Dilation and Surgical Management in Vaginal Agenesis: A Systematic Review

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Abstract

INTRODUCTION: The management of vaginal agenesis currently is determined by geographical location and surgeon preference. The optimal treatment is unknown and the majority of articles on technique and outcome focus on personal case series with little standardization of reporting and follow up.

METHODS: 6691 articles concerning the management of vaginal agenesis were systematically reviewed, with 162 fitting the inclusion criteria.

RESULTS: Only 1 randomized control trial was included with the remaining articles made up of case series or case reports. The bowel vaginoplasty method was most commonly reported historically with 945 patients and 45 articles included. The Vecchietti procedure had the shortest operative time but the most number of urological injuries (2.1%). The split thickness procedure had the highest infection rate (4.2%) and re-operative rate (7.84%).

CONCLUSION: Overall, the conservative method using dilation had the least number of complications, with an average vaginal length of 6.65 cm (+/- 1.39cm). However, with an operative procedure full consent and understanding of the need for postoperative dilation with the majority of techniques is imperative.

Keywords: management, vaginal agenesis

Brief Summary: A systematic review of the management of vaginal agenesis in MRKH and AIS to determine the optimal outcome.

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Introduction

Vaginal agenesis can occur in a number of different settings. It can be a congenital condition where it may be an isolated anomaly, or as part of a specific disorder of sexual development (DSD) such as in androgen insensitivity syndrome (AIS), or it may occur in association with a number of other anomalies. An absent or small vagina may also occur secondary to radiotherapy or surgery. Vaginal agenesis resulting from either Mayer-Rokitansky-Kuster-Hauser Syndrome (MRKH) or AIS affects between 1 in 4000 and 1 in 13000 girls respectively, worldwide(1). There is considerable confusion caused by inaccurate or differing uses of a number of expressions relating to an absent or small vagina (Table 1). Absent vagina refers to vaginal agenesis and AIS for the purpose of this paper and is generally diagnosed in adolescents presenting with primary amenorrhea or more rarely primary infertility. But even in these 2 diagnoses, some vagina may be present, and this may vary from no vagina and no hymen (in some women with vaginal agenesis), to 3 -5 cm length of vagina as is usually the case in AIS.

Currently, there are many methods described in the literature for creating a functional neovagina. However, the best method has yet to be determined using a rigorous randomized control trial. The majority of articles published review outcomes of personal case series with no standardized assessment of indications, initial vaginal length, intraoperative or postoperative complications, or outcome measures both from a functional and anatomic perspective. Without standardized approaches to outcomes and follow up the comparison of methods of vaginoplasty is difficult.

Historically, surgical creation of a neovagina was described as early as 460-377BC by Hippocrates(2). However, it wasn't until 1898 when Abbe described the use of a mold

following the opening of the perineum by a medical practitioner in 2 women to maintain a vaginal opening for intercourse(3). Over the course of the first half of the 20th century both surgical and non-surgical methods of neovagina creation were described (Baldwin (bowel segment)(4), Frank's dilation(5), McIndoe's modification of Abbe's split thickness graft(6)). Towards the middle of the 20th century modifications of traditional methods such as Sheares modification of the McIndoe procedure (7), Creatsas modification of William's vaginoplasty(8) and new methods (Vecchietti(9), and the plastic surgery flaps were introduced) were described (Table 2). Additionally, case series of vaginoplasty also included summaries of complications and an attempt to qualify functional outcome. The end of the 1980s marked a change in surgical practice with the introduction of laparoscopic assisted procedures, which decreased the morbidity the patient experienced from surgery, and the length of inpatient stay. Finally in 2012, the first attempt at a prospective randomized control trial was published by Cao *et al.* comparing the outcomes of laparoscopic peritoneal (traditionally the Davydov method) and laparoscopic sigmoid vaginoplasty for 40 patients(10).

