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Wound Closure Technologies

Clinical Evidence

for mesh fixation with tissue adhesive

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Summary

Abdominal hernia repair remains one of the most commonly performed surgical procedures worldwide, with inguinal being the most common form of herniorrhaphy, accounting for 71% of all hernia repairs in the UK alone [1] [2].

Despite the well-established clinical success of tension-free herniorrhaphy using an implanted surgical mesh, the prevalence of long-term groin discomfort following surgery remains a relevant clinical problem with groin pain reported in up to 50% of patients who underwent the open or 'Lichtenstein' procedure and in almost 29% of patients who underwent laparoscopic herniorrhaphy [3] [4].

One of the principle causes of groin discomfort following hernia repair has been identified as nerve irritation and/or nerve entrapment, caused by mechanical disruption from sutures, spiral tacks or staples, that are used to fix the mesh in place to the underlying tissue [3]. This has spurred investigation of using adhesives – both fibrin and cyanoacrylate-based as alternatives for mesh fixation, since this approach eliminates direct nerve contact and nerve entrapment. Both of these adhesives have a well-established history of use in medical procedures – cyanoacrylate has been used as a surgical tissue adhesive since the 1960s and fibrin glue has been used effectively for more than 20 years in a range of clinical applications [5].

This publication includes summaries of 10 peer-reviewed articles, identified following a review of the literature for studies using adhesive-based fixation of hernia mesh. From these studies, a total of 1,924 cases of hernia mesh fixation are described, using 5 different, commercially available, medical grade adhesives. In all studies reviewed, low rates of hernia recurrence were observed (0.78% for both open and laparoscopic procedures and 0.35% for laparoscopic procedures alone). Additionally, mesh fixation with n-butyl-2-cyanoacrylate did not result in increased operation time, duration of hospital stay, time to return to normal daily activities, or incidence of groin pain (either acute or chronic), compared to standard (sutured) mesh fixation.

In addition to a review of existing clinical data, results from a recent pre-clinical study by AMS (Plymouth) Ltd. are presented that demonstrate the efficacy of a novel hernia mesh fixation device (FX001) in a large animal model. Whereas previous clinical studies have relied on a needle and syringe or custom-fabricated device for adhesive delivery, this evaluation reviewed the use of the 'all-in-one' FX001 device, combining a laparoscopic instrument with n-butyl-2-cyanoacrylate adhesive for both hernia mesh fixation and peritoneal closure.

The pre-clinical and clinical data presented demonstrates the use of adhesives as effective alternatives to mechanical forms of hernia mesh fixation.

1.Kingsnorth A, LeBlanc K. Hernias: inguinal and incisional. Lancet. 2003 Nov 8;362(9395):1561-71.
2.Dabbas N, Adams K, Pearson K, Royle G. Frequency of abdominal wall hernias: is classical teaching out of date? JRSM Short Rep. 2011 Jan 19;2(1):5.
3.Kim-Fuchs C, Angst E, Vorburger S, Helbling C, Candinas D, Schlumpf R. Prospective randomized trial comparing sutured with sutureless mesh fixation for Lichtenstein hernia repair: long-term results. Hernia. 2012 Feb;16(1):21-7.
4.Brügger L, Bloesch M, Ipaktchi R, Kurmann A, Candinas D, Beldi G. Objective hypoesthesia and pain after transabdominal preperitoneal hernioplasty: a prospective, randomized study comparing tissue adhesive versus spiral tacks. Surg Endosc. 2012 Apr;26(4):1079-85.
5.Testini M, Lissidini G, Poli E, Gurrado A, Lardo D, Piccinni G. 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 Jun;53(3):155-60.

