

## ORIGINAL RESEARCH

# Evaluation of Suture Free 3-D Mesh in Patients With Inguinal Hernia- A Pilot study

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### ABSTRACT

**Purpose:** The use of prosthetic implants in inguinal herniarepair is considered as gold standard. The conventional prosthesis used earlier were static and passive and there were complications related to the direct fixation of these prosthesis, such as bleeding, nerve entrapment, hematoma, pain and discomfort. So, to improve the results and to assess the post-operative complications after inguinal hernia repair with 3D suture-less prosthesis, we performed a prospective study. **Methods:** From September 2015 to March 2017, 50 patients with inguinal hernia underwent inguinal repair with Proflor ( Insigntra). The patients were evaluated pre operatively clinically and by ultrasound. Patients were assessed postoperatively at seven days, three months and six months. **Results:** According to the visual analog scale the pain ranged from one to three during the first week and no pain was reported after one week. There were no recurrences and post operative complications except for seroma in one patient. Ultrasound findings showed that all the implants delivered were well placed. **Conclusions:** This suture-less dynamic implant technique could be considered as an alternative method to decrease complications of hematoma formation, chronic pain and nerve entrapment after inguinal hernia repair.

**Keywords:** Inguinal hernia, Proflor, sutureless.

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### INTRODUCTION

It is estimated that 75% of all the hernias are groin or inguinal hernias with 66% being direct and 33% being indirect. In the late twentieth century E. Bassini approximated the conjoint tendon to the inguinal ligament using sutures [1]. The modern era of inguinal hernia repair started in 1962 with Usher, who first used a polypropylene flat mesh [2,3]. Lichtenstein developed the so called "Tension free" hernia repair [4-8]. In the last decade, the prosthetic hernia techniques have been expanded with the use of static three dimensional structures. Recent studies have started to depict the pathogenesis of hernia as a degenerative disease of the organ of abdominal wall due to compressive damage [9, 10]. So the ideal implant for inguinal hernia repair should mimic the biomechanics of the groin. The primary considerations are to reduce complications associated with invasive fixation and improve the quality of tissue ingrowth within the implant. Therefore, a newly designed Proflor mesh was developed. In the present study, 50 cases with inguinal hernia were repaired by

a novel suture-less technique using the proflor self folding polypropylene 3-D mesh in pre-peritoneal space and were analysed with regard to recurrence, post operative complications hematoma, seroma, chronic pain, patient discomfort and time of return to normal activity.

### MATERIAL AND METHODS

Fifty patients diagnosed with inguinal hernia ( direct, indirect or both) undergoing hernia repair with a 3-D suture-less Proflor mesh in the Department of General Surgery, Guru Nanak Dev Hospital attached to Government Medical College Amritsar were included in the study (table I and II)). The study was approved by the local ethics committee and informed consent was obtained from all the patients. All pediatric patients and patients with recurrent inguinal hernia were excluded from the study.

**Surgical technique:** Spinal anaesthesia or local anaesthesia was the anaesthesia of choice. Skin incisions (4-8 cm) were performed directly above and

centred on the internal inguinal ring. Dissection was performed through Scarpa's fascia to the aponeurosis of the external oblique muscle. Soft tissue retractors were used to assist in optimising access to the surgical field. Exposure of the superficial inguinal ring was gained and inguinal canal was opened. Dissection of the cord and the sac was performed. For direct hernia, after opening the aponeurosis of external oblique, we performed dissection of the sac from the groin structures. Once hernia sac was fully isolated, the transversalis fascia was breached as wide as necessary to detach the sac with its content from posterior wall.

**Isolation of spermatic cord:** For Indirect hernia after the skin incisions and opening aponeurosis of external oblique muscle, dissection of cord was done and hernia sac was defined. Precise dissection of the sac was performed. Dissection of the cord and the sac at the level of the internal ring was done.

**Creating the pre-peritoneal space:** Before releasing the sac into the abdominal cavity, a blunt finger guided dissection of the parietal peritoneum from the posterior abdominal wall was performed. 360° finger guided dissection of the peritoneum provided an adequate space to place the disc of the Proflor mesh. Peritoneum was inspected prior to insertion of the implant to ensure there are no openings.

