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Minimally Invasive Repair of Pectus Excavatum:
A 13-year Experience At a Tertiary Surgical Center

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Doutor Tiago Alexandre Henriques-Coelho**

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Ao meu irmão Francisco,

Para que te inspire e desafie o potencial que possui.

**MINIMALLY INVASIVE REPAIR OF PECTUS EXCAVATUM:
A 13-YEAR EXPERIENCE AT A TERTIARY SURGICAL CENTER**

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ABSTRACT

Background/Purpose: Pre-surgical automatic and personalized bar bending for pectus excavatum (PE) correction allows a correct size and shape of the bar using 3D computerized tomography (CT) scan. This study retrospectively reviews the experience at a tertiary pediatric center for surgical correction of PE and analyses the impact of the pre-bended bar in Nuss procedure (NP).

Methods: Patients who underwent a NP from January 2000 to December 2013 were included. Data regarding demographics, previous PE correction, anesthesia, surgery and complications were obtained from clinical files. Statistical analysis was performed between patients who received pre-surgical automatic bended (AB group) or classic manual bended (MB group) bars. Data are presented as median (range).

Results: A total of 139 (78% male) patients were operated. Median age at the time of surgery was 14.7 years (range, 7-30 years). Ten patients (7%) had been previously submitted to Ravitch procedure. Since 2007, the automatic pre-bended bar was used in 96 patients (69%). MB and AB groups were identical for gender, age and symmetry of the defect, but patients in MB group had a higher median Haller index. A thoracic epidural catheter was placed in almost every patient (98%). In AB group, surgery lasted less time, the hospital length of stay was shorter and complication rate was lower. There was no mortality. Complications included pneumothorax, skin erosion, bar displacement, wound infection and bar infection. The bar was removed after a longer period in the AB group.

Conclusion: The actual surgical technique using pre-bended bars is safe and quick, with a low complication rate.

KEY WORDS: Nuss procedure; minimally invasive surgery; pre-bended prosthesis; chest wall deformity.

1. INTRODUCTION

Pectus Excavatum (PE) is the most common congenital chest wall deformity and several procedures have been described to manage this deformity. Donald Nuss introduced the minimally invasive repair of PE (MIRPE) technique in 1998 [1]. Since then, there has been a worldwide significant increase in the number of patients with PE treated by the Nuss procedure (NP). It is currently a first-line approach for PE in many centers, regarding being a much less radical operation with better cosmetic results than previous techniques such as Ravitch procedure [2]. Other innovative approaches are under evaluation, such as vacuum treatment [3], custom-made silicone implants [4], the pectoscope [5], pectus tunneloscopy [6] and the magnetic mini-mover [7].

Original Nuss procedure describes an intraoperative manual bar bending assisted by a template that reproduces the patients' thorax morphology. This laborious protocol is time-consuming and often results in imperfections that could adversely compromise the correction success [8, 9]. In order to overcome these disadvantages, a new system that allows pre-surgical automatic and personalized modeling and bending of the bar prosthesis was described to predict the correct size and shape for each patient, based on 3D computerized tomography (CT) scan images [10]. Our group already described the advantages of personalized prosthesis modeling and bending. In the present study, we review the experience in a tertiary center for surgical correction of PE comparing the pre-bended bar group with historical controls.

2. MATERIAL AND METHODS

2.1. Study Design

This retrospective observational study enrolled 139 patients submitted to PE surgical correction by the Nuss procedure from January 2000 to December 2013, at Pediatric Surgery Department of Centro Hospitalar São João in Porto, Portugal. The Health Ethics Committee of Centro Hospitalar São João approved the study. Data was obtained from paper and digital clinical files of the selected patients. Criteria for surgical correction was based not only on objective parameters as the Haller index or physiologic compromise, but also on the psychological effects and body-image distortion associated with PE deformity. The preoperative protocol included electrocardiogram, echocardiogram and computerized tomography (CT) scan. Follow-up period after the procedure ranged from a minimum of 2 months and a maximum of 45 months.

2.2. Evaluated Parameters

Patients submitted to Nuss procedure were divided in two groups: those that underwent MIRPE procedure with an intra-operative manual bended (MB) metal bar (historic controls) and those with pre-surgical automatic bended (AB) metal bar personalized in accordance to their 3D CT scan. Demographic data, deformity characterization, surgical data and complications were collected. Regarding demographic data, gender, age at surgery and history of previous surgery were acquired. Morphologic characterization of the deformity by CT scans included Haller index (HI) and symmetry (Type 1 – symmetric; Type 2 - asymmetric). Surgical data included: type of bar bending (manual or pre-bended), number of bars placed, duration of surgery, duration of anesthesia, type of postoperative analgesia, length of hospital stay, need for Pediatric Intensive Care Unit (PICU), early complications (considered as

occurring intra-operatively or during the initial hospital stay), late complications (during follow-up), average time with the bar and mean age at bar removal.

