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Systematic review: the use of vaginal mold in current vaginoplasty surgeries – techniques and materials

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Abstract: This paper presents a study of the techniques and materials used in vaginoplasty surgeries performed around the world. It consists of a systematic review that covered the identification, selection and critique of primary studies of topics involving the use of vaginal molds in surgeries for different patients: women with Mayer-Rokitansky syndrome; and transgender patients who underwent sex reassignment surgery (CRS), that is, patients with gender dysphoria. The researches made in the chosen databases, after applying the criteria of inclusion and exclusion of articles, resulted in 19 publications, which represented the basis of the construction of this work. It also focuses on the description of the technologies, materials and methods used in the manufacture of vaginal molds used in surgery. In all studies, the molds have the function of maintaining the structure of the neovagina, thus avoiding vaginal stenosis, besides fixing the material used as a graft in the new cavity, covering it, favoring epithelization.

Keywords: Vaginoplasty. Bioateriais. Vaginai mold.

Introductin

A systematic review is a secondary and retrospective study that brings together several primary studies that address the same issue to be discussed and evaluated, in this case a vaginoplasty surgery, which uses, in the postoperative period, a vaginal mold, formed by a base covered by graft. The work involved the study of techniques and materials applied in surgery and presents five main applications of vaginal molds.

As described previously, the two main groups of patients who undergo vaginoplasty surgery, with a need to use vaginal mold are: the patient who presented a Mayer-Rokitansky syndrome; and sex reassignment operation patients, that is, transgender people.

In both groups, it is sought the creation of a neovaginal cavity, which can be made by different techniques. After the vaginal canal is constructed, it is necessary to use a mold to keep the width and depth of the vagina intact, and also to fix the material used as a graft that will cover the created cavity, which will facilitate epithelization.

Mayer-Rokitansky-Kuster-Hauser syndrome

The Mayer-Rokitansky-Kuster-Hauser syndrome (MRKH), better known as Rokitansky's syndrome, is a disorder that occurs in women and mainly affects the reproductive system. It represents a malformation characterized by complete or partial agenesis of the vagina and uterus, causing them to be underdeveloped or absent. This syndrome represents the second most common cause of primary amenorrhea, a gynecologic cause where the first menstruation does not occur (menarche) [1,2].

There are two types of MRKH syndrome, being types 1 and 2. Type 1 is characterized by an isolated absence of the proximal two-thirds of the vaginal cavity, while type 2 is marked by other malformations, including vertebral, cardiac and urological abnormalities, for example[1].

Individuals with this syndrome have a normal karyotype, regular ovarian hormone function, and external genitalia. Thus, the development of secondary sexual characteristics and adolescent progress is normal. However, women affected by the syndrome generally do not have menstrual periods due to the absent uterus, and although the fact that women with this condition can not withstand pregnancy, they can have children through assisted reproduction[1,2]

The treatment goal, whether done conservatively or surgically, is to provide the patient with a suitable passageway for penetration, facilitating a satisfactory sexual intercourse. The functional neovagina created, will allow the patient to achieve physical and psychological balance[3].

Gender Dysphoria

Patients with gender dysphoria (transgender) present persistent discomfort with the sex imposed at birth. Because of a sense of inadequacy in the social role of this genre, these people have an unalterable conviction that they were born in the wrong body, causing great psychological distress from early youth.

According to the International Classification of Diseases, revision 10 (ICD-10), the following three criteria must be detected before an individual can be diagnosed with gender dysphoria: (I) the person has the desire to live and be accepted as a member of the opposite sex; (II) this desire is usually accompanied by a sensation of discomfort or inappropriateness of the anatomical sex; and (III) the desire to undergo hormonal surgery and / or treatment to make your body as congruent as possible with the preferred sex, causing the primary and secondary characteristics of the sex to be lost in order to gain those of the opposite sex[4, 6.]

When the diagnosis and indication for surgery are confirmed, the individual initiates hormone therapy, developing, as a consequence, relatively acceptable breast tissue. Thus, early hormonal treatment may turn procedures, such as maxillofacial surgery, unnecessary or less invasive in these patients. In this way, it is believed that the best treatment is either hormonal therapy or gender shaping surgery that transitions the

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individual into the desired gender, playing a crucial role in relieving their psychological discomfort[4].

