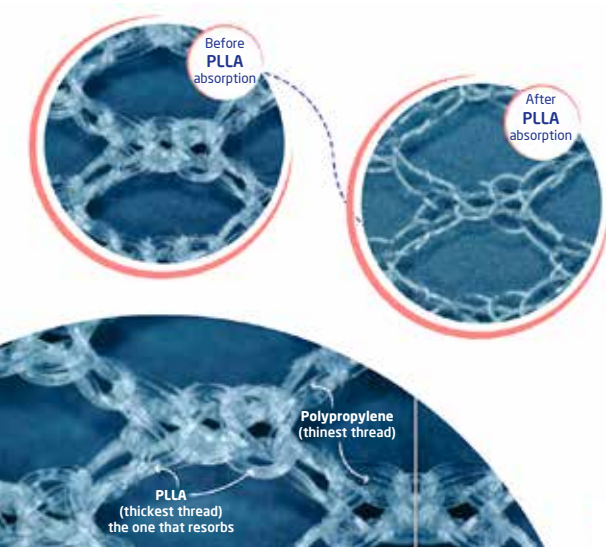


CLUB HERNIE REGISTRY

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 \pm SD)	63.5 \pm 14.1 years
Gender	95 males (51%), 93 females (49%)
BMI (mean \pm SD)	28.3 \pm 5 kg/m ²

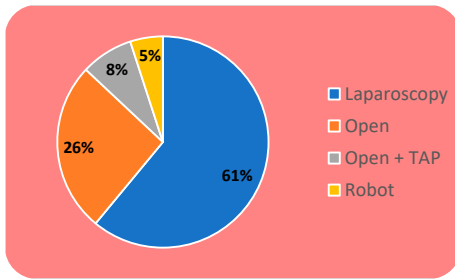
HERNIA CHARACTERISTICS

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

2

Per-operative data

SURGICAL TECHNIQUE

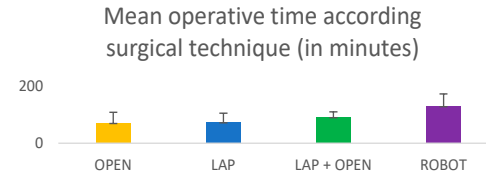


Laparoscopic technique was used for 61% of patients

FIXATION

26 % of 4DVENTRAL® were not fixed
 28% were fixed with adhesive
 24% with separate absorbable stitches
 22% other

OPERATIVE TIME

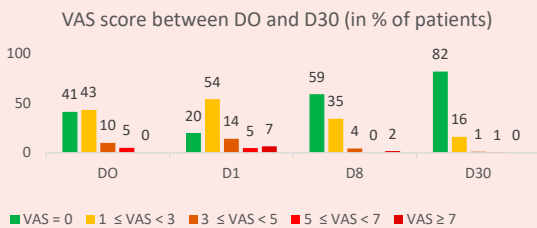


Global mean time of surgery (all techniques) was 80 ± 39 minutes (minimum 24 minutes, maximum 210 minutes)

3

Post-operative outcomes

PAIN



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

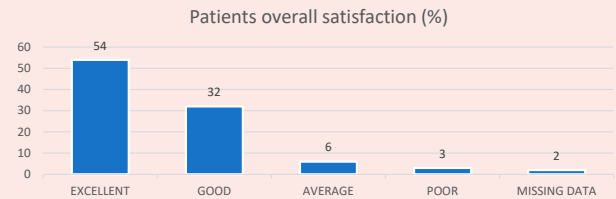
82%
no pain
D30

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.

4DVENTRAL® is a class III medical device manufactured by COUSIN BIOTECH S.A.S. The CE conformity has been carried out by the notified body SGS Belgium NV (CE1639). The management system of COUSIN BIOTECH S.A.S is certified for compliance with ISO 13485 standard. Please read carefully the instructions for use before using the device.

The IFU is available electronically at: <https://www.cousin-biotech.com/en/implant-notice>

Reference : ABV4DVGB01- 05/01/24

Non contractual pictures and texts. Specifications likely to be modified without notice.

Cousin Biotech S.A.S au capital de : 340 656 € • 398 460 261 RCS Lille • N°TVA FR 34 398 460 261

Cousin Biotech is the legal manufacturer of the medical devices proposed by Cousin Surgery.



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