Int Urogynecol J (2005) 17: 50–53
DOI 10.1007/s00192-005-1345-y

ORIGINAL ARTICLE

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# Bladder augmentation using Pelvicol™ implant for intractable overactive bladder syndrome

Received: 13 January 2005 / Accepted: 5 June 2005 / Published online: 7 July 2005


**Abstract** The objective of the study was to evaluate the effectiveness of an implant of porcine dermis to augment the bladder in women with refractory overactive bladder syndrome (OAB). Twelve women underwent a Pelvicol™ bladder augmentation. A visual analogue score for severity of incontinence and a quality of life questionnaire was carried out pre-operatively and at 12 months post-operatively. Follow up cystoscopy was carried out in three women in addition. Three women were dry and cured; five women were significantly improved; two women were slightly improved and the procedure was unsuccessful in the remaining two women. There were no significant complications and voiding was spontaneous in every case. A bladder augmentation using porcine dermis may have a role in the surgical management of non-neuropathic women with OAB that has failed to respond to conservative therapy.

**Keywords** Overactive bladder syndrome · Pelvicol™ · Bladder augmentation

## Introduction

Urinary incontinence is an extremely common and socially embarrassing condition, which considerably affects the lives of those sufferers [1]. Approximately 35% of non-neuropathic women with urinary incontinence are subsequently found to have overactive bladder syndrome (OAB) [2]. The cardinal symptoms of this syndrome are frequency, nocturia, urgency and urge incontinence, and this occurs when the bladder contracts either spontaneously or on provocation [3]. OAB may be helped by conservative treatment such as bladder retraining [4], biofeedback [5] and hypnotherapy [6]. However, most patients are commenced on pharmacological treatment with anticholinergic drugs and the majority of patients may be cured or improved by these conservative means [7]. Approximately 10% of patients are refractory to conservative therapy and will require surgical intervention [8].

Surgical techniques such as phenolisation [9] and bladder transection [10] were widely used in the past, but have been abandoned, since they have high complication rate and at best, a short period of effectiveness. The "Clam" enterocystoplasty operation was originally described in 1982 [11] for the treatment of congenital day and night enuresis, secondary to detrusor instability. It has since become the operation of choice for overactive bladder for neuropathic and non-neuropathic patients alike. The success rate of enterocystoplasty has been claimed to be as high as 90%, but there is a significant morbidity as a consequence [8]. These include voiding dysfunction and up to 25% of female non-neuropathic patients will have to self catheterise [12]. There is also a significant increase in urinary tract infections [13] and there are concerns regarding metabolic changes, since there is a known metabolic acidosis with respiratory compensation and hyper chlorinaemia [14]. Approximately 10% of patients will also experience profound diarrhoea due to disruption of the entero-hepatic circulation of bile salts [15]. By far, the major concerns are of a malignancy to develop either in the bladder remnant or in the incorporated bowel segment [16].

Pelvicol™ is an acellular flat porcine dermis, which has been extensively used throughout the body for reconstruction and provides a permanent repair [17]. This study was carried out to evaluate the use of Pelvicol™ to augment the bladder in women with refractory OAB.

## Methods

Twelve women (age range 32–79 years; mean 52 years) were recruited in the study. Approval for the study had

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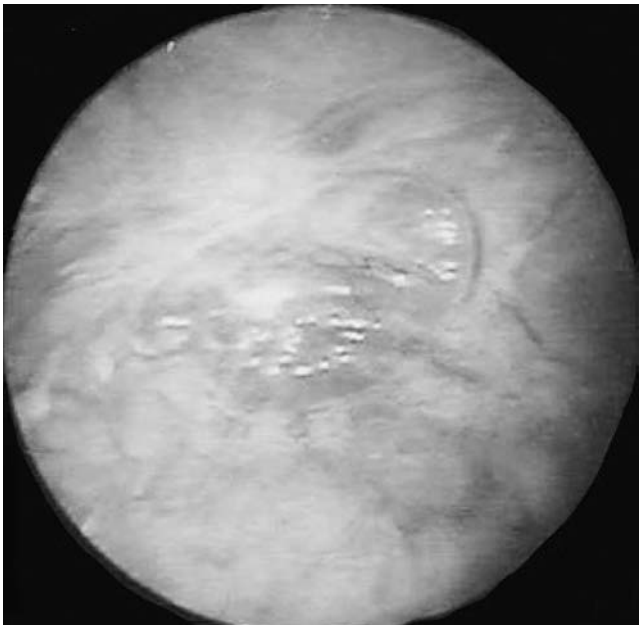

**Fig. 1** Cystoscopic appearance at 12 months following Pelvicol™ implant cystoplasty

been granted by the Local Research Ethics Committee. All women had previously undergone urodynamic studies confirming detrusor wave contractions and had completed a course of conservative treatment with either physiotherapy or anticholinergic medication or both. All women were taught pre-operatively to self catheterise in case of voiding dysfunction post-operatively.

