

COMBI MESH PLUS

THE NEW ANGIOLOGICA POLYPROPYLENE MESH WITH A SPECIAL POLYURETHANE TREATMENT

Tensile strength combined with anti-adhesion property

The new Combi Mesh Plus prosthesis is the result of the latest ANGIOLOGICA technical developments in the field of biomaterials used in the surgical repair of abdominal wall defects.

The Combi Mesh Plus is a monofilament polypropylene mesh with a special polyurethane treatment on one of its surfaces.

The polyurethane surface, when placed in contact with the peritoneal cavity, has demonstrated a clear advantage in reducing the formation of intestinal adhesions with the polypropylene mesh.

Besides this, the new type of integration of the PU with the PP mesh (an ANGIOLOGICA patent), eliminates every possibility of detachment of the PU layer from the PP base.

Due to its polyurethane surface, the Combi Mesh Plus combines all the features of the classical ANGIOLOGICA polypropylene meshes with a unique ability to reduce adhesion formation.

The Combi Mesh Plus is especially indicated for all types of ventral hernias or when treating large abdominal wall defects. In addition, it can be particularly useful when a direct closure of the abdomen can be difficult or dangerous, as in re-operations, or obese patients, or chronic obstructive pulmonary disease patients.

To facilitate the identification of the polypropylene layer, a coloured polypropylene thread has been loosely inserted on the polypropylene layer of the Combi Mesh Plus. This can be easily pulled out once the prosthesis has been inserted.

PRECLINICAL STUDY

RATIONAL

Prosthetic material is commonly used in the repair of hernias or other defects of the abdominal wall. Having to replace a defect in the abdominal wall, the inner part of the prosthetic material is often found in contact to the viscera of the peritoneal cavity and this can cause tenacious adhesions between the intestinal ansae and the prosthetic material. The migration or the infection of the prosthesis are other complications that can be noticed with this type of repair. The prosthesis currently in commerce are generally built in form of mesh and made of biocompatible materials. The most commonly used materials are polypropylene and PTFE.

Various studies have shown that both of these materials have a good parietal incorporation and reduce the risk of hernia recurrence, nevertheless none of these materials seems to protect completely from the risk of adhesions between the prosthesis and the intestinal ansae.

The search of new prosthetic materials or new types of coating is therefore important in order to improve the results currently reached in the treatment of the hernias and especially of the big defects of the abdominal wall or incisional hernias, where often it is not possible to interpose the parietal peritoneum between the prosthetic material and the peritoneal cavity.

OBJECTIVES

Several experimental studies made by ANGIOLOGICA B.M. Srl have shown that an inner coating of laminar polyurethane (PU) applied to the internal surface of a polypropylene mesh (PP) can reduce the number of tenacious adhesions between the intestinal ansae and the prosthetic material.

The present study wants to examine the behaviour of a new composite mesh built by spraying a very thin layer of polyurethane (PU) to the internal surface of a polypropylene mesh (PP) and to verify if this latest generation mesh is able to:

