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ORIGINAL ARTICLE

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# Randomized trial of porcine dermal sling (Pelvicol™ implant) vs. Tension-free Vaginal Tape (TVT) in the Surgical treatment of stress incontinence: a questionnaire-based study

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**Abstract** The objective of this study was to compare porcine dermal sling (Pelvicol™ implant, Bard) with tension-free vaginal tape (TVT) in the surgical treatment of stress incontinence. One hundred and forty-two women with genuine stress incontinence (GSI) were randomly assigned to either Pelvicol™ implant pubovaginal sling ($n = 74$) or TVT ($n = 68$). They were followed up at a minimum of 6 months (range 6–24 months), with a median follow-up of 12 months. The majority ($n = 109$) of procedures were carried out in a day surgery unit. The median operation time was 35 minutes (range 15–60) in the TVT group and 30 minutes (range 20–80) in the Pelvicol™ implant group; 81% of the TVT group and 77% of the Pelvicol™ implant group were able to void urine within 24 hours, and had insignificant residual bladder volumes. The prevalence of postoperative symptomatic voiding dysfunction was 3.4% after TVT and 1.4% after Pelvicol™ implant. Nine percent of the TVT group developed de novo urge incontinence and 6% of the Pelvicol™ implant group had de novo urge incontinence 6 months after the procedure. Postoperative evaluation was done at the outpatient department, and a postal questionnaire was also completed to determine subjective continence status. The patient-determined cure rate was 85% in the TVT group and 89% in the Pelvicol™ implant group. The Pelvicol™ implant sling had a comparable patient- determined success rate with TVT and should be considered in the surgical treatment of women with genuine stress incontinence.

**Keywords** Pelvicol™ implant · Porcine dermal sling · Tension-free vaginal tape · TVT

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## Introduction

Sling procedures have been used in the treatment of female urinary incontinence for almost a century. Goebell and Stockell [1] used the pyramidalis muscle to form a muscular sling beneath the urethra, and Franheim added strips of rectus fascia left attached to the pyramidalis. This combination, called the Goebell–Stockell–Franheim procedure, was popular for some time [1]. Aldridge [2] in 1942, described a sling procedure using rectus sheath, which has been recognized as the predecessor of modem sling techniques. However, the Aldridge sling procedure was associated with a high surgical morbidity and poor long-term results [3].

Since then, many modifications of the surgical technique have been proposed. Slings have been fashioned from homologous sources, including fascia lata, vaginal wall and dura mater, or from synthetic materials such as Mersilene, polytetrafluoroethylene, polypropylene and silicone. Synthetic sling materials such as tension-free vaginal tape (TVT, Gynecare) have been popular since their introduction in 1995 [4]. Although TVT has a high success rate, there are concerns regarding its operative safety in relation to injury to major blood vessels, such as the external iliacs [5, 6], and bladder and urethral perforation [7, 8]. Moreover, there is concern regarding long-term safety with respect to urethral erosion, which is a potential risk when synthetic materials are used for this purpose [9].

Porcine dermis bladder slings (Zenoderm, Ethicon) have previously been described [10,11]. The initial porcine grafts were cross-linked with aldehyde. The problem with long-term aldehyde cross-linked implants is that they may develop foci of calcification, which can be extensive [12]. However, when cross-linked with isocyanate, the porcine grafts did not cause mineralization for a period of 2 years in animal studies [13]. It was subsequently shown that isocyanate cross-linking was the preferred method, which also resists biodegradation. Human skin fibroblasts are capable of growing and surviving for at least 7 weeks on intact porcine dermal

grafts [14]. Pelvicol™ implant (Bard) is a natural, non-allergenic, flexible and strong biological matrix that is readily incorporated into host tissue and effects a permanent repair [15].

To our knowledge there are no studies comparing Pelvicol™ implant with TVT in the surgical management of stress incontinence in women. The aim of this study was to compare Pelvicol™ implant with TVT with respect to complications and questionnaire-based subjective outcomes.

