

# Surgical Vaginoplasty Treatment for Gender Dysphoria and Mayer-Rokitansky-Küster-Hauser Syndrome: A Systematic Review and Meta-analysis

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## Abstract

**BACKGROUND:** About 430,000-1,000,000 Gender Dysphoria- and Mayer-Rokitansky-Küster-Hauser-patients undergo vaginoplasty each year. Various surgical procedures are available, but direct comparisons are lacking. This inhibits well-informed decision making by patients and healthcare professionals. **OBJECTIVES:** Highlight information gaps, weaknesses and strengths of today's vaginoplasty techniques. **SEARCH STRATEGY:** A systematic search in Medline, EMBASE, Web of Science and Scopus until March 8, 2022 was conducted, by PICO method and PROSPERO registration. **SELECTION CRITERIA:** Original retrospective studies on complete neovaginal creation in adult Gender Dysphoria- and Mayer-Rokitansky-Küster-Hauser-patients and discussing anatomical outcome, Quality of Life, satisfaction, sexual function, complications and/or complaints. **DATA COLLECTION AND ANALYSIS:** Data was extracted and methodological quality and potential bias were assessed. The 95% confidence intervals were calculated with DerSimonian and Laird random-effects. **MAIN RESULTS:** A total of 47 articles were eligible. Surgery took 198 minutes with 10.2 cm vaginal length. Major complications included 5% hemorrhage, 1% gastrointestinal complications, 1% prolapse, 3% tissue necrosis and 6% stenosis, with 31% revisions. Patients reported 25% excessive discharge, 6% pain, 11% fecal- and 17% urinary issues and one case of hair growth. Patients also reported 95% aesthetic- and 93% anatomical satisfaction, 10% overall dissatisfaction and 1% regret. Reports showed 75% sexual activity, 13% dyspareunia, 87% sensation and 84% overall functional satisfaction. **CONCLUSIONS:** Multiple vaginoplasty techniques demonstrated safe and acceptable outcomes, with significant improvement of Quality of Life and self-image. However, standardized validation tools are needed for well-informed decision-making. Direct technique comparisons with similar cohorts and exploration of tissue-engineering methods are critical for future surgical advancements.

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**DATA COLLECTION AND ANALYSIS** : Data was extracted and methodological quality and potential bias were assessed. The 95% confidence intervals were calculated with DerSimonian and Laird random-effects.

**MAIN RESULTS** : A total of 47 articles were eligible. Surgery took 198 minutes with 10.2 cm vaginal length. Major complications included 5% hemorrhage, 1% gastrointestinal complications, 1% prolapse, 3% tissue necrosis and 6% stenosis, leading to 31% revisions. Patients reported 25% excessive discharge, 6% pain, 11% fecal- and 17% urinary issues and one case of hair growth. Patients also reported 95% aesthetic- and 93% anatomical satisfaction, 10% overall dissatisfaction and 1% regret. Reports showed 75% sexual activity, 13% dyspareunia, 87% sensation and 84% overall functional satisfaction.

**CONCLUSIONS** : Multiple vaginoplasty techniques demonstrated safe and acceptable outcomes, with significant improvement of Quality of Life and self-image. However, standardized validation tools are needed for well-informed decision-making. Direct technique comparisons with similar cohorts and exploration of tissue-engineering methods are critical for future surgical advancements.

**KEYWORDS** : Gender Dysphoria / Mayer-Rokitansky-Küster-Hauser syndrome / vaginoplasty / patient-reported outcomes / complications

### **FUNDING**

None.

## **Introduction**

### **Vaginoplasty**

Various neovagina creation methods are available, when a normal vagina is absent due to congenital or acquired diseases. Non-surgical methods (like vaginal dilation and traction) used to be the first choice of treatment, they are successful and avoid surgery-related risks.<sup>1-3</sup> However, non-surgical methods are associated with vaginal prolapse, shorter vaginal depths, low patients' satisfaction, long-term agony and mental as well as emotional stress.<sup>4,5</sup> Vaginoplasty should arguably result in an anatomically and functionally normal vagina, be minimally or non-invasive, avoid dilation necessity and prevent scars, stenosis or contracture.<sup>6,7</sup> Many physicians and patients prefer surgery, as non-surgical vaginoplasty takes 2-24 months and surgical correction

is often required to improve or allow sexual activity and to restore severe defects with extra-vaginal tissue. Surgical vaginoplasty is therefore gaining interest as therapeutic strategy for women with absent vagina or vaginal malformation, with 39,000-650,000 estimated annual surgeries<sup>11</sup> \* Based on 3,904,727,342 female inhabitants in 2021 with 1:1,500-10,000 MRKHS patients, this results in 39,047-650,788 vaginoplasty surgeries for 10-25% surgical vaginoplasty treatment..<sup>5,8</sup> Over 20 vaginoplasty methods have been advocated the past centuries, each with specific (dis)advantages and so the ideal method is a matter of debate.<sup>9</sup> These surgical approaches are generally specified as cavity dissection procedure with or without grafting technique.

