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Prosthetic material fixation in open inguinal hernioplasty: suture vs. synthetic glue★

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ABSTRACT

Introduction: The use of synthetic glues has become normal practice in several surgical fields. The objective of this study is to compare the short and medium term results of glue and conventional suture in the fixation of the prosthesis in open inguinal hernia repair with a plug and patch technique.

Materials and methods: A comparative prospective study was conducted on 198 patients with a diagnosis of a non-recurrent inguinal hernia subjected to open surgery and randomly assigned to mesh fixation with cyanoacrylate glue (n = 101) or with suture (n = 98). The demographic characteristics, short-term complications, hospital stay, time off work, hernia recurrence, and chronic inguinal neuralgia, were analysed.

Results: The overall morbidity was 13.9% in the glue group, and 30.9% in the suture group. No undue inflammatory reactions or mesh migration were observed in the group. The postoperative stay was 14.7 h for the glue group, and 19.1 h in the suture group (P < .0001). No differences were found regarding days off work. The short-term morbidity was higher in the suture group (19.6% vs. 10.9%). After one year, there was one recurrence in the suture group (1%), and none in the glue group. However, the incidence of moderate/severe intensity chronic neuralgia was 2.9% in the glue group, and 10.3% in the suture group (P=.03).

Conclusion: The use of cyanoacrylate is safe and effective in open inguinal hernia repair, with good results in the short and medium term.

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Introduction

Inguinal hernia repair surgery is most commonly performed in the field of general surgery[1]. The use of prosthetic material has been a significant improvement in the results with a significant decrease in the number of recurrent hernias 2. However, chronic groin pain remains a rare but with significant impact on the personal and professional life of the patient, with a highly variable incidence ranging between 10 and 30%[3] and is today the most important long-term morbidity of this surgery. It has been reported that the suture of the prosthesis to the tissue could play a role in the pathogenesis of this complication due to the possible compression or entrapment of nerves, and this has stimulated the research for atraumatic means for fixing prostheses.

Synthetic glues have been in the market for 50 years[4], with a variety of indications in various surgical specialties[5]. At present, a surgical glue based on N-butyl-2-cyanoacrylate and methacryl-oxy-sulfolane monomer is used, which maintains a low temperature of polymerization with few inflammatory reactions.

The objective of this study is to test the effectiveness and safety of cyanoacrylate glue in inguinal hernioplasty comparing short and medium term results in patients undergoing open inguinal hernia repair with plug and patch technique, anchoring the prosthesis with cyanoacrylate or sutures.

Material and Methods

A prospective randomized study blinded for the patient and the observer, conducted between September 2009 and May 2011, including 225 patients older than 16 years diagnosed with inguinal hernia undergoing open inguinal hernia repair with plug and patch technique.

We established the following criteria for exclusion: recurrent hernia, femoral hernia, emergency-intervened hernias, large inguinoscrotal hernias, hernial orifice larger than 3 cm, morbid obesity, chronic groin pain preoperatively and unavailability for follow-up for one year.

The randomization process was performed by software 24 h prior to surgery, with patients being assigned to fixation of the prosthesis with cyanoacrylate glue (group A) or with sutures (Group B).

Exclusion clauses were established by intraoperative findings (hernial orifice size, size of the hernia) or the surgeon. All patients were informed of the study and possible treatment options, obtaining their consent.

Perioperative data and follow-up were collected prospectively using the MS Excel software package (Microsoft Corp., Redmond, WA, USA.).

Interventions were performed by surgeons at the Hospital General Yague, under the supervision of two of the authors of the study (AEM and JLS).

All patients were operated under general or local-regional anesthesia. They were administered a single dose antibiotic prophylaxis with first-generation cephalosporin in the 30 minutes before the skin incision. An inguinal incision was practiced, with sectioning and ligation of the subcutaneous vessels and opening of the external oblique aponeurosis safeguarding the ilioinguinal nerve. Both flaps were dissected taking care not to injure the ilio-hypogastric nerve in the upper channel. If any nerve was severed, ligation of the proximal end was performed being sutured to the muscle[6]. Dissection and invagination of the hernial sac and any lipoma was performed, severing the cremaster as little as possible. A polypropylene plug was applied to the hernial orifice, applying a polypropylene patch (105.4 g/m^2 density, PerFix Plug, Bard Medical, Georgia, USA) on the inguinal floor.

