DEVELOPMENT AND INITIAL EVALUATION OF A VAS DEFERENS VALVE

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Summary: In 17 cases of vasectomy, the external diamter of vas deferens was found to be 2.07 ± .27 mm (Mean ± S. D.) with a range from 1.7 to 2.8 mm. The internal diameters were 0.93 ± 0.13 at 5 g and 1.24 ± 0.16 mm at 100 g insertion force applied to the measuring cone, with lumen ranges from 0.7 to 1.2 and 1.0 to 1.7 mm, respectively. The left-right variations in the same individual were of a similar order as between different individuals.

Measurements in 6-10 *kg* rhesus monkeys revealed an internal vas diameter around 0.6 mm with the measuring cone only eased in. At considerably high pressure the vas could be distended to show an internal diameter around 1 mm. The external diamters ranged from 1.5 to 2 mm. Local application to the vas *in vivo* or *in vitro* of alpha or beta adrenergic blocking agents, and sodium nitrate had no appreciable effects on the diameters.

Three types of valves were developed and tested. The tap-like and the rotary valves were not satisfactorily leak-proof. But the valve with stop-cock mechanism was found to be satisfactory. It was further tested by examining the ejaculate obtained by the method of electro-ejaculation after implanting the valve in the monkey vas. The stop-cock valve is being proposed as a working model for producing reversible vas-occlusion.

Key Words : vas deferens vas valve reversible vasocclusion

INTRODUCTION

Vasectomy, a simple surgical procedure, (13) is the most common operation in elective surgery as an effective and permanent form of family planning in many countries. In India 2.5 million vasectomies are proposed annually(16). The figure for vasectomies in the U.S.A. approached 1 million in 1972 (1). With increasing popularity of the operation the number of people desiring to have their vasectomy reversed is also increasing (14). Interest in reversible vasocclusion has been growing in view of its usefulness as a simple means of birth control as also for child spacing through repeated "on" and "off" positioning. Several approaches are conceivable, e.g. the plug, (18) the clip, (15) and the valve (14). We pursued the latter approach of a vas valve which holds the promise that once implanted it can be operated repeatedly through the intact scrotal wall by either the bearer himself or the physician.

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Diameter of the vas lumen:

From 17 vasectomy patients about 1/2 cm long piece of vas deferens was excised about 2-3 cm above the upper poles of the testes in each case and internal diameter measurements were made with the help of a measuring cone mounted on a spring balance (Fig. 1). With the help

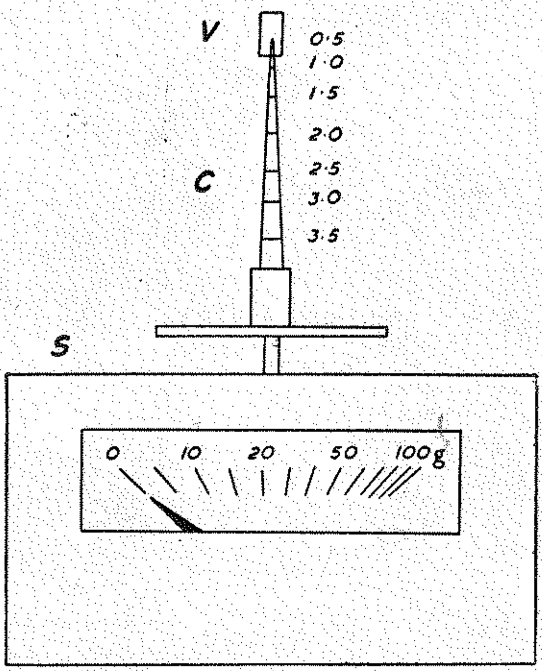

Fig. 1: Device for measuring the vas diameters consisting of a metallic cone mounted on a spring balance having a scale of 0-100 g. The cone has a rounded tip with a diameter of 0.5 mm and markings on its surface indicate diameter increments at successive steps of 0.5 mm.
V = vas, C = metallic cone, S = scale

of this apparatus it was possible to measure the vas diameters at different forces of cone insertion. For the purpose of uniformity two force levels i.e. 5 *g* and 100 *g* were chosen for these measurements. The external diameter was estimated by comparing the vas width at the middle of the excised piece with the same measuring cone by placing it behind the cone.

