Opinion

Twenty-five years of the low-cost, noninflatable, Shah Indian penile prosthesis: The history of its evolution

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January 26, 2021, marked the 25th anniversary of implantation of the first Indian penile prosthesis. The prototype that was implanted was a pair of simple silicon rods; the patient was a 28-year-old school teacher who had failed to consummate his marriage due to severe erectile dysfunction, and had not benefited from intrapenile injections and venous ligation surgery (this was in 1996– the pre Viagra® era). After the implant surgery, he was able to have successful intercourse, fathered two daughters and was going strong 10 years later. Since then, the Shah Indian penile prosthesis has evolved through many models to reach its present form which is currently the most commonly implanted penile prosthesis in India (1098 implants were sold between January 2016 and January 2021, as per company sales figures). Presented here is the evolution of the Shah Indian implant so that an understanding of the various modifications may help optimize the utilization of this implant.

THE NEED AND THE PROTOTYPE

When I started my andrology practice in 1990 penile prostheses were not available in India. The ever innovative Dr. D. D. Gaur had brought an assortment of implants from his trips abroad and would pull out an appropriate size during surgery, autoclave it and then implant it. To save cost, he would often implant only one side and even published his results recommending a single implant.[1] Cost continued to be a major barrier when penile prostheses were finally imported into India and the majority of men whom I advised a penile prosthesis could not afford it (even at Rs. 24000 in those days). That led to the quest for some indigenous device that could be used to help these desperate men.

The initial goal was very limited – I was just looking for a plain silicon cylinder that could be implanted in the penis, and I approached plastic surgeons, silicon importers, and other device manufactures. None could help. Then, I came across the Chhabra Hydrocephalic shunt which was being manufactured in India by a company called Surgiwear in a remote factory in Uttar Pradesh. This was a fairly complex silicon device and I thought that if they could make this, they should be able to provide me with a silicon rod. I contact their managing director who happened to be a surgeon and an alumnus of King George Medical College, Lucknow. Dr. G. D. Agarwal was interested and promised to work with me on it, but another 2 years passed because their factory was being upgraded. Then, in 1993, he contacted me and after mutual discussions he provided me with a simple silicon rod [Figure 1a], similar to the small-Carrion implant, but stiffer. This is the device that was implanted in the first 3 patients over a 1 year period while we studied their outcomes.

LENGTH ADJUSTMENT OPTIONS

As more patients came up for surgery, we realized that a large inventory would be needed to match different penile lengths. To reduce this need, the next model was designed to have an adjustable length. The implant had a hollow distal tip in to which a rounded plug would fit [Figure 1b]. The hollow segment was 3 cm long and could be cut to reduce the length as required. This was quite an ingenuous solution but restricted the length adjustment to a maximum of 3 cm. Hence, another version was developed in which the proximal end was made trimmable with grooves every 0.5 cm [Figure 1c] and a rear tip cap to round the end after it had been trimmed. The trimmable segment was 8 cm long and thus this single implant could be adjusted to any length.

HAVING THE CAKE AND EATING IT TOO

The hardness of elastomers like silicon is measured using the Shore Durometer test.[2] Soft silicon has a low Shore score while stiff silicon has a high Shore value. Our initial implant was made of moderately stiff, Shore A 50, silicon; this gave adequate stiffness and manageable concealment, but we wondered whether we could increase the stiffness and yet improve the ease of concealment.

Thus was born the concept of a differential rigidity implant. We designed a new implant combining silicon of different stiffnesses [Figure 1d]: There was a tip of very soft silicon (Shore A 10) to reduce risk of perforation, an anterior segment of very stiff silicon (Shore A 70) to provide

