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Post-operative complications following feminizing genitoplasty in moderate to severe genital atypia: Results from a multicenter, observational prospective cohort study

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Summary

Disorders/differences of sex development (DSD) are congenital conditions in which there is atypical chromosomal, gonadal and/or phenotypic sex. While there remains controversy around the traditionally binary concept of sex, most patients with DSD are reared either male or female depending on their genetic sex, gonadal sex, genital phenotype and status of their internal genital

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tract. This study uses prospective data from 12 institutions across the United States that specialize in DSD care. We focused on patients raised female. Eligible patients had moderate to severe genital atypia (defined as Prader score >2), were ≤2 years of age at entry, and had no prior genitoplasty. The aim of this study is to describe early post operative complications for young patients undergoing modern approaches to feminizing genitoplasty. Of the 91 participants in the cohort, 57 (62%) were reared female. The majority had congenital adrenal hyperplasia (CAH) due to 21-hydroxylase deficiency (n = 52), 1 had ovotesticular syndrome, 2 had mixed gonadal dysgenesis and 2 had partial androgen insensitivity syndrome (PAIS). Of the 50 participants who received early genitoplasty, 43 (86%) had follow-up at 6–12 months post-surgery. Thirty-two participants (64%) received a clitoroplasty, 31 (62%) partial urogenital mobilization and 4 (8%) total urogenital sinus mobilization. Eighteen percent (9/50) experienced post-surgical complications with 7 (14%) being rated as Clavien-Dindo grade III. Both parents and surgeons reported improved satisfaction with genital appearance of participants following surgery compared to baseline. This information on post-operative complications associated with contemporary approaches to feminizing genitoplasty performed in young children will help guide families when making decisions about whether or not to proceed with surgery for female patients with moderate to severe genital atypia.

Keywords

Atypical genitalia; Congenital adrenal hyperplasia; Urogenital sinus reconstruction; Disorders of sex development

Background

Complications after surgery to restore functional female anatomy in patients with disorders/differences of sex development (DSD) and genital virilization have been reported in a retrospective fashion and typically include a single surgeon or single institutional series of dated surgical approaches [1–5]. The incidence of DSD is estimated to range from 1:1000 to 1:5000 [6,7]. The most common diagnosis associated with moderate to severe genital atypia in genetic females is congenital adrenal hyperplasia (CAH) [8]. Based on data from national case registries and neonatal screening programs, the incidence of CAH ranges from ~1:14,000 to 1:18,000 births [9]. Less common causes of genital atypia among children reared female include mixed gonadal dysgenesis, PAIS, 5-alpha-reductase deficiency and ovotesticular syndrome.

The treatment of this complex and heterogenous group of patients is now ideally managed by multidisciplinary teams composed of the patient (when old enough), the family members, endocrinologists, geneticists, surgeons and mental health providers [4,10]. Achieving “typical” female appearance and function in patients with moderate to severe genital atypia requires complex surgical reconstruction. Specifically, in females whose anatomy has been virilized, this requires several steps: (1) determining the severity and location of the confluence of the urethra, vagina and common urogenital sinus (Fig. 1a), (2) separating the common urogenital sinus, (3) bringing the separated urethra (former common urogenital sinus) and vaginal opening to the perineum (Fig. 1b), (4) introitoplasty, and (5) treating

significant clitoromegaly [11–16]. Importantly, such procedures have evolved over time requiring any consideration of surgical outcomes to include data from contemporary approaches to feminizing genitoplasty. For example, modern principles involve preservation of the nerves to the urinary sphincter to preserve continence of urine and preservation of the nerves to the clitoris to preserve sexual function [11,12,16,17]. Historically, surgical complications of feminizing genitoplasty include vaginal stenosis, labial and introtial scarring, urethra-vaginal fistulae, and urinary incontinence [3,5]. Herein, we give a detailed report of the surgical techniques employed and outcomes of participants reared female who received feminizing genitoplasty, or are being observed without surgical intervention, from clinics that provide multidisciplinary care including contemporary approaches to early surgery.

