

Inflatable penile prosthesis: site-specific malfunction analysis

BB Garber^{1*}

¹*Division of Urology, The Graduate Hospital, Philadelphia, Pennsylvania, USA*

The purpose of this study was to analyze retrospectively the exact site(s) of device failure of a large series of Mentor Alpha I inflatable penile prostheses. The study consisted of 442 patients implanted over a 12-year period. Only those patients who developed a device malfunction and returned for re-evaluation by the author were included. The exact site(s) of device malfunction were obtained from a review of operative reports. The average length of follow-up in this series was 63 months, ranging from 1 to 138 months. In all, 22 (4.98%) patients developed device malfunction and returned for evaluation, including six (3.9%) of the 154 infrapubic devices and 16 (5.6%) of the 288 scrotal devices. Of these 22 patients, three declined revision and 19 were reoperated on by the author. The exact site of malfunction differed in the infrapubic vs scrotal implants. Most malfunctions of the scrotal device involved tubing fractures at the pump strain reliefs, whereas infrapubic device malfunctions typically involved the cylinders or the reservoir. A review of these malfunction patterns may assist the manufacturer in further improving the reliability of this prosthesis, and may assist implanting surgeons in planning operative procedures.

International Journal of Impotence Research (2003) 15, 22–25. doi:10.1038/sj.ijir.3900942

Keywords: penile prosthesis; malfunction; infrapubic/scrotal devices

Introduction

The availability of sildenafil,¹ an effective oral phosphodiesterase type 5 inhibitor approved for the treatment of erectile dysfunction (ED), has tremendously increased both the number of patients seeking treatment and the number of physicians rendering such treatment. When oral therapy fails, is contraindicated, or results in side effects, alternate therapies are available. Approved second-line therapies include vacuum-constriction devices,² along with intracavernous and intraurethral administration of alprostadil.^{3,4} Transcutaneous medications⁵ and new oral medications^{6–8} are under active investigation. Arterial^{9,10} and/or venous^{11,12} procedures are available for highly selected individuals. However, despite widespread enthusiasm for minimally invasive approaches, there are many men whose ED is refractory to such therapy. These men, not infrequently, elect penile prosthesis insertion.

Multiple-component inflatable penile prostheses (IPPs) provide adequate penile girth, length, and

rigidity, while allowing flaccidity when not needed for sexual activity. A penile implant is the only ED treatment that allows a man to obtain and maintain a rigid erection at any time and for any length of time. They are not cumbersome like vacuum-constriction devices, and they avoid the penile/urethral discomfort and unpredictable response that often occurs with injectable or transurethral medications. Despite these advantages, many patients are reluctant to choose an implant because of the surgical procedure and its attendant risks, including subsequent device malfunction.

Currently available IPPs have greatly improved mechanical reliability compared to earlier models.¹³ Many series have reported overall mechanical reliability rates for these devices.^{14–21} The present series was compiled to document the exact site of malfunction of a large series of Mentor Alpha I devices, and to document any differences in the malfunction patterns of the scrotal and infrapubic versions.

Patients and methods

During a 12-year period, 463 men with organic impotence underwent implantation of a Mentor Alpha I IPP to correct organic erectile dysfunction. Patients undergoing primary or secondary implantation were

*Correspondence: BB Garber, MD, Box 686, Bryn Mawr, PA 19010, USA.

E-mail: bgarber@comcast.net

Received 16 January 2002; revised 26 April 2002;

accepted 6 August 2002

included in this analysis. Preoperative evaluation for primary implant candidates typically included a detailed urologic and sexual history and physical examination. Laboratory evaluation included the measurement of serum testosterone, prolactin, glucose, creatinine, urinalysis, urine culture, and prostate-specific antigen levels. Most underwent duplex Doppler evaluation of penile hemodynamics before and after intracavernous injection of prostaglandin E1, and/or nocturnal penile tumescence and rigidity testing. Written informed consent was obtained prior to IPP insertion. All men had tried and failed less invasive ED treatment modalities. All had sterile urine cultures preoperatively, and all received one intravenous dose of vancomycin and gentamicin prior to the skin incision. The operative techniques have been described previously.^{22,23}

Follow-up data were obtained from a review of medical records and operative reports. Only those patients who developed a device malfunction and returned for re-evaluation by the author were included. In all, 21 patients were excluded from the present analysis, including two intraoperative cylinder aneurysms caused by maximal cylinder inflation with an open corporotomy, two postoperative cylinder aneurysms related to device abuse,²⁴ and 17 (3.7%) who developed periprosthetic infection and were explanted.

