

**CONTIGEN OR MACROPLASTIQUE? A FIVE YEAR FOLLOW-UP****Aims of Study**

A prospective randomised trial comparing the use and efficacy of bulking agents Glutaraldehyde cross-linked bovine (GAX) collagen (Contigen) and microparticulate silicone (Macroplastique) was presented at the ICS in Denver (1) Women with urodynamic stress incontinence were randomised to Contigen or Macroplastique. The women included in this study were either unfit for surgery or had failed previous continence surgery. No objective difference was found in the efficacy of the two substances. Analysis of Quality of Life showed a significant improvement after both treatments ( $p < 0.05$ ) but no difference between the two groups. The aim of this study was to look at the longer term effects on quality of life of both substances in the treatment of urodynamic stress incontinence and to assess whether any difference between the two groups could be found in the longer term.

**Methods**

Assessment of Quality of Life was performed using the Kings Health Questionnaire (KHQ) (2). Questionnaires were sent out to women who were followed up on the telephone or by a visit to the hospital. Information was obtained on further continence procedures and any current medication for bladder complaints. Those who had undergone further continence procedures were excluded from the Quality of Life analysis. The Wilcoxon sign rank test was used to compare the pre and post treatment quality of life data, whilst the Mann Whitney U test was used to compare Contigen and Macroplastique. Symptoms of frequency, urgency, urge incontinence and stress incontinence were assessed using the KHQ symptom score.

**Results**

Sixty women were included in the original analysis. 26 had Contigen and 34 had Macroplastique. Four women have since undergone a TVT (all had had Contigen), one a urinary diversion (Macroplastique), one an insertion of a long term supra-pubic catheter (Contigen), although this was primarily inserted as she had voiding difficulties and had performed self catheterisation prior to initial treatment. Four have since died. Ten women have been lost to follow up, which has left forty women (14, Contigen and 26, Macroplastique) with data suitable for this long term Quality of Life analysis. Their mean age prior to treatment was 70 years (range 52- 86 years) and their mean age now is 76 (range 58 – 92 years). Their mean follow up period was 54 months (range 36 – 80 months). Of those currently on medication, two women are taking tolterodine and one oxybutunin, empirically. One woman currently takes bethanecol for mild voiding difficulties.

Analysis of Quality of Life scores demonstrated a significant change in the following domains; Incontinence Impact, Role limitations, Physical limitations, Emotions/sleep and Severity measures (See table 1). There was no difference between Contigen and Macroplastique.

Table 1: Kings Quality of Life Domains

Quality of Life domain	Pre treatment	At 5 years	p-value*
General health perception	37.7	40.6	0.318
Incontinence Impact	79.3	56.7	0.002*
Role limitation	52.3	33.3	0.13*
Physical limitation	59.0	40.4	0.19*
Social limitation	39.7	26.2	0.068
Personal relationships	50.0	18.3	0.104
Emotions	55.5	31.9	0.001*
Sleep/ energy	45.9	41.2	0.194
Severity measures	73.6	53.3	0.007*

There was a significant improvement in symptoms of stress incontinence (0.000), urge incontinence (0.036) and frequency (0.004). There was no significance difference in the symptom of urgency. 62.5% of women still use pads 'all of the time' This was not significantly different to pad usage prior to treatment. Type of pad was not identified.

### **Conclusions**

At five years pad usage is unchanged although the symptom of stress incontinence and Quality of Life remain improved. This would confirm that the use of bulking agents continues to be a worthwhile form of treatment for women who are unable to undergo other surgical interventions. There would appear to be no statistical difference in outcome of Quality of Life between Contigen and Macroplastique, although there maybe a trend towards a higher incidence of redo surgery in the Contigen Group. However, the numbers are too small for statistical analysis.

### **References**

1. Anders K, Khullar V, Cardozo et al. Gax Collagen or Macroplastique. Does it make a difference? 1999. Neurourology and Urodynamics. Vol 18. No 4. 297-298
2. Kelleher C et al. A new questionnaire to assess the quality of life of urinary incontinent women. 1997. Br J Obstet Gynaecol; 104: 1374-1379