

SURGICAL APPLICATION PROTOCOL FOR IFABOND™ ADHESIVE IN HAEMOSTATIC PROCEDURES DURING HEPATECTOMY

DEFINITION

A hepatectomy is performed to remove a malignant tumour, more rarely a benign tumour or a parasitic cyst. The liver is divided into 8 segments, numbered from I to VIII. A right hepatectomy consists of the removal of segments V to VIII; the procedure is referred to as right extended if it also covers other segments of the liver. A left hepatectomy removes segments II, III and IV, and may also be extended to remove other segments. A hepatectomy can remove up to 80% of the liver mass; if the hepatic tissue is healthy, the liver has the ability to regenerate itself and to return to its full normal mass following this surgery.

A total hepatectomy is performed prior to a liver transplant.

Several parenchymal section methods are used. The hepatectomy section is performed in gradual steps on each occasion, by crushing or pulverising the hepatocytes to **reveal the vascular and biliary pedicle** which are bound and sectioned electively. Thus, access to the pedicles may be performed by ultrasound dissection, by crushing using a simple metallic clamp or by water-jet dissection etc.

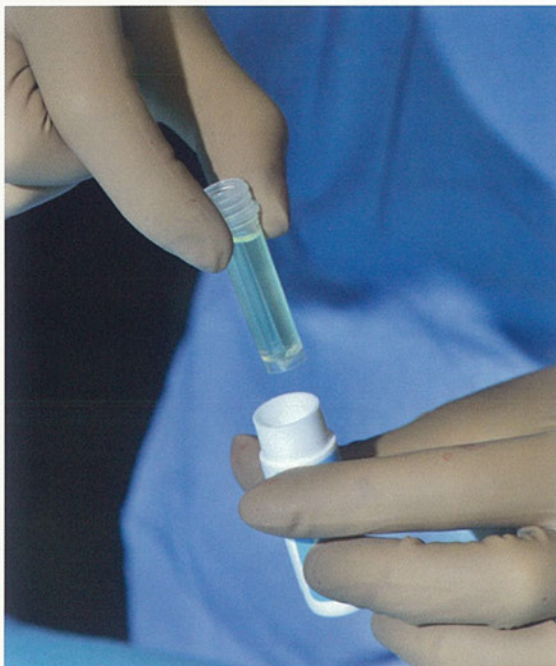
OBJECTIVES

Perioperative bleeding is limited using clamping. The clamping periods are limited and the clamps are used sparingly, especially as the structure of the hepatic parenchyma has changed.

At the end of surgery and also following elective ligation of the vascular and biliary pedicles, the **IFABOND™** adhesive is applied to **improve haemostasis**.

METHOD

- Required quantity of IFABOND™ adhesive: between 1.5 ml and 3 ml depending on the size of the sectioned hepatic surface (1.5 ml treats 150 cm²).
- Applicator: Ifajet spray

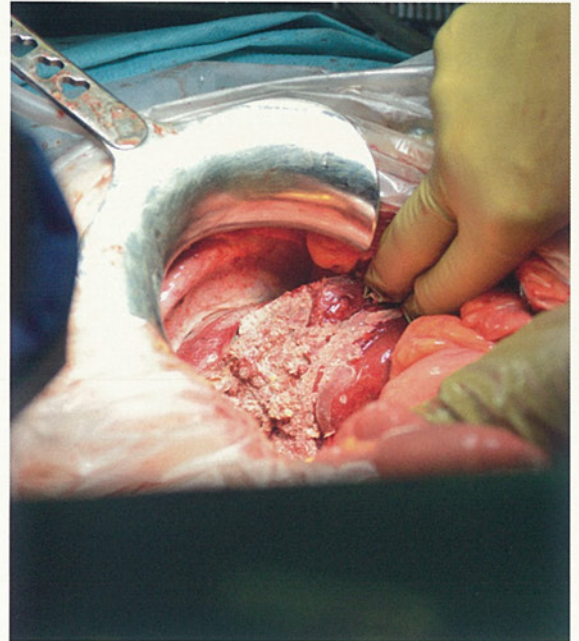
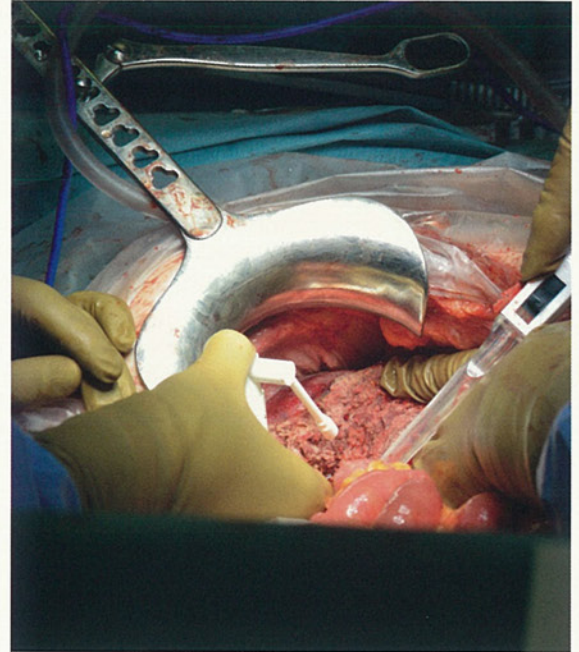


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• In open surgery, on the liver section (or the hepatic bed in the case of a total hepatectomy):

- Dry the section using a compress in order to limit excess blood or bile (the glue will then have stronger adhesion to the tissue).
- Using the spray prepared earlier, spray IFABOND™ across the entire section surface.
- During polymerisation, the adhesive forms a watertight film which prevents effusion.
- Carefully reposition the liver, preserving the adhesive film which has formed.

