Experience with a bone anchor sling for treating female stress urinary incontinence: outcome at 30 months

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OBJECTIVES

To evaluate the clinical and video-urodynamic outcome in women with by stress urinary incontinence (SUI) treated with a bone-anchored pubovaginal sling.

PATIENTS AND METHODS

The study included 70 women with SUI (as evaluated by a clinical examination, a voiding questionnaire, a short pad-test and video-urodynamics) who had a bone-anchor sling procedure, with or without cystocele repair, from January 1999 to December 2001; they were re-evaluated after a long-term follow-up (mean 30 months).

RESULTS

The long-term outcome showed a success rate of >95%; the clinical and video-urodynamic findings showed good functional and anatomical results, and an improvement in voiding performance in most patients. There was a low incidence of complications during and after surgery (2.8%).

CONCLUSIONS

This approach gives, in highly selected patients, a high success rate and low incidence of complications. The technique is easy to learn and the costs to the financing bodies and public healthcare are low, making it a candidate for an alternative procedure to the standard techniques for SUI.

KEYWORDS

female urinary incontinence, bone-anchored sling, video-urodynamics, outcome

INTRODUCTION

Female urinary incontinence has important socio-economic effects in all developed countries; the condition is most common in 50-69-year-old women, with a reported prevalence, depending on the population considered [1,2] and the different methods of analysis, of 10–50%. An epidemiological study in Italy in 1997, interviewing >5000 subjects (2767 men and 2721 women) and using a voiding questionnaire, reported that 11% of the women interviewed were incontinent [1]. That study showed that the incidence of urinary incontinence increased with age, exceeding 16% in women aged >70 years, with a much higher frequency of stress symptoms (56%). A more recent retrospective analysis [2] of 283 subjects (134 men and 149 women), examined clinically and urodynamically, showed that incontinence and detrusor overactivity, either associated with or without genital prolapse, were commonest in women aged 50–69 years. These epidemiological data highlight the social relevance of this pathological condition, and justify the continuous development of diagnostic and therapeutic tools to reduce the incidence of incontinence and improve the treatment outcome.

In women with stress urinary incontinence (SUI) secondary to urethral hypermobility or bladder prolapse the aim of surgery is to restore the correct anatomy of the urethra and bladder support, curing, or at least reducing, incontinence using transvaginal or abdominal procedures. Many published studies in the last 5 years enthusiastically describe the results of several 'mini-invasive' techniques recently introduced for treating female SUI [3–7]. However, the results reported for some of these procedures remain controversial. For example, some authors expressed reservations about safety and the incidence of perioperative complications related to the transvaginal tension-free technique, despite its high efficacy [3]. In the present study we report our experience with a bone-anchored pubovaginal sling in women with SUI, describing the surgical technique and the clinical and video-urodynamic outcome, highlighting the importance of carefully selecting patients and considering aspects of both the diagnostic phase and the follow-up.

PATIENTS AND METHODS

From February 1999 to December 2001 (34 months) we treated 70 women (mean age 61.2 years, SD 13.2) using a bone-anchored pubovaginal sling; all the women were in the menopause and had SUI. The patients were first evaluated by a case history and physical examination; for the former we used a voiding diary and the voiding version of the King's Health questionnaire. All the selected patients were assessed before surgery by blood and urine examination, the International Continence Society (ICS) short provocative pad-test, and uroflowmetry and video-urodynamics, to allow an accurate clinical and instrumental diagnosis. All patients were also assessed before surgery by renal and pelvic ultrasonography to exclude any associated pathologies.

For the urodynamic studies standard urodynamic equipment was used (300 Urodesk; Siem, Milan Italy) with fluid-filled lines and transducers. For the video-urodynamic studies the patient was standing and then the pressure-flow study was repeated with the woman seated. Bladder pressures were measured using a 6 F double-

