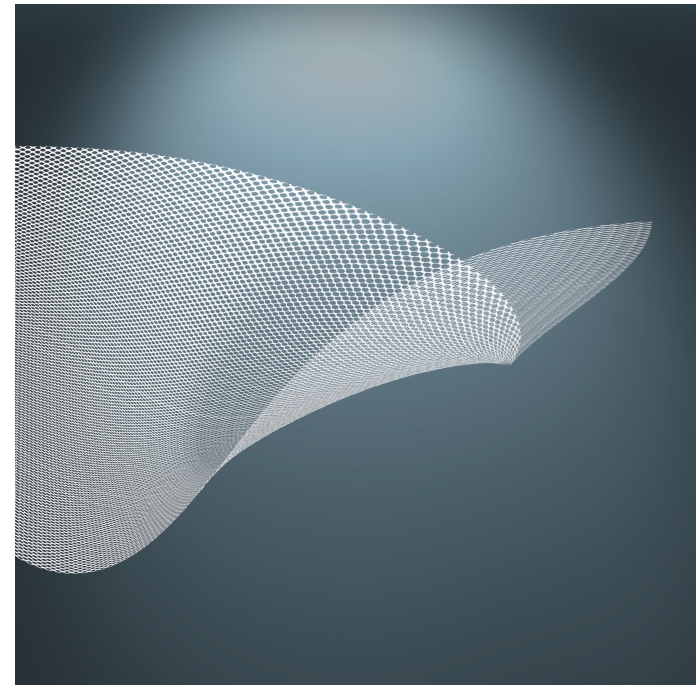


4D Mesh Flat et 4D Mesh Anatomique

- T DUGUE
- A DABROWSKI
- Clinique de St Omer
- MESH 16 Juin 2017

4DMESH[®] STUDY Introduction.