Vaginoplasty techniques generally differ with respect to applied donor tissue, with penile-inversion- and penoscrotal surgery as MtF-specific methods.<sup>27</sup> However, skin volume is not always sufficient, especially with hypoplasia due to hormone therapy initiation in early adolescence.<sup>28</sup> Alternative methods use skin flap- or (laparoscopic) bowel segment approaches<sup>29,30</sup> or experiment with amnion grafts, oral mucosa or decellularized tissue. Gender surgeons prefer the inverted penoscrotal technique, but no consensus exists on the ideal technique. Publications of complications and patient-reported outcomes are limited, with only one review comparing outcome of various surgical techniques.<sup>31,32</sup> Initially, publications referred to MtF patients as male transsexuals with male pronouns, which gradually changed to female identity recognition. Initially, surgery aimed for male genitalia removal and measured post-surgical marriage quantity without partner awareness of original genitals. Today, patient-reported outcomes emphasis on aesthetics and functionality and require the neovagina to be hairless, moist and minimally 11 cm deep and 3 cm wide, with labia minora, majora and a sensate clitoris.<sup>14,25</sup>

MRKH vaginoplasty methods are Davydov-, Intestinal-, McIndoe-, Skin flap-, Vecchietti- or Wharton-Sheares-George technique. There are few MRKHS comparative reviews on complications and patient-related outcomes and non to compare surgical techniques. Earlier, vaginoplasty outcome was assessed by neovagina length, sexual activity and whether patient or current partner was sexually satisfied.<sup>43-45</sup> Today, sexual function and vaginoplasty satisfaction are assessed through extensive patient-centred questionnaires.

## Objective

We attempted to evaluate peri-operative- and post-operative outcomes of MRKH- and GD-patients for various vaginoplasty techniques based on anatomy, complications, satisfaction, Quality of Life (QoL), sexual functioning and complaints. We hope this comparison will facilitate in further vaginoplasty development by highlighting weaknesses and strengths and that it will aid in well-educated decision making by patients and healthcare professionals when selecting a procedure. By revealing current information gaps, focal points for future research can be determined.

## Methods

### Protocol and guidance

This review was conducted in accordance to Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines.<sup>46</sup> The protocol was registered (May 19, 2021) in PROSPERO (CRD42021249785).

### Eligibility criteria

Studies had to meet all **inclusion criteria** : (i) original paper on surgical, complete neovagina creation; (ii) written in English; (iii) a peer reviewed journal publication; (iv) discuss anatomical outcome, Quality of Life, satisfaction, sexual functioning, complications and/or complaints; (v) [?] 6 months Follow Up; (vi) patients [?] 18 years during surgery; (vii) and [?] 10 MRKHS patients or transwomen. Study exclusion for one or more satisfied **Exclusion criteria** : (i) unspecified surgical technique, vaginoplasty combined with other treatment or as non-primary surgery; (ii) merged results of patient and control group or of different patient types; (iii) or merged results of different vaginoplasty techniques.

## Search strategy

A strategic, three-step search was performed in bibliographic databases Medline, EMBASE, Web of Science and Scopus (Core Collection) by a medical information specialist (R.d.V.), to identify relevant publications up to March 8, 2022. This PICO-search with (MeSH) terms (including synonyms and closely related words), looked for *Transgender persons* and MRKH patients (**P** articipants), *Sex reassignment surgery* and *vaginoplasty* (**I** ntervention), and *neovagina* combined with anatomy, satisfaction, sexual function, Quality of Life, complaints or complications (**O** utcome). Next, references were screened ('snowball' method) and a 'related search' on initial 200 Google Scholar hits was performed by a PhD candidate (J.S.). Duplicates were removed and a Mendeley 1.19.4 (Mendeley Ltd.) database was formed. The searches are included (Figure S12).

## Study selection

Two researchers (J.S. and F.G.) independently screened titles and abstract for eligibility criteria using End-Note Library 20.1, with with discrepancies resolved by a third reviewer. Remaining articles were assessed independently for full content. Disagreements were resolved through discussion between the two authors.

