International Journal of Science and Research (IJSR)
ISSN: 2319-7064
SJIF (2022): 7.942

Utility of Non-Absorbable Knitted Surgical Polypropylene Mesh - A Post Market Clinical Follow Up Study

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Abstract: ***Use of meshes is a current standard in the hernioplasties performed these days. With several varieties of meshes available in the surgeon's armamentarium, polypropylene meshes are one of the common meshes used. Though meshes have been in use since last few decades, there are known complications associated with their use too, including foreign body reaction and infection. This post market clinical follow up study was done to assess the clinical performance, safety and acceptability of the Non-Absorbable Knitted Surgical Polypropylene Mesh and to determine if any undesirable events occurred. A total of 51 subjects participated in the study. All the subjects benefitted out of the surgeries where Non-Absorbable Knitted Surgical Polypropylene Mesh was used with excellent intended results. Additionally, no adverse events related to the use of the material were recorded in the study.***

Keywords: hernia, surgery, mesh, polypropylene

1. Introduction

The surgical treatment of hernia has become of the most commonly performed procedure in general surgery and can be performed using a variety of techniques. The 19th century marks the beginning of the modern era of hernia surgery with the appearance of the Cooper and Scarpa manuscripts. In 1984, E. Bassini introduced the idea that the weakness of the posterior wall of the inguinal canal is responsible for the production of a hernia. As a result, he introduced the idea of strengthening the posterior wall by suturing the lower edge of the deep abdominal muscles to the femoral arch.[1]

The revolution in the treatment of hernias began with the use of the principle of 'Tension-Free hernioplasty', in which the tension in the structures of the inguinal canal disappears, an idea promoted by French surgeons J. Rives and R. Stoppa. They used a polymer mesh for the first time in the repair of the hernia.[1]

The concept of using a mesh to repair hernias was introduced decades ago and is now standard in most countries and widely accepted as superior to primary suture repair. As a result, there has been a rapid growth in the variety of meshes available. Materials like polypropylene, the expanded polytetrafluoroethylene (ePTFE) and polyester are the most commonly used in various meshes available today.[1–4]

Dolphin Mesh® is a monofilament synthetic non – absorbable, sterile surgical mesh composed of an isotactic crystalline stereoisomer of polypropylene, a synthetic linear polyolefin. It is used in hernia repair and weak tissue support.

The purpose of this study was to conduct the Post Market Clinical Follow up (PMCF) for the Non-Absorbable Knitted Surgical Polypropylene Mesh (Dolphin Mesh®, manufactured by Futura Surgicare Pvt Ltd, Bangalore, India)

Primary Objective

The primary objective of this post market clinical study was to assess the clinical performance, safety and acceptability of the Non-Absorbable Knitted Surgical Polypropylene Mesh.

The study end points included

Any signs of infection after surgery

Any delayed absorption occurred

Any mesh rejection shrinkage or migration occurred

Any incidence of recurrence of hernia

Ease of use using Likert's scale (1-5)

Secondary Objective

The secondary objective was to determine any undesirable events under normal condition of use and identify the presence of any new emergent risks, known and unknown residual risk. The study also focused on identifying possible systematic misuse or off-label use of the device.

2. Materials and Methods

The study was a retrospective, single centre study. The study was retrospective since the product is in use for 15 years. The study was conducted in the hospital where the Principal Investigator had performed the surgeries. The data was collected from the surgeon who is the PI for the study who had used Dolphin Mesh®- Non absorbable Knitted Surgical Polypropylene Mesh manufactured by Futura Surgicare Pvt Ltd, Bangalore, India for the following indication:

1) Hernia repair
2) Weak tissue support

The Post Market Clinical study to find out clinical performance and safety of the Non absorbable Knitted Surgical Polypropylene Mesh, got the Ethical approval from ACE Independent Ethics Committee (DCGI Reg.No. ECR/ 141/ Indt/ KA/ 2013/RR-19, NABH Certificate No. EC-CT-2018-0029) dated 20th November 2021.