Comment : IFABOND™ remains stable in the applicator throughout the procedure. It is not necessary to use the entire product immediately after preparation. Clean the applicator tip with physiological saline solution as required.



RECAP

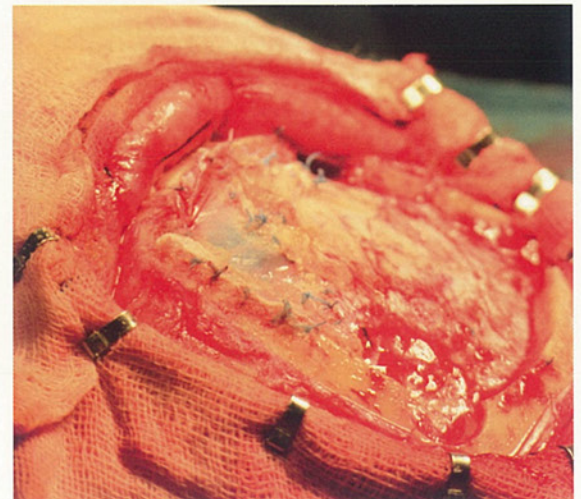
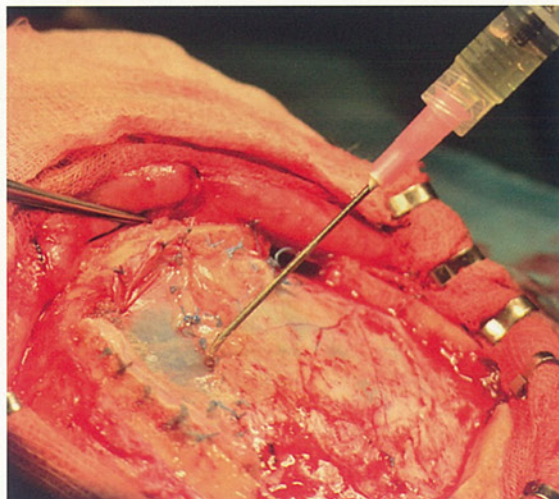
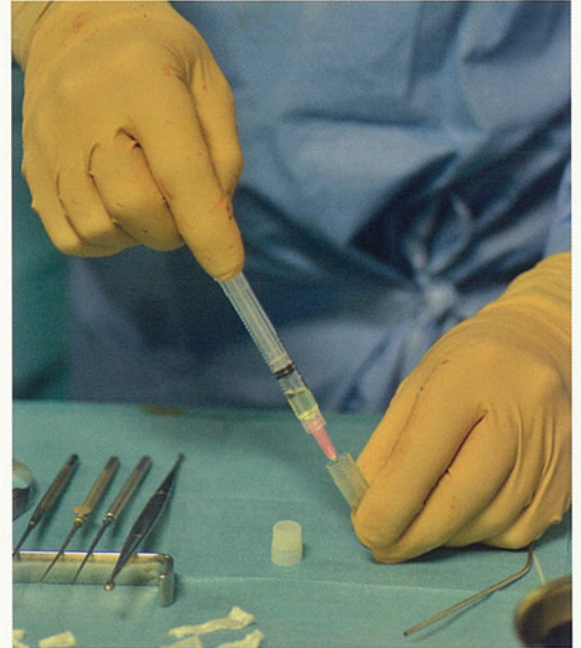
- A minute amount of adhesive is sufficient.
- Rapid polymerisation time of less than 30 seconds.
- After 30 seconds, it is safe to touch the bonded surface.
- Up to 2 minutes after application, it is possible to remove the adhesive by spraying it with physiological saline solution.
- After two minutes, the area can be washed.
- Partial resorption at 3 months.
- Degradation of cyanoacrylate at 6 months.

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SURGICAL APPLICATION PROTOCOL FOR IFABOND™ ADHESIVE FOR DURAL CLOSURE (DURA MATER) FOLLOWING A CRANIOTOMY

METHOD

- Required quantity of IFABOND™ adhesive: between 0.5 ml and 1.5 ml, depending on the length of the suture line.
- Applicators: atraumatic or cathlon syringe.
- Irrespective of how the dura mater is closed (dura mater, pericranium, neuro-patch), apply IFABOND™ droplet by droplet along the line of sutures, starting at the upper section of the area to be treated by allowing the droplet of adhesive to spread along the suture line:
 - The amount of adhesive required for adhesion is greatly reduced by the strength of the bond,
 - The adhesion process (speed of adhesion of the biological or synthetic tissue) can vary depending on the presence of blood, which catalyses the polymerisation speed (semiinstantaneous adhesion in contact with blood, or in around 1 minute in contact with serum).



Comment : IFABOND™ remains stable in the syringe throughout the procedure. It is not necessary to use the entire product immediately after preparation. Clean the applicator tip with physiological saline solution as required.