## Data extraction

Data from included studies was extracted according to a predefined standard. Neovagina lengths and operation times were pooled per surgical technique. Complications were reported as number of events and categorized hemorrhagic (transfusion and hematoma), gastrointestinal (rectal injury and recto-vaginal fistula), vaginal prolapse, tissue necrosis (of urethra, glans, clitoris and labia), (meatal or neovaginal) stenosis and revisions. Complaints included excessive mucous production, (genital) pain, (vaginal) hair growth, fecal- and urinary issues. Patient-reported satisfaction with anatomy and aesthetics, overall dissatisfaction and experienced regret were assessed. Sexual function included dyspareunia (pain during intercourse), experienced (erotic and orgasmic) sensation, sexual activity and satisfactory-graded sex life. Standardized questionnaires for aesthetics (Female Genital Self-Image Scale; FGSIS) and QoL were assessed separately and not included in the meta-analysis. Information was correlated and presented.

## Risk of bias and quality of evidence

Methodological quality, for critical evaluation and not for methodological filtering,<sup>47,48</sup> of included studies was assessed through the Newcastle Ottawa Scale (NOS).<sup>49</sup> Potential bias was identified through the National Heart, Lung, and Blood Institute (NIH) Study Quality Assessment Tool for Observational Cohort and Cross-sectional Studies<sup>11</sup> Checklist at [www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools](http://www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools).

## Data synthesis

By statistical analysis in Stata version 14.0 (StataCorp LLC, College Station, TX), operation times and anatomy were pooled by **metan**, with 95% confidence interval (CI) and effect size calculation by DerSimonian and Laird random-effects.<sup>50</sup> Complications, complaints, satisfaction and sexual function were pooled by **metaprop**, with 95% Wilson CI and DerSimonian and Laird random-effects,<sup>51</sup> after variance stabilization by Freeman-Tukey double-arcsine-transformation and heterogeneity determination by I-square measures.<sup>52</sup>

## Results

### Study selection and Characteristics

The PRISMA flow diagram of the meta-analysis is shown in (Figure 1). A total of 3954 articles were identified. Of 47 included articles (overview in table i), 19 reported on operation times (Figure S1), 26 on

vaginal length (Figure 2), 40 on surgical complications (Figure S2), 20 on complaints (Figure S3), 30 on satisfaction (Figure S4), 40 on sexual function (Figure S5) and 9 on QoL (table ii). A high intercontinental diversity of patient-population and techniques was observed (Figure S6a/S6b).

## Risk of bias of included studies

Quality of nonrandomised studies was assessment by NOS and judgment of: study group selection; group comparability; and ascertainment of exposure or outcome of interest (Figure S8). Manuscripts were judged as 31 (66.0%) (B) high risk of bias, 15 (31.9%) (C) very high risk of bias and one (2.1%) (A) high quality, based on likelihood of bias and completeness of reporting (Figure S9). Bias was assessed with the NIH tool (Figure S10). Studies were judged as 1 (2.1%) (A) bad, 9 (19.1%) (B) poor, 19 (40.4%) (C) fair, 18 (38.3%) (D) good and 0 (E) excellent (Figure S11). In both assessments no weighting was used. MOOSE guidelines were followed.<sup>53</sup>

## Synthesis of results

Surgical outcomes of 2927 MtF Gender Dysphoria-patients were reported in 32 articles (Figure S7a). The majority is treated by penoscrotal- or penile-inversion vaginoplasty, to allow reconstruction from local tissue as the inversed penile skin forms the neovaginal cavity and penile/scrotal skin the external genitalia with alternative neovaginal lining by an intestinal- graft-, Skin flap- or Combined interventions. Treatment of 853 MRKHS-patients was reported in 15 articles and predominantly (44,20%) involved Davydov surgery. Even though non-surgical MRKH-treatment options are associated with low satisfaction, vaginal prolapse, fatigue, long-term agony and mental as well as emotional stress,<sup>4,5</sup> this is still favoured by many patients and physicians. The intestinal surgery proportion of MRKH-patients, differs significantly from GD-patients ( $p < 0.00001$ ) based on one-tailed Z-score Calculation (Figure S7a). The Skin flap vaginoplasty proportion of MRKH- and GD-patients, are not significantly different. Vecchietti-, Davydov- and Intestinal vaginoplasty can alternatively be performed laparoscopically to decrease complication rates,<sup>54</sup> all other techniques are performed by open or vaginal approaches.

