International Continence Society August 22-26, 1999 29th Annual Meeting Denver, Colorado USA

Category No. 8 | Video Demonstration | Ref. No. 388

Abstract Reproduction Form B-1

Author(s): S C Radley, C R Chapple & J A Lee

Double Spacing

Institution City Country: Royal Hallamshire Hospital, Sheffield, UK

Double Spacing

Title (type in CAPITAL LETTERS): TRANSURETHRAL IMPLANTATION OF MACROPLASTIQUE FOR STRESS INCONTINENCE: EVALUATION OF A PORCINE MODEL

Aims of Study Macroplastique is an injectable, particulate silicone polymer used in the treatment of stress urinary incontinence in women. However, the precise mechanisms of its action *in vivo* remain uncertain. In this study we have developed a pig model to evaluate the anatomical location and histological appearance of Macroplastique. We have also evaluated its appearances in an isolated pig urethra preparation and in a single human specimen.

Methods Transurethral implantation of Macroplastique into the proximal urethra was performed in 3 female large white pigs. The procedure was performed under general anaesthesia with the animal in the lithotomy position and followed normal clinical practice as closely as possible. 1-3 ml was placed in three or four documented sites, with visible partial occlusion of the urethral lumen at the time of injection. 6 weeks later the animals were killed by overdose of anaesthesia. At post-mortem, total cystourethrectomy was performed and the bladder was inflated with formalin. Block dissection and histological examination of the tissues was then carried out.
In order to provide information on the immediate appearances of implanted Macroplastique, isolated pig urethrae (with bladder still attached) were injected using a recently developed surgical training model (B.J.Urol., in press). Following injection, these specimens were also dissected and examined histologically. In addition, a single human sample retrieved at colposuspension from a woman who underwent Macroplastique implantation for stress incontinence 12 months previously, was examined. All sections were stained using haematoxylin / eosin and Masson's trichrome.

Results When injected in the training model preparation, the implants were white and soft and easily extruded from the tissues when blocks were taken. The Macroplastique was located in the subserosa. When implants were examined after 6 weeks in the treated animals, they were ovoid in shape, with the long axis parallel to the urethra. They were reddish-brown in colour and had a rubbery consistency. When blocks were taken from these specimens the material was firm and showed no tendency to extrude. In every case the location of the implant was as documented at the time of injection. In two animals the external dimensions of the implants at 6 weeks (measured by micrometer, n = 8) was not significantly different from the original volume injected at each site ($p > 0.3$ Student's t test) :

Mean volume injected 1.94 ± 0.22 ml (mean ± sem)
Mean volume at 6 weeks 1.80 ± 0.26 ml (mean ± sem)

Category No.

Video Demonstration

Ref. No. (Page 2) 388

Abstract Reproduction Form B-2

Authors(s): S C Radley, C R Chapple & J A Lee

The implants had a sub-serosal location, lying outside the smooth muscle of their urethral wall. They therefore abutted on the external aspect of the urethral smooth muscle, the intrinsic architecture of which was undisturbed. A thin, discontinuous connective tissue capsule up to 0.5 mm in thickness had formed around individual implants. No evidence of needle-tracks was seen and there was no evidence that implanted material had migrated since the time of injection.

Histological examination showed, inside the bolus, a florid, giant-cell, foreign-body-type reaction with fibrosis and ingrowth of small vessels. A central cavity containing non-organised Macroplastique was found in several implants, particularly those over 10 mm in diameter, indicating on-going organisation at 6 weeks in the larger implants. The human sample was fragmented and only a small area of capsule was included. However, the material available showed an abrupt transition between organised Macroplastique and loose areolar tissue surrounded by fat, suggesting that the anatomical location was similar to that in the treated animals. The histological appearances were otherwise indistinguishable from those seen in the pig specimens. No evidence of non-organised Macroplastique was seen.

Conclusion: The pig provides a useful model for the assessment of transurethral injection therapy. Macroplastique remains at its injection site, which in practice appears to be mainly subserosal. From an initial soft paste, it is substantially organised into firm nodules at six weeks. In view of the human data, these nodules appear to be stable for at least 12 months. There was no evidence of diffuse periurethral fibrosis or of fixed urethral narrowing. We suggest that Macroplastique assists urethral closure by organising into firm sub-serosal nodules which expand the periurethral tissues, thereby augmenting pressure transmission to the proximal urethra.

Source of Funding: Supported by a grant from Uroplasty.