The purpose of this review is to summarize objectively all available evidence regarding techniques of vaginoplasty in women with vaginal agenesis or AIS, including intraoperative and postoperative (both short and long term) complications and outcomes of surgical and nonsurgical techniques from the last 20 years in an attempt to guide clinical practice. Currently, the type of neo-vaginal creation is dictated not by rigorous evidence but solely by surgeon experience and preference and thus where in the geographical world the patient is residing. Other conditions where there is an absent vagina in the context of

multiple other anomalies (such as a cloacal anomaly) or an atretic vagina (secondary to surgery or radiotherapy) require special consideration of the additional problems, which make any attempt at comparison between operative techniques even more difficult. Conditions where there is a uterus present also require very careful consideration regarding the possibility of allowing a fertility potential – and in many parts of the world this option will then influence the management of the absent vagina (and/or cervix)(11).

Methods:

A search of all published literature restricted to the management of vaginal agenesis in patients with Mayer-Rokitansky-Kuster-Hauser Syndrome (MRKH) or Androgen Insensitivity Syndrome (AIS) since 1898 was conducted using pubmed, medline (on a weekly basis), ovid as well as hand searches for relevant articles not initially identified using the search parameters. Results were then restricted to systematic reviews, randomized control trials, controlled clinical trials, observational studies and case series (of 5 or more cases) since 1992. Non-English articles, case reports of operative description, repeat vaginoplasty after failed primary procedure, double reporting of results and where there were associated urogenital (including lower urinary or anorectal) anomalies were all excluded. However, case reports of rare complications were reviewed for possible inclusion. All potential studies identified were assessed for inclusion and any disagreement between the reviewing authors was resolved through discussion. The two review authors then independently assessed the included articles looking for the following extracted data: patient population, intraoperative complications (i.e. injury to bowel or bladder, hemorrhage requiring transfusion, conversion to an open procedure if a laparoscopic

procedure), operative time, objective length and width of neo-vagina and short and long term postoperative complications (i.e. short term: length of stay, infection, hematoma, anastomotic leak, versus long term: failure, prolapse, cancer, colitis, stenosis, scarring, vaginal discharge, venous thrombo-embolic event, death). Results of sexual function and satisfaction will be included in another published review article (to be submitted to the International Journal of Urogynecology and pelvic floor reconstruction with the title Systematic Review of Sexual Satisfaction following the Management of Vaginal Agenesis).

For included studies we have assessed results reported including the possibility of inherent author biases and patient attrition. Given the potential of variation in results reported, we attempted to dichotomize data for analysis. Data were then synthesized and analysis was carried out using statistical software.

Results:

A total of 6691 articles were identified using the key search words “vaginal agenesis”, “Müllerian agenesis” plus “management” up to July 2013. A total of 162 articles were identified and reviewed (Figure 1). The studies included were carried out in a number of countries including Australia, China, Italy, Great Britain, Canada, USA and Brazil. In the majority of the studies, no information was provided on the indication for the particular treatment offered, there was no blinding of either the patients or the clinicians with only one study having randomized care. The majority of studies were observational case series with no standardization of objective outcomes and need for ensuring adequate long term follow. There was evidence of papers containing a certain amount of author bias due to triage practices within the country where patients are referred directly for surgical

correction to tertiary centers such as in Poland, Italy and Germany(12). Additionally, for these same centers, many women may not ever be referred as they have already been successful in neo-vaginal creation using dilation or intercourse, and there is no way of accounting for these patients and measuring their outcomes.

Overall, 162 articles were included accounting for 4326 patients (3 articles were included in 2 different vaginoplasty methods because of an attempt to compare techniques (10, 13)). The vaginoplasty method using the bowel was the most published with 45 different peer reviewed articles with a total of 945 patients(10, 13-58). The full thickness flap method (including muscle flaps, rotational flaps and bladder tissue) was the least researched in the English language literature with only 168 patients fulfilling the inclusion criteria (59-70).

Intraoperative Experience:

Overall, the shortest operative time utilizes the Vecchietti Procedure (19 papers, 934 patients) with an average time of 44.45 minutes (+/- 17.7 minutes) (71-90) versus the average time of 181.2 minutes (+/- 59.8 minutes) with bowel vaginal reconstruction (including both laparoscopic and open approaches). For the split thickness graft methods (including McIndoe technique (of skin), buccal mucosa, oxidative cellulose and amnion) operative time varied greatly between 15 to 20 minutes and 245 minutes (91)((92-127).