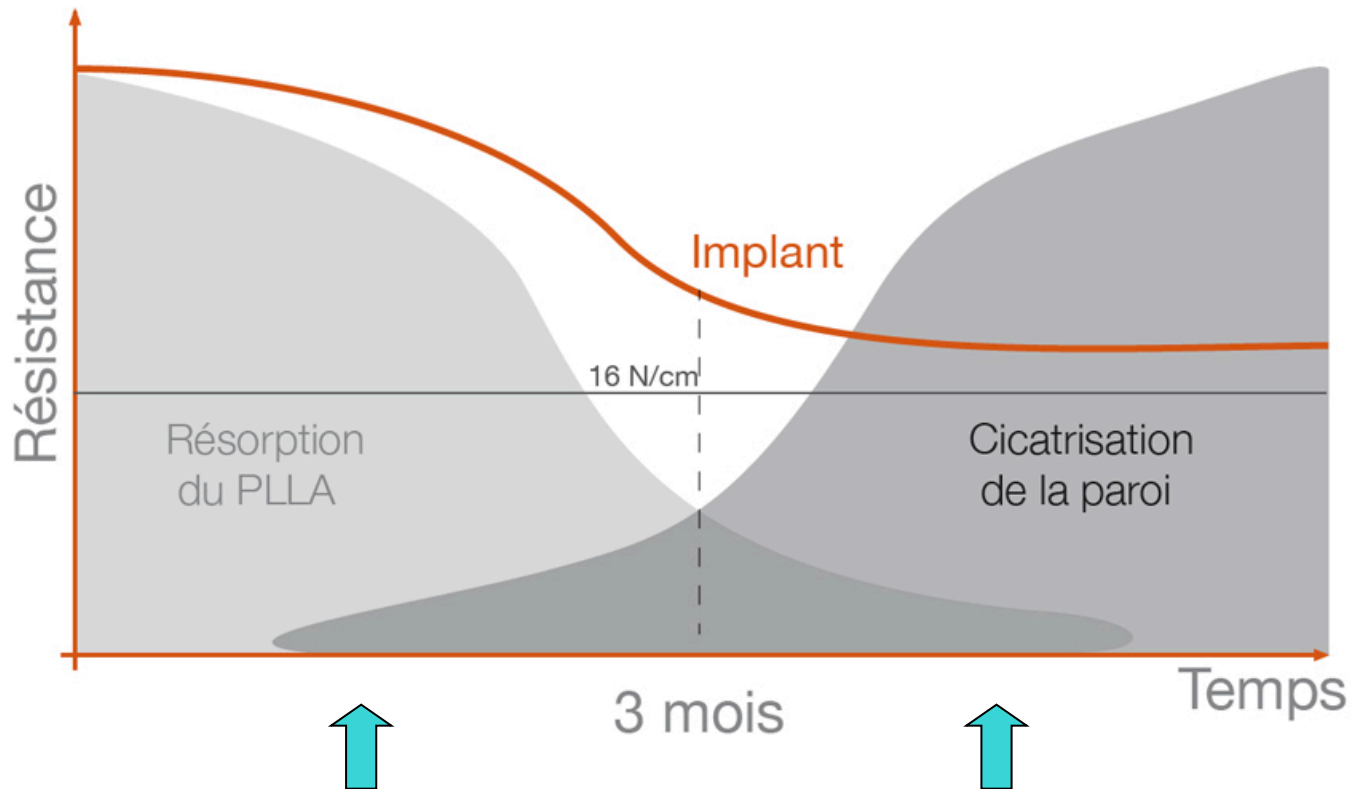


Caractéristiques

- Polypropylène (25%)
 - Monofilament
 - Léger
- PLLA (75%)
- Taux de résorption = 75%



Evolution de la résistance de l'implant



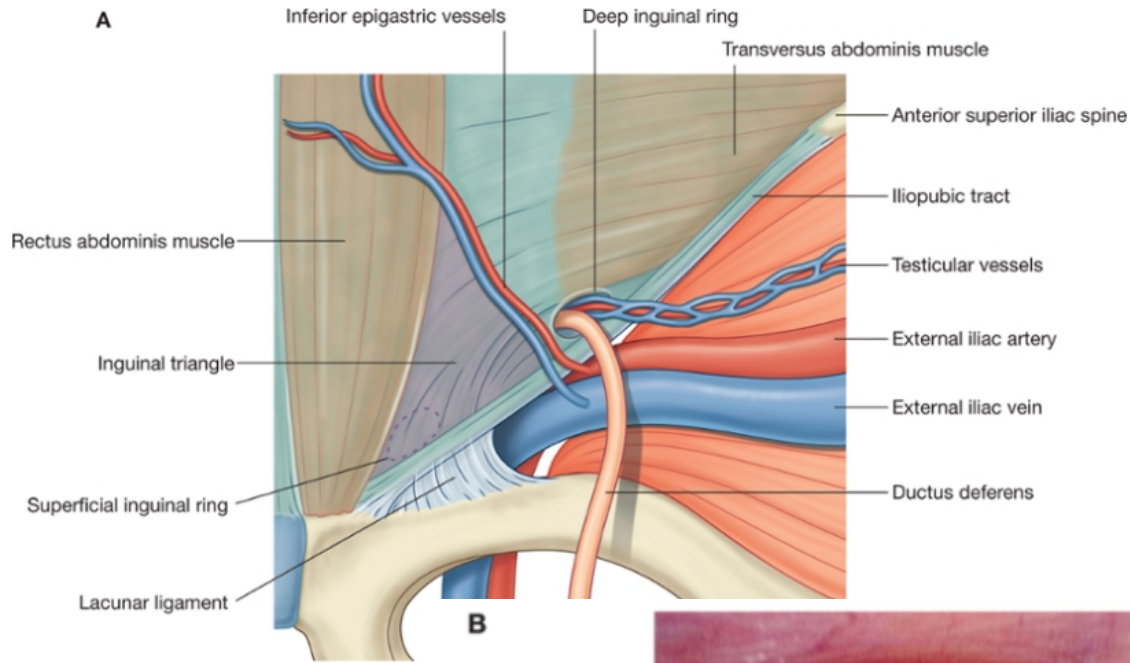
Très haute résistance de l'implant : limite les récives, **sécurité**

Résistance supérieure aux 16N/cm requis.
La fibrose prend le relais.
Implant adapté à la paroi abdominale : **confort** du patient

