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## Does the modelling of the pectus bar affect its stability? Rationale for using a short flat bar

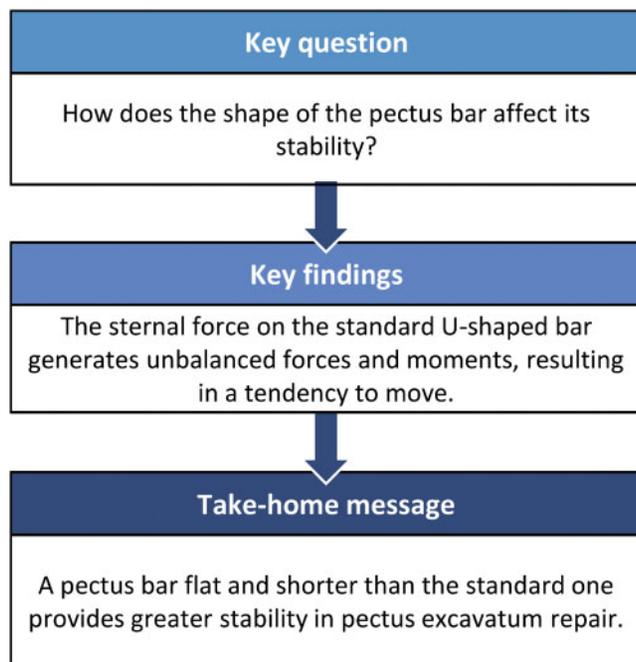
David Pérez<sup>a</sup>, Oscar Martel <sup>b,\*</sup>, Alejandro Yáñez <sup>b</sup>, José R. Cano <sup>a</sup>, Alberto Cuadrado <sup>b</sup>,  
Gara Torrent<sup>a</sup> and Luis López<sup>a</sup>

<sup>a</sup> Thoracic Surgery Section, Hospital Universitario Insular de Gran Canaria, Las Palmas, Spain

<sup>b</sup> Department of Mechanical Engineering, University of Las Palmas de Gran Canaria, Las Palmas, Spain

\* Corresponding author. Department of Mechanical Engineering, University of Las Palmas de Gran Canaria, Edificio de Ingenierías, Campus de Tafira, 35017 Las Palmas, Spain. Tel: +34-92-8451483; fax: +34-92-8451484; e-mail: oscar.martel@ulpgc.es (O. Martel).

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### Abstract

**OBJECTIVES:** Although the Nuss procedure for pectus excavatum is still associated with a non-negligible risk of postoperative bar displacement, the potential effects of the length and shape of the bar on its corrective ability and stability have not been sufficiently studied. The aim of this study was to determine how the modelling of the pectus bar affects its stability and whether an alternative configuration of the implant can improve clinical success.

**METHODS:** Simulated implantation of bars with different shapes and sizes in a computational model was carried out. A 250 N sternal force was applied to the bars, and the resulting forces and moments on the fixation points were identified. Afterwards, a clinical trial was carried out in a group of patients with pectus excavatum, some of whom received long inverted U-shaped bars and some of whom received implants designed from the computational results.

**RESULTS:** When U-shaped bars were tested, the sternal force generated unbalanced horizontal reaction forces (16 vs 61 N) and large reaction moments at the ends of the bar, conferring the tendency to slide and to rotate, respectively. No lateral or rotational destabilizing forces occurred in the case of a flat bar. Cosmetic outcomes, postoperative times and hospital stays were similar in both clinical groups. However, 2 cases (2/15) of bar flipping occurred in patients who received the conventional bar.

**CONCLUSIONS:** The shape of the bar is a determinant of its stability. A flat, shorter pectus bar provides adequate correction of the deformity with less tendency for bar displacement in the repair of pectus excavatum.

