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Quality of life outcomes after minimally invasive repair of pectus excavatum utilizing a new set of metallic bars and stabilizers☆

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ABSTRACT

Background/Purpose: The aim of the study was to evaluate the postoperative quality of life (QoL) of patients who underwent minimally invasive repair of pectus excavatum (MIRPE) with a newly designed bar and bar stabilizers.
Methods: We conducted a prospective randomized study in which patients were operated either with standard perpendicular stabilizers (control group) or with the newly designed oblique stabilizers (intervention group). All patients were evaluated 6 months after the operation with the Pectus Excavatum Evaluation Questionnaire (PEEQ).
Results: There were 16 patients in the control group and 14 in the intervention group. Mean age was 17 (SD: 3.3, range 14–27) years. There were no demographic differences between groups. Two patients in the control group and one in the intervention group were repaired with two bars instead of one. There was one reoperation in each group. There was a significant difference between the pre- and postoperative scores, in both groups, in the patient body image domain (control group: 9.5 to 3; $p < 0.01$; intervention group 10 to 3; $p < 0.01$), as well as in the psychosocial domain (control group: 13.5 to 24, $p < 0.01$; intervention group: 15 to 24, $p < 0.01$). With regards to the patients' perception of physical difficulties before and after MIRPE, the difference between pre- and postoperative scores was greater in the intervention group (8 to 12, $p < 0.01$) than in the control group (10 to 11, $p = 0.04$). The mean length of stay was 4.5 and 5 days in the intervention group and the control group, respectively.
Conclusion: Our study showed that patients who underwent MIRPE with the newly designed bars and stabilizers had non-inferior outcomes than patients reported in the literature who underwent MIRPE with standard bars and stabilizers. We found slightly better outcomes in patients in the intervention group compared to the control group, but larger studies will be needed to confirm if those differences are statistically significant.
Level of evidence: II

Pectus excavatum (PE) is characterized by a depression in the anterior chest wall, and it occurs approximately in 1 every 1000 children. Shortness of breath and exercise intolerance are common in patients with PE and may result in self-withdrawal from social activities. Patients with PE have lower self-esteem and higher incidence of depression than the general population [1].

Since non-surgical measures have limited effects, surgical correction of PE is the standard of care, and the minimally invasive repair of PE (MIRPE) described by Nuss is the gold standard technique [2,3]. There are however, in our opinion, some features of the materials used for the operation that can be improved. Some of those improvements are: elimination of the notches at the ends of the bar, a change in the chemical components of the bar, a better system to affix the stabilizers to the bar, and a change in the orientation and shape of the stabilizers to improve their apposition to the rib cage, among others [4,5]. With these improvements in mind we designed a new set of bar and bar stabilizers, and conducted a randomized trial to compare the pre- and postoperative quality of life (QoL) of patients undergoing MIRPE with the standard equipment or with our newly designed set. The results of the study are presented here.

1. Methods

1.1. Study design and population

We conducted a prospective randomized clinical trial between October 2017 and September 2018. All patients underwent MIRPE with a new set of titanium bars that have smooth edges, and stabilizers

☆ Sao Paulo Medical School Institutional Review Boards (CAPPesq no. 1.633.063).
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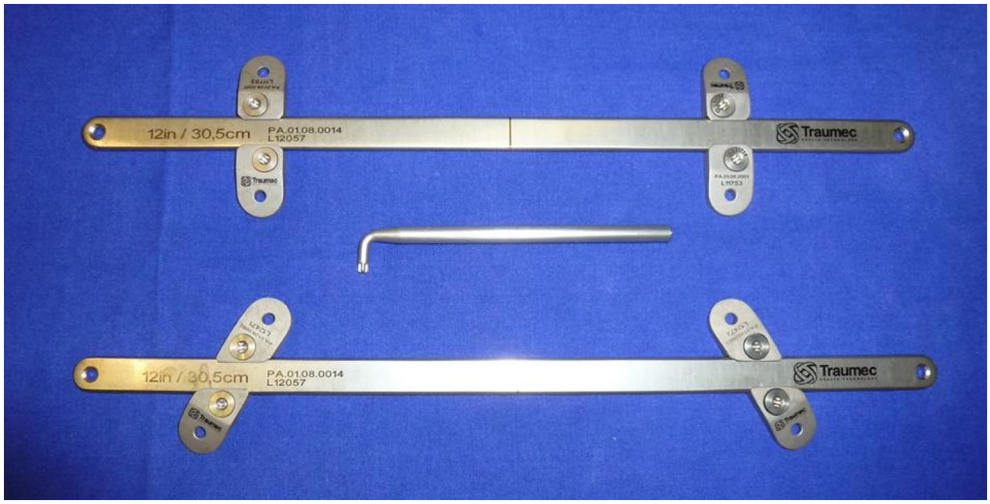