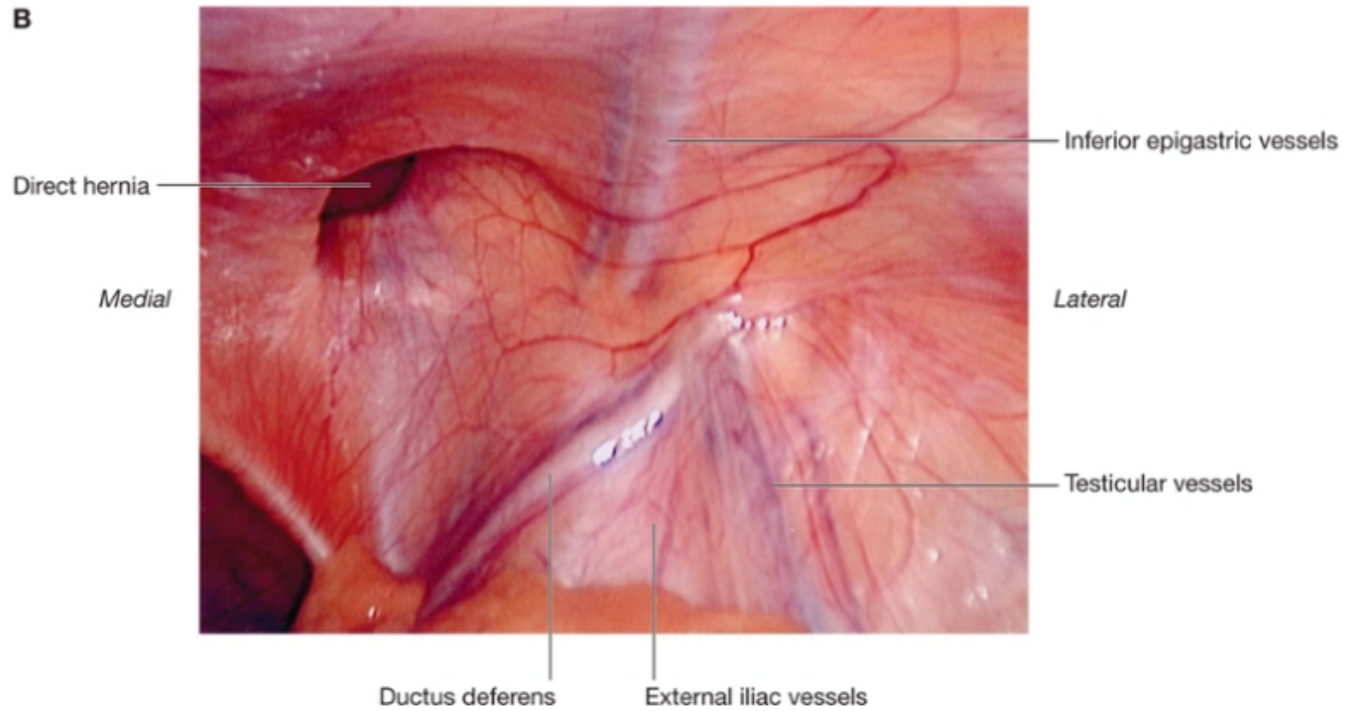
Avantages

Allégé (30g/m ²)	↘ réaction inflammatoire
Macroporeux	↘ risque de seromes
Résistance (>16N/cm)	Renfort adéquat
PLLA	Fibres de collagène // et non “cross-linked”
Elasticité	Flexible et confortable
Monofilament	↘ risques d'infection
SR	Concept évolutif
Shrinkage	↘ récives (rétraction des bords)

