

Is the “Handcrafted Sling” Actually a Low-Cost, Risk-Free Option? Study Performed on Mice

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Abstract: *Despite good polypropylene results, studies are necessary to knowledge on tissue reaction. Eighteen, Wistar rats were used, divided into two groups of nine: Group A: the area between muscle planes was filled with a 0.5 cm fabric (TVT®) and in Group B, was filled with a 0.5 cm fabric (Prolene®). The animals were sacrificed after 100 days for histological and stereological analysis. The inflammatory process and collagen fiber deposit were higher and more significant in animals from the Group B. The fabric developed for use in the abdominal wall caused an inflammatory reaction stronger than fabric developed for vaginal use.*

Keywords: Cost, Sling, Polypropylene

1. Brief Summary

The search for a low cost alternative to the fabrics developed for urinary incontinence is important, but to know the inflammatory aspects of these alternatives is a way to protect the surgeons from future problems.

Abbreviations

SUI: Stress urinary incontinence

TVT®: Tension free vaginal tape

PTFE: polytetrafluoroethylene

2. Introduction

Stress urinary incontinence (SUI) affects millions of women around the world, causing deterioration in quality of life which is closely related to a higher life expectancy, as the prevalence of urinary incontinence increases with age [1, 2].

Many techniques for correcting SUI have been developed throughout the years, being the ones based on the concept of the sling, described by Schultze in the late 19th century, the more currently used [2, 3]. Changes in the technique and materials used in slings have been described by different authors, but the popularization of this concept was achieved by Umsted & Petros in the late 20th century and was later modified by Delorme at the beginning of the 21st century [1, 2, 4].

Currently, retropubic and transobturator prefabricated slings with type 1, polypropylene synthetic fabric are the available option in the market. However, due to high cost, their use becomes difficult in public hospitals working with limited financial resources [2, 5, 6]. This situation encouraged studies on low-cost alternatives that could

allow for applying the sling concept for the treatment of SUI patients in the public system.

The option found in some patient-care facilities was the manual manufacturing of a synthetic loop, 1.0 to 1.5 cm wide and 20 to 30 cm long, made of polypropylene fabrics developed to be used in the abdominal wall (PROLENE®) measuring 20 x 20 cm or 30 x 30 cm, which, although being classified as type I, have different weight, elasticity and porosity than those developed for vaginal use [4, 6, 7, 8, 9].

In spite of good results with the use of the “handcrafted sling” described in medical literature, there are doubts as regards the tissue repair brought about by these fabrics, which, being type I, have different appearance and can thus induce inflammatory reactions and tissue repair of varying severity [3, 4, 5, 6, 7, 10].

The purpose of this research is to evaluate histological characteristics in tissue repair caused by type 1 polypropylene fabrics, by the same company, better developed for use in different sites (vagina and abdomen).

3. Materials and Methods

For this research, 18 large, 20-week-old, Wistar rats were used, divided into two groups, and receiving a 5 x 5 mm piece of polypropylene mesh implanted between two abdominal muscle layers. Group A received the Tension free vaginal tape (TVT®) fabric and Group B received the Prolene® fabric (table 1), being this material removed 100 days after its implantation.

Animal surgical manipulation and anesthesia followed the Ethical Committee’s standards in animal research.

Qualitative and quantitative studies on inflammatory response and tissue repair were conducted.

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The qualitative study evaluated the histological characteristics classifying an inflammatory process as acute, sub acute and chronic, according to Vizzotto [11].

The quantitative study was conducted by means of a morphometry on absolute volume and volumetric density of collagen fibers, aided by the M42 grid (Tonbridge™).

4. Results

In Group A, two animals died in the first week, while there were no deaths in Group B.

In the qualitative evaluation in both groups, inflammatory reaction was classified as subacute ($P=0.1044$). Nevertheless, when analyzing isolated characteristics of the inflammatory process (figure 1), it was observed that vascular congestion ($p=0.0376$), monomorphonuclear infiltration ($p=0.0449$) and granulation tissue ($p=0.0008$) were more severe in Group B (Table 2).

Morphometry revealed a significant accumulation ($p=0.0010$) of collagen fibers in Group B (figure 2), which received a Prolene® fabric implant (Table 3).