Group A: Fixing with cyanoacrylate adhesive (Glubran 2®, GEM SRL, Viareggio, Italy) by applying one drop per cm^2, being therefore possible to make the fixation of the plug and patch with half the container (0.5 mL; allows to use a single cyanoacrylate ampule for bilateral cases) avoiding any contact between the needle and the tissues or the prosthesis (freely dropping drop). The petals of the cap were kept below the edges of the hernial orifice and the glue was applied in the interface between the plug and the tissue. After placement of the patch in its final position, a drop of cyanoacrylate was applied on the pubic tubercle maintaining pressure during 10 s with subsequent application of additional cyanoacrylate on the perimeter of the prosthesis, ending with the closing of the slot around the cord ("tie") with glue. Excessive application of glue was avoided. The spermatic cord and genitofemoral nerve were retracted to avoid any direct contact with the glue until it solidified, thereby preventing any thermal damage. No suture was used except for closing the hernial sac in case of accidental opening.

Group B: fixing the plug and patch with non-absorbable monofilament suture.

An approximation of the aponeurosis was conducted using a continuous absorbable suture and of the skin with staples

without drainage. No infiltration of the wound with local anesthetics was performed. A postoperative analgesia protocol was prescribed with nonsteroidal antiinflammatory drugs (NSAIDs) 3 daily doses for 3 days.

All patients were included in a follow-up protocol with visits on the first postoperative day, a week from the intervention, a month, 6 months and 12 months from the date of operation.

They were followed by a surgeon not related to the technique used. The assessed parameters are detailed in Table 1.

Hernias were classified according to the classification of the European Hernia Society depending on the relation between the neck of the hernial sac and the inferior epigastric vessels[7].

Seroma was defined as accumulation or drainage of serous fluid without skin ecchymosis, fever or pain.

Hematoma was diagnosed as accumulation or drainage of blood or drainage with bruising of the adjacent tissues and/or the scrotum with discomfort but no fever.

Table 1 - Assessed Parameters

Age
Gender
Potential risk factors
Type and laterality of hernia
Short-term morbidity
Inflammatory reactions
Migration of the prosthesis
Seroma
Hematoma
Wound infection
Acute postoperative pain
Postoperative stay (hours)
Return to work activity (days)
Percentage of patients returning to work at 30 days
Long-term morbidity
Chronic groin pain
Hernia recurrence

Infection was defined as one that occurs within the first 30 days of intervention, involving subcutaneous tissue and skin around the incision, along with at least one of the following criteria: purulent drainage from the incision; isolation of pathogenic microorganisms in a culture of fluid or tissue obtained aseptically from the incision; presence of signs or symptoms of infection (pain, fluctuation, redness...); or diagnosis of surgical site surface infection by the surgeon in charge[8].

Postoperative pain was analyzed according to the need to administer additional analgesics from those prescribed by the surgeon.

The return to work activity was computed in days from the date of surgery. In patients that were retired or unemployed, the computation was performed until the resumption of normal daily activity.

Chronic pain was defined as persistent and annoying pain in the upper thigh, groin or scrotum with or without sensory impairment. This type of pain was assessed using a visual analog scale (VAS) from 0 (no pain) to 10 (unbearable pain). Chronic inguinal neuralgia was diagnosed when the VAS score was equal to or greater than 4 at the 6 and 12 month follow up visits.

Hernia recurrence was defined as palpable hernia in the groin area excluding femoral hernias arising after inguinal hernia repair. In case of doubt, a scan of the inguinocrural area was performed.

Monitoring was considered completed after the 12 month follow up visit.

Statistical analysis was performed using the Predictive Analytics Software package 17.0.3 (IBM, Armonk, NY, USA). We used the mean and standard error of the mean (SEM) to describe quantitative variables and their frequencies. We assessed the normal distribution of quantitative variables using the Kolmogorov-Smirnov test. For comparison of mean numeric variables the Student t test was used for normal distribution and the Mann-Whitney U test when a normal distribution was not followed. For qualitative data the X2 test and Fisher's exact test were used. Results were considered statistically significant if $p \leq 0.05$.

Results

A total of 225 patients were included in the study, of which 198 completed the follow up protocol (168 men, 30 women, mean age 55 with range 20-85). About 21% of cases were intervened in an outpatient major surgery circuit in an integrated unit in the hospital, partially independent.

