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Author(s):

A.E. Bent, J. Foote, S. Siegel, G. Faerber, R. Chao, and A. Gormley Double Spacing

Institution City Country

> Title (type in CAPITAL LETTERS)

Double Spacing

Greater Baltimore Medical Center, Baltimore, Maryland

CONTIGEN® IMPLANT IN THE TREATMENT OF STRESS URINARY INCONTINENCE WITH HYPERMOBILITY

<u>AIMS OF STUDY</u>: This was a prospective multi-center study to assess the efficacy of glutaraldehyde cross-linked collagen (Contigen®) in the treatment of stress urinary incontinence (SUI) associated with urethral hypermobility (UH). <u>**METHODS**</u>: Ninety women with SUI and UH were treated with 1-3 injections of Contigen® implant administered over a maximum period of six months between July/96 and August/98. Voiding diaries, quality of life questionnaires, and incontinence grade assignment were completed at baseline and 3, 6, and 12 months after the last injection. Leak point pressures were performed at baseline and 12 months. Success was determined as dry or improved (improvement of at least one incontinence grade).

<u>RESULTS</u>: Mean age was 58.1 years and incontinence was grade 1 in 17, grade 2 in 69, and grade 3 in 4. Two injections were placed in 66 and three injections in 21. Fifty-four patients (61%) were improved (n=25) or dry (n=29) at last follow-up with an average of 1.8 injections using 11 cc of implant. Using an end-point analysis (status at last follow-up), the life table analysis estimates that 50% of the patients will be dry or improved at 12 months. Of the 21 patients withdrawing prior to 6 months, 7 showed an improvement of one continence grade, and 3 were dry. Patients with improved leak point pressures at 12 months also had an improved incontinence grade ($p \le 0.05$).

<u>CONCLUSIONS</u>: Contigen® has proven efficacy in 61% of women with SUI and hypermobility. The duration of improvement appears to be 6 months in 65% and 12 months in 50% of patients. This therapy may be especially useful in older patients at surgical risk or as an interval measure in selected candidates. (Supported by C.R. Bard, Inc., Covington, GA)