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Customized Vacuum Bells for Pectus Excavatum Treatment: A Novel Design Approach

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***Abstract*—*Pectus Excavatum* is the most common form of thoracic deformity, characterized by the depression of the anterior chest wall. The most widely used non-surgical treatment involves the daily application of the *Vacuum Bell*, an external medical device that uses negative pressure to lift the sternum outwards. Nevertheless, the *Vacuum Bell* is only available in four sizes, making it difficult to apply to all possible cases of deformation. In addition, the variability of the surface to be treated and prolonged use can make the application uncomfortable, leading to decreased compliance and treatment discontinuation, thus compromising its effectiveness.**

In this context, the study was conducted with the aim of producing customized *Vacuum Bell* models. Starting with the 3D scanner acquisition of the patient, it was possible to reconstruct the three-dimensional model of the chest. Therefore, a specifically implemented MATLAB script enabled the identification of the surface to be treated and the semi-automatically drawing of the 3D curve outlying the deformation. Using this curve, via CAD software, it was then possible to proceed with the modelling of customized *Vacuum Bells*, whose profile adapts to the specific conformation of the patient's chest. Finally, a *Vacuum Bell* prototype was realized using additive manufacturing techniques.

***Index Terms*—*Pectus Excavatum*, *Vacuum Bell*, Customized devices, Additive manufacturing**

I. INTRODUCTION

Pectus Excavatum is the most common thoracic malformation, accounting for approximately 90% of chest wall deformities [1], [2]. It is estimated that one child out of every 300-400 newborns presents the defect, with a higher prevalence among male subjects [3]. *Pectus Excavatum* is characterized by the depression of the anterior thoracic wall, due to the abnormal and excessive growth of the rib cartilages, which tend to push the sternum inward, causing a depression [4]. In severe cases, the sinking of the sternum causes a reduction of thoracic volume and a compression and displacement of the heart, compromising its normal functioning [5]. Patients typically report chest pain and breathing difficulties, especially during physical activities but also at rest. However, even in less severe cases, the aesthetic appearance remains a cause of psychological discomfort for patients [6]. Typically, the deformity is noticed by the parent or paediatrician and is then confirmed by consultation with a specialist. The onset of the defect typically occurs in childhood and tends to worsen with growth, reaching the peak during adolescence [1]. After puberty, the malformation tends to stabilize.

To date, several approaches, both surgical and conservative, are employed for the treatment of *Pectus Excavatum* [7]. Surgical intervention involves the insertion of metallic supports aimed at remodelling the rib cage and alleviating functional issues [8], [9]. However, surgery carries severe post-operative pain and considerable risks due to the introduction of metallic bars close to the heart and lungs. As a result, it is only considered in the most severe cases or after the patient's skeletal maturity, when conservative treatment becomes ineffective. Consequently, especially in mild to moderate cases, conservative treatment proves to be a viable alternative, especially in young patients. Indeed, the treatment takes advantage of the greater flexibility of the rib cage and ribs in children, determined by the presence of soft and flexible cartilage. As the child grows, the cartilage is then gradually replaced by bone tissue, making the rib cage stiffer and less flexible and, consequently, more difficult to correct. The most common non-surgical approach involves the use of the *Vacuum Bell* (VB) [10]–[12], an external medical device that creates the vacuum inside it to lift the sternum upwards (Fig. 1). It consists of a silicone bowl-shaped ring with an upper transparent window, that allows inspection during positioning; through a hand pump, it is then possible to apply the negative pressure inside. Commercially *Vacuum Bells* are available in three standard sizes (16, 19, and 26 cm in diameter respectively) [14], plus a model specifically designed for female patients, but they often fail to satisfy the wide range of cases to be treated. In addition, the treatment with the VB can generate various types of discomfort in patients, including chest pain, subcutaneous bleeding, dorsalgia, and transient paresthesias of the upper limbs. Furthermore, the variability of the surface to be treated, the possible asymmetry of the affected area, and prolonged use can make the device uncomfortable and negatively impact compliance and treatment effectiveness [15]. Lastly, the cost of

