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SURGICAL TECHNIQUE

A multicentre evaluation of a new surgical technique for urethral bulking in the treatment of genuine stress incontinence

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This prospective study assesses the surgeon and patient acceptability of a new implantation device for transurethral Macroplastique injection, as well as the safety and effectiveness of the technique. Ten women with genuine stress incontinence were recruited at each of four participating urogynaecological centres. Treatment was performed in an outpatient or day case setting and follow up took place at six weeks and three months after treatment. Those in whom treatment had failed were offered re-treatment. The operator acceptance of the device was rated as excellent or acceptable in 95% after the first treatment and 100% after re-treatment. Urethral insertions were rated acceptable in 92·5%. Pain was scored as mild to moderate in 89% of all insertions. The overall success rate was 74·3% at three months with an implantation rate of 1·35 which appears to be comparable to published endoscopic data. We have concluded from this study that the Macroplastique implantation device is safe to use and provides simplified, yet effective alternative to the endoscopic implantation of urethral bulking agents.

Introduction

Many options are available for the treatment of female genuine stress incontinence. Women are usually offered physiotherapy or surgery to improve genuine stress incontinence. There are a large number of different operations, but the standard surgical treatment appears to be colposuspension[1]. Objective cure rates for this procedure have been reported to be in the range of 80%–90%[2]. However, this is associated with significant morbidity; 10% of women develop *de novo* detrusor instability post-operatively and 14% subsequently develop prolapse[2]. Other authors reported that only 44%–52% of women may be both continent and complication free after colposuspension[3,4].

Periurethral injections of bulking agents have been shown to be effective for treating genuine stress incontinence with improvement rates of up to 70%–90% and cure rates around 50%[5]. They offer the benefits of reduced morbidity and complication rates. Periurethral injections can also be performed using local anaesthetic techniques in the outpatient environment. While initial studies showed the potential for this technique, defined treatment groups have only been identified in recent years[6]. In the last 60 years, several injectable urethral bulking agents have been used. New materials have also been introduced which have fewer side effects[7], but the method of delivering the material has remained constant. Accurate needle placement is not as easy as it might appear, and there is a learning curve to master the technique. For example, after performing 40 endoscopically controlled procedures the quantity of material needed can be expected to fall to almost 30% of the initial amount required[8].

Macroplastique (Uroplasty bv, Geleen, The Netherlands) has been employed for the treatment of genuine stress incontinence since 1991. It consists of solid polydimethylsiloxane elastomer implants in a hydrogel carrier suspension. Several publications reporting on female endoscopic treatment[9–13] describe cure rates between 33% and 67% in the short term, with a success rate between 68% and 75% . Long term success rates are reported as 48% to 72%[10,11,14,15].

We report on a multicentre study using a new device aimed at simplifying the transurethral implantation technique and minimising problems associated with endoscopic procedures. The primary aim of this study

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as to evaluate surgeon and patient acceptability of the device. Secondary aims were to assess the safety and effectiveness of the technique.

Methods

Forty women with genuine stress incontinence were recruited sequentially from urodynamic clinics and treated between January and August 1998. Inclusion and exclusion criteria are detailed in Table 1. The four centres were Barnsley District General Hospital, Hope Hospital, Birmingham Heartlands Hospital and Chesterfield and North Derbyshire Hospital. These centres are situated at Barnsley, Manchester, Birmingham and Chesterfield. Each of the four centres treated 10 women, all of whom gave signed informed consent. Twenty-eight of these women had not undergone previous continence surgery. Ethical committee approval was obtained for a preliminary study[16] and was not deemed necessary for this study, as the device was Conformité Européenne (CE) marked. The investigators were not familiar with the endoscopic technique and attended a formal implantation workshop before this evaluation.

The Macroplastique implantation device (Uroplasty bv, Geleen, The Netherlands), was developed as a needle-positioning device. It provides the surgeon with an alternative implantation technique for the treatment of female genuine stress incontinence. The device has a central fluid drainage channel, an external measuring scale and three angled needle entry ports (Fig. 1). It is designed to provide consistent bolus placement at predefined angles into three equally spaced locations. Size 20 Gauge injection needles are designed with a locator pin to provide exact bevel orientation and precise injection depth.

Operator acceptance and ease of urethral insertion of the device were scored using three-point scales. Acceptance was graded as excellent, acceptable or unacceptable. Ease of insertion was graded as acceptable resistance, unacceptable resistance or no resistance.

Women were given pre-operative medication (oral temazepam 10–20 mg, rectal diclofenac sodium 100 mg). The procedure was performed under aseptic conditions with the patient in the lithotomy position. Local anaesthetic gel was inserted into the urethra 10-15 minutes before the implantation procedure (2% lignocaine hydrochloride, 20 mL). The bladder was filled with 300 mL 0·9% normal saline. Stress leakage was demonstrated.

