

## Ten Years of Experience with Various Penile Prosthesis in Korean

Hyung Ki Choi, In Rae Cho and Zhong Cheng Xin

Currently there are more than 10 types of penile prosthesis available, ranging from the very simple to the very sophisticated. We review our experiences with various penile prosthesis, with particular regard to the complication rate. From Dec. 1983 to Jul. 1993, we implanted 295 penile prosthesis of eight different types. The average age of patients was 44 years. Every patient was evaluated with various multidisciplinary diagnostic approaches. The etiologies of impotence were vasculogenic 29%, diabetogenic 22%, spinal cord injury 16%, pelvic bone injury 11%, etc. The types of implanted prosthesis were AMS malleable 143, Jonas 42, Dynaflex 36, Hydroflex 8, Uni-Flate 1000 2, AMS 700 CXM 58, Ultrex 3, Mentor alpha-1 3 and the mean follow-up period was 34 months. The diameters of implanted prosthesis were from 9.5 mm to 13 mm, mostly 9.5 mm (52.9%). The length of implanted prosthesis were from 10 cm to 20 cm, mostly 16~18 cm (68.8%). Cases with uneven diameters or lengths were 20 (6.8%). The intraoperative complications were 1 corporeal rupture and 1 bladder rupture, and the postoperative complications were 2 prosthesis infections, 2 mechanical failures, and 1 prosthesis infection with mechanical failure. In those 4 patients reimplantations were successful. More than 99% (290/291) patients still have functioning prosthesis.

Every prosthesis has their advantages and disadvantages. Factors to be analysed in the selection of proper prosthesis should include patients economic status, education, personality, social activity, hand dexterity, and penile size. So far, by our 10 years experience, we believe that 3-piece inflatable prosthesis especially AMS 700 CXM, which is designed to fit the oriental penile size, is excellent in quality and reliability.

**Key Words :** Penile prosthesis, complication, AMS 700 CXM

The first successful penile prosthesis implantation was performed using carved bone implanted in corpus cavernosum, rationale being os penis or baculum found in many mammals (Bretan 1989). After the development of the semirigid prosthesis made of silicone, currently there are more than 10 types of penile prosthesis available, ranging from the simple to the very sophisticated. Penile prosthesis implantation with improvements in

prosthesis and surgical skills can produce higher operative success rate and better satisfaction. It is highly acceptable mode of treatment in diabetic, vasculogenic, traumatic, and neurologic impotent patients and selected psychogenic impotent patients (Small *et al.* 1989; Montague 1989).

Every prosthesis has its advantages and disadvantages, with 1~2% possibility of complications such as infection (Brooks 1988; Kabalin and Kessler 1988; Radomski and Herschorn 1992). Thus the patient's need, level of education, age, economic status should be considered. We hereby reviewed our clinical experiences with prosthesis, with particular emphasis on the complications.

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## MATERIALS AND METHODS

From December 1983 to July 1993, 295 patients have penile prosthesis implanted after thorough multidisciplinary diagnosis and examinations and thus confirmed of having organic cause of impotence in the Sex Clinic in the Department of Urology, Yonsei University Hospitals in Seoul, Korea. There were 6 patients with repeated operations. The patient ages ranged from 20 to 78 with mean age of 44. The patient age groups comprise of 40's 86 (29.2%), 30's 84 (28.5%), 50's 61 (20.7%), 20's 36 (12.2%), 60's 21 (7.1%), 70's 6 (2.0%), 10's 1 (0.3%), mostly being in the 40's.

Except in the diplegic patients, the patient was under general or spinal anesthesia. The patients were shaved and scrubbed with povidone iodine solution for minimum of 20 minutes. Antibiotic solution containing an aminoglycoside and a cephalosporin, was used profusely according to the general surgical principles. In case of 3-piece prosthesis, physiologic saline was used as filling solution, and the reservoir was placed in the pelvic cavity after digital dilatation through the external inguinal ring. The pump was placed in the subdartos pouch of scrotum and a negative suction drain was inserted via newly made stab wound on the inguinal area of the opposite site of the reservoir. The urethral catheter was inserted before the incision and removed on the first day after the operation. Parenteral antibiotics were used beginning 24 hours before the operation and kept on through the seventh day. With monitoring white blood cell count the antibiotics were maintained for another 1 to 2 weeks.

After reviewing the hospital records, the cause of erectile failure, the prosthesis implanted, the length and size, the site of incision, operation time, intraoperative considerations, complications are reviewed.

