

Parietex™ Composite Ventral Patch for primary and incisional hernia repair

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Key words

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Abstract

Backgrounds: Ventral hernia repair with a preformed device is a frequent intervention, but few reports exist with Parietex™ Composite Ventral Patch. The aim was to evaluate the results of this mesh with the open intraperitoneal onlay mesh (open IPOM) technique.

Methods: Observational retrospective single institution study of all consecutive patients intervened for ventral or incisional hernia with a diameter inferior to 4 cm, from January 2013 to June 2020. The surgical repair was performed according to the open IPOM technique with Parietex™ Composite Ventral Patch.

Results: A total of 146 patients were intervened: 61.6% with umbilical hernias, 8.2% with epigastric hernias, 26.7% with trocar incisional hernias, and 3.4% with other incisional hernias.

The global recurrence rate was 7.5% (11/146). Specifically, it was 7.8% in umbilical hernias, 0% in epigastric hernias, 7.7% in trocar incisional hernias and 20% (1/5) in other incisional hernias. The median time for recurrence was 14 months (IQR: 4.4–18.7). The median indirect follow-up was 36.9 months (IQR: 27.2–49.6), and the median presental follow-up was 17.4 months (IQR: 6.5–27.3).

Conclusion: The open IPOM technique with a preformed patch offered satisfactory results for the treatment of ventral and incisional hernias.

Introduction

Primary ventral hernias have an elevated prevalence. Umbilical hernias affect around 2% of the adult population,¹ and represent between 6% and 14% of all the abdominal wall hernias,² while epigastric hernias signify from 1.6% to 3.6% of the total.³ Incisional hernias after abdominal wall closure have an equally high prevalence and occur in 12.8% (range: 0%–35.6%) of the intervened patients.⁴ Minimally invasive surgery has been linked to a reduction in the risk of incisional hernia thanks to a decreased size of the incisions. Nevertheless, port site hernias have an incidence of 1.7% (range: 0%–5.4%),⁵ with the umbilical port remaining as the most frequent location for trocar incisional hernia.⁶ Moreover, with a prospective evaluation and an adequate follow-up, they can be diagnosed in up to 27.6% of the patients intervened.⁶

The treatment of umbilical hernias with a prosthetic mesh reduces hernia recurrence compared to hernia suture, without increasing the complication rates of the surgical wound.⁷ The treatment currently recommended by the guidelines of the European Hernia Society (EHS) is the placement of a preperitoneal flat mesh in the preperitoneal space.⁸ Another highly described technique is the placement of a preformed composite mesh in the intra-abdominal or preperitoneal space.^{9–11} These prostheses are self-expandable, which facilitates its placement through the hernia defect.⁹ The recurrence rate described with these meshes stands between 1.7%¹² and 15.7%.¹³ Furthermore, they present a dual layer of antiadherent material to prevent the formation of adhesions in cases of intraabdominal placement.¹⁴ However, some cases have been reported of late complications due to severe bowel adhesions and bowel migration of the mesh.¹⁴

The different prosthetic devices available in the market demonstrate varied biological properties.¹⁵ Furthermore, not all devices are currently supported by a similar number of publications describing their results. Ventralex™ Hernia Patch (BD, Franklin Lakes, NJ, USA) has many articles on its favour,^{11,13,16–22} closely followed by Proceed® Ventral Patch (Ethicon, Johnson & Johnson, New Brunswick, NJ, USA).^{10,12,23–25} In opposition, the use of C-QUR V-Patch™ (Maquet Gentige Group, Germany) has only been described in two observational articles^{26,27} and Parietex™ Composite Ventral Patch (Medtronic, Minneapolis, MN, USA) has only been evaluated in one prospective single-arm trial.⁹

The aim of this study was to evaluate the results of the treatment of primary ventral hernia and incisional hernia with the open intra-peritoneal onlay mesh (open IPOM) technique using Parietex™ Composite Ventral Patch. The secondary outcome was to determine the needed follow-up for recurrence diagnosis.

Methods

This article was written according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies.²⁸

Study design

Retrospective observational study.

Setting and participants

We included all consecutive patients who underwent the surgical repair of an umbilical, epigastric or incisional hernia through the open IPOM technique using the preformed mesh Parietex™ Composite Ventral Patch (Medtronic, Minneapolis, MN, USA). Patients were intervened from 1st January 2013 to 30th June 2020 in the Abdominal Wall Surgery Unit of a tertiary referral centre.

