B. Braun Closure Technologies
Clinical Evidence for Histoacryl®
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Histoacryl® is a n-butyl-2-cyanoacrylate tissue adhesive. Applied to the skin, the monomer hardens almost immediately in contact with physiological liquids. Histoacryl® is widely used in many medical disciplines, including emergency care, internal medicine, ophthalmology and dentistry.

The most frequent indications for use of Histoacryl® are:

- Surgical incision closure
- Laceration closure
- Mesh fixation

For all these indications several reviews and clinical trials have been published to describe the individual technical approach, benefits and risks. Different reviews were published in the last years regarding the use of tissue adhesive for haemostasis in active bleeding of gastrointestinal varices, concerning the treatment of lacerations and incisions with tissue glues two systematic reviews are available (1, 2). In the last years several clinical trials have also been performed to analyse the outcome of cyanoacrylates for mesh fixation.

**Histoacryl® for laceration closure**

The management of lacerations requires keeping the cleaned wound edges together until natural healing occurs. Traditionally, sutures either absorbable or non-absorbable are applied for this purpose. The disadvantage of sutures is postoperative pain that is associated with the procedure by stitches, which also needs the application of local analgesics. Furthermore, for the removal of non-absorbable suture material patients have to come back to the physician. Tissue adhesives are a good alternative to sutures as the liquid monomer is applied over the wound and forms a strong bond over the approximated wound edges. Elmasalme et al. (3) described the method of skin closure with tissue adhesives as follows: ‘The edges of the wound have to be approximated leaving no gap between them and kept together with fingers or forceps. A thin layer of Histoacryl® is then applied to the wound. If reposition is necessary, the glue has to be wiped off immediately. The edges are kept together for 60 – 90 seconds until polymerization is finished. No further care is needed as Histoacryl® film disappears after approximately one week.’ The use of tissue adhesives is limited to small wounds without tensile strength. The main target of most published clinical trials comparing tissue glues versus sutures for wound closure, is the postoperative cosmetic outcome, postoperative pain and costs.
Rationale

Histoacryl® for incision closure

Tissue adhesives have become more and more standard for closing small lacerations and it is now also used for incision closure. The premises are equal for both situations, because both indications need the approximation of wound edges and must keep together until wound healing. The technical approach is similar, Yulevich et al. (4) described the method as follows: ‘Two skin hooks are placed in the corners of the incision, the skin is lifted and with the tip of a small surgical forceps, eventual appearing subcutaneous material is pushed back into the wound. Then, the hooks are pulled away and pushed down lightly. By this a good aesthetic appearance can be achieved and Histoacryl® is prevented from leaking into the wound. A thin white line indicates a good wound approximation. Histoacryl® is then applied to the wound in a thin layer with long movements. It is essential that a film of Histoacryl® is formed that will keep the edges together in the postoperative course’. The crucial difference between incisions and lacerations is that pain as outcome measure is irrelevant as patients received anaesthesia for the incision anyway. The other concerns like cosmetic result, time for procedure and costs are also relevant for this indication.

Figure 1: Application of tissue glues for laceration closure
**Histoacryl® for mesh fixation**

The treatment of inguinal hernias is the most common surgery worldwide (8, 9). The most common technique used to treat an inguinal hernia is the open surgical approach according to Lichtenstein (10). It is based in a tension-free preperitoneal implantation of a polypropylene mesh, which strengthens the abdominal wall. Main benefits of the Lichtenstein technique are the low complication rate and a low recurrence rate (11); however, postoperative pain and chronic irritation have also been observed (12). For the fixation of the mesh there are several options available for the surgeon (suture, stapler, tacks). These fixation methods may lead to the above mentioned complications. In the last few years more and more the non-traumatic fixation by using tissue adhesives has been applied to reduce postoperative pain rate. Fibrin glue or based on cyanoacrylate glue are available for this purpose. The fixation of the mesh is done by drop-wise application of the glue. In the literature, several publications are available that describe the application of cyanoacrylate glue for the fixation of a surgical mesh in the open as well as in laparoscopic inguinal hernia repair (8, 10, 11, 13 - 15, 32 - 34, 36 - 39).
Clinical Evidence

Farion et al. (1) summarized in their Systematic Review the best available clinical evidence for tissue adhesive for laceration closure in children and adults. Randomized controlled trials comparing tissue adhesive versus standard wound closure procedures (suture, strips or staples) for laceration in children and adults in emergency settings and primary care setting were included. As parameters the cosmetic result, pain, procedure time and the complication rate were assessed. The cosmetic outcome was evaluated as a primary outcome by a blinded plastic surgeon using different cosmetic scores.

Eight trials compared tissue adhesive versus suture or strips and there was one study comparing two different tissue adhesives. There was no significant difference regarding the cosmetic result between the two different closing treatments (tissue adhesive versus standard wound closure). The pain rate was significant lower and time to perform the closure was significant faster with tissue adhesive. Using standard wound closure methods the rate of dehiscence was significant lower compared to tissue glue, in contrast erythema was significantly rarely seen with tissue adhesive than with standard wound closure procedures. Other complications were not recorded. There was one study comparing two different tissue glues (Histoacryl® versus octyl-cyanoacrylate). No difference was observed in regard to cosmesis, pain, complications and time for procedure. One study also analysed the economic effect of sutures versus tissue adhesive for closing lacerations. They found that the use of absorbable suture increased cost of 2.4 times and non-absorbable sutures of 8.8 times in comparison to tissue adhesives.

The authors described the use of tissue adhesives as a suitable alternative in comparison to standard wound closure materials like sutures, staples and strips for simple traumatic laceration closure. Tissue adhesives offer the advantage of a lower pain rate and a faster procedure time, whereas the complications rate is more or less comparable with both treatments (sutures and adhesive glues).

Elmasalme et al. (3) treated over 2,600 small lacerations in the emergency rooms using Histoacryl®. They indicated in their publication that the use of this tissue adhesive has the advantages that it did not require local anaesthesia, gloves or suturing. Furthermore, this method is simple, fast, inexpensive and can be perfected with minimal training. The success rate was very high.
**Göktas and colleagues** (16) compared tissue adhesives and suturing for the repair of lacerations in the emergency department. Histoacryl® was analysed in comparison to non absorbable polypropylene suture material in regard to the cosmetic outcome, costs, patient, and physician satisfaction. In total 92 patients with lacerations equal or shorter than 5 cm were enrolled in the investigation. Patients were randomly allocated to one of the different treatment groups and examined for 3 months. The groups were comparable in respect to the cosmetic appearance at 10 days and 3 months postoperatively using the Visual Analogue Scale (VAS). Application of Histoacryl® resulted in a greater satisfaction of the patient and the blinded surgeon. Also costs were significantly reduced when Histoacryl® was applied in comparison the suture.

The authors concluded that the use of Histoacryl® is cheaper than sutures for the repair of lacerations and it results in a greater satisfaction of the patient and the surgeon. The cosmetic results are similar with both treatments. Their results indicated that Histoacryl® is a cost-effective alternative to suture repair for selected laceration in emergency settings.

**Charters et al.** (17) compared butyl-cyanoacrylate and octyl-cyanoacrylate glue for the closure of lacerations in children. In total, 63 laceration located in the scalp, ear and face area were closed. Patients were equally distributed to the different used products and consecutively treated. The pain rate, the bonding time, the application and wound closure were assessed. The data showed that the use of butyl-cyanoacrylate resulted in lower pain than octyl-cyanoacrylate glue. Regarding the bonding time all used devices achieved high scores in terms of bonding but comments were made to the prolonged bonding time of octyl-cyanoacrylate. The nurses who applied the glues commented that butyl-cyanoacrylate was more easy to apply and was the best glue in terms of wound closure. Octyl-cyanoacrylate was found to be less successful in the closure of scalp wounds although good results were obtained on small fascial lacerations. In conclusion, all glues lead to satisfactory results in terms of wound closure and easy use, however the use of butyl-cyanoacrylate leads to the more consistent results and to higher scores.

Several clinical studies have been performed which compared the use of Histoacryl® versus octyl-cyanoacrylate glue (Osmond et al.) or versus suture material for the closure of paediatric lacerations (18 - 22). In these studies it has been reported that the use of Histoacryl® is faster and less painful than suture repair for laceration closure. The complication rate as well as the cosmetic result were similar and comparable. The butyl-cyanoacrylate glue was described as an acceptable alternative to conventional suturing which prevents suture removal and leads to a more efficient use of physician time.

The comparison with octyl-cyanoacrylate glue showed that both glues are comparable in regard to pain rate, complication rate, cosmetic outcome and time to performed the wound repair.

**CONCLUSION:** The use of butyl-cyanoacrylate glue such as Histoacryl® is a good alternative to conventional suturing for closure of low tension lacerations. Tissue adhesive glue is significantly faster and less painful than suturing. Tissue adhesive glue has the same cosmetic outcome as suturing when used for the repair of simple lacerations, but the need for suture removal is eliminated. In comparison to suture repair the application of tissue adhesive glue is less expensive and leads to a higher satisfaction of the patient and of the surgeon.
# Clinical Evidence

Table 1: Trials comparing tissue adhesives versus standard wound closure procedures for laceration.

