NICE advice

Cyanoacrylate glue for hernia mesh fixation

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is cyanoacrylate glue. It is used for mesh fixation in hernia repair procedures.
- The **innovative aspects** are that using glue limits trauma to surrounding tissues. Innovative applicators have also been developed for precise, accurate placement of the adhesive.
- The intended **place in therapy** would be as an alternative to mechanical mesh fixation methods such as sutures and tacks in people having surgical hernia repair.
- The **main points from the evidence** summarised in this briefing are from 3 systematic reviews and 2 randomised controlled trials, including a total of 1,374 people who were randomised to cyanoacrylate glue groups. These studies show that cyanoacrylate glue is as effective as alternative methods of mesh fixation, such as mechanical methods or fibrin glue. The evidence does not show any advantage of cyanoacrylate glue for the incidence of postoperative chronic pain.
- **Key uncertainties** around the evidence or technology are the comparative costs of alternatives in the NHS, because there is no clinical consensus on standard mesh fixation methods.

- **Experts advised** that, although the main potential advantage of cyanoacrylate glue is that it could help avoid traumatic complications such as chronic pain, studies with follow up beyond 1 year after the procedure are needed to evaluate this outcome.
- The **cost** of cyanoacrylate glue (including applicators) for hernia mesh fixation range from £97 to £230 per unit (excluding VAT) for laparoscopic procedures, and from £65 to £230 per unit (excluding VAT) for open procedures. There is no consensus about standard mesh fixation methods in the NHS. Clinical expert advised an estimated cost of tacking devices was appropriately £206 (ranging from £160 to £241). Companies and experts estimated that the cost of a box of 12 sutures ranged from £23 to £92.

The technology

Cyanoacrylate glue is a synthetic adhesive with various uses. This briefing reviews 3 types of cyanoacrylate glue for medical use for hernia mesh fixation.

All 3 glues have good tensile strength. They polymerise rapidly on contact with tissue fluids then degrade slowly until they are fully absorbed by the body. Each has a different applicator for mesh fixation.

Histoacryl LapFix

Histoacryl (B Braun Surgical) consists of n-butyl-2-cyanoacrylate (a pure butyl ester) and is used for open and laparoscopic procedures. The Histoacryl LapFix applicator (designed for laparoscopic surgery) includes Histoacryl glue and a syringe and cannula.

LiquiBand Fix8

The LiquiBand Fix8 device (Advanced Medical Solutions) consists of n-butyl-2-cyanoacrylate adhesive in liquid form, preloaded into an applicator device. Two versions are available; 1 designed for laparoscopic procedures and another for open surgery. LiquiBand Fix8 devices are also indicated for secondary use for peritoneal closure and topical wound closure.

Glubran2

Glubran2 (GEM/Sela Medical UK), also known as Glubran, is synthetic biodegradable cyanoacrylate-based glue (an n-butyl-cyanoacrylate) modified by the addition of a monomer synthesised by the company. The Glutack device has been designed to apply Glubran2 in precise

drops. Two versions of Glutack are available; 1 designed for laparoscopic procedures and another (Glutack Short) for open surgery.

Innovations

Using glue instead of mechanical mesh fixation methods aims to avoid the trauma associated with tissue penetration.

Potential benefits include:

- reduced postoperative and chronic pain
- fewer postoperative complications, such as seroma formation or nerve injury
- reduced risk of hernia recurrence
- reduced length of hospital stay
- earlier return to work and usual activities
- improved patient quality of life.

Compared with fibrin-based (biologic) glues, which have lower adhesive strengths, synthetic cyanoacrylate-based technologies use less glue and need less time for setting. Fibrin glues must also be refrigerated during storage, whereas cyanoacrylate glue can be stored at room temperature.

There have also been innovative developments in the tools used to apply the glues to make them easier to use and make delivery more accurate. Some applicators require manual assembly before use. Others are preloaded and only require activation or priming before use.

Current care pathway

Standard mesh fixation methods in the NHS vary according to the surgeon's preferences and the requirements of each procedure (for example, hernia size and location, surgical approach and type of mesh). Sutures and other mechanical methods such as tacks have traditionally been used for mesh fixation, but traumatic penetration of the abdominal wall can damage blood vessels and nerves. Some types of tacks remain as permanent foreign bodies, and they have been reported to migrate, resulting in chronic pain and other complications.

