Automatic pre-bended customized prosthesis for *Pectus Excavatum* minimal invasive surgery correction

João L. Vilaça[1,2], Tiago Henriques-Coelho[3], Tony R. Soares[1], Jaime Fonseca[4], ACM Pinho[5], Pedro L. Rodrigues[1], Jorge Correia-Pinto[1,6]

***Abstract*— *Pectus excavatum* is the most common deformity of the thorax. A minimally invasive surgical correction is commonly carried out to remodel the anterior chest wall, by employing an intrathoracic convex prosthesis in substernal position. The process of prosthesis modeling and bending still remains an area of improvement. The authors developed a new system, i3DExcavatum, which can automatically model and bend the bar preoperatively based on a thoracic CT-scan. This paper presents a comparison between automatic and manual bending.**

The i3DExcavatum was used to personalize prosthesis for 41 patients who underwent *pectus excavatum* surgical correction between 2007 and 2012. Regarding the anatomic variations, the soft tissue thicknesses external to the ribs show that symmetric or asymmetric patients have always asymmetric variations by comparing both patients' sides. It highlighted that the prosthesis bar should be modeled according to each patient ribs position and dimension. The average differences between the skin and costal line curvature lengths were 84±4 mm and 96±11mm, for male and female patients, respectively. On the other hand, the i3DExcavatum ensured a smooth curvature of the surgical prosthesis and was capable to predict and simulate a virtual shape and size of the bar for asymmetric or symmetric patients.

In conclusion, the i3DExcavatum allows preoperative personalization according to the thoracic morphology of each patient. It reduces surgery time and minimizes the margin error induced by the manual bended bar shape that only uses a template that copies the chest wall curvature.

***Index Terms*— *Pectus Excavatum*, biomedical engineering, pediatric surgery, personalized prosthesis**

I. Introduction

PECTUS EXCAVATUM is characterized by a sternum and costal cartilage depression. It is the most common congenital chest malformation occurring between 1 in 400 and 1 in 1,000 births, more frequently in boys than girls in a ratio of 3-5:1 [1].

Despite patients with *pectus excavatum* may occasionally experience symptoms, the reason for seeking medical help are, in most cases, related psychological and social aspects surrounding the body image [2, 3]. The minimally invasive surgical correction of *pectus excavatum* was described by Donald Nuss and consists in the insertion of a metal pre-bended bar through two axillary incisions in the retro-sternum space where it stays between two and three years [4]. The anterior chest concavity is evident in patients with the malformation, affecting mainly the lower third of the sternum and ribs than the upper two thirds [5]. Last decade this procedure had a worldwide spread and is currently a first-line approach for *pectus excavatum* in many centers [6].

Commonly, the prosthesis is modeled intra-operatively, by manually bending the metal bar, using a template that copies the patient's thorax morphology. This process is slow, fastidious for the surgical team, dependent upon the surgeon's experience, needs intraoperative adjustments and, many times, leaves imperfections at the prosthesis surface [7-9]. These shortcomings could be surpassed if the final form of the bar is predicted based on thoracic CT-scan and a system that could automatically bend the bar.

The authors developed a new technology including (1) software to predict the size and virtual shape of the bar based on the chest CT-scan and (2) hardware apparatus to automatically bend the bar - i3DExcavatum system [10].
This work describes the i3DExcavatum system practice for bending the bar for Nuss operation, and compares the internal anatomic references used for automatic bending with the external costal grade references used for hand-bending process.

II. Materials and Methods

A. *Patients and Pre-operative Study*

From 2007 to 2012, 41 patients were evaluated for *pectus excavatum* at Pediatric Surgery Department, Hospital S. Joao,

*Corresponding to: João L. Vilaça; Life and Health Sciences Research Institute (ICVS), School of Health Sciences, University of Minho, 4710-057 Braga, Portugal; Tel: +351 253604881; Fax: +351 253 604 847; E-mail: joaovilaca@ecsaude.uminho.pt

1 ICVS/3B's Laboratory Associated PT, School of Health Sciences, University of Minho, Campus de Gualtar, Braga, Portugal;

2 DIGARC – Polytechnic Institute of Cávado and Ave 4750-810 Barcelos, Portugal;

3 Pediatric Surgery Department, Hospital São João, Porto, Portugal;

4 Industrial Electronics Department, University of Minho, 4710-057, Portugal;

5 Mechanical Department, University of Minho, 4710-057 Guimarães, Portugal;

6 Pediatric Surgery Department, Hospital de Braga, Braga, Portugal;

Porto, Portugal. All patients underwent an exercise and posture program in an attempt to halt the progression of the deformity. The minimal invasive surgical correction with the Nuss procedure was offered when this conservative failed.