Safety assessments were considered for all the subjects during the surgery. Acceptable surgical practice was followed for the management of contaminated or infected wounds. In handling this mesh material; care was taken to avoid damaging the surface of the material with surgical instruments as this could lead to fracture of the material in use. Care was taken to avoid damage while handling the surgical mesh. Clinical activity was assessed using local standard of care and the appropriate response criteria as determined by the local available Surgeon.

Performance characteristics listed in the Table 1 below were assessed during the PMCF study.

Table 1: Performance parameters

Performance Parameters	Definition
Ease of handling	Ability to handle the mesh without causing any damage
Thin and Light weight	The thin and light weight mesh have less foreign body reaction and are more elastic
Flexibility	Flexibility is the quality of being easily bent
Tensile strength of mesh	The tensile strength of mesh material indicates the ability of the material to withstand stress during procedure and protect the wound during extended period of healing
Sterility	Sterile meshes are free from all microorganism and prevent the surgical site infections
Porosity	Mesh porosity is the ratio of pore to total area. Mesh has porosity for high visibility & colonization
Mesh material	Ability of mesh material to achieve the intended performance

The number of subjects randomized for this study was selected based on simple random sampling technique.

The descriptive analysis was done as per the Statistical Random Sampling Analysis.

Since the purpose of this study was descriptive, there was no formal sample size calculations based on comparative hypothesis testing. Statistical analysis will be descriptive (e.g., reporting means, standard deviations, medians, minima, and maxima for continuous variables and patient counts, frequencies and percentages for categorical variables).

With a confidence interval of 95% and expected positive response in 95% and adverse event of 3% the sample size was determined to be 45.

The entire duration of the study was five months.

Inclusion Criteria

Adult patients who are ≥ 18 years old, who have undergone hernia surgery in whom the Dolphin Mesh® -Non absorbable Knitted Surgical Polypropylene Mesh was used for hernia repair and weak tissue supports were included.

Exclusion Criteria

Subject sensitive or allergic to polypropylene

Results

The PMCF data was evaluated through Clinical PMCF data summary and Clinical Case Study reports for each subject on whom Non absorbable Knitted Surgical Polypropylene Mesh was used.

As per the PMCF Checklist collected, 51 subjects have been chosen to the PMCF study out of which 71% (36) are male and 29% (15) are female. PI used this Non absorbable Knitted Surgical Polypropylene Mesh for hernia repair.

As per the PMCF checklist collected from 51 subjects, the surgical procedures involved for hernia repair and various types of hernia observed in these 51 subjects is given below in the table 2.

Table 2: List of surgical procedures where the Dolphin Mesh® was used

Surgical Procedures:	Open surgical procedure Laparoscopic surgical procedure
Type of Hernia:	Inguinal Hernia Umbilical Hernia Incisional Hernia Ventral Hernia Preperitoneal Hernia

Three subjects (6%), nine subjects (18%), eight subjects (16%), eleven subjects (21%), twelve subjects (23%), seven subjects (14%) and one subject (2%) were recruited from the age groups 20-30, 31-40, 41-50, 51-60, 61-70, 71-80 and 81-90 respectively.

The clinical safety and efficacy of the Non absorbable Knitted Surgical Polypropylene Mesh was evaluated by asking questions related to the clinical parameters. The PI was asked to rate conditions based on the occurrence of these parameters to the subjects while they were undergoing surgery.

The safety parameters and the rating given by the user for each of the clinical parameters are given below.

Table 3: Clinical Safety Parameters evaluated.

