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Evaluation of Fatigue for a Pectus Bar Removal Surgical Tool Design for a Safe Clinical Practice Use Setting

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ABSTRACT

The Nuss procedure is a minimally invasive procedure for the correction of pectus excavatum - a chest wall deformity which results in the placement of a metal bar inside the chest cavity. The bar is removed after approximately two years. Surgeons report that the currently available tools for the extraction of the bar are frequently slow and suboptimal. Previously, we had proposed a novel design of the tool which showed deficiencies when experimentally tested. Then, with the aid of CAD and finite element analysis, modifications to the original design were adopted to drastically increase the factor of safety. However, there is a need to determine whether the effects from repetitive loading will affect the performance of the tool over a long duration and to investigate the accumulation of damage and, hence, fatigue. In this paper, repetitive loading and fatigue analysis are performed to predict the life cycle of the tool and to further ensure that the tool is safe for utilization prior to the clinical evaluation of the prototype by the surgeon.

Keywords: finite element analysis, fatigue, surgical tools, Nuss procedure.
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1 INTRODUCTION

Pectus excavatum (PE), also called sunken or funnel chest, is a congenital chest wall deformity which is characterized, in most cases, by a deep depression of the sternum (Fig. 1). This condition affects primarily children and young adults and is responsible for about 90% of congenital chest wall abnormalities [5]. Typically, this deformity can be found in approximately one in every 400 births and is inherited in many instances [6]. Among various PE treatment options, the minimally invasive technique for the repair of PE, often referred to as the Nuss procedure, has been proven to have a high success rate, satisfactory aesthetic outcome and low interference with skeletal growth [6].

Fig. 1: Patient with PE.

The Nuss procedure involves placing a metal bar(s) (Fig. 2) underneath the sternum forcibly changing the geometry of the ribcage. Apart from a physical improvement, positive psychological results are attributed to surgical correction [3,4] because the normal shape of the chest is restored, reducing embarrassment, social anxiety, and depression [2].

Fig. 2: Pectus bar (left), a hole at the end of the pectus bar (right).

The pectus bar removal process starts with making incisions in the side of the torso in the same locations as the ones made during the implantation. The bar is curved when placed in the chest so it must be straightened prior to safe removal. A pair of tools for pectus bar removal, called benders by the manufacturer, are used to straighten the bar. Surgeons identify two problems associated with using these tools. First, a significant portion of the bar has to be exposed to place the tool in such a way to provide a counterforce and this straightening action must be worked up the length of the bar under the skin on each side of the patient. Second, engagement of the commercial tool with the end of the bar can be obstructed by tissue growth.

Motivated by those issues, we had previously designed [7,8], using a CAD software, an optimized surgical tool for the pectus bar extraction and performed finite element analysis (FEA) to validate our approach (Fig. 3).

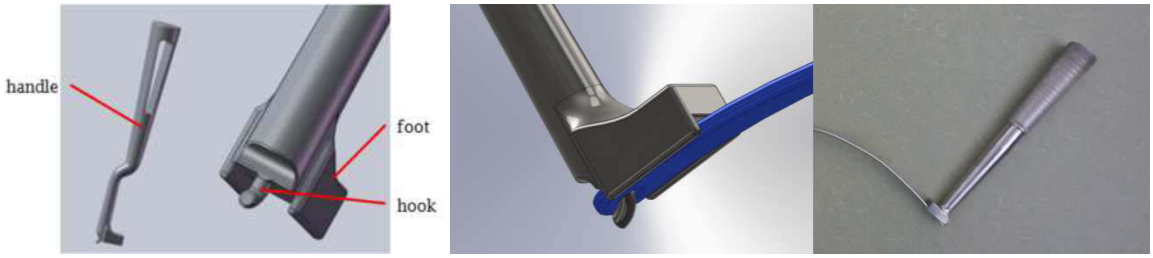

Fig. 3: Final design: whole tool, hook and lever arm (left), simulation of the tool-bar engagement (middle), metal prototype engaged with the pectus bar (right).