Included patients had an umbilical or epigastric hernia with a defect inferior to 4 cm, classified as small or medium according to the EHS classification,²⁹ or an incisional hernia with a defect inferior to 4 cm, classified as W1 according to the EHS classification.²⁹ All patients were older than 18 years.

Patients that had lateral abdominal wall hernias, recurrent hernias, with a defect ≥ 4 cm, with closure of the hernia defect and with lack of follow-up were excluded.

The study was approved by the Institutional Clinical Research Ethics Committee (CEIC-2711). All patients signed the informed consent for the surgical intervention. Permission was obtained to waive the informed consent for the study.

Intervention

The open IPOM technique was initiated with the dissection and reduction of the hernia sac. The hernia defect was measured intra-operatively. A 4.6 cm Parietex™ Composite Ventral Patch was used for hernias with a defect of less than 2 cm. Hernias with a defect between 2 and 3 cm received the 6.6 cm mesh, and the 8.6 cm mesh was used preferably for hernias with a defect from 3 to 4 cm. However, the ultimate decision of the mesh size

depended on the surgeons' preference. The mesh was predominantly placed intraabdominal, although there were cases of preperitoneal placement. The prosthesis was fixed to the abdominal wall with absorbable sutures on the four cardinal points. Additional interrupted stitches were given to the 6.6 cm mesh, and a complete additional double crown of continuous suture was given to the 8.6 cm mesh. All patients received prophylactic antibiotic.

Follow-up

Patients were scheduled presential outpatient visits in 1 month, 6 months, and 1 year. Early in the study an additional 2-year evaluation was added. Later, the 1-year and 2-year visit were substituted by telephonic consultation with the surgeons from the Unit, and symptomatic patients were scheduled presential visits.

An indirect follow-up was added for the purpose of this study, which was based on the consultations to the patients' primary care doctor and the abdominal computerized tomography (CT) studies demanded by the surgeon or performed for other causes.

Variables

Data was extracted from the electronic medical records. Demographic variables were sex, age (years), body mass index (BMI), smoking habit, comorbidities (diabetes, chronic obstructive pulmonary disease and other comorbidities) and Charlson Comorbidity Index.³⁰

Surgical data collected were the type of intervention (programmed versus urgent), type of hernia (umbilical, epigastric, port site incisional hernia or other incisional hernia), diameter of the hernia defect, classification according to the EHS,²⁹ diameter of the mesh, and mesh to defect ratio.

Early postoperative outcomes were the hospital stay, wound complications classified as seroma, hematoma and surgical site infection (SSI), and grading of the complication according to the Clavien-Dindo classification.³¹

Long-term postoperative outcomes were the assistance to outpatient visits (1 month, 6 months, 1 year, and 2 years), time of presential follow-up, time of indirect follow-up, postoperative CT scan, recurrence, time to recurrence, surgical repair of the recurrence, and other late adverse events.

Statistical analysis

Categorical variables were described as numbers and percentages. Quantitative variables were described with mean and standard deviation (SD) if they followed a normal distribution and with median and interquartile range (IQR) if they followed a non-normal distribution. The distribution of the variables was determined through the Shapiro–Wilk test. The recurrence was graphically represented with a Kaplan–Meier curve, adjusting the results according to the survival tables obtained. A *P*-value <0.05 was considered statistically significant. The analysis was performed with SPSS Statistics 26® (IBM, Chicago, IL).

Results

A total of 204 patients underwent the open IPOM technique with Parietex™ Composite Ventral Patch from 1st January 2013 to 30th June 2020 at our institution. The excluded patients were eight patients with lateral abdominal wall hernias, 32 patients with recurrent hernias, 12 patients with a defect ≥ 4 cm, five patients with closure of the hernia defect and one patient with lack of follow-up. Therefore, 146 patients entered in the analysis with a primary umbilical or epigastric hernia with a defect inferior to 4 cm or an incisional hernia with a defect inferior to 4 cm (Fig. 1).