## Patients and methods

One hundred and forty-two women were randomly assigned to either TVT ($n = 68$) or Pelvicol™ implant ($n = 74$) over a period of 24 months. This was a randomized controlled trial with no allowance for patient preference. The experimental arm was Pelvicol™ implant sling and the control arm was TVT sling. The study was approved by the local research ethics committee (LREC). Sixty-eight women underwent the TVT procedure and 74 underwent Pelvicol™ implant. All women who had cystometrically proven genuine stress incontinence were included in the study. Women in whom bladder surgery was contraindicated (detrusor instability) and women who were unhappy to be randomized were excluded from the study. All subjects were given an explanation of the study and informed consent was obtained. Surgery was only offered after conservative therapy had proved unsuccessful.

Preoperative evaluation of all women included a standardized history and physical examination, urine dipstix and culture, a 7-day urinary diary and urodynamic evaluation. The postoperative evaluation also included examination of the case notes with regard to operating time, intra- and postoperative complications, voiding problems and other complications.

The median age was 54 years (range 32–91) in the TVT group and 53 years (range 34–79) in the Pelvicol™ implant group. There were 64 parous and four nulliparous women in the TVT group (median = 2 children), 65 parous and 9 nulliparous women in the Pelvicol™ implant group (median = 2 children). The demographics of the women are shown in Table 1. Fifty women in the TVT group and 59 in the Pelvicol™ implant group had their procedures carried out in the day surgery unit (DSU), and the remainder were carried out in the main theatre complex with a planned overnight stay.

The TVT procedure was performed as described by Ulmsten [18], except that the operation was carried out under general or regional anesthesia. The Pelvicol™ implant sling was performed as described by Barrington [16]. The day surgery patients were given a total intravenous anesthetic using propofol (Diprivan), with additional local anesthetic (20 ml 1% bupivacaine) to the suprapubic area. The majority of main theatre patients were given a spinal anesthetic for medical reasons. After preparing the vagina and suprapubic area with aqueous iodine, an 18 Fr Foley catheter was inserted and the midurethra identified. A 2.5 cm long vertical incision was made at the midurethral level. A suburethral tunnel was made with scissors until the pubic ramus was reached, and the endopelvic fascia was perforated using Roberts' forceps. The procedure was repeated on the other side. A catheter guide was inserted down the Foley catheter and used to deviate the bladder and the urethra to the side opposite to sling insertion. A full-length no.1 polyglactin (Vicryl, Ethicon) was sutured to each end of a 10–12 × 2 cm strip of Pelvicol™ implant, leaving the free ends equidistant in length. Two minimal (1 cm) incisions 6 cm apart were made in the abdominal skin just above the superior border of the pubic ramus. A 15° Stamey needle was passed down the medial side of the each abdominal incision and guided digitally behind the pubic ramus and through the defect in the endopelvic fascia into the vagina. One end of the Vicryl suture was passed through the eyelet in the Stamey needle, which was withdrawn upwards.

The needle was passed down a second time, but on this occasion iv was inserted at the lateral margin of the incision, leaving a bridge of rectus sheath over which the suture could be tied. The procedure was then repeated on the opposite side, after which the catheter was removed. The sling was pulled upwards so as to lie under the midurethra with minimal tension.

A cystoscopy was carried out to ensure lower urinary tract integrity: no bladder perforations were identified in this study in either group. The bladder was filled to the volume at which urinary leakage was seen on urodynamic testing. If a general anesthetic had been used, the patient was then woken and asked to cough. The sutures were elevated, thereby adjusting the sling, until the woman had become continent with cough provocation. The sutures were then tied loosely over the rectus sheath, the skin incisions closed and the bladder emptied. Once the woman was able to void with residuals of less than 100 ml, or the voided volume was twice that of the residual volume, she was discharged.

The outcomes measured were cure rates of stress incontinence at 2–6 months, 12 months and 24 months; levels of significant morbidity and quality of life using a questionnaire; health economic costs to the National Health Service (NHS) and symptom severity.

Follow-up evaluation was carried out after 2–6 months 12 and 24 months in the outpatient department by patient symptoms, and also a postal questionnaire was completed to determine subjective continence status (Questionnaire 1). The improvement analysis is subjective and determined with the help of the questionnaire used. Criteria for cure were: no leakage on cough stress test, quality of life (QoL) improvement >90%, and patient-determined continent status as dry. Improved means no leakage on cough stress test, QoL improvement >75% but <90%, and an improvement in the patient-determined continent status. All patients not fulfilling these criteria were considered failures. Statistical analysis was done using $\chi^2$, Mann– Whitney and Fisher's exact tests where appropriate to look for differences in variables between the treatment arms.

