Peters SURGICAL

Cyanoacrylate mesh fixation for laparoscopic inguinal hernia repair:

a prospective, multicenter, single-arm study

Dams A, Vankeirsbilck J, Poelmans S, Kerschaever I, Borreman P, Berwouts L, De Mulder W, Colle J, Beunis A, Dhooghe V, Van De Winkel N, Allaeys M, Ruyssers M, Haesen D, Van der Speeten K. Surg Endosc. 2023 Dec;37(12):9105-9115.

- Inguinal hernia repair is **one of the most common surgical procedures.**
- **More than 20 million cases** are treated annually worldwide = 10-15% of all surgical procedures.
- Chronic postoperative pain remains the most significant long-term complication of inguinal hernia repair (0,5 to 16% of patients), posing a considerable burden on the global healthcare system.
- **Minimal-invasive laparoscopic inguinal hernia repair** has become a well-established treatment option, offering potential benefits compared to open repair :
  - → **faster postoperative recovery**
  - → **decreased postoperative pain**
  - → **earlier return to normal daily activities**
  - → **better cosmetic results**

Among the fixation methods, surgical glues have become increasingly popular, showing promising postoperative outcomes leading to greater surgeons and patients satisfaction.

Methodology

STUDY OBJECTIVE
To assess the efficacy of the n-hexyl cyanoacrylate glue Ifabond® for mesh fixation in laparoscopic inguinal hernia repair.

DESIGN
Prospective, multicenter, single-arm, observational registry.

SURGICAL PROCEDURE
No complementary mechanical mesh fixation (sutures/tacks/staples) during TEP and TAPP procedures.

5 Hospitals (Belgium)

9 surgeons

Period of **8 years**

613 patients

978 hernias

SELECTION OF PATIENTS

- Patients scheduled for laparoscopic TAPP or TEP with a standard or lightweight polypropylene mesh and surgical tissue glue fixation with Ifabond®

TAPP: transabdominal preperitoneal
TEP: totally extraperitoneal

EXCLUSION CRITERA

- Life expectancy of less than one year
- Recurrent hernias
- Known allergy to the components of the glue

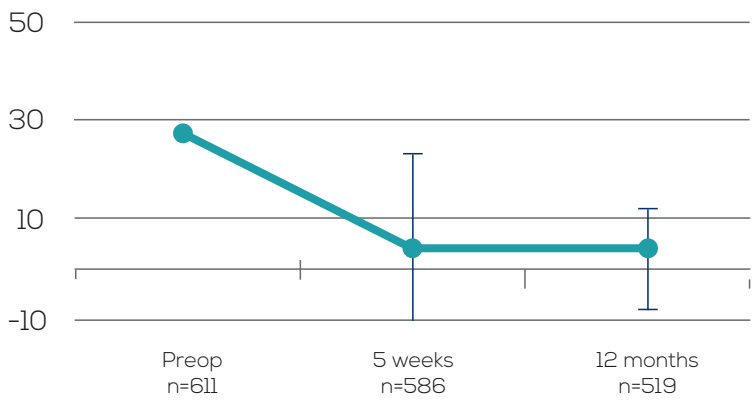
PROCEDURAL CHARACTERISTICS (N=613)		
LAPAROSCOPIC TECHNIQUE	TAPP	TEP
% patients (n)	95,4% (585)	4,6% (28)
MESH TYPES	**Standard polypropylene 100 g/m² – pore area of 1.1 mm²**	**Lightweight polypropylene 37.8 g/m² -pore area of 1.8 mm²**
% patients	88,1% (540)	11,9% (73)
IMPLANTABLE SURGICAL GLUE (Class III): Ifabond®, sterile, non-toxic, biocompatible, biodegradable.		
Mean volume (n=609)	1,57mL ± 0,50 ml	
Usability of the glue (n=604)	4,76 ± 0,76	
OPERATING TIME		
Mean time (n=586)	35,05± 15,14 min	

ENDPOINTS AT 5 WEEKS AND 12 MONTHS

- **Primary outcome:** prevalence of chronic pain at 12 months postoperatively (Visual Analogue Scale) Pain was classified into mild (1–30 mm), moderate (31–60 mm) and severe (61–100 mm)
- **Secondary endpoints:** intraoperative complications, postoperative complications, analgesic intake during follow-up, quality of life using the EuroQol (EQ-5D-3L health index and EQ-VAS), hernia recurrences, re-interventions during follow-up, operating time, intraoperative usability of the glue, length of hospital stay.
- All procedures were prospectively scored for quality of Ifabond™ mesh fixation using a scoring system ranging from 1 (bad) to 3 (moderate) to 5 (excellent) recorded by the participating surgeons.

Primary outcome:

VAS (VISUAL ANALOG SCALE) PAIN SCORE (MEAN)



The mean pain was significantly lower at 5 weeks and 12 months.