The preoperative protocol included chest CT-scan with assessment in both genders of several indices based on the degree of reduction of sterno-vertebral distance (Figure 1):

a) Index of Flatness (iF) – ratio between transverse diameter of the thorax and anteroposterior distance of left hemithorax – iF = DE/HJ;

b) Index of Asymmetry (iA) – ratio between anteroposterior distance of right and left hemithorax – iA = FG/HJ;

c) Index of Haller (iH) – ratio between transverse diameter of the thorax and reduced anteroposterior diameter of the thorax – iH = DE/BC;

d) Index of Depression (iD) – ratio between the anteroposterior distance of left hemithorax and reduced anteroposterior diameter of the thorax– iD = HJ/BC.

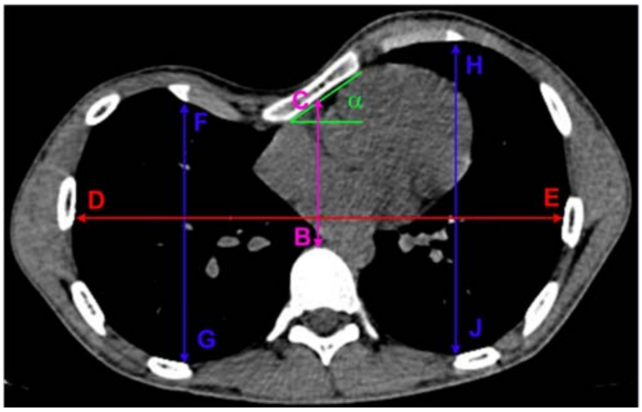

Fig. 1. Representation of a CT slice at deepest sternum point. Diagram presenting several distances to determine anatomic indexes: α (angle of sternum rotation); distance D-E (transverse diameter of the thorax); distance C-B (reduced anteroposterior diameter of the thorax); distance H-J (anteroposterior distance of left hemithorax); distance F-G (anteroposterior distance of right hemithorax).

Moreover sternum angle was also calculated.

Despite of some groups revealing Haller's index superior of 3.20 to 3.25, used as the main criteria to surgery correction [11, 12], our group focused in aesthetic parameters, valuating all the psychological effects of this kind of deformation in the life of our patients.

B. Automatic Bar Bending using the i3DExcavatum

The authors developed the i3DExcavatum system (Figure 2) which allows automatic and personalized modeling/bending of surgical prosthesis used for *pectus excavatum* surgical correction. The automatic bar modeling, by selecting the prosthesis size and shape according to the patient thoracic morphology, comprises the following steps:

a) 3D reconstruction of the thoracic grade from 2D DICOM (Digital Imaging and Communications in Medicine) slices of preoperative chest CT data scan;

b) 3D segmentation of the structures comprising the ribs and the sternum using image processing techniques;

c) Automatically detection of the sternum deepest point based on voxels coordinates of the sternum structure. This point allows a definition of a prosthesis plane that is perpendicular to the sternum;

d) Identifying the coronal plane, that includes the mid-axilla line, that limits the anterior position to the ribs and consequently the initial and final point of the prosthesis and the horizontal body plain that include the intercostal space immediately above the sternum deepest point;

e) Based on d) a limiting box is defined where the intercostal space is inserted;

f) Automatic positioning of the sternum in a position predicted for the correction of *pectus excavatum*, based on the maximum point in the ribs belonging to the intercostal space - correction factor of the sternum, having this position the possibility of later manual modification by the user;

g) Virtual simulation of the most appropriate surgical prosthesis size and shape to repair the defect.

Fig. 2. i3DExcavatum system.