Additionally, physical models and metal prototypes of the tool were built in order to allow evaluation of various design variants by the potential end users - the surgeons from the Children's Hospital of the King's Daughters, where the Nuss procedure was developed. In the previous paper [8] we described steps, based on the initial metal prototypes performance, taken to ensure that the tool will withstand high static loads. The tools have been recently used on one subject as a part of a clinical study (EVMS IRB #11-12-FB-0281, ODU IRB #11-204).

The tool is supposed to be used, according to the principle of operation (Fig. 4), multiple times a day throughout the year. This repetitive loading can accumulate damage leading to fatigue failure and destruction of the tool in the long term. Therefore, we performed fatigue analysis to investigate the tool’s life cycle and to ensure that patient safety will not be affected.

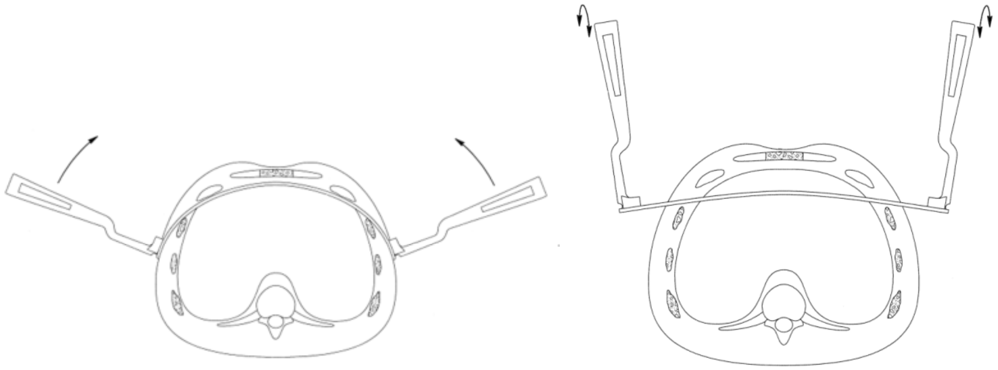

Fig. 4: Initial stage of the bar bending process (left), dislodging the straightened pectus bar (right).

Fatigue analysis can utilize either a S-N (stress-life) or an E-N (strain-life) approach for predicting the life (number of loading cycles) of a part under cyclical loading. The first method works well in predicting fatigue life when the stress level in the structure falls mostly in the elastic range, whereas the latter is applied when plastic strains are considered as an important factor in the damage calculation.

2 METHODOLOGY

We utilized the previously developed CAD model of the tool to extract, after removing unnecessary features (fig. 5 left) like fillets and chamfers, which have just an aesthetic character, a model of the hook – a component that carries the majority of the loading and, hence, in danger of fatigue over time. This model was then converted to IGES format to provide the best interoperability with a finite element analysis (FEA) preprocessor – HyperMesh (Altair®, MI, USA). A solid model of the hook was converted to a FE model containing 9,188 tetrahedral elements. This procedure allowed us to save computation time and reduce the risk of errors during import to the FEA environment.

The new tool design clearly identifies that a 133 N force applied to the handle results in a total force of 820 N applied on the top of the hook (Fig. 5 right). This force is linearly distributed over four nodes.

We assumed stainless steel 17-4 H900 as the material for the hook. In this case, the modulus of elasticity is 207 GPa and yield strength is 1,275 MPa. For the rest of the metal prototype (handle and foot), we assumed stainless steel 304 with the same modulus of elasticity and yield strength of 758 MPa.

Since the tool will undergo low cycle loading, we utilized the strain-life method with signed von Mises stress combination method. The signed von Mises stress method is recommended over the other stress combination methods such as von Mises or Tresca. We utilized the Smith-Watson-Topper (SWT) mean stress correction because the SWT equation predicts that no fatigue damage occurs when the maximum stress is zero or negative (i.e., compressive), which is more conservative when the tensile loading is applied. Rainflow stress cycle counting is the most frequent form of stress cycle counting. Rainflow counting is used to determine the possible impact of the most destructive stress cycles. It is only applicable for stress cycles in a single and constant direction. Also in this method, chronological information is not used and any minor "noise" cycles are discarded as being irrelevant [1]. Approximation techniques based on the Neuber method which approximate the plastic stress-strain state from linear analysis runs are utilized to decrease the number of nonlinear simulation results.