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>No. Patient</th>
<th>Product</th>
<th>Cosmesis</th>
<th>Pain/Satisfaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Farion et al.</td>
<td>2002</td>
<td>912</td>
<td>SWC: 366&lt;br&gt;Adhesive: 506</td>
<td>SWC = Ad</td>
<td>Pain: Ad &lt; SWC</td>
</tr>
<tr>
<td>Göktas et al.</td>
<td>2002</td>
<td>92</td>
<td>Histoacryl&lt;sup&gt;1&lt;/sup&gt;: 46&lt;br&gt;Suture: 46</td>
<td>H = S</td>
<td>Satisfaction: H &gt; S</td>
</tr>
<tr>
<td>Charters et al.</td>
<td>2000</td>
<td>63</td>
<td>Butyl-cyanoacrylate vs. Octyl-cyanoacrylate</td>
<td>NR</td>
<td>Pain: BCA &lt; OCA&lt;br&gt;Satisfaction: BCA &gt; OCA</td>
</tr>
<tr>
<td>Osmond et al.</td>
<td>1999</td>
<td>94</td>
<td>Histoacryl&lt;sup&gt;1&lt;/sup&gt;: 47&lt;br&gt;Octyl-cyanoacrylate: 47</td>
<td>H = OCA</td>
<td>Pain: H = OCA</td>
</tr>
<tr>
<td>Barnett et al.</td>
<td>1998</td>
<td>163</td>
<td>Histoacryl&lt;sup&gt;1&lt;/sup&gt;: 83&lt;br&gt;Sutures: 80</td>
<td>H = S</td>
<td>NR</td>
</tr>
<tr>
<td>Simon et al.</td>
<td>1997</td>
<td>61</td>
<td>Histoacryl&lt;sup&gt;1&lt;/sup&gt;: 30&lt;br&gt;Suture: 31</td>
<td>H ≥ S</td>
<td>Pain: H &lt; S&lt;br&gt;Satisfaction: H &gt; S</td>
</tr>
<tr>
<td>Bruns et al.</td>
<td>1996</td>
<td>61</td>
<td>Histoacryl&lt;sup&gt;1&lt;/sup&gt;: 30&lt;br&gt;Suture: 30</td>
<td>H = S</td>
<td></td>
</tr>
<tr>
<td>Quinn et al.</td>
<td>1993</td>
<td>81</td>
<td>Histoacryl&lt;sup&gt;1&lt;/sup&gt;: 41&lt;br&gt;Suture: 40</td>
<td>H = S</td>
<td>Pain: H &lt; S</td>
</tr>
</tbody>
</table>

NR: Not recorded; = equal, > significant better for cosmesis or significant higher for satisfaction; < significant lower for pain and complication or significant faster for procedure time, H: Histoacryl<sup>1</sup>, S: Suture, BCA: Butyl-cyanoacrylate, OCA: Octyl-cyanoacrylate, Ad: Adhesive tissue glue, SWC: Standard wound closure
<table>
<thead>
<tr>
<th>Procedure time</th>
<th>Complication</th>
<th>Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ad &lt; SWC</td>
<td>H = OCA</td>
<td>H &lt; S</td>
</tr>
<tr>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>H = OCA</td>
<td>H = OCA</td>
<td>H &lt; OCA</td>
</tr>
<tr>
<td>H &lt; S</td>
<td>H = S</td>
<td>NR</td>
</tr>
<tr>
<td>NR</td>
<td>NR</td>
<td>NR</td>
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<tr>
<td>H &lt; S</td>
<td>H = S</td>
<td>NR</td>
</tr>
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</table>
A Systematic Review (SR) was performed by Coulthard et al. (2) to determine the effect of various tissue adhesives versus conventional skin closure techniques (suture, staples, tapes) on the wound healing of surgical skin incisions.

In total eight randomized controlled trials including 630 patients were eligible for this SR. These trials compared tissue adhesive glues versus suture and two of these trials analysed also tissue adhesives versus tapes. The primary parameter was the proportion of dehiscence. As secondary endpoints wound infection, patient and surgeon satisfaction, the cosmetic appearance of the wound rated by the patient and the surgeon and costs were evaluated. Butyl and octyl-cyanoacrylate were used as a tissue adhesive glue in 4 trials. Catgut, Dexon™, polypropylene, nylon and poliglecaprone were applied as suture material for wound closure.

In regard to dehiscence, infections, satisfaction with the cosmetic result (rated by the patient and the surgeons) no significant differences were found between tissue adhesive glues and suture material. Also, no differences could be observed for infection, satisfaction and the cosmetic outcome rated by the patient when tissue adhesive glues were compared with tapes; however, a significant difference was recorded for this comparison in respect to the cosmetic result rated by the surgeon obtaining a better rating for tissue adhesive glues.

The authors concluded that there are no differences in the rate of dehiscence, wound infection, satisfaction or the cosmetic outcome after surgical wound closure with tissue adhesive glues or sutures. Further trials should be conducted investigating the efficacy of tissue adhesive glues in areas with high tissue tension or in patients with impaired wound healing.

In 2011, this Systematic Review was updated by Coulthard et al. (23). Six additional randomised controlled trials were included. In total, 1152 patients were enrolled in 14 RCTs. The data showed that suture material was significantly better in regard to dehiscence. In contrast, to tissue adhesives the suture was faster to apply but the incidence of infection was comparable with both devices. No differences could be found regarding patient’s and surgeon satisfaction or costs.

The authors concluded that the use of suture is faster in comparison to tissue adhesive glues and that the application of suture leads to a lower dehiscence rate than tissue adhesive glues. Although tissue adhesive glues

N-butyl-2-cyanoacrylate glue for incision closure

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N-butyl-2-cyanoacrylate glue for incision closure
represent an alternative to conventional wound closure methods. The surgeon must be aware of the fact that if higher tension is needed upon an incision the use of these glues may increase the dehiscence rate in comparison to suture material. Therefore, more randomised clinical trials should be performed to investigate the outcome of tissue adhesive glues in comparison to conventional closing methods in patients with surgical site of high tension.

Bozkurt et al. (24) compared butyl-cyanoacrylate glue with interrupted non-absorbable suture for closing wound after head and neck surgery. Eighty patients undergoing different head and neck surgical procedures received either suture material (N = 32) or cyanoacrylate glue (N = 48) for wound closure. Patients were examined after 2 weeks, 1 and 3 months postoperatively. The complication rate, the cosmetic result and the satisfaction were assessed.

The length of the incision was comparable in both groups. Wound closure with cyanoacrylate glue was significantly faster than with suture (33.39 ± 9.77 vs. 504.38 ± 169.27 sec.; p = 0.001). The cosmetic result was rated good in the cyanoacrylate group. Complications were not observed in any treatment group. After three months no wound dehiscence, wound infection and hypertrophic scar was seen. An excellent closure of the wound with butyl-cyanoacrylate was obtained. Patient were satisfied with the result in the glue group. Cosmetic outcome was rated equal or better than suture closure because of the absence of suture marks and a lesser degree of scar formation. Costs were 4.5 times higher for the glue than for suture repair.

The study indicated that wound closure with cyanoacrylate glue is easy and fast and results in a good cosmetic outcome with a low complication rate.

Ozturan and colleagues (25) investigated the outcome of butyl-cyanoacrylate glue in patients scheduled for an elective rhinoplastic surgery. The skin closure was performed by the application of non-absorbable suture material polypropylene or cyanoacrylate glue. Patients were allocated to the different treatment groups by randomisation. The cosmetic outcome was rated by two blinded surgeons. Patients were examined once a week until the first month and thereafter once a month until 3 months postoperatively.

In total 101 patients were enrolled. No dehiscence, haematoma or seroma was seen in either treatment group. The closure with suture material took more time to perform as the procedure with tissue adhesive glue (155 ± 25 sec vs. 55 ± 10 sec; p < 0.01). Also the cost for the glue was lower than for the suture material. The cosmetic outcome rated by the surgeon was comparable in both groups.

This randomised controlled trial showed that the application of cyanoacrylate glue is a safe and efficient alternative to suturing for wound closure. The use of cyanoacrylate glue eliminates the need for suture removal and related distress.

Amiel et al. (26) performed a study to evaluate the performance of butyl-cyanoacrylate glue for the closure of tension free incisions in children. The cosmetic outcome and the complication rate were assessed. Children (N = 1,098) undergoing different surgical procedures obtained Histoacryl® for wound closure. Cosmetic outcome was rated by the parents using a scale from 0 - 5. Redness was seen in 5.5 %, wound dehiscence was observed in 1.1 % and discharge from the wound in 1.9 % of the cases. The cosmetic outcome obtained very good score (4.73 of max. 5; 95 %).

The authors concluded that butyl-cyanoacrylate is a successful alternative to sutures for the closure of low tension incisions in paediatric population. The application of the glue was safe and effective with a low complication rate and with a excellent cosmetic result.

CONCLUSION: Cyanoacrylate glues is an effective alternative for the closure of surgical wounds. Application of these glues is safe, quick and leads to excellent cosmetic results. Infection rate is extremely low and patient satisfaction is high because no sutures have to be removed (26, 27). These glues are recommended for skin closure in almost all paediatric inguinal incisions, thoracoscopic and laparoscopic incisions as well as minor trauma and other carefully selected incisions under low tension (4).
## Clinical Evidence

Table 2: Trials comparing tissue adhesive glues versus standard wound closure for incisions.

