

Hernia Repair: Challenges and Innovations; Our Initial Experience with Dynamic Implants

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Abstract: *Hernia is a common surgical condition and surgery for hernia is the most commonly performed surgery. A large variety of surgical procedures are done to treat hernias. Still the problems of recurrence and chronic pain, post operatively affect the quality of life of the patients. Practice of surgery has marched from being merely life and limb preserving to being enhancer of post operative quality of life. Patient reported outcomes take precedence over clinical outcomes and this has encouraged surgeons to innovate. New innovative method of treatment of hernias with 3 D dynamic implants which result in regenerative hence physiological healing of hernias is discussed. We also present our initial experience with these implants.*

INTRODUCTION

Hernia is a very common, benign condition. Most of the surgeons perform hernia surgeries in large numbers using variety of techniques. Hernia surgery is performed in all kinds of surgical set ups ranging from very basic to most advanced and it is done everywhere may it be rural, semi-urban and urban areas in all the countries throughout the world. Hernia surgery is performed by surgeons- juniors as well as seniors i.e... experienced and not so experienced. Bassini's repair was a gold standard treatment for inguinal hernias before the introduction of meshes as prosthetic materials. Herniorrhaphies were replaced with hernioplasties using meshes and Lichtenstein procedure became gold standard treatment. Laparoscopic management of hernias with use of meshes came in, but needed costly equipment and a learning curve to master the technique of laparoscopic treatment of hernias. Laparoscopic treatment is associated with higher risks and complications for management of a benign surgical condition (hernia), more so in inexperienced hands. Meshes used in open hernia repair are made up of various materials with different weights and pore sizes. The management of this benign condition with meshes helped in reducing the rate of recurrent hernias significantly. Recurrences in cases after mesh repairs and mesh associated significant complications like inguinodynia are observed in patients. These complications have a significant impact on quality of life of the patients. Polypropylene mesh induced inflammation and fibrosis leading to formation of scar like tissue with involvement of the vas, vessels of the spermatic cord and nerves in the inguinal canal are becoming a cause of concern as these can lead to complications like - abnormal fertility, ischemic orchitis and neuralgias. Surgeons need to relook at the physiology of inguinal canal which is a dynamic structure and we need to understand the etio-pathogenesis of hernia as a disease. Studies have shown that hernia is a degenerative disease and this has been shown on histological studies of the tissues of the inguinal canal. Repair of dynamic inguinal canal needs to be of a dynamic nature instead of static and fixed meshes which should induce regeneration of healthy tissues. 3-D dynamic implants are very useful in physiological hernia repair.

REVIEW OF LITERATURE

Inguinal hernia most probably has been a disease ever since mankind existed. It occurs in different kinds of animals, particularly primates; even prehistoric human beings were affected with the disease. The surgical history of inguinal hernias dates back to ancient Egypt. From Bassini's heralding of the modern era to today's mesh-based open and laparoscopic repairs, this history parallels closely the evolution in anatomical understanding and development of the techniques of general surgery¹. Accounting for 75% of all abdominal wall hernias, and with a lifetime risk of 27% in men and 3% in women, inguinal hernia repair is one of the

most commonly performed surgeries in the world². In the United States, inguinal herniorrhaphy accounts for approximately 800,000 cases yearly³. It is estimated that of all hernias, 66% are indirect and 33% direct⁴.

Hernias are typically repaired through a surgical procedure called herniorrhaphy, in which the surgeon repairs the hole in the abdominal wall by sewing surrounding muscle together or by placing a patch called "mesh" over the defect. Most surgeons make an incision at the site of the hernia in order to gain access to the defect, although some surgeons prefer to do these procedures laparoscopically. During a laparoscopic hernia repair, the surgeon makes very small incisions to pass through specialized instruments and an endoscope, a device that allows the surgeon to see the abdominal area without opening the patient up. Laparoscopic hernia repair generally results in less postoperative pain and recovery time than open surgery.

Current inguinal hernia operations are generally based on anatomical considerations. Failures of such operations are due to lack of consideration of physiological aspects. Many patients with inguinal hernia are cured as a result of current techniques of operation, though factors that are said to prevent hernia formation are not restored. Therefore, the surgical physiology of inguinal canal needs to be reconsidered. A physiologically dynamic and strong posterior inguinal wall and the shielding and compression action of the muscles and aponeuroses around the inguinal canal are important factors that prevent hernia formation or hernia recurrence after repair. In addition, the squeezing and plugging action of the cremasteric muscle and binding effect of the strong cremasteric fascia, also play an important role in the prevention of hernia.