Results

Of the 442 patients remaining for analysis, a total of 22 (5.0%) developed a device malfunction and returned to the author for evaluation. This included six (3.9%) of the 154 patients with infrapubic devices, and 16 (5.6%) of the 288 patients with scrotal devices. The length of time from implantation to device failure for these 22 patients is illustrated in Table 1. Nineteen of the 22 consented to reoperation, and form the basis of this report.

The exact sites of malfunction of the scrotal and

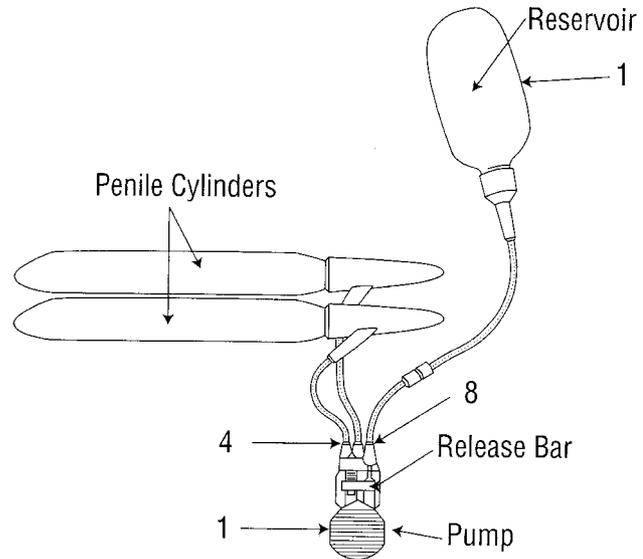


Figure 1 Exact malfunction sites of Mentor Alpha I scrotal implants.

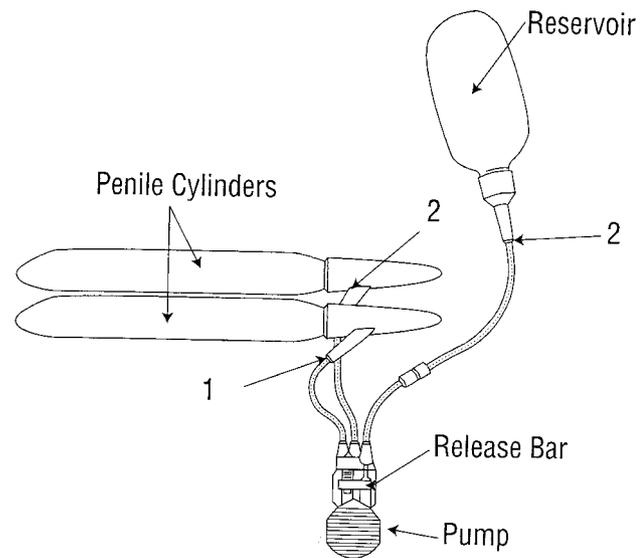


Figure 2 Exact malfunction sites of Mentor Alpha I infrapubic implants.

Table 1 Time to implant failure

Interval from implantation to device failure (months)	Number of patients
01–11	0
12–23	1
24–35	3
36–47	2
48–59	11
60–71	4
72–83	0
84–95	0
96–107	0
108–119	1
Total 22	

infrapubic devices are illustrated in Figures 1 and 2, respectively. Of the six infrapubic implants that malfunctioned, two involved the junction of the silicone tubing with the reservoir strain relief, two involved the junction of the cylinder strain relief with the proximal cylinder, one involved the junction of the silicone tubing with the cylinder strain relief, and one declined revision (Figure 2). Of the 16 scrotal implants that malfunctioned, eight involved the junction of the silicone tubing from the reservoir with the pump strain relief, four involved the junction of the silicone tubing from a cylinder with the pump strain relief, one involved a direct leak from the pump bulb, one involved a leak from