Measurements of the human vas deferens are shown in Table I. The external diameter ranged between 1.7 and 2.8 mm with a mean value of 2.07 ± 0.27 mm, and the internal diameter at 5 *g* had a mean value of 0.93 ± 0.13 mm, while at 100 *g* it was 1.24 ± 0.16 mm. Left right variations of vas diameters were also measured in the rhesus monkey (6-10 *kg* weight) after obtaining the vas from a place where the scrotum joins the abdominal wall. These measurements around 0.6 to 0.7 mm with the cone just eased in. The external diameters ranged from 1.5 to 2 mm.

TABLE I: External and internal diameters of human vas deferens*.

Subject No.	*External diameter*	*Internal diameter* 5 *g*	100 *g*
01	2.3	0.9	1.3
	2.2	1.0	1.2
02	1.9	1.1	1.4
	1.9	1.2	1.45
03	2.6	1.0	1.3
	2.6	0.9	1.2
04	2.3	1.1	1.7
	2.3	1.1	1.6
05	1.8	1.0	1.3
	2.1	0.9	1.2
06	1.8	0.8	1.0
	1.6	0.9	1.15
07	2.2	1.2	1.5
	1.9	1.0	1.35
08	2.0	0.75	1.0
	1.9	0.9	1.2
09	1.9	1.0	1.35
	1.7	1.1	1.35
10	2.1	0.8	1.15
	2.2	0.8	1.1
11	2.0	0.8	1.1
	1.9	0.9	1.15
12	1.8	0.9	1.1
	1.7	1.0	1.2
13	2.3	0.9	1.2
	2.8	0.8	1.1
14	2.2	0.8	1.25
	2.2	0.9	1.3
15	2.1	0.8	1.2
	2.2	0.9	1.2
16	2.0	1.0	1.25
	2.1	1.0	1.25
17	2.0	0.8	1.05
	1.7	0.7	1.05
Mean ± SD :	2.07 ± 0.27	0.93 ± 0.13	1.24 ± 0.16

*All measurements in mm; 5 g and 100 g of internal diameter columns indicate measurements after an insertion force of 5 gram and 100 grams applied towards the longitudinal axis of the measuring cone. First line against each subject shows measurements of the left vas and second line those of the right vas.

These findings evidently have a bearing on the valve design. Thus, in order to fit snugly into vas lumina of different sizes in the human the connecting endpieces of valves should ideally have an external diameter range of 0.7 to 1.2 mm at 0.1 mm increments. For use in the monkey the external endpiece diameter should similarly correspond to the vas measurements made in the monkey.

Development of the valve and initial evaluation:

Choice of Material: Teflon (Poly-tetrafluoroethylene) was used for constructing the valves because it hardly produces any tissue reaction due to its chemical inertia. It is light but hard enough to retain its shape and render it machinable and has enough resilience to compensate microscopic surface irregularities left even after careful manufacture, which greatly facilitates obtaining of leak-proof models. Teflon has low coefficients of friction and anti-stick characteristics (9) which is a built-in guarantee against the device getting stuck at any time.

In the human where the vas has an internal diameter of 0.9 mm or above an all Teflon model is feasible. However, Teflon tubings having an external diameter of less than 0.9 mm and an internal diameter of about 0.4 mm are not only difficult to machine, they are also very soft. The rhesus monkey vas allows insertion of the valve endpieces having an external diameter not more than 0.6 mm. Therefore, for use in the monkey, stainless steel tubings of appropriately graded sizes were employed for making the valve end pieces.

The different valves and their components were drilled and turned on a watchmaker's lathe under visual control through an operating microscope.

Development of Valves. Several designs were tested. A tap-like valve with a lever was discarded as too clumsy. Its follower was a rotary valve as shown in Fig. 2 (left side diagrams). No separate lever is necessary to turn this rotary valve in the "on" or "off" position as one of the endpieces itself serves as a lever for actuating the device. Furthermore, with a view to employment in the human later on, a kink of about 30° in the otherwise fairly straight vas deferens would easily be palpable in the intact scrotum to discern clinically the "on" or "off" position after surgical implantation of the device. The overall dimensions are of such an order that the "on" or "off" position can be brought about by manipulation through the intact scrotum. However, no leak-proof model of this design was obtained with the technology available to us.

The third type of valve had a stop-cock design (Fig. 2, right side diagrams). With the central plunger down the device it is in the "open" position (Fig. 2, top right), the circular groove in the plunger connecting the ducts in the either side of the valve body. With the plunger up (Fig. 2, bottom right) the valve is in the "closed" position, and the smooth circular plunger fits tightly into the round vertical canal of the valve body and prevents fluid from going from one end of the device to the other.

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Ind. J. Physiol. Pharmac.