**Table 1** Patient, demographics

| Variable | TVT ($n = 68$) | Pelvicol ($n = 74$) | $P$ $\chi^2$ test |
|---|---|---|---|
| Age (years) | 54 (32–91) | 53 (34–79) | 0.213 |
| Parity (no. of children) | 2 (0–6) | 2 (0–4) | 0.214 |
| Duration (months) | 24 (6–120) | 24 (6–72) | 0.202 |
| Pads (number) | 2(0–7) | 3 (0–10) | 0.626 |
| Hysterectomy | 25 (36.8%) | 24 (25.7%) | 0.310 |
| Previous incontinence surgery | 8 (11.8%) | 10 (13.5%) | 0.513 |

## Results

Statistical analysis failed to detect significant differences between TVT and Pelvicol™ implant at $P = 0.05$ for age, parity, duration of incontinence (months), preoperative pad usage, hysterectomy and previous incontinence surgery (Table 1). The median follow-up of both groups was 12 months (range 6–24). There was no significant difference with respect to primary or secondary procedure, type of anesthesia (general or spinal), operation time (minutes) and stay between the two groups (Table 2).

There were no major intraoperative complications, such as bladder or urethral perforations and injury to major blood vessels. In the TVT group 9 (13.2%) patients developed retention up to 1 week, and 6 (8.1%) developed retention up to 6 weeks in the Pelvicol™ implant group (Table 3). Of the TVT group 62 (91%) and 66 (89%) of the Pelvicol™ implant group had no voiding difficulties; release of the sling was required to treat voiding dysfunction in 2 (3%) of the TVT group and 5 (7%) of the

**Table 2** Operation details

| Variable | TVT ($n = 68$) | Pelvicol ($n = 74$) | $P$ $\chi^2$ test |
|---|---|---|---|
| Primary procedure | 63 (92.6%) | 66 (89.2%) | 0.475 |
| Secondary procedure | 5 (7.4%) | 8 (10.8%) | 0.567 |
| General anesthetic | 64 (94.1%) | 65 (87.8%) | 0.195 |
| Spinal anesthetic | 4 (5.9%) | 9 (12.2%) | 0.250 |
| Operation time (minutes) | 35 (15–60) | 30 (20–80) | 0.294 |
| Length of stay (days) | 1 (1–5) | 1 (1–12) | 0.173 |

**Table 3** Complications

| Variable | TVT ($n = 68$) | Pelvicol ($n = 74$) |
|---|---|---|
| None | 55 (80.9%) | 57 (77%) |
| Retention $<1$ week | 9 (13.2%) | 7 (9.5%) |
| Retention up to 6 weeks | 1 (1.5%) | 6 (8.1%) |
| Hemorrhage | 2 (2.9%) | 3 (4.1%) |
| Infection | 1 (1.5%) | 0 |
| Severe pain | 0 | 1 (1.4%) |
| No voiding problem | 62 (91.2%) | 66 (89.2%) |
| Clean intermittent self-catheterization | 3 (3.4%) | 1 (1.4%) |
| Release of sling required | 2 (2.9%) | 5 (6.8%) |
| Urethral dilatation | 1 (1.5%) | 2 (2.7%) |

**Table 4** Incontinence pad use

| | | TVT ($n = 68$) | Pelvicol ($n = 74$) |
|---|---|---|---|
| Preop | Mean | 3.15 | 2.73 |
| | Median | 3 | 2 |
| | Range | 0–20 | 0–10 |
| Postop | Mean | 0.46 | 0.64 |
| | Median | 0 | 0 |
| | Range | 0–4 | 0–8 |

$P = 0.443$ (Pearson's $\chi^2$ test)

**Table 5** Improvement analysis

| Improvement | TVT ($n = 68$) | Pelvicol ($n = 74$) |
|---|---|---|
| 90–100% | 51 (75%) | 56 (75.7%) |
| 75–90% | 7 (10.3%) | 10 (13.5%) |
| $<75\%$ | 10 (16.1%) | 8 (10.9%) |
| Dry | 58 (85.3%) | 66 (89.2%) |
| Improved | 6 (8.8%) | 2 (2.7%) |
| Failed | 4 (5.8%) | 6 (8.1%) |

Pelvicol™ implant group; 3 women in the TVT group and 1 in the pelvicol™ implant group required permanent intermittent self-catheterization (CISC), as sling revision failed to improve the voiding dysfunction (Table 3).