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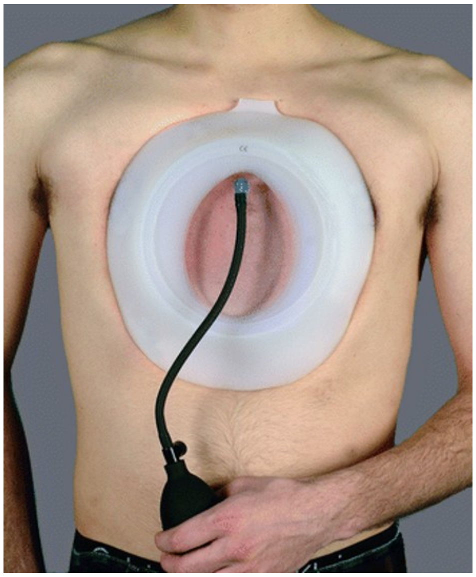

Fig. 1: *Vacuum Bell* application: the hand pump enables the application of vacuum inside the *Vacuum Bell* to lift the sternum upwards. Taken from [13].

each device is around 600 euros and is usually not covered by the healthcare system, leaving the families to bear the expense.

To solve such side effects, the current study proposes the realization of affordable customized *Vacuum Bell* models specifically designed according to the patient's body and chest morphology, as well as personal needs. A customized device will hopefully make the application more comfortable, thus improving patient compliance and increasing treatment effectiveness. To the authors' knowledge, only the studies by Carfagni et al. [16] and by X. Deng et al. [17] report on customized VB, however no one has ever used software that allows precise identification of the deformed surface for the design of the VB profile. Consequently, the following study aimed to acquire the patient's chest using a handheld 3D scanner to generate the corresponding 3D model, in the form of point cloud. Thereafter, the development of a dedicated script in MATLAB allowed for identifying the best surface for the VB positioning and semi-automatically drawing the curve outlying the deformation. This curve was then used in CAD software to model the customized *Vacuum Bell* with a three-dimensional profile. Finally, a customized VB prototype was realized by silicone injection into a mould printed in polylactic acid (PLA).

II. METHODS AND MATERIALS

The procedure initially involved acquiring the patients' chest anatomy (Fig. 2a) using a handheld 3D scanner. The 3D scanner Revopoint POP 2 [18] applies the principle of binocular and micro-structured light, ensuring easy and fast acquisition with high accuracy (up to 0.05 mm). The 3D scanner, consisting of two infrared cameras, allows the acquisition of patients at a distance of approximately 30-40 cm and without tissue damage. Thanks to its scanning speed of 10 fps and the built-in 6-degree-of-freedom gyroscope integrated within it, the scanning process took an average of 1-2 minutes. With an appropriate mount, a mobile phone can be incorporated into the tripod to display the object being acquired in real-time, check the optimal distance of the scanner from the patient, and set the most suitable acquisition parameters. Before acquisitions, a scanner calibration and brightness adjustment are always performed. The Revopoint POP 2 scanner generates 3D models, as point clouds, that reproduce the shape and dimensions of the patients' chests (Fig. 2b).

Eleven patients, with a clinical diagnosis of *Pectus Excavatum*, were acquired during regularly scheduled outpatient visits at the Giannina Gaslini Institute in Genoa (Italy). The

