Fixation-free Inguinal Hernia Repair
Using a Dynamic Self-retaining Implant

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ABSTRACT

Inguinal hernia repair remains controversial, despite advances in technique and materials. Conventional implants are typically static (passive) and do not move in concert with the groin’s motility. Inguinal hernia repair with mesh fixation on dynamic groin structures are not tension free, and are associated with tissue tearing, bleeding, hematoma, and nerve entrapment—all which might contribute to mesh dislocation.

The poor quality of tissue ingrowth within static meshes/plugs embodies another crucial issue in prosthetic hernia repair. Because the prosthetics used for inguinal hernia repair are incorporated by rigid fibrotic tissue (hence the term “scar plate”), the regressive tissue leads to shrinkage and reduction of the mesh surface area—a significant cause of recurrence and discomfort.

To improve inguinal hernia repair, a new 3D dynamic (inherent recoil), self-retaining implant has been developed. It achieved excellent outcomes in the porcine model, and demonstrated that the dynamic compliant movement and recoil of the 3D prosthetic structure within the groin’s natural tissues allowed for the critical cyclical physiologic loading that is missing with other implants. Because enhanced biologic response and improved quality of tissue ingrowth result from its dynamic interactions with groin tissue, the shrinkage of the implant is nearly absent, even after long-term implantation. We discuss this dynamic hernia repair concept in this report.
The use of this new 3D implant represented a faster and simpler surgical approach to inguinal hernia repair.

The procedure was based on the centrifugal expansion of the device, whose design features converted ejection forces into gripping forces, and avoided the need for suturing the implant (eliminating a cause of complications related to prosthesis fixation).

**MATERIALS AND METHODS**

The implant system.

The 3D dynamic compliant hernia system was a dual system consisting of a disposable dilation and deployment tool of PVC, combined with a synthetic, permanent polypropylene 3D implant (ProFlor,™ Insightra Medical, Inc., Irvine, California) (Fig. 1). The implant possesses a multi-lamellar shaped central core of specially worked polypropylene strips that are formed on 2 floating rings to create an open 3D structure with inherent recoil. The two edges of the petals are comprised of reinforced polypropylene that offers resiliency to the structure. The lateral aspect of the core is made of soft, lightweight, large porous, polypropylene construction; this composition facilitates the gripping of the hernia border to the lateral aspect of the implant core. A flat, large porous, low-weight polypropylene disk helps protect the hernia repair and, facing the peritoneum, stabilizes the implant. The rationale of the implant’s unique 3D geometry is its ability to transform expulsion forces into lateral gripping forces.

Two sizes (boxed together with their respective delivery devices) are available, as shown in Fig 1:
- 25-mm diameter core and 15-mm thick implant with a flat disc of 60-mm diameter, weighing 0.792 grams.
- 40-mm diameter core and 15-mm tick implant with a flat disc of 70-mm diameter, weighing 1.453 grams.

The delivery device is composed of smooth, transparent PVC (Fig 1), and comprises a body with an enlarged distal edge (extremity; olive) that is intended to dilate the hernia opening prior to implantation. There is a flange on the delivery device for a stop to indicate the depth of penetration and prevent over insertion, and a hollow section in the flange is intended as spermatic cord indicator that orients the implant. A plunger is inserted at the proximal extremity of the device that can be
turned in either block- or free-delivery mode by simply twisting the stab horizontally. The predilation of the hernia defect that is achieved by the enlarged distal edge of the device helps augment the gripping action of the muscles and simplify insertion of the prosthesis.

**Procedural steps in indirect hernia repair.**

After skin incision and opening of the oblique interne aponeurosis, dissection and elevation of the cord onto a rubber band followed. This defined the hernia sac location and internal ring. *(Explanatory comments are provided in italics.)*

- Removal of adhesions and scar tissue. At this stage, meticulous removal of adhesions and scar tissue around the internal inguinal ring was performed.
  
  This step was very important because fibrosis and adhesion bridges between the sack and internal inguinal ring impaired the shutter mechanism of the muscular structure of the ring. Therefore, adhesiolysis helped to reactivate the sphincteral function of the internal ring. It was also important to avoid visceral protrusion when the abdominal pressure increased.

- Preparation, ligation, and amputation of the sac. The next steps were: free preparation, high ligation, and amputation of the sac (Fig. 2).

  Although hernia sac amputation is a controversial strategy in static hernia repair, it is recommended by some clinicians. Sac amputation was a crucial maneuver during our procedure that incorporated the 3D dynamic implant. In fact, returning the entire hernia sack into the peritoneal cavity might lead to immediate or early recurrence if the procedure is not carried out under certain conditions (ie, when the implant is too small for the hernia opening). Also, if the sack was cut off (and a small implant used), the flat sutured peritoneal sheath would not re-form a sacculation for several weeks or months. During this period, the stabilizing properties of the preperitoneal disc maintained the implant in place, allowing tissue ingrowth within the dynamic implant. As a result, a defin-
The maneuver was straightforward, and was carried out in a short time period. Despite the presence of epigastric vessels close to the medial border of the internal ring, injury to these vascular structures did not occur since they were readily detachable from the peritoneal sheath. Note that this procedure was also feasible through the use of other implants that were introduced through the internal ring (to cover the posterior aspect of the groin).

Preparation of the 3D implant. The 3D implant was at least 10-15% wider than the hernia opening to ensure that the prosthesis remained in the hernia defect through centrifugal expansion after release into the hernia opening. The implant was compressed with the thumb and forefinger (Fig. 4) and inserted into the chamber of the delivery device (Fig. 5). The implant core remained compressed into the chamber, while the preperitoneal disk was fully deployed outside the chamber (Fig. 6). During implantation, the plunger of the device was loaded by rotating it in block position until the detent stops rotation.

