Title:
A Semi-Automatic Computer-Aided Method for Personalized Vacuum Bell Design

Authors:
Monica Carfagni, monica.carfagni@unifi.it, University of Florence, Italy
Flavio Facchini, flavio.facchini@meyer.it, Children's Hospital A. Meyer of Florence, Italy
Marco Ghionzoli, marco.ghionzoli@meyer.it, Children's Hospital A. Meyer of Florence, Italy
Antonio Messineo, antonio.messineo@meyer.it, Children's Hospital A. Meyer of Florence, Italy
Michaela Servi, michaela.servi@unifi.it, University of Florence, Italy
Francesca Uccheddu, francesca.uccheddu@unifi.it, University of Florence, Italy
Yary Volpe, yary.volpe@unifi.it, University of Florence, Italy

Keywords:
CAD, Reverse Engineering, design customization, vacuum bell

DOI: 10.14733/cadconfP.2017.207-211

Introduction:
Chest wall deformities, or abnormal development and appearance of the chest, may be congenital or acquired and may be divided into different categories [12]. The most common category divides these deformities into *Pectus Excavatum* (also known as funnel or sunken chest) and *Pectus Carinatum* (also known as pigeon chest). The *Pectus Excavatum* (PE) is by far the most frequent chest deformity with an incidence of 1 in 300-1000 live births with a male/female ratio of approximately 4:1 and with a tendency to become more evident during adolescence [3, 15, 16]. PE is characterized by an abnormal overgrowth of sternal and costal cartilages which results in a depression of the sternum and costal cartilages [6] as shown in Fig. 1a.

Though PE is an asymptomatic disease in most cases (95% of cases according to [5]), its aesthetic appearance often cause emotional stress for the child/adolescent. On the contrary, in severe cases, PE is more than just a cosmetic condition since it can be associated with respiratory difficulties and with altered cardiac functions [10].

Worst severe deformities can be repaired surgically via, for instance, Ravitch or Nuss procedures [11]; asymptomatic patients with mild deformities can be treated conservatively by using the so called *Vacuum bell* (VB), also referred to as treatment by *cup suction*.

VB was developed by E. Klobe, an engineer who was himself suffering from PE, and consists of a bowl shaped device (to place upon deepest point of PE) and a hand pump capable of producing a negative pressure that lifts the sternum upwards, lessening the severity of the deformity [7]. The body is made of a silicone ring and a transparent polycarbonate window. Three different sizes (i.e. 16, 19 and 26 cm in diameter) as well as a model fitted for young women of VB exist as shown in Fig.1b [8].

The VB size is chosen according to the gender, the patient age and the ventral surface. The variability of the surface to be treated, the possible asymmetry of the caved-in area and the prolonged use (VB was generally used twice a day for a minimum of 30 minutes [8]), can make the device uncomfortable, and in some cases ineffective, for the patient.

In order to cope with these issues, the development of a *Personalized Vacuum bell*, i.e. a VB appositely designed on the patient chest, is advisable. Actually, the design of a customized device minimizes side effects thus increasing patient compliance and reducing time to treat the deformity. Despite personalized approaches in medicine proves to increase benefits and reduce risks for patients by improving both the safety and the efficacy of medical processes and products, the design of personalized VB has not been investigated so far.

Accordingly, the main aim of the present paper is to develop a semi-automatic computer-aided method (to be used by not-expert user, e.g. medical staff) for customized vacuum bell design. The proposed solution proposes a procedural CAD modelling strategy taking advantage from Reverse Engineering techniques. In detail, the main idea is to acquire the patient chest region using a 3D scanner and to define a set of rules to create the 3D model of a personalized VB. The obtained part can be manufactured using, for instance, additive manufacturing technologies.

(a) (b)

Fig. 1: Chest picture of an adolescent affected by a moderate/severe form of *pectus excavatum* [16] (a) and Different sizes of the vacuum bell [8] (b).

Method:

With the aim of designing a personalized VB two main tasks have been carried out:

1. Acquisition and processing of the 3D chest geometry
2. VB semi-automatic CAD generation and physical prototype construction

Acquisition and processing of the 3D chest geometry

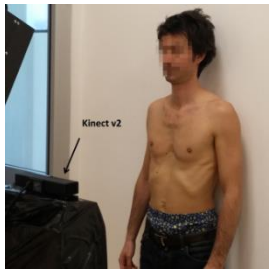
Acquiring 3D chest geometry is an essential task for a proper customization of the Vacuum Bell. Such an application requires the availability of a real-time depth acquisition system in order to minimize artifacts caused by patient movement. A number of 3D scanners that could serve this purpose are nowadays available in the market. These may be roughly divided into two main categories: professional 3D scanners (e.g. Romer Absolute Arm, Konica Minolta Range7, Aicon 3D System StereoScan) and low-cost devices such as, for instance RGB-D cameras (e.g. Kinect, Intel RealSense, Occipital Structure) and time-of-flight (ToF) cameras (e.g. Kinect v2). Even if this last typology of devices was specifically conceived to address topics related to face analytics and tracking, scene segmentation, hand and fingers tracking, gaming and Augmented Reality, they prove to have the potential to be used as a 3D scanner. Moreover, they are particularly suited for almost instantaneous acquisitions that are, as mentioned above, one of the most important pre-requisites for the proposed method.

