)	44	0.249
IPSS score (range) ^{mwu}	4 (0-22)	37	5 (0-23)	30	0.216
Quality of life (range)	0 (0-4)	37	1 (0-6)	30	0.037*
Frequency voiding chart "			•		
Day frequency	7.4 (3-14)	13	7.5 (4-17)	13	P=0.952
Night frequency	1 (0-1)	13	2 (1-3)	13	P=0.952
Functional bladder capacity	390 <mark>(</mark> 200-610)	13	405 (250-830)	13	P=0.552

^{Mwu}=The Mann-Whitney U test is used to compare pre-and postoperative outcomes,

^w= The Wilcoxon Signed Rank test is used to compare the paired data pre-and postoperative,

*=significant at significance level of 0.05

Patient reported outcome measurement

From the 68 transgender men 12 were not approached as they already completed the more comprehensive PROM. The excluded group had gGAS during the same timeframe and had the same pre-operative counseling and post-operative follow up. From the 56 eligible transgender men, 16 could not be reached and 40 completed the PROM (response rate 71%). Figure 5 shows the flow chart of included transgender men and table 4 displays the results of the PROM. The small majority of transgender men were satisfied or very satisfied with the esthetical results of the penis (63%) and neo-scrotum (65%). Around 50% were satisfied or very satisfied with the functional outcome (e.g. voiding and sexual functioning). The vast majority agreed or strongly agreed that the surgery increased their self-esteem (80%), would recommend the surgery to others (70%), would undergo the surgery again (77%) and indicated that the outcomes match their expectations (78%). We found no associations between complications and results from the PROM. Responses of the



Figure 5 Flow chart of transgender men eligible for completion of the PROM

Table 4: Results from the patient reported outcome measurement

	Very satisfied	Satisfied (2)	Neutral (3)	Unsatisfied	Very unsatisfied
	(1)			(4)	(5)
How Satisfied are you with:					
The appearance of your penis?, n (%)	9(22.5)	16(40)	7(17.5)	6(15)	2(5)
The appearance of your scrotum?, n (%)	5(12.5)	21(52.5)	8(20)	4(10)	2(5)
Your current voiding pattern?, n (%)	7(17.5)	14(35)	14(35)	4(10)	1(2.5)
Your sex life?, n (%)	2(5)	16(40)	13(32.5)	6(15)	3(7.5)
The sexual functioning of your penis?, n (%)	2(5)	16(40)	13(32.5)	6(15)	3(7.5)
	Strongly agree (1)	Agree (2)	Neutral (3)	Disagree (4)	Strongly disa- gree(5)
To what extent do you agree with the follow-					
ing statements:					
The surgery increased my self-esteem as a	15(37.5)	17(42.5)	7(17.5)	1(2.5)	0
man. n (%)					
I would recommend this surgery to others.n (%)	18(45)	10(25)	9(22.5)	0	3 (7.5)
Looking back, I would undergo the surgery all	26(62.5)	6(15)	7(17.5)	1(2.5)	1(2.5)
over again. n (%)					
The surgical outcomes match my expecta-	8(20)	23(57.5)	4(10)	4(10%)	1(2.5%)
tions.					
n (%)					

Table 5	Summary of	responses of	the satisfaction	with sexual	function question
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metoidoiplasty		
satisfaction	'n	Responses
Very satisfied	0	Feeling of the phallus is good.
Satisfaction	10	The phallus feels like a real penis
		The sexual feeling is unchanged
		I have orgasms
Nor satisfied or unsatisfied	7	No partner, not sexually active, low sexual desire, feeling is good but small for
		penetration
Unsatisfied	3	Unable to penetrate
Vey unsatisfied	1	Not much has changed
		Too small to penetrate
phalloplasty		
satisfaction	n	Responses
Very satisfied	2	Feeling of the phallus is good.
Satisfaction	6	Although I cannot penetrate my orgasm is good and the feeling in the phallus is
		getting better.
		More confidence because of sexual intercourse
Nor satisfied or unsatisfied	6	Sometimes penetration is painful for partner. Asexual relation
Unsatisfied	3	No penile implant jet,
Vey unsatisfied	2	Malposition of the penile implant
		No feeling in the phallus
		Phallus is to short

DISCUSSION

This clinical follow up study of gGAS without UL shows favorable surgical and urinary function outcomes (storage and voiding function). A urinary complication rate around 10 % was recorded (e.g. stenosis of the perineal orifice), which is significantly lower than urinary complications after gGAS with UL reported in the literature (10,10). Still, a small majority of transgender men were satisfied and very satisfied with the functional outcomes. The main reason for dissatisfaction with sexual function was the absence of a penile implant (which they were still awaiting for). With concern to voiding, around 50% were satisfied and very satisfied, while 35% scored neutral. Objective urological outcomes, however, showed good functional results. The vast majority of transgender men agreed and strongly agreed the surgery increased their self-esteem, would recommend it to others, would undergo the surgery again and indicated that the outcomes matched their expectations. These results show predominant favorable outcome after gGAS without UL as seen from a care takers point of view. Additional benefits of gGAS without UL is a less visible donor site in of the ALT flap and the SCIP flap compared to the free radial fore arm flap. Since we

offer transgender men a choice to undergo gGAS with or without UL, one third deliberately chose to refrain from UL and as stated before, for this group, having no complications after surgery outweighed the urge to void while standing. For two transgender men the circumstances were decisive in the decision to undergo gGAS without UL. Personal preference of the transgender men was also decisive with concern to the colpectomy. Performing a colpectomy has a number of advantages; it can have an effect on the male self-esteem (e.g. no vaginal discharge during arousal, and by closing the vaginal cavity a more masculine perineum is created) (15). It also proved to reduce urethral fistulas in case of gGAS with UL (14). At our center the colpectomy is mandatory before gGAS with UL. The colpectomy, however, is a challenging procedure that comes with potential complications of the lower urinary tract system, intra-operative blood loss and postoperative voiding complaints (15). In case of gGAS without UL a colpectomy can be omitted and therefore the concomitant complications can be avoided. In this study, we were able to demonstrate the anticipated benefits of this procedure with concern to the peri- and postoperative outcomes. No urethral fistulas or strictures occurred postoperatively. Both complications predominantly occur at the transition of the fixed to the pendulant part of the neo-urethra after gGAS with UL and are not expected as this part is only created when performing gGAS with UL. In this cohort eight transgender men developed obstructive voiding due to stenosis of the skin that surrounds the urethral meatus. In those, a minor surgical revision was performed. Patients were discharged from the hospital one day postoperatively without a transure thral catheter. The removal of the transure thral catheter one day post-operatively is justified by the fact that we did revise the urethral meatus, but only the surrounding skin. The reduction of complications compared to transgender men who undergo gGAS with UL is associated with less secondary operations and outpatient hospital visits, which may have a positive effect on total healthcare costs in this population. With concern to urinary storage and voiding function, there was no difference in IPSS scores, FVC and uroflowmetry pre-and postoperatively. The QoL with concern to voiding increased with one point, from delighted to pleased which was a statistical significant decline. This statistical significant increase showed no clinical consequence as there was no difference in IPSS score before and after the gGAS without urethral lengthening. As the anatomical position of the urethral is

unchanged one would expect no change in voiding. For this the placing a supra pubic catheter becomes due (which is the standard during gGAS with UL in most centers) and the transurethral catheter is removed during the hospital stay and when patient are mobilizing. In our experience the catheter is removed on day 4 or 5 and thus patient leave the hospital without catheter. One transgender man in this selective group indicated that he is not able to fully live as a man because he is unable to void standing. Another one was unable to use a special voiding devise after the gGAS which enabled him to void while standing before the operation. Other reasons for dissatisfaction with voiding were: voiding against the scrotum, problems with urinating and discomfort at the perineal orifice. For the majority in this selective group, voiding while sitting is not seen as a shortcoming and one can postulate that this does not negatively influence the gender dysphoria. We have to be cautious with this however as the questions on the effect of voiding in a sitting position on gender dysphoria in transgender men was not addressed. Results after GAS show high satisfactory results with concern to esthetical and functional outcomes, while rates of dissatisfaction and regret are low. Causes of dissatisfaction and regret can be related to unmet expectations, treatment outcomes or complications and can occur throughout the transition process(5). In this study no transgender man indicated regret after genital GAS without UL. Dissatisfaction (unsatisfied or very unsatisfied) with esthetical and functional surgical outcomes were scored however by a minority of transgender men in this study but did not result in regret. Extensive pre-operative counseling during this shared decision making process contributed to these results. The outcomes of the open questions (table 5) will aid in further developing of the pre-operative counseling process. It should be noted that UL in a later stage would be challenging since the labia minora and infundibular tissue (needed for pars fixa creation) are excised. GGAS has proven to positively influence sexual functioning with concern to masturbation, use of genitals during sex, engaging in sexual relations and sexual role (3,4,5). At the time of completion of the PROM about 50 % of transgender men were satisfied or very satisfactory with the sexual function. For the transgender men with phalloplasty's this is partly due to the lack of a penile implant which they were still awaiting for and lack of sensitivity in the phallus. For the transgender men with a metoidioplasty the lack of length and the inability to have sexual intercourse was the main reason for dissatisfaction. In

accordance to previous studies gGAS increased self-esteem and the outcomes after surgery matched the expectations (3,4,5). The results (with concern to sexual functioning and wellbeing) from these studies and the results of the PROM used in our study, emphasize the importance of extensive and thorough pre-operative counseling of these transgender men, where personal preferences, expectations and goals are weighted out against outcomes and limitations in order to make a tailored decision based on shared decision making. Results of pre-operative counseling and PROMs were already emphasized in previous studies(3). At our center a decision aid is developed through collaboration with health care professionals and representatives of the transgender association. This decision aid helps transgender men to make a well-considered decision with regard to GAS (8).

Strengths of this study comprise the number of patients, the completeness of data, and the incorporation of patient-reported outcomes. This has resulted in the thorough description of a surgical approach that may be suitable for a subgroup of transgender men. This is the first publication on gGAS without UL and therefore we have chosen to focus on describing the technique and showing outcomes after the procedure and partly comparing it with outcomes before the procedure. In later studies we will compare gGAS without to gGAS with UL. Limitations of this study included: the relatively low number of transgender men who completed the urinary function assessment and the exclusion of transgender men who completed the more comprehensive questionnaire. Another limitation is that the IPSS was used, for it is not validated for transgender people. Still, we think that it is of value as it contains questions which address both the storage and voiding phase and the outcomes indicate symptoms in both female and male patients. Furthermore, this is the only validated questionnaire available for assessment of voiding function in patients without incontinence for urine. A non-validated PROM which was developed by the health professionals was used. It is difficult to state what the influence of the gGAS without UL was on the assessed parameters from the PROM and whether there is a relationship between the surgery and the outcomes. Still we think the outcomes give an indication about the results of the gender affirming process on a whole. As the operative phase was part of the affirming process in this study, outcomes of this PROM also reflect on outcome of the surgical phase in this

highly selected and well counseled group. Moreover, some of the questions specifically addressed the influence of the gGAS. The fact that the majority of this group would recommend the surgery to others also says something about the whole affirming process in this selected and well counseled group of transgender men. So with the interpretation of these results one has to keep in mind that this is a selected group who were extensively counseled and were motivated to undergo this procedure.

Conclusion

In our population of transgender-men opting for gGAS, one third chose to undergo this without UL after extensive pre-operative counseling. The procedure shows low complication rates with preservation of storage and voiding function. Favorable results with concern to patients satisfaction is reported after surgery emphasizing the importance of thorough patient counseling and shared decision making. GGAS without UL is a valuable option which should be included in the pre-operative counseling and should be incorporated in the surgical armamentarium of surgeons in centers specialized in masculinizing genital gender affirming surgery.

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CHAPTER 4

Scrotal reconstruction in transgender men undergoing genital gender affirming surgery without urethral lenghtening: a stepwise approach.

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SUMMARY

Background: Scrotal (re)construction, scrotoplasty, is performed as part of gender affirming surgery in transgender men.

Objective: To describe, step-by-step, our scrotal reconstruction technique in transgender men undergoing genital gender affirming surgery without urethral lengthening.

Material and methods:

A twenty-nine-year-old transgender men underwent scrotal reconstruction and phalloplasty without urethral lengthening. For this purpose, the traditional scrotal reconstruction technique in patients that undergo urethral lengthening was modified. The patient is placed in lithotomy position. A pedicled horseshoe-shaped pubic flap, clitoral hood and U-shaped labia majora flaps are used for scrotal reconstruction. The inner part of the labia minora (this is used to reconstruct the fixed part of the neourethra) is resected. The cranially pedicled U-shaped labia majora flaps are rotated 90 degrees medially to bring the neo-scrotum in front of the legs. Pedicled labia majora fat pads (LMFP) are released bilaterally and relocated in the neo-scrotum to achieve bulkiness. The meatus and vaginal orifice are diverted underneath the scrotum and a perineostomy is performed.

Results: We present our scrotoplasty technique as a step-by-step video guide. The technique results in the reconstruction of a perineostomy at the perineal scrotal transition, an augmented neo-scrotum, minimal visible scars and proper neo-perineal length.

Conclusion: Scrotal reconstruction using a horseshoe-shaped pedicled pubic flap, LMFP and two cranially pedicled U-shaped labia majora flaps results in a neo-scrotum that resembles the biological scrotum closely in terms of bulkiness, size, shape, tactile sensation and anatomical position.

Video article available at: 10.1016/j.urology.2020.09.017

CHAPTER 5

The surgical techniques and outcomes of secondary phalloplasty after

metoidioplasty in transgender men: an international, multi-center case series.

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J Sex Med. 2019 Nov;16(11):1849-1859.doi: 10.1016/j.jsxm.2019.07.027.Epub 2019 Sep 18.

SUMMARY

Background: Some transgender men express the wish to undergo genital Gender Affirming Surgery (gGAS). Metoidioplasty and phalloplasty are procedures that are performed to construct a neophallus. gGAS contributes to the physical wellbeing, but dissatisfaction with the surgical results may occur. Disadvantages of metoidioplasty are the relatively small neophallus, the inability to have penetrative sex and often difficulty to void while standing. Therefore, some transgender men opt to undergo a secondary phalloplasty after metoidioplasty. Literature on secondary phalloplasty is scarce.

