

# THE MENTOR ALPHA 1 PENILE PROSTHESIS WITH RESERVOIR LOCK-OUT VALVE: EFFECTIVE PREVENTION OF AUTO-INFLATION WITH IMPROVED CAPABILITY FOR ECTOPIC RESERVOIR PLACEMENT

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## ABSTRACT

**Purpose:** Auto-inflation is a common and annoying complication of 3-piece penile prostheses. In the published literature the rate is approximately 11% with a 2% operative revision rate. We report the results of a review of 160 Alpha 1 and NB implants (Mentor Corp., Santa Barbara, California) with the new lock-out valve located on the reservoir to treat impotence. We compared it with 339 Alpha 1 implants with the standard reservoir. We also investigated the lock-out reservoir for ectopic nonretropubic implantation.

**Materials and Methods:** We compared 339 Alpha prostheses with the standard reservoir that were implanted between January 1, 1998 through December 31, 1999 and 160 with the new lock-out valve placed since January 2000 with at least 6 months of followup. Implants were further stratified as first time (virgin) or revision-replacement of a previous implant. In 8 patients with a scarred or obliterated retroperitoneal space the lock-out reservoir was placed superior to the transversalis fascia and beneath the abdominal musculature.

**Results:** Kaplan-Meier estimated 1-year survival was not significantly different in terms of mechanical failure ( $p = 0.57$  and  $0.85$ ) revision for any cause ( $p = 0.92$  and  $0.92$ ), patient dissatisfaction ( $p = 0.35$  and  $0.11$ ) or infection ( $p = 0.64$  and  $0.94$ ) for all implants and virgin implants only, respectively. Only 2 patients (1.3%) with a lock-out valve complained of auto-inflation initially and the problem resolved in each after instruction on how to operate the device. Of the patients in the earlier series 11% complained of auto-inflation and 2% required operative correction. None of the 8 patients with an ectopic reservoir location complained of auto-inflation.

**Conclusions:** Our results indicate that the lock-out valve prevents early auto-inflation. Addition of the lock-out valve does not impact the revision rate compared with the same implant with a standard reservoir. In patients with a scarred retroperitoneal space the lock-out valve offers the penile implant surgeon a decreased probability of auto-inflation with ectopic reservoir placement.

**KEY WORDS:** penis, prostheses and implants, postoperative complications, impotence

Auto-inflation or failure to deflate occurs when the cylinders of a hydraulic penile prosthesis chronically does not deflate completely or does not stay deflated. The patient achieves partial erection, causing embarrassment and sometimes pain. The problem is common in the early postoperative period and it is caused by abdominal pressure forcing fluid from the reservoir into the cylinders. If auto-inflation persists after 6 months, the condition is permanent and surgical correction may be considered.

The body reacts to any foreign body implantation by surrounding the object with a fibrous capsule.<sup>1,2</sup> All components of the prosthesis are surrounded by capsule. Capsule formation is considered complete by 3 months.<sup>3</sup> If the cylinders remain inflated during the first 3 months, the patient may never be able to deflate the prosthesis completely because a tight capsule around the reservoir prohibits full filling of the reservoir at deflation. On the other hand, if the cylinders remain deflated for the first 3 months, the reservoir capsule is capacious, allowing full deflation. A reservoir with a lock-out valve could prohibit common and annoying auto-inflation early in the postoperative period. It would also ensure that

the prosthesis remains deflated to encourage capacious capsule formation around the reservoir.

Many patients who need a prosthesis have a scarred or obliterated retroperitoneal space due to previous surgery, such as prostatectomy, cystectomy, renal transplantation and/or radiation therapy. Surgeons may be reluctant to implant a 3-piece prosthesis in these cases because of difficult reservoir placement. Because the lock-out reservoir is oblivious to surrounding pressure, it can be placed in an ectopic location without concern for auto-inflation (fig. 1). We report our experience with the lock-out valve and compare it with our previous series of Alpha prostheses with the standard reservoir. We studied auto-inflation prevention, revision rates and ectopic locations in difficult cases.