The sample had a similar sex distribution, 52.1% males and 47.9% females, with a mean age of 56.5 years (SD: 16.1), a median BMI of 29.7 kg/m² (IQR: 25.6–33.3), and a median Charlson Comorbidity Index of 2 (IQR: 0–3) (Table 1).

The most frequently intervened hernias were umbilical hernias (90/146; 61.6%) and port site incisional hernias (39/146; 26.7%), followed by epigastric hernias (12/146; 8.2%) and other incisional hernias (5/146; 3.4%). Primary ventral hernias were classified according to the EHS as small in 36.3% (53/146) of the cases and medium in 33.6% (49/146). Periumbilical incisional hernias (M3) were more frequent (38/146; 26%) than M2 incisional hernias (6/146; 4.1%). The Parietex™ Composite Ventral Patch size used was 4.6 cm in 42.5% (62/146), 6.6 cm in 38.4% (56/146), and 8.6 cm in 19.2% (28/146). The mesh to defect ratio had a median of 3.3 (IQR: 2.8–4.4). In all cases the hernia defect was left unclosed. Most surgeries were performed in an outpatient setting (117/146; 80.1%).

The early postoperative complications were the presence of seroma in 6.2% (9/146), hematoma in 4.8% (7/146), and SSI in 6.8% (10/146). There was one (0.7%) grade III complication according to the Clavien-Dindo classification, due to a seroma that required drainage through percutaneous puncture (Table 2).

The global hernia recurrence during follow-up was 7.5% (11/146). Specifically, the hernia recurrence rate in umbilical hernia was 7.8% (7/90), 0% (0/12) in epigastric hernia, 7.7% (3/39) in port

Table 1 Demographic data

	n: 146 n (%) Median (IQR)
Sex—Male: female	76 (52.1): 70 (47.9)
Age [†] (years)	56.5 (16.1)
BMI (kg/m ²)	29.7 (25.6–33.3)
Smoking habit	
Non-smoker	97 (66.4)
Active smoker	27 (18.5)
Former smoker	22 (15.1)
Diabetes	25 (17.1)
COPD	8 (5.5)
Charlson Comorbidity Index	2 (0–3)

[†]Mean (SD).

Abbreviations: BMI, body mass index; COPD, chronic obstructive pulmonary disease.

site hernias, and 20% (1/5) in other incisional hernias (Fig. 2). The median follow-up time for recurrence was 14 months (IQR: 4.4–18.7), with only one recurrence diagnosed over 2 years (Fig. 3). The median follow-up on present visits was 17.4 months (IQR: 6.5–27.3), while the median indirect follow-up was 36.9 months (IQR: 27.2–49.6). The assistance to the outpatient

Table 2 Hernia characteristics, surgical treatment, and early results

	n: 146 n (%) Median (IQR)
Type of hernia	
Umbilical	90 (61.6)
Epigastric	12 (8.2)
Port site incisional	39 (26.7)
Other incisional	5 (3.4)
Diameter of the hernia defect (cm)	2 (1.5–2.5)
<2 cm	60 (41.1)
≥ 2 cm to <3 cm	57 (39)
≥ 3 cm to <4 cm	29 (19.9)
EHS classification	
Small	53 (36.3)
Medium	49 (33.6)
M2W1	6 (4.1)
M3W1	38 (26)
Type of surgery	
Programmed	138 (94.5)
Urgent	8 (5.5)
Mesh diameter (cm)	
4.6 cm	62 (42.5)
6.6 cm	56 (38.4)
8.6 cm	28 (19.2)
Mesh to defect ratio	3.3 (2.8–4.4)
Hospital stay (days)	
0 days	117 (80.1)
1 day	22 (15.1)
≥ 2 days	7 (4.8)
Early postoperative complications	
Seroma	9 (6.2)
Hematoma	7 (4.8)
Surgical site infection	10 (6.8)
Complications according to Clavien–Dindo classification	
Grade I	14 (9.6)
Grade II	10 (6.8)
Grade III	1 (0.7)

Abbreviations: EHS, European Hernia Society.