All patients were randomly assigned to fixation of the prosthesis with cyanoacrylate (n = 101 cases with 105 hernias) or sutures (n = 97 cases with 102 hernias). Figure 1 shows the design of the study. Mean follow-up was 16 months (12-20 months) in both groups. Data on the type of hernia and laterality, as well as potential risk factors are shown in Table 2.

No intraoperative complications were observed nor any cases of prosthesis migration were detected, since no early recurrence or unusual appearance of tumors in the subcutaneous tissue of the area was diagnosed.

No surgical time was computed, as we observed a difference of little importance in previous studies.[9-11]

The mean postoperative stay (Fig. 2) was 14.7 h in the glue group and 19.1 h in the suture group ($p < 0.0001$).

Postoperative complications are shown in Table 3.

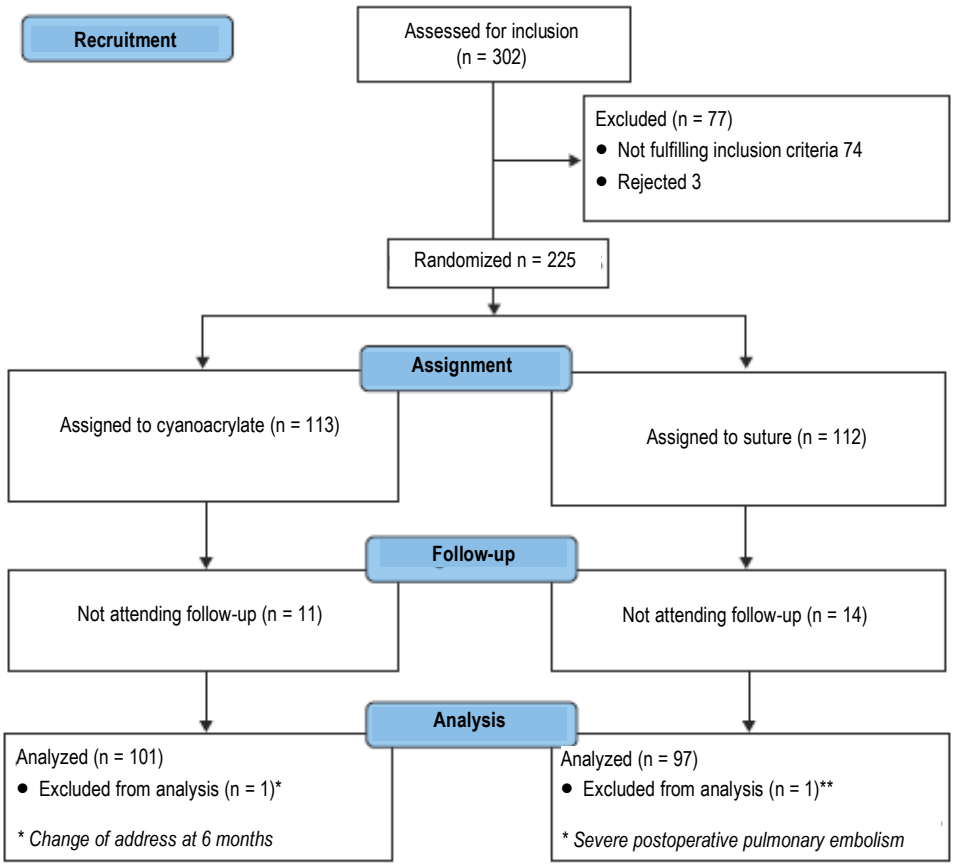

Figure 1 – CONSORT flow diagram of study design

Postoperative pain was controlled adequately with the standard pattern of NSAIDs, and it was not necessary to use rescue patterns in any case. No cases of wound infection or inflammatory reactions on the skin were observed for the two groups.

The average time off work was 33 days for the cyanoacrylate group and 37 days for the suture group (p = 0.28). At 30 days after surgery, 53% of patients in the glue group and 55% in the suture group had returned to work or normal activity (p = 0.76).

In the long-term follow-up we observed one case of recurrence in the suture group that was detected after one year and was re-operated, observing a recurrence near the pubic tubercle. No relapses were detected in the glue group (p = 0.3).