**Placement of implant:** Appropriate sized Proflor 3-D suturefree mesh was selected according to the defect size (fig.1). Implant was loaded into the delivery device aligning the lamella with the flange notch indicator as per device instructions. The loaded delivery device was inserted into the hernia defect.

In indirect hernias the flange notch indicator was aligned with the spermatic cord and the delivery

device was inserted until the stop flange was flush with the internal ring (indirect hernia) or transversalis fascia (direct hernia). Using the plunger the implant was deployed while retracting the delivery device from the defect. The pre-peritoneal disc was adjusted with the forceps. The transversalis fascia was positioned around the petals (fig. 2).

**Stress or pull test:** Since the patient was in local or regional anaesthesia, patient was asked to cough and confirm if the implant remains in place. The aponeurosis of the external oblique muscle was closed and the cord was left below it.

## RESULTS

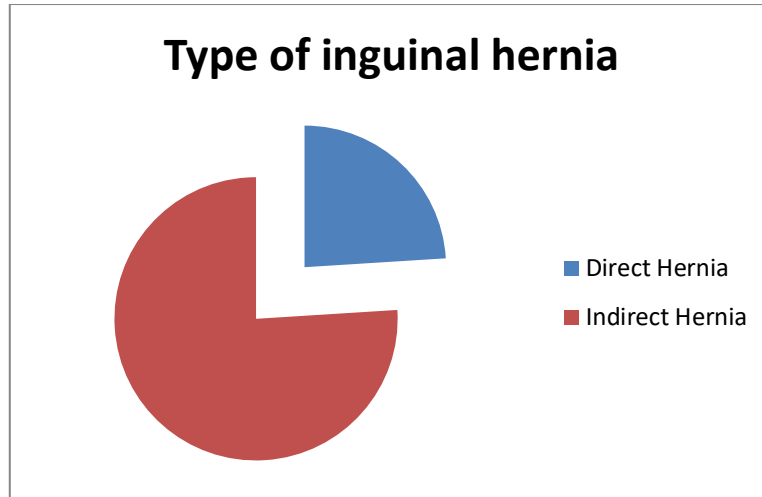
Short term and long term post-operative complications were evaluated with respect to recurrence, post-operative pain, and condition of wound, mobility and return to normal work. There was no early complication reported except seroma in one patient (2%). Seroma reported was small in size and resolved spontaneously. Mild acute post-operative pain was present in all the patients with a mean duration of two days. Pain was assessed by VAS score and in the first post-operative week ranged from 0-3 which was resolved after a mean duration of two days. Pain score was evaluated at first week, three months and six months post-operatively. None of the cases of pain were reported at any of the time periods except during first week (Table III). Ultrasound findings after three months were used to assess the correct placement of the implant. No migration of the implant was reported in any of the patients until six months. There were no reported cases of recurrences in all 50 cases on follow ups. There were no reported cases of graft rejection as wound remained healthy on post operative follow ups.

**Table 1: Showing patient characteristics**

| No. of patients  | N= 50        |
|------------------|--------------|
| Mean Age (years) | 55-60 (57.5) |
| Sex ratio (M/F)  | 50/0         |

**Table 2: Showing distribution of direct and indirect hernia.**

| Diagnosis       | Number | Percentage |
|-----------------|--------|------------|
| Direct hernia   | 12     | 24%        |
| Indirect hernia | 38     | 76%        |
| Total           | 50     | 100%       |



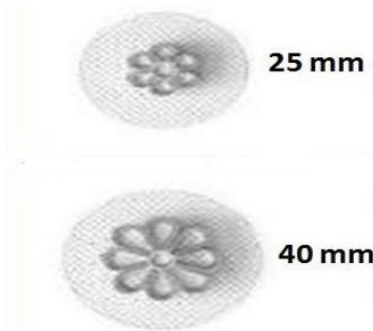
**Table 3: Showing visual analog scale**

| Pain score | Remarks         |
|------------|-----------------|
| 0          | No pain         |
| 1-3        | Mild pain       |
| 4-6        | Moderate pain   |
| 7-9        | Severe pain     |
| 10         | Unbearable pain |