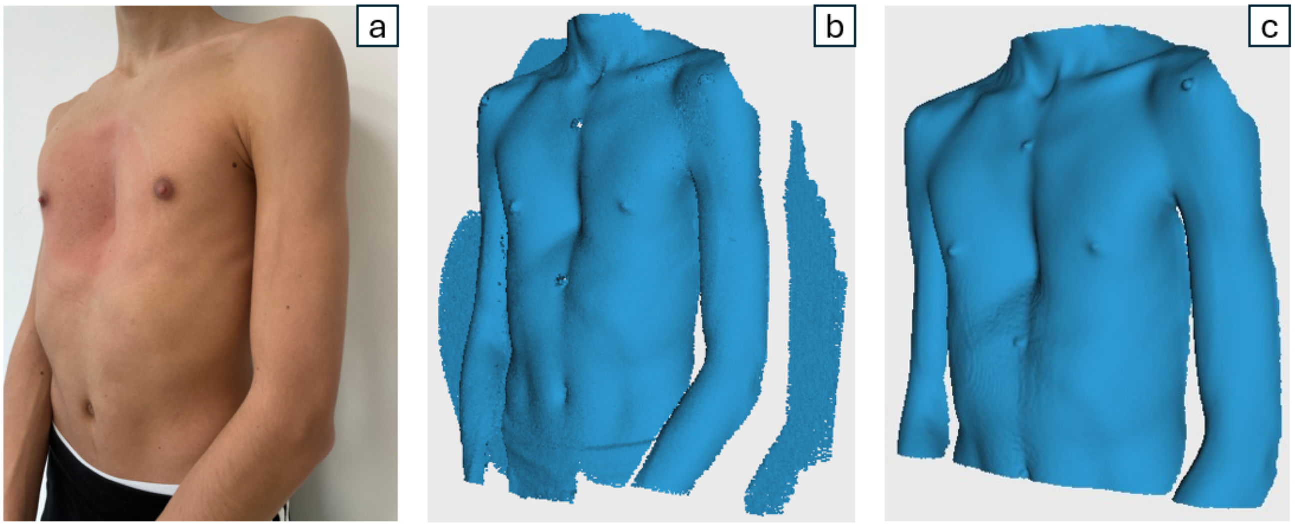

Fig. 2: The images show three different representations of a patient's chest: (a) Photograph; (b) Point cloud; (c) Mesh.

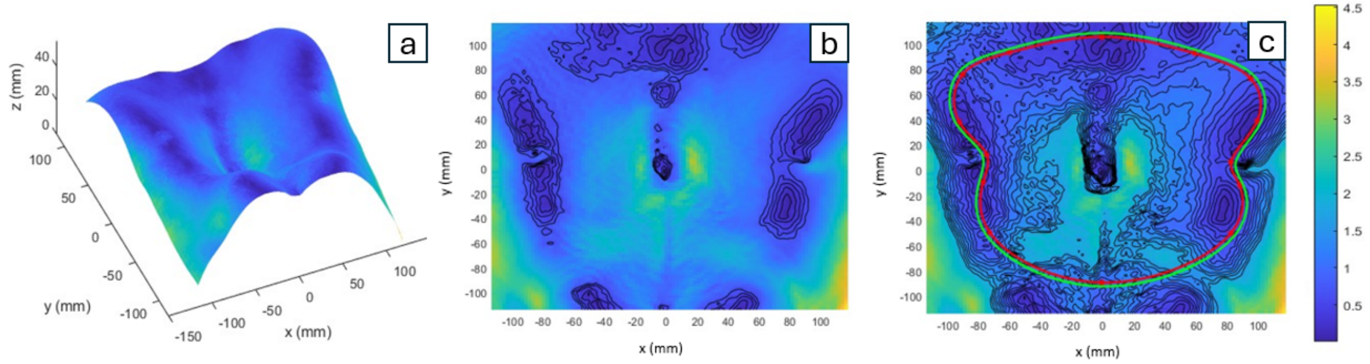

Fig. 3: An overview of the process by which the MATLAB script defines the curves outlying the deformation: the coloured bar on the right-hand side shows the gradient magnitude. Where the gradient magnitude has a lower value, the surface is less steep (in blue), while areas with a more significant deformation are shown in yellow. (a) The coloured mesh showing the variation of the deformation slope; (b) The coloured mesh with the contour lines, calculated based on the gradient magnitude, overlaid on it; (c) By increasing the number of contour lines, it is possible to display the most appropriate areas where points can be selected to generate splines automatically. The red and green splines represent the inner and outer contour of the *Vacuum Bell* base, respectively.

subjects involved in the study were aged between 4 and 17 years. All subjects voluntarily participated in the study and parents' written consent was obtained. Patients were required to stand upright, with their shoulders against the wall, arms by their sides, and to remain as still as possible during the acquisition. Acquisitions were performed from shoulder to shoulder, moving the 3D scanner along horizontal trajectories. After the scanning process, the acquired data were processed using a dedicated post-processing software (Revo Studio [19]): registration, alignment, and noise removal were performed to align the point clouds, obtained from multiple scans, and remove any redundant points. Then, meshes corresponding to the point clouds were generated (Fig. 2c).

