

A Comparative Study of Fibrin Glue versus Sutured Mesh Fixation for Lichtenstein Inguinal Hernia Repair

¹Dr. Girish T U, ²Dr. Yetigadda Dinesh Reddy

¹ Associate professor Dept. of surgery JSS University Mysore, Mysore, Karnataka, India.

² Post graduate General surgery JSS University Mysore, Mysore, Karnataka, India.

Abstract

Key Words – Fibrin glue, Lichtenstein hernioplasty, Post-operative pain, Foreign body sensation

Introduction- Inguinal hernia repair is one of the most frequently performed surgical operations. The most commonly performed inguinal hernia repair today is the Lichtenstein repair. In recent years, mesh fixation using fibrin glue instead of sutures has become popular. Both clinical and experimental trials demonstrate that fibrin sealant is a feasible option for mesh fixation in hernia repair.

Methods- Cases were selected on the basis of randomised sampling technique. 50 patients had been enrolled in this 12-month observational study and were received either sutures or fibrin glue-Tisseel for hernia mesh fixation. Pain, post-operative analgesia requirement within 24 hours, local numbness, hematoma, seroma are evaluated by physical examination on days 3, 7 and 15 after surgery and long term outcomes like chronic pain, sensation of an extraneous body, recurrence, length of operation and time to return to work or normal activity have be assessed postoperatively at 1, 3, 6, and 12 months.

Results- In our study the fibrin glue sealant group demonstrated a low incidence of short term outcomes like postoperative pain, post-operative analgesia requirement, seroma formation, and also low incidence of long term outcomes like chronic pain, sensation of an extraneous body with short hospitalization and no increased risk of hernia recurrence.

Conclusion - our study favors the use of human fibrin glue for hernia mesh fixation in Lichtenstein Hernioplasty which is better tolerated than sutures and is not associated with an increased risk of hernia recurrence.

Keywords: Fibrin glue, Lichtenstein hernioplasty Foreign.

Introduction

Inguinal hernia repair is one of the most frequently performed surgical operations, the morbidity and recurrence rates have decreased in the last 2 decades because of the introduction of open tension-free hernia surgery with mesh. Nevertheless, the incidence of recurrence in nonspecialized centres is still high, and postoperative pain and discomfort are common. The most commonly performed inguinal hernia repair today is the Lichtenstein repair. A flat mesh is placed on top of the defect, it is a "tension-free" repair that does not put tension on muscles.¹ Following Lichtenstein hernia repair, up to 25% of patients experience prolonged postoperative and chronic pain as well as discomfort in the groin. One of the underlying causes of the discomfort is the compression or irritation of nerves by the sutures used to fixate the mesh. Biological sealants such as fibrin sealant have a long history in surgery, where they are used primarily for sealing and haemostatic purposes. Their exceptional safety record is attributable to their complete biodegradability and physiologic mechanism of action. Both clinical and experimental trials demonstrate that fibrin sealant is a feasible option for mesh fixation in hernia repair.²

The aim of this study is to investigate short-term outcomes like pain, post-operative analgesia requirement within 24 hours, hematoma, seroma, and long term outcomes like chronic pain, sensation of an extraneous body, recurrence, length of operation and time to return to work/normal activity following inguinal hernioplasty performed by the Lichtenstein technique with mesh fixation by fibrin glue comparing with sutures.

Materials and Methodology

The present study was conducted in the Department of surgery, JSS Hospital, JSS Medical College, Mysuru on patients diagnosed with inguinal hernia during the period of August 2013 to September 2014.

Study Design

Randomized control trial

Study Period

The present study was conducted during August 2013 to September 2015

Method of Collection of Data

Source of Data: Patients presenting with inguinal hernia at department of surgery in JSS Hospital.

Selection of Cases

Following evaluation, patients were grouped into Suture(S) and Glue (G) accordingly as per the surgery chosen by the patient.

Inclusion Criteria

- All patients with evidence of primary uncomplicated inguinal hernia admitted in JSS Hospital.
- Patients above 18 years age.
- Patients undergoing elective Lichtenstein mesh hernioplasty.

Exclusion Criteria

- Age less than 18 years.
- Patients with recurrent and complicated hernias.
- Emergency inguinal hernia repair.
- Laparoscopic inguinal hernia repair.

