

Does tunica anatomy matter in penile implant?

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Background: Overall prosthesis survival is important in penile implant, which remains the final viable solution to many patients with refractory erectile dysfunction (ED). This paper is to retrospectively study the role of the anatomy of tunica albuginea (TA).

Methods: From March 1987 to March 1991 while the TA was regarded as a circumferential single layer, 21 organically ED men, aged from 27 to 77, received penile prosthesis implantation and were allocated to conventional group. From August 1992 to March 2013 while the tip of Hegar's dilator was categorically directed medial-dorsally during corporal dilatation derived from newfound TA as a bi-layered structure with a 360° complete inner circular layer and a 300° incomplete outer longitudinal coat, 196 ED males, aged from 35 to 83, underwent penile implant and were categorized to advanced group. The model of prosthesis was recorded. Prosthesis loss rate and survival time were analyzed and the follow up period ranged from 22.4-26.4 (average 24.3) years and 0.4-20.6 (average 15.8) years to the conventional and advanced group respectively.

Results: To the conventional and advanced group, the number of inflatable and rigid type prosthesis used were 2, 19 and 15, 181 respectively, whereas the prosthesis loss was encountered in 50.0% (1/2), 15.8% (3/19) and 0.0% (0/15), 0.6% (1/181) respectively. And the prosthesis survival time were 5.1-6.3 (5.7) years, 1.3-26.4 (15.2) years and 6.1-16.2 (11.2) years, 0.4-20.6 (15.3) years to the conventional and advanced group respectively. Statistical significance was noted on prosthesis loss in groups ($P=0.01$) while the Mentor Acuform stood out in prosthesis survival.

Conclusions: Anatomy-based managing maneuver appears to deliver better surgery success in penile implant. Tunica anatomy is significant in performing implant surgery.

Keywords: Tunica albuginea in human penis (TA in human penis); penile implant; prosthesis extrusion; prosthesis loss

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Introduction

The erectile rigidity of the human penis depends on sinusoids of the corpora cavernosa (CC) which function as a hydraulic system (1). It seems that the human CC are destined to encounter erectile dysfunction (ED), a kind of inability either to attain or maintain rigid erection for satisfactory intercourse (2,3). Interestingly the penis of every quadriceps is free of rigidity problem because it unexceptionally owns a rigid bone. It seems that human benefits nothing from penile evolution which advances

os penis (a rigid body) to human CC (hydraulic system) if rigidity speaks volume (4,5). Not surprisingly pursuits for penile rigidity appear eternally endless in human history. The development of penile implant may be a good example. An implanted penis may mitigate rigidity problem, unfortunately it may risk the single penis at the expense of compromising tissue integrity once the CC is implanted.

Although the introduction of phosphor-di-esterase-5 inhibitors has significantly changed the therapeutic modalities in ED since 1998 (6), penile implantation is still

the final viable solution to many patients with refractory erectile problem because it has been the best option to achieve reliable penile rigidity thus far (7). However, many candidates hesitate to this treatment because it is not natural and they are afraid of some unavoidable situations such as prosthesis loss, sinusoidal damage, revision surgery requirement, etc. Penile extrusion is one of the major concerns (8-10).

Modern intracavernous prosthesis has been available since 1950 (11). Both cylinders are the major components in each types of prosthesis including inflatable, semirigid and mechanical ones. The tunica albuginea (TA) is the envelop of the cylinders which preclude the penile shaft from too supple to provide sufficient rigidity for fulfilling intromission. The bi-layer structure of the TA was not elucidated as late as 1991 in the team of Lue (12). It was depicted as a 360° complete inner circular layer and a 300° incomplete outer longitudinal coat which varied much either the strength or thickness at specific anatomical locations (13). In particular, there is an exclusive inner layer in between the 5 and 7 o'clock positions of the CC, the border between the CC and the corpus spongiosum. This region is vulnerable to prosthesis extrusion due to a paucity of the tuck outer longitudinal layer (14). Thus the attending surgeon may have no idea of this. We subsequently regarded this new found TA as a blueprint and derived a manual dexterity of handling the Hegar's dilator medial-dorsally toward the distal ligament of glans penis during corporal dilatation in penile implant surgery. Herein we analyze our clinical outcome before and after this change in 1991.

