Diagnosis and treatment of faecal incontinence: Consensus statement of the Italian Society of Colorectal Surgery and the Italian Association of Hospital Gastroenterologists

Italian Society of Colorectal Surgery (SICCR)
Italian Association of Hospital Gastroenterologists (AIGO)

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ABSTRACT

Faecal incontinence is a common and disturbing condition, which leads to impaired quality of life and huge social and economic costs. Although recent studies have identified novel diagnostic modalities and therapeutic options, the best diagnostic and therapeutic approach is not yet completely known and shared among experts in this field.

The Italian Society of Colorectal Surgery and the Italian Association of Hospital Gastroenterologists selected a pool of experts to constitute a joint committee on the basis of their experience in treating pelvic floor disorders. The aim was to develop a position paper on the diagnostic and therapeutic aspects of faecal incontinence, to provide practical recommendations for a cost-effective diagnostic work-up and a tailored treatment strategy. The recommendations were defined and graded on the basis of levels of evidence in accordance with the criteria of the Oxford Centre for Evidence-Based Medicine, and were based on currently published scientific evidence. Each statement was drafted through constant communication and evaluation conducted both online and during face-to-face working meetings. A brief recommendation at the end of each paragraph allows clinicians to find concise responses to each diagnostic and therapeutic issue.

Keywords: Faecal incontinence; Anorectal manometry; Endoanal ultrasonography; Biofeedback; Sphincteroplasty; Post anal repair; Rectopexy
INTRODUCTION

Faecal incontinence (FI) can severely affect the quality of life of patients by limiting their social life and relationships, causing depression and confinement. Although the commonly accepted definition of FI appears simple (“failure to control the elimination of stool and/or flatus recurring for >3 months”) \(^1^2\), FI covers several conditions. These can be classified, according to the underlying pathophysiological mechanisms, into stress incontinence \(^3\), urge (active) incontinence \(^4^6\), passive incontinence \(^4\), faecal soiling,\(^2\) which includes “post-defecatory incontinence” \(^2^4\), and overflow incontinence due to faecal impaction, very frequent in children with encopresis and elderly patients \(^7^8\).

Before embarking on the diagnostic and therapeutic work-up, a complete clinical history should always be collected. This includes detailed questions on bowel habits, diets, comorbidities, and ongoing pharmacological therapies altering bowel motility or neuromuscular function.

The identification of risk factors for FI is another fundamental issue. Age is a recognized risk factor both in men and in women \(^9^10\). Obstetric injuries, gynecological and ano-rectal surgery should always be investigated. Multiparty, urinary incontinence, obesity, reduced physical activity, functional limitations, current cigarette smoking, diabetes, hypertension, presence of neurologic disease, depression and use of psychoactive drugs can all increase the likelihood of FI in women over 62 years of age \(^11^12\).

Diabetes, multiple sclerosis, cognitive deterioration and systemic sclerosis can affect the integrity of ano-rectal function. Chronic diarrhoea, irritable bowel syndrome, or cholecystectomy are independent risk factors for FI \(^13\). Constipation due to obstructed defecation is another recognized risk factor for post-defecatory incontinence.

However, a preliminary rectal examination is essential to the workup of FI in order to detect any signs of organic and functional disease of the anus and distal rectum \(^14^16\). This should also include a careful inspection of the anus and perineum not only in resting but also
during straining and squeezing\textsuperscript{15,16}, looking at anal symmetry and morphology, perineal descend rectal prolapse and scars\textsuperscript{17}. Inspection must include the scratch reflex\textsuperscript{18}. Vaginal examination in women with FI must be considered, since vaginal delivery can cause FI through anal sphincter and pelvic floor injury\textsuperscript{19,20}. Given the possible association between pelvic organ prolapse and FI\textsuperscript{21-23}, examination of external genitalia, perineum, and vagina with a speculum, as well as bimanual pelvic examination, is mandatory\textsuperscript{24}. Major advances in understanding the pathophysiologic mechanisms and in developing new diagnostic and therapeutic strategies have been achieved in recent decades, but there is still uncertainty about the optimal diagnostic and/or therapeutic procedure to be adopted for each type of FI.

METHODS
To reach an Italian consensus statement on the diagnosis and treatment of FI, the two main scientific Italian societies interested in this topic, the Italian Society of Colorectal Surgery (SICCR) and the Italian Association of Hospital Gastroenterologists (AIGO), nominated a pool of experts to constitute a joint committee. The members of the SICCR/AIGO Joint Committee were selected on the basis of their experience in treating functional pelvic floor disorders. The Committee developed a consensus on the diagnostic and therapeutic aspects of faecal incontinence (FI) in adults, including a set of graded recommendations based on a review of the literature and, where present, on evidence-based medicine. A search of the literature was carried out using the online database of PUBMED, MEDLINE and COCHRANE to identify articles published in English before December 2014. This used specific keywords related to the different diagnostic tools, medical treatments and surgical techniques for FI.
The recommendations of the Committee were graded on the base of the levels of evidence in accordance with the criteria of the Oxford Centre for Evidence-Based Medicine\textsuperscript{25} (Table 1).

In the development of the consensus statement, the Committee identified 4 key areas: 1) Scoring systems, 2) Diagnostic techniques, 3) Conservative treatment, 4) Surgical procedures. Each chapter contains specific themes defined by the Committee and the recommendations provided.

The process of drafting the consensus statement involved constant communication and evaluation conducted online and during face-to-face working meetings. During these meetings, levels of evidence and grading of the recommendations were discussed in order to reach a final agreement of 90% or more in all covered areas.

This consensus statement was structured to offer simple and clear recommendations for clinical practice.

1. SCORING SYSTEMS

1.1. Scoring systems for assessing the severity of FI

Scoring systems are a useful tool for the objective assessment of the severity of FI. The Cleveland Clinic Incontinence Score (Wexner score)\textsuperscript{26} is widely used because it is practical, easy to use and to interpret. It has never been validated in a prospective study.

The scale takes into account 5 parameters, each scored on a scale from “0” to “4”. A score of “0” indicates perfect control, whereas a score of “20” means complete incontinence. The St. Mark’s incontinence score\textsuperscript{27} is a modification of the Wexner scale and it is more detailed, consisting of 7 items. It shows a correlation with patients’ subjective perception\textsuperscript{28,29}, but has not yet been validated. Both the Wexner score and St. Mark’s are widely adopted in clinical practice although they have been criticized because flatus incontinence
seems to be a redundant item when considering FI. Furthermore, the Wexner score does not include urgency. The Pescatori scale takes into account both degree and frequency of symptoms, but it has not yet been validated. The Revised Faecal Incontinence Scale (RFIS) consists of 5 items that are scored from “0” to “4”. The internal and test-retest reliability of RFIS has recently been validated, but the small sample size provides limitations concerning the generalizability of the data.

All the above mentioned scores have a bias in common: this is the absence of cut-off values to stratify the severity of the incontinence into clinical categories (i.e. mild, moderate and severe). This issue limits the utilization of all the scoring systems in the evaluation of therapeutic outcomes. In conclusion, there is no evidence so far regarding which of all these different tools can effectively best serve both patients and clinicians.

1.2. Utility of daily diaries in the evaluation of the severity of FI

Patients can be encouraged to keep a daily diary in order to attempt to record symptoms more precisely but, so far, diaries are not supported by the literature and evidence. Their use in clinical practice can be difficult and time-consuming, but they can provide different outcomes from questionnaires.