The choice of mesh fixation method is not likely to significantly affect the broader care pathway, although it may affect operative and recovery times. Post-procedural complications such as chronic pain may need ongoing management.

The following publications have been identified as relevant to this care pathway:

- NICE technology appraisal guidance on laparoscopic surgery for inguinal hernia repair
- The HerniaSurge Group (European Hernia Society) international guidelines for groin hernia management.

Population, setting and intended user

The technologies are intended to be used in people having abdominal hernia repair with mesh. Cyanoacrylate glue may be contraindicated in:

- people with known hypersensitivity to cyanoacrylate or formaldehyde
- people with known preoperative systemic infections or uncontrolled diabetes
- conditions known to interfere with wound healing
- pregnancy.

It is incompatible with certain types of mesh (such as biological or bioabsorbable meshes).

When used for mesh fixation, cyanoacrylate glue is prepared by nurses and applied by experienced surgeons in the operating theatre in secondary care. Introductory training may be needed on first use, including in how to prime applicator devices.

Costs

When the cost of the fixation technologies is excluded, the associated cost of the hernia repair procedure itself is expected to be similar regardless of fixation method. A single procedure (unilateral or bilateral) typically requires only 1 applicator device for glue or tacks.

Technology costs

All costs exclude VAT.

Histoacryl LapFix

Histoacryl LapFix is available as:

- a single set, which includes a cannula, a syringe, and two 0.5 ml ampoules of Histoacryl glue and costs £134.34
- a box of 5, which includes 5 cannulas, 5 syringes and 5 ampoules of 0.5 ml Histoacryl glue and costs £482.42.

Extra glue is available separately as a box of 5 ampoules at £59.59 or a box of 10 at £110.13.

LiquiBand Fix8

LiquiBand Fix8 is supplied in boxes of 6. The version for laparoscopic procedures costs £1,199.94 and the version for open procedures costs £390.

Both are pre-assembled and terminally sterilised and do not require any additional consumable products.

A single laparoscopic Fix8 device contains 1.5 ml adhesive, enough for at least 40 applications of 12.5 mg adhesive each. The minimum number of 12.5 mg applications for the LiquiBand Fix8 open device is 45.

Glubran2

Glubran2 adhesive is available in boxes of 10, with glue volumes of either 0.5 ml at a total cost of £900 or 1.0 ml at a total cost of £1,200.

The Glutack applicator (for either laparoscopic or open procedures) is available separately at a cost of £110 each.

Costs of standard care

There is no consensus about standard mesh fixation methods in the NHS. There is no fixation cost when no fixation method is used.

- Tacking devices (complete with tacks) were estimated to cost approximately £206 (ranging from £160 to £241) by clinical experts; and £1,400 to £2,190 by 1 of the cyanoacrylate glue companies.

- One expert suggested costs for fibrin glue of approximately £150 to £300 per procedure.
- One of the companies reported that a box of 12 sutures costs around £60 to £90; a clinical expert estimated between £23 and £92.
- Cost estimates for stapling devices were less clear but costs of £145 or £312 were proposed by 1 of the experts.

Resource consequences

Cyanoacrylate glue is currently used in the NHS as 1 of the options for hernia mesh fixation. There are unlikely to be significant resource consequences of adopting the technology. No changes in facilities or infrastructure are needed. Minimal training is necessary.

There may be implications for resource use if chronic pain management is not needed (because glue causes less trauma to tissues than mechanical fixation methods), if length of hospital stay is reduced, or if recurrence is avoided.

Regulatory information

Histoacryl is a CE marked class III medical device regulated under the Medical Devices Directive (1993/42/EC) Annex II (4). The Histoacryl LapFix Pack is a procedure pack in accordance with MDR 2017/745/EEC art. 22, which has no direct risk class assigned. The applicator that is provided with Histoacryl LapFix Pack is the only applicator that is recommended for use with Histoacryl glue. The applicator is a CE marked class IIa medical device. The company intends to renew regulatory approval to allow ongoing availability in the UK beyond June 2023.