RECAP

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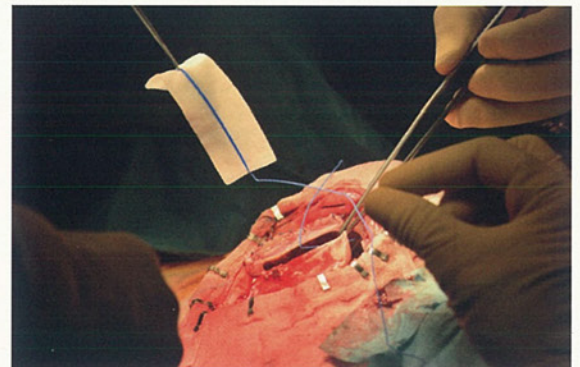
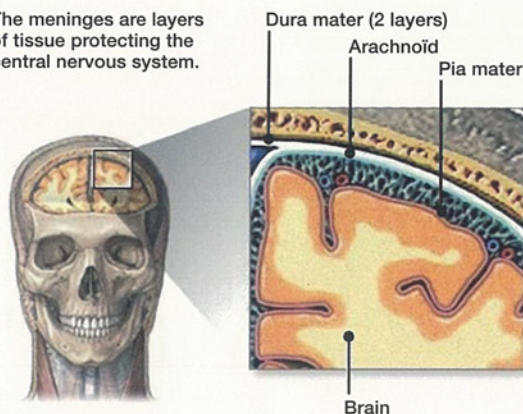
A craniotomy is a procedure employed to access the brain during neurosurgery. This procedure facilitates removal of an abscess, a haematoma or ablation of a tumour. A craniotomy is performed by first making an incision into the scalp, then by lifting and turning back the scalp tissue. Then the skull is sectioned by creating a cranial flap and finally **the dura mater** is opened. Following surgery, the bone flap is replaced and secured.

The dura mater is a thick, fibrous membrane which adheres to the bone. This membrane surrounds and protects the entire central nervous system (spinal cord, brain). It is the most external and the most resistant of the three membranes which make up **the meninges** together with the pia mater (the finest internal layer) and the arachnoid (a layer of average thickness which resembles a spider's web). The dura mater is visible just above **the orbit**.

The dura mater continues out via two major extensions, the falx cerebri (vertical, between the two cerebral hemispheres) and the tentorium cerebelli (horizontal, between the cerebral hemispheres above and the cerebellum below).

The dura mater descends much further than the spinal cord and ends at the second sacral vertebra.

The meninges are layers of tissue protecting the central nervous system.

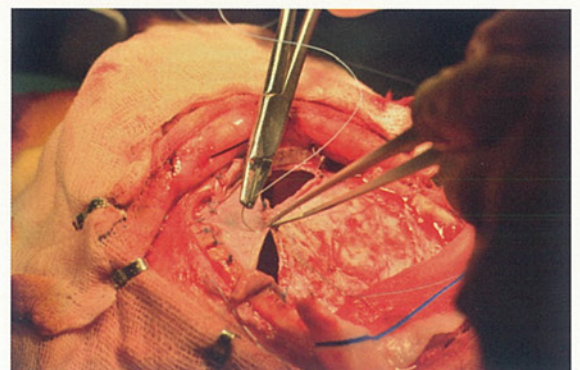


OBJECTIVES

After completing the intra-dural surgery, the surgeon performs an overlock to guarantee a resistant and perfectly leak-tight closure of the dura mater. At this point in the surgery, there is a risk of leaks and effusion of the cerebrospinal fluid (CSF) which may lead to serious post-operative complications.

The dura mater can be closed:

- dura mater/dura mater (if it has not been damaged),
- dura mater/pericranium (membrane covering the external area of the cranium, a piece of which has already been removed and which will be used as a graft),
- dura mater/neuro-patch (synthetic material).



Comment : The «intensive» use of diathermy on the dura mater (haemostasis) poses a problem as it can cause the dura mater to retract, thus complicating its closure. IFABOND™ adhesive allows the surgeon to perform perfect microhaemostasis.

SURGICAL APPLICATION PROTOCOL FOR IFABOND™ ADHESIVE FOR DURAL CLOSURE (DURA MATER) FOLLOWING A CRANIOTOMY

OBJECTIVES

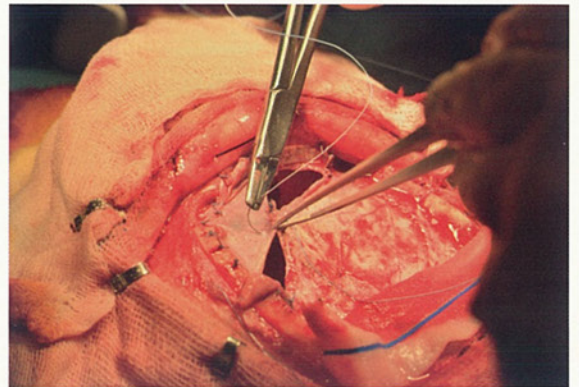
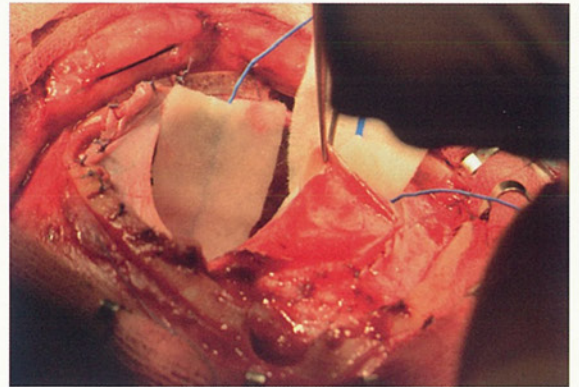
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METHOD

- Required quantity of IFABOND™ adhesive: between 0.5 ml and 1.5 ml, depending on the length of the suture line.
- Applicators: atraumatic or cathlon syringe.
- Irrespective of how the dura mater is closed (dura mater, pericranium, neuro-patch), apply IFABOND™ droplet by droplet along the line of sutures, starting at the upper section of the area to be treated by allowing the droplet of adhesive to spread along the suture line:
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 - The adhesion process (speed of adhesion of the biological or synthetic tissue) can vary depending on the presence of blood, which catalyses the polymerisation speed (semiinstantaneous adhesion in contact with blood, or in around 1 minute in contact with serum).



