Slings for Urinary and Fecal Incontinence

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13.1 Slings for Urinary Incontinence

13.1.1 AdVance/AdVance XP

In a study between February 2006 and April 2009, of 230 consecutive patients treated with the AdVance sling, 21.3% (49 patients) had acute urinary retention after removal of the catheter. One patient (0.4%) had urinary infection with fever 10 days after sling implantation, treated with antibiotics, and one patient (0.4%) showed local wound infection 8 days after surgery and was treated with oral antibiotics. No further treatment was necessary. One patient (0.4%) suffered chronic perineal pain and five patients (2.2%) reported mild perineal discomfort for 4–6 weeks, but these patients did not need any pain medication. One patient showed pubic symphysitis 4 months after sling implantation. During explantation there were no local signs of inflammation. Further diagnostics revealed the Guillain–Barrè syndrome as the causative pathology [1].

In another study 80 patients were treated with the AdVance and AdVance XP (39–41, respectively). No peri-operative complications were reported. There were a total of 9 and 12 device- or procedure-related complications in AdVance and AdVance XP arms. There were two serious AEs (adverse events) in the AdVance

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group. One was symphysitis, which occurred at day 54 post-implantation. The patient underwent catheterization and received antibiotics and symptoms resolved at 8 weeks of treatment. The second AE was an infection of tendon adductor longus 41 days post-operation. The event resolved with the antibiotic treatment.

In the AdVance XP group, there were three serious AEs. One patient with an urge of urinary incontinence received medication with several anticholinergics for 6 months followed by transection of one arm of the sling (urgency symptoms disappeared). Two patients with persistent urinary retention underwent transection of one arm of the sling. In both cases, the symptoms were resolved and continence improved. No sling explantation was required in either treatment group [2].

The most frequent complication that occurs after implantation of AdVance is urinary retention. This usually resolves spontaneously in few days after surgery, or at most in few weeks. These patients require therefore to be adequately cared for in the post-operative period. If there is a minimum residual, the first therapeutic approach will be pharmacological with the administration of anticholinergics. The association between high-dose anticholinergics and intermittent self-catheterization or derivation by suprapubic or transurethral catheter (4–5 times/day) is recommended in cases of severe residual urine.

It is necessary to pay special attention during catheterization; in fact in several patients, urethral perforations were found caused by the maneuver itself (Fig. 13.1a, b).

If, therefore, self-catheterization appears to be difficult to perform, it will be advisable to place a small indwelling catheter or suprapubic derivation for the time necessary to resolution of urinary retention.

Very rarely (<1%) could be a retention that persists over time that can be settled by bilateral or unilateral section of the sling under endoscopic surveillance, which should be performed at least after 3–4 months of the device implantation.

In case of failure of the Advance implant, if indications to the implant were correct, it has to be considered an improper placement of the sling. The passage too lateral or dorsal of the needles can in fact cause a worsening of incontinence.

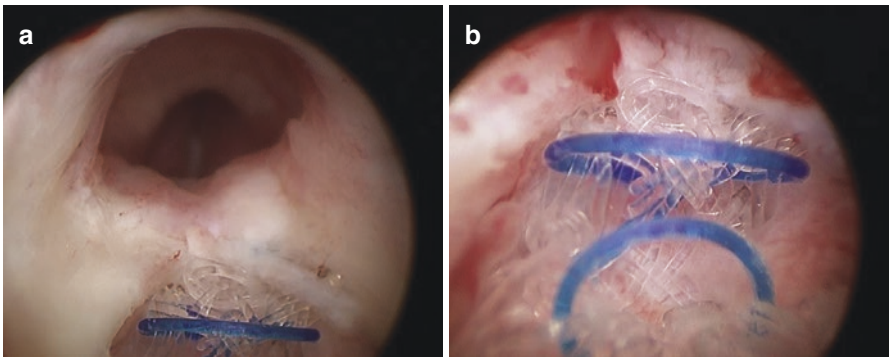

Fig. 13.1 (**a**, **b**) Three months after Advance implant. Radiotreated patient with urethral erosion due to traumatic catheterization for urinary retention

This condition is due to dorsal traction of the urethra that will keep it pervia, getting worse the sphincter functionality. In this case you will need to intervene through section of the two side arms and the new Advance implant in the correct position.