2.3. Automatic Bar Bending

The selection of the prosthesis size and shape was based on 3D reconstruction of the thoracic grade from 2D DICOM (Digital Imaging and Communications in Medicine) slices of preoperative chest CT data scan. A sequence of automatic image processing techniques simulated the most appropriate surgical prosthesis to the patient. After this simulation, the system bends the bar with a precision of micrometers using an electromechanical apparatus with real-time monitoring and control [10].

2.4. Nuss Procedure

The Nuss procedure was performed under general endotracheal anesthesia. A thoracic epidural block for intra-operative and post-operative pain control was used. A Foley catheter was placed. All patients received a pre-operative course of prophylactic antibiotic regimen. Patient was supine positioned with both arms abducted at the shoulders. Bilateral 1.5-2.5 cm transverse thoracic incisions between the anterior and midaxillary lines were used. A 5mm 30 degree thoracoscope was inserted one or two intercostal spaces below the right thoracic incision and the chest was insufflated with CO₂ until 6 mmHg. Under endoscopic guidance, a subcutaneous-substernal-subcutaneous tunnel was raised anteriorly from both incisions to the top of the pectus ridge. In MB group the pre-operative chest measurement was reconfirmed and a bar was selected for bending into the desired chest-wall curvature (this step was absent in AB group). The sterilized convex metal bar was inserted and advanced across the mediastinum in the retro-sternal space under thoracoscopic vision. The bar was then flipped and positioned in the correct place. In MB two stabilizers were placed whereas in AB group no stabilizers were used. A chest

tube was placed using the incision for 5mm trocar. After surgery a chest radiography was performed to confirm adequate lung expansion and to reveal the final positioning of the bar.

The prosthesis was removed after two to three years. This procedure was performed under general anesthesia using the previous incisions as an outpatient procedure.

2.5. Pain Control Protocol

An epidural catheter was placed in the region of T5-7 to assure analgesia in the dermatomes affected by the surgery. Infusion comprised a local anesthetic (bupivacaine or levobupivacaine) and an opioid (morphine). During hospital stay, the epidural catheter was left in place for pain management for 3-6 days. In cases of epidural failure, intravenous patient controlled analgesia (PCA) and oral analgesia was used.

2.6. Statistical Analysis

Data were analyzed with *IBM SPSS Statistics*® 21.0. To characterize variables, descriptive statistics was used and normality of data was tested by Shapiro-Wilk test and Normal Q-Q Plots. Parametric and nonparametric comparisons were performed as appropriate. Variables median age at surgery, median Haller index, surgery duration, anesthesia duration, post-operative lengths of stay and median period with the bar for both groups were analyzed using Wilcoxon-Mann-Whitney U test. Chi-square and Fisher's Exact test were used for categorical variables such as gender, epidural catheter, need for PICU and complications. Statistical significance was set at $P < 0.05$ for all tests.

3. RESULTS

3.1. Demographic Data and Deformity Characterization

Data are summarized in Table 1. A total of 139 patients underwent PE surgical correction by Nuss procedure. From these, 43 patients received a manual bended bar (MB group) and 96 patients received an automatically pre-bended bar (AB group) after 2007. Eleven patients (8%) had scoliosis. One patient was diagnosed with Poland syndrome and two with Marfan syndrome. Regarding previous surgery, one patient was submitted to a neonatal thoracotomy for a diaphragmatic hernia and ten patients (7%) had been previously submitted to Ravitch procedure. None of the patients were previously submitted to a Nuss procedure. There was a male preponderance (78%) and patients' age ranged from 7 to 30 years (median age 14.7 years). Both groups were identical for gender, age and symmetry of the defect, but MB patients had a higher Haller index.

3.2. Surgical Data

Data are summarized in Table 2. Only one bar was used. Thoracoscopy was always used. There was no need for blood transfusion. Surgery duration in the group of patients with automatic bended bar was significantly lower than in the MB group in average 48 minutes (120 vs. 72, $p < 0.001$). Figure 1 represents surgery duration along the years evaluated. A statistically significant decrease in the intra-operative time was found. Length of stay was significantly reduced around 2 days (7 vs. 5, $p < 0.001$) with the introduction of the automatic pre-bended bars after 2007. A thoracic epidural catheter was used in all but 3 patients and is assumed as the most often used method for pain control in 98% of the patients.

3.3. Complications

Table 3 summarizes early and late complications. There was no mortality. In general, there were less complications in the AB group (9.4% vs. 48.8%, $p<0.001$). Regarding early complications, patients in the MB group had a higher rate of pneumothorax (11.6% vs. 1%, $p<0.05$) requiring intervention (percutaneous drainage, chest tube insertion or endotracheal intubation). Incidental findings on postoperative control x-ray with spontaneous resolution and no need for intervention, such as residual pneumothorax, pleural effusion or subcutaneous emphysema, were not considered. In MB group, there was one episode of internal mammary artery injury, without repercussions. Epidural catheter-related complications occurred in both groups: in MB patients, there was a case of transient Horner's syndrome that reverted after removal of the catheter and there were two cases of catheter exteriorization in the AB group. Besides transient extremity paralysis was reported in both groups, patients recovered completely. Regarding late complications, there were bar displacements requiring intervention (MB – 3 vs. AB – 1, $p=0.088$), surgical wound infections (MB – 1 vs. AB – 2, $p=0.674$), bar infection (MB – 2 vs. AB – 2, $p=0.587$) or over-correction (MB – 1 vs. AB – 0, $p=0.309$). There was a significantly higher rate of skin erosion in the MB group (MB – 6 vs. AB – 0, $p<0.001$).

