Short Review

Stents for Vasectomy Reversal

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ABSTRACT

Introduction

This review describes the role of stents for vasectomy reversal. The development started from temporary exteriorized stent towards absorbable and non absorbable hollow stents. Until now no stents for vasovasostomy have been commercialized despite the good results in various studies.

Material & methods

PubMed search was performed to obtain the literature regarding the use of different stent types for vasectomy reversal. Full text articles were then extracted from various data banks and analyzed. The outcomes of the studies were ranked in tables focusing on type of stents, study design, outcomes and possible significant complications.

Results and conclusion

During the last decades, several studies have been performed on the use of stents for vasectomy reversal. The outcomes differ significantly per study. A remarkable aspect is that stents probably provide less sperm leakage and thus granuloma formation. As far as we know the granuloma formation might have a detrimental effect on the anastomosis and outcome of vasovasostomy. Whether to use exteriorized temporary, absorbable or non-absorbable stents for better results remains unclear from the literature. A well-designed comparative study between different type of stents and a conventional two-layer anastomosis is needed to prove its beneficial value.

INTRODUCTION

Double layer microscopic reconstruction vasovasostomy is still standard of care in vas reconstruction after vasectomy. Operating times vary between 80-150 min depending on the use of a one- or two-layer technique and the technical difficulties to encounter. Next to the difficult technical performance, it is frequently annoying that initial good sperm results can decline several weeks to months later. The cause of this decline is probably due to secondary stricturing especially if you initially start with semen samples of satisfying quality. Those patients undergoing a re-vasovasostomy have even a greater chance of developing partial or complete stricturing of the new anastomosis area. Achieving perfect alignment of the several tissue layers of the vas wall and so obtaining optimal healing with permanent patency is the primary goal for many investigators in using stents for reconstruction. Multiple studies have been performed over the last decades to investigate whether stents could facilitate in this reconstruction with equal or even superior results. Several types of stents were used for reconstruction. This review will demonstrate the different outcomes of the various stents used and point out whether stents have a place in reconstructing the vas deferens.

SURGICAL TECHNIQUES FOR VASOVASOSTOMY & ERGONOMICS

Macroscopical versus microsurgical technique

In the early beginning vasovasostomies were done macroscopically. Macroscopic re-approximation represents the development of an anastomosis done without any type of optical magnification [1,2]. Because microscopical reconstructions led to better results compared to macroscopical reconstructions, the majority of surgeons switched over to the microscopical procedure [3-6]. It is important to learn the proper hand and finger positions for holding microsurgical instruments; ergonomic principles to prevent hand and finger tremors and functioning of the various parts of the operating microscope. To visualize fine structures in the operating field optical loupes (2.5x to 3.5) areused. Structures more then 3 mm in diameter can be optimally approached with these optical loupes. For smaller structures an operating microscope is absolutely necessary. The disadvantage of optical loupes is the fact that the surgeon must hold his head virtually motionless in order to keep the structures in the operating field in focus. If the power of magnification increases it is even harder to maintain a fixed focus.

Operating microscopes provide light that is coaxial to the field of view and offers adequate illumination of the operating field [7-9]. In contrast with the surgical loupes, focusing of the microscope is done electronically by moving the head of the microscope rather then moving your own head which is time consuming and less precise. Eyepieces are available in several strengths. Diopter scales are provided on the eyepiece for individual adjustment. Double vision should be corrected by adjusting the interpupillary distance. This binocular view permits stereoscopic viewing. Most microscopes have binocular tubes that can be adjusted to various angles. A diploscope configuration is useful for most microsurgical procedures. The eyepieces of the surgeon are directly opposite the eyepieces of his assistant. Such an arrangement uses a single objective lens and a beam splitter to provide the surgeon and the assistant with one-half of the available light each. The advantage of this system is that the assistant uses the same amount of magnification as the surgeon. The cooperation is in this way more efficient. The magnification changer permits variation in magnification. The length of the binocular tubes, the power of the eyepiece, the properties of the magnification changer and the focal length of the objective lens determine magnification. Objective lenses are available in focal length ranging from 150-400mm. For each 25 mm increase in focal length, the objective lens will focus 25 mm farther away from the operating field. Magnification decreases, and the size of the field of view increases, as the focal length of the objective lens increases. If the focal length is to short than the surgeon is forced to assume a kyphotic position if it is too long he is required to stand up. This illustrates that optimal care has to be taken for the exact positioning of the microscope because non optimal visualization can be of bother during the entire operation.