LiquiBand Fix8 is a CE marked class IIb medical device. Both LiquiBand Fix8 (open and laparoscopic) devices are approved for use in the UK under Medical Device Regulations effective March 2022 to March 2025. The glue is preloaded and not available as a separate product.

Glubran2 is a CE marked class III medical device. The Glutack applicator (and Glutack Short) is a CE marked class IIa medical device. The devices have been registered to the Medicines and Healthcare products Regulatory Agency (MHRA) by a UK Responsible Person for GEM, and UKCA (UK Conformity Assessed) mark preparation is in progress.

The following company field safety notices for these technologies have been identified:

In February 2022, Advanced Medical Solutions recalled LiquiBand Fix8 open devices to instigate a

number of design changes to overcome a mechanical defect which had caused uncontrolled leakage of glue from the distal tip of the device (update to field safety notice: 01-31-2022-001-FSCA). The company hopes to return the product to market from 30 June 2022.

In April 2021, B Braun Surgical recalled some batches of Histoacryl in which incomplete polymerisation had led to reduced adhesive forces (MHRA reference: 2021/003/009/601/001). The clinical risk was considered acceptable with no risk to patients except a possible operating time extension if an alternative fixation method was needed. The company has advised that the incident has now been resolved and availability of all Histoacryl products is back to normal levels.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

The most common type of abdominal hernia (inguinal) affects more men than women. The risk of herniation generally increases with age because of weakening of the tissues.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement for medtech innovation briefings. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Five studies are summarised in this briefing, all of which focused on inguinal hernia repair. For laparoscopic procedures, 2 systematic reviews and 1 randomised controlled trial (RCT) are included. For open procedures, 1 systematic review and 1 RCT are included. Fifteen RCTs included cyanoacrylate glue as 1 of the treatment arms, a total of 3,807 people. Of these, 1,374 people were randomised to receive treatment using cyanoacrylate glue.

Comparators were:

- mechanical fixation methods (sutures, tacks, staples and self-gripping mesh)

- fibrin-based glues
- no fixation.

Results were reported as descriptive statistics (such as proportions), odds ratios (OR), or relative risk (RR), with 95% confidence intervals (CI) and statistical significance ($p<0.05$).

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

Overall assessment of the evidence

The overall quantity of evidence (number and size of studies) is good. Although a formal quality assessment has not been carried out, the availability of multiple systematic reviews with meta-analyses provides some assurance of reliability and generalisability. The reported outcomes are relevant to the NHS care pathway, but none of the published clinical trials was carried out in the UK. Evidence from the NHS context could add value, especially if detailed economic comparisons are needed in future.

Some companies have developed novel applicator devices, but evidence of their specific benefits is rarely supported by published literature.

Laparoscopic procedures

Habib Bedwani et al. (2021)

Study size and design

A systematic review including 15 RCTs with a total of 2,109 participants. Five RCTs used cyanoacrylate glue as 1 of the treatment arms (Brugger et al. 2011; Jani 2016; Liew et al. 2017; Moreno-Egea 2014; Subwongcharoen and Ruksakul 2013). There was a total of 552 people in these 5 studies, 275 of whom were randomised to treatment using cyanoacrylate glue.

Intervention and comparator(s)

The systematic review compared all types of glue (including cyanoacrylate glue) with mechanical mesh fixation (sutures, tacks or staples). A subgroup analysis of chronic postoperative inguinal pain reported separate results for fibrin sealant and cyanoacrylate glue. Two studies used Histoacryl glue, 1 used Glubran (GEM), 1 used Endocryl (Samarth Life Sciences), and 1 used Ifabond (Peter's Surgical).

Key outcomes

The incidence of chronic postoperative inguinal pain was reported in 13 of the included studies. There was no significant difference in chronic postoperative inguinal pain between cyanoacrylate glue and mechanical fixation methods (relative risk [RR] 0.68, 95% confidence interval [CI] 0.38 to 1.22; p=0.19).

Strengths and limitations

The systematic review included 15 RCTs. Laparoscopic procedures included both transabdominal preperitoneal (TAPP) and total extraperitoneal repair (TEP) approaches. Results specific to cyanoacrylate glue were only available for 1 outcome (chronic postoperative pain). Length of follow up was only reported for recurrence rates (median 12 months) and not specifically for the cyanoacrylate glue group; the length of follow up for chronic pain was not reported.

