NICE advice

Fasciotens for abdominal wall closure

Medtech innovation briefing
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www.nice.org.uk/guidance/mib321

Overview

NICE has developed a medtech innovation briefing (MIB) on fasciotens for abdominal wall closure.

The information provided includes a description of the technology, how it's used and its potential role in the treatment pathway. A MIB also includes a review of relevant published evidence and the likely costs of using the technologies, but they are not NICE guidance and do not make any recommendations on the value of using the technologies.

Summary

- The **technology** described in this briefing is fasciotens. It uses controlled traction to aid abdominal wall closure.
- The **innovative aspects** are that the technology allows closure of complex hernias and the open abdomen, reducing the need for mesh bridging or component separation.

- The intended **place in therapy** would be alongside standard care to aid abdominal wall closure for complex hernias and open abdomen treatment (laparostomy) in which the gut and other intraperitoneal organs are exposed.
- The **main points from the evidence** summarised in this briefing are from 6 studies (1 prospective observational study, 2 retrospective observational studies and 3 case studies) including a total of 96 people. The evidence suggests that fasciotens may be a useful technology to aid abdominal wall closure.
- **Key uncertainties** around the evidence are that it is non-comparative with small sample sizes. None of the studies were based in the UK and they may not be generalisable to the NHS.
- **Experts advised** that fasciotens is a novel technology and has the potential to aid earlier closure of open abdominal wounds, reduce pain and reduce the length of hospital stay. Experts noted that current evidence is limited and agreed that multicentre comparative studies are needed to realise the potential benefits in a larger population.
- The **cost** of fasciotens abdomen is £3,995.50 (excluding VAT) per device. The cost of fasciotens hernia is £1,760 and the fasciotens hernia carrier is £3,650. These costs are in addition to standard care costs.

The technology

The fasciotens abdomen and hernia (Fasciotens) devices are used for complex hernias or open abdomen treatment (laparostomy) in which the gut and other intraperitoneal organs are exposed. They use controlled vertical traction to aid abdominal wall closure. The company claims that the technology prevents retraction of the fascia and abdominal wall during open abdomen treatment and allows the surgeon to 'stretch' the abdominal wall in a controlled way.

The fasciotens devices consist of a stand and a suspended thread retainer that hangs over the abdomen during treatment. Six sutures tied to each fascial margin of the open wound are then fastened to the device's thread retainer at the same tension using fixing clips. The traction applied to the abdominal wall or fascia can be adjusted using a screw mechanism. The overall applied traction is displayed on a scale attached to the device and can be adjusted throughout treatment. The fasciotens abdomen device has 2 supporting feet that are placed on the chest and anterior pelvic ring during treatment. The fasciotens

hernia device is screwed onto the fasciotens hernia carrier and can be attached to a bedside rail or table for stability.

Innovations

The company claims that the technology is the only device that brings quantifiable vertical tension to the abdominal wall and allows abdominal closure, reducing the need for mesh bridging or component separation. The company claims that it prevents fascial retraction, increases intra-abdominal volume, and preserves the integrity of the abdominal wall, enabling direct closure of complex hernias and the open abdomen.

Current care pathway

Management of the open abdomen after a laparostomy includes using dressings or impermeable devices, such as a Bogota bag or negative pressure wound therapy devices, to protect the exposed organs and limit fluid leakage. The abdomen may be left to heal by secondary intention or delayed closure may be done using sutures, mesh repair, skin grafts, muscle flaps or a combination of these. The choice of closure technique depends on the size of the wound and other clinical considerations. A clinical expert noted that leaving a wound to heal by secondary intention or delaying closure is associated with increased complications.

Complex hernias are typically treated by surgical repair using synthetic mesh. Botulinum toxin may be injected into the muscles around the hernia to increase elasticity. They can also be treated with component separation, a surgical technique in which the abdominal muscles are separated to increase cover of the abdominal wound. Using this technique often means healthy abdominal wall muscle is cut away. There is an increased risk of seroma, haematoma, infections, and a lateral bulging because of the muscles weakening.