Comment : IFABOND™ remains stable in the syringe throughout the procedure. It is not necessary to use the entire product immediately after preparation. Clean the applicator tip with physiological saline solution as required.

RECAP

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- After two minutes, the area can be washed.
- Partial reabsorption at 3 months.
- Degradation of cyanoacrylate at 6 months.

IFABOND™ est un dispositif implantable, marqué CE 0499, de classe III, qui par son action adhésive et hémostatique, constitue une alternative ou un complément à l'agrafage, aux sutures ou à tout autre moyen utilisé lors d'interventions chirurgicales ; avant toute utilisation se reporter à la notice accompagnant le produit ; dispositif médical intra GHS, fabriqué en France par la Société FIMED et distribué par la Société VITALITEC INTERNATIONAL.

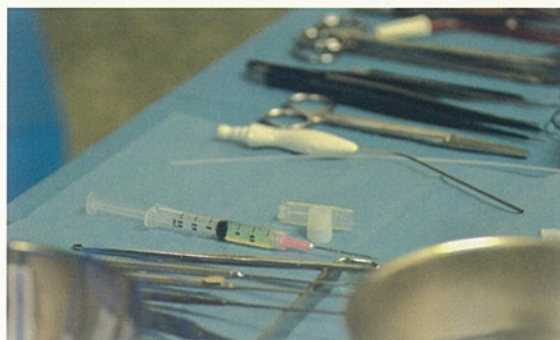
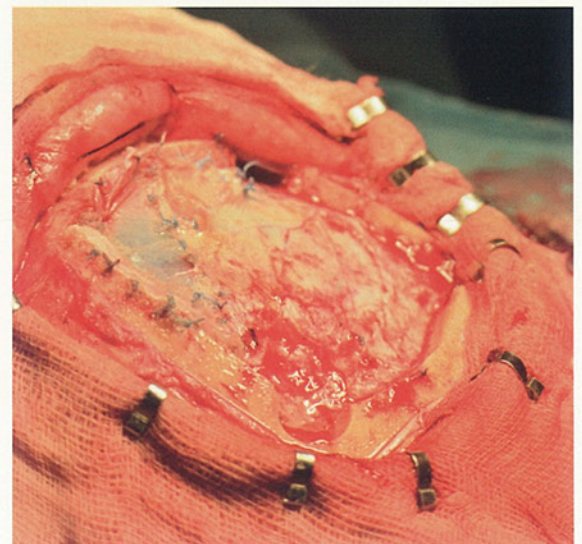
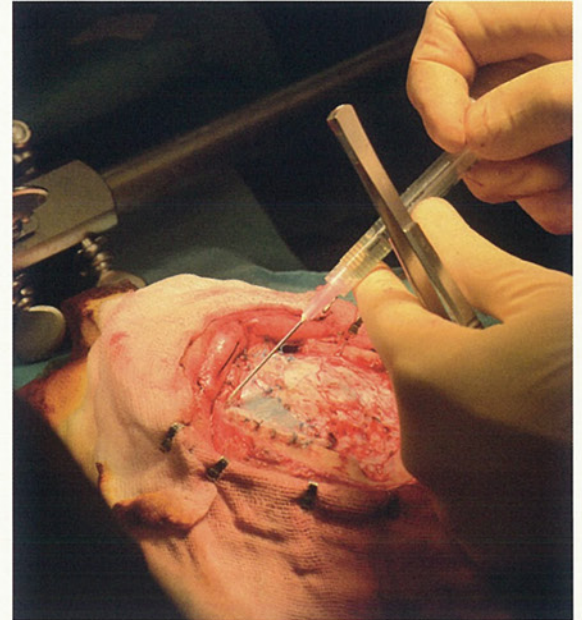
THE IMPORTANCE OF A PURIFIED SYNTHETIC SURGICAL GLUE IN CURRENT NEUROSURGERY

J.J. Lemaire, A. Coste, T. Khalil, V. Achim, G. Coll
[Clermont-Ferrand University Hospital Centre]

IFABOND is a highly-purified sterile synthetic glue with which high-hold delicate sutures can be made without biological risks for patients.

It was tested and approved by our team for dural closure and bone flap and bone fragment repositioning, notably for the posterior cranial fossa, or for closing burr holes. Of note, it was therefore able to favourably replace mechanical fixation of the posterior cranial fossa flap.

The following points were noted: preparation by the nursing personnel is very simple and rapid; an extremely small amount of glue is required for adhesion because of the adhesive strength; the adhesion process (speed of adhesion of biological or synthetic tissue, bone or implantable material) can be modulated according to the presence of blood which catalyses the speed of adhesion; adhesion can thereby be obtained almost instantly (blood) or in approximately 1 minute (serum).