5. Discussion

Repairing defects in anatomical supporting structures, whether congenital or acquired, is the focus of several surgical techniques, and using synthetic materials, with mesh implants, to improve the result of these treatments has been a research goal since the 19th century [12, 13, 14]. The use of these materials helps to reinforce supporting anatomical structures without creating tension in suture lines, which could increase the risk of treatment failure [5, 13, 15].

Using autologous or heterologous absorbable biologic components, like porcine small intestinal submucosa, has been associated with a low degree of inflammatory reaction and adhesiveness in abdominal viscera [15]. However, synthetic materials such as polypropylene and extended polytetrafluoroethylene (PTFE) are advantageous since they are easily obtained and have a high degree of neovascularization and fibroblastic response, ensuring higher implant incorporation and fixation [3, 16].

Polypropylene is the material with the best characteristics for the repair of supporting defects resulting from injuries or functional loss of anatomical structures [17, 18, 19, 20]. Absorbable materials, such as bovine pericardium and porcine small intestinal submucosa, and non-absorbable materials, such as PTFE, did not show outcomes similar to polypropylene [19, 20].

Different types of materials, autologous or heterologous, have been used to treat SUI, showing similar success rates, but with varying risks and costs [1, 3, 21, 22].

The variation between performances of two different types of fabrics is directly related to the characteristics of their constituent materials: Thickness of the mesh used, pore

size, type of weaving and material resistance. The combination of mechanical characteristics is extremely important for success rates of the procedure performed [22, 23].

Structurally, polypropylene fabrics are classified according to the number of constituent filaments and pore size. They can be monofilament or multifilament and have macropores (bigger than 75 microns) or micropores (smaller than 10 microns) [15, 22, 24].

Histological changes such as differential collagen remodeling, inflammation and local edema may contribute to anti-incontinence mechanisms. Studies show that the factor with higher impact in inflammatory reaction and fibroplasy caused by polypropylene fabric seems to be pore size. [1, 5, 9, 10, 22, 25, 26].

Nevertheless, the question to be made is up to what extent severe inflammatory reaction is an ally to the surgeon, since the presence of low quantities seems to be associated with a higher risk of relapse of the disease to be treated [18, 19, 20, 22, 26, 27].

In this assay, qualitative evaluation showed that predominance of characteristics in the chronic phase of the inflammatory process, such as the presence of granulation tissue and monomorphonuclear infiltration, was more evident in animals implanted with a polypropylene fabric of higher weight (Prolene®), thus recommending its use for the abdominal wall. Vascular congestion, characteristic of this acute phase, was also predominant in this group, although it could have been influenced by the fact that animals were not transfused before material removal, even when there was bias present in both groups.

Predominance of granulation tissue and monomorphonuclear infiltration draws attention to a tendency of an inflammatory process chronification, occurring earlier than in animals implanted with TVT®. This must be carefully interpreted since there are no guarantees that integration of adjacent tissues will occur within acceptable limits. It is important to mention that this situation occurred between two muscle layers which are more resistant tissues than urethra and vaginal mucosa.

The higher quantity of collagen deposit induced by Prolene® fabric compared to TVT® is a reason for concern as this could mean a higher proneness to encapsulate, although this aspect has not been identified in this study.

These aspects indicate that fabrics, although considered type 1, do not induce the same inflammatory reactions.

This study was conducted on laboratory animals (mice) so it is appropriate to transfer its outcomes to humans, but it is known that the induced scarring repair is not the same and, hence, it is not cautious to state that similar clinical outcomes can be expected with both fabrics. The use of one fabric for another purpose, other than the one recommended by its manufacturing company, only in the abdomen and not in other areas, like the vagina, can be

considered an “out-of-label” use, with the risk of potential complications under the responsibility of the physician taking such decision.

Taking this situation into account, prospective and randomized clinical studies could help clarify this issue and also determine greater protection measures for physicians practicing in public hospitals and using this treatment for stress urinary incontinence.

Under this experiment conditions, the fabrics evaluated caused an inflammatory reaction with different isolated characteristics which, however, were not enough to change the final classification of the inflammatory process.

The fabric developed for use in the abdominal wall caused an inflammatory reaction with an increased tendency to chronification and an increased deposit of collagen fibers compared to the fabric developed for vaginal use.

Conflict of Interests

We have no conflict of interest in this research.

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