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FIVE YEAR CLINICAL ASSESSMENT OF PATIENTS TREATED WITH COAPTITE® UROLOGICAL BULKING AGENT

Aims of Study

Advances in the last decade have resulted in endoscopic injection of bulking agents for the correction of stress urinary incontinence and vesicoureteral reflux being a treatment of choice. The primary attributes of a bulking agent, biocompatibility, ease of use, lack of migration, and durability of results, are key factors for wider utilization of the procedure. Clinical studies with Coaptite soft tissue bulking agent were initiated in 1996 on 27 patients. While the study was designed for one-year follow-up after treatment, some patients have been evaluated five or more years later. Coaptite is a highly biocompatible cohesive implant developed from synthetic components with an extensive history of safe use in drugs and medical devices. The durability of Coaptite results from the ceramic like spherical particles of synthetic calcium hydroxylapatite (CaHA) that are very low in solubility.

Methods

Patients with a history of intrinsic sphincteric dysfunction were enrolled in a prospective clinical study that was conducted at one site in the U.S. and two sites in the U.K. Patients meeting the entrance criteria (stress incontinence with limited hypermobility) were evaluated at baseline with activity pad tests, urodynamics, voiding diary, and QOL. Three injection techniques (transurethral, periurethral, and suprapubic) were utilized. The patients were followed for the one-year following last injection per study protocol. More recently, it was possible to evaluate nine patients, located after five years, with some of the outcome measures previously utilized. Additional clinical studies are confirming the findings from the initial study.

Results

The data from assessment of the clinical studies one year after final treatment verified that Coaptite: is biocompatible; does not require antigenicity testing; is compatible with standard instrumentation; did not cause pain at the injection site; remained at the injection site and did not migrate; improved all of the outcome measures (>83% median pad weight reduction for all tests and >80 % reduction in pad usage); and has an acceptable safety profile. The follow up after five years demonstrated Coaptite to be durable for over five years with no evidence of migration (X-ray) or ossification. For some of the patients who were treatment failures or whose symptoms changed, the Coaptite implant did not interfere with subsequent surgery. There was overall sustained improvement in the patients that were assessed after more than five years.

Conclusions

This study and additional clinical evaluations have demonstrated that Coaptite is a biocompatible, easy to use, effective, and durable treatment for urinary stress incontinence. Expanded clinical results from a larger, comparative clinical study continue with initial results comparable to these results.