

Macroplastique[®] Clinical Data

Ghoniem, G., Corcos, J., Comiter, C., Westney, O.L., & Herschorn, S. (2010). Durability of urethral bulking agent injection for female stress urinary incontinence: 2-year multicenter study results. *J Urol*, 183, 1444-1449.

PURPOSE: We evaluated the durability of the urethral bulking agent Macroplastique[®] for stress urinary incontinence in a 24-month study in women with a previously documented successful outcome 12 months after the last injection.

MATERIALS AND METHODS: In a multicenter study females diagnosed with stress urinary incontinence primarily due to intrinsic sphincter deficiency successfully treated with Macroplastique, defined as ≥ 1 Stamey grade improvement 12 months from baseline, were followed for 24 months to assess the sustained therapeutic response. Outcome measures were Stamey grade, Patient Global Impression of Improvement, Physician Assessment of Improvement, 1-hour pad weight, Incontinence Quality of Life scores and safety assessment.

RESULTS: At 24 months 56 of 67 patients (84%) had sustained success since 12 months, of whom 45 of 67 (67%) were dry (Stamey grade 0). Of the dry patients at 12 months 33 of 38 (87%) maintained cure at 24 months. Also, 12 of 29 patients (41%) considered improved at 12 months were dry at 24 months. Overall Incontinence Quality of Life scores and all subscales showed statistically significant improvement from baseline ($p < 0.001$). Mean pad weight was 24 gm at baseline, and 4 gm at 12 and 24 months. Patient and physician assessments rated 85% of patients dry or markedly improved 24 months after the last treatment.

CONCLUSIONS: Substantial, durable results were sustained during 2 years with 84% of patients maintaining significant Stamey grade improvement from the 12-month assessment. Two-thirds of patients were dry at 24 months. The durability of Macroplastique shows its effectiveness as a viable long-term therapy for female stress urinary incontinence primarily due to intrinsic sphincter deficiency.

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