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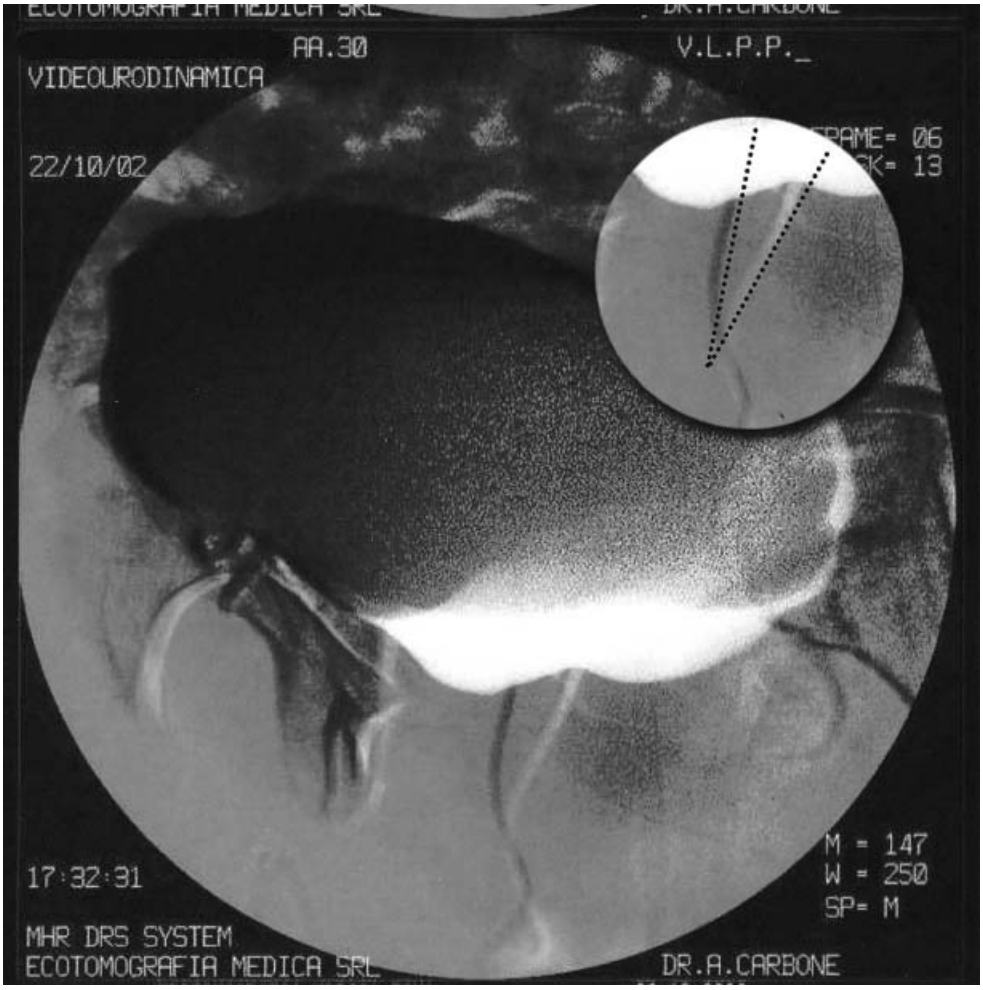


FIG. 1.
Morphological and functional modification of the bladder base, urethral axis and posterior urethrovesical angle at rest (as the positive) and during abdominal effort (as the negative). Digital post-processed and superimposed images.

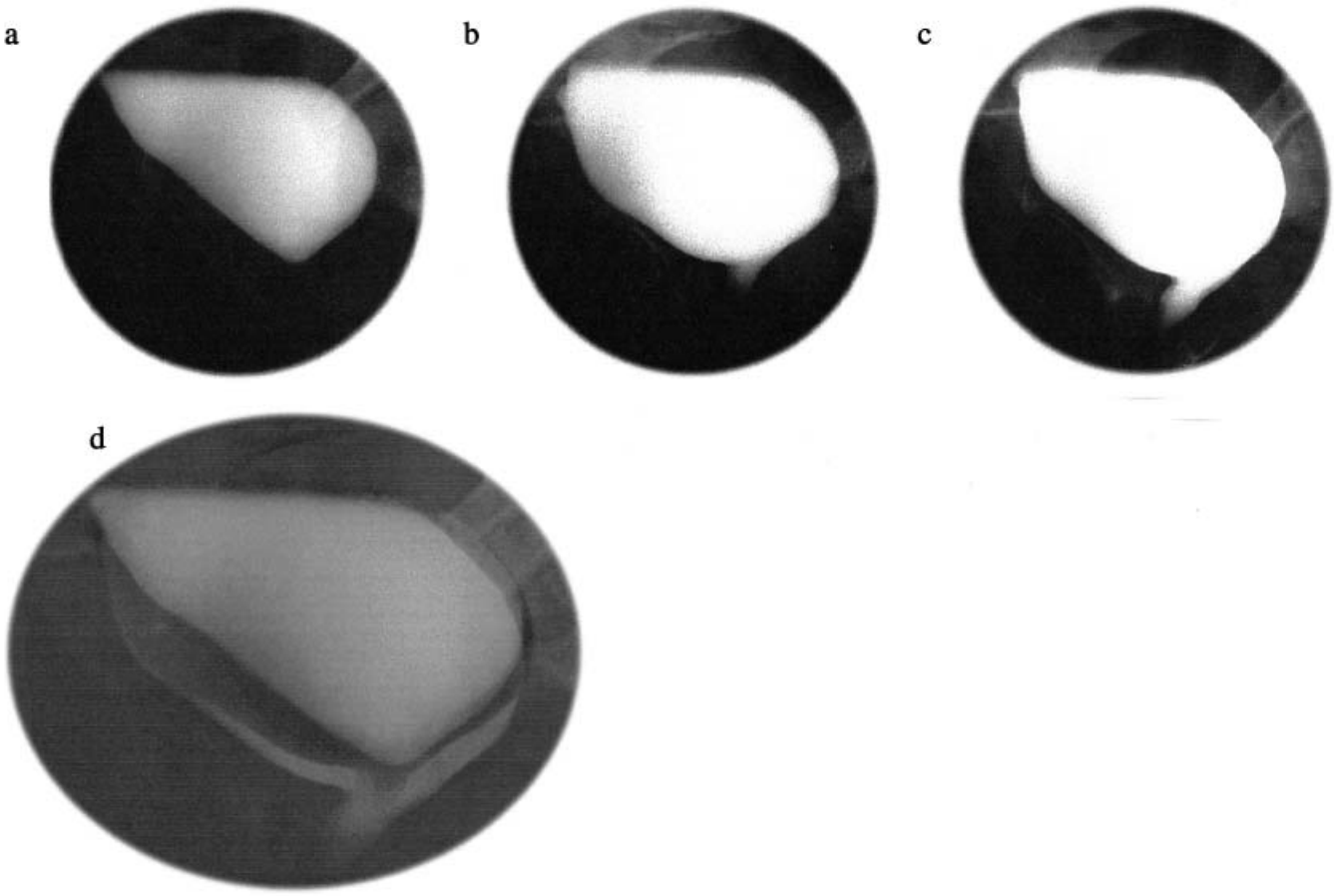
lumen catheter and abdominal pressures using a rectal balloon catheter. Urodynamic studies complied with the ICS guidelines for good urodynamic practice [8], by filling the bladder with contrast medium at room temperature (30 mL/min). Superficial electrodes were used to record perineal electromyography.

