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Dynamic graciloplasty versus implant of artificial sphincter for continent perineal colostomy after Miles' procedure: Technique and early results

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Summary

Abdominoperineal resection (APR) is still the standard surgical treatment of anorectal cancers close to the dentate line. Unfortunately, a permanent iliac colostomy is a severe limitation of the quality of life. Attempts to construct a continent perineal colostomy after anorectal excision have been made over the last 15 years with uncertain benefits. We report on our early results of two different procedures consisting of a laparoscopic approach to abdominoperineal rectal excision, fashioning a perineal colostomy with dynamic graciloplasty or implant of an artificial sphincter. Between 2000 and 2004, a total of six patients underwent laparoscopic abdominoperineal resection or reversal of Miles' procedure and construction of perineal colostomy with dynamic graciloplasty (three cases) or implant of an artificial bowel sphincter (three cases). A diverting loop ileostomy was constructed in all patients to prevent contamination. Data concerning the perioperative management, postoperative morbidity and mortality and function after total anorectal reconstruction at the time of discharge, at postoperative month 1 and after ileostomy closure were collected and evaluated in a prospective non-randomised fashion. No early postoperative complications occurred in both groups. No late complication occurred in the dynamic graciloplasty group, whilst one patient of the artificial sphincter group had an ulceration of the tubing and the control pump through the suprapubic skin and the labium skin respectively on postoperative day 35. Another patient in this group, with an erosion of the transposed colon wall, died of myocardial infarction on postoperative day 75 after removal of the prosthesis. Postoperative stay after artificial sphincter implant and dynamic graciloplasty ranged from 12 to 27 days and 16 to 24 days, respectively. The loop ileostomy was closed at postoperative month 3 in all remaining patients except for one in the dynamic graciloplasty group, who died one day before hospitalization for ostomy closure because of an accidental, not disease/operation related reason. Follow-up of patients of the dynamic graciloplasty and artificial sphincter groups ranged from 3 to 24 months and 2.5 to 9.5 months, respectively. Patients in the dynamic graciloplasty group had no complications and follow-up showed satisfactory continence (SF36 form). All patients in the artificial sphincter group had late local complications with erosion of the prosthesis through the wall, its consequent removal and construction of a permanent iliac colostomy. Laparoscopic APR has been reported to be as safe as open APR. There are no published, available data on laparoscopic APR and laparoscopic reversal of Miles' procedure with total anorectal reconstruction with either dynamic graciloplasty or implant of artificial sphincter. Preliminary results showed that laparoscopic APR and APR reversal with continent perineal colostomy and dynamic graciloplasty may be a possible option in selected patients whilst the implant of an artificial sphincter should not be considered as a safe surgical option in such patients.

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Dynamic graciloplasty, laparoscopic dynamic graciloplasty, artificial sphincter, laparoscopic implant of artificial sphincter, continent perineal colostomy, laparoscopic Miles' procedures, laparoscopic total anorectal reconstruction

Introduction

Abdominoperineal rectal excision (APR) is a highly invalidating procedure resulting in a permanent iliac colostomy and severe psychological implications for patients. The laparoscopic approach to Miles' procedure may improve the patient's postoperative quality of life in term of less pain and faster recovery [1], but still does not affect the consequences of such an invasive surgical treatment. Perineal instead of iliac colostomy has been suggested in order not to change the patient's body image, but the management of such stomas is often more demanding than that of conventional stomas, above all if mechanical colonic rehabilitation is unsuccessful.

Over the last 20 years, two different procedures have been proposed to create a continent perineal colostomy: dynamic graciloplasty and implant of an artificial sphincter [2, 3]. The transposition of the gracilis muscle to create a neoanal sphincter was introduced by Pickrell in 1952 [4]. Both single and double wrap procedures have been performed over the years but the results were often unsatisfactory and therefore the procedure was considered unreliable. To improve results, Cavina introduced the electrical stimulation of the transposed gracilis muscle, thus preventing its atrophy [5]. Such a technique may fail because the gracilis, which is a fast-twitch muscle, is incapable of prolonged contraction without exceeding fatigue. Experimental animal studies showed that long-term low-frequency electrical stimulation of a fast-twitch fatiguable muscle may convert it to a slow-twitch fatigue-resistant muscle. Based on these principles the technique of dynamic graciloplasty was then introduced to treat incontinent patients with deficient anal sphincter, patients with anorectal agenesis and selected patients who must undergo or have undergone an abdominoperineal excision [6–8].

On the other side, a new artificial sphincter, first designed for urinary incontinence and then introduced in 1996 for the treatment of faecal incontinence, consisting of an occlusive cuff, a control pump and a pressure-regulating balloon (American Medical Systems, Minnetonka, MN, USA), has also been implanted after APR in order to create a continent perineal colostomy, with interesting but still controversial experimental and clinical results [9–11, 3].

Large series have been reported over the years showing the results of reconstruction of an electrically stimulated gracilis neoanal sphincter after an abdominoperineal excision (Miles' procedure) performed through the open approach [12, 2]. Only a few reports of such a procedure performed through the laparoscopic approach have been published in the international literature [13]. Even less reports are available on the implant of the artificial sphincter after Miles' procedure, none of them through a fully laparoscopic approach.

The authors report the first comparative study of laparoscopic APR or APR reversal with construction of a continent perineal colostomy by means of either the AMS artificial bowel sphincter (American Medical Systems, Minneapolis, MN, USA) or dynamic graciloplasty.

Material and methods

Between 2000 and 2004, a total of six patients underwent laparoscopic abdominoperineal resection or reversal of Miles' procedure and construction of perineal colostomy with dynamic graciloplasty (three cases) or implant of an artificial bowel sphincter (three cases). During the first two years the artificial bowel sphincter was always implanted, whereas in the last years the dynamic graciloplasty procedure was performed. A diverting loop ileostomy was constructed in all patients to prevent wound contamination.

Approval of the study was obtained from the Hospital Ethical Committee. Informed consent was obtained in all cases, after discussion of all warnings, precautions and contraindications of the scheduled procedure and the device to be implanted. A standard mechanical bowel preparation was performed the day before surgery. Prophylactic antibiotics active against both anaerobic and aerobic bacteria (i.e. metronidazole and a 3rd generation cephalosporine) were prescribed.

