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CLINICAL ARTICLE

Gynecology

Treatment for vaginal agenesis: A prospective and comparative study between vaginal dilation and surgical neovaginoplasty

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Abstract

Objective: To compare, in terms of anatomical, functional, and sexual aspects, two types of treatment for women with vaginal agenesis: progressive dilation or surgical neovaginoplasty.

Methods: Women with vaginal agenesis underwent either dilation treatment using the Frank method or surgical treatment using the modified Abbé-McIndoe technique with oxidized cellulose. Patients were evaluated 3–6 months after treatment for a follow-up including medical history, physical examination, general satisfaction, clinical aspect of the vagina, Female Sexual Function Index, and three-dimensional pelvic floor ultrasound.

Results: In total, 20 women with vaginal agenesis were included in the present study; nine in the dilation group and 11 in the surgical group. A comparison between the groups (vaginal dilation and surgical neovaginoplasty) showed efficacy in neovagina formation after both treatments, with a statistically significant difference between the pre- and post-treatment periods (P value pre- × post-dilation group <0.0001 and P value pre- × post-surgical group <0.0001). There were no statistical differences in total vaginal length measurements (P value post-dilation × post-surgical = 0.09) or Female Sexual Function Index scores ($P = 0.72$) after both treatments.

Conclusion: Both treatments had satisfactory efficacy and positive outcomes for patients with vaginal agenesis concerning anatomical, functional, and sexual aspects, with minimum complications in the surgical group. Dilation treatment can remain the first-line therapy.

KEYWORDS
3D ultrasound, Mayer-Rokitansky-Küster-Hauser syndrome, vaginal agenesis, vaginal dilation, vaginoplasty

1 | INTRODUCTION

Vaginal agenesis is one of the clinical manifestations of genital malformation and has been studied in recent decades to include these patients under the female population.[1] The diagnosis is associated with Mayer-Rokitansky-Kuster-Hauser syndrome in 90% of cases and represents 1:4000 female live births.[1] This syndrome is characterized by the absence of the upper two-thirds of the vagina and the uterus. Only 10% of these patients are found to have a uterus but no cervix.[1,2] The diagnosis is usually made in young women with clinical amenorrhea or dyspareunia.[2,3]

Vaginal agenesis can also be found in patients with complete androgen insensitivity syndrome, which is characterized by normal male karyotype (46,XY) and a phenotype ranging from undermasculinized genitalia, despite the presence of testicles, to the development of all female secondary characteristics.[4]

The most important steps in the effective management of vaginal agenesis are correct diagnosis of the underlying condition, evaluation for associated congenital anomalies, and psychosocial counseling in addition to treatment or intervention to address the functional effects of genital anomalies. Up to 53% of patients with Müllerian agenesis have concomitant congenital malformations, especially of the urinary tract and skeleton.[5] Mullerian, renal, cervicothoracic somite abnormalities (MURCS) is a developmental disorder that primarily affects the reproductive and urinary systems.[6]

The treatment of vaginal agenesis consists of creating a vagina that allows for satisfactory intercourse. The American College of Obstetrics and Gynecology (ACOG) recommends the conservative approach, known as dilation treatment, as the first-line therapy and that surgery should be reserved for non-responding cases.[2,3] When vaginal dilation treatment is not possible or is unsuccessful, patients can undergo surgical neovaginoplasty.[2,3]

Surgical treatment can be performed using several techniques that have been developed over recent decades, including different types of graft, namely: the Baldwin technique (intestinal segments)[7]; the Vechietti technique (vaginal traction)[8]; the Davydov technique (peritoneal graft)[9,10]; the Abbé-McIndoe technique (skin graft)[11,12]; and the modified Abbé-McIndoe technique (oxidized cellulose),[13-16] which has been performed over the years to achieve the main goal of satisfactory intercourse with minimum complications.[17,18] The objective of all treatments is to create an adequate neovagina that allows for satisfactory sexual intercourse and quality of life.[17-22]

Based on this scenario, the objective of this study was to carry out a prospective comparison between vaginal dilation and surgical treatment using the modified Abbé-McIndoe technique with oxidized cellulose as the graft for the construction of a neovagina for the treatment of vaginal agenesis. In addition, a secondary objective was to clarify the association between multiple variables, such as total vaginal length (TVL), sexual satisfaction, personal satisfaction, possible complications, ultrasonographic evaluation, and conservative or surgical treatment for vaginal agenesis.