3.4. Bar Removal

From a total of 139 patients, 91 (65.5%) are already without bar. The bar was removed later in the AB group [median period with the bar, 28 months (range, 2-45 months) vs. 32 months (range, 18-45 months), $p<0.001$]. There was no statistical difference in median age at removal [16.9 (range 10.3-24.2) vs. 17.4 (range 10.6-32.8), $p=0.067$].

4. DISCUSSION

Patients with PE may occasionally experience symptoms, such as complaining of decreased tolerance performing extenuating exercises. Other physical disabilities include recurrent upper respiratory tract infections such as pneumonia, poor feeding, retarded growth, poor posture and even scoliosis. Nevertheless, in most cases, the reasons for seeking medical care are related to psychosocial features surrounding body image. Loss of self-esteem and social activities avoidance are common in this group of patients. Moreover, there is evidence that surgical repair of PE considerably improves body image and cardiorespiratory limitations on physical activity, improving patients' quality of life [11]. Some groups presently use HI values greater than 3.20 to 3.25 as the main criterion for surgical correction [12]. Our group adopted a patient-based approach, considering aesthetic parameters and assessing all physical and psychological effects of the deformity, such as body image distortion.

Nuss procedure was mainly intended for pre-pubertal child. Besides optimal age for repair is still unclear, it is currently recommended for patients between 8 and 12 years [1, 13]. A balance between the younger patients' chest softness and malleability and the older patients' maturation to understand and cooperate is desirable. Our average ages were higher – 14.4 and 14.9 years for MB and AB groups respectively. We believe this is an advantage: at first, rib cage flexibility is still preserved; furthermore, this prevents recurrence of PE due to early correction. Even though, only further studies can validate the impact of this hypothesis.

Several diagnostic tests can be performed before patients undergo MIRPE procedure. CT scan is routinely requested in our department. High-resolution assessment of the deformity allows automatically personalization of the bar bending process. It also reports cardiac or lung compression and displacement showing the significant internal morbidity of what is often described as a purely cosmetic deformity. On the other hand, CT scans produces significant radiation and the benefit-risk ratio

is still unknown [14]. Chest fast MRI was recently suggested for pre-operative workup and Piccolo and colleagues [15] obtained accurate measurements of the chest avoiding CT scan radiation exposure.

Our center has been through important changes in the MIRPE procedure since 2007. A new concept of morphology-based, patient approach was developed by creating the *i3DExcavatum* system [10]. Meticulous assessment of individual chest wall morphology and calculation of bar size and shape for automatic bending is based on 3D reconstruction of costal grade; on the other hand, classic manual bending is based on external shape of the thorax. Even for asymmetric patients, this resulted in the appropriate size and better shape of the bar [10]. Smooth and precise bending of the bar and enhanced fitting with uniform strength distribution applied by the prosthesis over the ribs are main advantages. When compared with the Nuss traditional method, this system consistently showed better results [10]. In our experience, we found a statistically significant reduction in surgery time after the introduction of automatic bending in 2007. This is one of the major advantages of this new approach. Per year analysis revealed a consistent tendency of surgery time reduction along the years and from 2000 to 2013, the procedure duration was reduced to half of time. However, we cannot exclude the learning curve in the first years of implementation of the NP in our center. It is important to notice that complication rates were lower with a faster procedure, revealing the safety and effectiveness of this modelling system.

Differences between soft tissue thicknesses of left and right thoracic wall sides exist in every patient, irrespectively to their PE symmetry [16]. Furthermore, this tissue varies with age, sex and body mass index. Accordingly, a particular advantage might exist in two groups: asymmetric or female patients. Park and colleagues [17] began to adopt asymmetric bar shaping techniques and a symmetric repair was achieved successfully. Even though, they recognized how challenging and laborious is to manually bend the bar for different thoracic configurations. Software such as *i3DExcavatum* can precisely assist bar modeling in order to achieve uniform strength exerted by the prosthesis on the ribs in this group of patients. Regarding female patients, breast development has already started in many girls that undergo

MIRPE procedure. Manual bending of the bar can account additional errors due to breast tissue. In our series, around 56% of the patients exhibited one form of asymmetric chest wall morphology based on their chest CT. Regardless chest wall morphology, symmetrically shaped bars are applied in the classic Nuss technique.

