

Appendix Table 6. The Effects of Medical Devices 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
Robinson, 2003(117) N = 24, mixed or stress 4 month followup	Urethral device (NEAT) –sterile urethral insert with disposable applicator	Reliance Insert sterile balloon device	Negative pad test	(9/13) [7/11]	1.09 (0.61; 1.93)	0.06 (-0.32; 0.44)	No Intention to treat. Single blind. Randomization and allocation concealment not reported. Baseline data confirmed adequacy of randomization. Sample size not justified.
Nygaard, 1995(81) N = 20, urodynami c stress UI No followup	40 minute standardized aerobics sessions wearing a Hodge pessary with support	40 minute standardized aerobics sessions wearing a super tampon	Continent during exercise	(7/20) [12/20]	0.6 (0.3; 1.2)	-0.25 (-0.55; 0.05)	No intention to treat. Open label. Block randomization. Allocation concealment not reported. Baseline data not reported. Sample size not justified.
Thyssen, 2001(69) N = 94, predominant stress UI 1.25 month followup	Conveen Continenace disposable Intravaginal device	Contrelle continence tampon	Self Reported Continenace	(34/94) [45/94]	0.76 (0.54; 1.06)	-0.12 (-0.26; 0.02)	No Intention to treat. Open label. Block randomization. Allocation concealment not reported. Baseline data not reported. Sample size not justified.
Bo,1999(80) N = 122, urodynami c stress UI 6 month followup	Vaginal cones of 20, 40, and 70g for 20 minutes/day	Untreated control group offered use of a continence guard	Objective cure as <2g leakage on pad test with standardized bladder volume Subjective cure as (number of women stating that condition was	(4/29) [2/32] (2/29) [1/32]	2.2 (0.4; 11.2) 2.2 (0.2; 23.1)	0.08 (-0.08; 0.23) 0.04 (-0.07; 0.15)	Intention to treat. Single blind. Computer generated random numbers stratified by baseline leakage. Allocation concealment unclear. Baseline data confirmed adequacy of randomization. Baseline data confirmed adequacy of randomization. Sample size justified.

			“unproblematic” after treatment)				
Seo, 2004(119) N = 120, any UI 1.5 months followup	Pelvic floor exercise (5 second contraction and 10 second relaxation, 3-5 times for >5 minutes/day) and functional electrical stimulation biofeedback (35Hz-50Hz for 24 seconds); 2 training sessions/week	Vaginal cone ,150g dumbbell- shaped made of fine ceramic material	Self reported improvement in urinary incontinence	(55/60) [53/60]	1.0 (0.9; 1.2)	0.03 (-0.07; 0.14)	Intention to treat not stated. Open label. Randomization and allocation concealment not reported. Baseline data not reported. Sample size not justified.
Robinson, 2003(117) N = 24 with mixed or stress 4 month followup	Urethral device (NEAT) sterile urethral insert with disposable applicator packaged with device	Reliance insert sterile balloon type device	Success as a 50% or greater reduction in urine loss	(9/13) [6/11]	1.3 (0.7; 2.4)	0.15 (-0.24; 0.53)	No Intention to treat. Single blind. Randomization and allocation concealment not reported. Baseline data confirmed adequacy of randomization. Sample size not justified.
Thyssen, 2001(69) N = 94, predominant stress UI 1.25 month followup	Conveen continence disposable intravaginal device guard, CCG made of hydrophilic polyurethane requires soaking in water before being placed on a handle like applicator for insertion	Contrelle Continence Tampon, CCT, coloplastic made of hydrophobic polyurethane and supplied ready- assembled within an applicator, allowing insertion directly into the vagina with no manual	Self reported Improvement in stress urinary incontinence	(38/94) [34/94]	1.1 (0.8; 1.6)	0.04 (-0.10; 0.18)	No Intention to treat. Open label. Block randomization. Allocation concealment not reported. Baseline data not reported. Sample size not justified.

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Bo,1999(80) N = 122, urodynamic stress UI 6 month followup	The vaginal cones of 20, 40, and 70g for 20 minutes/day	Use of a continence guard	Urinary continence and almost continent	(5/29) [1/32]	5.52 (0.68; 44.49)	0.14 (-0.01; 0.29)	Intention to treat. Single blind. Computer generated random numbers stratified by baseline leakage. Allocation concealment unclear. Baseline data confirmed adequacy of randomization. Baseline data confirmed adequacy of randomization. Sample size justified.

*Bold- significant differences at 95% confidence level. CCT = Contrelle Continence Tampon; CCG = Conveen Continence Guard; NEAT = new urethral device; UI = urinary incontinence.