Postoperative Length of Stay:

The length of postoperative stay has significantly reduced since the introduction of a laparoscopic approach, decreasing to a mean of two days compared to the 8 or 9 days in the past with the Vecchietti, peritoneal and bowel methods. Both graft techniques (full and split thickness) required the longest length of stays with an average of 14 days.

Complications were split into 3 time frames for simplicity: intraoperative, immediate and long-term postoperative complications (Figure 2). Only 2 deaths were reported and occurred with the bowel and split thickness vaginoplasty methods. Prior to the advent of routine prophylactic antibiotic use, many more deaths had occurred in the bowel vaginoplasty group.

Intraoperative Complications:

Intraoperative complications were obviously non-existent in the conservative (dilation) approach, though one mention of neo-vaginal vault rupture was reported during vaginal lengthening using coitus (128). Urological injuries, including injury to bladder or ureters or postoperative urinary retention, (2.1%) occurred most commonly using the Vecchietti approach whereas bowel injuries occurred more commonly with peritoneal approach (2.6%)(83, 129-141). Bleeding was associated more often with the bowel approach with 19 transfusions reported, an overall higher estimated blood loss (EBL) of around 302.5ml and 9 postoperative hematomas were also described.

The remaining complications focus on the postoperative period. Postoperative ileus (1.1%, n=10/945) and anastomotic leak (n=3/945) occurred more frequently following bowel vaginoplasty but was followed closely by the split thickness method of repair. Given that the success of the split thickness procedure is dependent upon graft integration it is worth noting that it has the highest infection rate (n=29/688) at 4.2%, which is not statistically significant compared with the other methods of vaginal creation using ANOVA analysis. The split thickness method had the most number of reoperations (7.84%, n=54), although this was not statistically significantly different. The re-operative rate included scar revisions (from harvesting of the graft site), graft failure and dehiscence, which

required surgery to either repair the initial graft or placement of a brand newly harvested graft.

With respect to long-term outcomes, the vaginal length achieved with surgery is longest using the bowel method (with a weighted average of 12.87cm). We did not calculate statistical significance between the different surgical techniques due to the heterogeneity not only between the surgical techniques but also between the surgical and conservative methods in terms of starting vaginal length (which ranged from flush with the perineum to more than 3 cm in 43/200 patients(8, 101, 142-151) to omission of information in the majority of papers). Additionally, there was heterogeneity in terms of attempts at using dilation prior to surgery and the duration of postoperative follow-up, which ranged from 4 weeks up to 50 years(152). Dilation resulted in the shortest average vaginal length of 6.65cm (13, 101, 122, 128, 133, 153-173). All vaginas were at least 2 finger-breadths wide.

Urinary incontinence (not defined) occurred primarily with graft vaginoplasty, however, the data was slightly skewed by the inclusion of 1 article by Borkowski *et al.* in 2008 which included 37 patients with bladder flaps for vaginoplasty where 19 described symptomatic urinary incontinence postoperatively(62).

Less frequent long-term complications included vaginal hair growth, vaginal prolapse, condylomata and vaginal carcinomas (both squamous cell and adenocarcinoma). Vaginal hair growth only occurs with techniques, which mobilized the vulvar hair-bearing areas into the vagina (i.e. Creatsas (3/200) or full thickness flaps using the pudendal area (n=19/168)). Neo-vaginal prolapse was reported to occur with all techniques except for the Vecchietti, Davydov and Creatsas's modification of William's vaginoplasty methods.

