COUSIN SURGERY

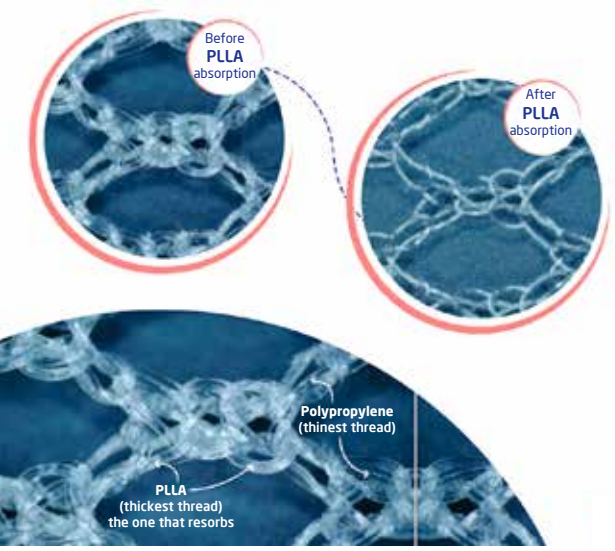
SFCP-CH
Société Française de Chirurgie Pariétale
Club Hernie

CLUB HERNIE REGISTRY

Efficacy and safety of the 4DVENTRAL® for the extraperitoneal treatment and reinforcement of ventral hernias. Interim report of data collected to date in Club Hernie registry for 4DVENTRAL®

STUDY DESIGN

Prospective study with a retrospective recruitment, longitudinal and multicentric register conducted by general and / or digestive surgeons focusing on the treatment of ventral hernias by using the 4DVENTRAL® .



OBJECTIVE OF THE REGISTRY

TO ASSESS THE PERFORMANCE OF THE DEVICE

- Improvement in the patient's quality of life (pain, discomfort, impact on daily quality of life)
- Recurrence (between 1, 2 and 5 years after surgery)

TO ASSESS THE SAFETY OF THE DEVICE

- Intraoperative and post-operative complications (between 1, 2 and 5 years after surgery)
- Number of reinterventions

FOLLOW UP

- 190 patients with clinically diagnosed ventral hernias who underwent surgery using the semi-resorbable 4DVENTRAL® implant were included
- Mean follow-up was realized at 2.4 ± 1.1 years (minimum 0.6 years, maximum 5.4 years)

RESULTS

1 Pre-operative data

DEMOGRAPHIC CHARACTERISTICS

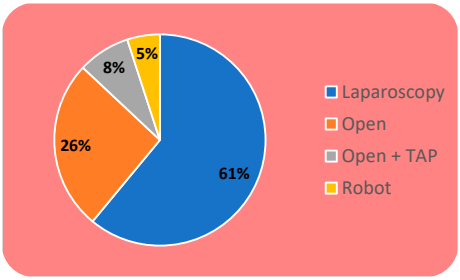
Age (mean ±SD)	63.5 ± 14.1 years
Gender	95 males (51%), 93 females (49%)
BMI (mean ± SD)	28.3 ± 5 kg/m²

HERNIA CHARACTERISTICS

Type of hernia	N	%
Primary hernia	80	42
Incisional	107	53
Missing data	3	2
TOTAL	**190**	**100**

2 Per-operative data

SURGICAL TECHNIQUE



Laparoscopic technique was used for 61% of patients

FIXATION

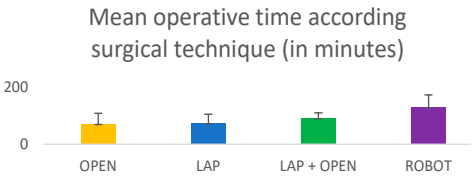
26 % of 4DVENTRAL® were not fixed

28% were fixed with adhesive

24% with separate absorbable stitches

22% other

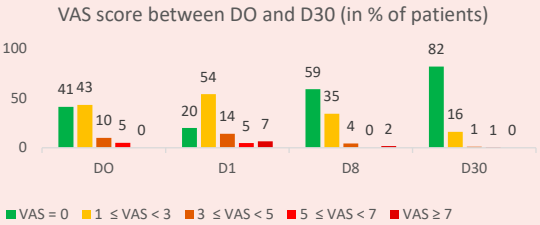
OPERATIVE TIME



Global mean time of surgery (all techniques) was 80 ± 39 minutes (minimum 24 minutes, maximum 210 minutes)

3 Post-operative outcomes

PAIN



Patient's general pain was improved at D1, D8 and one month after surgery

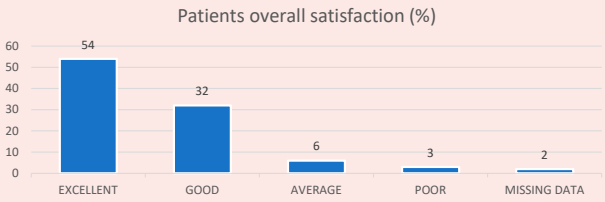
82% no pain D30

RECURRENCE & ADVERSE EVENTS

0% adverse events due to the mesh

0% recurrence at 2,4 years

PATIENT'S SATISFACTION



86% satisfaction

CONCLUSION

This present study highlights good safety and performance after 4DVENTRAL® implantation for the treatment of ventral hernias.
Given the low rate of per-operative or post-operative complications, the absence of major complications, the benefit-risk ratio seems favourable.