Bar displacement leads to imperfect correction or complete failure of the procedure. Nuss technique suggests simple fixation of the bar to adjacent subcutaneous tissue. In 2002, Croitoru and Nuss proposed a lateral stabilizer as a solution for this serious problem and reported a reduction from 15% to 5% in bar migration rate [18]. Pre-bended bar used by our group have a unilateral stabilizer incorporated in the bar. Instead of using lateral stabilizers, a multiple point pericostal fixation technique was presented by Park and colleagues [17] as a better approach, with lower rates of displacement – around 0.5% - and less difficulty on insertion and removal. However, this is a time-consuming step.

Vergunta et al [19], along with Dr. Nuss and Dr. Croitoru groups, support the use of 2 bars in severe or older patients and already routinely use them in most patients. Pressure distribution over a wider area and increased mechanical stability is provided using two bars placed above and below the midpoint of the deformity, with one stabilizing plate for each, on opposite sides of the chest. On the other hand, they may cause over correction in some patients. Every patient enrolled in the present study only received one bar. We admit that patients with Grand Canyon type of PE can benefit from two bars.

Even being a minimally invasive procedure, the Nuss technique is associated with important postoperative pain and in some patients this was described as a crucial limiting factor. In our institution, all patients that underwent the MIRPE procedure received thoracic epidural catheter anesthesia during hospital stay. With this approach, postoperative pain was successfully managed with a very high success rate. Epidural analgesia kept the patients comfortable and stable and reduces bar displacement. It is now clearly known that in order to reduce this complication is also important to ensure that the bar is

stably fixed and comfortably located and that there is no major trauma to the chest wall after the procedure [17].

Cardiac or lung injury is one of the major complications of MIRPE procedure. It can occur during retrosternal tunnel dissection, Nuss bar introduction or bar removal because anterior mediastinal space is very narrow. In our center, we use thoracoscopy (VATS) to aid dissection and no cases of cardiac injury were described, except for one patient with internal mammary artery injury. Darlong [6] recently presented an innovative technique for real-time endoscopic vision of the retrosternal tunnel blind spot, named pectus tunneloscopy. This comprises the use of a hollow transparent tube for bar conduit along with thoracoscope insertion. As no additional cost, time or skin incision is needed, this can be a safe route to avoid rare but fatal cardiopulmonary injuries. Other approaches comprise the use of a more dorsally placed laparoscopic dissector instead of the Nuss introducer [20] or even a modified bilateral thoracoscopy technique [21].

5. CONCLUSION

During a 13-year period, MIRPE procedure was safely performed in pediatric patients, even after previous Ravitch surgery and with associated musculoskeletal disorders. Our department was very successful with thoracic epidural catheter anesthesia, crucial for a better post-operative pain control. Nuss procedure using automatic pre-bended bars improved the outcomes, significantly reducing the time-consuming step of manual bending during surgery. After some years of learning curve, the actual surgical technique with pre-bended bar is very safe and quick, with a low complication rate.

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LEGENDS

Figure 1. Intra-operative time progression of Nuss procedure along the years.

There was a statistically significant decrease in intra-operative time (vertical axis) during the years evaluated (horizontal axis). The vertical line in the year 2007 indicates the introduction of the *i3DSurgical* system. Median duration and range are presented in the grey box.

Table 1. Demographic data and deformity characterization.

	Manual Banded (MB)	Automatic Banded (AB)	P value
n (%)	43 (31%)	96 (69%)	-
Gender, male-to-female ratio	33:10	75:21	0.858
Median age at surgery (range), years	14.4 (8-21)	14.9 (7-30)	0.098
Previous Ravitch procedure, n (%)	3/43 (7%)	7/96 (7%)	0.948
Median Haller Index (range)	3.95 (1.99–6.49)	3.32 (2.08–6.50)	0.008
Symmetric (type 1) (%)	44%	44%	0.959