Fig. 1. The smooth metallic bar with perpendicular stabilizers (above) and with oblique stabilizers (below), with the dedicated screwdriver between them.

that have a screw to attach them to the bars (Traumec Tecnologia e Implantes, São Paulo, Brazil). In addition to these features, two different stabilizer models were produced. One model was designed to attach to the bar in a perpendicular orientation, similar to standard stabilizers. The other model, intended to reduce the incidence of bar dislodgment, was designed to attach to the bar in an oblique orientation, which makes them sit perpendicularly to the ribs on which they lie (Fig. 1). Patients were randomly assigned to be operated with the perpendicular stabilizers (control group) or the oblique (intervention group) stabilizer.

The study was approved by the University of São Paulo Medical School Institutional Review Board (CAPPesq 1.633.063). The ClinicalTrials.gov study identifier was NCT03087734.

1.2. Clinical information

The minimal age for inclusion was 11 years. Patients with congenital heart diseases, complex chest wall anomalies, previous failed PE repair, previous thoracic operations, bleeding disorders, or major anesthetic risks such as malignant hyperthermia were excluded from the study. We collected preoperatively all demographic data as well as the PE severity measurements determined by computerized tomography.

All operations were done by the same two surgeons (MLT and JRMC) following the technique described in the literature [6–8].

1.3. QoL assessment

Patients' psychosocial status was assessed before the operation and 6 months postoperatively. The Pectus Excavatum Evaluation Questionnaire (PEEQ) is a disease-specific QoL evaluation tool developed at Old Dominion University. It consists of 11 questions addressed to the patient and 13 questions addressed to the parents. Answers are given according to a Likert-type scale that ranges from 1 to 4, reflecting the frequency of a particular feeling or a particular behavior. For data analysis, the questions were grouped into 3 domains (body image, psychosocial aspects, and physical difficulties) for patients, and 4 domains (psychosocial aspects, physical difficulties, self-awareness, and parental concern) for parents [9].

1.4. Statistical analyses

Data analysis was presented descriptively by means and standard deviations, and by absolute and relative frequency. An evaluation of the internal consistency of the questionnaire was carried out by means of a Cronbach alpha analysis in order to allow the assessment of the difference between the means of each domain of the questionnaire for the pre- and postoperative period, according to the following classification: "almost perfect" (>0.80), "substantial" ($0.61 > \alpha \leq 0.80$), "moderate" ($0.41 > \alpha \leq 0.60$), "reasonable" ($0.21 > \alpha \leq 40$) or "small" (<0.21) [10]. For the analyses between pre- and postoperative answers in the same group, the non-parametric Wilcoxon test or the parametric Student *t*-test was used, depending on the normality of the data. To compare differences between groups the non-parametric Mann–Whitney *U* test or the parametric independent *t*-test was used. The analyses were performed using the Statistical Package for Social Sciences (SPSS) 23.0 computer software with a significance level of 5% for statistical tests.

2. Results

A total of 30 patients were included in the study, 16 in the control group (perpendicular stabilizer) and 14 in the intervention group (oblique stabilizer). The mean age was 17 ± 3.3 (range 14–27) years, with male (90%) predominance. All patients were followed up during the 6-month study period. The demographics and surgical characteristics of both groups are shown in Table 1.

Two patients in the control group and one in the intervention group underwent MIRPE with two bars instead of one. There was one reoperation in the control group (bar dislodgment with rotation on its own axis), and there was one reoperation in the intervention group (rupture of the intercostal muscle with the right end of the bar slipping inside the thoracic cavity). Both reoperations required correction with two bars.

There was a significant difference between the pre- and postoperative composite scores of the patients' body image domain in both control and intervention arms. The difference between pre- and

Table 1
Demographic, surgical characteristics and length of stay of control and intervention arms.