2 | MATERIALS AND METHODS

The present study was a prospective parallel-group study based on the STROBE Statement,[23] a checklist of items that should be included in reports of cohort studies.

2.1 | Participants and setting

The present study was carried out at the Hospital São Paulo, the referral hospital of high complexity from Escola Paulista de Medicina, Federal University of São Paulo (UNIFESP), Brazil. The study protocol was approved by the Human Research Ethics Committee of UNIFESP. This protocol was not a randomized or double-blind clinical trial. The choice of patients was clear and all had opted for the treatment due to the rarity and delicacy of the pathology.

The eligibility criteria were the diagnosis of vaginal agenesis and the desire for an effective and affordable treatment. The exclusion criterion was not wanting to actively take part in the study.

In total, 20 patients with vaginal agenesis were included in the study. Eighteen patients had never been treated before; two patients were undergoing treatment for the second time. One patient underwent neovaginoplasty (the Baldwin technique, 18 months old) and another had an unsuccessful neovaginoplasty (the Abbé-McIndoe technique, 9 years earlier).

The patients were informed of the options and asked to select one of the two treatments: dilatation or surgical neovaginopasty. The patients voluntarily signed the informed consent form to participate in this project. They were then divided into two groups based on their choice: vaginal dilation group ($n = 9$) or surgical group ($n = 11$).

All patients who were included in this project underwent a medical interview (medical history, complaint, and symptoms), a physical examination, karyotyping, pelvic magnetic resonance imaging and three-dimensional pelvic floor ultrasound before treatment. All stages of the treatment were carried out by the first two authors.

The TVL was measured from the vaginal apex to the hymen every month in both groups up to 3–6 months, with an approximate average of 4 months, by the same examiner using an Ayres spatula marked in centimeters.

2.2 | Dilation treatment

All patients who chose dilation over surgery were instructed on how to perform the exercises, such as how long the treatment was valid for. They were also instructed to purchase vaginal dilators (from the website www.vaginismus.com) and to bring them to the visit before starting the exercises.

The exercises should be carried out once a day for at least 10 min for 3 months by gently inserting the dilator into the vagina and pushing it back and forth, as well as rotating it in wide circles to stretch the length and width of the vagina, respectively. The patients were instructed to use standardized force during vaginal dilation (until pain perceived). Patients attended follow-up visits every month in order to evaluate the need to use a larger dilator. The first evaluation was conducted between 3 and 6 months, with a 4-month average.

2.3 | Surgical treatment

All patients underwent spinal anesthesia and were placed in a lithotomy position (Figure 1). A transurethral catheter was inserted to empty the bladder and 40 mL of a solution containing 1:200 000 epinephrine was injected into the tissue between the bladder and the rectum.