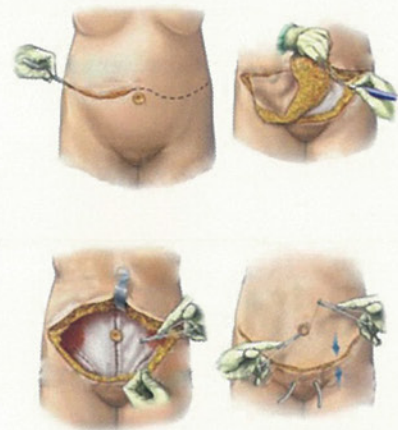
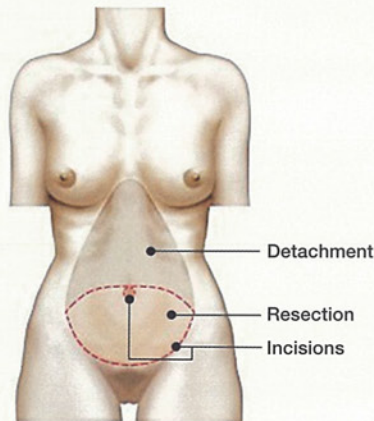
There is no doubt that IFABOND™, the highly-purified synthetic glue, has its place among the neuro-surgical technical equipment for making closures and anchoring certain biomaterials, and moreover, without any technical constraints for medical and paramedical teams.

SURGICAL APPLICATION PROTOCOL FOR IFABOND™ ADHESIV IN HAEMOSTATIC AND ADHESIVE PROCEDURES DURING ABDOMINOPLASTY

DEFINITION

Abdominoplasty or abdominal dermolipectomy is a surgical procedure which is performed to correct a dystrophic abdomen, in other words, with an altered shape. There are three types of excess which cause this dystrophy: an excess of fat (removed by liposuction), an excess of abdominal skin (the abdominal «apron» is removed and the skin retightened) and laxity of the abdominal muscles. Abdominoplasty is proposed following pregnancy or weight loss and the main benefit is aesthetic.

Standard abdominoplasty consists of resectioning the abdominal wall by cutting a cross-shaped flap of skin below the navel. This procedure is **often preceded by liposuction** of the area in question in order to preserve the fascia and therefore to reduce the risk of lymphorrhoea. The upper flap is pulled down and its lower edge sutured to the pubis; the navel is returned to its correct position. The scar is located around the navel and the pubis and curves upwards in a concave shape to respect the natural folds of the skin.



OBJECTIVES

This surgery enables:

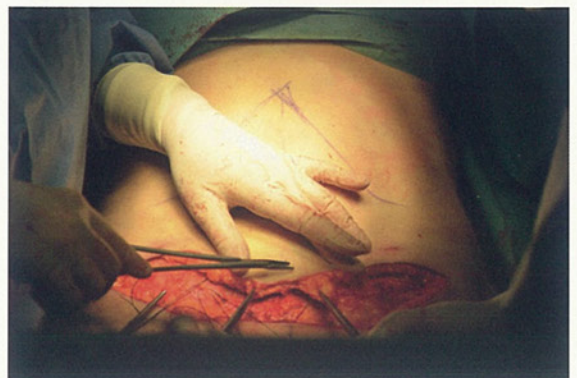
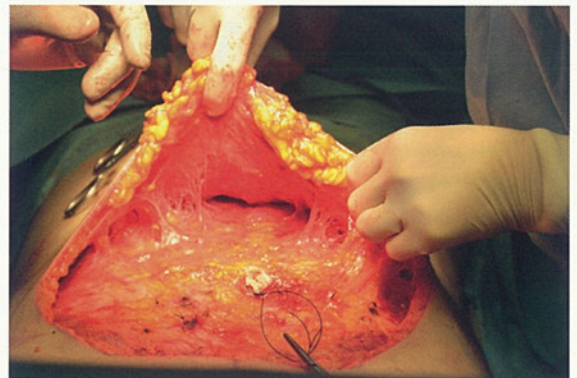
- the removal of excess skin;
- the prevention of possible scarring in the lower section of the abdomen, below the navel;
- the elimination of excess fat which is also found between the navel and the pubic area (via liposuction);
- the muscles of the abdominal wall, which have been separated, to be brought together.

This reconnection of the muscles refines the figure and reduces protrusion of the stomach.

Perioperative and postoperative risks:

- Haematoma, which is prevented by careful perioperative haemostasis and drainage by aspiration.
- Lymphatic effusion, which is relatively common, can occur several days or weeks following surgery, and may require repeated puncture and/or further surgery to perform drainage.

IFABOND™ surgical adhesive is used to improve haemostasis and to promote tightening of the supraumbilical tissue.