13.1.2 I-Stop TOMS

Not many data are available in the literature about this device. In two prospective case series, 143 patients were included with 1-year follow-up and the reported success rates (>50% improvement) were excellent [3]. Yiou et al. recently described the prospective results of 40 patients treated with the TOMS™ with a 2-year follow-up; seven patients required additional treatment between the first year and the second year after implantation (five PRO-ACT balloons, two artificial urinary sphincter [AUS]). No post-operative complications were reported after 12 months [4].

A total of 103 patients were followed up for 12 months. The surgical procedure was considered easy to perform. Treatment satisfaction was >90%. The post-void residual urine volume did not increase substantially, and acute urinary retention did not occur. The perineal pain scores were very low at follow-up. Wound infection was seen in two patients at the 1-month follow-up [5].

One of the complications can be the infection occurring in both the early and post-operative late stages. The problem of infection after surgery can be attributed to a placement of the sling, which is more superficial than other devices. The treatment of the infection consists of antibiotic therapy.

Being positioned more distally and more superficially than Advance, it is possible to treat any failure by positioning an Advance implant correctly considering that the indications for placement of TOMS are similar to those of Advance (residual sphincter function).

13.1.3 Virtue

McCall [6] identified 32 consecutive male patients who were implanted with the Virtue Quadratic (VQ) sling over the study period. One patient was excluded due to no follow-up. Median follow-up was 55 months. Median pre-operative and post-operative pads per day were 3 (interquartile range: 1–3) and 2 (1–2.5). There were 21 (68%) patients who were considered procedure failures. Two (7%) patients reported chronic pain following placement and seven (22%) underwent subsequent sling explant due to pain or for failure (1 vs. 6). Six (20%) patients underwent subsequent AUS placement. Failure was more likely in patients with external beam radiation therapy (6; 19%) ($P = 0.02$). There was no association between procedure failure with age ($P = 0.65$) or severity of incontinence ($P = 0.17$). The results shown in this study demonstrated a significant procedure failure and complication rate. The authors do not recommend the use of the VQ sling and have abandoned all further implantation of the device.

Opposite results have been described by Ferro et al. [7], where 72.4% of patients had pre-operative mild incontinence (1–2 pads/day), while nine patients used 3–5 pads/day. There were a total of 17 complications, which occurred in 29 patients (58.6%); all were Clavien–Dindo grade I. At 12-month follow-up, patients showed a significant improvement in 24-h pad test (128.6 vs. 2.5 g), the number of pads per day (2 vs. 0), ICIQ-SF score (14.3 vs. 0.9) and USP score for SUI (4 vs. 0), and outcomes remained stable at 36 months. At the last follow-up, the median score on the PGI-I questionnaire was 1 (very much better).

13.1.4 Reemex

The first results of this system were published by Sousa-Escandò et al. in 2004. In a multicenter European study with 51 patients with a mean follow-up period of 32 mo, 33 patients were cured (64.7%). Almost all patients needed at least one readjustment of the sling under local anesthesia. The sling had to be removed in three cases: in one case urethral erosion occurred, and three mild perineal hematomas were seen. Perineal discomfort or pain was very common and was treated with oral pain medication [8, 9].

Considering the various interventions to which patients should be subjected for further adjustments, there is a high risk of infection. The risk of infection is increased by the presence of a foreign body located at a subcutaneous level (variotensor) that has to be reached through an incision to obtain a re-tension. To treat this frequent complication, is not always enough antibiotic therapy, but in most cases it has to be removed the device. This maneuver is made difficult by the incorporation of the network in the subcutaneous tissue that forms a fibrosis around the mesh component and complicates removal. The infection, associated with the mechanical pressure and the chronic stimulation on the urethra, especially if atrophic, may cause erosion of the urethra itself. This ulceration will give rise to continuous infections with high risk of abscess and, if not treated, to erosion. In case of erosion of the urethra, the first treatment must be the removal of the device and the placement of a urinary catheter to facilitate the spontaneous healing of the urethral mucosa, or recut the wound borders and make a direct suture in more severe cases.

Since Reemex is a treatment that causes an obstruction on the urethra to prevent the leakage of urine, in some cases it can cause urinary urgency. To improve this problem, it is possible to proceed or with the loosening of the cords, to reduce the pressure of the network on the urethra, or through conservative treatment with administration of drug therapy (anticholinergics), which could however cause an increase in the post-void bladder residual.