Clinical Safety parameters evaluated	PI satisfaction from the Non absorbable Knitted Surgical Polypropylene Mesh
Discomfort from Polypropylene Surgical Mesh	None of the subjects had any discomfort from the use of Polypropylene Surgical Mesh
Surgical Site Infection in subject	This Polypropylene Surgical Mesh didn't induce surgical site infection to any of the subjects under the study
Allergic reaction to the mesh material	None of the subjects showed any allergic reaction to the mesh material
Transitory local irritation at the wound site	Surgical mesh didn't develop any transitory local irritation at the wound site to any of the subjects
Transitory inflammatory reaction	Surgical mesh didn't induce any transitory inflammatory tissue reaction to any of the subjects
Any contamination which led to the illness and injury to the subject	Polypropylene Surgical Mesh didn't cause any contamination which led to the illness and injury to any of the subjects
Pain or swelling in the wound site	The subjects under the study didn't face any kind of pain or swelling in the wound site
Any wound dehiscence	There was no wound dehiscence observed on any of the subjects under study
Incidence of recurrence of hernia in subject	There was no incidence of recurrence of hernia on any of the subject after the surgical procedure
Mesh migration or shrinkage after the surgical procedure	There was no complication like mesh migration or shrinkage noted on any of the subjects after the surgical procedure
Incidence of mesh rejection after the surgery	There was no incidence of mesh rejection observed on any of the subjects after the surgery
Prolong the hospital stay due to delayed wound healing	The subjects under the study didn't have to prolong the hospital stay due to delayed wound healing
Any complication after the use of Surgical Polypropylene Mesh	None of the subjects had reported any complication after the use of Surgical Polypropylene Mesh

All the subjects considered for PMCF study benefitted out from surgeries using Dolphin Mesh®- Non absorbable Knitted Surgical Polypropylene Mesh, which showed the safety of using this product on the subjects with better efficacy proven clinically.

The clinical Performance of the product was evaluated by asking the user to give satisfactory rating in the PMCF checklist for the performance categories in section "Product Performance". The scale was given on 1-5 where 1- is given as Poor and 5 as Excellent. The PI had given rating to each attribute to each and every subject and the rating in percentage given for each attribute is given below.

Table 4: Rating of the Performance attributes

S. No	Performance attribute	Rating in percentage
1	Ease of handling	100%
2	Thin and light weight	100%
3	Flexibility	100%
4	Tensile strength of mesh	100%
5	Sterility	100%
6	Porosity	100%
7	Mesh material	100%
Overall rating		100%

The overall rating for the performance attributes of Non absorbable Knitted Surgical Polypropylene Mesh was 100% which is "Excellent"

As per the PMCF checklists collected from 51 subjects, none of the subjects have shown any signs of infection after the surgery.

There was no occurrence of mesh rejection or migration in any of the subjects. There was no recurrence of hernia in any of the subjects. Ease of use of Non absorbable Knitted Surgical Polypropylene Mesh was assessed using Likert's scale and as per the PMCF checklists collected from 51 subjects, PI strongly agreed that the Dolphin Mesh®- Non absorbable Knitted Surgical Polypropylene Mesh is easy to use. There were no new risks identified for the Non absorbable Knitted Surgical Polypropylene Mesh. Hence, it was concluded that no additional risks were imposed by the product.

In none of the PMCF checklists the PI had reported any side effects/adverse events to any of the subjects who had undergone the surgery using the Dolphin Mesh®-Non absorbable Knitted Surgical Polypropylene Mesh and proves that it is safe and effective.

The PI had given overall rating for the overall product experience as 10 which are excellent. PI had reviewed the Product label and instructions for use (IFU) supplied along with the Dolphin Mesh® - Non absorbable Knitted Surgical Polypropylene Mesh and rated the effectiveness of the Product label and IFU. PI had given "Excellent" for all the 8attributes. PI agreed that the IFU and Product Label are having the required details as per their expectation.

3. Discussion

Surgical prosthesis today is an indispensable tool in the surgeon's armamentarium for management of abdominal wall hernia. In 1890, Theodor Billroth suggested that the ideal way to repair hernias was to use a prosthetic material to close the hernia defect. In 1955, Dr. Francis Usher focused his attention on the materials that could solve existing problems. Finally, in 1958, Usher published his surgical technique using a polypropylene mesh, and 30 years later the Lichtenstein repair (known today as "tension free" mesh technique) was popularized for hernia repair. Lichtenstein published the results of 3,125 hernioplasties, in which he used a polypropylene mesh placed above the transversal is fascia. In their study only 4 cases recurred. [1,3,5]

Until 1958, the treatment for abdominal wall hernias was suture based and the major problem faced by the then

surgeons were the increased rates of recurrence of hernia. With the advent of meshes, the treatment outlook changed.[4]

Among them the polypropylene (PP), polyester (PE), and expanded polytetrafluoroethylene (ePTFE) based meshes are the one used extensively.