Dynamic graciloplasty

Electronic implants and equipment

Neurostimulator (Figure 1 a and b). The implantable pulse generator (Medtronic InterStim Model

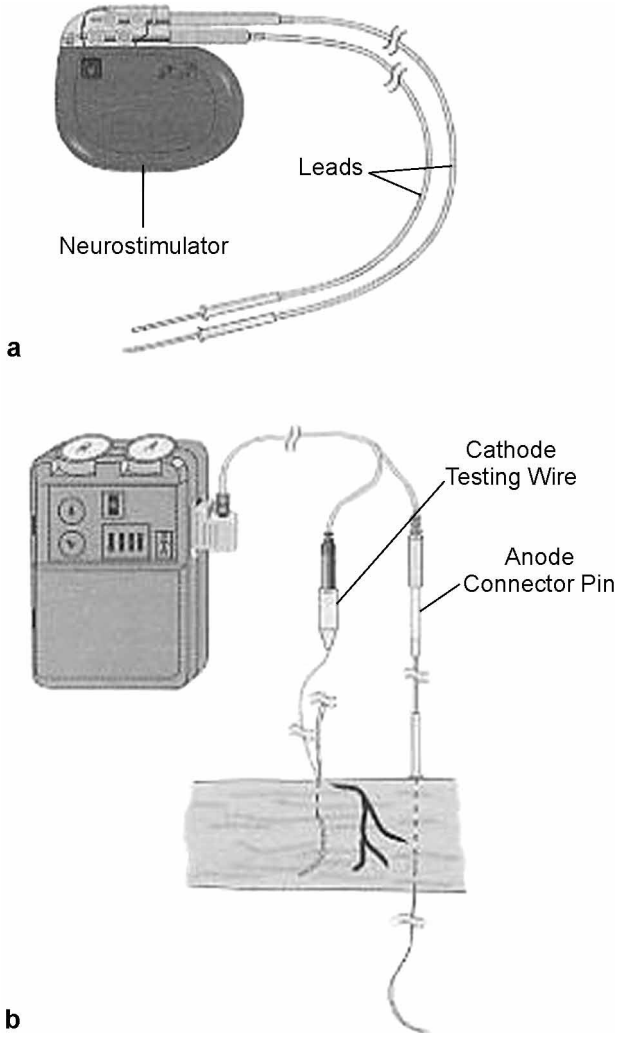

Figure 1. (a) Implantable pulse generator, (b) leads and test stimulator for dynamic graciloplasty.

3023 — Medtronic, Minneapolis, MN, USA) is a quadripolar neurostimulator and a multiprogrammable device designed to deliver a therapy through electrical stimulation when connected to the lead system. It operates on a sealed battery and electronic circuitry to provide controlled electrical pulse stimulation.

Leads. The two leads are designed to be implanted intramuscolarly (Medtronic InterStim Model 4350 lead — Medtronic, Minneapolis, MN, USA) near the nerve pedicle of the transposed gracile muscle.

Test stimulator. The test stimulator (Medtronic Model 3625 — Medtronic, Minneapolis, MN, USA) is used for intraoperative test stimulation in order to optimize the lead position for the cathode.

Surgical Technique

The patient is on the table in the lithotomy position. Legs are placed in the stirrups and abducted. The donor leg stirrup is checked to see whether adduction of the leg during the fashioning of the gracilis wrap is possible (Figure 2).

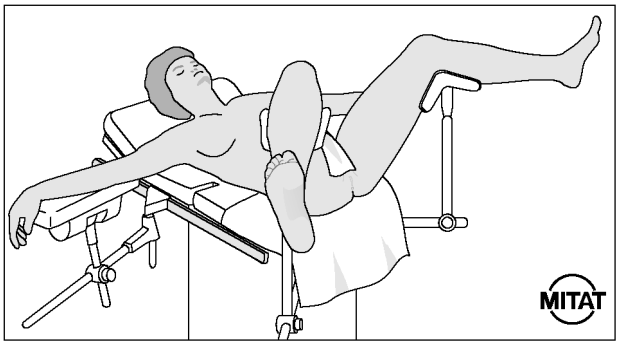

Figure 2. Patient position for laparoscopic APR (Lloyd-Davis position). For dynamic graciloplasty, the donor leg is abducted as much as possible and gently extra rotated.

The abdomen and the donor leg are prepared for sterile surgery. The inner thigh of the non-donor leg is also prepared. The donor leg is prepared with iodine solution down to the ankle, with a drape around the foot. Perineum and buttocks are similarly swabbed, including the scrotum in males and the vulva and vagina in females. The male patient's scrotum is draped out of the way of the sterile field. Donor leg draping should provide access to the thigh and the area below the knee where the gracilis tendon is attached.

When a laparoscopic approach is performed, the left leg is used as the donor leg. This allows to lower the right stirrup in order not to have the right leg hampering the surgeon's movements during the splenic flexure mobilization step of surgery.

In this way a two-team surgery may be performed, with one surgeon operating through the laparoscope and the other performing the gracilis muscle harvesting.

Abduction of the donor leg allows the optimal exposure of the gracilis muscle that can often be palpated under the skin of the inner thigh.

Same-stage laparoscopic abdominoperineal resection and perineal colostomy with dynamic graciloplasty

The perineal portion of the operation starts by closing by suture the anus and incising the perianal skin down to the subcutaneous fat of the ischiorectal fossa. After division of the anococcygeal ligament, the presacral space is entered. The levator muscles, retracted downward, are then divided. After

ligature-division of the inferior haemorrhoidal vessels the hand of the surgeon is introduced into the pelvis. The hand is advanced bluntly along the sacrum in the avascular plane right external to the Waldeyer's fascia. The plane of perineal dissection reaches that of laparoscopic dissection posterior to the rectum. The airtight seal of the perineal wound is maintained by introducing a sterile pad. This allows to continue a combined laparoscopic perineal dissection.

Laparoscopic reversal of Miles' procedure with perineal colostomy and dynamic graciloplasty

Opposite to the laparoscopic abdominoperineal excision, the reversal of Mile's procedure with total anorectal reconstruction starts with the take-down of the colostomy in the left flank and dissecting free the colonic stump in order to check from the ostomy incision the feasibility of the operation through a laparoscopic approach.

Graciloplasty procedure

The gracilis muscle is an auxiliary adductor muscle which lays superficial on the internal aspect of the thigh. Its tendon is usually long and is attached to the tibial tuberosity. The gracilis is long and thin with a proximal neurovascular pedicle. The blood supply is provided by a branch of the circumflex iliac artery, while the nerve is a branch of the obturatory nerve (Figure 3 a–c).

Two short incisions are made on the medial aspect of the left thigh to identify the gracilis muscle. The muscle is then dissected free using sharp and blunt dissection. Any distal artery that is encountered is divided. A third incision, about 2.5 cm in length, is made over the tibial tuberosity. At this level the tendon of the gracilis muscle is attached and has to be cut after completion of the muscle and tendon mobilization. After identification of the tendon, it is gently freed by blunt finger dissection. Once the tendon is divided, the mobilized muscle is pulled through to the upper thigh incision. This is the most crucial part of the preparation of the gracilis muscle, since the dissection of the proximal third of the muscle has to be done preserving the neurovascular pedicle. The neurovascular pedicle of the gracilis muscle enters on its postero-lateral side. Test stimulation is used to precisely locate the nerve pedicle and check the contraction of muscular fibres (Figure 4). When necessary, careful dissection has to be continued to ensure that a muscle length sufficient for the fashioning of a proper wrap is mobilized.

The mobilized gracilis muscle is temporarily protected until the perineal incision is done and the colon is transposed to the perineum. A standard lenticular perineal incision including the anus is performed in patients who undergo an abdominoperineal resection while a longitudinal incision is preferred in those patients who undergo a reversal of Miles' procedure. To protect the muscle it may be either replaced in the thigh incision or covered with a moist sterile laparotomy pad.