Aim: To explore the reasons for secondary phalloplasty, describe the surgical techniques and report on the clinical outcomes.

Methods: Transgender men who underwent secondary phalloplasty after metoidioplasty were retrospectively identified in seven gender surgery clinics (Amsterdam, Belgrade, Bordeaux, Austin, Ghent, Helsinki, Miami and Montreal). Pre-operative consultation, patient motivation for secondary phalloplasty, surgical technique, peri-operative characteristics, complications and clinical outcomes were recorded.

Main Outcome Measures: The surgical techniques, patient motivation and outcomes of secondary phalloplasty after metoidioplasty in transgender men.

Results: Eighty-three patients were identified. The median follow-up was 7.5 (range 0.8-39) years. Indicated reasons to undergo secondary phalloplasty were: having a larger phallus (n=32,38.6%), being able to have penetrative sexual intercourse (n=25,30.1%), metoidioplasty was a first step towards phalloplasty (n=17,20.5%) and/or to improve voiding from a standing position (n=15,18.1%). Each center had their preferential techniques for phalloplasty. A wide variety of surgical techniques were used to perform secondary phalloplasty. Intraoperative complications (revision of microvascular anastomosis) occurred in three (5.5%) patients undergoing free flap phalloplasty. Total flap failure occurred in one (1.2%) patient. Urethral fistula occurred in 23 (30.3%) patients and strictures in 27 (35.6%).

Clinical Implications: A secondary phalloplasty is a suitable option for patient who previously underwent metoidioplasty.

Strength & Limitations: This is the first study to report on secondary phalloplasty in collaboration with eight specialized gender clinics. The main limitation was the retrospective design.

Conclusion: In high-volume centers specialized in gender affirming surgery, a secondary phalloplasty in transgender men can be performed after metoidioplasty with complication rates similar to primary phalloplasty.

Keywords: Phalloplasty; Metoidioplasty, Transgender men, Gender Affirming Surgery, Genital Surgery

INTRODUCTION

Genital Gender Affirming Surgery (gGAS) in transgender men is considered challenging and complex. Transgender men report an improved quality of life after gGAS.^{1,2} Two options exist to perform gGAS in transgender men: the metoidioplasty and the phalloplasty.^{3,4}

In the 1970s Laub et al. first described the main principles of the metoidioplasty, and several refinements have been published since.⁵ In metoidioplasty, local tissue is used to construct a neo-phallus. Hormonal treatment causes stimulation of clitoral hypertrophy. The hypertrophied clitoris is released and extended to reconstruct the neo-phallus and neo-glans. In those who opt for urethral lengthening, the native urethra is lengthened to reach the tip of the neo-penis, enabling some to void while standing.^{6,7} Advantages of this technique are the erectile capabilities, preservation of genital erogenous and tactile sensation, limited donor-site scar formation, a single-stage procedure and considerably lower costs compared to a phalloplasty. Possible drawbacks are a relatively small neo-penis, that limits the possibility of having penetrative sexual intercourse and voiding from a standing position.^{8,9}

The evolution in microsurgery enabled the use of free flaps to construct a neo-phallus. In 1984 Chang et al. first described the phalloplasty technique using a free radial forearm flap (FRFF).¹⁰ Since then, several phalloplasty techniques using either pedicled, free and combination flaps have been described.^{9,11} The advantages, in comparison to a metoidioplasty, are a larger neo-penis and the possibility to implant a penile prosthesis to enable penetrative sexual intercourse.^{12,13}

Some transmen, who underwent metoidioplasty, express the wish to undergo secondary phalloplasty. There are two reasons to perform a secondary phalloplasty. A secondary phalloplasty can be performed as a planned second stage after metoidioplasty or in patients who are unsatisfied with their metoidioplasty. Nowadays, patients who opt for gGAS are informed about both options. In a process of counseling and shared decision making the transman decides to undergo either a metoidioplasty or a phalloplasty. Several studies have addressed the incidence of secondary phalloplasty and reported rates ranging from 10% to 25%.^{68,14,15} In general, the risk of complications is greater in secondary surgical interventions. Scarred tissue and changed surgical

anatomy makes secondary surgery theoretically more challenging. Therefore, we hypothesize that in comparison to primary phalloplasty, secondary phalloplasty is associated with a higher complication rate.

There is a lack of knowledge in the published literature on patient motives, surgical techniques, feasibility, safety, and outcomes of secondary phalloplasty. Also, most published literature on surgical techniques and outcomes after gGAS in transgender men are based on single center experiences, that include a limited number of patients. Hence, the aim of this study was to explore the patient reasons for secondary phalloplasty, describe the surgical techniques, report the clinical outcomes and evaluate the patient-experienced outcomes.

METHODS

Centre and patient selection

Sixteen centers worldwide, each of them high-volume centers specialized in GAS, were invited to be part of the study. Representatives of seven centers who performed secondary phalloplasty agreed to contribute data. These were: the Amsterdam UMC (VU University), Belgrade University Hospital, University Of Miami Health System, Gender Reassignment Surgery Montreal, Helsinki University Hospital, Crane Surgical Services, Bordeaux University Hospital and Ghent University Hospital. In all centers, transgender men who underwent secondary phalloplasty after metoidioplasty were retrospectively identified. Data were collected at each study site by surgical team members and anonymized before it was shared in a central database. The anonymized data was reviewed and analyzed centrally at the Amsterdam UMC (VU University). According to the Dutch Central Committee for Human Research, retrospective medical research is exempt from an institutional review board (IRB) approval.

Data collection: retrospective chart review

Electronic standardized forms were used to collect center specific and patient data. The following institution-specific information was filled in by the surgeon and collected:

Surgical team composition
- Main center to perform GAS in their country
- Type of health-insurance coverage
- Amount of metoidioplasty and phalloplasty procedures performed per year
- Stages of genital surgery
- Preferred phalloplasty flap type
- Pre-operative counseling towards secondary phalloplasty in the center (precategorized into three methods of counseling: secondary phalloplasty is actively offered to all patients with a current metoidioplasty, is only discussed if the patients how a strong desire or very restrained to perform a secondary phalloplasty even if there is a strong patient desire.)
- Postoperative outpatient visit schedule

Retrospective chart review was performed, and the following patient data were recorded after metoidioplasty:

- Patient demographics (age at metoidioplasty, age at phalloplasty, history of smoking, history of drug use, surgical history, psychiatric comorbidity and somatic comorbidity)
- Reason for secondary phalloplasty (information in the medical records was first collected and based on this information five main reasons were identified. These reasons were: a larger phallus, ability to have penetrative sexual intercourse, metoidioplasty was the first step towards phalloplasty, wish to void while standing and a category 'other'.)
- Surgical technique (urethral lengthening technique and meatus localization)
- Surgical and urological outcomes including intraoperative complications, postoperative complications (hematoma, wound infection and skin necrosis). Only complications that required (surgical) intervention were scored.
- Urological complications (fistula and strictures)

The following data were recorded after secondary phalloplasty:

- Surgical technique (phalloplasty type and urethral lengthening technique)
- Operative characteristics (operation time and hospitalization duration)

- Intraoperative complications (hemorrhage and re-do microvascular anastomosis),
- Postoperative complications (hematoma, complete/partial flap failure and wound infection)
- Urological complications (fistula and stricture)
- Scheduled additional phalloplasty correction surgeries
- Clinical outcomes (last outpatient clinic visit, penile implantation, ability to have penetrative sexual intercourse and/or to void while standing (retrospectively identified from patient medical record)
- Physician recorded information in the medical records was used as a proxy for patients' overall satisfaction. The local data collectors used the information provided in the medical records to estimate the patient overall satisfaction on a 4-point scale (very satisfied, somewhat satisfied, somewhat dissatisfied and very dissatisfied).

Data analyses

Continuous variables were presented as means with standard deviations or as medians with ranges. Descriptive analyses were performed using IBM SPSS Statistics Version 22 data analysis software (IBM Corp., Armonk, NY USA). As the study objective was to investigate the secondary phalloplasty procedures in general, and the sample size was limited, no subgroup comparisons were made per study site or flap type. Eighty-three patients were included in the study. One patient had a follow-up of less than six months after secondary phalloplasty and was excluded from the analysis regarding the outcomes after secondary phalloplasty. Postoperative complications after metoidioplasty and secondary phalloplasty were subdivided an analyzed in three groups: (1) intraoperative complications, (2) postoperative complications and (3) urological complications.

RESULTS

Surgical technique

Patients were screened and counselled pre-operatively in accordance with the Standard of Care (SOC).¹⁶ All patients had a surgical history of metoidioplasty, resulting in a lengthened urethra, extended clitoris and a neo-scrotum.

Secondary phalloplasty surgery was performed using a pedicled flap and/or free flap. For phalloplasty shaft reconstruction, pedicled flaps were raised from the groin, thigh or lower abdomen (e.g., groin flap (GF), anterolateral thigh (ALT) flap, abdominal flap (AF) and the gracilis muscle flap (GMF)). Free flaps (e.g., FRFF, fibula flap (FF), latissimus dorsi (LD) flap, ALT free flap) were raised from a remote location and require microvascular arterial and venous anastomosis. The flap artery was anastomosed end-to-side (E-S) to the superficial femoral artery, and the flap vein end-to-end (E-E) to the great saphenous vein.

Multiple surgical techniques for urethral reconstruction were utilized: a tube-in-tube flap configuration, use of full-thickness skin grafts(FTG), buccal mucosa or the use of a second fasciocutaneous flap. Reconstruction was performed in either a one- or two-stage procedure, based on the surgeons preference.

The redundant metoidioplasty shaft skin, former clitoral hood skin, was excised (Figure 1a and 1b). This skin may be used as a FTG to cover the base of the neophallus. Subsequently, the penile glans (former glans clitoris) was completely degloved and denuded to allow it be buried in the phalloplasty. Positioning of the degloved clitoris varied based on the surgeons preference. Nerve cooptation was performed in free flap phalloplasty between the ilioinguinal nerve and/or the clitoral nerve and the cutaneous nerves of the phalloplasty flap. For clitoral nerve cooptation, one of the two dorsal clitoral nerves was isolated (Figure 1c) and later anastomosed end-to-end (E-E) to the phalloplasty flap nerve.

The reconstructed pars pendulans in the metoidioplasty, former labia minora skin with or without buccal mucosa, was carefully separated from the penile shaft and glans (Figure 1d). The

required urethra size to lengthen the urethra to the top of the phalloplasty was determined and the urethral anastomosis was performed onto the previously lengthened pars pendulans (former metoidioplasty meatus) in a spatulated manner (Figure 1e and 1f). If the patient did not prefer complete urethroplasty, the existing meatus of the metoidioplasty could have been localized in the penoscrotal angle or penile shaft of the secondary phalloplasty. If necessary, the scrotum was repositioned more anteriorly by performing an advancement of the existing scrotoplasty. A suprapublic and Foley catheter are left in place (Figure 1g).

Figure 2 illustrates the pre-and post-operative views of several patients that underwent secondary phalloplasty.



Figure 1. Surgical technique for secondary phalloplasty. (A) Preoperative view. (B) Excision of the metoidioplasty shaft skin. (C) Isolation of a dorsal nerve of the ditoris for phalloplasty flap nerve anastomosis. (D) Separation of the urethra from the metoidioplasty shaft. (E) The use of a fasciocutaneous flap for additional lengthening of the pars pendulans. (F) The pars pendulans is sufficiently lengthened to allow localization of the neomeatus on top of the secondary phalloplasty. (C) A second fasciocutaneous flap is used to form the secondary ⁷⁸ phalloplasty shaft. The degloved clitoris is buried in the phalloplasty.



Figure 2. Pre-and postoperative views of secondary phalloplasty. (Case 1) Secondary phalloplasty was performed using 2 sensate superficial circumflex iliac artery perforator flaps to reconstruct the neourethra and neophallus shaft; the neomeatus is localized on top of the phalloplasty. (Case 2) The neourethra and neophallus shaft were reconstructed with a tube-in-tube anterolateral thigh flap; the neomeatus is localized on top of the phalloplasty. (Case 3) Anterolateral thigh flap was used to reconstruct the neophallus shaft; no urethral lengthening was performed, and the meatus remained localized in the scrotum. (Case 4) Tube-in-tube free radial forearm flap was used to reconstruct the neourethra and neophallus shaft.

Inter-center variability in peri-operative protocols

Considerable variation existed in peri-operative care and protocols between the participating centers (Table 1). In four of seven centers surgeons only discussed the possibility to undergo secondary phalloplasty with patients who expressed a strong wish to undergo phalloplasty. In three centers secondary phalloplasty was routinely discussed with patients. In one clinic, a metoidioplasty was routinely performed as a first step towards phalloplasty. Also, differences existed in surgical team composition, genital surgery health insurance coverage, number of GAS procedures performed annually (range 10-150 per year) and the postoperative outpatient visit schedule.

