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**Title:** SURGERY VS COLLAGEN FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE (SUI): 1 YEAR FOLLOW-UP RESULTS OF A MULTICENTRIC RANDOMISED TRIAL (RCT)

**Aims of Study:**

To compare submucosai urethral collagen injection to surgery for the treatment of female SUI with regard to efficacy, patient quality of life (QoL) satisfaction and complications.

**Methods:**

Multicenter ROT, \*collagen injection = 1 to 4 injections in 6 months. FU starts after last injection, surgery = option of Burch, sling or ENS. Pre-op evaluation + FU visits at 1-3-6-12 months: interview + UDS + satisfaction + QoL (SF36+IIQ)

Per protocol analysis (missing = failure)

Cure defined as having a 24<sup>H</sup> pad test < 2.59 and no secondary intervention

Clinically acceptable difference in result of 20% between the 2 interventions defined by a large survey of 400 physicians.

**Results:**

133 women with SUI, 66 received collagen, 67 underwent surgery(6 BNS, 24 Sling, 24 Burch). 2 refused collagen, 13 refused surgery.

*Success of intervention (by 2. 5g pad test and verbal update) at 12 months*

Endpoint	Collagen	Surgery	Difference	95% Confidence interval for difference	P value
	Proportion of successes	Proportion of successes			
12 months	24/64 (53.1%)	39/54 (72.2%)	-19.1	(-36.19, -2.00)	0.017

At 12 months there is a 19.1% difference in terms of success (within the 20% acceptable difference initially defined). There is no statistical difference in 7 of the 8 domains of the generic QoL questionnaire SF 36, no statistical difference in the disease specific questionnaire IIQ (45.2 ± 18.4 for the collagen group vs 41.6 Difference 17.6 for the surgical group (p=0.3062). No statistical difference in the satisfaction index between collagen and surgery (22.8% vs 20.4% not satisfied and 51.6% vs 66.7% completely satisfied) p=0.228. Complications (36 events for collagen vs 84 events for surgery p=0.003) are significantly less frequent and

severe with collagen.

**Conclusion:**

Using the strict criteria of a 24 H pad test <2.59 and satisfaction and QoL as outcomes this ROT supports the use of collagen as first line treatment in most of SUI when surgical treatment is considered.

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