Table F4. KQ 1: Surgical treatments for fecal incontinence: randomized controlled trials and quality ratings

| **Author, Year** | **Study Aim** | **N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration** | **Study Groups**  (n per group) | **Patient-Reported Outcomes**  (primary outcome **bolded** if known) | **Reported Results (Benefits)\*** | **Risk of Bias (Inverse of Quality)** |
| --- | --- | --- | --- | --- | --- | --- |
| **Anal sphincter repair** | |  |  |  |  |  |
| Davis, 2004[47](#_ENREF_47) | Is adjuvant biofeedback after anal sphincter repair superior to sphincter repair alone? | N=38  n=31  100% F: 60 yr  Structural  T: surgery; BF duration NR  FU: 3mo, 6mo, 1 yr | **T**: Anal sphincter repair + adjuvant biofeedback starting 3 mo post- surgery (18)  **C**: Anal sphincter repair (20) | **CCFIS, patient satisfaction**, FIQL | At 1 y post-surgery (9 mo. after BF initiation), differences in change in CCFIS (-5.8 points treated vs. -4.1 points control), pt. satisfaction and FIQL component scores were not significant. Overall FIQL not reported. Power not reported. Excluded post-randomization data on 18% of sample. | High |
| Hasegawa, 2000[50](#_ENREF_50) | Is anal sphincter repair with fecal diversion superior to sphincter repair? | N=27  n=27  96% F; 46 yr  Mixed  T: surgery  FU: mean 34mo | **T**: Anal sphincter repair + stoma (fecal diversion)  (13)  **C**: Anal sphincter repair (14) | **CCFIS** | Statistical test of difference in scores at followup only: mean CCFIS improved 5.7 points in stoma group vs. 4.4 in controls. Power not reported. Trial stopped early due to high rate of complications, and no treatment advantage | High |
| **Anal sphincter replacement** | |  |  |  |  |  |
| O’Brien, 2004[49](#_ENREF_49) | Effectiveness of artificial bowel sphincter (ABS) vs. conservative management for severe FI | N=14  n=13  93% F; 63 yr  Mixed  T: surgery  FU: 3 mo, 6 mo | **T**: Artificial Bowel Sphincter (Action Neo-sphincter®) (7)  **C**: Conservative medical management (7) | **CCFIS**, SF-36, AMS QoL scale, BDI | Statistical test is of difference in scores at followup not change from baseline. Excluding one patient with a surgical failure that required colostomy and two colostomy revisions, greater CCFIS improvement noted in treated vs. controls at 6 mo (14 vs. 3 points); 3 mo not reported. Significant improvement in AMS-QoL, SF-36 (mental) with surgery; no difference in BDI, SF-36 (physical). Underpowered study. | High |
| **Other surgeries** |  |  |  |  |  |  |
| Yoshioka, 1999[21](#_ENREF_21) | Compare total pelvic floor repair (TPFR) vs. gluteus maximus (GMT) transposition (without e-stim) (GMT) for postobstetric neuropathic FI | N=24  n=24  100% F; 60 yr  Obstetric: intact sphincter  T: surgery  FU: 18 mo. | **T1**: Total pelvic floor repair (TPFR) (12)  **T2**: GMT without electrical stimulation (12) | CCFIS, self-rated improvement, bowel habit, rectal evacuation, fecal urgency, fecal soiling | Within-group analysis at 18 mo: Same CCFIS improvement (6.1 points) and “good” functional result rating (7 of 12 patients) both groups. No difference in bowel habit, urgency or soiling by group. No power calculation. Authors report limited experience with GMT. | Moderate |
| van Tets, 1998[34](#_ENREF_34) | Effectiveness of postanal repair vs. total pelvic floor repair (TPFR) for neurogenic FI | N=20  n=20  100% F; 55 yr  Neurogenic  T: surgery  FU: 3 mo | T1: Postanal repair (11)  T2: Total pelvic floor repair (TPFR) (9) | Browning & Parks Incontinence Score | At 3 mo, 45% in postanal repair group reported improvement vs. 33% in TPFR group. No statistical comparison of patient-reported outcome measure. Power not reported. | Moderate |