Patients and methods

From March 1987 to March 1991 while the TA was regarded as a circumferential single layer, 21 organically ED men, aged from 27 to 77, received penile prosthesis implantation and were allocated to conventional group. From August 1992 to March 2013 while the TA was known as a bi-layered structure with a 360° complete inner circular layer and a 300° incomplete outer longitudinal coat (Figure 1), 196 organically ED males, aged from 35 to 83, underwent penile implant and were categorized to advanced group.

As a rule a circumferential approach was standard for semirigid, mechanical prosthesis such as AMS600, AMS650, AMS Dynaflex, Duraphase (Figure 2A), Mentor malleable, Mentor acuform; a penoscrotal incision was used for implanting AMS ambicor and an extend pubic approach

(Figure 2B,C) was specifically used for performing AMS700 CX implantation.

After the neurovascular bundle was protected, corporotomy was made on the CC (Figure 3A). Manual dexterity of handling the Hegar's dilator was the major difference in those patients between the conventional and advanced group. During corporal dilatation, the tip of Hegar's dilator was categorically directed medial-dorsally toward the distal ligament to avoid direct pressure on the region between the 5 and 7 o'clock position where the TA was composed of merely inner circular layer (Figure 3B,C). The intracavernosal pillars were kept lateral to both cylinders which have to be in the medial-dorsal positions, rooms one and two rather than rooms three and four (Figure 3D). After prosthesis was tailored to fit the CC, the corporotomy incision was closed with 6-0 nylon continuously with exact apposition of the TA and subsequently with interrupted sutures at each 2.5-cm interval for enhancement. The tubing system was fashioned and then the overlying fascia layers and skin were closed with 5-0 chromic suture layer by layer. The pain level was assessed with a 100-mm visual analog scale (VAS) at 2, 4, 8, 12 and 24 hours post surgery.

The model of prosthesis was recorded. Follow-up of patients including prosthesis survival, revision or end of patients' life till August 2013. An anterior-posterior view of pelvis was undergone whenever patient revisited for either re-check or close observation. Proximal migration occurred merely in patients with semirigid prosthesis implant in 2 and 15 men to conventional and advanced group respectively ($P=0.04$) (Figure 4). Furthermore the prosthesis loss and revision surgery were analyzed and made when required (Figure 5). Six males concerning the penile length underwent penile elongation uneventfully (Figure 2A). Statistically student's *t*-test or chi-squared test was either applied whenever necessary.

Results

General data of the 217 patients are summarized in Table 1. To the conventional and advanced group, the number of inflatable and rigid type prosthesis used were 2, 19 and 15, 181 respectively, whereas the prosthesis loss was encountered in 50.0% (1/2), 15.8% (3/19) and 0.0% (0/15), 0.6% (1/181) respectively. Among them three men requested prosthesis removal and was excluded from statistical analysis. And the prosthesis survival time were 5.1-6.3 (5.7) years, 1.3-26.4 (15.2) years and 6.1-16.2