	Amsterdam	Belgrade	Miami	Helsinki	Bordeaux	Montreal	Austin	Ghent
Patients included (n)	27	13	4	5	2	4	6	22
Surgical team composition	Plastic surgeon, urologist and gynecologist	Plastic surgeon, urologist, gynecologist and pediatric surgeon	Plastic surgeon, urologist and gynecologist	Plastic surgeon	Plastic surgeon	Plastic surgeon	Plastic surgeon and urologist	Plastic surgeon and urologist
Main center performing gender affirming surgery in your country?	Yes	Yes	No	Yes	No	Yes	No	Yes
Health insurance coverage of genital gender affirming surgeries ?	Yes, full coverage	Partially; metoidioplasty with urethral lengthening is covered. Phalloplasty, testicular implants and penile implants are not	Yes, full coverage	Yes, full coverage	Yes, full coverage	Yes	Yes, full coverage depending on insurer	Yes, full coverage
Metoidioplasty procedures per year, since (year)	10-20, since 1989	10-20, since 1993	10-20, since 2010	0-10, since 2003	0-10, since 2008	Unknown, since 2011	90-100, since 2013	0-10, since 2006
Phalloplasty procedures per year, since (year) ^a	20-30, since 1989	30-40, since 1995	0-10, since 2010	10-20, since 2003	0-10, since 2014	Unknown, since 2013	150, since 2013	30-40, since 1992
Stages of phalloplasty surgery*	One-stage	One-stage or two-stage	Two-stage	One-stage	One-stage	One-stage	Two-stage	One-stage
Preferred flap type for secondary phalloplasty	FRFF and ALT	LD	FRFF	GMF	FRFF	FRFF	FRFF and ALT	FRFF and ALT
Pre-operative counseling towards secondary phalloplasty?	Only discussed in case of strong desire	Actively offered in all patients with a metoidioplasty	Actively offered in all patients with a metoidioplasty	Only discussed in case of strong desire	Only discussed in case of strong desire	Only discussed in case of strong desire	Actively offered in all patients with a metoidioplasty	Actively offered in all patients with a metoidioplasty and as first step towards phalloplasty
Postoperative outpatient visit	3 weeks, 3,6 and 12 months	1,2 and 4 weeks, 3,6 and 12 months	2 and 4 weeks, 3,6 and 12 months	1 and 4 weeks, 3,6 and 12	1,3,6 and 12 months	1,3,6 and 12 months	2,3 and 4 weeks	2 and 4 weeks, 3,6 and 12 months. After

Table 1: Inter-institutional characteristics

schedule for local patients				months, and then 3,5 and 10 years				one year, there is a yearly follow-
								up
^a primary and secondary phalloplasty, * one-stage consists of construction of the phalloplasty and complete urethroplasty, two-stage includes construction of the phalloplasty and complete urethroplasty which is additionally closed in the second stage, ALT=anterolateral thigh, FRFF=free radial forearm flap, GMF=gracilis muscle flap, LD=latissimus dorsi								

Patients demographics

A total of 83 transgender men were included who underwent secondary phalloplasty. An overview of the patient demographics is given in Table 2. The main reasons to undergo secondary phalloplasty were having a larger phallus(n=32, 38.6%), the ability to have sexual intercourse(n=25, 30.1%), metoidioplasty was performed previously as a first step towards phalloplasty (n=17,20.5%) and the ability to void from a standing position(n=15, 18.1%). The median time between metoidioplasty and secondary phalloplasty was 4.5 (0.7-36) years. The mean clinical follow up time was 7.5 (0.8-39) years and was calculated as the time between metoidioplasty surgery and the last outpatient clinic visit.

Table 2: Patient demographics

Number of patients	83
Mean BMI, kg/m ² ± SD	24 ± 3
Mean age at metoidioplasty, years ± SD	32 ± 10
Median time between metoidioplasty and secondary phalloplasty, years (range)	4.5 (0.7-36)
Median clinical follow up time, years (range)	7.5 (0.8-39)
Able to void while standing after metoidioplasty	33 (45.2%)*
Reason(s) for secondary phalloplasty, n (%) ^D	
Larger phallus	32 (38.6%)
Ability to have penetrative sexual intercourse	25 (30.1%)
Metoidioplasty was first step towards phalloplasty	17 (20.5%)
To void while standing	15 (18.1%)
Other	2 (2.4%)
Unknown	1 (1.2%)
Comorbidities, n (%)°	
Psychiatric	19 (22.9%)
Drugs usage history	1 (1.2%)
Smoking history	26 (31.3%)
Surgical history, n (%)°	
Mastectomy	83 (100%)
Hysterosalpingo-oophorectomy	83 (100%)
Colpectomy	31 (37.3%)
History of cross-sex hormone therapy	83 (100%)
BMI=body mass index, *data available for 73 patients, =multiple answers possible, =prior to secondary	
phalloplasty	

Surgical characteristics and urological outcomes after metoidioplasty

An overview of the surgical and urological outcomes is presented in Table 3. No intraoperative complications were reported, while 12 (14.5%) patients developed postoperative complications. Urethral lengthening was performed in 81 (98%) patients, of which 12 (14.8%) developed an urethral stricture and 19 (23.5%) had an urethral fistula.

	Number of patients (%)
Intraoperative complications	0 (0%)
Hemorrhage	0 (0%)
Postoperative complications ⁶	
Hematoma	5 (6%)
Wound infection	5 (6%)
Skin necrosis•	2 (2.4%)
Urethral lengthening	81 (98%)
Urethral stricture	12 (14.8%) •
DUS	8 (9.8%)
PUS	4 (4.9%)
Urethral fistula	19 (23.5%) •
DUF	11 (13.6%)
PUF	8 (9.9%)

Table 3: Surgical and urological outcomes after metoidioplasty

^o= within three weeks, =requiring debridement, •N=81 with urethral lengthening, DUF= distal urethral fistula (fistula at the distal urethral anastomosis and/or the penile shaft), DUS= distal urethral stricture (stricture at the distal urethral anastomosis and/or penile shaft), PUF= proximal urethral fistula (fistula at the proximal urethral anastomosis and/or the fixed part of the urethra), PUS= proximal urethral stricture (stricture at the proximal urethral anastomosis and/or fixed part of the urethra), IPSS=International Prostate Symptom Score

Surgical characteristics and outcomes after secondary phalloplasty

An overview of the surgical outcomes is presented in Table 4. The median follow-up time after secondary phalloplasty was 16 (range 10-266) months (calculated as time between phalloplasty surgery and the last outpatient clinic visit). The mean operation time was 427±110 minutes.

Re-do vascular anastomosis had to be performed in three (3.6%) patients. Total flap failure occurred in one ALT patient and was successfully salvaged with a new FRFF flap.

Of 81 patients who previously underwent metoidioplasty with urethral lengthening, 77 (95.1%) patients had additional lenghtening of the pars pendulans. For lengthening, a tube-in-tube flap configuration was performed in 44 (57.1%), a second fasciocutaneous flap in 21 (27.3%), buccal mucosa in 10 (12.9%) and full-thickness skin grafts in two (2.6%) patients. The meatus was localized on top of the phalloplasty in 72 (86.8%) patients, top of the previous metoidioplasty in 9 (10.8%) and the perineum in two (2.4%) patients. The median hospitalization was 11 (range: 4-38) days. Of 77 patients that underwent additional urethral lengthening, 76 patients had a minimum follow-up of six months. Of 76 patients, 23 (30.3%) developed an urethral fistula and 27 (35.6%) an urethral stricture.

Penile prosthesis were implanted in 21 (25.6%) patients of whom 15 (71.4%) reported the ability to have penetrative sexual intercourse. Voiding from a standing position was possible in 69 (90.8%) patients.

Physician reported information in the medical record that was used as a proxy for overall patients satisfaction was available for 66 patients of whom 65 (98.5%) were (very or somewhat) satisfied with surgery.

Table 4: Surgical and urological outcomes after secondary phalloplasty

	Number of nationts (%)
Total	83 (100%)
Free radial forearm flap	41 (49.4%)
Anterolateral thigh flap	22 (26.5%)
Latissimus dorsi flap	8 (9.6%)
Gracilis muscle flap	5 (6.0%)
Abdominal flap	4 (4.8%)
Groin flap	2 (2.4%)
Lateral upper arm flap	1 (1.2%)
Median clinical follow up time, months (range)	16 (10-266) [°]
Intraoperative complications	
Hemorrhage	0 (0%)
Re-do microvascular anastomosis	3 (5.5%) [∆]
Postoperative complications ^o	31 (37.8%)
Hematoma	7 (8.5%)
Complete flap failure [¢]	1 (1.2%)
Partial flap failure with loss of skin	16 (19.5%)
Phalloplasty wound infection	7 (8.5%)
Urethral lengthening	77 (95.1%)
Urethral stricture	27 (35.6%)•
DUS	25 (32.9%)
PUS	3 (3.9%)
Urethral fistula	23 (30.3%)•
DUF	17 (22.4%)
PUF	6 (7.9%)
^e = one patient had a follow-up of less than six months and was excluded from the	analysis regarding postoperative complications and urological

^{*} = one patient had a follow-up of less than six months and was excluded from the analysis regarding postoperative complications and urological complications, ^AN=55 with free flap phalloplasty, ^e within three weeks, ^e=phalloplasty shaft flap and/or flap for urethral reconstruction, •N=76 with urethral lengthening and minimum follow-up of six months, DUF= distal urethral fistula (fistula at the distal urethral anastomosis and/or the penile shaft), DUS= distal urethral stricture (stricture at the distal urethral anastomosis and/or penile shaft), PUF= proximal urethral fistula (fistula at the proximal urethral fistula (fistula at the proximal urethral anastomosis and/or the fixed part of the urethra), PUS= proximal urethral stricture (stricture at the proximal urethral anastomosis and/or fixed part of the urethra), PUS= proximal urethral stricture (stricture at the proximal urethral anastomosis and/or fixed part of the urethra), PUS= proximal urethral stricture (stricture at the proximal urethral anastomosis and/or fixed part of the urethra), PUS= proximal urethral stricture (stricture at the proximal urethral anastomosis and/or fixed part of the urethra), PUS= proximal urethral stricture (stricture at the proximal urethral anastomosis and/or fixed part of the urethra), PUS= International Prostate Symptom Score .

Table 5: Patient reported and clinical outcomes after secondary phalloplasty

	n (%)					
Total	82 (100%)					
Scheduled correction surgeries	10 (12.2%)					
Penile implants ^Δ	21 (25.6%)					
Able to have penetrative sexual intercourse with implant	15 (71.4%)					
Able to have penetrative sexual intercourse without implant*	0 (0%)					
Reason:						
No rigidity	30 (73.2%)					
No sensation [■]	3 (9.1%)					
Able to void while standing	69(90.1%) •					
Overall patient satisfaction ^						
Somewhat satisfied	30 (45.5%)					
Very satisfied	35 (53%)					
Somewhat dissatisfied	1 (1.5%)					
Very dissatisfied	0 (0%)					
[△] =At the time of reporting, *N=41, •N=76 with urethral lengthening, ^N=66 (retrospectively scored from patients medical records),						
■N=33 with phalloplasty flap nerve anastomosis.						

DISCUSSION

The present study is the first international research collaboration of gender surgeons to investigate the pre-operative consultation, surgical techniques and the clinical outcomes of secondary phalloplasty procedures in transgender men. The main reasons to undergo secondary phalloplasty were having a larger phallus, being able to have sexual intercourse and/or void from a standing position. Surgical outcomes showed that secondary phalloplasty can be performed with complication rates similar to primary phalloplasty.

Flap related complications

Rates on complete flap loss after primary phalloplasty vary from 0.7% to 4.9%.^{11,13,17-19} Various rates have been reported depending on the phalloplasty type. After FRFF phalloplasty, a flap loss rate of 0.7-3% is reported, 2% after AF phalloplasty, 3% after GF, 2.2% after ALT and 4.9% after FF phalloplasty. In our study, total flap loss occurred in one (1.2%) patient after ALT phalloplasty and is accordance with the published literature. Vascular anastomotic revision was performed in three (5.5%) patients after free flap phalloplasty and is considerably lower compared to published anastomotic revision rates of 12% after FRFF phalloplasty.^{13,17} Possible explanation for these relatively low vascular flap related complications in our cohort could be the gained extensive surgical experience of the gender surgeons and improved surgical preoperative assessment over time. For example, a preoperative computed tomography angiography is increasingly performed to evaluate the feasibility of free/pedicled flaps to allow precise surgical planning.

Urological complications

The ability to void from a standing position is an important reason for transgender men to undergo primary phalloplasty. Of 83 transgender men undergoing secondary phalloplasty, 15 (18.1%) indicated that the ability to void while standing was their main goal. Unfortunately, urological complications (e.g., urethral fistulae and strictures) occur frequently after phalloplasty and can delay the possibility to void from a standing position. The reported rates of urethral fistulas after FRFF primary phalloplasty range from 10% to 68%, and strictures from 14% to 58%.^{12,19-23} The present case series, with a fistula rate of 30.3% and stricture rate of 35.6%, indicates that secondary phalloplasty

can be performed with similar neo-urethral complication rates. As expected, the majority of these complications occurred at the distal part of the neo-urethra, since most of the complications after metoidioplasty were solved before secondary phalloplasty.

Patient selection and counseling

Good patient counseling and selection are key to achieve successful surgical outcomes. Proper patient counseling involves realistic pre-operative expectations, discussing the risks and benefits of the surgical procedure, post-operative management and long-term follow-up.²⁴ In this study a difference in the pre-operative counseling towards secondary phalloplasty and follow-up scheme among the institutions was noticed. Possible explanation for the difference in pre-operative counseling could be the difference in healthcare coverage and a shift towards more patientcentered care.

There is a great inter-country variability in insurance coverage for GAS. Underinsured patients have insufficient access to gender-affirming healthcare such as mental health counseling and proper preoperative counseling.²⁵ Also, secondary procedures (e.g., prosthesis implantation and surgical corrections) are not always covered by insurance. Yet, in many countries these insurance coverage policies are changing, so are the accessibility, affordability and availability to undergo (secondary) phalloplasty.²⁶

Over time, patients have become increasingly more involved in surgical decision. Firstly, the metoidioplasty was described as a first step towards phalloplasty in a staged phalloplasty approach.²⁷ The phalloplasty was considered to give the best final results with regard to function and cosmesis.²⁸ Now, there are multiple surgical options and patients' preferences are an important part of the shared-decision making process.

In our cohort the majority of 83 patients were dissatisfied with their initial metoidioplasty (desire for larger phallus, desire for penetrative sex, desire to void while standing =87%). This underlines the need for proper patient counseling before genital GAS. To improve the pre-operative counseling process,

a decision aid was developed recently to further involve patients in the decision making process.²⁹ Hopefully, this will result in less secondary phalloplasty procedures in the future.

Patient selection for metoidioplasty or phalloplasty is also influenced by surgeon factors including surgical experience and volume. It is likely that non-highly specialized gender surgeon who is more familiar with performing a metoidioplasty is less eager to perform a phalloplasty, and vice versa. Also, as seen in our study, a wide variety of surgical techniques is available to perform (secondary) phalloplasty. Therefore, surgeons should be aware of alternative surgical procedures that they may not offer and refer when appropriate to minimize secondary surgical procedures.

International collaboration

The number of people who apply for transgender healthcare, including GAS, has increased drastically recently. Yet, the available literature on GAS is limited, lacks patient reported outcomes measures and standardization concerning surgical and urological outcomes.³⁰ This makes is very difficult, if not impossible to draw generalizable conclusions on these outcomes. There is an urgent need for more strong evidence-based research to assist surgeons and patients in making a well-informed surgical decision. International research collaboration among specialized gender clinics provides an opportunity to standardize outcome measures, acquire high quality data and learn alternative ways of doing things. This international collaboration among specialized gender clinics is a first attempt in achieving standardized data collection.