SURGICAL APPLICATION PROTOCOL FOR IFABOND™ ADHESIV IN HAEMOSTATIC AND ADHESIVE PROCEDURES DURING ABDOMINOPLASTY

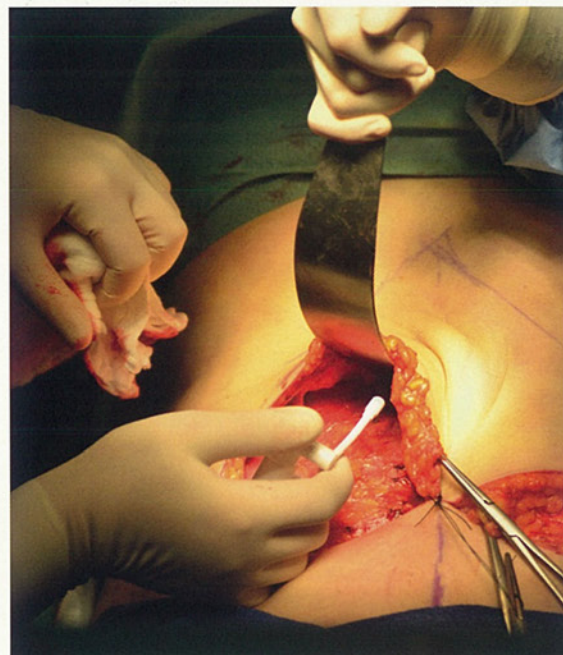
METHOD

- Required quantity of IFABOND™ adhesive: between 1.5 ml and 3 ml depending on the size of the surface to be treated (1.5 ml treats 150 cm²).
- Applicator: Ifajet spray (choose between 2 diffusers).
- After reconnection of the resected edges of the abdominal wall (via a central point below the navel):
 - Using the spray prepared earlier, spray IFABOND™ from each side of the abdominal cavity (moving the spray to the left then to the right of the navel); if necessary, apply pressure to the abdomen to promote tissue adhesion.
 - Clean the applicator tip with physiological saline solution as required.
 - Apply IFABOND™ to the entire length of the lower edge of the wall in order to achieve haemostasis (by way of polymerisation, the adhesive forms a watertight film which prevents unwanted effusion).

Comment : IFABOND™ remains stable in the applicator throughout the procedure. It is not necessary to use the entire product immediately after preparation. Clean the applicator tip with physiological saline solution as required.

RECAP

- A minute amount of adhesive is sufficient.
- Rapid polymerisation time of less than 30 seconds.
- After 30 seconds, it is safe to touch the bonded surface.
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THE LAPAROSCOPIC PROMONTOFIXATION SURGICAL TECHNIQUE IFABOND™ GLUE FIXATION

Dr Jean-Philippe Estrade (Marseille)

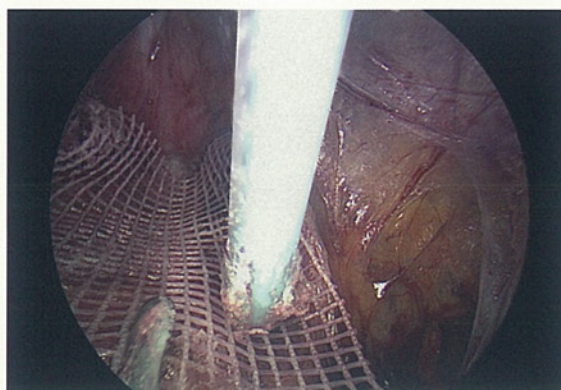
Laparoscopic promontofixation is a surgical procedure which requires standardisation of laparoscopic techniques and involves several operating stages.

These operating stages include: laparoscopy and exposure of the surgical site; dissection of the fascia and prosthetic positioning; prolapse reduction; and, finally, closure of the dissection planes.

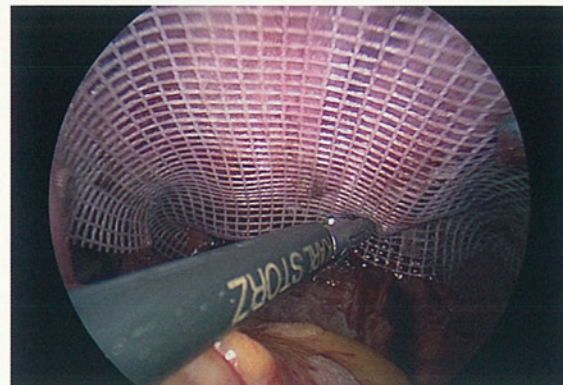
DISSECTION OF THE RECTOVAGINAL WALL

This type of dissection is complete, even up to the levator ani muscles on each side and is then refined in the centre to go as far down to the rectum and its relevant part of the dissection as possible.

A rectovaginal prosthesis is cut, the glue allows a tension-free fixation of the levator ani muscles that is as far lateral as possible in order to avoid taking hold of the lower part of the rectum. A correctly positioned prosthesis is glued to the vagina with the upper edge at the peritoneal opening. The peritoneum is closed by oversewing the peritoneum of the Cul de Sac of Douglas, the prosthesis and the uterosacral ligaments with non-absorbable thread.



Fixing of the mesh



Fixed mesh - test of resistance

VESICOVAGINAL DISSECTION

This type of dissection is interrupted at the first signs of trauma to the collagen fibres preventing full dissection. A prosthesis of the same type is positioned, which is initially fixed to the isthmus with non-absorbable thread. Very fine glue is also applied to the vaginal part, with the prosthesis being fixed after withdrawal of the vaginal valve.

CONCLUSION

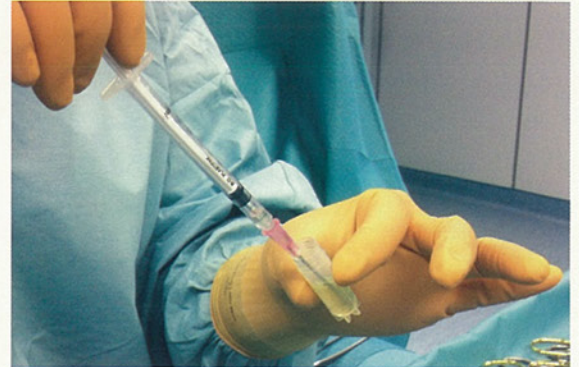
The principle of synthetic glue is based on fractional distillation of the glue, which is distributed drop by drop. Very liquid glue is applied to the prosthesis and makes contact with the vaginal tissue, and polymerisation is visible after a few seconds, guaranteeing fixation. Excess glue forms an amalgam, which prevents good contact between the prosthesis and the vagina. A 1.5 ml vial is sufficient according to 10 procedures performed.