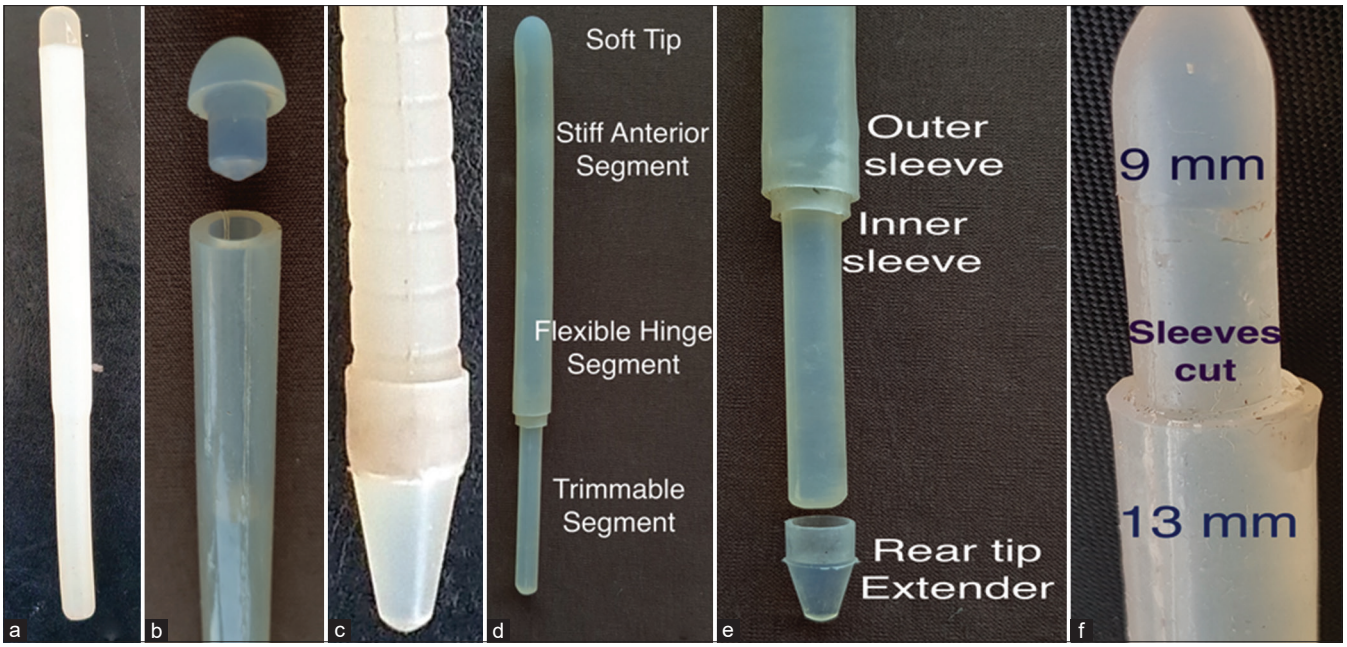

Figure 1: Evolution of the Shah penile prosthesis. (a) Silicon rod prototype. (b) Distal hollow trimmable segment. (c) Proximal trimmable segment. (d) Differential rigidity implant. (e) Double sleeves. (f) Selective distal sleeve removal

rigidity to the penile shaft, a central 5 cm zone of soft silicon (Shore A 25) to act as a flexible hinge at the base of the penis for concealment, and a moderately firm (Shore A 50) posterior crural segment that could be trimmed and fitted with rear tip extenders.

This design worked well – there was good stiffness once the base was supported during insertion and there was good concealment when the implant was sized so that 2–3 cm of the hinge protruded beyond the symphysis. Therefore, we had to create a range of implants of different sizes so as to achieve an optimal fit in penises of different lengths. Based on our clinical experience, we opted for 4 models which differed in the length of the anterior stiff zone.

To make it easy for the surgeon, the models were numbered to match the stretched penile length (SPL) from symphysis pubis to mid glans. Thus, with hinge (WH) WH09 was meant for a SPL of 9–10 cm and had a 7 cm anterior stiff segment followed by the hinge segment. WH11 was meant for a SPL of 11–12 cm and had a 9 cm stiff segment followed by the hinge segment. Moreover, there was WH 13 for a SPL of 13–14 cm with 11 cm of stiff segment, and WH15 for SPL of 15 cm and above, with a 13 cm stiff segment.

The original nonhinged model was also retained with the code OH01 (OH– nO Hinge) and was recommended for short penises (<9 cm) which had insufficient length for adequate hinge action, and also for very fibrosed corpora where there was marked discrepancy in the length of the two corpora, requiring implants of different lengths, since OH01 could be shortened by being cut anywhere without concern for hinge action.