The device was inserted into the urethra, advanced until fluid drainage was observed through the central channel, and withdrawn until drainage ceased, identifying the level of the bladder neck. The device was then withdrawn an additional 10 mm before implantation.

The tip of the device was angled towards each injection site to aid penetration of the urethral mucosa. At the six o'clock position, a 2·5 mL bolus of Macroplastique was implanted, and a further 1·25 mL was implanted at each of the ten and two o'clock positions. All procedures were performed using the standard Macroplastique administration gun. The women were asked to rate the level of pain experienced during the procedure. Pain was graded as mild, moderate or severe. The women were discharged after spontaneous voiding was achieved. A prophylactic antibiotic was provided for five days (e.g. Trimethoprim 200 mg twice daily).

Follow up was performed at six weeks and three months after initial treatment. The outcome was determined by means of subjective rating by the investigators. Women were classified as dry, markedly improved, slightly improved or unchanged. Success was defined as those women who were dry or markedly improved. Women in whom the treatment failed were offered re-treatment after their three-month follow up. Re-treatment was performed with an additional 5 mL of Macroplastique and women were followed up in the same manner as after their initial treatment. The collected data from the four centres were analysed by an independent research monitor.

A Pearson χ^2 test was used to determine homogeneity between centres.

Table 1. Key inclusion and exclusion criteria. GSI = genuine stress incontinence.

Inclusion	Exclusion
Urodynamically proven GSI	Neurogenic or unstable bladder
No detrusor overactivity (< 15 cm water)	History of vesicoureteric reflux
Normal pressure voiding studies	Congenital or traumatic anatomical defects
Minimal or no utero-vaginal prolapse	Moderate/severe utero-vaginal prolapse
No improvement of incontinence in last 12 months	Previous urethral bulking agent injection therapy
Age > 18 years	History of intra-urethral devices
Negative urine culture	Untreated urinary tract infection
Post-void residual urine < 100 mL	History of haematuria
Not pregnant or < 12 months postpartum	
Signed informed consent	

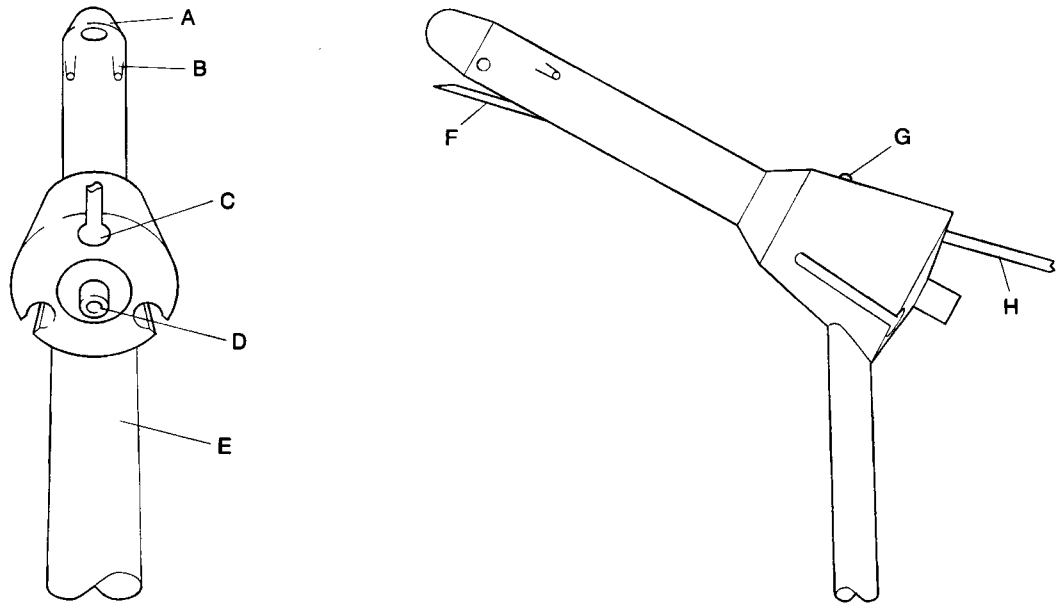

Fig. 1. The Macroplastique implantation device. A. drainage port; B. needle exit port; C. needle locator guide; D. drainage channel; E. handle; F. needle tip; G. locator peg; H. needle shaft.

Results

Analysis of patient characteristics revealed that patient groups in the four centres were not significantly different (i.e. age, body mass index, smoking habits, history of previous surgery, etc.).