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Patient</th>
<th>Product</th>
<th>Cosmetic outcome</th>
<th>Dehiscence rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ozturan et al.</td>
<td>2001</td>
<td>43</td>
<td>Histoacryl® vs. Dexon™ suture</td>
<td>H = CS</td>
<td>NR</td>
</tr>
<tr>
<td>Sinha et al.</td>
<td>1997</td>
<td>86</td>
<td>Butyl-cyanoacrylate vs. suture</td>
<td>BCA ≥ S</td>
<td>BCA ≥ S</td>
</tr>
<tr>
<td>Keng et al.</td>
<td>1989</td>
<td>1152</td>
<td>Tissue adhesive glue vs. suture</td>
<td>TAG = S</td>
<td>S &lt; TAG</td>
</tr>
<tr>
<td>Dowson et al.</td>
<td>2006</td>
<td>168</td>
<td>Butyl-cyanoacrylate vs. non-absorbable suture</td>
<td>BCA = S</td>
<td>BCA = S</td>
</tr>
<tr>
<td>Coulthard et al.</td>
<td>2004</td>
<td>630</td>
<td>Tissue adhesive glue vs. suture</td>
<td>TAG = S</td>
<td>TAG = S</td>
</tr>
<tr>
<td>Coulthard et al.</td>
<td>2004</td>
<td>101</td>
<td>Butyl-cyanoacrylate vs. polypropylene suture</td>
<td>BCA = S</td>
<td>No dehiscence</td>
</tr>
<tr>
<td>Bozkurt et al.</td>
<td>2008</td>
<td>80</td>
<td>Butyl-cyanoacrylate vs. polypropylene suture</td>
<td>BCA ≥ S</td>
<td>0 % vs. 0 %</td>
</tr>
</tbody>
</table>

NR: Not recorded, TGA: Tissue adhesive glue; S: Suture, BCA: Butyl-cyanoacrylate; H: Histoacryl®; CS: Catgut suture; = equal; < significant faster or lower; > significant longer
<table>
<thead>
<tr>
<th>Infection rate</th>
<th>Satisfaction</th>
<th>Procedure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAG = S</td>
<td>TAG = S</td>
<td>S &lt; TAG</td>
</tr>
<tr>
<td>0 % vs. 0 %</td>
<td>BCA = S</td>
<td>BCA &lt; S</td>
</tr>
<tr>
<td>BCA = S</td>
<td>BCA = S</td>
<td>BCA &gt; S</td>
</tr>
<tr>
<td>TAG = S</td>
<td>TAG = S</td>
<td>NR</td>
</tr>
<tr>
<td>No infection</td>
<td>BCA = S</td>
<td>BCA &lt; S</td>
</tr>
<tr>
<td>No infection</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>H = CS</td>
<td>NR</td>
<td>H &gt; CS</td>
</tr>
<tr>
<td>No infection</td>
<td>NR</td>
<td>H &lt; S</td>
</tr>
</tbody>
</table>
Polypropylene meshes are used for the treatment of inguinal hernia repair. For the fixation of the mesh different methods are available. The atraumatic mesh fixation with glue is one possible option and has been applied frequently in the last years because it leads to lower chronic pain in comparison to the fixation with sutures or tackers which often caused nerve irritation. These glues are applied drop-wise onto the mesh to fix the mesh onto the tissue. After a few days the mesh is integrated and covered by granulation tissue. The n-butyl-cyanoacrylate glue, Histoacryl® is indicated for the tension free fixation of hernia meshes. Histoacryl® can be applied in the open Lichtenstein technique as well as in laparoscopic (TAPP) hernia repair.

Currently a multicenter, 3-arm, randomised controlled trial is conducted by Paajanen and colleagues (NCT01592942) in Finland. This trial is performed to find out the most safe, painless and most cost-effective fixation method for inguinal hernia repair.

Three different techniques are compared for mesh fixation during Lichtenstein repair. The hypothesis of the trial is that the mesh fixation with Histoacryl® is safe, simple and cheap compared to other conventional fixation techniques used for Lichtenstein repair. To investigate this, in one group a partly absorbable mesh is fixed with non-absorbable suture and in the second group the non-absorbable Optilene® Mesh is fixed with Histoacryl®. In the third group a self adhesive mesh is implanted for inguinal hernia repair. Primary endpoint of the study is the pain rate within 5 years. Secondary parameters are costs, cost-effectiveness and quality of life. In total 650 patients will be included. Since August 2012 patients are recruited and the completion of the trial is expected for May 2015. The study has been registered under www.clinicaltrials.gov.

Mikhail et al. (36) compared the use of synthetic glue for mesh fixation in open inguinal hernia repair using the plug and patch technique. In this study patients randomly received a n-butyl-2-cyanoacrylate glue or a monofilament non-absorbable suture material for fixation of the mesh. In total 198 patients were enrolled; 101 in the glue group and 97 in the suture group. The recurrence rate, chronic pain, short-term complications (seroma, haematoma, infection), length of hospital stay and the time to return to work were analysed within the two fixation groups. Patients with primary inguinal hernia were randomised and the hernia were classified according
to the European Hernia Society (EHS) Guidelines. The patients were followed up after one day after surgery and one week, every month, and 6 and 12 months postoperatively.

The overall morbidity was 13.9 % in the glue group and 30.9 % in the suture group. No mesh migration or inflammation was observed. There were no differences in regard to seroma or infection within the two fixation groups. Significant more hematomas developed in the suture group compared to the glue group (10.3 % vs. 3.0 %; p = 0.03). The rate of chronic pain was significant higher in patients receiving the suture material for fixation than in the glue group after 6 and 12 months post-operatively (3.9 % vs. 12.3 %; 2.9 % vs. 10.3 %, p = 0.03). Post-operative stay in the hospital was shorter in the glue group compared to the suture group (19.1 hours vs. 14.7 hours; p < 0.001). No difference was observed in regard to time to return to work. In the suture group one recurrence occurred (1 %) whereas no recurrence was seen in the glue group. Short-term complication rate was higher after the use of the suture material than with synthetic cyanoacrylate glue (19.6 % vs. 10.9 %).

The authors conclude that the n-butyl-2-cyanoacrylate glue is safe and effective for mesh fixation in open inguinal hernia repair.

The study of Shen et al. (37) examined the effectiveness of n-butyl-2-cyanoacrylate glue (NBCA) compared with a non-absorbable suture for mesh fixation after Lichtenstein repair. The allocation of the patients in the two groups was performed by randomization. A light weight polypropylene mesh was implanted in all patients. The patient was unaware of the method used for mesh fixation. The following parameters were studied: the length of postoperative hospital stay, pain rate, operation time and the incidence of complications. Follow-up examinations were done within 15 months postoperatively (after 1 week, 1, 3, 6, 9, 12 and 15 months after surgery). Hypothesis of the study was that the difference in recurrence rate was higher than 15 % between the two groups.

In total 110 patients with primary unilateral inguinal hernias were randomised (55 in each group). The data showed that the application of the synthetic glue significantly reduces the duration of the operation (39.6 min. vs. 43.6 min; p < 0.001). Furthermore, both post-operative and chronic pain were significantly reduced in the glue group compared to the suture group; p < 0.05. None patient in the glue group experienced chronic pain whereas, chronic pain was documented in 6 patients of the suture group. The length of hospital stay was similar in both groups (2 ± 1 days). No recurrence and wound infections were reported in either group. No allergic reactions were observed after application of the glue. However, the hematoma rate was significantly increased in the suture group compared to the cyanoacrylate glue group (N = 10 vs. N = 2). The length of hospital stay was comparable within the two treatment groups.

N-butyl-2-cyanoacrylate glue is effective and safe for mesh fixation during Lichtenstein repair. The authors recommended to apply the glue drop wise and not fully distribute over the net-work to prevent the formation of seroma, hematoma and wound infection. The use of the synthetic glue leads to significant lower postoperative and chronic pain and less hematoma formation than suture material for mesh fixation. Wound infection and recurrence rate were not increased after glue fixation in comparison the suture fixation.

Treepongkaruna et al. (38) conducted a consecutive cohort study to assess the outcome of synthetic n-butyl-2-cyanoacrylate glue for mesh fixation in Totally Extraperitoneal laparoscopic (TEP) hernia repair. The authors reported the first 15 patients who had been treated with this fixation method. The outcome of the study was postoperative pain, recurrence and chronic pain. Patients with unilateral inguinal hernia were enrolled and a partly absorbable mesh was implanted and fixed with cyanoacrylate glue. The follow-up was performed after 4, 8, 12, 24, 36 and 48 hours by using the Visual Analogue Scale (VAS). In addition, the use of analgesic was recorded. Recurrence and chronic pain were evaluated within 3 months postoperatively.

The results indicated that postoperative pain was comparable with data obtained after the use of staples for fixation. No recurrence and no chronic pain were observed. One seroma was seen which spontaneously resolved after 2 months. No displacement of the mesh could be observed. None patient died.

