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CLINICAL EXPERIENCE WITH COAPTITE® UROLOGICAL BULKING AGENT

Aims of Study

Clinical experience with bulking agents has shown the potential for the treatment of urinary stress incontinence. Prospective clinical studies were initiated in 1996 and expanded significantly in 2000 to evaluate the efficacy and durability of Coaptite for the treatment of urinary stress incontinence.

Methods

Coaptite was designed and developed to be a biocompatible and durable urological bulking agent for the treatment of urinary stress incontinence. Coaptite is a cohesive implant based upon durable ceramic-like spherical particles of synthetic calcium hydroxylapatite (CaHA). The pilot clinical study initiated in 1996 was conducted in one site in the U.S. and two sites in the U.K. The clinical study was expanded to a multicenter, randomized comparative study being conducted in the U.S. The patients are assessed at baseline and periodically for at least one year using pad weight tests, pad usage and QOL outcome measurements. Stamey grade evaluation was also conducted in the expanded comparative study.

Results

The clinical studies have demonstrated that Coaptite was easy to inject with standard instrumentation, did not require antigenicity pre-testing, did not cause pain at the injection site, remained at the injection site, and is biocompatible with an acceptable safety profile. In the comparative study, in the first 46 patients that have been assessed after one year, Coaptite has shown greater rates of improvement in Stamey grade, pad weight reduction and wet pads than bovine collagen.

	Improvement of One Stamey Grade	90% Pad Weight Reduction	No Wet Pads per Day
Coaptite	75%	50%	43%
Bovine Collagen	50%	43%	28%

Additional comparative results at twelve months were reduced leakage in all categories in the 24 hour pad test and greater cure rate (by all evaluation methods) for the Coaptite patients. There were twice as many patients without improvement with bovine collagen. The first one hundred patients with six month follow up have similar results. These results are consistent with the results from the pilot study.

Assessments were completed in twelve patients more than five years after treatment of twelve of the patients were able to be completed. For nine where there was improvement at one year, there was sustained reduction in leakage from the activity pad test and in number of wet pads per day demonstrating the durability of Coaptite. In addition, for the long-term patients, there was no evidence of migration or ossification nor did the Coaptite interfere with subsequent surgery if required.

Conclusions

The prospective clinical studies have demonstrated that Coaptite is a safe, effective and, importantly, durable treatment for urinary stress incontinence. These studies will continue so as to provide additional clinical results.