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Construction of a stable nipple valve with processed dermal sheep collagen for continent ileostomy and urostomy*

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Summary. Complications of the nipple valve system used for continent urostomy and ileostomy basically consist of incomplete (or complete lack of) adhesion of the invaginated serosal surfaces of the valve. A novel concept in fixation of the valve by means of the intussusception of a newly developed biomaterial (processed dermal sheep collagen; PDSC) was tested. The implanted PDSC is characterized by induction of fibroblast invasion and formation of new collagen fibers, initial high tensile strength, bio-inertion and (slow) biodegradation. It was implanted between the serosal surfaces of the invagination in 14 dogs without the application of the commonly used staples and synthetic mesh. Good permanent fixation was obtained in all cases after the PDSC had been sutured in place. As the observation time advanced up to 2 years, an increased amount of newly formed collagen was seen anchoring the serosal surfaces firmly together via the implanted PDSC with apparent slow degradation. In none of the test animals did complications accur. The first clinical trial was successful.

Key words: Collagen – PDSC – Continent ileostomy – Continent urostomy

The Kock operation combining continent ileostomy and urostomy has greatly improved the quality of life for hundreds of patients [3, 5]. Continent ileostomy, if successful, obviates the need for external appliances. Although the method has been modified several times, especially at the site of the nipple valve system, complications are still seen with this valve.

In the usual procedure used in constructing the valve, close attention is paid to maintaining the integrity of the shape of the valve and therefore its function. This is currently done by:

1. Scoring the serosa by electrocautery
2. Fixing the invagination with four rows of staples
3. (Sometimes, in addition to staples) implanting a synthetic mesh (Marlex, Mersilene or Prolene at the base of the invagination.

These measures have lowered the complication rate but do not exclude the chance of disinvagination [2, 4].

The main problem is still non-adhesion of the serosal surfaces of the nipple, which causes slippage of the valve and subsequent loss of function. The precautions used so far to prevent slippage (stapled fixation and application of synthetic mesh) can themselves cause secondary complications: immediate ischemia of the bowel wall or non-lasting fixation because of migrating staples. Fistulation can occur when synthetic mesh is used.

The aim of our investigation was to induce serosal adhesion in the nipple and to test the feasibility of initial fixation without the use of staples and synthetic mesh.

Materials and methods

Processed dermal sheep collagen

The biomaterial known as processed dermal sheep collagen (PDSC) [1] consists of the split skin of sheep treated with pretanning procedures such as are used in the production of chamois leather followed by tanning in a glutaraldehyde (0.625%) solution. The gamma-sterilized collagen fibers matrix thus obtained has great tensile strength comparable to that of industrially processed chamois leather.

Previous research [1] has shown the following features: (a) induction of fibroblast invasion, which produces new collagen fibers in the implanted material, without the presence of inflammatory cells; (b) biodegradability, so that the material is resorbed after a time depending on the degree of tanning, the method of sterilization, and the species in which it is implanted; and (c) biocompatibility, which means no immunologic reaction is observed.

In the present study PDSC was implanted as an intermediate between the two serosal layers of the invagination.

