

## Ventralax – A cost effective IPOM (IntraPeritoneal Onlay Mesh) repair for small umbilical hernias by open method

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### ABSTRACT

Background: Both the best surgical technique and the best equipment to employ in this treatment are still up for discussion when it comes to ventral hernias. Owing to the lower cost/efficiency ratio, the open technique is more likely to be used for small size faults. However, laparoscopy yields superior results for medium-sized problems while being more expensive. This study examines the outcomes of a straightforward and successful laparoscopic mesh repair method for small- to medium-sized ventral lesions utilizing the Ventralax® ST patch

### Method:

Between January 1, 2023 and January 31, 2024, 30 patients with ventral primary nonobstructive abdominal wall defects (up to 3 cm) treated laparoscopically using the intraperitoneal onlay mesh repair technique with Ventralax® patch (22 patients) and Ventralax® ST patch (8 patients). Results were prospectively analyzed based on postoperative complications, postoperative pain, recurrent hernia, and quality of life.

### Results:

The technique was used in 30 patients with umbilical hernia (64.5%), patients with juxta-umbilical hernia (19.3%), and patients with epigastric hernia (16.1%). Out of these, 12 patients had nonreducible (nonobstructive) hernia. The median operating time was 55 minutes (range 40–80 min). Minor complications were recorded in 16.1%. The mean hospitalization time was 1.24 days (range 1–2). After a median follow-up of 39 months (range 20–81), the recurrence rate was 11.1% and nil ( $p = 0.010$ ), and other complaints were recorded in 11.1% and 3.3% of patients ( $p = 0.293$ ), for Ventralax® patch and Ventralax® ST patch, respectively

**Keywords:** *Hernia, Symptoms, Surgery, laparoscopy, Patients*

### 1. INTRODUCTION

A ventral hernia affects about 25% of people worldwide.<sup>1</sup> In the United States (US), ventral hernias account for around one-third of all hernia repairs, primary hernias for two-thirds, and incisional hernias for one-third.<sup>2</sup> Even though the majority of

minor abdominal wall defects don't cause any symptoms, surgery is frequently necessary to prevent immediate, potentially fatal consequences including acute incarceration or strangulation. The expense of therapy is extremely high; in the US alone, ventral hernia repairs are estimated to cost 3.5 billion dollars a year.<sup>3</sup> Mesh reinforcement is currently a regularly used procedure for hernia repair. It is strongly advised for hernias greater than 4 cm and recommended for repairs of hernias larger than 2 cm.

Owing to the lower cost/efficiency ratio, the open technique is more likely to be used for small size faults. However, laparoscopy yields superior results for medium-sized problems while being more expensive. Regarding the kind of mesh to use, how to separate components, and how to handle complicated patients who have certain kinds of hernias, opinions differ.<sup>4</sup>

A variety of prosthetic devices that are intended to strengthen the abdominal wall and avoid adhesions to the intraperitoneal viscera have been made available in recent years for the treatment of small and medium abdominal wall abnormalities.<sup>5</sup> These types of meshes, called Ventralex® and Ventralex ST (Bard®, Davol Inc., CR Bard Inc., RI, USA), are intended for intra-abdominal insertion in an open approach.<sup>6,7</sup> It is challenging, if not impossible, to place the mesh behind the defect in an open technique without making an incision larger than the deficiency. In contrast, the laparoscopic procedure makes this implantation much simpler and requires fewer incisions, a shorter hospital stay for postoperative problems, and a lower rate of recurrence.<sup>8</sup>

This paper describes our experience using Ventralex® to repair minor and medium-sized ventral lesions with a straightforward and efficient laparoscopic method.