When prolapse occurred using bowel vaginoplasty, both mucosal and entire neo-vaginal prolapse were described. Several different methods have been described to repair neo-vaginal prolapse but this is beyond the scope of this article. The carcinomas (n=23) described included both squamous cell and adenocarcinoma, with adenocarcinoma only occurring when bowel mucosa was transpositioned for creation of a neovagina(148). Carcinoma occurred most commonly using the split thickness method, however that may be because the split thickness method has the longest reported follow up (up to 50 years). Individually, condylomata and vaginal cancer have been reported in the neo-vaginal literature. Looking specifically at that relationship, a review of 33 women following neo-vaginal creation primarily using Vecchietti's method (and the bowel method) were referred for evaluation of human papilloma virus (HPV) lesions; 27 tested positive for the low-risk HPV, 6 for high-risk HPV, 3 had vaginal intra-epithelial neoplasm (174) grade 1, 2 grade 2 VAIN and 1 adenocarcinoma was diagnosed(175). Of these lesions, 17 were located on the vulva and 16 within the neo-vagina. All the vulvar lesions and 10 of the 16 neo-vaginal lesions were condylomata. These findings suggest that papanicolaou testing guidelines that are set out by individual regulatory bodies throughout the world should apply to sexual active women with neo-vaginas as well, keeping in mind that the majority of low risk HPV subtype will spontaneously resolve (176) and that the interpretation of results may be difficult due to the altered tissue. Only 3 case report of vaginal colitis in the literature on vaginal agenesis(177) could be found and is much more commonly reported in the setting of bowel vaginoplasty as a long term complication in the congenital adrenal hyperplasia (CAH) and cloacal repair vaginoplasty literature(178) (Table 2).

Discussion:

This review was initially planned as a systematic review to determine the optimal management of isolated vaginal agenesis due to MRKH or AIS. However, unfortunately, the literature available was non-standardized and heterogenous with differing amounts of details available regarding patient characteristics, follow up and complications discussed. Because of the diverse range of details available with mixed information and follow-up, the use of the recommended methodology from the Preferred Reporting Items from Systematic reviews and Meta-Analyses (PRISMA) checklist for meta-analyses was unfortunately not possible(179).

The only RCT regarding vaginoplasty compared the use of bowel versus a laparoscopic peritoneal approach with a significant smaller intraoperative blood loss (65 versus 200ml), shorter operative time (100.4 versus 217.8 minutes) and decreased duration of inpatient stay (6 versus 10.5 days) with the laparoscopic peritoneal approach. Postoperatively, the mean vaginal length was not statistically significantly different between the 2 groups, however, abdominal discomfort and foul vaginal secretions during intercourse were increased in the bowel vaginoplasty group.

Never the less, given the current choice of correction of vaginal agenesis differs depending on where in the world the patient is geographically located, it was important to examine the currently available literature to determine the pros and cons of the individual methods and recommend an initial course of action for correction of vaginal agenesis so that the patient's informed consent for vaginal creation is as accurate as possible in respect to possible options and complications.

The American Congress of Obstetricians and Gynecologists in 2013 recommends that vaginal dilation be recommended as first line for correction of vagina agenesis. The articles focusing on dilation have high successes rates ranging between 43-94.5%(172), with a success rate of 94.5% being reported in the largest cohort group (159). Never the less, there are only 28 papers and 802 patients in the English literature with reasonable methodology. It is worth noting that dilation is the preferred technique in the UK, Australia, USA and parts of Russia suggesting that it is a widely used technique that should have more follow-up data relating to it. As well, Routh *et al.* reviewed the cost of dilation versus vaginoplasty and found that even with dilation failures requiring surgery in the future, dilation was overall more cost effective by \$US 17,724 (180) with only one article publishing their exact estimated average costs of \$US 2,397 for length of stay and use of tissue-engineered biomaterial for the graft (127). Although many surgical techniques imply that they are used for failed dilatation, the criteria for failure are not defined, neither in terms of length of time trialing dilatation, timing of commencement of dilatation in terms of patient maturity nor support given for dilatation. Furthermore, the time required for successful creation of a vagina through dilation ranges considerably between 2 months to 11 months(159) with the average in most articles around 5 to 6 months. Another issue pertains to vaginal agenesis in an adolescent who may not be emotionally ready to commit to daily dilation, does she constitute a failure if a vagina is not created through dilation at her 6-month follow-up? These same papers describing surgical techniques often state the negative aspect of dilatation and the reason for the failure of this approach, as the need to use the dilator daily. Yet they fail to acknowledge that dilation or the use of a post operative vaginal mold is required for their surgical technique often for at least 3 months in