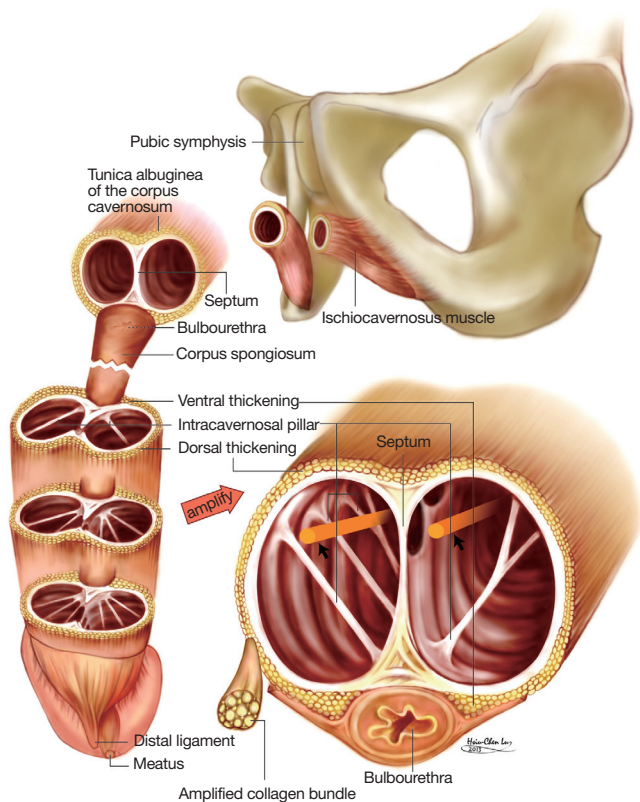


Figure 1 Schematic illustration of the fibrous skeleton in the human penis. The tunica albuginea of the corpora cavernosa (CC) is a bilayered structure in which the inner circular layer completely contains the sinusoids and, together with the intracavernosal pillars, supports them. There is a paucity of outer layer bundles at the region between the 5 and 7 o'clock positions where there is close contact with the corpus spongiosum. Distally, they are grouped into the glans penis forming the distal ligament, located at the 12 o'clock position of the distal urethra. The median septum is incomplete with dorsal fenestration at the pendulous portion of the penis and is completed where the penile crura are formed.

(11.2) years, 0.4–20.6 (15.3) years to the conventional and advanced group respectively. Statistical significance was noted on prosthesis loss ($P=0.01$) and proximal migration ($P=0.04$) in groups while the Mentor acuform stood out in prosthesis survival. Overall loss of penile length and coldness of glans penis were frequently complained by patients, 61.9% (13/21), 59.7% (117/196) and 61.9% (13/21), 65.8% (129/196) to the conventional and advanced group respectively regardless of prosthesis model. Cylinders swinging in the CC was common, which was relevant with the semirigid models and was 19.0% (4/21), 12.8% (25/196) to the conventional and advanced group respectively. One

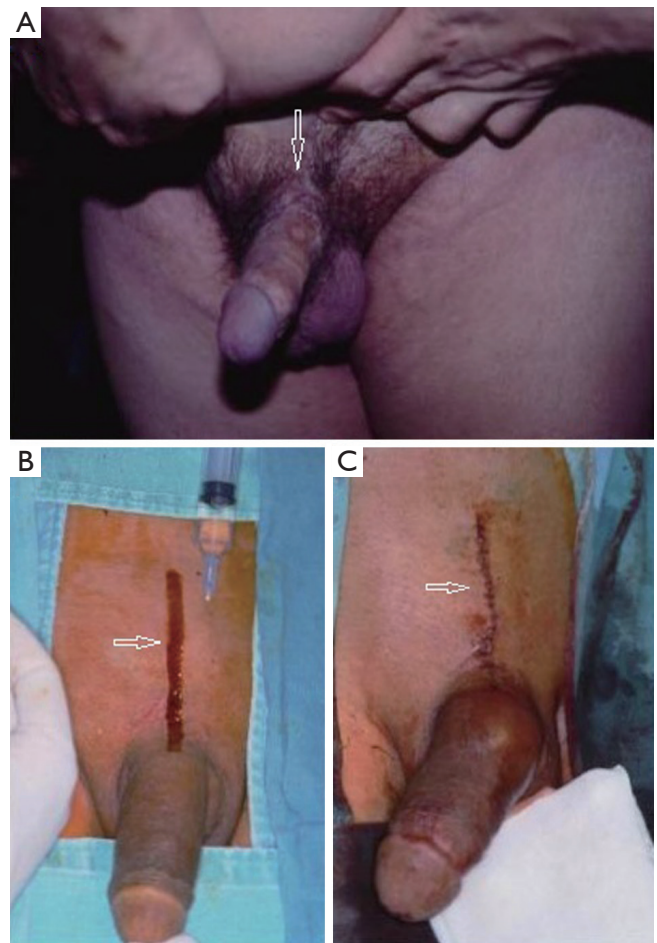


Figure 2 Photos of approaches for penile implant. (A) A circumferential approach was used for a 52-year-old diabetic male for implanting Duraphase. Note a further penile elongation (arrow) was revised owing to noticeable loss of penile length; (B) an extended pubic incision was marked (arrow) and prepared for implanting an AMS700CX in a 57-year-old man; (C) the penile implant was finished while the wound was fashioned (arrow).