**Keywords:** Pectus excavatum • Nuss procedure • Finite element analysis

#### ABBREVIATIONS

MIRPE	Minimally invasive repair of pectus excavatum
PE	Pectus excavatum

## INTRODUCTION

Since the introduction of the minimally invasive repair of pectus excavatum (MIRPE) developed by Nuss *et al.* [1] for paediatric patients, the procedure has rapidly gained acceptance among surgeons and patients due to the reduced associated trauma, fast recovery and good cosmetic results [2]. However, this surgical technique has been widely reported to be associated with adverse effects such as severe postoperative pain and dislocation of the bar [3, 4]. The latter complication is a major concern for thoracic surgeons and a reason to restrain from performing MIRPE, especially in adolescents or adults, in whom the incidence of dislocation is higher than that in paediatric patients [5, 6].

For this reason, surgeons dedicated to correcting congenital chest wall deformities have focused their research on improving bar stability mainly by improving fixation techniques. However, the effect of the length and shape of the bar on its stability remains poorly understood.

Based on the hypothesis that the length and curvature of the traditional bar may promote the emergence of dislocating forces, whereas a flat, shorter bar could provide equivalent defect correction with greater stability, we designed a 2-phase study to assess the outcomes of implanting bars of 2 different configurations in patients with pectus excavatum (PE). In the first phase of the study, a computational analysis was carried out focusing on the biomechanical aspects related to the corrective ability and stability of bars of 2 different lengths and curvatures implanted in a 3-dimensional PE simulated model. In the second phase, a single-centre clinical study was conducted with 30 patients with PE who underwent the Nuss procedure. Half of them received a bar with a flat design based on previous computer simulations, whereas the other half received standard bars with the conventional length and curved shape.

## MATERIALS AND METHODS

### First phase: finite element analysis

A computational finite element analysis was carried out to determine the distribution of stress as well as the reaction forces and moments acting on the bar. A 3-dimensional computed tomography reconstruction of the ribcage of a 15-year-old male patient with PE (Haller index 4.7) was used to simulate bar insertion. Two different bar geometries were studied: the standard-length uniformly curved bar (standard bar) and a flat 25% shorter bar (short flat bar).

Bars were modelled using SolidWorks Simulation 2016 (Dassault Systèmes, Suresnes, France) and numerically simulated with ABAQUS FEA 2017 (Dassault Systèmes, Suresnes, France). The mechanical properties assigned to the simulated bars were equivalent to those of the actual Biomet pectus bars (Zimmer Biomet, Warsaw, IN, USA) usually used in our department. To determine the actual mechanical properties of these bars, a 3-point bending test of a 9-inch long Biomet pectus bar was carried out, resulting in 900 MPa yield strength and 180 GPa elastic modulus.

The simulated implantation of the standard bar was carried out by mimicking the procedure of a conventional operation, i.e. support on the anterior ribs and fixation with stabilizers located at both ends of the bar, at the level of the middle axillary lines (Fig. 1). In the simulated implantation of the short flat bar, the implant was fixed to the costal arches at the level of the anterior axillary lines.

Based on previous measurements of an intraoperative force [7], a 250 N maximum sternal simulated force was applied on the bar ('action force'). Taking into account that actual bar implants are never symmetrical in the axial or in the sagittal plane (given that neither the human anatomy nor the bar geometry is perfectly symmetrical), the sternal force was applied on different points of the bar: centred (ideal conditions) and with offsets of 5%, 10%, 15%, 20% and 25% of the distance between the fixation points on the anterior ribs (actual conditions). Moreover, a variable  $\alpha$ -angle on the sagittal plane was also considered, with values 0°, 5°, 10° and 15° (Fig. 1).

Resulting forces and moments on the fixation points (reaction forces) and stress values along the implants were calculated. The von Mises equivalent stress was used to determine plastic failure deformation (yield) because it is the best failure criterion for ductile materials such as stainless steel. To study the 2 main possible bar displacements, i.e. lateral sliding and flipping [8], forces and moments were depicted in the transverse and the sagittal planes, respectively.

### Second phase: clinical study

Patients (or their parents or legal guardian) were asked to sign an informed consent form before entering the study. The experimental group included 15 adolescent or young adult patients with symmetrical PE, managed with the Nuss surgical procedure between 2011 and 2013. These patients received short flat bars, which were fixed with wires to the rib arcs at the level of the anterior axillary lines. Based on previous computational findings, no stabilizer plates were used in this group. The control group included 15 patients who had been operated on by the same surgical team between 2007 and 2011 (retrospective control group). Control patients received the longer inverted U-shaped standard bars, which were fixed on the midaxillary lines with lateral stabilizers.

