Inflatable Penile Prosthesis Implantation Without Corporeal Dilation: A Cavernous Tissue Sparing Technique

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Purpose: We compared the advantages and disadvantages of initial penile implantation with vs without prior dilation of the corpora cavernosa.

Materials and Methods: Patients implanted for the first time with a 700CX™ or an antibiotic coated 700CX InhibiZone™ 3-piece prosthesis by a single surgeon during January 2005 to December 2006 were included in the study. They were randomized to penile implantation without (group 1) or with (group 2) penile dilation. Postoperative pain was measured on the day after surgery and at day 7 postoperatively. Perioperative and postoperative complications were recorded. Residual erectile activity without prosthesis inflation was evaluated using the International Index of Erectile Function at 3-month intervals for 9 months. Patients recorded penile length and girth during maximum sexual stimulation during this time.

Results: A total of 100 patients were included in the study. Intraoperative complications occurred in 2 group 1 and 3 group 2 patients. Postoperatively complication rates and types were similar in the 2 groups. Pain was significantly greater in group 2 ($p < 0.01$). Immediately postoperatively, and at 3 and 6 months penile length was significantly greater in group 1 than in group 2 ($p < 0.05$). Mean International Index of Erectile Function scores were higher in group 1 (12, range 10 to 14 vs 7, range 6 to 8).

Conclusions: Results suggest that penile dilation is not necessary in primary implantation cases.

Key Words: penis, prostheses and implants, outcome and process assessment (health care), penile erection, complications

Abbreviations and Acronyms

IIEF = International Index of Erectile Function

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Penile implants to restore erectile rigidity have been used for many years. Inflatable implants have been discussed starting in 1973 with the simple inflatable implant[1] through to the present with increasing refinement of the device. Penile implants now have an important secondary role in treatment for organic irreversible erectile dysfunction. Implantation also remains effective for erectile dysfunction, resulting in high patient and partner satisfaction,[2] which can be even higher than that of oral therapy.[3] In 200 patients at Italian institutions the AMS 700® penile prosthesis was associated with 98% patient satisfaction and 96% partner gratification.[2]

The standard technique of penile prosthesis implantation includes the dilation of each corpus using Hegar or Brooks dilators to facilitate cylinder insertion. This procedure

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may severely damage residual erectile tissue, contributing to postoperative pain and favoring a fibrotic tissue response.[4,5] Dilation requires time and may produce perforations in the proximal or distal corporeal ends.[6] Reimplantation of an inflatable 3-piece prosthesis in a patient with severe corporeal fibrosis is a greater surgical challenge for even the most experienced surgeons. Priapism,[7,8] injection therapy[9] or vascular insufficiency[10] may give rise to fibrosis of the corpora cavernosa. The most severe fibrosis can result from removing an infected penile implant.[11] In such cases the critical task of scarred corporeal body dilation is needed to allow the new implant to be positioned. For initial implants there may be no need for such dilation since erectile tissue is spongy and easy to expand. Preserving as much erectile tissue as possible may enhance a more natural response to sexual stimulation even in patients implanted with a penile prosthesis. We report the advantages and disadvantages of initial penile implantation without prior cavernous dilation.

PATIENTS AND METHODS

Patients

Study patients underwent penile implantation from January 2005 to December 2006. All patients were operated on at a single center by the same surgeon (IM). Eligible patients were naïve implant recipients. Included in the study were men with erectile dysfunction who did not respond to oral or intracavernous treatments. Excluded from study were those with severe corporeal fibrosis on physical examination and those requiring reimplantation, including that due to previous prosthesis removal because of infection or another cause. Patients were randomized to penile implantation without (group 1) or with (group 2) penile dilation and were blinded to treatment group.

Implantation

The surgical procedure was that described for the penoscrotal approach[1] using the 700CX or antibiotic coated 700CX InhibiZone 3-piece prosthesis. The patient was catheterized with a 16Fr Foley catheter and a self-retaining circular retractor with elastic hooks was placed over the genitalia. A 3 cm incision was made at the perioscrotal junction at the mid raphe and carried down to the superficial/dartos fascia. The corpora cavernosa were exposed on each side of the spongiosum. A small incision was made on the corpora cavernosa to expose the corporeal spongy tissue. In a standard procedure the next step was to dilate the corpus cavernosum spongy tissue with a blunt Hegar dilator. This step was included or omitted.

After opening the corporotomy the Furlow inserter was inserted directly proximal and distal only once to measure with it. We did not use the blue proximal introducer in any case. Usually we note no special difficulty during Furlow insertion. The proximal cylinder was placed in the proximal cavernous body and the distal half of the cylinder was brought through the distal corporeal body using a Furlow inserter. We do not use Metzenbaum scissors in naive cases since they are too sharp but scissors are useful in corporeal fibrosis cases to find the right way into the corpora.

After the Furlow inserter was placed proximal into the crura it was inserted inside the cylinders with the aid of a forceps handle. A needle was passed through the glans penis, avoiding the urethra, and the accompanying thread was used to pull the cylinder close against the distal glans. The procedure was repeated on the contralateral side. The abdominal reservoir was positioned in the retropubic space (space of Retzius) and connected to the pump, which was inserted in a scrotal subdartos pouch.

