

Mechanical Reliability of AMS Hydraulic Penile Prostheses

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The mechanical reliability of AMS hydraulic penile prostheses implanted in 203 patients from April 1985 to June 1995 were evaluated. AMS Hydroflex prosthesis showed the highest incidence of mechanical failure (18.8 %; 6 / 32 patients) during a mean follow-up period of 94.5 (64–117) months. Mean functioning time of the prostheses until malfunction was 50 (0–100) months. Bilateral fractures at junction of rear reservoir and inflation chamber were found in 3 patients. AMS Dynaflex had a failure rate of 2.4 % (2 / 85 patients) for an average of 35.3 (1–59) months. One patient showed complete fracture of silicone ball covering the proximal end of rear reservoir onto which rear tip extenders are snapped. Regarding 3-piece inflatable prosthesis, AMS 700, AMS 700CX and AMS Ultrex had failure rates of 11.1 % (1 / 9 patients), 10.5 % (2 / 19 patients) and 4.0 % (1 / 25 patients) during a mean follow-up period of 116.4 (103–125), 79.0 (60–94) and 44.4 (22–57) months, respectively. The verified causes of the mechanical failures were a tiny rupture of the cylinder in one case of AMS 700, an incomplete fracture of input tube in one case of AMS 700CX and a pump malfunction in one case of Ultrex. However, none of 33 cases of AMS 700CXM showed mechanical failure for an average of 21.3 (2–43) months. Therefore, AMS 700CXM and Ultrex seem to be very reliable, and the reliability of AMS Dynaflex was much higher than that of AMS Hydroflex. However, the long-term reliability of these devices needs more time to be determined.

Key Words: AMS penile prosthesis, 3-piece prosthesis, Self-contained prosthesis, Mechanical failure

INTRODUCTION

Penile implants can be divided into two general types, nonhydraulic and hydraulic. Nonhydraulic devices are commonly referred to as semirigid rod prostheses, and hydraulic devices are often referred to as inflatable prostheses. The original inflatable

prosthesis design of Scott has now been extended and modified to include the original 3-piece inflatable prosthesis, a 2-piece prosthesis, and one piece self-contained inflatable prosthesis.

The most common complication of the inflatable penile prosthesis is mechanical malfunction. Mechanical malfunction has declined from rates as high as 61 % to a level below 5 % since the late 1970s (Kessler, 1981 ; Joseph et al., 1984 ; Montague DK, 1990). The current models of the AMS 3-piece hydraulic prosthesis (AMS 700CX, AMS Ultrex, AMS Ultrex Plus) use triple-ply cylinders with input tubing protection, a sutureless connector system, kink-resi-

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stant tubing, and seamless reservoirs. The mechanical reliability of these devices is considerably better than that of earlier models. Fluid leak, however, continues to be a problem in the inflatable penile prostheses. An additional modification of inflatable penile prosthesis technology is the development of the one piece self-contained prosthesis of which cylinder contains a pump, reservoir and inflation chamber. American Medical Systems (AMS) introduced Hydroflex prosthesis, a unicomponent inflatable device in 1985. Hydroflex was praised for its simplicity of implantation and high patient satisfaction. Yet 5 years later this device was no longer marketed because of high rate of mechanical failure and its place has been taken by the new AMS Dynaflex. We have implanted AMS hydraulic penile prostheses in 203 patients since April 1985, and our experience with their mechanical failure is reported here.

MATERIALS AND METHODS

Since the first implantation of AMS hydraulic penile prosthesis (a 3-piece AMS 700) on April 26, 1985, a total of 203 patients have undergone implantation of various types of AMS hydraulic prosthesis until June 1995. Prior to introduction of the CX cylinder, AMS 700 penile prostheses were placed into 9 patients from April 1985 to December 1986. Following this, we implanted AMS 700CX into 19 patients from September 1987 to August 1990. Thereafter, AMS Ultrex prosthesis has taken the place of AMS 700CX. The Ultrex prostheses were implanted into 25 patients from October 1990 to September 1993. AMS 700CXM prostheses were implanted into 33 patients from December 1991 to May 1995. Regarding the

one piece self-contained prosthesis, Hydroflex prostheses were implanted into 32 patients between October 1985 and March 1990. Thereafter, Dynaflex prostheses were implanted into 85 patients between August 1990 and June 1995 (Table 1).