Procedure

All the 50 patients were admitted and a detailed history and clinical examination was carried out as per written proforma. Preoperatively the patients were offered options of either sutures or fibrin glue for the fixation of the mesh in LICHENSTEINS HERNIOPLASTY repair for inguinal hernia, and were educated about the advantages, disadvantages, type of anaesthesia, and also the approximate cost of each of the procedure.

A total of 50 patients were enrolled in this 12-month observational study and were divide into 2 groups of 25 patients each, in which one group received sutures - SUTURE group (S) and the other group received fibrin glue - FIBRIN GLUE group (G) .

Patients were advised and encouraged to ambulate and start their activities of daily life as early as possible. Prophylactic oral antibiotics are given for duration of 5 to 8 days, of which parenteral antibiotics are given for at first 72 hours. Analgesics were given at 12 hour interval for a period of 3 to 5 days, shifted on to oral tablets as early as possible.

Patients were observed for any complications like pain, post-operative analgesia requirement within 24, 48, 72 hrs, hematoma, seroma formation (evaluated by physical examination) on days 3, 7 and 15 after surgery. Patients were discharged once free of complications. Stitches are removed on 10th day after surgery and long term outcomes like chronic pain, sensation of an extraneous body, recurrence, length of operation and time to return to work or normal activity had been assessed postoperatively at 1, 3, 6, and 12 months with regular follow ups.

The Visual Analogue Scale (VAS) is a subjective measure of pain. It consists of a 10cm line with two end- points representing ‘no pain’ and ‘worst pain imaginable’. Patients are asked to rate their pain by placing a mark on the line corresponding to their current level of pain. The distance along the line from the ‘no pain’ marker is then measured with a ruler giving a pain score out of 10. The score can be used as a baseline assessment of pain with follow-up measures providing an indication of whether pain is reducing or not.

Statistical Methods used are

1. Descriptive Statistics
2. Chi-square Test
3. Contingency co-efficient tests
4. “T” test Independent

Results

1. Age Distribution: Among the fibrin glue group, the maximum subjects were from >61 years age (10, 40%), followed by 41-60 years (9, 36%) and age groups <40 years (6, 24%). Among suture method group majority of subjects were from >61 years age (9, 36%), followed by 41-60 years (9, 36%) and age groups <40 years (7, 28%). This difference in age group is not statistically significant.

2. Comparison of The Diagnosis: Among the fibrin glue group, the maximum subjects were having Right direct inguinal hernia (9, 36%), followed by Right indirect hernia (7, 28%), B/L direct inguinal hernia (3, 12%), left direct inguinal hernia (3, 12%) and left indirect hernia (3, 12%). Among suture method group majority of subjects were Right direct inguinal hernia (6, 24%), followed by Right indirect hernia (6, 24%), left direct inguinal hernia (6, 24%), left indirect hernia (5, 20%) and B/L direct inguinal hernia (2, 8%). This difference in age group is not statistically significant. (table1)

Table 1: Comparison of diagnosis between two groups

Type of hernia	Procedure and Technique			
	Hernioplasty with Fibrin Glue fixation of mesh		Hernioplasty with Suture fixation of mesh	
	n	%	n	%
B/L Direct IH	3	12.0	2	8.0
L- Direct IH	3	12.0	6	24.0
L- Indirect IH	3	12.0	5	20.0
R- Direct IH	9	36.0	6	24.0
R- Indirect IH	7	28.0	6	24.0
Total	25	100	25	100

3. Comparison of operative time- The mean length of surgery in fibrin glue group was 36.7±6.1 minutes, which was slightly more than in suture group 36.1±8.9 minutes. However, this difference was not statistically significant. (table 2)

Table 2: Comparison of length of surgery between two groups

	Procedure and Technique			
	Hernioplasty with Fibrin Glue fixation of mesh		Hernioplasty with Suture fixation of mesh	
	Mean	SD	Mean	SD
Length of operation (min)	36.7	6.1	36.1	8.9