The Valsalva leak-point pressure (VLPP) was measured with the patient standing and with a bladder volume of 150 mL during the videocystometry. The VLPP value was considered to be the abdominal pressure recorded during the Valsalva manoeuvre when leakage occurred [9]; if there was no leakage the VLPP was repeated at 250 mL [10] and at maximum cystometric capacity. The morphological and functional aspects of the bladder base, urethral axis and posterior urethrovesical angle were evaluated at rest and during the Valsalva manoeuvre, using a post-processed, digitized analysis of radiographic superimposed images (Figs 1 and 2). A standard pressure-flow study was recorded to measure the detrusor pressure at maximum urinary flow rate ($PdetQ_{max}$) and Q_{max}, with simultaneous electromyography to exclude any associated perineal floor dysfunction. A digital fluoro-angiographic system was used for X-ray monitoring.

Patients were excluded from the study if the VLPP was <50 cmH_2O, considering this threshold as highly indicative of intrinsic sphincter deficiency [9]. According to the physical and video-urodynamic findings the patients were divided in two groups: those with urethral hypermobility (group A, 30 women) and those with associated cystocele (ICS prolapse stage I or II; group B, 40). Patients in group A had the 'mini-invasive' surgical procedure by inserting the sling directly through a transvaginal approach, while in group B the sling was positioned through a transcolpotomy approach followed by a perineorraphy to correct the genital prolapse. In both the procedures the In-Fast™ device was used (Influence Inc., American Medical Systems, San Francisco, CA), a disposable tool originally sterilized in ethylene-oxide. This device consists of: (i) a gelatine-coated knitted polyester fabric sling (5.5×2 cm) with four holes at its edges, rendered passive with a thin layer of fluoropolymer (Vascutek Ltd, http://www.vascutek.com); (ii) two miniature nickel-titanium screws (5.5 mm long and 1.7 mm diameter) pre-loaded with a #1 polypropylene suture; (iii) a disposable battery-operated screw inserter. Fluoropassivation technology of the gelatine-coated sling ensures that the fluoropolymer molecules bond with the polyester matrix, giving an interpenetrating molecular network at the interface between the two polymers. The device costs 620 Euro.

All the patients were evaluated 30 days after surgery by a history and physical

FIG. 2. The evaluation of the bladder base and detection of urinary leakage at rest (a), during abdominal effort (b, c) and as digital post-processed and superimposed images (d).



examination, blood and urine tests, and an ultrasonographic assessment of the postvoid residual urine volume. The assessment was repeated at a mean (SD, range) of 11 (3, 8–14) months with a history and video-urodynamics, and in the long-term, at 30 (6, 24–36) months by a voiding questionnaire, physical examination, pad-test, digital video-urodynamics and evaluation of the VLPP.