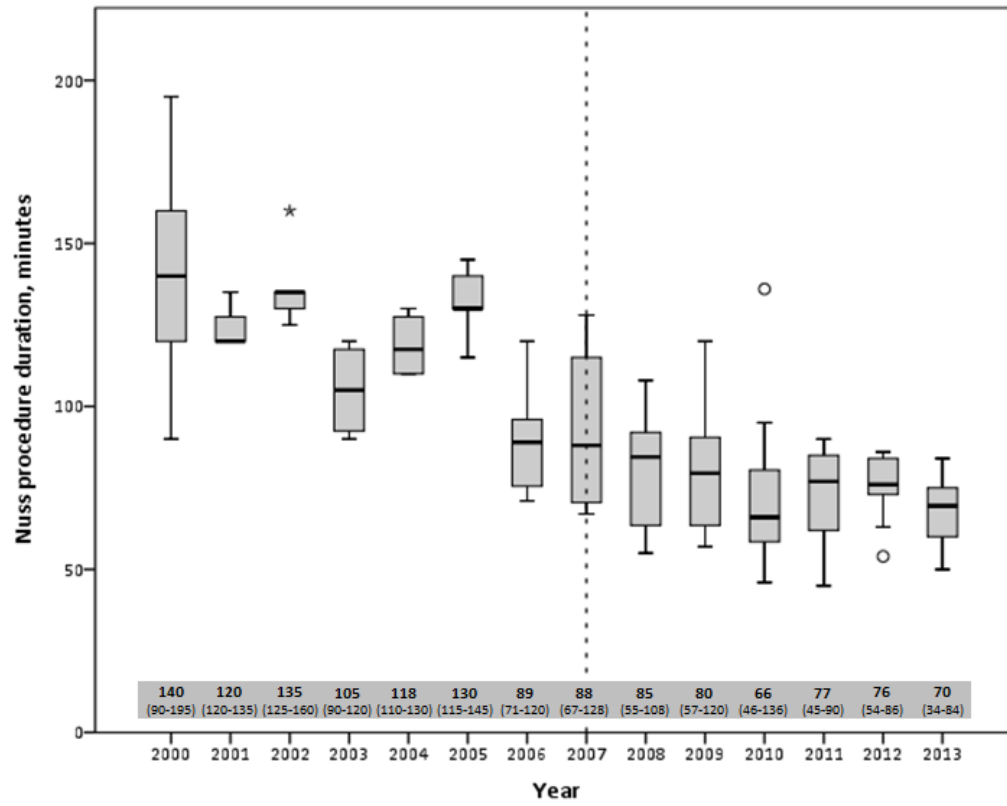
Table 2. Surgical data.

	Manual Bended (MB)	Automatic Bended (AB)	P value
Surgery duration , median (range), <i>minutes</i>	120 (60-195)	72 (45-136)	< 0.001
Anesthesia duration , median (range), <i>minutes</i>	155 (70-120)	133 (75-215)	< 0.001
Epidural catheter , <i>n (%)</i>	42 (98%)	94 (98%)	0.928
Need for PICU , <i>n (%)</i>	28 (65%)	1 (1%)	< 0.001
Post-operative length of stay , median (range), <i>days</i>	7 (4-18)	5 (2-11)	< 0.001

Table 3. Early and late complications.

	Manual Bended (MB)	Automatic Bended (AB)	P value
Total of complications, n (%)	21/43 (48.8%)	9/96 (9.4%)	< 0.001
Early complications, n (%)			
Injury of internal mammary artery	1 (2.3%)	0	0.309
Pneumothorax requiring intervention	5 (11.6%)	1 (1%)	0.011
Transient Horner's syndrome	1 (2.3%)	0	0.309
Transient extremity paralysis	1 (2.3%)	1 (1%)	0.525
Epidural catheter exteriorization	0	2 (2%)	0.475
Pericarditis	0	0	-
Hemothorax	0	0	-
Infectious complications	0	0	-
Cardiac or lung perforation	0	0	-
Late complications, n (%)			
Bar displacement	3 (6.9%)	1 (1%)	0.088
Surgical wound infection	1 (2.3%)	2 (2%)	0.674
Bar infection	2 (4.6%)	2 (2%)	0.587
Over-correction or carinatum deformity	1 (4.8%)	0	0.309
Skin erosion	6 (13.9%)	0	0.001
Others			
Hemothorax, bar allergy, thoracic chondrodystrophy	0	0	-

Figure 1



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ANEXOS

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Submitting the manuscript

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All manuscripts (including figures) must be submitted to the Journal of Pediatric Surgery through our Web site (<http://ees.elsevier.com/jpedsurg/>). Submission items should include separate files for a cover letter, title page, abstract, manuscript text, references, legends for table/figure, tables, and figures. Revised manuscripts should also be accompanied by a unique file (separate from the cover letter) with responses to reviewers' comments. The preferred order of files for electronic submission is as follows: cover letter, response to reviews (revised manuscripts only), title page, manuscript file(s), table(s), figure(s). Files should be labelled with appropriate and descriptive file names (e.g., SmithText.doc, Fig1.eps, Table3.doc). Upload text, tables and graphics as separate files. Do not import figures or tables into the text document; submit them as separate files. Complete instructions for electronic artwork submission can be found via the journal home page. All manuscripts must be submitted double-spaced in English. Please visit <http://ees.elsevier.com/jpedsurg/> to submit your manuscript electronically. The website guides authors stepwise through the creation and uploading of the various files. Note that original source files, not PDF files, are required. Once the submission files are uploaded the system automatically generates an electronic (PDF) proof, which is then used for reviewing. All correspondence, including the Editor's decision and request for revisions, will be by e-mail. All pediatric surgical image manuscripts, operative technique manuscripts, Letters to the Editor, and Replies to Letters to the Editor should be submitted to Dr. Grosfeld online. Correspondence concerning abstracts, book reviews, notices, reports of meetings, and other announcements should be addressed to Dr. Grosfeld by mail or e-mailed to jpedsurg@iupui.edu.