Highest publication quantity involved penoscrotal SRS, that was reported in 18 out of 32 GD-related articles, with continuous attention since 1995 (Figure S7b). Davydov was reported in the majority of MRKHS-surgeries, due to simplicity and good aesthetics.<sup>55</sup> The oldest publication (1987) involved penile-inversion vaginoplasty and stayed unpublished next until 2009, when vaginoplasty publications and performed techniques grew rapidly. The oldest included MRKHS publication dates from 2008 and Wharton-Sheares-George (2019) is the latest surgical technique.

### Surgical outcomes - complications

The average vaginoplasty duration is 198.0 min (152-244 min) (Figure S1). Combined vaginoplasty (312 min) is the longest procedure, where penile-inversion- (216 min) or penoscrotal (286 min) surgery is combined with a secondary approach. SRS duration increased with required tissue quantity for reconstruction and were slightly longer (216-378 min) than MRKH-procedures (26-300 min).

Pooled complications showed 5% hemorrhage and 1% gastrointestinal complications (peri-operative), and 1% prolapse, 3% tissue necrosis, 6% stenosis and 31% revisions (long-term post-operative) after complications or patient-reported aesthetic complaints (Figure S2).

Combined vaginoplasty reported most hemorrhagic complications (29%) (Figure S2a). Hemorrhage only resulted from SRS, was often non-severe and treated non-operatively by dressings, transfusion, cooling or adrenalin injection. Bleedings resulted from hematoma, necrosis, infection, dilation injury, granulation or fistula and delayed wound healing. Associated risk factors are clotting disorders and smoking, peri-operative estrogen continuation (depending on administration route and also decreases bleeding during sponge body dissection by erectile reflex elimination) and NSAIDs are sometimes avoided (Hontscharuk et al. 2021).

Gastrointestinal complications were predominantly reported after SRS, with 2% after penile-inversion- and penoscrotal surgery and 3% after intestinal vaginoplasty (Figure S2b) and were associated with dilation injury, infection and retraction, abscess, hematoma or (rare) neovaginal malignancy. Recto-neovaginal fistula presented after peri-operative rectal injury or vascular lesion by perineal dissection and may require temporary colostomy or graft interposition between rectum and vagina. Rectal injury may be avoided by meticulous dorsal preparation from perineal body to prostate along Denonvilliers fascia to the tips of seminal vesicals.

Intestinal vaginoplasty reported most prolapses (4%) (Figure S2c), after inadequate vaginal canal dissection or non-adherence of skin grafts, with BMI as only known predictor. Treatment entailed neovaginal flap repositioning/reinsertion (using fibrin glue) and revisions for mucosal prolapse, whereas sacropexy (graft fixation to the sacrospinous ligament) or penoscrotal apex fixation to Denonvillier's fascia help avoid prolapse.

McIndoe surgery reported most tissue necrosis (17%) (Figure S2d), often at points of maximum tension (i.e., the vaginal introitus) due to vascular spasm, restricted blood flow or altered blood supply after transverse lesion of the spinal cord. Smoking, diabetes and cardiopulmonary conditions are predictors and may be reduced by patient-behaviour. Treatment involved local wound care and surgical debridement or reconstruction for major necrosis, but labia majora disunion or graft loss was sporadically observed.

Most reported complication is introital-, meatal- or vaginal stenosis<sup>14,58</sup> and is mainly seen after penile-inversion vaginoplasty (19%) (Figure S2e), due to lack of compliance with dilation (or regular intercourse) to prevent contraction in the initial 3 post-operative months. Treatment entailed daily self-dilation, pelvic floor physiotherapy and occasional revisions after suture line rupture by forceful dilation. Meatal stenosis is treated by urethral dilation or meatotomy with optional resection of corpus spongiosum remains that obstruct urine flow by thickening during excitement. Predictor for meatal stenosis is early transurethral catheter removal, whereas prolonged catheterization increases risk of urinary tract infections. A pedicled flap from rectosigmoid colon or four sutures at the introital, mucosa-peritoneum interface during Davydov surgery help avoid stenosis.

Revisions were reported after penile-inversion- (37%), penoscrotal- (29%), intestinal- (42%) and combined (12%) SRS (Figure S2f), for introital/meatal stenosis, necrosis, prolapse, fistula, hematoma, infection/wound dehiscence, corpora tissue resection and mostly esthetical enhancement (of labia). High revision rates were associated with full health-insurance coverage and post-operative transparency of options and rarely led to patient regret or dissatisfaction with (aesthetic or functional) surgery outcome.

Wharton-Sheares-George interventions reported no complications.

## Anatomy

The average neovagina length was 10.18 cm (9.05-11.31 cm) (Figure 2). Intestinal vaginoplasty reported the longest (13.08 cm) and Wharton-Sheares-George the shortest neovagina (7.60 cm). Only Intestinal- and Penoscrotal vaginoplasty resulted in 'successful' lengths of  $\geq 11$  cm. Complications were associated with length reduction and dilation prevents up to 4 cm depth loss in the first 10 post-operative days.