The authors concluded that n-butyl-2-cyanoacrylate glue can be used for effectively mesh fixation in TEP repair. The cost are lower than with fibrin glue and the effectiveness in terms of recurrence and complications is comparable with staples. Chronic pain was not detected.
Clinical Evidence

Brügger et al. (39) investigated in their randomised controlled trial the use of n-butyl-2-cyanoacrylate glue versus spiral tacks for mesh fixation after Transabdominal Preperitoneal inguinal hernia repair (TAPP) in regard to postoperative hypoesthesia. Patients were randomly allocated to the different fixation methods. Primary endpoint of the study was the prevalence of hypoesthesia. As secondary parameters the postoperative pain, chronic pain, morbidity, recovery time to return to normal activity and the complication rate were assessed. After discharge the patients were examined after 6 weeks, 6 and 12 months and after a median of 38 months postoperatively. A partly absorbable mesh was implanted in all participants and the patients were blinded to the mesh fixation technique. The hypothesis of the study was an improvement of the prevalence of postoperative hypoesthesia from 45 % in the tacks group to 15 % in the glue group after mesh fixation.

Eighty patients 40 in each group were randomised. At all postoperative time points hypoesthesia was reported more often in the tacks group than in the glue group (6 weeks: 32 % vs. 6 %; 6 months: 38 % vs. 14 %; 12 months: 34 % vs. 13 % and between 13 and 56 months: 32 % vs. 4 %; p < 0.05). In both treatment groups postoperative pain decreased over time, but no difference in regard to intensity was seen within the two groups. At early time points the percentage of painful areas was significant higher in the group receiving tacks in comparison to patients whose meshes were fixed by gluing (6 weeks: 26 % vs. 11 %; 6 months: 23 % vs. 11 %; p < 0.05). At later time points no difference was found. In regard to the other secondary parameters such as recurrence rate, time to return to normal activity and late morbidity no difference was observed within the both treatment groups.

The authors summarize that no differences were found in the clinical incidence or intensity of postoperative pain. But hypoesthesia was more common and more severe after the use of tacks in comparison to cyanoacrylate glue for mesh fixation. In contrast to chronic pain, the intensity of hypoesthesia did not significantly decrease over time after the fixation of the mesh with tacks. Therefore, synthetic n-butyl-cyanoacrylate glue is an important alternative for mesh fixation during laparoscopic inguinal hernia repair, because this technique leads to fewer sensory disruption.

In a preliminary study conducted by Farouk et al. (11) it has been demonstrated that the use of butyl-cyanoacrylate glue for mesh fixation and subsequently in wound closure in Lichtenstein inguinal hernia repair is safe and leads to no early recurrence. Jourdan et al. (13) reported their first experience with n-butyl-cyanoacrylate glue in laparoscopic repair. Seven patients with inguinal hernia were successful treated with mesh fixation by cyanoacrylate glue. No complications and recurrence were observed. They described n-butyl-cyanoacrylate as an effective, inexpensive device which helps to reduce costs in comparison to the use of staples for mesh fixation. The overall cost is approximately one tenth the cost of a stapling instrument and the operation time is not increased by using the glue.

Kim-Fuchs et al. (32) performed a randomized study to compare butyl-cyanoacrylate glue versus absorbable suture for the fixation of a polypropylene mesh in Lichtenstein repair in regard to chronic pain. The recurrence rate, patient satisfaction, complications and the operation time were also evaluated. Patients were examined after 3, 12 months and 5 years postoperatively.

In total, 264 patients with an inguinal hernia were recruited in one centre in Switzerland; 133 patients were randomly allocated to suture fixation (group 1) and 131 patients received Histoacryl® for mesh fixation (group 2). The rate of chronic pain after 3 months was 16 % in group 1 and 10.1 % in group 2, after 12 months 10.2 % in group 1 and 5.4 % in group 2 and after 5 years chronic pain was detected in 12.2 % of the patients treated with sutures and in 4.2 % receiving cyanoacrylate glue for mesh fixation. These differences were not significant. One only recurrent hernia was seen after 3 months in the sutureless group. No additional recurrences were observed after 12 months. The final recurrence rate after 5 years was 5.8 % with suture fixation and 10 % using cyanoacrylate glue, p = 0.379. The application of Histoacryl® significantly reduces the operation time in contrast to suture material, p = 0.01. No reoperation or mesh infection were recorded. Haematoma was detected as a minor complication (group 1: 3.7 % vs. group 2: 2.3 %). Patients of both treatments groups were satisfied with the result and no significant differences were seen, p = 0.167.
The study indicated that the mesh fixation with cyanoacrylate glue for Lichtenstein repair was not inferior to suture fixation. The chronic pain rate was similar in both groups with a trend to lower pain in the glue group. In addition, the recurrence rate was comparable, with a slight trend to higher recurrence in the glue group. The use of cyanoacrylate glue for mesh fixation significantly reduces operation time. Therefore, the authors concluded that Histoacryl® is a good alternative to suture material for mesh fixation during inguinal hernia repair, especially for patients sensible for the development of chronic pain.

In a multicentre study conducted by Paajanen and colleagues (33) the clinical outcome of butyl-cyanoacrylate glue versus absorbable suture for mesh fixation for Lichtenstein repair was assessed. Patients were follow-up for 1 year. As parameters chronic pain, recurrence rate, complications and operation time were evaluated.

In each treatment group 151 patients were allocated by randomisation. A polypropylene mesh Optilene® mesh was implanted and fixed either with absorbable suture material or with butyl-cyanoacrylate in a drop wise fashion. Personal who performed the postoperative assessment were blinded to the treatment procedure. The use of glue reduces the operation time about 2 - 4 min. but the difference was not significant; p = 0.112. The consumption of analgesia was similar in both groups and the pain scores were also comparable after 24 hours, 7 days, 1 month and 12 months. In each group 2 recurrences were observed (1.4 %). Wound infection occurred in 2 cases of the suture group and 5 cases of the glue group, p = 0.448. In each treatment group one reoperation was performed due to persisting infection.

In conclusion, the study showed that the fixation of the mesh for inguinal hernia repair was safe and feasible. Operation time using cyanoacrylate glue was shorter, chronic pain was not influenced and also the complication rate was not increased in comparison to suture material.

Kukleta et al. (15) assessed the use of n-butyl-cyanoacrylate glue for mesh fixation in trans abdominal preperitoneal (TAPP) repair in over 1300 cases. The safety and biocompatibility of Histoacryl® was also evaluated in animal studies. In a clinical study the safety and efficacy of n-butyl-cyanoacrylate was evaluated in 1336 cases with uni- and bilateral inguinal hernias. Different types of meshes were used and fixed either by tacks (N = 136) or cyanoacrylate (N = 1336). Follow-up was 98 months. The following parameters were evaluated pain, patient satisfaction, complication rate and costs. In animal studies Histoacryl® showed good tolerance and biocompatibility. A good integration of the mesh was also seen. The effectiveness in regard to the fixation of the mesh in comparison to suture material was comparable. Clinical results showed no complications that were related to the procedure after the fixation of the mesh with n-butyl-cyanoacrylate. No mesh infection and no wound infection could be observed. The overall recurrence rate was low with 0.7 % (staple: 2.3 % vs. glue 0.37 %). Patients rated their satisfaction high which leads to a termination of the use of staples for mesh fixation in the routine TAPP repair and was only used for the treatment of difficult recurrence repair. A cost comparison showed that the application of n-cyanoacrylate glue reduces costs about 2.5 times in comparison to staples.

By this study the safety and efficacy of Histoacryl® could be proven in experimental investigations. Furthermore, the patient’s satisfaction was high, pain and the costs were reduced after TAPP repair in comparison to the use of staples.

Testini et al. (14) investigated the application of butyl-cyanoacrylate glue, fibrin glue and suture material for the fixation of a plug or a mesh for an elective inguinal hernia repair in respect to short and long-term outcomes.

Patients were randomized to non-absorbable polypropylene suture material (N = 59), or fibrin glue (N = 52) or butyl-cyanoacrylate (N = 56). Patient and the observer who assessed the outcome were blinded. Patients were examined after 3, 7 and 15 days after surgery and 1, 3, 6 and 12 months postoperatively. Pain, numbness, hematoma, seroma, wound infection and urinary retention were defined as short-term outcome and chronic pain, sensation of extraneous body and recurrence were evaluated as long-term parameters. The time to perform the operation as well as the time to return to work were also documented. The result was that the postoperative stay and the time to return to work were comparable between the three treatment groups. (Hospital stay: suture: 32.6 h, fibrin glue: 30.8 h and cyanoacrylate glue: 32.0 h, respectively; Time to return to work: suture: 20.4 d, fibrin glue: 20.3 d and cyanoacrylate: 19.8 d, respectively). There was also no difference in operation time. The total morbidity rate was significantly higher in the suture material than in the fibrin and cyanoacrylate glue group (39 % vs. 9.6 % vs. 10.7 %; p < 0.001). This trend was also seen in the short and long term morbidity. Short-term morbidity: suture 27.12 % vs.
Clinical Evidence

Fibrin glue 9.62% (p = 0.01) vs. cyanoacrylate glue 8.93%; p = 0.004. Long-term morbidity: suture 11.86% vs. fibrin glue 0%; p = 0.001 vs. cyanoacrylate glue 1.78%; p = 0.03. No recurrence occurred. Chronic pain, hematomas, and numbness were significantly higher in the suture group than in the fibrin or cyanoacrylate glue group. Sensation of the extraneous body was recognized in 5 cases in the suture group (8.47%), no case was observed in the fibrin group and 2 cases were documented in the cyanoacrylate group (1.78%).