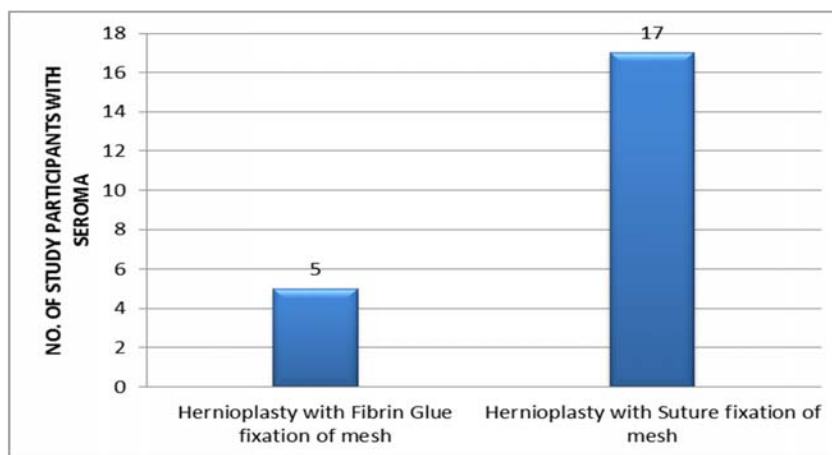
4. Comparison of seroma incidence

The incidence of seroma in fibrin glue group was 20 % (5/25), which was much lesser than suture fixation group (68%, 17/25). This difference was statistically significant. (Table 3 and graph 1).

Table 3: Comparison of seroma incidence in two groups

Procedure and Technique	Seroma			
	N		Y	
	n	%	n	%
Hernioplasty with Fibrin Glue fixation of mes	20	80.0	5	20.0
Hernioplasty with Suture fixation of mesh	8	32.0	17	68.0

P=0.001, chi-square test



Graph 1: Comparison of seroma incidence in two groups

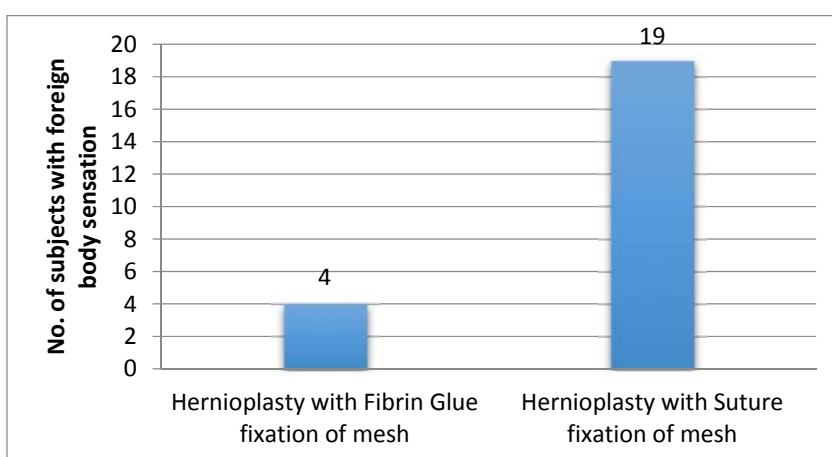
Comparison of foreign body sensation

The incidence of foreign body sensation in fibrin glue group was 16 % (4/25), which was much lesser than suture fixation group (76%, 19/25). This difference was statistically significant. (Table 4 and graph 2).

Table 4: Comparison of foreign body sensation in two groups

Procedure and Technique		Foreign body sensation			
		N		Y	
		n	%	N	%
Procedure and Technique	Hernioplasty with Fibrin Glue fixation of mesh	21	84.0	4	16.0
	Hernioplasty with Suture fixation of mesh	6	24.0	19	76.0