1.3. Use of quality-of-life scales in clinical practice or research trials

The patient’s perception of FI is a critical point in the management of this condition, and it is clearly aimed at improving the overall quality of life (QoL) of patients. Various QoL scoring systems have been proposed: (a) the 36-item short Medical Outcomes Questionnaire, (b) the Gastrointestinal Quality of Life Index, designed to assess all gastrointestinal symptoms and therefore not specifically for FI, and (c) the Fecal Incontinence Quality of Life Scale (FIQL). This last questionnaire consists of 29 items divided into four scales: lifestyle, coping-behavior, depression and embarrassment. The
Italian version of the FIQL has been developed by Altomare et al. and prospectively validated with appropriate cultural and linguistic adaptations 38.

1.4. Expert panel recommendations.
The adoption of a single severity scale should be recommended not only for research purposes but also in clinical practice, despite a low grade of evidence (5-D).

Daily diaries are not standardized, but they can be useful in certain situations, such as rehabilitative treatments, in order to better verify the outcomes (5-D).

The use of FIQL is recommended for research trials and can also be suggested in clinical practice in spite of low evidence (5-D).

2. DIAGNOSTIC TECHNIQUES

2.1 Imaging
2.1.1. Imaging techniques to assess or predict the risk of FI

Generally speaking, the rationale behind the use of imaging techniques in faecal incontinence (FI) is simple. Having a vision by means of the truth is certainly better than leaving a lot to the imagination39. In a brief time, well before the exact cause and pathophysiology of the disease can be ascertained in singular cases, a great deal of useful information can be obtained by using a simple imaging test. This consists of slow intrarectal injection of a given amount (max 400mL) of semisolid radiopaque contrast medium under fluoroscopic control 40;41 to check for the following: (a) the ability (or not) to retain the total volume injected without leakage; (b) the first leakage volume; and (c) the total leaked volume. In addition, the rectal size on lateral view, the anal canal width and the posterior anorectal angle (ARA°) can also be measured. This adds specificity to the
diagnosis and distinguishes those patients with enlarged rectal ampulla and faecalomas (megarectum) from those with small, incompliant ampulla commonly associated with inflammatory or radiation proctitis. The effectiveness of this diagnostic test, i.e. defecography (D), in directing the diagnosis has been proven in two different studies at the receiver operating curve (ROC) analysis and at analysis of variance (ANOVA), respectively with an accuracy of 79%, specificity of 93% and a false-negative rate of 14.2% limited to patients with minor incontinence only. However, anal endosonography (AES) is mandatory for a definite characterization of the anal sphincter anatomy. The technique uses a 10-to-16 MHz, 360° rotating transducer with three-dimensional (3-D) reconstruction, near-field focusing in the range of 5-45 mm, transverse resolution of less than 0.05 mm, and lateral resolution of 0.5-1.0 mm. It has been recommended by an International Joint Report as the gold standard to assess anal sphincter morphology and to detect any defect in sphincter integrity. More precisely, AES can indicate whether the internal or external anal sphincter, or the puborectalis muscle, is damaged and give the exact extent of circumference and length of the defect in relation to anal canal levels, as well as the presentation of sphincter remnants. When compared with intraoperative results, the accuracy of the technique for locating the defect in incontinent subjects is 100% for the external anal sphincter and 95.5% for the internal anal sphincter. As an alternative, three-dimensional tomographic transperineal ultrasonography (3-D TPUS), has been credited with obtaining comparable results to document anal sphincter defects, levator ani muscle avulsion and tears, and hiatal ballooning, i.e. area ≥ 25 cm². Recently however, some studies claim that endocoil MR imaging, a more time-consuming and expensive examination than ultrasonography, is better in the diagnosis of external sphincter atrophy. Furthermore, pelvic MR using a phased-array external coil is a very suitable imaging approach for determining abnormal pelvic floor descent and pelvic organ prolapse, which are two separate but often coexistent pathologic entities in patients.
with FI. Traditionally, the degree of pelvic floor laxity is measured with two reference lines: the H line, which represents the hiatal widening and extends from the inferior aspect of the symphysis pubis to the posterior wall of the rectum at the level of the anorectal junction (ARJ); and the M line, which represents the hiatal descent and extends perpendicularly from the pubococcygeal line (PCL) to the posterior end of the H line. Increased pelvic floor laxity is present when the H line exceeds 6 cm, and when the M line exceeds 2 cm in length \(^{56}\), with or without evidence of intra-anal intussusception.

2.1.2 Imaging before anorectal surgery

Regardless of the pathology and the surgical procedure, preoperative AES should always be performed to check for even subtle sphincter defects which might predispose to continence impairment \(^{57}\). Post-operatively, without any radiation hazard, a combined imaging protocol, including 3-D TPUS and/or dynamic pelvic magnetic resonance imaging (MRI) \(^{58};^{59}\) has been recommended for both reducing the risk of FI and assessing the functional outcome of surgery.

2.1.3. Expert panel recommendations

The effectiveness of defecography has been proven in orienting the diagnosis of FI (3b-C).

Anal endosonography (AES) is mandatory to define anal sphincter anatomy and any defect in sphincter integrity (3b-B).

As an alternative, 3D ultrasonography is useful to document anal sphincter defects, levator ani muscle avulsion and tears (3b-B).

A combined protocol of 3D ultrasonography and dynamic pelvic MRI can be recommended for FI risk and functional outcome after surgery (3b-C).
2.2 Endoscopy

2.2.1. Diagnostic role of endoscopy in FI.

The first examination of the patient should include an anoscopy as part of a broader clinical examination with the aim of discovering the cause and describing the condition. As anorectal malignancy or proctitis can cause FI, all patients with such disorders should be considered for flexible sigmoidoscopy as indicated by their age, family history, and previous endoscopic evaluation. The evaluation should also assess for prolapsing hemorrhoids, rectal prolapse, and rectoceles.

If there is coexisting constipation or diarrhoea, the appropriateness of performing colonoscopy can be evaluated according to ASGE guidelines, to look for red alert signs and symptoms. In the presence of diarrhoea, colonoscopy with histological examination must be considered to exclude microscopic colitis.

2.2.2. Expert panel recommendations.

Endoscopy could be useful for diagnosing diseases that exacerbate FI, but data from controlled trials or cohort studies are not available in this regard (5-D). Colonoscopy is not a routinely diagnostic test for FI; it must be considered only in the presence of diarrhea (5-D).

2.3. Anorectal manometry

2.3.1. Role of anorectal manometry and manometric parameters in FI

Anorectal manometry measures the anal canal and rectal pressures, rectal sensation and compliance, but it is only one of the diagnostic tools in FI. Low anal resting pressure and alteration of squeeze pressure are the most frequent manometric signs observed in patients with FI. Maximum squeeze pressure had the
greatest sensitivity and specificity; at a cut-off <60 mmHg in females and <120 mmHg in males, sensitivity was respectively 60% and 67%, while specificity was 78% and 67%. The maximum resting anal canal pressure was less sensitive and specific than the maximum squeeze pressure. Similar parameters have been described and studied by other authors. Anal resting pressure had a sensitivity of only 32%. Lam et al. showing that lower anal pressures, shorter sphincter length and smaller rectal capacity were positive predictive factors for FI in women. Both males and females can exhibit poor phasic response of the external anal sphincter to rectal distension. A recent report showed that deterioration in manometric parameters increases with the severity of FI with 91% sensitivity, 86% accuracy, and 62% specificity.

The pressure profile during squeeze may be compared with the resting profile. If the voluntary squeeze effort results in normal or increased pressure, the main deficiency resides in the internal anal sphincter. If the squeeze effort fails to raise the anal sphincter pressure, it must be assumed that the external anal sphincter is further compromised. A special clinical setting is represented by pre and post-proctectomy manometry. Preoperative anorectal manometry can predict FI after proctectomy for rectal prolapse: patients with maximal squeeze pressures >60 mmHg have significantly better outcomes.