## Complaints

Complaint-reports were rare and included 25% excessive secretion, 6% genital pain, 42% hair growth, 11% fecal- and 17% urinary issues (Figure S3). Surgeons consider self-lubrication an advantage of Intestinal vaginoplasty and 28% of the patients consider it a gradually decreasing, non-excessive or non-irritating problem. All McIndoe patients complained about excessive secretion with scant as major issue and only this group reported hair growth. Davydov patients reported 8% excessive secretion during the initial 3 months. Pain (clitoral or pain during sexual arousal or intercourse) was reported after Penile-inversion- (4%) and Penoscrotal (8%) interventions. Fecal issues involved bowel complaints after intestinal SRS (3%) and fecal urgency or incomplete bowel emptying after penoscrotal (17%) interventions. Urinary issues (urgency, stress incontinence or misdirection of the stream) were solely reported with SRS after penile-inversion- (21%), penoscrotal- (21%) and combined (1%) surgery. Small prostates, pelvic floor dysfunction (by perineal

dissection) and urethral sphincter injury are known predictors for urinary incontinence and is often non-surgically resolved by medication or pelvic floor physiotherapy.

## Satisfaction

Patient-reported outcomes (Figure S4) included 10% overall dissatisfaction, 1% regret, 95% aesthetics- and 93% anatomical satisfaction. Highest reports were seen for dissatisfaction after Intestinal vaginoplasty (23%), overall satisfaction after Combined interventions (98%) and anatomical satisfaction after McIndoe-, Peritoneal- and Vecchietti surgery (100%). Sporadic regret was reported after Penile-inversion- (4%) and Penoscrotal interventions (1%), and was associated with hair, clitoral pain and lower satisfaction. One patient regretted an unfulfilling new life and another (without mentioned cause) would undertake surgery again.

## Sexual functionality

Pooled outcomes (Figure S5) showed 75% sexual activity, 13% dyspareunia, 87% sensation and 84% function satisfaction. Penoscrotal surgery (61%) reported lowest and Skin flap surgery (100%) the highest sexual activity. Dyspareunia was reported for all except Wharton-Sheares-George technique. McIndoe-surgery (69%) reported lowest and Intestinal vaginoplasty (98%) reported highest dyspareunia. Functionality was reported good/excellent for Combined-, Intestinal-, Penoscrotal- and Peritoneal surgery, acceptable for McIndoe- and poor for Penile-inversion surgery. Intercourse initiation varied with 6-8 months, if desired, or at 70% epithelialization.

Most MRKH-patients initiated intercourse 1-4.5 months after intestinal-surgery and after Skin flap-surgery with 110.3% improvement despite dyspareunia. All sexually active patients from a mixed cohort declared full functional- and aesthetic satisfaction. All MRKH-patients were highly to fully satisfied. After McIndoe- and intestinal-vaginoplasty there was respectively one complaint on excessive secretion and sexual arousal. Fertility was restored in 3 MRKH-cases. Wharton-Sheares-George surgery required molds for 6 months, with increased FSFI-scores from 6 to 12 post-operative months. Most peritoneal-vaginoplasty patients had full functional- and anatomical satisfaction within 12 months, except for one mild dyspareunia complaint (resolved by lubrication) and one case of sexual dysfunction due to vaginal stenosis. GD-patients were less sexually active, but FSFI-scores were similar for transwomen after intestinal- and penile-inversion vaginoplasty and for MRKHS-patients after sigmoid vaginoplasty. SRS-subjects mostly confirmed sexual responsiveness, although orgasmic capacity was post-surgically diminished in some to most patients. Penile-inversion-surgery reported [?]50% sexual dysfunction with good overall and aesthetic satisfaction, but low functionality satisfaction (caused by inadequate depth, lubrication issues, sexual discomfort and sporadic ejaculation, clitoral erection and pain during initial penetration or after sex). Most penoscrotal-patients had regular intercourse, adequate or satisfactory depth and achieved neoclitorus-stimulated orgasms. Excessive erectile tissue, recurrent bleeding after or suture line rupture during intercourse, pain, cosmetical dissatisfaction, orgasm difficulties, inadequate depth, stenosis or insensate clitoris (corresponding with penile-inversion-patients) caused sexual dysfunction. Some SRS-complaints about sexual function, are correlated to gender dysphoria and the old male body physique. Penoscrotal-surgery significantly increased femininity and sexual activity.

