Table F8. KQ 2: Adverse effects of surgical treatments for fecal incontinence in randomized controlled trials

| **Author, Year** | **Study Aim** | **N Randomized; n Analyzed; % Female; FI Etiology; Treatment and Followup**  | **Study Groups** **(n per group)** | **Patient-Reported Outcomes** **(primary outcome bolded)** | **Reported Harms**  | **Attrition\*** |
| --- | --- | --- | --- | --- | --- | --- |
| **Surgical Treatments** |
| ***Anal sphincter repair*** |
| Hasegawa, 2000[50](#_ENREF_50) | Is anal sphincter repair with fecal diversion superior to sphincter repair? | N=27n=27F: 96%MixedT: surgeryFU: mean 34 mo  | **T**: Anal sphincter repair + stoma (fecal diversion)(13)**C**: Anal sphincter repair (14) | **CCFIS** | Overall: No nonserious AEs reported.T: 12 serious AEs in 13 patients; wound infection, parastomal hernia, prolapsed stoma, incisional hernia at stoma site.C: 3 serious AEs in 14 patients; wound infection, fistula, fecal impaction.Trial stopped after 3 yrs due to high rate of complications and no treatment advantage in anal sphincter repair + stoma group. | None |
| ***Anal sphincter replacement*** |
| O’Brien, 2004[49](#_ENREF_49) | Effectiveness of artificial bowel sphincter (ABS) vs. conservative management for severe FI | N=14n=13F: 93% MixedT: surgeryFU: 3 mo, 6 mo | **T**: Artificial Bowel Sphincter (Action Neo-sphincter®) (7)**C**: Conservative medical management (7) | **CCFIS**, SF-36, AMS QoL scale, BDI | Overall: No nonserious AEs reported. Serious AEs:T: 43%; failure of perineal wound healing that required explant and colostomy (14%), prolonged hospital stay, inability to evacuate without assistance, delayed healing of perineal wound that required resuturingC: None | 7%\*T: 14%C: None  |
| ***Other surgeries*** |  |  |  |  |  |  |
| Yoshioka, 1999[21](#_ENREF_21) | Total pelvic floor repair (TPFR) vs. gluteus maximus transposition (without electrical stimulation) for post-obstetric neuropathic FI | N=24n=24F: 100%Obstetric: intact sphincterT: surgeryFU: 18 mo | **T1**: Total pelvic floor repair (TPFR) (12)**T2**: GMT without estim (12) | CCFIS, FI improvement bowel habit, rectal evacuation, urgency, soiling | Overall: No nonserious AEs reported.T1: 8% serious AEsT2: 25% serious AEsWound sepsis, wound hematoma, fecal impaction most common.  | None |
| Deen, 1993[51](#_ENREF_51) | Compare total pelvic floor repair (TPFR) vs. anterior levatorplasy vs. postanal repair for neurogenic FI | N=36n=20F: 100%Neurogenic T: surgeryFU: 6 mo, 2 yr | **T1**: TPFR (12)**T2**: Anterior levatorplasty (12)**T3**: Postanal repair (12) | Complete continence, FI freq, extent of FI (0-10) | AEs during surgery not reported. Serious AEs NR by group: Wound infection (1), iatrogenic incision of anterior wall of anorectum (1). More nonserious AEs with TPFR & anterior levatorplasty vs. postanal repair (42% dyspareunia, 42% dyspareunia vs 0); | None |
| ***Surgical vs nonsurgical*** |
| Osterberg, 2004[29](#_ENREF_29) | Compare levatorplasty vs. anal plug electro-stimulation for neurogenic FI | N=70n=59F: 88%NeurogenicT: surgery vs 4 wks (median)FU: 3 mo, 1 yr, 2 yrs | **T1**: Anterior levatorplasty (31)**T2**: Anal plug electrostimulation(28) | MISS, stool freq, pad use, physical & social handicap, deferring time | Overall: NRSerious AEs:T: 3%; wound infectionC: NoneNonserious AEs:T: NoneC: 9%; pain, burning sensation in vagina most common. | 16%\*T: 11%C: 20% |
| ***Sacral neurostimulation (SNS)*** |
| Tjandra, 2008[44](#_ENREF_44) | Is SNS better than best supportive care for FI? | N=120n=113 (7 failed SNS pre-test)F: 93% (est.)MixedT: 1 d up to 1 yrFU: 3 mo, 6 mo, 1 yr | **T:** SNS (53)**C**: Supportive care=diet, oral bulking agents, PFMT; met with pelvic floor team 12-18x/1 yr.(60) | CCFIS, bowel diary, FIQL, SF-12 | Overall: No serious AEs reported.T: pain at implant site (6%); seroma (2%); vaginal tingling (9%)C: constipation from Immodium (10%) | None |
| Leroi, 2005[28](#_ENREF_28) | Effectiveness of SNS with stimulation ON vs OFF for FI in new SNS recipients | 34 pts received SNS but N=27 randomized;n=24F: 91%MixedT: 1 mo x 2FU: 2 mo: 1 mo x 2 | Crossover, no washout**T1**: Stimulation ON (27)**T2**: Stimulation OFF (27) | FI count, CCFIS, FIQL, urgency episodes, postponing defecation, bowel movements | NR during trial period. Prior to randomization during implantation period, 4 patients withdrew due to unresolved pain (3) and recurrent infection (1). | 10%\* |

\* Attrition calculated by the MN EPC based on the number randomized
ABS=artificial bowel sphincter; AE=adverse effects; AMS=American Medical Systems; BDI=Beck Depression Inventory; C=Comparator ; d=day; CCFIS=Cleveland Clinic Florida Fecal Incontinence Score; est.=estimated; estim=intra-anal electrostimulation; F=Female; FI=Fecal Incontinence; FIQL=Fecal Incontinence Quality of Life Instrument; freq=frequency; FU=followup; GMT=gluteus maximus transposition; IAS=internal anal sphincter; IBS=irritable bowel syndrome; ICIQ-BS=International Consultation Incontinence Questionnaire Bowel Symptoms; MISS=Miller’s Incontinence Score System; mo=month; NA=not applicable; NR=not reported; PFMT=pelvic floor muscle training; PP=per protocol analysis; pt=patient; QoL=Quality of Life; SECCA=Radiofrequency anal sphincter remodeling; SF-12=MOS Short-Form 12-item Health Survey; SF-36=MOS Short-Form 36-item Health Survey; SNS=sacral nerve stimulation; T1=Treatment group 1; T2=Treatment group 2; T3=Treatment group 3; TPFR=total pelvic floor repair; wk=week; x=times; yr=year