Polypropylene is a non-absorbable polymer, used widely because of its inertness and biocompatible nature. PP is a linear aliphatic hydrocarbon with a methyl group attached to alternate carbon atoms on the chain backbone (-C3H6-). As a result, it is nonpolar in nature, highly hydrophobic, electrostatically neutral and resistant to biological degradation.

Well-known mesh-related complications include nerve entrapment, mesh erosion, mesh exposure and pain. Mesh implantation triggers a cascade of reactions. The injury at implantation induces a blood–material interaction resulting in provisional matrix formation surrounding the biomaterial. Following this, an acute inflammatory response develops. Subsequently, during the chronic inflammatory response, monocytes and lymphocytes can be found surrounding the mesh implant. Finally, there is a foreign-body giant cell formation through fusion of these cells, as they fail to degrade the foreign body. [4,6]

PP meshes are presented in both coated and uncoated forms. The uncoated are used outside of peritoneal cavity, and the coated ones are designed for intraperitoneal use. These materials are made in a variety of forms, either with mono or multifilament, or with a unique density and size. However, the optimal density and porosity remains unknown. Both the materials are not without complications and the main disadvantage is its heavy-weight nature (*i.e.* the strength of PP is far greater than what is required physiologically).[4]

Therefore, abdomen is present with more foreign body and its resultant intense inflammatory response lead to side effects and complications including formation of thick scar and contraction of the mesh. This can further aggravate the compliance problems and lead to hernia recurrence as the mesh “shrinks” (30 to 50%). This shrinkage nature of PP meshes necessitates pre-placement calculations by the surgeons to achieve a correct fit. This response can vary depending on its density, filament size, pore size, architecture, and the individual response of each carrier. The clinical consequences of an intense biological response can be chronic pain, intestinal adhesions and discomfort.[4]

The most important properties of meshes are found to be the type of filament, tensile strength and porosity. These determine the weight of the mesh and its biocompatibility. The tensile strength required is much less than originally presumed and light-weight meshes are thought to be superior due to their increased flexibility and reduction in discomfort. Large pores are also associated with a reduced risk of infection and shrinkage. For meshes placed in the peritoneal cavity, consideration should also be given to the risk of adhesion formation.[2]

Recently light weight PP mesh has been introduced to overcome the complications of heavy-weight mesh. This mesh has been designed in such a way that decreased PP contents with much less stiffness of the abdominal wall, increased mobility, and significantly less pain.[2,4]
Currently, the use of polypropylene mesh represents the best option for management of patients diagnosed with inguinal hernia. Polypropylene has proven physical, chemical and biological properties, and is currently the most widely used allograft in the treatment of inguinal hernias. Polypropylene meshes are durable and have a low infection risk but they have little flexibility and a high adhesion risk.[1,2]

A study to evaluate the effectiveness, biocompatibility, as well as the immediate and long-term complications in textile allografts used in open surgery of inguinal hernia repair in 255 cases was conducted.

Only 1.5% required immediate reintervention before discharge to evacuate hematoma. The short duration of hospitalization, the quality price ratio, the good postoperative results, as well as the rapid socio-professional reintegration, render the use of polypropylene mesh in inguinal hernia surgery very attractive for patients. During the 7-year duration of the study, there were no cases of recurrence of the hernia. This is due, both to the extensive experience in the medical centers included in the study and as well as to the quality of materials used. There were no reinterventions required in the current study and no prolongation of hospitalization was needed.[1]

Postoperative mesh-related infection bothers both surgeons as well as patients, because it is complicated to manage. When conservative treatment fails, it is inevitable to remove the infected mesh. Late-onset mesh infection is rare in clinical practice, while late-onset mesh infection with intestinal fistula is even rarer.