All patients received multimodal analgesic therapy including epidural block in the postoperative period. The bars were removed between 24 and 27 months postoperatively. The patients'

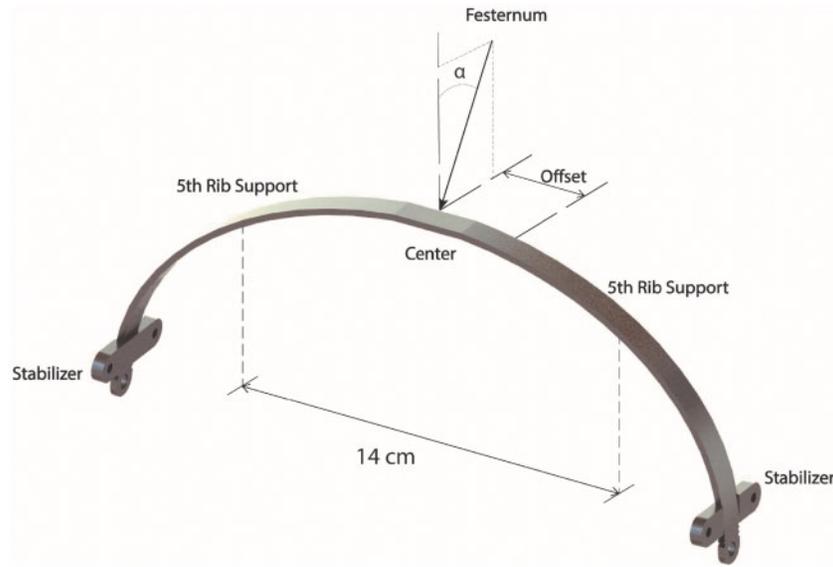


Figure 1: Boundary conditions and loads considered in the finite element analysis of the standard bar.

Table 1: Maximum von Mises stresses (MPa) for both bars

$\alpha$ (°) % Offset	Standard bar				Short flat bar			
	0	5	10	15	0	5	10	15
0	307	311	313	312	541	548	549	546
5	304	309	310	309	537	543	544	540
10	294	296	298	299	522	527	528	524
15	277	277	280	282	497	501	501	498
20	261	263	265	266	462	467	467	463
25	253	253	255	256	418	424	423	419

Offset was a percentage of the bar length.

age and sex, implant length, hospital stay, operation times for insertion and removal, pain on postoperative day 4, pain at discharge, complication rate and cosmetic result as perceived by the patient and by the surgeon were recorded.

Statistical analyses were performed with SPSS v24.0 (IBM, Chicago, IL, USA). Both groups were compared using the Mann-Whitney *U*-test, because normality of data could not be assumed. Cosmetic results were assessed using a 0–3 scale: patients and surgeons scored the results according to their respective perceptions (poor = 0, fair = 1, good = 2 and excellent = 3). Pain was also scored on a 0–3 scale in a descriptive way (severe = 3, moderate = 2, mild = 1 and no pain = 0). The confidence level was set at  $\alpha = 0.05$ ; *P*-values  $\leq 0.05$  were considered significant. This study was approved by the ethics committee of our institution.

## RESULTS

### Finite element analysis

Regarding stress distribution along the implanted bar, maximum von Mises stresses were located on the contact point, where the sternal force was acting on the bar in all the studied cases (Fig. 2). Table 1 shows the maximum von Mises stress values for all the finite element simulations. Maximum stresses were higher with the short flat bar

than with the standard bar in every case. However, the stress level was well under the yield strength (900 MPa); thus the flat shape and reduced length of the bar did not cause bar strength-related issues.