Original articles are preferred and are accepted for publication on the condition that they are contributed solely to this journal. Papers should be as brief as possible, consistent with the subject. **As of December 31, 2012, Case**

Reports are no longer accepted by the Journal of Pediatric Surgery. Authors have the option of submitting to the new open access, online-only companion journal, Journal of Pediatric Surgery Case Reports (<http://www.jpascalereports.com>). Dr. Grosfeld welcomes submissions to the Pediatric Surgical Images Section

that display the classic radiologic or pathologic childhood surgical disease or showcase new developments in imaging relevant to pediatric surgery. Plain radiography, Ultrasound, CT (including 3-D/helical), MR (including MRA, MRCP) and scintigraphy images may be used. Text and image reproductions are to be up no more than 2-3 journal pages (approximately 5-7 typewritten pages). Content should focus on the radiographic diagnosis and include 2 to 3 images along with a supporting clinical photograph when appropriate. References should be limited to a maximum of 10-12. A brief unstructured abstract and up to 6 keywords should accompany the submitted work.

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The *Journal of Pediatric Surgery* subscribes in general to the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals"(N Engl J Med 336:309-315, 1997).

Preparing the manuscript

Manuscripts must be submitted electronically, preferably in Microsoft Word. References and figure legends must appear at the end of the manuscript. Please refrain from using endnotes as references or automatic list numbering because these features are lost in conversion: simply type the reference number in parentheses in the text and type the reference list. Formatting, such as Greek letters, italics, super and subscripts may be used: the coding scheme for such elements must be consistent throughout. Authors are responsible for applying for permission for both print and electronic rights for all borrowed materials and are responsible for paying any fees related to the applications of these permissions.

Please be sure to include an accurate mailing address (including US zipcode, or postal code for other countries) telephone and fax numbers, and an email address for editorial communications and for reprint requests. All proofing is sent via email.

A brief structured abstract of the paper with the headings *Background/Purpose, Methods, Results, and Conclusions* should precede the body of the paper, to run no more than 200 words, and **to replace any summary section at the end of the article**. Following the abstract should appear several words for the purposes of indexing to be titled: KEY WORDS. The body of the paper should lead off with a minimum of 2 to 5 sentences, setting the general train of thought, before any headings.

Measurements should be in the metric system.

Illustrations and tables

Figures and tables should be cited in order in the text; their position should be marked in the margin of the manuscript. Arabic numbering should be used for both figures and tables. Legends for illustrations should be **typewritten, double-spaced, on a separate sheet, and included at the end of the manuscript. A legend must accompany each illustration.**

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Each table should be provided in a separate file and appropriately numbered. Legends should appear with the same sheets as the tables. The contributor must bear all costs connected with printing color illustrations.

References

References should be compiled at the end of the article according to the order of citation in the text, not alphabetically. **They should be typewritten, double-spaced, under the heading REFERENCES. All reference**

information must be accurate. Abbreviations for titles of medical periodicals should conform to those used in the latest edition of *Index Medicus*. **Give inclusive page numbers.**

Examples of references

Journal article, one author:

1. Valayer J: Conventional treatment of biliary atresia: Long-term results. *J Pediatr Surg* 1996;31:1546-1551.

Journal article, two or three authors:

2. Atwell JD, Spargo PM: The provision of safe surgery for children. *Arch Dis Child* 1992;67:345-349.

Journal article, more than three authors:

3. Seo T, Ito T, Ishiguro Y, et al: New neonatal extracorporeal membrane oxygenation circuit with a self-regulating pump. *Surgery* 1994;115:463-472.

Journal article, in press:

4. Coran AG: The hyperalimentation of infants. *Biol Neonate* (in press)

Complete book:

5. Rowe MI, O'Neill JA, Grosfeld JL, et al: *Essentials of Pediatric Surgery*. St Louis, MO, Mosby Year-Book, 1995

Chapter of book:

6. Skandalakis JE, Gray SW, Ricketts R: The esophagus, in Skandalakis JE, Gray SW (eds): *Embryology for Surgeons*. Baltimore, MD, Williams & Wilkins, 1994, pp 65-112

Paper presented at a meeting:

7. Bealer JF, Vanderwall K, Adzick NS, et al: A new treatment option for patients with congenital diaphragmatic hernia. Presented at the 14th annual meeting of the International Fetal Medicine and Surgery Society, Newport, RI, May 3-6, 1996

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Updated April 2013

Table 1 Guidelines for the reporting of clinical research data in the *Journal of Pediatric Surgery*