After the simulation approval in step g), the i3DExcavatum system bends the bar with precision of micrometers (Figure 2) [10]. It uses an electromechanical apparatus (composed of a motor, a ramp and a piston that produces a translational movement, perpendicular to the axis of the prosthesis) with real-time monitoring and control.

With this system the calculation of bar size and shape for automatic bending is based on 3D reconstruction of costal grade and not on the external shape of the thorax, as occurs in classical manual bending.

C. Surgical Technique: Comparison of Hand-Bending vs. i3DExcavatum system

All surgical procedures were carried out using sterilized bars that were automatically customized for the patient, and pre-bended in the i3DExcavatum [10]. The surgical approach was the one previously described by Nuss, in which bar stabilizers were used on both sides of the rib cage and wired to the bar. The patients, who are currently followed periodically in outpatient clinic, were discharged home after 2 to 4 days, through which the catheter was left in place.

In order to estimate the skin-to-costal margin errors induced by handmade approach, in both genders was measured the distance between the skin and the costal margin in the horizontal plane, including sternum deepest point at four different sites (Figure 3). Moreover, the length over the skin (skin line) and the length above the external surface of the costal grade (costal line) at the sternum deepest point coronal plane were evaluated.

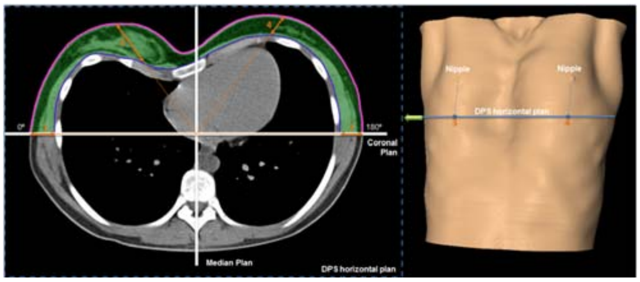

Fig. 3. Representation of a CT slice at deepest sternum point. It also shows the coronal plane at the mid-axillaries lines; skin line (length over the skin - pink); costal line (length over the bone grade - blue); and the skin-to-costal distances: (1) – Right segment: distance between skin and costal margin at 0º; (2) – Left segment: distance between skin and costal margin at 180º; (3) – Right breast segment and (4) - Left breast segment between skin and costal margin in the angle corresponding the nipples level.

By comparing distances, perimeters and areas between skin and costal lines in male and female patients, through use of One Way Repeated Measures Analisys of Variance (SigmaStat 3.5), the skin-to-costal margin error was analyzed, and statistical significance was found to be set at $P < 0,05$.

D. PEEQ - Pectus Excavatum Evaluation Questionnaire

The 41 patients were questioned by telephone: 25 patients answered themselves and 26 questionnaires were answered by their parents (8 patients had already removed the bar). This questionnaire was developed by Lawson et al. in order to quantify the physical and psychosocial effects after the *pectus excavatum* surgical correction [13]. The PEEQ consists in 25 questions, which can be answered according to the following options: 1 - very happy, 2 - almost always happy; 3 - almost always unhappy; 4 - very unhappy or 1 - always, 2 - often, 3 - sometimes and 4 - ever (depending on the questions involved).

All questions were performed before and after surgery. The results were statistically analyzed by the Wilcoxon Signed Ranks Test using SPSS software (version 15.0, SPSS Inc., Chicago, IL, USA).

III. Results

A. Thoracic Indexes

To characterize our population, we calculate several thoracic indexes as described previously (Table 1 and Figure 1). Haller index revealed values of 3.16±0.09 in total population with no significant differences between genders. The FG/HJ index, an index of asymmetry, had ranged values of 0.86 and 1.24 (1.00±0.01), with minor differences among male and female. Twelve patients (29%) had a FG/HJ index value ≤0.90 or ≥1.10 (data not showed). An average of 10.63±1.6° in sternal angle reveals a slight rotation of the sternum in *pectus excavatum* patients.

