Treatment of inguinal and crural hernias using three-dimensional HI-TEX® Contact prostheses with grips (Manufacturer: TEXTILE HI-TEC, France):
Collection of clinical data on 69 cases

1. Introduction

This data collection was set up within the framework of the HI-TEX® Contact meshes post-marketing surveillance plan. It allows evaluating safety and performances of HI-TEX® Contact meshes used in the treatment of inguinal and crural hernias and to consolidate the pre-marketing clinical data. The data obtained aim to update the clinical evaluation and thus to improve the risk management during the life cycle of the device.

2. Material and methods

2.1. Methodology

It is a non-interventional scientific evaluation subjected and accepted by French independent administrative authority (CNIL) according to the regulations in force. The data recorded by the surgeons were collected by means of a pre-established marketing follow-up form. These data include demographic and peroperative data as well as the results of a follow-up visit. We are reporting on a group of 69 cases operated between November 2009 and August 2010 for an inguinal or crural hernia in 3 sites (Cf. Appendix 1).

2.2. Objectives

The main objective was to evaluate the harmlessness of HI-TEX® Contact meshes in their normal use by the collection of possible complications after operation. The secondary objective is to evaluate the performances of HI-TEX® Contact meshes in their normal use by the collection of the recurrence rate and the clinical evolution of the patient.
2.3. Assessment criteria

The assessment criteria were as follows:

- **Main assessment criterion**
  To assess the level of complication during the immediate postoperative period in a short term follow-up.

- **Secondary assessment criteria**
  To assess the level of recurrence and reoperation during the immediate postoperative period in a short term follow-up.

2.4. Prosthetic device

The HI-TEX® Contact prostheses consist of polyester multifilaments impregnated with aliphatic polyurethane (poly(ether urethane), PEU). These implants have a three-dimensional « honeycomb » knitted structure. Meshes have atraumatic grips on both sides avoiding the use of any fixation system.

One of the references of the range is an anatomical prosthesis including a visual reference mark facilitating his positioning.

Implants are available in several sizes: 8x13, 9x13, 10x15, 15x15 and 15x20 (en cm). The anatomical reference exists either in 11x15cm or 12x16cm.

These implants are used in coelioscopy or laparotomy as abdominal wall reinforcement meshes placed in extraperitoneal position for:
- Inguinal and crural hernias
- Small eventrations
- Recurrences.

The anatomical reference is used under coelioscopy in groin hernia in the adult (inguinal and crural hernias). The prosthesis is introduced by a trocar under endoscopy via the transabdominal preperitoneal approach (TAPP, the most used) or completely extraperitoneal (TEP).

These implants have several advantages:
- Unique porous structure to favor quick tissue ingrowth and colonization.
- Elasticity and excellent multidirectional mechanical properties close to human tissue.
- Impregnation of the implant with poly(ether urethane) to increase the rigidity of prosthesis.
- Fixation free prosthesis with atraumatic « grips » on both sides who allow reducing postoperative pain.

Three references were used for this cases series:
- CONT A+
- CONT 3+
- CONT 3A, anatomical reference
3. ANALYZES

Patients included in this clinical data collection were divided in 2 groups according to the surgical approach used: laparotomy or coelioscopy. The characteristics of each group and the results obtained are presented separately in this report.

The population concerned corresponds to the major population requiring parietal reinforcement for groin hernia or eventration and not having the counter-indications described in the note.

3.1. Laparotomy group = Lichtenstein technique

3.1.1. Patient characteristics

The 39 patients included in laparotomy group are aged between 27 and 81 years old (mean of 55.82 years) and are a majority of men (36 mean and 3 women).

The body mass index (BMI) was calculated for 36 patients:
- 12 patients have a normal stoutness (BMI ranging between 18.5 and 25)
- 19 patients including 3 older than 65 years old are in overweight (BMI ranging between 25 and 30)
- 5 patients including 1 older than 65 years old have a moderate obesity (BMI ranging between 30 and 35).

No patient (33 provided) exerts repeated physical efforts in their daily activity.

Population repartition by age

All included patients had an inguinal hernia: right inguinal hernia in 53.8% (21/39), left inguinal hernia in 43.6% (17/39), and bilateral inguinal hernia in 2.6% (1/39) of cases. For 1 patient, it was a recurrence.
Hernias localization

![Bar chart showing hernias localization]

3.1.2. Surgery

For the majority of cases (97.4%, 37/38 provided) a general anesthesia was practiced. One patient had a locoregional anesthesia.

The intervention’s duration was between 15 to 55 minutes (32.03 minutes on average).

![Bar chart showing intervention duration in minutes]

The patients who had unilateral hernia were treated by the installation of a single prosthesis and the patients who had bilateral hernia were treated by the installation of two prostheses.