For each patient, the psychological eligibility, before performing the surgery, is evaluated by qualified professionals, properly trained in mental health and experienced in gender dysphoria evaluation. Such assessment is done through several counseling sessions, according to the standards of transgender health care[5].

The goals of the procedure, which can be done only by surgical intervention, are: to create a female vulva; a deep vaginal cavity and wide enough to facilitate penetration; a sensitive clitoris; and the majus and minus labiums, with the fewest surgical complications[5].

Objectives

As the amount of scientific information is increasing regarding the use of a vaginal mold in surgeries for the formation of neovaginas, it is necessary to optimize this information, so that will be better used. The amount of people who depend on this technology increases every day, being indispensable the development of studies and research related to the subject.

Among all the articles studied, there is a lot of information about the techniques used, and very few about the mold itself. The lack of research in this area is evident, and in return, there is a huge demand of patients who depend on this technology.

Thus, a systematic review was developed bringing together several primary studies, based on the same theme, described above. The objective is to identify materials and methods used in surgeries, specifically in the case of mold, in order to obtain an evaluation of the eligibility, safety and effectiveness of the entire process.

Materials and methods

The first step of all scientific work consisting of a systematic review is the elaboration of a question that is sufficiently clear, objective and directed to the research topic to be developed. Thus, its elaboration was allowed using a tool designated by the acronym PICO. In this, the letters correspond to: "P" the population, "I" the intervention, "C" the comparison, and "O" the outcome. The strategy for preparing the PICO question is used to identify what the question should specify.

In this way, the defined question was: "In patients with Mayer–Rokitanky syndrome and / or patients with gender dysphoria, where both groups undergo vaginoplasty surgery, the mold used to maintain the vaginal cavity open made by a relatively rigid material with skin graft compared to a flexible and biocompatible material, results in better post–surgical results? ".

From this, research was done to search for scientific articles in BIREME, PUBMED, PORTAL CAPES, LILACS and CLINICAL TRIALS databases. The keywords were: vaginal mold, vaginoplasty, Mayer–Rokitansky syndrome, sex reassignment surgery and transgenitalization.

The researches in the databases were written without crossing the keywords, and in each one, all articles were selected and included in a spreadsheet made in Excel. It is important to note that all keywords were researched in three different languages: Portuguese, English, and Spanish.

The first exclusion criterion applied was the repetition of articles. After excluding all repeated articles, a second criterion was proposed, excluding all articles that did not fit the theme, with the exclusion of the majority. Then there was a third criterion, which excluded articles with incomplete texts, and also did not contribute significantly to the research.

Figure 1 shows the tool used for the identification, selection, eligibility, and inclusion of articles. The study resulted in an initial result of 1,121 articles, and after the application of all the exclusion criteria, this number reduced to 19. From then on the articles were studied and evaluated.

Development

Vaginoplasty

Vaginoplasty is a surgical procedure characterized by the creation of an artificial vaginal cavity, applied in cases of congenital absence of the vagina due to vaginal agenesis, or in cases of operation for sexual reassignment, where there is no vaginal cavity1. Thus, vaginoplasty has a considerably positive impact on the quality of life of these patients[5].

The main method to construct the vaginal cavity in a patient with Rokitansky's syndrome is by dissecting tissues between the rectum and the bladder. For trans patients, this process is also performed, but mainly by the penile inversion method, representing the final phase of the process of gender conformation. Both procedures are done surgically, although there are also non–surgical techniques for the creation of a neovagina in patients with the described syndrome.

Several complications can be verified in these procedures, the main ones being:

Vaginal stenosis, which represents the most common complication that can occur. It is characterized by significant closure or narrowing of the neovagina, associated with misuse or abandonment of the mold in the postoperative period. If the patient has a long and correct postoperative period of dilatation, neovagina will not be closed nor narrowed in terms of diameter and length[1];

Fistulas formation, which represent the most serious complication in such procedure. If fistula formation occurs during

the operation, the original procedure should be abandoned and treatment to close the fistula should be instituted first1. The fistula represents the formation of a canal that abnormally communicates two internal organs or an internal organ with the surface of the body;

Rectal or urethral lesions, characterized by being common intraoperative complications due to the occurrence of damage to the rectum and urethra, respectively[5];

Infections in general, which may be manifested in the short–term postoperative period[5];

Long resting time and very intense pain in the graft donor region[5].