B. Clinical Data and automatic bending using the i3DExcavatum

41 patients were operated with a range of age between 7 and 29 years old (15±0.5) and a male-to-female ratio of 6:1. Haller index as all other assessed thoracic indices were not different among genders (Table 1). The mean length of surgery was 81 minutes with a range of 55 to 120 minutes and the mean length of anesthesia was 133 minutes ranged between 74 and 200 minutes. Among the 41 patients, 39 received an epidural catheter maintained along 2 to 4 days after surgery. The other 2 patients were subjected to patient-controlled analgesia. The mean length of stay was 5.6 days, with a range of 4 to 8 days of stay. Only one patient required intensive care. At moment, 15 patients had already removed the bar, 10 in ambulatory regime and the others 5 with one day surgery. The average of length with implanted bar was 30 months, with a range of 18 and 40 months regarding complications and there were one partial relapse (2.4%). There were no bar shifts identified, but there were two cases of chronic pain (4.9%). One abscess (steel rejection) was described (2.4%).

TABLE 1. Thoracic indexes based on chest CT-scan assessment.

	Male (n=35)	**Female (n=6)**
α (degreesº)	10.49± 1.62	11.5±5.80
iD	1.86±0.05	1.92±0.15
iH	3.14±0.10	3.23±0.27
iA	1.00±0.01	1.02±0.04
iF	1.69±0.03	1.68±0.05

When compared with Nuss classical method, the i3DExcavatum system showed better results. Statistical significant difference were found between the two techniques (i3DExcavatum system versus Nuss classical method) regarding the need for PICU (polyvalent intensive care unit) (1/15 versus 30/9, p=0.001), surgery time (81 min versus 128 min, p=0.001) and hospitalization days (6 days versus 8 days, p=0.002).

The surgical prosthesis modeled and bended by the i3DExcavatum (Figures 4 and 5) allows us to have the right size and better shape of the bar for *pectus excavatum* repair by Nuss procedure even for asymmetric patients. When applied the bars fit always perfectly in the patients.

C. Comparison of hand-bending vs. i3DExcavatum criteria

The skin-to-costal margin distances varied depending on the site of measurement (Table 2). These distances reached highest values at mid-axillary lines (both genders) and under the breasts mainly in females. Moreover significant (P<0.05) differences were detected between the skin and the costal lines in both genders.

TABLE 2. Skin-to-costal margin measurements based on chest CT-scan

	Male (n=35)	Female (n=6)
Distances (mm)		
Right segment	23.6±1.1	22.6±3.0
Left segment	24.1±1.0	19.3±3.0
Right breast segment	11.3±1.0	25.7±3.3*
Left breast segment	11.8±1.0	22.0±2.1*
Curvature lengths (mm)		
Skin line	452±9	441±27
Costal line	368±9ǀ	345±24ǀ
Skin-to-costal lines difference	84±4	96±11

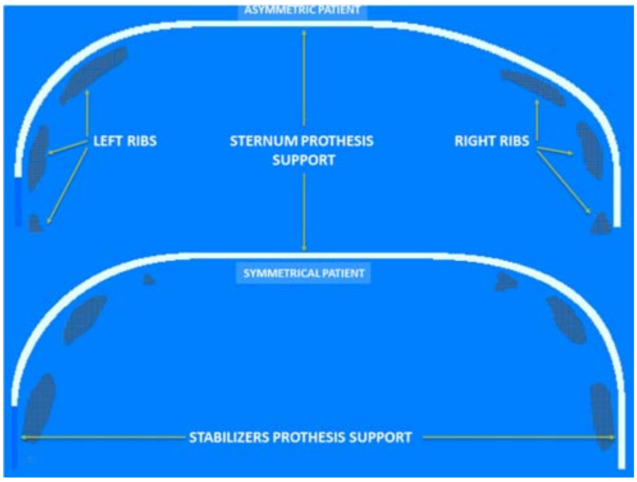

Fig. 4. Virtual prosthesis modeled using the i3DExcavatum system for asymmetric and symmetric patients.

Fig. 5. Representation of the differences between two bended prosthesis: (A) bended manually and (B) bended using the i3DExcavatum system.

D. *PEEQ - Pectus Excavatum Evaluation Questionnaire*

Table 3 summarizes the PEEQ results. All psychosocial problems (self-image problems, self-esteem, frustration, sadness, social isolation) were reduced (statistically significant) after the surgical correction. On the other hand, non-significant improvements were found regarding the exercise tolerance, chest pain and weight gain. Finally, significant improvements were found considering the breathing difficulties and fatigue.