## MATERIALS AND METHODS

From January 1, 1998 to April 1, 2001 a single surgical team implanted 499 Alpha 1 penile prostheses. From January 1, 1998 through December 31, 1999 the standard reservoir was used for 284 virgin implants and 55 revision-replacements. Beginning in January 1, 2000 the lock-out valve reservoir was used in 114 virgin implants and 46 revisions. All implants were placed via a high scrotal incision and preoperative preparation was the same in all cases, as previously described.<sup>4</sup> All reservoirs were filled to rated capacity and no back pressure test was performed. All implant cylinders were manually deflated on postoperative day 1 and at 1

Accepted for publication May 10, 2002.

\* Financial interest and/or other relationship with American Medical Systems, Mentor, Lilly ICOS and AMT.

† Financial interest and/or other relationship with Pfizer and Merck.

‡ Financial interest and/or other relationship with American Medical Systems, Mentor, Lilly ICOS, AMT, Interneuron, Sepacor and Urometrix.



FIG. 1. Nonenhanced reservoir is deflated in left hand, while reservoir with lock-out valve is not deflating in grasp of right hand.

month the patients were taught to maintain the implant deflated for the next 2 months except when using it.

Data were abstracted from medical records and collected from patient interviews. Auto-inflation and ectopic reservoir placement were specifically noted. All data were entered into a computerized database and analyzed by a third party. Information collected included patient birth date, implantation date, etiology of impotence, type of implant, revision history and reason for revision. Revision reasons were classified as mechanical failure, patient dissatisfaction, infection and medical causes. The lock-out valve was assessed by date of implant, chart review and confirmation with the manufacturer.

The rate of 1-year survival after revision for mechanical reasons, medical reasons, infection or patient dissatisfaction was compared in the 2 groups. Because results could be confounded due to previous penile implantation, model comparisons were performed in the whole series and for virgin implants. Data management and analysis were performed using a commercially available statistical package. Survival rate estimates were calculated using the Kaplan-Meier product limit method and compared with the log rank test after performing the Grambsch-Therneau global test of the proportional hazards assumption.<sup>5,6</sup>

All charts were reviewed for the patient complaint of auto-inflation or failure to deflate completely. Patients who initially complained and did not elect surgical correction were interviewed to ensure that the problem had spontaneously resolved. In the initial series of nonlock-out valve reservoirs patients were not specifically queried whether auto-inflation was a problem. It was only recorded if they complained. In the lock-out valve group each patient was specifically asked and the penis was examined for auto-inflation in the immediate postoperative period.

Ectopic reservoir placement was decided at surgery. If the retropubic space or lower peritoneal cavity was scarred, an

ectopic reservoir location was chosen. A space was created between the anterior abdominal musculature and transversalis fascia cephalad to the external inguinal ring. The reservoir was placed into this created space and filled with normal saline. The lock-out valve was positioned facing toward the spine. During the study period the reservoir was placed ectopically in 8 cases.

## RESULTS

Table 1 lists Kaplan-Meier estimated 1-year survival rates by failure type in the 2 study cohorts. In the group with standard reservoir placement early auto-inflation was recorded as a complaint in 37 patients (11%). In 20 cases the problem resolved and in 11 the problem persisted but was not bothersome enough for surgery. Six patients (2%) elected correction and hydraulic capsulotomy resolved the problem. In the lock-out valve group 2 patients complained of early auto-inflation, which resolved after teaching the patient how to operate the device.

Of the 8 lock-out valves placed ectopically 3 were palpable beneath the abdominal musculature but not bothersome (table 2). None of these patients experienced auto-inflation but 1 required revision for unilateral proximal cylinder migration. The reservoir was untouched. There were no revisions for mechanical failure, infection or patient dissatisfaction.

## DISCUSSION

Historically auto-inflation has occurred in 2 and 3-piece prostheses.<sup>1-3,7-9</sup> It was initially believed that auto-inflation was the result of not making a large enough space for the reservoir. Any space created for the reservoir at surgery has vanished by the next morning as the retroperitoneal contents surround the reservoir. Today most authorities believe that auto-inflation is caused by a tight reservoir capsule contracting around the reservoir.<sup>7</sup>

Capsule development is thought to be complete at 3 months. When the patient is instructed how to operate the prosthesis, he should be encouraged to deflate it daily, thereby, maintaining the cylinders empty and the reservoir full. This state encourages a capacious capsule around the reservoir that should enable complete deflation and also protect the reservoir from the abdominal pressure that caused auto-inflation in the immediate postoperative period.