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SUMMARY OF CLINICAL EVIDENCE

AUTHOR	YEAR	TYPE OF STUDY	No. OF PATIENTS	PROCEDURE TYPE	TYPE OF n-butyle CA	Comparator	Mesh Type	Time to repair	Peritoneal repair	Complications (N)
Kukleta JF et al.	2012	Retrospective	1336	TAPP	Glubran	N/A	Polypropylene	Not disclosed	glue suture	No Infections, 5 hernia recurrences
Brugger L et al.	2012	RCT	80	TAPP	Glubran	Tacks	Polypropylene	90min(glue) Vs 85min(suture)	by suture	No infections, Haematoma: sutures(1), glue(3), Hernia recurrence: suture(1), glue(2)
Shen YM et al.	2012	RCT	110	Open	Component Medical Adhesive	Suture	Polypropylene	39min(glue) Vs 43min(suture)	by suture	No hernia recurrences, or wound infections. Haematoma: sutures(10), glue(2), chronic pain: suture(6), glue(0)
Kim-Fuchs C et al.	2012	RCT	264	Open	Histoacryl	Suture	Polypropylene	73min(glue) Vs 79min(suture)	by suture	No significant difference in post-op groin pain (n=21 for sutures Vs 13 for glue), or hypoesthesia (n=15 for sutures Vs 13 for glue), 1 hernia recurrence (glue), Haematoma: sutures(5), glue(3)
Paajanen H et al.	2011	RCT	302	Open	Glubran	Suture	Polypropylene	34min(Glue) Vs 36min(Suture)	Not disclosed	Haematoma: sutures(14), Glue(11), Wound infection: sutures(2), Glue(5). Hernia recurrence: sutures(2), Glue(2)
Testini M et al.	2010	Retrospective	156	Open	Glubran	Suture Fibrin	Polypropylene	54.2-56.2min	Not disclosed	Post-op pain higher with sutures(7), than Glubran(2) or Fibrin(2), Mobidity 38.98% (sutures), 9.62%(fibrin), 10.71%(Glubran). No hernia recurrences
Agresta F et al.	2007	Retrospective	76	TAPP	Glubran	Suture	Not disclosed	40.2min(glue) Vs 42.1min (suture)	Not disclosed	No Major, 1 seroma(sutures), 2 oedema(glue)
Nowobilski W et al.	2004	RCT	46	Open	Indermil	N/A	Polypropylene	<60min	by glue	chest infection(5), urine retention(1), wound oedema(1), haematoma(3), nerve pareses(2), penial/scrota oedema(11) (all patients with primary bilateral hernia)
Helmy AHI	2000	RCT	59	Open	Histoacryl	N/A	Not disclosed	Not disclosed	N/A	No hernia recurrences
Jordan IC and Bailey ME	1998	Retrospective	7	TEP	Indermil	N/A	Polypropylene	<60min	by glue	chest infection(5), urine retention(1), wound oedema(1), haematoma(3), nerve pareses(2), penial/scrota oedema(11) (all patients with primary bilateral hernia)

Summary of Clinical Evidence

Hernia. 2012; 16(2): 153-162.

Efficiency and safety of mesh fixation in laparoscopic inguinal hernia repair using n-butyl-2-cyanoacrylate: long-term biocompatibility in over 1,300 mesh fixations.

Kukleta JF, Freytag C, Weber M.

In this retrospective analysis of laparoscopic hernia repair using n-butyl-2-cyanoacrylate (Histoacryl) for mesh fixation, researchers observed fast application of the glue, reduced postoperative pain, 0.0% infection rate, low recurrence rate, shorter hospital stay and no adverse effects.

INTRODUCTION

In adult patients, most inguinal hernias are treated by implanting a prosthetic mesh. To prevent mesh dislocation and thus recurrence, different types of fixation have been proposed. In contrast to penetrating fixation known to cause acute chronic pain, adhesive fixation is becoming increasingly popular as it reduces markedly the risk of injury and chronic pain. Apart from the biological sealants (e.g., fibrin glue), surgical adhesives include a group of synthetic glues and genetically engineered protein glues. For example, cyanoacrylate is used in various medical and veterinary indications due to its fast action, excellent bonding strength and low price.

OBJECTIVE

The main objective of this paper was to communicate positive results obtained using n-butyl-2-cyanoacrylate glue to fix prosthetic meshes in over 1,300 TAPP repairs of primary and recurrent inguinal hernias. The secondary objective was to highlight the rationale (e.g., safety) for using non-fibrin based glue in this type of procedure.

METHOD

We present the in vitro and in vivo data necessary for the approval of n-butyl-2-cyanoacrylate Histoacryl® glue. We use an equivalent glue, Glubran-2®, to fix prosthetic meshes in 1,336 laparoscopic TAPP repairs.