TABLE 3 – PEEQ results before and after surgical correction

		Before Surgery	After Surgery
Compo-nent	**Patients (n=25)**		
Psycho-social	Esthetic thorax aspect with shirt‡	2.44	1.32*
	Esthetic thorax aspect without shirt‡	2.92	1.36*
	Need for surgical correction‡	3.16	1.48*
	Bullying §	3.76	4.00*
	Avoid some daily situations§	2.72	3.83*
	Hide thorax§	2.72	3.83*
	Chest appearance§	2.28	3.80*
	Shame§	2.60	3.88*
	Self-esteem§	3.21	4.00*
Physical§	Physical exercise difficulties	3.40	3.81
	Respiratory difficulties	3.56	3.67
	Fatigue resistance	3.12	3.48
	Pais (n=26)		
Psycho-social§	Irritability	2.85	3.83*
	Frustration	2.64	3.87*
	Depressed	2.63	3.86*
	Restless	2.75	3.83*
	Solitary	3.20	3.96*
	Bullying	3.41	3.95*
Physical §	Physical exercise difficulties	3.62	3.58
	Chest pain	3.77	3.58
	Respiratory difficulties	3.48	3.74*
	Fatigue resistance	3.40	3.83*
	Weight gain	3.29	3.36
Self-conscience§	Swimwear reluctance	2.23	3.96*
Parents concern§	How often parents are concerned about the son/daughter life?	1.85	3.20*

‡Scale: 1 = very happy; 2 = almost always happy; 3 = almost always unhappy; 4 = very unhappy.
§Scale: 1 = always; 2 = often; 3 = sometimes; 4 = ever.
*Significant improvement in surgical outcome with p<0.05 according to the *Wilcoxon Signed Rank Test*.

IV. CONCLUSION

The Nuss technique is a much less demanding surgical procedure that avoids significant dissection minimizing blood loss. For these reasons, it is becoming the most worldwide accepted procedure for surgical correction of *pectus excavatum* [6]. However, there are always space for improvements and innovation, even in a revolutionary surgical technique like Nuss procedure.

This paper describes a new methodology that firstly uses chest CT-scan as a tool for predicting the size and shape of the most appropriate bar for each patient. Then, a hardware use this information in order to bend the bar into the defined shape by the software. To this extent, the i3DExcavatum was a successful technological application with several advantages: a) personalized determination of the bar size and shape; b) smooth and precise bending of the bar; c) better fitting with a uniform strength distribution exerted by the prosthesis over the ribs.

Anatomical internal references were compared to external in order to highlight that regardless *pectus excavatum* malformation's symmetry, there are always variations between left and right sides' soft tissues. Using a template that only copies the chest wall curvature can require intraoperative readjustments as the distance between skin and ribs differs with patient's side as well as with the position along thoracic cage.

Moreover, soft tissues along the thoracic wall are also dependent on age, sex, and body mass index of each patient. On female patients, breast tissue could induce additional errors in bar manual conception. Therefore, within the ei3DExcavatum, the prosthesis is always modelled and bent according to position and dimension of the ribs. This might be a particular advantage in asymmetric or female patients. In fact, asymmetric patients are the most difficult cases and the classic manual bending is particularly challenging in those situations. Park et al experienced these kinds of difficulties, encouraging them to develop a variety of manual bending techniques adapted for the different morphologic variations of *pectus excavatum* [14]. To obtain the skills needed to manually bend different bar shapes for different thorax configurations are difficult, fastidious and it is necessary an important hand experience [14].

However, to get uniform strength distribution exerted by the prosthesis on the ribs in asymmetric thoraxes requires complex calculations difficult to accurately accomplish without the assistance of software such as i3DExcavatum. On the other hand, in female patients the estimation of the bar size based on external skin approach can introduce significant difficulties namely if we operate the patients during adolescence when breast development already started.

The PEEQ results, which evaluate the psychological, social and self-image effects are in accordance to previous studies [3, 13]. However, one may conclude that psychosocial and physical aspects were improved with the *pectus excavatum* surgical correction.

Hereupon, automatic pre-bending bar using i3DExcavatum allowed a reduction in the time consuming step of manual bending during the surgery, minimizing errors induced by a manual bended bar shaped based in the skin line.

Acknowledgments

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