<i>Methods:</i>		
Reported	Not Applicable	Reporting detail
<input type="checkbox"/>	<input type="checkbox"/>	The number and practice type of all institutions where cases were performed
<input type="checkbox"/>	<input type="checkbox"/>	The number of surgeons who actually operated in the study (& the relative number of cases for each).
<input type="checkbox"/>	<input type="checkbox"/>	The prior experience of participating surgeons in performing the reported intervention
<input type="checkbox"/>	<input type="checkbox"/>	The precise timeline during which all patients were treated in the study (e.g. Jan 1995 to March 1998)
<input type="checkbox"/>	<input type="checkbox"/>	A clear description of how patients were selected into the study. This should include relevant inclusion and/or exclusion criteria.
<input type="checkbox"/>	<input type="checkbox"/>	The number of eligible patients at the study sites excluded during the timeline of the study
<input type="checkbox"/>	<input type="checkbox"/>	A clear description of the study population from which the patients were selected.
<input type="checkbox"/>	<input type="checkbox"/>	A clear description of the relevant diagnostic criteria used to identify cases
<input type="checkbox"/>	<input type="checkbox"/>	A clear description of critical aspects of operative technique and perioperative care
<input type="checkbox"/>	<input type="checkbox"/>	Statement as to whether any attempts were made to standardize operative technique or perioperative care (and how this was accomplished).

<i>Results:</i>		
Reported	Not Applicable	Reporting detail
<input type="checkbox"/>	<input type="checkbox"/>	The range and mean of all relevant demographic and baseline variables
<input type="checkbox"/>	<input type="checkbox"/>	The range and median (not mean) for length of follow-up reporting
<input type="checkbox"/>	<input type="checkbox"/>	Relevant outcome variables are presented with appropriate measures of range and variability (e.g. standard deviation)
<input type="checkbox"/>	<input type="checkbox"/>	Methods for measuring outcomes of interest are clearly described
<input type="checkbox"/>	<input type="checkbox"/>	Statement regarding whether any data is missing (and how missing data is addressed in the analysis of outcome variables)
<input type="checkbox"/>	<input type="checkbox"/>	Number and appropriate details regarding all complications

<i>Additional details for studies reporting more than one treatment group (e.g. controls):</i>		
Reported	Not Applicable	Reporting detail
<input type="checkbox"/>	<input type="checkbox"/>	Mean and range for all relevant demographic and baseline variables for all treatment groups.
<input type="checkbox"/>	<input type="checkbox"/>	The range and median (not mean) for length of follow-up reporting for each treatment group.
<input type="checkbox"/>	<input type="checkbox"/>	A precise timeline during which all patients were treated for each group
<input type="checkbox"/>	<input type="checkbox"/>	Outcome variables being compared between groups are presented with appropriate measures of variability (e.g. standard deviation)
<input type="checkbox"/>	<input type="checkbox"/>	Measures of type II error (P-values) for comparison statistics are presented with actual values if $P = .01$ or larger (e.g. $P = NS$ and $P < .05$ are not acceptable)
<input type="checkbox"/>	<input type="checkbox"/>	A description of how patients were selected into each treatment group
<input type="checkbox"/>	<input type="checkbox"/>	A statement is made as to whether the same surgeons operated on patients from different treatment groups

Manuscripts concerning clinical research should follow a uniform set of reporting guidelines. The guidelines, listed above, were developed from sound clinical research principles and are designed to improve the reporting accuracy of clinical data pertaining to surgical conditions. With more accurate and transparent reporting of study methodology and outcomes data, readers of the Journal will be better able to gauge the relevance of reported results to their own clinical practice. Although not all of the recommended reporting guidelines below are applicable to every clinical study, it is important that all details relevant to your study are clearly reported in the manuscript. Please check the appropriate boxes below to verify compliance with these guidelines and return this sheet with the manuscript at the time of submission. Compliance with these guidelines in combination with subsequent content revisions will be considered by the editor in the final decision regarding publication of your manuscript.

Do CA c/ parecer favorável DC
8/8/2013

Exmo. Senhor
Presidente do Conselho de Administração do
Centro Hospitalar de S. João – EPE

Hospital São João -
Paulo Bettencourt
Adjunto da Direcção Médica

AUTORIZADO

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Presidente do Conselho de Administração

[Signature]
(Prof. Doutor António Ferreira)

Directora Clínica Enfermeira Directora Vogal Executiva Vogal Executivo

[Signature] *[Signature]* *[Signature]* *[Signature]*

(Dra. Margarida Tavares) (Enfermeira Eurídice Fortes) (Dra. Paula Barroca) (Dr. João Oliveira)

Assunto: Pedido de autorização para realização de estudo/projecto de investigação

Nome do Investigador Principal: Pedro Manuel Correia-Rodrigues

Título do projecto de investigação: *Minimally Invasive Surgical Repair of Pectus Excavatum: A Single Institution's 10-year Experience Review*

Pretendendo realizar no(s) Serviço(s) de Cirurgia Pediátrica do Centro Hospitalar de S. João – EPE o estudo/projecto de investigação em epígrafe, solicito a V. Exa., na qualidade de Investigador/Promotor, autorização para a sua efectivação.

Para o efeito, anexa toda a documentação referida no dossier da Comissão de Ética do Centro Hospitalar de S. João respeitante a estudos/projectos de investigação, à qual endereçou pedido de apreciação e parecer.

