

## COMPARISON BETWEEN PORCINE DERMAL IMPLANT (PERMACOL™) AND SILICONE INJECTION (MACROPLASTIQUE) FOR URODYNAMIC STRESS INCONTINENCE

### Hypothesis / aims of study

Urinary stress incontinence is a common debilitating condition, which affects a large proportion of the female population of the United Kingdom. The majority either do not seek help within secondary care or are treated conservatively by physiotherapists teaching pelvic floor exercises. For those that seek a surgical cure, there are numerous operations available but no one operative procedure is suitable for all women. A proportion is not suitable for anaesthesia, or cannot afford the recuperation time following major surgery. Also a proportion will seek further assistance after previous failed corrective surgery. It is for these latter groups of women that urethral bulking agents may be used which offer a quick usually outpatient based treatment with a short recovery period. Previous bulking agents were short lasting with low success rates and Macroplastique (Uroplasty) which is amongst the most commonly used in the United Kingdom in recent trials only had a success rate of 25%. Permacol™ (Tissue Science Laboratories) is a new sterile solution of acellular crosslinked porcine collagen matrix. It has been used extensively throughout the human body and is licensed for permanent injection. This study was therefore carried out to compare the effectiveness of these two urethral bulking agents.

### Study design, materials and methods

Ethical approval and informed consent was obtained for this study. Fifty women with urodynamically proven stress incontinence were recruited and randomised to receive either Permacol or Macroplastique injection. There were twenty five patients in each group. Their mean age was sixty-one years (range 28-80 years). The majority of the Permacol patients were injected periurethrally (n=21) and the remainder were injected transurethrally. All Permacol injections were performed under cystoscopic control and injection ceased when the urethra was seen to occlude by the bulking agent or a negative cough test. The Macroplastique injections were carried out using the 'Macroplastique Injection System' which uses a transurethral approach and injection ceased when a negative cough test was achieved. An ICS standard one hour pad test was carried out prior to the injection and a subjective analysis of incontinence made using a Stamey scoring system. In addition Kings College Questionnaire was completed. The women were followed up at six weeks and at six months using the same criteria.

### Results

Fifty women with urodynamic stress incontinence were randomised to receive either Permacol or Macroplastique therapy. Success or failure was unrelated to the patient's age, severity of incontinence or a history of previous surgery. The results of the treatment were evaluated at six weeks and six months post treatment. Preoperatively there were no significant differences in pad losses, Stamey score or King's score between the two groups. At six weeks follow-up, of the twenty-five Permacol patients treated, 16(64%) were improved on quantified pad losses out of which 15(62.5%) were rendered dry defined as a urine loss > or = to 2 grammes. 8 (32%) patients were unchanged and 1(4%) got worse on pad losses. 16 (64%) had a reduction of 1 or more grades on the Stamey scoring system and 15 (60%) had a reduction in their King's score. Unfortunately one Macroplastique patient died before six weeks follow-up due to medical reasons. Of the twenty-four Macroplastique patients 13 (54%) were improved using the pad test criteria of which 10(41.6%) were dry at six weeks. 9/24 (37.5%) were unchanged and 2(8%) got worse on pad losses. 11/24 (46%) had reduction in their Stamey score of one or more grades and 10/24 (42%) were improved on their King's score. At six months, one women in the Permacol group had withdrawn, 15 (62.5%) were improved on pad losses of which all 15(62.5%) were dry, 7 (29%) were unchanged, 1got worse and 1 had relapsed on pad losses. 14 (58%) had reduction on Stamey scoring system and 14 (58%) had reduction in their King's score. In the Macroplastique group, 10 (41.6%) were improved on pad losses out of which 9 (37.5%) were dry, 7 (29%) were unchanged, 5

(20.8%) were worse and 2(8%) had relapsed on quantified pad losses. 10 (41.6%) had reduction in their Stamey score and 7(29%) were improved on their King's score.

### **Concluding message**

This prospective randomised study has shown that Permacol injection when used as a urethral bulking agent has a higher cure rate for urinary stress incontinence than Macroplastique and these results persist until the follow up period of 6 months.

### **References**

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