The women were placed in the Lloyd-Davies position under a general anaesthetic and in all but one case, a pfannesteil incision was carried out. The rectus sheath was incised and the recti abdomini muscles separated to gain access into the retro-pubic space or Cave of Retzius. The dome of the bladder was incised and the incision continued to within a couple of centimetres of the ureteric orifices on each side. A 12 × 10 cm piece of Pelvicol™ implant (Bard, UK) was then trimmed to produce an oval or elliptical shape. The Pelvicol™ implant was then turned slightly diagonally so that the maximum length, which is from one corner to the opposite, lay transversely. Initially, these corners were sutured to the apex of the bladder incision on each side using dissolvable 2/0 Vicryl sutures. The edges of the porcine implant were then sutured to the bladder edges using the same sutures. At this point, the peritoneum was then opened and the omentum mobilised downwards to cover the implant and to give it a vascular supply. In two cases, the omentum was too short and therefore the Pelvicol™ implant was simply covered by peri-vesical fat. A 20 g supra pubic catheter was inserted under direct vision and a drain used to drain the retro-pubic space.

Intravenous antibiotics were given intra-operatively only, and a cystogram organised for 28 days post-operatively. In three patients, follow-up cystoscopy was organised for 6 months post-operatively.

The women completed a Kings College Hospital Quality of Life (KCH QoL) Questionnaire pre-operatively, which was repeated at 12 months post-operatively for comparison. In addition, a visual analogue scale was completed to give an indication of the severity of incontinence, ranging from 0 indicating no incontinence to 10 that was the most significant incontinence the patient could perceive. In addition, the women were asked if they would recommend the operation to a friend. Non-parametric (Mann–Whitney) analysis were used to test for statistical significance.

Follow up urodynamic studies were carried out in four women: all women completed a post-operative frequency volume chart and a bladderscan was carried out to measure residual bladder volume.

## Results

The operation time ranged between 80 and 150 min with a mean and median time of 115 min. All 12 cystograms carried out at 28 days post-operatively showed no leaks and voiding was spontaneous in all women, in that none were required to self catheterise. Post-operative residual volumes measured by bladderscan were all less than 100 ml.

The length of stay ranged between 4 and 21 days with a mean of 7.4 days and a median of 6 days. However, these results are skewed by the fact that one woman stayed for 10 days for social reasons and one for 21 days for a severe wound infection related to her insulin-dependant diabetes becoming out of control.

The subjective results are shown in Table 1. One woman was lost to follow up, but just prior to moving out of the area had been the subject of an article in the local newspaper claiming complete success of her symptoms. Including this woman, three women were completely dry as a result of the procedure and five were significantly improved. Two women were slightly improved and in the remaining two women there was no change in symptoms. There was no significant improvement in general health perceptions and in personal relationships, but in all other domains of the KCH QoL, there were statistically significant improvements, particularly in incontinence impact, role limitation and emotions. There was also a highly significant reduction in perception of incontinence as shown by the visual analogue scale. Out of the 11 women who replied, 10 would recommend the operation to a friend, which included 2 in whom the operation was unsuccessful.

The pre- and post-operative frequency volume chart results are shown in Table 2. Overall, there is a reduction in day and night urinary frequency, which reflects the subjective improvement. Four women agreed to follow up urodynamic studies: these included both women who had no change in symptoms. In these two women, there was no change between the pre- and post-operative urodynamics. In one woman who was only