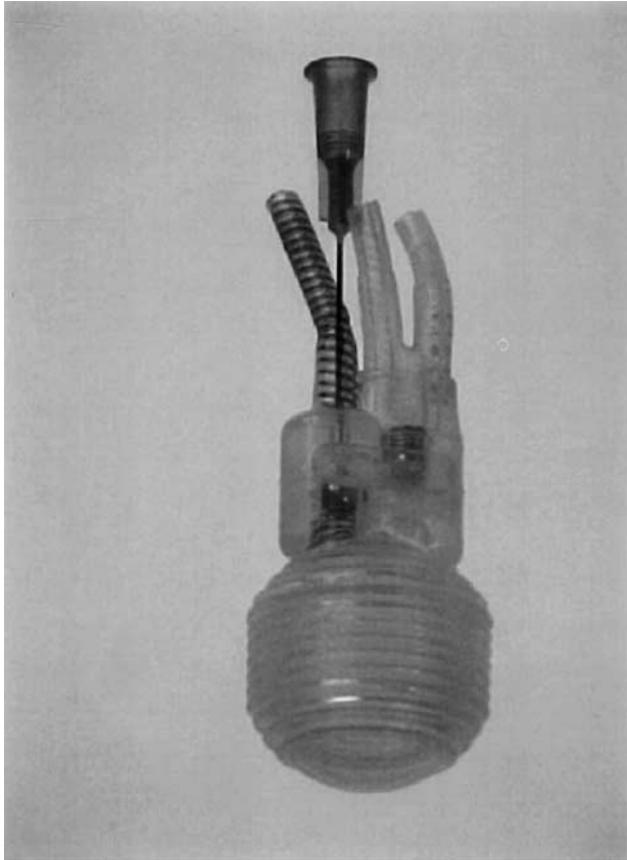


Figure 3 22-gauge needle placed into site of leakage at junction of reservoir tubing with pump strain relief.

the body of the reservoir, and two declined revision (Figure 1). The reservoir leak occurred immediately after a laparotomy and colon resection, and it is strongly suspected that there was an operative injury to the reservoir. The most common type of malfunction seen in this series is illustrated in Figure 3.

Discussion

The Mentor Alpha I prosthesis consists of two polyurethane cylinders preconnected to a pump via silicone tubing, and a separate reservoir. This prosthetic configuration requires only one connection, but necessitates an infrapubic and a scrotal version. The infrapubic cylinder/pump combinations have longer segments of silicone tubing between the cylinders and the pump, to allow for pump placement in the most dependent portion of the scrotum. In addition, in December 1992 the pump was enhanced so that the tubing and strain reliefs were reinforced and lengthened.²¹

In Randrup *et al's*¹⁴ 1993 series of 333 devices, nine (2.7%) developed a split in the exit tubing from the pump. However, this series predates the

enhanced pump, and the malfunctions were not stratified by surgical approach.

Goldstein *et al's*¹⁷ 1993 multi-institutional series of 434 Alpha I's detected five cases (1.2%) of tubing leakage where the tubing entered/exited the pump, four of which occurred in scrotal devices. They found a statistically significant ($P < 0.001$) greater chance for a tubing leak with a scrotal approach. The percentage of patients with an enhanced pump was not specified in their series.

Wilson *et al's*²¹ series of 1381 scrotal devices documented that the enhanced pump improved the mechanical reliability of the Alpha I scrotal device. However, the present series reveals that the most frequent sites of malfunction of the scrotal version continue to be the junctions of the silicone tubing with the pump strain reliefs. Interestingly, no patient in the present series had a malfunction of an unenhanced Alpha I pump.

The sites of malfunction found in the present series differed depending on whether a scrotal or infrapubic device/surgical approach was used. The scrotal device/surgical approach seems to increase the chance that a leak will develop at the tubing-strain relief junctions on the pump. The exact cause(s) of these findings are unclear. These findings may be due to chance alone. It should be noted that site-specific malfunction analysis could only be carried out on those patients who developed a malfunction and returned for reoperation by the author. This leaves open the possibility that some patients developed a malfunction and did not return to the author, or went elsewhere for treatment. However, prior investigators have documented a statistically significant greater risk for a tubing leak with the scrotal device/approach.¹⁷ It is conceivable that there are manufacturing differences between the scrotal and the infrapubic models, which may contribute to this malfunction pattern. It is also possible and even likely that the pump tubing is subject to different stresses depending on whether the infrapubic or scrotal model/approach is employed. Further investigation will be required to determine whether one or more of these factors is etiologic.

Conclusions

The Mentor Alpha I inflatable penile prosthesis is available in infrapubic and scrotal versions to accommodate either surgical approach. The present series suggests, but does not prove, that the exact site of device malfunction is typically different in the infrapubic vs scrotal versions. Analysis and knowledge of these malfunction patterns may assist the manufacturer in further improving the reliability of this implant, and can assist implanting

surgeons in planning primary or secondary operative procedures.