A subcutaneous tunnel about two-three fingers wide is created between the upper leg incision and the perineal wound using blunt finger dissection. This should allow enough room for muscle transposition without tearing and excessive traction. Especially in Miles' reversals HF and instrument dissection may be necessary to separate scarry tissue. The muscle should pass freely through the tunnel without constriction.

The gracilis muscle is pulled through the tunnel from the upper thigh incision and the wrap around the transposed colon is tested. Three different wrap configurations are possible, depending on the muscle length: gamma and epsilon wrap (360° wraps), and alpha wrap (270° wrap) which is preferred with short muscles. 360° wrap configuration should be used to provide optimal muscle contraction. We prefer to fashion a modified alpha configuration with muscle split which allows the construction of a 360° wrap even in case of a short gracilis muscle (Figure 5).

Once the possible wrap has been checked the gracilis is unwrapped and retracted through the tunnel. At this stage the two leads have to be implanted in the muscle at the level of the neurovascular pedicle.

The needle connected to the lead for the anode is inserted into the muscle approximately 2–5 cm from the pedicle. The lead has to be inserted perpendicular to the muscle fibres. Care should be taken in order to have both the electrode coil and tip lying well within the muscular tissue. To provide optimal muscle contraction, the implant of the lead for the cathode is carried out under the guidance of test stimulation using the attached testing wire. The needle connected to the electrode is passed through the muscle fibres in the proximity of the nerve pedicle. The optimal location for needle insertion is looked for. This location is in the area where the best contraction of the muscle is produced at the lowest amplitude. When a good contraction is achieved the lead is inserted into the muscle as described for the anode. Care should be taken to avoid damage of nerve branches. When the lead position is verified the testing wires are cut off and the leads are definitely anchored to the muscle (Figure 6).

Hence the muscle is again pulled through the tunnel to reach the perineal wound. Care must be

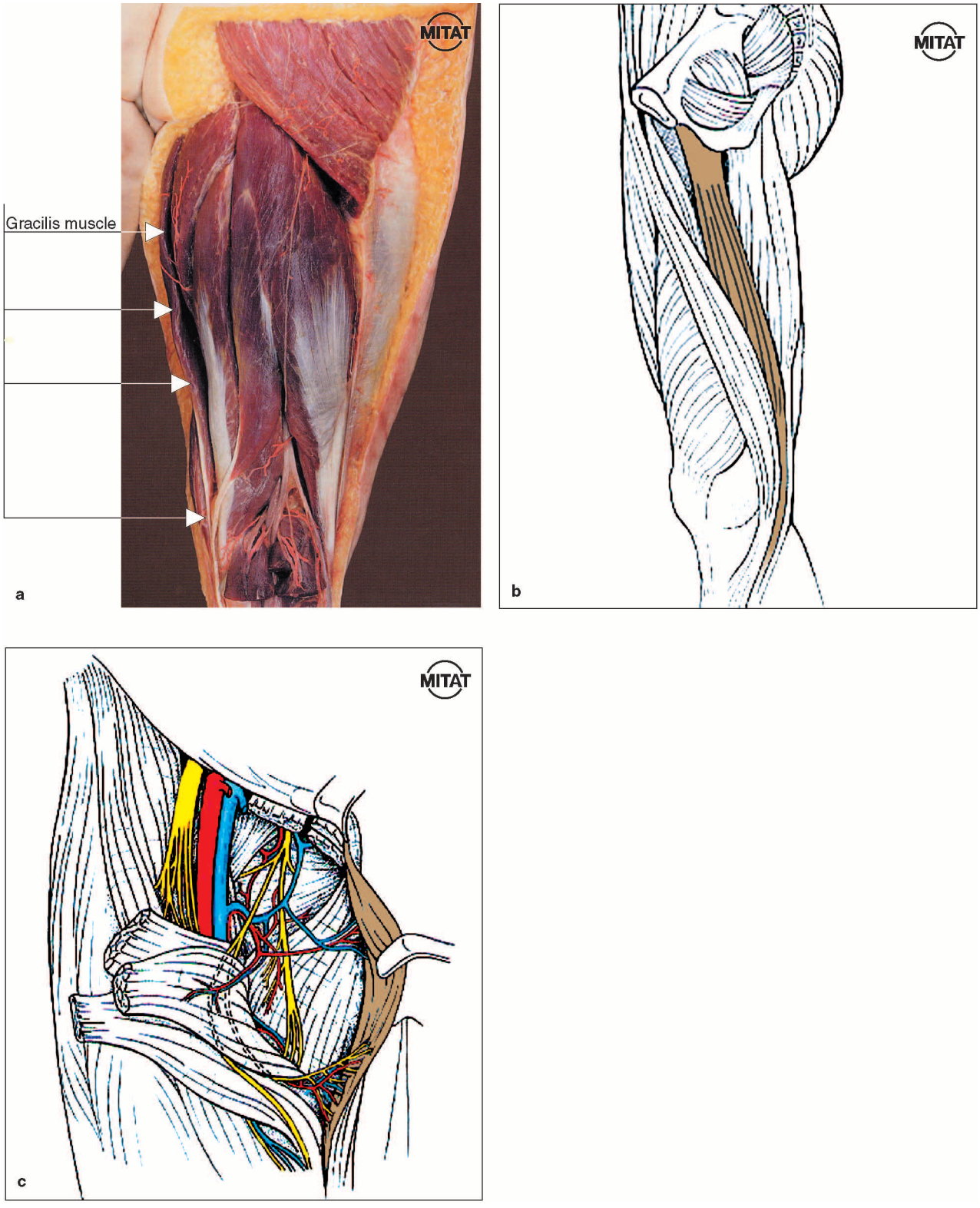

Figure 3. Anatomy of the gracilis muscle. The muscle lays superficial on the internal aspect of the thigh (a). Its tendon is attached to the tibial tuberosity (b). The gracilis is long and thin with a proximal neurovascular pedicle, its blood supply is provided by a branch of the circonflex iliac artery, while the nerve is a branch of the obturatory nerve (c).

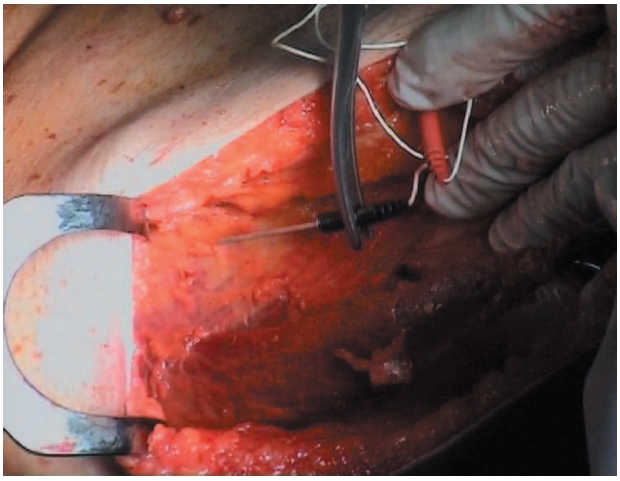

Figure 4. Test stimulation to assess the exact site of the neurovascular pedicle.