**Table 1** Pelvicol cystoplasty results using Kings College Hospital Quality of Life

| Kings QoL | | Patient no | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | Mean | Median | *P* diff |
| General health perceptions | Pre-op | 100 | 25 | 100 | 75 | 75 | 0 | 50 | 25 | 0 | 100 | 50 | 25 | 52.08 | 37.50 | 0.4237 |
| | Post-op | N/a | 0 | 100 | 25 | 25 | 25 | 50 | 25 | 50 | 100 | 0 | 25 | 38.64 | 25.00 | |
| Incontinence impact | Pre-op | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100.00 | 0.0016 |
| | Post-op | N/a | 25 | 100 | 75 | 0 | 100 | 75 | 0 | 0 | 100 | 0 | 25 | 45.45 | 25.00 | |
| Role limitations | Pre-op | 100 | 100 | 100 | 100 | 100 | 83 | 66 | 100 | 100 | 100 | 100 | 67 | 93.0 | 100.00 | 0.0017 |
| | Post-op | N/a | 33 | 100 | 33 | 0 | 83 | 50 | 17 | 0 | 100 | 0 | 0 | 45.45 | 25.00 | |
| Physical limitations | Pre-op | 100 | 100 | 100 | 100 | 83 | 33 | 50 | 100 | 100 | 100 | 100 | 83 | 87.42 | 100.00 | 0.0106 |
| | Post-op | N/a | 67 | 100 | 33 | 0 | 83 | 67 | 33 | 0 | 100 | 0 | 0 | 43.91 | 33.00 | |
| Social limitations | Pre-op | 100 | 78 | 100 | 67 | 78 | 22 | 44 | 67 | 78 | 100 | 89 | 22 | 63.09 | 67.00 | 0.0197 |
| | Post-op | N/a | 22 | 100 | 33 | 0 | 67 | 11 | 11 | 0 | 100 | 0 | 0 | 31.27 | 11.00 | |
| Personal relationships | Pre-op | 100 | 67 | 100 | 100 | N/a | 0 | 100 | 33 | 67 | N/a | 100 | N/a | 70.38 | 67.00 | 0.1248 |
| | Post-op | N/a | 0 | 100 | 33 | N/a | 78 | 67 | 0 | 0 | N/a | N/a | N/a | 39.71 | 0.00 | |
| Emotions | Pre-op | 100 | 100 | 100 | 78 | 78 | 78 | 33 | 78 | 56 | 100 | 100 | 89 | 82.50 | 78.00 | 0.0097 |
| | Post-op | N/a | 33 | 100 | 11 | 0 | 78 | 11 | 11 | 0 | 100 | 0 | 11 | 32.27 | 11.00 | |
| Sleep/energy | Pre-op | 100 | 67 | 100 | 100 | 100 | 50 | 67 | 50 | 67 | 100 | 100 | 75 | 81.33 | 71.00 | 0.0289 |
| | Post-op | N/a | 33 | 100 | 83 | 17 | 67 | 67 | 33 | 0 | 100 | 0 | 33 | 48.45 | 33.00 | |
| Severity measures | Pre-op | 100 | 100 | 100 | 100 | 92 | 75 | 100 | 75 | 67 | 100 | 100 | 75 | 90.33 | 96.00 | 0.0151 |
| | Post-op | N/a | 75 | 100 | 42 | 0 | 75 | 83 | 25 | 0 | 100 | 0 | 33 | 48.45 | 33.00 | |
| Visual analogue scale | Pre-op | 10 | 9 | 10 | 10 | 9 | 10 | 9 | 10 | 7 | 10 | 10 | 8 | 9.25 | 9.00 | 0.0060 |
| | Post-op | N/a | 3 | 10 | 1 | 0 | 9 | 7 | 2 | 1 | 10 | 0 | 3 | 4.20 | 2.00 | |
| Improvement | | Dry | Signif imp | No change | Signif imp | Dry | Slight imp | Slight imp | Signif imp | Signif imp | No change | Dry | Signif imp | | | |
| Recommend to a friend | | N/a | Yes | Yes | Yes | Yes | Yes | No | Yes | Yes | Yes | Yes | Yes | | | |

**Table 2** Pre- and post-operative frequency volume chart

| | Patient no | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| Pre-operative day frequency | 14 | 18 | 16 | 14 | 15 | 12 | 12 | 16 | 11 | 6 | 10 | 16 |
| Post-operative day frequency | N/a | 5–6 | 16 | 7 | 8 | 11 | 7 | 8 | 9 | 8 | 6 | 5 |
| Pre-operative night frequency | 3 | 4–5 | 6 | 2–3 | 6 | 0 | 1 | 2–3 | 2 | 2 | 1 | 3 |
| Post-operative night frequency | N/a | 1 | 6 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 0 | 2 |

slightly improved, pre-operative urodynamics showed contractions up to 30 cm $H_2O$ but no detrusor wave activity was seen post-operatively. In the remaining woman who was significantly improved, detrusor wave contractions were still seen but the maximum amplitude was reduced from 40 to 15 cm $H_2O$. It would therefore appear that subjective results are as reliable an indicator of outcome as objective results.

Follow up cystoscopy showed that the Pelvicol™ had been incorporated completely into the bladder which was covered over by urothelium with only a small area of inflammation at the dome of the bladder to indicate the site of the porcine dermal implant (Fig. 1).