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TREATMENT OF INGUINAL HERNIAS WITH SYNTHETIC GLUE ACCORDING TO LICHTENSTEIN TECHNIQUE (IFABOND™)

Dr. Olivier CAS. Gastroenterological surgery.
Medical Surgical Centre, WALLERSTEIN Foundation, 33740 ARES, FRANCE

The LICHTENSTEIN technique is used in the treatment of inguinal hernias and consists of positioning a *prosthetic reinforcement on the posterior wall of the inguinal canal*. It is a reproducible and reliable technique and does not present visceral or vascular risk, unlike retroperitoneal techniques. It can be performed under local anaesthesia and is perfectly suitable as an outpatient procedure. The reliability of the technique is excellent (1% recurrence within 10 years)⁽¹⁾, but the absence of reinforcement of the entire myopectineal orifice may lead to the secondary development of a femoral hernia. However, the technique is often associated with chronic inguinal pain (30% within 1 year, of which 6% led to disabling discomfort)^(2, 3, 4), the onset of which brought about trauma of the iliohypogastric or ilioinguinal nerves, either from surgery or attachment of the plate in parietal anchoring (suture thread or staples)^(5, 6, 7). Deliberate sectioning of these nerves is recommended by certain authors to prevent this type of pain⁽⁸⁾.



Preparation of the IFABOND™ glue.

The objective of this paper is to underline the advantage of using woven 3D prosthetic reinforcement together with a synthetic cyanoacrylate adhesive (IFABOND™, Fimed SAS) which ensures a quick, reliable and straightforward fixation, without biological or infectious risk to the patient, which also maintains the expandable properties of the reinforcement in keeping with the «tension-free» concept of the technique.

SURGICAL PROCEDURE AND FIXATION

The oval-shaped prosthetic reinforcement has an upper longitudinal strip covered with an external flap.

Three absorbable sutures fix the prosthesis to the pubic tubercle without burdening the periosteum and inguinal ligament. No other suture or staple is used.

The ready-to-use glue is available with the prosthesis as part of a kit or separately. A 1 ml syringe fitted with an 18 G metal needle is filled with the glue.

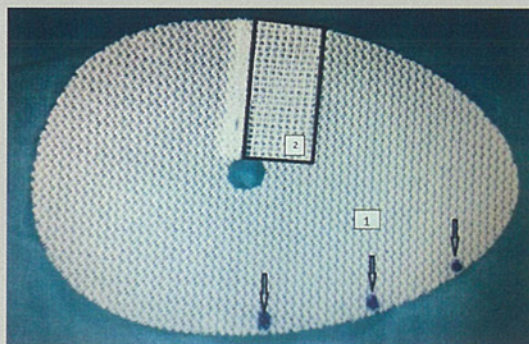
During application, polymerisation occurs in less than one minute, which ensures a reliable fixation. A continuous line of glue is applied along the inguinal ligament and up to the pubic tubercle.

The reinforcement extends inside the pubic insertion of the rectus abdominis muscle to which it is applied with drops of glue.

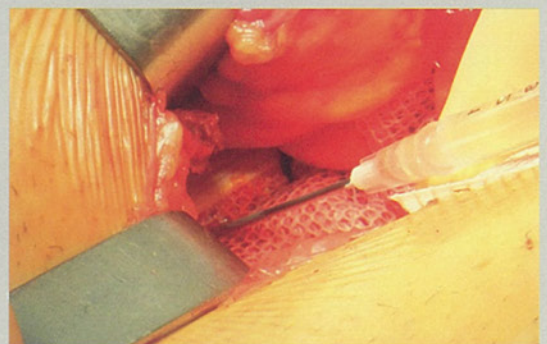
The external edge of the internal flap of tissue is glued in a continuous line to the musculofascial plane and is pushed outside the spermatic cord.

The external flap of tissue is applied to the internal oblique plane with drops of glue.

The flap descends behind the spermatic cord which is, in turn, glued to the free edge of the inguinal ligament, accentuating the staggered path of the spermatic elements in the inguinal canal, between the deep and superficial inguinal ring. The aponeurosis of the external oblique muscle is sutured in front of the spermatic elements.



Pre-split strip
1: anchoring sutures; 2: external flap (for a right inguinal hernia)



Gluing the pubic tubercle and inguinal ligament (right inguinal hernia)

TREATMENT OF INGUINAL HERNIAS WITH SYNTHETIC GLUE ACCORDING TO LICHTENSTEIN TECHNIQUE (IFABOND™)

MATERIAL AND METHOD

From February 2010 to December 2012, open repair surgery was performed for 324 inguinal hernias in 257 patients.

Apart from performing a simple suture on a young female patient, repair was prosthetic in 323 cases (99.7%), of which 311 were LICHTENSTEIN (96.3%) and 12 preperitoneal reinforcement (10 according to RIVES at 3.1%, 2 according to STOPPA at 0.6%). Since March 2011, the procedure has been consistently offered as outpatient surgery, whether uni- or bilateral.

Since then, outpatient surgery has accounted for 82% of cases, amongst which no patients have been fully hospitalised or rehospitalised.

General anaesthesia was performed in 78% of cases and locoregional in 22% of cases.

Infiltration of the muscular wall was carried out under long-acting local anaesthesia (NAROPEINE 7.5 mg) at the end of the procedure (10 ml per surgical site). Patients were allowed to stand up 2 hours after surgery.

Analgaesic and anti-inflammatory treatment was prescribed.

Physical rest was recommended for 10 days.