Variable	Perpendicular stabilizer (n = 16)	Oblique stabilizer (n = 14)	p
Male	14 (87.5%)	13 (92.9%)	0.62
Age (years)	17.81 (±2.92)	17.64 (±3.54)	0.75
Weight (kg)	59.2 (47.25–61.97)	58.28 (±9.57)	0.72
Height (m)	1.72 (±0.06)	1.77 (±0.09)	0.11
Body mass index (kg/m^2)	19.53 (±3.45)	18.51 (±2.47)	0.46
Haller index	4.33 (±1.22)	3.93 (±0.83)	0.50
Operated with 2 bars	2 (12.5%)	1 (7.1%)	0.62
Reoperation	1 (6.3%) ┼	1 (7.1%) ╪	0.92
Length of stay	5 (4–6)	4.50 (4–6)	0.42

┼ Bar dislodgment; ╪ Bar slipped into thoracic cavity.
Parametric: Independent samples *t*-test (mean ± standard deviation); Nonparametric: Mann-Whitney *U* test (median, interquartile range); Nominal: chi-square test.

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Table 2
Control group patient's answers to PEEQ in pre and post-operative period.

n = 16	Presurgery		Postsurgery	
	Very happy/ happy	**Unhappy/ very unhappy**	**Very happy/ happy**	**Unhappy/ very unhappy**
Looks in general	3 (18.8%)	13 (81.2%)	16 (100%)	0(0%)
How looks without shirt	2 (12.5%)	14 (87.5%)	16 (100%)	0(0%)
Spending rest of life as chest looks now	1 (6.2%)	13 (93.8%)	16 (100%)	0(0%)
Body Image	**Median (IR): 9.5 (9–10)**		**Median (IR): 3 (3–4.75)**	**p < 0.01***
	Very often/ Often	**Sometimes/ Never**	**Very often/ Often**	**Sometimes/Never**
Kids make fun of child because of chest	2 (12.5%)	14 (87.5%)	0(0%)	16 (100%)
Avoids doing things	8 (50%)	8 (50%)	0(0%)	16 (100%)
Hides chest	11 (68.8%)	5 (31.2%)	0(0%)	16 (100%)
Bothered because of the way chest looks	12 (75%)	4 (25%)	0(0%)	16 (100%)
Feels shy/self-conscious because of chest	8 (50%)	8 (50%)	0(0%)	16 (100%)
Feels bad about self	4 (25%)	12 (75%)	0(0%)	16 (100%)
Psychosocial aspects	**Median (IR): 13.5 (10–19)**		**Median (IR): 24 (24–24)**	**p < 0.01***
	Very often/ Often	**Sometimes/ Never**	**Very often/ Often**	**Sometimes/ Never**
Has trouble exercising	5 (31.2%)	11 (68.8%)	0(0%)	16 (100%)
Chest caused shortness of breath	3 (18.8%)	13 (81.2%)	2 (12.5%)	14 (87.5%)
Chest caused child to be tired	6 (37.5%)	10 (62.5%)	1 (6.2%)	15 (93.8%)
Physical difficulties	**Median (IR): 10 (7–12)**		**Median (IR): 11 (10–12)**	**p = 0.04***

Categories are presented grouped: Very happy + happy; Unhappy + very unhappy; Very often + often; Sometimes + never.
IR: Interquartile Range; p: statistically difference; *p ≤ 0.05. Difference between means in the same group for pre and postsurgery analyzed using Wilcoxon test.

postoperative answers in psychosocial aspects domain was significant in both arms.

The difference between the pre- and postoperative scores on the patients' perception of physical difficulties was greater, and statistically significant, in the intervention group than in the control group. The PEEQ scores before and after surgery in the control group and the intervention group are presented in Tables 2 and 3, respectively.

The study showed significant differences in the parental perception of the patients' QoL before and after MIRPE in both groups (control group Tables 4; intervention group Table 5).

Internal consistency was substantial for most of the data, with the exception of the assessment of the physical difficulties domain in the postoperative period for both patients and parents (Cronbach's α: 0.489; 0.084, respectively).

When comparing the responses to the questionnaire between the two groups (perpendicular and oblique stabilizers), there was no statistical difference for any of the questions, as shown in Table 6.

