Tissue Reinforcement with GORE® BIO-A® Material in Large Hiatal Hernias
A Prospective Clinical Study

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INTRODUCTION

The use of meshes after repair of a crural defect is still under debate. In light of a recurrence rate up to 20% in larger defects, the augmentation of the hiatal closure with a mesh prosthesis seems to be advisable. However, severe complications due to mesh migration and erosion have been reported. GORE® BIO-A® Tissue Reinforcement is a three dimensional resorbable mesh which has demonstrated to be a ideal "scaffold" facilitating tissue generation and healing without the risk of a non-resorbable implant.

PATIENTS AND METHODS:

In this prospective single centre study, 24 patients with a hiatal defect of more than 4 cm were enrolled. There were 14 males and 10 females, the types of hiatal hernia were: 8 large axial hernias, 7 paraesophgeal hernias and 9 "upside down stomach situations. 4 patients had a recurrence of the hernia, one patient a second recurrence. None had previously received any type of mesh implant at the hiatus.

All operations were performed laparoscopically. After closure of the hiatus with sutures, a u-shaped GORE® BIO-A® Tissue Reinforcement was placed and secured across the sutured hiatus (Fig 1-4).

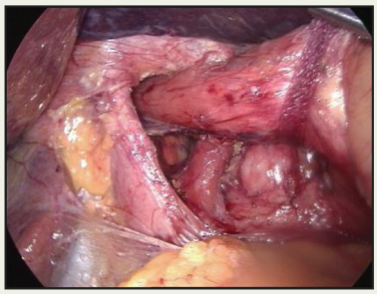

Fig. 1: Dissection of hiatal defect

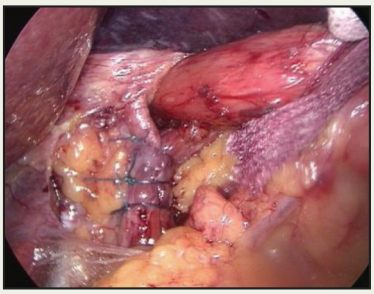

Fig. 2: Closure of the defect

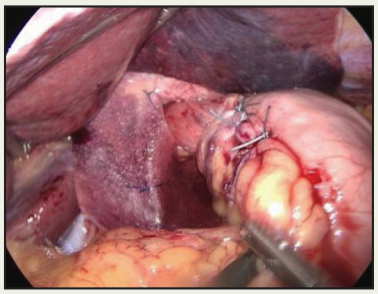

Fig. 3: The mesh is in position, the fundoplication complete

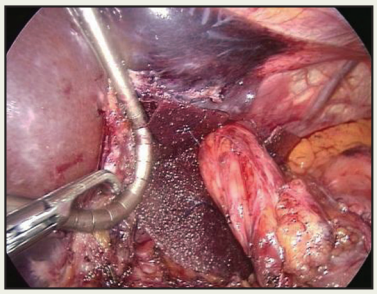

Fig.4: Mesh placement after hiatal closure of a second recurrence hernia

RESULTS

Median OR time was 81 minutes, no intraoperative complications were observed. One patient suffered from prolonged dysphagia over a three week time period.

All patients received a postoperative barium swallow at day three and a gastroscopy at 12 and 24 months. At a median follow up of 14 months (range 12-24 months) no recurrence could be demonstrated through these diagnostic measures. No complications connected to the mesh implantation have so far occurred.

CONCLUSIONS

In this patient group, the use of GORE® BIO-A® Tissue Reinforcement has so far led to a very favourable clinical outcome. Keeping in mind that the implant is resorbed after 6 months the closure of the hiatal defect was maintained. Hopefully these encouraging first results will be further substantiated by an on-going multicenter trial with a planned enrolment of 100 patients.

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