The participation of a multidisciplinary team, with accompaniment of professionals specialized in the approach of the sexual disorders, is fundamental for a good evolution, even before the surgical approach. This is necessary because, since surgery is relatively complex and presents uncomfortable postoperative, there is a very high probability of the patient's resistance to accepting the neovagina as a functional organ[7].

There are several non–surgical and surgical treatment techniques described in the literature for the correction of vaginal agenesis[3], as well as several surgical treatment techniques for CRS. However, this work will mention two techniques applied in patients presenting with Rokitansky's syndrome, and a technique applied in trans patients.

Treatment options, which may consist of surgical and non–surgical vaginoplasty, depend on several factors, including patient preparation, preference and expectations, and certainly the surgeon's experience[8].

Techniques applied in patients with Rokitansky's syndrome

Frank Method

Frank's method, which consists of a non–surgical procedure, uses manual physiotherapy techniques performed by the women affected by the syndrome to form the vaginal cavity. It is a technique that requires time and motivation of the patient, which should be reinforced by the companion who supervises her case[1]. This method is usually applied in women who already have a certain vaginal length before initiating treatment[9].

The basis of this approach is graduated dilation of the vaginal cavity, made by means of dilators, which are placed against the vagina and pressed firmly for 15 minutes, twice a day or more frequently. As the ideal length of the cavity is reached, the frequency and the pressure applied to the vagina decrease progressively[1].

Due to the characteristics of the method, compliance is considered weak in patients with complete absence of the vagina, since these patients suffer much discomfort and abandon treatment with the dilator[1].

Several studies have shown that women who can not complete the treatment using the Frank method have a lower mean vaginal length at the beginning of treatment than those who completed it[9].

Although non–surgical techniques for the creation of a neovagina have been reported, medical surgeons prefer the surgical method, since the time interval of the treatment using the Frank method for example is long and can reach up to two years duration[10].

McIndoe Method

The McIndoe method, which consists of a surgical procedure, represents the creation of a vagina by the blunt dissection of tissues and structures located between the bladder and the rectum, with a dermal coating used as a graft. This surgical procedure was initially conceived by Abbe and later modified by McIndoe[11].

The surgical procedure based on this technique follows approximately the following steps:

Firstly, after local anesthesia, the patient is placed in a lithotomy position[11], that is, placed in the supine position, with the head and shoulders slightly raised, the thighs being well flexed on the abdomen, separated from each other;

The catheterization of the urethra is then performed. Generally a small amount of methylene blue is instilled through the catheter into the bladder in order to detect a possible injury due to dissection performed in the wrong way and can be diagnosed as soon as possible. If the blue colored fluid is aspirated, it means that the direction of dissection in relation to the bladder is incorrect[1];

Then the labium minus are separated, and an incision of approximately 0.5 cm is made in the region of the cavity to be formed. So the shear dissection is performed, reaching an ideal vaginal length, usually 10–12 cm 11;

The space is coated instead by a skin graft removed from the buttocks, thigh or suprapubic region[1], which is cast on a base, forming a vaginal mold, presenting a bottom surface facing oustide, so that it is in contact with the newly created vagina.

Finally, the edges of the labium majus are sutured together to help hold the mold in place during the first postoperative week. After seven days the labial sutures and the template are removed, and the cavity is inspected to evaluate the progress of epithelialization, and healing[1]. Generally, the mold is sanitized with physiological saline under pressure;

After the surgical procedure, the patient is still instructed to perform exercises four to six times a day with a dilator to stimulate the dilation of neovagina. Initially, this dilation is considered by the vast majority of patients to be heavy and painful, but over time, it becomes less frequent and difficult. The final result consists of a cavity measuring approximately

10 to 12 cm deep and three fingers wide[1].

The main disadvantages related to this procedure are: surgical complexity; severe pain at the site of the skin graft; scar due to graft removal; possibility of keloid formation at the donor site; and if the patient does not perform the dilation exercises, the neovagina may contract and cause the canal to close, necessitating a new surgery[8].

Several modifications of the McIndoe technique have been proposed, especially in relation to the material used as coating of the cavity. The main applications of these materials in vaginoplasty surgery include, in addition to the use of skin grafts: allogeneic amniotic membrane; peritoneal layers; and autologous buccal mucosa.