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

- NICE's medtech innovation briefing on cyanoacrylate glue for hernia mesh fixation
- NICE's guideline on pancreatitis
- NICE's guideline on the diagnosis and management of abdominal aortic aneurysm
- NICE's guideline on the assessment and initial management of major trauma

- NICE's interventional procedures guidance on negative pressure wound therapy for the open abdomen.

Population, setting and intended user

Fasciotens is intended for use alongside standard care to aid abdominal wall closure in complex hernias or during open abdomen treatment. The company says that it can be used for kidney, liver, digestive tract and urological conditions, and for infections, injuries, accidents and wounds.

Fasciotens is likely to be used by colorectal, upper gastrointestinal and general surgeons in secondary care settings, such as operating theatres and intensive care units. The company offers training and support to healthcare professionals for the first time they use fasciotens, and other additional support as needed. The company says that training is typically in the clinical application of the device, set up, best practice and aftercare, and maintaining the device. The company also says that it has videos and user guides on its website.

Costs

Technology costs

Fasciotens abdomen costs £3,995.50 (excluding VAT) per device. Fasciotens hernia costs £1,760 and the hernia carrier is £3,650 (excluding VAT). Fasciotens abdomen and hernia are single use only and should be disposed of after use. The fasciotens hernia carrier is reusable. The company provides free training.

Resource consequences

Fasciotens hernia has been trialled in 8 hospitals across England and Scotland.

Fasciotens is intended to be used alongside standard care, so it initially costs more than standard care alone. The company claims that the technology could lead to cost savings by shortening length of stay in intensive care units and reducing the number of surgical revisions. There is no published evidence to support these claims. The company says that no changes to facilities or infrastructure are needed to adopt the technology.

Regulatory information

Fasciotens hernia and abdomen are CE marked class I sterile medical devices.

Equality considerations

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

No equality issues were identified.

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

Six studies are summarised in this briefing, including a total of 96 people. The evidence includes 1 prospective observational study, 2 retrospective observational studies and 3 case studies.

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

Overall assessment of the evidence

The evidence base for fasciotens abdomen is limited and comes from non-comparative observational studies and case studies that involve a relatively small number of people. None of the included studies were done in the UK and results may not be generalisable to clinical practice in the NHS. The evidence suggests that the fasciotens devices may be a useful technique to aid abdominal wall closure. Further evidence from larger randomised

comparative studies comparing fasciotens abdomen with standard care would be useful. Useful outcomes for further research include time to fascial closure, adverse events, length of stay, number of additional operations needed, and long-term follow up. Further studies should also evaluate which specific populations may benefit from the technology.

Niebuhr et al. (2020)

Study size, design and location

Prospective multicentre observational study of 21 people with complex hernias in Europe.

Intervention and comparator

Fasciotens abdomen, no comparator.

Key outcomes

Initial average fascial distance was 17.3 cm (range 8.5 to 44). After application of fasciotens abdomen, fascial distance decreased by 9.8 cm (range 1 to 26) to an average of 7.5 cm (range 2 to 19 [r=0.62]). The average increase of fascial length was 9.8 cm. All hernias were closed with moderate tension. In 19 patients, closure was reinforced by a mesh inserted with a sublay technique, and 2 closures were done with an intraperitoneal onlay mesh. The average immediate postoperative pain measured on a visual analogue scale was 2.5 (0 to 6). The average hospital stay was 14.5 days (range 6 to 75). Four patients had surgical site infections that were treated with a vacuum-assisted closure system.

Strengths and limitations

The main limitation of this study is the non-comparative design. Without a control, early fascial closure cannot be attributed to fasciotens abdomen. The study has a small sample size and was not done in the UK, so the results may not be generalisable to clinical practice in the NHS.

Niebuhr et al. (2021)

Study size, design and location

Retrospective multicentre study of 50 people with complex abdominal wall hernias in Europe.

Intervention and comparator

Fasciotens hernia, no comparator.

