

Porcine Versus Polypropylene Sling For Stress Urinary Incontinence - Results Of A 10 Year Randomised Control Study

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10 year RTC comparing:
Pelvicol™ (Bard Urology) - a natural, non-allergenic, flexible and strong biological matrix derived from porcine dermis
TVT™ (Ethicon Inc.) – a macroporous type 1 polypropylene synthetic mesh

142 patients randomised to Pelvicol™ (74) or TVT™ sling (68)
 > 128 patients completed 3 year follow-up (90% response rate)
 > 98 patients completed 10 year follow-up (69% response rate)

Outcome measures:

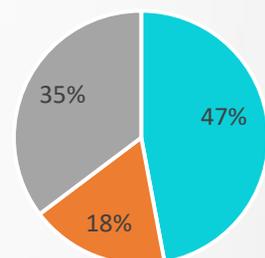
Primary:

Patient determined continence status
 (Success = cured or >90% improved)
 (Improved = ≥75 <90% improved)
 (Failed = <75% improved)

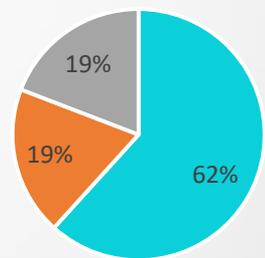
Secondary:

Repeat continence surgery
 Use of incontinence pads
 Adverse events
 Patient satisfaction

Pelvicol™ cure rates at 10 year follow-up



TVT™ cure rates at 10 year follow-up

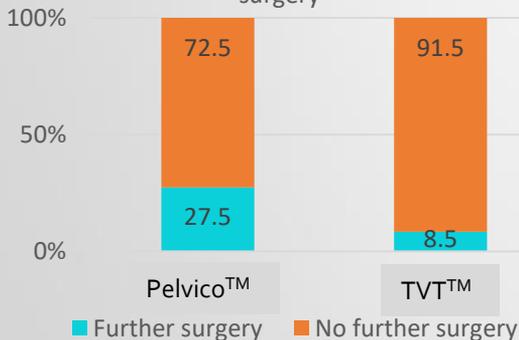


■ Success ■ Improved ■ Failed

| Patient determined continence status | 3 Year Follow-Up | | 10 Year Follow-Up | |
|--------------------------------------|-------------------|--------------|-------------------|--------------|
| | Pelvicol™ N=68 | TVT™ N=60 | Pelvicol™ N=51 | TVT™ N=47 |
| Success (≥90%) | 56 (82.4%) | 53 (88.3%) | 24 (47.2%) | 29 (61.8%) |
| Improved (≥75 <90%) | 7 (10.3%) | 3 (5.0%) | 9 (17.5%) | 9 (19.1%) |
| Failed (<75%) | 5 (7.3%) | 4 (6.7%) | 18 (35.3%) | 9 (19.1%) |

p = 0.5 (Success at 3 vs 10 years), *p = 0.03* (Success at 10 years)

Need for repeat anti-incontinence surgery



| Secondary Outcomes | 3 Year Follow-Up | | 10 Year Follow-Up | |
|-----------------------------------|-------------------|--------------|-------------------|--------------|
| | Pelvicol™ N=68 | TVT™ N=60 | Pelvicol™ N=37 | TVT™ N=43 |
| Intermittent self catheterisation | 2 (2.9%) | 2 (3.3%) | 0 | 0 |
| Difficulty voiding | 4 (5.9%) | 5 (8.3%) | 2 (5.4%) | 6 (13%) |
| Pelvic pain | 1 (1.5%) | 1 (1.7%) | 3 (8.1%) | 4 (9.3%) |
| Dyspareunia | 0 | 2 (3.3%) | 3 (8.1%) | 3 (6.9%) |

Patient satisfaction:

The majority of patients in both groups would have the operation repeated again if needed, 62% in the Pelvicol™ group and 77% in the TVT™ group. 62% in the Pelvicol™ group would recommend the operation to a friend and 72% in the TVT™ group.

Discussion:

- 2015 Cochrane review on synthetic mesh slings, concluded established effectiveness and a good safety profile, although highlighted lack of long-term data and data on allogenic material slings.
- Both cure rates declined at 10 years compared to 3 years: Pelvicol 82% to 47%, TVT 88% to 62% (significantly greater reduction in the Pelvicol group).
- Our re-operation rate of 8.5% in TVT group comparable to other 10 year follow-up studies who reported 7.8%¹. Re-operation rate of 27.5% significantly higher in the Pelvicol group, suggests Porcine slings inferior in the longterm.

Declaration of interests – none

1. Aigmueller, T, Trutnoyko G, Tamussino K, Kargl J, Wittmann A, Surtov M, Frudinger A, Riss P, Bielic-Radicic, V, Ten-year follow-up after the tension-free vaginal tape procedure, American Journal of Obstetrics & Gynecology, 2011, Volume 205, Issue 5, 496.e1 - 496.e5