For a better understanding of the sliding mechanism, the forces on both bars, centred and with the maximum offset ( $\alpha = 0^\circ$  in both cases), are shown in the transverse plane (Fig. 3A–D). According to basic equilibrium principles, withstanding the 250 N downwards sternal force requires upwards reaction forces of an equivalent magnitude. However, with the inverted U-shaped standard bar, the application of a force on a convex surface generated horizontal reaction forces that did not actually counteract the effect of the sternal force; therefore, we called them ‘parasitic forces’. In the theoretical ideal conditions of a centred sternal force, such lateral 75 N forces would be opposite and symmetrical, so that they would not have destabilizing effects (Fig. 3A). Conversely, in real conditions, where the sternal force would be offset (Fig. 3B), the action of the resulting unbalanced horizontal forces (16 and 61 N for a 25% offset), produced a tendency of the bar to slide. Intermediate offset values (5%, 10%, 15% and 20%) produced forces ranging between both situations. With the short flat bar, however, due to the fact that it lacks convexity, no horizontal destabilizing forces were generated (Fig. 3). Varying the  $\alpha$ -angle for the different offsets generated only slight differences in the forces on the transverse plane.

To illustrate the mechanism leading to the flipping tendency, forces and moments for the standard bar were represented on the sagittal plane (Fig. 4). To prevent bar rotation, the stabilizers should withstand a certain reaction moment for any  $\alpha$ -angle different from zero (actual conditions). The reaction moment increased with increasing  $\alpha$ -angle for all the considered offsets (Fig. 5); thus, the greater the angle, the stronger was the tendency of the bar to rotate. With the short flat bar, the sternal force would be applied almost on the same axis of the ribs support ( $L \approx 0$ ), so that the tendency to rotate would be almost null.

### Clinical results

Table 2 shows the clinical data. Both groups included more male patients than female patients in approximately the same

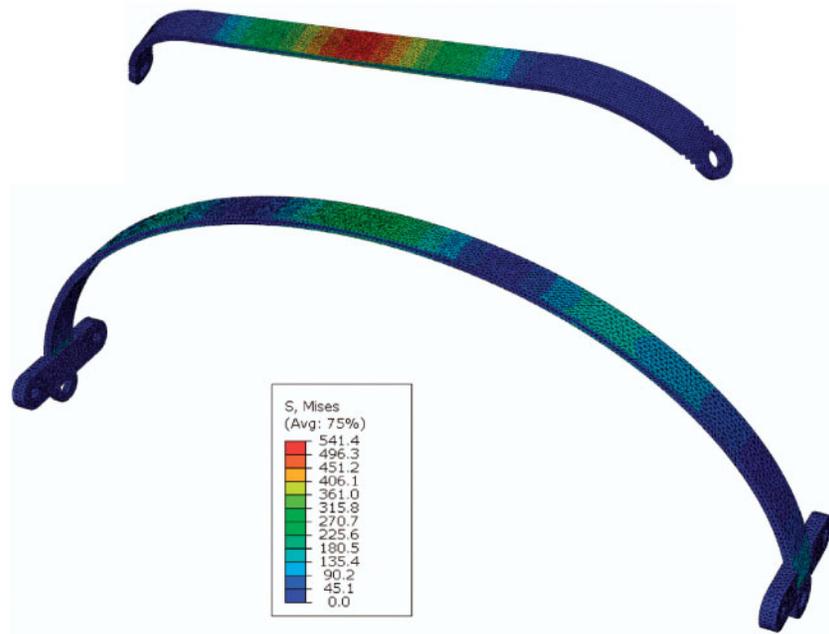


Figure 2: Von Mises stress (MPa) in the case of a centred load and a 0°  $\alpha$  angle (upper bar: short flat bar and lower bar: standard bar).