## 2. METHODOLOGY

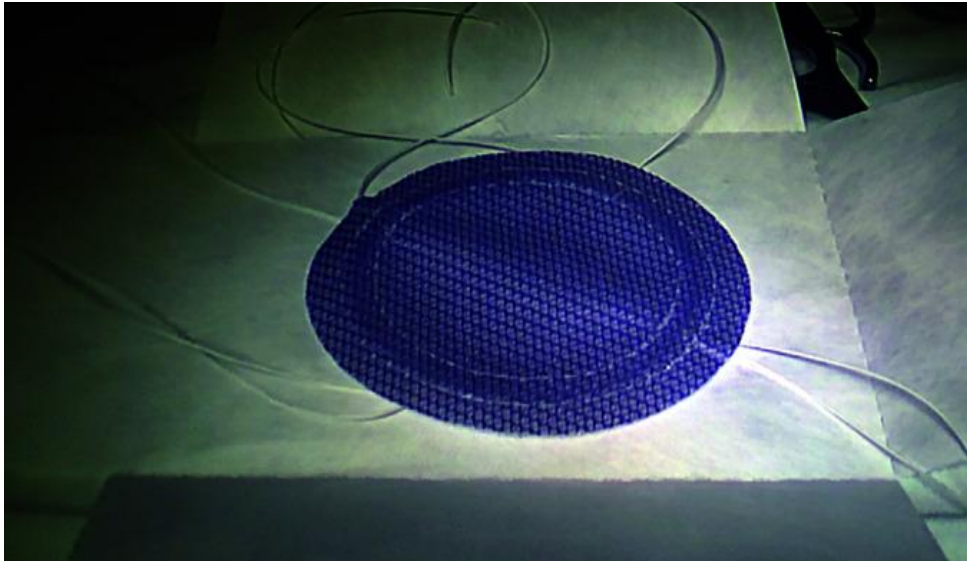
Between January 1, 2023 and January 31, 2024, 30 patients underwent surgery for small and medium (up to 3 cm) primary ventral hernias, using intraperitoneal onlay mesh repair (IPOM) with Ventralex® or Ventralex Sepra Technology (ST) (Bard®, Davol Inc., CR Bard Inc., RI, USA), performed by a single surgeon, were enrolled in this prospective study.

The inclusion criteria were: (1) ventral (umbilical, paraumbilical, or epigastric) nonobstructed primary hernia; (2) parietal defect up to 3 cm; (3) operated using IPOM technique; (4) with Ventralex® or Ventralex Sepra Technology (ST) (Bard®, Davol Inc., CR Bard Inc., RI, USA). The exclusion criteria were: (1) additional concomitant surgery; (2) patients with relative contraindications to elective repair, such as: severe obesity (body mass index [BMI] over 35 kg/m<sup>2</sup>), poorly controlled diabetes mellitus (HbA1c  $\geq$  8%);<sup>4</sup> (3) severe comorbidities, such as: chronic pulmonary diseases, ascites, and advanced neoplasms; (4) repeated prior surgery.

Immediate postoperative follow-up consisted in visits at 10, 30, and 90 days, respectively. The short-term results of the procedure were assessed based on postoperative complications, pain, recurrent hernia, and the quality of life. The visits included satisfaction level, recurrence of symptoms, the scale of postoperative pain. Chronic pain was evaluated using the Carolinas Comfort Scale and Visual Analog Scale. For long-term analysis, a survey was conducted based on the referral of recurrent hernia, chronic pain, and quality of life; 25 patients were lost during follow-up (13 patients with Ventralex® patch, and 12 patients with Ventralex® ST patch)

## 3. MATERIAL

For ventral hernia repair we used Ventralex® or Ventralex Sepra Technology (ST)® (Bard®, Davol Inc., CR Bard Inc., RI, USA) mesh, designed for intra-abdominal placement in open approach (**Figure 1**). We used patch sizes either 6.4 cm or 8 cm. The largest size currently available on the market (8 cm) limited the indication for defects to up to 3 cm, as the remaining 5 cm were necessary to insure optimal overlapping. The sides of these meshes have different purposes: the side that comes in contact with the abdominal wall is made up of polypropylene, for improving tissue integration, while the other (the visceral side) is made up of expanded polytetrafluoroethylene (ePTFE) (Ventralex®) or hydrogel barrier (Ventralex ST®), resorbable within 30 days, for minimizing tissue attachment and to protect the viscera during the healing process.<sup>6,7</sup> For laparoscopic approach, the two strips provided for open surgery (used for fixing the edges of the defect) were removed, as they were no longer necessary for mesh placement.



**Figure 1: Local examination**



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Hosp. No: CARE093566241  
Ref by: OP

**ULTRASONOGRAPHY OF ABDOMEN**

**Liver** : The liver is normal in size (12.5 centimeter). The parenchymal echotexture is increased. No evidence of any focal lesion. The intra hepatic vasculature appears normal. There is no evidence of intra or extra hepatic biliary ductal dilatation.