References

- 1 Goldstein I *et al.* Oral sildenafil in the treatment of erectile dysfunction. *N Engl J Med* 1998; **338**: 1397–1404.
- 2 Levine LA, Dimitriou RJ. Vacuum constriction and external erection devices in erectile dysfunction. *Urol Clin North Am* 2001; **28**: 335–341.
- 3 Porst H. The rationale for prostaglandin E1 in erectile failure: a survey of worldwide experience. *J Urol* 1996; **155**: 802–815.
- 4 Leungwattanakij S, Flynn V, Hellstrom WJG. Intracavernosal injection and intraurethral therapy for erectile dysfunction. *Urol Clin North Am* 2001; **28**: 343–354.
- 5 McVary KT *et al.* Topical prostaglandin E1 SEPA gel for the treatment of erectile dysfunction. *J Urol* 1999; **162**: 726–731.
- 6 Wagner G. Apomorphine SL (Uprima[®]): a new treatment for the management of erectile dysfunction. *Int J Imp Res* 2001; **13** (Suppl 3): S1–S2.
- 7 Padma-Nathan H *et al.* On-demand IC351 (Cialis[™]) enhances erectile function in patients with erectile dysfunction. *Int J Imp Res* 2001; **13**: 2–9.
- 8 Porst H *et al.* The efficacy and tolerability of vardenafil, a new, oral, selective phosphodiesterase type 5 inhibitor, in patients with erectile dysfunction: the first at-home clinical trial. *Int J Imp Res* 2001; **13**: 192–199.
- 9 Lizza EF, Zorogniotti AW. Experience with the long-term effect of microsurgical penile revascularization. *Int J Impot Res* 1994; **6**: 145–152.
- 10 Goldstein I, Hatzichristou DG, Pescatori ES. Pelvic, perineal, and penile trauma-associated arteriogenic impotence: pathophysiologic mechanisms and the role of microvascular arterial bypass surgery. In: Bennett AH, ed. *Impotence. Diagnosis and management of erectile dysfunction*. WB Saunders: Philadelphia, 1994, pp 213–228.
- 11 Wespes E, Moreire de Goes P, Sattar AA, Schulman C. Objective criteria in the long-term evaluation of penile venous surgery. *J Urol* 1994; **152**: 888–890.
- 12 Lue TF, Donatucci CF. Dysfunction of the venoocclusive mechanism. In: Bennett AH, ed. *Impotence. Diagnosis and management of erectile dysfunction*. WB Saunders: Philadelphia, 1994, pp 197–204.
- 13 Montague DK, Angermeier KW. Penile prosthesis implantation. *Urol Clin North Am* 2001; **28**: 355–361.
- 14 Randrup E *et al.* Clinical experience with Mentor Alpha I inflatable penile prosthesis. Report on 333 cases. *Urology* 1993; **42**: 305–308.
- 15 Wilson SK, Wahman GE, Lange JL. Eleven years of experience with the inflatable penile prosthesis. *J Urol* 1988; **139**: 951–952.
- 16 Garber BB. Mentor Alpha 1 inflatable penile prosthesis: patient satisfaction and device reliability. *Urology* 1994; **43**: 214–217.
- 17 Goldstein I *et al.* Safety and efficacy outcome of Mentor Alpha-1 inflatable penile prosthesis implantation for impotence treatment. *J Urol* 1997; **157**: 833–839.
- 18 Garber BB. Inflatable penile prosthesis: results of 150 cases. *Br J Urol* 1996; **78**: 933–935.
- 19 Dubocq F *et al.* Long-term mechanical reliability of multi-component inflatable penile prosthesis: comparison of device survival. *Urology* 1998; **52**: 277–281.
- 20 Govier FE *et al.* Mechanical reliability, surgical complications, and patient and partner satisfaction of the modern three-piece inflatable penile prosthesis. *Urology* 1998; **52**: 282–286.
- 21 Wilson SK, Cleves MA, Delk JR. Comparison of mechanical reliability of original and enhanced Mentor Alpha I penile prosthesis. *J Urol* 1999; **162**: 715–718.
- 22 Garber BB, Marcus SM. Does surgical approach affect the incidence of inflatable penile prosthesis infection? *Urology* 1998; **52**: 291–293.
- 23 Garber BB. Outpatient inflatable penile prosthesis insertion. *Urology* 1997; **49**: 600–603.
- 24 Garber BB. Mentor Alpha-1 inflatable penile prosthesis cylinder aneurysm: an unusual complication. *Int J Impot Res* 1995; **7**: 13–16.