One-layer versus two-layer microsurgical reconstruction

Scarification and stricturing are believed to be the major causes of failure. According to Silber’s original concept, the anastomoses are made in two layers. Some urologists prefer a modified one-layer technique, which is easier to perform, quicker, and believed to induce less scarification and stricturing. Fischer and Grandmyre [10] compared the two techniques in a group of 40 patients, and found that the patency rates were comparable. However the mean operation time was 167 min for the two-layer technique and 96 min for the modified one-layer procedure. Herrel et al., [11] performed a systematic review on outcomes of microsurgical vasovasostomies. A total of 31 studies were examined including 6633 patients. Incidence of patency for modified 1-layer technique was similar to that after a 2-layer procedure with a meta-IR of 1.04 (95% CI, 1.00-1.08). They could not confirm a difference in outcome when comparing single vs multilayer anastomoses. In a German study [12] the outcome rate of a two layer microsurgical vs a monolayer reconstruction was investigated using a patient questionnaire. The time interval between vasectomy and reversal was 9.5 years for the double-layer patients and the outcomes were compared with a historical one-layer group. In the double-layer group patency rates were 86 % and birth rate 24%. In the control one-layer group the shorter average occlusion interval was 6.9 years and resulted in a patency rate of 87 % and pregnancy rate of 48%. This was not a randomized comparative study and the control group had a shorter average obstructive interval, which could be of great importance. It remains unclear from the literature whether a two-layer anastomosis is more superior to a one layer reconstruction.

STENTS FOR VASECTOMY REVERSAL

Temporary exteriorized stents

Most studies on exteriorized stents used a temporary stent that was removed after several days or weeks after surgery (Table 1). Temporary stented reconstructions have disadvantages: because the stents are exteriorized they provide a greater risk for sperm leakage and infection; this could lead to sperm granuloma, anti-sperm antibody formation, vasitis and loss of patency from scar tissue formation [13-15]. Despite these possible disadvantages [16] recently published a study overlooking the medical records of 82 patients who underwent a loup assisted vasovasostomy using a prolene stent. The tail of a luminal stent (Prolene 3-0) was inserted into the lumen of the abdominal end of the vas. The other end of the stent had a needle that was passed through the lumen and penetrated the wall of the testicular end of the vas. After six weeks the stent was removed. They recorded patency and pregnancy rates (96,1% and 41.2 %) especially in a subgroup with obstructive intervals < 7 years. These outcomes are however comparable with microscopically assisted vasovasostomy results.

Table 1: Temporary stents.

Temporary stents				
Author(s)	**Type of stent**	**Study design**	**Outcome**	**Complications**
Lykins et al	polyethylene (PE10)	Comparative animal study in 12 dogs: indwelling tube for 3 weeks ->anastomosis 6.0 polypropylene vs 6.0 polyglycolic acid . After 3 weeks removal of stent under general anesthesia	Bilateral orchiectomy /spermatic cord performed after 3 months followed by vasography for patency: 85% patency in polyglycolicsuture use 58% polypropylene suture use	Perivasal fibrosis seen in 50% using polypropylene versus 25% fibrosis using polyglycolicacid
Shessel et al	2.0 nylon exteriorized stent (removal after 7-10 days)	Human study in 10 patients: Single layer 6 or 7.0 proleneapproximation over stent	70% pregnancy rate after 2 years follow up ((comparable with more complex microsurgical reconstructions)	
Urry et al	Silastic stent (temporary) vs chromic stent (absorbable)	Comparative animal study in 12 dogs: 6x silasticvs 6x chromic	100% patency with silastic stent vs 40% in chromic stents, superior sperm quality in silasticstents	2 chromic showed no intravasalabsorption on with more testicular histological changes
Jeon et al	Prolene 3.0 exteriorized stent (removed after 6 weeks)	Retrospective human study 82 men : anastomosis 6.0 nylon approximation suture over stent	patency and pregnancy rates (96,1% and 41.2 %) especially in a subgroup with obstructive intervals < 7 years.	4 men developed epididymitis successfully treated .