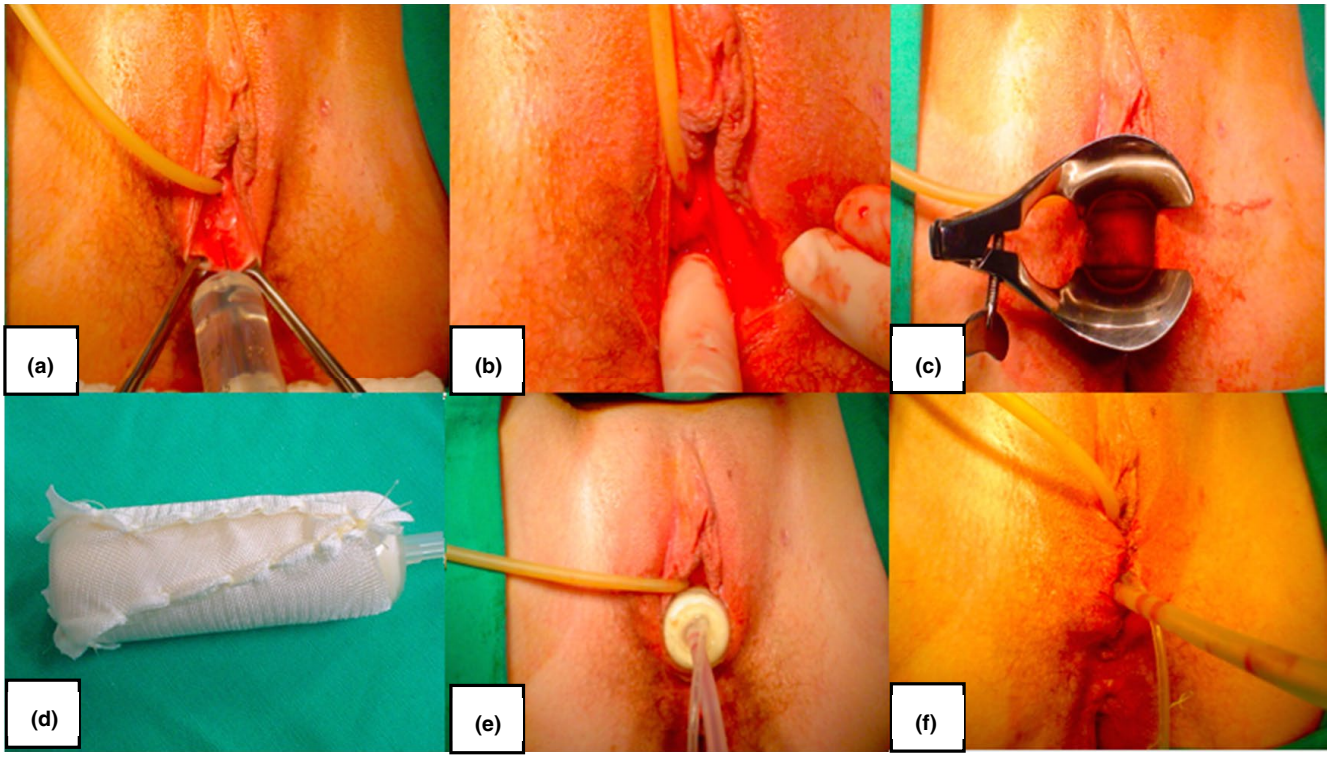

FIGURE 1 Neovaginoplasty surgery using the Abbé-McIndoe technique: (a) adrenaline infiltration; (b) blunt dissection of the rectovesical space; (c) formation of the vaginal canal visualized through a speculum; (d) silicone prosthesis coated with oxidized regenerated cellulose; (e) positioning of the prosthesis in the newly formed canal; (f) suture of labia majora

The patients underwent the modified Abbé-McIndoe technique with oxidized regenerated cellulose.[13-16] A transversal incision was made in the area of the vaginal dimple and a tunnel was bluntly created up to a vaginal length of 8–9 cm. In three cases, the puborectalis muscle had to be incised to expand the vaginal amplitude.

Following dissection, hemostasis was performed before the insertion of the prosthesis covered with oxidized regenerated cellulose. At the end of the procedure, three absorbable sutures (polyglactin) were made between the labia majora to close the vaginal introitus and to keep the prosthesis inside the neovagina. The prosthesis was removed 5 days after surgery and the neovagina was irrigated with sterile saline solution. Before hospital discharge, patients were instructed on the correct use of the prosthesis to prevent premature closing of the neovagina.

The patients were advised to use the prosthesis all day, including at night while sleeping, and to take it out only in for a bowel movement, to urinate, and to take a shower.

2.4 | Clinical follow-up

All patients in the dilation group were followed up every month from the start of treatment. The patients who had had surgery were followed up every week for 1 month and every month thereafter.

During follow-up, the newly created vaginal canal (aspect, amplitude, and length) was analyzed using a speculum and by digital vaginal examination. All patients were allowed to have sexual intercourse 2 months after surgery or when the vaginal length was greater than 5 cm.

2.5 | General satisfaction

After treatment, patients were required to answer three questions:

1. Grade the received treatment from 0 to 10.
2. Would you undergo the treatment once again? (yes or no).
3. Would you recommend the treatment to another patient? (yes or no).

2.6 | Evaluation of sexual function

Sexual function was evaluated based on the Female Sexual Function Index (FSFI) translated and validated into a Portuguese version.[24]

The questionnaire consists of 19 questions, which inform on five domains of sexual response: desire and subjective stimulation, lubrication, orgasm, satisfaction, and pain or discomfort. The final score (total score: minimum 2, maximum 36) is obtained by

adding the weighted scores for each domain and multiplying by a numerical factor. The higher the score, the better the sexual wellbeing.