FILM TD



By laparoscopy (TAPP/TEP)
-> 3D anatomy



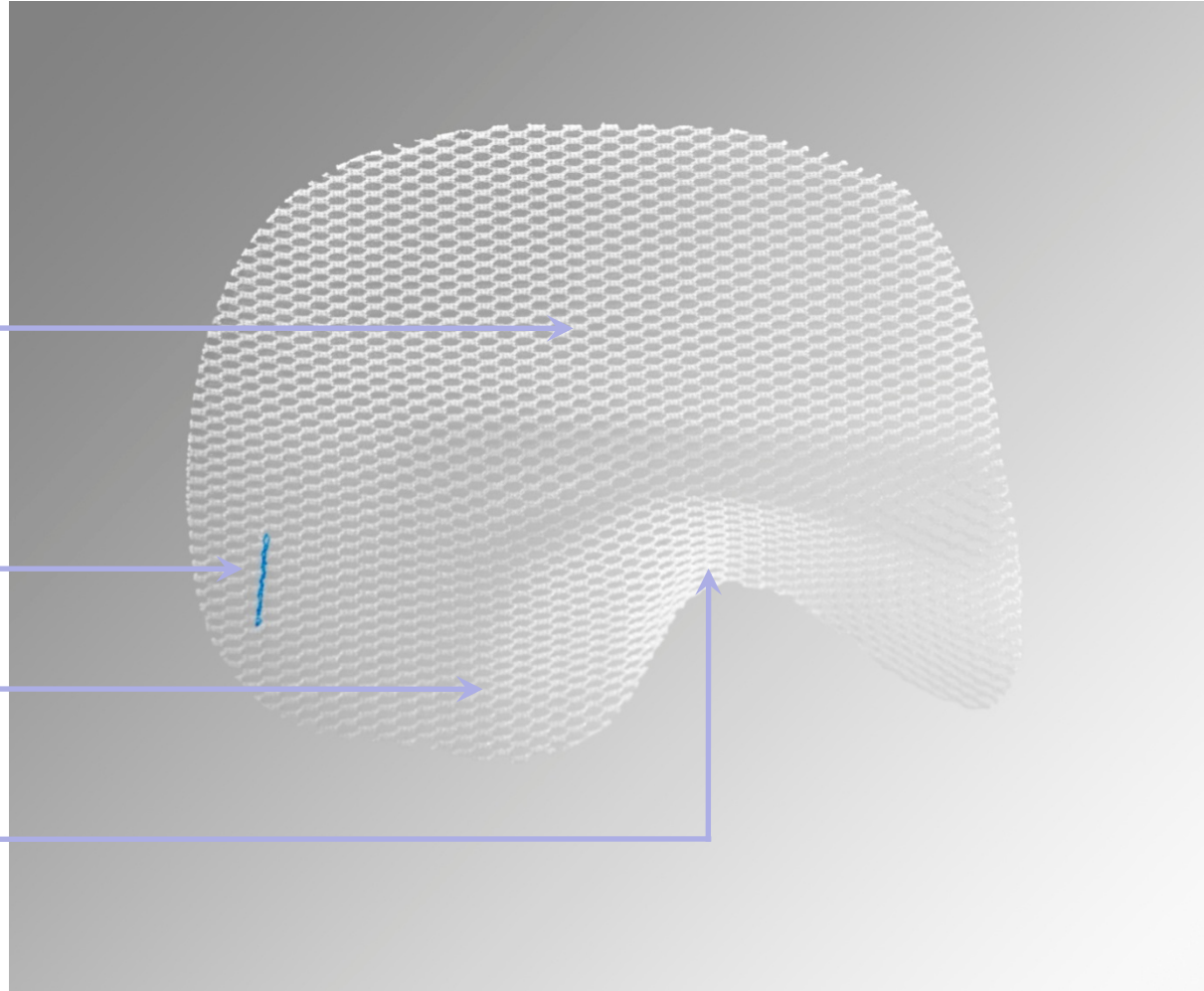
Hydrophilic material (PLLA)
with gentle **gripping effect**

Large flat surface
for wide cover of
direct and indirect
Hernia sites

Landmark for Pubis

Sufficient material
to cover Cooper's ligament

Wave designed to
hover the elements
of the spermatic
cord





Treatment of the inguinal
hernia with a 4DLap

Blue landmark for the pubis

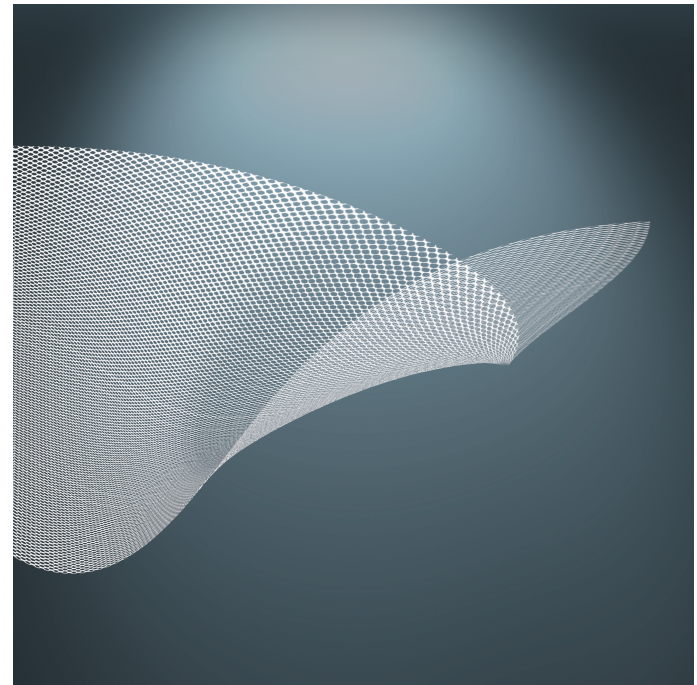
4DLap is in place.
Closure of the peritoneum
Fixation, maybe...

