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## **Vasectomy and vasectomy reversal : development of newly designed nonabsorbable polymeric stent for reconstructing the vas deferens**

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## **Chapter 9**

### **Summary & conclusion**

## Chapter 1

**Objective:** To give an overview of the different vasectomy techniques utilized and try to explore from the literature what method of vasectomy could give the lowest risk of early recanalization. What is the exact definition of early recanalization. Should persistent non-motile spermatozoa after vasectomy primarily be considered as early recanalization or as a succesful vasectomy outcome? In this review we also try to provide answers to this problem.

*Results:* The no-scalpel technique has, besides lower complication rates, no advantages compared to the conventional technique. Simple ligatures of the vasal ends provide, due to sloughing, the highest chance of recanalization (1-5%). Cautery of a vasal segment over a length of more than 1 cm and interposition of fascial sheath, together with the technique of folding back of vasal ends, brings the best results. Resection of long segments is probably not necessary to improve results. Resection of long segments provides more complications and reduces the opportunities of vasectomy reversal. Percutaneous vasectomies using silicone plugs should be rejected.

Leaving the testicular side open at the time of vasectomy could be advantageous. Open ended vasectomies could be of benefit when considering future vasectomy reversal. Sperm granuloma development at the testicular-end in open vasectomies has the advantage of preventing irreversible damage to the testis, improving the chances of successful reversal. The sperm granuloma development could act as pressures relieve valve also reducing postvasectomy epididymal congestive pain.

Besides two consecutive samples of azoospermia, persistent non-motile sperm ( $<10.000/\text{ml}$ ) should also be considered as a criterion for success. Early recanalization is defined as persistence of motile sperm four months after vasectomy.

*Conclusion(s):* Well designed randomized trials have to be conducted to prove that open-ended vasectomy, without resection of long segments and cautery of the abdominal end over at least 1 cm in combination with fascial interposition, is probably the method of choice in an era where the incidence of divorces are high and the chances of a restored child wish with a new partner is considerable. Persistent non-motile sperm ( $<10.000/\text{mL}$ ) seven months after vasectomy should be defined as a successful outcome and not as early recanalization.

## **Chapter 2**

*Introduction:* We determined the percentage of patients with nonmotile sperm 12 weeks after vasectomy and estimated the time needed for eventual azoospermia in these patients. We also recorded the percentage of patients with recurrence of nonmotile sperm after initial azoospermia post-vasectomy.

*Materials & Methods:* A review was done of the semen analysis of vasectomies performed in a 2-year period. Vasectomies were performed in an outpatient department of the University Hospital of Maastricht. Semenanalysis were performed in a group of volunteers from 4 months until 24 months after vasectomy. Amount and motility of sperm in postvasectomy semen samples were recorded. All the men were referred by the general practitioner for vasectomy.

*Results:* Nonmotile sperm was found in 33% of the patients 12 weeks after vasectomy. The mean time to azoospermia was 6.36 months. Nonmotile sperm after initial azoospermia was found in 5 of 65 patients.

*Conclusions:* Azoospermia as a criterion for sterility leads to unnecessary prolonged semen analysis in a large percentage of the vasectomized patients. Reappearance of nonmotile sperm was found in an unexpectedly high percentage.

### **Chapter 3**

This review chapter starts with a description of the microscopical vaovasostomy technique. The role of optical loupes versus microscopes is discussed. Details of the microscope like length of binocular tubes, power of the eyepiece and the power of the magnification changer are reviewed. 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. The use of high quality surgical instruments is of utmost importance for a successful vasovasostomy. Various microsurgical instruments are described and their mechanical properties and functions are discussed.

### **Chapter 4**

*Introduction:* In this series we present the results of a retrospective analysis of 66 vasovasostomy procedures performed between 1983 and 1991.

*Materials & Methods:* Obstructive intervals and serum antisperm antibodies were correlated with pregnancy and patency rates.

*Results:* With obstructive intervals of less than 5 years a patency rate of 100% (31/31) was obtained. Even more than 10 years after reversal, pregnancy occurred in 25% (2/8) of the patients. Preoperative serum antisperm antibodies were correlated with pregnancy rates. Patients with a high agglutinin titre of 1/64 obtained a pregnancy rate of 23% (3/13). Those men who had no circulating antisperm antibodies in their blood had a significantly better chance in obtaining pregnancy (pregnancy rate 80%). In this study we accounted for an overall pregnancy rate of 51.5% (34/66) versus an overall patency rate of 84.8% (56/66).

*Conclusion:* Neither long obstructive intervals nor high antisperm antibody titres should dissuade a surgeon from performing a vasovasostomy procedure

## Chapter 5

*Objective:* In this review article we want to investigate the current opinions regarding the influence of post vasectomy sperm granuloma, antisperm antibodies development and subsequent epididymal and/or testicular tissue changes on vasovasostomy results.

*Methods:* literature search was performed using MEDLINE database on factors influencing outcome of vasectomy reversal.

*Results:* Sperm granulomas occur in 10-30% of men who underwent a vasectomy. These sperm granulomas develop mainly at the epididymal area. Increased epididymal pressure leads to tubular ruptures causing fibrosis of the epididymal ductules and possible obstruction. Rupturing of these epididymal tubules is the probable cause of antisperm antibodies formation.

