



## Effectiveness and properties of the biological prosthesis Permacol™ in pediatric surgery: A large single center experience



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### H I G H L I G H T S

- Use of biological prosthesis is well known for the treatment of complicated abdominal defects in adults surgery but not in pediatric surgery.
- We analyzed the largest case series present in the literature in pediatric surgery.
- Looking at our results the use of Permacol™ seems to be safe and feasible in pediatric complicated abdominal wall closure.

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### A B S T R A C T

**Introduction:** The use of prosthetic patches of non-absorbable materials represents a valid tool in the treatment of abdominal wall and diaphragmatic defects in pediatric age. In recent years research has developed biological dermal scaffolds made from a sheet of acellular matrix that can provide the desired support and reduce the occurrence of complications from non-absorbable implant. We present our experience and a systematic review to evaluate the use of biologic prosthesis for abdominal wall closure in pediatric patients.

**Methods:** The study from January 2009 to January 2015 involved 20 patients treated with Permacol™ implant. We observed postoperative complications only in patients treated for abdominal wall closure, which is the major indication for the use of Permacol™. We conducted a systematic review and meta-analysis (according to PRISMA) on PubMed/Medline, Scopus and EMBASE regarding the use of biological prosthesis in pediatric population considering the incidence of complications as the primary outcome.

**Results:** 3/20 patients experienced complications: 2 patients with skin necrosis healed conservatively and 1 of them developed laparocoele. Thus only 1 patient with incisional hernia had significant surgery complication. In patients who were permanently implanted with Permacol™ it has not determined adverse reactions with optimal functional outcome.

**Conclusions:** In accordance with the few data (case reports and case series) reported in literature about pediatric patients, our experience in different pathologies and applications has shown the effectiveness of Permacol™, in particular for the non-occurrence of infections, that often affect the use of prosthesis.

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### 1. Introduction

Abdominal wall defects (giant omphalocele and gastroschisis) and diaphragmatic hernia repair has historically seen the use of

prosthetic patches of non-absorbable materials (Dacron, Polypropylene, Goretex, Goretex dual mesh with antibiotic) which represented a valid solution. However, they are not integrated in the surrounding tissues and can be a source of infection and complications in the medium–long term [1–3]. In the newborn, particularly in case of abdominal wall defects, the prosthesis is usually covered with very thin skin flaps, with poor representation of the subcutaneous tissue, increasing the risk of skin necrosis,

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infection and recurrence of the defect. The case studies, referring to such rare diseases, are numerically limited and there are no prospective randomized trials that allow a comparative analysis of the results. Research in recent years has developed biological dermal scaffolds made from a sheet of acellular matrix that can provide the desired support and reduce the occurrence of complications from non-absorbable implant (Permacol, Alloderm, Surgisis). Since 2001 Permacol™ Biological Implant has been successfully used in some pediatric and neonatal surgical cases, in particular to repair abdominal wall defects and congenital diaphragmatic hernia [4–7]. It is a sterile acellular sheet derived from porcine dermal collagen, indicated for reconstruction, recontouring and reformation of human soft connective tissue particularly where loss of dermis has occurred, and as a supporting tissue in surgical procedures such as abdominal wall hernias and defects. Permacol™ Biological implant is crosslinked for durability and has a low adhesion profile. The main benefits include strength, biocompatibility and incorporation into the host tissue with associated cell and microvascular ingrowth and with no evidence of sensation, irritation or hypersensitivity reaction [8]. At our Institution Buzzi Children's Hospital we have been using Permacol™ Biological implant from 2009, treating a vast series of patients if compared to the literature published to date. We present our experience on the use of biologic prosthesis for abdominal wall closure in pediatric patients trying to define the safety of biological prosthesis in this population. We also report the results of a systematic review performed to give a meta-analytic pooled estimate of the rate of complications, to assess the safety of the procedure.