## Quality of Life

Patient-reported QoL was studied in 9 articles (table ii), with one MRKHS-patient assessment mixed with intestinal-patients, showing 22.2% mild/moderate post-operative depression. Happiness after Intestinal-vaginoplasty was normal, with 100% slight-to-extreme satisfaction with life.<sup>59-61</sup> QoL after Penile-inversion-vaginoplasty was normal<sup>62</sup> and partnered patients scored higher on vitality, social functioning and mental health. Penoscrotal-surgery improved personality, lifestyle, self-esteem and overall QoL<sup>63,64</sup> with low depression-scores and normative anxiety.<sup>64,65</sup> It also increased body and femineity satisfaction.<sup>66-69</sup> Skin-flap

GD-patients reported minimal depression, due to decreased sexual satisfaction.<sup>70</sup> More in general, anatomical satisfaction and sensation increased, whereas genital pain correlated to decreased QoL-scores.

## Comment

### Principal finding Gender Dysphoria patients

Penile-inversion- and Penoscrotal-surgery received far more attention than Intestinal- or Combined-interventions, which causes a bias. Penoscrotal-vaginoplasty is considered the best SRS-option, but reported high complaint- and revision-rates, overall dissatisfaction and low sexual activity. Neovagina depth and anatomical satisfaction were correlated for MtF-patients.

### Principal findings MRKHS patients

MRKH-articles were few and diverse, likely due to non-surgical alternatives. Davydov-surgery is the longest and most performed MRKH-surgery, with high sexual activity and high aesthetic-, anatomical- and sexual function-satisfaction. Surgery dissatisfaction was low, but much dyspareunia, excessive discharge, ‘unsuccessful’ lengths and some granulation and neovagina obliteration were seen. MRKH QoL-assessments were mostly lacking.

## Discussion

### Main findings

A high intercontinental diversity of patient-population and techniques was observed. No European or North-American MRKH-surgeries were performed, likely due to pre-adolescent surgeries.<sup>71</sup> In Asia tradition and religion gravely impact abstinence and inhibition of pre-marital sex and willingness to discuss these topics. SRS-surgeries were longer than most MRKH-surgeries, as complete female genitalia apposed to 1/3 of the vagina were recreated.

A single-centre Peritoneal-vaginoplasty and combined-SRS comparison, indicated a higher complexity of SRS. SRS mainly caused hemorrhage of vascularized tissue (i.e. corpus spongiosum),<sup>31</sup> whereas MRKH-patients predominantly showed intercourse-related bleeding.<sup>70</sup> Bleeding-dependence on surgical experience has been suggested.

Gastrointestinal complications were reported after penile-inversion-, penoscrotal- and Davydov-vaginoplasty, but perineal dissection and less invasive surgery make intra-operative observation of fistula hard. Dependence on surgical experience is suggested and pre-operative bowel-preparation is important.<sup>72</sup>

Most SRS-techniques and intestinal-vaginoplasty in MRKHS-patients reported prolapse. Prolapse affects 50% of parous women<sup>73</sup> and vaginoplasty patients mostly [?]50 years. Pelvic floor differ across gender,<sup>74</sup> so long-term hormonal treatment might affect prolapse.<sup>73</sup> Our transgender treatment centre occasionally treats transwomen for long-term prolapse (10-20 post-operative years),<sup>75</sup> which is believed to increase over time.<sup>58,76</sup>

Tissue necrosis (likely due to tissue tension) was reported after penile-inversion-, penoscrotal- and McIndoe-vaginoplasty. Avoiding corpus spongiosum resection minimized necrosis,<sup>72</sup> that significantly hampered functional- and overall satisfaction.<sup>77</sup>

Stenosis was the most common complication and reported for most techniques. It hampered QoL through sexual dysfunction and dissatisfaction, often lead to revisions and decreased with surgical experience and



graft quantity in transwomen. Higher SRS-reported stenosis might relate to inherent scrotal skin properties, causing narrowing by retraction and relocation after shortening or by incomplete corpus spongiosum resection.

Revisions were reported for all SRS- and none MRKH-techniques. Mixed patient-cohort showed higher MRKH-patient satisfaction, likely by population-specific expectations and surgical complexity due to anatomical dissimilarity. MRKH-patients were completely satisfied with anatomy, even for ‘unsuccessful’ lengths. SRS-patients were only anatomically satisfied after Penoscrotal-surgery (with ‘successful lengths’ [?] 11 cm). Revisions were inverse proportional to graft size (through stenosis, retraction and necrosis).