| Deen, 1993[51](#_ENREF_51) | Compare effectiveness of total pelvic floor repair (TPFR) vs anterior levatorplasy vs. postanal repair for neurogenic FI | N=36  n=20  100% F; 51 yr  Neurogenic  T: surgery  FU: 6 mo, 2 yr | T1: Total pelvic floor repair (TPFR) (12)  T2: Anterior levatorplasty (12)  C: Postanal repair (12) | Complete Continence, FI freq per month extent of FI (0-10) | 33% in anterior levatorplasty & 42% in postanal repair reported complete continence. Multiple between-group comparisons reported. FI freq not reported at 6 mo. At 2 y, median (range) FI freq per month was 2 (0-12) for TPFR, 5 (0-30) for anterior levatorplasty, and 10 (0-30) for postanal repair; only comparisons reported are of scores at followup and not of differences from baseline. Data on degree of FI not usable. Power not reported. | High |
| **Surgical vs. nonsurgical** | |  |  |  |  |  |
| Osterberg, 2004[29](#_ENREF_29) | Compare levatorplasty vs. anal plug electro-stimulation for neurogenic FI | N=70  n=59  88% F; 66 yr  neurogenic  T: 1 d-5 wk  FU: 3 m, 1 yr, 2 yr after treatment completion | T1: Anterior levatorplasty (31)  T2: Anal plug electrostimulation: 12 sessions (20 min each) with therapist over 4-5 weeks.  (28) | Miller’s Incontinence score (0-18), stool freq, pad use, physical & social handicap, deferring time | No statistical comparison of between group differences at any time point for any outcome (within group change from baseline only). Miller’s Incontinence score improved 6-7 points with surgery, which was 2-2.5 points more than anal plug e-stim improvements at 3 m, 1 yr and 2 yr. Stool freq. did not change in either group. Pad use decreased in both groups; physical and social handicap and deferring times improved with surgery. Underpowered study. Excluded post-randomization data on 16% of sample. | High |
| **Surgically-implanted sacral neurostimulation (SNS)** | | |  |  |  |  |
| Duelund-Jakobsen, 2013[31](#_ENREF_31) | Determine whether stimulation at 75% and 50% of the sensory threshold (ST) is as effective as stimulation at ST in pts receiving SNS for FI | N=19  n=17 (3 mo.)  95% F; 60 yr  Mixed  T: 3 x 4 wks  FU:1 mo., 2 mo., 3 mo. | Crossover. Wash-out wk 1 of 4 wk trmt  T1: Stimulation at ST (19)  T2: Stimulation at 75% of ST (19)  T3: Stimulation at 50% of ST (19) | FI freq, bowel habits, CCFIS, Vaizey, GSRS-IBS, FIQL, patient satisfaction | Improvement in mean FI freq. did not differ significantly across ST settings. Mean change in CCFIS, Vaizey score, bowel habits, GSRS-IBS and pt satisfaction did not differ significantly across settings. Coping subscale of FIQL improved in ST and 50% of ST groups vs 75% of ST over study period, but no additional significant changes in other FIQL subscales. Power not reported. Excluded 11% from 3 mo. analysis. | Moderate |
| Duelund-Jakobsen, 2012[23](#_ENREF_23) | Which of 5 SNS settings restores efficacy in adults with existing SNS and sustained loss of efficacy? | N=15  n=15  % F: NR; 54 yr  Mixed  T: 5 x 4 wks  FU: 20 wks; 11 unblinded for 12 more wks at chosen SNS setting | Crossover  T1- T5: test 5 SNS stimulator settings (4 wks each), then unblinded and observed for 12 more wks) at preferred setting | FIQL, CCFIS, bowel diary with FI episodes, Vaizey, GSRS-IBS, patient satisfaction | Bowel diary scores including FI episodes significantly improved with high-frequency stimulation and low and prolonged pulse width; FIQL embarrassment improved at 2 settings. No significant differences in any other outcomes between settings at 20 wk. Improvement sustained at 32 wk (excluding data from 4 subjects). 8 of 11 satisfied with treatment. Sparse sample information; only mean age, years of FI in text. | High |