On palpation the rounded appearance of the top of the device and the cornered appearance of its bottom indicates the "open" position, and the prominent rounded appearance on the top and an even surface at the bottom signified the "closed" position (Fig. 2). With these

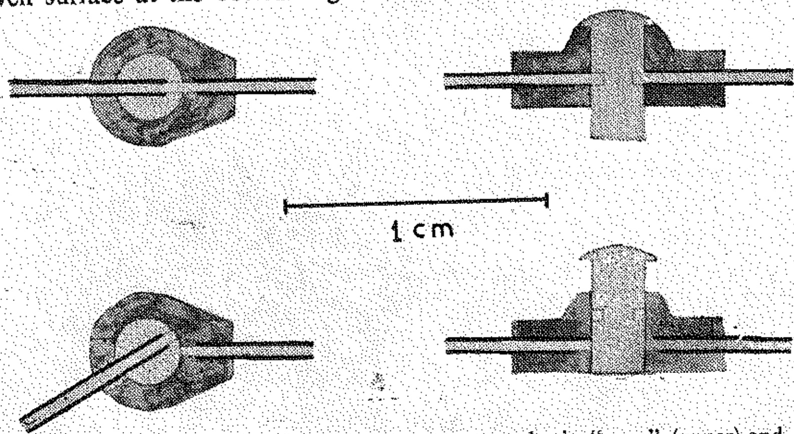

Fig. 2: Left side diagrams show the scale drawings of a rotary type valve in "open" (upper) and "closed" (lower) positions. Right side diagrams show the sections through a stop-cock type valve in the "open" (upper) and "closed" (lower) positions. Markings on the plunger indicate the circular groove.

indications it should be quite easy to palpate the device though the intact scrotum after implantation, and to check whether it is in the "open" or "closed" position. For implantation in the monkey stainless steel tubes (0.55 mm outer diameter and 0.35 mm inner diameter) were used as the material for end pieces. External surfaces of these tubes were serrated for better fixation in the valve body and the vas deferens. The actual pictures of designs are depicted in Fig. 3. The valves on the left side are in the "closed" position while those on the right side are in the "open" position.

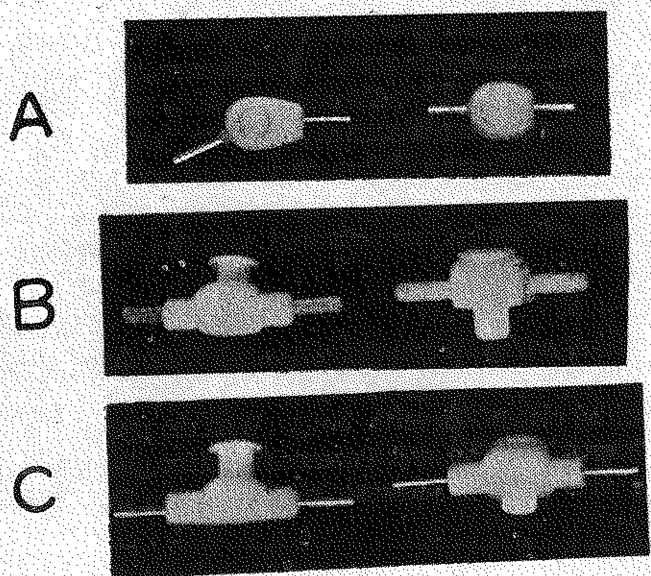

Fig. 3: Photographs of the vas-valves (magnification 2 X).
A. Rotary valve, closed position (left) and open position (right)
B. Stop-cock type for use in the human male, closed position (left) and open position (right)
C. Stop-cock type with end pieces made of stainless steel tube for use in the monkey, closed position (left) and open position (right).

Initial Evaluation : All valves were tested for being leak-proof with tap-water under a pressure of 140-150 mm Hg. The tap-like and the rotary valves were not satisfactory in this respect. The stop-cock valves, however, were leak-proof under these conditions and were implanted into the rhesus monkey vas deferens for further evaluation; and ejaculates obtained by electroejaculation were examined pre- and post-operatively. The first pair of valves (stop-cock model) was implanted in the "open" position into a monkey of 4 *kg* body weight on November 26, 1971. After about 6 months the valves were found to be patent and firmly in place, and could be manipulated for change into the "closed" or "open' position. Subsequently sexually nature male rhesus monkeys (8-10 *kg*) were trained and tested by electro-ejaculation (19) several times before and at various intervals after implantation. In one of the first monkeys of this weight range in contrast to pre-operative findings no spermatozoa were seen in the ejaculate on several occasions about one month after bilateral implan-tation of devices in the "open" position. Only on one occasion about 6 spermatozoa per low power field were seen. They were all non-motile, and the morphology was inconspicuous. A review of the operation sites demonstrated obstructed devices. It was felt that the obstruction may be due to the clogging of the groove in the plunger, the depth of which was of the order of 0.2 mm. The devices were left in place. Only the plungers were exchanged on both sides with new ones having a groove depth of about 0.5 mm. After this both devices were patent again. Necrosis in the surrounding tissues that could have occurred as a result of mechanical pressure of the implanted valves was never noticed. It may be commented that the circular nature of the groove in the plunger was determined more by technical manufacturing considerations with an eye towards obtaining leak-proof specimen than by physiological considerations which would rather ask for a straight line of communication.