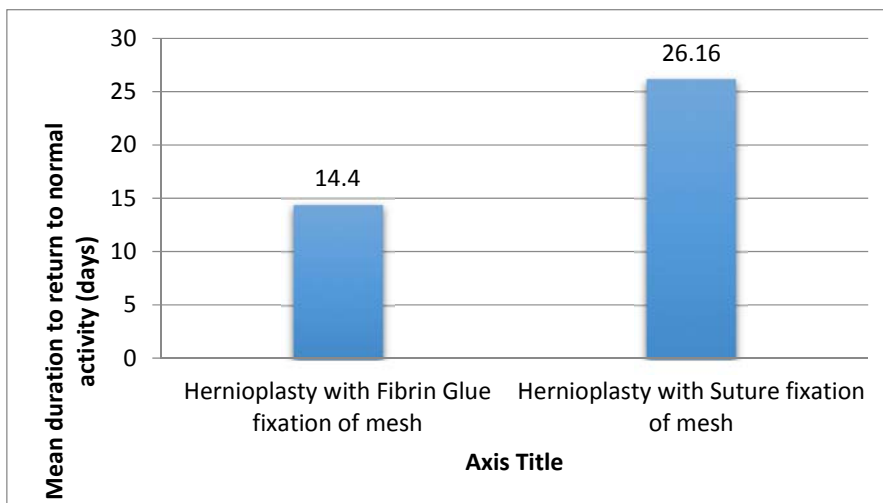
P<0.0001, chi-square test



Graph 2: Comparison of foreign body sensation in two groups

7. Comparison of time to return to normal activity

The mean time to return to normal activity in fibrin group was 14.4±4, which was much less compared to suture fixation group 26.16±7.55. This difference was statistically significant. (graph 3)



Graph 3: Comparison of time to return to normal activity in two groups

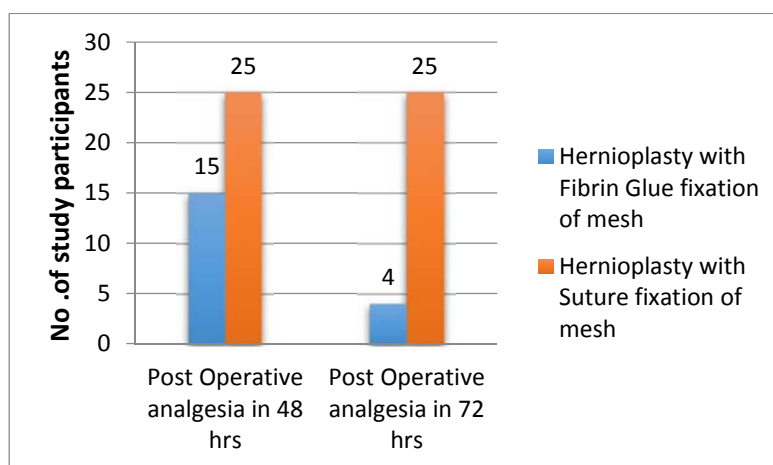
Comparison of post-operative analgesia requirement

At 24 hrs post-operative period, all the subjects in both groups required analgesia. However, at 48 hrs post-operative period 15/25 (60%) of subjects in fibrin glue group required analgesia compared to (25/25,100%) of suture fixation group required

analgesia. This difference was statistically significant. Similarly, at 72 hrs post-operative period, 16 % (4/25) of fibrin glue group required analgesia, compared to 100 % (25/25) in suture fixation group. This difference was also statistically significant. (table 5 and graph 4)

Table 5: Comparison of post-operative analgesia in two groups at different point of time

		Procedure and Technique				p
		Hernioplasty with Fibrin Glue fixation of mesh		Hernioplasty with Suture fixation of mesh		
		n	%	N	%	
PO analgesia in 24 hrs	Y	25	100.0	25	100.0	NA
PO analgesia in 48 hrs	N	10	40.0	0	.0	
	Y	15	60.0	25	100.0	<0.0001
PO analgesia in 72 hrs	N	21	84.0	0	.0	
	Y	4	16.0	25	100.0	<0.0001



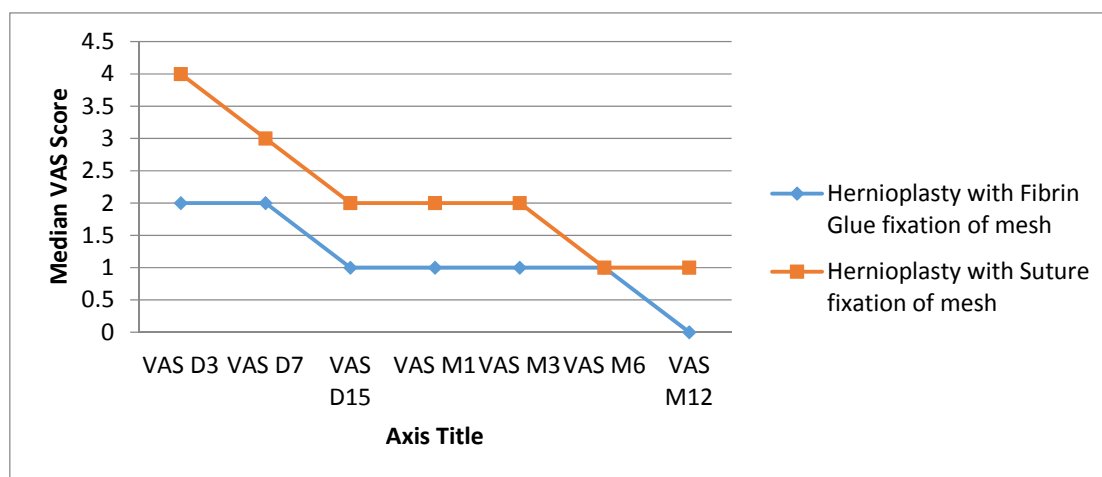
Graph 4: Comparison of post-operative analgesia in two groups at different point of time