For all patients, the reference used was CONT 08-13 A+. The only patient who had a bilateral hernia was treated for one side with 1 prosthesis CONT 08-13 A+ and the other side with mesh in polyester, three-dimensional structure and impregnated of equine collagen (IRPC 3D).

All prostheses implanted had the same size: 8x13 cm.

All the 40 implanted prostheses in this patient group were fixed. According to the Lichtenstein procedure, 3 points of fixation were carried out in 2-0 prolene suture: 1 point to inguinal ligament and 2 points to internal oblique muscle.

The hospitalization duration was between 1 to 6 days (3 days on average).
3.1.3. Postoperative visit
All patients were reviewed during a postoperative visit at 35 days on average (from 20 to 60).

3.2. Coelioscopy group

3.2.1. Patient characteristics
The 30 patients included in the coelioscopy group are aged between 21 and 81 years (mean of 53.3 years) and are a majority of men (26 men and 4 women).
The body mass index (BMI) was calculated for the 30 patients:
- 13 patients have a normal stoutness (BMI ranging between 18.5 and 25)
- 16 patients including 3 older than 65 years old are in overweight (BMI ranging between 25 and 30)
- 1 patient aged of 66 years old presents a moderate obesity (BMI ranging between 30 and 35).
Fourteen (14) patients on 29 exert repeated physical efforts in their daily activity.
Two patients (2/30) were suffering from a crural hernia (bilateral 1/30, left 1/30). The other 26 patients were having either a direct inguinal hernia (9/30 bilateral, right 1/30, left 1/30) or an external oblique inguinal hernia (4/30 bilateral, 5/30 right, 6/30 left). One patient was suffering from a left external oblique scrotal inguinal hernia and one patient from a right direct and external oblique inguinal hernia.

Hernia size varied approximately from 8 to 20 mm for 43 defects:
- 3 hernia size < 10 mm
- 12 hernia size of 10 mm
- 17 hernia size of 15 mm
- 2 hernia size < 20 mm
- 9 hernia size of 20 mm

In any case, it was a recurrence.

3.2.2. Surgery
For the 30 patients, the protheses were introduced by a trocar under endoscopy via extraperitoneal technique (TEP).

A general anesthesia was practiced for all patients.

The intervention duration was between 15 to 50 minutes (32.03 minutes on average).
The patients who had unilateral hernia were treated by the installation of a single prosthesis and patients who had bilateral hernia were treated by the installation of two prostheses.

References CONT D+ and/or G+ of two different sizes were used: 14 implants of size 11x15 cm and 18 implants of size 12x16 cm. The reference CONT 3+ of size 10x15cm was used in 12 cases.

None of the 44 prostheses was fixed. The right direct and external oblique inguinal hernia was treated with a single prosthesis.

The hospitalization duration for 29/30 patients was between 1 to 4 days (1.72 days on average).
3.2.3. Postoperative visit
All patients were reviewed during a postoperative visit at 35.13 days on average (from 22 to 69).

Time of follow-up visit (in days)

4. RESULTS

4.1. Tolerance data

- peroperative

No peroperative complication was recorded in the laparotomy group.
One peroperative complication was recorded in the coelioscopy group: it was a peritoneal breaking.

- postoperative

Laparotomy group (Lichtenstein technique)

Six complications were recorded at the postoperative visit:
- A discrete upstream edema related to the mesh incorporation (2.6%, 1/39)
- A hematoma (2.6%, 1/39).
- Four pain (10.2%, 4/39). Two patients presented pain until the 3rd postoperative week and one patient presented pain of constraint type until the 2nd postoperative week.

Three patients felt a constraint. One patient described a pain of constraint type and another patient described a constraint certainly related with the inflammatory process.
In addition, one patient presented a discrete cicatricial pain at the end of the evening, another patient some normal twinges following efforts of load wearing and a last one brought back some small tugging.

Twenty-nine (29/32) patients went back to a current activity at the postoperative visit.
**Coelioscopy group (TEP)**

**Five (5) complications** were recorded at the postoperative visit. It was:
- 2 testicular syndromes (6.67%, 2/30)
- 3 seromas (10%, 3/30)

One of the 2 testicular syndromes occurred following a sexual relation. This complication was accompanied with pain evaluated at 2 on a visual analogue scale (VAS).

The second testicular syndrome was of moderate intensity during 21 days. This same patient presented also a seroma whose regression was almost complete at 31 days postoperative. This patient reported a much moderated residual pain evaluated at 1 on the visual analogue scale (VAS). He had a voluminous scrotal inguinal hernia and presented banal after-effects of surgery.

Regarding the 2 other seroma, only one was associated to a pain also much moderated, evaluated at 1 on the visual analogue scale (VAS).

Most patients described small postoperative constraints during generally 4 to 5 days. These constraints were related to the surgery and the inflammatory reaction induced by the implant. No patient has constraint or discomfort related to the prosthesis.