Tavares et al. (2020)

Study size and design

Systematic review including 13 RCTs. Five studies included cyanoacrylate glue as 1 of the treatment arms (Brugger et al. 2011; Jani 2016; Liew et al. 2017; Moreno-Egea 2014; Subwongcharoen and Ruksakul 2013). A total of 1,947 hernia repair procedures were included in the full review, 275 of which used cyanoacrylate-based glue. Median follow up was 12 months (range 1 to 38).

Intervention and comparator(s)

Cyanoacrylate-based glue was compared with fibrin-based glue. The study also reported results of meta-analyses within glue subtypes (which compared each type of glue with a range of mechanical fixation methods). Two studies used Histoacryl glue, 1 used Glubran, 1 used Endocryl and 1 used Ifabond.

Key outcomes

When comparing cyanoacrylate glue with mechanical fixation, there was no difference in the rate of hernia recurrence (odds ratio [OR] 1.05, CI 0.18 to 6.18, p=0.96), postoperative haematoma or seroma (OR 0.78, CI 0.41 to 1.50, p=0.46), or urinary retention (OR 0.51, CI 0.05 to 5.68, p=0.58). There were no significant differences in these outcomes when cyanoacrylate was compared with fibrin glues.

Strengths and limitations

Both TAPP and TEP procedures were included. Mechanical fixation methods included sutures, tacks and staples. Indirect methods were used when comparing cyanoacrylate-based glues with fibrin-based glues. Results were detailed enough to report some outcomes from studies that directly compared cyanoacrylate glue with mechanical fixation methods, but may have been statistically underpowered.

Habeeb et al. (2020)

Study size, design and location

An RCT including 3 treatment arms with a total of 798 people who had TAPP procedures in Egypt.

Intervention and comparator(s)

The study compared mesh fixation using Histoacryl cyanoacrylate glue (n=266) and tacks (n=266) with no fixation (n=266).

Key outcomes

The authors report that there were no statistically significant differences between cyanoacrylate glue and no fixation for postoperative pain, postoperative complications, length of procedure, length of hospital stay or chronic groin pain at 18-month follow up. Postoperative pain and complications were more common with tacks than with cyanoacrylate glue. Chronic pain was reported by 19 people (7%) in the cyanoacrylate group, 53 people (20%) in the tacks group, and by 5 people (2%) in the no fixation group.

Procedure length was greater than 60 minutes for 32 people (12%) in the cyanoacrylate group, compared with 98 people (37%) in the tacks group and 24 people (9%) in the no fixation group. Hospital stay was greater than 1 day for 28 people (11%) in the cyanoacrylate group, 62 people (23%) in the tacks group and 14 people (5%) in the no fixation group. The proportions of people able to return to work and normal activity within 1 week were 83% (221 out of 266) of those treated with cyanoacrylate, 43% (115 out of 266) of those treated with tacks and 90% (238 out of 266) of those who had no mesh fixation.

Hernia recurrence rates were low, with 2 in each of the cyanoacrylate and non-fixation groups, and 1 in the tacks group. Haematoma or seroma was most commonly reported in the cyanoacrylate group (14 people, 5%), compared with 3 people (1%) in the tacks group and only 1 (0.4%) in the no fixation group. There was 1 wound infection in a patient in the tacks group; no mesh infections

were reported.

Strengths and limitations

This was an RCT with a large sample size. Multiple outcome measures were considered, but statistical comparison was summarised across all 3 treatment arms (not reported separately for cyanoacrylate glue compared with tacks). In the abstract the authors claim there were no significant differences between cyanoacrylate glue and no fixation for several measures, but did not provide supporting data for this direct comparison. Although immediate postoperative pain scores were referenced in the abstract and methods, they were not clearly reported in the results. Several continuous measures were reported as binary outcomes (grouped according to values above and below a threshold), reducing the value of the available data.