Key outcomes

Initial fascial distances ranged from 8 cm to 44 cm. Most people (94%) had a fascial distance over 10 cm. Fascial distance was significantly reduced in all but 1 case. Mean fascial distance was reduced from 16.1 cm (standard error of the mean [SEM] 0.8) to 5.8 cm (SEM 0.7). The stretch gain was 10.2 cm (SEM 0.7; $p<0.0001$, Wilcoxon matched-pairs signed-ranks test). Direct closure was achieved in 45 cases (90%) and 41 people were treated with a mesh augmentation in a sublay position. Six people (12%) had postoperative complications and 3 people (6%) needed surgery again.

Strengths and limitations

The main limitation of this study is the retrospective non-comparative design. Without a control, fascial closure cannot be attributed to fasciotens hernia. The study was not done in the UK, so the results may not be generalisable to clinical practice in the NHS.

Fung et al. (2022)

Study size, design and location

Retrospective multicentre study of 20 people with an open abdomen in Germany.

Intervention and comparator

Fasciotens abdomen, no comparator.

Key outcomes

Initial average fascial distance was 15 cm (range 8 to 23) and the average duration of open abdomen was 3 days. At relook laparotomy 48 hours after application of fasciotens abdomen, the average fascial distance reduced to 10 cm (range 6 to 17; p=0.0081). Primary fascial closure was achieved without mesh or component separation in an average of 7 days (range 3 to 24). In 12 patients, fasciotens abdomen was applied with a negative pressure wound therapy system, and in 8 patients it was applied with an alternative temporary abdominal closure system. The average duration to primary fascial closure for patients with septic open abdomen was 7.5 days, and for non-septic open abdomen was 7 days. During follow up, 2 patients developed an incisional hernia.

Strengths and limitations

The main limitation of this study is the retrospective non-comparative design. Without a control, early fascial closure cannot be attributed to fasciotens abdomen. The study has a small sample size and was not done in the UK, so the results may not be generalisable to clinical practice in the NHS.

Bloemendaal (2022)

Study size, design and location

Case study of 3 people with complex hernias in the Netherlands.

Intervention and comparator

Fasciotens hernia with robotic arm surgery, no comparator.

Key outcomes

Initial hernia widths ranged from 7 cm to 10 cm. Hernia closure was completed in all cases. Operative time ranged from 186 minutes to 255 minutes. Length of stay ranged from 2 days to 3 days.

Strengths and limitations

This is a narrative article with 1 case study. It is limited in methodological detail and

generalisability.

Hees and Willeke (2020)

Study size, design and location

Case study of 1 person with an open abdomen caused by peritonitis in Germany.

Intervention and comparator

Fasciotens abdomen, no comparator.

Key outcomes

Initial fascial distance was 12 cm. After application of fasciotens abdomen, the intraoperative measurement of fascial distance was 4 cm and the abdominal wall was closed. The patient was discharged 8 days after abdominal closure and had no adverse events.

Strengths and limitations

This is a narrative article with 1 case study. It is limited in methodological detail and generalisability.

Fung et al. (2019)

Study size, design and location

Case study of 1 person with an open abdomen caused by necrotising pancreatitis in Germany.

Intervention and comparator

Fasciotens abdomen, no comparator.

Key outcomes

Initial fascial distance was 15 cm. During abdominal exploration 48 hours after fasciotens abdomen application, the fascial distance reduced by 5 cm. The abdominal wall was successfully closed 2 weeks after the device was applied.

Strengths and limitations

This is a narrative article with 1 case study. It is limited in methodological detail and generalisability.

Sustainability

No sustainability benefits have been identified for the technology.

Recent and ongoing studies

Fasciotens to treat an open abdomen – a prospective cohort study. ClinicalTrials.gov identifier: NCT04033614. Status: recruiting. Indication: abdominal compartment syndrome, acute necrotising pancreatitis, intra-abdominal hypertension and peritonitis. Device: fasciotens abdomen. Estimated completion date: August 2026. Country: Germany.

Expert comments

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

Four experts commented on this briefing. Three out of 4 experts had knowledge of or had used this technology before.