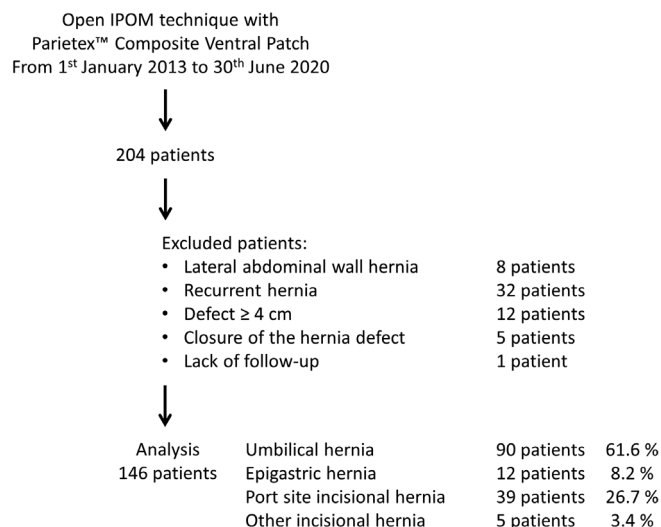


Fig. 1. Flowchart of participants in the study.

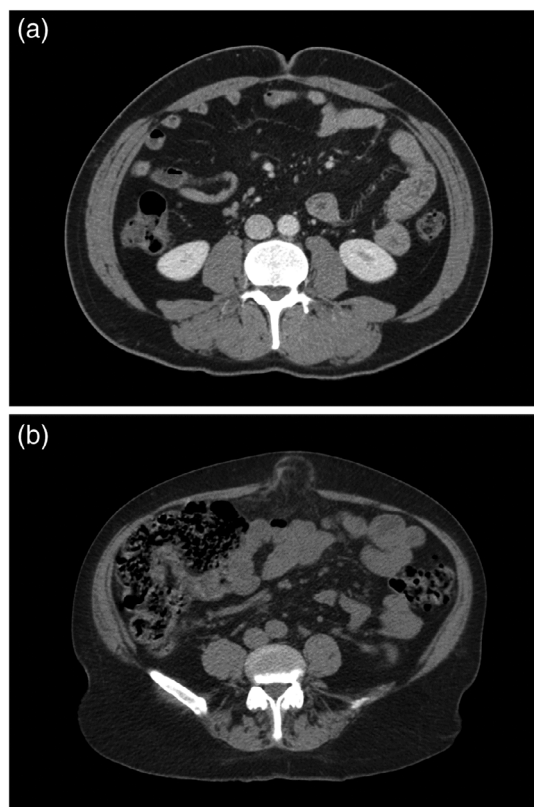


Fig. 2. Follow-up CT scans showing no recurrence (a) and hernia recurrence (b).

visits was 100% in 1 month, 74.7% in 6 months, 67.8% in 1 year and 48.6% in 2-years follow-up. A total of 53 patients (36.3%) underwent a CT scan during the follow-up period, either demanded by the surgeon or performed for other causes. Bulging was present in a 30.2% (16/53) of patients with CT scan. There were three cases of mesh excision: two cases (1.4%) due to pain associated with foreign body reaction and one case (0.7%) of small bowel occlusion due to firm adhesions of the mesh (Table 3).

Discussion

The open IPOM technique with Parietex™ Composite Ventral Patch in our study achieved an acceptable recurrence rate of 7.5% (11/146), within the range between 1.7%¹² and 15.7%¹³ described in the literature. The PANACEA study published by Berrevoet *et al.*^{9,32} represents the only direct comparison of our study. They included 126 patients with primary umbilical and epigastric hernia with a defect <4 cm who underwent an hernioplasty with the same type of mesh that we used in our study. They achieved a 2-year follow-up in 101 patients, who had a hernia recurrence of 3% (3/101), an inferior rate than our 6.8% (7/102) of hernia recurrence in primary ventral hernia. However, the study by Berrevoet *et al.*³² had a reduced hernia defect, with a mean of 1.8 cm (SD: 0.8), compared to our median of 2 cm (1.5–2.5), and they performed a closure of the fascial defect. Moreover, Berrevoet *et al.*⁹ experienced a 19.8% of attrition, a factor that could have increased the recurrence