RESULTS

Among the implants of 3-piece inflatable prostheses, AMS 700, AMS 700CX and AMS 700 Ultrex showed incidences of mechanical failure at the rate of 11.1 % (1/9 patients), 10.5 % (2/19 patients) and 4.0 % (1/25 patients) with a mean follow-up of 116 (range, 103–125), 79.0 (range, 60–94) and 44.4 (range, 22–57) months, respectively. The mechanical failure in one patient of AMS 700 occurred 72 months after the implantation and was due to leak from a tiny rupture of the cylinder in its mid-shaft. Of the two patients of AMS 700CX with mechanical failures, one showed fluid leak from input tube due to an incomplete fracture at the site about 1 cm from connector upon reoperation. This mechanical malfunction occurred 66 months after the implantation. The cause of the mechanical failure in the other patient, which occurred at 55 months postoperatively, could not be specified because of high risk of anesthesia for revision. The mechanical failure in one patient of Ultrex occurred 5 months after the implantation and was a pump malfunction. However, none of 33 patients of AMS 700CXM showed mechanical failure with a mean follow-up of 21.3 (range, 2–43) months (Table 1, 2).

The Hydroflex prosthesis showed the highest incidence of mechanical failure, 18.3 % (6/32 patients) for an average of 94.5 (range, 64–117) months. There were a total of 10 failures in 6 patients.

Table 1. Type, number of patients and follow-up period of AMS hydraulic penile prostheses implanted from April 1985 to June 1995.

Type of implanted prostheses	Patients No. of implantation	Period of implantation	Mean follow-up period, month(range)
3-piece			
700	9	Apr. 1985~Dec. 1986	116.4(103~125)
700CX	19	Sep. 1987~Aug. 1990	79.0(60~94)
700CXM	33	Dec. 1991~May. 1995	21.3(2~43)
Ultrex	25	Oct. 1990~Sep. 1993	44.4(22~57)
1-piece			
Hydroflex	32	Oct. 1985~Mar. 1990	94.5(64~117)
Dynaflex	85	Aug. 1990~Jun. 1995	35.3(1~59)
Total	203		

Functioning time in these cases ranged from 0 to 100 months with an average of 50 months. Four patients showed bilateral while 2 showed unilateral mechanical failure. Bilateral fractures were found at junction of rear reservoir and inflation chamber in 3 patients (complete fracture at one side in 2 patients). Upon reoperation, the site of fluid leaks in 2 patients (bilateral in 1 and unilateral in 1) could not be identified. The cause of mechanical failure in the remaining one patient could not be specified because he declined further surgery. The Dynaflex prosthesis showed a mechanical failure rate of 2.4 % (2/85 patients) with a mean follow-up of 35.3 (range, 1–59) months. The mechanical failure in one patient which occurred at 12 months postoperatively was due to leak from the site of a complete fracture of silicone ball covering the proximal end of rear reservoir onto which rear tip extenders are snapped. However, the site of leak in the other patient, which occurred at 16 months postoperatively, could not be identified upon reoperation (Table 1, 2).

DISCUSSION

From the time of its introduction in 1973 by Scott et al, the American Medical Systems inflatable penile prosthesis has undergone periodic design changes to improve device reliability and longevity while maintaining a high degree of patient and partner satisfaction. The model AMS 700 came out to solve several problems associated with short-term and long-term reliability. The changes include a new pump design, a spherical reservoir, kink-resistant tubing, a new cylinder design that includes a soft conical tip, soft blunted rear tip extenders, reinforced expandable cylinders, a polytetrafluoroethylene (Teflon)-sleeved input tube and