Limitations

The study's main limitation was the retrospective design. Retrospective data gathering was performed by various people located in multiple centers worldwide. Furthermore, selection bias and the lack of a control group increases the risk of overestimating or underestimating the outcomes rates. Also, physician reported information in the medical record were used as a proxy for overall patients satisfaction, possibly reducing the reliability of our findings. In addition, not having patientreported outcomes makes it difficult to provide unique information on the impact of a secondary phalloplasty from a patient's perspective.

Strengths of our study comprise the high number of patients that are included. In addition, participation of various international specialized gender clinics to provides an unique insight into the secondary phalloplasty procedure globally.

Conclusion

In high-volume centers specialized in gender affirming surgery, a secondary phalloplasty in transgender men can be performed after metoidioplasty with complication rates similar to primary phalloplasty. There are variations among the centers in the management of secondary phalloplasty. In the emerging gender affirming surgery field, more international research collaboration among gender clinics is essential to acquire high quality data and enhance a transfer of expertise and knowledge.

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CHAPTER 6

Surgical management and outcomes of flap loss after primary phalloplasty in transgender men: a 30-year experience.

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SUMMARY

Background: Primary phalloplasty in transgender men can be performed using a single or double flap to reconstruct the neophallus shaft and/or urethra. After reconstructive flap surgery, there is a risk of vascular complications. These may result in total or partial loss of the used flaps and have a negative impact on the quality of life of transgender men. Surgical management after loss of the flap(s) used for the primary phalloplasty presents a challenge to the reconstructive surgeon.

Objective: To describe the surgical reconstructive management after primary phalloplasty flap loss in transgender men and report on the clinical and patient reported outcomes.

Methods: All transgender men who underwent a secondary reconstructive procedure after failure of the primary procedure between January 1989 and January 2018, at the Amsterdam University Medical Center, The Netherlands were identified. A retrospective chart review was conducted, recording relevant demographic and clinical data. In addition, patients were invited to complete a non-validated questionnaire consisting of open and close-ended questions regarding surgical outcomes, (sexual) functionality and sexuality.

Results: Fourteen patients underwent a secondary reconstructive procedure of the penile shaft and/or neo-urethra after primary phalloplasty flap loss and were included in this study. Of 14 patients, eight patients underwent primary phalloplasty using a single flap and six patients using a double flap. In patients that underwent single flap phalloplasty with urethral lengthening, flap loss often resulted in the loss of both the neo-urethra and penile shaft. In double flap phalloplasty, loss of the neo-urethra and/or shaft more often occurred separately.

Eleven patients were reached and invited for completing the follow-up questionnaire, nine completed the questionnaire. Most patients (n=6/14) were satisfied with the appearance of their neo-phallus after salvage surgery and all patients indicated that, when looking back, they would still choose to undergo the surgery.

Conclusion: Flap loss after primary phalloplasty in transgender men is a serious complication leading to additional patient distress. Secondary reconstruction after flap loss is a challenging procedure

that requires a multidisciplinary approach. Successful secondary reconstruction of the phalloplasty can be performed using a second or third pedicled or free flap. After secondary reconstruction, most patients are satisfied with the final result.

Introduction

The number of transgender men that undergo genital Gender Affirming Surgery (gGAS), including phalloplasty, has increased significantly over the last decade.¹ Often, transgender men express the wish to be able to void while standing and/or to be able to engage in penetrative sexual intercourse.² On average, transgender men experience a good quality of life and report satisfactory sexual function after phalloplasty.^{3,4}

Various (fasciocutaneous) flaps can be used for phalloplasty surgery. For example a free radial forearm flap (FRFF), free or pedicled anterolateral thigh (ALT) flap, (pedicled) abdominal flap (AF), groin flap (GF) and the latissimus dorsi (LD) flap.⁵ Phalloplasty can be performed with or without urethral lengthening (UL). In transgender men that undergo phalloplasty without UL, one flap is used to reconstruct the phalloplasty shaft only and the native urethral meatus is localized at the perineal scrotal junction.

In phalloplasty with UL, the neo-urethra is reconstructed and consists of two parts: the neo pars fixa and the neo pars pendulans. Reconstruction of the neo pars fixa is for the most part a standardized procedure using local infundibular and labia minora tissue.^{6,7} There are multiple surgical options for reconstruction of the pendulant part of the neo-urethra.

In single flap phalloplasty, the neo-urethra can be reconstructed using a tube-within-a-tube configuration were shaft and the neo-urethra are reconstructed using the same flap. The FRFF, for example, is often used for single flap phalloplasty. Alternatively, one flap is used for the shaft whereas the urethra is made by prelamination with full-thickness skin grafts (FTG) or buccal mucosa.⁸⁻¹¹ In double flap phalloplasty, shaft and neo-urethra are reconstructed by combining two separate fasciocutaneous flaps (e.g., small RFFF strip with ALT or double GF, GF with labia minora flap).¹⁰⁻¹³

Possible complications of pedicled and/or free flap phalloplasty are venous, arterial or combined thrombosis. This can result in phalloplasty shaft and/or neo-urethral loss.^{14,15}

In single flap phalloplasty with neo-urethral prelamination, loss of the shaft automatically causes loss of the pendulant part of the neo-urethra. Isolated neo-urethral loss in tube-within-a-tube

RFFF has been described.¹⁶ After double flap phalloplasty, the loss of one of the two flaps may occur independently. It is important to emphasize that loss of one of the two flaps is not the same as total loss of the neophallus. Inner flaps used for neo-urethral reconstruction are known to be most at risk for vascular complications due to outer flap swelling and the difficulty to monitor the flap clinically. ¹⁷

The majority of flap failures occur in the first 72 postoperative hours, and in particular the first 24 hours.¹⁸ Clinical monitoring techniques consisting of checking flap temperature, flap color, capillary refill and hand-held Doppler ultrasonography (in case of doubt) are performed every hour, followed by clinical monitoring every two hours for the following three days and then every eight hours until the patient is being discharged from the hospital.

If a compromised phalloplasty flap is suspected, surgical re-exploration is performed. In double flap phalloplasty, a compromised inner flap may be treated by releasing the stitches in the outer flap to decrease tension caused by the flap.

Due to difficult inner flap monitoring, possible neo-urethral necrosis is often observed clinically for the first time after removal of the transurethral catheter. Also, patients may complain of an inability to void and/or have necrotic discharge from the neo-urethra.

To date, surgical management of flap failure after phalloplasty and the long-term follow-up are poorly described.

Here, we describe the feasibility and secondary surgical reconstructive management after primary phalloplasty flap loss in transgender men, as well as the long-term patient-reported outcomes after these procedures.

Methods

Study setup and participants:

All transgender men who underwent a secondary reconstructive procedure using a new flap after primary phalloplasty flap loss between January 1989 and January 2018 at the Amsterdam University Medical Center, The Netherlands were identified.

A retrospective, cross-sectional study was conducted by analyzing the medical records of all transgender men who underwent secondary reconstruction procedure after loss of the primary phalloplasty flap. Only transgender men with such a resulting defect after failure of the primary phalloplasty that a secondary phalloplasty using a new flap was needed to reconstruct the neophallus shaft and/or urethra were included. Transgender men with limited defect after primary phalloplasty which did not require a new flap were excluded.

Ethical statement

The study was approved by the Institutional Medical Ethical Committee of the Amsterdam University Medical Center (VUmc; METC, reference number 2018.625). All patients provided written informed consent for participation and publication of their photographs.

Procedures

All identified patients were invited to complete a questionnaire to asses patient satisfaction. The questionnaire was digitally administered. A retrospective chart review was conducted for all identified patients.

Outcomes

The following outcomes were recorded after primary phalloplasty:

• Primary phalloplasty surgical characteristics; The use of a single or double flap for phalloplasty, type of flap for phalloplasty shaft reconstruction, type of urethral reconstruction technique (e.g. use of a fasciocutaneous flap or prelamination using FTGs or buccal mucosa),

• Description of flap failure and cause of failure; (failure of phalloplasty shaft and/or neo-urethra failure, time interval between primary phalloplasty and flap loss, cause of flap failure (arterial or venous thrombosis or secondary corrections (e.g. thinning out of phalloplasty shaft) and the degree of flap failure. The degree of flap failure was retrospectively identified from the operative reports and reported as the percentage of total flap surface. The percentage of the failed flap was subjectively estimated by the surgeon peri-operatively.

• Time between primary phalloplasty and secondary reconstructive procedure

After secondary reconstructive surgery, the following outcomes were recorded:

•Secondary phalloplasty surgical characteristics; used flap(s) for reconstruction of the neo-shaft, type of urethral reconstruction technique (e.g., prelamination using FTGs, use of a fasciocutaneous flap or the use of buccal mucosa).

• Clinical and surgical outcomes after secondary phalloplasty; ability to void from a standing position and the ability to have penetrative sexual intercourse.

• Patient reported outcome measures; the questionnaire contained both closed- and open-ended questions. This questionnaire was designed by a team of plastic surgeons, urologists and psychologists at our institution combining/modifying instruments used in earlier studies.¹⁹ The questionnaire is aimed at all transgender men who undergo genital GAS, and is filled in preferably one year after the last surgery. It comprises questions pertaining to surgical outcomes, functionality and sexuality. Satisfaction with various outcomes was assessed using a five-point Likert scale: (1) very satisfied to (5) very dissatisfied. A similar scale was also used to assess the level of agreement with various statements: (1) strongly agree to (5) strongly disagree (e.g., "The surgery increased my self-esteem as a man"). Additional free text boxes were included to allow patients to further clarify their (dis)satisfaction. The questionnaire is presented in attachment 1. The questionnaire was entered digitally by the patient in a private setting.

In addition, patient demographics (age at primary phalloplasty, body mass index (BMI), history of smoking and/or drug use, somatic comorbidity, surgical history and clinical follow-up time) were recorded.

Analyses

Data was analyzed descriptively on case-by-case basis (for background and surgical characteristics) and frequencies of the total sample (for the PROM-data). Data from the open-

ended questions were analyzed qualitatively, by the first author and reviewed by all other authors using thematic content analyses in three steps: coding, theming and calculation of frequencies.

Results

A total of 179 transgender men underwent phalloplasty in the study time period. Fourteen men (8%) underwent a reconstructive procedure after flap loss and were included in this study. Patient demographics are presented in Table 1.

Primary phalloplasty

Of 14 included patients, eight had undergone a single flap phalloplasty and a six a double flap phalloplasty as primary procedure. Urethral lengthening was performed in 13 out of 14 patients.

Table 1 lists the causes of flap loss and the clinical details of the lost flap after primary phalloplasty. Of 14 patients that developed flap failure, six were due to arterial thrombosis, five with venous thrombosis, two after extensive flap thinning in a later phase and in one patient the FTG used for neo-urethral reconstruction did not survive.

Secondary reconstructive procedure

The surgical management and outcomes after failure of the primary phalloplasty is presented in Table 1. The secondary reconstructive procedure was performed after a median time of 15 (range 1-272) months. In one patient, the procedure was performed during the initial hospital admission.

Follow- up (months)	38	R	289	12	8 4	104	40	72	8	134	288	176	e,	113	
Functional outcomes	Able to void while standing. Able to have penetrative sexual intercourse with penile prosthesis.	Patient preferred to undergo salvage surgery without urethral lengthening.	Able to void while standing. Able to have penetrative sexual intercourse using an extra thick condom	Unknown, lost to follow- up	Able to void while standing. Able to have penetrative sexual intercourse without penile prosthesis	Unknown, lost to follow- up	Able to void while standing	Able to void while standing	Able to void while standing	Unable to void while standing due to a spraying uninary stream	Unable to void while standing due to recurrent urethral strictures	Able to void while standing	Able to void while standing and able to have sexual penetrative intercourse after penile prosthesis implantation.	Able to void while standing	
Timing after first surgery (months)	.	00	272	2	5 days	23	44	13	116	ş	10	e	16	ş	
Secondary reconstruction	Contralateral ALT for penile shaft	GF for penile shaft	Roll-in-roll RFFF for penile shaft and neo-urethra	AF for penile shaft and FTG neo-urethra	Contralateral ALT for penile shaft	Contralateral ALT for penile shaft without neo- urethra reconstruction	Contralateral RFFF for neo- urethra	Contralateral RFFF for neo- urethra	GF for neo- urethra	RFFF for neo- urethra	RFFF for total neophallus	GF for penile shaft and FTG for neo-urethra	RFFF for neo- urethra and shaft	GF for penile shaft and FTG for neo-urethra	
Flap loss	Total loss of ALT penile shaft. Vital RFFF	Total loss of ALT penile shaft. Vital RFFF	Fifty percent loss of GF shaft including the FTG neourethra	Total loss of GF penile shaft and FTG neourethra	Total loss of ALT penile shaft	Total loss of ALT penile shaft	Total loss of RFFF neourethra	Total loss of RFFF neourethra	Total loss of RFFF neourethra	Total loss of FTG neourethra	Total loss of phalloplasty	Sixty percent loss of AF penile shaft and total loss of FTG neourethra	Total loss RFFF neourethra and fifty percent loss of ALT penile shaft	Total loss of phalloplasty	
Arterial or venous trombosis?	Venous	Arterial	Venous	Arterial	Venous	Arterial	Arterial	Venous	Arterial	Arterial	Unspecified	Venous	Neither	Neither	
Postoperative complications?	+1 day: increasingly livid skin color and swelling of ALT flap	+1 day: increasingly pale and cold flap. No bleeding after puncturing with needle	+2 days: signs of venous compromised flap (bluish color, increased swelling and warmth)	+ 3 days: progressive avascular tissue necrosis	+1 day: signs of venous compromised ALT flap (bluish color, increased swelling and warmth)	+1-3 days: increasingly pale and cold flap	+3 weeks: complete necrosis of the RFFF neo- urethra was observed at outpatient clinic	+2 days: bluish discoloration of the RFFF	+10 hours: absence of Doppler signal at RFFF top and increasingly paleness of the visible RFFF.	+3 weeks: complete necrosis of the FTG neo- urethra was observed at the outpatient clinic	+1 day: undiminished pale white and cold flap	+8 days: increasingly bluish color of phalloplasty top and base	+4 days: necrosis of the +8 months: thinning of the +8 months: thinning of the ALT using liposuction and fat excision3 days: after thinning necrosis of ALT flap.	+2 years: thinning of the meophallus using liposuction and fat excision. +4 years: additional thinning of the neophallus. +4 days: after thinning, +4 days: after thinning, occurred of the AF flap occurred occurred	Arm Flap
Intraoperative complications ?			Suboptimal perfusion in phalloplasty top treated with Dextran '40'	Increasingly diffusely pale flap treated with Dextran '40'		1	Revision of arterial microvascular anastomosis due to poor imflow. Phalloplasty skin is sutured under tension.	1	Arterial microvascular anastomosis had to be revised three times.	1	Increasingly diffusely pale white and cold flap. No bleeding after puncturing with needle. Attributed to vasospasm of the flap.			A split skin graft is placed on the dorsal lining of the neophallus to prevent circular tension.	Groin flap LUAF= Lateral Upper
Urethral lengthening? (Yes/no). technique	Yes, flap-in flap	Yes, flap-in- flap	Yes, FTG	Yes, FTG	Yes, flap-in- flap	°N	Yes, flap-in- flap	Yes, flap-in- flap	Yes, roll-in-roll	Yes, FTG	Yes, roll-in-roll	Yes, FTG	Yes, flap-in- flap	Yes, FTG	nickness Graft, GF=
Type phalloplasty flap	ALT and RFFF	ALT and RFFF	GF	GF	ALT and RFFF	ALT	ALT and RFFF	ALT and RFFF	RFFF	ALT	LUAF	AF	ALT and RFFF	AF	lap, FTG= Full TI
History of smoking	٩	٩	Yes	٩	Yes	٩	٩	Yes	Yes	Yes	٩	۶	Ŷ	Ŷ	ree Forearm F
Somatic comorbidity				-			Previous Non- Hodgkin Lymphoma	Chronic uninary tract infections			Dyslipidemia and hypothyroidism			Previous ovarian cancer	gh, RFFF=Radial F
BMI (kg ^{/m²})	8	28	21		20	27	25	24	21	8	R	59	28	25	erolateral Thi
Age at surgery (years)	32	5	8	42	52	27	8	8	45	R	31	Ŗ	τ. Ο	37	1al flap, ALT= Anti
Patient number	-	5	m	4	S.	υ	٢	ø	6	10	п	12	51	14	GAF= Abdomir