DISCUSSION

An external vas diameter of about 2 mm in the natural state would make middle parts of the valve with an overall measurement of 4 to 5 mm as illustrated in this paper, palpable and discernable against the vas deferens in the intact scrotum as also would still leave it small enough not to give any unnecessary feeling of a foreign body. The rather small internal dia-meter of the monkey vas led to the use of small size stainless steel endpieces. In the human, however, a compromise between manufacturing considerations, mechanical stability of endpieces, and the given vas lumen range would suggest all Teflon models with end-piece of 0.9,1.0,1.1, and 1.2 mm external diameters for snug fitting on implantation. The middle part of the valves could remain of the same standard size. The observed left right vas variations in the same person preclude a correlation of vas sizes to parameters of the individual like age, weight, height etc.

Measuring with rod-shaped gauges of diameter increments of 0.1 mm Brueschke *et al.* (5) reported 0.85±0.07 mm (Mean± SD) vas lumen diameter when the guages were inserted with "no resistance", and 1.06±0.12 mm when inserted until met with "significant resistance". The external diameter was found to be 2.8±0.43 mm. Other authors quote an average vas lumen of approximately 0.55 mm distendable up to 1.2 mm in a series of 100 vasectomy patients (14). Vas lumen measurements vary greatly with varying insertion forces applied to the measuring device, especially so in the lower insertion force range which explains the slightly smaller internal diameter with "no resistance" and the "medium" diameter with "significant resistance" as reported by Brueschke *et al.* (5). Similarly, it could explain the very small average lumen and increase in its diameter when distended as reported by Freund & Davis and quoted by Hulka & Davis (14). It may be noted that lumen of 1.2 mm at extreme distendability (14) corresponds closely to the 1.24 mm lumen diameter at 100 *g* insertion force as observed in the present study.

What physiological and pathophysiological effects of the valve can be anticipated? It seems that for all practical purposes vasocclusion has no lasting deleterious effects on either spermatogenesis or endocrine function of the testis (7, 8, 16, 17, 22, 23). Recent studies demonstrate that sperm antibodies which are relatively uncommon in normal serum can be detected in 30 to 50% of sera from vasectomised men (2, 3, 14). It may, however, be noted that no impairement of fertility in mice has been reported despite a rather high titre of experimentally produced circulating sperm antibodies in both the male and the female (10).

To predict the effects of an "open" valve at the level of vas physiology is greatly hampered by grave lacunae of knowledge. Though the anatomy of the vas deferens is fairly well known, (4,6,21) our understanding of sperm storage and sperm transport "at rest" and during ejaculation is still incomplete (4,14,20). How the vas motility will be affected by an open valve interposed in the length of the vas deferens, and what role it can have in the transport, storage and delivery of the sperms can be decided only by future investigations.

Freund and Davis (12) found 60-70% of spermatozoa in a normal ejaculate of men to arise from parts proximal (i.e. testicular) to the site of vasectomy. This means that some of the effects are likely to be determined by where exactly on the vas length the valve may be implanted.

Recently in a series of 14 rebbits and 16 guinea pigs with reversible intravasal occlusive device (RIOD), Free (11) reported a 75% pregnancy rate in matings with the device in the "open" mode. However, to be able to assess the success of the implanted device it would seem necessary to interpret these encouraging results against the background of pregnancy rates in comparable matings without any implanted device.