the postoperative period. Others routinely use surgical techniques as first line approach. In Creatsas' series of 200 women, surgical vaginoplasty is offered at the first visit if the patient is interested in sexual activity and dilation is only offered if the vaginal dimple is more than 2.5cm(144). In contrast, in Jasonni's retrospective review, a vagina of 3 to 5 cm was considered a failure of dilation and patients were offered William's vaginoplasty(101). It is worth noting that in some areas of the world patients with absent vagina present with primary infertility and are only then discovered to have uterine agenesis (and not vaginal agenesis as they have already created their vagina through intercourse). As these women have been sexually active, it is difficult to know how much vagina had been present before intercourse began (personal communication between Dr. Y. Sharma and Dr. S. Grover). An article from Norway describes repeated coitus as a method for vagina creation(181). Again re-iterating, the majority of the surgical technique papers mention the need for postoperative dilation or use of a vaginal mold (except in the case of Creatsas's modification of William's vaginoplasty and the bowel vaginoplasty). This can be required from 6 to 8 hours a day with the peritoneal technique(83) and up to 24 hours a day for up to 3 to 6 months followed by nightly insertion with the split-thickness technique(102) or daily dilation (sometimes upwards of 3 times per day) and then on a regular ongoing basis or until regular sexual activity commences. The question to pose is, if patients were non compliant with dilation for neo-vagina creation, that is, they had failed the dilation technique, how can surgeons ensure compliance postoperatively, especially considering that failure of the split thickness technique is directly attributed to non compliance with mold insertion. Furthermore, McVearry *et al.* describe faster time to intercourse (around 6

weeks) with a combination of dilation and physiotherapy support giving more credit to the success of dilation with a multidisciplinary support team(182).

The majority of the articles fail to mention the issue of timing of surgery if undertaken, in terms of ensuring adequate maturity of the individual to undertake the very important follow-up care. The clinicians undertaking the Vecchietti in Germany do use a screening technique with psychological assessment prior to undertaking surgery although do not inform the reader of the rate of delay/deferring surgery due to lack of psychological readiness(74).

The endpoint in terms of the type of skin lining the vagina is mentioned in the literature though the importance of this finding in terms of outcome is not completely understood. Vaginal mucosa-like lining of the neo-vagina is achieved by using peritoneal lining, traction, dilation, and various graft-like methods. Although the technique of achieving this is different for both Vecchietti and dilation, the process is the same for creation of a space (one by traction, the other by pressure). Davydov is not dissimilar, although lined by peritoneum (which is very similar to the use of an amnion graft), which converts to vaginal mucosa as seen through biopsies of the neo-vagina by Fedele *et al.* showing iodine positive vaginal epithelium(83). In contrast, the use of bowel results in an intestinal-like mucosa, which universally produces a significant amount of discharge in the first three to six months. Of the grouped patients having bowel vaginoplasty in our analysis 7.5% (n=70) describe prolonged or bothersome (foul smell, having to wear a pad daily, daily douching) vaginal discharge, which was listed as a long-term complication potentially interfering with surgical satisfaction in some cases. Some proponents of bowel vaginoplasty report decreased problems with lubrication during intercourse with the

bowel technique and that this discharge initially is not an issue. Here we must wait for the other promised review by the authors.

Secondly, many of the surgical advocates comment on the inadequate vaginal length through the use of dilation, however, the average length in this review of vaginal dilation was 6.65cm, with the largest cohort by Edmonds *et al.* quoting 232 of 245 patients with lengths over 6 cm. The literature would suggest that 6.6 cm is ideally the length of vagina necessary for satisfactory sexual activity, which poses the question regarding what should be the final goal of vaginal length(183)? Furthermore, is measuring a vaginal length a valid outcome measure or should it be satisfactory sexual intercourse without pain? Finally, sexual partners can change throughout life meaning that the initial vagina created may be just right at the time of creation but may need to be smaller or larger later on. Thus with a surgical technique this is difficult to alter and fraught with risks, whereas coitus or dilation allows for patient controlled creation.