Although a strong consistent anal resting pressure can be one determinant of continence after proctectomy for ulcerative colitis, squeeze pressures cannot influence the functional results. Radio-chemotherapy for rectal cancer can affect anorectal function. A recent meta-analysis has demonstrated a potential worsening of manometric anorectal parameters after radio-chemotherapy.

2.3.2. Anorectal manometry in the presence of evident sphincter damage

Decreased resting and squeeze pressures have been found in 90% of patients with anal sphincter injury. In another study incontinent patients with and without sphincter
defects had similar severity scores, but those with defects had a significant decrease in resting pressures. In any case, anal pressures are generally lower in incontinent patients with and without sphincter defects. In this way anorectal manometry cannot detect the integrity or lesions of the anal sphincter. Anal canal pressure does not correlate perfectly with continence because of the wide range of normal pressures\textsuperscript{74,79,80}.

2.3.3. Anorectal manometry to guide therapeutic choices

Manometric findings of severely reduced anal resting pressure and/or squeezing pressure, supported by images of external anal sphincter defects, suggest the need for surgical repair\textsuperscript{81,82}. Manometry can guide the rehabilitation approach\textsuperscript{81-84}. In particular, reduced anal resting pressure suggests the need for biofeedback, sometimes combined with electrostimulation. Reduced rectal sensation can be restored by sensory retraining with biofeedback or volumetric rehabilitation\textsuperscript{81,84-86}. On the other hand, multimodal rehabilitation can be ineffective in the presence of significant sphincter lesions\textsuperscript{84}.

2.3.4. High-resolution manometry for measuring rectoanal function.

High-resolution manometry provides the interpolation of manometric recordings into highly detailed topographical and colored plots of intraluminal pressure events. This technique has not yet been sufficiently studied in the anorectum. Preliminary observations show that anorectal manometry and high-resolution manometry are significantly correlated although anal sphincter pressures recorded by high-resolution manometry tend to be higher than traditional manometry\textsuperscript{87,88}. Recently 3D-high-resolution manometry has been demonstrated to give a better pressure recording of the anal canal, thus providing a more useful physiological assessment of anorectal function\textsuperscript{89}.

2.3.5. Expert panel recommendations
Anorectal manometry is a useful tool in FI but alone it does not provide sufficient grounds for the diagnosis (3b-C).

Low anal resting pressure and alteration of squeeze pressure are the most frequent manometric signs observed in FI (3a-B).

No typical motor patterns are present in FI regardless of clinical conditions. (3-C)

Patients with evident sphincter defects have lower resting pressures (3a-B)

Anorectal manometry is a useful guide to therapeutic options in FI, but it is difficult to assess its real impact on management. (3b-B).

High resolution manometry is a promising technique, but further studies are needed to recommend it in clinical practice (4-C).

2.4. Neurophysiological tests

2.4.1. Neurophysiological tests and their clinical usefulness in FI

Neurophysiological tests should be performed in FI patients who have a low anorectal pressure with no obvious explanation, a negative workup or abnormal workup without anorectal anatomical explanation and in neurological diseases.

The neurophysiological tests commonly used to investigate FI are: (a) electromyography (EMG), (b) pudendal nerve terminal motor latency (PNTML), (c) sacral latency test (SLT), (d) somato-sensory evoked potentials (SEPs) of pudendal nerve and (e) motor evoked potentials (MEPs) 90-94.

The tests allow the assessment of the external anal sphincter (EAS) function by studying the pudendal nerve and its terminal branches (EMG, PNTML), the sacral roots (SLT) and the transmission of nervous signals within the central nervous system (SEPs, MEPs). The neurogenic damage to EAS may be caused by lesions of motoneuron I, central neuron,
and efferent axons, or of motoneuron II and efferent fibres from the sacral spinal cord to
the nerves entering the anal sphincter $^{95-98}$.

Surface EMG cannot prove neurogenic sphincter damage, but may be used to perform
biofeedback therapy $^{99}$. Needle EMG of EAS may show denervation and can be used to
distinguish myopathic damage, neurogenic damage, or mixed damage of EAS $^{6;100-102}$.
Needle EMG is the only established technique for identifying anal neurogenic injury $^{46}$. The
severity of EMG findings is not related to the severity of incontinence $^{103;104}$.

Concentric needle EMG agrees well with EAS for mapping the sphincter and identifying
damaged areas $^{101;105}$, but ultrasound is more sensitive when compared to surgical and
histological evidence $^{106}$, and is less invasive.

PNTML measures latency time between direct stimulation of the pudendal nerve and EAS
contraction. PNTML, unlike needle EMG, does not show direct neurological damage and
results can be influenced by body type, gender, and patient age. Physician skills and
experience may also play a role $^{107-110}$.

Pudendal neuropathy is reported in up to 70% of patients with FI and in 60% and 85%
respectively of patients with sphincter injury and pathologic perineal descent $^{107}$.

In patients with sphincter damage and prolonged latency of the pudendal nerve, an early
study reported that sphincteroplasty would give poor results $^{111}$, but later studies have not
confirmed this relationship $^{112-114}$. Prolonged PNTML can be considered a contributing
factor to developing FI in patients undergoing surgery for rectal prolapse $^{115}$. Unfortunately,
PNTML is not useful as a reliable predictor of the postoperative function $^{116;117}$. On the
other hand, PNTML may underestimate the nerve damage since the latency measured
reflects the function of the most rapidly conducting nerve fibres $^{68}$.

The routine use of PNTML in patients with FI is debatable and the lack of consensus as to
its accuracy and reliability as a predictor for the postoperative outcome has limited its use
$^{113}$. 

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2.4.2. Expert panel recommendations.

Pudendal nerve assessment is performed by EMG or PNTML testing (3b-B).

Needle EMG is the only established technique for identifying anal neurogenic injury (2a-B).

PNTML is not a reliable predictor of pudendal nerve injury and post-surgical function. There is no clear evidence to support PNTML in patients with FI (4-C).

3. CONSERVATIVE TREATMENTS

3.1 Pharmacological therapy

3.1.1. Currently used drugs and their efficacy in the management of FI

Drug treatments include stool bulking agents, calcium polycarbophil and constipating agents, including loperamide, codeine, amitriptyline, atropine, and diphenoxylate. Antidiarrheal agents decrease stool frequency, which may in turn limit the number of incontinence episodes.

In a dated study, loperamide, codeine, and diphenoxylate decreased stool frequency to the same degree, but loperamide and codeine were more effective than diphenoxylate in decreasing the sense of urgency. Drugs which enhance sphincter tone, such as topical phenylepherine and oral sodium valproate may be also used to treat FI. A recent Cochrane review on drug treatment for FI has identified few studies on this topic and underlines that the focus of most trials has been diarrhoea rather than on FI.

In patients who exhibit overflow incontinence associated with faecal impaction, disimpaction provides cessation of soiling. Impaired anorectal sensation, lower anal squeeze pressures, reduced sphincter integrity, and neurogenic abnormalities are all factors that may determine incontinence in the presence of faecal impaction. Some
evidence suggests that elimination of faecal impaction is critical to improving continence in incontinent nursing home residents with constipation. A recent Cochrane review showed that the use of a laxative in geriatric patients can reduce faecal soiling. On the other hand, all the trials included in the review had small sample sizes and short duration of follow-up.

When FI is associated with diarrhoea, the tricyclic antidepressant drugs may be effective. Amitriptyline has been used empirically to improve symptoms in patients with idiopathic FI and irritable bowel syndrome. In an open-label study, treatment with amitriptyline prolonged colonic transit time and led to the formation of firmer stools.

3.1.2. Expert panel recommendations
Antidiarrheal agents and those which enhance anal sphincter tone may decrease stool frequency and limit the number of incontinence episodes (3b-B).
The use of a laxative in incontinent patients with faecal impaction can reduce faecal soiling and improve continence (3b-B).
There is limited evidence to recommend antidepressant drugs in FI (4-C).