If the patient maintains the cylinders partially inflated during the 3 months of capsule formation, the reservoir capsule tightens around a partially full reservoir. Complete deflation of the prosthesis is then not possible. The patient complains of partial erection all the time. Forceful penile squeezing while deflating can achieve additional deflation but the cylinders promptly refill.

The lock-out valve works by responding to fluid pressure changes in the tubing to the prosthesis and not to pressure from the reservoir (fig. 2). Because it is located at the apical end of the reservoir, the lock-out valve allows fluid to flow bidirectionally. During cylinder deflation the valve opens to positive pressure in the tubing. During cylinder inflation when the collapsed pump bulb recovers, negative pressure

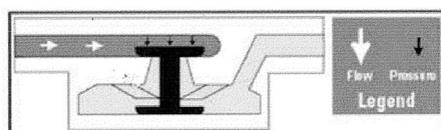
TABLE 1. Kaplan-Meier estimated 1-year survival by failure type in virgin and revised implants

Lock-Out Valve	No. Implants	% Any Revision (95% CI)	% Mechanical (95% CI)	% Infection (95% CI)	% Medical (95% CI)
Virgin + revised implants:					
No	339	90.6 (87-93)	97.8 (96-99)	95.5 (93-97)	97.3 (95-99)
Yes	160	91.3 (86-95)	98.7 (95-100)	94.5 (89-97)	98.6 (94-100)
p Value		0.9225	0.5714	0.6482	0.4131
Virgin implants only:					
No	284	92.3 (89-95)	98.1 (96-99)	96.4 (93-98)	97.5 (95-99)
Yes	114	92.6 (86-96)	98.3 (93-100)	96.1 (90-99)	99.1 (94-100)
p Value		0.9203	0.8468	0.9378	0.3572

TABLE 2. Characteristics of the patients who received an ectopically located reservoir in the right groin

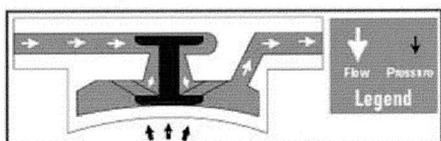
Pt. No.	Medical History	Easily Palpable	Any Revision
1	Radical cystoprostatectomy with ileal loop	No	No
2	Radical cystoprostatectomy with neobladder	Yes	No
3	Radical cystoprostatectomy with ileal loop + colostomy	No	No
4	Radical cystoprostatectomy with ileal loop, adjuvant chemotherapy, corporeal fibrosis due to injection therapy	No	Yes for proximal cylinder migration
5	Radical cystoprostatectomy with rt. colon pouch	No	No
6	Radical retropubic prostatectomy + previous 3-piece penile prosthesis	Yes	No
7	Radical cystoprostatectomy with neobladder	Yes	No
8	Radical retropubic prostatectomy + pelvic radiation	No	No

No auto-inflation.



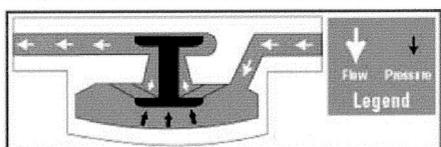
**Lock-out State**

The lock-out state (poppet is seated or closed) prevents fluid transfer from the reservoir to the pump and cylinders.



**Inflate State**

Immediately after squeezing the pump, fluid moves from the reservoir to the pump because the rebound of the bulb generates a negative pressure which unseats (opens) the poppet.



**Deflate State**

Fluid is flowing from the cylinders through the pump and lock-out valve to the reservoir due to the pressure generated in the system by squeezing the cylinders and release bars which unseats (opens) the poppet.

FIG. 2. Mechanics of lock-out valve

opens the valve. The fluid in the reservoir flows in and out due to prosthesis fluid pressure. There must be negative pressure from the pump side for fluid to flow from the reservoir. Elevated reservoir pressure, such as that due to the Valsalva maneuver, does not result in fluid flow from the reservoir.