The use of allogeneic amniotic tissue, which does not originate from the patient itself, brings with it the inherited disadvantage of allograft rejection and the high risk of transmission of infectious diseases. The use of the peritoneum has the disadvantage of requiring the opening of the peritoneal cavity, characterizing another surgical procedure, which should be strongly avoided. The use of autologous buccal mucosa, which means to use the patient's own graft, although it does not leave external scars, presents as disadvantages the morbidity related to removal of the mucosa from the donor site and the need for a relatively long time to reach a functional vagina[1,11].

Techniques applied in patients with gender dysphoria

Penile Inversion Method

The penile inversion method, which consists of a surgical procedure, represents the creation of a vagina, by the inversion of the penis, where there is the formation of the vulva; vaginal cavity; clitoris; and minus and majus labium[5].

Since this is an extremely complex procedure, it is necessary that patients be admitted to the intestinal preparation through specific medications, and when they start the surgery, they also receive antibiotic prophylaxis[5].

The surgical procedure based on this technique follows approximately the following steps:

First, after epidural anesthesia, the patient is placed in a lithotomy position and the surgical area is disinfected[5];

Then, a catheter is placed in the urethra, and a circumcision is performed at the base of the foreskin. The skin of the penis and the urethra are separated from the cavernous bodies[14];

The dorsal neurovascular bundle is then also separated from the cavernous bodies, leaving the penile glans and the foreskin vascularized;

Then, the neovaginal space is dissected until a depth of approximately[14] cm is reached. The correct identification of anatomical layers, avoiding lesions in the urethra, prostate, seminal vesicles, sphincter and bladder, is essential[14];

Then, of a part of the glans of the penis and the foreskin, the neoclitoris and the minus labium are sculpted, respectively. The scrotal skin is excised to define the majus labium[14];

As in the McIndoe method, the newly formed space is covered by a mold, formed by a base, on which is sewn a skin graft, mainly removed from the abdominal region. The deep surface of the graft is facing outwards so that it is in contact with the wall of the vaginal canal created[11];

Finally, the edges of the majus labium formed are also sutured together to keep the mold in place for the first seven postoperative days. As in the McIndoe method, after surgery, the patient is instructed to perform exercises with a dilator or vaginal shaper in order to stimulate the dilatation of the formed cavity[14]. For the penile inversion procedure, the main disadvantages are also: surgical complexity, which causes many people to become discouraged to perform it; long postoperative period and with several complaints of pain and complications; the scar that remains in the donor site of the skin graft; and the need for a new surgery in the event of vaginal stenosis, due to a lack of correct use or abandonment of the vaginal mold[14].

Applications of the vaginal molds

As seen previously, the success of the surgical procedure, in both cases presented, is directly related to the use of the vaginal molds in the postoperative period.

The molds used, whose diameters vary between 2.5 and 3.5 cm, according to the phenotypic characteristics of each patient[12], can be rigid or malleable. The rigid ones often cause a series of complications, such as: graft loss; fibrosis; contracture; bladder or rectal fistula related to pressure; and, mainly, patient discomfort. Malleable molds, however, reduce the number of these occurrences, but may present other disadvantages, including: instability; assembly complexity; and most important, the lack of commercial availability[13].

In the sections 2.4.1 to 2.4.5 follow the main types of vaginal molds used both in patients with Rokitansky's syndrome and in patients with gender dysphoria. It is important to note that these applications are described in series reports of cases, that is, performed in several patients.

Condom filled with foam covered by amniotic membrane

In most of the articles selected, there is the report of the use of rubber condoms filled with foam, forming the base of the

vaginal mold, presenting amniotic membrane covering this basis, replacing the skin graft. The human amniotic membrane is characterized as a protective biological tissue, applicable to wounds and burns, as it acts as a facilitator of epithelization. Thus, it is seen as an ideal graft of tissue to cover the vaginal cavity formed by dissection[1].

However, the amniotic membrane requires extremely precise preoperative screening11. Serum from all donors need to be tested for hepatitis B, hepatitis C, AIDS (human immunodeficiency virus – HIV), and syphilis. Thus, the membrane is collected under sterile conditions by some seronegative donor during a cesarean delivery, and can be stored in normal saline at 4°C with crystalline penicillin for up to 72 hours1.