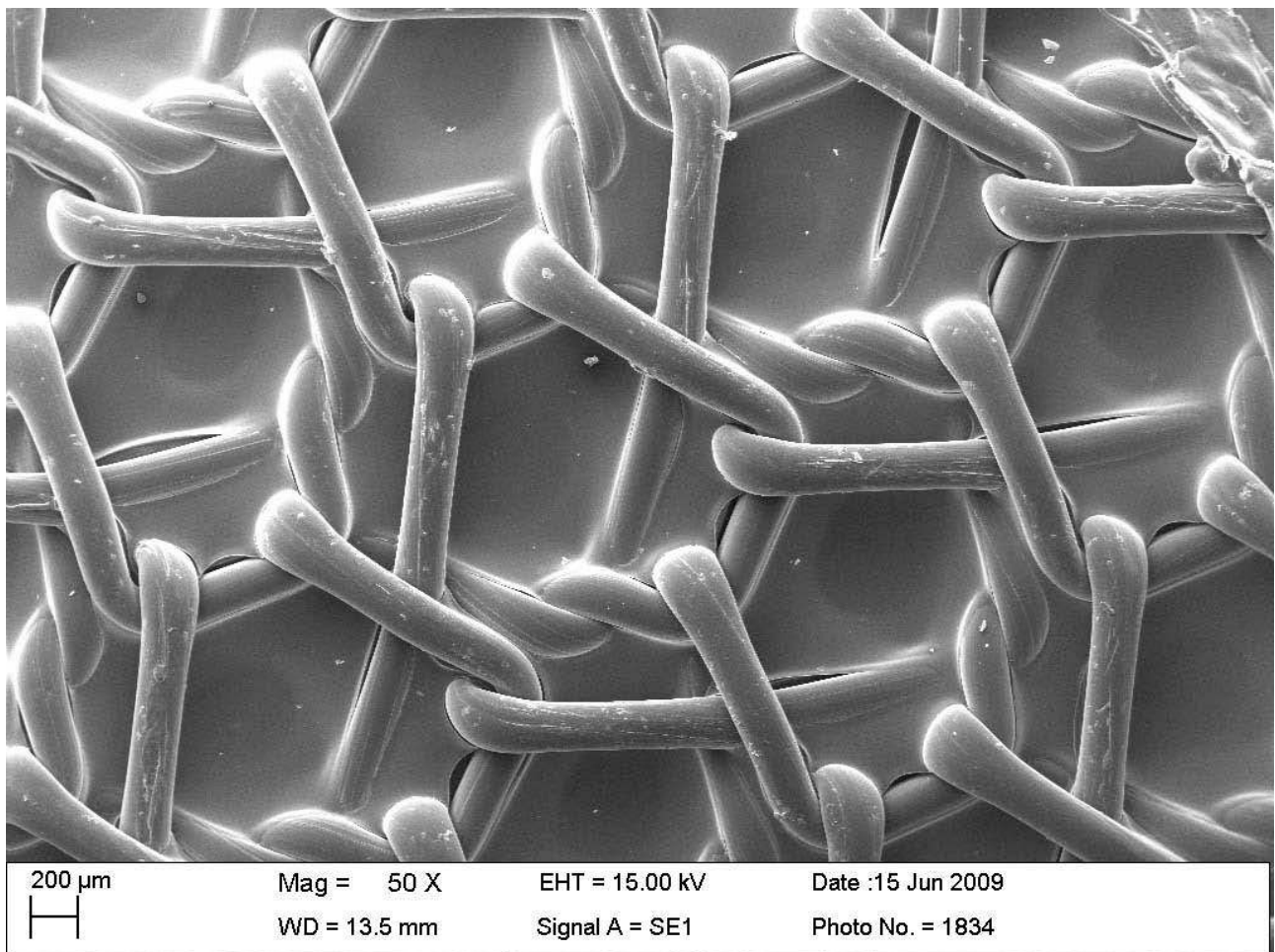
- Reduce the risk of adhesions between the prosthesis and the intestinal ansae
- Reduce the risk of formation of seroma
- Develop a good degree of incorporation with the extraperitoneal tissues.
- Be resistant to infection and degradation

MATERIALS AND METHODS

For the study rabbits NZW of 3 kilos have been used. The used model has been the total substitution of the abdominal wall in which the prosthetic material is directly set in contact with the peritoneal cavity.

Such model is more unfavourable compared to the one of partial substitution in which the prosthetic material is covered by parietal peritoneum.

The meshes have been explanted at 15 and 30 days. These two time-points have been demonstrated effective during previous studies in order to verify the behaviour of the prosthetic implant.