Referred pain in a large percentage of treated patients is due to compression and irritation of the mesh on the superficial perineal nerves. This symptom is often treatable with painkillers and anti-inflammatories, but sometimes leads to the patient's request to remove the device. In case of failure of Reemex, it is possible to implant a functional sling or an artificial urinary sphincter (AUS). If the residual

sphincter function is valid and the membranous urethra shows hypermobility or prolapse, then you can choose for a functional sling (Advance) that has to be positioned more cranially than Reemex. In the remaining cases, the gold standard is represented by AUS. In case of damage of the urethral bulb, the positioning of AUS should be trans-cavernous or it should be placed more proximally, where the urethra appears intact.

13.1.5 ATOMS

The long-term results (2 years' follow-up) of the ATOMS® have been described in two prospective cohort studies including 137 patients. The success rate (<50% reduction in pad use) varies from 72% to 91%. Sling was performed in 4–35%. The most important reasons for sling removal were erosion and infections (47–40% of cases). Sixty-eight percent of cases present transient pain, which disappears within the first 3 months, but in three cases sling removal following persistent serious pain was reported [9, 10].

Being ATOMS a combined device, there is a high risk of infection due to the silicone parts. There is a great difficulty in removing the trans-obturator mesh that anyway, if infected, must be completely removed (Fig. 13.2a, b).

As well as for the other devices that cause obstruction of the urethra, ATOMS can determine atrophy for chronic stimulation and consequent erosion, especially considering the presence of an inflatable cushion placed on the mesh, on which the patient may cause further compression and recumbency, causing a worsening local condition (Fig. 13.3a, b).

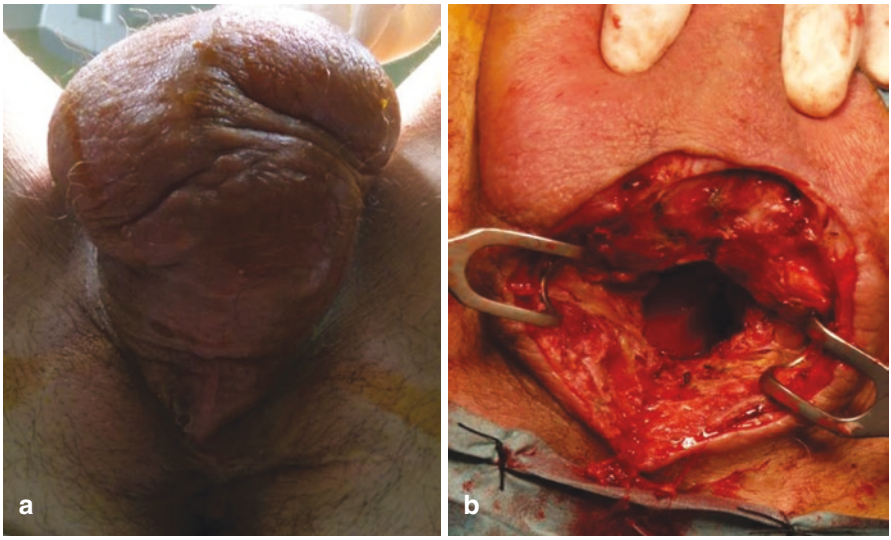

Fig. 13.2 (**a**) Perineal–scrotal abscess after ATOMS implant. (**b**) Post-abscess drainage

