EVALUATION OF THE BIOCOMPATIBILITY OF PROSTHETIC MATERIALS IN THE ABDOMINAL WALL SURGERY - EXPERIMENTAL STUDY -

SUMMARY. We have conducted an experimental study whose objective was the examination of the behaviour of intramuscularly and intraperitoneally implanted prosthetic mesh fragments in Wistar rats. Two types of prosthetic materials were used: Ultrapro and Prolene, which were implanted in two lots of rats. The observations were made during a period of 21 and 90 days respectively after implantation. At the above-mentioned intervals a part of the animals of each lot were euthanized and the state of the implant, its relationship with the host tissue and the histological modifications were evaluated. The observations made during the entire period of the research showed a good tolerance of the animals subjected to the experiment to the implanted materials; no modifications at the implantation place or rejection or supra-infection were found. The histological examination made after 21 days at the level of both the muscular implant area (thigh musculature) and the peritoneum showed a proliferation of conjunctive tissue which wrapped each of the mesh threads, between which developed newly-formed capillaries, fibroblastic type cells, lymphocytes, hysteocytes, macrophages and giant cells of foreign body type. 90 days after the implantation, the histological modifications were basically the same, with a more intense development of the fibrous component and the presence of a phagocytizing process of the implanted material.

It results from the study that the biomaterials used as intramuscular and intraperitoneal implants were well tolerated and integrated by the tissues of the animals used in the experiment and can be used in the treatment of the parietal abdominal defects.

Key words: abdominal wall surgery, synthetic prosthetic materials, biocompatibility

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INTRODUCTION

In the past few decades the use of prosthetic materials in the treatment of hernias has produced an important amount of publications. The clinical and experimental studies offered the opportunity to obtain interesting data about the characteristics of the prosthetic materials implanted in the organism, but without reaching a generally valid concept regarding the issue of the relationship between these materials and the host organism. The study of the compatibility between a synthetic material and the host organism has imposed the introduction of the notions of biomaterials and biocompatibility.

In order to study the biocompatibility aptitudes of the synthetic meshes used in the surgical reinforcement of the abdominal wall we have conducted an experimental study whose objective was to study the behaviour of fragments of intramuscularly and intraperitoneally implanted prosthetic meshes on Wistar rats.

MATERIALS AND METHODS

The tested medical device (mesh) was represented by fragments of two variants of mesh:

- variant I – ULTRAPRO (Monovigl - prolene-composite, Polyglecapon 25 / Polypropylene);
- variant II: PROLENE (Polypropylene Knitted Non-absorbable)

During the experiment the configuration of the two medical devices will represent test I and test II.

Macroscopically, there are no manifest differences between the two materials. The only differences consisted in the size and shape of the mesh loop, the thread thickness and colour.

The two materials were implanted in lots of Wistar rats, 150 – 180 g adult males, each lot comprising 5 individuals. Two lots were constituted for each material, test I and test II. The materials were intramuscularly implanted deep in the thigh muscle, on the internal part, and intraperitoneal. After the introduction of the material fragments in the above-mentioned areas, the surgical wound was closed by suture with non-absorbable thread. Then the animals were kept under close observation to watch the postoperative evolution and the healing process of the wound. The post-implantation observations were carried on for 21 and 90 days respectively.

After 21 days two animals of each lot were euthanized and the tissues in contact with the implants were examined both macroscopically and histologically. The histological examination was made on fragments of muscular tissue, parietal and visceral peritoneum in the contact area with the implanted material. The tissues were processed through the classical histological method: fixation in formalin, introduction in paraffin, sectioning at 5 – 7 mm and colouring with eosin haemotoxiline.

90 days after the implantation the other animals of each lot were examined, the objectives of the evaluation being the same: the state of the implant, its relationship with the host tissues and the histological modifications produced.

RESULTS

After the intramuscular and intraperitoneal implantation, the surgical wounds on the thigh and in the abdominal wall healed without complications in approximately 5 – 7 days. 21 days after the surgery the wound which served to introduce the implanted mesh fragments was cicatrized per primam, practically having the aspect of a white line.

The implanted materials in both test I and test II did not influence the general state of the animals in the experiment, these quickly and easily overcoming the postoperative period. During the entire period of observation, in the first 21 days the animals in all the lots did not show modifications at the implantation place or rejection or supra-infection phenomena.

The examination after 21 days of the tissues in contact with the two implanted prosthetic materials, on a part of the animals subjected to the experiment revealed the following:

- The intraperitoneal introduction of the two types of mesh caused a reaction of both the parietal peritoneal serosa and the epiploon. The material fragments were embedded by fibro-conjunctive proliferation which fixed them to either the peritoneal serosa or in the epiploon mass by limited adherence areas.
- At the level of the thigh muscular tissue where the two materials were inserted, after 21 days a local reaction of the intermuscular (interstitial) conjunctive tissue was observed, which embedded, as in the case of the peritoneum, the implanted material fragments and fixed them between the muscular fascia.

The histological examination of both the muscular area and the peritoneum reveals the following aspects:
- In the thigh musculature, in both tests, the presence of material fragments caused a proliferation of the inter-fascicular conjunctive tissue 21 days after implantation, which separately wrapped each thread in circular fibres between which newly-formed capillaries developed, and a mobilization of cells where numerous fibroblasts, lymphocytes, hysteocytes, macrophages, and even giant cells of foreigner body could be observed.

- Just as in the intermuscular conjunctive space, the introduction of mesh fragments in the peritoneal cavity stimulated a similar reaction of proliferation and organization of newly-formed tissue which wrapped the mesh threads, organizing the same granular reaction around them.

90 days after the implantation we evaluated the clinical examination and the potential modifications present in the implantation area at the animals which were not euthanized after 21 days. After euthanasia we examined the modifications appeared in the contact area between the implanted material and the host tissue. The local modifications were macroscopically and microscopically evaluated.

The general state of the subjects was normal during the entire period of the experiment. The anatomical areas where the implantation was made did not show modifications in volume, abnormal sensitivity or mobility troubles. The implants in test I and II were completely integrated by fibro-conjunctive proliferation, but with a much higher intensity then after 21 days.

The histological examination of the tissue developed in the contact area with the implant material showed, at both intermuscular and intraperitoneal level, the same proliferating reaction of a newly-formed tissue rich in macrophage monocytes, fibroblasts, newly-formed capillaries and giant cells, just as after 21 days, with the difference that the fibrous component showed a greater development and the phagocytizing process of the implanted material was more advanced.

**CONCLUSIONS**

Neither variant of mesh evaluated after implantation in the two established anatomical areas (intramuscular, intraperitoneal) showed acute rejection effects, both were well integrated and did not influence the healing process of the surgical wounds.

In both tests the presence of the implantation material locally caused a fibro-conjunctive proliferation of newly-formed tissue composed of collagen fibres, newly-formed capillaries, fibroblasts, macrophage monocytes and giant cells of foreigner body.

The conjunctive tissue developed around the mesh fragments wraps and fixes the implanted material on all the surfaces.

Around the threads of the implanted material granuloma of foreign body are structured, which slowly phagocytize it.

It results from the study that the biomaterials used as intramuscular and intraperitoneal implants fall into the category of bio-tolerant materials and can be used in the treatment of parietal abdominal defects.

**REFERENCES**