**Gall Bladder** : The Gall Bladder is partially distended.

**Spleen** : The spleen is normal in size (9.4 centimeter) and echotexture.

**Pancreas** : Head appears normal, body and tail obscured by bowel gas

**Right Kidney** : The Right kidney measures: 9.1 x 4.5 centimeter.  
Right kidney appears normal in size and echotexture.  
No evidence of pelvicaliectasis or calculus.

**Left Kidney** : The Left kidney measures: 10.2 x 4.8 centimeter.  
Left kidney appears normal in size and echotexture.  
No evidence of pelvicaliectasis or calculus.

**Bladder** : The Urinary Bladder is partially distended

**Prostate** : The Prostate is normal in size (Volume – 19 cubic centimeter) and echotexture. The capsule is intact.

A defect of size 1cm seen in the paraumbilical region with protrusion of omental fat as its content.

**IMPRESSION:**

- Grade I Fatty liver
- Paraumbilical hernia

for  
  
**DR. K.S. RAMPRASATH, MBBS, DNB.,**

**Note:**

This report is only a professional opinion based on the real time image findings and not a diagnosis by itself. It has to be correlated and interpreted with clinical and other investigation findings. Review scan is advised, if this ultrasound opinion and other clinical findings / reports don't correlate.

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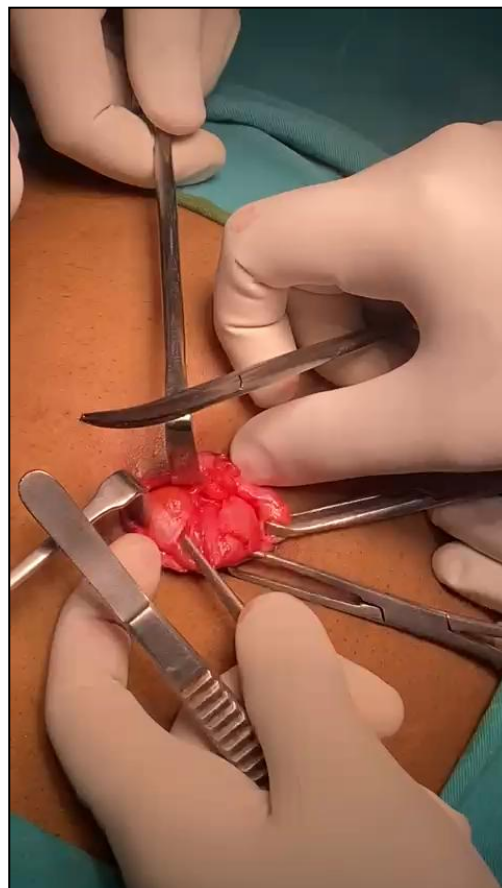
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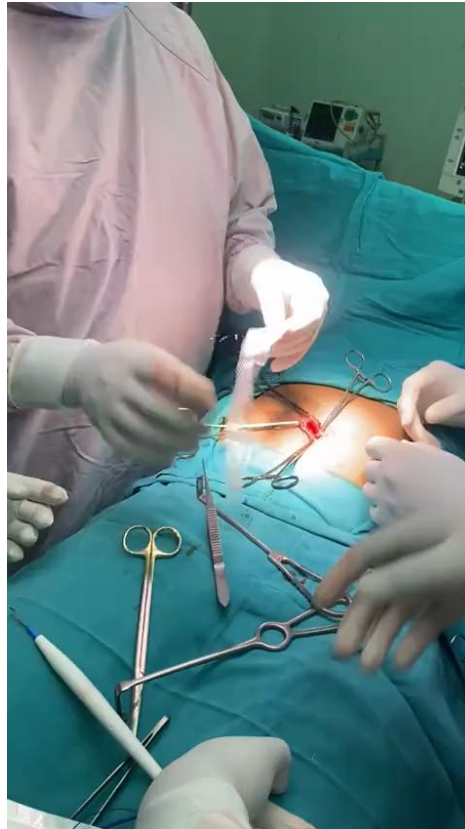