McIndoe-, peritoneal- and intestinal-surgery for MRKH- and GD-patients reported vaginal discharge. Only penile-inversion- and penoscrotal-SRS reported genital pain, which hampered post-operative QoL-improvement. SRS reported urinary issues due to small prostates and pelvic floor dysfunction, that hampered overall satisfaction.

Penile-inversion- and Penoscrotal-techniques reported 1-4% patient regret. Regret is often used as argument by transgender-care opponents but strict WPATH-regulations should prevent this and likely explain why regret was only studied for GD-patients. Regret was sporadic or because of surgery-unrelated reasons.

Sexual activity was lowest for GD-patients, with 21-100% amongst MRKH-patients. McIndoe-surgery reported highest inactivity for a married-cohort, so a false negative could be present as adults undergo vaginoplasty to initiate sexual activity independent of marital status.

## Strength and limitations

This is the first systematic review on nine vaginoplasty techniques with MRKH- and GD-patients and assessing a wide diversity of complications, satisfaction and function. The methodological quality, in line with PRISMA-guidelines, formed a strength. Diverse assessment scales for sexual function and coitus-centred, sexual activity assessment and uncorrected cohort variation, need to be considered for result reliability. These discrepancies invalidate quantitative comparison and emphasize need for standardized validation tools. More criticism was reported amongst GD-patients especially on aesthetics and penetration depth, where perhaps fertility restoration is more important for MRKH-patients. Most comprised studies had medium risk of bias and lacked control groups, blinding of assessors and cofounder assessment. Lastly, high cohort size diversity, technique article quantity, (loss at) follow-up, recruitment and outcome assessment, are points of consideration.

## Interpretation

It is impossible to identify one ideal vaginoplasty technique, due to lacking high-quality evidence and study heterogeneity. Tissue engineering alternatives were not included and could bring unexpected success, that should be further clarified in future research.

## Conclusions

Vaginoplasty developments are rapidly evolving. However, MRKHS-patients and transwomen have to face incomprehension, ignorance and internal challenges daily. Vaginoplasty forms a relatively safe and acceptable solution that improves their QoL and self-image. This meta-analysis showed weaknesses and strength of technique specific (patient-reported) outcomes, by inconsistencies, information gaps, lack of standardization and of comparative research with similar cohorts for well-informed decision-making. No ideal vaginoplasty method can be identified and a technique is still selected based on an expertise-based rather than an evidence-based decision. This, together with exploration of tissue-engineering, is critical for future surgical advancements. We sincerely hope that this review provides an overview of today's options for well-educated decision, and formed a starting point for further background reading.

Supplementary data are available at *BJOG* online.

## Contribution to authorship

J.S.: conceptualization, methodology, formal analysis, investigation, data curation, writing – original draft and visualization. F.G.: data analysis, validation, writing – review & editing and supervision. M.B.B.: Writing – review & editing. J.P.R.: Writing – review & editing. R.d.V.: Investigation and data curation. T.S.: conceptualization, supervision and writing – review & editing. J.H.: conceptualization, supervision and writing – review & editing.

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## Disclosure of interest

None.