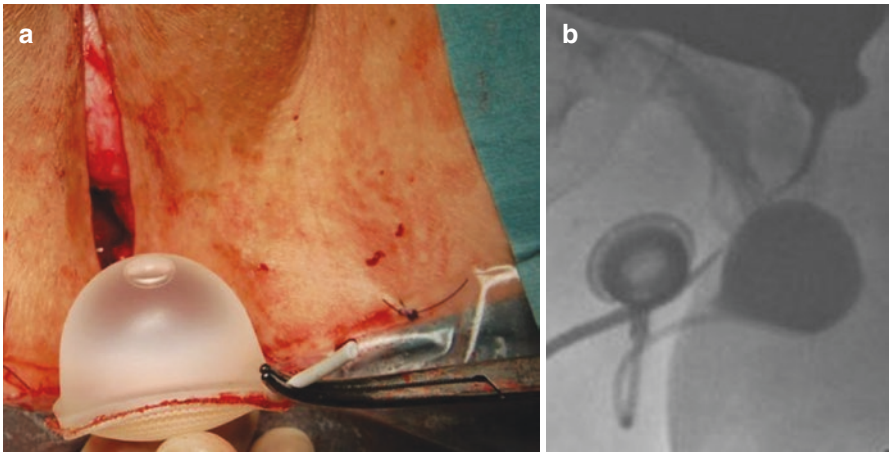

Fig. 13.3 (**a**) Extrusion of inflatable cushion that is the cause of recumbency. (**b**) Cystourethrography shows recumbency of urethra that is the cause of pain for the patient

Even for the ATOMS, in case of erosion, it will be necessary to remove the device and subsequently to implant an AUS, distally to the ATOMS site.

13.1.6 Argus and Argus-T

Regarding ARGUS sling by retropubic approach in a cohort of 48 patients with a mean follow-up of 7.5 months, Romano showed a cure rate of 73% [11]. Three urethral perforations during surgery were reported, and the sling had to be removed in five patients (10.4%). Seven patients had acute urinary retention, and, except for one patient in which the sling needed to be loosened, it resolved spontaneously.

Dalpiaz [10] revaluated 29 male patients who received an Argus® and reported a complication rate of 35%. Overall 24 patients (83%) experienced a total of 37 complications at a median follow-up of 35 months, including 10 (35%) in acute urinary retention. The sling was removed in ten patients (35%) due to urethral erosion (three patients), infection (two patients), system dislocation (two patients), urinary retention (two patients), and persistent pain (one patient). Eight men (27%) complained of significant perineal pain, necessitating continuous oral analgesics. In one patient, ureteral reimplantation was done due to ureteral erosion from a dislocated sling. As regards the displacement of the sling, the mechanism is probably due to the retro-pubic positioning of the Argus, which through a continuous tensioning determines the rotation and migration of the device.

Recently Bochove-Overgaauw [12], in 100 consecutive patients, reported an overall success rate (defined as patients who were cured and improved) of 92% at the first evaluation 6 weeks after surgery and 72% (68 of 95) after a median FU of 27 months (range 14–57). A revision procedure to tighten the sling via the suprapubic incision was done in 24 patients once, in seven twice and in one patient three

times. Regarding complications they occurred in 55 patients. In 11 patients, the sling had to be removed due to infection refractory to antibiotic treatment [6], erosion through the bladder/urethra [3], sling rupture [1], and hypersensitivity/pain [1]. Of these patients, three had been treated previously with radiotherapy for local recurrence of prostate cancer, and two had been diagnosed and treated with incision of urethral strictures or bladder neck stenosis before Argus implantation. Regarding ARGUS-T, Siracusano [13] reported an overall successful rate of 86.2% (157/182 patients) at the median follow-up of 22 months. In particular, analyzing the patient who underwent a previous radiotherapy, only the 61.2% of patients (30/49) obtained a successful result. None complication occurred intra-operatively while in 26 of 182 patients (14.2%), a post-operative complication, such as infection in 9 of 182 patients (4.9%), urethral erosion in 1 of 182 patients (0.5%) and hypercontinence in 16 of 182 patients (8.8%), was observed. The overall removal rate was 9.3% (17/182 patients). Transient inguinal or perineal pain was reported by 72 of 182 (38.5%) patients. The pain disappeared within 1 month with the administration of analgesics.

Over the last few years ARGUS system was replaced by ARGUS-T device, which is certainly advantageous when the sphincter function is anatomically compromised. In fact, this device is certainly less invasive than the AUS and at the same time does not preclude a subsequent implant of the artificial sphincter as the bulbocavernosus muscle has remained intact.

Interdisciplinary Comment

Slings as a support of the puborectalis muscle have been an attempt to improve the anal sphincteric function in fecal incontinence, but they did not work despite an initial interest. Luckily, in the small sample of patients, no relevant complications have been described in the short and long terms. Slings failure can be attributed to our persisting ignorance of the physiology of anal continence.