An enterocutaneous fistula in a 67 year old who underwent a plug repair with polypropylene mesh of the right inguinal hernia has been reported. As one of the short-term complications after inguinal hernia repair, mesh infection frequently occurs but rarely leads to ileocutaneous fistula. The fistula developed 8 years after inguinal hernia plug repair with polypropylene mesh. No immediate short term or long term complications were observed in the present study.[7]

In a study on thirty patients who underwent laparoscopic ventral incisional hernias repair with polypropylene mesh, omentum was always positioned over the loops of bowel for protection. At a mean follow-up of 14 months, 20 patients underwent ultrasonic examination to detect adhesions. It was observed that laparoscopic ventral incisional hernias repair with polypropylene mesh and omental interposition was not associated with visceral adhesions in the majority of patients.[8]

Patients presenting with incisional hernia >5 cm in length or width received open polypropylene mesh repair and were followed up for two years. Nineteen females formed the study population. Two (10.5%) recurrences were recorded in two years. Seroma collection and stitch sinus were the primary complications observed; none progressed to develop wound infection. All patients were satisfied with the outcome at two years.[9]

A systematic review to determine whether polypropylene (PP) implants for inguinal, ventral hernia or pelvic floor surgery are associated with the development of systemic autoimmune syndromes was conducted. It was concluded that there is no evidence to suggest a causal relationship between being implanted with a PP mesh and the occurrence of autoimmune disorders.[6]

A study in 226 patients to compare early and late outcomes after inguinal hernia repair with the heavy weight mesh (HW) and light weight mesh (LW) during a 3 year follow-up period found no significant difference in wound complications, hernia recurrence and chronic pain after Lichtenstein hernioplasty, by using of LW and HW meshes. The usage of the LW mesh was associated with less feeling of foreign body than that of the HW mesh.[10]

A meta-analysis and systematic review noted that the mesh material does not affect recurrence or infection in ventral hernia repair and that surgery can be safely performed with any mesh including PP.[11]

A laparoscopic approach is associated with a decreased infection rate compared to open repair independent of mesh type.

Ventral hernia repairs can be safely performed using either monofilament PP or multifilament PET mesh with comparable rates of mesh infection and hernia recurrences. [11]

Mesh selection should be tailored to each patient, subpopulation, and situation, with a continuation of head-to-head device trials to garner more long-term data.

In another study by Geisler et al, it was noted that after bowel preparation, nonabsorbable mesh can be used for elective repair of incisional hernia in the presence of open bowel with an expectation of minor morbidity, minimal risk of infection, and an acceptable rate of recurrence.[12]

Nonabsorbable mesh can be used for elective repair of parastomal hernia in a similar setting with a lowrisk of infection independent of surgical approach.[12]

The overriding benefit of a PP mesh, however, is that even with its propensity to incite infection; the infections often been treated themselves without the removal of mesh. Additionally, many of the risks associated with PP are being modulated by adjusting mesh weight and porosity to promote more or less tissue in-growths. Though obviously not an inert material, PP meshes are considered to be a stable material provides an adequate service to save life.[4]

4. Conclusion

The retrospective PMCF study included 51 subjects in which Dolphin Mesh® Non-Absorbable Knitted Surgical Polypropylene Mesh was used during the open and laparoscopic surgical procedure. The study focused to check the occurrence of complications after the long-term use of the product. There were no complications listed below associated with the use of polypropylene mesh in the 51 subjects under this study viz., infection, delayed absorption, mesh rejection or migration, shrinkage and recurrence of hernia.

This retrospective PMCF study has proven the safety and performance of using the Dolphin Mesh® Non-Absorbable Knitted Surgical Polypropylene Mesh.

5. Future Scope

Despite the clinical success and vast body of knowledge that has been gained regarding manufacturing of surgical meshes, material properties, and surgical procedures, it is obvious that the ideal mesh has not been developed. All of the known complications have opened a great number of opportunities to create a new generation of surgical meshes. Several milestones were achieved with the use of meshes; and new bioprosthetics hold promise for improving results. However, it must be remembered that that the way the mesh is placed is as important as the type of mesh used. Despite the new materials available, surgical skill still has a major role in preventing hernia recurrence. Future research will continue to focus on the surgical techniques and biomaterials to achieve the best outcomes.

Acknowledgement

None

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