Depositions of these humoral immune complexes in the epididymis and/or testis area have a complementary negative effect on these tissues. Open-ended vasectomies could have a beneficial effect on the prevention of granuloma formation at the epididymal area. Granuloma formation at the testicular open vasectomy end will eventually lead to reduced pressures in the epididymis, preventing further damage. Despite these advantageous aspects of open-ended vasectomy no scientific study has proven up to now that better vasovasostomy results are obtained with this open-ended technique. Human and animal studies suggest that vasectomy causes changes in interstitial tissues of the epididymis with much more densely occupied fibers. Testis tissue is less frequently damaged due to obstruction than the epididymis region. Probably a lot of pressure is already released at the epididymal area as described previously. If changes in the testis occur, it results in increased seminiferous wall thickness, focal interstitial fibrosis and changes in the interstitial area. It is unclear whether these changes are reversible after vasovasostomy? From animal studies we know that progression of these changes are probably reduced but not reversed. Animals with smaller testicles after vasectomy showed more severe

changes of the seminiferous tubules and higher levels of antisperm antibodies were measured. The effects of tissue damage to the epididymis and testis on vasovasostomy results in men remains still unclear. Literature on this subject is rare and describes small series. Although it seems obvious, until now no well designed study is performed to verify whether these tissue alterations have a detrimental effect on semen quality after vasectomy reversal.

*Conclusion:* Open-ended vasectomies could have a beneficial effect on the prevention of epididymal and testicular tissue changes, granuloma formation and antisperm-antibodies production. Despite these advantageous aspects of open-ended vasectomy no scientific study has proven up to now, that better vasovasostomy results are obtained with this open-ended technique.

## **Chapter 6**

*Introduction:* Vasectomy has become popular since it is the safest surgical method for contraception. It is known that approximately 6 % of the men that undergo vasectomy will seek reversal (vasovasostomy). This operation is, however, technically demanding and relatively time-consuming. This study was based on the hypothesis that a polymeric mini-stent can facilitate and accelerate vasovasostomies.

*Materials&Methods:* A mini-stent was manufactured out of a cross linked hydrogel biomaterial, which was synthesized from N-vinyl-pyrrolidinone (NVP), n-butylmethacrylate, and (triethyleneglycol) dimethacrylate. The device was tested in 28 rabbits, which were divided over two equal groups. In one group, the vasa deferentia were dissected and reanastomosed via microsurgical one-layer technique (end-to-end group). In the other group, the vasa deferentia were dissected and reattached through implantation of a mini-stent.

*Results:* Sperm counts revealed 100 % patency in both groups, i.e. all vasovasostomies were successful. It was experienced that the operation was easier and faster in the case of the mini-stent, probably since the mini-stent keeps the lumens of both vas ends exactly in line during suturing.

*Conclusion:* This study demonstrates the feasibility of the mini-stent. Further work is necessary to evaluate the utility of this approach for clinical vasovasostomies.

## **Chapter 7**

*Objective(s):* To investigate the use of a newly designed stent in the reconstruction of the vas deferens

*Materials and Methods:* In 26 New Zealand White rabbits, 13 conventional one-layer microscopic reconstructions were compared with 13 stented reconstructions of the vas deferens. The newly designed nonabsorbable polymeric stent was shaped to facilitate the rejoining of the two loose ends of the vas deferens, using a central ridge to prevent migration. Semen was collected before and after surgery, using an artificial vaginal system (26 samples before and 115 samples after surgery). The individual and average total sperm count, motility and progressive motile sperm density (PMSD) were compared after surgery for both groups. After the final semen analysis, rabbits were killed and patency was assessed histologically at the site of the anastomosis.

*Results:* After an initial decline, the mean total sperm count increased in both groups. The increase was significantly larger ( $p=0.05$ ) in the stented rabbits. The mean motility and PMSD showed no significant differences between both groups ( $p=0.11$  and  $0.71$  respectively).

Histological examination of the anastomosed area showed partial obstruction ( $>50\%$  narrowing of the original lumen) in five of the 13 conventionally treated rabbits, with no strictures in the



stented group. Despite the narrowing in the conventional group the patency rates were not affected. The mean (range) operating time for the conventional and stented groups was 132 (99-168) and 98 (62-113) min, respectively ( $p<0.001$ )

*Conclusion:* The total sperm counts, motility and PMSD showed no or little difference after surgery between the conventional and stented rabbits. The stented reconstruction was easy, had no secondary stricturing and reduced the operating time.

## **Chapter 8**

*Objective:* To investigate whether a newly designed non absorbable polymeric stent for the reconstruction of the vas deferens provided less stricturing at the site of the anastomosis in comparison with the conventional microsurgical reconstruction of the vas deferens.

*Design:* Prospective randomized study in 26 rabbits, comparing the one-layer microscopical sutured procedure with a biocompatible stent.

*Setting:* University animal laboratory center

*Interventions:* Pre- and postoperative average total sperm count, motility and progressive motile sperm density levels (PMSD) were measured. Histological sections were taken from the area of the anastomosis, testes and epididymis after final semen analysis.

Main outcome measures: Rates of stricture and semen parameters

*Results:* The vas deferens of the rabbits that received a stent, showed an inflammatory reaction within the vas wall, adjacent to the stent. Transmural histiocytic or eosinophilic reactions were seen in 2/13 (15%) of the stented animals, with atrophy of the epithelium. Histological cross-sections of the stented vas deferens demonstrated patency. Microscopically sutured rabbits showed more partial obstructions at the site of the anastomosis 5/13 (38%) with transmural infiltration of lymphocytes and histiocytes. Despite these partial obstructions the vasa were

patent. There was a statistically significant difference in favor of the stent with respect to the total sperm count ( $p=0.05$ ). No differences were seen in motility ( $p=0.057$ ) or PMSD's ( $p=0.13$ ).

*Conclusions:* The newly developed stent provided patency rates comparable with the conventional one-layer microscopic procedure but showed significantly less stricturing of the anastomoses.