The goal of this study is to report on 6–12 month surgical follow-up of patients receiving feminizing genitoplasty from a multicenter prospective study involving 12 institutions in the United States. Importantly, this study considers only contemporary surgical approaches to the treatment of patients with virilization of female anatomy [4,11,13–15]. Previously, we reported on the baseline characteristics of this cohort with genital atypia, documenting the phenotype, diagnosis and sex of rearing [18]. We also reported on parent psychosocial well-being and adjustment, as well as predictors of psychosocial stress in parents of children with atypical genitalia [18–21]. While preliminary reports on short-term cosmetic outcomes (rated by parents and surgeons) in children who receive early genitoplasty exist [22,23], this report extends our knowledge by focusing on a larger sample of participants reared female.

Material and methods

This NIH-sponsored research is an ongoing, prospective, observational, multicenter study assessing medical, surgical and psychological outcomes in children and families affected by severe to moderate genital atypia due to DSD. Institutional review approval was obtained at each participating center prior to patient enrollment (UCSF IRB 13–12811) Participants were prospectively enrolled from 12 children’s hospitals across the United States that specialize in DSD care, each with a multidisciplinary team. Data were de-identified and transferred into a REDCap database. Inclusion criteria were participants had moderate to severe genital atypia (which was defined by Prader >2), were ≤2 years of age at entry, and had no prior genitoplasty surgery. Exclusion criteria were: infants and children with malformations of organ systems other than urogenital and families with a limited comprehension of either English or Spanish.

To determine Prader scores, providers at each site performed a standardized genital examination, assessing the stretched phallic length, presence and positioning of the urethral meatus, gonad type (imaging, visualization, or biopsy), presence and degree of chordee, appearance of labia or scrotum, and the presence of a vagina and uterus (by imaging or cystoscopy).

This report focuses on participants reared female who either did or did not receive early feminizing genitoplasty. Variables collected include karyotype, DSD etiology, type of surgery (based on review of the operative report), post-operative complications and parent

and surgeon subjective evaluation of the participants genital appearance (cosmesis score) on a four point Likert scale prior to surgery and at 6–12 months follow-up post-surgery. Post-operative complications were scored on the Clavien-Dindo grading system, with grade III or higher signifying the need for further intervention. Cosmesis was graded as: 1 good, 2 satisfied, 3 dissatisfied and 4 very dissatisfied. Cosmesis scores are presented as either count and percentage or mean (standard deviation). Comparison of mean cosmesis scores between matched groups, for example, mother vs father or mother at baseline vs at 6 months, were analyzed using Student's *t*-tests for paired data. Calculations were done and figures created in R (version 3.6.1 (2019–07–05)). Results corresponding to *p*-values <0.05 are described as significant.

Results

Of the 91 participants in our total multi-institutional prospective cohort, 57 (62%) were reared female. The majority of those raised female had 46, XX DSD due to CAH (91%, n = 52). Additionally, 2 were diagnosed with partial androgen insensitivity syndrome (PAIS, 46XY), 2 with mixed gonadal dysgenesis (1 patient with 45XO/46XY and 1 other is mosaic 45X/46XY/47XXY) and 1 with ovotesticular syndrome (47XX with trisomy 21). Participants' Prader scores at study enrollment ranged from 3 to 5: 7 (12%) were rated as having Prader 5 at birth, 20 (35%) Prader 4 and 30 (53%) Prader 3 genitalia.