Open procedures

Van Steensel et al. (2019)

Study size and design

A systematic review including 23 RCTs. Eight studies included cyanoacrylate glue as 1 of the treatment arms (Dabrowieki et al. 2012; Hoyuela et al. 2017; Kim-Fuchs et al. 2011; Moreno-Egea 2014; Nowobilski et al. 2004; Paajanen et al. 2011; Ronka et al. 2015; Shen et al. 2011). The total number of participants in these 8 RCTs was 1,832, with 833 randomised to treatment using cyanoacrylate glue.

Intervention and comparator(s)

The main study compared adhesional or self-gripping fixation methods (including cyanoacrylate glue, fibrin glue and self-gripping mesh) with sutures. Subgroup analyses compared cyanoacrylate glue with sutures for postoperative pain, chronic pain and rate of recurrence. Three of the 8 studies used Histoacryl glue, with the remainder each using Glubran (GEM), Glubran2, Ifabond, Indermil (Loctite) and Compont (Beijing Compont Medical Devices).

Key outcomes

Postoperative pain scores were lower with cyanoacrylate compared with sutures after 1 week (mean difference -0.77, CI -1.48 to -0.05, p=0.04) and 1 month (-0.43, CI -0.72 to -0.14, p=0.004). After 12 months there were no significant differences between cyanoacrylate glue and sutures for chronic pain (OR 1.36, CI 0.77 to 2.42, p=0.29), and hernia recurrence (OR 1.53, CI 0.48 to 4.86, p=0.47). Overall, the length of procedure was approximately 6 minutes shorter for self-adhering or

self-gripping methods when compared with suturing.

Strengths and limitations

This was a systematic review, which included 23 RCTs with some relevant subgroup analyses (including cyanoacrylate-based glues).

Matikainen et al. (2020)

Study size, design and location

An RCT including 3 treatment arms with a total of 625 people who had Lichtenstein hernioplasty in Finland.

Intervention and comparator(s)

Histoacryl cyanoacrylate glue was used for mesh fixation (n=216). Comparators were non-absorbable sutures (n=216) or self-gripping mesh (n=202). After 5 years, the numbers of people remaining in the trial were 177 in the cyanoacrylate glue group, 170 in the sutures group and 167 in the self-gripping mesh group.

Key outcomes

After 5 years of follow up, there were no significant differences between the 3 treatment groups in the incidence of chronic pain, recurrence requiring reoperation, overall reoperations or patient satisfaction.

Strengths and limitations

This multicenter trial had a large sample size with long-term follow up. A similar proportion of people in each group was lost to follow up. People were not clinically examined at final follow up so results rely on patient-reported outcomes. Statistical comparisons were across all 3 treatment arms; no subgroup analyses were reported. This study was previously reported by Ronka et al. (2015) at 1-year follow up, and the same people had been included in the Van Steensel et al. (2019) systematic review.

Sustainability

No environmental sustainability benefits were identified. All devices are single-use.

Recent and ongoing studies

A total of 20 relevant trial registration records were identified, 7 of which had been published and considered in the literature search (Brugger et al. 2011; Dauser et al. 2016; Fouda et al. 2020; Hoyuela et al. 2017; Matikainen et al. 2016; Matikainen et al. 2020; Moreno-Egea 2014), and 1 of which terminated early because of poor patient recruitment (NCT03429374). Six studies were due to have completed, but no associated results or publications were identified (NCT02197585; NCT02507830; NCT02932033; NCT03678272; NCT04272424; ACTRN12620000742976). One trial (OMEGA: A multicenter randomised controlled trial of Only MEsh fixation with a Glue Applicator comparing traumatic versus atraumatic fixation of the mesh in ventral/incisional laparoscopic repair) was highlighted by a company, but few details were provided and the trial is not yet registered online. A further 6 studies were currently ongoing and not yet due for completion, 1 of which is in the UK:

- Post-market clinical follow-up study to evaluate the safety and performance of LiquiBand FIX8 open hernia mesh fixation device. ClinicalTrials.gov identifier: NCT04059640. Status: recruiting (last updated: March 2022). Estimated study completion date: February 2024. Indication: inguinal hernia (open procedure). Device: LiquiBand Fix8 (no comparator). Country: UK.

