Appendix 4

Delta Mesh background and Technical notes

Introduction

Stable hiatal reconstruction is mandatory for successful hiatal hernia surgery. However, postoperative stability is challenged by significant axial- and bilateral-acting tensile forces, tender and vulnerable muscles without fascial envelopes, and variations of the specific three-dimensional angular composition of the esophageal hiatus in the sagittal and frontal planes. Various techniques of onlay-mesh application have not shown a transparent breakthrough compared to conventional hiatal hernia surgery.

These results led to a fundamentally new closure concept that does not aim to cover the defect, but to induce stable internal reinforcement of the crura. Therefore, a new type of mesh was developed that is specifically adapted to the three-dimensional anatomy of the hiatus and its specific functional requirements.

Innovation

The underlying principle of the DM is the anatomical and functional reconstruction of the disrupted esophageal hiatal unit against the background of its crucial importance for CODIS. Central requirements for the DM were avoidance of an intra-abdominal position, exclusive contact only with the targeted crura, muscle shielding from adjacent abdominal organs, induction of a stable three-dimensional muscle-mesh complex, constructional resistance to the prevailing axial and bilateral tensile forces, safe and easy mesh fixation, small size and simple handling in laparoscopic procedures.

Results

Shape and material

The DM is V-shaped, 30x40x11 mm in size. It is based on the three-dimensional principle of a T-profile, which creates two longitudinal compartments for stable embedding of the left and right crus. This creates a three-dimensional, bi-angular adhesion system with an enlarged integration surface for the muscle tissue. The DM is made of polyvinylidene fluoride, which best matches the natural consistency of the crura and facilitates surgical adjustment to the individual anatomy.

Centrefold

The centerfold arises vertically along the longitudinal midline of the wings and determines the decisive three-dimensional structure of the DM. It creates the two compartments of the T-profile for comprehensive muscle embedding and provides an active edge-to-edge interlocking of the crura. The DM height is limited to 11 mm, which thus allows for complete coverage by the crura. The centerfold supports the longitudinal and torsional stability of the DM and always ensures its standardized exact concentric positioning in the hiatal midline.

Bilateral wings

Both wings unfold autonomously retrocrurally due to the construction and elasticity of the DM. They have a maximum width of 30 mm at the base to provide intensive muscle integration in this area of maximum axial and bilateral tensile forces and to create a stable retrocrural back shield to protect the crura from the transecting forces of the straining hiatal sutures. As the tensile forces in the hiatus decrease towards the posterior, the DM can taper towards the tip without losing stability. The resulting delta shape of the DM significantly facilitates retrocrural positioning of the wings behind the crura.

Location

The DM is placed in the widened esophageal hiatus, inverted, with the base up and the tip down directly below the esophagus. When the threaded first hiatal suture is closed, the DM is automatically positioned concentrically, covered by both crura and shielded from the abdominal cavity.

Fixation

The DM fixation and hiatal closure are simultaneously achieved by the reverse closure technique. The crucial first suture (0-Prolene 0.9m, CT-2 Plus; PROLENE™, Ethicon® Endo-Surgery Inc., USA) takes 8–10 mm of the left crus directly below the esophagus, is threaded extracorporeally along the DM base, and after insertion of the DM through an 11 mm trocar, the right crus is correspondingly grasped in a horizontal line. Closure is performed with a tight locking suture in the extracorporeal technique under tension. This first suture neutralizes all bilaterally acting forces. Therefore, all other 1-2 sutures further below only capture both crura and the base of the centerfold and provide the final closure of the hiatal defect. Additional fixation is not required.

Discussion

Onlay-mesh techniques in common hernia surgery focus on the simple but successful approach to cover a defect by an attached flat mesh. However, these techniques require a large mesh-tissue contact area, reliable structures for mesh fixation, the absence of sensitive adjacent hollow organs and predominant axial instead of bilateral tensile forces. All those prepositions are absent in the hiatal area. In particular, hiatal hernia repair is not about somehow closing a defect,

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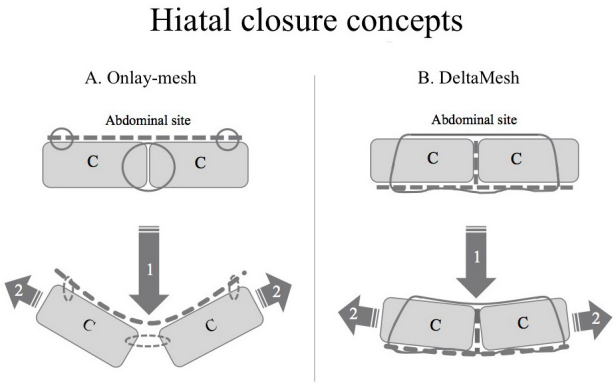

Figure S4 Comparison of hiatal closure concepts. (A) Despite the hiatal coverage by an intraabdominal onlay-mesh, axial force vectors ① continuously strain the sutures between the crura (C) and bilateral forces ② additionally pull the muscles apart underneath the mesh. (B) In DeltaMesh implantation the axial forces support the firm pressing of the crura into its retroabdominal compartments and the bilateral forces are resisted by the edge-to-edge integration of the crura with the centrefold.

but about restoring a fundamental functional structure that is part of the interacting organ system CODIS.

Therefore, the specific architecture of the hiatus was transferred to a corresponding three-dimensional composition of the DM, matching the requirements of inner hiatal enhancement. The T-profile is designed to activate stable edge-to-edge interlocking of the crura and to achieve high joint stability in a bi-angular fusion system. These constructional advantages exceed the stability of common single-angular systems with flat, surface-covering onlay-meshes (*Figure S4*).

Due to its retrocrural position, the DM is shielded from abdominal organs and contact is focused almost exclusively on the targeted crura. Despite its small size, the three-dimensional structure seems to provide sufficient surface area for deep muscle integration.

The easy handling of the DM is based on the small size, elasticity, and ease of grasping the centerfold for positioning. Fast and reliable DM anchoring is obtained by integration into the regular sutures of the hiatoplasty, thus providing a time-saving simplification in laparoscopic procedures. The DM construction and the reverse closure technique ensure that the centerfold is always exactly in the intercrural midline after closure and both wings are retrocrurally unfolded, regardless of hernia size, tissue quality, or surgical variations.

The DM length is intraoperatively adjusted to the size of the defect. The reverse closure technique neutralizes all tensile forces already by the first suture. Therefore, all further sutures can be positioned quickly, tension-free and at a wide distance. This not only saves time, but also helps to preserve the crucial blood supply to the crura. The developed proportions of the DM are suitable for the vast majority of hiatal hernia patients. However, a ready-made DM in different sizes and design could be an important option in the future and may expand indication for the three-dimensional closure technique of i.e. incisional hernias.

The DM concept seems to eliminate various disadvantages of common two-dimensional onlay meshes as the great variability in terms of size, shape, type, placement, fixation, and surgical assessment. Furthermore, during laparoscopic positioning of a flat onlay-mesh, the diaphragm is straightened and stretched by the CO2 pressure. However, CO_2 venting inevitably causes the diaphragm to fall back to its normal anatomical angles, leading to uncontrolled folding of the fixed onlay mesh with the risk of undefined mesh-tissue adhesion complexes found at recurrency surgery.

Conclusions

The new three-dimensional DM provides the stable bi-angular crura closure for hiatal hernia patients. The newly described technique of reverse closure is simple, time-saving, and integrates cruroplasty and DM fixation without the need for additional sutures. The three-dimensional DM closure concept is standardized, reproducible, and independent of the shape or size of the hiatal hernia.

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