The surgical approach for participants who received early genitoplasty included multiple techniques to facilitate separation of the urogenital sinus, bring the vagina and urethra to a female-typical position, address clitoromegaly and fashion the introitus (Fig. 1b). Of the 57 participants raised female, 50 (88%) underwent some type of early feminizing genitoplasty. All of these patients who underwent surgery had vaginoplasty. Specifically, 38 (76%) had clitoroplasty, 31 (62%) partial urogenital mobilization, 4 (8%) complete urogenital sinus mobilization, 3 (6%) underwent an ASTRA (Anterior sagittal transrectal) approach for exposure of a high confluence of the urogenital sinus, 41 (82%) a perineal flap (Fortunoff flap) to augment the posterior vagina, 24 (48%) had use of excess common urogenital tissue to augment the anterior vagina (3 of the 24 were described as spiral flaps) and all patients received introitoplasty (labial majoraplasty and minoraplasty). Clitoroplasty was defined as removal of any erectile tissue within the corporal body or ventral glans clitoris while preserving the dorsal neurovascular bundle. For 2 of the participants clitoroplasty was performed during a separate surgical procedure over a year after the initial vaginoplasty. Age at surgery was 14.1 (8.9) months [Mean (SD)].

Nine (18%) patients had post-surgical complications with 7 (14%) of them being Clavien-Dindo III grade. Please see Table 2 for details of the complications. Two patients (both with CAH) in the surgical cohort had urinary tract infections post-surgery that resolved with antibiotics (Clavien-Dindo II). Among the 12 centers involved the number of surgeries performed per site ranged between 1 and 15. There was no correlation between Prader score and cosmesis rating for parents (mother: r = 0.18, p = 0.22, father: r = 0.07, p = 0.67). There was a correlation between Prader score and cosmesis for surgeons at baseline (r = 0.45, p = 0.01), however this correlation did not remain at follow up of 6 or 12 months. Additionally, there was no association between Prader score and complications both at 6 and 12 months.

Additional analysis was performed to see if there was difference in cosmesis rating at baseline and follow up over time. For mothers who give a worse cosmesis rating at baseline they are significantly less likely to follow up at 6 and 12 months ($p = 0.03$). For fathers who give a worse cosmesis rating at baseline they are trending but not significantly less likely to follow up ($p = 0.06$). There is no correlation between cosmesis score and likelihood of surgeon follow up ($p = 0.45$).

For all groups, compared to baseline cosmesis assessment of the genitalia, there was a statistically significant improvement of appearance after surgery. At baseline there was also a significant difference between parents and surgeons, with parents being more satisfied with appearance than surgeons; these differences between raters were no longer present at 6 and 12 months after surgery (Table 1). Fig. 2 shows cosmesis scores over time for mothers, fathers and surgeons.

Participants with No Surgery.

Seven participants were initially observed without genitoplasty, with 1 undergoing genitoplasty two years after study entry. Three participants who have not undergone feminizing genitoplasty did receive gonadal surgery to establish a diagnosis and as part of their treatment for DSD. An additional 2 participants, 1 with CAH and the other with PAIS continue to be observed with no surgery. Of note, among the participants who did not receive early genitoplasty, none reported having urinary tract infections during follow-up compared to 2 participants in the surgery group who did (4%) ($p = 0.59$). None of the participants who received a gonadal biopsy for diagnostic purposes experienced complications related to the laparoscopic biopsy and/or discordant gonad removal. Three patients who did not have surgery had long term follow up on cosmetic ratings. One patient started at baseline with good cosmesis rating (highest rating) from both mother and father and this persisted in the six month follow up. At 12 months the mother still rated the cosmesis as good while the father rated is satisfied (second highest marker). Another patient started at baseline with mother rating the cosmesis as satisfied while the father rated it as good. Six month follow up was not recorded but at 12 month follow the mother rated the cosmesis as good and the father rated it as satisfied. The final patient had satisfactory cosmesis at both baseline and 12 month follow up.

Discussion

In the present cohort of patients raised as girls with Prader 3–5 genitalia, 91% received earlier feminizing genitoplasty. A variety of contemporary techniques were used for surgical reconstruction illustrating the individualized approach needed for this heterogenous group of patients. Of the participants who underwent feminizing genitoplasty, 12% experienced significant Clavien-Dindo complications requiring additional surgery.