Absorbable intravasal stents

In the early 1980s more studies were reported using absorbable material as an intravasal stent (Table 2). Redman [17] used an intraluminal stent of catgut in 20 patients and achieved an overall pregnancy rate of 65%; the successful group included three patients who had a vasectomy >10 years earlier. Montie et al., [18] reported a study in a dog model; one group had a conventional sutured vasovasostomy with 6/0 silk and the other three groups were reconstructed with intraluminal stents using either 3/0 polyglycolicacid or 3/0 chromic catgut, using different types of approximation sutures. The best results were with the chromic catgut stents, and 6/0 catgut sutures for the anastomosis. Silk sutures resulted in severe granuloma formation and should therefore be rejected as a suturing material. Absorbable hollow stents were created to simplify the procedure and reduce operating time; these created perfect alignment of the vas deferens ends, and after 2-4 weeks most stents were dissolved. Nuwayser et al., [19] were amongst the first to develop such a stent; they used starch, collagen and polyester as stent materials. The best results were seen in the polyester group, with patency in all 19 samples and rapid absorption at 10-14 days. The histological assessment showed excellent healing at the anastomotic site, with the presence of normal epithelium and no stricturing. There was plentiful sperm in the lumen, with normal sperm morphology. Flam et al., [20] used an absorbable hollow polyglycolic acid stent, and described advantages of ease of anastomosis, reduction of perivasal inflammation as a result of minimal extravasation of sperm, maintenance of luminal patency, and satisfactory approximation of the vas deferens ends after placing of the stent. Remarkably, they reported more perivasal inflammation at the anastomotic site of an unstented controle group. This sperm leakage and inflammatory reaction could increase the risk of late scarring. Hollow, biflanged, hydrolysable, self-retaining stents of polyglycolic acid were used by Berger et al., [21] in a randomized prospective comparative study between a stented and a modified two-layer vasovasostomy group in rats and dogs. The outcome suggested better patency rates in the stented group (80% vs 20%).

By contrast Rothman et al., [22] in 1997 reported an extensive prospective randomized study comparing a microscopic two-layer vasovasostomy with an absorbable polyglycolic acid stent in 116 men who had a vasectomy reversal. In all, 64 men had a stented reconstruction and 52 were repaired with a two-layer microscopic reconstruction. Paternity rates were significantly better in the unstented group. A bias in this study was the incomplete follow-up; in many cases only one semen sample was investigated per subject after surgery, and this undermines a well-documented comparison of patency rate. Nevertheless, information (by letter, telephone or outpatients visits) on paternity was available for 95% of patients, showing significantly better results in the non-stented group (51 vs 22%).

Table 2: Absorbable stents.