Table 2 - Demographic data and risk factors

Variable	Fixing method; No. (%) of patients	
	Cyanoacrylate (n = 101)	Suture (n = 97)
Age *	54.3 ± 1.47	56.3 ± 1.51
Gender		
Male	87 (86.1)	82 (84.5)
Female	14 (13.9)	15 (15.5)
Hernia type		
Direct	21 (20.8)	16 (16.5)
Indirect	76 (75.2)	74 (76.3)
Laterality		
Right	47 (45.5)	42 (43.2)
Left	50 (49.5)	50 (51.5)
Bilateral	4 (3.9)	5 (5.2)
Risk Factors		
Chronic bronchitis	6 (5.9)	5 (5.2)
Prostatism	4 (4.0)	5 (5.2)
Chronic Constipation	5 (5.0)	4 (4.1)

* Mean ± standard error of the mean
p> 0.05 for all variables.

Table 3 - Postoperative complications in the first 30 days

Complication	Fixing Method; No. (%) of patients		p
	Cyanoacrylate (n = 101)	Suture (n = 97)	
Seroma	8 (7.9)	9 (9.3)	0.73
Hematoma	3 (3.0)	10 (10.3)	0.03
Wound infection	0	0	-

Table 4 - Assessment of chronic inguinal neuralgia

Visual analog scale	Fixing Method; No. (%) of patients		p
	Cyanoacrylate (n = 101)	Suture (n = 97)	
6 months			
≥ 4	4 (3.9)	12 (12.3)	0.03
≥ 7	0	2 (2.0)	0.1
12 months			
≥ 4	3 (2.9)	10 (10.3)	0.037
≥	7 0	2 (2.0) *	0.1

* Permanent foreign body sensation besides pain.

Chronic Pain assessment was performed by VAS at 6 months and again at one year, taking point 4 of the scale as the cutoff for moderate pain and 7 for severe pain (Table 4). The difference between the two groups in the case of moderate pain was statistically significant at both 6 months and one year. With

regard to severe pain (VAS ≥ 7), we observed two cases in the suture group and none in the glue group, this difference was not statistically significant. Both cases relate also a nagging and permanent feeling of foreign body in the groin intervened. One of these 2 patients also recognized a worsening of pain with sexual intercourse. Both patients were referred to the Pain Unit.

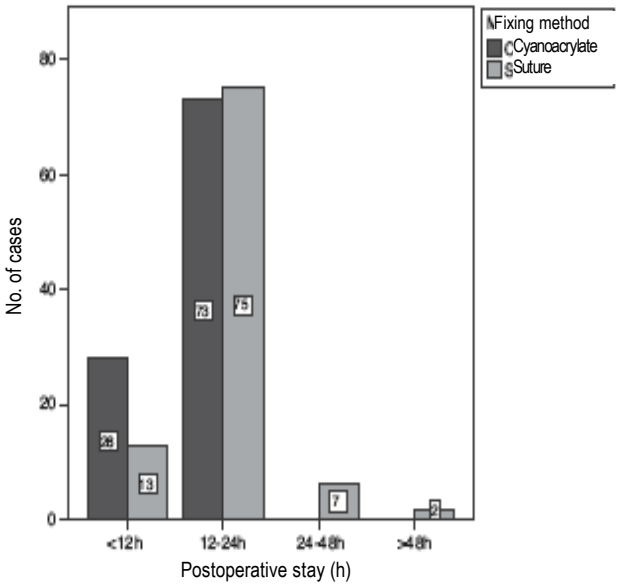

Figure 2 – Grouped postoperative stay in hours

Discussion

Inguinal hernia repair is a simple surgical procedure with low morbidity. However, a small percentage of patients are afflicted with chronic pain in the groin, scrotum and/or the root of the thigh after surgery. The high rates of recurrence observed with suture techniques [2,6,12] relegated this neuralgia into the background. Today, with the routine use of mesh, recurrence rates range between 0 and 2% and chronic pain is becoming the leading cause of long term morbidity[2.13]. In a Danish study with 1652 patients undergoing inguinal or femoral hernioplasty, a chronic neuralgia rate of 11-17% was detected[14]. Other authors such as Perkins and Kehlet report an overall incidence of chronic neuralgia of 12%[15]. Chronic pain persisting after healing is observed in 30% of cases. It is generally a mild pain and has no impact on the patient's life. In 3% of cases, the pain is of such a degree that impacts on the daily activities of the patient, sometimes preventing their participation in paid employment. 50% of patients report a feeling of paresthesia or "tingling" in the groin or thigh operated[16].

