

Gore Bio-A Tissue Reinforcement in large and recurrence hiatal hernia

A new standard of care?

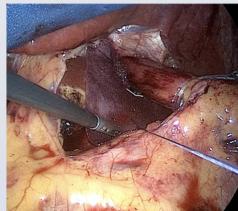
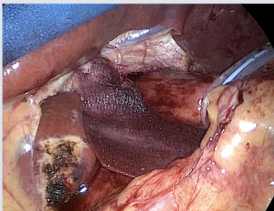
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Introduction

The high recurrence rate after fundoplication surgery in large hiatal hernias is still a challenge. The concept of reinforcing the hiatal region with a mesh prosthesis seems to be advisable. However, complications such as mesh migration are feared. The Gore Bio-A Tissue Reinforcement consists of a biosynthetic material, which is completely absorbed within 6 months and leads to the desired amplification by the induced scarring.

Methods

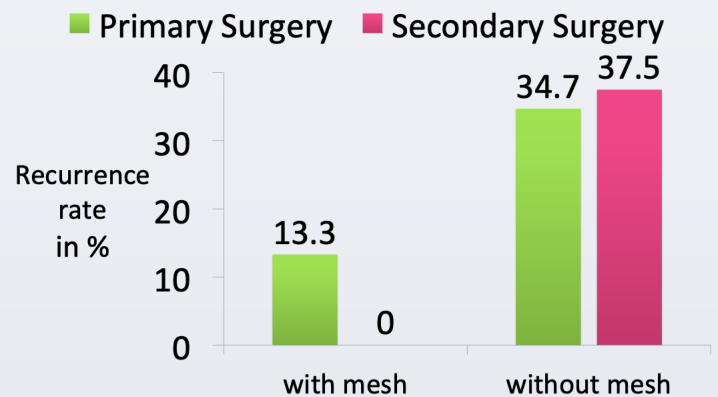
Retrospective and comparative analysis of 28 patients (19 female / 9 male) in the age between 58-84 years (mean 71 ± 13 years) with large hiatal hernia (group A, n=15) or recurrence hiatal hernia after standard surgery (group B, n=13) which received fundoplication surgery with Gore Bio-A Tissue Reinforcement; compared to 52 patients (29 female / 23 male) in the age between 35-91 (mean 63 ± 28 years) with large hiatal hernia (group C, n=49) or recurrence hiatal hernia (group D, n=10, thereof 5 recurrence hernias from group C + 2 second relapse) which received non-reinforced surgery. Follow up was done 3 months after operation and a patient survey in December 2016.



Results

Groups A and B showed an overall recurrence rate of 7.1 % (n=2) while groups C and D showed a recurrence rate of 33.9 % (n=20). In group A 13.3 % (n=2) of the patients primarily treated with a Gore Bio-A Tissue Reinforcement have been diagnosed with a recurrence hiatal hernia (case 1 after 4 months, case 2 after 26 months).

In Group C 34.7% (n=17) showed a relapse of hiatal hernia, of which 14 patients (28.6%) needed additional surgery. No recurrence in the secondary surgery group B with Gore Bio-A Tissue Reinforcement has been recorded, while 3 patients (37.5%) in the secondary surgery group D showed reappearance of hiatal hernia. 2 of these patients received a second revision of non-reinforced surgery without reappearance of relapse.



Discussion

The observation period of the standard surgery group is from 2010 – 2016 while the data of the intervention group was recorded only from 2014 – 2016. The short observation period is connected to the novelty of the technique. One could argue that the difference between the observation period can lead to statistic bias. With four exceptions (between 30 and 47 months) all recurrence hiatal hernias in the standard surgery group have been located within 18 months after operation. However, more research has to be done and it is desirable to obtain more data or a randomized controlled trial.

Conclusion

We suggest that Fundoplication surgery with Gore Bio-A Tissue Reinforcement is a safe and reliable technique. It is leading to less revision surgeries compared to standard surgery and it is a beneficial technique in secondary hiatal hernia repair.