Designed to solve laparoscopic challenges

- 4DLap is a **cut-able** 3D mesh: adaptable to surgeon's shape needs
- 4DLap is easily rolled in a tube shape from top to bottom and passed through a 10mm trocar. The rolled-up mesh is then simply unrolled over the inguinal anatomy
- The material of the mesh is **hydrophilic** (75% PLLA) which is ideal during placement as the mesh holds by itself to the abdominal wall - **gentle gripping effect**
- The 3D wave design which conforms to the inguinal anatomy and the medial landmark allow **quick and precise** positioning
- 4DLap is **macroporous and transparent**: it is easy to see the anatomy through the mesh: avoids any risks of fixation incident

Gripping effect, easy orientation, adaptable: key elements to help the surgeon and save their time

4DMESH[®] STUDY



STUDY DESIGN

Observational, national, multicentre, non-comparative with descriptive purpose

Main objective: **Assess the incidence and the severity of chronic postoperative pain at 1 year** in patients who have a 4DMESH® implant, in current conditions of use.

Primary endpoint:

Early and late postoperative chronic pain at 1 month and 1 year:
Visual Analogical Scale (VAS)

Secondary objectives: Assess the effectiveness and the safety of the device estimating the per and postoperative complication rate.

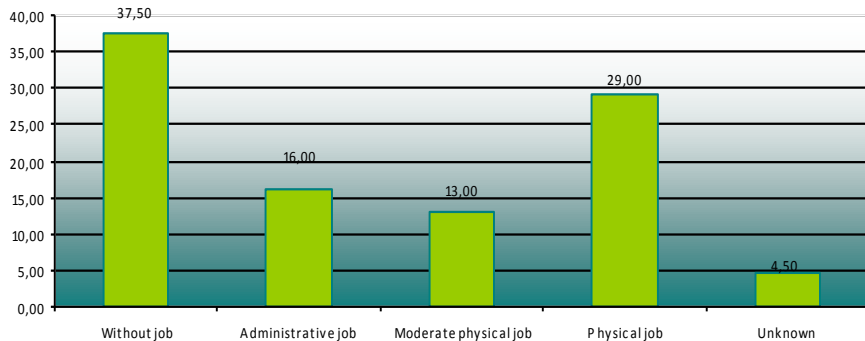
Secondary endpoints:

Recurrences and postoperative complications at 1 month and 1 year,
The operative time,
Prosthesis handling,
Recovery of physical, sports and professional activities.

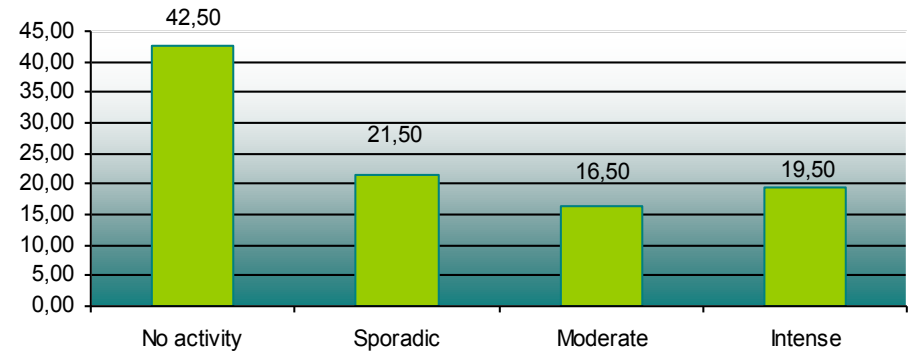
STUDY POPULATION

- o 200 patients included and followed between 12 and 24 months
- o Men 95%, women 5%
- o Average age: 57.6 years (min. 20, max. 91)
- o BMI between 19.33 kg/m^2 and 35.18 kg/m^2
- o Never smoked, stopped or occasional smoker 85.9%, daily smoker 14.1%

Professional activities (%)