Comparison of post-operative pain at different point of time - The median VAS score at postoperative day 3 in fibrin glue group was 2 and was lesser than 4, in suture fixation group. This difference was statistically significant. Similarly, at day7, day 15, 1 month, 3 month, 6th month and 12 month, the

median VAS score (2,1,1,1,1,0)in fibrin glue group was significantly lower than suture fixation group(3,2,2,2,1,1). In fibrin glue fixation group, the pain reached almost 0, by 12th month.

Table 6: Comparison of post-operative pain in two groups at different point of time

	Procedure						P
	Hernioplasty with Fibrin Glue fixation of mesh			Hernioplasty with Suture fixation of mesh			
	Mean	SD	Median	Mean	SD	Median	
VAS_D3	2.28	.84	2.00	4.00	.76	4.00	<0.0001
VAS_D7	1.60	.65	2.00	3.16	.90	3.00	<0.0001
VAS_D15	1.20	.41	1.00	2.16	.85	2.00	<0.0001
VAS_M1	1.1	.3	1.0	1.8	.7	2.0	<0.0001
VAS_M3	1.0	.0	1.0	1.7	.7	2.0	<0.0001
VAS_M6	1.0	.0	1.0	1.4	.5	1.0	<0.0001
VAS_M12	.2	.4	.0	1.2	.4	1.0	<0.0001



Graph 5: Comparison of post-operative pain in two groups at different point of time

Discussion

This is a prospective comparative study, comparing 50 patients who had undergone lichtensteins hernioplasty for inguinal hernia, of which 25 had undergone mesh fixation with fibrin glue and the other 25 with prolene sutures. In the present study the mean length of surgery i.e the operative time required in fibrin glue group was 36.7±6.1 minutes, which was slightly more than in suture group 36.1±8.9 minutes.

In the present study the incidence of seroma in fibrin glue group was 20% (5/25), which was much lesser than suture fixation group 68% (17/25). This difference was statistically significant with a p value of 0.001, similarly to the study conducted by M. Canziani, *et al.* for fixation of mesh using fibrin glue in 40 patients there was hematoma formation only in 3 patients (3/40) and no seroma formation in any patient. [3]

In the present study none Of the study groups had hematoma where as in a study conducted by Negro P, *et al.* [9] i.e study on use of fibrin glue versus sutures for mesh fixation in open tension-free Lichtenstein repair of inguinal hernia Patients who received fibrin glue were also less likely to experience hematoma than those in the suture group (P = 0.001).

In the present study the incidence of foreign body sensation in fibrin glue group was 16% (4/25), which was much lesser than suture fixation group (76%, 19/25). This difference was statistically significant with a p value of <0.0001 similar to study conducted by Mario Testini, *et al.* [4] on a single-surgeon randomized trial comparing sutures, human fibrin glue for mesh fixation during primary inguinal hernia repair two cases (3.39%) of chronic groin pain were reported in patients in the suture group and sensation of extraneous body was reported in

5 (8.47%) patients who received sutures. There were no reported cases in the fibrin glue group.

In the present study the mean time to return to normal activity in fibrin group was 14.4±4, which was much less compared to suture fixation group 26.16±7.55. This difference was statistically significant with a p value of <0.0001, where as in the study conducted by Mario Testini, *et al.* [5] there was no significant difference between the groups in terms of mean postoperative stay or mean time to return to work.