- A clinical study to evaluate the clinical performance and safety of LiquiBand Fix8 versus AbsorbaTack for hernia mesh fixation and peritoneal closure in groin hernia repair. ClinicalTrials.gov identifier: NCT04009213. Status: active, not recruiting (last updated: January 2022). Estimated study completion date: March 2023. Indication: groin hernia (laparoscopic procedure). Device: LiquiBand Fix8. Comparator: AbsorbaTack. Country: US.

- Laparoscopic groin hernia repair by a 3D ENDOLAP visible mesh with or without LiquiBand Fix 8 mesh fixation. ClinicalTrials.gov identifier: NCT02781870. Status: recruiting (last updated: July 2020). Estimated study completion date: May 2025. Indication: groin hernia (laparoscopic procedure). Device: LiquiBand Fix8. Comparator: no fixation. Country: Belgium.

- A randomised clinical trial comparing two different mesh fixation techniques in open retromuscular ventral hernia repair. Trial reference: ISRCTN95370808. Status: ongoing (last updated: October 2021). Estimated study completion date: July 2023. Indication: ventral hernia (open procedure). Device: cyanoacrylate glue (brand not stated). Comparator: suture. Country: Greece.

- Therapeutic outcomes of mesh fixation with suture versus glue in inguinal hernia repair with Lichtenstein method. Trial reference: IRCT20200404046936N3. Status: recruiting (last updated: June 2020). Estimated study completion date: not reported. Indication: inguinal hernia (open procedure). Device: cyanoacrylate glue (brand not stated). Comparator: suture. Country: Iran.
- Mesh fixation with cyanoacrylate in the open repair of inguinal hernia: a comparative study. Trial reference: JPRN-UMIN000005453. Status: recruiting (last updated: April 2022). Estimated study completion date: not reported. Indication: inguinal hernia (open procedure). Device: cyanoacrylate (brand not stated). Comparator: suture. Country: Spain.

Expert comments

Comments on this technology were invited from clinical experts working in the field. The comments received are individual opinions and do not represent NICE's view.

All 4 experts had used this technology before.

Level of innovation

One expert described mesh fixation using cyanoacrylate glue as a major innovation compared with tacking devices. Another described it as a novel approach that enables a move away from traumatic, mechanical mesh fixation methods. One expert felt it was only a minor variation, noting that different forms of glue (fibrin) have been used for many years. They explained that the operation and mesh remained the same, and that the difference was in the way that the mesh was fixed in place.

Potential patient impact

Experts advised that at least 70,000 inguinal hernia repairs are done in the UK each year, and most would be eligible for cyanoacrylate glue use. One expert estimated that less than 10% of NHS hospitals currently use cyanoacrylate glue for hernia mesh fixation.

All 4 experts agreed that there would be a reduced risk of complications compared with mechanical mesh fixation methods. Three of the experts noted the reduced risk of chronic pain, with 2 commenting that the incidence of nerve damage would be reduced. One also mentioned that immediate postoperative pain was likely to be reduced. Two experts advised that the risk of hernia recurrence is reduced when using glue; 1 explained that it is possible to extend the mesh across a

wider area in laparoscopic transabdominal preperitoneal (TAPP) and extraperitoneal (TEP) inguinal hernia repairs. The other expert suggested that chronic pain is a greater concern than hernia recurrence because it is possible to carry out another hernia repair, but not always to resolve chronic pain. One expert thought that thin people who have a low body mass index may particularly benefit from glue use, because they have a greater risk of nerve damage from mechanical mesh fixation methods. Another expert commented that young people tend to have a higher rate of chronic pain, and probably have more chance of benefit from cyanoacrylate glue use.

One of the experts noted that evidence suggests that improved clinical outcomes associated with cyanoacrylate glue may lead to a shortened length of hospital stay, and a quicker return to normal activities. Two experts commented that avoiding complications such as pain and recurrence could reduce the need for further management, avoiding visits to primary and secondary care, potential reoperation and absences from the workplace.

Potential system impact

All 4 experts agreed that adopting cyanoacrylate glue has little impact on staff resources, equipment or care setting. Applicator devices were considered by 2 experts to be simple to use for mesh fixation (1 said that peritoneal closure using glue can be technically challenging in TAPP repairs). All experts agreed that minimal training is needed. One said that this can be achieved on the job. One said 20 cases or less would be needed to get the required experience but another believed that up to 50 cases may be needed before the operator can apply the glue efficiently. One expert emphasised that nurses also need minimal training to understand how to prepare the device for use.