A common complication in the surgical cohort was vaginal stenosis which is likely to require further surgery at puberty. The rate of vaginal stenosis observed in our cohort is consistent with previously reported outcomes [9,11,23]. The true incidence of stenosis is likely to be higher and will not be accurately identified until after patients reach puberty or attempt vaginal intercourse. For this reason, we will continue to follow our current cohort of

study participants as they mature. Vaginal stenosis after feminizing genitoplasty is repairable with good functional outcomes [4,24].

Prior to surgery, surgeons were more dissatisfied than parents with the appearance of the virilized genitalia of participants (although most parents were dissatisfied and/or opted for surgery for their child). Prior to surgery there was no correlation between Prader score and cosmesis rating for both mothers and fathers while was a strong correlation for surgeons. We interpreted this difference as being driven by surgeons, who work with many DSD patients, having a set idea of what they would consider to be a higher scoring cosmetic anatomy compared to parents who may have just been exposed to their own children's and have less experience with the range of anatomical variation. However, parents and surgeons reported improved satisfaction with genital appearance of participants following surgery compared to baseline. Thus, improved cosmesis with modern approaches to feminizing genitoplasty is attainable. Further study is needed to understand why surgeons and parents differ in their ratings of cosmesis, as well as why parents who rated their child's genital cosmesis as satisfactory or better went on to choose early genitoplasty for their daughter. We do not have enough data from patients who did not undergo surgery to make conclusions about how cosmesis scores change or remain stable.

There are several limitations to our study. Our results do not address outcomes concerning urinary continence, sexual function or patient satisfaction with cosmetic appearance of the genitalia or patient satisfaction with timing of genitoplasty. All of these important outcomes will be assessed as the children in our study mature into later childhood and adolescence. Additionally, some parents did not complete the general cosmesis measure. Another important limitation are the granular details available as part of the study. For example, 2 patients ended up having clitoroplasty as a second procedure after initial vaginoplasty only. Regrettably, we did not collect data about the surgical decision making processes between parents and providers. Understanding why families opted to go forward with an additional procedure is very important for counseling and we plan to study this with qualitative interviews in future studies. We also do not have data on the granular decision making of the 8 mothers who rated their children's cosmesis as "good" but then proceeded to elect surgery. Finally, we are limited with the follow up for patients who are non operative as these families do not maintain ongoing clinic visits with pediatric urologists. In future study it will be critical to ensure we do everything possible to retain patients long term, including studying these children with the help of other providers such as pediatric endocrinologists. However, despite these limitations, the data presented here are important to inform caregivers about the pros and cons of early genitoplasty within the context of modern surgical approaches.

We conclude that early surgery to restore female-typical anatomy in patients with moderate to severe genital atypia due to DSD, the majority of whom are affected by CAH, results in satisfactory short-term outcomes and a 12% complication rate requiring further surgical treatment. This information is essential for parents to determine if early surgery is in the best interest of their child. Longer term follow-up of the surgical and psychological outcomes of study participants who received early genitoplasty (as well as those who did not) is

underway to further guide parents and healthcare teams who aim to optimize care for young patients with DSD.

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Abbreviations

CAH	congenital adrenal hyperplasia
DSD	disorders/differences of Sex Development
NIH	National Institutes of Health
PAIS	partial androgen insensitivity