All the patients completed and returned the questionnaire. Overall, a significant decrease in pad score was noted in both groups ($P < 0.01$) but there was no significant difference between groups ($P = 0.44$) (Table 4). The women were asked to describe their satisfaction as a score ranging from 0 to 10, and the mean score was 8.03 for TVT and 8.05 for Pelvicol™ implant, with a median of 9 for both groups. Subjective improvement analysis [18] divided these women into three groups (90%–100%, total cure; 75%–90%, significant improvement; and $< 75\%$, failure). Fifty women (74%) in the TVT and 56 (76%) in the Pelvicol™ implant group were completely cured; 7 (10%) of the TVT group and 10 (14%) of the Pelvicol™ implant group were significantly improved, and 10 (16%) in TVT group and 8 (11%) in the Pelvicol™ implant group reported an improvement of $< 75\%$ (Table 5). However, the patient-determined continence rate in the TVT group was 85%, compared to 89% in the Pelvicol™ implant group ($P = 0.992$), and 9% ($n = 6$) of the TVT group and 3% ($n = 2$) of the Pelvicol™ implant group felt significantly improved. Only 4 patients in the TVT group and 6 in the Pelvicol™ implant group considered themselves as failures with respect to stress incontinence. Only these failed cases underwent urodynamics. Fifty-two (76.5%) women in the TVT group and 62 (80%) in the Pelvicol™ implant group would have the sling procedures again if they became incontinent; 8 women in the TVT group and 9 in the Pelvicol™ implant group would not have the sling again ($P = 0.228$); 84% of the Pelvicol™ implant group and 71% of the TVT group would recommend the operation to a friend, which is statistically significant ($P = 0.014$).

## Discussion

The results of this study suggest that a porcine dermal sling procedure (Pelvicol™ implant) is an acceptable method of treatment for all cases of genuine stress incontinence, and the results are comparable with those of the TVT procedure. The patient-determined continence rate was comparable (TVT 85%, pelvicol—implant 89%) and was accomplished with no significant long-term urinary retention. It is likely that the choice of sling material does not affect outcome in terms of cure rates if excess tension is avoided [3]. DeLancey [17] had proposed that the endopelvic fascia and the pubourethral ligaments provide support to the urethra. Hence, pressure from above compresses the urethra against the suburethral layer, keeping its lumen closed. The suburethral slings [18] (TVT and Pelvicol™ implant) provide passive resistance and support, rather than actively elevating and compressing the urethra. This allows more effective transmission of intra-abdominal pressure to the urethra, thereby rendering the women continent. With Pelvicol™ implant the dissection is slightly greater than with TVT, but this is offset by the reduced risk to viscera and major blood vessels [5, 6], as the tip of the Stamey needle is blunt and also it is guided digitally through [16]. This minimizes postoperative complications such as voiding problems. Although more women 6 (8%) developed retention for up to 6 weeks, only 1 in the Pelvicol™ implant group required long-term intermittent self-catheterization, compared to 3 in the TVT group.

Problems related to erosion of the sling material, through the urethra or the vagina, appear to be almost

exclusive to synthetic materials. Although in this study we did not encounter erosion with TVT, there have been reports of sling erosion [19] into the vagina, bladder and urethra with TVT and other synthetic materials [9, 20].

During the last decade pubovaginal sling procedures have been done using autologous or cadaveric fascia. Some women complain of pain after facial harvesting, and in some the rectus fascia is not available because of previous surgery. moreover, Sadhukan et al. [35] recently reported infection problems with human cadaveric fascia.