Overall operator acceptance of the device was rated as either excellent or acceptable in 95% (38/40) after the first treatment and 100% (18/18) after re-treatment. Urethral insertion was rated by the operators as acceptable in 92·5% (37/40) of the first procedures. Minimal urethral dilatation was required in 4/58 procedures.

Eighty percent (32/40) of the women went home on the same day after the first procedure. The overall success rate was 52·5% (21/40) at the three-month follow up (one treatment). Re-treatment was offered to all 19 women with an unsuccessful outcome (slightly improved or unchanged). Three chose colposuspension, two wished no further treatment and 14 women (35%) were re-treated. Eight of these women were either cured or significantly improved after re-treatment.

Four women of the markedly improved group requested re-treatment in an attempt to upgrade the outcome to dry. Of these four women, one remained markedly improved and the remaining three became dry. This did not influence the overall outcome rating as these women had already been classified as a treatment success after the first injection. All re-treatments were performed distal to the initial implantation site.

Three months after re-treatment, the overall success rate was 74·3% (29/39) (Table 2). One of the women was lost to follow up after re-treatment and was therefore excluded. The average rate of implantation to achieve these results in this series was 1·35.

Table 2. Results after first treatment and after re-treatment. Values are given as *n* (%), unless otherwise indicated.

	After 1st Treatment		After 2nd Treatment	
Follow up interval	6 weeks	3 months	6 weeks	3 months
Number of patients	40	40	39*	39*
Results				
Dry	8 (20)	8 (20)	14 (35·9)	16 (41)
Markedly improved	11 (27·5)	13 (32·5)	11 (28·2)	13 (33·3)
Slightly improved	10 (25)	11 (27·5)	5 (12·8)	4 (10·3)
Unchanged	10 (25)	7 (17·5)	7 (17·9)	6 (15·4)
Missing	1 (2·5)	1 (2·5)	2 (5·1)	0 (0)

*One patient was lost to follow up.

A total of 55 pain scores were documented. Women described the pain experienced as mild or moderate in 89% (49/55) implantation procedures. Two women requested a general anaesthetic for re-treatment.

Seven women had retention for more than 48 hours and two of these required indwelling catheterisation. As is common in transurethral procedures, transient haematuria and dysuria were evident in 63·3% of the women.

Discussion

Endoscopic implantation techniques require considerable training. Their successful use is associated with a learning curve[17]. The Macroplastique implantation device was designed to standardise the injection process and simplify the implantation technique without compromising success rates. In a preliminary study similar bolus formation and bladder neck apposition to the endoscopic technique was observed cystoscopically[16]. This study evaluated the use of the device for the treatment of genuine stress incontinence in an outpatient setting. This technique was easy to learn and perform by surgeons who had no previous experience with this device. Furthermore, no previous experience with endoscopic implantation of urethral bulking agents is necessary.

The Macroplastique implantation device is the result of a long term development programme[16,18]. It is a well designed device for urethral insertion and placement of Macroplastique. It has an advantage in that it is short, light-weight and easily handled. The procedure is easier to perform than endoscopically guided implantation. Surgeons rated the device as highly acceptable. The overall success rate of the procedure was 74·3% (29/39), which is comparable to published data using endoscopic techniques[1,9–12,19].

Successful outpatient treatment was achieved in the Barnsley and Manchester centres. In the other centres, the surgeons chose to perform the procedures in a day case setting. Only two women requested general anaesthesia for re-treatment. Most women found the procedure acceptable and were discharged on the same day. The only reason for admission was urinary retention. The rate of urinary retention in this study is comparable to previously reported rates using urethral bulking agents[12]. Transient urinary retention (< 48 h) was managed by intermittent catheterisation. The two women with persistent voiding problems were managed with indwelling catheters. There were no voiding problems observed at three month follow up.

Using the device, the average volume of Macroplastique used per patient was 6·8 mL. The number of injections performed to achieve our success rate compares very favourably with previously published data[8]. The advantage of the device is consistent bolus placement at a pre- determined depth and site. This may explain the low number of re-treatments and the lower volume used.

It is unknown whether the increased success rate at re-treatment was due to the secondary procedure alone, overcoming a learning curve, or a combination of both. It is interesting that the success rate of the women who underwent re-treatment was 71% (12/17).

It is important to note a success rate of 71% in women who had not had previous incontinence surgery. This is in contrast to the widely accepted indication for urethral bulking agent therapy reported as being type III intrinsic sphincter deficiency[14,20–23]. Further subjective follow up of the patient cohort is intended at 12 and 24 months.

In conclusion, the Macroplastique implantation device can be used as a safe outpatient or day-case implantation procedure. This device provides an effective alternative to the endoscopic implantation of urethral bulking agents in the management of genuine stress incontinence.

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