SURGICAL TECHNIQUES

All the patients started antibiotic therapy with ceftriaxone 2 g intravenously 24 h before the surgical procedure, and all had spinal anaesthesia, after which they were prepared in the lithotomy position, thoroughly disinfected and the bladder catheterized with a 16 F Foley catheter with the balloon inflated with 10 mL of saline, and any residual urine evacuated. In both procedures the gelatine-coated polyester sling was soaked for 15 min in rifampicin 600 mg [11].

For the 'mini-invasive' technique (group A), traction is applied to the catheter to make the Foley balloon adhere to the bladder neck. The index finger is used to push the vaginal wall upward to the back of the symphysis pubis, at the same time displacing the urethra to the opposite side to avoid any lesion to the urethra and bladder. The battery-operated screw inserter is then positioned in the vagina just below the bladder neck and 2 cm lateral to the urethra (Fig. 3A), while the vaginal wall is pushed up to ensure adhesion to the pubis surface, again displacing the urethra. After the inserter is switched on the screws easily penetrate the pubis. After removing the inserter the pre-loaded polypropylene sutures remain connected to the screws for the sling anchoring, and the channel created by the screw insertion between the vaginal wall to the pubic bone is dilated using an angled clamp (Fig. 3B-C). The same operation is executed on the opposite side. Cystoscopy is then used to verify bladder integrity. Using a right-angle clamp, a submucosal tunnel is created just below the bladder neck in the vaginal wall between the holes made by the screw insertion in the vagina (Fig. 3D), and the sling (Fig. 3E) positioned through the tunnel at mid-urethral level (Fig. 3F). The polypropylene suture is inserted bilaterally in the pre-punctured holes at the extremity of the sling and then ligated. To avoid excessive tension on the suture and possible urethral obstruction, during this last phase we insert a cystoscope through the urethra.

For the transcolpotomy technique (group B), after infiltrating the vesicovaginal septum by vasoconstricting drugs, and in the paraurethral spaces, (Fig. 4A), a longitudinal colpotomy is performed. Then the paraurethral space is dissected bilaterally through the colpotomy until the endopelvic fascia is digitally opened (Fig. 4B-C). The device is inserted in this space and activated to fix the screws in the pubic bone bilaterally

FIG. 3. a) The screw inserter positioned laterally to the urethra, below the bladder neck; b) dilatation of the channel created by the screw insertion between the vaginal wall and the pubic bone using an angled clamp; c) the angled clamp used to dilate the channel; d) the submucosal tunnel created between the bladder neck and the anterior vaginal wall; e) the gel-coated Dacron sling; f) the sling positioned through the tunnel at the mid-urethral level.