| Tjandra, 2008[44](#_ENREF_44) | Is SNS better than best supportive care for FI? | N=120  n=113  (7 failed test SNS)  93% F; 63 yr  Mixed  T: 1 d up to 1 yr  FU: 3 m, 6 m, 1 yr | T: SNS (single surgeon) plus 3 stimulator adjust-ments/1 yr. (53)  C: Diet, oral bulking agents, PFMT; met with pelvic floor team 12-18x/1 yr | CCFIS, FI episodes, FI days/wk (bowel diary), FIQL, SF-12 | Between-group differences in changes from baseline not reported; results are within-group changes from baseline. Significant decrease in CCFIS (-14.8 points), mean FI episodes (9.5 to 3.1), days of FI/wk (3.3 to 1), and all FIQL domains with SNS. Control CCFIS improved at 3 mo. only; controls had no significant improvement in other outcomes. No power calculation; adjusted for multiple comparisons. | Moderate |
| Michelson, 2008[24](#_ENREF_24) | Does switching off SNS stimulator at night affect FI in adults with existing SNS? | N=20  n=19  95% F; 59 yr  Mixed  T: 3 wks. each  FU: 6 wks: outcomes assessed after both periods only | Crossover, no washout  T1: SNS on 24 hr/d x 7 d/wk for 3 wks  T2: SNS off at night for 3 wks | CCFIS, Vaizey, defecation frequency, urge episodes, liquid + solid episodes, days with soling | No base values reported for any measures. Median CCFIS and Vaizey increased (worse) by 1 point during OFF at night period. Days with soiling increased by 1; urge episodes unchanged. Power not reported. | High |
| Leroi, 2005[28](#_ENREF_28) | Effectiveness of SNS with stimulation ON vs. OFF for FI in new SNS recipients (1-3 mo after SNS implantation) | N=34 pts  n=24  91% F; 57 yr  Mixed  T: 1 mo x 2  FU: 1 mo, 2 mo | Crossover, no washout  T1: Stimulation ON  (27)  T2: Stimulation OFF (27) | FI count, CCFIS, FIQL, urgency episodes, postponing defecation, bowel movements | Median improvement in CCFIS 2 points greater in stimulation ON vs OFF period (1 mo), but difference not significant. Authors report statistically significant improvement in median FI count, but data in graph & not usable. No significant changes in urgency episodes, delay in postponing defecation, and number of BM per week between groups at 1 mo. Results for FIQL not reported. Power not reported. RCT excluded post-randomization data on 21% of sample. | High |

\*Significant = statistically significant  
AE=Adverse Effects; AMS=American Medical System; AM=anal manometry; BDI=Beck Depression Inventory; BM=bowel movement; CCFIS=Cleveland Clinic Fecal Incontinence Score; C=Comparator/control; d=day; Est=estimated; Estim=Electrostimulation; F=Female; FI= Fecal incontinence; FICA=Fecal Incontinence and Continence Assessment; FIQL=Fecal Incontinence Quality of Life scale; FU=Followup; FDA=Food and Drug Administration; freq=frequency; GI=gastrointestinal; GSRS-IBS=Gastrointestinal Symptom Rating Scale for Irritable Bowel Syndrome; HAD=Hospital Anxiety and Depression Scale; IAS=internal anal sphincter; IBS=irritable bowel syndrome; mo=month; NR=Not Reported; NSD=No Significant Difference; pt=patient; pd=period; analysis; QoL=Quality of Life; SF-12=Short-Form-12 health survey; SF-36=Medical Outcomes Study Short-Form 36-item Health Survey; surg=surgery; T1=Treatment group 1 T2=Treatment group 2 T3=Treatment group 3; Vaizey=Vaizey Fecal Incontinence Score; VAS=Visual Analogue Scale; wk=week; yr=year