RESULTS

Standardized tests to detect sensitization, irritation, genotoxicity or systemic toxicity demonstrated the safety and biocompatibility of Histoacryl®, which met all requirements, including those of ISO 10993. Histological long-term studies in rabbits yielded results comparable to routine suture fixations, with full integration of the mesh into the abdominal wall. The clinical results showed the following advantages: fast application of the glue, reduced postoperative pain, 0.0% infection rate, continuously low recurrence rate and shorter hospital stay. No adverse effects and no complaints were recorded.

CONCLUSION

The experimental and clinical data demonstrate the safe use and the excellent cost-benefit ratio of n-butyl-2-cyanoacrylate compared with other techniques of mesh fixation.

PMID: 22015810 (PubMed - indexed for MEDLINE) PMCID: PMC3315639

Surg Endosc. 2012; 26(4): 1079-85.

Objective hypoesthesia and pain after transabdominal preperitoneal herniorrhaphy: a prospective, randomized study comparing tissue adhesive versus spiral tacks.

Brügger L, Bloesch M, Ipaktchi R, Kurmann A, Candinas D, Beldi G.

(Department of Visceral Surgery and Medicine, Bern University Hospital, University of Bern, 3010, Bern, Switzerland.)

In a single centre RCT evaluating laparoscopic inguinal hernia repair, patients were randomized to mesh fixation using Glubran® n-butyl-2-cyanoacrylate adhesive or titanium spiral tacks. The use of adhesive was found to significantly reduce post-operative hypoesthesia and pain.

BACKGROUND

Irritation of inguinal nerves with laparoscopic hernia repair may cause chronic neuralgia and hypoesthesia. Hypoesthesia in particular is generally not assessed objectively. We objectively investigated hypoesthesia and chronic pain after transabdominal preperitoneal inguinal hernia repair (TAPP) with titanium spiral tacks (STs) compared with tissue adhesive (TA) for mesh fixation.

METHODS

Mesh fixation in 80 TAPP procedures was randomized to fixation with ST (n = 40) or TA (n = 40). The outcome parameters included hypoesthesia assessed with von Frey monofilaments, early postoperative and chronic pain with the visual analog scale (VAS), morbidity (surgical-site infection, hematoma/seroma, relapse of hernia, trocar hernia), and recovery time to normal activity.

RESULTS

Median (range) follow-up was 38 (13-56) months. Demographic and baseline parameters were similar in the two groups. Prevalence of hypoesthesia was significantly higher at all postoperative times in the ST group (6 weeks: 32 vs. 6%; 6 months: 38 vs. 14%; 12 months: 34 vs. 13%; 13-56 months: 32 vs. 4%). Mean hypoesthesia scores over all time points were significantly higher in the ST group. The percentages of regions with hypoesthesia (abdominal, inguinal, or genitofemoral) following all procedures were higher in the ST group after 6 weeks (14 vs. 2%), 6 months (15 vs. 5%), and 13-56 months (22 vs. 4%). The intensity of pain decreased significantly in both groups over time.

CONCLUSION

Postoperative hypoesthesia depends on the method of mesh fixation during TAPP and is significantly reduced with TA compared with stapling.

PMID: 22044970 (PubMed - indexed for MEDLINE)

Surgery. 2012; 151(4): 550-555.

NBCA medical adhesive (n-butyl-2-cyanoacrylate) versus suture for patch fixation in Lichtenstein inguinal herniorrhaphy: a randomized controlled trial.

Shen YM, Sun WB, Chen J, Liu SJ, Wang MG.

(Department of Hernia and Abdominal Wall Surgery, Beijing Chao-Yang Hospital, Beijing, China.)

In this single center RCT, n-butyl-2-cyanoacrylate was compared to sutures for mesh fixation in open surgical repair of inguinal hernia. While there was no difference between the two groups for hernia recurrence, infection and duration of post-operative stay, less patients from the adhesive group experienced pain and operative time was reduced.

BACKGROUND

We compared the effectiveness of n-butyl-2-cyanoacrylate (NBCA) and traditional suture for patch fixation in Lichtenstein tension-free herniorrhaphy for inguinal hernias.