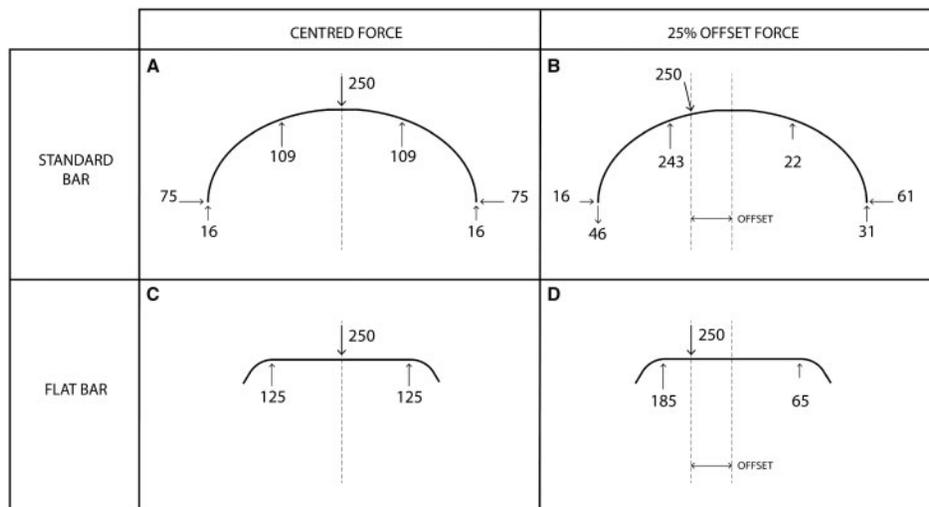


Figure 3: Forces (N) on the transverse plane.

proportion. All operative procedures were uneventful. The use of a short flat bar required statistically significant shorter operative times. Surgeons generally agreed that removal and insertion were easier and safer with the short flat bar. Patients in both groups perceived good cosmetic outcomes without significant differences. Surgeons perceived slightly better cosmetic outcomes in the experimental group (though the difference was also not significant), which might be due to the fact that the lateral incisions were smaller because no stabilizers were used. Most patients in both groups reported moderate to severe pain, which is usual in adults and late adolescents. No significant differences in pain perception were found between the groups. In the control group (receiving the standard bar), 2 cases of bar flipping occurred that required hospitalization and repositioning of the bar. No bar displacements occurred in the group who received the short flat bar.

## DISCUSSION

The original shape of the pectus bar resembles a wide inverted U with the ends of the bar towards the middle or posterior axillary lines, where they are fixed [1]. The obvious discordance between the bone concavity in PE and the metal implant convexity generates forces on the bar that are conveyed to the ribcage. Most of these forces are necessary to elevate the sternum; however, a fraction of them generate bar instability. The clinical consequence is dislocation of the bar, a complication that prevents correction and requires a new surgical intervention. As a consequence, a large number of surgeons perceive bar dislocation as a major technical issue to overcome in MIRPE.

With the aim of enhancing stability, some surgeons have focused on improving bar fixation techniques in different ways:

routine use of 1 or 2 stabilizers [9, 10]; wire suturing of stabilizers [11]; increasing the number of sutures and using additional points of fixation [10, 12, 13] or using novel fixation devices, such as the claw fixator and the hinge plate [14]. A different approach consists of using multiple bars—either routinely in all patients [15] or only in patients at high risk of dislocation [16]—or using connected bars, the so-called bridge technique, which is considered to make the bar unrotatable [17]. Such recent modifications to the original procedure have allowed highly experienced surgeons

to successfully perform MIRPE in adolescent and adult patients [3, 14, 18, 19]. However, although using reinforced fixation systems does not reduce the intrinsic tendency of the bar to be displaced, it does increase the complexity of the operation, hinder reproducibility of the procedure, increase the number of required incisions and prolong the operating time. In addition, removing 2 bars can be more complicated and is associated with higher risks than removing only 1 bar [20].

We present an alternative way of approaching the bar instability issue. Instead of trying to improve the fixing systems, we decided to reduce the forces that generate the instability of the bar. Therefore, this study addressed both issues: the stresses involved in the implant's corrective action and the reaction forces and moments involved in its stability, in a simple and rigorous way. In particular, we studied whether a bar with a novel modelling could provide suitable correction of the deformity and whether the bar's curvature and length affected its stability. Currently, an increasing number of surgeons are using short bars to perform PE repairs, driven by the good clinical outcomes of a large series



Figure 4: Forces and reaction moment in the sagittal plane in the standard bar.