Two experts indicated that the length of procedure may be shortened if glue is used for both mesh fixation and peritoneal closure. Lessening the need for ongoing management of complications, and avoiding recurrence, could slightly reduce the overall burden on the healthcare system.

All experts indicated that cyanoacrylate glue has the potential to replace the routine use of tacks and other mechanical fixation devices. The potential economic impact depends very much on the standard care comparator. As highlighted by 1 of the experts, cyanoacrylate glue would inevitably cost more than no mesh fixation. Another advised that cyanoacrylate glue costs substantially less than fibrin glue. Two experts believed that cyanoacrylate glue is likely to cost about the same as current standard care, when the whole care pathway is taken into consideration. One expert suggested that cyanoacrylate glue may ultimately prove less costly than tacks because of reduced long-term resource use. One expert commented that cyanoacrylate glue products are easy to store and do not require refrigeration; another suggested that shelf life should be taken into

consideration.

General comments

The experts confirmed that a variety of mesh fixation methods are commonly used in the NHS. The decision on which 1 to use is likely influenced by the procedural approach and which technologies are available locally. Three experts described using tacks for laparoscopic procedures, and 2 referred to using sutures for open surgery. One of the experts routinely used fibrin glue.

In hernia repair procedures, cyanoacrylate glue can be used for both mesh fixation and for peritoneal closure. One expert believed that the glue's main advantages (such as speed of use) are most evident when used for these 2 purposes within a single procedure. One expert was uncertain about the relative effectiveness of mesh fixation with cyanoacrylate glue when compared with self-gripping mesh (which similarly has the benefit of avoiding tissue trauma). However, when self-gripping mesh is used, it takes more time to suture the peritoneum (than when the peritoneum is glued).

Although not reported in the included studies, anecdotal evidence from 1 expert suggests that some clinicians are reluctant to use cyanoacrylate glue because they are not sure whether the fixation is as strong as with tacks, and are concerned about the risk of hernia recurrence.

One expert considered that the evidence could be strengthened by additional high-quality randomised controlled trials comparing recurrence rates. Another suggested further research comparing cyanoacrylate with more established glues. Three experts noted that the length of study follow up should extend to at least 1 year after the procedure (to evaluate prevalence of chronic pain). One expert suggested that longer studies (up to 10 years) are needed for a better understanding of relative rates of recurrence. One of the experts considered the design of the applicator device to be 'key', and implied that a comparative evaluation of device functioning would be helpful. Three experts emphasised that applicators must be easy to use; 1 provided a further explanation that this could affect how quickly the operation could be done (and so the number of procedures that could be completed in a day). Cost comparisons should consider the frequency of applicator device malfunctioning, which can result if glue is not loaded correctly or a blockage occurs. Three experts reported that they sometimes needed to replace LiquiBand Fix8 devices because of problems with glue delivery; this adds to the cost and can add a few extra minutes to the length of the procedure.

One of the experts commented that their experience and research (based on the laparoscopic LiquiBand Fix8 device) had led to them to no longer using tacks in TAPP repairs and laparoscopic

intraperitoneal onlay mesh (IPOM) repairs. Another expert noted that all of the procedures they had carried out using Histoacryl had been day cases, with no reports of chronic pain.

Expert commentators

The following clinicians contributed to this briefing:

- Rob Bethune, consultant surgeon, Royal Devon University Healthcare NHS Foundation Trust. Advisory consultant to Advanced Medical Solutions.
- Marianne Hollyman, consultant upper gastrointestinal surgeon, Somerset NHS Foundation Trust. Did not declare any interests.
- Aali J Sheen, consultant surgeon, Manchester University NHS Foundation Trust. Did not declare any interests.
- Paul Wilson, consultant in general surgery, University Hospitals of Morecambe Bay NHS Foundation Trust. Advisory consultant to Advanced Medical Solutions.

Development of this briefing

This briefing was developed for NICE by Cedar Health Technology Research Centre. The interim process and methods statement for medtech innovation briefings sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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