3.2 Rehabilitative treatment (RT)
3.2.1 Role of RT in FI
Functional FI is an indication for RT: uncontrolled studies report improved continence in about 70% of patients after biofeedback therapy (BFB). Similar percentages are reported when rehabilitative is used in FI secondary to organic diseases such as post-partum incontinence, post-surgical incontinence, descending perineum syndrome, rectocele, and rectoanal intussusception. Patients with rectal prolapse and neurological diseases are fairly unresponsive. A few studies have suggested that
adding exercises or biofeedback, or both, does not enhance the outcome of conservative management \(^{130}\).

In fact, biofeedback therapy and pelvic floor exercises are considered the first-line options in treating FI in patients who do not respond to dietary devices or drugs \(^{131-133}\). Even if RT fails, there are no side effects. It will not affect future decisions regarding therapy \(^{134;135}\).

3.2.2 *Comparison among rehabilitative procedures*

There is no universally accepted therapeutic algorithm and no specific criteria for evaluating the efficacy of RT \(^{130}\). The techniques used, such as biofeedback therapy, kinesitherapy, anal-electrostimulation and volumetric rehabilitation, can vary greatly in rehabilitation programs among centres. For this reason, the results of studies are not comparable \(^{136}\).

Eighteen randomized trials sustain the use of biofeedback therapy in FI \(^{130}\). Biofeedback therapy is aimed at improving voluntary external anal sphincter contraction \(^{83;136;137}\). Another effect is training of synchrony for anal sphincter responses during rectal distention \(^{138}\). Finally, biofeedback therapy may be used to improve rectal sensation and sphincter responsiveness to balloon distention with the use of instruments that simultaneously monitor sphincter contractions \(^{139}\). Some authors have combined biofeedback therapy with kinesitherapy for the pelvic and perineal muscles as supported by two randomized controlled trials \(^{124;125}\). Nevertheless, when used alone, one randomized controlled trial shows that biofeedback therapy is superior to pelvic floor exercises.

RT could improve rectal sensations. Such RT may be performed through biofeedback therapy ("sensory retraining") \(^{140}\) or volumetric rehabilitation, using an inflated balloon \(^{139}\), or water enemas of decreasing volume \(^{83}\). Neither biofeedback therapy nor volumetric rehabilitation is supported by randomized controlled trials.
Anal-electrostimulation can be used to treat FI. The assumption is that anal-electrostimulation can induce muscle contraction by direct stimulation or indirectly via peripheral nerve stimulation. A Cochrane Library review on 4 randomized trials raised concerns on the utility of anal-electrostimulation in FI because: (a) in clinical practice anal-electrostimulation would seldom be given in isolation without exercises and other advice; (b) there is no sufficient evidence for assessing the effectiveness of anal-electrostimulation; (c) there is not enough evidence on how to select patients suitable for anal-electrostimulation, nor on which modality of electrical stimulation is optimal.

3.2.3 Rehabilitation versus other therapeutic techniques

There are no suitable trials testing drug treatment versus any other conservative treatment including RT. There are no studies on the usefulness of RT before surgery. Only one randomized trial has studied adjuvant biofeedback therapy following sphincter repair: there was no difference between the groups as regards continence scores, but adjuvant biofeedback therapy improved the patient's QoL. This report confirmed data from previous studies showing partial improvement with biofeedback therapy used after sphincteroplasty. A review on functional disorders after rectal cancer resection examined the effects of rehabilitative treatment on FI taken from 15 papers, including 11 non-randomized prospective studies. The methodological quality of the studies was evaluated according to the Methodological Index for Nonrandomized Studies (MINORS) scale. The review concluded that RT improves post-surgical anorectal function.

3.2.4 Management of patients who do not respond to RT

It is not clear how non-responsive patients should be managed. In one study report a mini-irrigation system was used in 50 patients with passive FI and/or evacuation difficulty who
had not responded to biofeedback therapy. Two-thirds of the patients believed their symptoms were improved and wanted to continue using the system\textsuperscript{149}. Rehabilitation can identify those “non-responders” who should be next in line for more invasive therapeutic procedures\textsuperscript{84}.

3.2.5 Medium- and long-term effects of RT

Lasting improvement has been observed in patients with FI up to 1 year after rehabilitative treatment\textsuperscript{150}. In a randomized study comparing biofeedback therapy vs kinesitherapy, 53% of biofeedback therapy patients reported adequate relief at a 12-month follow–up compared with 35% of patients in the kinesitherapy group\textsuperscript{133}. Improvement in faecal urgency and subjective rating of bowel control was also maintained at 2 years’ of follow-up in incontinent patients who had undergone biofeedback therapy with different exercise regimens\textsuperscript{151}.

3.2.6. Expert panel recommendations.

After drugs, rehabilitation is the treatment of choice in incontinent subjects (2a-B)

Several randomized trials sustain the use of biofeedback therapy in FI (1a-A)

The combination of biofeedback and kinesitherapy can be useful in FI (1b-B)

There is no sufficient evidence to recommend anal-electrostimulation (4-C)

A partial improvement of continence can be achieved with biofeedback after sphincteroplasty (2b-B).

Rehabilitation improves anorectal function after anorectal surgery (3a-B)

RT can identify patient non-responders for whom more invasive therapies are needed (3b-C)

RT can maintain medium and long-term effects (1b-A)
3.3. **Anal plug and Peristeen**

3.3.1. *The efficacy of anal plugs to control FI*

Four randomized studies\textsuperscript{152-155} with 136 participants and a Cochrane review\textsuperscript{156} have evaluated the efficacy of anal plugs (AP).

The main results can be summarized as follows: (a) no trial compared AP with other treatments; (b) APs are poorly tolerated and 1/3 of patients stop using the AP due to discomfort\textsuperscript{156}; (c) although efficacy was shown in all trials, improvement in FI and QoL scores was hardly evaluable\textsuperscript{156}. Only one study showed positive effects of AP compared to no intervention\textsuperscript{154}. When used in malformations, there was a 57.1% success rate in children with congenital imperforate anus and 22.2% in patients with spina bifida\textsuperscript{155}. The Cochrane study\textsuperscript{156} concludes that AP could be useful in selected patients as a substitute for other forms of management or as an adjuvant treatment option; (d) different sizes\textsuperscript{153} or material of production can influence tolerance and efficacy, and polyurethane plugs are better tolerated than polyvinyl plugs\textsuperscript{152}.

“PROCON” and “PROTECT” can be considered as intelligent plugs: they have a “barrier” function and allow an early identification of stool arrival in the rectum. One multicentre study on 11 patients demonstrated a significant reduction in incontinence score and an overall significant improvement in QoL\textsuperscript{157;158}.

3.3.2. *Role of Peristeen (transanal irrigation) in FI*

Six case series and retrospective studies\textsuperscript{159-164}, with 914 neurological patients, and a randomized controlled trial\textsuperscript{165} versus conservative management in 87 spinal cord-injured patients, have demonstrated the efficacy of Peristeen. Successful outcome was achieved in 46-68% of patients\textsuperscript{159;160;160;162}.

3.3.3. **Expert panel recommendation.**

*No sufficient data are available to recommend anal plug in clinical practice (5-D)*
Some evidence supports the use of Peristeen in FI (2b-B)

4. SURGICAL PROCEDURES

4.1. Injectable bulking agents

4.1.1. Main indications for use of bulking agents

The injection of a biocompatible bulking agent (BA) in submucosal or intersphincter space is presumed to increase the pressure of the anal cushions, improving the closure of the anal canal at rest. The main indications for use of BA are passive faecal incontinence, post-defecatory leakage, and involuntary gas escape without forewarning. Several studies have suggested that patients with an intact, but degenerate, internal anal sphincter (IAS) should undergo injection of BA.

