

## **Author's response to reviews**

**Title:** Frequency and patterns of early recanalization after vasectomy

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## **Response to reviewers' comments**

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### **Frequency and patterns of early recanalization after vasectomy**

Michel Labrecque, Melissa Hays, Mario Chen-Mok, Mark A Barone and David Sokal

We first thank again the two reviewers for their thoughtful and constructive comments. Only reviewer no 2 (Timothy Hargreave) had (general) comments requiring a response. Our response to each comment follows.

#### *General*

1. The analysis seems well done but I will always have some doubts about the underlying clinical trial data. Their failure rate is much higher than I see in my practice and indeed if I have 5% of men coming back with failed vasectomies I would quickly get no more referrals. This makes me think that their technique of fascial interposition is subject to technical error as it is difficult to envisage how recanalisation can occur if there is a sheet of fascia between the ends of the vas and if the ends of the vas lie indifferent tissue compartments. I conclude that in the context of mass vasectomy practice with surgeons of differing expertise that cautery and fascial interposition is the best technique but the reason for this is probably because of varying expertise of the vasectomy surgeons and difficulties in achieving a true fascial interposition.

We acknowledged the reviewer comments by adding a paragraph in the Discussion section on page 16-17. We stressed as suggested that failure/recanalization risk may be partly explained ~~We acknowledged the reviewer comments by adding a paragraph in the Discussion section on page 16-17. We stressed as suggested that failure/recanalisation risk may be partly explained~~ by technical error due to surgeons' expertise.

“

“The level of expertise of participating surgeons in the two studies may explain differences between the results observed with the four occlusion techniques. Some of the surgeons involved in the FI trial were not well-experienced with the FI technique and different methods of FI were used in the cautery study; despite some training provided before starting the study, technical errors may partly explain the high failure and recanalization risk encountered with this technique. In fact, FI may be difficult to adequately master.[19] In the cautery study, excellent results obtained with thermal cautery and FI combined may be due to the extensive expertise of the two participating surgeons with this technique. Differences in the level of expertise of participating surgeons would not however influence the findings and conclusions related to the failure/recanalization ratio within each individual technique.”

~~Level of expertise of participating surgeons in the two studies may explain differences between the results observed with the four occlusion techniques. Many surgeons involved in the FI trial were not well-experienced accounted with the FI technique; despite some training provided before starting the study, technical errors may partly explain the high~~

~~failure and recanalization risk encountered with this technique. In fact, FI may be difficult to adequately master. In the cautery study, excellent results obtained with thermal cautery and FI combined may be due to the extensive expertise with this technique detained by the two participating surgeons. Differences in the level of expertise of participating surgeons do not however influence the findings and conclusions related to the failure/recanalization ratio within each individual technique.”~~

2. I also have some questions about whether all of their cases were recanalisation or whether in some case sperm were sequestered in the seminal vesicles. When their recanalisation analysis is based on motility then it is indeed likely to be recanalisation but when the estimates are based on numbers of sperm this is less certain. It would be nice to see some recognition of this in their discussion.

We also acknowledge this fact. Actually there was already a paragraph in the Discussion section concerning this potential bias.

“Semen analysis data from two of the four cautery study sites were limited to sperm concentrations, so we could not consider sperm motility when adjudicating charts from the cautery study. The risk of early recanalization may have been underestimated without this information. Using the results from the two sites where motility was assessed and the consensus criteria that include motility (see Table 1), early recanalization was presumed in 1% (1/99) and 18% (18/97) of cases with cautery with and without FI, respectively, whereas according to the classification obtained without motility, these figures were 0% (0/99) and 9% (9/97). Some argue that motility found as early as ~~three~~ weeks after vasectomy is either due to a surgical error or to early recanalization. “

3. The point is made that in the early stages there may be continuing appearance of sperm until the vas has become properly occluded and that the current recommendation to wait 3-4 months before testing for sterility is reasonable. However, if they are correct and there really are a lot of early recanalisation except when cautery and fascial interposition are used together would it be possible to shorten the interval from the current 3-4 months before testing for sterility if everyone used cautery and fascial interposition? If yes then their findings have some clinical significance if no then these early recanalisation really do not matter provided that current post vasectomy semen analysis guidelines are followed.

We added a sentence in the Result section, p 11, highlighting this finding

“Motility and high sperm count decreased rapidly with all occlusion techniques over the following weeks with no motility observed with thermal cautery combined ~~with~~and fascial interposition ~~six~~6 weeks after vasectomy. “

We also further discussed in the Discussion section the clinical implication of this finding:

“When thermal cautery combined with fascial interposition was performed, no cases were classified as early recanalizations and motile sperm were cleared in all cases by six weeks post-vasectomy. These findings suggest that the current 12-week interval after the procedure before testing for sterility[15, 16] could be shortened with this technique.”

~~When thermal cautery combined with fascial interposition was performed, no cases were classified as an early recanalizations and motile sperm were cleared in all cases by six weeks post-vasectomy. These findings suggest that the current eight to 14 weeks interval after the procedure before testing for sterility could be shorten with this technique.”~~

Finally, we added a sentence in the Conclusion:

“If early recanalization can be reliably prevented, the currently recommended 12-week waiting period before performing the post-vasectomy semen analysis[15, 16] could probably be shortened”.