

Appendix Table F144. Comparative effectiveness of bulking agents (individual RCTs)

Reference sample	Active	Control	Definition of outcome	Randomized active/control	Active events/rate	Control events/rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Continence										
Mayer, 2007 ⁵⁶⁷ 296/0	Calcium hydroxylapatite (CaHA)	Bovine Dermal Collagen	Cure rate or Stamey grade 0 at 12 months	158/138	51/32	37/27	1.20 (0.84; 1.72)	0.05 (-0.05; 0.16)		
Bano, 2005 ⁴⁸⁷ 50/0	Peri or transurethral porcine dermal implant injection (Permacol)	Transurethral silicone injection (Macroplastique)	Urinary continence (negative pad test)	25/25	15/60	9/36	1.67 (0.90; 3.08)	0.24 (-0.03; 0.51)		
Schulz, 2004 ⁵⁹³ 40/0	Periurethral route of injection of bulking agent-dextran copolymer	Transurethral route of injection of bulking agent-dextran copolymer	Objective urinary continence (dry in pad test)	20/20	1/5	3/15	0.33 (0.04; 2.94)	-0.10 (-0.28; 0.08)		
Ghoniem, 2009 ⁵³³ 247/0	Transurethral injection of Macroplastique	Transurethral injection of Contigen®	Number of Stamey grade dry	122/125	45/37	31/25	1.49 (1.01; 2.18)	0.12 (0.01; 0.24)	8 (4; 152)	121 (7; 235)
Ghoniem, 2009 ⁵³³ 247/0	Transurethral injection of Macroplastique	Transurethral injection of Contigen®	Patient assessment - dry	122/125	34/28	25/20	1.39 (0.89; 2.19)	0.08 (-0.03; 0.18)		
Ghoniem, 2009 ⁵³³ 247/0	Transurethral injection of Macroplastique	Transurethral injection of Contigen®	Physician assessment - dry	122/125	43/35	32/26	1.38 (0.94; 2.02)	0.10 (-0.02; 0.21)		
Strasser, 2007 ⁵⁹⁸ 63/0	Transurethral ultra-sonography-guided injections of autologous myoblasts and fibroblasts	Conventional endoscopic injections of collagen	Continence	42/21	38/90	2/10	9.50 (2.53; 35.63)	0.81 (0.66; 0.96)	1 (1; 2)	810 (656; 963)
Lightner, 2009 ⁵⁶² 344/0	Zuidex Implacer	Contigen® endoscopic guidance	Dry rates	227/117	83/37	52/44	0.82 (0.63; 1.07)	-0.08 (-0.19; 0.03)		

Appendix Table F144. Comparative effectiveness of bulking agents (individual RCTs) (continued)

Reference sample	Active	Control	Definition of outcome	Randomized active/control	Active events/rate	Control events/rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Improvement in Incontinence										
Lightner, 2001 ⁵⁶¹ 364/0	Injection of bulking agent 1.0 mL Durasphere max 5 times with a minimum 7-day interval	Injection of bulking agent bovine collagen max 5 times with a minimum 7-day interval	Improvement of 1 or more continence grades	176/188	76/43	79/42	1.03 (0.81; 1.30)	0.01 (-0.09; 0.11)		
Bano, 2005 ⁴⁸⁷ 50/0	Peri or transurethral porcine dermal implant injection (Permacol)	Transurethral silicone injection (Macroplastique)	Improvement in urinary incontinence (pad test)	25/25	15/60	10/40	1.50 (0.84; 2.67)	0.20 (-0.07 ;0.47)		
Bano, 2005 ⁴⁸⁷ 50/0	Peri or transurethral porcine dermal implant injection (Permacol)	Transurethral silicone injection (Macroplastique)	Improved urinary incontinence scores (Stamey)	25/25	14/56	10/40	1.40 (0.77; 2.53)	0.16 (-0.11; 0.43)		
Bano, 2005 ⁴⁸⁷ 50/0	Peri or transurethral porcine dermal implant injection (Permacol)	Transurethral silicone injection (Macroplastique)	Improved urinary incontinence scores (Kings College Hospital Quality of Health Questionnaire)	25/25	14/56	7/28	2.00 (0.98; 4.10)	0.28 (0.02; 0.54)	4 (2; 57)	280 (18; 542)
Schulz, 2004 ⁵⁹³ 40/0	Periurethral route of injection of bulking agent-dextran copolymer	Transurethral route of injection of bulking agent-dextran copolymer	Subjective improvement in urinary incontinence	20/20	6/30	7/35	0.86 (0.35; 2.10)	-0.05 (-0.34; 0.24)		

Appendix Table F144. Comparative effectiveness of bulking agents (individual RCTs) (continued)