plastic connectors. Having progressed through various designs (700PP, 700PPL, 700PPR, 700PPS, 700PPT), another new design, AMS 700CX was marketed in 1983. Unlike the previous AMS 700 designs, the 700CX (controlled expansion) cylinder has an inner silicone layer, a middle reinforced fabric layer, and a silicone outer sheath that negates the risk of aneurysmal dilatation and can be used with a great degree of safety even in patients who had weakened tunica or who require corporeal reconstruction (Furlow and Motley, 1988). Nickas et al(1994) reported that 4-year survival of the AMS 700CX device was 85 %, whereas earlier versions of the device had 4-year survival of 46 %. Of the 117 failures they encountered in early devices, 41 % was from cylinder leaks and 16 % was due to fluid leaks which could not be further specified. Pescatori and Goldstein(1993) noted a 16 % incidence of leaks during the 4-year followup of 51 patients who had received the AMS 700CX device, none of which were cylinder leaks. Upon reoperation, 6 of the 8 leaks were found to be at or near the connector site, and the site of the remaining 2 leaks could not be identified. They proposed that connectors were considered as the components at risk for pressure-associated fluid leaks. Quesada and Light(1993) found a 0.7 % incidence of cylinder leaks in a series of 214 patients who received CX cylinders. They used life table analysis to predict an 89 % \pm 6 % 6-year survival for the device as a whole. No aneurysmal dilatation of the cylinders occurred. We experienced one case of cylinder leak out of 9 patients of AMS 700 but no leak of the 700CX cylinders. The leak in the one case of our 700CX prostheses was also found to be from the ruptured input tube near the connector site. The AMS also

Table 2. Incidence and kind of mechanical failure, functioning time of the implanted AMS hydraulic penile prostheses until malfunction.

Type of implanted prostheses	Patient No.of malfunction(%)	Mean functioning time of implants until malfunction, month(range)	Kind of mechanical failure(No.)
3-piece			
700	1(11.1)	72	cylinder leak(1)
700CX	2(10.5)	60.5(55,66)	tube leak(1),unknown(1)
700CXM	0(0.0)	0	
U1trex	1(4.0)	5	pump malfunction(1)
1-piece			
Hydroflex	6(18.8)	50(0-100)	fracture(3),unknown(3)
Dynaflex	2(2.1)	14(12,16)	fracture(1),unknown(1)

produces a smaller version of the AMS 700CX prosthesis: the AMS 700CXM device. This device is suitable for implantation into a small penis and a penis with marked fibrosis of corpora cavernosa due to infection, priapism and so on. There is no report about long-term reliability of the AMS 3-piece inflatable prosthesis in Korea but a pump failure occurred 1 week after implantation of 700CXM (Choi et al., 1994). We did not experience any mechanical failure in 33 patients of 700CXM for an average of 21.3 months. However, the question of how long this prosthesis will last can only be answered by careful evaluation of the data gathered from long-term follow-up. The Ultrex cylinder is a modification of the CX cylinder. As in the CX cylinder, it provides controlled girth expansion. Unlike the CX cylinder, however, the middle polypropylene-lycra layer of the Ultrex is woven in such a way that it allows for additional longitudinal expansion of up to 20% of the total cylinder length (Montague and Latin, 1992). Thus, the AMS 700CX was phased out of the market after introduction of the Ultrex. Since the Ultrex cylinder is constructed essentially of the same materials as the CX cylinder, similar survival rates are expected. The only mechanical failure that we experienced was a pump malfunction in a patient. The long-term reliability of this device also needs more time to be determined.

Hydroflex is a unicomponent inflatable device introduced in 1985. When the pump which is located on the most distal portion to the prosthesis is compressed, fluid is transferred from the proximal reservoir into the expandable rigid inflatable penile shaft. Deflation is achieved by manipulating a deflation valve behind the inflation pump. The mechanical reliability of this device was good in early experiences (Mulcahy, 1988; Kabalin and Kessler, 1989), but Riehm et al (1993) reported the mechanical failure of 79% (11/14 patients) during a mean follow-up period of 58 months. Functioning time in these patients ranged from 0 to 53 months, with an average of 24.1 months. Six patients showed unilateral while 5 bilateral mechanical failure. Also in our experience, the Hydroflex showed high incidence of mechanical failure (18.3%; 6/32 patients) during a mean follow-up period of 94.5 months. Functioning time was from 0 to 100 months with an average of 50 months. This device was no longer marketed and its place has been taken by Dynaflex, a new self-contained inflatable penile prosthesis. The Dynaflex introduced in May 1990 is designed to compete with the flaccidity and rigidity

provided by a two-piece prosthesis. The rear tip extenders of the Dynaflex are tapered so the increased cylinder girth does not include difficult proximal placement. The Dynaflex possesses a longer and improved inflation pump than that of the Hydroflex. Prosthesis deflation is accomplished by holding the penis downward. We experienced mechanical failure rate of 2.4% (2/85 patients) for an average of 35.3 months. Functioning time in these 2 patients was 12 and 16 months, respectively. A long-term follow-up is also needed to determine the reliability of this device.

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