The use of sutures to anchor the prosthesis can result in periosteitis pubis, muscle ischemia, a pinched nerve or a foreign body reaction in addition to presenting a risk of injury to the surgeon[17]. This has prompted the use of biological or synthetic adhesives in the attachment of the mesh. In 1996, Farouk published the first study on the use of cyanoacrylate in tension-free inguinal hernioplasty[18]. Since then studies on the application of cyanoacrylate in inguinal hernia repair have been few and even fewer if the technique used is plug and patch[11.19]. However, this type of glue has been used successfully since the 60s in various surgical fields such as the closing of cutaneous wounds and incisions, cerebral vascular embolization, hemostasis of gastric variceal bleeding and the closing of biliopancreatic leakages[20-23].

The study found no difference between glue and suture regarding tissue integration or inflammatory reaction around the mesh[24]. Intense inflammatory reactions with necrosis were observed with short chain cyanoacrylates (methyl and ethyl-cyanoacrylate), whereas long chain cyanoacrylates (butyl and isobutyl-cyanoacrylate) produced only mild inflammation due to their low temperature polymerization (45 ºC) avoiding any thermal nerve injury[25]. Furthermore, butyl-2-cyanoacrylate is simple to apply and requires low quantities with fast drying (5-7 s), low toxicity and excellent adhesion to tissues.

In a 2010 study comparing cyanoacrylate, fibrin glue and suture for the fixation of the mesh, similar results to those of our study were found, with no significant differences between both adhesives[11].

In a recent paper, Paajanen et al. confirm the possibility of anchoring the mesh with cyanoacrylate although they did not detect any difference between glue and suture regarding acute or chronic pain, infection, hematoma or recurrence. To be noted that this study was followed up through phone calls[10].

In our study, the overall morbidity rate was lower in the group of glue, with better long-term, consistent with the results of other authors[4,11,24]. This difference is probably due to the lesser degree of injury to nerves and vessels. Although we detected no difference in time off work between both groups, hospital stay was higher in the suture group perhaps in connection with hematomas developed in this group.

Given the difference in cost between the suture and synthetic glue (4 € vs. 165 € during the study period), cyanoacrylate could be reserved for specific cases, such as patients with high risk of bruising, patients with blood transmitted diseases such as HIV and patients with significant preoperative pain in the groin area.

Conclusion

Cyanoacrylate-based synthetic adhesives can be used in anchoring the mesh in inguinal hernia repair without risk of migration or higher rates of relapse. While their use has a lower rate of chronic neuralgia, more studies are needed to find out the various factors that can influence the development of this neuralgia such as patient age, the presence of preoperative pain and weight of the mesh.

Conflict of interest

The authors declare no conflict of interest.