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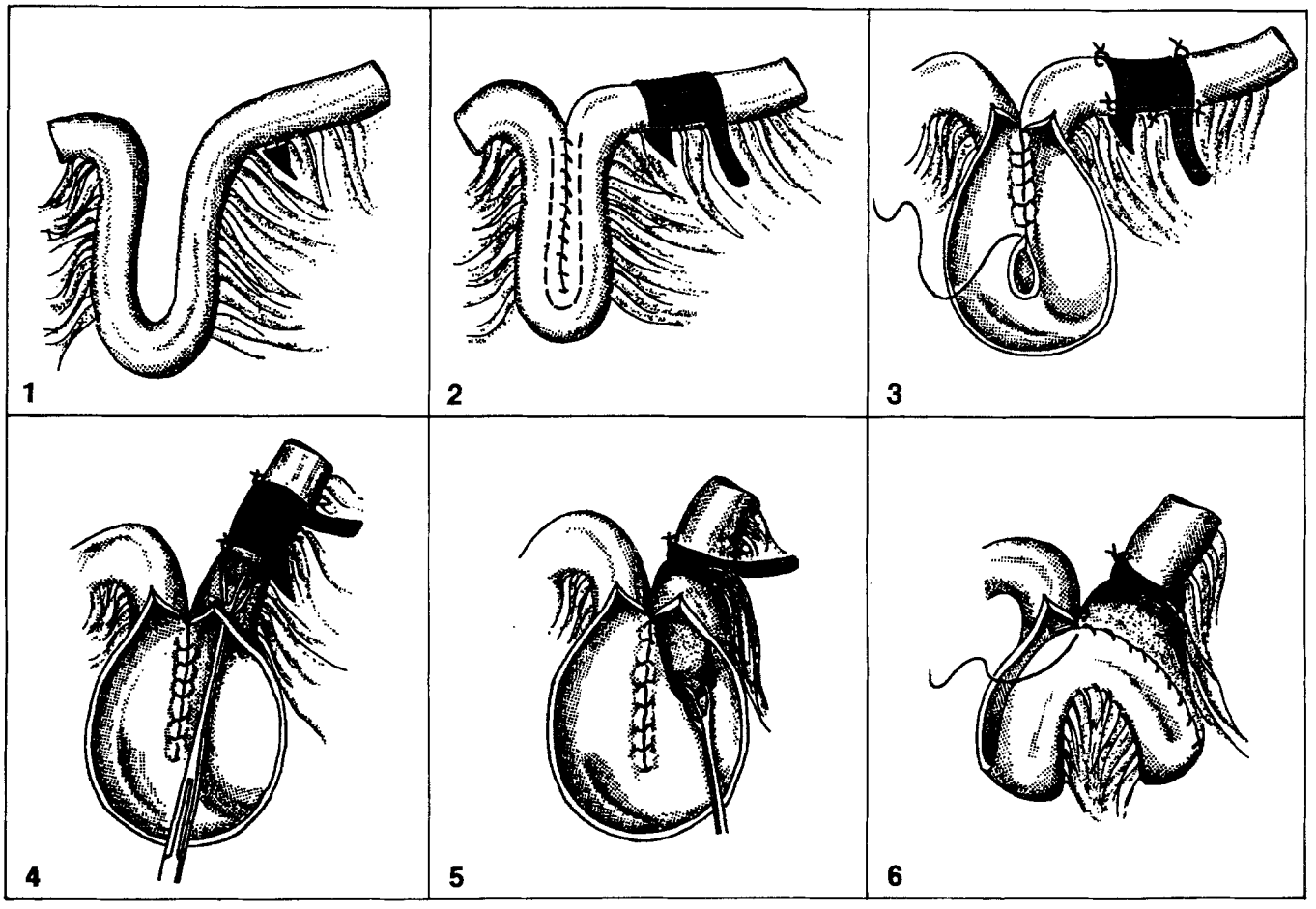

Fig. 1. U-folded ileal segment

Fig. 2. Attachment of the PDSC and suturing both limbs together

Fig. 3. Opening of the U-folded ileal segment

Fig. 4. Invagination of the ileum into the reservoir

Fig. 5. Completion of the invagination

Fig. 6. Closure of the pouch

Methods

The experiments were performed in 14 mongrel dogs (mean weight 25 kg). All dogs were anesthetized with 0.5–1.0 g/kg thiopental i. v. as an induction and then received halothane after intubation.

During the intervention, saline Flagyl and Eusaprim were administered i. v. This was repeated on the first day after the operation and after the second day normal feeding was resumed. The operations were performed under usual sterile conditions. At pre-assessed times the dogs were sacrificed and samples were taken for histological investigation and micro-angiography.

Operation technique. The operation started with a normal midline laparotomy. The colon was transected from the ileum with the aid of the GIA stapling instrument. The terminal ileum was measured and folded into a U shape as indicated in Fig. 1.

Firstly, the bowel distal to the folded segment was prepared by making a hole in the mesentery at the site of the valve to be constructed. Then the PDSC was shaped and sutured with interrupted sutures (Dexon 3-0) around the distal half of the future valve, as shown in Fig. 2. As shown in Fig. 2, the material is brought proximally through the mesentery around the entire bowel. After fixation of the PDSC, a sling of PDSC is left which will be used after the intussusception is completed.

The pouch is constructed by suturing both limbs together with continuous Dexon 3-0 sutures. Then the bowel is opened and the limb with the PDSC distal to the pouch to be constructed is invaginated into the pouch (Fig. 3–5). After the invagination, the valve is secured by six interrupted sutures (Dexon 3-0 circumferentially at the top of the valve through both seromuscular layers and the PDSC in between. To prevent disinvagination of the valve, a sling of PDSC is brought through the mesentery at the top of the nipple and sutured to the PDSC at the opposite side.