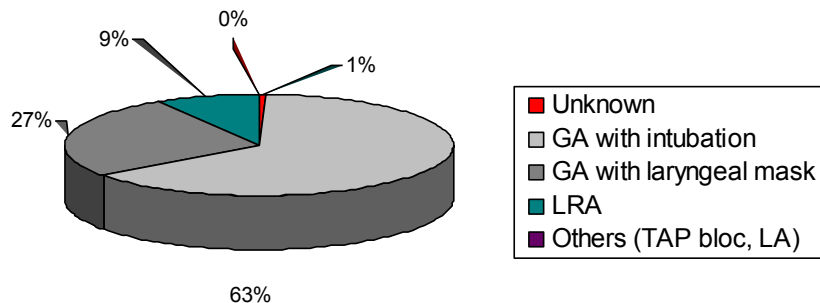


Sports activities (%)

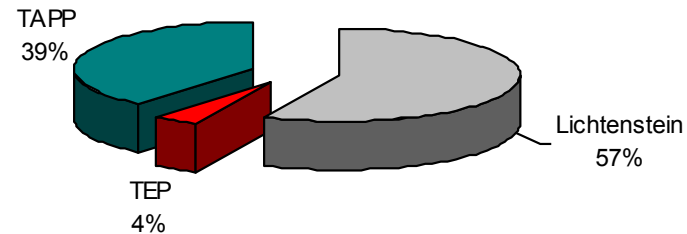


SURGERY

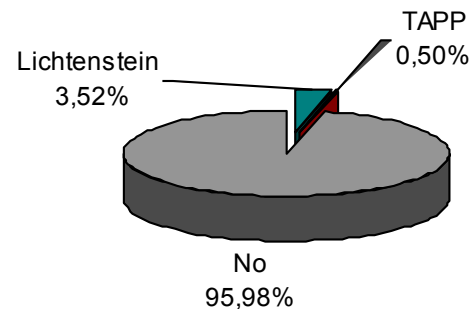
Anesthesia



surgical technique

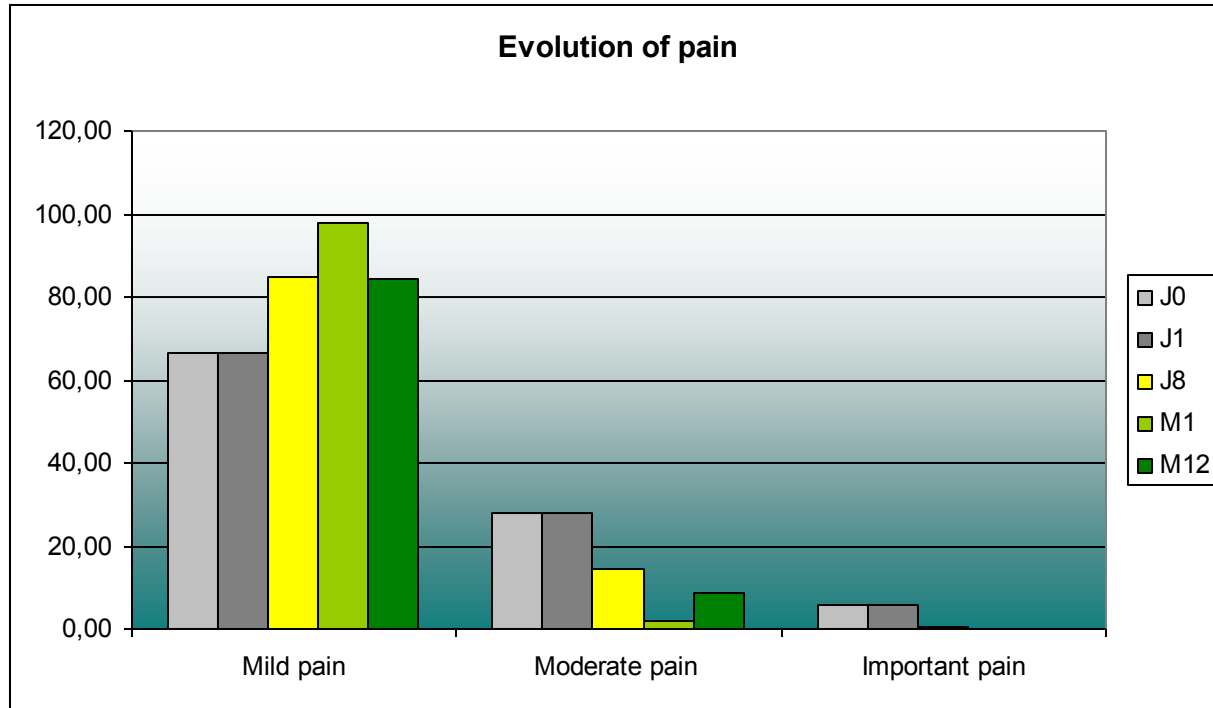


Conversion to another surgery



Associated surgical step (Lichtenstein)	%
Resected hernia sac	45,69
Non resected hernia sac	54,31
Transversalis Fascia approximation	8,66