**Figure 3: Intraoperative**



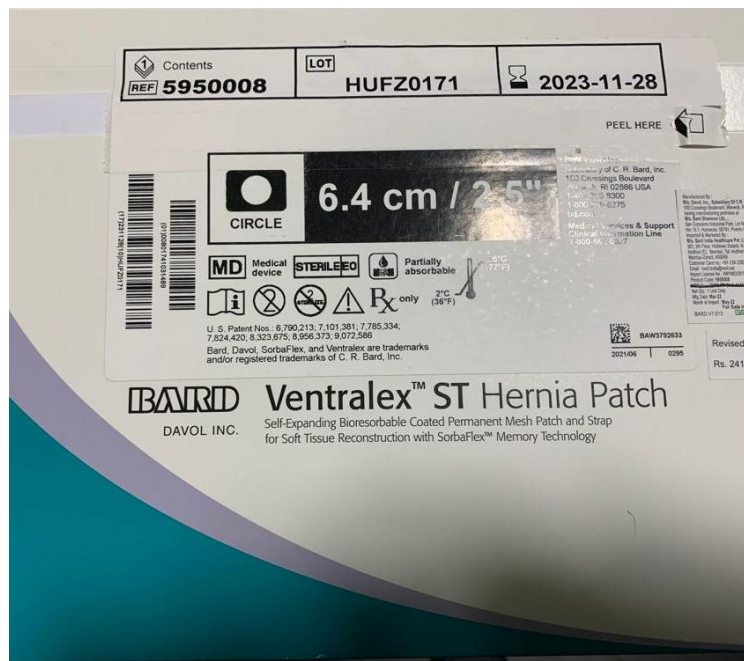
**Figure 4: intraoperative**





**Figure 5: Intraoperative**

Ventralex® ST patch is a composite self-expanding and bioresorbable patch. It has a polypropylene (PP) side that remains in contact with the abdominal wall, encouraging tissue growth and integration. The visceral side is made of expanded polytetrafluoroethylene (ePTFE), facing the intraperitoneal space and providing a permanent barrier against adhesion formation.



**Figure 6: Ventralex patch**



Figure 7: Gross and Histology findings at 1, 8, 16 and 32 weeks.

### SorbaFlex™ Memory Technology

Polydioxanone (PDO) monofilament is commonly used in other well-known surgical products (e.g. suture). Unique in its flexibility and tensile strength, it facilitates patch insertion and proper placement. Absorption via hydrolysis is essentially complete in 24-32 weeks.