The FSFI was applied between 3 and 6 months of follow-up, only once per patient. Anatomical success was defined as a TVL longer than 6 cm, which allowed the easy introduction of two fingers, based on previous studies conducted in the same hospital.[13-16]

2.7 | Ultrasonographic evaluation

Three-dimensional pelvic floor ultrasonography was carried out using a translabial probe located perpendicular to the vulva of the patients, who were placed in the lithotomy position, before and after treatment (3 and 6 months), by the same examiner.

Two-dimensional ultrasound images were acquired with a cutting point below the symphysis pubis and with the bladder almost full. Three-dimensional ultrasound images were acquired during rest, during the Valsalva maneuver, and during muscle contraction, with visualization of the symphysis pubis, urethral meatus, the vaginal canal, puborectalis muscle, and the anal canal.

During the three maneuvers (at rest, Valsalva, contraction), the genital hiatus and the thickness of the puborectalis muscle were measured in a perpendicular axis, standardized as 05 and 07 h (Figure 2).

2.8 | Statistical analysis

The Mann–Whitney non-parametric tests and GraphPad Prism 6 software were used to carry out the statistical analysis.

3 | RESULTS

The sample was homogeneous between the groups (dilation/surgical), according to clinical characteristics, with only a difference in height, which, when corrected by body mass index (calculated as weight in kilograms divided by the square of height in meters), did not show a significant difference (Table 1).

A comparison between the groups showed efficacy in neovagina formation after both treatments when compared to the patients' clinical manifestations prior to treatment (Table 2), with a statistically significant difference between the pre- and post-treatment periods (*P* value pre- × post-dilation group <0.0001 and *P* value pre- × post-surgical group <0.0001).

TABLE 1 Clinical characteristics of the dilation and surgery groups

	Dilation group	Surgery group	*P* value
Diagnosis	*n* = 9 MRKH	*n* = 9 MRKH *n* = 1 MURCS *n* = 1 MORRIS	
Age (years)	Mean 24.88	Mean 22.54	0.11
Weight (kg)	67.77	53.81	0.06
Height (m)	1.66	1.59	0.04*
BMI (kg/m^2)	24.48	21.60	0.13
TVL pre (cm)	1.44	1.27	0.23

*$P < 0.05$.

Abbreviations: BMI, body mass index; MORRIS, complete androgen insensitivity; MRKH, Mayer-Rokitansky-Kuster-Houser syndrome; MURCS, Mullerian, renal, cervicothoracic somite abnormalities; TVL, total vaginal length.

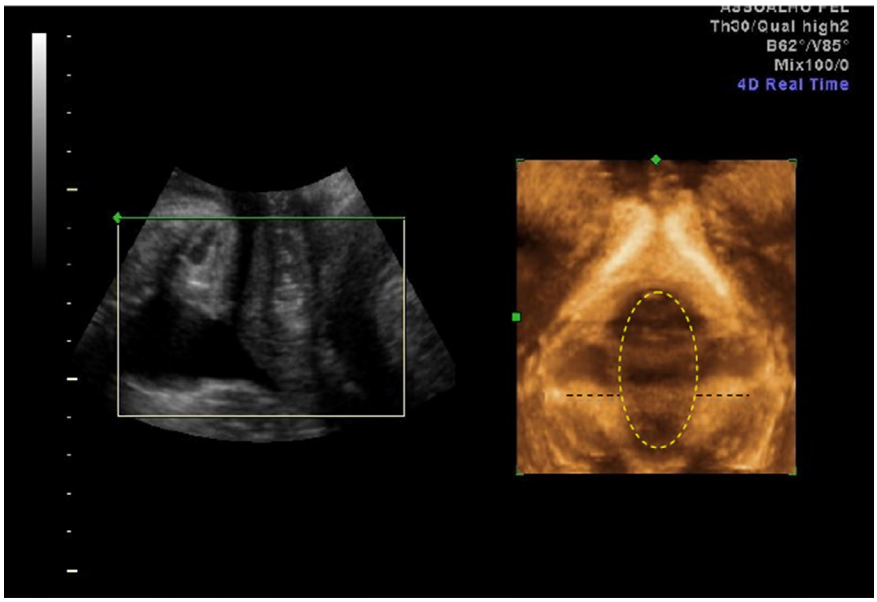

FIGURE 2 Three-dimensional ultrasound at rest in sagittal view (left) and axial (right). The yellow ellipse represents the genital hiatus measurement at rest. The dashed lines represent thickness measurements of the puborectal muscle bilaterally (05 and 07 h)