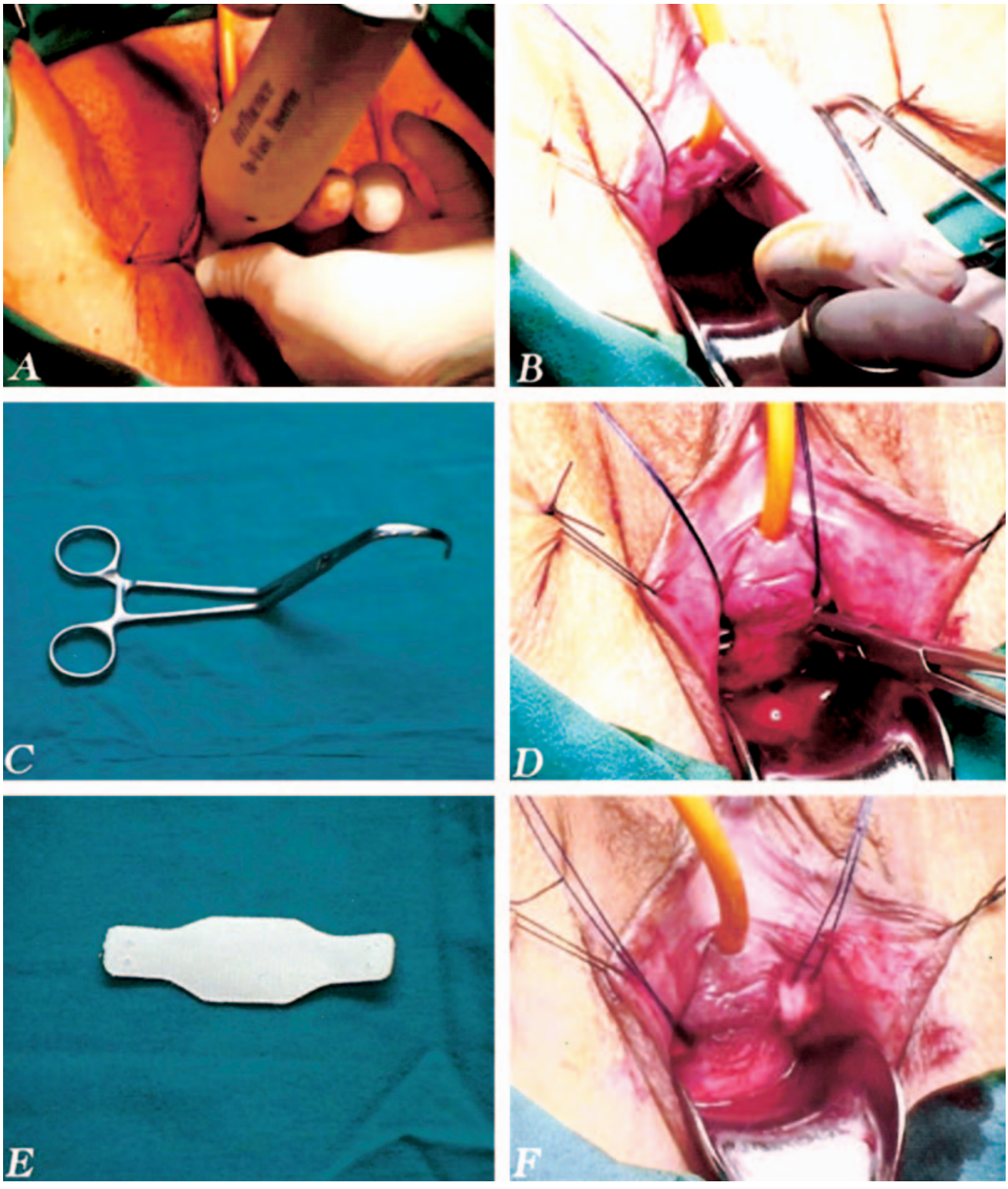


FIG. 4. The (a) infiltration of the vesicovaginal septum and the paraurethral spaces by vasoconstricting drugs; b) bilateral dissection of the paraurethral space through a wide colpotomy; c) digital wide opening of the endopelvic fascia; d) insertion of the screw through the paraurethral spaces; e) sling positioned at mid-urethral level; f) perineorraphy to move the pubocervical fascia to the middle using polyglycolic acid sutures.