Porcine dermal slings have been used in the treatment of stress incontinence for many years with high success rates [10, 11]. Zenoderm, however, was withdrawn from the market as it failed various toxicity tests [31, 32] and was shown not to be permanent, as it was cross-linked with gluteraldehyde. Pelvicol$^{TM}$ implant is cross-linked with isocyanate, thereby avoiding mineralization and tissue toxicity [15]. In a series of acute and chronic implantation studies in animals [33] no allergenic responses were observed. Histology on the implant sites showed no inflammatory reactions. The patented process, with its organic and enzymatic extractions, cross-linking and sterilization, has been shown to inactivate and remove bacteria and viruses should they be present in the starting material. Although there is a theoretical risk of transmissible diseases, such as Creutzfeld-jakob disease, and the materials can be potential fomites for disease, so far none has been reported by the other surgeons [15]. The resultant material is strong, safe, non-allergenic, readily colonized by host cells, and is not broken down once implanted [32]. The material is also being used in anterior and posterior vaginal wall prolapse repairs [21] and sacrocolpopexy [22]. Interestingly, in our study more women (84%) would recommend Pelvicol$^{TM}$ implant than TVT (71%), which is statistically significant ($P = 0.014$).

Postoperative complications such as de novo urge incontinence and voiding dysfunction are comparable in both groups. The combined complication rate of urge incontinence and symptomatic long-term voiding dysfunction is 11% in the TVT group, compared to 8% in the Pelvicol$^{TM}$ implant group. This is less than the rates reported in other studies [23, 24].

Our questionnaire-based study demonstrates that most patients experienced an improvement in incontinence after both procedures, with comparable results, and remained satisfied at a median follow-up of 12 months. The questionnaire is most effective at estimating the overall continence status and patient satisfaction on survey completion. This method of follow-up is intended to avoid the bias invariably introduced by the patient–doctor relationship, the physician interpretation of patient status, and inaccuracies in and misinterpretation of the medical records. Nevertheless, the patient survey method of follow-up is limited by the lack of urodynamic confirmation of the exact etiology of patient-reported incontinence. In addition, the method is probably not an accurate means of determining the interval between surgery and recurrent incontinence. However, because since the patient is reminded daily of their continence status, and as patient perception of improvement is an important consideration, patient-reported subjective percentage improvement was included in our analysis.

Moreover, the relationship between objective evaluation and subjective symptoms is known to be vague. Since the most recent publication from the Standardization Committee of the International Continence Society [39], many clinicians use the pad weighing test as a post-treatment outcome measure. However, Simmons et al. [40] have shown that the 1-hour pad test is a useful baseline measure of incontinence, but its poor repeatability suggests that it is not an optimal measure of post-treatment change. Some patients report that they are still wet, and others report that they are still wet despite objective testing showed that they are cured.

As demonstrated by several authors, we believe that use of a questionnaire facilitates accurate assessment of outcomes following incontinence surgery [25–27, 34, 36–38]. We used a questionnaire that was adapted from Trockman et al. [27] in a large survey series. To validate patient answers, we conducted a retest analysis by asking the women to complete the questionnaires again when they were followed up at the outpatient clinic. This confirmed the consistency of the answers. All the patients completed the questionnaire, which indicated that all the questions were easily understood. These findings confirm that a questionnaire is useful to estimate continence status and patient satisfaction at the time of completion of survey. The average cost of the Pelvicol$^{TM}$ implant sling is £147 per patient, whereas TVT costs £464 per patient. Hence Pelvicol$^{TM}$ implant is significantly cheaper than TVT, which has huge cost implications to the NHS.

In conclusion, the Pelvicol$^{TM}$ implant pubovaginal sling is a safe, effective and minimal-access technique for the treatment of female urinary incontinence. We also found, as did others [28, 29, 34, 36–38], that most surgical failures after a sling procedure, including TVT and Pelvicol$^{TM}$ implant, present within the first 3 months, and that successful results seem to persist over time. Nevertheless, at least 5 years of follow-up are required to establish the long-term durability of surgery. Although the statistical differences with respect to subjective outcome failed to reach any significance, the Pelvicol$^{TM}$ implant sling can be safely considered in the management of women with stress incontinence. In our opinion, the Pelvicol$^{TM}$ implant pubovaginal sling deserves to be included as a recognized operation for the surgical management of female stress urinary incontinence.