The subsequent step consisted of identifying and outlying the area affected by the deformity and to be treated. Consequently, the resulting meshes were imported into MATLAB where a dedicated developed script enabled the identification of the deepest point of the depression and, through gradient calculation, provided valuable insights into the variation of the deformation slope. Based on gradient modulus, the mesh faces were displayed in different colours, allowing regions to be highlighted according to the degree of deformation (Fig. 3a).

A user-friendly graphical interface then allowed the coloured mesh to be displayed and the contour lines, calculated based on the gradient magnitude, to be overlaid on it (Fig. 3b). In this way, the user could interact with the contour lines via keyboard input, gradually increasing the gradient magnitude, to visualize and identify the most suitable surface for *Vacuum Bell* positioning. The user was then asked to manually select a dozen points, based on the contour lines enclosing the areas with the lowest gradient. Once the points have been selected, using MATLAB's *csvn* command and applying a translation with respect to the centroid, it is possible to automatically generate two 3D splines (Fig. 3c), that define the base of the VB. The splines were then imported into CAD software (Creo Parametric) as the basis for modelling the customized *Vacuum Bell* (Fig. 4a).

Once the design of the VB was defined (Fig. 5), an analysis was conducted to identify the most suitable material for the

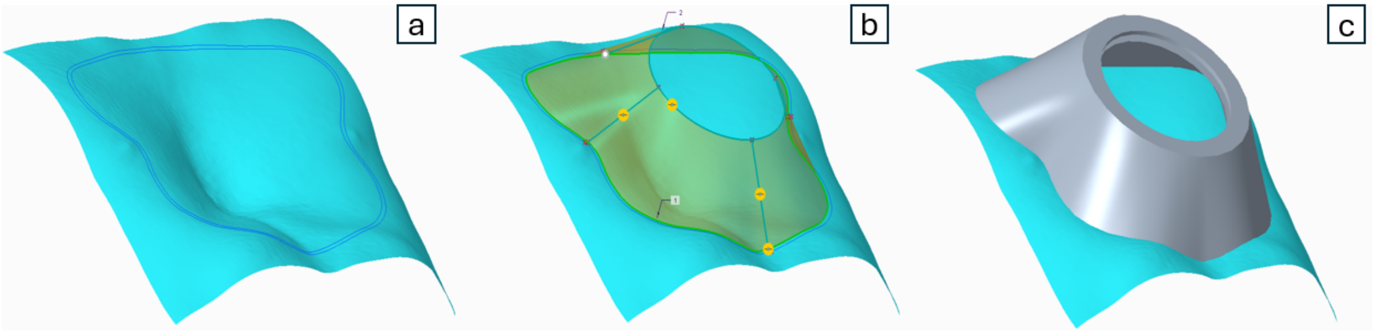

Fig. 4: *Vacuum Bell* modelling process: (a) 3D splines, obtained in MATLAB, are imported into CAD (Creo Parametric); (b) The *boundary blend* command allowed surface modelling; (c) The complete design of the VB overlaid on the chest.

