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Title: MACROPLASTIQUE IMPLANTATION IN WOMEN WITH STRESS URINARY INCONTINENCE
USING A NEW TRANSURETHRAL IMPLANTATION TECHNIQUE

Aims of Study:

This ongoing randomised controlled study evaluates two implantation levels for transurethral Macroplastique implantation with the Macroplastique implantation device (MID). As the device allows midurethral placement of the bulking agent, the standard implantation site is compared to a more distal placement in order to determine the best implantation site. The new implantation technique does not require cystoscopy and simplifies and standardises the injection process. The 24F device is inserted into the urethra and transurethral injection is carried out via a needle guiding system, which results in consistent bolus placements at 2, 6 and 10 o'clock positions. The implantation procedure is safe, requires local anaesthesia only and is performed in the outpatient department.

Methods:

Patients are recruited from referrals to the Urogynaecology department. 63 women with urodynamically proven Genuine Stress Incontinence have been entered into the study since July 1999. Only 3 women have been diagnosed to have Type III stress incontinence (intrinsic sphincter deficiency). The majority of women did not have any previous surgical treatment for urinary incontinence but most had undergone pelvic floor retraining. All women completed a standard ICS 1-hour pad test, urodynamic assessment and Frequency/Volume Chart and Quality of Life and patient questionnaires before and after treatment. The first 16 women were treated with the prototype Macroplastique implantation device before the MID became available. The two implantation devices are of the same design, with the difference of the commercially available MID being a single-use item.
All treatments were performed under local anaesthetic by the investigator.

Results:

The average age at first Macroplastique implantation was 52 years (range 31 – 77 years). 59 women received their treatment in the outpatient department and out of those 8 were treated in as "One-Stop" patients after urogynaecological assessment on the same day. 4 women were treated in the Daycase Unit due to staffing problems. Data on completed follow-up are available for 16 patients.
Success was defined as patients who were either cured or markedly improved and treatment failure as patients who were only slightly improved or unchanged.
At 1 year after treatment (or 3 months after retreatment) the subjective patient outcome was cured or markedly improved for 8 women, giving a 50% success rate by subjective patient self-assessment. The objective outcome rating as assessed by the surgeon was cured or markedly improved for 11 women, which gives a preliminary objective success rate of 68.5% for the patients who completed the initial follow-up.

The group of 5 patients classified as treatment failures included 1 patient who withdrew from study prior to retreatment. 9 women underwent repeat Macroplastique implantation. 2 patients out of the markedly improved group were retreated on request to achieve dryness. The 6 women who were initially assessed as treatment successes (at 3month follow-up) maintained their treatment success at 1 year after treatment. These are only preliminary results and we expect to be able to present follow-up data for the majority of study patients at the time of the meeting.

Conclusions:

Success rates using the new technique were found to be similar to results achieved using the endoscopic route.[1] The simpler technique using the Macroplastique implantation device represents an advancement in the technique of implanting a urethral bulking agent.

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[1]A multicentre evaluation of a new surgical technique for urethral bulking in the treatment of genuine stress incontinence. Br J O G 2000; 107: 1035-39