Inguinal hernia repair still remains a problem because of: a) high recurrence rates seen in the hands of the junior surgeons; b) risky dissection of the inguinal floor in the Bassini/Shouldice repair and c) infection and chronic groin pain following mesh repair.

The successful management of any problem depends on the understanding of its patho-physiology. In this context, some questions related to the physiology of the inguinal canal or factors that prevent herniation still exist. Lateral and cephalad displacement of the internal ring beneath the transversus abdominis muscle and approximation of the crura results in a shutter mechanism at the internal ring⁵. When the arcuate fibers of the internal oblique and transversus abdominis muscle contract, they straighten out and move closer to the inguinal ligament (shutter mechanism) at the inguinal canal^{6,7}. This opposite movement (upward & downward) of the same muscle needs proper explanation. The term "obliquity of the inguinal canal" is not a perfect description since the spermatic cord is lying throughout its course on the transversalis fascia. Repeated acts of crying, thereby increasing the intra-abdominal pressure do not increase the incidence of hernia in new born babies inspite of the almost absent "obliquity of the inguinal canal" or "shutter mechanism". Similarly, every individual with a high arch or a patent processus vaginalis does not develop hernia⁸. Factors that are said to prevent herniation are not restored in the traditional techniques of inguinal hernia repair and yet 70-98% of patients are cured. Inguinal hernia repair is one of the most common performed surgical procedure. Inguinal hernia repair is associated with long term

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risks of pain and discomfort. In 1996 Cunningham et al were the first to report a pain incidence of 63% after one year⁹. Five years later, in a large cross sectional cohort study the rate of chronic pain was 29%. This complication was associated with functional impairment in more than half of those with pain¹⁰. Chronic pain accounted for restriction in daily activities in up to quarter of patients¹¹. In an updated review the risk of a chronic pain state with clinically significant effects on daily activities was about 12%¹². The foreign body response to meshes resulted in axonal edema, loss of myelinated axons, peri and endoneuronal edema and subsequently pain¹³. Pain may also be dependent on the method of fixation. Sutures may cause ischaemia, muscle contraction or nerve damage resulting in pain. This is corroborated by the fact that removal of sutures can be effective treatment in patients with pain¹⁴.

There are several techniques for mesh implantation, but most involve sutures to anchor a mesh in position and prevent migration, wrinkling and curling. Sutures that anchor the mesh are blamed for extensive tissue tension and nerve entrapment leading to prolonged post operative pain. Even the application of absorbable sutures instead of non-absorbable ones does not solve the problem.

Chronic groin pain following inguinal hernia repair is a significant, though under-reported problem. Complications associated with sutured fixation of the mesh have prompted surgeons to use atraumatic fixation using substances such as human fibrin glue. These adhesives have shown reduced incidence of chronic groin pain, foreign body sensation and groin numbness in both randomised trials and observational studies¹⁵. Avoiding chronic groin pain should be a prime goal for any hernia surgeon, considering that 5-7% of patients with post-herniorrhaphy groin pain will sue their surgeons¹⁶. Practice of surgery has marched from being merely life and limb preserving to being enhancer of post operative quality of life. Patient reported outcomes have always taken precedence over clinical outcomes and this has encouraged surgeons to innovate¹⁷. Introduction of polypropylene prosthesis by Francis Usher, brought an era of progressively decreasing recurrence rates. Success with polypropylene meshes is associated with formation of mesh aponeurosis scar tissue complex. Inflammatory response induced by polypropylene is integral to mesh aponeurosis scar tissue complex formation, but continuation of inflammation beyond this complex has raised many concerns. Markers of inflammation continue to play around for years in the polypropylene implanted tissues around inguinal region¹⁸. The debate now is about potential polypropylene induced insults to structures contiguous to inguinal region. Insult to testicular vasculature, adjoining nerves and vas can lead to ischemic orchitis and even atrophy. Myelin degeneration, endoneuronal and perineuronal edema, fibrosis and axon loss can be induced by polypropylene leading to chronic neuropathic inguinodynia. Entrapment of vas in mesh aponeurosis scar tissue cicatrix can impair the vas motility and intraluminal motility leading to obstructive azoospermia apart from dysejaculation. Post herniorrhaphy secondary infertility in males cannot be wished away despite the lack of randomised trials which are not possible due to ethics of obtaining preoperative semen parameters¹⁹. Hence a rethink on polypropylene meshes is required as meshes have been regarded as mechanical overkill. Complications associated with meshes are probably due to mesh contraction and entrapment of structures of inguinal canal in the scar tissue.