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## Editorial comment

**The search for the best material for suburethral slings has been on since the first sling procedure was described in the early 20th century. The early slings used harvested autologous muscle or fascial grafts, which required large incisions. However, the use of prepared slings of synthetic material or treated cadaver or animal grafts allowed these slings to be inserted with small cosmetic incisions, minimal tissue dissection, less postoperative pain and shorter hospitalization. Porcine dermis urethral slings have been in use for a considerable time and have not gained popularity, presumably because of their lower efficiency or lack of availability. The newer modified porcine dermis, which resists biodegradation, may improve long-term effectiveness. The tension-free vaginal tape has only recently been developed and has gained wide international popularity, even before the first randomized trial was published. This is in no small part because of evidence which has been produced that this is a day-only stay procedure, which is relatively safe and has good short-term results, which have been confirmed on personal physician use. Nevertheless,**

**there are real risks with synthetic mesh, especially once there is lower urinary tract or genital tract penetration. On the other hand, there are theoretical risks of implanting allogenic material, either treated cadaver or from animals, of known or unknown transmissible diseases. Therefore, the search for the best sling material goes on; however, the answer will only be found in good animal and human and studies such as this prospective randomized trial**.

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**Study No.** □□□

## Urinary Symptoms Questionnaire

1. How much leakage of urine do you have now?

*Please tick one answer*

None ○
Mild ○
Moderate ○
Severe ○

From the list below choose **ONLY THOSE PROBLEMS** that you have at present. **LEAVE OUT** those do not apply to you.

2. If you do now leak urine, how does it usually occur

Mostly with coughing, sneezing or physical activity ○
Usually not with physical activity, but leakage occurs suddenly with an urge to pass urine before it can be controlled ○
Leakage of urine often occurs in both of the situations described above ○
Not sure when leakage occurs ○

3. How much improved is your urinary leakage compared to before the sling operation?

**Please answer both questions**

*Please tick one answer*

a)
100% better ○
90% better ○
80% better ○
70% better ○
60% better ○
50% better ○
40% better ○
30% better ○
20% better ○
10% better ○
The same ○
Worse than before the sling surgery ○

b)
Totally cured ○
Much improved ○
Slightly improved ○
No improvement ○
Worse than before ○

4. Did you wear any protective pads for urine leakage before the operation?

Yes ○
No ○
If yes how many pads per day? ○

***If no, please go to question No. 6***

5. If you are still wearing pads, how many do you use in 24 hours? ○

6. How often do you pass urine during the day?

*Please tick one answer*

At least every hour ○
Every 1 to 2 hours ○
Every 3 to 4 hours ○
Longer than every 4 hours ○

7. How many times per night do you wake up from sleep to pass urine? ○

8. If your incontinence returned after sling operation how long after surgery was it? ○

9. If incontinence returned after sling operation how did it happen?

*Please tick one answer*

Gradually over months ○
Suddenly over a few days or week ○

10. Do you currently use a catheter to empty the bladder?

Yes ○
No ○
If yes, how many times/day? ○

11. Do you have any difficulty in emptying your bladder?

*Please tick one answer*

No ○
Mild ○
Moderate ○
Severe ○

12. Do you have any uncontrollable urge to empty your bladder?

No ○
Mild ○
Moderate ○
Severe ○

***If No, please go to question 13.***

12a. Was this urge present before the operation?

Yes ○
No ○

13. Since your sling operation, do you have problems with pelvic pain?

Yes ◯
No ◯

14. Is sexual intercourse painful?

Yes ◯
No ◯
Not sexually active ◯

15. Overall how satisfied are you with the results of sling operation?

*Please tell us in figure*

0 - Not satisfied

10 - Very satisfied

16. If you were employed outside the home, how soon were you able to return to work?

Days ☐ Weeks

17. Knowing what you know now, would you have the sling operation again?

Yes ◯
No ◯

18. Would you recommend sling operation to a friend?

Yes ◯
No ◯
Not sure ◯

Comments

**THANK YOU, PLEASE CHECK THAT YOU HAVE ANSWERED ALL THE QUESTIONS**