## RESULTS

The etiologies of impotence were vasculo-

Table 1. Etiology of impotence

Etiology	No. pts.(%)
Vasculogenic	86(29.2)
Diabetogenic	66(22.4)
Spinal cord injury	48(16.3)
Pelvic bone injury	33(11.2)
Primary failure	20( 6.8)
Neurogenic	14( 4.7)
Iatrogenic	6( 2.0)
Idiopathic	8( 2.7)
Corporeal fibrosis	14( 4.7)
; Peyronie's dis.	5
Priapism	1
Paraffinoma	2
Reinsertion*	6

\*Reinsertion: include transferred 2 cases

genic 29.2%, diabetogenic 22.4%, spinal cord injury 16.3%, pelvic bone injury without spinal cord injury 11.2%, etc. The 6 iatrogenic cases composed of 5 patients who underwent radical cystectomy due to locally invasive bladder tumor, and 1 patient who received with rectal cancer. The 14 cases of fibrosis of corpus cavernosum composed of 5 cases of Peyronie's disease, one case of priapism, two cases of paraffinoma, and six repeated implant cases including 2 having received operations in other hospitals (Table 1).

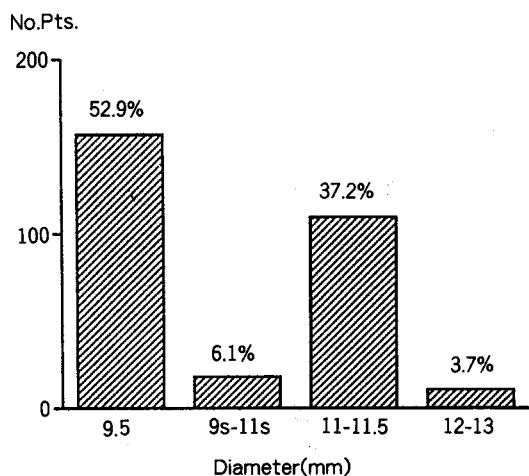
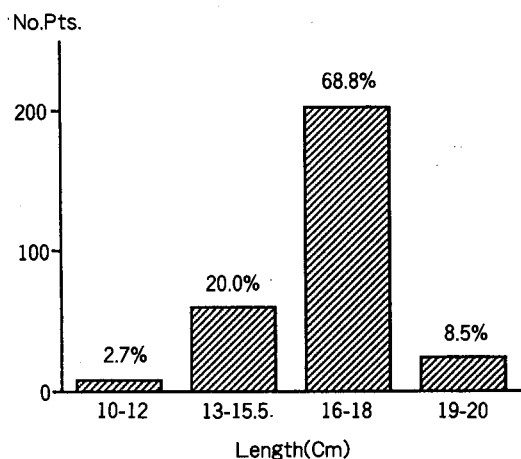
Malleable and self-inflatable type were implanted through scrotal or penoscrotal incisions, and 2-piece and 3-piece inflatable prosthesis were mostly implanted with penoscrotal or transverse scrotal incisions, and one case with 3-piece inflatable prosthesis was implanted through suprapubic approach.

The implanted prosthesis were 8 in types. Malleable 165 cases (AMS malleable 143, Jonas 42), self-inflatable 44 cases (Dynaflex 36, Hydroflex 8), 2-piece inflatable Uni-Flate 1000 2 cases, and 3-piece inflatable were 64 cases (AMS 700 CXM 58, Ultrex 3, Mentor alpha-1 3). The mean follow-up period was 34 months (Table 2).

Diameters were 9.5 to 13 mm and 52.9% were 9.5 mm and 37.2% were 11~11.5 mm (Fig. 1). The lengths were 10~20 cm range with 16~18 cm most commonly used (68.8%, Fig. 2).

**Table 2. Type and follow-up period of penile prosthesis**

Type	No.Pts.(%)	Average follow-up period
AMS 600	143(48.5)	3Yr 8M(7M-7Yr 11M)
Jonas	42(14.2)	3Yr 9M(3M-9Yr 9M)
Dynaflex	36(12.2)	2Yr 1M(4M-3Yr 3M)
Hydroflex	8( 2.7)	5Yr 9M(4Yr 11M-7Yr 3M)
Uniflate 1000	2( 0.7)	3Yr 3M(3Yr 3M)
AMS 700 CXM	58(19.7)	5M(2M-2Yr 5M)
Ultrex	3( 1.0)	1Yr 5M(11M-1Yr 10M)
Mentor alpha-1	3( 1.0)	2M(2M)
Total	295(100.0)	2Yr 10M(2M-9Yr 9M)