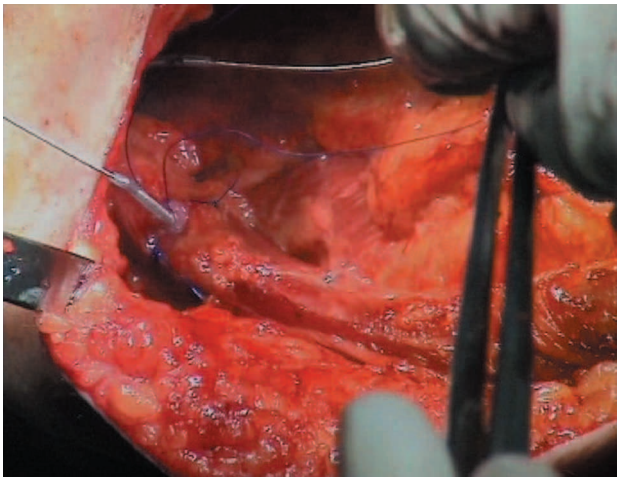

Figure 6. Both leads (anode and cathode) are implanted and fixed to the muscle fibres with polypropylene sutures.

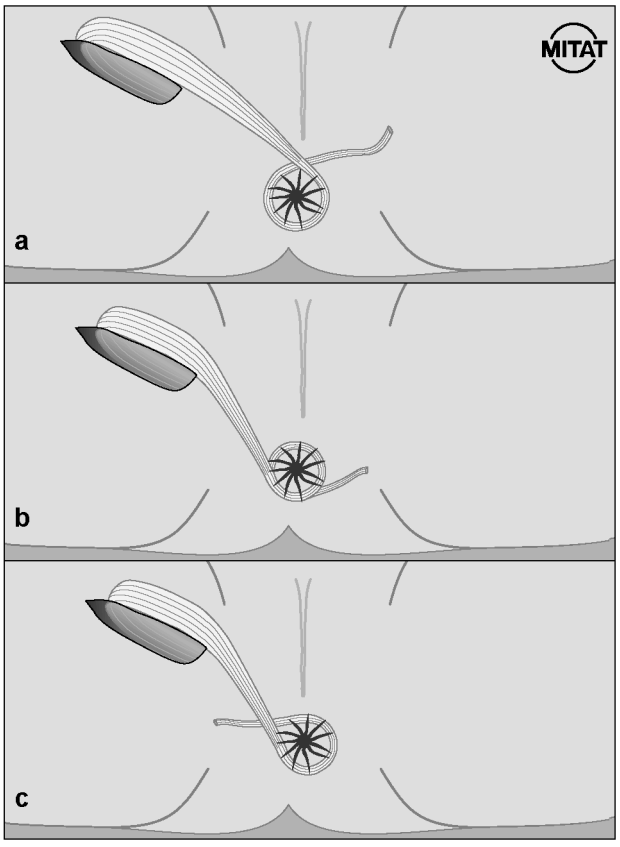

Figure 5. Different types of gracilis wrap: gamma type (360°, long muscle requested), omega type (360°, long muscle requested), alpha type (270°, optimal configuration for shorter muscles). The muscle split variant of the alpha configuration allows to fashion a 360° wrap with shorter muscles.

taken not to twist the muscle during transposition. An alpha wrap with muscle split is fashioned around the closed colonic stump (Figure 7). If necessary, the hip of the leg may be adducted to gain a few extra centimetres of muscle length. It must be checked that the tendon does not exert exceeding pressure on the bowel, thus causing possible injury to the wall, nor on the muscle which could cause muscle entrapment and result in poor performance. The latter complication is avoided with the muscle split procedure. At the end two fingers should pass between the wrap and the wall of the colonic stump. The tendon of the gracilis muscle is then anchored ipsilateral to the donor leg to the periostium of the ramus inferior of the pubic bone with two 0 polypropylene sutures.

A subcutaneous pocket for the neurostimulator is created by blunt dissection on the left flank. A tunnelling tool is used to tunnel the leads from the upper thigh incision to the neurostimulator pocket. The connector pins of the two leads are inserted into the neurostimulator sockets and fixed by turning clockwise the setscrews with a specially designed hex wrench (Figure 8 a–c). At the end the neurostimulator is placed into the subcutaneous pocket allowing some slack in the leads at both the neurostimulator and the electrode sites. The implant of the neurostimulator may be performed as a second operation under local anaesthesia one month later [14]. In such a case the surgeon must first search for the two leads with maximum care to avoid inadvertent dangers during the dissection manoeuvres. Connection of the leads to the neurostimulator is accomplished as previously described.

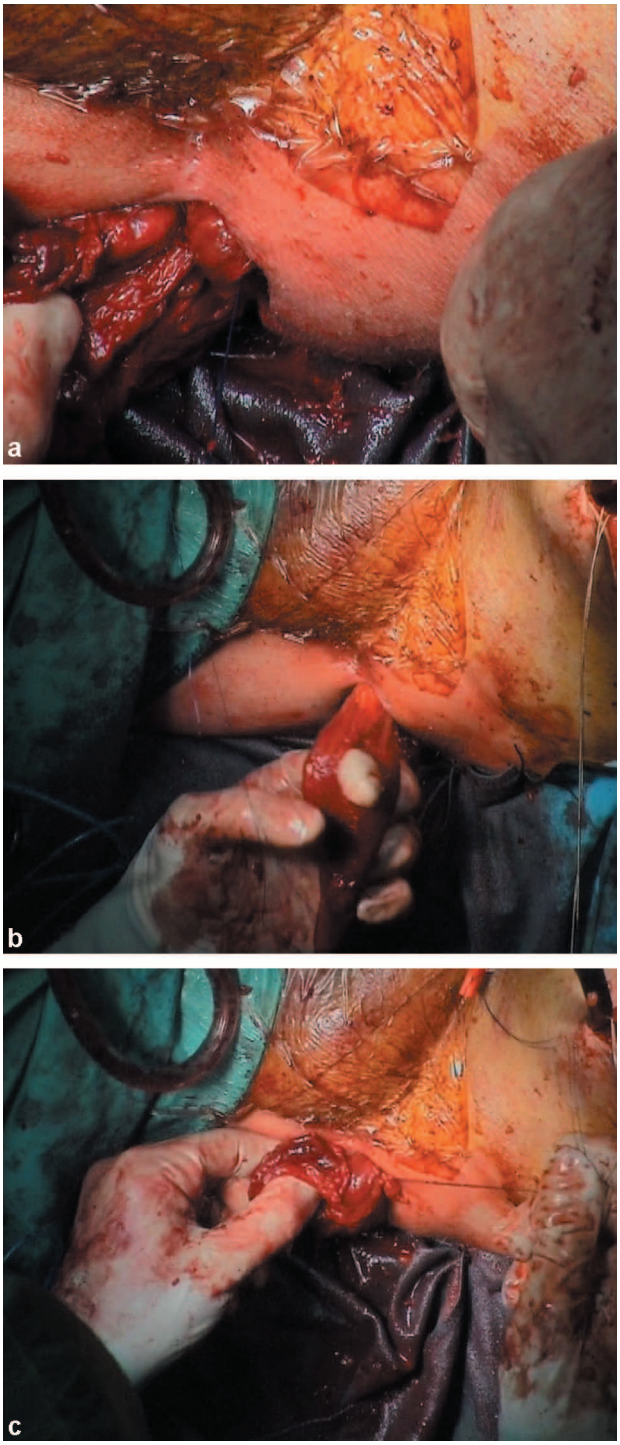

Figure 7. (a) The colonic stump is withdrawn through the perineal wound. (b) Muscle split. (c) Completion of the modified muscle split alpha wrap around the colonic stump.