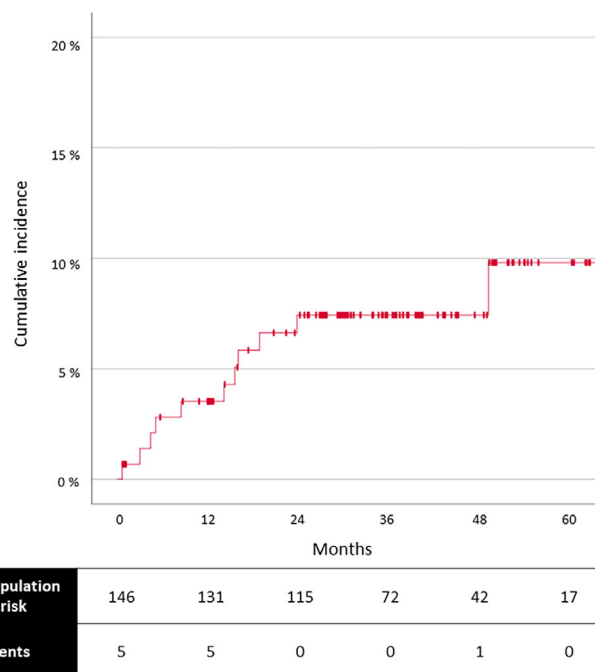


Fig. 3. Incidence of hernia recurrence after surgical repair.

rate as stated in their article. Interestingly, our study included information of the long-term outcomes of port site incisional hernia repair with Parietex™ Composite Ventral Patch, which had a 7.7% (3/39) recurrence.

Compared to other meshes, the recurrence rates of our study were only outperformed by C-QUR V-Patch™. With this mesh, a recurrence rate of 2.4% with a median follow-up of 37 months was

Table 3 Results of long-term follow-up

	n: 146
	n (%) Median (IQR)
Recurrence	11/146 (7.5)
Umbilical	7/90 (7.8)
Epigastric	0/12 (0)
Port site incisional	3/39 (7.7)
Other incisional	1/5 (20)
Time to recurrence (months)	14 (4.4–18.7)
<1 year	5 (3.4)
1–2 years	5 (3.4)
>2 years	1 (0.7)
Surgical intervention of the recurrence	7/11 (63.6)
Follow-up (months)	
Presental	17.4 (6.5–27.3)
Indirect	36.9 (27.2–49.6)
Assistance to outpatient visits CT scan during follow-up	
1 month	146 (100)
6 months	109 (74.7)
1 year	99 (67.8)
2 years	71 (48.6)
CT scan during follow-up	53 (36.3)
Free of recurrence	28/53 (52.8)
Bulging	16/53 (30.2)
Recurrence	9/53 (17)
Late mesh complications	3 (2.1)

Cheng *et al.*²⁷ while Keating *et al.*²⁶ objectified a 3.8% recurrence rate with a follow-up ranging from 18 months to 51.6 months. Nevertheless, both studies assessed recurrence through telephonic interviews. The studies analysing the results of Proceed® Ventral Patch^{10,12,23–25} have reported a recurrence rate ranging from 1.7%¹² to 12%.²³ The one with a similar recurrence rate than our study was the MORPHEUS trial by Ponten *et al.*¹⁰ who obtained a recurrence rate of 8.4% with a 2-year follow-up.

As previously stated, Ventrallex™ Hernia Patch represents the preformed mesh with more evidence published.^{11,13,16–22} The recurrence with this patch ranges from 2% described by Vychnevskaja *et al.* with a follow-up of 28.5 months¹⁸ to 15.7% reported by Bensaadi *et al.* with a follow-up of 30 months.¹³ More specifically, our study reached similar recurrence rates than the reports from Victor *et al.*²² who had a 6.5% recurrence rate, and the 8.3%–8.9% stated by Berrevoet *et al.*²⁰ and Tollens *et al.*²¹ Porrero *et al.*¹¹ published the vastest series with this mesh, including 1359 patients with a follow-up of 4.1 years, reaching a recurrence 3.9% recurrence rate. Some differences between this article and our series were the preferential placement of the prosthesis in the preperitoneal space (93.4%) and the aponeurotic closure (79.6%). The fascial closure was also proposed by Tollens *et al.*²¹ arguing a reduction in bulging. In our study, we preferred a tension-free bridging of the defect, although bulging was detected in 30.2% of the patients who underwent a follow-up CT scan (16/53).