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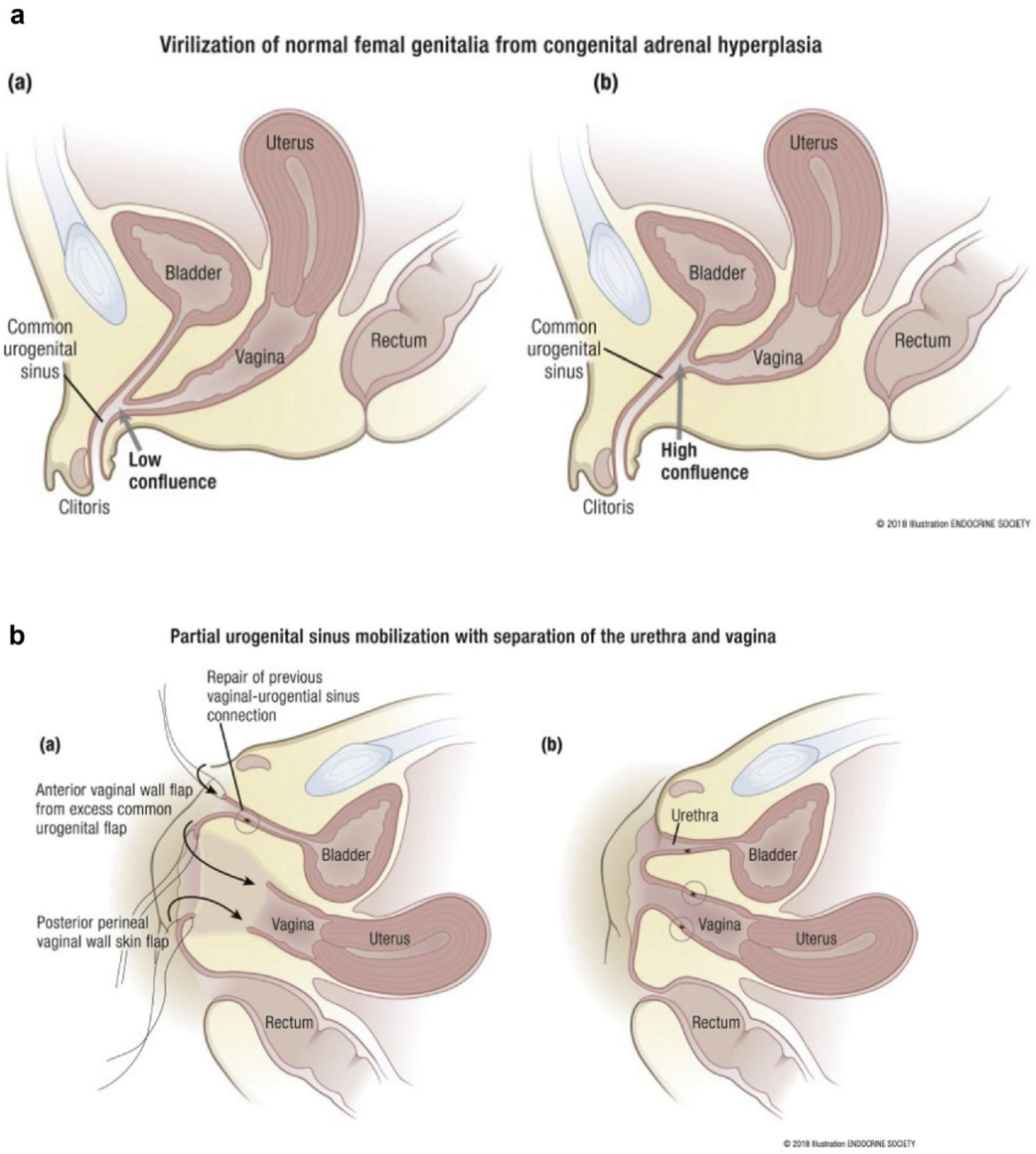