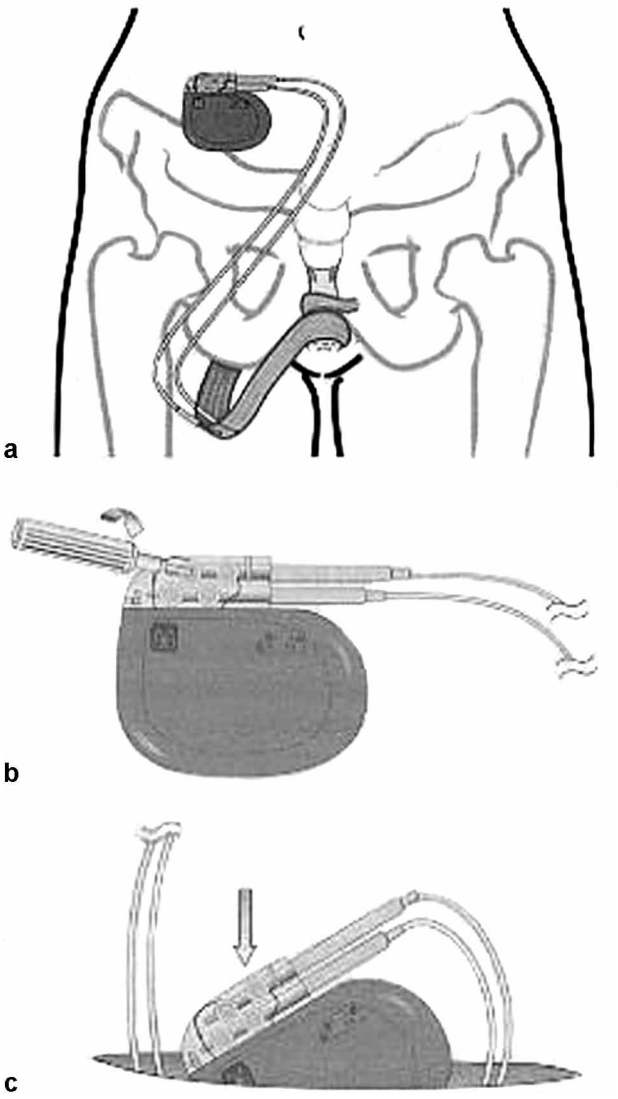

Figure 8. (a–c) Implant of the pulse stimulator after tunnelling of the leads and creation of a subcutaneous pouch.

All wounds are closed after having been irrigated with an antibiotic solution. Subcuticular polypropylene sutures are used for the leg wounds and interrupted 3–0 polydioxanone sutures for fixing the colonic stump to the perineal skin (Figure 9).

A covering loop ileostomy is then constructed. The last ileal loop (at a distance of 10–15 cm from the ileocaecal valve) is gently brought through the laparoscopic incision on the right flank, using a Babcock forceps. A plastic rod passed through the mesentery is used to support the loop. A transverse incision is made by electrocautery on the afferent side of the loop and a standard diverting ileostomy is fashioned.

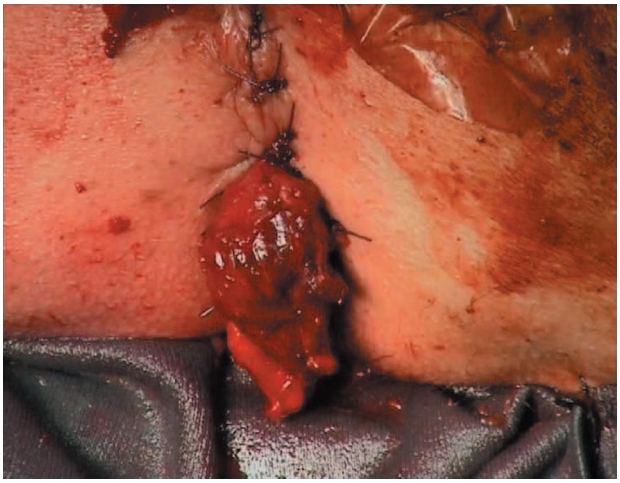

Figure 9. Final view of the continent perineal colostomy by means of dynamic graciloplasty.

Closure of the stoma

The electrical stimulation of the gracilis muscle is started after complete healing of all wounds and continued for 8 weeks according to a training protocol designed to allow the conversion of fast-twitch to slow-twitch muscle. At this point the patient undergoes a last operation, the ileostomy closure.

Artificial sphincter

Components

The artificial bowel sphincter (ABS) (American Medical Systems, Minnetonka, MN, USA) prosthesis is a fluid-filled, solid silicone elastomer device designed to treat severe fecal incontinence. It simulates normal sphincter function by opening and closing the bowel at the control of the patient. Main components are:

- the occlusive cuff available in different sizes, with cuff length ranging from 7 to 14 cm and cuff width ranging from 2 to 3.4 cm. In the first two patients a narrow 7 cm-long cuff was used, in the last case a 8 cm-long cuff was preferred.
- The pressure-regulating balloon controls the amount of pressure exerted by the occlusive cuff. It is available in seven pressure ranges, from 51–60 cm H_2O to 111–120 cm H_2O. In all reported cases the lower pressure range balloon was preferred.
- The control pump is divided into two parts: the upper part contains the resistor and valves needed to transfer fluid to and from the cuff. It also contains the deactivation button. The lower part (bottom half) is a bulb that the patient squeezes and releases to transfer fluid within the device.

The three components are attached to each other with kink-resistant tubing.

Surgical Technique

Patient position and OR layout mirror that described for dynamic graciloplasty. Laparoscopic abdomino-perineal excision is accomplished following the same steps as described above. The laparoscopic part of the procedure requires only three ports placed in the standard position for left colonic and rectal resection. Tissue dissection is achieved by ultrasonically activated scissors (Ulracision, Ethicon EndoSurgery, Cincinnati, OH, USA) during the whole laparoscopic step of the procedure. At first, the full mobilization of the splenic flexure is carried out. The inferior mesenteric vein is secured by harmonic scissors, while the inferior mesenteric artery is controlled and divided at its origin by endolinear vascular stapler or between absorbable clips. The lateral attachment of the sigmoid and descending colon are dissected free after clear identification of the left ureter. A nerve sparing technique with total mesorectal excision was accomplished in all cases. The dissection is continued down to the pelvic floor: soft tissue is dissected by harmonic scissors flush with the pelvic sidewalls. The laparoscopic step of the procedure is concluded once the anterior dissection reaches a level well below the seminal vescicles in males or well into the rectovaginal septum in females. After completion of the perineal step of the dissection, the specimen is removed (Figure 10 a and b) and the occlusive cuff implanted around the bowel before fashioning the perineal colostomy, at about 3 cm from the suture line (Figure 11 a and b). The balloon and the control pump are implanted through a suprapubic incision respectively in the prevesical space of Retzius and in a pouch bluntly created in the scrotum or labium (Figure 12). The position and the function of the occlusive cuff are checked with the laparoscope (Figure 13). A temporary loop ileostomy is constructed for protection through the trocar incision on the right flank.