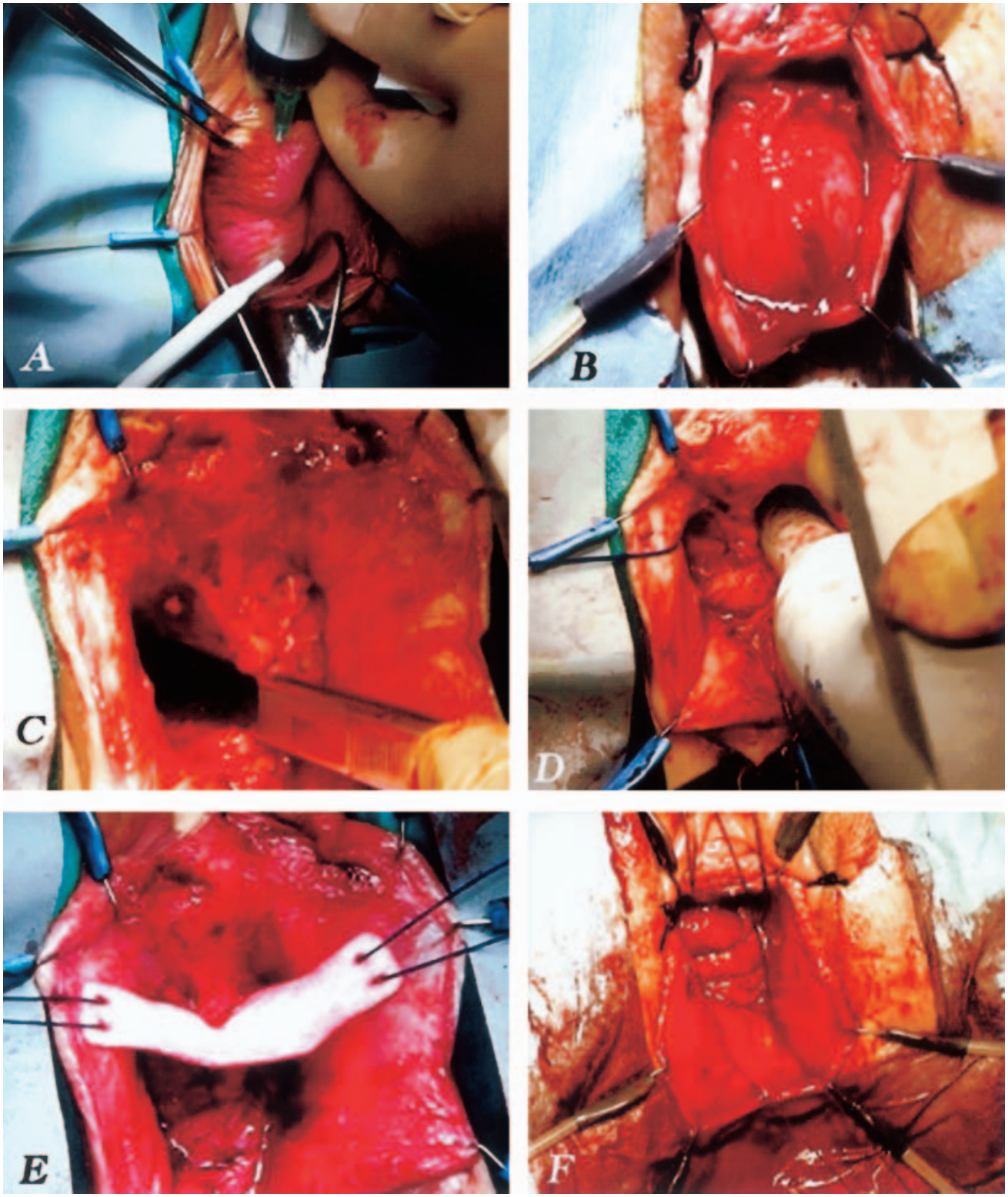


TABLE 1 The results of the short provocative pad-test, uroflowmetry and video-urodynamics and VLPP before and after surgery, and the continence rates during the follow-up

	Group A		Group B	
Variable	before	after	before	after
Pad test, g; n (%) before/after				
<30	3 (10)	1 (3)	8 (20)	2 (5)
30–50	10 (33)	–	18 (45)	–
51–80	8 (27)	–	3 (8)	–
>80	9 (30)	–	11 (28)	–
Uroflow and video-urodynamics: mean (SD)				
Q_{max}. mL/s	26.18 (12.17)	18.24 (5.48)†	21.79 (9.5)	17.1 (6.3)†
Cystometric capacity, mL	320 (44)	367 (49)*	310 (39)	333 (41)*
$PdetQ_{max}$. cmH_2O	26.4 (14.3)	40.4 (13.7)†	28.3 (20.6)	42.3 (10.9)†
VLPP, cmH_2O; n (%)				
negative	3 (10)	–	9 (23)	–
50–60	9 (30)	–	10 (26)	–
>60	18 (60)	–	19 (50)	1 (2.6)
Mean (SD)				
Operative duration, min	–	32 (9)	–	46 (5)
Hospital stay, days	–	2.8 (0.18)	–	3.66 (1.05)
Continence rate, n (%) at				
1 month				
cured	–	28 (93)	–	38 (95)
improved	–	2 (7)	–	2 (5)
failed	–	–	–	–
8–14 months				
cured	–	29 (97)	–	37 (93)
improved	–	1 (3)	–	3 (8)
failed	–	–	–	–
2–3 years				
cured	–	29 (97)	–	36 (90)
improved	–	1 (3)	–	3 (8)
failed	–	–	–	1 (3)‡

**P < 0.05; †P < 0.01; ‡ includes patients who had the device removed.*

(Fig. 4D). The procedure continues as described for group A until the sling is positioned (Fig. 4E). After sling ligation, a perineorraphy is performed to shift the pubocervical fascia to the middle, using polyglycolic acid sutures (Fig. 4F). The excess vaginal mucosa is surgically removed and lastly the vaginal wall is closed by sutures of polyglycolic acid 'rapid' (lactide polymer).

Before closing the vaginal wall the operating field was irrigated with rifampicin solution (600 mg/50 mL) at the end of both surgical procedures, and an iodine medication inserted in the vagina and removed after 18 h; the 16 F Foley catheter was routinely removed after 18–36 h. All the patients had an intravenous infusion of 1 L of saline after surgery, and continued intravenous antibiotics for up to 48 h, followed by oral antibiotics (cefixime 400 mg/day for up to 7 days). The day after surgery all the patients were allowed to stand.

RESULTS

The mean (SD) follow-up was 30 (6) months. Before surgery the King's Health Questionnaire showed a prevalence of irritative over obstructive symptoms in group A, but in group B obstructive symptoms were more common. In groups A and B, respectively, 17 and 25 patients had uncontrolled urinary leakage at rest, while five and 11 had nocturnal urinary leakage. None of the patients in either group had fecal incontinence.

The results of the short provocative pad-test, uroflowmetry, videocystometry, video pressure-flow study and VLPP before and after surgery are shown in Table 1. Detrusor overactivity before surgery ($PdetQ_{max}$ 35–48 cmH_2O) was recorded in two patients in group A and one in group B ($PdetQ_{max}$ 76 cmH_2O). Furthermore, there was urgency and reduced cystometric capacity in two patients in group A, with a mean at first desire to void of 69 (33) mL, and at strong desire of 180 (42) mL, and in all 40 in group B, with respective means of 77 (22) and 161 (44) mL. The simultaneous radiological evaluation showed urethral hypermobility with a pathological increase in urethral axis angle in group A, and confirmed the physical examination findings for prolapse in group B.