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REFERENCES

1. Ager, J.W., H.H. Werley, D.V. Allen, F.P. Shea and H.Y. Lewis. Vasectomy - who gets one and why? *Am. J. Public Health*, **64** : 680-6, Jul. 1974.
2. Alexander, N.J., B.J. Wilson and G.D. Patterson. Vasectomy : Immunologic effects in rhesus monkeys and men. *Fertil. Steril.*, **25** : 149-56, Feb. 1974.
3. Ansbacher, R., K. Keung-Yeung and J.C. Wurster. Sperm antibodies in vasectomized men. *Fertil. Steril.*, **23** : 640-3, Sep. 1972.
4. Batra, S.K. Sperm transport through vas deferens: Review of hypotheses and suggestions for a quantitative model. *Fertil. Steril.*, **25** : 186-202, Feb. 1974.
5. Brueschke, E.E., M. Burns, J.H. Maness, J.R. Wingfield, K. Mayerhofer and L.J.D. Zaneveld. Development of a reversible vas deferens occlusive device. I. Anatomical size of the human and dog vas deferens. *Fertil. Steril.*, **25** : 659-72, 1974.
6. Brueschke, E.E., L.J.D. Zaneveld, R. Rodzen and D. Berns. Development of a reversible vas deferens occlusive device. III. Morphology of the human and dog vas deferens : a study with the scanning electron microscope. *Fertil. Steril.*, **25** : 687-702, Aug. 1974.
7. Bunge, R.G. Plasma testosterone levels in man before and after vasectomy. *Invest. Urol.*, **10** : 9, 1972.
8. Derrick, F.C. Jr., W.L. Glover, Z. Kanjuparamban, C.B. Jacobson, M. McDougall, K. McCowin, H. D. Mercer and L.D. Rollins. Histologic changes in the seminiferous tubules after vasectomy. *Fertil. Steril.*, **25** : 649-58, Aug. 1974.
9. Donald I. McCane. "Polytetrafluoroethylene" in : Encyclopedia of Polymer Science and Technology. Vol. 13, 623-54. Edited by Mark, H.F., N.G. Gaylord, N.M. Bikales. Interscience Publishers, New York, London Sydney, Toronto, 1970.
10. Edwards, R.G. Immunological control of fertility in female mice. *Nature* (London), **203** : 50-3, Jul. 1964.
11. Free, M.J. Animal experiments with reversible intravasal occlusive device (RIOD). Proc. Int. Union of Physiol., Vol. XI, p. 326, 26th Int. Cong. Physiol. Sc., New Delhi, 1974 (Abstract).
12. Freund, M. and J.E. Davis. Disappearance rate of spermatozoa from the ejaculate following vasectomy. *Fertil. Steril.*, **20** : 163, 1969.
13. Hackett, R.E. and K. Waterhouse. Vasectomy — reviewed. *Am. J. Obstet. Gynecol.*, **116** : 438-55, June, 1973.
14. Hulka, J.F. and J.E. Davis. Vasectomy and reversible vasocclusion. *Fertil. Steril.*, **23** : 683-96, Sept. 1972.
15. Jhaver, P.S., J.E. Davis, H. Lee, J.F. Hulka and G. Leight. Reversibility of sterilization produced by vas occlusion clip. *Fertil. Steril.*, **22** : 263-9, Apr. 1971.
16. Kothari, L.K. Vasectomy for contraception — physiological perspectives. *Ind. J. Physiol. Pharmac.* **17** : 209-12, Jul-Sept., 1973.
17. Kothari, L.K., P. Mishra and R.K. Mishra. Effect of bilateral vasectomy on the structure and function of the testes. *Amer. J. Sur.*, **126** : 84-88, 1973.
18. Lee, H.Y. Experimental studies on reversible vas occlusion by intravasal thread. *Fertil. Steril.*, **20** : 735, 1969.
19. Mastroianni, L. Jr. and W.A. Manson Jr. Collection of monkey semen by electroejaculation. *Proc. Soc. Exp. Biol. Med.*, **112** : 1025-7, 1963.
20. Mitsuya, H., J. Asai. Application of x-ray cinematography in urology : I. Mechanism of ejaculation. *J. Urol.*, **83** : 86, 1960.
21. Popovic, N.A., D.G. McLeod and A.A. Borski. Ultrastructure of the human vas deferens. *Invest. Urol.*, **10** : 266-77, 1972.
22. Rosemberg, E., S.C. Marks Jr., P.J. Howard Jr. and L.P. James. Serum levels of follicle stimulating and luteinizing hormones before and after vasectomy in men. *J. Urol.*, **111** : 626-9, May, 1974.
23. Wieland, R.G., M.C. Hallberg, E.M. Zorn, D.E. Klein and S.S. Luria. Pituitary-gonadal function before and after vasectomy. *Fertil. Steril.*, **23** : 779-81, Oct. 1972.