The study showed that fibrin glue and butyl-cyanoacrylate glue were better tolerated than suture material for mesh fixation. Furthermore, the outcome regarding morbidity and chronic pain was significantly better after the use of fibrin glue or cyanoacrylate glue in comparison to non-absorbable suture material in the short- and long-term perspective. The authors recommended to use glues for tension-free open inguinal hernia repair with the plug and mesh technique.

The application of butyl-cyanoacrylate glue was evaluated versus fibrin glue by Agresta et al. (34) for the fixation of a partly absorbable mesh in inguinal hernia repair using the TAPP technique. Patients with unilateral and bilateral hernias were enrolled in two centres in Italy. The mesh was fixed either by the application of fibrin glue (N = 40) or butyl-cyanoacrylate glue (N = 36). Minor and major complications and chronic pain were assessed. The examination were conducted after 10 days, 2 months, and 12 months postoperatively. No minor or major complications occurred. Severe pain was not reported until 10 days postoperatively. Mild pain was detected in 10.5% of all patients 3 months postoperatively. Within 7 days 90% of the patients had returned to normal activities and after 14 days the remaining ones. All patients reported a satisfaction after 3 months follow-up.

The procedures was described by the authors as effective, easy to perform and with good clinical results.

Nowobilski et al. (8) performed a randomised controlled study to compare suture and butyl-cyanoacrylate glue for the fixation of the mesh in Lichtenstein inguinal hernia repair.

In the control group the polypropylene mesh was fixed with non-absorbable suture material. In total 46 patients were included and randomised to the control group (N = 24) and to butyl-cyanoacrylate (N = 22). The operation duration was comparable in both treatment groups (suture: 42.1 min. vs. glue: 40.1 min.). No difference was also seen regarding costs (suture: 30.4 € vs. glue: 34.4 €). No recurrence was detected after a mean follow-up of 4.7 months. A significant lower pain score was observed in the glue group compared to the suture group one day postoperatively; p = 0.0025. A trend to less analgesic consumption and faster return to normal activity was observed.

The authors concluded that the use of butyl-cyanoacrylate for mesh fixation in Lichtenstein hernia repair seems to be a new safe method, gives excellent results and good cosmetic outcome.

Helbling et al. (10) reported their preliminary results of sutureless versus the use of suture material for mesh fixation in Lichtenstein repair. The finale results of this study was published by Kim-Fuchs et al (32). After the randomisation of 46 patients and a follow-up of 3 months an interims analysis was performed. Twenty-four patients were randomised to the suture group which received polydioxanone suture material for mesh fixation after open inguinal hernia repair. In the sutureless group Histoacryl® was used to fix the mesh (N = 22). After 3 months no recurrence was observed. Minor pain was seen after 3 weeks in 8 patients in the suture group and in 4 patients in the glue group, 3 months postoperatively 4 patients in the suture group and 1 patient in the sutureless group recorded minor pain. Local numbness was documented in 14 vs. 10 and 10 vs. 6 patients 3 weeks and 3 months postoperatively in the suture group and sutureless group, respectively. In total 10 patients receiving suture material returned to normal activity after 3 weeks in comparison to 12 patients obtained cyanoacrylate glue. After 3 months all patients except one in the suture group returned to normal activity.

The result in the Histoacryl® group was excellent and no significant difference was seen in comparison to the suture group. No glue related complications were observed. Although the result did not show any statistical significance there was a trend to a slight better clinical outcome in the glue treated group therefore, the study was continued.
CONCLUSION:
The published clinical data showed that butyl-cyanoacrylate glue is safe and effective for mesh fixation in open as well as for laparoscopic inguinal hernia repair. A low intra- and postoperative morbidity and a better outcome in comparison to suture material has been demonstrated. In comparison to other glues like fibrin the fixation is faster. Low recurrence rates, a shorter postoperative hospital stay, reduced chronic pain and a lower complication rate has been observed in comparison to suture or staples. In comparison to staples and fibrin the use of butyl-cyanoacrylate glue is more cost effective.
Table 3: Trials comparing tissue adhesive glues for mesh fixation.

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Patient</th>
<th>Product</th>
<th>Technique</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mikhail et al.</td>
<td>2012</td>
<td>198</td>
<td>Butyl-cyanoacrylate vs. non-absorbable suture</td>
<td>plug</td>
</tr>
<tr>
<td>Paajanen et al.</td>
<td>2011</td>
<td>302</td>
<td>Butyl-cyanoacrylate vs. non-absorbable suture</td>
<td>Lichtenstein</td>
</tr>
<tr>
<td>Testini et al.</td>
<td>2010</td>
<td>156</td>
<td>Butyl-cyanoacrylate glue vs. fibrin glue vs. non-absorbable suture</td>
<td>Lichtenstein</td>
</tr>
<tr>
<td>Treepongkaruna et al.</td>
<td>2012</td>
<td>15</td>
<td>Butyl-cyanoacrylate vs. absorbable suture</td>
<td>TEP</td>
</tr>
<tr>
<td>Brügger et al.</td>
<td>2012</td>
<td>80</td>
<td>Butyl-cyanoacrylate vs. spiral tacks</td>
<td>TAPP</td>
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<tr>
<td>Jourdan et al.</td>
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<td>7</td>
<td>Butyl-cyanoacrylate glue</td>
<td>TEP</td>
</tr>
<tr>
<td>Kim-Fuchs et al.</td>
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<td>264</td>
<td>Histoacryl® vs. absorbable suture</td>
<td>Lichtenstein</td>
</tr>
<tr>
<td>Shen et al.</td>
<td>2012</td>
<td>110</td>
<td>Butyl-cyanoacrylate glue</td>
<td>Lichtenstein</td>
</tr>
<tr>
<td>Testini et al.</td>
<td>2010</td>
<td>156</td>
<td>Butyl-cyanoacrylate vs. non-absorbable suture</td>
<td>Lichtenstein</td>
</tr>
</tbody>
</table>

NR: Not recorded, > better or faster, = equal, < smaller or lower, H: Histoacryl®, BCA: Butyl-cyanoacrylate, S: Suture, T: Tacks, NS: Not significant
<table>
<thead>
<tr>
<th>Chronic pain</th>
<th>Recurrence</th>
<th>Operation time</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BCA &lt; S</strong></td>
<td><strong>0 % vs. 1 %</strong></td>
<td><em>NR</em></td>
<td><strong>12 Months</strong></td>
</tr>
<tr>
<td>p = 0.03</td>
<td>p = 0.30</td>
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<tr>
<td>2.9 % vs. 10.3 %</td>
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<tr>
<td><strong>BCA &lt; S</strong></td>
<td><strong>0 % vs. 0 %</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>p = 0.027</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 % vs. 10.9 %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>BCA = Tacks</strong></td>
<td><strong>0 %</strong></td>
<td></td>
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<tr>
<td>6 Months 17 % vs. 24 %; p = 0.566</td>
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<tr>
<td>12 Months 16 % vs. 9 %; p = 0.465</td>
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<tr>
<td>13 - 56 Months 8 % vs. 7 %; p = 1.00</td>
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<tr>
<td><strong>BCA = NS</strong></td>
<td><strong>6 % vs. 3 %</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>p = 0.603</td>
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<td></td>
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<tr>
<td><strong>NR</strong></td>
<td><strong>0 %</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>H vs. S</strong></td>
<td><strong>1.4 % vs. 1.4 %</strong></td>
<td></td>
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<tr>
<td>p = 0.379</td>
<td></td>
<td></td>
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<tr>
<td>3 Months 10.1 % vs. 16 %; p = 0.155</td>
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<tr>
<td>12 Months 5.4 % vs. 10.2 %; p = 0.440</td>
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<tr>
<td>60 Months 4.2 % vs. 12.2 %; p = 0.108</td>
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<tr>
<td><strong>BCA = S</strong></td>
<td><strong>0 % vs. 0 %</strong></td>
<td></td>
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</tr>
<tr>
<td><em>p</em> = 0.113</td>
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<td></td>
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<tr>
<td>39 ± 6 min. vs. 43 ± 6 min. p &lt; 0.001</td>
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<tr>
<td><strong>BCA &lt; staples</strong></td>
<td><strong>90 min. vs. 85 min.</strong></td>
<td></td>
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<tr>
<td>p = 0.872</td>
<td></td>
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<tr>
<td><strong>NR</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>H &lt; S</strong></td>
<td><strong>54.2 vs. 56.2 vs. NS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>p = 0.113</td>
<td></td>
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<tr>
<td>34 min. vs. 36 min.</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>NR</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>54.5 min.</td>
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</table>

**Chronic pain**

- BCA < S
  - p = 0.03
  - 2.9 % vs. 10.3 %

- BCA < S
  - p = 0.027
  - 0 % vs. 10.9 %

- BCA = Tacks
  - 6 Months 17 % vs. 24 %; p = 0.566
  - 12 Months 16 % vs. 9 %; p = 0.465
  - 13 - 56 Months 8 % vs. 7 %; p = 1.00

**Recurrence**

- 0 % vs. 1 %
  - p = 0.30

- 0 % vs. 0 %
  - p = 0.603

**Operation time**

- 39 ± 6 min. vs. 43 ± 6 min. p < 0.001

- 81.53 ± 37.98 min.

