

FAILURE OF PORCINE XENOGRAFT SLING IN A RANDOMISED CONTROLLED TRIAL OF THREE SLING MATERIALS IN SURGERY FOR STRESS INCONTINENCE.

Hypothesis / aims of study

Although urethral slings are now commonly used to treat female stress urinary incontinence there remains uncertainty about the most suitable materials and devices to use. A multicentre, randomised, controlled trial was initiated to compare the efficacy and morbidity of three techniques for performing sling surgery as a surgical treatment for stress urinary incontinence in women. These were the Tension Free Vaginal Tape (TVT), Porcine Xenograft (Pelvicol) sling, and the short autologous fascial sling technique, or "Sling on a string". We present the results of an independent, interim analysis of outcomes, before recruitment was completed.

Study design, materials and methods

The study required 260 patients to have a 95% chance of detecting a 10% difference in quality of life scores with 80% power. Preoperative assessment included urodynamics, pad test, BFLUTS score and Euro Quality of life (QOL) score. Primary outcome measures were to be Change in BFLUTS and Euro QOL at 6 months and 12 months. Lengths of stay, hospital re-admissions and re-operations were also recorded. Ethical approval was obtained in all participating centres.

Results

Four centres had recruited 139 patients who were well matched at baseline for severity of leakage and all symptom and QOL scores. For this interim analysis, follow up data was available for 97 patients at 6 months and 70 patients at 12 months. The table shows the key outcomes at 12 months.

Table shows the key 12month outcomes from BFLUTS in actual numbers (percentages in brackets). SUI = Stress Urinary Incontinence. BFLUTS = Bristol female lower urinary tract symptom score.

	TVT		Pelvicol		Fascia	
	6	12	6	12	6	12
Months of follow up	6	12	6	12	6	12
Number of patients recruited	42		48		47	
Number followed up	31	26	40	28	33	20
SUI some to all of the time	5(20)	3(17)	8(24)	11(47)	4(12)	3(19)
SUI bothersome or worse	5(24)	3(21)	18(79)	18(79)	4(26)	4(26)
Mean Change in total symptom score	-21	-18.5	-15	-8	-13	-13
			p=.664	p=.453		
Mean change in total problem score	-22	-22	-13.5	-8	-14.5	-14
Dissatisfied or worse	7(30)	5(30)	13(38)	13(66)	10(40)	5(28)
			p=.446	p=.113		
Reoperations for incontinence		0		6		0
				p=.005		

Interpretation of results

There are no significant differences between the groups at six months follow up. Whilst there appear to be trends indicating less satisfactory results for Pelvicol at 12 months these were not statistically significant. However, the re-operation rate for delayed failure of Pelvicol was significantly worse than either TVT or Fascia, for which this never occurred. Review of these 6 patients shows that all were initially relieved of their incontinence but suffered a delayed (more than 6 months) and sudden failure of support. All were again cured once reoperated on.

Concluding message

The investigators feel that it is no longer ethical, nor possible, to remain equipoised when offering the three trial alternatives to potential patients. Recruitment to the Pelvicol arm has therefore been closed but the trial will continue to completion for TVT and autologous fascia.

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