After this procedure the pouch is closed (Fig. 6) and the outlet is brought through the right side of the abdominal wall and a flat stoma is constructed about 1.5 cm protruding above the abdominal skin.

The PDSC of the nipple is sutured to the abdominal fascia with interrupted sutures (Dexon 3-0), followed by fixation of the pouch to the abdominal wall. The intervention is finished by closure of the abdominal wall.

Results

All dogs recovered from the operation and were observed for various periods up to 2.5 years. All animals were continent for stools and gas, and catheterization was easy

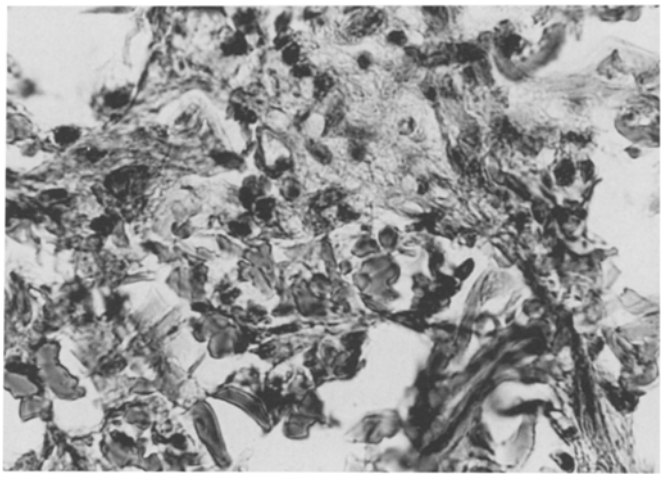

Fig. 7. Invasion of fibroblasts in the PDSC matrix. (2 weeks postoperatively, HA-staining, 400×)

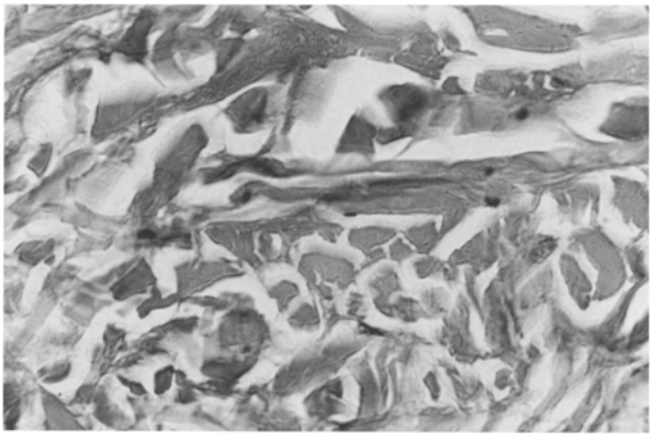

Fig. 8. Newly formed collagen fibers and (inactive) fibroblasts. (36 months post-operatively, HA-staining, 400×)

to perform. At post-mortem examination a good fixation of the invagination was present. The PDSC between the two serosal layers could only be separated by sharp dissection.

Histological examination of the graft showed fibroblasts between the collagen fibers of the PDSC and newly formed collagen fibers anchoring the serosal surfaces and the implanted PDSC (Fig. 7).

The longer the period of survival the more new collagen was seen, while at the same time the PDSC slowly degraded (Fig. 8). There were no signs of lymphocyte infiltration, and only a few macrophages were observed.

Micro-angiography showed distinct vascularization in the PDSC as early as 5 days after the operation.

Discussion and conclusion

The problem encountered in the fixation of the nipple valve in the continent ileostomy basically consists in the absence of permanent adhesion between the serosal surfaces in this invaginated valve. Staples and meshes alone, while mostly giving good initial fixation, never give permanent fixation. Moreover, these materials can cause additional complications. Permanent fixation only occurs when a proper amount of adhesion has been induced. In contrast to the haphazard induction of adhesion with the techniques used so far, the PDSC material consistently induces the desired adhesion by fibroblast reaction resulting in newly formed collagen. Additional advantages of the material are that it is bio-inert and has a high tensile strength.

All those characteristics fulfill the criteria that need to be met in the construction of a stable nipple valve without the disadvantages of the commonly used staple and mesh techniques, viz. good initial fixation of the nipple invagination and subsequently serosal adhesion.

The technique with PDSC was first successfully applied clinically in Amsterdam. Following our initial cooperation a successful study in a series of 70 patients has recently been reported by Noll and Schreiter [6].

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