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## ORIGINAL PAPER

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# Serous-lined extramural ileal valve as a new continent cutaneous urinary outlet: an experimental study in dogs

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Abstract A new technique for the construction of a cutaneous continent catheterizable outlet suitable for urinary reservoirs is presented. The technique entails the creation of an ileal reservoir outlet by implantation of a tapered ileal segment into a serous-lined extramural tunnel. The procedure was carried out in eight experimental dogs, and the results were compared with a control group of five dogs for which a nontunnelled tapered ileal outlet draining a similar reservoir was constructed. Clinical, radiological and urodynamic evaluation provided evidence that this new outlet is easily catheterizable. Its continence mechanism is more reliable than that of a simple tapered outlet.

**Key words** Continent diversion · Cutaneous stoma · Experimental

Construction of cutaneous continent urinary diversion requires the creation of a stable and reliable valve to maintain continence and which allows easy catheterization. Various intestinal sphincter designs have been proposed. Hinman classified continent outlets into four types according to their mechanism of action [15]: (a) antiperistaltic ileal segments [13]; (b) imbricated or tapered ileal segments resulting in passive tubular resistance [29]; (c) outlets using the pressure equilibration principle, including an ileal spout valve [3], flutter valve [4], inkwell hydraulic valve [6], intussusception nipple [17] or ileal servomechanism sphincter [18]; (d) flap valves, which are created by the incorporation of tubular structures within the wall of the reservoir such as the appendix [25]; fallopian tubes [31]; parts of

the ileum [32]; or tubularized cecal segments [19]. This multiplicity of techniques implies that none is optimal. Many of the above techniques rely on an inert and even unphysiologic mechanism, and problems and malfunctions soon appear. We report here on a new outlet technique suitable for a continent catheterizable urinary reservoir.

### **Materials and methods**

Experimental animals

Thirteen mongrel dogs weighing 20–25 kg were used for the experiment. The procedures were carried out with the animals under general anesthesia. Thiopental sodium (20 mg/kg) was used for induction and maintenence of anesthesia, with endotracheal intubation and mechanical ventilation.

Experimental groups and operative procedures

Group I: (tapered and tunnelled ileal outlet)

This group comprised eight dogs. A 40-cm-long segment of the terminal ileum was isolated and the continuity of the bowel reestablished. The isolated bowel was divided into a 30-cm-long oral and a 10-cm-long caudal segment. The oral segment was turned into an S-configuration. A running seromuscular suture using 4/0 silk was used to join the two adjacent distal limbs together close to their mesenteric border (Fig. 1a). The intestine was then incised at its antimesenteric border by a diathermy knife. The result was the creation of two intestinal flaps joined at their base. The opened intestinal edges of the proximal limbs were approximated using 3/0 continuous polyglactin acid. The short caudal ileal segment was tailored around a 14F catheter at its proximal two-thirds (Fig. 1b). The tapered intestinal segment was inlaid into the prepared intestinal serous-lined trough, and its spatulated end was then anastomosed to the distal end of the intestinal tunnel using 4/0 polyglactin-interrupted sutures. The ileal flaps were then approximated in front of the buried segment, converting it into a serous-lined tunnel (Fig. 1c). The reservoir was then closed, leaving its lower aspect open. The latter was anastomosed to the opened bladder dome (Fig. 1d). The intact distal end of the tunnelled segment was brought out to a suitable site in the abdominal wall as a flush