With regard to the risk of prolapse of the bowel segment neovaginas, Lenaghan *et al.* reported a very high rate of prolapse at 10% following sigmoid vaginoplasty (with 6 mucosal prolapses in 60 patients (only one MRKH, the remaining with gender dysphoria)(38), whereas O'Connor *et al.* failed to describe any prolapse in their series of 10 cases(46). Prolapse of vaginal mucosa has also been reported to occur following the dilation technique. No reports of prolapse have been reported following the Vecchietti or peritoneal (Davydov) methods– either due to lack of reports, the relatively short postoperative follow up interval or possibly because the traction thread tracts offer some scarring and thus support.

The problem with many of the long-term complications is that the articles published are only starting to look at these complications more remote from surgery. Thus the next 25 years of literature will give us better ability to counsel patients regarding the potential long term complication of surgery. As well, only since 1992 has laparoscopy started to be used for neo-vaginal creation and is now starting to become the standard of care in MRKH and AIS patients where operative approaches are being used. The major complication rates (i.e. death and venous thromboembolic events) anecdotally have decreased since laparotomy has been phased out or only reserved for very difficult procedures or intraoperative complications.

The limitations of this review include differences in technical terms used to describe surgical techniques making grouping of methods challenging, the split thickness method has changed substantially since Abbe's first description in 1898(3), and finally complications and follow up are not uniformly described.

In terms of concluding the best method of neovaginal creation, this review has failed. However, the review does provide an overall summary of surgical complications and highlights the need for long-term follow up of these patients. It also highlights what would be the most valuable now would be more formal randomized control trials (RCT) or given the difficulty with the practicality of such an undertaking a more standardized approach to patient evaluation and decision to undertake a surgical procedure, accurate description of operative procedure (which with the advent of laparoscopy allows for easy dissemination of video recording of procedures), and thorough long-term follow up utilizing similar assessment tools.

As the only RCT between bowel vaginoplasty and peritoneal approaches, suggests fewer problems with the peritoneal approach combined with the fact that it does seem that undertaking significant bowel surgery when a less invasive procedure offers similar outcomes, that the less invasive approach should be used. Furthermore, consideration of enhanced support for the dilation technique may improve success negating the need for surgery only to very rare instances

The review further reiterates, that while awaiting guidance of the optimal approach, the need for conservative approaches for the initial management, with dilation being considered the first line option. Surgical procedures should be utilized for failure or refusal to dilate with full understanding of the need for long-term dilation or use of a vaginal mold postoperatively similar to the length of time required initially for vaginal creation. The review also highlights the need for more standardized reporting of indications for surgery, complications of surgery and long-term follow-up. Ultimately the decision to proceed with neo-vagina creation rests upon both the young affected and her treating (surgical) team.

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Legend of Figures:

Figure 1: Literature Review of Management of Vaginal Agenesis

Table 1: Standardization of Nomenclature in Vagina Agenesis

Table 2: Definition of Vaginoplasty Techniques

Table 3: Summary of Short and Long-Term Outcomes of Management of Vaginal Agenesis

Figure 1: Literature Review of Management of Vaginal Agenesis

1 Table 1: Standardization of Nomenclature in Vagina Agenesis

Nomenclature	Definition	Commentary
<p>Vaginal agenesis/vaginal aplasia</p> <p>Agenesis or aplasia = Non formation of a part</p>	<p>Congenital absence – although this can still include the presence of the lower 1/3 of the vagina which is thought to develop from caudal growth of the vaginal plate. The distal most portion of the sinovaginal bulb forms the hymenal tissue and some vaginal agenesis patients may have a hymen(184).</p>	<p>Authors using this expression often do not report the size of the original vagina. The minimal/maximal length that a surgical approach would or would not be used is usually not defined</p>
<p>MRKH (Mayer-Rokitansky-Kuster-Hauser Syndrome)</p>	<p>Described independently by these clinicians in 1829(185), 1838(186), 1910 and 1961 with all 4 descriptions referring to congenital absence of the vagina and an absent or rudimentary uterus and associated renal/skeletal anomalies (Kuster)(187) due to arrest of Mullerian duct development.</p>	<p>Specifically refers to vagina agenesis with or without associated abnormalities. Hauser differentiated AIS from MRKH(188).</p>
<p>Vaginal hypoplasia</p>	<p>Hypoplasia from the greek <i>plasis/plassein to mold/form</i> meaning under</p>	<p>Some vaginal agenesis do have some vagina so it would be best to avoid</p>