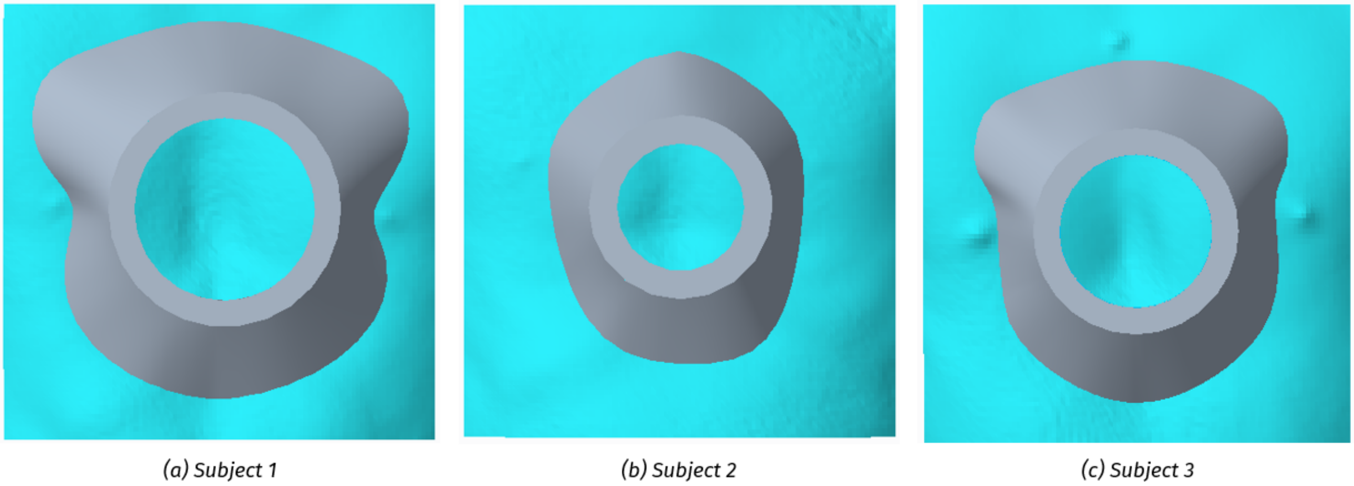

Fig. 5: Customized *Vacuum Bell* models whose 3D profile adapts to the specific conformation of the patient's chest and personal needs: (a) Subject 1 is a 16-year-old boy who presents a pronounced symmetrical chest deformity. The customized VB is designed to treat the area affected by the deformity precisely; (b) Subject 2 is a 4-year-old boy with a particularly prominent abdomen, which makes it challenging to use the standard *Vacuum Bell*. The imperfect adhesion of the standard device in the lower part caused air to enter with the patient's movements. Furthermore, in such small children, the smallest size of the standard *Vacuum Bell* often turns out to be too large in proportion to the size of the child's chest, again causing a lack of air-tightness. It was therefore necessary to design a customized device that was smaller and, at the same time, took into account the patient's specific anatomy; (c) Subject 3 is a 14-year-old boy with an asymmetrical thorax. The patient had stopped treatment for six months because of nipple discomfort from using the standard VB. In this case, the customized model was designed in such a way that it could exclude the nipple halos, to make it more comfortable for the patient.

manufacturing. It is crucial that the material can be flexed and compressed, while maintaining the vacuum inside the device and being comfortable for the patient. Two different types of resins (Flexible 80A (Fig. 6a) and Elastic 50A (Fig. 6b)), produced by the US company Formlabs, were initially identified and tested to 3D print the device by stereolithography (SLA). Although SLA can be used to produce *Vacuum Bell* models quickly and with very good accuracy, the two resins used proved to be too stiff and unsuitable for the intended application. Consequently, it was decided to manufacture the device by injecting silicone into the mould, printed in polylactic acid (PLA). Smooth-on Dragon Skin 10 NV silicone (Fig. 6c) [20] was chosen for its low viscosity, which allowed it to be easily poured into the mould. In addition, its hardness (10 Shore A), similar to the calculated hardness of the original *Vacuum Bell*, and its skin-safe certification make it ideal for this type of application. The silicone was injected with a syringe through the upper holes of the mould. Subsequently, two vacuum cycles were performed to remove any air bubbles in the silicone, that could have compromised the structure of