**Fig. 1. Diameter of prosthesis.****Fig. 2. Length of prosthesis.**

Cases with uneven diameters or lengths were 20 (6.8%). The causes of uneven diameters were vasculogenic 6, and others 2. In 18 cases the diameters were identical in spite of different length, and the differences were 0.5 cm 5, 1 cm 11, and 3 cm 2 cases. The two cases were spinal cord injury and diabetogenic cases. The two cases with different diameters were both cavernosal fibrosis patients. The patient with paraffinoma complication was treated with identical length and right 9.5 and left 11.5 mm in diameter, and one patient with priapism has respective diameter and length with right 11.5 mm 16 cm, and left 9.5 mm 13 cm.

There was 7 (1.7%) incidences of complication. The intraoperative complications were 1 corporeal rupture, and 1 bladder rupture and the postoperative complications were 2 prosthesis infections, 2 mechanical failures, and 1 prosthesis infection with mechanical failure (Table 3).

Case 1 was spinal cord injury patient inflicted for 16 years. He received Mentor alpha-1 implantation. During operation, a breaking sound was heard when modeling, and a 0.5 cc sized hematoma was developed at the glans but did not expand until the end of operation. The hematoma resolved at the fifth day and the patient was discharged at the seventh day. On the thirteenth day after the operation, the patient visited with complaint of penile hematoma, and immediately operated on. The diagnosis was the rupture of tunica albuginea at the right side of glans penis, and the treatment was consisted of primary closure of tunica albuginea.

Case 2 was a patient who had been treated after traffic accident due to bladder and large bowel perforation five years earlier, and had received a malleable type of penile prosthesis implantation two years before. The patient was dissatisfied with the prosthesis, and thus elected to have 3-piece inflatable. In the process of blunt dissection through left inguinal canal for a reservoir insertion, the bladder was ruptured thus the reservoir was inserted on the opposite side and a suprapubic cystostomy was made on the bladder.

Case 3 was a traffic accident patient who have received penile amputation, left orchiectomy.

Table 3. Complication cases

Pt. No.	Age	Type	Etiology	Complication	Interval to complication	Treatment	Comment
1	37	Mentor alpha-1	Spinal cord injury	Corporal perforation	2W	Primary closure	Intraoperative modeling
2	31	AMS 700 CXM	Pelvic bone injury	Bladder rupture		Suprapubic cystostomy	S/P Malleable penile prosthesis
3	31	AMS 600	Pelvic bone injury	Prosthesis infection	Rt. 6M Lt. 7M	Remove and 1Yr later reinsertion with AMS 700 CXM	Penile reconstruction with gracilis myocutaneous flap
4	30	AMS 700 CXM	Pelvic bone injury	Pump failure & scrotal hematoma	1W	Pump exchange with testicular prosthesis remove	S/P Lt. testicular prosthesis
				Prosthesis infection	4W	Remove and 8M later reinsertion with Jonas	1Yr later reinsertion with testicular prosthesis
5	36	AMS 600	Spinal cord injury	Prosthesis infection	8W	Remove	T11 complete paraplegia
6	50	Dynaflex	Vasculogenic	Rt. cylinder rupture Lt. fluid leak	15M ?	Remove and reinsertion with Ultrex	
7	45	Uniflate 1000	Vasculogenic	Pump failure	13M	Remove and reinsertion with Jonas	

tomy, and colon diversion 3 years earlier due to accidental penile amputation, and left testicular rupture, and anal external sphincter injury. He had received urethroplasty and penoplasty utilizing gracilis muscle flap in February of 1990, and have received malleable type penile prosthesis implanted 13 months later. Six months after implantation, the right side prosthesis had to be removed due to distal penile infection and skin erosion. The left side prosthesis removed one month later due to prosthesis infection. The patient received AMS 700 CXM, a 3-piece inflatable, which completed functional and structural rehabilitation.

Case 4 patient had received left orchiectomy and artificial testicle implantation due to pelvic bone fracture and left testicular rupture 6 months earlier. In January of 1991, he received a 3-piece prosthesis implantation under the impression of vasculogenic and neurogenic impotence. Hematoma persisted after 7 days, which required hematoma evacuation and removal of testicular prosthesis. The mechanical failure of pump was found and thus removed, and the prosthesis itself was removed 3 weeks later due to infection. A malleable type of prosthesis was implanted after 8 months, and a testicular prosthesis was implanted one year later. He still have functioning both prosthesis without any problem.