Level of innovation

All 4 experts agreed that fasciotens is a novel technology and has the potential to improve patient outcomes. Two experts felt that fasciotens is the first in a new class of procedure. Two experts said that a similar technique using medial tension is used outside the UK but

noted that this is less controlled and tension is applied to sutures one at a time. One expert said that fascial tension devices are being added to the British Hernia Society Registry because it feels that more devices using a similar concept will continue to be developed.

Three experts said that fasciotens would be used alongside current standard care to complement current techniques and aid patient recovery. One expert said that it could be particularly helpful in closing open abdomens that have not closed within 48 hours because of fascial retraction or concerns about component separation. They also noted that it would need to be used alongside negative pressure wound therapy for open abdomen treatment to manage fluid secretion and prevent adhesions. One expert felt that fasciotens could replace current standard care techniques such as synthetic mesh and component separation.

Potential patient impact

Experts agreed that fasciotens has the potential to aid earlier closure of open abdominal wounds, which could lead to less pain, shorter hospital stays, and improved long-term outcomes for patients. Two experts said that patients may also benefit from reduced use of prosthetic materials, such as mesh, minimising foreign materials in the body. Experts agreed that patients having open abdomen treatment after various conditions and people with large hernias may benefit from this technology. One expert specified that most abdominal wounds will be closed during a first revisit to theatre and said that the technology would be used for patients with persistent retraction of the abdominal wall. Two experts said that there may be a risk of pressure sores from the feet of the fasciotens abdomen device, or excess stretching of the abdominal wall, which could cause tearing and weakness. Two experts said that there is a risk of increased abdominal pressure and hernia recurrence, but 1 noted that the data reports fewer risks than current wound closure techniques.

Potential system impact

All 4 experts said that fasciotens has the potential for cost savings compared with standard care. That is, if it reduces the length of stay, the number of surgical revisions and use of other resources, such as negative pressure wound equipment or prosthetic materials. One expert felt that there would be more cost savings if fasciotens was used in high-risk open abdomens and larger hernias. Three experts agreed that surgical staff

would need to be trained, but 2 experts noted that the technology is easy to use, and that training would be minimal. One expert said that training would consist of observing 2 cases and performing 2 to 3 cases with supervision. One expert felt that there may be an increase in costs to sterilise the fasciotens hernia carrier but noted that standard hospital processes would be used to do this. All experts agreed that fasciotens could be used at most district general hospitals. Three experts said that they may use 5 to 10 fasciotens devices per year, but noted that this is in a district general hospital, and the number for tertiary centres may be up to twice this amount. One expert noted that they perform more complex abdominal wall reconstruction surgeries so would use more fasciotens hernia devices than fasciotens abdomen devices at their centre.

General comments

One expert commented that fasciotens can be difficult to put together initially because it requires a number of steps to assemble. But they noted that training videos and support from the company are available to guide clinicians. Three experts agreed that multicentre (potentially international) randomised trials are needed to confirm the potential benefits because the number of eligible patients per centre is low. One expert said that data on the costs of using fasciotens abdomen for open abdomen treatment in different populations is needed to see if there is a difference in potential benefits between groups. Experts noted that potential useful outcomes from future research include length of stay, use of synthetic mesh, incidence of incisional hernia after abdominal wall closure, subsequent surgeries and quality of life.

Expert commentators

The following clinicians contributed to this briefing:

- Mr Luke Meleagros, consultant surgeon, North Middlesex University Hospital. Did not declare any interests.
- Mr Andrei Mihailescu, consultant general surgeon, Tameside and Glossop Integrated Care NHS Foundation Trust. Invited by the company to their annual conference to find out more about the device and interact with other surgeons who have used it.
- Mr Praminthra Chitsabesan, consultant colorectal, complex abdominal wall reconstruction and general surgeon, York and Scarborough Teaching Hospitals NHS Foundation Trust. Did not declare any interests.

- Ms Olga Rutka, consultant in emergency surgery and major trauma, Liverpool University Hospitals NHS Foundation Trust. Did not declare any interests.

Development of this briefing

This briefing was developed by NICE. 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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