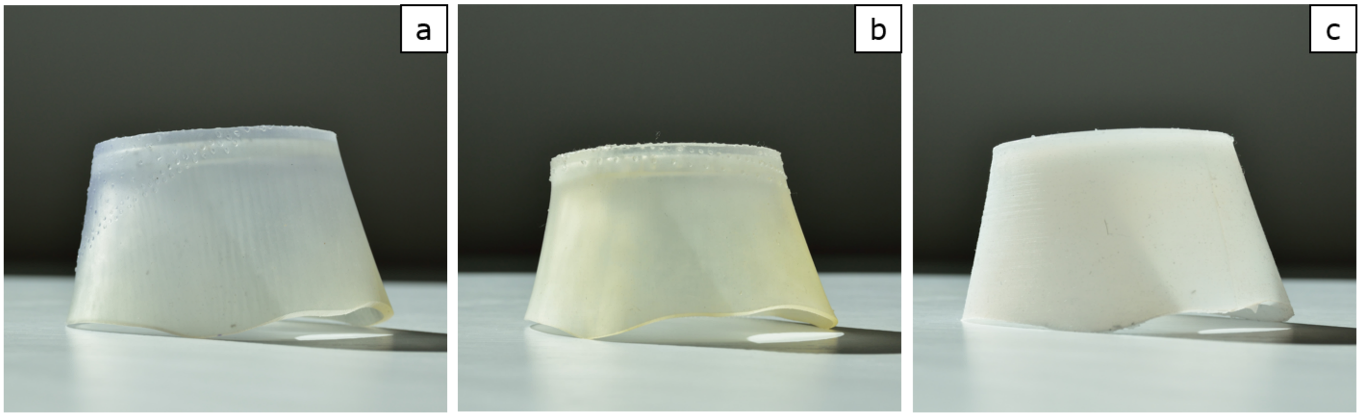

Fig. 6: Different materials used in the customized *Vacuum Bell* manufacturing process: (a) Formlabs Flexible 80A resin; (b) Formlabs Elastic 50A resin; (c) Smooth-on Dragon Skin 10 NV silicone.

Fig. 7: The mould, made of polylactic acid (PLA), enabled to produce customized *Vacuum Bell* by silicone injection. The dimensions of the mould shown are 150 mm in diameter and 84 mm in height.

the final *Vacuum Bell*. The silicone was cured inside the mould for 24 hours at room temperature. The *Vacuum Bell* was then removed from the mould and placed in an oven at 80°C for two hours to increase the material's physical properties. Finally, the aforementioned silicone was used to make a scaled-down prototype of a customized VB (Fig. 7).

III. RESULTS

The infrared 3D scanner is harmless for patients and allows for quick and accurate acquisition, even by less experienced users. Thanks to the smartphone screen connected to the scanner, the user can view in real-time the acquired images and adjust the distance from the subject. On the other hand, the implementation of the script in MATLAB enabled the visualization of the patient's chest mesh with different colours according to its conformation. The coloured mesh was particularly useful as it provided insights into the area affected by the deformity, any asymmetry, and changes in the chest's slope. In particular, it became crucial when designing a customized *Vacuum Bell*, as it allowed for visualizing the most suitable area for its anchoring. By selecting about ten points on the mesh, the script automatically generated the curve that enclosed the defect and defined the profile of the *Vacuum Bell*. This type of automation significantly sped up the subsequent CAD modelling process. Through Creo Parametric, it was then possible to design customized *Vacuum Bells*, whose profile was adapted in three dimensions to the specific conformation of the patient's chest.

The customized *Vacuum Bell* was then manufactured using three different materials to test the most suitable one for the application. Finally, once the most appropriate material has been identified, a scaled-down prototype of customized *Vacuum Bell* was fabricated by injecting the silicone inside the PLA mould. The Dragon Skin silicone used for the customized VB fabrication ensures enough flexibility to fit the patient's chest comfortably, while also being stiff enough to maintain vacuum inside.