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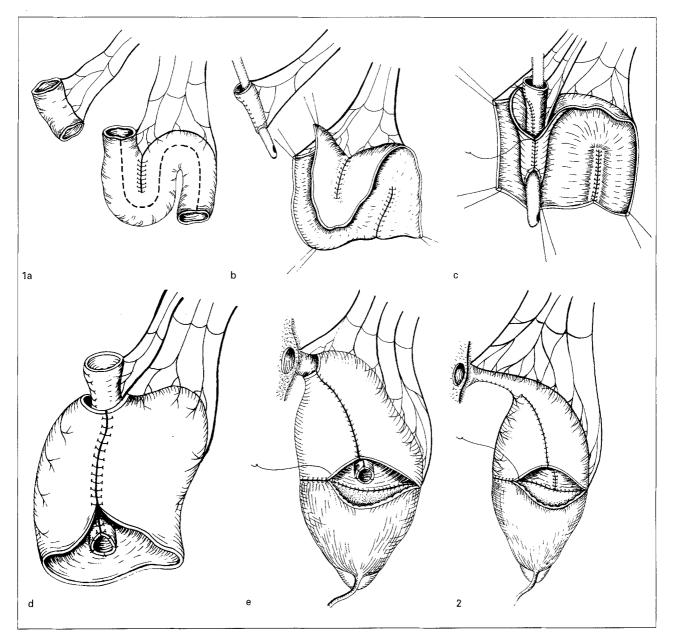


Fig. 1 a A 40-cm-long segment of the terminal ileum is isolated and divided into 30-cm oral and 10-cm caudal lengths. The oral segment is turned into an S-configuration. The distal two limbs are fixed together using 4/0 continuous seromuscular silk suture. b The antimesenteric border is incised creating a serous-lined ileal tunnel. The short caudal segment is tailored at its proximal two-thirds around a 14F catheter. c Implantation of the spatulated tailored segment within the ileal tunnel. d The anterior wall of the reservoir is closed

leaving the lower aspect open. e The opened reservoir is anastomosed to the opened bladder dome. The mouth of the tunnelled segment is brought out as flush cutaneous stoma

Fig. 2 A similar ileal reservoir is created and augmented to the opened bladder. It is drained by a direct nontunnelled tapered ileal outlet

cutaneous stoma (Fig. 1e). A 12F rubber catheter was left as a stent for 10 days.

### Group II: (tapered simple ileal outlet)

This group included five dogs for which the detubularized ileal reservoir was drained by a mere tapered ileal segment. The technique entailed creation of an ileal reservoir from the proximal three-fourths of a 40-cm-long ileal segment. The remaining one-fourth served as an outlet after tapering of its proximal two-thirds around a 14F rubber catheter (Fig. 2). The untapered distal end of the outlet segment was brought out as a flush stoma. A 12F catheter was left stenting the outlet for 10 days. The opened bottom of the reservoir was anastomosed to the bladder dome as in group I. Parenteral antibiotics and fluids were given for 5 days, followed by an oral fluid diet for 2 days and then solid foods as tolerated.

### Evaluation

Animals began voiding immediately postoperatively and they were examined for visible leakage through the urinary stoma. Intermittent catheterization was performed once a week to test the outlet patency and to wash out mucous secretions. The animals were observed for a minimum of 20 weeks postoperatively. Ascending cystography was carried out to demonstrate the radiographic anatomy of the reservoir as well as the competence and stability of the valve. A double-lumen pressure catheter was inserted per urethra. One channel was connected to an electronic transducer for pressure recording and the other for bladder filling. The glans penis was firmly tightened using elastic vessel loop to prevent urethral leakage maintaining the pressure during bladder filling. Slow-fill water cystometry (rate 20 ml/min) was carried out and the leakage pressure was noted. A 10F pressure profile catheter was used to record the valve closure pressure profile. The infusion rate was 2 ml/min and the withdrawal speed 1 mm/s. An initial measurement was carried out while the reservoir was empty. Recordings were then repeated after every 100-ml filling increment of the reservoir. The dogs were then put to death for necropsy assessment. The outlet valves were grossly examined and microscopic sections obtained for histopathologic examination.

### Results

All animals survived the surgical procedures. All the stomas remained viable and could be catheterized with a soft 12F rubber catheter. No animal had leakage of urine via the stoma in group I, while all the stomas in the dogs of group II were wet. Ascending cystography (gravity pressure 60 cm H<sub>2</sub>O) confirmed the clinical evidence of valve competence in all dogs of group I. No evidence of contrast leakage could be observed in any of the animals (Fig. 3a). Moreover, combined ante- and retrograde cystopouchgraphy demonstrated the radiologic anatomy and stability of the valve (Fig. 3b). On the other hand, leakage of contrast was consistently observed on filling of the reservoir in all dogs of group II.