In the present study, the requirement of analgesia in the 24 hrs post-operative period, all the subjects in both groups required analgesia. However, at 48 hrs. Post-operative period 15/25 (60%) of subjects in fibrin glue group required analgesia compared to (25/25,100%) of suture fixation group required analgesia. This difference was statistically significant. Similarly, at 72 hrs. Post-operative period, 16% (4/25) of fibrin glue group required analgesia, compared to 100% (25/25) in suture fixation group. This difference was also statistically significant with a p value of <0.0001 at both 48 and 72 hrs similar to the study conducted by M. Canziani, *et al.* [6] 40 patients underwent mesh fixation with 2 ml of human fibrin glue in which postoperative pain occurred in two patients, while chronic pain occurred in one patient; the remaining 37 patients were pain-free and post-operative analgesia requirement was less due to the low incidence of postoperative pain and short hospitalization.

In the present study post-operative pain both short term and long term, the median VAS score at postoperative day 3 in fibrin glue group was 2 compared to 4, in suture fixation group. This difference was statistically significant. Similarly, at day7, day 15, 1 month, 3 month, 6th month and 12 month, the median

VAS score (2,1,1,1,1,0) in fibrin glue group was significantly lower than suture fixation group (3,2,2,2,1,1). In fibrin glue fixation group, the pain reached almost 0, by 12th month in comparison with the study done by Negro P, *et al.*^[9] the mean pain score was significantly lower in the fibrin group than the sutures group (2.5 vs. 3.2, P < 0.001). At 1 month, significantly fewer patients in the fibrin glue group reported pain, numbness, and discomfort compared with patients in the sutures group (all P < 0.05). Fibrin glue patients also experienced less intense pain (0.6 vs. 1.2; P = 0.001), whereas by the end of 3 months, the differences between groups had disappeared, except for numbness, which was more prevalent in the sutures group. By 12 months, very few patients reported complications. In the present study none of the study groups had recurrence similar to the study conducted by Colvin HS, *et al.*^[7] in which Glue fixation was not associated with an increased risk of hernia recurrence and also in the study done by Mario Testini, *et al.* where there is no recurrence in any of the groups.

Conclusion

The ultimate aim in hernioplasty procedures is to decrease the post-operative complications and morbidity of the patient without any increased risk of hernia recurrence. This study compares the post-operative morbidity of mesh fixation with Tisseel fibrin glue in Lichtenstein Hernioplasty over sutures. Tisseel fibrin glue for mesh fixation in the Lichtenstein repair of inguinal hernia shows advantages over sutures, including lower incidence of complications such as post-operative pain, post-operative analgesia requirement, seroma formation, foreign body sensation, chronic discomfort and time to return to normal activity.

Hence our study favours the use of human fibrin glue for hernia mesh fixation in Lichtenstein Hernioplasty which is better tolerated than sutures and is not associated with an increased risk of hernia recurrence.

References

1. Malangoni MA, Gagliardi RJ. Hernias. In: Townsend CM, Beauchamp RD, Evers BM, Mattox KL, editors. Sabiston's Textbook of Surgery. 17th edition. Philadelphia: Elsevier-Saunders; 2004. 1199-218.
2. John T Jenkins, Patrick J O'Dwyer. "Inguinal hernias". British Medical Journal. BMJ 336 (7638): 269-272.
3. Nilsson E, Kald A, Anderberg B, *et al.*, Hernia surgery in a defined population: a prospective three year audit. Eur J Surg 1997;163:823-9
4. Mario Testini, MD, Germana Lissidini, MD, PhD, Elisabetta Poli, MD, Angela Gurrado, MD, Domenica Lardo, MD, and Giuseppe Piccinni, MD: A single-surgeon randomized trial comparing sutures, N-butyl-2-cyanoacrylate and human fibrin glue for mesh fixation during primary inguinal hernia repair. Can J Surg. 2010 June; 53(3):155-160
5. Bracale U, Rovani M, Picardo A, Merola G, Pignata G, Sodo M *et al.* Beneficial effects of fibrin glue (Quixil) versus Lichtenstein conventional technique in inguinal hernia repair: a randomized clinical trial. Hernia. 2012 Nov 20.
6. Colvin HS, Rao A, Cavali M, Campanelli G, Amin AI. Glue Versus Suture Fixation of Mesh During Open Repair of Inguinal Hernias: A Systematic Review and Meta-analysis. World J Surg. 2013 Oct; 37(10):2282-92.

7. Canziani M, Frattini F, Cavalli M, Agrusti S, Somalvico F, Campanelli G. Sutureless mesh fibrin glue incisional hernia repair. Hernia. 2009 Dec 13(6):625-9.