At the time of application, the membrane is removed from the saline bath and placed on the foam filled condom, the mesenchymal surface facing outwards to adhere to the surface of the formed vaginal cavity11. The long axis of the amniotic membrane is placed parallel to the long axis of the condom, its lateral edges are approximated on each side, and then sewn. The customization of the template to the size of the created vaginal cavity is of paramount importance, so that there is no pressure necrosis. Once dimensioned and constructed properly, the mold is inserted into the neovagina [1].

After approximately seven days of the surgical operation, the mold removal takes place. At this time, a second amniotic membrane application is performed, and if necessary, after a further seven days, a third application is performed[11].

As a result of this application, epithelization is considered to be rapid, but the use of allogeneic tissues, such as the amniotic membrane, carries the disadvantage of tissue rejection and the risk of transmission of infectious diseases from donor to recipient. In addition, membranes have been shown to be easily contaminated before or after transplantation[11].

Several patients had vaginal stenosis, neovagina shortening, rectovaginal fistula, uterus vesicle fistula and excess skin in the vaginal introitus – corrected only after a new surgery. The cases related to the main complications, being stenosis and shortening of the vagina, were due to the incorrect use of the vaginal mold in the postoperative period[7].

Vaginal Tissue Cultured In Vitro

Another very frequent application in the studies is the use of a base 2 cm in diameter and 12 cm long, consisting of any material, covered by a condom, and, covering this base, a patient's own autologous vaginal tissue) , cultured in vitro, acting as a graft[10]. Thus, only patients with a MRKH syndrome can go through this operation and use a mold that is constituted by this technique, since they usually present the lower third of the vagina or a vaginal vulva, not found in transgender patients.

The procedure performed to obtain this epithelium consists in first performing a biopsy of the vestibule of the vagina of 1cm^2 of thickness[10].

The biopsy then undergoes a process of enzymatic dissociation and the resulting cells are plated and incubated in a device with chemical solution, consisting of a substance designed for the growth of untransformed cell types, in a serum–free formulation[11].

After one week, once the cells reach 70–80% confluence, cultures are further sown for an additional eight days in order to obtain a fully differentiated mucosal tissue[10].

The time interval between biopsy and total mucosal tissue differentiation is approximately two weeks. At the end of cultures, autologous reconstructed vaginal tissues reach about 314 cm^2 and are collected from plaques. They are then washed in PBS (phosphate–saline buffer solution), and mounted on gauze embedded with hyaluronic acid[10, 11].

The cultured tissue is fixed to the base with bilateral points, and the cell layer is placed so that it faces the walls of the newly created cavity, remaining with the patient for five postoperative days. After this, the mold is removed and the vagina examined[10, 11]. The patient is instructed to use the vaginal mold during the six successive weeks[10].

After four months of follow–up, the epithelization from the transplanted tissue was observed throughout the formed neovaginal wall. In addition, no cases of stenosis were reported and sexual intercourse was reported as satisfactory by both partners[10,11].

From this, it may be noted that the technique appears to offer several advantages. Because the graft is autologous and orthotopic (that is, the cultured tissue comes from a viscera that is in its proper place, being transplanted in the same position as it was)[11] there is a low risk of rejection or infections derived from the donor, besides minimizing the discomfort of the patient and avoiding permanent scars, since this procedure leaves no visible scars in relation to graft removal[10].

Among the disadvantages is the fact that the procedure using this technique can be performed only in centers that have tissue culture laboratories, such as hospitals with burn units or large reference centers. In addition, because the procedure is performed in two stages, the first one is characterized by the biopsy, and the second by the vaginoplasty itself, the surgery must be planned in association with the laboratory so that the surgical procedure is done only when the tissue is ready[11].

Finally, as this study reports the first case of application of vaginal tissue grown in vitro in humans (previously tested only in mice), the technique indicates that the use of the vaginal mold is done for a prolonged time, and intercourse is avoided for a relatively long period of time, to prevent the formation of a vaginal septum and other complications[10]. Thus, the use of in vitro cultured vaginal tissue is in its initial application phase, and it is necessary to acquire more experience before drawing definitive conclusions, which justifies a more in–depth study[11].

Cica–Care

In this application we present a vaginal mold formed by silicone gel sheets (Cica–Care) as the base, covered by skin graft. The silicone gel sheets are commonly found in most hospitals, available in sterile packages.