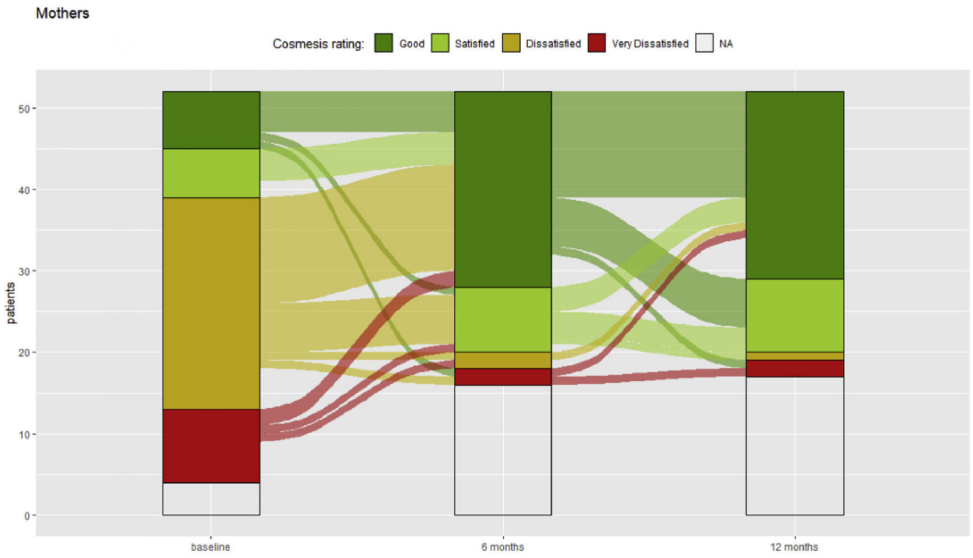
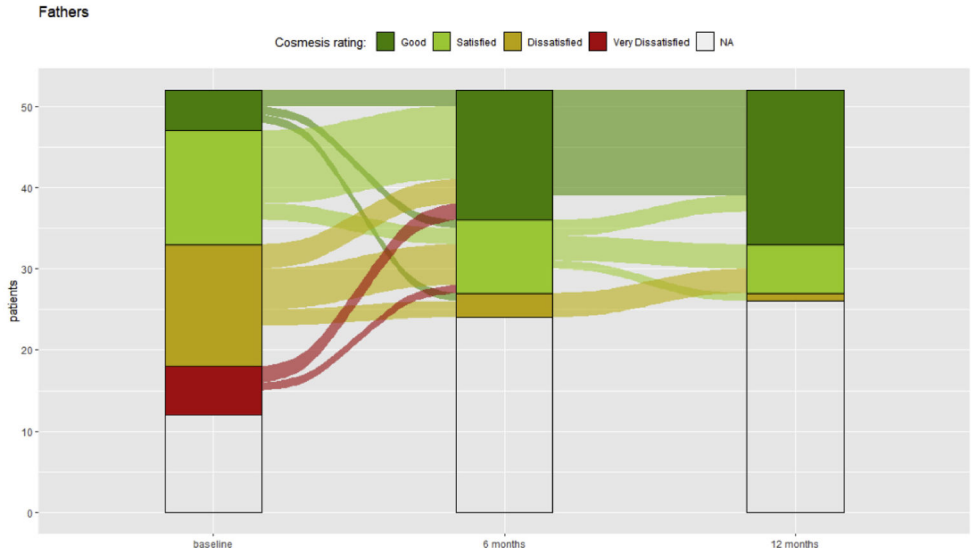