Early postoperative complications in our study were low, with a 6.2% (9/146) rate of seroma, a 4.8% (7/146) rate of hematoma, and a 6.8% (10/146) rate of SSI. In the literature, the seroma rates ranged between 1.1%¹⁷ and 10.9%,²² the proportion of hematoma varied from 0.7%¹¹ to 8.3%,²⁴ and the rates of SSI stated between 1.3%¹¹ and 12.8%.²³ Thus, the complication rates described in our series were within the range that has been previously reported. Ponten *et al.*¹⁰ concluded in favour of the flat polypropylene preperitoneal mesh in the MORPHEUS trial considering a reduced overall 2-year complication rate of 22.1% compared to 32.5% with Proceed® Ventral Patch. This outcome included all early postoperative complications, recurrence, and mesh excision during the first 2 years of follow-up. In our series, the overall 2-year complication rate was 24%, an inferior rate than the 32.5% defined by Ponten *et al.*¹⁰

Mesh positioning is another factor to consider when using preformed patches, to avoid late postoperative complications. Current guidelines recommend the placement of a flat preperitoneal mesh to avoid complications such as bowel obstruction or enterocutaneous fistula formation, which have been reported with intraabdominal mesh placement.⁸ This also allows for the use of a cheaper mesh compared to coated preformed patches. In our study, we gradually abandoned the intraabdominal mesh placement, and by the end of the study, most of the meshes were implanted in the preperitoneal space. Nowadays, we reserve the use of flat preperitoneal mesh for defects that are close to each other and form a longer-than-wider defect, while single round defects tend to receive a preformed patch.

Finally, the secondary outcome was to determine the needed follow-up for recurrence diagnosis. The guidelines of the EHS recommend a 2-year follow-up to detect the recurrence,³³ while

Köckerling *et al.*³⁴ recommended a minimum of 10 years of follow-up after the surgical correction of an incisional hernia. However, umbilical and port site incisional hernias represent a highly prevalent disease that can challenge the outpatient visits agenda. Some studies reported that most of the recurrences were diagnosed during the first year,^{9,22,23} while Berrevoet *et al.*²⁰ and Vychnevskaja *et al.*¹⁸ with Ventrallex™ Hernia Patch detected recurrences along the first 2 years. In our study, most recurrences were diagnosed during the first 2 years, with only one case diagnosed over this time through an abdominal CT scan. Therefore, we concluded that a 2-year follow-up was still required for the recurrence diagnosis.

A limitation of the study was that the hernia defect was left unclosed. Current guidelines for treatment of umbilical and epigastric hernias suggest the closure of the hernia defect, although it was acknowledged that there was insufficient evidence in open surgery to support this statement.⁸ Many studies have left the defect open^{12,16,18,19,22} with acceptable recurrence rates ranging from 1.7%¹² to 6.5%,²² and even in the MORPHEUS trial there was a 14% of cases without fascial closure.^{8,10} However, trends in abdominal wall surgery have evolved towards a complete anatomical restoration with mesh reinforcement,³⁵ which results in a reduced rate of seroma and recurrence.³⁶

Another limitation of the study remains in its retrospective design, where we were limited to the analysis of the available data. The optimal evaluation would include a physical and radiological examination at 2-year follow-up, even though this surveillance has been inevitably affected by elevated rates of attrition.^{9–11} Nevertheless, considering that the results with Parietex™ Composite Ventral Patch have exclusively been addressed by the PANACEA trial,^{9,32} we believe that our study provides valuable data of the outcomes of this mesh in the ordinary clinical practice. Finally, we conclude that the open IPOM technique with Parietex™ Composite Ventral Patch offered satisfactory results for the treatment of ventral and incisional hernias in terms of early complications and long-term recurrences.

Author contributions

Alberto G. Barranquero: Conceptualization; formal analysis; investigation; methodology; writing – original draft. **Rafael Villalobos Mori:** Conceptualization; methodology; writing – original draft. **Yolanda Maestre González:** Conceptualization; investigation; writing – original draft. **Gian Pier Protti:** Conceptualization; data curation; investigation; methodology. **Guillermo López Soler:** Data curation; investigation. **Fernando Villarreal León:** Data curation; investigation. **Irvin Jair González Alfaro:** Data curation; investigation. **Jorge Juan Olsina Kissler:** Supervision; validation; writing – review and editing.

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Conflict of interest statement

None declared.

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