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Title (type in CAPITAL LETTERS): **AN INNOVATIVE IMPLANTATION DEVICE FOR TRANSURETHRAL INJECTION: REPORT ON A MULTICENTER EVALUATION**

Aims of Study To evaluate acceptance of the Macroplastique Implantation Device (MID) by surgeons and overall treatment acceptance by patients. Safety and effectiveness of the implantation technique were also assessed.

Methods Investigators in four hospitals in the UK took part in a prospective multicenter study after attending a workshop on the implantation technique with the device. Ten women with genuine stress incontinence (GSI) were recruited from urodynamic clinics in each treatment center. Women with detrusor overactivity, significant utero-vaginal prolapse or previous urethral bulking agent injection therapy were excluded from the study. A total of 12 women had undergone previous continence surgery.

The grade of incontinence was assessed subjectively. Treatment was carried out in an out-patient or day-case setting. All women agreed to undergo Macroplastique® implantation under local anesthesia. Pre-medication (usually temazepam 20mg p/o and diclofenac 100mg p/r) was given. Implantation procedures were carried out in a standardized fashion using the MID and a customized 20 gauge implantation needle together with the standard Macroplastique administration gun. The volume of Macroplastique implanted per treatment was 5cc (one woman received 7.5cc at initial implantation). Women were asked to rate the level of pain experienced during the procedure as mild, moderate (acceptable) or severe (unacceptable). The surgeons rated ease of insertion of the MID as acceptable resistance, unacceptable resistance or no resistance. Operator acceptance was scored using a three-point scale (excellent, acceptable and unacceptable). Women were allowed home after spontaneous voiding was achieved. Follow-up took place at six weeks and three months after treatment. Outcome was determined by subjective investigator rating: dry, markedly improved (no further treatment required), slightly improved or unchanged. Success was defined as those women who were dry or

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markedly improved. Repeat implantation was offered if the initial treatment outcome was judged unsuccessful.

Results Patient characteristics in the four groups were not significantly different as determined by the Pearson Chi-square test. Investigators rated 92.5% (37/40) of urethral insertions of the MID as acceptable. Minimal dilatation of the urethra was required in 4/58 procedures. Surgeon' s acceptance of the device was rated as either excellent or acceptable in 95% (38/40) of first procedures and 100%

(18/18) at re-treatment. The majority of women tolerated the procedure well and scored pain experienced during the implantation procedure as mild- moderate in 89% (49/55). Two women requested a general anaesthetic for their re-treatment. Side effects observed included dysuria, haematuria and temporary voiding difficulties. Only two of the seven women who had retention for more than 48 hours required indwelling catheterization. The initial success rate was 52.5% (21/40) at three months. Eight of fourteen women were successfully re-treated after initial treatment failure. The overall success rate after re-treatment was 74.3% (29/39) with an implantation rate of 1.35 and an average volume of 6.8ml of Macroplastique used per patient. One woman was lost to follow-up. An overall success rate of 71% was found for the 28 women who had not had previous incontinence surgery.

Conclusions The MID has been developed over many years [1,2]. It is easy to handle and safe to use. The MID enables a simplified transurethral implantation technique which is easy to learn. Transurethral injection through the device leads to consistent bolus placement at predetermined depth. The MID provides an effective alternative to the endoscopic implantation of urethral bulking agents. The success rate of 71% in women without previous incontinence surgery supports its use as a minimally invasive first line treatment of female GSI.

References

1. Usman F, . A new outpatient treatment for stress incontinence in women with Macroplastique bladder neck injection. Abstract from the 22nd Annual Meeting of the International Urogynecology Association, Amsterdam, The Netherlands, July 1997
2. Link C, . Transurethral Macroplastique injection with the UroProbe device: a minimally invasive and outpatient based treatment. Abstract from the 23rd Annual Meeting of the International Urogynecology Association , Buenos Aires, Argentina, November 1998