POSTOPERATIVE FOLLOW-UP



STUDY POPULATION

604 patients opérés avec la 4 DMesh entre 12 juin 13 et 14 mars 17 (45 mois d'inclusion)

Suivi à 1 mois : consultation de routine

Suivi à 3 mois : consultation si douleurs persistantes

Suivi à 24 mois : consultation téléphonique

Suivi à 60 mois : consultation téléphonique

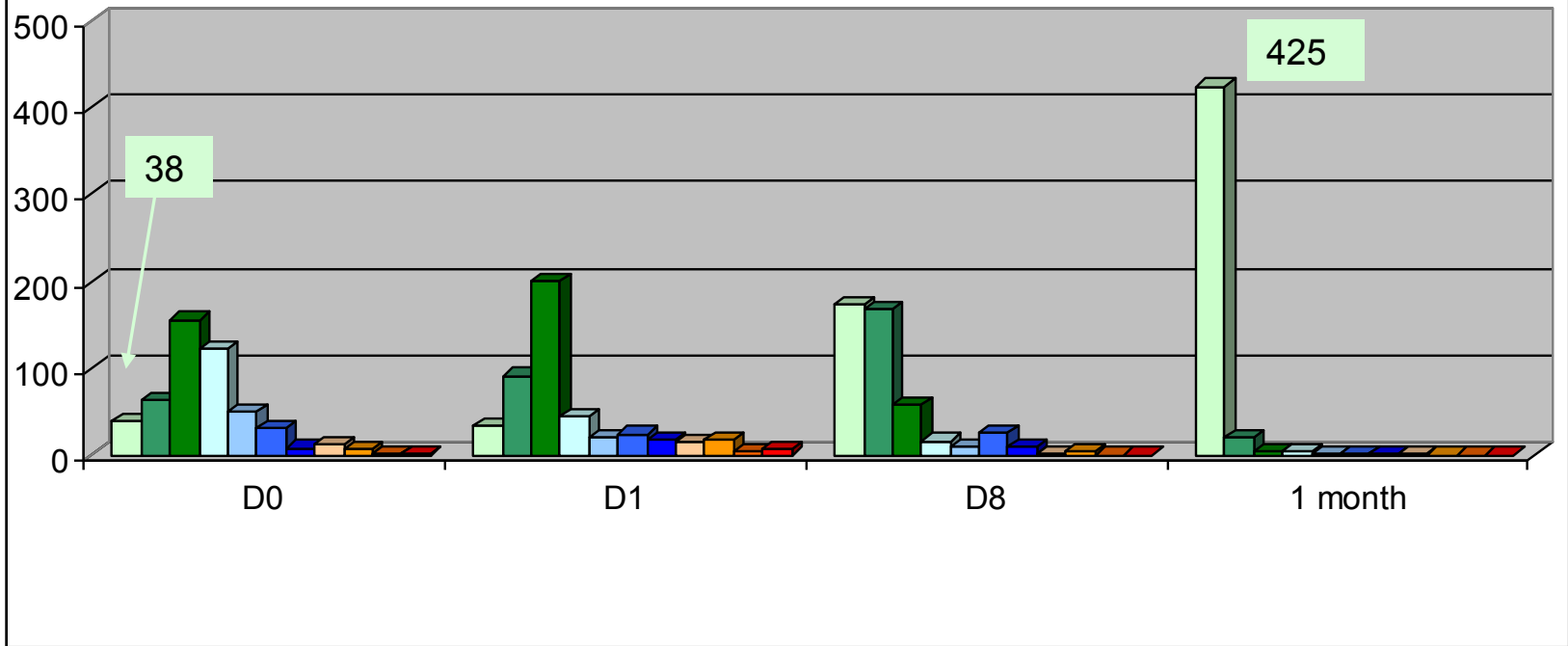
90% des patients à 1 mois de suivi (464 patients)