Assessment and Statistics

In each group we determined implantation procedure duration, and the number and type of intraoperative and postoperative complications. Postoperative pain was measured using a visual analog scale of 1—minimal to 10—maximal pain. Assessment was done the day after surgery and day 7 postoperatively. Perioperative and postoperative complications were recorded. Residual erectile activity after implantation was evaluated at 3-month intervals for 9 months by determining erectile function upon sexual stimulation without prosthesis inflation. Assessment was based on patient reporting using IIEF questions 1 to 3 on the nature of the erection in terms of frequency, rigidity and ability to penetrate. The score on each question was 0 to 5, with the higher score representing a more positive outcome, for a total score of 0 to 15. Patients were instructed on measuring penile length and girth during maximum sexual stimulation during this time. We used the t and chi-square tests with SPSS®, version 11.0 and statistical significance considered at $p < 0.05$.

RESULTS

Patient Characteristics

A total of 100 patients were included in the study with 50 each randomized to groups 1 and 2. The table lists patient characteristics. Of the patients 70 received a standard 700CX and 30 received an antibiotic coated 700CX InhibiZone. The distribution of the 2 devices was similar in the 2 groups.

Outcome

Mean operative time was significantly less without penile dilation (35 minutes, range 25 to 45 vs 47, range 35 to 60, $p < 0.05$). Intraoperative complications occurred in 1 patient with crural perforation and 1 with urethral perforation in group 1 compared with 1 with crural perforation and 2 with crossovers in group 2 (p not significant). Crural perforation was done with the Furlow inserter by probably moving it in a wrong direction. Postoperative complication rates and types were similar in the 2 groups, including day 5 infection and

Patient Characteristics

	Group 1	Group 2
Mean ± SD age at implantation	59.2 ± 6.2	60.3 ± 5.4
Mean ± SD yrs erectile dysfunction	3.5 ± 1.3	4.2 ± 1.1
No. primary etiology (%):		
Vascular insufficiency	11 (22)	10 (20)
Diabetes mellitus	10 (20)	11 (22)
Peyronie's disease	7 (14)	5 (10)
Neurogenic causes	6 (12)	8 (16)
Pelvic surgery/trauma	11 (22)	12 (24)
Other organic condition	5 (10)	4 (8)
% Previous treatment:		
Only oral phosphodiesterase 5 inhibitor	10	8
Only intracavernous injection	6	6
Oral + intracavernous	80	80
Other (vacuum device etc)	2	2

postoperative hematoma in 1 case each in group 1, and a single day 10 infection in group 2. In groups 1 vs 2 median postoperative pain on the visual analog pain scale was 2 (range 1 to 3) vs 1 (range 1 to 3) on postoperative day 1, and 7 (range 5 to 12) vs 5 (range 3 to 8) on postoperative day 7, respectively. Pain was significantly greater in group 2 than in group 1 ($p < 0.01$).

Preoperatively penile length was 8.9 (range 7 to 9.5) vs 9.2 cm (range 6 to 9.9) in group 1 vs 2. Immediately postoperatively, and at 3 and 6 months penile length was significantly greater in group 1 than in group 2, that is 10.2 (range 9 to 11.2), 10.1 (range 9.2 to 11.5) and 10.0 cm (9.5 to 12.5) vs 8.5 (range 7 to 9.2), 8.3 (range 6.8 to 9.1) and 8.0 (range 6.2 to 8.9), respectively ($p < 0.05$). IIEF scores were higher in group 1. In group 1 vs 2 mean IIEF scores on questions 1 to 3 after implantation were 12 (range 10 to 14) vs 7 (range 6 to 8). We did not record penile prosthesis activated length.

DISCUSSION

Distal dilation may be difficult and may give rise to the intraoperative complications of cross dilation and proximal perforation as well as other intraoperative complications that may occur during implantation, such as difficult corporotomy closure and urethral trauma.[6] Intraoperative complications were less common in nondilation group 1 but the difference was not significant. Two crossovers were noted in group 2 with dilation, involving septal perforation between the corpus cavernosum, leading to the placement of each cylinder in the same corpus. The inevitable additional manipulation associated with this correction would have caused further damage to corporeal tissue. Absent dilation during penile implantation also resulted in a significant 12-minute decrease in operative time.

Periprosthetic infection is a serious complication of penile implantation and gram-negative infection usually manifests within the first 3 months after surgery. Later infection with Staphylococcus epidermidis may not become apparent until 1 year or longer after implantation. Previously reported infection rates for primary implantation are about 1.8%.[12–14] Infection rates in our 2 cohorts were similar to published rates and to each other at 2%.

There was a significant decrease in postoperative pain in patients without dilation, which may be attributable to corporeal trauma during dilation. This is substantiated by the fact that residual sexual function was retained in a significantly higher proportion of patients who did not undergo dilation. After implantation higher IIEF scores were noted in group 1 patients, indicting greater sexual function. A common reason for patient dissatisfaction with a penile implant is the nature of erection produced with the implant, ie penile length and girth.[15] Sildenafil has been used to enhance prosthetic erection and with statistically significant improvements in sexual satisfaction reported.[16] In our series penile nondilation resulted in greater penile length in the immediate postoperative period, and at 3 and 6 months. This may be important to patient satisfaction but it was not assessed. In conclusion, our results suggest that penile dilation is not needed at primary implantation and there are significant patient advantages in terms of shorter operative time, less postoperative pain and greater retained, residual sexual activity than with the standard technique.

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