IV. DISCUSSION

The work [21] aimed to introduce innovative tools that could improve the *Vacuum Bell* realization techniques. Currently, there are few studies related to the development of customized devices for correcting *Pectus Excavatum* [16], [17]. In particular, analyzing the state of the art, the previous studies had yet to adopt a standardized strategy for defining the contour of the deformity. It was the physician who traced, on the patient's chest, the curve delimiting the deformation, which was then used in the subsequent modelling phase to define the base of the *Vacuum Bell*. However, this method is strongly influenced by the operator's experience and is subject to potential evaluation errors. Therefore, the development of a graphical interface was intended to be a support tool in defining the *Vacuum Bell* profile for physicians and non-expert users.

Another innovative aspect was having defined a three-dimensional profile of the *Vacuum Bell* base. This profile, in contrast to the two-dimensional one, adapted more closely to the shape of the patient's chest, ensuring better correction and greater air-tightness during application. In addition, the *Vacuum Bells* were designed not only to adapt to the patient's specific thoracic conformation, but also to take into account the patient's personal needs. As a result, customizing the profile in three dimensions allowed the realization of devices that can adapt to all shapes and body types, even those of female patients. Indeed, the ultimate goal was to create a medical device with which the patient could feel more comfortable, as this affects both the application time and the treatment's overall success.

Nevertheless, the current project has halted upon reaching the design phase of the customized VB and the realization of an initial prototype. More patients have been analyzed to determine the effectiveness of the final product and design. Long-term analyses are also currently underway to assess patient comfort improvements and treatment outcomes for the participants involved. As prolonged observation periods of patients are required, especially in the case of children whose bodies are still growing, quantitative results will be included in a future extension of the work.

Finally, another aspect to consider is how often the *Vacuum Bell* should be replaced with a new one. A new device will, in fact, be necessary depending on the patient's growth and changes in chest deformation. This aspect is currently being analyzed to determine how often a growing child needs a new device. Certainly, using additive technology with a suitable material would help reduce costs and manufacturing times, while also eliminating the need to print a new mould every time.

V. CONCLUSION

The conducted study has allowed the definition of a standardized procedure for creating customized *Vacuum Bell* models. More in detail, it introduced a method for defining the contour of the deformation that is more precise than current techniques, where the physician manually traces the curve delineating the deformation on the patient's chest. Therefore, the development of a graphic interface was intended to be a support tool in defining the profile of the *Vacuum Bell*. As a result, the process is highly intuitive and easy to repeat; once the vacuum bell prototype is realized, the post-processing and the physical manufacturing process remain the same for all subsequent models. The processing of the 3D scan data is semi-automatically handled by MATLAB; the operator only has to finalize the 3D design of the VB using reference splines. In the future, however, we aim to automate that process as well.

Furthermore, customizing the *Vacuum Bell* profile in three dimensions should allow a better correction and ensure greater air-tightness during application. Taking into account the specific needs of the subject, it was possible to develop devices that might be more comfortable, potentially enhancing compliance. Finally, compared to standard *Vacuum Bells*, the proposed manufacturing method would allow for low-cost realization of customized models. In fact, it is estimated that the cost of each *Vacuum Bell* is around 300 euros, less than half of the original one.

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REFERENCES

[1] E. W. Fonkalsrud, "Current management of pectus excavatum," *World journal of surgery*, vol. 27, pp. 502–508, 2003.

[2] C. Brochhausen, S. Turial, F. K. Müller, V. H. Schmitt, W. Coerdt, J.-M. Wihlm, F. Schier, and C. J. Kirkpatrick, "Pectus excavatum: history, hypotheses and treatment options," *Interactive cardiovascular and thoracic surgery*, vol. 14, no. 6, pp. 801–806, 2012.

[3] D. Jaroszewski, D. Notrica, L. McMahon, D. E. Steidley, and C. Deschamps, "Current management of pectus excavatum: a review and update of therapy and treatment recommendations," *The Journal of the American Board of Family Medicine*, vol. 23, no. 2, pp. 230–239, 2010.

[4] A. C. Koumbourlis, "Pectus excavatum: pathophysiology and clinical characteristics," *Paediatric respiratory reviews*, vol. 10, no. 1, pp. 3–6, 2009.