ADDITION OF SLEEVES

The initial implants were 11 mm in diameter and seemed to fit most patients well. However, we observed that over time, the corpora relaxed around the implant, and if the implants were loosely fitted to start with, they tended to wobble within the corpora, resulting in instability. Hence, arose the need for implants of different diameters. Making different diameters for all four models would have resulted in a large inventory which would have increased cost and affected availability and we thought of adding a removable sleeve to the implant. The sleeve could be cut and removed to reduce the diameter of the implant by 2 mm.

This proved very useful but we found that the best results were obtained when the implant was fit snuggly in the corpora, and an even wider range of diameters was needed. Hence, we thought of having two removable sleeves [Figure 1e]. Removing only the outer sleeve would reduce the diameter by 2 mm, and removing the inner sleeve would reduce the diameter by an additional 2 mm. Thus, a single implant could go from 13 mm to 11 mm to 9 mm in diameter (in models WH09 and WH11) or from 15 mm to 13 mm to 11 mm (in models WH13 and WH15).

Having two removable sleeves was a new idea that had never been implemented before and we frequently faced the problem of the sleeves sticking together. Numerous modifications were made to try and solve the problem. Finally, in the current model, the problem has been solved by making the sleeves out of different grades of silicon and making the outer sleeve a little looser. Till today,

this is the only noninflatable implant in the world that offers the flexibility of two removable sleeves. It is also the only semi-rigid implant available in a 15 mm diameter (for models WH13 and WH15).

A unique advantage of the double sleeves became evident with further use. In many patients (50% in our experience), the tip of the corpus is significantly narrower than the main penile shaft. Thus, frequently, it will be found that the shaft can accommodate a wide dilator up to the level of the coronal sulcus, but only a narrower dilator is able to reach the tip of the corpus in mid glans. In this situation, if one uses a wide implant to get a good fit in the corpus then it will not reach the distal end, and the glans will be unsupported and floppy. If a narrower implant is used then the glans will be well supported but the implant will wobble in the corpora resulting in insufficient stability and rigidity.

With the two sleeves on the implant, it became possible to achieve both goals by selectively removing the distal 2–3 cm of the sleeves through a circumferential incision. This makes the distal part of the implant 4 mm narrower in diameter than the rest of the implant [Figure 1f]; the narrow segment fits well in the glans while the remaining wide implant will fit well in the shaft.

SPECIAL ADVANTAGES IN DIFFICULT SURGERIES

The implant has proved very versatile in dealing with complications or difficulties during surgery. Since there is no steel core, a suture can be safely placed through the implant. Hence, when there is a corporal perforation one can position the implant correctly, away from the perforation, and fix it to the tunica with a couple of sutures. This will prevention migration of the implant and allow the perforation to heal.

Again, because there is no metal core in the implant it can be cut anywhere. Thus, when dilating very fibrous corpora, if one side can be only partially dilated then one implant can be cut at any level to fit the shorter corpus. Similarly, if there is a segment of a corpus that cannot be dilated adequately then a segment of the implant can be shaved to narrow it selectively so that the tunica can be closed over it without the need for a patch.

A THINKING IMPLANTER'S IMPLANT

However, there is one major disadvantage of this hinged implant – it has to be used intelligently by a surgeon who understands its design. The original non-hinged model was a simple, one-size-fits-all, implant that needed no planning. Most malleable implants in the market are like that. However, the Shah implant with hinge requires the surgeon to understand how the implant functions. He needs to choose the implant model correctly, as per the patient's penile length, so as to obtain optimal rigidity and flexibility. The corporal diameter has to be accurately measured so that the widest implant can be placed and sleeves removed only as necessary. Error in choosing the correct model, or in adjusting the sleeves, would result in failure to benefit from the special features of this implant and could result in inadequate rigidity or poor concealment.

However, correctly and intelligently used, the Shah Indian penile prosthesis gives very satisfactory results[3,4] and has helped make implant therapy accessible to many men who otherwise would have remained untreated.

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