The mean operative duration is shown in Table 1; intraoperative bleeding was significant (1050 mL) in only one patient in group B because of a lesion in a vaginal wall vein, which required a blood transfusion. After catheter removal five patients in group A and four in group B had minimal residual urine (<100 mL), which was not apparent at the 30-day evaluation. Only one patient had complete retention on catheter removal that needed 10 days of clean intermittent catheterization. Three patients in group A and four in group B had persistent discharge 2 weeks after surgery but they required no other treatment or medication. The hospital stay after surgery is also shown in Table 1.

Only the relevant clinical data are reported at the short- and medium-term follow-up, i.e. continence, failure and complication rates, as they are more representative of the efficacy and safety of the surgery (Table 1). At 1 month two patients each in group reported mild pelvic pain, which was successfully cured by oral NSAIDs.

Reported symptoms and the outcome at the medium-term follow-up were not significantly different from the long-term results except for a higher rate of urgency, incidence of dysuria or abdominal straining during voiding (17% in group A and 10% in group B), and a higher incidence of 'de novo' detrusor overactivity (two patients in group A and one in group B) on cystometry.

For continence we considered as 'cured' patients who were completely dry and those with 'sporadic incontinence' (fewer than one episode of minimal leakage over a month);

'improved' was defined as minimal residual incontinence (one or two minimal leaks over a week). At the long-term evaluation all patients in group A had clearly improved, as assessed by the voiding questionnaire, and none reported pelvic pain or dyspareunia; 28 (94%) reported being completely continent, as confirmed by the absence of urinary leakage on a stress test and by a negative pad-test (Table 1), so that they were considered cured. One patient reported sporadic incontinence, which was considered irrelevant, and this patient was considered 'cured'. The remaining patient had minimal residual incontinence at maximum abdominal strain and thus was considered improved; she had a marked reduction in pad usage (>80%). Three patients (10%) sometimes had to change position during voiding, bending forward from the chest and/or using mild abdominal straining, to complete bladder emptying.

At the long-term follow-up in group B, 37 (93%) patients had a clear decrease in symptoms, as confirmed by the voiding questionnaire; one still had pelvic pain associated with dyspareunia, caused by pubic periostitis, which was successfully treated by local magnetotherapy. Continence was restored to 35 (88%) patients, confirmed by no urinary leakage on a stress test and a negative pad-test (Table 1). Three (8%) patients reported sporadic incontinence which was considered irrelevant, and they were considered 'cured'. Two (5%) patients had recurrent vaginal vault prolapse but had only minimal residual incontinence, and were thus classed as improved. Three patients (8%) also sometimes needed to change position during voiding, using mild abdominal straining to complete bladder emptying. Two patients in group B had an anaerobic infection of the sling which required removal of the device (accomplished easily); these two were excluded from the long-term video-urodynamic evaluation but in one the incontinence recurred and she was considered a 'failure', whilst the second had minimal residual incontinence and was considered 'improved' (Table 1).

The long-term video-urodynamic evaluation showed a slight reduction in Q_{max} in both groups and a trend to increased $PdetQ_{max}$ (Table 1). The VLPP was negative in all patients in group A and in 97% in group B; video-urodynamics confirmed leakage in one who reported rare urinary leakage. In two women in group A detrusor overactivity before surgery completely resolved afterward, while one had 'de novo' detrusor overactivity. No de novo detrusor overactivity was detected in group B and it resolved completely in the patient who had detrusor overactivity before surgery. All patients in both groups had an increase in mean maximum cystometric capacity (Table 1).