13.2 Slings for Fecal Incontinence

Firstly proposed as treatment of stress urinary incontinence [14], the use of Anal Slings has gained popularity and this mini-invasive technique has opened new possibilities in the field of faecal incontinence. Therefore, it is not exempt from adverse reactions. Depending on the surgical technique and the material of the implanted mesh, we can observe mild-to-moderate side effects such as post-operative pain, infection, faecal retention, incontinence recurrence, de novo urgency and rectal erosion. The majority of them appeared in the short-term follow-up (within 12 months), and resolved spontaneously or with medical treatment, but still there is a non-predictable, inter-individual variability.

Slings differ in their composition, going from the adynamic Thiersch silver wire (now completely abandoned) to Dacron-reinforced Silastic sling, Mersilene mesh,

Polypropylene mono/multifilament implants or partially/completely readsorbing nets. Unfortunately, none of them have proved to be the ideal material, in terms of resistance, tolerance, tissue integration and costs. Although the polypropylene is considered by many authors the material of choice, a report by Clavé et al. [14] proved that the PP is not inert, and processes like haematomas in the site of implantation alter the physical and mechanical properties of the polymer, because of the accumulation of blood-derived fatty acids and radical oxidative products. This mechanism explains the reason why multifilament PP, non-knitted non-woven PP and composite implants are more frequently associated with infection and subsequent degradation. On the contrary, monofilament PP and re-adsorbing nets are involved in a fibrous reaction, which leads to a complete disappearance of fibroblasts and maturation of collagen, with better integration of the mesh.

Different outcomes have also been observed depending on the different routes of mesh implantation.

The anal encirclement is definitely the most hazardous technique, associated with a large variety of side effects. The subcutaneous implant is at high risk of skin or mucosal erosion with subsequent infection or rectal ulcer. In addition, it acts as an obstruction causing constipation and faecal impaction if too tightened [15]. Devesa et al. [16], using a silicon band like the Flat Drain Jackson-Pratt® and suturing the hollow ends with a small piece of a Marlex® mesh, reported good controls of symptoms, but a high index of complications. Among these, early side effects included spontaneous break of the sling in 6% of patients probably due to the inadequate method of closing the device. Late complications regarded skin erosion and consequent infection in 6% of patients and breaking of the sling in 23% of cases, requiring, for half of them, the sling removal and its eventual re-implantation.

The retropubic access has proved to be superior in terms of adverse events, which, though, are still consistent as demonstrated in the very limited series of eight patients who underwent the procedure by Yamana et al. [17]. In one patient the polyester mesh caused a wound infection in the early post-operative period, while another patient developed a rectal ulcer, necessitating the sling explant. Incontinence recurrence, combined de novo urinary urgency or urinary retention is also advocated to be a potential side effect in this peculiar route, probably due to the proximity of the mesh to the bladder, thus also interfering with urinary continence.

The trans-obturator approach reduces the risk of bladder, bowel and vascular and vaginal injures with the needle passage, and has shown a low rate of complications [18, 19]. The Food and Drug Administration (FDA)-approved protocol for TOPAS system [20] demonstrates the safety and feasibility of this technique applied in a series of 152 patients. None of them reported skin extrusion or exposure of the material, nor rectal ulcer, being the central core of the sling pre-attached to a porcine dermis in order to protect the rectum. The most common adverse event was a mild post-operative pelvic and groin pain/discomfort (27%), which resolved spontaneously (36%) or required a non-surgical treatment (62%). A very low rate of serious AEs included faecal incontinence recurrence that needed a re-operation, incision site infection treated by oral antibiotics and other systemic disorders in fragile patients.

In conclusion, trans-obturator anal sling placement is a safe, effective procedure if correctly performed, provided a good knowledge of the implanted material. However, care should be taken in case of mild-to-severe adverse reactions such as pain, infection and faecal incontinence recurrence [21].

Interdisciplinary Comments

The perineal pain is the main complication of this procedure as well as the risk of infection. The surgical technique needs to be improved in terms of long-term outcomes as it happened for trans-obturator approach for the treatment of post-prostatectomy urinary incontinence.