The vaginal mold is made using a silicone gel adhesive sheet and a 16 French Foley urinary catheter. The sheet, measuring 15cm x 12cm, is split in half to make two strips in order to be wrapped around the Foley catheter. No suture is required to adhere the gel sheets to the catheter because of its self–adhesive property[15].

The complete silicone mold is approximately 6.5 cm long and 2.5 cm in diameter, and can expand after inflation of the catheter until they reach an average of 3.0 cm in diameter[15].

The skin graft is then harvested and wound around the base, with the inner surface facing outwardly, to adhere to the formed vaginal cavity, in the same manner as in previous applications. The margins of the graft are then sutured so that it is stabilized around the base of the mold[15].

With the catheter balloon deflated, the vaginal mold is inserted into the neovagine. The balloon is then inflated, enlarging the diameter of the mold, and the labium majus are sutured to prevent involuntary displacement of the balloon. Five days after the surgical procedure, the catheter is again deflated and the vaginal mold is removed[15].

For this application, the neovagina was satisfactorily rebuilt, but there were many reports of severe pain at the graft donor site. The vaginal mold was reused as a dilator for 6 to 10 months to prevent contraction of the cavity[15].

Because Cica–Care sheets have smooth gel consistency, they provide comfort and wide applicability to irregular three–dimensional defects. Therefore, the length and diameter of the mold can be easily adjusted according to the selection of the desired size of the sheet, or by changing the number of wraps around the Foley catheter. Moreover, due to the durability of the silicone gel sheet, it can be reused as a postoperative dilator, supporting repetitive sterilization[15].

However, this is a method that uses skin graft, and therefore, presents great rejection of patients in performing it. The intense pain reported by the patients at the graft donor site is the main reason for their withdrawal from the surgery design[15].

Mold made of porous plastic laboratory centrifuge tube

A fourth highly successful application in vaginoplasty surgeries is the use of a rigid, disposable porous base made of a plastic centrifuge tube with a conical bottom (approximately 50 ml). This base is covered by skin graft, removed from a donor site.

In the plastic tube, easily found in hospitals and laboratories, several holes are made, traversing all its extension, with the function of storing the fluids originated from the neovagina, after the procedure. The bottom of the tube has an opening, through which gauze is placed inside, used to care for the wound. In this way, the gauze allows the absorption of the fluid discharge, allowing a quick and easy cleaning in the dressing changes[16].

On this basis, formed by the tube and gauze in its interior, the skin graft is sewn, constituting the vaginal mold. It is then inserted into the formed vaginal cavity, suturing the bottom of the tube into the labium majus in order to hold the mold firmly in place[16].

This application presents as advantages: the use of a simple base, made of a plastic tube, readily available; possibility of carrying out the frequent exchange of gases located inside the tube, which absorb the fluids from the neovagina; and the possibility of using a vaginal shower to clean the mold in case of local infection[16].

However, several complications have also been reported, such as: vaginal stenosis; fistula formation; pain in the donor site of the graft; infection; traumatic devascularization; and accumulation of fluid under the graft due to poor drainage[16].

As the mold is formed of a rigid material, with no possibility of personalizing it to the patient, it becomes practically impossible to minimize the complications caused by its non–ideal size, both in diameter and length. In addition, it is a very painful technique due to the use of skin graft[16].

Interceed

Summing up, the last application presented in this work consists of a vaginal mold made of any material as base, covered by an Interceed sheet, an absorbable adhesion barrier, used with graft.

Interceed is a whitish, regenerated cellulose tissue that has the objective of reducing the risk of adhesions by creating a gelatinous layer between the surfaces involved in surgical procedures[11], being an absorbable herbal product that provides a matrix for aggregation of platelets. Oxidized cellulose acts as a protective coating on the neovaginal surface to allow tissue from the vaginal cavity to be epithelialized, since cells in the dissected space between the rectum and bladder have pluripotent potential for tissue differentiation[17].

For construction of the application, the Interceed sheet is wrapped around the base of the mold, and then the edges of the sheet are sewn so that it does not come off. The product is then inserted into the neovagina, where it remains for about three days. After removal of the mold, the vagina is washed with saline solution and the neovaginal cavity is examined. At this point, it is expected that the oxidized cellulose has been completely absorbed. Patients are instructed on how to use

the vaginal mold, until frequent sexual intercourse begins[11].