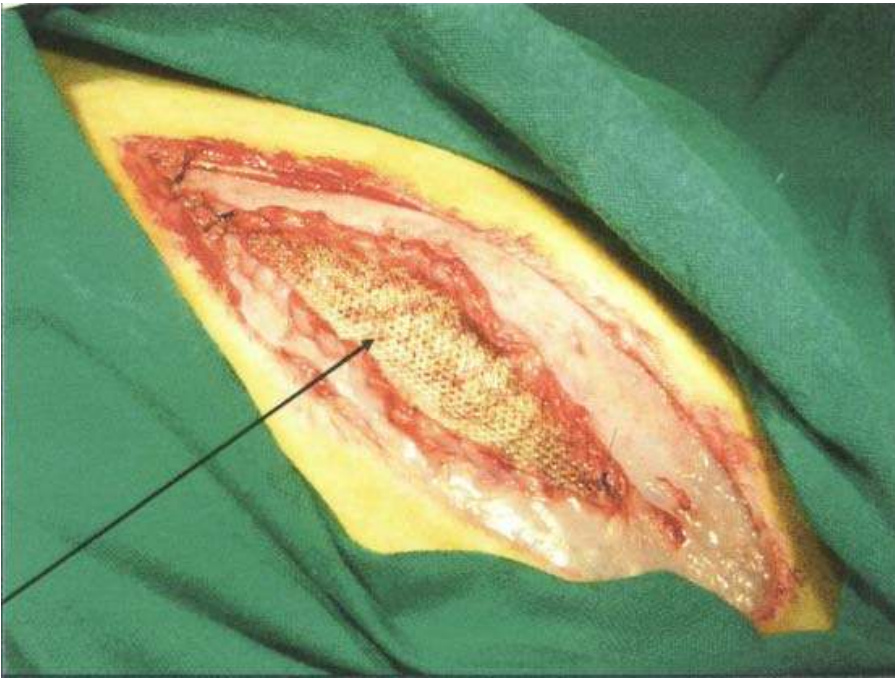


RESULTS

IMPLANT

The Combi Mesh Plus were very easy to model and manage during the implant, so that it was very easy to suture them to the abdominal wall. The PU side is smoother than the PP side, and the blue suture is facilitating the identification of the two sides. The mesh is easily adapted to the surrounding tissues (**images 1 – 2**).

(images 1 – 2).