Return to physical activity, including sport, was allowed after that period.

Systematic review was carried out at 1 month.

RESULTS

Eleven patients (3.4%) presented post-operative pain (paresthesia, funicular or spermatic pain) that was considered disabling, as it was not relieved by the prescribed treatment. Nine regressed at 1 month without affecting their return to sport and professional activities. Two continued beyond a month, of which one case was associated with testicular hypotrophy. One patient presented long-lasting pain in the form of suprapubic hyperalgesia.

One patient undergoing bilateral repair presented acute unilateral pain of the funicular topography with no anomalies on echographic examination, and totally regressed in 10 days.

Return to physical activity appeared significantly easier, which was probably linked to the expandable woven 3D prosthetic reinforcement and to the absence of parietal traction caused by the sutures commonly used to fix the prosthesis to the muscular plane. One young male patient, an elite sportsman, returned to training 10 days after surgery, 2 weeks less than a contralateral repair performed 3 years earlier using the same technique and a non-woven polypropylene reinforcement fixed with absorbable sutures.

CONCLUSION

The combination of an expandable woven prosthesis and fixation along the parietal planes by means of highly purified synthetic glue (IFABOND™) remained in line with the «tension-free» characteristic of inguinal hernia repair in adults according to the LICHTENSTEIN technique.

The IFABOND™ glue allowed a quick and safe fixation, without biological risk to the patient. Glue is a reliable alternative to commonly used sutures and staples.

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IFABOND™ est un dispositif implantable, marqué CE 0499, de classe III, qui par son action adhésive et hémostatique, constitue une alternative ou un complément à l'agrafage, aux sutures ou à tout autre moyen utilisé lors d'interventions chirurgicales ; avant toute utilisation se reporter à la notice accompagnant le produit ; dispositif médical intra GHS, fabriqué en France par la Société FIMED et distribué par la Société VITALITEC INTERNATIONAL.

SURGICAL APPLICATION PROTOCOL FOR IFABOND™ ADHESIVE IN THE REPAIR OF AN INGUINAL HERNIA

DEFINITION

An inguinal hernia, which may be congenital or acquired, is a swelling of the groin area caused by the movement of an area of the peritoneum, which may contain abdominal organs (usually this a part of the small intestine, sometimes the large intestine and, in some cases, the bladder), through the inguinal canal (for an indirect hernia, which is the most common) or straight through the abdominal muscles (for a direct hernia).

OBJECTIVES

Whether the surgical approach is open or laparoscopic, the surgeon must support and secure the tissues using an appropriately sized wall reinforcement implant (made of polypropylene and/or polyester). The wall reinforcement implant is secured to prevent its movement in order to allow the formation of satisfactory fibrous tissue.

METHOD

Required quantity of IFABOND™ adhesive: between 0.5 ml and 1 ml according to the size of the reinforcement.

Applicators:

For the Lichtenstein technique, the short applicator measuring 15 cm, reference MB4, is recommended.

For the laparoscopic approach, the long applicator measuring 37 cm, reference MB3, is recommended.

One of the features of these applicators is that the surgeon can bend the tips to facilitate the precise distribution of the adhesive.

Woven/knitted (mesh) wall reinforcement implant, polypropylene and/or polyester:

Irrespective of the surgical approach, apply a few droplets of adhesive, drop by drop, either by allowing the adhesive droplet to fall onto the implant and then diffuse through the implant mesh, or by applying pressure to the implant using

the applicator until polymerisation of the adhesive takes place. In this case, turn the applicator 90° to free it and repeat the operation.

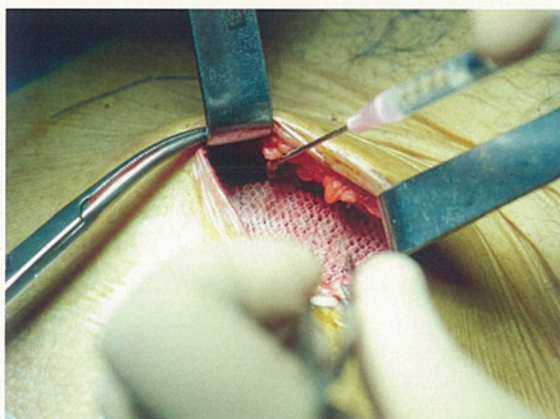
Clean the applicator tip with physiological saline solution as required.

Non-woven/non-knitted (microperforated) polypropylene wall reinforcement implant:

Irrespective of the surgical approach, position the implant and allow it to be impregnated by the surrounding serosa.

Apply a few droplets of adhesive, drop by drop, onto the internal section of the reinforcement which is in contact with the tissue, fold edge of reinforcement towards you, using an instrument, then apply pressure to the external part of the implant.

Turn the applicator 90° to free it and repeat the operation for each droplet of adhesive.



RECAP

- A minute amount of adhesive is sufficient.
- Rapid polymerisation time of less than 30 seconds.
- After 30 seconds, it is safe to touch the bonded surface.
- Up to 2 minutes after application, it is possible to remove the adhesive by spraying it with physiological saline solution.
- After two minutes, the area can be washed.
- Partial resorption at 3 months.
- Degradation of cyanoacrylate at 6 months.

IFABOND™ is a Class III implantable medical device, marked CE 0499, which, by means of its adhesive and haemostatic action, offers an alternative or complement to staples, sutures or any other technique employed during surgery; prior to any application, please read the information leaflet enclosed with the product; intra-GHS medical device, manufactured in France by FIMED and distributed by VITALITEC INTERNATIONAL.