## Discussion

This study has shown that bladder augmentation using a Pelvicol™ porcine dermal implant is effective in the management of refractory or intractable OAB. The technique is easy to learn and the procedure time is considerably quicker than an enterocystoplasty. Although the length of time of surgery was wide, almost all the longer operations were at the beginning of the series, which reduced dramatically with experience. The morbidity of this procedure is low, with no voiding dysfunction and only one patient suffered from a urinary tract infection that required rotational antibiotics. The porcine implant is readily incorporated into the body as shown by the fact that there were no leaks on cystogram 1 month post-operatively and on cystoscopy which revealed complete integration of the graft.

The technique is primarily a retro-peritoneal procedure, and as a consequence there was neither bowel dysfunction nor disruption to acid base metabolism. The likelihood of malignant transformation, therefore, would be expected to be insignificant in these women.

In many ways, the operation resembles a detrusor myectomy which has also been shown to be effective for this condition [18], but is certainly much simpler to perform. However, most detrusor myectomies have taken place in neuropathic patients where the bladder wall is thicker. All women in this series were non-neuropaths and no assumptions can therefore be made as to its effectiveness in neuropathic patients. Porcine dermal grafts of a similar nature are available in larger sizes, which could be used for this indication.

The place for radical surgery for refractory OAB is changing with the advent of intravesical injections of botulinum toxin [19], but if such injections are unsuccessful and enterocystoplasty considered inappropriate, then bladder augmentation using Pelvicol™ may be considered as a useful adjuvant in these circumstances.

## References


1. Brocklehurst JC (1993) Urinary incontinence in the community—analysis of a MORI poll. Br Med J 306:832–834
2. Cardozo LD, Stanton SL (1980) Genuine stress incontinence and detrusor instability; a review of 200 patients. Br J Obstet Gynaecol 87:184–190
3. Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, van Kerrebroeck P, Victor A, Wein A (2002) The standardisation of terminology of lower tract function. Neurourol Urodyn 21:167–178
4. Holmes DM, Stone AR, Bary PR, Evans C, Stephenson TP (1983) Bladder training: 3 years on. Br J Urol 55:660–664
5. Cardozo LD, Stanton SL, Hafner J, Allan V (1978) Biofeedback in the treatment of detrusor instability. Br J Urol 50:250–254
6. Freeman RM, Boxby K (1982) Hypnotherapy for incontinence caused by detrusor instability. Br Med J 248:1831–1832
7. Anderson KE, Appell R, Cardozo CD, Chapple C, Drutz HP, Finkbeiner AE, Haab F, Vela Navarrete R (1999) The pharmacological treatment of urinary incontinence. BJU Int 84(9):923–947
8. Stephenson TP, Mundy AR (1994) The urge syndrome. In: Mundy AR, Stephenson TP, Wein AJ (eds) Urodynamics—principles, practice& application, 2nd edn. Churchill Livingstone, London, pp 263–275
9. Blackford HN, Murray KHA, Stephenson TP, Mundy AR (1984) The results of transvesical infiltration of the pelvic plexuses with phenol in 116 patients. Br J Urol 56:647–649
10. Mundy AR (1983) The long term results of bladder transection for urge incontinence. Br J Urol 55:642–644
11. Bramble FJ (1982) The treatment of adult enuresis and urge incontinence by enterocystoplasty. Br J Urol 54:693–696
12. Stephenson TP, Mundy AR (1985) Treatment of the neuropathic bladder by enterocystoplasty and selective sphincterotomy or sphincter ablation and replacement. Br J Urol 57:27–31
13. Fenn N, Conn IG, German KA, Stephenson TP (1992) Complications of clam enterocystoplasty with particular reference to urinary tract infection. Br J Urol 69:366–368
14. Nurse DE, McCrae P, Stephenson TP, Mundy AR (1988) The problems of substitution cystoplasty. Br J Urol 61:423–426
15. Barrington JW, Fern-Davies H, Adams R, Evans W, Woodcock J, Stephenson TP (1995) Bile acid dysfunction after clam enterocystoplasty. Br J Urol 76:169–171
16. Barrington JW, Fulford S, Griffiths D, Stephenson TP (1997) Tumours in bladder remnant after augmentation enterocystoplasty. J Urol 157:482–486
17. Harper C (2001) Permacol: clinical experience with a new biomaterial. Hosp Med 62:90–95
18. Swami KS, Feneley RCL, Hammonds JC, Abrams P (1998) Detrusor myectomy for detrusor overactivity: a minimum 1-year follow-up. Br J Urol 81:68–72
19. Harper M, Fowler CJ, Dasgupta P (2004) Botulinum toxin and its applications in the lower urinary tract. BJU Int 93(6):702–706