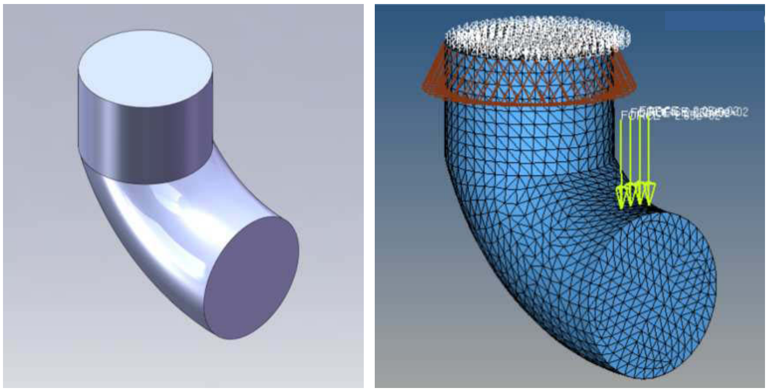

Fig. 5: The hook: CAD model (left), FE model with constraints and forces (right).

Since E-N theory utilizes uniaxial strain, the strain components need to be resolved into one combined value, using signed von Mises stress, for each calculation point, at each time step, and then used as equivalent nominal strain applied on the E-N curve (Fig. 6).

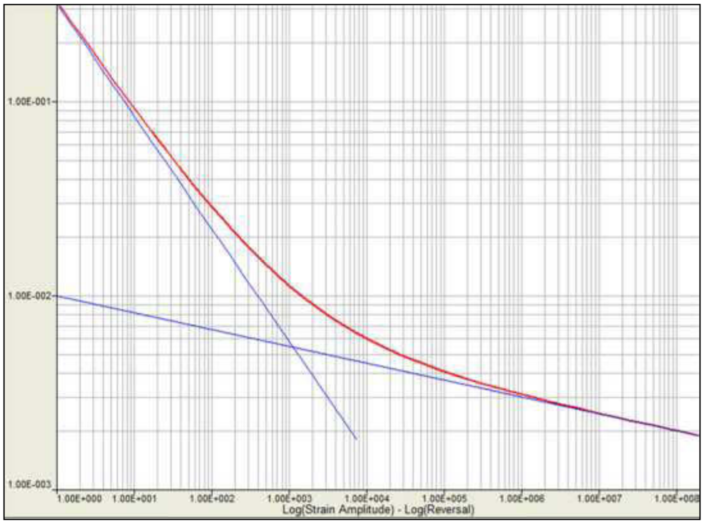

Fig. 6: E-N curve for stainless steel 17-4 H900.

According to Fig. 7, loading is applied by a surgeon from 0% until loading reaches 100% of its value in about two seconds. Then, loading decreases to 70% in one second which is caused by relaxation and subsequently loading is increased again to 100%. There are three changes of loading from 100% to 70% and then again to 100%. After that sequence, the tool undergoes relaxation to 0% in 2 seconds. This loading profile was used with RadiOSS (Altair®, MI, USA) – a FEA solver.

Palmgren-Miner's linear damage summation rule was used which says that failure is predicted when:

$$\sum D_i = \sum \frac{n_i}{N_{if}} \geq 1$$

where:

- N_{if} is the material's fatigue life from its E-N curve at a combination of stress amplitude and mean stress level *i*,
- n_i is the number of applied stress cycles at load level *i*, and
- D_i is the cycle ratio (cumulative damage).

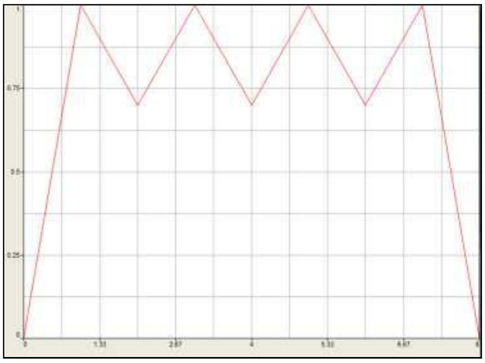

Fig. 7: One cycle of loading versus time.