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REFERENCES

1. Rutkow IM. Surgical operations in the United States. Then (1983) and now (1994). Arch Surg. 1997;132:983–90.
2. Collaboration EUHT. Mesh compared with non-mesh methods of open groin hernia repair: systematic review of randomized controlled trials. Br J Surg. 2000;87:854–9.
3. Poobalan AS, Bruce J, Smith WC, King PM, Krukowski ZH, Chambers WA. A review of chronic pain after inguinal herniorrhaphy. Clin J Pain. 2003;19:48–54.
4. Helbling C, Schlumpf R. Sutureless Lichtenstein: first results of a prospective randomised clinical trial. Hernia. 2003;7:80–4.
5. Cerquella C, Martínez Santos C, Moreno Azcoita M, Fernández Lobato R, Fernández Luengas D, Serantes A. Aplicaciónn de histoacryl en dermolipectomías y eventraciones. Cir Esp. 2000;67:119–20.
6. Amid PK. Causes, prevention, and surgical treatment of postherniorrhaphy neuropathic inguinodynia: triple neurectomy with proximal end implantation. Hernia. 2004;8:343–9.
7. Miserez M, Alexandre JH, Campanelli G, Corcione F, Cuccurullo D, Pascual MH, et al. The European hernia society groin hernia classification: simple and easy to remember. Hernia. 2007;11:113–6.
8. Horan TC, Gaynes RP, Martone WJ, Jarvis WR, Emori TG. CDC definitions of nosocomial surgical site infections, 1992: a modification of CDC definitions of surgical wound infections. Infect Control Hosp Epidemiol. 1992;13:606–8.
9. Nowobilski W, Dobosz M, Wojciechowicz T, Mionskowska L. Lichtenstein inguinal hernioplasty using butyl-2-cyanoacrylate versus sutures. Preliminary experience of a prospective randomized trial. Eur Surg Res. 2004;36: 367–70.
10. Paajanen H, Kossi J, Silvasti S, Hulmi T, Hakala T. Randomized clinical trial of tissue glue versus absorbable sutures for mesh fixation in local anaesthetic Lichtenstein hernia repair. Br J Surg. 2011;98:1245–51.
11. Testini M, Lissidini G, Poli E, Gurrado A, Lardo D, Piccinni G. A single-surgeon randomized trial comparing sutures, Nbutyl-2-cyanoacrylate and human fibrin glue for mesh fixation during primary inguinal hernia repair. Can J Surg. 2010;53:155–60.
12. O'Dwyer PJ, Alani A, McConnachie A. Groin hernia repair: postherniorrhaphy pain. World J Surg. 2005;29:1062–5.
13. Collaboration EUHT. Repair of groin hernia with synthetic mesh: meta-analysis of randomized controlled trials. Ann Surg. 2002;235:322–32.
14. Bay-Nielsen M, Perkins FM, Kehlet H, Danish Hernia Database. Pain and functional impairment 1 year after inguinal herniorrhaphy: a nationwide questionnaire study. Ann Surg. 2001;233:1–7.
15. Perkins FM, Kehlet H. Chronic pain as an outcome of surgery. A review of predictive factors. Anesthesiology. 2000;93:1123–33.
16. Courtney CA, Duffy K, Serpell MG, O'Dwyer PJ. Outcome of patients with severe chronic pain following repair of groin hernia. Br J Surg. 2002;89:1310–4.
17. Jourdan IC, Bailey ME. Initial experience with the use of Nbutyl-2-cyanoacrylate glue for the fixation of polypropylene mesh in laparoscopic hernia repair. Surg Laparosc Endosc. 1998;8:291–3.
18. Farouk R, Drew PJ, Qureshi A, Roberts AC, Duthie GS, Monson JR. Preliminary experience with butyl-2-cyanoacrylate adhesive in tension-free inguinal hernia repair. Br J Surg. 1996;83:1100.
19. Benizri EI, Rahili A, Avallone S, Balestro JC, Cai J, Benchimol D. Open inguinal hernia repair by plug and patch: the value of fibrin sealant fixation. Hernia. 2006;10:389–94.
20. Mutignani M, Tringali A, Khodadadian E, Petruzziello L, Spada C, Spera G, et al. External pancreatic fistulas resistant to conventional endoscopic therapy: endoscopic closure with N-butyl-2-cyanoacrylate (Glubran 2). Endoscopy. 2004;36:738–42.
21. Seewald S, Groth S, Sriram PV, Xikun H, Akaraviputh T, Mendoza G, et al. Endoscopic treatment of biliary leakage with n-butyl-2 cyanoacrylate. Gastrointest Endosc. 2002;56:916–9.
22. Dhiman RK, Chawla Y, Taneja S, Biswas R, Sharma TR, Dilawari JB. Endoscopic sclerotherapy of gastric variceal bleeding with N-butyl-2-cyanoacrylate. J Clin Gastroenterol. 2002;35:222–7.
23. Qureshi A, Drew PJ, Duthie GS, Roberts AC, Monson JR. n-Butyl cyanoacrylate adhesive for skin closure of abdominal wounds: preliminary results. Ann R Coll Surg Engl. 1997;79:414–5.
24. Losi P, Burchielli S, Spiller D, Finotti V, Kull S, Briganti E, et al. Cyanoacrylate surgical glue as an alternative to suture threads for mesh fixation in hernia repair. J Surg Res. 2010;163:e53–8.
25. Toriumi DM, Raslan WF, Friedman M, Tardy ME. Histotoxicity of cyanoacrylate tissue adhesives. A comparative study. Arch Otolaryngol Head Neck Surg. 1990;116:546–50.