- **Positioning.** The complex delivery device containing the implant was positioned into the hernia opening, with special care that the spermatic cord was pulled laterally from the hernia opening (for indirect hernia). The delivery tool was then advanced into the hernia opening until its flange stopped against the muscular wall (Fig. 7). Additional moderate pushing/turning of the device facilitated better deployment of the preperitoneal disk. The device was slightly pulled back until no more compression was exerted, but remained in tight contact with the ring. At this stage, the plunger could be turned to ejection mode and pressed to push/position the implant into the defect; the preperitoneal disk remained beyond the hernia opening.

Because the olive ring of the implant was larger than the hernia opening, the introduction of the device provoked dilatation of the muscular frame of the internal ring that allowed the reactivation of the internal ring’s shutter mechanism—which might otherwise be blocked by fibrotic degeneration in indirect hernia protrusion. The fibrotic fibers impaired the sphincterial activity of the internal ring, and dilatation helped to break the rigid fibers that impeded the movement of this muscular structure. The impaired shutter mechanism has been described as a common pathogenetic factor for the etiology of indirect hernia.

- **Implantation.** After pushing the plunger of the delivery device, the implant was delivered into the hernia frame (and the empty tool was easily removed). The implant automatically expanded into the hernia defect to fill the gap completely. (Fig. 8) The round lateral surface of the implant core must be positioned on the same plane of the internal ring to achieve co-planar alignment of the 3D implant to the anterior aspect of the hernia opening. The spermatic cord must be positioned laterally to the implant (Fig. 9).

If the leveling of the implant was not achieved during the initial attempt, a simple adjustment of the device was achieved by gripping the small central polypropylene ring with forceps to move the implant into the defect (Fig. 10). Occasionally, because a portion of the preperitoneal disk remained outside the hernia defect, the disc edge was mechanically deployed beyond the opening by forceps.

- **Stress testing.** At this stage, the procedure has been completed. The implant fully obliterated the hernia defect, and the preperitoneal disc interfaced the peritoneum against the posterior aspect of the abdominal wall (Fig. 11). To ensure the effectiveness of the self-retaining placement of the 3D implant, the implant was stress tested (Fig. 12). The 3D implant was loaded by inserting the delivery device through the internal ring to the anterior aspect of the hernia opening (Fig. 13). Then, the device was loaded by rotating it in block position until the detent stops rotation.
implant, the surgeon could apply a stress test. If the procedure was performed under local anesthesia, the patient was invited to cough. By coughing, the squeezing action of the internal ring converted the ejection forces into gripping forces, and allowed the implant to firmly grip the internal ring. In cases of procedures in general anesthesia, the surgeon gripped the central ring of the implant core with forceps and attempted to remove the implant with moderate force.

During the stress tests, the implant can be ejected after powerful coughs, shots, or a strong pull with forceps. Testing did not affect the effectiveness of the procedure, since the implant bumped against the sutured fascia and held the device in place after wound closure (due to anteroposterior buffer effect). Moreover, our experimental data in porcine demonstrated that tissue incorporation occurred within few hours, being that the implant glued into the hernia opening by the advancing tissue incorporation.18

- After checking for hemostasis, the external oblique was sutured. Skin closure was subdermal, and avoidance of wound drains occurred.

**Procedural steps in direct hernia repair.**

- Dissection of the sac. After opening the externus aponeurosis and elevating the cord onto a rubber band, a dissection of the sac from the groin structures to the hernia opening in the fascia transversalis was performed. Removal of any adhesions and scar tissue around the hernia opening was undertaken.
  - After full isolation of the hernia sac, the transversalis fascia was breached (as wide as necessary) to detach the peritoneal sacculation (with contents) around its posterior aspect.
  - Finger-guided dissection. A finger-guided dissection (or mechanical adesiolysis with mounted pad) of the parietal peritoneum from the posterior abdominal wall was performed to accommodate the placement of the preperitoneal disc of the implant. The released sack was then replaced into the abdominal cavity.
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Figure 11. Schematic representation of the implant obliterating an indirect hernia opening.

- Preparation of the 3D implant. Preparation of the 3D implant for delivery into the hernia opening was performed as described above for indirect hernia.

- Implantation. The delivery of the implant was performed as described above for indirect hernia.

- Positioning. Specific attention was accorded to the deployment of the preperitoneal disc to cover the internal ring to avoid future protrusion of indirect hernia.

- Stress testing. After positioning the implant into the hernia frame, a stress test was mandatory. If the procedure was carried out under local anesthesia, the stress test was performed by having the patient to cough one or more times. If the procedure was performed under general anesthesia, a stress test assessed the self-retaining behavior of the implant by having the surgeon slightly pull the implant outward by gripping the small central ring of the core with forceps. Observations on stress testing were applicable as noted for indirect hernia.

- After checking for hemostasis, the external oblique was sutured. Skin closure was subdermal, and avoidance of wound drains occurred.

REFERENCES


DISCUSSION

Although treatment of inguinal protrusions includes one of the most common surgical procedures performed today, neither the surgical community nor industry has proposed/implemented significant changes in technique and material for decades. Currently, no gold standard exists, and high post-operative complication rates, and discomfort and chronic pain characterize its treatment.

In an effort to utilize current and forward-looking concepts in the physiology/biodynamics of the inguinal region, pathogenesis of protrusion disease, and emerging technology, we have developed an operative schema that improved patient outcomes in inguinal hernia repair.

CONCLUSION

We report a newly developed repair technique for the surgical treatment of inguinal hernia. This technique incorporated current physiologic concepts, pathogenesis, emerging devices, and new procedures. The surgical community might utilize it as an additional option to improve and actualize the technical aspects of hernia repair procedures.