METHODS

A total of 110 patients with primary unilateral inguinal hernia were assigned randomly to either experimental or control groups. In the experimental group, NBCA adhesive was used during Lichtenstein herniorrhaphy; traditional suture was used in the control group. We evaluated operation time, postoperative duration of stay, visual analogue scale (VAS) pain score, incidence of chronic pain and hematoma formation, and hernia recurrence.

RESULTS

There was no hernia recurrence or wound infection in either group. In the experimental group, 2 local hematomas occurred while no patients experienced chronic postoperative pain; in the control group, 10 hematomas occurred, and 6 patients experienced chronic pain. There was no difference in postoperative duration of stay between the groups ($P > .05$), but the experimental group had a lesser operation time and postoperative VAS score ($P < .05$).

CONCLUSION

The use of NBCA medical adhesive in tension-free inguinal herniorrhaphy is effective and safe.

PMID: 22088820 (PubMed - indexed for MEDLINE)

Hernia. 2012; 16(1): 21-27.

Prospective randomized trial comparing sutured with sutureless mesh fixation for Lichtenstein hernia repair: long-term results.

Kim-Fuchs C, Angst E, Vorburger S, Helbling C, Candinas D, Schlumpf R.

(Clinic of Surgery, Kantonsspital Aarau, Aarau, Switzerland.)

In a single center RCT evaluating n-butyl-2-cyanoacrylate (Histoacryl) versus sutures for hernia mesh fixation, the use of adhesive was found to significantly reduce operating time while offering comparable low rates of long term complications.

BACKGROUND

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 these complaints are the compression or irritation of nerves by the sutures used to fixate the mesh. We compared the level and rate of chronic pain in patients operated with the classical Lichtenstein technique fixated by sutures to patients with sutureless mesh fixation technique.

METHODS

A two-armed randomized trial with 264 male patients was performed. After consent, patients were randomized preoperatively. For the fixation of the mesh we used either sutures with slow-absorbing material (PDS 2.0) (group I, n = 133) or tissue glue (Histoacryl) (group II, n = 131). Follow-up examinations were performed after 3, 12 months and after 5 years.

RESULTS

Patient characteristics in the two groups were similar. No cross-over between groups was observed. After 5 years, long-term follow-up could be completed for 59% of subjects. After 5 years, 10/85 (11.7%) patients in group I and 3/70 (4.2%) in group II suffered from chronic pain in the groin region ($P = 0.108$). The operation time was significantly shorter in group II (79 min vs 73 min, $P = 0.01$). One early recurrence occurred in group II (3 months). The recurrence rate was 0 and 0% after 12 months and 5.9% (5/85) and 10% (7/70) after 5 years in group I and group II, respectively ($P = 0.379$).

CONCLUSION

After 5 years, the two techniques of mesh fixation resulted in similar rates of chronic pain. Whereas recurrence rates were comparable, fixation of the mesh with tissue glue decreased operating room time significantly. Hence, sutureless mesh fixation with Histoacryl is a sensible alternative to suture fixation and should be especially considered for patients prone to pain.

PMID: 21789654 (PubMed - indexed for MEDLINE)

Br J Surg. 2011; 98(9): 1245-1251.

Randomized clinical trial of tissue glue versus absorbable sutures for mesh fixation in local anaesthetic Lichtenstein hernia repair.

Paajanen H, Kössi J, Silvasti S, Hulmi T, Hakala T.

(Kuopio University Hospital, Kuopio, Finland; Central Hospital of Mikkeli, Mikkeli, Finland.)

In a multi-centre RCT comparing sutures to n-butyl-2-cyanoacrylate adhesive (Glubran) for mesh fixation in open herniorrhaphy, post-operative analgesic use, rates of pain, infection and recurrence were found to be similar between both groups, indicating the feasibility of using adhesives for this application without compromising postoperative outcome.

BACKGROUND

Chronic pain may be a long-term problem related to mesh fixation and operative trauma after Lichtenstein hernioplasty. The aim of this study was to compare the feasibility and safety of tissue cyanoacrylate glue versus absorbable sutures for mesh fixation in Lichtenstein hernioplasty.

