Macroplastique® Clinical Data

Ghoniem, G., Corcos, J., Comiter, C., Bernhard,P., Westney, O.L., & Herschorn, S. (2009). Cross-linked polydimethylsiloxane injection for female stress urinary incontinence: Results of a multicenter, randomized, controlled, single-blind study. *J Urol. 181*, 204–210.

PURPOSE: In a pivotal trial we evaluated the effectiveness and safety of Macroplastique® as minimally invasive endoscopic treatment for female stress urinary incontinence primarily due to intrinsic sphincter deficiency.

MATERIALS AND METHODS: A total of 247 females with intrinsic sphincter deficiency were randomized 1:1 and treated with a transurethral injection of Macroplastique or Contigen®. The latter group served as the control. Repeat treatment was allowed after the 3-month followup. Effectiveness was determined 12 months after the last treatment using Stamey grade, pad weight and Urinary Incontinence Quality of Life Scale scores. Safety assessment was recorded throughout the study.

RESULTS: After 12 patients were excluded from study 122 patients received Macroplastique injection and 125 received Contigen injection. Mean patient age was 61 years and the average history of incontinence was 11.2 years. Of the patients 24% had undergone prior incontinence surgery. At 12 months after treatment 61.5% of patients who received Macroplastique and 48% of controls had improved 1 Stamey grade. In the Macroplastique group the dry/cure rate was 36.9% compared to 24.8% in the control group ($p < 0.05$). In the Macroplastique and control groups the 1-hour pad weight decrease was 25.4 and 22.8 ml from baseline ($p = 0.64$), and the mean improvement in Urinary Incontinence Quality of Life Scale score was 28.7 and 26.4 ($p = 0.49$), respectively.

CONCLUSIONS: Macroplastique injection was statistically more effective than Contigen for stress urinary incontinence primarily due to intrinsic sphincter deficiency with a 12.1% cure rate difference. Macroplastique can be administered on an outpatient basis. It should be considered a primary or secondary treatment option for stress urinary incontinence.

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