Total implant – the prosthesis is perfectly adapted to the parietal defect

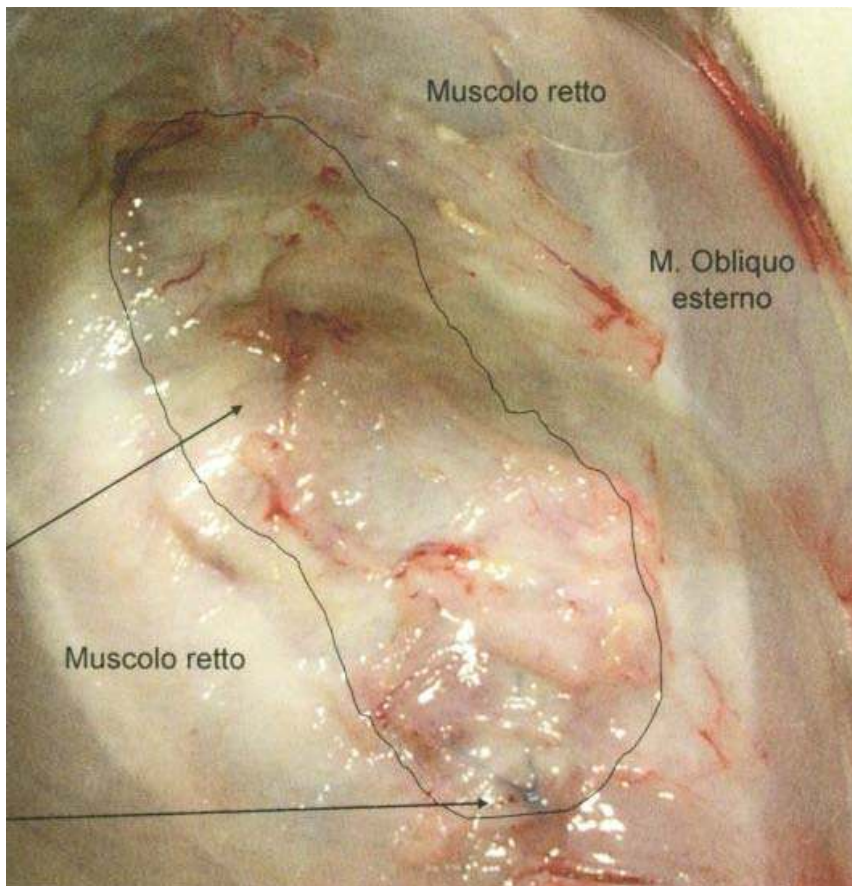


Close-up view

EXTERNAL WALL

The Combi Mesh Plus is perfectly incorporated with the abdominal wall muscles and with the subcutaneous tissue, at 15 and 30 days.

The incorporation is characterized by a complete coating of fibrous tissue which represents a neo-fascia identical to the muscular one. This surface is well vascularised and the mesh is recognizable only because of a border between the edge of the mesh and the surrounding tissues (**image 3**)



(**image 3**)

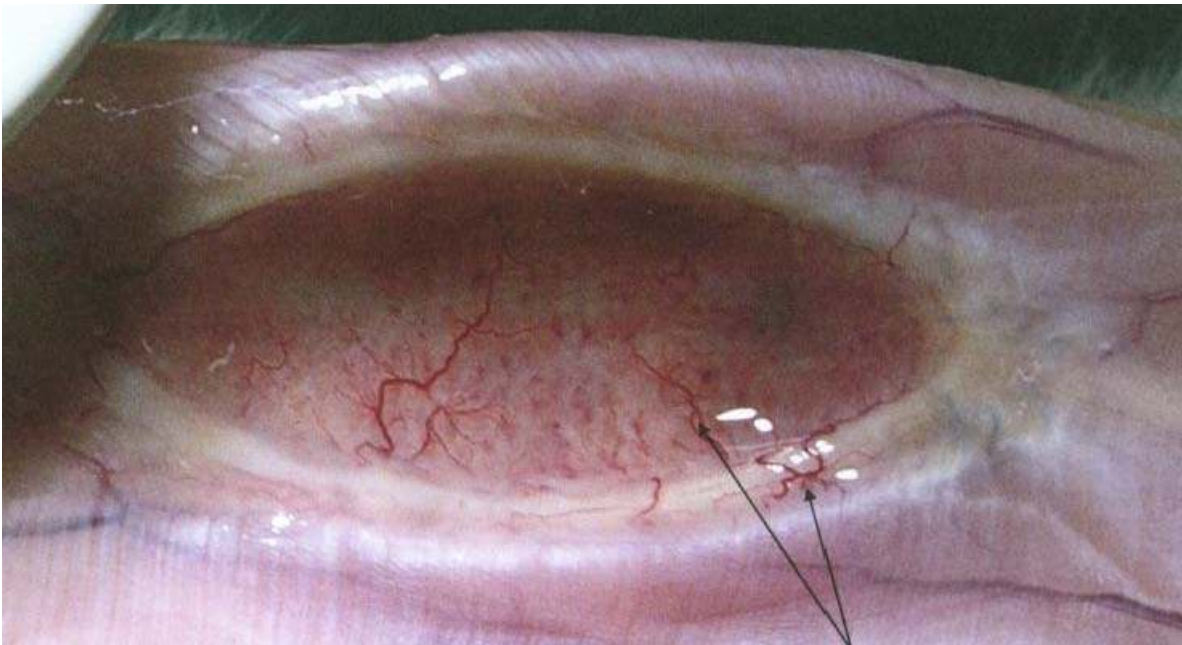
In no case we have observed the presence of infection or detachment of the prosthesis.