Fig. 1.

a. Lower urogenital anatomy of mild (a) and severe (b) virilization from congenital adrenal hyperplasia. Note the low confluence in (a), where the vagina and urethra meet close to the skin, in contrast to (b), where the confluence of the vagina and urethra is close to the bladder neck. Used with permission [Illustration ENDOCRINE SOCIETY] [9]. b. Partial urogenital mobilization with separation of the urethra and vagina. Note the separation in (a) of the vagina and urethra with utilization of the excess common urogenital sinus to form the anterior vaginal wall (b) and utilization of the posterior perineal skin flap (a) to form the posterior vaginal wall(b). Used with permission [Illustration ENDOCRINE SOCIETY] [9].





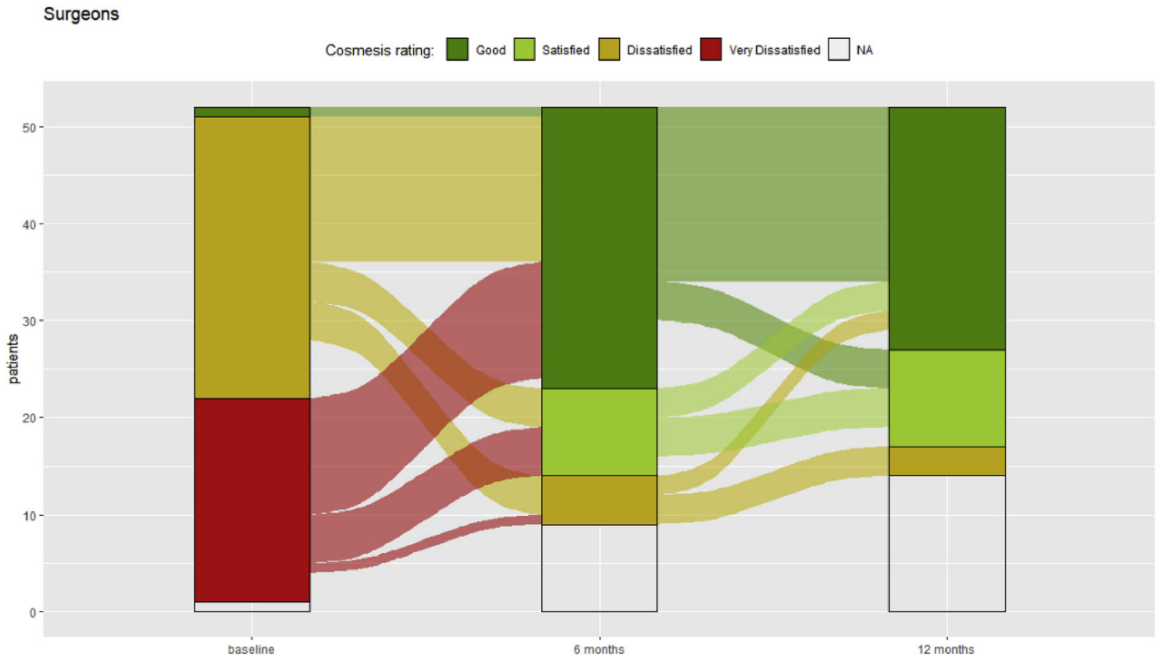
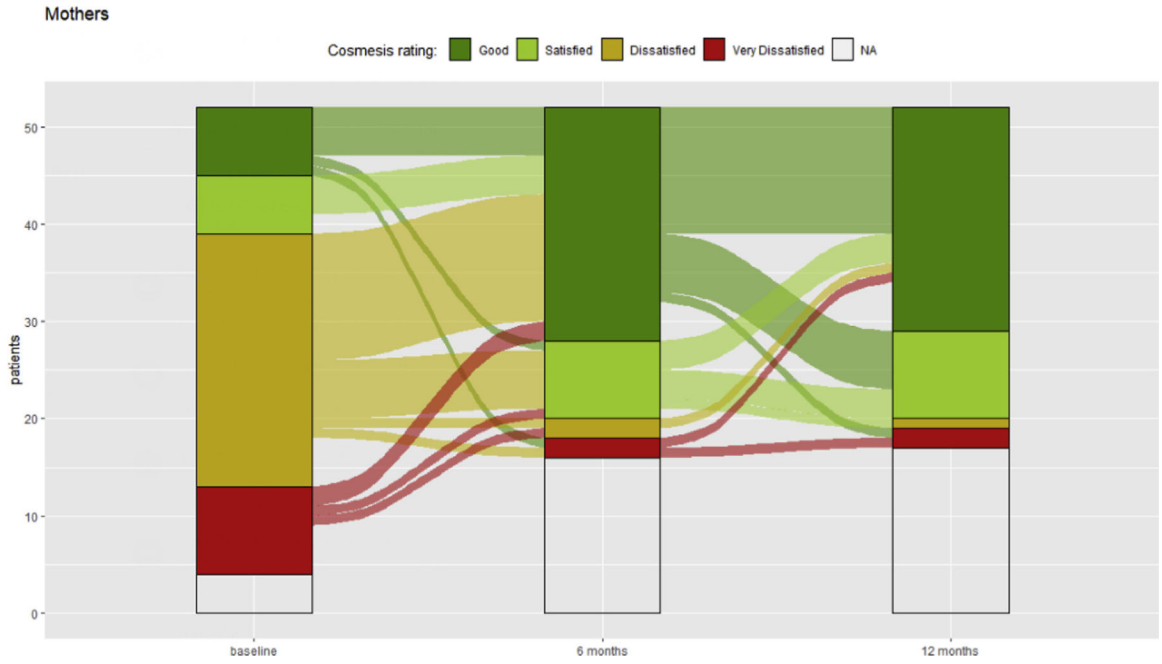