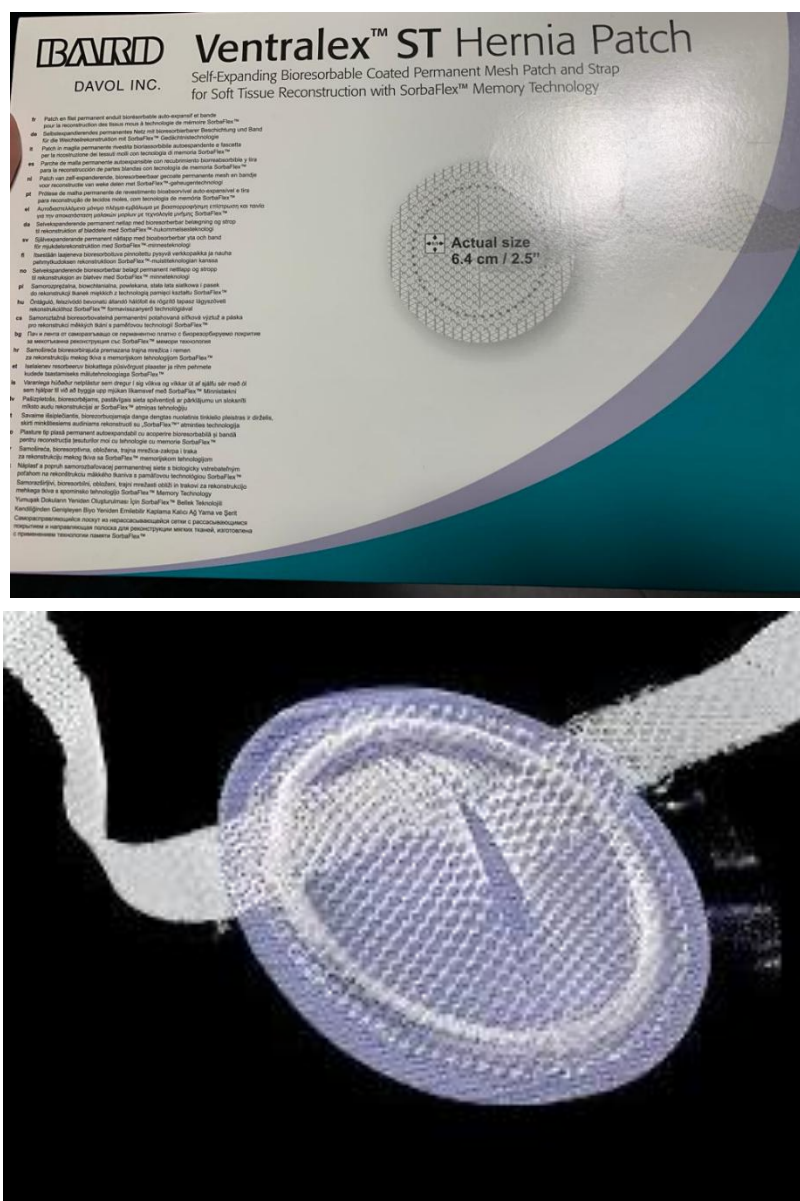


Figure 8, 9: ST Hernial Patch

Ventral hernia is classified as epigastric, paraumbilical, umbilical, and or Spigelian hernias. The most common ventral



abdominal wall hernia is the umbilical hernia

Simple tension Hernial Patch

#### Advantages

- Simple tension free intra abdominal mesh repair
- Minimal dissection and fixation required
- Small size defect less than 2cm hernias are often successfully closed
- Duration of surgery is less than 45mins
- Post operative hospital stay is less than 48 hours
- Reduced chance of post operative complications
- Negligible recurrence
- Cost effective technique compared to laparoscopic IPOM
- Three sizes available for coverage of larger defects to smaller trocarsite closures.
- RESULTS:
- The age of the patients in our study ranged from 25 to 78 years (median 53), with a male/female ratio of 35/58 and a BMI ranging 18.5 – 43.7 kg/m<sup>2</sup> (median 28.7). Only one patient with a BMI above 35 kg/m<sup>2</sup> (43.7 kg/m<sup>2</sup>) was included in the study group because of significant abdominal pain. All other similar patients were advised to lose weight prior to surgery.
- The topography of the ventral hernia was mainly umbilical (60 cases; 64.5%). Patients with parietal defects up to 3 cm were included in our study; 15.1% (14 patients) with defect ≤ 1 cm, 84.9% (79 patients) with defect between 1–3 cm ([Figure 4](#)).



**Figure 4.**

- Postoperative results at 10 days in a 52-year old male after 3 cm umbilical hernia repair with Ventralex® ST patch. Trocar and suture sites are visible.
- The main comorbidity was hypertension (28 cases; 30.1%). Regarding the mesh size, 79 (84.95%) of large size (8 cm), 14 patches (15.05%) were medium size (6.4 cm), and no small size patches were used. The median operating time was 55 minutes (range 40–80 min). The mean hospitalization time was 1.24 days (ranging 1–2) ([Table 1](#)).



**Table 1. Clinical, Pathological, and Operative Data of the Patients**

Clinical Characteristics	N=30(Percent)
Topography of ventral hernia	
Umbilical	(64.5%)
Juxta-umbilical	(19.3%)
Epigastric	(16.1%)
Hernia reduction	
Reducible	(76.3%)
Non-reducible, nonobstructed	(23.7%)
Associated pathologies	
Well-controlled diabetes	(7.52%)
Hypertension	(30.1%)
Chronic constipation	(25.8%)

Postoperative complications were recorded in 15 cases (16.1%): 6 cases with seroma (necessitating evacuation in 2 cases, while the other were treated conservatively), 9 cases with superficial hematoma (treated conservatively). There were no late postoperative complications.

The postoperative pain was directly proportional to the degree of satisfaction. At the 90 day visit, no patient referred any pain or discomfort related to the procedure. There was no significant difference in terms of scale of patient satisfaction and the scale of pain were correlated with the location of the abdominal wall defect or with the size of the patch used. (Table 2).