Case 5 patient had been suffering from complete paraplegia of thoracic 11th level spinal cord injury, and have removed prosthesis 8 weeks after implantation due to prosthesis infection. He could not be followed. In the case 3 and 4 the causative organism was *Staphylococcus* species, and in the case 5 the causative organism was not found.

Case 6 patient had received a Dynaflex prosthesis, which had an immediate mechanical failure on the left side, and the other side also fail to perform properly after 15 months. The diagnosis was mechanical failure of prosthesis. AMS Ultrex prosthesis was implanted after 20 months. On the operative field the previous prosthesis had ruptured right side and compressed left side.

Case 7 patient had received Uniflate 1000 prosthesis, which had pump failure after 13

months. He received Jonas type of prosthesis 22 months after the initial operation.

Thus, case 1 and 2 patients have well functioning prosthesis, and in the 4 out of 5 patients from case 3 to 7, reimplantation was successful. Except the case 5, more than 99% (290/291) patients are still having functioning prosthesis.

## DISCUSSION

In 1958, Beheri successfully implanted two separate polyethylene rods as intracavernosal rigid stents, and he reported excellent long-term results in his experiences with 700 patients in 1966 (Beheri 1966; Bretan 1989). Small and coworkers in 1975 described a surgical approach with a new type of paired sponge-filled silicone prostheses. In 1977, Finney introduced the Flexi-Rod prosthesis. Unlike the Small's device, this silicone prosthesis contained a hinge section to enable the prosthesis to bend. Subsequently in 1980 Jonas prosthesis enabled bending of the prosthesis into any position desired by making silicone rubber with a core of twisted silver wire. AMS 600 was developed by replacing silver wire with stainless steel wire (Dorflinger and Bruskewitz 1986). These two prostheses are the mostly commonly used non-inflatable malleable prostheses. To circumvent the problem of permanent erection, Scott and coworkers (1973) described their initial use of an inflatable implantable prosthesis composed of a pump, a reservoir, and a cylinder to control erection and flaccidity at will. The Mentor and AMS prototypes of inflatable prosthesis were reported to have mechanical failure rates of 50 %, but the improvements on the cylinder materials and connectors made possible of wide spread use of AMS 700 CXM, Ultrex, and Mentor alpha-1, etc (Wilson *et al.* 1988; Montague and Lakin 1992; Goldstein *et al.* 1993; Pescatori and Goldstein 1993).

The prosthesis are classified into 3 types in broad, malleable, hinged and inflatable. The inflatables are self-inflatable, 2-piece, and 3-piece types. Jonas and AMS are malleables,

DuraPhase and OmniPhase are hinged types. Self-inflatables are Hydroflex and Dynaflex, the 2-piece being Uni-Flate 1000, and the 3-piece inflatables are AMS 700 CXM, Ultrex, and Mentor alpha-1, etc (Montague 1989).

In Korea, the penile prosthesis implantation began in 1983, and there are considerable accumulation of experiences. Our department first utilized malleables, but recently have popularized the 3-piece inflatables (Chang and Choi 1987; Oh *et al.* 1990; Choi and Kim 1992; Cho *et al.* 1993).

The malleables have silver or stainless wire in the center, which enables the prosthesis bent during the coitus or voiding thus preventing protruding of prosthesis. However it is permanently erected, thus makes patient uncomfortable to be in the public bath, and mildly uncomfortable during the daily life. Even its shortcomings of not changing its length and width, it has the lowest complication rate, and easy to install and carries almost no complication. Its economic price and simplicity makes this type of prosthesis satisfaction over 80% (Dorflinger and Bruskewitz 1986; Cho *et al.* 1993).

The self-inflatable types of a pump, a cylinder, and a reservoir all built in one piece is easier to install than the 3-piece types. It is more natural than the malleables but it does not provide any increase in girth or length with inflation and has relatively high mechanical failure rates. The Hydroflex penile prosthesis was introduced for commercial distribution in 1985 but 5 years later this device was no longer marketed or available. The Dynaflex prosthesis was introduced in May 1990 but it has no reliable follow up reports. Due to superiority of 3-piece inflatables, self-inflatable types are almost abandoned currently (Montague 1989; Choi and Kim 1992; Riehm *et al.* 1993).