UNDERSTANDING ETIOLOGY AND PATHOGENESIS

Etiology and pathogenesis of inguinal hernia still represent an open question. Despite the advances in surgical materials and techniques, little progress has been achieved concerning the dilemma of hernia origin. In recent literature few articles are focused in examining the changes of the tissue structures in the inguinal region affected by hernia protrusion.

To fill this lack of knowledge, Amato et al studied the tissue specimen of 30 fresh male cadavers with inguinal hernias. In these cadavers tissue samples were excised from the structures close to the hernia orifice

following a specific method. The samples were subjected to histological study.

In order to accomplish an adequate control of the study group, in 15 autopsied male subjects without hernia tissue specimens were resected from equivalent sites of the inguinal area with the same *modus operandi*. The tissue excised from the hernia border demonstrated multiple histological changes of the structures surrounding the hernia. In all resected specimens the most significant feature was a constant verified fibrohyaline degeneration of the myocytes, often surrounded by fatty dystrophy of the muscle fibers.

Besides inflammatory infiltration composed by lymphohistiocytic and plasmacellular elements, they found important changes of the venous structures, such as venous congestion and vein fibrosis. More significant findings were detected on the arterial structures: thickening of the arterial wall due to medial hyperplasia leading to subocclusion or even complete obstruction of the arterial patency. Several nerve axons were detected between the altered myocytes. The nervous structures clearly demonstrated fibrotic degeneration and manifest atrophy of the axons as well as the thickening of the myelin sheath.

On deeper analysis of the histological changes of the tissue bordering the hernia opening, several outcomes were imagined regarding the possible impact this damage has on the physiology and kinetics of the groin: Degenerative changes of motor nerves and thickened myelin sheath which have been seen, could be linked to the reduced motile activity leading to muscle atrophy and, consequently, to a reduced contractile response (as a physiological barrier) to the visceral impact when abdominal pressure arises.

A decreased blood supply leading to ischemic degeneration of the groin structures may represent the result of the artery sub occlusion or obstruction, Venous congestion, vein fibrosis and inflammatory infiltrate could embody the outcome of a steady compressive effect exerted by the abdominal viscera to which follows tissue congestion and impaired metabolism.

Hyaline degeneration, fibrosis and fatty dystrophy of the muscle fibers within the groin could be the result of the chronic, degenerative changes to the vascular and nervous components seen in that area. These multifactorial damages are probably amplified by the effect of the visceral compression upon the lower abdominal wall²⁰.

All these findings could also explain the alterations of the collagen in the groin area evidenced by several scientists, the described results of the histological study in tissue bordering the hernia opening could represent a further contribution in understanding the reasons of the multifactorial causes leading to the weakening of the inguinal area and to hernia protrusion

As of now, the techniques being used for hernia repair, cover the inguinal area which is one of the most mobile areas in the human body, with static meshes which are suture fixed to surrounding structures. Meshes are flat and as these are fixed with sutures this leads to stiffness and shrinkage of the implant. This is a cause of discomfort and chronic pain. The shrinkage of the mesh can set free the hernia opening, which was previously covered with mesh, this is a prelude to hernia recurrence. The 3 D dynamic implants used in hernia repairs do not cover, but full thickness obliterates the muscular gap where hernia arises. These dynamic implants promote the re-growth of healthy tissues in the area of the hernia opening, establishing a condition similar to normal abdominal wall structures. These dynamic implants move in harmony with the inguinal structures promoting regeneration of new and vital tissue inside the structure and enabling a true barrier which closes the hernia orifice. The dynamic implants do not require any fixation. The dynamic implant does not shrink, does not cause discomfort and it causes a lower post operative pain.

The results of combined procedure, scar removal, dilation and implant delivery, led to thoughtful suggestions regarding the anatomy and the physiology of the inguinal canal. The procedural adhesiolysis during indirect inguinal hernia repair has always shown the well described

concentric muscular arrangement formed by the internal oblique and transversus muscles. This circular shaped muscular structure is often recognised as a static barrier that, due to weakness and/or together with other causes, fails in its role and allows indirect inguinal hernia protrusion. Its steady tightening motion after divulsion and the insertion of a lamellar implant is always accompanied by a strong gripping action, which is not seen prior to divulsion. This indicates that it could correspond to a sphincter: the 'inguinal sphincter.' The impairment of this sphincter could be the cause of the inguinal canal's patency and the development of hernia²¹.