**Follow-up**

- 15 Months
- 3 Months
- 5 Years
- 1 Year
<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Patient</th>
<th>Product</th>
<th>Technique</th>
</tr>
</thead>
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<td>Agresta et al.</td>
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<td>76</td>
<td>Butyl-cyanoacrylate vs. fibrin glue</td>
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<td>Nowobliski et al.</td>
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<td>Butyl-cyanoacrylate vs. suture</td>
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<td>Helbling et al.</td>
<td>2003</td>
<td>46</td>
<td>Histoacryl® vs. absorbable suture</td>
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<td>Kukleta et al.</td>
<td>2011</td>
<td>1336</td>
<td>Butyl-cyanoacrylate vs. tacks</td>
<td>TAPP</td>
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<tr>
<th>Chronic pain</th>
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<th>Operation time</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>mild pain 10.5 %</td>
<td>NR</td>
<td>55.57 min. ± 15.2</td>
<td>1 Year</td>
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<tr>
<td>BCA &lt; S</td>
<td>0 % vs. 0 %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>H &lt; S</td>
<td>0 % vs. 0 %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BCA &lt; T</td>
<td>BCA = 0.37 % vs. T = 2.3 %</td>
<td></td>
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</tr>
<tr>
<td>NR 55.57 min. ± 15.2</td>
<td>3 Months</td>
<td>BCA = S 40.2 min. ± 10.5</td>
<td>3 Months</td>
</tr>
<tr>
<td>BCA = 0.37 % vs. T = 2.3 %</td>
<td>98 Months</td>
<td>Suture = 42.1 min. ± 9.1</td>
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</tr>
</tbody>
</table>
Key Messages

• Histoacryl® consists of monomeric n-butyl-2-cyanoacrylate, which polymerises quickly in connection with tissue fluids.

• Histoacryl® is available in two colours, translucent for facial application and blue which enables an easy control over the quantity applied.

• Histoacryl® is indicated for the closure of smooth and fresh skin wounds, for closure of skin in endoscopic incisions, sclerosation therapy of large oesophageal and fundus varices and for mesh fixation.

Laceration closure:

• Closure of lacerations with cyanoacrylate glues is a simple and fast method (3).

• Cyanoacrylate glue is a suitable alternative to conventional wound closure like staples and sutures for simple traumatic laceration closure (1, 3).

• Cyanoacrylate glues offer the advantage of a lower pain rate and faster procedure in comparison to sutures, whereas the complication rate is more or less comparable with other treatment methods (1, 19 - 22).

• Histoacryl® is a cost-effective alternative to suture repair for selected laceration in emergency settings. Cosmetic result is comparable with both techniques but patient and surgeon satisfaction is higher after cyanoacrylate glue application in comparison to suture material (16).

• In comparison to suture repair the use of cyanoacrylate glue is atraumatic and eliminates the need for suture removal.

• Comparison between butyl-cyanoacrylate glue and octyl-cyanoacrylate glue showed that both glues are comparable in regard to pain rate, complication rate, cosmetic result and time to perform the wound repair, but butyl-cyanoacrylate glue was more costeffective than octyl-cyanoacrylate glue (18).

• Cyanoacrylate glues act as a protective barrier and therefore, reduce the risk of infection (22).
Incision closure:

- Wound closure of incision with cyanoacrylate glues is easy, fast and results in a good cosmetic outcome with a low complication rate (24, 26).

- Application of cyanoacrylate glue is a good and effective alternative to suturing for wound closure of low tension incisions. The use of cyanoacrylate glues eliminates the need for suture removal and related distress (24, 25, 28 - 30).

- Although tissue adhesive glues present an alternative to conventional wound closure the surgeon must be aware of the fact that if higher tension is needed upon an incision the use of cyanoacrylate glue can increase the dehiscence rate in comparison to suture material (23). For wounds under high tension intracutaneous sutures should be applied in addition to the use of glues (35).

Mesh fixation:

- Histoacryl® showed good biocompatibility and was well tolerated in in vivo investigations. Comparison with suture material for mesh fixation indicated the effectiveness of Histoacryl® glue for mesh fixation (15, 36, 37).

- Mesh fixation with butyl-cyanoacrylate glue is feasible, has a low intra- and postoperative morbidity rate and a better postoperative outcome in comparison to suture fixation (8, 10, 14, 32, 36, 37).

- Application of the butyl-cyanoacrylate glue is fast, leads to a low recurrence rate and a short hospital stay. Furthermore, postoperative pain and wound infection rate are low and return to normal activities and return to work is fast (15).

- The butyl-cyanoacrylate can be applied in open inguinal hernia repair as well as in laparoscopic hernia repair (10, 11, 13 - 15, 32, 33, 36 - 39).

- Butyl-cyanoacrylate glue is a fast acting glue, offers a excellent binding strength to the tissue, is more cost-effective than tacks and fibrin glue, faster and stronger than fibrin glue and less painful than suturing and tacks (15, 33).

- N-butyl-2-cyanoacrylate glue is effective for mesh fixation during Lichtenstein repair (36, 37). The glue should be applied in a drop wise manner and not fully spread over the mesh to avoid the formation of seroma, hematoma and wound infection. The use of synthetic glues leads to a significant lower postoperative and chronic pain rate and less hematoma formation than suture material for mesh fixation. Wound infection and recurrence rate were not increased after glue fixation in comparison to suture fixation (37).

- N-butyl-2-cyanoacrylate glue can be used for effectively mesh fixation in TEP repair. It shows lower cost than using fibrin glue and its effectiveness in terms of recurrence and complications is comparable to staples. Chronic pain is not detected (38).

- Hypoesthesia is more common and more severe after the use of tacks in contrast to n-butyl-2-cyanoacrylate glue for mesh fixation. Synthetic n-butyl-2-cyanoacrylate glue is an important alternative for mesh fixation during laparoscopic inguinal hernia repair, because this technique leads to fewer sensory disruption (39).
Tissue adhesives for traumatic lacerations in children and adults.
Departments of Pediatrics and Medicine, University of Ottawa, Emergency Medicine, Children's Hospital of Eastern Ontario, 401 Smyth Road, Ottawa, Ontario, Canada, K1H 8L1.
farion@cheo.on.ca

BACKGROUND: Tissue adhesives have been used for many years to close simple lacerations as an alternative to standard wound closure (sutures, staples, adhesive strips). They offer many potential advantages over standard wound closure, including ease of use, decrease in pain and time to apply, as well as not requiring a follow-up visit for removal. Many studies have compared tissue adhesives and standard wound closure to determine the cosmetic outcome as well as these other secondary outcomes in their respective study populations. However, due to the wide variation in study parameters, there are no generalisable, definitive answers about the effectiveness of tissue adhesives. No study has been adequately powered to assess differences in complications, which are rare.

OBJECTIVES: To summarize the best available evidence for the effect of tissue adhesives in the management of traumatic lacerations in children and adults.

SEARCH STRATEGY: We searched the Cochrane Controlled Trials Register (CD ROM 2001 Issue 4), the Cochrane Wounds Group Specialized Trials Register (Nov 2001), MEDLINE (1966 to Oct 1, 2001), and EMBASE (1988 to Sept 1, 2001) for relevant randomised studies, and we contacted relevant authors and manufacturers of tissue adhesives to inquire about other published and unpublished trials.

SELECTION CRITERIA: We included RCTs comparing tissue adhesives versus standard wound closure or tissue adhesive versus tissue adhesive for acute, linear, low tension, traumatic lacerations in an emergency or primary care setting. Trials evaluating tissue adhesives for surgical incisions or other types of wounds were not considered.

DATA COLLECTION AND ANALYSIS: Data from eligible studies were extracted by one reviewer and checked for accuracy by a second reviewer. Two reviewers independently assessed masked copies for quality. Outcomes of cosmesis (subgroups of age, wound location and need for deep sutures), pain, procedure time, ease of use and complications were analysed separately for two comparisons: 1) tissue adhesive versus standard wound care; and 2) tissue adhesive versus tissue adhesive.
MAIN RESULTS: Eight studies compared a tissue adhesive with standard wound care. No significant difference was found for cosmesis at any of the time points examined, using either Cosmetic Visual Analogue Scale (CVAS) or Wound Evaluation Score (WES). Data were only available for subgroup analysis for age; no significant differences were found. Pain scores (Parent VAS WMD −15.7 mm; 95% CI −21.9, −9.5) and procedure time (WMD −5.6 minutes; 95% CI −8.2, −3.1) significantly favoured tissue adhesives. No studies reported on ease of use. Small but statistically significant risk differences were found for dehiscence (favouring standard wound care NNH 25 95% CI 14, 100) and erythema (favouring tissue adhesive NNH 8 95% CI 4, 100). Other complications were not significantly different between treatment groups. Only one study was identified that compared two tissue adhesives (butyl-cyanoacrylate (Histoacryl®) versus octyl-cyanoacrylate (Dermabond®)) for pediatric facial lacerations. No significant difference was found for cosmesis using CVAS at 1 – 3 months, or using WES at 5 – 14 days and 1 – 3 months.