3. Discussion

The stabilizers used in the control group of the study were designed to attach to the bar in a perpendicular orientation, like the standard stabilizers available in the market. However, they had a few differences: we incorporated a screw that allows them to be attached to the bar at any location, and a have larger channel that allows them to also be used with patient-specific customized bars. The stabilizers used in the intervention group of the study also had these features, but additionally were designed to attach to the bar in an oblique orientation. This feature, in our opinion, provides improved adaptability to the patient's rib cage and reduces the incidence of bar dislodgement.

Some studies have shown a lack of correlation between the severity of the PE, as measures by imaging studies, and the PEEQ scores, suggesting that the mere presence of the deformity leads to body image and psychosocial difficulties [11,12]. Although in Brazil the Haller index is not a determinant of insurance coverage, all patients in our study underwent a computerized tomography. The mean Haller index was

Table 3
Intervention arm patient's answers to PEEQ in pre and post-operative period.

n = 14	Presurgery		Postsurgery	
	Very happy/ happy	**Unhappy/ very unhappy**	**Very happy/ happy**	**Unhappy/ very unhappy**
Looks in general	2 (14.3%)	12 (85.7%)	14 (100%)	0(0%)
How looks without shirt	1 (7.1%)	13 (92.9%)	14 (100%)	0(0%)
Spending rest of life as chest looks now	1 (7.1%)	13 (92.9%)	14 (100%)	0(0%)
Body Image	**Median (IR): 10 (9–12)**		**Median (IR): 3 (3–4.5)**	**p < 0.01***
	Very often/ Often	**Sometimes/ Never**	**Very often/ Often**	**Sometimes/Never**
Kids make fun of child because of chest	3 (21.4%)	11 (78.6%)	0(0%)	14 (100%)
Avoids doing things	8 (57.1%)	6 (42.9%)	0(0%)	14 (100%)
Hides chest	10 (71.4%)	4 (28.6%)	2 (14.3%)	12 (85.7%)
Bothered because of the way chest looks	13 (92.9%)	1 (7.1%)	0(0%)	14 (100%)
Feels shy/self-conscious because of chest	8 (57.1%)	6 (42.9%)	0(0%)	14 (100%)
Feels bad about self	6 (42.9%)	8 (57.1%)	0(0%)	14 (100%)
Psychosocial aspects	**Median (IR): 15 (7.75–16)**		**Median (IR): 24 (20.75–24)**	**p < 0.01***
	Very often/ Often	**Sometimes/ Never**	**Very often/ Often**	**Sometimes/ Never**
Has trouble exercising	8 (57.1%)	6 (42.9%)	0(0%)	14 (100%)
Chest caused shortness of breath	2 (14.3%)	12 (85.7%)	0(0%)	14 (100%)
Chest caused child to be tired	6 (42.9%)	8 (57.1%)	1 (7.1%)	13 (92.9%)
Physical difficulties	**Median (IR): 8 (6–10.25)**		**Median (IR): 12 (11–12)**	**p < 0.01***

Categories are presented grouped: Very happy + happy; Unhappy + very unhappy; Very often + often; Sometimes + never.
IR: Interquartile Range; p: statistically difference; *p ≤ 0.05. Difference between means in the same group for pre and postsurgery analyzed using the Wilcoxon test.

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Table 4
Control arm parent's answers to PEEQ in pre and post-operative period.