70% des patients à 2 ans de suivi (408 patients)

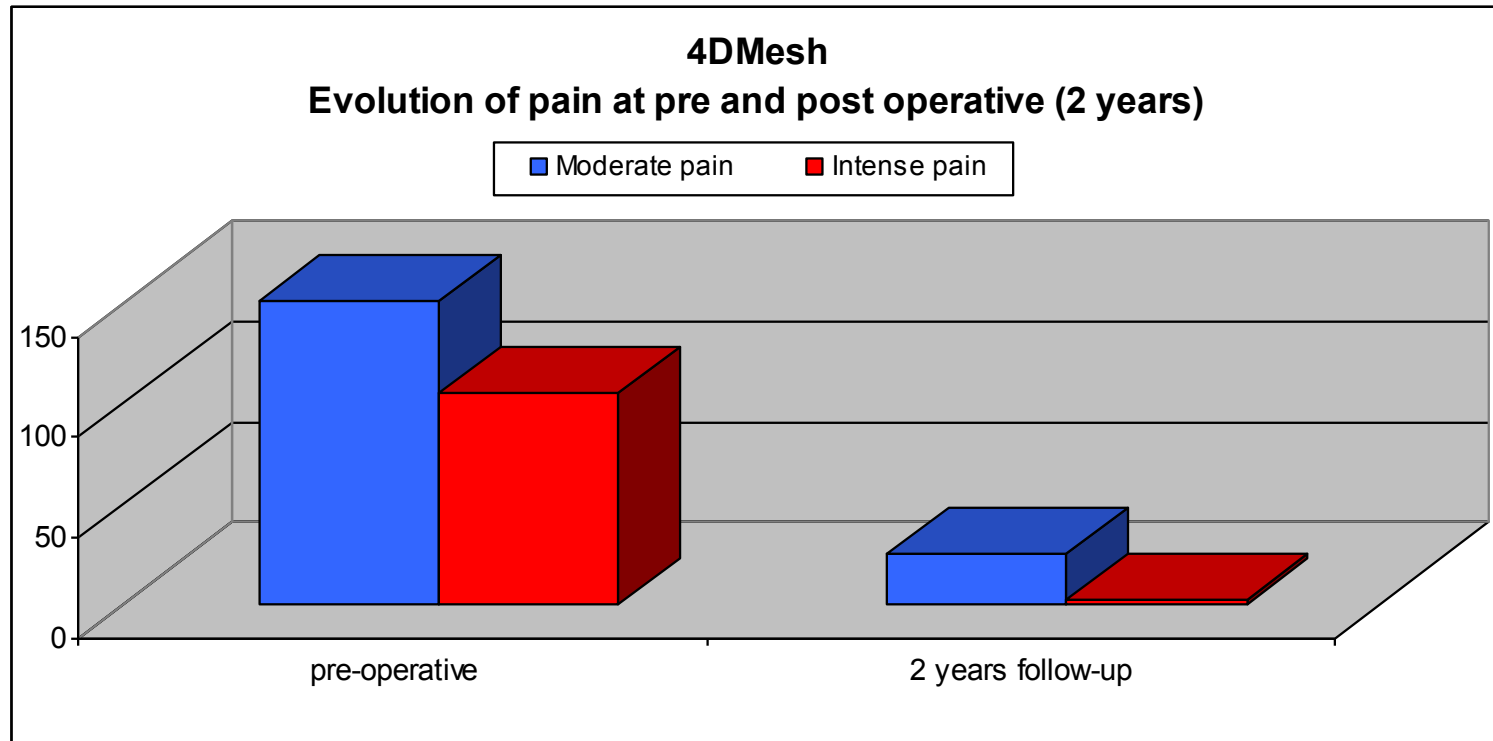
0% des patients à 5 ans de suivi

POSTOPERATIVE FOLLOW-UP

4Dmesh
Evolution of pain from surgery to 1 month follow-up
VAS scores



POSTOPERATIVE FOLLOW-UP



Moderate pain: >3 et ≤ 6

Intense pain >6

POSTOPERATIVE FOLLOW-UP



One reoperation (for constant pain)

No recurrence.

POSTOPERATIVE FOLLOW-UP

Patient's feeling