Similarly, no significant difference was found in pain, procedure time or complications. Results for ease of use were incomplete as reported.

REVIEWER'S CONCLUSIONS: Tissue adhesives are an acceptable alternative to standard wound closure for repairing simple traumatic lacerations. There is no significant difference in cosmetic outcome between tissue adhesives and standard wound closure, or between different tissue adhesives. They offer the benefit of decreased procedure time and less pain, compared to standard wound closure. A small but statistically significant increased rate of dehiscence with tissue adhesives must be considered when choosing the closure method (NNH 25).

Use of tissue adhesive in the closure of small incisions and lacerations.

Elmasalme FN, Matbouli SA, Zuberi MS.
Department of Pediatric Surgery, Maternity and Children Hospital, Jeddah, Saudi Arabia.

Over the last 10 years, in the operating rooms of Maternity and Children Hospital, Jeddah, more than 3,200 surgical incisions of skin made for minor surgical operations were closed without suturing by using tissue adhesive Histoacryl Blue. In addition to this, in the emergency rooms over 2,600 small lacerations of skin on various parts of the body were also repaired by the same technique. The method has certain distinct advantages over conventional suturing. The success rate was very high.
The objective of this study was to compare the applications of Histoacryl® Blue (HAB) and suturing regarding cosmetic outcome, cost and patient and physician satisfaction in the emergency department (ED). A total of 92 consecutive adult patients with lacerations equal to or shorter than 5 cm were enrolled in the study. Patients were randomized to either HAB or suturing. Ten-day and three-month cosmetic outcomes were evaluated via visual analogue scale (VAS) by a blinded surgeon. Cosmetic outcome, cost and patient and physician satisfaction of both groups were compared. Only 52 patients completed the follow-up at three months. Twenty-eight had been repaired with sutures and 24 with HAB. The differences regarding ten-day and three-month cosmetic outcome scales between the patients repaired with HAB and sutures were not statistically significant. Application of HAB resulted in greater satisfaction of the patient and the physician ($p = 0.007$ and $p = 0.0001$, respectively). Costs of HAB were significantly lower than sutures ($p = 0.0001$). It is concluded that HAB is a cheaper method of laceration repair and results in greater satisfaction of both patients and physicians, while cosmetic outcomes were comparable. These results suggest that HAB is a viable alternative to suturing for selected lacerations in the ED.
Charters A.
School of Nursing & Midwifery, University of Sheffield, Winter Street, Sheffield S3 7ND, UK.

The purpose of this study was to determine which single-use wound adhesive is the most appropriate in terms of ease of use, minimal pain on application, adequate bonding time and wound closure. The three wound adhesives audited were Indermil® (n-butyl-cyanoacrylate), Liquiband® (n-butyl-cyanoacrylate) and Dermabond® (octyl-cyanoacrylate).

SAMPLE AND SETTING: The study was conducted in an urban paediatric emergency department treating over 39,000 patients annually. The sample was taken from the client population presenting with lacerations requiring tissue adhesive closure, within the limitations of the study (n = 63).

METHODOLOGY: A non-blinded comparative study was performed. Children presenting with an appropriate laceration were assigned to receive either Indermil®, Dermabond® or Liquiband®. The wounds were closed following the guidelines stated by the individual manufacturers. The nurses administering the tissue adhesive were asked to complete the audit form post closure and to comment on the procedure in descriptive terms.

RESULTS: Scalp wounds accounted for 79 % (n = 50) of all the lacerations closed in the study. None of the glues were reported to be completely pain-free. However, the Liquiband® tissue adhesive produced an average pain score of only 0.1, whereas the Dermabond® tissue adhesive scored the highest at 0.97. The nurses using the tissue adhesives reported that Liquiband® was the best tissue adhesive in terms of wound closure and ease of use. However, the only tissue adhesive to report a 100 % success rate was Indermil®.

DISCUSSION AND RECOMMENDATIONS: All of the tissue adhesives examined produced satisfactory results in terms of wound closure and ease of use. However, the Liquiband® tissue adhesive produced the most consistent results, scoring higher in most of the categories when compared with the other tissue adhesives.
Tissue adhesives for closure of surgical incisions.

Coulthard P, Worthington H, Esposito M, Elst M, Waes OJ. Oral and Maxillofacial Surgery, University Dental Hospital of Manchester, Higher Cambridge Street, Manchester, UK, M15 6FH.

BACKGROUND: Sutures, staples and adhesive tapes are the traditional methods of wound closure, whilst tissue adhesives have entered clinical practice more recently. Closure of wounds with sutures enables meticulous closure, but sutures may induce tissue reactivity and they usually require removal. Tissue adhesives offer the advantages there are no sutures to remove later for the patient and no risk of needlestick injury to the surgeon. Tissue adhesives have been used primarily in emergency rooms but this review looks at the use of tissue adhesives in the operating room where surgeons are increasingly using these for the closure of surgical skin incisions.

OBJECTIVES: To determine the relative effects of various tissue adhesives and conventional skin closure techniques on the healing of surgical wounds.

SEARCH STRATEGY: The Cochrane Wounds Group Specialised Trials Register, The Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE and EMBASE were searched. Bibliographies of review articles were checked for studies outside the handsearched journals and wound care product manufacturers were contacted.

SELECTION CRITERIA: Randomised controlled clinical trials only.

DATA COLLECTION AND ANALYSIS: Screening of eligible studies and data extraction was conducted independently and in triplicate whilst assessment of the methodological quality of the trials was conducted independently and in duplicate. Results were expressed as random effect models using weighted mean differences for continuous outcomes and relative risk with 95% confidence intervals for dichotomous outcomes. Heterogeneity was investigated including both clinical and methodological factors.

MAIN RESULTS: Eight RCTs were included (630 patients). No statistically significant differences were found between various tissue adhesives and sutures (8 trials) for dehiscence, infection, satisfaction with cosmetic appearance when assessed by patients’ or surgeons’ general satisfaction. Nor were differences found between a tissue adhesive and tapes (2 trials) for infection, patients’ assessment of cosmetic appearance, patient satisfaction or surgeon satisfaction. However a statistically significant difference was found for surgeons’ assessment of cosmetic appearance with mean difference 13 (95% CI 5 to 21), the higher mean rating for the tissue adhesive group.
REVIEWERS’ CONCLUSIONS: Surgeons may consider the use of tissue adhesives as an alternative to sutures or adhesive tape for the closure of incisions in the operating room. There is a need for trials in all areas but in particular to include patients that require incision closure in areas of high tension and patients of general health that may impair wound healing.

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Tissue adhesives for closure of surgical incisions.
Coulthard P, Esposito M, Worthington HV, van der Elst M, van Waes OJ, Darcey J.
Department of Oral and Maxillofacial Surgery, School of Dentistry, The University of Manchester, Higher Cambridge Street, Manchester, UK, M15 6FH.


BACKGROUND: Sutures, staples and adhesive tapes are the traditional methods of wound closure, whilst tissue adhesives have entered clinical practice more recently. Closure of wounds with sutures enables meticulous closure, but they may show tissue reactivity and can require removal. Tissue adhesives offer the advantages of no risk of needlestick injury and no requirement to remove sutures later. Tissue adhesives have been used primarily in emergency rooms but this review looks at the use of tissue adhesives in the operating room where surgeons are increasingly using these for the closure of surgical skin incisions.

OBJECTIVES: To determine the relative effects of various tissue adhesives and conventional skin closure techniques on the healing of surgical wounds.

SEARCH STRATEGY: For this update we searched the Cochrane Wounds Group Specialised Register (Searched 17/11/09); The Cochrane Central Register of Controlled Trials (CENTRAL) – The Cochrane Library Issue 4 2009; Ovid MEDLINE – 1950 to November Week 1 2009; Ovid EMBASE – 1980 to 2009 Week 46; EBSCO CINAHL – 1982 to 17 November 20098. No date or language restrictions were applied.

SELECTION CRITERIA: Only randomised controlled clinical trials were eligible for inclusion.

DATA COLLECTION AND ANALYSIS: Screening of eligible studies and data extraction were conducted independently and in triplicate whilst assessment of the methodological quality of the trials was conducted independently and in duplicate. Results were expressed as random effects models using mean difference for continuous outcomes and relative risks with 95 % confidence intervals for dichotomous outcomes. Heterogeneity was investigated including both clinical and methodological factors.
MAIN RESULTS: This update identified an additional six trials resulting in a total of fourteen RCTs (1152 patients) which met the inclusion criteria. Sutures were significantly better than tissue adhesives for minimising dehiscence (10 trials). Sutures were also found to be significantly faster to use. For all other analyses of infection, patient and operator satisfaction and cost there was no significant difference between sutures and tissue adhesives. No differences were found between tissue adhesives and tapes (2 trials) for minimising dehiscence, infection, patients assessment of cosmetic appearance, patient satisfaction or surgeon satisfaction. However a statistically significant difference in favour of using tape was found for surgeons’ assessment of cosmetic appearance (mean difference 13, 95% CI 5 to 21). Tapes were also demonstrated to be significantly faster to use than tissue adhesives as were staples (1 trial). No other outcome measures were analysed in this group. One trial compared tissue adhesives with a variety of methods of wound closure and found both patients and clinicians were significantly more satisfied with the alternative closure methods than the adhesives. In this same trial tissue adhesives were significantly less time consuming to use. For the remaining outcomes of dehiscence and infection no difference was observed between groups. This trial also compared high viscosity with low viscosity adhesives and found that high viscosity adhesives were less time consuming to use than low viscosity tissue adhesives. For all other outcomes of dehiscence, infection, patient satisfaction and operator satisfaction there was no statistically significant difference between high and low viscosity adhesives.