Closure of the stoma

Three months are requested to achieve a complete healing of the perineal wound and colostomy. During this period the cuff around the colonic stump is left empty in order not to jeopardize the bowel wall with exceeding pressure.

Data concerning the perioperative management

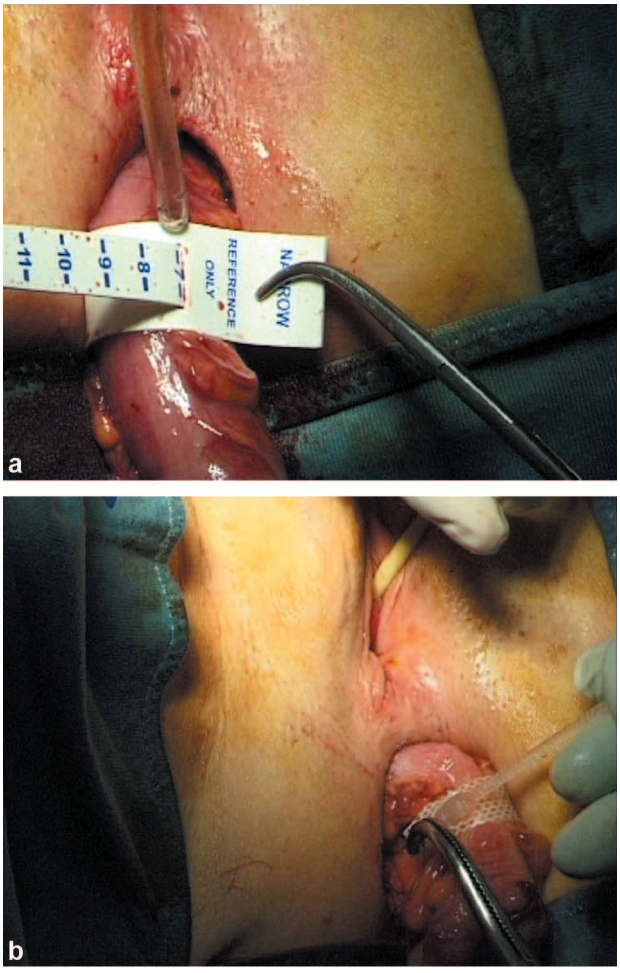

Figure 10. (a and b) Completion of the anorectal resection with total mesorectal excision. The descending colon is pulled through the perineal wound and divided with an endolinear stapler.

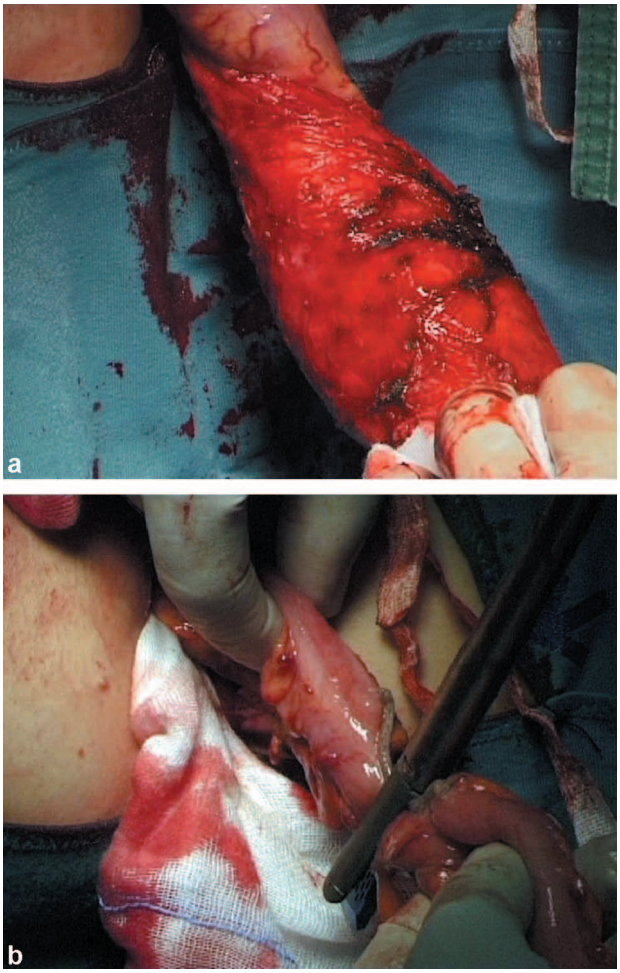

Figure 11. (a and b) Placement of the ABS rectal cuff after assessment of the most suitable cuff diameter.

and course, early and late postoperative morbidity and mortality as well as function after total anorectal reconstruction at the time of discharge, at postoperative month 1 and after ileostomy closure were collected and evaluated in a prospective nonrandomised fashion. Early postoperative complications were considered all those that occurred within 30 days after the operation, whereas all those that occurred after the first postoperative month were considered late complications. A contrast enema with fluid contrast medium was scheduled before ileostomy closure to assess the function of the neosphincter and the integrity of the mucosa at this level (Figure 14 a and b). Besides that, in the artificial sphincter group flexible endoscopy was always performed before ileostomy closure. All patients were trained on how to control the activation and release mechanism of the prosthesis or the stimulator.

In the graciloplasty group the level of continence and quality of life were evaluated with the SF-36 comprehensive questionnaire before and after ileostomy closure.

Results

Table 1 shows the indications for artificial sphincter implant and dynamic graciloplasty, and the patient data sets.

Operating time was longer in the dynamic graciloplasty group (Table 1). No difference in postoperative stay was found after laparoscopic APR/APR reversal with continent perineal colostomy by artificial sphincter implant or dynamic graciloplasty (Table 1). One patient in the dynamic graciloplasty group was converted to open surgery after preliminary laparoscopy. This patient also underwent the

Figure 12. The balloon and the control pump are implanted through a suprapubic incision in the prevesical space of Retzius and in a pouch bluntly created in the scrotum or labium, respectively.

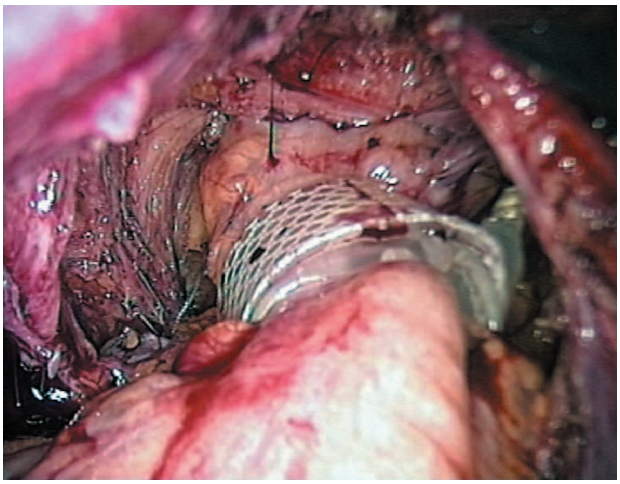

Figure 13. Laparoscopic view of the implanted artificial bowel sphincter.

re-implant of the right urethers in the bladder after take-down of right uretherostomy.