In both experimental groups the recorded basal pressure of the reservoir ranged from 6 to 9 cm H<sub>2</sub>O, with a mean pressure of 7 cm  $H_2O$ . In group 1, the maximum pressure recorded within the reservoir reached a mean value of 72 (range 60-85) cm H<sub>2</sub>O. No leakage was observed from any stoma even with pressure values (as high as 100 cm H<sub>2</sub>O) during abdominal manual compression. It was observed that the valve closure pressure profile was higher than the pressure within the reservoir. It increased with the increase in pressure within the reservoir, maintaining an effective pressure gradient (Fig. 4). Moreover, the effective functional continence zone of the valve showed progressive elongation when the reservoir pressure increased. In the empty pouch the continent zone of the valve measured 5 cm while at maximum reservoir filling the length of valve reached 8.5 cm. In group II: Filling cystometry resulted in leakage via the stoma at a reservoir pressure of 30 cm H<sub>2</sub>O. The magnitude of the leakage increased with more filling and/or manual

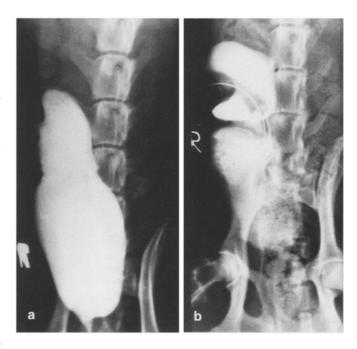


Fig. 3 a Retrograde cystopouchgram demonstrating a continent outlet. b Combined ante- and retrograde cystopouchgram showing the negative defect of the valve

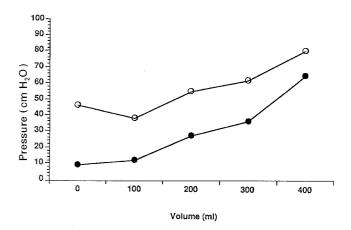


Fig. 4 Pressure profile of the valve plotted against reservoir pressure with different filling volumes. Note the maintained pressure gradient throughout the filling phases

abdominal compression. Outlet profilometry demonstrated progressive reduction of the closure pressure gradient on bladder filling beyond 30 cm H<sub>2</sub>O (Fig. 5).

Gross examination of the necropsy specimens showed a well-maintained and stable ileal valve cuffed with healthy ileal flaps. The valve system was mounted and built in the wall of the reservoir. The outlet tract was straight, permitting an easy catheterization (Fig. 6). Histologic sections showed healthy ileal flaps embracing the inner buried ileal segment. A clearly evident serous-lined microscopic plane was seen between the two ileal components. Moreover, no evidence of abnormal inflammatory reaction, scarring and/or calcifications could be observed (Fig. 7).

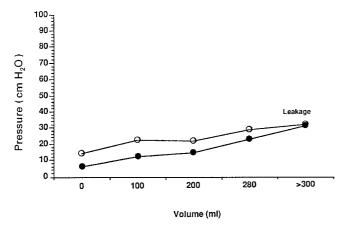


Fig. 5 Outlet profilometery of the direct tapered ileal outlet. Note the narrow pressure gradient and the overlapping of the pressures at reservoir filling beyond 30 cm  $\rm H_2O$  (300 ml), resulting in leakage



Fig. 6 Necrosy specimen of the anteriorly opened bladder and reservoir showing the anatomic configuration, patency and stability of the ileal valve