METHODS

Lichtenstein hernioplasty was performed under local anaesthesia as a day-case operation in one of three hospitals. The patients were randomized to receive either absorbable polyglycolic acid 3/0 sutures (Dexon®; 151 hernias) or 1 ml butyl-2-cyanoacrylate tissue glue (Glubran®; 151 hernias) for fixation of lightweight mesh (Optilene®). Wound complications, pain, discomfort and recurrence were identified at 1 and 7 days, 1 month and 1 year after surgery.

RESULTS

A total of 302 patients were included in the study. The mean(s.d.) duration of operation was 34(12) min in the glue group and 36(13) min in the suture group (P = 0.113). The need for analgesics was similar during the first 24 h after surgery. Five wound infections (3.4 per cent) were detected in the glue group and two (1.4 per cent) in the suture group (P = 0.448). The recurrence rate at 1 year was 1.4 per cent in each group (P = 1.000). The rates of foreign body sensation, acute and chronic pain were similar in the two groups. Logistic regression analysis showed that the type of mesh fixation did not predict chronic pain 1 year after surgery.

CONCLUSION

Mesh fixation without sutures in Lichtenstein hernioplasty was feasible without compromising postoperative outcome. Registration number: NCT00659542 (http://www.clinicaltrials.gov).

PMID: 21710480 (PubMed - indexed for MEDLINE)

Can J Surg. 2010; 53(3): 155-160.

A single-surgeon randomized trial comparing sutures, n-butyl-2-cyanoacrylate and human fibrin glue for mesh fixation during primary inguinal hernia repair.

Testini M, Lissidini G, Poli E, Gurrado A, Lardo D, Piccinni G.

(Section of General Surgery, Department of Applications in Surgery of Innovative Technologies, University Medical School of Bari, Italy.)

In an RCT comparing mesh fixation devices used during open surgical repair of primary inguinal hernia, fibrin glue or n-butyl-2-cyanoacrylate was found to be better tolerated by patients than sutures, with significantly lower short and long-term rates of morbidity experienced.

BACKGROUND

We sought to determine the efficacy of sutures, human fibrin glue and n-butyl-2-cyanoacrylate for mesh fixation in patients undergoing the plug and mesh procedure for groin hernia.

METHODS

A total of 156 patients with 167 inguinal hernias (11 bilateral) underwent a plug and mesh procedure and were randomly assigned to received either sutures (n = 59 hernias), human fibrin glue (n = 52) or n-butyl-2-cyanoacrylate (n = 56) for mesh fixation.

RESULTS

The overall morbidity rate was 38.98% in the suture group, 9.62% in the fibrin glue group and 10.71% in the n-butyl-2-cyanoacrylate group (suture v. fibrin glue, $p < 0.001$; suture v. n-butyl-2-cyanoacrylate, $p < 0.001$). There was no significant difference in morbidity between the fibrin glue and n-butyl-2-cyanoacrylate groups. Overall, short-term morbidity was significantly higher in the suture group (27.12%) than in the fibrin glue (9.62%, $p = 0.01$) or n-butyl-2-cyanoacrylate (8.93%, $p = 0.004$) groups, but there was no significant difference between the fibrin glue and n-butyl-2-cyanoacrylate groups. There was no significant difference between the groups in terms of mean postoperative stay (32.6 h in the suture group v. 30.8 h in the fibrin glue group v. 32.0 h in the n-butyl-2-cyanoacrylate group) or mean time to return to work (20.4 d in the suture group v. 20.3 d in the fibrin glue group v. 19.8 d in the n-butyl-2-cyanoacrylate group). Overall, long-term morbidity was significantly higher in the suture group (11.86%) than in the fibrin glue (0%, $p = 0.001$) or n-butyl-2-cyanoacrylate (1.78%, $p = 0.03$) groups. There was no recurrence in any of the groups. Two cases (3.39%) of chronic groin pain were reported in patients in the suture group. A sensation of extraneous body was reported in 5 (8.47%) patients who received sutures and in 1 (1.78%) patient in the n-butyl-2-cyanoacrylate group; there were no reported cases in the fibrin glue group (suture v. fibrin glue, $p = 0.01$; suture v. n-butyl-2-cyanoacrylate, $p = 0.03$; fibrin glue v. n-butyl-2-cyanoacrylate, $p = 0.30$).