The result of biopsies made long after the procedure identified complete epithelization after five months in all samples. However, in most cases the vagina became stenotic at two months post surgery (because the patients did not use the dilator correctly, as seen). In addition, the samples collected by the biopsies were composed of a connective tissue permeated by numerous inflammatory cells. In several cases, traces of oxidized cellulose were also observed, and therefore not fully absorbed by the body[17].

The vaginal reconstruction with oxidized cellulose seems to be a safe and effective procedure with minimal morbidity and discomfort, besides presenting antibacterial and absorbable properties. This process is generally described as an attractive method, since the procedure of obtaining the graft is not related to an operative procedure; and the material is readily available for use[17].

However, the Interceed sheet is contraindicated in the presence of ostensive infection, and also does not act as a hemostatic agent and should be used only after rigorous hemostasis, since its properties are inactive in contact with blood, making it difficult to use in general surgeries[17].

Finally, a systematic review, published in the Cochrane Database of Systematic Reviews, in 2008, compared the results of 16 clinical trials to evaluate the effectiveness of four barrier products in preventing adhesions in women undergoing pelvic surgery: Interceed , Gore–Tex, Seprafilm and fibrin. It was observed that, in most trials, Gore–Tex was more effective than Interceed[18].

Results

As mentioned, three exclusion criteria were applied, which were removed due to: presence of duplicates; existence of articles that did not fit the theme; and also the presence of articles that did not specify any information related to the vaginal molds.

In this way, the research initially presented [1],121 articles. After excluding the repeated articles, there were 869. Then, most of the articles were excluded, after the removal of those that did not fit the theme, leaving 153. Eight articles were eliminated because they did not present the complete text. Of the 145 remaining, 126 were excluded because they did not specify any information about the vaginal mold, leaving 19 articles, which represented the basis of this work.

Discussion

Surgery performed in both cases is characterized by a complex, irreversible procedure, besides being a process that involves psychological difficulties and disorders both for the patient and for others involved.

The main goal of the surgery is to avoid vaginal constriction and get a good sexual function from the vagina. However, among the applications presented, the surgical return mainly occurs for two reasons: due to the incorrect use of the vaginal mold; or because the graft is formed by a material not favorable to the epithelization of the new surface.

One of the most frequent post–surgical problems, the so–called vaginal stenosis is usually caused by the fact that the mold consists of a rigid and not comfortable material, leading to non–compliance with the dilatation protocol of the newly formed canal. This is due to the patient's anxiety related to possible pain during the movement or reinsertion of the mold into the new cavity[19].

However, the use of a graft material that does not present favorable characteristics to the cavity epithelization, promotes difficulties related to the requirement of a post–surgical period that is much larger than normal.

In this work, applications of rigid molds and others with certain malleability, for example, cica–care were presented. As expected, the rigid molds caused a series of complications, the main one being the discomfort of the patient. On the other hand, the cica–care presented as a mold of low assembly complexity, stable, and mainly, without presenting severe discomfort to the patient in the postoperative period, favoring its correct use, and avoiding the stenosis of the vaginal cavity. However, in the application involving cica–care, skin grafts were used to cover the base of the mold, this being the technique considered as conventional.

This method, which involves the use of skin grafts, presents several negative points, such as: intense pain at the site of the donor site; require the presence of a team of plastic surgeons to prepare the skin graft; require long surgical and hospitalization period; and finally, to present an unfavorable aesthetic result, since the donor site of the graft usually presents a wide and visible scar.

However, the skin graft may be replaced by other types of materials, such as amniotic membrane, in vitro cultured tissue, or also regenerated oxidized cellulose. Grafts composed of biological tissues present complications due to the physiological differences of these substrates, due to the use of allogenic tissue; and non–applicability of autologous tissues in patients with gender dysphoria because they do not have a vaginal vestibule. As oxidized cellulose has inactive properties in contact with blood, making it difficult to apply.

The molds and grafts presented in this study are clearly obtained improvised, without consistent and safe standards.

Untested materials are used for their applicability, characterizing the necessity of a standard product. Condom filled with foam and centrifuge tube are improvised and unsafe examples, used every day in vaginoplasty procedures, as well as skin grafts, which as evidenced, present a diversity of negative points.

Although there are methods that have yielded relatively good (but not ideal) results for both mold and graft, they have not been used together, and thus, nothing can be said about the effectiveness of both used together. In addition, the existence of some material considered ideal for forming a mold or graft has not been proven in any study.