The 3-piece inflatable prosthesis has advantages of being most natural of all the currently available prosthesis. The inflatable prosthesis has innate diameter of 12 mm and can be inflated up to 18 mm, and Ultrex is even capable of elongation in length (Montague and Lakin 1992). With the disadvantage of operative correction in case of mechanical

failure, it is our experience AMS 700 CXM, Ultrex, and Mentor alpha-1 are the best prosthesis available today (Goldstein *et al.* 1993; Pescatori and Goldstein 1993). Especially, AMS 700 CXM is designed to fit the oriental penile size, and thus could be performed without difficulty in every Korean males. Since its introduction at our clinic two years ago, except only one early complication (Case 4 as started earlier) there has been no mechanical failure. Ultrex with its elongation capability, is suitable for bigger sized penis, and Mentor alpha-1 has its advantages in rigidity and easy pumping mechanism but its poor cosmetic outcome during the flaccid state is a major disadvantage compared to the AMS 700 CXM.

Thus every prosthesis has their advantages and disadvantages. Factors must be analysed in the selection of proper prosthesis, such as patient's economic status, education, personality, social activity, hand dexterity, and the penile size.

The 30's and 40's are the ages of the most patients who received implantation, which is lower compared to the other reports (Dorflinger and Bruskewitz 1986; Kabalin and Kessler 1988; Wilson *et al.* 1988; Montague and Lakin 1992). It is believed to be due to acceptance of loss of potency in the older age group, and our patient population included many of the traumatic impotence patients, especially after traffic accidents.

The etiologies of impotence were vasculogenic 29.2%, diabetogenic 22.4%, traumatic 27.5% (spinal cord injury 16.3%, pelvic bone injury without spinal cord injury 11.2%) (Table 1) which showed relatively lower incidence of vasculogenic and diabetogenic types (70-80%) and much higher incidence of traumatic (less than 10%) compared to previous reports (Brooks 1988; Radomski and Herschorn 1992).

The most recent report on 112 experiences with Mentor alpha-1 by Goldstein and 12 other board certified urologists in USA (1993) describes incision sites as prepubic 25, penoscrotal 34, and scrotal 41 cases. The solution used in reservoirs are physiologic saline in 73 cases and radiopaque material in 27 cases. We have used physiologic saline and applied penoscrotal incision in all of our cases

except one because it had no risk of injuring dorsal penile nerves and there was no technical difficulty in reservoir insertion.

The ready-made prosthesis are designed to fit average American males, which are large for Korean males especially in diameter, but there was no specific problem relating to length. The most commonly inserted prosthesis were diameter of 9.5 mm with 59% of total cases, which were available in Jonas, AMS malleable, and AMS 700 CXM. Other prosthesis are available in sizes larger than 12 mm in diameter. In USA the most commonly inserted size were 13 mm (Dorflinger and Bruskewitz 1986). The length of prosthesis were ranged 16-18 cm in 70% of cases, which is similar with other Korean (Oh *et al.* 1990) and overseas reports (Dorflinger and Bruskewitz 1986; Goldstein *et al.* 1993).

The reported intraoperative complications were corporeal rupture, bladder rupture, profuse bleeding, difficult dilatation, septal and albugineal perforation (Goldstein *et al.* 1993). In our series, cavernosal dilation was difficult in the cavernosal fibrosis patients, but there was no complication. And there were 4 cases of septal perforation, which required no specific therapy. There was no albugineal rupture or urethral injury, but one case of albugineal rupture during remodeling of prosthesis after implantation (Case 1).

Wilson (1992) described a straightening method of prosthesis implantation in Peyronie's disease by rupturing fibrous plaque after modeling. It carries 2% risk of urethral rupture. Our case of similar complication (Case 1) is performed by Dr. Wilson at our hospital with Mentor alpha-1 implantation. Thus a great care is necessary during modeling after implantation by always reminding of possibility of albugineal rupture.

Goldstein *et al.* (1993) described a series of 112 cases of implantation, and one case of adhesion in the vicinity of reservoir due to pelvic bone fracture. One of our patients had similar complication of bladder injury due to adhesion. The patient has unsatisfactory implantation of malleable prosthesis previously in other clinic. During the 3-piece type implantation, a great care was taken not to

injure perivesical space but due to severe adhesion, the bladder was ruptured during dissection. Immediate intraoperative cystogram was taken to evaluate the extent of the injury, and after confirming of minor degree of injury, a suprapubic cystostomy was done and other side was dissected to have reservoir implanted. It is due to severe adhesion after previous bladder and bowel rupture that resulted in bladder rupture during implantation (Case 2). Thus, a special care must be made in case of pelvic bone fracture or bladder rupture patients in 3-piece prosthesis implantation. If dissection is difficult or technically impossible, malleable or self-inflatable type could be chosen.