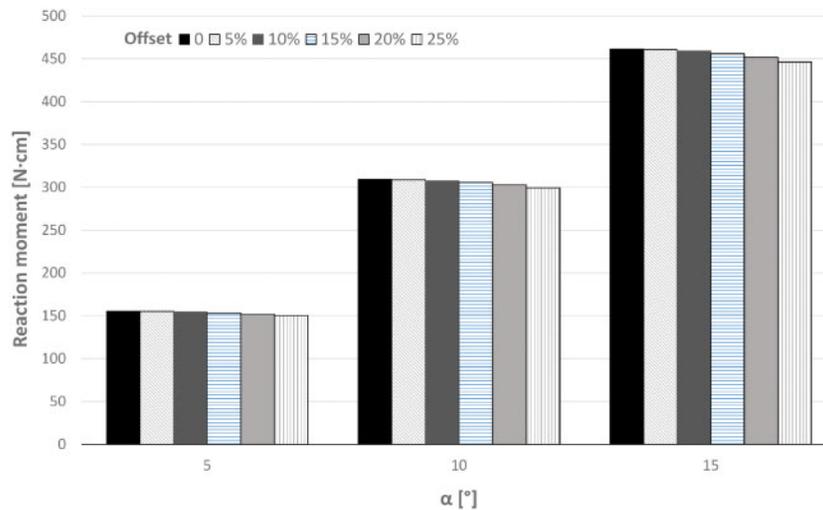


Figure 5: Reaction moment (N\*cm) versus the angle (°) of sternum force (values shown are the sum of the moments of the 2 stabilizers).

Table 2: Clinical results

	Standard bar (n = 15)				Short flat bar (n = 15)				P-value
Bar length (inches)	14 (11.5-16)				12.5 (9.5-13)				
Sex ratio (male:female)	12:3				11:4				
Age (years)	24 (14-27)				20 (16-24)				
Bar implantation operative time (min)	120 (90-144)				85 (68-110)				<0.001
Cosmetic result, patients' perceptions	Poor	Fair	Good	Excellent	Poor	Fair	Good	Excellent	0.757
	0	1	11	3	0	2	10	3	
Cosmetic result, surgeons' perceptions	Poor	Fair	Good	Excellent	Poor	Fair	Good	Excellent	0.455
	1	4	9	nt1	2	1	10	2	
Pain on postoperative day 4, verbal descriptor scale	No	Mild	Moderate	Severe	No	Mild	Moderate	Severe	0.567
	0	2	9	4	0	1	9	5	
Pain at discharge, verbal descriptor scale	No	Mild	Moderate	Severe	No	Mild	Moderate	Severe	0.904
	0	6	8	1	0	5	10	0	
Dislocation ratio	2/15				0/15				
Hospital stay [bar implantation (days)/bar removal (h)]	8 (5-11)/24 (24-48)				7 (7-11)/24 (24-24)				
Bar removal operative time (min)	103 (75-140)				56 (45-80)				<0.001

Continuous variables are expressed as median (min-max).

of patients [21]. Reduction in bar length implies that its 2 traditional long curved ends, which form a small angle with the central region, are eliminated, such that a shorter bar leads to an overall less curved configuration in comparison with a longer one. Current recommendations for the modelling of the central region of the bar are consistent with the traditional strategy of maintaining a curved shape at this area [22], because some over-correction is thought to be necessary [23]. The novelty of our modelling is that, in addition to being shorter, according to the results of the computerized simulation, the bar was also modelled completely flat in its central part.

The capacity of both the longer curved standard bar and the short flat bar to resist the sternal force was analysed through the finite element method. In the computer simulation, standard bars showed lower stress values than short flat ones (Table 1), but the bar material withstood such stress without problems, so that both bar types showed suitable corrective ability. In the clinical phase of the study, the degree of correction in patients receiving the short flat bar did not differ from that of patients receiving the standard bar.