### **Discussion**

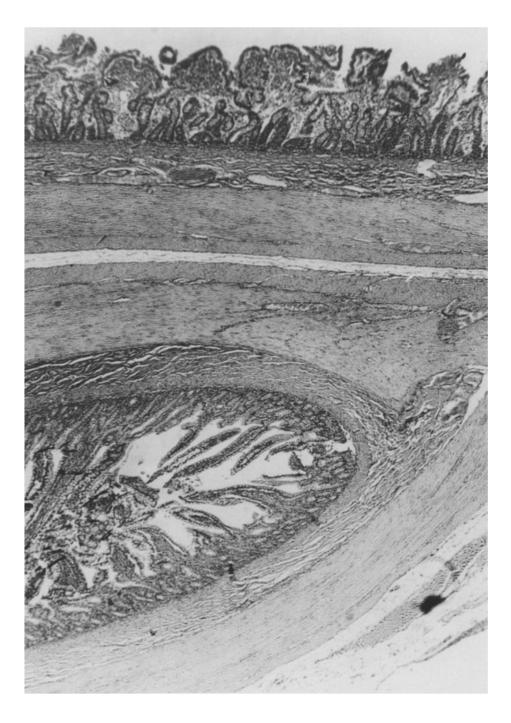
A high-capacity, low-pressure reservoir with a reliable continence mechanism is the ultimate goal of a successful continent urinary diversion. Although satisfactory results have been achieved with the creation of an optimal urinary reservoir [14], the construction of an efficient outlet remains a problem. The ideal outlet should be constructed from a readily available and surgically versatile intestinal segment without the need for synthetic materials. It should provide reliable continence at any given pressure within the reservoir and allow easy catheterization in the long term with feasible endoscopic access and minimal need for surgical revision.

The intussuscepted ileal nipple valve [17, 30], plicated/stapled ileum with or without ileocecal valve reinforcement [5, 23, 24, 27–29], Benchekroun hydraulic valve [6, 7, 21] and tunneled appendix [9–11, 16, 26] are currently the most clinically useful surgical techniques for construction of a continent outlet.

Since the introduction of an efferent nipple outlet with Kock's procedure, the technique underwent a series of technical modifications in order to reduce the high complication rate. The problems of nipple continent stoma include valve malfunction with urinary leakage, parastomal hernia, catheterization difficulties, ischemia and/or fistula [30]. In the first report by Kock et al. [17], more than 50% of patients required reoperation for valve failure. Skinner et al. [30] emphasized a number of technical modifications including stapling the nipple to the back wall of the pouch, replacing the Marlex collar with polyglycolic acid mesh around the base of the nipple and devascularization of about 8 cm of the ileal mesentry. The incidence of late complications following these technical refinements has been reduced from 47% to 22%. The incontinence rate was reduced from 25% to 15% and consequently the reoperation rate has been minimized from 36% to 15% of patients. A noteworthy observation is that creation of two nipples (afferent and efferent) in an ileal reservoir requires an extra 30 cm of the bowel for valve construction and six to eight rows of metallic staples to fix the valves. Moreover, the risk of stone formation and the cost of the staples are not negligible.

Continent outlets using plicated or tapered ileum with or without ileocecal reinforcement were utilized by many urologists [5, 23, 24, 27–29]. The principle was evolved from the Gilchrist procedure, which was first described in 1950 [13]. Rowland et al. [29] initially used the plication technique of the ileal outlet, reporting problems of both incontinence and catheterization difficulties in one-fourth of the patients. Further modifications were adopted in the form of tapering and stapling the terminal ileum with the addition of a few silk sutures at the ileocecal junction to reinforce the area of the ileocecal valve. The continence rate has been improved, reaching more than 90% following these modifications [27]. Similar results have been reported by Bloch et al. [8] and Lockhart et al. [24]. However, some urologists do not accept the use of ileocecal segment as long as the patient has enough and healthy

Fig. 7 Histopathologic pincture of a cut section of the valve. Note the healthy buried ileal segment cuffed by intact ileal flaps. No evidence of inflammatory reaction, scarring and/or calcifications. H&E, X40



ileum. Exclusion of the ileocecal segment may result in shortening of the intestinal transit time and subsequent development of malabsorption syndrome and diarrhea. These sequalae are much more manifest in patients who have undergone previous bowel resection as well as in children with myelomeningocele [22]. Surgical reconstruction of the ileocecal valve has been advocated to restore the transit time and avoid chronic diarrhea [12]. Therefore, it may be advisable to leave the natural ileocecal valve undisturbed and preferably utilize a continent reservoir from the ileum.