Only one patient on 29 does not regain a current activity at the postoperative visit. The time of return for 24/30 is between 4 to 15 days (8.42 days on average).

![Time of return to current activity (in days)](chart)

**4.2. Efficacy data**

No reoperation and no recurrences were recorded on the 2 groups studied.
4.3. Device quality data

The quality of the device was assessed, based on several criteria in the coelioscopy group:

**Handling/comfort of use of the prosthesis:** it was deemed very satisfactory in 86.2% (25/29) and satisfactory in 13.8% (4/29) of cases.

**Flexibility:** it was deemed very satisfactory in 86.2% (25/29) and satisfactory in 13.8% (4/29) of cases.

**Facility of introduction into a trocar:** it was deemed middle in 86.2% (25/29) and satisfactory in 13.8% (4/29) of cases.

**Facility of installation and of positioning:** it was deemed very satisfactory in 89.7% (26/29) and satisfactory in 10.3% (3/29) of cases.

**Shape memory of implant after his installation:** it was deemed very satisfactory in 89.7% (26/29) and satisfactory in 10.3% (3/29) of cases.

**Adhesion to tissue:** it was deemed middle in 86.2% (25/29) and satisfactory in 13.8% (4/29) of cases.

**Facility of repositioning:** it was deemed very satisfactory in 89.7% (26/29) and satisfactory in 10.3% (3/29) of cases.

**Shape of the implant:** it was deemed middle in 86.2% (25/29) and satisfactory in 13.8% (4/29) of cases.

**Comfort of the patient:** it was deemed middle in 86.2% (25/29) and satisfactory in 13.8% (4/29) of cases.

**Labeling:** it was deemed clear in all cases (29/29).

**Packaging:** it was deemed appropriate and secure in all cases (29/29).

**Operating instructions:** it was deemed comprehensible in all cases (29/29).

5. Conclusion

Eleven (11) complications were reported in this study. No complication implicates the safety of the patients or the benefit-risk ratio. All these complications are awaited complication for treatment of inguinal and crural hernia and the sequela are simple.

In particular, several current studies show a high rate of chronic pain with the Lichtenstein technique (1, 2), 5% to 45% according to the studies. This rate higher than in laparoscopy can be explained by the nervous terminations catches in the suture and by the chronic irritation of the ilioinguinal and iliohypogastric nerves in contact with the prosthesis (1).

Regarding seroma, this observation is frequently recorded after inguinal hernia surgery. It corresponds to a tissular secretion filling of the cavity occupied by the hernia. This inguinal collection could appear immediately after the surgery. In the majority of cases, a spontaneous resorption is achieved following few weeks.

No recurrence neither reoperation were recorded in this post-marketing follow-up in a short-term period on HI-TEX® Contact prostheses. This result, very promising, will have to be confirmed by a longer follow-up period.

Finally, it’s important to note that no infection or intolerance were recorded.
The results obtained in the group of patients operated by the Lichtenstein technique confirm safety and part of performances of the range HI-TEX® Contact. Indeed, these results don’t allow concluding on the effectiveness of grips because all prostheses were fixed according to the recommendation of the Lichtenstein technique. In addition, the Lichtenstein technique being associated to a high rate of chronic pain, it is difficult to interpret the rate of pain evaluated at 10.2%. Nevertheless, no constraint or discomfort directly related to the prosthesis was recorded. Moreover the pain recorded is of short duration for 3 patients and not considered as a chronic pain (3).

The complete safety and performance assessment of the range HI-TEX® Contact has been made thanks to the data analysis obtained following the use of the implants in coelioscopy without fixation. Indeed, the effectiveness of the grips could be highlighted by the absence of recurrence and pain directly related to the prosthesis or the presence of grips.

(1) « Etat actuel du traitement de la hernie inguinale », Edouard Pélissier e-mémoires de l’Académie Nationale de Chirurgie, 2009, 8 (2) : 31-33


APPENDIX 1

LIST OF OPERATING CENTERS

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<thead>
<tr>
<th>Surgeon</th>
<th>Address</th>
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<tr>
<td>Dr LONJON</td>
<td>Clinique Gale de Marignane</td>
<td>General and visceral surgery</td>
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<tr>
<td></td>
<td>Avenue Général R. Salan</td>
<td></td>
</tr>
<tr>
<td></td>
<td>13700 MARIGNANE</td>
<td></td>
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<tr>
<td>Dr MAGNE</td>
<td>Clinique Tivoli</td>
<td>Parietal digestive surgery</td>
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<tr>
<td></td>
<td>91,rue de Rivière</td>
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<td></td>
<td>33000 BORDEAUX</td>
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<tr>
<td>Dr BERTOLASO</td>
<td>Clinique du Pont de Chaume</td>
<td>Visceral surgery</td>
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<tr>
<td></td>
<td>330, avenue Marcel Unal</td>
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