No early postoperative complications occurred in either group. No late complications occurred in the dynamic graciloplasty group.

All three patients of the artificial sphincter group had late complications. In one patient tubing and control pump ulceration through the suprapubic skin and the labium skin respectively, occurred on post-operative day 35 and was treated conservatively. In this patient the ileostomy closure was delayed for three months. Afterwards the patient was followed up for three more months when a complete erosion of the cuff through the colonic wall occurred. Hence, the prosthesis was removed and a permanent iliac colostomy constructed. Another patient, with an erosion of the transposed colon wall which occurred on postoperative day 46, died of myocardial infarction on postoperative day 75: this patient had been discharged after 12 days and readmitted for treatment consisting of prosthesis removal and construction of a permanent iliac colostomy. The last patient in this group underwent ileostomy closure after three months. Two months later, erosion of the colonic stump occurred caused by the cuff pressure: also in this case the treatment consisted in the removal of the implant and the fashioning of an iliac colostomy.

The loop ileostomy was closed at postoperative month 3 in all patients in the dynamic graciloplasty group except for one, who died one day before hospitalization for ileostomy closure because of an accidental, not disease/operation related reason (fracture of femur).

Follow-up of patients in the artificial sphincter and dynamic graciloplasty groups ranged from 2.5 to 9.5 months and 3 to 24 months respectively (Table 1).

Good continence for solid stools and flatus was found in the patients of the artificial sphincter group before erosion caused by the cuff pressure. No QoL instrument was used to better assess physical and social functioning in these patients.

In the patients of the dynamic graciloplasty group who were followed up, the SF36 comprehensive questionnaire showed satisfactory quality of life and level of continence after ileostomy closure (social functioning and physical function assessment).

Discussion

The number of APR performed in most of countries world-wide has decreased continuously in the last years, due to the use of stapling devices, the improvement of surgical technique and the combination of neo-adjuvant treatments. Nevertheless there are still patients whose disease may benefit only of such an invasive and radical operation. In these cases the surgeon's goal should be to treat cancer minimizing the changes in post-operative quality of patient's life.

Starting from this background and with a long-lasting experience in laparoscopic colorectal surgery, we evaluated the combination of laparoscopic ano-rectal excision with a continent perineal colostomy by means of either the implant of the AMS artificial bowel sphincter or dynamic graciloplasty.

Table 1. Patient data sets

Gender	Age	Asa	Indication	Procedure	Length	Postop stay*	Follow-up**
F	57	II	Epidermoidal anal canal cancer	Laparoscopic APR+ artificial sphincter	230	27	9.5
F	57	II	Anal canal adenocarcinoma	Laparoscopic APR+ artificial sphincter	270	14	2.5
M	76	III	T1 rectal cancer (4 cm from the anal verge)	Laparoscopic APR+ artificial sphincter	250	12	4.5
M	42	I	Previous Miles' for anorectal Crohn disease	Laparoscopic Miles reversal (perineal colostomy+ dynamic graciloplasty)	300	20	24
M	74	II	Anal canal adenocarcinoma	Laparoscopic APR+ dynamic graciloplasty	300	16	3.5
M	65	II	Previous Miles' for rectal cancer (5 years)	Miles reversal (perineal colostomy+ dynamic graciloplasty) (converted)	540	24	15

* days.
** months.

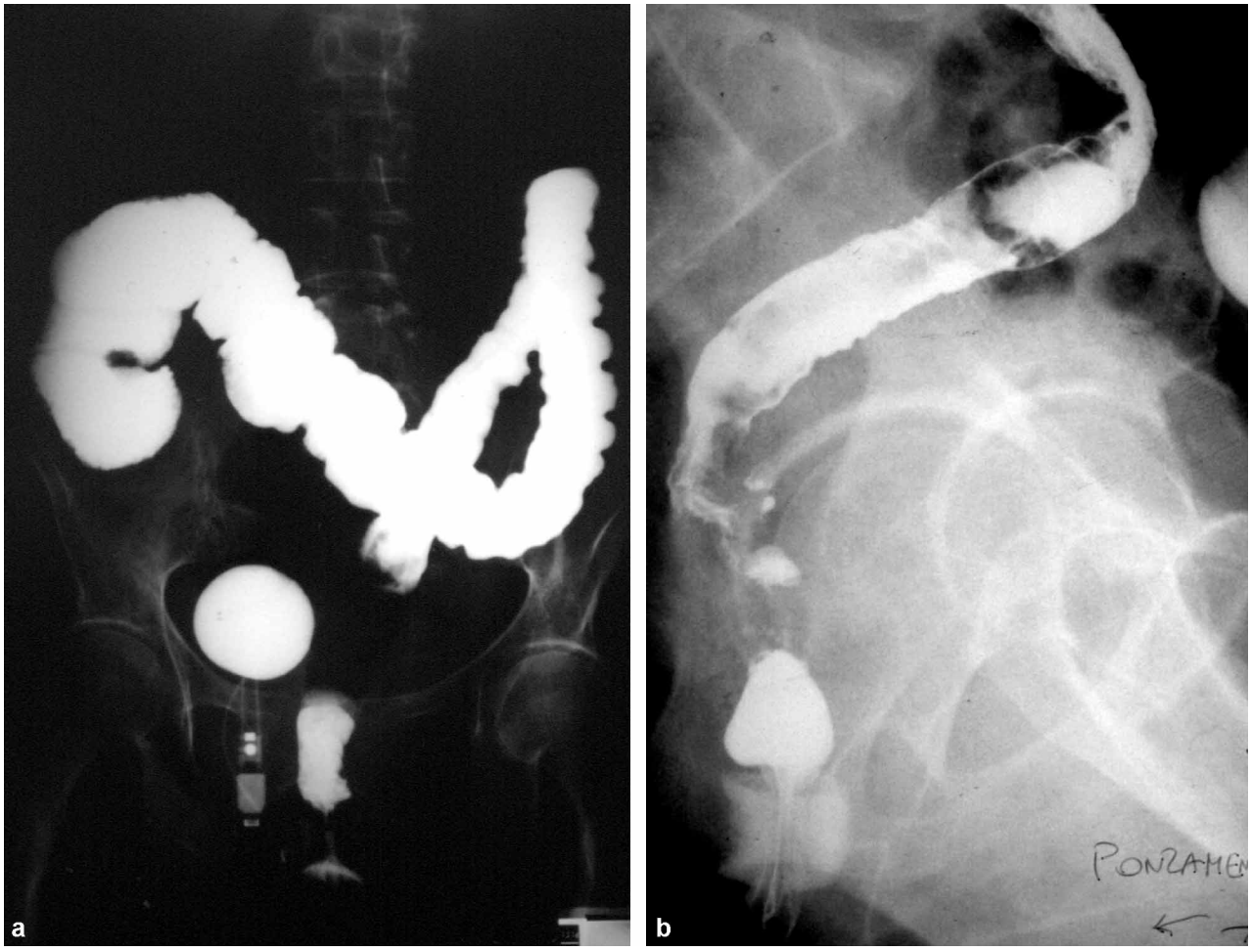

Figure 14. (a and b) Control contrast enema after ABS implant; (b) shows complete continence during strain.

