

On a New Neovaginal Prosthesis of PLA (Polylactic Acid)

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ABSTRACT

Vaginal dilation is proposed as the first choice treatment for patients with vaginal aplasia, but many patients with MRKH or Rokitansky syndrome (and cases with CAIS) may require a vaginoplasty. It is also necessary to make vaginoplasty in patients with vaginal or cervico-vaginal atresia with a functional uterus before performing an utero-neovaginal anastomosis, also in trans-sexual men.

Keywords: Vaginoplasty, Skin graft, Biocompatibility, Epidermization.

INTRODUCTION

In any case, the aim of vaginoplasty is the formation of a satisfactory vagina in appearance, function, and feeling without additional morbidity^{1,2}.

Historically, the creation of a neovagina with an inert prosthesis or synthetic mold and a split-thickness skin graft (McIndoe technique) has been the most common surgical procedure³⁻⁷. However, this method of skin graft lining may be associated with scars (permanent scar at graft donor area – thigh, buttock or abdomen-), graft failure, strictures and contractures of the neovagina

in addition to other surgical complications⁸. Thus in our opinion, the major inconvenient of the McIndoe procedure are those related with:

1. The making of the skin graft and the permanent scar in the donor area; and
2. The prostheses used as mold; many of which are not properly anatomically designed, are of artisanal fabrication and the material might be of certain weight and stiffness that can produce bedsores on the recto-vaginal septum or necrosis of the bottom of the urethra and hypospadias. Solving or improving both aspects, skin graft and prosthesis used, the McIndoe

technique might be the most appropriated, simple and with better anatomical and functional results. To avoid the skin graft, good results have been currently achieved by simply covering the prosthesis with Interceed®⁹⁻¹¹. Marzieh et al.¹² have also obtained good results, with evidence of squamous epithelization of the neovaginal vault, using no grafts. These last authors¹² explain this neovaginal epithelization through the immature squamous metaplasia that results from the proliferation of pluripotential subcolumnar reserve cells, but as it happens during normal vagina embryology¹³ it is more likely to occur due to epidermization from the urogenital sinus that in the adult woman is the vaginal introitus. Thus, the epithelization of the vagina seems possible using no grafts, or as suggested by Acién and Acién¹⁴ the use of a Polylactic Acid (PLA) mesh as biogenerative scaffold could also achieve good results.

And regarding the neovaginal prostheses, the vaginal mold can be designed in varied shapes by using different materials, such as silicon¹⁵, foam rubber, wood, plastic, glass, Teflon, Dexon, vacuum expandable condom¹⁶, a simple syringe^{7,17}, or a polyethylene bag¹⁸. We have used a Dexon prosthesis of 14 × 4 cm. However, this Dexon prosthesis is a bit long, of equal diameter at bottom and entrance and slightly heavy and in some cases, has caused decubitus injury on the urethra provoking light hypospadias. Therefore, it would be of interest a lighter and better adaptable prosthesis considering the dimensions of the normal vagina, both in the fundus and the

introitus. So, Acién et al.¹⁹ have designed a new prototype adapted to the vagina of normal women, which has been patented and presented in 2nd International Meeting on MRKH syndrome (Warsaw, Poland, 26-28 May 2016).

The basic and novel features of this new prototype of prosthesis for neovaginas include:

1. A significant reduction in the proximal diameter to remain at introitus and lower third of the vagina (13 × 3.8→2 cms).
2. An anterior recess of the lower half for urethral protection.
3. Minimum weight, hollow, drainage hole at both ends and somehow shorter than the previous model prosthesis but that still protrudes slightly in the vulva.
4. Hole at the lower end allowing passage of extraction cord.
5. Associated to an adaptable and removable plate at its outer end with 4 holes for fastening tapes or fixing belt. And
6. The adaptable plate allows vertical positioning of the prosthesis for coating with mesh and/or skin graft, prior to their introduction and placement in neovagina. Both the prosthesis body and plate have been fabricated with PLA (biodegradable polymer derived from lactic acid), a material that has been chosen due to its biocompatibility and stimulation of epithelial regeneration properties²⁰⁻²⁵. As a phantom to be used as maintenance, same prostheses covered with silicon have been prepared (chosen material due to its biocompatibility, smooth and antiadherent

characteristics). Thus, the designed PLA prosthesis is prepared to be used for the surgical technique and postoperatively, while the coated silicone version would be easier to be self-placed at daily home use.

Ación et al.¹⁹ have suggested that this new prototype prosthesis of PLA adapts perfectly to the length and diameter required in women to perform neovagina. It is rigid but light, with protection for urethral area and other soft tissues, allowing the muscles of the pelvic floor and vulva to maintain the prosthesis in situ even without external clamping. Thus, the design allows that the neovagina (following a modified McIndoe technique) is done without skin graft (using only the prosthesis of PLA, or associated with a possible PLA mesh^{26,27}, or with Interceed© as biocompatible and biodegradable mesh used as biogenerative scaffold), allowing an easier almost outpatient surgery, without further dermal scarring and providing women with more comfort and functionality. And under such circumstances, the McIndoe surgical procedure might then be the most appropriate, simplest and with best anatomical, sexual and psychological results of the surgical techniques for neovagina overcoming the limitations of the procedure as practiced currently.

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