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MACROPLASTIQUE® FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE: TWO-YEAR OUTCOME

Hypothesis / aims of study

Collagen injection is used widely to treat female stress urinary incontinence secondary to intrinsic sphincter deficiency (ISD). In spite of short-term satisfactory success rates, the long-term outcome results are much less favorable (1, 2). This is a two-year extension study to evaluate the durability of Macroplastique injection for treatment of female stress urinary incontinence secondary to ISD.

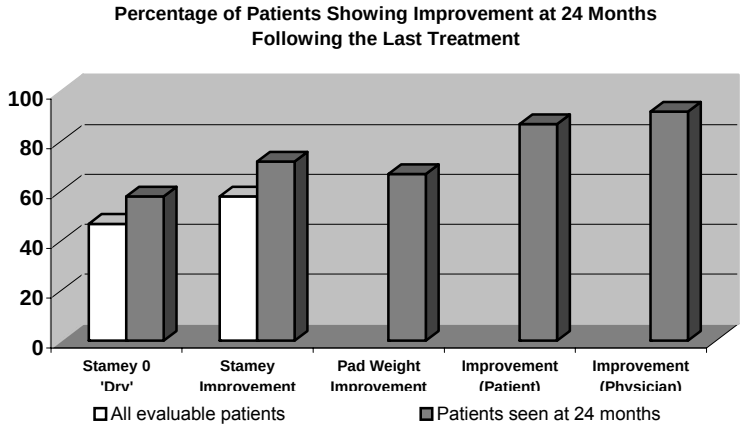
Study design, materials and methods

One-hundred-twenty-two females diagnosed with ISD were treated with Macroplastique in a single-blinded, multicenter study. A maximum of two treatments were allowed; the second treatment occurring immediately after patients' initial 3 month follow up. Mean age was 61 years with an average incontinence duration of 11 years and all patients received prior incontinence treatment. Outcome measures included Stamey's grading, Patient Global Impression of Improvement (PGI-I), Physician Assessment of improvement, pad weight, and Incontinence Quality of Life (I-QoL) scores. Safety parameters were measured throughout the study. Of the 122 subjects, 89 were evaluable for efficacy parameters at two years following their last treatment with 72 attending their 24 month visit and 17 seeking alternative incontinence therapies prior to their 24 month visit (analyzed as treatment failures). Of the remaining 33 patients, 21 were lost to follow-up or withdrawn, and 12 have not yet attended their 24 month visit.

Results

For the 89 evaluable patients, the retreatment rate was 46% (3 months after initial treatment) with a mean volume of 4.6 ml with first treatment and a mean volume of 4.5 ml with the second treatment; mean total volume injected per patient was 6.8 ml. At twenty-four months post-treatment, 58% (52/89) of evaluable patients had improved at least one Stamey grade from baseline, with 47% (42/89) of patients considered 'dry' at 24 months (Stamey grade = 0). Of patients who attended the 24 month visit, 72% (52/72) of patients had improved at least one Stamey grade from baseline, with 58% (42/72) of patients 'dry' (Stamey grade = 0). Physician's assessment of improvement indicates 8% of treated patients are unchanged from baseline. In the GPI-I analysis, 13% of subjects considered themselves unchanged from baseline. No physician or patient assessments indicated a worsening from baseline. The pad weight test indicated a mean change in urine loss of 22.8 ml (sd=30.1) and 67% of patients showed improvement from baseline with a reduction of at least 50% in urine loss. The average improvement in I-QoL score is 24.4 units (sd=23.8), with a 32.5 unit improvement in the Social Embarrassment Subscale (sd=31.7). Macroplastique demonstrated an acceptable safety profile and no unanticipated adverse device effects were reported during the course of the study. The most common transient symptoms lasting $\leq$ 48 hours after treatment were delayed voiding, pain at implantation site, dysuria and hematuria.

The most common treatment related adverse events included urgency and frequency, though none were considered to be serious by the physician



Interpretation of results

Substantial and durable results were observed with Macroplastique as a minimally invasive treatment of female stress urinary incontinence. Nearly three-fourths of subjects followed to two years had a significant improvement in Stamey grade and more than half of evaluated patients were cured at 24 months post-treatment. These results translated to a marked improvement in I-QoL scores.

Concluding message

Macroplastique has been shown to be a safe and effective treatment for female stress urinary incontinence, with sustained results through two years.

References

1. Gorton E, Stanton S, Monga A, et al. 1999. Periurethral collagen injection: a long-term follow-up study. *BJU Intl*; 84: 966-71.
2. Chrouser KL, Fick F, Goel A, et al. 2004. Carbon coated zirconium beads in β-glucan gel and bovine glutaraldehyde cross-linked collagen injections for intrinsic sphincter deficiency: continence and satisfaction after extended follow-up. *J Urol*; 171: 1152-1155.

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