Effectiveness of dynamic graciloplasty and artificial sphincter in the achievement of continence was compared and reported only in one study published in 2003 where both procedures were performed for treatment of severe faecal incontinence and not after total ano-rectal excision [15].

Patients with indication for conventional abdominoperineal rectal excision were informed about this new procedure and selected after written consent. Patient selection was based on disease-related clinical criteria and a performance status index (Karnowsky) with a cut-off value = 80 (no severe impairment of psyco-physical functions, capability of controlling the implanted disposals).

Selection criteria for laparoscopic APR/APR reversal with continent perineal colostomy by means of dynamic graciloplasty or artificial sphincter implant are shown in Table 2.

One patient of the artificial sphincter group had an epidermoidal cancer of the anal canal. Surgery was indicated because he refused radiation therapy, proposed as the first choice treatment.

Two patients in the dynamic graciloplasty group with permanent iliac colostomy after APR performed ten and five years earlier, were selected for a laparoscopic reversal of Miles' procedure with continent perineal colostomy.

Laparoscopic APR may be performed according to oncologic principles and has been reported to be as safe as open APR with significant benefits in terms of postoperative quality of life [16].

In our series, postoperative hospital stay did not differ from that of standard open APR. Postoperative pain was minimal as shown by the daily assumption of pain-relieving medications, and this was most likely due to the laparoscopic approach that avoids large abdominal incisions.

Contrary to what has been reported by other authors the postoperative infection rate was nil in both groups [17,11,18,19]. Great care was paid during the whole procedure to avoid contamination of the prosthesis or the electronic implants. A temporary ileostomy was always constructed and kept for three months in order to decrease the risk of wound infection at the prosthesis/implant site.

The ABS device is an evolution of the AMS 800 device for urinary incontinence: the main difference being that the prosthesis is available in different cuff lengths and widths. The surgeon should determine the approximate cuff length and width with the help of a specially designed cuff sizer. Furthermore, maximum care is needed to implant the pressure regulating balloon, the control pump and the relevant tubing: the devices should be placed deep in the prevesical space or in a dependent pouch in the scrotum or labium. The pump should be placed in a bluntly created pouch, deeply enough to make the deactivation button being still palpable from outside. Failure in correct positioning of the control pump and tubing caused skin ulceration in our first patient.

In order to avoid ischemic complications a larger cuff was mostly preferred in our cases. Notwithstanding that, in all patients where the ABS device was implanted partial or complete erosion of the prosthesis occurred one to three months after activation.

Such a complication is also reported after implant for faecal incontinence with a rate of about 50% [15,18]. Lack of soft tissue around the transposed colonic stump is most likely the main reason for this late complication in our small series. Before occurrence of this complication the continence achieved was good in all cases: contrast enema showed a well functioning neosphincter with good continence for injected fluids even under abdominal strain. In fact, a small enema may sometimes be required to help clean the bowel and avoid stool impaction.

Flexible endoscopy at postoperative month 1 showed no changes in the bowel mucosa at the level of the neosphincter. After the first month the transposed colon may encounter ischemic problems due to the chronic exposure to an exceeding external pressure. This may be the side mechanism that contributed to the erosion of the bowel wall.

Dynamic graciloplasty seems to be a better technique to achieve continence after construction of a perineal colostomy in patients who undergo or underwent APR. Similar data are reported by other authors with much larger series of open operations [12, 2]. The gracilis muscle has specific anatomical features that make it the most suitable muscle for transposition to the perineum with the intent of creating a neosphincter around an incontinent anus or a colonic stump in case of perineal colostomy. Unfortunately, the gracilis is a fast-twitch muscle incapable of prolonged contraction without fatigue, opposite to what happens with the slow-twitch anal sphincter. The studies of Salmons and Heriksson demonstrate that long-term low-frequency electrical stimulation may convert a fast-twitch muscle to a slow-twitch muscle resistant to fatigue [21]. Thus, continuous electrical stimulation has been applied to the gracilis to overcome the anatomical and physiological limits of the muscle to be transposed for treatment of faecal incontinence or creation of a continent perineal colostomy after abdominoperineal anorectal resection. The latter operation is a long and challenging procedure with a high postoperative complication rate mainly consisting of

Table 2. Selection criteria

Laparoscopic APR with continent perineal colostomy	Severe cardiac or respiratory insufficiency, multiple adhesions	Impossibility to bring the colonic stump down to the perineum without exceeding tension. Ischemic stump. Very short gracilis (only for graciloplasty) Presence of cardiac pace-maker contraindication for dynamic graciloplasty	T1–T2 N0 (ideal indication) T3 N0 (neoadjuvant RT required) N+ (neoadjuvant RT required) M+ (absolute contra indication) Adequate margine of clearance after resection	= or >80		CT scan, MRI, PET scan (in order to assess tumor stage and exclude locally advanced tumors)	5 × 5 RT, standard Chemo Radiation Treatment (mandatory in case of suspected N+ patients)
	General contraindications to laparoscopy	Anatomical contraindications	Disease, stage	Karnof sky index	Time lapse	Preop work-up	Neoadjuvant treatment
Laparoscopic APR reversal with continent perineal colostomy	Severe cardiac or respiratory insufficiency, multiple adhesions	Impossibility to bring the colonic stump down to the perineum without exceeding tension. Ischemic stump. Very short gracilis (only for graciloplasty)	Rare benign diseases (Crohn's disease) Malignancy previously treated with APR M+ absolute contra indication	= or >80	= or >5 years after Miles for cancer. Any time after Miles for benign diseases	CT scan, MRI, PET scan (in order to exclude local or distant tumor repetition)	

wound infections and often requiring re-interventions [17, 22, 19, 20]. In our small number of cases no such complications occurred and no re-operation was required. The small number of cases performed does not allow us to make definitive conclusions, nevertheless the laparoscopic approach to APR/APR reversal, which minimizes possible intraoperative contamination, may decrease the incidence of postoperative infections in these patients.

Concerning the construction of the neosphincter, the authors found that the modified alpha design with muscle split [23] allows fashioning a 360° wrap even with shorter gracilis muscles without the need for more complicated enhanced procedures as that described by Shatari [24].

Far from being definitive, our preliminary results showed that, at present, the implant of the ABS should not be considered a possible option for continent perineal colostomy after laparoscopic APR, even in selected patients. Furthermore, data on long-term tolerance of the ABS device are not yet available.

On the other side, though limited due to the small number of cases treated, our early results show that laparoscopic APR and APR reversal with continent perineal colostomy and dynamic graciloplasty may be a possible option in selected patients, with minimal incidence of complications and acceptable postoperative quality of life.

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