n = 16	Presurgery		Postsurgery	
	Very often/ Often	**Sometimes/ Never**	**Very often/ Often**	**Sometimes/ Never**
Irritable	10 (62.5%)	6 (37.5%)	1 (6.2%)	15 (93.8%)
Frustrated	8 (50%)	8 (50%)	0(0%)	16 (100%)
Sad/depressed	7 (43.8%)	9 (56.2%)	0(0%)	16 (100%)
Restless	3 (18.8%)	13 (81.2%)	1 (6.2%)	15 (93.8%)
Isolated	7 (43.8%)	9 (56.2%)	2 (12.5%)	14 (87.5%)
Made fun of	0 (0%)	16 (100%)	0(0%)	16 (100%)
Psychosocial aspects	**Median (IR): 15.5 (12.5–19.5)**		**Median (IR): 24 (22.25–24)**	**p < 0.01***
	Very often/ Often	**Sometimes/ Never**	**Very often/ Often**	**Sometimes/ Never**
Have trouble exercising	5 (31.2%)	11 (68.8%)	1 (6.2%)	15 (93.8%)
Have chest pain	0 (0%)	16 (100%)	1 (6.2%)	15 (93.8%)
Have shortness of breath	2 (12.5%)	14 (87.5%)	0(0%)	16 (100%)
Feel tired	3 (18.8%)	13 (81.2%)	0(0%)	16 (100%)
Have problems gaining weight	9 (56.2%)	7 (43.8%)	3 (18.8%)	13 (81.2%)
Physical difficulties	**Median (IR): 15 (12.25–19.75)**		**Median (IR): 18.50 (17.25–19.75)**	**p = 0.01***
	Very often/ Often	**Sometimes/ Never**	**Very often/ Often**	**Sometimes/ Never**
Reluctant to wear bathing suits	14 (87.5%)	2 (12.5%)	1 (6.2%)	15 (93.8%)
Self-consciousness	**Median (IR): 1 (1–1)**		**Median (IR): 4 (4–4)**	**p < 0.01***
	Very often/ Often	**Sometimes/ Never**	**Very often/ Often**	**Sometimes/ Never**
How often parent is concerned about effects of pectus on child's life	14 (87.5%)	2 (12.5%)	1 (6.2%)	15 (93.8%)
Caregiver concern	**Median (IR): 1 (1–1)**		**Median (IR): 4 (4–4)**	**p < 0.01***

Categories are presented grouped: Very often + often; Sometimes + never.
IR: Interquartile range; p: statistically difference; *p ≤ 0.05. Difference between means in the same group for pre and postsurgery analyzed using the Wilcoxon test.

4.33 (±1.22) in the control group, and 3.93 (±0.83) in the intervention group. This confirms that all patients in the study had severe defects.

The main goal of the PE correction is to improve the patient's self-esteem, body image, and physical difficulties, if present [13,14] . Since these are subjective features, the optimal way to evaluate outcomes is by a thorough evaluation of the overall patient's QoL. We compared the QoL of our patients prior to the operation, and 6 months after the operation. The 6-month time point was chosen based on a study that showed that the strongest changes in the body image perception, the self-esteem and the psychological domain take place in the first 6 weeks post MIRPE, whereas the major changes in emotional limitation take place between 6 weeks and 6 months after the operation [10].

We found a remarkable difference in the patients' perceptions of their body image before and after MIRPE. For instance, about 90% of the answers to the question “How do you feel about the way you look without your shirt on?” in both groups was “unhappy” or “mostly unhappy” before the surgery. After the surgery, all patients answered “happy” or “mostly happy”. These findings are in agreement with literature results [15].

Table 5
Intervention arm parent's answer to PEEQ in pre and post-operative period.

n = 14	**Presurgery**		**Postsurgery**	
	Very often/ Often	**Sometimes/ Never**	**Very often/ Often**	**Sometimes/ Never**
Irritable	8 (57.1%)	6 (42.9%)	0(0%)	14 (100%)
Frustrated	8 (57.1%)	6 (42.9%)	0(0%)	14 (100%)
Sad/depressed	10 (71.4%)	4 (28.6%)	0(0%)	14 (100%)
Restless	6 (42.9%)	8 (57.1%)	0(0%)	14 (100%)
Isolated	4 (28.6%)	10 (71.4%)	1 (7.1%)	13 (92.9%)
Made fun of	1 (7.1%)	13 (92.9%)	0(0%)	14 (100%)
Psychosocial aspects	**Median (IR): 13.50 (12–21.25)**		**Median (IR): 24 (23.75–24)**	**P < 0.01***
	Very often/ Often	**Sometimes/ Never**	**Very often/ Often**	**Sometimes/ Never**
Have trouble exercising	7 (50%)	7 (50%)	2 (14.3%)	12 (85.7%)
Have chest pain	2 (14.3%)	12 (85.7%)	0(0%)	14 (100%)
Have shortness of breath	3 (21.4%)	11 (78.6%)	0(0%)	14 (100%)
Feel tired	4 (28.6%)	10 (71.4%)	1 (7.1%)	13 (92.9%)
Have problems gaining weight	5 (35.7%)	9 (64.3%)	3 (21.4%)	11 (78.6%)
Physical difficulties	**Median (IR): 14 (13.25–17)**		**Median (IR): 19 (17–20)**	**p < 0.01***
	Very often/ Often	**Sometimes/ Never**	**Very often/ Often**	**Sometimes/ Never**
Reluctant to wear bathing suits	8 (57.1%)	6 (42.9%)	4 (28.6%)	10 (71.4%)
Self-consciousness	**Median (IR): 1 (1–2)**		**Median (IR): 4 (1–4)**	**p < 0.01***
	Very often/ Often	**Sometimes/ Never**	**Very often/ Often**	**Sometimes/ Never**
How often parent is concerned about effects of pectus on child's life	11 (78.6%)	3 (21.4%)	0(0%)	14 (100%)
Caregiver concern	**Median (IR): 1 (1–1.25)**		**Median (IR): 4 (3–4)**	**p < 0.01***