Reference sample	Active	Control	Definition of outcome	Randomized active/control	Active events/rate	Control events/rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Mayer, 2007 ⁵⁶⁷ 296/0	Calcium hydroxylapatite (CaHA)	Bovine Dermal Collagen	Improved by one Stamey grade at 6 months	158/138	97/61	71/51	1.19 (0.97; 1.46)	0.10 (-0.01; 0.21)		
Mayer, 2007 ⁵⁶⁷ 296/0	Calcium hydroxylapatite (CaHA)	Bovine Dermal Collagen	Improved by one Stamey grade at 12 months	158/138	83/53	57/41	1.27 (0.99; 1.63)	0.11 (0.00; 0.23)		
Mayer, 2007 ⁵⁶⁷ 296/0	Calcium hydroxylapatite (CaHA)	Bovine Dermal Collagen	Improvement of two Stamey scale units or being dry	158/138	66/41	46/33	1.25 (0.92; 1.68)	0.08 (-0.03; 0.19)		
Mayer, 2007 ⁵⁶⁷ 296/0	Calcium hydroxylapatite (CaHA)	Bovine Dermal Collagen	50% or more decline in 24-hour pad weight test at 12 months	158/138	81/51	54/39	1.31 (1.01; 1.70)	0.12 (0.01; 0.23)	8 (4; 116)	121 (9; 234)
Strasser, 2007 ⁵⁹⁸ 63/0	Transurethral ultra-sonography-guided injections of autologous myoblasts and fibroblasts	Conventional endoscopic injections of collagen	Substantial improvement in urinary incontinence	42/21	3/7	1/5	1.50 (0.17; 13.56)	0.02 (-0.10 ;0.14)		
Strasser, 2007 ⁵⁹⁸ 63/0	Transurethral ultra-sonography-guided injections of autologous myoblasts and fibroblasts	Conventional endoscopic injections of collagen	Slight improvement in urinary incontinence	42/21	1/2	6/29	0.08 (0.01; 0.65)	-0.26 (-0.46; -0.06)	-4 (-16; -2)	-262 (-461; -63)
Ghoniem, 2009 ⁵³³ 247/0	Transurethral injection of Macroplastique	Transurethral injection of Contigen®	Improvement of at least 1 Stamey grade at 12 months	122/125	75/61	60/48	1.28 (1.02; 1.61)	0.13 (0.01; 0.26)	7 (4; 85)	135 (12; 258)

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Reference sample	Active	Control	Definition of outcome	Randomized active/control	Active events/rate	Control events/rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Ghoniem, 2009 ⁵³³ 247/0	Transurethral injection of Macroplastique	Transurethral injection of Contigen®	Patient assessment - improved	122/125	45/37	39/31	1.18 (0.83; 1.68)	0.06 (-0.06; 0.17)		
Ghoniem, 2009 ⁵³³ 247/0	Transurethral injection of Macroplastique	Transurethral injection of Contigen®	Physician assessment - marked improvement	122/125	39/32	38/30	1.05 (0.73; 1.52)	0.02 (-0.10; 0.13)		
Ghoniem, 2009 ⁵³³ 247/0	Transurethral injection of Macroplastique	Transurethral injection of Contigen®	With a Stamey grade of 0 or dry outcome	122/125	45/37	31/25	1.49 (1.01; 2.18)	0.12 (0.01; 0.24)	8 (4; 152)	121 (7; 235)
Lightner, 2009 ⁵⁶² 344/0	Zuidex Implacer	Contigen® Endoscopic guidance	Reduction in urine leakage at least 50% on provocation tests	227/117	148/65	98/84	0.78 (0.69; 0.88)	-0.19 (-0.28; -0.09)	-5 (-11; -4)	-186 (-277; -94)
Lightner, 2009 ⁵⁶² 344/0	Zuidex Implacer	Contigen® Endoscopic guidance	Responder rate based on >50% reduction in incontinent episodes	227/117	122/54	78/67	0.81 (0.68 ;0.96)	-0.13 (-0.24; -0.02)	-8 (-46; -4)	-129 (-236; -22)
Lightner, 2009 ⁵⁶² 344/0	Zuidex Implacer	Contigen® Endoscopic guidance	One-grade improvement on Stamey score at 12 months	227/117	116/51	64/55	0.93 (0.76; 1.15)	-0.04 (-0.15; 0.08)		
Lightner, 2009 ⁵⁶² 344/0	Zuidex Implacer	Contigen® Endoscopic guidance	3 treatments needed for clinical effect	227/117	67/30	38/33	0.91 (0.65; 1.26)	-0.03 (-0.13; 0.07)		