AUTHORS’ CONCLUSIONS: Sutures were significantly better than tissue adhesives for minimising dehiscence and were found to be significantly faster to use. Although surgeons may consider the use of tissue adhesives as an alternative to other methods of surgical site closure in the operating theatre they must be aware that adhesives may take more time to apply and that if higher tension is needed upon an incision, sutures may minimise dehiscence. There is a need for more well designed randomised controlled trials comparing tissue adhesives and alternative methods of closure. These trials should include people whose health may interfere with wound healing and surgical sites of high tension.
The purpose of this study was to compare the mean duration and complication rates of cyanoacrylate application in head and neck incision closures to those performed with conventional sutures. Eighty patients who underwent head and neck surgical operations (20 thyroidectomies, 13 submandibular gland resections, 9 parotidectomies, 6 neck dissections in conjunction with other surgical procedures, 1 lateral rhinotomy, 1 thyroglossal cyst resection and 30 open neck biopsies) were included in the study. The incisions were closed either with interrupted suture technique (32 patients) or cyanoacrylate (48 patients). The duration of skin closure time was compared between the two groups with non-parametric Mann-Whitney U test and a P value < 0.05 was considered as statistically significant. The patients were followed up for complications at 2 weeks, 1 and 3 months after surgery. The two treatment groups were similar with respect to age, gender, and wound lengths (P = 0.27, 0.22 and 0.99, respectively). The mean wound length was 7.21 + 3.15 cm in the cyanoacrylate group and 7.22 + 2.99 cm in the suture group within a range of 5 - 15 cm. The mean closure time was 33.69 + 9.77 s in the cyanoacrylate group and 504.38 + 169.27 s in the suture group (P < 0.001). The patients in the cyanoacrylate group were satisfied with their scar appearances. No complication was observed in both the groups. Cyanoacrylates provide an easy and convenient application resulting in a faster wound closure as compared to the interrupted suture technique.

Cosmetic outcome of the columellar incision closure in external rhinoplasty patients has been a subject of discussion. This study was conducted to assess whether tissue adhesives provide an alternative option for sutureless closure of columellar skin incisions for cases utilizing open technique rhinoplastic surgery. One hundred and one patients undergoing external rhinoplasty were randomized to either topical application of butyl-cyanoacrylate or polypropylene sutures for columellar skin closure. The majority of tension on the wound edges was taken up using 5 - 0 chromic catgut. Cosmetic outcomes were evaluated by two otolaryngologists independently using visual analogue and Hollander wound evaluation scales in a blinded manner. There was no statistically significant difference in cosmesis between the surgeons’ evaluation scores for either type or repair of the columellar incision. Since the tissue adhesive forms its own protective barrier, post-operative care is simplified. Closure with adhesives eliminates the need for post-operative suture removal requiring an extra visit that should lead to more efficient use of physician and patient time. Butyl-cyanoacrylate performs cosmetically as well as standard suture closure of columellar skin incision used for external rhinoplasty.
Use of n-butyl-2-cyanoacrylate in elective surgical incisions—longterm outcomes.

Amiel GE, Sukhotnik I, Kawar B, Siplovich L.
Department of Urology, Bnai Zion Medical Center, Bruce Rappaport Faculty of Medicine, Technion Institute of Technology, Haifa, Israel.

BACKGROUND: Histoacryl® Blue (N-butyl-2-cyanoacrylate) is a tissue adhesive that has been used clinically for more than 20 years. In the last decade, n-butyl-2-cyanoacrylate has been used for cutaneous closure of low-tension lacerations in children and adults and has become a preferred method for closure of pediatric facial lacerations in many emergency rooms outside the United States. Many pediatric elective surgical procedures are performed in tension-free areas and may be suitable for closure with a tissue adhesive. In order to assess this approach, a retrospective study was conducted to evaluate the cosmetic outcomes and complications of the application of n-butyl-2-cyanoacrylate for the approximation of elective surgical incisions in a pediatric population.

STUDY DESIGN: Records of 1,098 patients, ages 1 month to 16 years, who, between January 1995 and December 1996, underwent one of the following: orchidopexy, inguinal hernia, umbilical hernia, or hydrocele repair were analyzed. In all patients, n-butyl-2-cyanoacrylate was applied to close the surgical incision. A 12-item questionnaire was created to assess the presence of complications and to determine shortterm and longterm cosmetic outcomes of the incision. Data were collected by conducting telephone interviews of family members.

RESULTS: Among the 1,033 children who were treated, 66 % had inguinal hernias, 15 % hydroceles, 15 % undescended testis, and 4 % umbilical hernias. Redness or tenderness at the incision site (5.5 %), discharge from the surgical wound (1.9 %), and wound dehiscence (1.1 %) were the main immediate complications after surgery. Overall satisfaction with the cosmetic outcomes of the surgical scar was high, with an average score of 4.73 out of 5 (94.6 %).

CONCLUSIONS: Our results demonstrate that administration of n-butyl-2-cyanoacrylate for the closure of small low-tension surgical incisions in the pediatric population is safe, has a low complication rate, and produces excellent cosmetic outcomes.
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, Corina.kim@insel.ch.

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, suture less mesh fixation with Histoacryl™ is a sensible alternative to suture fixation and should be especially considered for patients prone to pain.
Paajanen H, Kössi J, Silvasti S, Hulmi T, Hakala T. Kuopio University Hospital, Kuopio, Finland; Central Hospital of Mikkeli, Mikkeli, Finland.
hannu.paajanen@kuh.fi

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 24h 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).
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. mario.testini@chirgen2.uniba.it

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.
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. fagresta@libero.it

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 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.

CONCLUSIONS: 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.
Inguinal hernia repair, according to Lichtenstein, is very popular due to its minimal invasiveness (local anaesthesia), easy and reproducible technique, low recurrence rate, and low morbidity. However, recent publications demonstrate an elevated rate of chronic irritations and pain, probably due to tension or nerve compression by the fixing sutures. We, therefore, established a concept to avoid these sutures by attaching the prosthesis with glue. After a pilot study, a randomised prospective trial was started. The aim of our study was to compare the results of the classical Lichtenstein repair (group 1) vs. the ‘Sutureless Lichtenstein’ (group 2) in terms of postoperative complications and recurrences. Operative access and management of the hernial sac was equal to Lichtenstein for both groups. In group 1, we sutured the mesh with PDS® 2/0; in group 2, the mesh was glued with n-butyl-cyanoacrylate. In both groups, the operation was then completed according to Lichtenstein, and unrestricted activity was allowed after 2 weeks. A total of 46 patients have been operated on. The follow-up results at 3 weeks and [3 months] were: group 1 (n = 24) vs. group 2 (n = 22): recurrences 0 [0] vs. 0 [0], minor pain 8 [4] vs. 4 [1], local numbness 14 [10] vs. 10 [6]. No adhesive-related complications were seen. Patients will be followed for 2 years. The results in group 2 were excellent, and there was no difference vs. group 1. Furthermore, there was a tendency for better results in group 2. These results are very promising and justify a continuation of the study.

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

Kukleta JF, Freytag C, Weber M.

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-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-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-cyanoacrylate compared with other techniques of mesh fixation.
Prosthetic material fixation in open inguinal hernioplasty: suture vs. synthetic glue.

Eldabe Mikhail A, Palomo Luquero A, Reoyo Pascual JF, Seco Gil JL.
Servicio de Cirugía, Complejo Asistencial de Burgos, Hospital General Yagüe, Burgos, España.

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 post-operative 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.

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.

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.
Novel technique of mesh fixation with cyanoacrylate in totally extraperitoneal laparoscopic hernia repair: early experience.

Treepongkaruna SA, Subwongcharoen S.

Department of Surgery, Rajavithi Hospital, College of Medicine, Rangsit University Bangkok, Thailand. satreepong@gmail.com

Totally extraperitoneal laparoscopic hernioplasty (TEP) is an alternative surgery for inguinal hernia repair, but chronic pain is still a problem. The authors proposed the use of cyanoacrylate for mesh fixation instead of staples which might be the cause of chronic groin pain. The authors also innovated an instrument for delivery of cyanoacrylate for mesh fixation. The present article reported early experience in the first 15 patients who were treated with this technique. Early post-operative pain was comparable to a previous study, no recurrence and no chronic groin pain was detected after surgery.
Objective hypoesthesia and pain after transabdominal preperitoneal hernioplasty: 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. lukas.bruegger@insel.ch

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.

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


References