4.1.2. Efficacy of the most common bulking agents used in FI.

Analysis of six randomized trials, including 417 patients, concluded:

(a) Injection of BA versus placebo or sham injection. Two trials addressed this comparison. The first trial compared PTQ® (polydimethyl-siloxane elastomer) with a saline injection but the sample size was too small to detect significant differences. In addition, subjective perception of success was low in both groups, 23% versus 27%, p=0.73. The second trial compared PERMACOL® (porcine dermal collagen) injection versus sham injection. There was no difference in Cleveland Clinic faecal incontinence score (CCFIS) and faecal incontinence quality of life (FIQOL) at 12 months except for one domain of FIQOL.

(b) Comparison between two types of BA. Three trials addressed this comparison but no clear result was achieved. Two randomized trials compared PTQ® and Durasphere® (carbo-coated zirconium oxide beads). In the first trial 40 randomized
participants in both groups reported an improvement in CCFIS and FIQOL over a 12 month period, but PTQ was better than Durasphere® in terms of FI score and QoL. There were more adverse effects in the PTQ® group. In the second trial\(^{169}\) on 35 patients, CCFIS improved significantly in both groups at 6 weeks and 6 months, but not at 12 months. No significant improvement in mean SF-36 scores from baseline occurred at any follow-up sessions for either agent. Another trial with only 10 participants\(^{172}\) compared Bulkamid® (hydrogel cross-linked with polyacrylamide) and Permacol®. Even if Bulkamid® showed more improvement in incontinence scores than Permacol®, the trial was too small to detect differences between the groups.

(c) **Comparison of injection techniques.** One study\(^ {168}\) compared PTQ® injection under endoanal ultrasound guidance versus digital guidance. The group with ultrasound guidance achieved a better incontinence score and QoL. However, many of the reported data were not suitable for analysis, and there was a dropout at 12 months.

(d) **Comparison of methods.** No data are available about the injection of BA versus conservative treatment, injection of BA versus another minimally invasive or surgical intervention or large versus small volumes of BA\(^ {166}\).

### 4.1.3 Expert panel recommendations

BA injection can be used in patients with damaged or degenerated IAS with very limited evidence (5-D), although Permacol and Bulkamid show more evidence (4-C). However, Durasphere and ultrasound guided PTQ injections seem to give better results (3b-B).

### 4.2 SECCA technique

#### 4.2.1. Efficacy of the SECCA procedure
Temperature-controlled radio frequency energy delivered to the anal canal is an endoscopic therapy, called SECCA, which induces scarring, with deposition and shrinkage of collagen in the internal anal sphincter (IAS) muscle. A recent review of 10 uncontrolled studies including 220 patients showed an improvement rate of 70%, but with a high rate of complications after a follow up of 16 months \textsuperscript{173}. The success rate fell to 22% after a median 40 month follow-up \textsuperscript{174}.

4.2.2 Expert panel recommendation.
SECCA therapy seems to have a reasonably good percentage of early success but with a high complication rate and rapid deterioration of the results (4-C)

4.3 Malone anterograde continence enema (MACE) procedure

4.3.1 Efficacy of the MACE procedure
The Malone antegrade continence enema (MACE) is a surgical procedure used to create a continent cecal access in order to antegrade irrigate the colon so as to help evacuation, originally designed for intractable forms of constipation but also useful to give pseudocontinence by keeping the colon empty. A recent review evaluating 24 studies (676 patients) reported an overall continence (pseudocontinence) of 93% \textsuperscript{175}. A more recent study shows a similar success rate of 86% in 23 patients \textsuperscript{176} despite several postoperative complications \textsuperscript{175;177}. Furthermore, a modified Marsh & Kiff technique has been shown to be efficient in cleaning the whole colon and rectum and preventing accidental ileal reflux \textsuperscript{178}.

4.3.2 Expert panel recommendation
MACE can be considered to give pseudocontinence in selected patients with associated constipation or neurogenic bowel (3a-B).
4.4. Sphincter repair (SR)

4.4.1. Indications for SR in FI

SR is indicated in highly symptomatic patients with a defect of the EAS and is aimed at restoring the anatomical integrity of the injured sphincter. Various techniques are used for SR. End-to-end direct repair is usually favoured by gynecologists after obstetric tears as a primary anal sphincter repair. Colorectal surgeons prefer a delayed overlapping sphincteroplasty, which remains the treatment of choice for single EAS defects with or without concomitant IAS defect. Overlapping may be effectively advocated also for inveterate lesions and in elderly patients. Better results of primary repair with overlapping are obtained if the operation is performed by colorectal surgeons. The data available so far do not support replacement of sphincteroplasty with sacral nerve stimulation in patients with FI secondary to sphincter defects.

In cases of severe structural damage of the EAS due to wide or multiple lesions, sphincter repair is contraindicated because of the impossibility of identifying the residual sphincter to use for the repair, so other treatment options should be considered.

4.4.2. Surgical technique of SR

The anterior route represents the approach of choice for SR in obstetric lesions. However, a posterior repair can seldom be used for failed anterior sphincteroplasty, multifocal sphincter defects and neurogenic FI in order to avoid scar tissue in the site of previous surgery.

Several studies, including one prospective trial, have shown the usefulness of preserving the scar to anchor the suture during sphincteroplasty.
Six randomized trials \(^\text{192;204-208}\) and a Cochrane Review \(^\text{186}\) compared EEDR to OR and showed that there were no significant differences between the two techniques concerning flatus incontinence and FI in the long-term (36 months). A randomized controlled trial\(^\text{207}\) showed that functional results are unrelated to the type of suturing material (polyglactin vs. polydioxanone). A separate imbrication of the sphincters can be undertaken in the case of an isolated IAS defect \(^\text{16;209}\) (with high risk of failure \(^\text{190}\)), but in most cases both sphincters are included in the sutures \(^\text{184;190;192;195;207;210}\).

A prospective randomized trial \(^\text{211}\) compared the 1-year results of immediate repair of obstetric sphincter tears versus 12 hour delay SR and showed no differences. However, in primary anal sphincter repair \(^\text{190}\), hematoma formation, wound infection, faulty technique or an unrecognized second sphincter injury may lead to poor outcome, requiring delayed sphincteroplasty in \(0.3-5\%\) of patients \(^\text{201;212}\).

A prospective study by Briel et al. \(^\text{213}\) comparing patients with overlapping alone to those having overlapping combined with restoration of the rectovaginal septum and perineal body showed no significant differences in the long-term.

A redo-sphincteroplasty is indicated for persistent or relapsing EAS defect \(^\text{182}\). The results of a redo-overlapping are stable over time with a success rate of about \(50\%\) \(^\text{214;215}\) without significant modifications of continence score in the long-term \(^\text{215}\). Fecal diversion does not offer any advantage in terms of healing and functional results in a randomized trial \(^\text{216}\).

**4.4.3. Role of sphincteroplasty in traumatic cloacal repair**

Traumatic cloaca is often secondary to obstetric injury due to a wide episiotomy with a \(3^{\text{rd}}-4^{\text{th}}\) degree perineal tear \(^\text{212}\). Surgical repair with overlapping sphincteroplasty may reduce urgency and FI in \(65-86\%\) of patients and residual symptoms may be controlled by biofeedback \(^\text{212;217}\). Anterior overlapping sphincteroplasty, combined with a modified lotus petal flap, may significantly improve in the delayed repair of traumatic cloaca \(^\text{218}\).
4.4.4. Outcome predictive factors after sphincteroplasty

The preoperative condition of pudendal nerves\textsuperscript{219-221}, persistence of the sphincter defect\textsuperscript{222}, restoration of anal canal pressure\textsuperscript{223}, age $>$ 50 years, BMI, descending perineum\textsuperscript{180}, squeeze pressure\textsuperscript{224}, and incontinence duration\textsuperscript{225} may all negatively influence the outcomes of surgery. A CCIS $>$ 5 at 3 months follow-up, represents the only statistically significant factor of persisting FI\textsuperscript{181}. Similarly, a poor response at 3 years can predict poor function at 10 years\textsuperscript{226}.