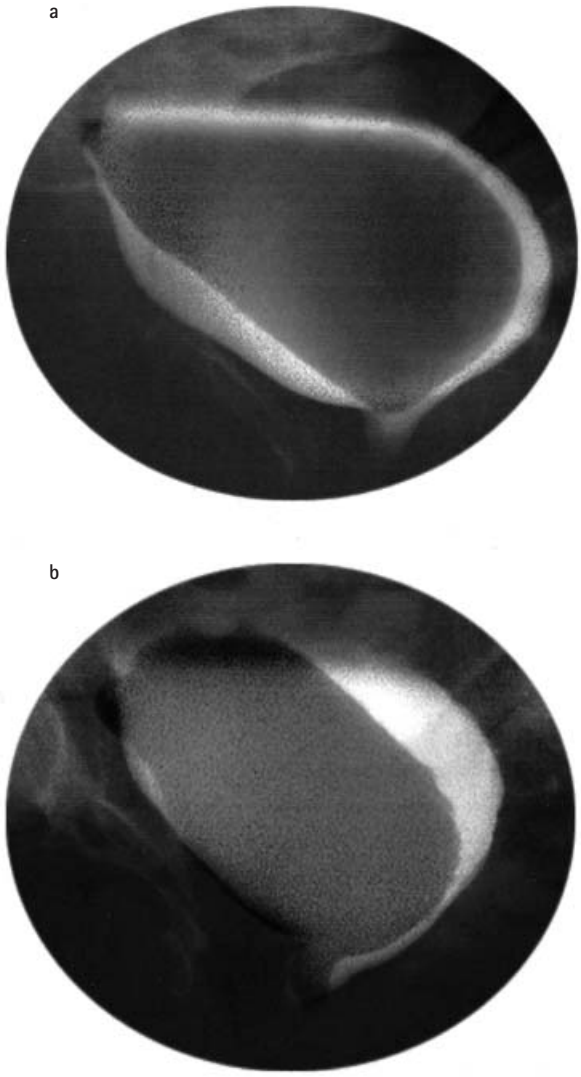


FIG. 5.
Restoration of the correct anatomical position of the urethrovesical junction in ***a,*** *stress conditions, and* ***b,*** *the voiding phase, assessed by post-processed digitized images (before surgery as the negative and after as the positive).*

In both groups of patients the morphological and radiological evaluation showed a return to the correct anatomical position of the urethral axis and the urethro-vesical junction at rest and under stress, with normal physiological bladder behaviour during the filling and voiding phases (Fig. 5A,B), with no vesico-urethral reflux or postvoid residual, and with a normal urethral lumen and morphology.

DISCUSSION

Recent reports have proposed many new 'mini-invasive' surgical procedures as alternatives to Burch colposuspension, still considered the 'reference standard' for female SUI. These techniques often require specific technical tools, which are continuously improved, but remain far from an accepted 'new standard procedure' because of the lack of an adequate follow-up in various reported series and the common complications.

Current opinion favours the pubovaginal sling over traditional abdominal colposuspension techniques, as the results are better in terms of efficacy, morbidity, hospital stay and costs to public healthcare and financing bodies [4,12]. The present high success rate (>95% clinically cured) is comparable with results reported by others [13], considering that those results are worse because the series included patients with intrinsic sphincter deficiency (in whom incontinence recurred in all). The present series included only highly selected patients, excluding those with type III incontinence. These considerations, and that the present patients had a good outcome with a short hospital stay and low cost, suggest that the bone-anchored sling could be considered technically a good procedure, allowing adequate support to be restored to the pubo-urethral complex and mid-urethra, thus giving satisfactory functional results, as shown by video-urodynamics.

The longer hospital stay and operative duration in group B was related to the need for longitudinal colpotomy and perineorraphy; the complication rate was also higher in this group. However, the success rate, good compliance with the procedure and the video-urodynamic results were similar in both groups, although voiding was slightly better in group A. Furthermore, the voiding questionnaire confirmed the positive final judgement of the patients about the procedures. Use of the technique was also supported by the ease with which it was learned, the short time required to train surgeons and the reproducibility of the procedure that potentially fulfils the high demand for these treatments in developed countries.

The only point of concern with this technique is related to possible complications caused by the alloplastic material used. For pubovaginal bone-anchored slings a recent study [6] described serious pubic osteomyelitis as an 'uncommon event', with a prevalence of 0.6% in 1000 patients. Moreover, osteomyelitis and osteitis pubis are risks associated with all surgery involving the space of Retzius, and have been reported after Burch colposuspension or Marshall-Marchetti-Krantz and Stamey urethropexy [14,15]. In addition, the present incidence of pelvic pain (7% in group A and 5% in group B) is similar to that reported elsewhere [13]. The present complication rate was in accord with others reported [4–6,16], encouragingly low (2.8%), most being infections of the suburethral alloplastic tape, with only minor complications related to insertion of the screws in the pubis, comparable to that reported previously [17].

We attribute this excellent outcome to appropriate patient selection; as noted by others [18,19] we underline the importance of a diagnostic evaluation before surgery, and particularly the use of video-urodynamics to simultaneously assess dysfunction and associated anatomical disorders, and during the follow-up to assess the anatomical and functional results. However, bone anchors must be considered foreign bodies, with potential risks of infection, and thus in accord with others [20] we recommend their judicious use under a prophylactic antibiotic regimen and with appropriate attention to sterile surgical technique. This technique is a valid alternative to Burch colposuspension in women with SUI caused by urethral hypermobility, with or with no associated mild prolapse, the only concern being the biocompatibility of the suburethral alloplastic tape.

CONFLICT OF INTEREST

None declared.

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Abbreviations: **SUI**, stress urinary incontinence; **VLPP**, Valsalva leak-point pressure; **ICS**, International Continence Society; **PdetQ**$_{max}$, detrusor pressure at maximum urinary flow rate.