We can conclude that the secondary repairing process of the implant of the Angiologica composite mesh in its external component in PP is characterized by a fast incorporation and by the formation of a fibrous neo-fascia similar to the natural one.

INTERNAL WALL

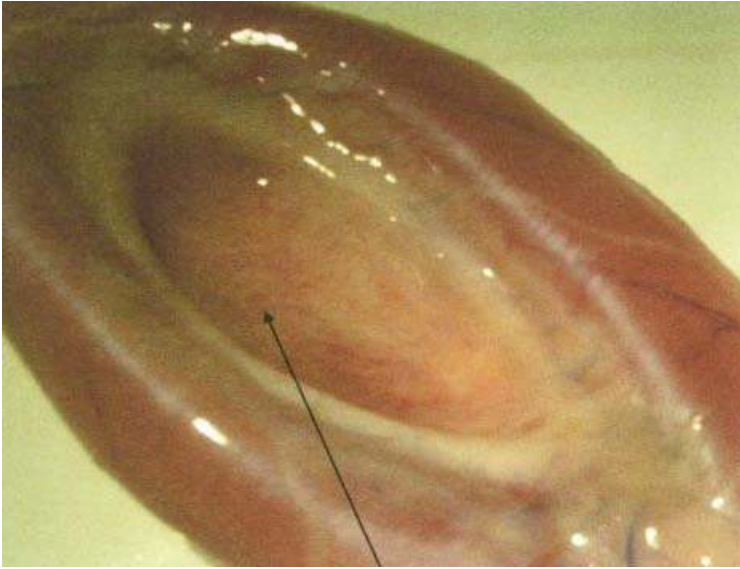
The biological implant response of the inside surface (PU) of the Angiologica composite mesh (PP-PU) has been evaluated at the same time-points and in the same animals in which we have studied the implant response of the external surface.

The mesh has shown an excellent biocompatibility at 2 and 4 weeks as demonstrated by a fast neo-peritonealisation characterized by the presence of neo-angiogenesis from the edges of the mesh and by the vascularised neo-peritoneum. (**images 4- 5-6**).

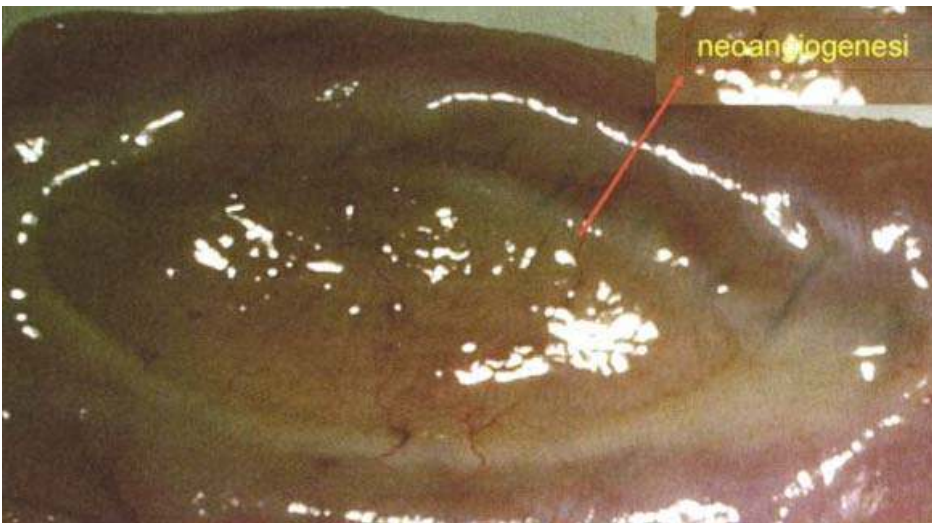


(image 4)

Neo-angiogenesis and neo-peritoneum



(image 5) Complete neo-peritoneum,
vascularised, no adhesions



(image 6) Complete neo-peritoneum, vascularised, no adhesions