Occurrence of a pudendal neuropathy seems to negatively affect the outcome, in fact the success rate in patients with normal preoperative PNTML is fairly good (between 55 and 80\%\textsuperscript{219-221}).

4.4.5. Durability of the results of sphincteroplasty

While the short-term outcomes of sphincteroplasty are good in $>$ 70\% of patients\textsuperscript{188;197;222;227}, they tend to deteriorate in the long-term with only 20-60\% of success at 5-10 years of follow-up\textsuperscript{188;198;222-224;226-231}. However, a recent review concludes that long-term QoL and satisfaction remain high\textsuperscript{232}.

4.4.6. Effects of sphincteroplasty on the QoL in FI patients

There are no prospective randomized trials on this topic, and no universally accepted tools are available to assess the QoL in these patients. A recent systematic review\textsuperscript{232} concluded that there are no strict correlations between function and QoL, because most patients are satisfied with surgery, in spite of suboptimal continence.

4.4.7 Expert panel recommendation
Sphincteroplasty is indicated in the case of limited sphincter damage by preserving the scars (2-B).

Functional results are unrelated to the type of suturing material (1b-A).

The results of a redo-overlapping sphincteroplasty for persistent EAS defects are stable over time (2-C).

Faecal diversion does not offer any advantage (2-B).

A poor response at 3 years after sphincteroplasty can predict poor function at 10 years (2-C).

Long-term QoL and satisfaction remain high after surgery in spite of functional results (2-C)

4.5 Postanal repair

4.5.1 Indications and role of postanal repair

Indications for postanal repair include patients with weak sphincter without demonstrable defects, with low resting pressure, and those who have previously failed or refused biofeedback therapy. The success rate is in the range of 15-87% depending on the definition of the success, length of follow-up and cause of incontinence. However, the results of surgery deteriorate over time, and only 1/3 of patients maintain the continence at 5 years follow-up. A pudendal neuropathy or an occult anal sphincter defect can explain the late worsening of continence.

4.5.2 Expert panel recommendation

Level postanal repair can improve continence in the short term, but late results are poor (3-C).

4.6. Sacral neuromodulation
4.6.1 *Indications for sacral neuromodulation*

Sacral Neuromodulation (SNM) can be considered for patients with FI with intact but weak anal sphincters or those with sphincter disruption up to 120 degrees of circumference\(^{196,233-239}\). The presence of EAS atrophy does not influence the outcome of SNM in patients with a sphincter defect\(^{240}\). SNM has also been indicated in patients with FI following rectosigmoid resection after failed conservative treatment\(^{241-245}\) and in selected patients with neurogenic FI\(^{24,246,247}\). It may also be useful in patients with double incontinence\(^{248,249}\). Lastly, SNM has shown a positive effect on FI occurring after surgery for rectal prolapse or Obstructed Defecation Syndrome\(^{250,251}\).

4.6.2. *Patient selection after Peripheral Nerve Evaluation test*

Improvement of at least 50% of incontinence scores and/or 50% reduction in the number of episodes during PNE test are considered the main selection criteria for permanent implant\(^{236,237}\). Use of a quadripolar electrode is significantly related to success\(^{252}\), while increasing age, coexistence of more than three chronic diseases and obesity are negative predictive factors\(^{253,254}\).

4.6.3. *Investigations to predict outcome*

*Anorectal manometry* does not provide predictive values and conclusive information for patient selection\(^{254,255}\).

*Neurophysiological test*. Anal sphincter electromyography and latency somatosensory evoked potentials have been shown to predict outcome with acceptable reliability\(^{256,257}\). Anal sphincter electromyography, however, is recommended by only 50-70% of Italian and French experts\(^{236,237}\).

*Anal Ultrasound* is mandatory for the assessment of the patients, but has no predictive role\(^{237}\).
4.6.4. Technical issues of the percutaneous nerve evaluation test

S3 foramen is the most frequently chosen nerve root and seems to be the most effective. Positive motor responses during percutaneous nerve evaluation (PNE) are highly predictive of a positive outcome of test stimulation with a quadripolar electrode, but correct lead placement could also be based on sensory response. Use of local or general anaesthesia does not influence outcome. Lateral fluoroscopy or ultrasound are required to identify the depth of the needle and computed tomography (CT) scan is required for patients with suboptimal sacral anatomy. In some individuals, bilateral stimulation may be more effective in relief of symptoms. Therefore, if unilateral PNE fails, a bilateral test should be considered. The tined quadripolar lead costs about 5 times more than the monopolar electrode but its clinical use is justified by a significantly higher response rate.

4.6.5. Functional outcomes in the short and long term

SNM has been shown to significantly improve outcome when compared with medical and rehabilitative therapy. After the PNE test, about 80% of patients receive permanent stimulation. Complete continence recovery is reported in 25-60% of patients with long-term therapeutic effect, although there is about a 10% loss of efficacy in the first 5 years.

4.6.6. Impact of outcomes on QoL

Although complete continence is achieved in 25-60% of cases, 70-80% of patients experience substantial improvement of their QoL.

4.6.7. Management of failures after implantation
Suboptimal therapeutic responses and adverse events are common in SNM. In case of failure, the stimulation parameters can be reprogrammed successfully in about 50% of the cases. In case of failure, a surgical revision is indicated.

After unsuccessful setting adjustments, a controlateral test could be proposed and, in case of failure, a surgical revision is indicated.

4.6.8. Mechanisms of action

The mechanism of action is unclear. A medullary polysynaptic reflex instead of direct stimulation has been demonstrated to activate pelvic muscle contraction.

PET scan, Sensory Evoked Potentials of the pudendal nerve, and MRI studies have demonstrated activation or inhibition of the central brain areas involved in the control of micturition and continence.

The increase in rectal sensations and improvement of rectal compliance suggest that SNM can act also at spinal levels. SNM may improve continence and urgency through alteration of colonic motility, particularly by increasing retrograde colonic propagating sequences in the left colon. Changes in blood flow, recorded by rectal doppler flowmetry during stimulation, provide further evidence that SNM affects autonomic function of the distal bowel.

Finally, a recent study demonstrated that in most patients the effect is maintained even when the pulse generator is switched off, suggesting that a long-lasting SNM could induce a form of brain neuroplasticity.

4.6.9. Costs of SNM

SNM is an expensive treatment. The implantable pulse generator accounts for most of the budget, indicating that the screening phase is crucial for cost cutting. The incremental cost effectiveness ratio for introducing SNM in Italy was € 28,285 per quality-adjusted life year.
(QALY) gained for patients with a structurally deficient anal sphincter and € 38,662 per QALY gained for patients with intact anal sphincters.\textsuperscript{282}

4.6.10. Tibial nerve stimulation (PTNS) as an alternative to SNM

Poor quality studies suggested that PTNS could be effective for FI. There are no studies that support maintenance of PTNS benefits in the long-term. It is difficult to compare studies, due to the measurements of outcome used, which include different PTNS schedule, timing and duration of treatment.\textsuperscript{283} Given the cheaper initial outlay, PTNS could offer a relatively affordable treatment in patients who have failed conservative management.\textsuperscript{265,284}

4.6.11: Expert panel recommendations

SNM for FI has a wide range of indications, however there is limited evidence for which is the best indication (4 C).