At 12 months, only 3,7% of patients reported pain level › 30 (moderate or severe- VAS - Visual Analog Scale).

Preoperative and postoperative mean pain score.
Paired T-test for change from baseline - *p<0,0001 vs preoperative scores

Quality Of Life

Patient's QoL increased significantly at 5 weeks and 12 months.

EQ-5D-3L (European Quality of Life 5 Dimensions 3 Level Version) scores: mobility, self-care, usual activity, pain/discomfort. EQ-VAS (European Quality of life-Visual Analogue Scale) general health score. p<0,0001 versus preoperative scores.

High surgeons satisfaction: Surgeons assessment intraoperative usuability : **4,76/5**

Tolerance

Ifabond® is a safe fixation method for laparoscopic inguinal hernia repair.

At 12 months, **only 2,7% of patients need pain medication.** No wound infection, 4 hernia recurrences after 12 months.

Intraoperative and postoperative complications	**% patients (n)**
Intraoperative complications (n=613)	**1,14% (7)**
Minor	85,71% (6)
Major	14,29% (1)
Postoperative complications at 5 weeks (n=588)	**16,33% (96)**
Minor	94,79% (91)
Major	5,21% (5)
› 5%: Hematoma	7,82% (46)
Wound infection	0%
Hernia recurrence	0,34% (3)

Intraoperative and postoperative complications	% patients (n)
Postoperative complications at 12 months	
Annoying sensation at the groin (n=519)	22,16% (115)
Pain at the groin (n=524)	13,74% (72)
Intake of analgesics because of pain at the groin (n=524)	2,7% (14)
Hernia recurrence between 5 weeks and 12 months	0% (1)
Death from unrelated cause (n=529)	0,19% (1)

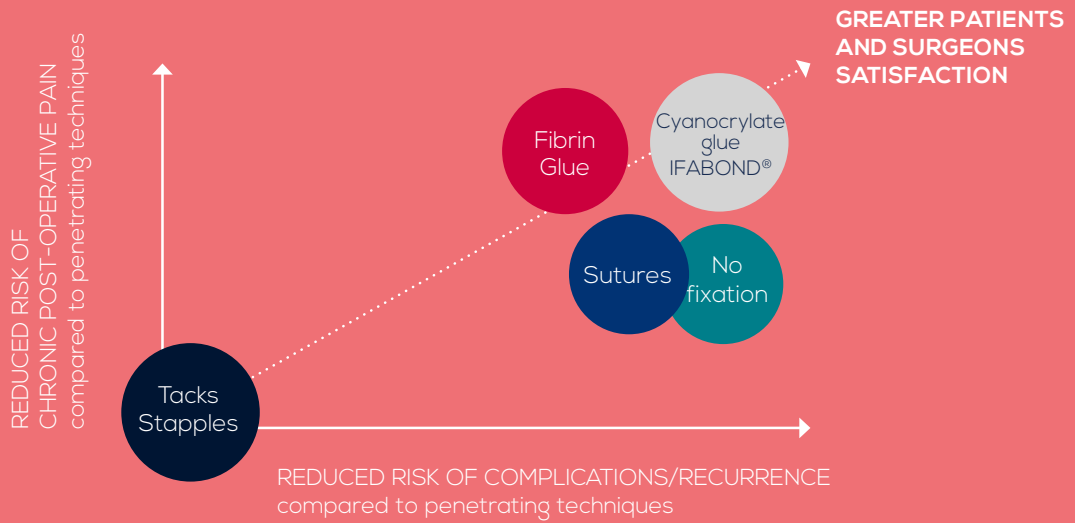
Thanks to the monitoring of a large number of patients and multiple evaluation criteria, **this study provides strong support for the safety, reliability and feasibility of Ifabond® in mesh fixation with:**

- → **Very high surgeon satisfaction score**
- → **Significant improvement in patients quality of life**
- → **Lower rate of chronic pain compared with penetrating fixation**
- → **Glue & Suture were ranked the highest for lowering the incidence of recurrence compared to traumatic fixation** (Non-penetrating fixation such as glue & no fixation had similar risks of complications).

Recent reviews have shown that non penetrating glue-based techniques for mesh fixation generally result in a lower rate of chronic pain, a lower occurrence of hematoma, and better early postoperative activity levels compared to penetrating fixation (tack and/or staple).

→ The results of this study demonstrate similar or improved pain levels with Ifabond® compared to those reported in other studies evaluating glue for mesh fixation.

RANKING OF FIXATION TECHNIQUES FOR HERNIA REPAIR ACCORDING TO BENEFITS FOR PATIENTS
(proposed based on textual data from Dams 2023 and Ibrahim 2020*)



* Ibrahim SR, Ward PJ. Tissue Adhesives for Hernia Mesh Fixation: A Literature Review. Cureus. 2020 Sep 16;12(9):e10494. doi: 10.7759/cureus.10494.

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