Absorbable stents				
Author(s)	**Type of stent**	**Study design**	**Outcome**	**Complications**
Redman	Intraluminal chromic catgut stent	Prospective human study 20 men, chromic catgut suture 6.0 for approximation of the anastomosis	100% patency rate achieved	
Montie et al	Dexon and chromic catgut stents	Comparative animal study in 19 dogs : Group 1 : 4 dogs no stent reconstruction with six 6.0 silk sutures for the anastomosis Group 2: 5 dogs intravasal stent 3.0 Dexon with six 6.0 silk sutures outer wall Group 3 : 5 dogs 3.0 chromic catgut intravasal stent with 6.0 silk sutures outer wall Group 4 : 5 dogs 3-0 chromic catgut intravasal stent with 6.0 chromic catgut sutures outer wall	After 3 months (group 1-3) and 6 months (group 4) testis and spermatic cord inclusing anastomosis resected. Vasography performed in all dogs for patency. Patency rates: Group 1 no stents 50% Group 2 dexon stent 60 % Group 3 chromic stent and silk 70% Group 4 chromic and chromic catgut 90%	Granuloma formation in silk anastomosis 79% versus 10 % in chromic catgut
Nuwayser et al	Stent from 3 absorbable polymers: starch,collagen, and a copolyester of lactide and glycolide	Initial study with guinea pigs showed good absorption of the starch and the copolyester , collagen took > 3 months to resolve. Followed by human study in 43 men comparing the different stents	Pregnancies occurred in: 12/13 in starch group 19/19 in the copolyester group 9/11 collagen group	No severe perivasal tissue reaction around anastomosis in the animal pilot study
Berger et al	Polyglycolic acid	Comparative animal study in 37 rats stents and no stents (randomized concept) Different diameter stents used (0.8128-0.9398 mm) and placed in 37 rats using 3 three 9-0 sutures for outer wall approximation Comparative animal study in 8 dogs one side stent and the other side two layer anastomosis 10-0 nylon	Rats study: 6 weeks after surgery the anastomosis was excised. Patency was examined by flow rate of saline through anastomosis area Flow rates in the non stented group was significantly less than in the group stented with larger stents (p<0.05) Dogs study: Two stented vasovasostomies were not patent five stents showed excellent healing no scarring and full epithelial continuity across the complete anastomic site Two layer vasovasostomies showed all patency but inadequate epithelial continuity	Small stents showed sperm leakage and granuloma formation. Larger stents (20 of 22) showed no granuloma formation vs 4/37 granuloma formation in a two layer anastomosis
Flamm et.al	Polyglycolic stent	Animal study 16 rats: Absorbable stents were eliminated within 4 weeks	Easy to perform procedure with excellent patency as confirmed by histologic investigation at 2, 4 and 6 weeks	Less perivasal inflammation probably due to reduced sperm leakage
Rothman et al	Polyglycolic stent	Human randomized prospective trial comparing stent and no stent	64 men stented and 52 non stented Conception occurred in 22 and 51% of all couples in the stented and non stented group (p=0.003) . Two layer anastomosis looks far superior	

Non-absorbable stent

Because of these conflicting results with absorbable hollow stents, Vrijhof et al., [23] developed in 2005 a permanent non absorbable inert polymeric stent (Table 3). The construction material of the stent was N-vinylpyrrolidone and n-butylmethacrylate, and the bifunctional cross-linking agent was tetraethylene glycol dimethacrylate. Shortly after introduction, the stent starts to absorb seminal and serous fluids, which alter the mechanical characteristics making the stent more flexible and elastic. A randomized prospective trial in rabbits was performed either using stents on both sides or a bilateral one-layer 8/0 non-absorbable polypropylene sutured anastomosis. After surgery, there was a significant difference between conventional and stented rabbits in the increased semen concentrations during the follow-up (P=0.050, linear regression analysis with random effects); the total sperm count increased in both treatment groups, but more in the stent group. No stricturing of the anastomotic area was seen in the stented group compared to the sutured one (0 versus 38%).

Table 3: Non-absorbable stents.

Non-absorbable stents				
Author(s)	Type of stent	Study design	Outcome	Complications
Vrijhof et al	N-vinylpyrrolidone and n-butylmethacrylate, and the bifunctional cross-linking agent was tetraethyleneglycoldimethacrylate	Comparative animal study in 26 rabbits :13 stented reconstructions of the vas deferens and 13 one-layer 8.0 prolene microscopically reconstructed . Anastomotic site was excised for examination months later	Mean motility and progressive motile sperm counts showed no differences between both groups (p=011 and 0.71)	Partial obstruction 5/13 microsurgicalanastomos esno strictures seen in the stented group

CONCLUSION

A regular double layer or one layer anastomosis remains subject to stricturing. An intravasal stent that couldprevent this local stricturing and thus gaining permanent patency would be beneficial. Of course long obstructive intervals and anti sperm antibodies contribute significantly to the sperm outcome. For a surgeon the technical outcome of a patent anastomosis is crucial. In the nineties Carbone et al., and Belker et al., [24,25] both described the adverse effect of partial obstruction on the final outcome of a vasectomy reversal. How often is a microscopical anastomosis partially strictured nevertheless providing good or reasonable sperm quality? After 2005 no studies have been published using intravasal stents for vasectomy reversal according to the PubMed data bank. As far as we know, non of the above described stents came into commercial production. Probably there is too little scientific support for its beneficial use. Only well designed multicenter randomized clinical studies with a sufficient number of patients and comparable groups using different type of stents, could probably provide us with the answer if a stent could be beneficial to patency and pregnancy rates. At least placing a stent is a less time consuming and an easier to perform procedure than a microscopic vasovasostomy.

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