CONCLUSION

The use of human fibrin glue or n-butyl-2-cyanoacrylate is better tolerated than sutures in tension-free inguinal open repair using the plug and mesh technique in terms of overall immediate results, and there is a better trend in the long-term data.

PMID: 20507786 (PubMed - indexed for MEDLINE) PMCID: PMC2878998

Surg Laparosc Endosc Percutan Tech. 2007; 17(2): 91-94.

Lightweight partially absorbable monofilament mesh (polypropylene/poliglecaprone 25) for TAPP inguinal hernia repair: Initial experience.

Agresta F, Baldazzi GA, Ciardo LF, Trentin G, Giuseppe S, Ferrante F, Bedin N.

(Department of General Surgery, Ospedale Civile, Via Forlanini, 71, 31029 Vittorio Veneto, Italy.)

In a retrospective analysis of patients who underwent TAPP hernioplasty using a mesh fixed with either Glubran® 2, n-butyl-2-cyanoacrylate adhesive, or Tissucol® fibrin sealant, no patients reported severe pain at 10 days post-surgery and there were no reports of night pain at 30 days post-surgery. Additionally, approximately 90% of patients were able to return to physical work within 7 days of surgery and 100% returned to work within 14 days. All patients reported complete satisfaction at the 3 month follow-up time point.

OBJECTIVE

An ideal mesh should produce slight foreign-body reactions and be compatible with the human organisms. Studies focusing on these aspects indicate that the use of mesh with less nonabsorbable material may reduce postoperative complications, insofar the web structure and its rigidity play an important role in compatibility. We evaluated retrospectively the patients of the past 1 year, who underwent laparoscopic transabdominal preperitoneal (TAPP) hernioplasty (without the use of any trocar and/or instrument of 10 mm in diameter) focusing attention on the feasibility of the technique and on the incidence of complications, especially those possibly related to the new type of mesh implanted.

METHODS

Between June 2004 and September 2005, 76 patients have been operated on by using TAPP hernioplasty (bilateral or unilateral) without any 10 mm instrument/optic/trocar, and by applying a lightweight composite mesh fixed by "glues" (fibrin sealant and n-butyl-2-cyanoacrylate).

RESULTS

The mean overall operative time was 55.57 (+/-15.2) minutes. All the procedures have been performed on a day surgery basis. We have registered any kind of major or minor morbidity (early or late), relapse, prosthesis rejection, and/or infection. We have registered no severe pain at 10 days; whereas a mild pain is still reported in 10.5% of our cases at a 3-month follow-up. The mean follow-up is 12.4 (+/-5.1; range 4 to 19) months.

CONCLUSION

On the basis of this our initial experience, TAPP hernioplasty with a lightweight composite mesh is feasible, effective, and easy to perform by experienced hands, with good results. The well-known characteristics of a mini-invasive and gentle approach, together with the type of mesh implanted and its fixation of related glues, might explain the encouraging results of our experience.

PMID: 17450087 (PubMed - indexed for MEDLINE)

Eur Surg Res. 2004; 36(6): 367-370.

Lichtenstein inguinal hernioplasty using n-butyl-2-cyanoacrylate versus sutures. Preliminary experience of a prospective randomized trial.

Nowobilski W, Dobosz M, Wojciechowicz T, Mionskowska L.

(Department of General and Gastroenterological Surgery, St. Vincent a'Paulo Hospital of Gdynia, Gdynia, Poland.)

In a single center RCT comparing sutures versus n-butyl-2-cyanoacrylate for mesh fixation in Lichtenstein open inguinal hernia repair, the average pain score was found to be significantly lower in the adhesive group in the first 24 hours after surgery. No major complications, or hernia recurrence occurred in either group up to the 3 month follow-up time point.

ABSTRACT

The Lichtenstein hernioplasty has become a popular method in inguinal hernia repair. This study compared two methods of mesh fixation and wound closure. Forty-six men with unilateral inguinal hernia were randomized into two groups. In the control group polypropylene mesh was anchored with 3/0 Dexon sutures, fascia and skin were closed with sutures 3/0 Dexon and 3/0 Monosof. In the study group, the mesh was secured with butyl-2-cyanoacrylate adhesive and the fascia and skin were also glued with the adhesive. The costs of materials, duration of the operation, amount of postoperative analgesic doses, pain score after the first and the 7th postoperative day and return to daily activity were recorded. No recurrences during the mean follow-up of 4.7 months were observed and the cosmetic effect was very good. In the study group with tissue adhesive the patients had significantly lower pain score after the first postoperative day and had a tendency to require less analgetic doses and to return earlier to their daily activity. Duration of the operation was similar in both groups. The cost of sutures and tissue adhesive used in both procedures was comparable. The use of tissue adhesive in mesh fixation and wound closure seems to be a promising technique in Lichtenstein hernia repair.