It should always be emphasized that for these procedures, using an appropriate vaginal cast is of paramount importance for successful results. The lack of commercial availability of a mold consisting of a base with greater malleability and that comply with the needs of users, as well as a graft that can bring favorable and supplementary properties to the application, is the main factor for the elaboration of this systematic review.

Conclusions

In recent years, there have been continuous reports on the reconstruction of numerous vaginal cavities with application of several techniques, and the main and most used can be identified in this work.

In a simplified way, it has been seen that the use of vaginal molds, at present, is done in an unstructured way, without conducting a study to identify which would be the best materials destined for this application. There are no comparisons between different techniques, and choosing one procedure over another requires taking into account the advantages and disadvantages of different methodologies.

The constant use of molds made of rigid bases and inadequate grafts, which cause surgical return, was the main motivation for this study.

The elaborated question of the introduction of this work cannot be answered, since none studied reported the use of a vaginal mold made of a flexible and biocompatible material for both the base and the graft. However, it is expected to carry out researches and studies that prove this, since the number of patients who need this technology increases every day.

From the analysis and evaluation of the applications presented, it is evident the necessity to have in the market a standard product, that is produced specifically for the procedure described in the work: the vaginoplasty. It would be very interesting to elaborate a product that would perfectly suit the two groups of patients presented, ending with the improvisation and the use of techniques and materials not tested when its applicability and effectiveness.

References

[1] R. Chaudhary, V. Dhama, S. Singh, R. Azad, "Vaginoplasty in mayer Rokitansky–Kuster–Hauser syndrome using amnion: a case series," International Journal of Reproduction, Contraception, Obstetrics and Gynecology, vol. 5, n. 11, pp. 3832–3839, 2016.

[2] B. R. Carvalho, et al., "Natural latex (Hevea brasiliensis) mold for neovaginoplasty," Revista Brasileira de Ginecologia e Obstetrícia, vol. 30, n. 1, pp. 31–35, 2008.

[3] M. S. Neto, E. C. Baracat, L. M. Ferreira, "Vaginal reconstruction by McIndoe technique with a vaginal expander mold," International Journal of Gynecology & Obstetrics, vol. 73, n. 2, pp. 165–167, 2001.

[4] K. Morcel, V. Lavoué, F. Jaffre, B. J. Paniel, R. Rouzier, "Sexual and functional results after creation of a neovagina in women with Mayer–Rokitansky–Küster–Hauser syndrome: a comparison of nonsurgical and surgical procedures," European Journal of Obstetrics & Gynecology and Reproductive Biology, vol. 169, n. 2, pp. 317–320, 2013.

[5] R. Rossi Neto, F. Hintz, S. Krege, H. Rübben, F. vom Dorp, "Gender reassignment surgery–a 13 year review of surgical outcomes," International braz j urol, vol. 38, n. 1, pp. 97–107, 2012.

[6] L. Zhu, H. Zhou, Z. Sun, W. Lou, J. Lang, "Anatomic and sexual outcomes after vaginoplasty using tissueengineered biomaterial graft in patients with Mayer–Rokitansky–Küster–Hauser syndrome: A new minimally invasive and effective surgery," The journal of sexual medicine, vol. 10, n. 6, pp. 1652–1658, 2013.

[7] S. W. Kim, et al., "Use of a silicone gel sheet vaginal mold in McIndoe vaginoplasty," Archives of plastic surgery, vol. 40, n. 5, pp. 652–655, 2013.

[8] K. J. Yu, et al., "A detachable porous vaginal mold facilitates reconstruction of a modified McIndoe neovagina," Fertility

and sterility, vol. 81, n. 2, pp. 435–439, 2004.

[9] J. Dornelas, et al., "Vaginoplasty with oxidized cellulose: anatomical, functional and histological evaluation," European Journal of Obstetrics & Gynecology and Reproductive Biology, vol. 163, n. 2, pp. 204–209, 2012.

[10] S. E. A. Araújo, P. P. P. Caravatto, A. J. B. A. Chang, F. G. C. M. Campos, M. Souza, "Impacto da vídeocirurgia na prevenção de aderências," Revista Brasileira de Coloproctologia, vol. 26, n. 2, pp. 208–216, 2006.