OUR EXPERIENCE

We have used 3 D dynamic implant in repair of 5 ventral hernia cases and 2 inguinal hernia cases at Department of Surgery, GMSH-16, Chandigarh. In all these cases implants were deployed and no sutures were used. All the patients were taken up under spinal anaesthesia after getting all routine investigations done. Out of ventral hernia cases, 3 were females and 2 were males. While both inguinal hernia cases were males. Two ventral hernia cases were incisional hernias and one patient had a recurrent paraumbilical hernia. Post operative period was uneventful and there was no significant post operative pain in the immediate post operative period. None of the patients had chronic pain following surgical procedure up to a follow up period of 9 months. No recurrence has been seen in these cases, even though it is a short period of follow up as yet. When we compare the results in terms of post operative pain and feeling of tightness/hardness seen in our other patients where we use meshes to repair hernias, it is not seen in cases of dynamic implants. This is our initial experience with use of dynamic implants and we need results in more cases and further studies to compare the benefits of dynamic implants as compared to static meshes.

TECHNIQUE AND FEATURES OF DYNAMIC IMPLANTS

INGUINAL IMPLANT

Inguinal implant eliminates the need for fixation and is 100% fixation free. It improves scar generation and hence reduces recurrence rates and improves patient comfort. There is a system to deliver this uniquely designed 3 D autostatic implant as a result of which the more the body tries to expel-the more it grips. It is a dynamic implant which moves with surrounding tissues and creates a thick, living progressive tissue barrier.

First the blocking adhesions of the sac are dissected out. Next we break the blocking adhesions in the muscle wall by divulsion that is by dilatation fracture. This is followed by introduction of dynamic implant that applies radial force to be gripped but allows physiologic movements. The rear disc of the implant helps in preventing expulsion and it also acts as a shield to prevent future muscle damage. The lamellar structure of the implant does not impinge on the spermatic cord. Implant is dynamic as it compresses and relaxes with change in intra-abdominal pressures. (Figure 1)

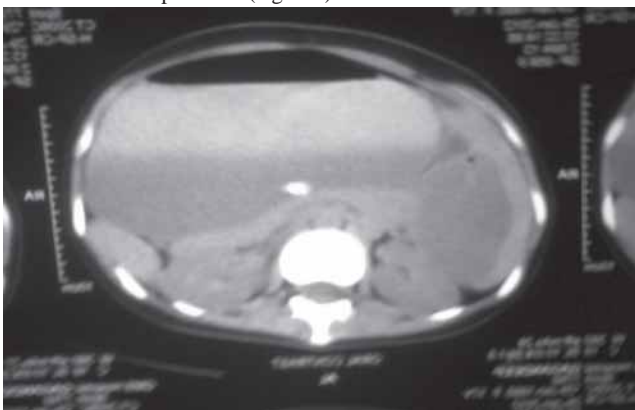


Figure 1

VENTRAL IMPLANT

In ventral hernia, sublay mesh with straps is placed in preperitoneal or retromuscular space. Straps help in elimination of suture fixation. Straps are 20mm wide and are brought out through tissue tunnels using specially designed needle which is 3mm wide. The straps roll out into a cylinder and get fixed by friction as elastic recoil increases outward force. Straps help in creating a very high holding force immediately after implantation. Straps are part of the implant and not an adjuvant. When there is increase in intra-abdominal pressure, load is transmitted to the straps and not to the tissues. Strap fixation gets stronger as it incorporates in the body. Tissue ingrowths help in incorporation of the straps into the tissues for the length of the tunnel.(Figure 2)

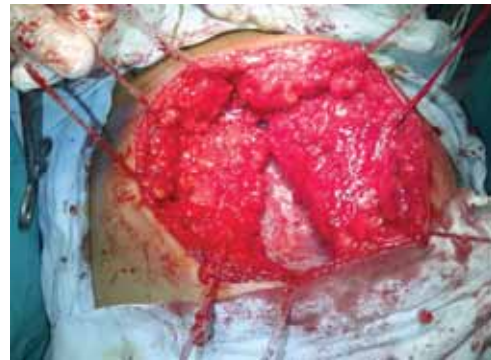


Figure 2

CONCLUSION

3-D dynamic implants promote a regenerative and physiologic healing for hernias which occur as a result of tissue degeneration. No suture fixation is required which helps in preventing various problems seen in post operative period. Dynamic implants help in improving quality of life of the patients.

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