PMID: 15591746 (PubMed - indexed for MEDLINE)

Egypt J Surg. 2000; 19(3): 276-283.

Lichtenstein repair of inguinal hernia: new modalities for mesh fixation; the use of tissue adhesive glue (Histoacryl; n-butyl-2-cyanoacrylate) to fix the mesh.

Helmy AHI

In an RCT evaluating n-butyl-2-cyanoacrylate for mesh fixation in open surgical repair of inguinal hernia, operative time was reported as less than 60min with over a third of procedures requiring less than 30 min, patients were released from the hospital in less than 2 days, and the majority of patients required no analgesia within one week of discharge.

ABSTRACT

The use of tissue adhesive glue to fix the mesh in inguinal hernia repair is an alternative for sutures and clips. One of these tissue adhesive is the histoacryl (n-butyl-2-cyanoacrylate). In our study 59 male patients whom they complain of having 75 inguinal hernia (43 unilateral and 32 bilateral) were recruited for such technique. This research focuses on the evaluation of this method. The procedure performed was the standard Liechtenstein -tension free repair for all inguinal hernias. The preoperative preparation, intraoperative time, use of antibiotics, use of post operative painkillers, patient satisfaction and return to work and the early and late complications were analyzed.

CONCLUSION

Most surgeons are still doing the traditional and usual method of mesh fixation in inguinal hernia repair. This new technique is recommended for the benefits found in our study.

Surg Laparosc Endosc. 1998; 8(4): 291-293.

Initial experience with the use of n-butyl-2-cyanoacrylate glue for the fixation of polypropylene mesh in laparoscopic hernia repair.

Jourdan IC, Bailey ME.
(Minimal Access Therapy Training Unit, Royal Surrey County Hospital, Guildford, England)

In a retrospective study of patients who underwent laparoscopic extraperitoneal hernia repair using cyanoacrylate-adhered mesh, no complications and no hernia recurrences were reported.

ABSTRACT

The Minimal Access Therapy Training Unit at The Royal Surrey County Hospital Guildford (UK) reports on the initial success with the use of n-butyl-2-cyanoacrylate glue for fixing polypropylene mesh during laparoscopic hernia repair. We report our experience with seven such repairs and describe the prototype glue dispenser and mode of application used to fix the mesh. This is the first reported use of glue in laparoscopic hernia repair.

PMID: 9703604 (PubMed - indexed for MEDLINE)

Abstracts

Evaluation of a novel laparoscopic device for hernia mesh fixation by n-butyl -2-cyanoacryalte adhesive

BACKGROUND

Most inguinal hernia repairs rely on mechanical forms of fixation such as tacks and sutures for mesh attachment over a defect. While effective, penetration of these fixatives into sensitive tissue may lead to chronic pain and injury post surgery. A new generation of engineered protein and synthetic glues (e.g. fibrin and cyanoacrylates), have been evaluated as fixation alternatives, providing fast and strong bonding without the disadvantages of tissue penetration. In this pre-clinical study, we evaluate the use of a novel hernia mesh fixation device (Figure 1), designed to laparoscopically deliver discrete volumes of n-butyl cyanoacrylate adhesive for the fixation of hernia mesh in inguinal hernia repair.

Figure 1: Hernia Mesh Fixation device, FX001 (AMS Plymouth Ltd.); a combination n-butyl-2-cyanoacrylate and laparoscopic delivery device

METHOD

A Transabdominal Preperitoneal (TAPP) approach to inguinal hernia repair was utilized in a swine model by a board certified laparoscopic surgeon. Polypropylene mesh (Prolene, Ethicon, Inc.) was secured at Cooper's ligament inferomedially, along the midline medially, and on the inferolateral and superiolateral quadrants utilizing the FX001 hernia mesh fixation device (Figure 2). To determine mesh migration following surgery, the outside borders of the mesh were marked using tacks (Pro-Tack, Ethicon, Inc.). Additionally, the FX001 device was evaluated for the re-approximation of peritoneum over the fixed mesh.