Fig. 2.

River diagrams of Cosmesis score over time point for mothers, fathers and surgeons.



Summary Figure.

River diagram of mother's cosemsis rating over time in DSD patients undergoing early feminizing genitoplasty

Table 1

Average cosmesis scores using a 4 point Likert scale assessment of genital appearance by parents and surgeons before (Baseline) and 6 and 12 months after surgery. Comparing assessments between time-points within each group.

	Baseline	Baseline vs 6 months	6 months	6 months vs 12 months	12 months
Mother	2.7 (0.9) [n = 54]	(37 pairs) p < 0.0001	1.5 (0.8) [n = 37]	(31 pairs) p = 0.73	1.5 (0.8) [n = 38]
Father	2.5 (0.9) [n = 45]	(29 pairs) p = 0.0002	1.5 (0.7) [n = 29]	(23 pairs) p = 0.27	1.4 (0.6) [n = 29]
Surgeon	3.2 (0.8) [n = 57]	(41 pairs) p < 0.0001	1.4 (0.7) [n = 42]	(33 pairs) p = 0.77	1.4 (0.6) [n = 39]

Comparing groups at each time-point.

	Mother	M vs F	Father	M vs S	F vs S	Surgeon
Baseline	2.7 (0.9) [n = 54]	(45 pairs) p = 0.058	2.5 (0.9) [n = 45]	(53 pairs) p = 0.0013	(44 pairs) p < 0.0001	3.2 (0.8) [n = 57]
6 months	1.5 (0.8) [n = 37]	(29 pairs) p = 0.83	1.5 (0.7) [n = 29]	(35 pairs) p = 0.74	(28 pairs) p = 0.66	1.4 (0.7) [n = 42]
12 months	1.5 (0.8) [n = 38]	(29 pairs) p = 0.81	1.4 (0.6) [n = 29]	(36 pairs) p = 0.60	(27 pairs) p = 0.83	1.4 (0.6) [n = 39]

Mean (SD) are shown. p-values obtained from student's *t*-tests for paired data.

Table 2

Complications by type of surgery in patients undergoing feminizing genitoplasty.

ID	Clitoroplasty	Vaginoplasty	External genitoplasty	Female urethroplasty	Perineoplasty	Urogenital Sinus Mobilization	Removal of Mullerian Remnants	Gonadectomy	Complication (multiple separated by comma)
1	1	1	1	0	0	NA	NA	NA	Vaginal Stenosis
2	1	1	NA	NA	NA	NA	NA	NA	separation of left labia minor flap, requires surgical correction
3	1	1	1	1	1	NA	NA	NA	Vaginal stenosis
4	1	1	1	0	1	NA	NA	NA	Vaginal stenosis, Adhesions left side labial separation
5	0	1	1	1	0	0	0	0	urethrovaginal fistula
6	1	1	1	1	0	NA	NA	NA	Mucosal skin tag. Removed
7	1	1	0	0	0	NA	NA	NA	Urinary tract infection
8	1	1	1	NA	NA	1	NA	NA	Urinary retention, dehiscence along labia majora borders bilaterally
9	1	1	1	1	1	1	NA	NA	vaginal stenosis, minimal separation perineal body, minor separation labia majora