Table 1: Patients demographics, flap loss characteristics and the subsequent management.

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Surgical management

As described earlier, loss of the pendulant neo-urethral flap and/or the phalloplasty shaft can occur. After a comprehensive multidisciplinary evaluation of the surgical feasibility and the patient's wishes, tailor-made salvage procedures were performed by a plastic surgeon and urologist.

Secondary reconstruction in case of isolated loss of the pendulant part of the neo-urethra

A necrotic pendulant part of the neo urethra, is surgically managed by performing a surgical debridement and construction of a temporary scrotostomy. Various free or pedicled flaps may be used for secondary reconstruction of the pendulant part of the neo-urethra depending on the flap(s) that were used for the initial phalloplasty.

The neophallus is incised ventrally and unfolded. The size of the urethral defect and the eventual size needed to close the ventral shaft of the phalloplasty without tension is determined. The harvested flap might have to be modified to include a part forming the ventral lining of the shaft and/or thinned out. Special caution is taken to prevent excessive thinning which may compromise the vascular supply.

Of four patients that developed necrosis of the pars pendulans, a GF was performed in one patient and a FRFF in three patients to reconstruct the neo-urethra.

In figure 1 a modified FRFF is shown. The FRFF was harvested (Figure 1a) and the urethral part tubularized and sutured around a 16 French Foley catheter (Figure 1b). End-to-end urethral anastomosis was performed between the previously lengthened pars fixa and the pars pendulans after spatulation of the anastomotic edges (Figure 1c). The other part of the FRFF, divided by a deepithelialized strip, was used to reconstruct the ventral outer lining of the neophallus shaft. Microvascular anastomosis was performed in the groin. The radial artery end-to-side (E-S) to the superficial femoral artery and the cephalic vein end-to-end (E-E) to the great saphenous vein.



Figure 1. FRFF neo-urethral reconstruction. A. Projected on the left arm a 11x4cm strip for reconstruction of the ventral shaft of the ALT and a 15 x3cm strip for the neo-urethral. They are divided by a de-epithelialized strip. **B.** The FRFF was subsequently harvested and the neo-urethral part folded around a 16 Ch. Foley catheter. The 11x4cm strip purposed to reconstruct the ventral shaft of the ALT can be seen **C.** The phallus was incised ventrally, urethral anastomosis was performed onto the previously lengthened pars fixa and the ventral outer lining of the ALT shaft was reconstructed. The FRFF anastomosis was performed in the left groin.

In figure 2 modified groin flap is shown. Preoperatively, the patient had an intact penile shaft and a scrotoplasty including testicular prosthesis (Figure 2a). The phalloplasty shaft was incised ventrally and unfolded (Figure 2b). A groin flap was outlined and harvested in the right groin (Figure 2c and 2d) and tunneled to the genital area (Figure 2e). After tubularizing the groin flap around a 16 French Foley catheter and performing the end-to-end urethral anastomosis, the phalloplasty was closed (Figure 2f). Also, in this patient, a part of the groin flap formed the ventral lining of the neophallus to prevent too much circular constriction.



Figure 2. Groin flap neo-urethral reconstruction. A. Preoperative genital view. **B.** The FRFF neophallus was incised ventrally and unfolded. **C.** Outlining of the 7x17cm groin flap. **D.** The groin flap was harvested. **E.** The groin flap was tunneled to the genital area. **F.** Direct postoperative result. The lack of skin on the ALT made it impossible to primarily close the ALT. The ventral lining of the phalloplasty is formed by the groin flap . Also the groin flap donor-site was closed primarily. A wound drain was placed in the penoscrotal angle.

Secondary reconstruction in case of isolated penile shaft loss

In case of necrosis of the penile shaft in double flap phalloplasty, the shaft is surgically debrided. A 16 French Foley catheter is placed into the vital neo-urethra and subsequently buried in the pubic or groin region. The meatus is sutured to the skin in the pubic or groin area. Important is to make sure that there is no tension on the vascular pedicle. A temporary scrotostomy is constructed. The dorsal nerve of the clitoris used for flap nerve anastomosis is marked with a metal clip to ensure it is easily localized during secondary reconstruction later on.

As with neo-urethral reconstruction, various free or pedicled flaps may be used for secondary reconstruction of the phalloplasty shaft. Of six patients that developed phalloplasty shaft necrosis, an ALT was performed in three patients and a GF, FRFF or AF in the other patients.

The neo-urethra has a tendency to shrink a little when buried. Therefore, during secondary reconstruction, the buried neo-urethra is dissected again. The length needed for a shaft is then measured. The size and dimensions needed for the new flap are projected on the donor-site. Based on our experience, thickness of the shaft flap should preferably not exceed 1 cm and can be preoperatively measured by ultrasonography or computed tomography (CT) ultrasonography.²⁰ This is essential to ensure closing of the flap for shaft reconstruction and prevent a compromised vascularization of the out and mainly the inner flap due to excessive tension. Unlike the flap used for neo-urethral reconstruction, thinning out of the shaft flap peri-operatively should be done carefully to preserve the sensate nerves.

After mobilization of the shaft flap it is and wrapped around the neo-urethra. The dorsal nerve of the clitoris that was marked previously is reattached to the sensate flap nerve.

In case of loss of the pendulant part of the neo-urethra as well as the shaft, the techniques mentioned above are combined to reconstruct a neo-phallus.

Patient-reported outcome measures

Out of 14 patients, a total of nine (64%) returned the completed questionnaire. The median time between salvage surgery and completion of the PROM was 26 (range 8-285) months. Table 2

provides the ratings of the close-ended questions. Most patients were 'satisfied' or 'very satisfied' (rated by 56% and 11%) with the appearance of their penis. All patients (strongly) agreed that when looking back, they would undergo the surgery all over again. Voiding and the sexual functionality after salvage showed the least positive scores.

	Rating, N(%)						
Statement	Very	Satisfied	Neutral	Unsatisfied	Very		
	satisfied				unsatisfied		
How satisfied are you with:							
The appearance of your penis?	1 (11)	5 (56)	1 (11)	2 (22)			
The appearance of your scrotum?	1 (11)	3 (33)	3 (33)	2 (22)			
Your current voiding pattern?	1 (11)	2 (22)	1 (11)	4 (44)	1 (11)		
Your health ?	3 (33)	4 (44)	2 (22)				
Your happiness in general?	2 (22)	6 (67)	1 (11)				
Your life in general?	2 (22)	6 (67)	1 (11)				
Yourself in general?	2 (22)	5 (56)	1 (11)	1 (11)			
Your sex life?	1 (11)	2 (22)	4 (44)	2 (22)			
The sexual functioning of your penis?		1 (11)	6 (67)	1 (11)	1 (11)		
	Strongly	Agree	Neutral	Disagree	Strongly		
	agree				disagree		
To what extent do you agree with the following							
statements:							
The surgery increased my self-esteem as a man	3 (33)	4 (44)	1 (11)		1 (11)		
I would recommend this surgery to others	1 (11)	5 (56)	3 (33)				
Looking back, I would undergo the surgery all	6 (67)	3 (33)					
over again							
The surgical outcomes match my expectations	1 (11)	2 (22)	4 (44)	1 (11)	1 (11)		

Table 2: Summary of patient-reported outcome scores

In Table 3, the themes and quotes emerging from the open-ended questions from the questionnaire are summarized. Responses to the questions were divided between satisfactory and dissatisfactory aspects. Most patients were satisfied with the received care, despite the major complications. In line with the response to the closed-ended questions, dissatisfaction was mostly (78%) related to a lack of sexual functionality of the penis, as well as voiding issues (44%). No specific dissatisfaction was reported regarding the salvage procedures. On a scale of one to ten (1=terrible and 10=excellent) patients reported an overall median satisfaction rate of 8 (range 5-9).

Table 3: Open-ended responses from nine patients.

Satisfaction	Торіс	Endorsed,	Example quote
Satisfied		N (20)	
	Hospital Care	7 (78)	Despite the major complications I am very satisfied with the received care from the nurses and surgeons
	Appearance phalloplasty	5 (56)	It looks just like a real penis
	Voiding pattern	4 (44)	I can void from a standing position
	Sex function	1 (11)	I can have penetrative sexual intercourse with a penis sleeve
Unsatisfied			
	Sexual function	7 (78)	I cannot use my penis to have penetrative sexual intercourse
	Voiding pattern	4 (44)	After urinating I still have urine dropping I have hair in my urethra
	Appearance phalloplasty	2 (22)	My penis is not rigid enough
	Hospital care	2 (22)	I am awaiting secondary corrections

Discussion

In this study, fourteen phalloplasty patients with free flap and/or pedicled flap loss after primary phalloplasty were presented. A variety of (modified) flaps was used for secondary reconstructive procedures. These flaps are commonly described in the field of reconstructive surgery. For example, the FRFF is often used for head and neck reconstructions. Despite being commonly used, in phalloplasty these flaps are subject to unique conditions that may increase the risk of flap loss. Flap failure after FRFF phalloplasty occurs in approximately 1-5% of the cases and partial flap failure in 2-11%.^{14,15,21,22} Van der Sluis et al. described a neo-urethra failure rate of 10% (2/19) after double flap phalloplasty.¹⁷

Preoperative planning

Proper preoperative planning (e.g. flap selection/dimensions and thickness) is essential to reduce postoperative complications and obtain functionally and esthetically favorable results. Appropriate flap thickness allows closure of the phalloplasty without causing excessive flap tension. This applies to the flap used for neo-urethra as well for the flap used for the shaft. It is true that flaps used for phalloplasty can be thinned out peri-operatively, however, there is a risk of sensate denervation of the flap. This is predominantly of importance if the flap is used for shaft reconstruction. In addition, excessive thinning out can compromise flap vascularization. Therefore, in our clinic (since 2018), we routinely measure flap thickness preoperatively using ultrasound. If the flap thickness exceeds one centimeter, we will not perform a phalloplasty.

Other techniques have been described to measure the flap thickness including a computed tomography (CT), magnetic resonance imaging (MRI) and three-dimensional imaging.^{20,23,24} Advantages of ultrasound are the cost-effectiveness, being widely available and having good penetration of soft tissue.²⁵ Advantages of CT and MRI include the ability to localize perforating flap arteries and vascular pedicles more precisely preoperatively.

The importance of preoperative flap thickness measurement increases as the prevalence of obesity and overweight has also increased dramatically over the past decades.²⁶ Some flaps in particular are at risk of being too thick for phalloplasty based on their anatomy (e.g. ALT, AF and GF/SCIP).

Also important are the preoperatively determined flap dimensions. Sufficient skin is required to enable closure of the neo-urethra and penile shaft, especially when performing a single flap tube-intube phalloplasty. In double flap phalloplasty, the flap used for neo-urethral reconstruction has to be slightly longer to enable urethral anastomosis onto the pars fixa. If the length of the flap is either too short or too long, it will result in a retracting or protruding neourethra and neo-meatus.

When used for phalloplasty, the dimensions of the shaft flaps are often larger in comparison to the described applications of these flaps in other fields of reconstructive surgery. These greater flap dimensions also increase the risk of flap necrosis due to insufficient vascular supply. When a tube-intube FRFF phalloplasty is performed, a large flap of at least 13x13cm is harvested. In phalloplasty the ulnar side of the flap, which is the farthest away from the vascular pedicle, is prone to hypoxia and subsequent necrosis.¹⁶ When performing a secondary reconstruction of the neo-urethra, the flap dimensions are usually greater in comparison to the flap dimensions used for neo-urethra reconstruction in primary phalloplasty. This is necessary due to several reasons: to adjust for possible loss of phalloplasty after neo-urethral flap inset to prevent circular constriction,. Also, the penile shaft tissue tends to be less pliable after primary phalloplasty due to the development of scar tissue. In

patients with insufficient penile shaft skin, we added a part to reconstruct the ventral lining of the phalloplasty to overcome this challenge.