Early auto-inflation occurred in 11% of the patients implanted with the standard reservoir model. While the condition resolved in most patients, it results in annoyance and the patient in turn consults the physician for an explanation. The new lock-out valve appears to prevent auto-inflation in most cases. The 2 cases of early auto-inflation can possibly be explained by incorrect positioning of the reservoir at surgery. If the poppet valve is touching something hard, such as the pubic bone, the lock-out valve is inactivated. When placing the lock-out valve reservoir, the open face of the valve should be facing the contralateral shoulder. After filling the reservoir we commonly remove the rubber-shod clamp from the reservoir tubing to assess leakage. When there is leakage, the reservoir is manually manipulated into a different orientation until backflow ceases.

Others have noted in small series that early results of the lock-out valve appear to indicate that it prevents auto-inflation.<sup>10-12</sup> To our knowledge we report the first series with 1-year outcomes. Kaplan-Meier 1-year survival data confirmed that adding the lock-out valve to the Alpha 1 does not appear to increase the early revision rate due to mechanical failure, patient dissatisfaction, infection or medical problems for all implants and for virgin implants. We plan to follow these cases for 5 years to determine whether there are any differences in the failure rate at longer followup.

In patients with nonenhanced reservoirs the surgical revision rate for auto-inflation was 2%. The lock-out valve series included no revisions for auto-inflation. The auto-inflation complaint rate was 11% in the nonenhanced series and it may have been higher if patients had been specifically questioned. All those with lock-out reservoirs were specifically questioned and examined for auto-inflation. Only 2 patients experienced the problem and it resolved rapidly when the devices were activated.

In patients with a scarred or obliterated retropubic space it is difficult to implant a 3-piece prosthesis. Placing the reservoir outside of the severely scarred pelvis, such as in the epigastrium or peritoneal cavity, has been described previously.<sup>2</sup> To avoid the problem of reservoir placement in a scarred retropubic space many surgeons place a semirigid or 2-piece implant, or make a separate incision for intraperitoneal placement. In those difficult cases of a scarred retroperitoneum the lock-out valve reservoir can be placed through the scrotal incision in an ectopic location beneath the abdominal musculature but superior to the transversalis fascia. In our experience placing a nonenhanced reservoir in this location results in bothersome auto-inflation because of proximity to the abdominal musculature. Ectopic reservoir placement avoids a second incision. There is shorter operative time and less postoperative pain. In addition, the patient receives a 3-piece prosthesis with optimal flaccidity and rigidity rather than a compromised 2-piece implant.

While auto-inflation is an annoying condition, it can usually be overcome by daily deflation for 2 months by the patient after device activation. Lock-out valve enhancement has an additional cost and nonenhanced reservoirs are still available. For routine implantation the surgeon and patient must decide whether the added cost is worthwhile to avoid the bothersome but usually not permanent condition of auto-inflation. We plan to place a lock-out valve reservoir in an ectopic location only in patients with an orthotopic neobladder. Otherwise the patient and surgeon discuss which implant is best.

On the other hand, placing the lock-out valve reservoir in cases of a scarred or obliterated retropubic space seems to us to make previously difficult cases much easier and less time-consuming. Most ectopic reservoir placements were done after cystectomy. In our practice, in which many implants are placed yearly, we commonly place reservoirs in the retropubic space after radical prostatectomy. However, many physicians are reluctant to do this procedure blindly and choose to make a second incision. Since men who undergo radical pros-

tatectomy represent one of the largest groups requiring a penile prosthesis, ectopic placement of the lock-out valve reservoir provides an advantage to the surgeon who performs implantation occasionally, allowing avoidance of a time-consuming second incision.

#### CONCLUSIONS

Lock-out valve enhanced reservoirs appear to prevent bothersome early auto-inflation and prevent the 2% need for surgical revision of a prosthesis due to auto-inflation. There does not appear to be any statistical difference in the revision rate due to any cause in patients with standard or lock-out valve enhanced reservoirs when followed for 1 year. The lock-out valve reservoir provides the surgeon with the option of ectopic nonretropubic reservoir placement in patients with a scarred or obliterated abdominal cavity.

John Vendel assisted with photography.

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