

Appendix Table 5. The Effects of Injectable Bulking Agents on Female Urinary Incontinence: Results from Randomized Controlled Clinical Trials*

Author Sample Followup	Active Treatment	Control Treatment	Outcome	Events /Active Treatment) [Events/Control Treatment]	Relative Risk (95% CI)	Risk Difference (95%CI)	Quality Issues
Strasser, 2007(115) N = 63, intrinsic sphincter insufficiency or stress UI 12 month followup	Transurethral ultrasonography -guided injections of autologous myoblasts and fibroblasts; regular training and trans vaginal electrical stimulation	Conventional endoscopic injections of collagen; regular training and trans vaginal electrical stimulation	Self Reported Continence	(38/42) [2/21]	9.50 (2.53; 35.63)	0.81 (0.66; 0.96)	Intention to treat. Single blind. Computer-generated randomization list with permuted blocks and ratio of 2:1. Allocation concealment unclear. Baseline data confirmed adequacy of randomization. Sample size not justified.
Bano, 2005(83) N = 50, urodynamic stress UI 6 month followup	Peri or transurethral porcine dermal implant injection (Permacol)	Transurethral silicone injection (Macroplastique)	Negative pad test	(15/25) [9/25]	1.67 (0.90; 3.08)	0.24 (-0.03; 0.51)	No Intention to treat. Open label. Randomization and allocation concealment not reported. Baseline data confirmed adequacy of randomization. Sample size not justified.
Corcos, 2005(67) N = 133, stress UI 13 month followup	Intraurethral collagen sub mucosal injection	Surgery (needle bladder neck suspensions, Burch, and slings).	Negative pad test	(34/66) [37/67]	0.93 (0.68; 1.28)	-0.04 (-0.21; 0.13)	Intention to treat. Centralized randomization stratified by center with randomly distributed blocks 4 and 6 in size. Allocation concealment adequate. Baseline data confirmed adequacy of randomization. Sample size justified.

Schulz, 2004(82) N = 40, urodynamic stress or mixed UI 12 month followup	Periurethral route of injection of bulking agent-dextran copolymer	Transurethral route of injection of bulking agent-dextran copolymer	Negative pad test	(1/20) [3/20]	0.33 (0.04; 2.94)	-0.10 (-0.28; 0.08)	Intention to treat. Open label. Computer generated block randomization scheme. Allocation concealment not reported. Baseline data confirmed adequacy of randomization. Sample size not justified.
Bano, 2005(83) N = 50, urodynamic stress UI 6 month followup	Peri or transurethral porcine dermal implant injection (Permacol)	Transurethral silicone injection (Macroplastique)	Improvement in pad test	(15/25) [10/25]	1.50 (0.84; 2.67)	0.20 (-0.07; 0.47)	No Intention to treat. Open label. Randomization and allocation concealment not reported. Baseline data confirmed adequacy of randomization. Sample size not justified.
			Improved urinary incontinence scores (Stamey)	(14/25) [10/25]	1.40 (0.77; 2.53)	0.16 (-0.11; 0.43)	
			Improved urinary incontinence scores (Kings College Hospital Quality of Health Questionnaire)	(14/25) [7/25]	2.00 (0.98; 4.10)	0.28 (0.02; 0.54)	
Appell, 2006(68) N = 173, stress UI 12 month followup	Transurethral radiofrequency energy collagen micro-remodeling	The sham treatment	Improvement >10 point I-QOL score	(53/110) [28/63]	1.08 (0.77; 1.52)	0.04 (-0.12; 0.19)	No intention to treat. Single blind. Computer generated randomization with ratio 2:1. Allocation concealment not reported. Baseline data confirmed adequacy of randomization. Sample size justified.
Lightner, 2001(162) N = 355, intrinsic sphincter deficiency and stress UI 12 month followup	Injection of bulking agent 1.0 ml Durasphere maximum 5 times with a minimum 7-day interval	Injection of bulking agent bovine collagen maximum 5 times with a minimum 7-day interval	Improvement of 1 or more continence grades	(76/176) [79/188]	1.03 (0.81; 1.30)	0.01 (-0.09; 0.11)	No Intention to treat. Double blind. Randomization and allocation concealment not reported. Baseline data not reported. Sample size not justified.

Schulz, 2004(82) N = 40, urodynamic stress or mixed UI 12 month followup	Periurethral route of injection of bulking agent-dextran copolymer	Transurethral route of injection of bulking agent-dextran copolymer	Improved continence	(6/20) [7/20]	0.86 (0.35; 2.10)	-0.05 (-0.34; 0.24)	Intention to treat. Open label. Computer generated block randomization scheme. Allocation concealment not reported. Baseline data confirmed adequacy of randomization. Sample size not justified.
Lee, 2001(163) N = 68 12 month followup	Periurethral injections of autologous fat from the anterior abdominal wall or buttock	Placebo (saline)	Cured or improved	(6/35) [6/33]	0.94 (0.34; 2.63)	-0.01 (-0.19; 0.17)	No Intention to treat. Double blind. Computerized randomization with random number tables. Allocation concealment not reported. Baseline data confirmed adequacy of randomization. Sample size justified.
Strasser, 2007(115) N = 63, intrinsic sphincter insufficiency or stress UI 12 month followup	Transurethral ultrasonography-guided injections of autologous myoblasts and fibroblasts; regular training and electrical stimulation	Conventional endoscopic injections of collagen; regular training and electrical stimulation	Substantial improvement in urinary continence Slight improvement in urinary continence	(3/42) [1/21] (1/42) [6/21]	1.50 (0.17; 13.56) 0.08 (0.01; 0.65)	0.02 -0.10; 0.14) -0.26 (-0.46; 0.06)	Intention to treat. Single blind. Computer-generated randomization list with permuted blocks and ratio of 2:1. Allocation concealment unclear. Baseline data confirmed adequacy of randomization. Sample size not justified.
Lightner, 2001(162) N = 355, intrinsic sphincter deficiency and stress UI 12 month followup	Injection of bulking agent Durasphere max	Injection of bulking agent bovine collagen	Incidence of urgency	(43/176) [22/188]	2.09 (1.30; 3.34)	0.13 (0.05; 0.21)	No Intention to treat. Double blind. Randomization and allocation concealment not reported. Baseline data not reported. Sample size not justified.

Strasser, 2007(115) N = 63, intrinsic sphincter insufficiency or stress UI 12 month followup	Transurethral ultrasonograph y-guided injections of autologous myoblasts and fibroblasts	Conventional endoscopic injections of collagen	UI	(4/42) [19/21]	0.11 (0.04; 0.27)	-0.81 (-0.96; - 0.66)	Intention to treat. Single blind. Computer-generated randomization list with permuted blocks and ratio of 2:1. Allocation concealment unclear. Baseline data confirmed adequacy of randomization. Sample size not justified.
Corcos, 2005(67) N = 133, stress UI 13 month followup	Intraurethral collagen sub mucosal injection	Surgery (needle bladder neck suspension, Burch, and slings)	Complete retention	(1/66) [9/67]	0.1 (0.0; 0.9)	-0.12 (-0.21; - 0.03)	Intention to treat. Centralized randomization stratified by center with randomly distributed blocks 4 and 6 in size. Allocation concealment adequate. Baseline data confirmed adequacy of randomization. Sample size justified.

*Bold- significant differences at 95% confidence level. QOL = quality of life; UI = urinary incontinence.