diabetic patient (4.8%) had prosthesis extrusion due to infection. The score of VAS varied from 11 to 45 mm with an average of 20.3 ± 11.1 mm.

Discussion

Penile implant has been rising although a temporary weaning down at the early beginning in the era of medical treatment of ED. It is exemplified in the states that the number of patients undergoing a penile prosthesis increased from 17,540 in 2000 to 22,420 in 2009 (7), implying this surgical intervention remains a viable solution. It is a common surgery

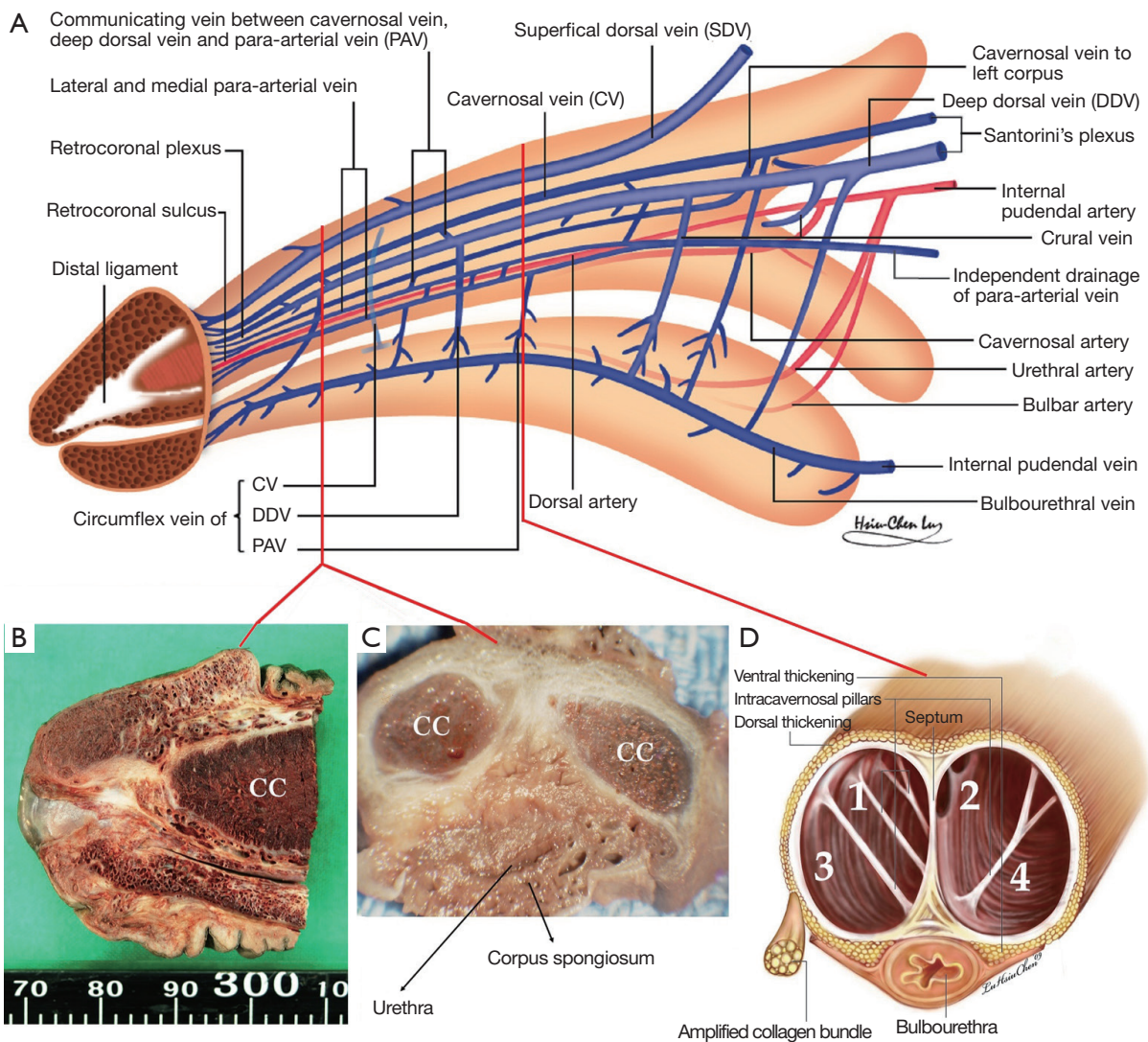


Figure 3 Illustration and photos of the related architecture for penile implant. (A) Vascular distribution of human penis in relation to the fibrous skeleton which is majorly composed of tunica albuginea. Note the distal ligament which is stout and strong; (B) A median section of the distal penis discloses the relation of the tunica and corpora cavernosa (CC). A thicker tunica on the dorsal aspect is pronounced, whereas a much thinner coat is noted on the ventral aspect. Note the large distal ligament; (C) A cross section of the distal CC. A paucity of outer longitudinal layer was characteristic between the five and seven o'clock positions which is much thinner and spreads out distally; (D) Illustration of cross section of mid-portion of the TA. The relationship between the TA and intracavernosal pillars was depicted. The room one and two are sound to house the prosthesis cylinder, but neither room three nor room four.

in the ED professional field. Thereafter it may be regarded as an easy surgery. It may deserve re-evaluation because many complications are still to be improved. Biomedical engineering improves the prosthesis coat, envelope, as well as the inner materials, interior design. Thus current ED males enjoy the advantages from biomedicine. However, the architecture of its envelope-to-be—TA was not underpinned in surgeons' mind until 1992. Does improvement result from

this elucidation? Further study is warranted.

The loss of length and glans coldness appears unavoidable. Fortunately many patients do not care much once the rigidity difficulty is mitigated. However, some males concern much on the condition that one's preoperative erectile length is no longer than 10 cm. Penile enhancement may benefit this situation (15,16). This management is proved to be a viable option because a postoperative retraction of the penile shaft

