RESULTS: Average biopsy weights were 0.149 g (range 0.084 to 0.227), average number of cells isolated was $931x10^6$ (range 380-$2110x10^6$), and average culture days 47.8 (range 41-60). Volume of material injected was 5.9 ml (range 3-11.6). Average pad use declined from 17 at baseline to 6 at 6 months, and incontinent episodes declined from 19 to 5, with only 9 patients having more than 3 leak episodes per day. Pad weight testing decreased from 20.6 gm at baseline to 3.7 gm at 3 months, and 0.8 gm at 6 months. There was a decrease in social impact scores from baseline to six months for physical recreation, emotional health, and feeling frustrated. Incontinence severity grading indicated 17 patients dry, and 10 improved at 6 months for a total of 27 of 32 (84%) dry and improved after one treatment. Only seven patients had a pad weight test over 2 gm. Current data indicates continued effectiveness at one year.
CONCLUSIONS: Endoscopic treatment of ISD with autologous chondrocytes is safe and effective. There is persistence of improvement at 12 months. Material may be conserved for a second injection if the initial treatment is not totally curative. Longer follow-up and comparative studies are needed to document the extended duration of effect compared to current bulking agents. (Supported by Reprogenesis, Inc, Boston, MA)

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GAX COLLAGEN OR MACROPLASTIQUE DOES IT MAKE A DIFFERENCE?

Introduction: Glutaraldehyde cross-linked (Gax) collagen and microparticulate silicone Macroplastique (MP) are used as bulking agents in the treatment of stress incontinence. GAX collagen is a purified bovine dermal collagen cross-linked with glutaraldhyde and dispersed in phosphate-buffered physiological saline. Macroplastique consists of textured silicone particles suspended in a liquid gel (polvinylpyrrolidone). The aim of this study was to compare the use and efficacy of the two substances in the treatment of female stress incontinence in a prospective randomised trial.

Methods: Women urodynamically diagnosed with moderate or severe urethral sphincter incompetence were randomised to either Gax or Macroplastique. The women included in this study were either unfit for major surgery or had undergone surgery which had failed. Women with detrusor instability, voiding difficulties, recurrent urinary tract infection or gross vaginal prolapse were excluded. Assessment involved a disease specific Quality of Life (QoL) questionnaire and a one hour pad test with a prefilled bladder of 250mls. Assessments were made prior to injection and again at one month, six months and twelve months. Objective improvement was defined as a reduction greater than 50% of the pre-treatment loss and cure was defined as a loss of <2g. Women who failed at any visit were offered another injection, up to a maximum of three. The injections were performed paraurethrally for both Gax collagen and Macroplastique.

Results: Sixty-two women were recruited, two women, both of whom had Gax were withdrawn due to protocol violations and have not been included in the analysis. Of the remaining sixty, twenty-six had Gax and thirty-four had MP. Their mean age was sixty-seven years (range 45- 88 years). Nineteen women (9-MP and 10-Gax) were considered unfit for major surgery and 41 (25-MP and 16-Gax) had had previous failed continence surgery. These women had undergone on a mean of 2.1 (range

1-4) continence procedures. The numbers of the women who had one, two or three injections are outlined in table 1.

Table 1: Numbers of women injected

Type	Injection 1 (n)	Injection 2 (n)	Injection 3 (n)
Gax collagen	26	7	1
Macroplastique	34	12	3

Table 2: Objective outcomes of injectables

	Cured n (%)	Improved n (%)	Fail n (%)
Gax collagen (injection 1)	3 (11)	7 (27)	16 (62)
Macroplastique (injection 1)	6 (18)	6 (18)	22 (64)
Gax collagen (injection 2)	0 (0)	4 (57)	3 (43)
Macroplastique (injection 2)	2 (16)	5 (42)	5 (42)
Gax collagen (injection 3)	0 (0)	1 (33)	2 (67)
Macroplastique (injection 3)	1 (100)	0 (0)	0 (0)

Subjective analysis of QoL showed no significant difference between the two groups either pre or post treatment. QoL did improve significantly in all women following treatment ($p < 0.05$).
The only difference between the two groups was the Gax collagen group had a significantly larger urinary loss on pre treatment pad weight test. There was no significant objective difference between the two groups comparing the pad weight loss post treatment at one, six and 12 months (table 3).

Table 3: Median Pad Test loss (ml) for both groups (Inter Quartile Range)

	Pretreatment	1 months	6 months	12 months
Gax collagen	**55.2** (18.0 - 80.2) n=26	**3.8** (0.6 - 38.2) n=24	**9.0** (0.9 - 51.0) n=13	**8.4** (1.6 - 34.0) n=10
Macroplastique	**22.0** (7.9 - 52.3) n=34	**3.7** (0.5 - 24.6) n=34	**9.8** (0.4 - 70.7) n=29	**0.7** (0.275-6.025) n=10

On the first injection, the mean volume of Macroplastique injected was 5.1mls and 9.2mls in the Gax collagen group which was significant ($p<0.001$).

Conclusion: This prospective randomised study does not show any difference in objective efficacy between GAX collagen and Macroplastique. The injected volume of Macroplastique was significantly lower than the volume of GAX collagen used. The initial pad test loss did not predict outcome.

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Tissue replacement by tension-free insertion of prolene tape (TVT technique according to Ulmsten) in urinary incontinence (UI): technical details, indications, specifications, results

Aims of study

Stress incontinence in women is frequently caused by a constitutional or age-dependent slackening of connective tissue. Surgical methods using body tissue for reconstruction are therefore doomed to failure in the