Use of the tined lead increases the response rate (3b-C) while other risk factors have poor reliability (4-C).

Motor response to the PNE test ensures high success rate but also sensory response alone is useful for the insertion of the electrostimulation; SNM is better than conservative treatment (2a-B) but its long-term success rate slightly deteriorates with time, requiring frequent adjustments of the electrostimulation parameters (3b-B).

The mechanisms of action are uncertain but the involvement of higher central brain areas is advocated (3b-C).

4.7 Rectal intussusception
4.7.1. *Pathophysiological relationship between rectal intussusception and faecal incontinence.*

FI, either passive or urge, can be secondary to rectal intussusception (RI). The prevalence of FI in patients with RI supports this relationship\(^{285}\). Defecography carried out in incontinent patients shows RI in 17-21\(^{286,287}\). Physiologic aspects of passive FI include intermittent activation of the recto-anal inhibitory reflex by intussuscepted rectum, appearance of abnormal rectal ‘prolapse waves’ and intermittent relaxation of the IAS\(^{288-291}\). Passive FI can be attributed in particular to a progressive and significant decrease in IAS pressure with increasing grade of RI\(^{288}\).

Urge FI may be related to an inappropriate firing of the rectoanal inhibitory reflex that leads to temporary reversal of the usual pressure gradient between the rectum and anus\(^{291}\).

Post-defecatory leakage is referred to as incomplete rectal emptying\(^{292}\).

4.7.2. *Treatment of FI associated with rectal intussusception*

There are no randomized trials on this topic. Rehabilitation is the first choice to treat both impaired defecation and FI secondary to RI\(^{83}\). Biofeedback has produced significant reductions in FI score\(^{293}\) better than surgery\(^{128}\), but patients with high-grade intussusception have poor results with biofeedback, suggesting a need for surgical treatment\(^{294}\).

The association of RI/FI should be considered as a negative predictive factor for Delorme procedure\(^{295}\), with only 33\% of cases improved\(^{296}\). Abdominal procedures include all types of laparotomic or laparoscopic rectopexy, anterior or posterior, associated or not with sigmoidectomy. A significant FI score improvement was obtained after transabdominal posterior rectopexy without any new onset of constipation\(^{297}\). Short and long-term results after anterior rectopexy have been shown to provide a significant improvement in
symptoms\textsuperscript{298}. D’Hoore\textsuperscript{299} popularized this procedure and several studies report a success rate of around 90\%\textsuperscript{300-307}.

Few studies have explored the efficacy of resection-rectopexy. Poor results and no significant reduction in incontinence scores were obtained\textsuperscript{308,309}.

4.7.3. Recurrence of FI and RI

The literature on this issue is very poor. Relapse RI and FI may be treated by a second surgical procedure\textsuperscript{304}.

4.7.4. Expert panel recommendation:

No randomized trials are available on this topic and, among several surgical options, ventral rectopexy seems to give the best results (4-C).

4.8. Rectal prolapse

Only case-series and few low-quality clinical trials have compared techniques for management of rectal prolapse. Main weaknesses include a wide range of surgical techniques, uncertain pathophysiology and different characteristics of the prolapse, and confusion arising from different timing and definitions for assessing outcome.

4.8.1. Patient selection for Altemeier, Delorme, or rectopexy

Since the perineal approach can be carried out under spinal, sometimes local, anaesthesia\textsuperscript{310}, it is generally believed that older, frail patients and those with important co-morbidities should generally undergo a perineal approach\textsuperscript{311}. The same choice could be considered for younger patients with severe co-morbidities or those unwilling to run the risk of sexual dysfunction due to pelvic nerve injury\textsuperscript{312}. Altemeier’s procedure or rectopexy usually
manages external prolapse >5 cm of length, while the Delorme procedure is usually reserved for smaller prolapse\textsuperscript{113}. Preoperative incontinence or constipation can affect the outcome of both the abdominal or and perineal approach\textsuperscript{313}.

4.8.2. Perineal versus abdominal approach.

Abdominal rectopexy is generally believed to result in fewer recurrences despite potentially higher morbidity, postoperative pain and length of hospital stay. One randomized trial\textsuperscript{314} stated, however, that abdominal rectopexy associated with pelvic floor repair provides better functional results than perineal rectosigmoidectomy because the latter implies removal of the rectal reservoir. In a metanalysis\textsuperscript{315} including 1140 patients, the recurrence rate was 20% for Delorme’s procedure and 5% for resection rectopexy after 2 years of follow-up. Another retrospective study\textsuperscript{316} reported similar results, but with lower morbidity and shorter hospital stay in the Delorme group.

The PROSPER trial\textsuperscript{317} attempted to answer three fundamental questions: which is better, a perineal or abdominal approach? Which is better, suture rectopexy or resection rectopexy? And which is preferred, the Delorme or Altemeier operation? The original target to recruit 950 patients was reduced to 300 patients and the actual number of patients included was 293. Only 49 patients were randomized for perineal vs abdominal approach and 213 for the Altemeier vs Delorme operation. At 1 year follow-up only 7 vs 13 of the perineal vs abdominal approach and 67 vs 57 of the Altemeier’s vs Delorme group have been evaluated, thus making the conclusions weak. There were no significant differences in recurrences after perineal or abdominal procedure. In the perineal group, recurrences were similar (24% Altemeier’s vs 31% Delorme) and FI and QoL did not differ between the two procedures. There was no significant difference in the number of recurrences in the perineal vs abdominal approach (19% vs 28%).
A new prospective randomized controlled trial (DeloRes) comparing Delorme technique versus rectopexy is still ongoing\textsuperscript{318}.

4.8.3. Suture rectopexy or mesh rectopexy

The recurrence rate after suture rectopexy and resection rectopexy was also investigated by the PROSPER trial\textsuperscript{317}. At 1-year of follow up only 15 suture vs 17 resection rectopexy patients were analyzed. In this subgroup, there were fewer recurrences in the resection rectopexy group (13\% vs 26\%) and there were no significant differences in FI and the improvement in QoL\textsuperscript{317}. Resection rectopexy seems to result in a lower recurrence rate.

4.8.4. Resorbable versus unresorbable mesh

There are no prospective trials and even a recent review of this topic has failed to provide a definitive answer\textsuperscript{319}. A minor risk of infection and penetration/fistulization of the surrounding organs is reported for resorbable mesh\textsuperscript{305;320}, but its use could be reasonably recommended.

4.8.5. Ripstein, Wells, Orr Loygue, ventral rectopexy: pros and cons

The Ripstein operation has virtually been abandoned because of the high risk of constipation\textsuperscript{321}. Most Authors who claim a low recurrence rate with acceptable risk of complications favor Wells rectopexy. De novo constipation, however, still can arise in a significant proportion of patients\textsuperscript{322}. Better functional results are reported after Orr-Loygue rectopexy with preservation of the lateral ligaments of the rectum\textsuperscript{323;324}. With this operation De novo constipation is rarely reported and the recurrence rate seems to be very low. However, no comparative studies with other techniques of rectopexy have been carried out. Ventral rectopexy involves a limited lateral mobilization of the rectum, thus preventing
nerve injury and deep ventral dissection from the vagina. Due to the low risk of recurrence and of de novo constipation, it is preferred nowadays by several colorectal surgeons 325.

4.8.6. Laparoscopic versus open approach rectopexy
A recent metanalysis has reviewed 8 comparative studies, including 467 patients, showing no significant difference in postoperative recurrence, incontinence and constipation between laparoscopic and open abdominal rectopexy 315. However, laparoscopic rectopexy has fewer post-operative complications and shorter hospital stay compared to open rectopexy and it provides better cosmetic results 315.

4.8.7. Expert panel recommendation
Elderly and frail patients could be best suited for perineal surgery, but no conclusive evidence is available (5-C).