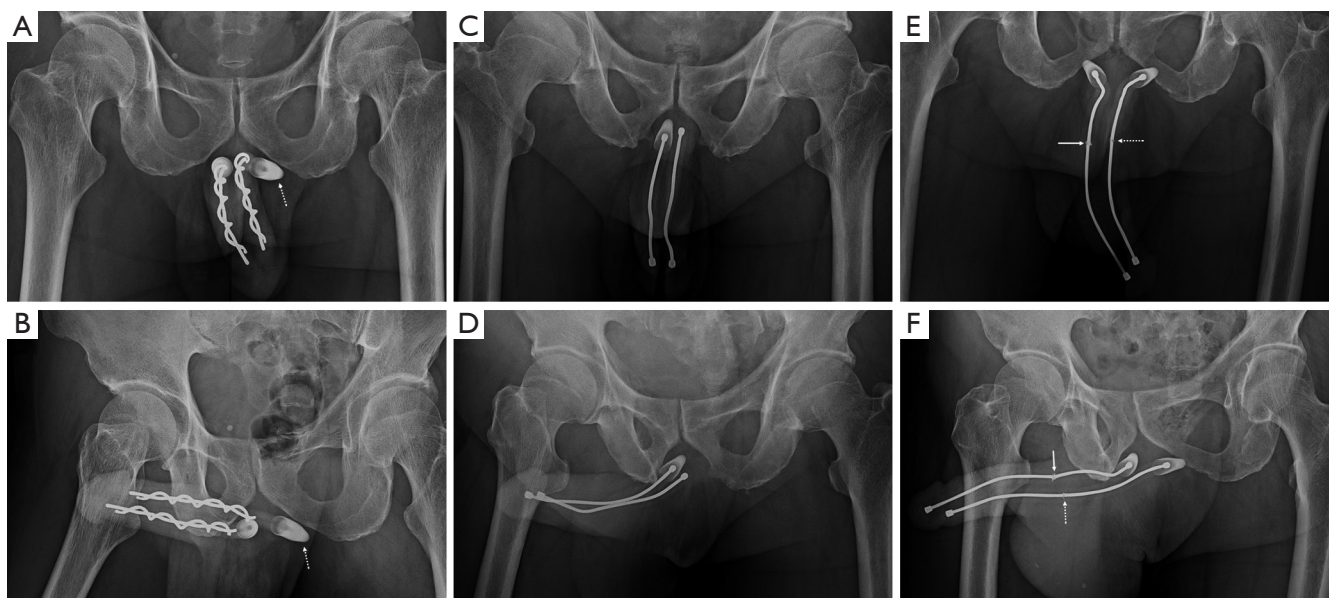


Figure 4 X-ray films of penile prosthesis *in situ*. (A) An AP view discloses a distal migration (left, dotted arrow) of an acuforn prosthesis in a 76-year-old male; (B) oblique view offers a clearer demonstration. Note the extender (dotted arrow) migrates proximally. Oblique view offers a clearer demonstration. Note the extender (dotted arrow) migrates proximally; (C) an AP view of an AMS600 discloses a discrepancy of bilateral CC length in a 66-year-old diabetic man. Note his left cylinder wears no extender and a dilatation could not reach to the ischial tuberosity; (D) oblique view gives a clearer demonstration which shows wider gap between the wire and the ischial tuberosity; (E) an AP view of an AMS600 discloses a wire ready to disruption (dotted arrow) in an 86-year-old diabetic man. Note his CC is symmetrical length; (F) oblique view shows a clearer demonstration which shows the penis is unable to remain neutral position. AP, anterior-posterior; CC, corpora cavernosa.