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References

1. Bauer RM, Mayer ME, May F, Gratzke C, Buchner A, Soljanik I, Bastian PJ, Stief CG, Gozzi C. Complications of the AdVance transobturator male sling in the treatment of male stress urinary incontinence. Urology. 2010;75(6):1494–8.
2. Lim B, Kim A, Song M, Chun JY, Park J, Choo MS. Comparing Argus sling and artificial urinary sphincter in patients with moderate post-prostatectomy incontinence. J Exerc Rehabil. 2014;10(5):337–42.
3. Van Bruwaene S, Van der Aa F, De Ridder D. The use of sling versus sphincter in post-prostatectomy urinary incontinence. BJU Int. 2015;116:330.
4. Yiou R, Bütow Z, Parisot J, Lingombet O, Augustin D, de la Taille A, Salomon L, Audureau E. Update on 2-year outcomes of the TOMS™ transobturator male sling for the treatment of male stress urinary incontinence. Neurourol Urodyn. 2015;35:44.
5. Grise P, Vautherin R, Njinou-Ngninkeu B, Bochereau G, Lienhart J, Saussine C, HOMme INContinence Study Group. I-STOP TOMS transobturator male sling, a minimally invasive treatment for post-prostatectomy incontinence: continence improvement and tolerability. Urology. 2012;79:458–63.
6. McCall AN, Rivera ME, Elliott DS. Long-term follow-up of the Virtue Quadratic male sling. Urology. 2016;93:213.
7. Ferro M, Bottero D, D'Elia C, Matei DV, Cioffi A, Cozzi G, Serino A, Cordima G, Bianchi R, Incarbone PG, Brescia A, Musi G, Fusco F, Detti S, Mirone V, de Cobelli O. Virtue male sling for post-prostatectomy stress incontinence: a prospective evaluation and mid-term outcomes. BJU Int. 2017;119:482.
8. Leizour B, Chevrot A, Wagner L, Droupy S, Costa P. Bandelette sous-urétrale rétropubienne ajustable Remeex® dans le traitement de l'incontinence urinaire d'effort masculine: résultats à un an. Prog Urol. 2017;27:238.
9. Bauer RM, Bastian PJ, Gozzi C, Stief CG. Postprostatectomy incontinence: all about diagnosis and management. Eur Urol. 2009;55:322.
10. Dalpiaz O, Knopf HJ, Orth S, Griese K, Aboulsorour S, Truss M. Mid-term complications after placement of the male adjustable suburethral sling: a single center experience. J Urol. 2011;186:604.
11. Romano SV, Metrebian SE, Vaz F, et al. An adjustable male sling for treating urinary incontinence after prostatectomy: a phase III multicentre trial. BJU Int. 2006;97:533.

12. Bochove-Overgaauw DM, Schrier B. Adjustable sling for the treatment of all degrees of male stress urinary incontinence: retrospective evaluation of efficacy and complications after a minimal followup of 14 months. J Urol. 2011;185:1363.
13. Siracusano S, et al. Argus-T sling in the treatment of male urinary incontinence: short-term evaluation in 182 patients. Pelviperineology. 2015;34:106–11.
14. Clavé A, Yahi H, Hammou JC, Montanari S, Gounon P, Clavé P. Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants. Int Urogynecol J. 2010;21(3):261–70.
15. Notaras MJ. The use of Mersilene mesh in rectal prolapse repair. Proc R Soc Med. 1973;66(7):684–6.
16. Devesa JM, Hervás PL, Vicente R, Rey A, Die J, Moreno I, Teruel D. Anal encirclement with a simple prosthetic sling for faecal incontinence. Tech Coloproctol. 2011;15:17–22.
17. Yamana T, Takahashi T, Iwadare J. Perineal puborectalis sling operation for faecal incontinence: preliminary report. Dis Colon Rectum. 2004;47(11):1982–9.
18. Brochard C, Queralto M, Cabarrot P, Siproudhis L, Portier G. Technique of the transobturator puborectal sling in fecal incontinence. Tech Coloproctol. 2017;21(4):315–8.
19. Cervigni M, La Torre F. Trans-Obturator Anal Sling. Perineology. ISSN:1973-4905, 27.
20. Mellgren A, Zutshi M, Lucente VR, Culligan P, Fenner D. A posterior anal sling for faecal incontinence: results of a 152-patients prospective multicentre study. Am J Obstet Gynecol. 2016;214:349.e1–8.
21. La Torre F, Velluti F, Farina A, Giuliani G, Coletta D, Iaquinandi F, Orsi E, De Anna L, Natale F, Cervigni M. Use of anal sling in the treatment of faecal incontinence. Pelviperineology. 2013;32:9–13.