Postoperative flap monitoring

In the published literature there is an increase of double flap phalloplasty procedures.^{17,27-29} A double flap phalloplasty has the advantages of preventing one major donor-site, having and independent vascular supply for the neo-urethra and offers the ability to combine flaps that are preferably used for the neo-urethra or the shaft based on the flap characteristics. When a free flap is chosen for neo-urethral reconstruction, the FRFF seems most suitable, because of the thin pliable skin and long vascular pedicle.³⁰ Most of the times, the donor-site can be closed primarily.

As mentioned, the success rate of microvascular salvage is directly related to early clinical recognition of a compromised flap. Recognizing a comprised phalloplasty shaft flap is less challenging in comparison to the neo-urethral flap. The neo-urethral flap is covered by the shaft flap and is also tubularized around a Foley catheter which remains inserted for one or more week(s). This considerably impedes or even makes it impossible to clinically examine the flap. As a result, compromised neo-urethral vascularization sometimes stay unnoticed until weeks postoperatively. To prevent this, implantable Doppler probes may be used. However, these have also been shown to be prone to false-positive signals leading to unnecessary surgical exploration.³¹

Flap loss after flap contouring

Primary phalloplasty with bulky flaps like the ALT and AF often depend on secondary debulking to improve functional and aesthetical outcomes.^{32,33} In our cohort, two patients lost their phalloplasty after thinning out of the flap with liposuction and direct excision in a later phase. No data is available in the literature on flap loss after phalloplasty thinning.

Total flap necrosis after thinning out of the flap has been described in some cases after flap surgery in general. When compared to liposuction, direct excision of fat has been marked the procedure with the highest risk of flap necrosis.^{33,34} Therefore, it is preferable to use a thin fasciocutaneous flap for primary phalloplasty that does not require secondary contouring. This emphasizes the importance of proper preoperative screening of patients to determine the surgical feasibility and limit postoperative complications.

Patient reported outcomes measurements

The median time between salvage surgery and completion of the PROM was 26 (range 8-285) months. After salvage surgery, most patients were satisfied or very satisfied with their neo-phallus. This may suggest that the final result is more important to transgender men than the impact of undergoing a salvage procedure. However, these outcomes can be prone to outcome bias due to the long time period between salvage surgery and the completion of the PROMs. It is known that illness adaption and perception over time can influence the patients' satisfaction after surgery. Favorable illness perception is associated with improved health outcome, while unfavorable illness perception is associated with worse outcomes³⁵. This underlines that patients' satisfaction after salvage surgery depends on other factors besides the surgery itself. Illness perception is multifactorial and is composed of behavioral, clinical, educational, and psychosocial components to improve one's illness perception through educative and psychotherapeutic counseling.³⁵

We identified factors that are of influence on the patient's satisfaction. Esthetic outcomes and the provided surgical care were aspects that contributed to positive patients' experiences. While the outcomes regarding phalloplasty urological and sexual functionality had a negative impact on patients' satisfaction. The relatively lower post-phalloplasty satisfaction with sexual function has also been reported after primary phalloplasty procedures. This can largely be attributed to the fact that many transgender men are unable engage in penetrative sex without the use of supportive devices after a phalloplasty, whether a primary or a salvage procedure.^{3,29}

Generally, having a rigid neophallus that enables penetrative sexual intercourse requires the insertion of a penile prosthesis. This procedure in transgender men is associated with a high complication rate up to 70% and often requires multiple revisions.³⁶ It has to be emphasized that these risks also remain applicable to patients that underwent a salvage procedure and want to have an erectile prosthesis implanted. Future research is needed to compare PROMs between transgender men with a primary phalloplasty and transgender men who needed to undergo a secondary reconstructive procedure.

Limitations and strengths

The retrospective design of the study is prone to bias and availability when collecting data. Furthermore, the study included a small number of patients. Strengths of our study include the unique description of surgical management after phalloplasty flap loss. In addition, data from this study can be used to optimize pre-operative counseling regarding flap loss complications and the outcomes of the subsequent management.

Conclusion

Total flap loss after primary phalloplasty in transgender men is a serious complication resulting in additional patient distress. The surgical management after primary phalloplasty flap loss is challenging and requires a multidisciplinary approach and careful preoperative planning. Despite being a serious complication, successful secondary reconstruction of the phalloplasty can be performed using a second or third pedicled or free flap. After secondary reconstruction, most patients are satisfied with the final result.

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PART 3

NOVEL SURGICAL TECHNIQUE

CHAPTER 7

The first experience of using the pedicled labia minora flap for urethral lengthening in transgender men undergoing anterolateral thigh and superficial circumflex iliac artery perforator flap phalloplasty: a multicenter study on clinical outcomes.

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SUMMARY

Objective: To describe the novel surgical technique of urethral lengthening in anterolateral thigh (ALT) and superficial circumflex iliac artery perforator flap (SCIP) phalloplasty with a pedicled labia minora flap (PLMF) and report on the clinical outcomes.

Methods: Between March 2014 and August 2018, 16 transgender men underwent phalloplasty with a PLMF for urethral lengthening at the Amsterdam UMC (VU university), the Netherlands and the Belgrade University Hospital, Serbia. Patient demographics, surgical characteristics, neo-urethra characteristics, intra- and postoperative complications, pre-and postoperative voiding evaluation and the length of hospital stay were retrospectively identified from chart reviews.

Results: The mean neo-urethral length was 16.8±2.3 centimeter, and the pars pendulans 11.7 ±2.2 centimeter. The neo-meatus was localized on top of the neophallus in 12 (75%) patients. No intraoperative complications occurred. Urethral fistula formation occurred in four (25%) patients and strictures in six (37.5%) patients. In three (18.7%) patients a (temporary) perineostomy had to be performed. Voiding from a standing position was possible in 9 (56.3%) patients.

Conclusion: The pedicled labia minora flap for urethral reconstruction, both pars fixa and pars pendulans, in phalloplasty is a feasible surgical technique in transgender men undergoing ALT or SCIP phalloplasty with sufficient labia minora tissue.

Introduction

Transgender men generally report an improved quality of life and satisfactory sexual function after genital gender affirming surgery (GAS).¹ The majority of transgender men that undergo phalloplasty express a strong desire to be able to void while standing.² For this purpose, the urethra has to be surgically lengthened.

The neo-urethra in transgender men consists of the native urethra, the pars fixa and the pars pendulans. Lengthening of the urethra is considered to be the highly challenging in phalloplasty, resulting in a significant complication rate. The most common complications are urethral fistulas and strictures. Reported fistula rates after phalloplasty vary from 10% to 55% and strictures from 14% to 58%.³⁻⁸ These complications may require additional surgery, cause significant discomfort and impede the possibility to void from a standing position.

Reconstruction of the pars fixa of the urethra is generally performed using the infundibulum and inner part of the labia minora. After colpectomy, the bulbospongiosus muscle can be used to cover the proximal urethral anastomosis and pars fixa, thereby reducing proximal urethra fistula incidence.^{4,9}

Reconstruction of the pars pendulans is significantly more difficult and many studies have been published in search of the ideal reconstruction technique.¹⁰ There are multiple surgical options for pars pendulans reconstruction: a tube-in-tube flap configuration, a second fasciocutaneous flap, use of full-thickness skin grafts and buccal mucosa. Each of these methods has its own advantages and disadvantages. A major disadvantage of a tube-in-tube flap configuration is the significantly larger flap design that causes a large donor site scar and the accompanying morbidity.¹¹ A second fasciocutaneous flap (e.g., a narrow free radial forearm flap(FRFF) or groin flap(GF)) can be used for urethral reconstruction in double flap phalloplasty, however this will create an additional donor site.⁶ Although partial urethral reconstruction can be performed using full-thickness skin grafts or buccal mucosa, reconstruction of the pars pendulans is more difficult because of its greater length.^{2,5,8,10}

To overcome these most of these disadvantages, a pedicled labia minora flap (PLMF) can be used for neo-urethral reconstruction of the pars pendulans in transgender men.¹² The PLMF uses labia minora tissue that is otherwise unused or even discarded. Advantages of the PLMF include the

prevention of additional donor sites for neo-urethral reconstruction, the favorable soft pliability and non-hair-bearing tissue.

The use of a PLMF has been proven to be a reliable technique for small urethral reconstructions in cisgender females and in transgender men undergoing metoidioplasty or latissimus dorsi (LD) flap phalloplasty.¹²⁻¹⁴ However, no literature is available on usage of the PMLF in other phalloplasty techniques in transgender men. Also, little is published regarding the anatomical basis and the surgical technique to harvest the flap.

In this study, we describe the surgical technique in detail and report on the clinical outcomes

Patients and methods

Between March 2014 and August 2018, 16 transgender men underwent anterolateral thigh (ALT) or superficial circumflex iliac artery perforator (SCIP) phalloplasty with a PLMF for urethral lengthening at the Amsterdam UMC, location VUmc (Amsterdam, The Netherlands) and the Belgrade University Hospital (Belgrade, Serbia). At the Amsterdam UMC, location VUMC we have been performing this technique since 2017. Since then, twenty six patients underwent phalloplasty with urethral lengthening. Of those, 11 (42.3%) underwent urethral lengthening with the PLMF. At the Belgrade University Hospital all patients (100%) underwent phalloplasty with PLMF for urethral lengthening, and all were included in the study. Standardized data collection of the included patients was performed by surgical team members using digital case report forms.

Retrospective chart data collection included: Patient demographics (age at phalloplasty, body mass index (BMI), history of drug use and/or smoking, somatic and psychiatric comorbidity and surgical history), surgical characteristics (phalloplasty type and surgical duration), neo-urethral characteristics (neo-urethral length, pars pendulans length and meatus localization), intra- and postoperative complications (bleeding, necrosis, urethral fistula and stricture), pre-and postoperative voiding evaluation ((Uroflowmetry and post-residual urine volume (only at the

Amsterdam UMC) and the ability to void while standing postoperatively) and the length of hospital stay

Preoperative assessment

In accordance with The Standards of Care, the patients are screened and counselled preoperatively.¹⁵ Patients attend a group-based educational program regarding the metoidioplasty and phalloplasty with or without urethral lengthening. Subsequently, patients that have the wish to undergo phalloplasty with urethral lengthening are physically examined to explore the various phalloplasty options. The definitive decision for a surgical technique is made by the patient based on their preference, the risk factors and the surgical feasibility.

At the Amsterdam UMC, a pre-operative decision aid for transgender men is additionally used.¹⁶ Main contraindications for phalloplasty surgery are a BMI less than 18 or above 30 and smoking (patients have to quit smoking for at least 3 months prior to surgery). During preoperative assessment, labia minora size was assessed by the surgeon (urologist or plastic surgeon) to determine surgical eligibility. The labia minora size is independent of age, parity, ethnicity, hormonal use, and history of sexual activity.¹⁷ To be eligible for this procedure, patients needed a labia minora size of at least five centimeters in length and a depth of at least two centimeters from the base to the edge, see Figure 1a. These cut off points are necessary to ensure sufficient labial tissue is available to localize the neo-meatus on tip of the phalloplasty. However, in case of persistent patients' preference and insufficient length of the labia minora, the PLMF can still be performed and the neo-meatus will be localized somewhere on the penile shaft. It is essential to inform patients that localization of the neo-meatus on the penile shaft will most likely limit the ability to void from a standing position and that a secondary procedure might be necessary to reconstruct the most distal part of the urethra to the tip of the phallus.

Data analyses

Continuous Gaussian variables were presented as means with standard deviations. Continuous non-Gaussian variables were presented as medians with ranges. The data were

analyzed centrally in Amsterdam. Postoperative complications were subdivided an analyzed in three groups: (1) intraoperative complications, (2) postoperative complications and (3) urological complications. Descriptive analyses were performed using IBM SPSS Statistics Version 22 data analysis software (IBM Corp., Armonk, NY USA).

According to the Dutch Central Committee for Human Research, retrospective medical research is exempt from an institutional review board (IRB) approval. All portrayed patients provided written consent for publication of their photographic material.

Surgical anatomy and technique

The labia minora are hairless mucocutaneous skinfolds with sebaceous glands and lack a layer of subcutaneous fat. The labia minora can be divided in an upper and lower part. The upper parts cover the clitoris, and are known as the clitoral hood or prepuce. The lower parts unite on the undersurface of the clitoris to form its frenulum. The labia minora is nourished by two arterial systems: an anterior system dominated by the external pudendal artery, obturator arteries and funicular arteries. The second (posterior) system is dominated by the internal pudendal artery (Figure 1b). The internal pudendal artery gives rise to two terminal branches: the clitoral branch and the perineal artery. The perineal artery supplies the labial parts by terminal branches that anastomose with counterparts from the opposite side.¹⁸ This results in an extensive vascular anastomosis network around the orifice and provides the basis for the pedicled labia minora flap (PLMF).

The PLMF technique of urethral lengthening can be performed in a similar fashion regardless of the flap used for creation of the neophallus shaft. The patient is placed in lithotomy position. The labia minora flap dimension is outlined extending distally from the base to the labia minora edges (Figure 1c). If the neoscrotum is reconstructed using bilateral labia majora V-Y flaps and a double vascularized horseshoe-shaped public flap, caution must be taken to ensure sufficient clitoral hood tissue is available to reconstruct the anterior aspect of the neoscrotum.¹⁹

The labia minora inner lining, clitoral hood and frenulum are subsequently incised according to the outlining. This results in two labia minora parts, the inner lining/surface to reconstruct the pars fixa and the outer part to form the PLMF (Figure 1d).

Pars fixa urethral lengthening is achieved by tubularization of the inner lining in a two layer fashion over a 18 French Foley catheter.

The glans clitoris is denuded, and one of the two dorsal clitoral nerves is dissected for further phalloplasty flap nerve anastomosis. The labia minora edges are incised along the interlabial furrows. This results in a cranially pedicled 'inverted V-shaped' flap consisting of clitoral hood skin and labia minora (Figure 1e). To reconstruct the pars pendulans, most of the pedicled labia minora flap is rotated 90 degrees and a small part of the PLMF is excised (Figure 1f). The PLMF is then tubularized around a 18 French Foley catheter in a two layer fashion (Figure 1g). Subsequently, the pars fixa and pars pendulans are anastomosed in a spatulated manner and the phalloplasty flap is wrapped around the neo-urethra. The meatus is preferably localized at the phalloplasty tip and the nerve of the phalloplasty flap is anastomosed to one of the dorsal clitoral nerves. In case of insufficient length of the PLMF, the meatus is placed at the phalloplasty shaft. Depending on the length, additional urethral plate reconstruction using buccal mucosa and re-localization of the meatus onto the phalloplasty tip may be performed three or more months postoperatively.