Categories are presented grouped: Very often + often; Sometimes + never.
IR: Interquartile range; p: statistically difference; *p ≤ 0.05. Difference between medians in the same group for pre and postsurgery analyzed using Wilcoxon test.

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Table 6
Comparison of PEEQ answers results between control and intervention arms.

		Control arm (n = 16)	Intervention arm (n = 14)	
Presurgery	**Cronbach's α**	**Median (IR)**	**Median (IR)**	**p**
Body Image – patients	0.833	9.5 (9–10)	10 (9–12)	0.193
Psychosocial aspects – patients	0.881	13.5 (10–19)	15 (7.75–16)	0.400
Physical difficulties - patients	0.784	10 (7–12)	8 (6–10.25)	0.294
Psychosocial aspects - parents	0.623	15.5 (12.5–19.5)	13.50 (12–21.25)	0.473
Physical difficulties - parents	0.801	15 (12.25–19.75)	14 (13.25–17)	0.580
Self-consciousness - parents	-	1 (1–1)	1 (1–2)	0.110
Caregiver concern - parents	-	1 (1–1)	1 (1–1.25)	0.448
Postsurgery	**Cronbach's α**	**Median (IR)**	**Median (IR)**	**p**
Body Image – patients	0.832	3 (3–4.75)	3 (3–4.5)	0.822
Psychosocial aspects – patients	0.699	24 (24–24)	24 (20.75–24)	0.498
Physical difficulties - patients	0.489	11 (10–12)	12 (11–12)	0.093
Psychosocial aspects - parents	0.679	24 (22.25–24)	24 (23.75–24)	0.355
Physical difficulties - parents	0.084	18.50 (17.25–19.75)	19 (17–20)	0.498
Self-consciousness - parents	-	4 (4–4)	4 (1–4)	0.101
Caregiver concern - parents	-	4 (4–4)	4 (3–4)	0.728

Difference between the medians of the different groups was analyzed using Mann–Whitney U test.
IR: Interquartile range.

Although some studies have shown that MIRPE has positive effects on the preoperative physical limitations experienced by some patients with PE, other studies have shown no differences [16,17]. In concordance to the latter, we found remarkable difference between the preoperative and the postoperative physical difficulties, in both groups. The difference was greater in the intervention group ($p < 0.01$, statistically significant) than in the control group ($p = 0.04$).

Improvements in the parental perception of the patient's emotional wellbeing and QoL after MIRPE have already been described, and was also found in our study, in all evaluated domains, in both study groups [18].

The postoperative length of stay was not statistically different between our study groups, but was shorter than historical length of stay in our institution, for patients operated with the bars and stabilizers available in the market (6.7 days, unpublished data).

There was one reoperation in each group, but the reasons were different. In the control group it was a case of bar dislodgment, commonly reported in the literature. In the case of the intervention group, the end of the bar eroded the intercostal muscle and penetrated with the stabilizer in the right pleural cavity. We believe that this complication could be avoided in the future by making the stabilizer longer. Both patients had uneventful outcomes after the reoperation.

Our study has several limitations including the lack of long-term follow up and the small sample size, among others.

4. Conclusion

Our study showed that patients who underwent MIRPE with the newly designed bars and stabilizers had non-inferior outcomes than patients reported in the literature who underwent MIRPE with standard bars and stabilizers. We found slightly better outcomes in patients in the intervention group compared to the control group, but larger studies will be needed to confirm if those differences are statistically significant.

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Declarations of competing interest

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