TABLE 2 Total vaginal length (TVL) comparison between the dilation and surgery groups before (pre) and after (post) treatments

	Dilation group		Surgery group	
Patients	Pre TVL (cm)	Post TVL (cm)	Pre TVL (cm)	Post TVL (cm)
1	1.00	6.00	1.00	6.00
2	1.00	7.00	3.00	6.00
3	1.00	6.00	1.00	5.00
4	2.00	12.00	0.00	6.00
5	1.00	4.00	1.00	8.00
6	1.00	6.00	4.00	8.50
7	1.50	2.00	1.00	7.00
8	3.00	6.00	0.00	7.50
9	1.50	6.00	1.00	8.00
10	—	—	1.00	8.00
11	—	—	1.00	8.00
Mean*	1.40	6.00	1.30	7.10
SD	±0.64	±2.51	±1.13	±1.10

P value pre- × post-dilation group <0.0001*
P value pre- × post-surgical group <0.0001*
P value pre-dilation × pre-surgical = 0.23
P value post-dilation × post-surgical = 0.09.
Abbreviation: SD, standard deviation.

There were no statistical differences in TVL measurements (*P* value post-dilation × post-surgical = 0.09) and FSFI scores (*P* = 0.72) after both treatments (Tables 2 and 3). The clinical aspects of the vagina were subjectively analyzed by the first two independent authors, with no differences regarding the appearance of the neovagina, such as presence or absence of active bleeding, the color of the vaginal mucosa and granulation tissue, in both groups in the 3–6 months after treatment. No vaginal wall adhesion was found in both groups.

Regarding perineal ultrasonography, the length of the genital hiatus at rest was greater in the dilation group than in the surgical group (*P* = 0.02), which shows that the preserved treatment has satisfactory efficacy if surgery is not the choice of the patient or the skill of the team (Table 4). The surgical group presented two minor complications: moderate bleeding 15 days after the procedure, which stopped without any intervention; partial stenosis of the vaginal canal after 3 months, which was solved with an increase in the rate of sexual intercourse. In the dilation group there were no complications.

Of the 20 patients included in the present study, only one patient in the dilation group was not able to continue the treatment due to pain and discomfort while performing the exercises. The patient was then reallocated to the surgical group. This was considered a dilation treatment failure, despite her unwillingness to perform the exercises.

3.1 | General satisfaction

The scores for the questions about satisfaction were 9.2 for the surgery group and 8.4 for the dilation group, with no statistical difference between the two groups.

TABLE 3 Female Sexual Function Index score comparison between dilation and surgery groups

Patients	Dilation group (*n* = 6)	Surgery group (*n* = 7)
1	30.00	13.80
2	4.40	2.00
3	3.20	31.50
4	29.60	3.20
5	6.60	5.40
6	14.80	30.20
7	—	6.20
Mean	14.76	13.18
SD	±11.25	±11.70

P value = 0.72.
Abbreviation: SD, standard deviation.

3.2 | Sexual function

Thirteen of the 20 patients answered the FSFI questionnaire in the period between 3 and 6 months after treatment (Table 3). Patients with TVL shorter than 5 cm did not have sexual intercourse and therefore did not answer the FSFI questionnaire. There was no significant statistical difference between the two groups (*P* = 0.72).

3.3 | Ultrasonographic evaluation of the groups

The groups were evaluated before and at 3–6 months after treatment. The parameters evaluated were mean genital hiatus size and the thickness of the puborectalis muscle, standardized as 05 and 07 h (Table 4).

Seventeen of the 20 patients underwent a three-dimensional pelvic floor ultrasound before treatment and after 3–6 months. Only three patients in the surgical group did not attend the pre-surgical visit and therefore did not undergo the first ultrasound.