Figure 2 shows the surgical procedure in a patient undergoing an ALT phalloplasty.



Figure 2. Anterolateral thigh phalloplasty with the pedicled labia minora flap for neo-urethral reconstruction. **A.** Preoperative view **B.** The inner lining of the labia minora is used for pars fixa reconstruction and the outer part is used as the pedicled labia minora flap. **C.** The pedicled labia minora flap is rotated 90 degrees. **D.** The anterolateral thigh flap is outlined. **E.** The anterolateral thigh flap perforator (descending branch of the lateral femoral circumflex artery) is identified and the flap is harvested. **F.** The anterolateral thigh flap is wrapped around a 18ch French Foley catheter. **G.** The anterolateral thigh flap is wrapped around the pedicled labia minora flap and the donor site is closed using split-thickness skin grafts. **H.** Postoperative result. The meatus is localized at the tip of the phalloplasty.

Postoperative care

Flap monitoring protocol

The highest risk time to develop vascular complication after flap surgery are the first postoperative days. Therefore the flap is regularly monitored by checking flap temperature, color and capillary refill. In addition, a hand-held Doppler ultrasonography is used to monitor the flap in case of doubt. In phalloplasty, the PLMF is buried in the phalloplasty shaft, which makes inner flap monitoring difficult.

Urinary catheter protocol

A suprapubic and Foley catheter is inserted during surgery and remains in place for about two weeks. The Foley catheter valve is closed and the suprapubic catheter is used to drain urine from the bladder. Two weeks after surgery, at trial without catheter is performed at the outpatient clinic. If there is necrosis of the PLMF it is likely to be noticed after removal of the Foley catheter.

Outpatient visit schedule

At the Amsterdam UMC, location VUmc, patients are scheduled for a follow-up visit three weeks, 3, 6 and 12 months postoperatively. A postoperative voiding evaluation is performed at the 12 months post-operative visit or earlier when necessary. At the Belgrade University Hospital, patients are seen at the outpatient clinic 1, 2, and 4 weeks, 3,6 and 12 months postoperatively. Postoperative voiding evaluation is performed if neourethral complications occur.

Results

The patient demographics, surgical and neo-urethral characteristics of the 16 transgender men that underwent phalloplasty with single-stage urethral lengthening using a PLMF are given in Table 1.

The mean neo-urethral length was 16.8 ±2.3 centimeter, and the pars pendulans 11.7 ±2.2 centimeter. All patients that were pre-operatively counseled to have a PLMF we were able to undergo this procedure and no per operative conversion to other urethral type was necessary. No intraoperative complications occurred. There was no complete flap failure. Urethral fistula occurred in four (25%) patients and strictures in six (37.5%) patients. All patients with an urethral fistula also had

a stricture distal of the fistula. Of six patients that developed a urethral stricture, three (18.8%) patients had only meatal stenosis. In three (18.8%) patients a temporary perineostomy had to be performed and they are awaiting stricture correction in the near future. Of 16 patients, 9 (56.3%) were able to void from a standing position postoperatively.

	N (%)	N (%)		
Number of patients included				
Amsterdam	11 (68.8%)	11 (68.8%)		
Belgrade	5 (31.3%)	5 (31.3%)		
Median age at phalloplasty, years (range)	25 (18-49)	25 (18-49)		
Comorbidities				
History of illicit drug use	0 (0%)			
Smoking of history	3 (18.8%)	3 (18.8%)		
Surgical history before phalloplasty				
Mastectomy	16 (100%)			
Hysterosalpingo-oophorectomy	15 (93.8%)	15 (93.8%)		
Colpectomy	12 (81.3%)	12 (81.3%)		
Median follow-up time, months (range)	14 (4-32)	14 (4-32)		
Scheduled additional surgeries	6 (37.5%)	6 (37.5%)		
Phalloplasty type	N (%)	N (%)		
SCIP, n (%)	10 (62.5%)	10 (62.5%)		
ALT	6 (37.5%)	6 (37.5%)		
Median surgical duration phalloplasty in minutes (range)	315 (240-412)	315 (240-412)		
Neo-urethra characteristics				
Mean neo-urethra length, centimeter ± SD	16.8 ±2.3	16.8 ±2.3		
Mean pars pendulans length, centimeter ± SD	11.7 ±2.2	11.7 ±2.2		
Meatus localization				
Top of phalloplasty	12 (75%)	12 (75%)		
Middle of phalloplasty	1 (6.3%)	1 (6.3%)		
Proximal third of phalloplasty	0 (0%)	0 (0%)		
Intraoperative complications	None	None		
Postoperative complications ²	3 (18.8%)	3 (18.8%)		
Bleeding ⁰	1 (6.3%)	1 (6.3%)		
Partial neo-urethra necrosis*	2 (12.5%)*	2 (12.5%)*		
Urethral fistula	4 (25%)			
DUF	4 (25%)	4 (25%)		
PUF	0 (0%)	0 (0%)		
Urethral stricture	6 (37.5%) [¢]	6 (37.5%) [¢]		
DUS	4 (25%)	4 (25%)		
PUS	2 (12.5%)	2 (12.5%)		
Uroflowmetry*	Preoperatively*	Postoperatively ^o		
Maximum flow in ml/s (range)	30 (14-46)	22 (17-25)		
Average flow in ml/s (range)	12 (6-23)	12.5 (5-14)		
Flow time in seconds (range)	25.2 (3.8-87.4)	25.6 (13.4-40.1)		
Voided volume in milliliter (range)	380 (50-540)	270 (158-486)		
Residual volume (ml)	50 (37-142)	0 (0-40)		
Able to void while standing	9 (56.3%)			
If no. reason:				
Spraying urine	3 (18.8%)	3 (18.8%)		
Meatus localization	4 (25%)	4 (25%)		
ALT=anterolateral thigh, DUF= distal urethral fistula (fistula at the distal ur	rethral anastomosis and/or th	e penile shaft), DUS= distal urethral		
stricture (stricture at the distal urethral anastomosis and/or penile shaft), fistula (fistula at the proximal urethral anastomosis and/or the fixed part of proximal urethral anastomosis and/or fixed part of the urethra), SCIP= sup	IPSS= international prostate s of the urethra], PUS= proxima perficial circumflex iliac artery	symptom score, PUF= proximal urethral l urethral stricture (stricture at the perforator, ² = within three weeks,		
 =required surgical debridement, "=required re-operation, "=necrosis occ	urreo in distal third of neo-un le for 11 natients 9 =data ava	etrira.*= performed only in Amsterdam, , ilable for 6 patients 124		

Table 1: Patient demographics, surgical characteristics, voiding evaluation and outcomes. +

*= four patients also had a fistula proximal to the stricture, *= data available for 11 patients, 9=data available for 6 patients.

Discussion

The ideal phalloplasty consist of creating a neo-phallus that has erectile ability, is reconstructed in a one-stage procedure, has erogenous/tactile sensation, has a good aesthetic result with minimal donor site morbidity and enables voiding from a standing position after neo-urethral reconstruction. The focus of most published research on phalloplasty has been mainly on the phalloplasty (shaft). The neo-urethra has received less attention and little is published on requirements for the 'ideal' neo-urethra in phalloplasty.

In transgender men, no ideal technique has been developed to reconstruct a neo-urethra that corresponds with the anatomical and histological features as the urethra in cisgender men. All urethral lengthening techniques have their own advantages and disadvantages concerning the donor site morbidity, tissue characteristics and applicability.

Donor site morbidity

Limiting donor site morbidity is important in transgender men undergoing phalloplasty. Fullthickness skin grafts for urethral reconstruction has been described to limit donor site morbidity. Major disadvantages are the multiple stages that are required to reconstruct the neo-urethra and the suboptimal vascular perfusion in large skin grafts. In 2005 Bettocchi et al. described the use of a pedicled labia majora flap to lengthen the neo-urethra in phalloplasty. A major drawback to this technique is that the labia majora is an essential component of the current neo-scrotal reconstruction technique.

Urethral lengthening in phalloplasty is mainly performed using a tube-in-tube configuration in FRFF phalloplasty. This technique causes a large donor site area, which is associated with morbidity such as impaired healing, esthetically unsatisfying results and different degrees of functional impairment or even loss.^{11,20} To minimize the large donor site area, a second free or pedicled fasciocutaneous flap for neo-urethral reconstruction can be used in double flap phalloplasty. However, this technique will create a second donor site and requires microsurgical anastomosis if a free flap is used. For both the tube-in-tube configuration and a second fasciocutaneous flap, tissue of around 3x13

centimeters is needed to reconstruct the pars pendulans. The PLMF overcomes the donor site issues of these techniques for urethral reconstruction. In the PLMF the urethra is lengthened using local labial tissue without causing an additional donor site for neo-urethral reconstruction and without interfering with the scrotal reconstruction.

Hairless

Conventional urethral reconstruction techniques (e.g. tube-in-tube FRFF) often use hairbearing skin for neo-urethral reconstruction. This can be accompanied with long-term complications like the formation of calculi, diverticula and hairballs.^{21,22} Pre-operative laser hair removal is possible, but is time consuming, expensive and not always permanent. The labia minora tissue used for the PLMF has the advantage of being completely hairless which makes pre-operative laser hair removal unnecessary.²³

Urethral fistula and strictures

Urethral fistula and strictures are the most common urethral complications after urethral lengthening in phalloplasty. After tube-in-tube urethral lengthening, a urethral fistula rate of 10% to 79% and stricture rate of 14 % to 74% is reported.^{3,24-26} After urethral lengthening using a second (fasciocutaneous) flap a fistula rate of 5-55% and stricture rate of 47%-64% is reported.^{6,27} Urethral lengthening with prelamination of a fasciocutaneous flap with either skin graft or vaginal graft is associated with a fistula rate of 15% to 22% and stricture rate of 21% to 32%.^{28,29} The use of buccal, labial or bladder mucosa for urethral lengthening has predominantly been described in reconstruction of a neourethra that is shorter in length with a reported fistula rate from 9% to 38% and stricture rate of 33%.^{30,31}

Our fistula rate of 25% consisted of only distal urethral fistula and is low in comparison to the published rates. An possible explanation could be the high number of patients (81.3%) that underwent a prior colpectomy and did not developed proximal urethral fistula. Our urethral stricture rate of 37.5% corresponds with the published stricture rates. Most strictures occurred in the distal third of the pars pendulans and the urological anastomosis sites. The distal part of the flap, which is the

farthest away from the vascular pedicle, is prone for hypo vascularization and subsequent complications. This risk may be limited by not using the most distal 2-3 centimeters of the labia minora to reconstruct the flap. A possible drawback is that the meatus may have to be localized in the penile shaft. These insights are also part of the surgeons learning curve.

Learning curve

As with all new surgical procedures, outcomes and performance tends to improve over time with increased experience. With the increase in experience, the surgeon is better able to notice and act in case of disruption of perfusion to **the PLMF** that can result in partial tissue loss. Proper patient selection is critical to achieve excellent outcomes with the PLMF and will improve over time as well.

It remains difficult to compare urological complications in the published literature and draw conclusions because of the major differences in urethral reconstruction techniques, phalloplasty techniques, the amount of included patients, neo-urethral length, variation in complication registration and follow-up time.

Disadvantages

There are limits of the applicability of the PLMF for pars pendulans reconstruction in comparison to the conventional techniques. The great variation in labia minora measurements is independent of age, parity, ethnicity, hormonal use, and history of sexual activity.¹⁷ Therefore, only a subset of transgender men is able to undergo this technique. However, the labia minora size can be increased in the presence of exogenous stimuli like stretching. For example, after stretching with weights, the labia minora can be as long as 200mm.³² In patients with insufficient labia minora length, this option may be offered to achieve the desirable labia minora length. However, more research to effectively evaluate the influence of stretching on the labia minora tissue (quality). Also, performing this technique in patients with limited labia majora and clitoral hood tissue may result in a smaller neoscrotum when using the using bilateral labia majora V-Y flaps scrotoplasty.¹⁹

An additional drawback is that the labia minora have notable sensitivity and are highly innervated along their entire edge. Hypothetically, this can cause an unpleasant sensation while voiding or

urinary catheterization. In our cohort, two patients complained of a unpleasant feeling in the pars pendulans during catheterization only. However, no complaints were reported during voiding.

Strengths and limitations

One of the strengths of this study is that it describes a feasible novel surgical technique. Also, most published data in the field of genital GAS consists of single-center experiences and by cooperating with other specialized GAS clinics, significantly more patients can be included. Limitations are the overall small amount of included patients and the lack of patient reported outcome measures.

Conclusion

The pedicled labia minora flap for urethral reconstruction in anterolateral thigh and superficial circumflex iliac artery perforator phalloplasty is a promising surgical technique in a subset of transgender men that has sufficient labia minora tissue. Advantages of this technique are a hairless urethra, preventing additional donor site and being a single-stage procedure. Additional research is needed to increase the applicability in transgender men.

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GENERAL DISCUSSION

The world is spinning faster and faster and every day new technological advances are made. The field of gender surgery is no exception. Procedures that seemed impossible only a few decades ago are starting to be considered as 'standard' today.

Currently, a wide variety of surgical procedures is offered to transgender men that have the wish to undergo genital gender affirming surgery (gGAS). In our center, the number of surgical options to create a masculine external genital has grown from five in 1989 to 12 surgical options currently (chapter 1). This increase reaffirms the fact that one ideal surgical technique to reconstruct the neophallus has yet to be found and that no one-size-fits-all surgical procedure exists.

The following outcomes are considered to be important goals of neo-phallus reconstruction¹ :

- Having an aesthetically pleasing neo-phallus and scrotum;
- The ability to void from a standing position;
- The ability to have penetrative sexual intercourse;
- Having tactile and erogenous sensibility.
- All with for the individual acceptable donor-site morbidity.