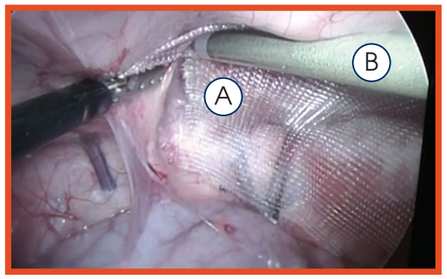

Figure 2: Polypropylene hernia mesh (A) laparoscopically adhered to inguinal region of pig using n-butyl-2-cyanoacrylate dispensed by FX001 device (B)

Fourteen days post surgery, the pigs were anesthetised and sacrificed prior to necropsy to observe and excise the fixed mesh sites. The peel force required to remove fixed mesh off adhered tissues was assessed. Mesh and tissue grafts were harvested, fixed, sectioned and stained for histological analysis.

RESULTS

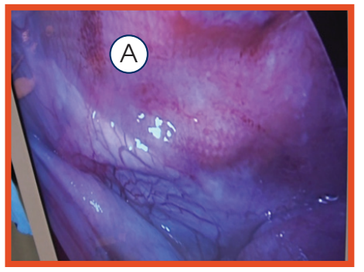

Figure 3: Laparoscopic view of hernia mesh (A) 14 days post fixation by FX001 device revealing advanced stage of fibrosis and tissue integration

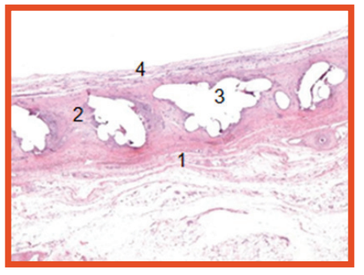

Figure 4: 2x cross-section of 2 week old graft site showing tight adherence of mesh to abdominal wall (1). Multinucleated giant cells and fibroblasts (2) surround individual mesh fibers (3). There is neo-mesotheliation covering the mesh (4) with moderate vascular content

Two weeks post surgery, mesh fixed by the FX001 device remained in place relative to the location of the marker tacks, and a high peel force was required to remove fixed mesh from adhered tissues. Gross examination and histological analysis confirmed no adverse inflammatory response to the adhesive administered by the FX001 device and also demonstrated a normal process of fibrosis and integration of the mesh into surrounding tissues (Figures 3&4). The study surgeon was also able to successfully close the peritoneal membrane over the fixed hernia mesh using the same FIX001 device (Figure 5).

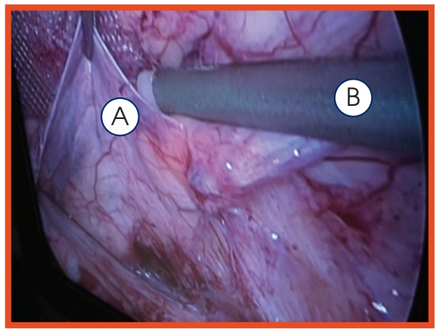

Figure 5: Re-approximation and fixation of the peritoneal membrane (A) post-mesh fixation using n-butyl-2-cyanoacrylate adhesive applied by the FX001 device (B)

CONCLUSION

In this evaluation, FX001 was successful in laparoscopically adhering hernia mesh to the inguinal region of a swine model. The strength of adhesion was sufficient to prevent mesh migration and allow for the process of fibrosis and integration of the mesh into surrounding tissues. Histological analysis confirmed no adverse inflammatory response to the mesh or to the n-butyl-2-cyanoacrylate adhesive. Previous studies performed to standard ISO 10993 for sensitization, irritation genotoxicity or systemic toxicity have also confirmed the biocompatibility of n-butyl cyanoacrylate adhesive used by FIX001. Additionally, the FX001 device demonstrated successful closure of the peritonial membrane following mesh fixation. These results indicate that fixation of mesh by FX001 may provide successful clinical hernia repair, while providing the benefits of non-invasive fixation.

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