The reversed (inkwell) intussuception hydraulic valve was proposed and utilized by Benchekroun and others [6, 7, 21]. The technique seems sophisticated, requiring much suturing in addition to the prolonged learning curve. Moreover, intermittent catheterization of the serous-lined stomal tract may evoke trauma, which may result in fibrosis and stomal stenosis. The reported complication rate following this technique ranged from 19% [7] to 40% [21] in the form of valve incompetence, fistula, necrosis and/or stomal stenosis.

Incorporation of a tubular structure within the wall of the reservoir seems to be the most reliable and physiological procedure to achieve continence. Different tubular structures have been used for construction of such a continent outlet [9-11, 16, 25, 26, 31], of which the appendix is the most common. Although the use of appendix does not require any staples for fixation, this technique has several limitations, rendering the use of appendix unfeasible in 18–30% of patients [9, 20]. The appendix may have been previously removed or irradiated, partially or completely obliterated or a seat of chronic inflammation. Some appendices may be too short or too adherent and not mobile enough for clinical use [9]. Moreover, the appendix has a limited diameter with poor surgical yield. This smallbore outlet has the risk of inadequate emptying and mucus retention, which may help stone formation in 32% of patients [11]. Hence, the surgeon has to be familiar with alternative outlet techniques when the use of appendix is aborted.

The proposed technique relies on the principle of implantation of a tubular structure within a serous-lined extramural tunnel [1, 2]. The outlet is constructed from the ileum, which is always available, well-vascularized and enjoys much surgical versatility. The active component of the valve is a tapered ileal segment cuffed and supported by two intact ileal flaps. The intestinal tunnel is serous lined, which carries minimal risk of hematoma formation, stenosis, scarring and/or calcification.

Moreover, the whole valve system is mounted and built in the reservoir wall, a fact which makes the competence of the valve essentially compatible with the changes in the reservoir pressure and/or its wall distention. Furthermore, valve construction does not require the use of synthetic materials, with a minimal risk of malfunction or stone formation. The mouth of the stoma is nontailored intact ileal stump, which carries a minimal risk of stomal stenosis and need for surgical revisions. In addition, the outflow tract is lined with ileal mucous membrane, which can tolerate the trauma of catheterization and enjoys rapid regeneration.

The present experiment included two outlet models. In the first group, the tapered ileal segment was incorporated within a serous-lined extramural tunnel [1, 2]. Construction of the valve in such a way could achieve continence through two interacting mechanisms: (a) The tubular resistance of the tapered ileal segment prevents leakage at low pressure during resting conditions. (b) The whole valve system is a part of the reservoir wall, which provides a dynamic mechanism acting during filling of the reservoir and or at higher pressure spikes. Urodynamic evaluation has demonstrated an effective closure pressure between the reservoir and the valve. The continent zone of the valve showed substantial and progressive elongation with further reservoir filling and/or stretch of its wall. In this manner, the valve enjoys a reliable continence mechanism at different pressure values during resting and stress conditions with higher pouch pressure. This fact dictates creation of an ileal reservoir mounted with a highly competent antireflux ureteral reimplantation mechanism to guard against upper tract deterioration. It has been found that the serous-lined extramural antireflux uretero-ileal reimplantation procedure is an efficient reflux prevention technique that could prevent reflux at any given reservoir pressure, as it works in relation to the intraluminal pressure of the reservoir [1, 2].

On the other hand, in group II the outlet was a mere tapered ileal segment directly draining the reservoir. The mechanism of continence in this group depends only on the tubular resistance of the tapered segment, which has a limited role in leakage prevention. In addition to the potential difficulty of catheterization due to yielding and kinking of the outlet tract, such an outlet has no safety mechanism to prevent leakage, especially during maximum filling of the reservoir and under stress conditions.

These excellent experimental results have encouraged us to employ this technique in the clinical setting.

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