The linear damage summation rule does not take into account the effect of the load sequence on the accumulation of damage due to a cyclic fatigue loading. However, it has been proved to work well for many applications.

3 RESULTS

By studying the average life of the top 0.1% elements (Tab. 1), it is shown that they are predicted to withstand over 1.4 $x10^5$ cycles. This number increases for the top 1% and 5% elements. Similarly, average damage is significantly below 1 for 0.1, 1, and 5% top elements. Those results suggest the expected life of the tool to be beyond the assumed time of usage at a hospital.

Average Top (%)	*Life $x10^6$*	*Damage $x10^{-5}$*
0.1	0.1433539	0.6975744
1.0	0.6491187	0.1540550
5.0	3.1672440	0.0315731

Tab. 1: Average fatigue life and damage.

According to Tab. 2, the shortest element life is 4.7 $x10^4$ cycles which is equal to over 34 years of using the tool in a busy hospital. However, by studying locations of the top five elements with the shortest life (Fig. 8), only one element (no. 2941) is located at the bend. In reality, the load is continuously distributed over a specific length where the hook interacts with the pectus bar, but for the purpose of this analysis four equivalent forces were applied which led to higher stresses at those four locations. Taking into account the element located at the bend, damage is predicted after a much longer time compared to the assumed usage of the tool.

Element	*Life $x10^6$*	*Damage $x10^{-5}$*
6336	0.0478119	2.0915300
2941	0.1135119	0.8809652
6731	0.1426931	0.7008045
7120	0.1686274	0.5930233
6105	0.1792967	0.5577348

Tab. 2: Life and damage of the top five elements.

Fig. 8 shows the predicted location of elements with the shortest life cycle, which matches our assumptions and verifies that they would be located where the highest stress was previously identified. However, due to the size of elements and magnitude of life cycle, resolution of the results is low. Therefore, we present averaged results (Fig. 9) which show the area that can be mostly affected by fatigue and significant improvement of the life cycle.

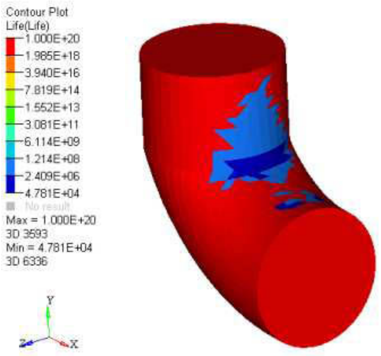

Fig. 8: Life contour without averaging.

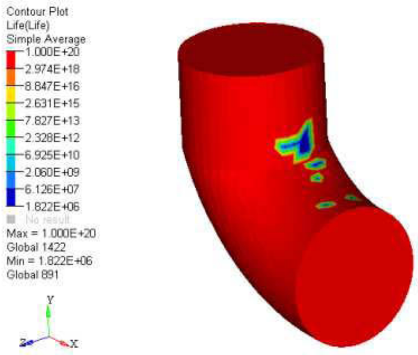

Fig. 9: Life contour with simple averaging.

Similarly, the highest damage is located at the bend (Fig. 10). Averaged results better represent the scenario and high gradient (Fig. 11) which indicates that only few elements are endangered by the fatigue process. Damage distribution follows as well our assumptions regarding where the damage can occur.

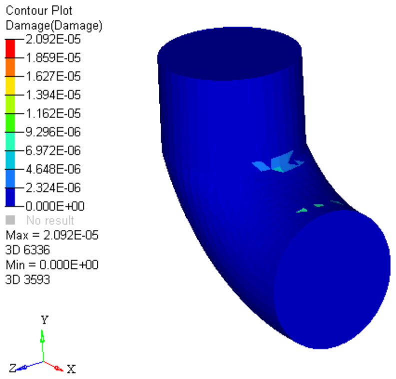

Fig. 10: Damage contour without averaging.