The post-operative complications are prosthesis infection, mechanical failure, SST (Super-Sonic Transport; Concorde) deformity, chronic pain, etc. (Kirkemo 1990) and the most serious complication is the prosthesis infection, which is reported to occur in 1 to 2% of cases (Montague 1987; Brooks 1988; Kabalin and Kessler 1988; Radomski and Herschorn 1992). In our series, 3 cases (1.0%) of infection was documented. The risk factors for infections are spinal cord injury, diabetes, reimplantation, simultaneous implantation of artificial urethral sphincter, redundant prepuce, and ileal conduit diversion (Thomalla *et al.* 1987; Kabalin and Kessler 1988; Radomski and Herschorn 1992).

The infection rate for spinal cord injury patients reported to be 10~20%, and these patients have decreased sensation on penis and increased incidence of urinary tract infection (Thomalla *et al.* 1987; Radomski and Herschorn 1992). We have observed 1 case in total or 48 cord injury patients (2.1%).

Diabetes were known to be susceptible to infections, from 15.6% (Bishop *et al.* 1992) to 2-3% in most reports (Montague 1987; Kabalin and Kessler 1988; Radomski and Herschorn 1992). It is currently no more of risk factor than other factors, and we have not seen any complication among 66 diabetes.

It is believed that simultaneous implantation of artificial urethral sphincter with penile prosthesis carries increased risk of infection (Thomalla *et al.* 1987). We have two urethral

injury in pelvic bone fracture patients of such problems, and implanted AMS malleable and AMS sphincter 800 separately with interval of 6 months each with different order of implant. The patients have well functioning prosthesis.

Reimplantation have reported increased risk of infection (Wilson *et al.* 1988), and was have not found such results in 6 of our cases. The type of prosthesis and the sites of incision are independent of infection (Montague 1987; Thomalla *et al.* 1987). In our series of patients, pelvic bone fracture patients had higher infection rates (6%, 2/33) than other patients. It is probably due to associated perineal or external genitalia injury which deters proper blood flow thus resulting in delayed wound healing. A special attention is advised in such patients.

The causative organism of prosthesis infection is *Staphylococcus* as reported by 56% of Kabalin and Kessler (1988) and 53% of Montague (1987). We reported 2 out of 3 cases (67%) of *Staphylococcus* infection.

The recommended treatment of implant infection is removal of prosthesis and reimplantation of another prosthesis after 3 to 6 months (Thomalla *et al.* 1987; Radomski and Herschorn 1992). In 2 cases of our three patients, the prosthesis were implanted after 12 months (Case 3) and 8 months (Case 4).

There were one paraplegia patient and two patients with pelvic bone fracture with infections, and the general and diabetic patients were free from infections. With accordance with general aseptic operating principles, the infection should not be a hassle. The general principles such as aseptic operating technique, perioperative antibiotic coverage, atraumatic shaving and cleansing, intraoperative antibiotic irrigation, and control of skin and urinary tract infection should be strictly observed (Thomalla *et al.* 1987).

The second most important complication is mechanical failure. In 110 inflatable cases, 3 cases (Case 4,6,7; 2.7%) had mechanical failure. AMS 700 CXM, Dynaflex, Uniflate 1000 each had one failures respectively. The AMS 700 CXM and Uniflate 1000 had pump failures, and reservoir leaking and rupture of cylinder was seen with one case of Dynaflex. The inci-

dence of mechanical failure is greatly varied by different series. Brooks (1988) described the rate of failure with Mentor 3-piece type of 17.6% among 51 cases during May 1983 to October 1984, 1.2% during November 1984 to November 1986. With recent improvements the complication rates are reported to be under 4% (Goldstein *et al.* 1993; Pescartori and Goldstein 1993) and we have not seen any complications after the Case 6 in February 1992.

There were six failure cases, one in the intraoperative and five with postoperative complications, thus making success rate of 97.9% (283/289), and among five postoperative complications and two transferred cases, reimplantation was successful in 6 cases, thus making success rate of over 99% (290/291). So we suggest that the strict adherence to the general surgical principles in choosing prosthesis lowers the failure rates and the postoperative complication rates.

In conclusion, so far by our 10 years experience, we believe that 3-piece inflatable prosthesis especially AMS 700 CXM, which is designed to fit the oriental penile size, is excellent in quality and reliability.

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