The abdominal approach is traditionally believed to be superior in terms of recurrence rate (2-B) but this has been questioned by a randomized controlled trial. Resection rectopexy results in a lower recurrence rate and is recommended in cases of constipation (2-C)

Among the rectopexy techniques, ventral rectopexy is preferred nowadays but without evidence (5-C); the laparoscopic approach should be preferred only because it is less invasive and more cosmetic (2-B).

4.9. Replacement of muscle and artificial sphincter

4.9.1 Rescue procedures for sphincter replacement
Despite the low success rate and the high percentage of complications, gluteoplasty (GLP), graciloplasty (GRP) or artificial anal sphincter (AAS) are options that may be
considered to replace the anal sphincter when extensive sphincter damage, muscle loss and pudendal neuropathy are involved 326.

4.9.2. Functional outcomes and QoL after GLP or GRP

The literature on GLP is poor as this operation is no longer performed despite a reported success rate of about 67-72% but a complication rate ranging from 35% to 64% has been reported 327;328. Uncontrolled studies have reported a success rate of about 62-78% for the GRP 329-331, and even more in cases of bilateral CRP 332. Dynamic GRP is currently the most studied and employed transposition procedure for anal incontinence. The neo-anal sphincter is connected to a pulse generator in order to allow permanent contraction, thus preventing fatigue 333. Success rates vary between 57% and 93% 334-338 and long-term results have success rates of between 62 and 72% at 2 years 339;340. A diverting stoma does not influence the results 339.

The complication rate of dynamic GRP is high (211 complications in 93 patients in a prospective trial) 337. However, despite the complications (obstructed defecation in >25% of cases 337;338;340;341) and imperfect continence, patients with GRP report a significant improvement in QoL 337;339.

4.9.3. Outcome of the artificial anal sphincter (AAS)

The implant of foreign material in the anorectal region carries a high risk of infection and requires early removal in 15-18% of the patients 342;343. A similar explant rate was reported using an AAS placed above the pelvic floor musculature by laparotomy 344. Good functional results are reported in >50% of patients who tolerated the AAS 342. In a prospective, non-randomized, trial 345 the incontinence scores improved significantly in 67% of the patients with a functioning neo-anal sphincter at 12 months of follow-up. The
device was removed in 41 out of 112 patients, a revision was made in 46% and device-related adverse events were registered in 96 patients. Long-term outcomes are disappointing: obstructed defecation occurred in seven and FI persisted in six patients out of 14 patients with a functioning device at 50 months of follow-up.\textsuperscript{346}

4.9.4. **Possible role of a magnetic anal sphincter**

A magnetic anal sphincter has recently been proposed\textsuperscript{347}: device removal was needed in 21.4% and perfect continence was reached in only 14.2% of patients. A multicenter European trial is ongoing.

4.9.5. **Expert panel recommendation**

Sphincter substitution with autologous muscle or implantable prosthetic devices can be considered a final rescue solution before colostomy. The success rate is good in the short term but declines with time and the complication rate is very high (3a-B)

4.10 **Prosthetic surgery with meshes in faecal incontinence with or without pelvic prolapse**

4.10.1. **Association between pelvic prolapse (PP) and FI**

FI is reported to be associated with pelvic organ prolapse in 50-75% of patients with rectal prolapse\textsuperscript{113}, 32-40% with rectal intussusception\textsuperscript{112,348-350} and 20-54% with genital prolapses\textsuperscript{351-357}. Up to 13-30% of patients with a rectocele and prolapse have FI, usually to a greater extent\textsuperscript{351,358,359}.
4.10.2. **Anatomical and functional developments in pelvic reconstructive surgery**

The Integral Theory System (ITS)\(^{360}\) hypothesizes a deterioration of connective tissue as the main cause of ligament laxity and thus of prolapses. The Tissue Fixation System (TFS) is a mini-invasive procedure achieving good results in the cure of prolapse and improving FI through reinforcement of ligaments with thin tapes\(^{361}\). Prostheses have increasingly replaced fascial surgery in recent years, aiming to obtain more efficient PP correction through tension-free meshes. In the absence of any randomized trials, the results are difficult to evaluate. A 3.2% erosion rate with the sacrospinous fixation of a CR-mesh is reported\(^{362,363}\) but other papers report higher (5-19%) erosion rates\(^{364-367}\).

4.10.3. **Indications for surgery in FI associated with PP**

The main indication for surgery for PP, independently of FI, is the worsening of QoL\(^{16,24}\), while there is a lack of consensus about the best surgical techniques to be used\(^{364,366-368}\).

4.10.4. **Effect of a PP correction with prosthesis on FI**

Thiersch’s operation could improve rectal prolapse and FI in high risk and elderly patients even if the recurrence rate is about 30-50%\(^{369-372}\). A transobturator anal sling, placed along the puborectalis muscle to create a support around the sphincter and suspend the rectum, may improve FI and RP in about 85% of patients\(^{373}\). Similar results have been obtained with a circumferential prosthesis surrounding the anal sphincter\(^{374}\). Posterior colporrhaphy ± levatorplasty for prolapse has better outcomes than prosthetic surgery without mesh related risks\(^{364,366-368}\) and improves FI in 56-73% of patients\(^{358,375,376}\). Laparoscopic ventral rectopexy\(^{377}\) for III stage prolapse has been reported to significantly improve FI in all patients. TFS procedure for urogenital prolapses brings cure of FI to 82.7%\(^{361}\), but no RCTs are available to confirm this result.
4.10.5. Postoperative complications

Mesh erosion is reported in 13.1% of vaginal operations and in about 3% of patients after open or laparoscopic sacrocolpopexy\textsuperscript{378}. Pain or dyspareunia have been reported in 38.6% of cases, but in more recent papers in 4-11% \textsuperscript{364,365,379}. There are <1% infections \textsuperscript{365,380}, while bleeding, hematoma, and injury to organs during mesh placement are rare. Thiersch procedure may cause skin erosion, breaking of the ring and faecal impaction\textsuperscript{369-372}. Data concerning perianal meshes\textsuperscript{373,374} are unavailable.

4.10.6 Expert panel recommendation

Surgery for FI associated with PP often requires an interdisciplinary team and mesh (non-absorbable) insertion carries a high risk of erosion and complications (2-B). Data on functional results in the long term are scarce and of poor quality (4-C).
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Ref Type: Conference Proceeding


Ref Type: Unpublished Work


## TABLE 1

Table 1. Levels of evidence and grading of the recommendations \(^{(25)}\)

<table>
<thead>
<tr>
<th>Levels of evidence</th>
<th>Grading of the recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a SR* with homogeneity of RCTs*</td>
<td>A Level 1 studies</td>
</tr>
<tr>
<td>1b Individual RCT with narrow confidence interval</td>
<td>B Level 2-3 studies or extrapolation from level 1 studies</td>
</tr>
<tr>
<td>2a SR with homogeneity of CSs*</td>
<td>C Level 4 studies or extrapolation from level 2 or 3 studies</td>
</tr>
<tr>
<td>2b Individual CS or RCT of low quality</td>
<td>D Level 5 studies or inconclusive studies of any levels</td>
</tr>
<tr>
<td>3a SR with homogeneity of CC* studies</td>
<td></td>
</tr>
<tr>
<td>3b Individual CC study</td>
<td></td>
</tr>
<tr>
<td>4 Case-series or CSs and CC studies of low quality</td>
<td></td>
</tr>
<tr>
<td>5 Expert opinion without explicit critical appraisal</td>
<td></td>
</tr>
</tbody>
</table>

*Abbreviations: SR (Systematic Review); RCT (Randomized Clinical Trial); CS (Cohort Study); CC (Case-Control)