**Table 2. Visual Analog Scale Score and Carolinas Comfort Scale Score on the 10-30-90 Postoperative Day Visits**

	Visit 1–day 10	Visit 2–day 30	Visit 3–day 90
Visual Analog Scale Score	N = 30		
No pain, number (%)	(76.3%)	(88.1%)	(97.8%)
Mild pain, number (%)	(8.6%)	(9.7%)	(2.1%)
Moderate pain, number (%)	(15.1%)	(2.1%)	0
Severe pain, number (%)	0	0	0
Carolinas Comfort Scale Score	N = 30		
Very satisfied, number (%)	(73.1%)	(78.5%)	(98.9%)
Satisfied, number (%)	(22.6%)	(19.3%)	(1.1%)
Neutral, number (%)	(4.3%)	(2.15%)	0
Unsatisfied, number (%)	0	0	0

After a median follow-up of 39 months (range 20–81), the recurrence rate was 11.1% (1 out of 9 patients) and nil ( $p = 0.010$ ), for Ventralex® patch and Ventralex® ST patch, respectively. Other complaints were recorded in 11.1% and 3.3% of patients ( $p = 0.293$ ), for Ventralex® patch and Ventralex® ST patch.

#### 4. DISCUSSION

In terms of cost/efficiency ratio, the laparoscopic approach outperforms the open one due to faster postoperative recovery, fewer complications, shorter hospital stays, and faster socio professional reintegration; this is true even though the laparoscopic instruments are more expensive.<sup>14</sup>

Even small abdominal wall defects can be safely and effectively repaired with laparoscopic surgery, which has several advantages over open surgery. These advantages include full peritoneal cavity exploration, improved visualization of the abdominal wall defect and identification of other potential wall defects, complete dissection of the properitoneal tissue, mesh mounting under direct vision, intraperitoneal mesh placement, and a lower rate of postoperative complications—particularly in obese patients or patients with other medical conditions. The European Hernia Society and the American Hernia Society's treatment guidelines for umbilical and epigastric hernias were used to categorize ventral hernias into three groups: small (0–1 cm), medium (more than 1 cm up to 4 cm), and large (above 4 cm).<sup>11</sup> Since the greatest Ventralex size (8 cm) required at least 5 cm of mesh to overlap and prevent hernia recurrence, our surgery was restricted to defects up to 3 cm. We employed special mesh for faults larger than 3 cm (not included in this study), which is only available in larger diameters, starting at 11 cm. They do, however, come at a higher cost and require tackers, which entail an elevated risk of postoperative pain and extra expenses.

Initially, we used the Ventralex® patch in open approach, in 41 patients, as it was designed. However, also using the laparoscopic approach for hernia repair with dedicated meshes, we have come to the conclusion that Ventralex® is more appropriate for laparoscopic than open approach. The IPOM repair with ePTFE mesh, with transfascial fixation is safer and more economical, especially in obese patients.<sup>16,17</sup> In 22 patients, we used the Ventralex® patch, that was significantly more difficult to maneuver during surgery when compared to Ventralex® ST, often resulting in suboptimal placement. Indeed, the long-term recurrence rate for Ventralex® patch was 11.1%, significantly higher when compared to Ventralex® ST patch ( $p = 0.010$ ). Therefore, we recommend the use Ventralex® ST instead of Ventralex® patch. However, studies on larger study groups are needed in order to confirm our findings.

When transfascially passed threads are used instead of tackers, many writers claim a decreased incidence of late complications or recurrences.<sup>16, 17</sup> Mesh fixing alone is enough (IPOM) for defects smaller than 1 cm, however attaching the defect suture to the mesh fixing (IPOM plus) appears to be the least recurrent method for bigger flaws.<sup>21</sup> In reference to pain following surgery, research indicates that 1–6% of patients experience discomfort at the transfascial transit of threads.<sup>22</sup> In our study, not a single patient experienced any pain or discomfort following the treatment at the 90-day visit.

#### 5. CONCLUSION

In summary, Ventralex® ST patch is a more straightforward and economical option for laparoscopic intraperitoneal onlay mesh repair of small to medium-sized ventral hernias than normal laparoscopic patches, and it yields better outcomes than Ventralex® patch.

#### Conflicts of Interest

The authors declare that they have no conflicts of interest

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