4 | DISCUSSION

The treatment of vaginal agenesis has been studied in recent decades to achieve better results for all patients. Dilation treatment is still considered the first-line therapy because it is safer, patient-controlled, and more cost-effective than surgery.[2,3] According to the outcomes of the present study, all patients who underwent dilation treatment achieved a satisfactory vaginal length of at least 6 cm during follow-up. All patients who had sexual intercourse after the treatment were satisfied according to the FSFI questionnaire.

The results of the present study agree with previous scientific statements. According to the Committee on Adolescent Health Care from ACOG, and other authors, non-surgical vaginal elongation by dilation should be the first-line approach.[2,3] When well-counseled and emotionally prepared, almost all patients will be able to achieve anatomical and functional success by primary vaginal dilation.[3]

TABLE 4 Ultrasonographic data of dilation and surgery groups: size of the genital hiatus in cm^2 and mean thickness (in cm) of the puborectalis muscle measured at 05 h (5H) and 07 h (7H)

	Dilation group			Surgery group				
	Pre	Post	*P* value	Pre	Post	*P* value	*P* value pre-dilation × surgical	*P* value post-dilation × surgical
At rest								
Genital hiatus	11.78	12.90	0.16	10.58	10.88	0.77	0.46	0.02*
5H	0.85	0.95	0.20	0.97	1.05	0.47	0.58	0.71
7H	0.89	0.94	0.69	1.02	1.00	0.85	0.22	0.82
Genital hiatus	12.01	12.21	0.74	11.63	10.98	0.77	0.54	0.35
Valsalva maneuver								
5H	0.95	1.02	0.35	0.95	0.99	0.58	0.83	0.98
7H	0.93	1.08	0.15	0.99	0.98	0.95	0.55	0.47
Genital hiatus	10.48	9.35	0.42	9.40	9.39	0.88	0.48	0.87
Contractions								
5H	0.89	0.95	0.40	0.90	0.95	0.75	0.79	0.92
7H	1.05	1.00	0.72	0.91	0.90	0.82	0.79	0.47

*$P < 0.05$.

In 2015, Willemsen and Kluviers[17] published a retrospective study that compared dilation and surgical treatment carried out using the Davydov technique. They showed that the results of both treatments were similar in relation to sexual satisfaction and TVL.

In their study, Callens et al.[25] determined a mean vaginal length of 9.1 cm after surgery and 7.5 cm after dilation, without significant differences, and no significant difference was found between the surgical vaginoplasty and dilation groups regarding psychosexual outcomes. However, the surgical procedures were quite different from that used in the present study.

Whereas Callens et al.[25] used abdominal routes, the Vecchietti and Davydov techniques, the technique mostly used at this medical service is the modified Abbé-McIndoe technique (Figure 1), with oxidized cellulose, which involves a shorter operating time and less pain and discomfort.[13-16] Neovaginas created with this technique have hormone receptors and histopathologic aspects similar to those observed in a natural vagina.[13-16] This may be the reason why Callen et al.[25] had more lubrication problems in patients with vaginoplasty than the present study. The most common causes of dissatisfaction with the Davydov technique are orgasm, pain during intercourse, low vaginal lubrication, decreased arousal, and shortness or stenosis of the vaginal canal.

In cases in which surgical intervention is required, referrals to centers with expertise in this area should be considered because few surgeons have extensive experience in construction of the neovagina and surgery by a trained surgeon offers the best opportunity for a successful result.[3,25] This recommendation from ACOG was applied in this project because it was performed by a multidisciplinary and specialized team in a referral medical center to maximize the positive outcomes and minimize the possible complications.[3]

Based on the results of this research, satisfaction was demonstrated to be the same in the two groups (conservative and surgical groups). In particular, the psychological effects of the diagnosis and the satisfaction of the treatment for vaginal agenesis should not be underestimated and need to be the aim of the management of vaginal agenesis.[17,25] It can be inferred from these data that pain was not a limiting factor for neovaginal formation and function in either group.