Some authors have identified several risk factors for bar displacement: the patient's age [16], the Haller index [24], the depression index [25] or the distance between the stabilizer and the point where the bar enters the thoracic cavity [26]. Some studies have also endorsed the hypothesis that shorter bars show lower displacement rates [23, 27, 28]; however, such studies were based only on clinical experience, whereas the biomechanical mechanisms underlying instability were not addressed in depth. The simulation in this study demonstrated that, under theoretical ideal conditions, i.e. static loading and perfect bar/anatomical symmetry, no displacement tendency would appear, either with a flat or with a curved bar, because reaction forces would be symmetrical (Fig. 3A–C). Real conditions are, however, different, because the human anatomy is not symmetrical and placing a bar in perfect symmetry is not possible. In addition, thoracic movements from breathing or from body flexion, extension or torsion, would change the relationship between the bar and the ribcage, thus leading to a non-static load of variable magnitude and direction. Thus, once a bar is inserted, it is always subjected to parasitic forces that might eventually result in bar displacement via either of the 2 well-known modalities—bar flipping or lateral sliding [8].

The analysis of the forces in this study showed that, under real load conditions, a sternal force applied on a standard curved bar generates asymmetrical horizontal reaction forces (Fig. 3B). The offset of the application of sternal force (usually due to the natural asymmetry of the deformity) influences the balance between reaction forces. The larger the offsets, the larger are the unbalanced parasitic forces. This finding is in agreement with Park *et al.* [8], who concluded that lateral sliding is the typical complication in cases of severe eccentric deformities. In contrast, with the short flat bar in the same conditions, horizontal parasitic forces are not generated (Fig. 3D), which confers the bar better stability regardless of the asymmetry of the deformity. On this basis, we recommend giving the bars a flat instead of a curved shape, at least at the contact point with the chest wall (most often the sternal surface) in order to avoid parasitic forces that could potentially lead to lateral sliding. To the best of our knowledge, this relevant technical detail, first mentioned by Nuss and Kelly [29], has never been studied before from a biomechanical point of view and, in our opinion, it has not received sufficient attention from the scientific community.

The tendency of the bar to flip was also analysed using the computational model, both under theoretical conditions, i.e. sternal force perpendicular to the bar, and under real conditions. In the first situation, there was no moment of force and, consequently, no tendency to rotate around the stabilizers. However, as mentioned previously, neither the human anatomy nor the bar is absolutely symmetrical. Therefore, a moment ( $M$ ) of a certain magnitude can be expected, as described by the following equation:

$$M = 250 \times L \times \sin \alpha$$

where  $L$  is the distance between the force application point and the support points, measured on the sagittal plane (Fig. 4). In a longer bar (larger distance),  $L$  and  $M$  are larger, which facilitates rotation. Ghionzoli *et al.* [30] came to a similar conclusion about the tendency of the bar to flip. Our clinical results showed no dislocation in patients with the short flat bar, whereas 2 rotational dislocations occurred in patients with the longer curved standard bar; this finding suggests that shorter bars have better stability against rotation. These results are in line with the clinical outcomes reported by Ghionzoli *et al.* and with the results of a large series of patients published by Pilegaard and Licht [26]. Thus, based on the results of our biomechanical study and supported by the discussed clinical results, we suggest that the pectus bar should be flat and that the ends should not reach beyond the anterior axillary line. In other words, a flat bar with trimmed ends should be used.

Easier insertion and removal and consequently shorter operation times are additional advantages of using a short flat bar rather than the standard one. Finally, when no stabilizer plates are used, smaller incisions are required.

## Limitations

One limitation of our study is that the clinical series is small, so the 2 flipping cases in the standard bar group versus none in the short flat bar group are not enough to be determinant. However, we are presenting these results mainly to explain the physical reasons of bar instability; the clinical trial is only a short experience to support our hypothesis. Further clinical outcome studies comparing standard and short flat bars are needed to prove the benefits of a short flat bar.

## CONCLUSIONS

The stability of an implanted pectus bar is directly associated with its shape. The curvature at the contact point with the chest wall was identified as the most relevant cause of lateral instability, whereas the lengths of the vertical lateral segments were found to account for the tendency to flip. On this basis, we postulate that using a pectus bar with a flat segment, which could be restricted to the sternal contact zone in a symmetrical pectus but should be longer towards the lateral position in asymmetrical deformities, would help reduce bar displacement in MIRPE.

**Conflict of interest:** none declared.

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