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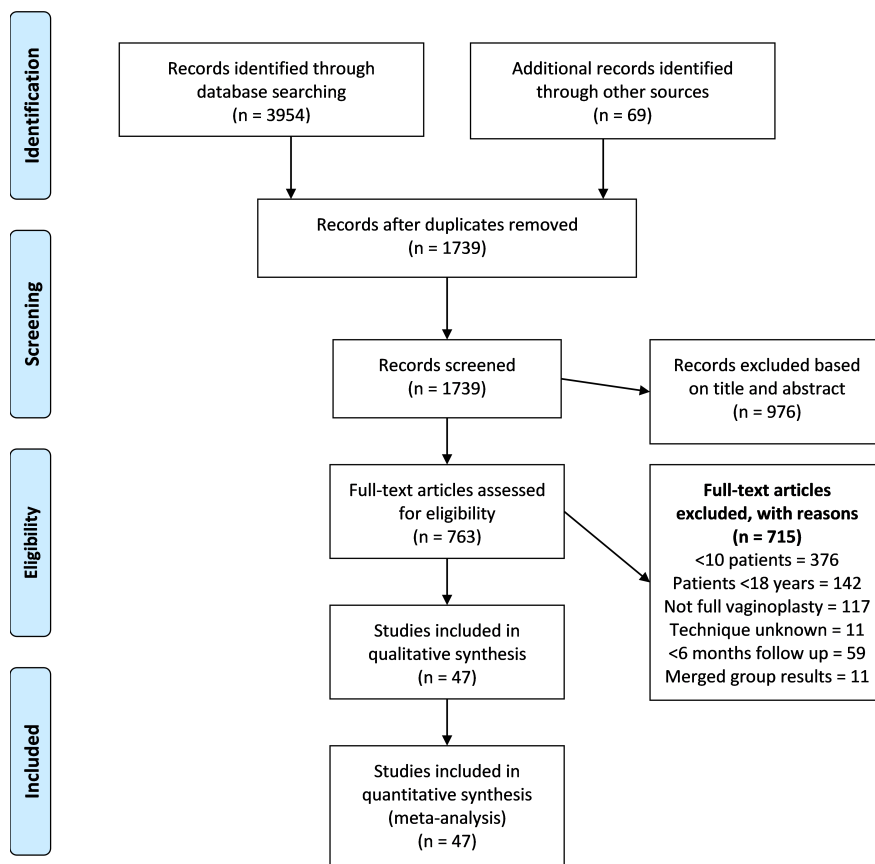
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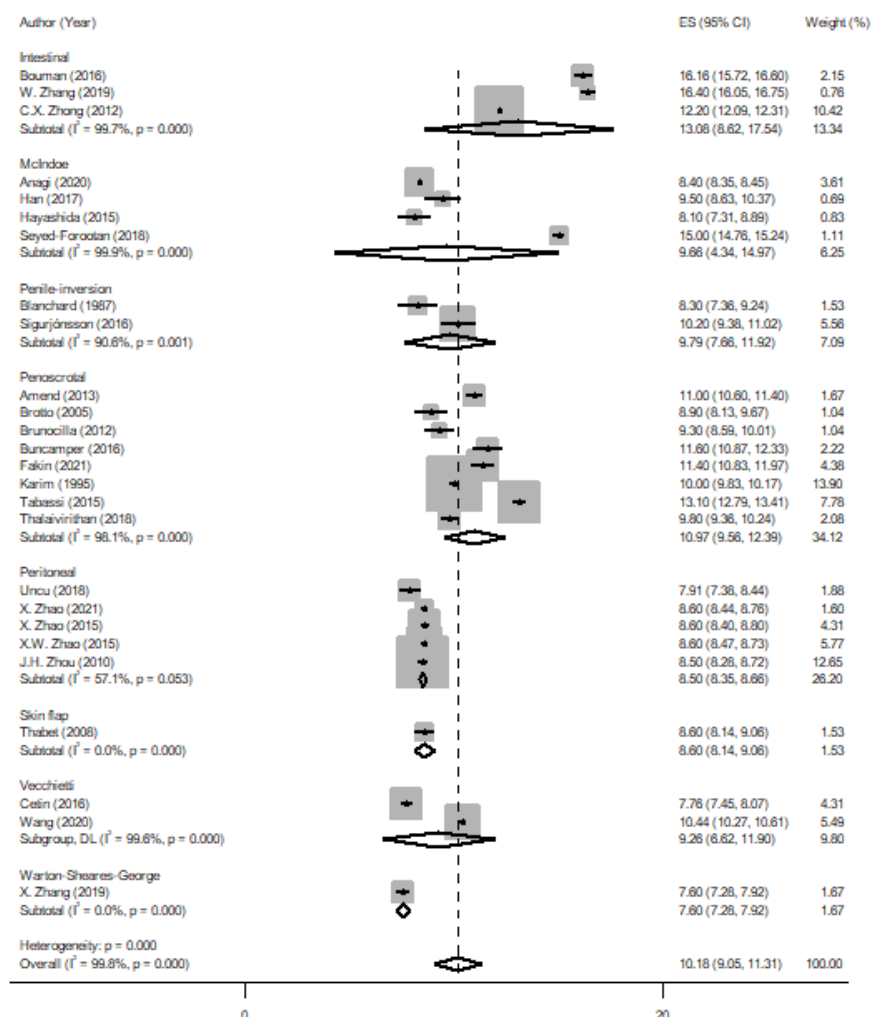
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# Anatomical depth (cm)



## Hosted file

Table i - Complications and outcomes.docx available at <https://authorea.com/users/497321/articles/578394-surgical-vaginoplasty-treatment-for-gender-dysphoria-and-mayer-rokitansky-k%C3%BCster-hauser-syndrome-a-systematic-review-and-meta-analysis>

## Hosted file

Table ii - Patient QoL assessment.docx available at <https://authorea.com/users/497321/articles/578394-surgical-vaginoplasty-treatment-for-gender-dysphoria-and-mayer-rokitansky-k%C3%BCster-hauser-syndrome-a-systematic-review-and-meta-analysis>