Surgical treatment was a feasible option for those patients who could not or did not want to undergo dilation treatment, which demands discipline, motivation, and patience. In this study, only one of the 10 patients in the dilation group gave up and asked for surgery, as she was not motivated to continue doing the exercises. Callens et al.[25] reported that 40% of the vaginoplasty patients had tried dilation therapy before having surgery but failed to reach success. Despite the technique used, the surgical treatment requires the patient to continue using the prosthesis every day and continue using it for a long period of time. That demands patience and consistency from these patients.[2,3,21,22,25]

Follow-up evaluations were carried out at least 3 months and a maximum of 6 months after the beginning of either treatment. After 6 months, the women who were under follow-up were considered treated and completely adapted to the new vaginal canal. However, all patients included in this study continue to be followed up and more information should be available in the longer term.

The study population included two patients who had been submitted to surgical treatment during childhood with no satisfactory result at the time. The authors avoid doing this procedure at an early age as it is difficult to perform the exercises or even use a vaginal prosthesis in babies or younger children. It is preferred that treatment should start when patients are teenagers and willing to start their sexual lives. Callens et al.[25] reported 40% of patients with multiple operations in the past because of vaginal shortening or complications. Both patients who had already been submitted to a surgical procedure at an early age were included in our study because they needed treatment

by virtue of unsuccessful previous treatment. They also had a TVL as short as a patient who had never had any previous treatment.

This study seems to be the first prospective study to show a lack of significant difference in terms of sexual function between the group treated with dilation and the group treated with surgery using the Abbé-McIndoe technique, even in a short period after treatment. All patients who had sexual intercourse after treatment were satisfied according to the FSFI results, as observed by Callens et al.[25]

In the present study, sexual function was measured using the FSFI. Several studies use score testing as a method to measure sexual function because of its reliability and practical application.[24,25]

Regarding three-dimensional pelvic floor ultrasound, there were no differences in the comparison between groups, except for genital hiatus measurement at rest, which was larger in the dilation group than in the surgical group after treatment. This could explain why some patients had a genital prolapse years after dilation treatment, as greater genital hiatus is known to be a risk factor for prolapse.[18]

The measurement of puborectal muscle thickness in cases of vaginal agenesis may be useful in the short term to assess the elasticity and functionality of the neovagina. Furthermore, in the long term, it can provide data for predicting the risk of genital prolapse in patients with neovagina, data that follow-up and measurement of this parameter can provide.

According to the scientific community, there are currently no prospective studies comparing the evaluation of vaginal dilation and surgical treatment for vaginal agenesis by three-dimensional pelvic floor ultrasound.[14] Therefore, this study has indicated a possible method to evaluate the pelvic floor in patients with vaginal agenesis.

4.1 | Strengths and limitations

The main relevance of this research is the possibility of offering a treatment option that is recommended in the scientific community with ethics, efficacy, and safety for a patient in an international reference center for the treatment of vaginal agenesis.

In addition, it is the first study to analyze sexual function in women with vaginal agenesis in relation to the selected treatment, either conservative or the Abbé-McIndoe surgical technique.

The homogeneous patient sample, standardized procedures, and prospective model are also strong points. The present study was not a randomized trial because of ethical issues.

The main limitation of this trial was the small sample size. However, vaginal agenesis is a rare disease, whose incidence is 1:4000 female births. The seriousness and scientific effort of this study are not diminished because of the difficulty including more patients.

Considering the statements above, the authors believe that the study's strengths overcome its limitations. As vaginal agenesis is a rare disease that affects young women and involves the sensitive issues of sexuality and self-esteem, disclosure of well-structured trials can contribute to gaining knowledge so that an increasing number of women can benefit from the results of the studies.

5 | CONCLUSION

Based on the study's findings, both techniques are effective and similar concerning sexual functional and anatomical aspects. Dilation treatment remains the first-line therapy with few described complications, satisfactory results, and essentially only requires the patient's willingness to adhere to the treatment.

Considering the encouraging outcomes of this project and the rarity of the evaluated clinical condition affecting young women, with an impact on their emotional sensibility, sexuality, and self-esteem, the authors suggest more well-structured trials should be carried out to better treat and benefit that population of young women.

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CONFLICTS OF INTEREST

The authors have no conflict of interest.

AUTHOR CONTRIBUTIONS

VRA contributed to project development, data collection, and writing the manuscript; CCT contributed to project development and proofreading/editing the manuscript; GVM and ZIKJDB proofread/edited the manuscript; MJBCG contributed to project development and proofreading/editing the manuscript; MGFS contributed to project development and proofreading/editing the manuscript.

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