	formation of an organ or tissue.	this expression. Most women with AIS have 3-5 cm of vagina.
Vaginal atresia	From the Merriam-Webster dictionary meaning “absence or closure of a normal body part”(189).	Best used when referring to vaginal obliteration secondary to trauma, radiation or previous surgery.

2 Table 2: Definition of Vaginoplasty Techniques

Techniques	Definition	Other Nomenclature used
Dilation	Intermittent manual pressure on the perineum to gradually create a vaginal canal	Frank's method, Ingram's Bicycle, D'Alborton (coitus) (190)
Vecchietti's	Upward surgical traction along the perineum with the use of an object	Modifications of Vecchietti's Technique (i.e. change of the original olive, including but not exclusive foley catheter ball)
Davydov's	Surgical inlay of peritoneum to line the vagina	
Sheare's Modification of William's Vaginoplasty	Blunt dissection to create a vulvovaginal pouch	Creatsas' Method, Wharton (191)
Full Thickness Flap	Rotation or Insertion of a harvested flap into a dissected vaginal opening	Singapore, Malaga (192), Labia
Split Thickness Flap	Insertion of a harvested split thickness flap into a dissected vaginal opening	Abbe-McIndoe, Oxidative Cellulose, Tissue-Engineered Biomaterial Graft, buccal mucosa, amniotic membrane
Bowel	Harvest of bowel mucosa for transplantation into a created vaginal	Jejunem, ileum, cecum, sigmoid

3

	opening	
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4 Table 3: Summary of Short and Long-Term Outcomes of Management of Vaginal Agenesis

Analysis	Dilation	Vecchietti (including both open and laparoscopy)* ¹	Davydov (including both open and laparoscopy)	Sheares	Full Thickness flap	Split thickness flap	Bowel Vaginoplasty (including both open and laparoscopy)
Total number of patients	802	934	500	289	168	688	945
Death						1	1
Venous Thrombo Embolic Event			1			3	1
Intraoperative Complications							
Bowel Injury		4	13			3	3
Urogenital Injury		20	10			7	3
Transfusion		2			1	7	19
Postoperative Complications							
Infection (including urinary tract)		24	9	1	3	29	22
Hematoma		5	1			6	9
Ileus/Bowel Obstruction							10
Abscess			1			2	5

Anastomotic leak						1	3
Dehiscence	1 (vault laceration)	3	1*2	10	2		
Necrosis	1	2		1	5	1	4
Need for rehospitalization/ Sugery		6	6	9	10	54	51
Problems with the graft					3	35	3
Fistula	1	3	3		4	11	2
LongTerm Complications							
Length (in cm)*3	6.65	7.87	8.86	11.49	8.93	8.84	12.87
Incontinence		1	1		20*4	15	3
Unacceptable Scarring		5 (Laparotomy)			7	55	11
Failure	123 (+ 12 refused)						
Spotting	2	1 (+ 3 hematuria)	2	3		14	24
Vaginal Discharge		1	3			9	56

Granulation Tissue		5	36	1		60	
Vaginal Hair Growth				3	21		
Condyloma				46		9	
Prolapse	9				1	6* ⁵	33* ⁶
Colitis							3

5 *1 18 Device difficulties, 1 gastric ulcer complication, 1 paralysis from laparoscopic positioning

6 *2 Intraabdominal mold migration

7 *3 All lengths weighted average including articles mentioning length with all width over 2 finger breaths when width reported
8 in cm-centimeters

9 *4 Majority of incontinence (19/20 cases) with Full Thickness Flap vaginoplasty from Borkowski *et al.* (61)

10 *5 Including 2 rectal prolapse

11 *6 Mucosal prolapse in 22 cases