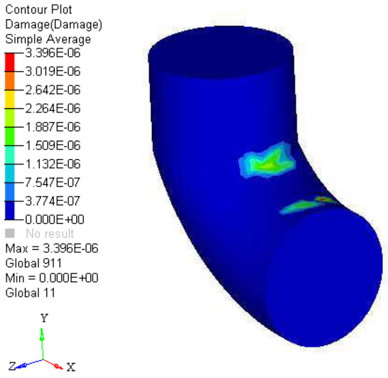

Fig. 11: Damage contour with simple averaging.

4 CONCLUSIONS

Motivated by concerns reported by surgeons, we previously employed an iterative method of applying CAD tools, FEA software and manufacturing of first conceptual models and then metal prototypes to update the initial designs of our tool and to maintain advantages that make our tool superior to the commercial bar benders currently being used by way of shortening the time of surgery which limits costs and reducing the risk of infection. Specifically, FEA proved that the updated design provided safety with all factors of safety above 1 and also provided the strength to withstand the stresses needed for the bar straightening process.

Prompted by the need to ensure long term endurance of our tool, we preformed fatigue analysis to verify that the tool is able to not only withstand static loading but also a repetitive sequence that mimics the bar straightening process.

The results showed that the tool would be safe for a time period much longer than the assumed usage even in a busy hospital, operating four cases per day. The analysis showed that the most vulnerable area was the area we expected to be potentially affected by fatigue, the bend on the hook, which verified the correctness of the analysis.

As the final step, the metal prototypes were successfully used by the surgeon from the CHKD in a clinical study to evaluate the actual bar removal procedure, at least for this patient, proving the adequacy of the design presented in the paper.

REFERENCES

[1] Downing, S.D.; Socie, D.F.: Simple rainflow counting algorithms, International Journal of Fatigue, 4, 1982, 31-40. DOI:10.1016/0142-1123(82)90018-4

[2] Einsiedel, E.; Clausner, A.: Funnel chest. Psychological and psychosomatic aspects in children, youngsters, and young adults, Journal of Cardiovascular Surgery, 40(5), 1999, 733-736.

[3] Krasopoulos, G.; Dusmet, M.; Ladas, G. ; Goldstraw, P.: Nuss procedure improves the quality of life in young male adults with pectus excavatum deformity, European Journal of Cardio-thoracic Surgery, 29, 2006, 1-5. DOI:10.1016/j.ejcts.2005.09.018

[4] Lawson, M. L.; Cash, T. F.; Akers, R.; Vasser, E.; Burke, B.; Tabangin, M.; Welch, C.; Croitoru, D. P.; Goretsky, M. J.; Nuss, D.; Kelly Jr., R. E.: A pilot study of the impact of surgical repair on disease-

specific quality of life among patients with pectus excavatum, Journal of Pediatric Surgery, 38(6), 2003, 916-918. DOI:10.1016/S0022-3468(03)00123-4

[5] Pretorius, S.E.; Haller, A.J.; Fishman, E.K.: Spiral CT with 3D Reconstruction in Children Requiring Reoperation for Failure of Chest Wall Growth after Pectus Excavatum Surgery, Clinical Imaging, 22(2), 1998, 108-116. DOI:10.1016/S0899-7071(97)00073-9

[6] Protopapas, A. D.; Athanasiou, T.: Peri-operative data on the Nuss procedure in children with pectus excavatum: independent survey of the first 20 years' data, Journal of Cardiothoracic Surgery, 40(3), 2008. DOI:10.1186/1749-8090-3-40

[7] Rechowicz, K.J.; McKenzie, F.D.; Bawab, S.Y.; Obermeyer, R.: Optimized surgical tool for pectus bar extraction, in Engineering in Medicine and Biology Society (EMBC), 2010 Annual International Conference of the IEEE, 2010, 1254-1257. DOI:10.1109/IEMBS.2010.5626425

[8] Rechowicz, K.J.; McKenzie, F.D.; Bawab, S.Y.; Obermeyer, R.: Application of CAD Analysis to Update the Design for a Pectus Excavatum Bar Extraction Tool, Computer-Aided Design and Applications, 2011. [In press]