[5] M. Servi, R. Furferi, Y. Volpe, M. Ghionzoli, and A. Messineo, "Towards a non-invasive pectus excavatum severity assessment tool using a linear discriminant analysis on 3d optical data," in *International Conference of the Italian Association of Design Methods and Tools for Industrial Engineering*. Springer, 2019, pp. 686–695.

[6] C. Steinmann, S. Krille, A. Mueller, P. Weber, B. Reingruber, and A. Martin, "Pectus excavatum and pectus carinatum patients suffer from lower quality of life and impaired body image: a control group comparison of psychological characteristics prior to surgical correction," *European Journal of Cardio-Thoracic Surgery*, vol. 40, no. 5, pp. 1138–1145, 2011.

[7] I. Abid, M. M. Ewais, J. Marranca, and D. E. Jaroszewski, "Pectus excavatum: a review of diagnosis and current treatment options," *Journal of Osteopathic Medicine*, vol. 117, no. 2, pp. 106–113, 2017.

[8] A. Williams and D. Crabbe, "Pectus deformities of the anterior chest wall," *Paediatric respiratory reviews*, vol. 4, no. 3, pp. 237–242, 2003.

[9] F.-M. Haecker, T. F. Krebs, and K.-U. Kleitsch, "Current development of minimally invasive repair of pectus excavatum (mirpe)," *Children*, vol. 9, no. 4, p. 478, 2022.

[10] F. M. Haecker and S. Sesia, "Vacuum bell therapy," *Annals of cardiothoracic surgery*, vol. 5, no. 5, p. 440, 2016.

[11] F.-M. Haecker and J. Mayr, "The vacuum bell for treatment of pectus excavatum: an alternative to surgical correction?" *European journal of cardio-thoracic surgery*, vol. 29, no. 4, pp. 557–561, 2006.

[12] M. Bahr, "Vacuum bell procedure according to eckart klobe (nonsurgical)," *Congenital Thoracic Wall Deformities*, p. 190, 2011.

[13] F. M. Haecker and M. Martinez-Ferro, "Non-surgical treatment for pectus excavatum and carinatum," pp. 137–160, 2016.

[14] I. Loufopoulos, I. G. Karagiannidis, S. Lampridis, S. Mitsos, and N. Panagiotopoulos, "Vacuum bell: is it a useful innovative device for pectus excavatum correction?" *Turkish Thoracic Journal*, vol. 22, no. 3, p. 251, 2021.

[15] L. Toselli, E. Chinni, M. Nazar-Peirano, M. Vallee, D. Sanjurjo, J. Martinez, and G. Bellia-Munzon, "Determinants of success associated with vacuum bell treatment of pectus excavatum," *Journal of Pediatric Surgery*, vol. 57, no. 11, pp. 550–554, 2022.

[16] M. Carfagni, F. Facchini, R. Furferi, M. Ghionzoli, L. Governi, A. Messineo, M. Servi, F. Uccheddu, and Y. Volpe, "A semi-automatic computer-aided method for personalized vacuum bell design," *Computer-Aided Design and Applications*, vol. 15, no. 2, pp. 247–255, 2018.

[17] X. Deng, P. Huang, J. Luo, J. Wang, L. Yi, G. Yang, S. He, X. Li, and S. Xiang, "A novel three-dimensional printed vacuum bell for pectus excavatum treatment: a preliminary study," *Journal of Cardiothoracic Surgery*, vol. 15, pp. 1–7, 2020.

[18] Revopoint POP 2 - https://www.revopoint3d.com/pages /face-3d-scanner-pop2. Accessed: October 2022.

[19] Revo Studio - https://www.revopoint3d.com/download/.

[20] Smooth-on Dragon Skin 10 NV - https://www.smooth-on.com/products/dragon-skin-10-nv/. Accessed: January 2023.

[21] C. Abello, "Development of tools for the design of a customized and affordable vacuum bell for the treatment of the thoracic malformation pectus excavatum," master thesis, DIBRIS, University of Genoa, Genoa, Italy, 2023.