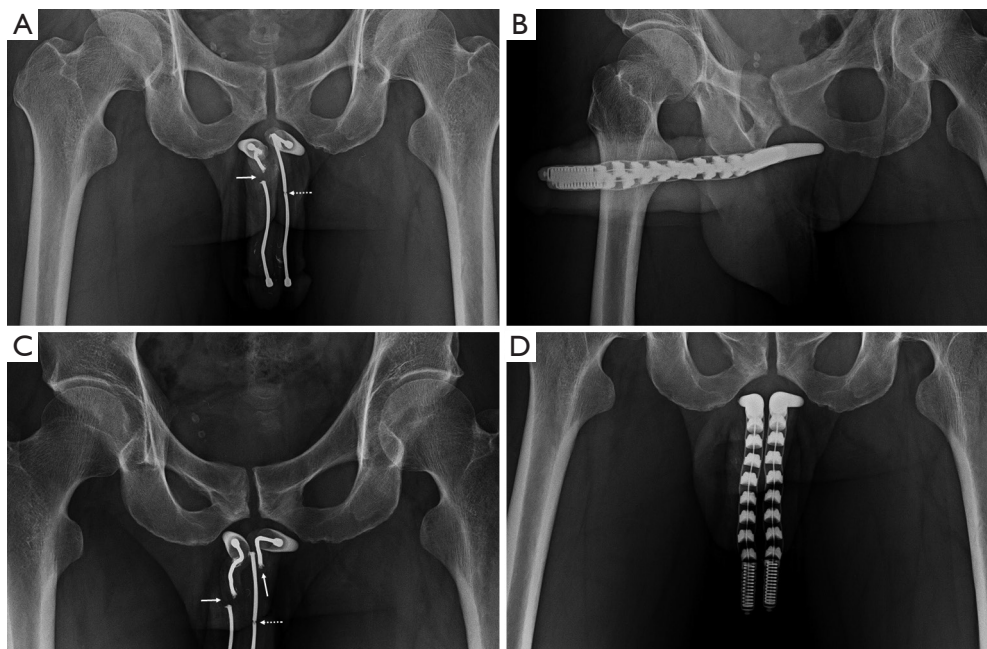


Figure 5 X-ray films of a 45-year-old male with penile prosthesis. (A) An AP discloses a complete disruption (arrow) of the right wire and an incomplete disruption of the wire (dotted line) in the left side both side cylinder in an AMS600; (B) however in an oblique view, the wire of left CC is complete disrupted (arrow), in the left side, there is a complete disruption (arrow) in addition to the incomplete disruption (dotted arrow); (C) a revision surgery was performed for implanting a Spectra prosthesis. This AP view discloses a sound implantation; (D) this oblique view further demonstrates prosthesis in good fashion. AP, anterior-posterior; CC, corpora cavernosa.

Table 1 Summary of 217 patients whom underwent penile implantation since 1987

Prosthesis model	No. of patients		Loss of length		Coldness of glans penis		Proximal migration		Prosthesis loss		Cylinders swinging	
	C ^b	A ^b	C ^b	A ^b	C ^b	A ^b	C ^b	A ^b	C ^b	A ^b	C ^b	A ^b
AMS600	5	41	3	23	3	23	0	3	1	0	1	8
AMS650	0	18	0	10	0	11	0	1	0	0	0	3
Duraphase	6	27	3	15	3	17	0	3	1	1 [1] ^c	1	1
Acuform	3	45	2	27	2	26	0	4	0	0	1	5
Malleable	5	42	3	28	3	27	2	4	1	0 [2] ^c	1	7
Spectra	0	8	0	4	0	5	0	0	0	0	0	1
Dynaflex	2	4	2	3	2	3	0	0	1	0	0	0
Ambicor	0	8	0	5	0	5	0	0	0	0	0	0
AMS700	0	3	0	2	0	2	0	0	0	0	0	0
Total	21	196	13	117	13	129	2	15	4	1 [3] ^c	4	25
P-value ^a	NA ^b		NS ^b		NS ^b		0.04		0.01		NS	

^a, univariate comparisons were performed using the student's *t*-test for parameters with continuous values and chi-squared test for continuity with discontinuous parameters as necessary; ^b, C, A, Na, Ns stand for conventional, advanced, not applicable and not significant respectively; ^c, this number was those patients who request removal of prosthesis despite the implant was intact *in situ*.

could be immune owning starched CC existing. We are looking for larger sample.