Each genital gender affirming surgical procedure has its own advantages and disadvantages with regard to these goals, the burden of treatment, and the risk of complications. Techniques may also be combined or modified to achieve the desired final outcome based on individual preference and surgical feasibility.

The importance of aesthetic appearance of the genitalia

"Phallus" is an ancient Greek word and refers to an erect penis that symbolizes potency and fertility. Correspondingly, "phalloplasty" refers to a surgical procedure that attempts to reconstruct a structure that is penis-like. In this surgical attempt the overall aesthetical appearance of the neophallus is an important goal. Increasing value is being attached to aesthetic appearance over the last decade. Now, more people than ever before are undergoing cosmetic procedures.² This trend also applies to aesthetic procedures of the genitalia.³ According to the American Society of Plastic Surgeons, the demand for labiaplasty rose by almost 40 percent in 2016 in comparison to 2015.⁴ And worldwide numerous men undergo penile enlargement procedures.⁵

Since the metoidioplasty is a technique to reconstruct a small neophallus, this procedure was introduced in the early 90's and has predominantly been described as a less-preferred alternative for transgender men who are not eligible for phalloplasty. ⁶ Additional disadvantages of a small neophallus include the inability to have penetrative intercourse and difficulty to void from a standing position.

However, our data shows that despite surgical developments over time, the metoidioplasty technique remains a preferred surgical treatment in a significant number of patients, independent of eligibility for phalloplasty (chapter 1). This suggests that the size of the neophallus is not the only aesthetical aspect which transgender men find important. In addition, the concept of what is considered 'aesthetically pleasing' varies across time and cultures. To give an example, when looking at ancient sculptures of gods and/or emperors like Zeus with massive bodies, one can notice their relatively small phallus. During that time, having a large penis was not considered favorably, nor was it a sign of strength or power. On the contrary, a small flaccid penis, was a sign of self-control and civilization.⁷

Voiding and urological complications

Phalloplasty can be performed with or without urethral (re)construction. Some transgender men express the wish to be able to void from a standing position. To enable this, the urethra has to be lengthened. Urethral lengthening is one of the most challenging aspects of GAS in transgender men. As shown in this thesis, it is associated with a high urological complication rate, especially in patients undergoing phalloplasty. In these patients, the incidence of urethral fistula and strictures is high.⁸ While colpectomy significantly reduces the risk of urethral fistula formation, the overall urological complication rate remains significant (chapter 2).

Unfortunately, an evidence-based diagnostic and treatment protocol for transgender men with urological complications is lacking. Furthermore, little is known of the (long term) effect of urethral lengthening on the urinary system. This lack of knowledge also creates challenges in providing patients with proper information regarding urethral complications.

Another problem is that assessment of the postoperative urological function proves difficult. At the Amsterdam UMC (location VUmc) patients undergo uroflowmetry before GAS and one year postoperatively. This test aims to objectify urological function by measuring the average and maximum rates of the urine flow. This is used to estimate the presence and severity of urethral blockage or obstruction. In non-transgender men, obstructions in the urinary tract, such as an enlarged prostate, can reliably be identified in this way. In contrast, uroflowmetry in transgender men is much more difficult to interpret. The neo-urethra in transgender men is made of the biological urethral tissue. In transgender men the uroflowmetry graph is often shaped as a 'plateau' or 'staccato', which in non-transgender men would indicate an obstruction or pelvic floor dysfunction requiring treatment. However, in transgender men this is not always the case, and these deviant shapes may be labeled as a 'normal' flow for a neourethra. A focus point for our department is to further research the correlation between the uroflowmetry results and the specific urological problems in transgender men.

As part of the standard postoperative follow-up, transgender men also complete the International Prostate Symptom Score (IPSS) pre-and postoperatively.

The IPSS is a validated questionnaire consisting of seven questions concerning urinary symptoms and one question concerning quality of life. ⁹ The main shortcoming of this questionnaire for use after GAS is the lack of questions regarding specific urethral symptoms after urethral lengthening In transgender men. For example is it known that transgender men often complain of post-void dribbling and a spraying urinary stream that may impede the possibility to void while standing.¹⁰ These specific topics are not included in the IPPS, but are important to assess the urological functioning in transgender men.

Ideally, a standardized and validated questionnaire needs to be developed and implemented specifically for transgender men. This would facilitate comparison of the outcomes of the various urethral lengthening techniques and have a better overview of the patient satisfaction.

In non-transgender men, the management of urethral complications such as strictures is complex with poor long-term success rates.^{11,12} The risk of recurrence depends on the extensiveness of the urethral defect, the localization, having multiple defects and the presence of an infection. In comparison to non-transgender men, the reconstructed neo-urethra in transgender men is subject to even higher complication recurrence rates.⁸ Unfortunately long-term outcomes of urological complication management are poorly described in the current literature. One can imagine that the success rates of managing these complications in a completely reconstructed neo-urethra is even more challenging.

In this thesis, various surgical approaches are described to prevent urological complications and thus decrease secondary procedures. Performing a colpectomy prior to GAS urethral lengthening lowered the occurrence of urethral fistula significantly (Chapter 2). After colpectomy, additional tissue including the bulbospongiosus muscle can be used to cover the urethral anastomosis. Short-term data from our center has proven that performing a colpectomy is a safe procedure. However, a learning curve is present and a (robot) assisted laparoscopically procedure is associated with less complications in comparison to an open procedure.¹³ Based on these results, it is recommended to perform a colpectomy prior to GAS with urethral lengthening. However, the long-term effects of colpectomy are not clear. In cisgender women, a colpectomy may be performed to treat vaginal cancer. This also includes the removal of tissue that anatomically supports the bladder and urethra. As a results severe urinary incontinence has been reported.^{14,15} In transgender men, more research is needed to assess the long term outcomes of colpectomy.

Although performing a colpectomy showed to be highly effective in reducing urethral strictures, a significant number of patients still developed urethral strictures (chapter ..). In addition, urethral fistulas are not prevented or treated by performing a colpectomy.

Despite the great progress in surgical techniques, the neo-urethra is still mainly reconstructed using skin tissue harvested as a full thickness graft or free/pedicled flap.¹⁶ This tissue differs significantly from urethral tissue in both function and histology. Skin is rigid, often hair-bearing (even after laser hair removal) and not designed to withstand long-term exposure to corrosive urine. With this in mind, we collaborated with the department of Urology at the Belgrade University Hospital to introduce a new surgical technique to reconstruct the neo-urethra using labia minora tissue (chapter 7). We hypothesized that labia minora would result in less urological complications due to being a non-hair bearing tissue, being more pliable and having an extensive vascular supply supporting proper tissue perfusion.¹⁷ The pedicled labia minora flap for urethral lengthening was performed in a subset of transgender men that had sufficient labia minora tissue (chapter 7). One-year postoperative results indicated that there was a significant learning curve, since the number of complications tended to decrease in subsequent patients. A larger number of patients and long-term results are needed to objectify our hypothesis and to assess the role of the pedicled labia minora flap for neo-urethral reconstruction.

For some patients, the importance of preventing urological complications outweighs their wish to void from a standing position. For those patients, the option to undergo GAS without urethral lengthening was offered since 2004. Since then, a significant number of transgender men (68/202, 34%) underwent GAS without urethral lengthening. None of these patients developed urethral strictures or fistulas and they reported a high overall satisfaction (chapter 3). Although, this option does not satisfy all goals of an "ideal" neo-phallus, it seems to be a good option for a substantial part of transgender men. It is also noteworthy that views on voiding differ geographically. Voiding from a standing position is common in most Western countries, while in Eastern and Asian countries voiding from a sitting position is more common.^{18,19}

Secondary surgical procedures

Surgical innovation is not just about finding the next big exciting technique. It can also involve new ways of preventing reoperations, reducing surgical complications and new ways to manage surgical complications.

Free flap surgery is considered a reliable and safe procedure for phalloplasty. The success rate of a free flap described in the literature is approximately 95% depending of the type of flap and recipient site.²⁰ Despite these high success rates, flap loss after phalloplasty still occurs at a rate of about 1% to 6% and is considered the most severe complication.^{16,21-23} Loss of the neo-phallus frustrates all goals of neo-phallus reconstruction. After flap loss a secondary reconstruction is usually performed.

Vascular flap related complications have decreased over time due to increased knowledge on flap surgery and improved surgical pre- and postoperative assessment. For example, a preoperative computed tomography angiography is increasingly performed to evaluate the feasibility of free/pedicled flaps to identify and locate suitable vascular structures, allowing for more precise surgical planning. Unfortunately, few studies have been published about ways to manage the loss of a (free) flap in phalloplasty surgery, and the use of a subsequent salvage flap. Salvage after flap loss is a difficult procedure and needs a multidisciplinary approach including extensive preoperative planning. Successful salvage of the phalloplasty can be performed using various flaps. Although being a major complication, most patients are (very) satisfied with a successful salvaged phalloplasty (Chapter 6).

In chapter 5 we presented a cohort of transgender men who underwent a secondary phalloplasty after metoidioplasty. A collaboration with six other specialized gender clinics revealed a great variability in the pre-operative counselling of these patients. In four of the seven centers the possibility of undergoing a secondary phalloplasty was only discussed with patients that showed a strong desire, whereas in one clinic a metoidioplasty was performed routinely as a first step towards phalloplasty. Each center also had their own preferences for performing a specific type of phalloplasty.

Shared decision making

Chapter 1 that gave an historical overview of the GAS treatments in transgender men, showed an increase of the surgical options from 5 in 1989 to 12 currently. Besides the added option to forego urethral lengthening, the variety and combination of flaps used for phalloplasty has especially increased. All techniques have their (dis)advantages regarding the afore mentioned goals and the concomitant (adverse) outcomes. For example, the radial free forearm flap (RFFF) phalloplasty is associated with extensive scarring on the forearm because of donor-site skin grafting.²⁴ If a transgender man prefers not to have extensive scar tissue on the forearm after, he can opt for anterolateral thigh (ALT) phalloplasty, superficial circumflex iliac artery perforator (SCIP) flap phalloplasty or a combination of flaps.

Transgender men therefore have a difficult task to carefully weigh the pros and cons in deciding what type of surgery to undergo. For this purpose, transgender men have to be actively involved in the decision making process. A general trend in health care shows a shift away from the historical paternalistic model of the physician-patient relationship, towards a more patient centered care.²⁵ This trend also applies to the field of gender surgery.

During the shared decision making (SDM) process the care provider and patient discuss the treatment options and their associated benefits and risks. This underlines the importance of monitoring complications and surgical outcomes in a standardized matter. A first step towards improving the SDM process has been made with the development of a decision aid for transgender men to assist them and the healthcare providers in a making well-informed decision for surgery.²⁶

Traditionally, morbidity and mortality outcomes have been recognized as the gold standard for judging quality of care in general surgery. ²⁷However, the definition of health has evolved to include outcomes such as happiness, quality of life and the ability to perform tasks of daily living. This change is deemed so important that in 1948 the World Health Organization (WHO) adapted their definition of health to 'a state of physical, mental and social well-being' and not just the absence of disease.²⁸ Patient reported outcome measures (PROMs) are designed to encompass and measure these aspects of health that can either not be directly observed or are not feasible to observe. A recent study has shown that the use of patient- centered outcome measurements (PROMs) improve the SDM process.²⁹

Unfortunately, in the field of gender surgery, there are currently no validated PROMs. However, recently literature has been published on the development of a PROM for adolescents and adults receiving gender-affirming treatments.^{30,31}

Future Perspectives

There is an urgent need for well-designed prospective studies to assess surgical outcomes, quality of life, sexual health and postoperative satisfaction in transgender men after gender affirming surgery.

Currently, a wide variety of surgical options is offered to transgender men to reconstruct the neophallus and neo-urethra, while we abandon other/older techniques. However, we do not have strong evidence to support these decisions. Performing a randomized controlled trial to compare these techniques would be unethical. Therefore, conducting prospective cohort studies would be the best option to compare surgical techniques and acquire higher quality data.

In addition to the current techniques based on transplantation of tissue, recent years have witnessed the emergence of tissue engineered medicine, thus creating even more opportunities for surgical procedures.^{32,33} However, literature has also shown that the risk of complications tends to increase when a new technique is introduced. Therefore, quality assurance (QA) programs have to be implemented in the field of gender surgery.

Our study on performing a secondary phalloplasty after metoidioplasty showed a difference in the follow-up scheme among the participating clinics. This variation makes it difficult to compare the outcomes of the surgical procedures. Regarding urethral complications for example, it makes a significant difference whether they are only subjectively scored or objectively proven (e.g. with a urethrogram or uroflowmetry).

Data standardization

Standardization of (surgical) outcomes and data in a common format is important to allow collaborative research and continuous monitoring of the quality of care. As mentioned, the number of medical specialties that are involved in providing surgical to transgender men are increasing. This growing complexity increases the risk of undesirable variation. Therefore, current evidence and expert consensus are needed to develop standardized outcome measures that can be used by all members of the clinical team. Other surgical fields have already implemented follow up protocols after complex surgical procedures.³⁴⁻³⁶ For example after breast cancer surgery, patients have a personalized follow-up schedule that may include doctors' visits, mammograms, bone density test and other tests based on the tumor specifications.³⁷ With the availability of electronic medical records, real-time data and standardized processes, a coordinated team can continuously measure quality of care and improve this care for transgender men.

Standardized data collection also creates an opportunity for proper long-term follow up. Data of long-term follow are is barely available in the field of gender surgery. These data are essential to reinforce conclusions made from initial trials or may even provide completely new insights. With the number of gender surgical procedures increasing significantly the last years, now is the time to include these patients in a long term follow up scheme.

Long-term follow and standardized data collection together also pave the way to assess the effectiveness of complication management. For example, the ability to void from a standing position may be impeded several years after performing a urethroplasty.

Research collaborations

Collaborating with other specialized gender clinics worldwide is urgently needed. In addition to having more patients included, collaboration with others enables one to access and share surgical techniques and skills, increase knowledge capacity and strengthen areas of weakness. Having a combined prospective database would provide important information on pre-operative and post-operative data. Research collaborations can also pave the way to accessing necessary funding.

Overall, genital gender affirming surgery in transgender men has come a long way. Despite of not

having the ideal phalloplasty technique yet, there is hope for transgender men due to the wide

range of options that are available and the developments that are ongoing.

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