Com os melhores cumprimentos.

Porto, 13 / Maio / 2013

O INVESTIGADOR/PROMOTOR

Pedro Correia-Rodrigues

13/05/2013 *[Signature]*

7. SEGURO

a. Este estudo/projecto de investigação prevê intervenção clínica que implique a existência de um seguro para os participantes?

SIM (Se sim, junte, por favor, cópia da Apólice de Seguro respectiva)

NÃO

NÃO APLICÁVEL

8. TERMO DE RESPONSABILIDADE

Eu, Pedro Manuel Correia-Rodrigues,
abaixo-assinado, na qualidade de Investigador Principal, declaro por minha honra que as informações prestadas neste questionário são verdadeiras. Mais declaro que, durante o estudo, serão respeitadas as recomendações constantes da Declaração de Helsínquia (com as emendas de Tóquio 1975, Veneza 1983, Hong-Kong 1989, Somerset West 1996 e Edimburgo 2000) e da Organização Mundial da Saúde, no que se refere à experimentação que envolve seres humanos. Aceito, também, a recomendação da CES de que o recrutamento para este estudo se fará junto de doentes que não tenham participado em outro estudo no decurso do actual internamento ou da mesma consulta.

Porto, 13 / 11 / 2013

Pedro Correia Rodrigues
O Investigador Principal

PARECER DA COMISSÃO DE ÉTICA PARA A SAÚDE DO CENTRO HOSPITALAR DE S. JOÃO

emitido na reunião plenária da CES

de 24, Jan, 2013

A Comissão de Ética para a Saúde
APROVA por unanimidade o parecer do
Relator, pelo que nada tem a opor à
realização deste projecto de investigação.

Filipe Almeida
Prof. Doutor Filipe Almeida
Presidente da Comissão de Ética

Parecer

Título do Projecto: Minimally Invasive Surgical Repair of Pectus Excavatum: A Single Institution's 10-year Experience Review

Nome do Investigador Principal: Pedro Manuel Correia-Rodrigues

Entidade Promotora: NA

Serviço onde decorrerá o Estudo: Cirurgia Pediátrica

Objectivo e concepção do Estudo:

Este projecto de investigação, inserido no âmbito da realização de Prova de Opção do Mestrado Integrado de Medicina, tem como objetivo

- Rever a técnica cirúrgica minimamente invasiva de reparação do pectus excavatum nos últimos 10 anos, no Serviço de Cirurgia Pediátrica do Centro Hospitalar de São João - EPE;

- Identificar/quantificar as principais complicações que advêm da técnica em causa;
- Avaliar o outcome dos doentes intervencionados;
- Relevar o benefício de uma abordagem minimamente invasiva;
- Avaliar a curva de aprendizagem de execução da técnica em causa.

Benefício/risco: Benefício - Os benefícios para os participantes e população em geral advêm da identificação e quantificação de complicações associadas à técnica, com vista à melhoria da execução da mesma e redução das mesmas. Risco – dada a natureza do estudo, não se lhe reconhecem riscos

Respeito pela liberdade e autonomia do sujeito de ensaio: NA

Confidencialidade dos dados: Os dados serão obtidos a partir de registos prévios dos processos clínicos dos doentes. Os mesmos serão trabalhados e publicados sem qualquer referência à identificação do doente (nome ou qualquer outro dado identificativo). É assim garantida a confidencialidade dos dados obtidos.

Elo de ligação: Tiago Henriques Coelho

Indemnização por danos: NA

Continuação do tratamento: NA

Propriedade dos dados: “Os dados obtidos serão propriedade exclusiva do promotor/Investigador, é assim referido, tal como a indicação da existência de critérios de publicação dos resultados da investigação.” Trata-se de um projecto que visa ainda a realização do projecto de opção de uma aluna do 5º ano, como é transparente na informação a disponibilizar aos participantes. A publicação dos dados é, assim, previsível.

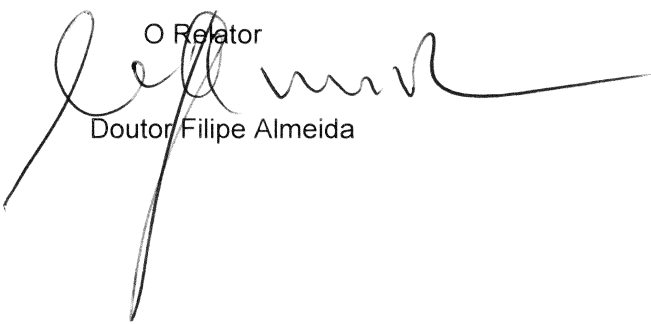
Curriculum do investigador: Adequado à investigação

Data previsível da conclusão do estudo: Julho 2014

Conclusão:

Considerados os objectivos e a metodologia que lhe será dedicada, proponho à CES um favorável à realização deste projecto de investigação.

Porto e H.S.João, 2013-05-24

O Relator

Doutor Filipe Almeida