## 2. Methods

The study (from January 2009 to January 2015) involved 20 patients treated with Permacol™. Main characteristics of the population analyzed are reported in Table 1. The patients were affected by the following pathologies: 6 giant omphaloceles (1 after abdominal repair with Goretex mesh); 4 gastroschisis (1 associated with colonic aganglionosis); 1 hypoplastic abdominal wall in congenital diaphragmatic hernia (CDH); 1 abdominal wall defect after multiple laparotomies for necrotising enterocolitis (NEC); 4 CDH: 2 late presentations (1 right, associated with pulmonary sequestration and 1 left + Morgagni-Larrey) and 2 recurrences after Goretex implant; 2 cloacal extrophies; 2 bladder neck incontinence, 1 in cloacal extrophy, and 1 in complex uropathies. 9 patients were males and 11 females. The age ranged between 1 day and 9 years. 10 patients were newborns, 6 infants (1 omphalocele after abdominal repair with Goretex mesh, 1 cloacal extrophy, 1 abdominal wall defect after multiple laparotomies for NEC, 2 late presentation of diaphragmatic hernia, 1 recurrence of left diaphragmatic hernia), 4 children (1 recurrence of left diaphragmatic hernia, 1 cloacal extrophy and 2 continent bladder reservoir). For surgical implant of Permacol™ we used large prosthesis (sizing from 5 × 5 cm to 10 × 15 cm). The thickness chosen was 1 mm for all cases. For abdominal wall closure, in cases of omphalocele, gastroschisis, abdominal hypoplasia, and cloacal extrophy, Permacol™ were fixed on the fascia with monofilament synthetic absorbable interrupted stitches (Glycolide-Trimethylene Carbonate 4/0). Sliding skin flaps were necessary to cover the prosthesis in 5 patients (2 giant

omphaloceles, 2 gastroschisis, 1 abdominoplasty in CDH, and 1 cloacal extrophy). (Fig. 1). One case of omphalocele with a large defect was repaired using two prosthesis of Permacol™ of 10 cm each in parallel. As in the previous cases implants were fixed using single stitches of monofilament synthetic absorbable suture (Glycolide-Trimethylene Carbonate 4/0). The Prosthesis was then covered creating wide skin flaps. For diaphragmatic repair we fixed Permacol™ on the edge of the diaphragmatic defect with monofilament synthetic non-absorbable interrupted stitches (Polypropylene 3–4/0). (Fig. 2). In two patients who required the creation of a continent bladder reservoir Permacol was placed to protect the bladder neck closure. Follow-up ranged from 6 months to 6 years (median follow-up time: 20 months). The systematic review of the literature was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) the search was applied in Medline (considering all years), and in Embase (considering all years). Search terms were as follows: “Abdominal biological prosthesis”; “Congenital abdominal wall defect AND biological prosthesis”; “Abdominal wall closure AND pediatric transplant”; “Permacol AND pediatric”; “Alloderm AND pediatric”; “Surgisis AND pediatric”. The Eligibility criteria for the meta-analysis are shown in the Table 1. Statistical analysis: Pooled estimates of complication rates were computed together with their 95% confidence intervals using a fixed effect model using Stata 14 (Stata Corp, College Station, TX, USA).

## 3. Results

We did not experienced any intraoperative challenges related with Permacol™ implant, the surgical procedure for the correction of the abdominal defects is standardized and is the same technical procedures applied to the non biological prosthesis. Follow-up, ranging from 6 months to 6 years (median follow-up time: 20 months), showed no infections related to the system of Permacol in any case. Three patients (1 gastroschisis; 1 abdominoplasty in CDH, and 1 cloacal extrophy) presented an ischemic necrosis with partial dehiscence of the skin overlying the implant, resulting in surfacing of the prosthesis (see Table 2). They were conservatively treated; the wound healed by secondary intention and removal of the prosthesis was not necessary. However, the patient with hypoplastic abdominal wall in CDH presented a laparocele. In patients with diaphragmatic hernia, there were no seromas or pleural effusions. After reaching an adequate development of the abdominal wall, patients with gastroschisis and omphalocele were subjected to removal of the prosthesis, at an age between 4 and 17 months (median 11 months), with good functional and cosmetic results. At the second operation in all patients the prosthesis appeared well integrated in the abdominal wall, not adherent to the viscera with the exception of 2 patients (outcomes of giant omphalocele) in which it was partially adherent to the liver. Histological examination showed prosthetic material coated with vascularized connective tissue and mild chronic inflammatory infiltrate, the presence of fragments of muscle tissue was also highlighted. 2/20 (10%) patients (gastro-esophageal reflux in giant omphalocele and incisional hernia in CDH) required implant of a second smaller prosthesis ( $\leq 5$  cm) to allow the closure of the abdominal wall without affecting hemodynamic and respiratory function. In

**Table 1**

Summary of the eligibility criteria for the review study.

|                       |   |
|-----------------------|---|
| Types of studies      | Clinical trials and/or observational studies including case series and case reports                             |
| Types of participants | Pediatric patients who had abdominal wall defects treated with biological prosthesis                            |
| Types of outcomes     | The main outcome was the incidence of surgical complication: infection; post incisional hernia; reintervention. |

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