**Table IV: Showing Post-operative complications**

| Complications           | Number | Percentage |
|-------------------------|--------|------------|
| Wound infection         | Nil    | 0%         |
| Recurrence              | Nil    | 0%         |
| Graft Rejection         | Nil    | 0%         |
| Migration of prosthesis | Nil    | 0%         |

**Fig. 1 Sizes of Proflor 3-D mesh**



**Fig 2: Mesh holding defect in fascia transversalis**



## DISCUSSION

Inguinal hernia repair remains a source of passionate debate today. The use of implants in the hernia repairs can be traced back to more than three decades ago but with complications such as patient discomfort, chronic pain, and recurrence of hernias. Lichtenstein introduced Tension-free hernioplasty with the advantages of low rate of morbidity, low rate of recurrence, short hospitalization and decreased post-operative pain. But based on the literature, the high rates of chronic pain in open groin hernia repairs cannot be overlooked [11]. According to the international association of the study of pain (IASP), the chronic post-operative pain can be defined as any pain reported by the patient beyond three months post-surgery. Based on some recent studies there is a great variability in the data regarding incidence of chronic pain [12, 13]. This can be due to different methods which are used to define pain. Such pain may be attributed to nerve entrapment in the sutures (neuropathic pain), or mainly a consequence of inflammatory fibrotic response to the placement of a foreign body. Recent studies have identified the pathogenesis of hernia as a degenerative disease of the organ of the abdominal wall due to compressive damage. The authors believed that dynamic function of the groin should be respected and inguinal hernias should be treated with dynamic implants [9]. These dynamic implants should mimic the biomechanics of the groin and should promote tissue regeneration to form an integral barrier against protrusion. On the other hand, static implants only serve as a physical barrier and are only fixed in various ways to the muscles and often on the sensory nerves. This goes against the dynamics of the muscles of the groin causing an inflammatory response that later on contributes to the chronic post-operative pain. So the physics of the implant used should be such that the implant itself eliminates fixation. Amato G of Italy presented a solution to this problem by developing a specially designed propylene 3D implant, Proflor [14, 15]. It served to translate outward visceral forces to cause a dynamic implant transformation that induced greater gripping forces at the hernia border. The Proflor implant used in this prospective study has several characteristics of the ideal implants. This complex 3-D geometry improves non-invasive fixation free and grip and also ensures a compliant dynamic scaffold that expands and contracts with muscle movement in the abdominal wall. It is made from non-absorbable polypropylene, is self-fixing, light weight and has large pore structure. The results are different from the clinical and biological response to the flat meshes. The advantages of the dynamic meshes such as rapid incorporation, less inflammatory response, regeneration of tissue instead of fibrotic scar growth are remarkable. The sutureless 3-D implant used in this prospective study well adapted to the dynamic movements of the abdominal wall. The ultrasound findings of these patients revealed well

placed implants with apparently healthy tissue in the vicinity. So, the results are same as evidenced by previous animal studies [15]. In all the patients under study, post-operative complications were negligible. The chronic pain was not reported in any of the subjects. The lower pain scores in suturefree 3 D mesh were due to its self retaining property, lesser tissue dissection and placement of mesh behind the fascia transversalis which is free of nerves. The complication such as bleeding, nerve entrapment, hematoma, pain and discomfort were totally absent (table IV). Due to the reduced inflammatory response, patients returned to normal activities within five to ten days. To follow-up the results, patients were investigated at the intervals of seven days, one month, three months and six months post-operatively. Ultrasound findings were in accordance with the clinical investigations.

## CONCLUSION

A newly developed hernia repair technique for surgical treatment of inguinal hernia utilizes a suture less implant with dynamic properties, which eliminate the fixation of the device. There was marked improvement in the elimination of complications associated with the invasive fixation. The surgical community might utilize it as an additional option to improve and actualize the technical aspects of the hernia repair procedures. However, the present study was only limited to a short term follow up of six months, further long term study needs to be done to assess the recurrences.

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