Although it seems occur in semirigid prosthesis, a proximal migration of implanted cylinders is one of the challenging issue in this study. Anatomy-based surgery prevents vulnerability of cylinder loss from distal CC and also enhances the prosthesis survival. A proximal migration appears uncommon in particularly once an implant male enjoy sex with female up position despite the patient is well informed preoperatively. A softer cylinder should be preferred if inflatable prosthesis is free from this issue. Could a further design sole this issue?

In this series, three males requested prosthesis removal despite the prosthesis was in good shape. Two older patients presented the reason that they prevented the disclosure of the implant to younger generation when deceased. A 57-year-old man, however, complained that the space occupying of implanted cylinder prevent the urethra from smooth patency in early 80s. Subsequently we advise to use as smaller cylinder as possible. It may contribute to many males presenting cylinder swinging within the CC. In our long term observation this may not be harmful. We therefore hesitate to agree the implant policy that a larger cylinder ought to be use (17).

The intracavernosal pillar originates from the inner circular layer of the TA and distribute from 2 o'clock or 10 o'clock to 6 o'clock positions. It acts much similar

a strut in an aircraft wing and are fundamental to the structural integrity. During dilatation of the CC in preparing space for housing a prosthesis cylinder, it together with sinusoids may suffer from damage if a Hegar's dilator tamps the CC fully. We therefore keep the dilatation as little as possible. The direction of the dilator is directed a little medially and dorsally to the distal ligament which is stout and strong.

In conclusion, we presented our experience of using this techniques in penile implant based on newfound anatomy. It offers an encouraging outcome although further evidences are still to be supplied.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: It is an extension of the clinical application of an approved institutional review board of China Medical University and all patients received informed consent.

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