Among low-cost devices, capable to acquire the entire chest with a time lower than 1 sec, the 2nd-generation Kinect device (Kinect v2), has been selected . The Kinect v2 use a continuous wave time-of-flight (CW-TOF) camera with a resolution of 512 × 424 pixels capable of acquiring at a maximum frequency of 30 Hz. The operating field is defined by a 70° horizontal and 60° vertical view angle and a depth range of 50–4500 mm [4].

This sensor presents several technical benefits compared with competitor mid-range cameras. First of all, it offers a larger horizontal as well as vertical field of view. Then, the different depth sensing technology (i.e. ToF vs. structured light) allows to obtain point clouds with a better resolution, especially when compared with Kinect v1 sensor.

The sensor has been placed centrally over the thorax of the patient (standing up straight against a wall), approximatively orthogonal to the wall and at a distance of about 65 mm (see Fig. 2a).

Data acquisition has been carried out using a dedicated software, developed by means of the open source library libfreenect2 [9], which is a cross-platform library that allows access to the Microsoft Kinect v2 device. For data processing three auxiliary libraries have been used: PCL (point cloud library [13]), VTK (Visualization Toolkit [17]), and Qt [14]. An image of the devised tool is shown in Fig. 2b.



(a)

(b)

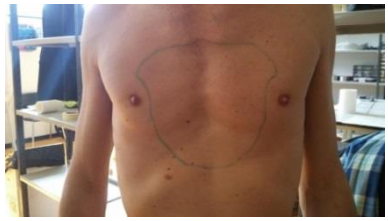
Fig. 2: Kinect v2. Setup (a) and devised tool for the acquisition and the processing phases (b).

The acquired point cloud has been processed in order to reduce noise, has then been triangulated and properly oriented in 3D space. Moreover, NURBS surfaces of the chest, necessary for the subsequent step of VB generation, have been built.

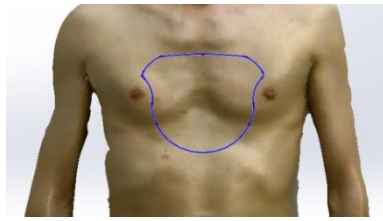
VB semi-automatic CAD generation

The main idea behind the semi-automatic generation of the VB foresees the definition, directly from the medical staff, of the area to be treated (see Fig. 3a). In this way the personalized VB may have dimensions and shape more suitable and comfortable for the patient; moreover, the VB will produce the required negative pressure, that lifts the sternum upwards, precisely in the caved-in area.

Obviously, to make the automatization possible, the area to be treated needs to be drawn directly in a CAD environment by using, for instance, a spline on the acquired 3D chest geometry (see Fig 3b).



(a)



(b)

Fig. 3: Area to be treated sketched on the chest by the medical staff (a) and the same area drawn using a spline in a CAD environment (b).

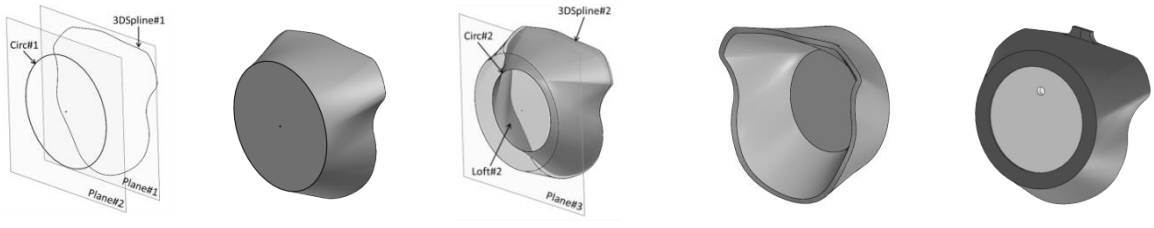
As a consequence, an archetypal model of the VB has been built in Siemens NX 11 so as to take full advantages of the parametric-variational CAD modeler [1, 2]. In particular, such a model has been realized as follows:

1. by importing the chest geometry obtained in the previous step (NURBS surfaces);
2. by defining a plane (*Plane#1*) parallel to the wall (*W_Plane*) and passing through the point of the surface at the maximum distance from *W_Plane*;
3. by manually sketching a 2d spline delimiting the area to be treated (see Fig. 3b) on *Plane#1*;
4. by projecting the spline onto the chest surface (*3Dspline#1*);
5. by defining a plane (*Plane#2*) parallel to *Plane#1* at a distance equal to 130% of the ratio between the area and the perimeter of the *3Dspline#1*;
6. by drawing a circumference (*Circ#1*) on *Plane#2*, centered in the barycenter of the 2D spline and with a diameter so that its area is equal to 30% of the area defined by the *3Dspline#1* (see Fig.4a);
7. by building a volume loft (*Loft#1*) between *3Dspline#1* and *Circ#1* (see Fig.4b);
8. by defining a plane (*Plane#3*) parallel to *Plane#2* and placed at a distance equal to 8 mm, directed towards the chest;
9. by drawing a circumference (*Circ#2*) on *Plane#3* centered with *Circ#1* and with a diameter equal to 70% of the *Circ#1*;
10. by offsetting (5 mm) the external surface of the *Loft#1* thus defining the surface *SLoft#1*;
11. by intersecting *SLoft#1* with the chest surface so that to obtain a new 3D spline (*3Dspline#2*);
12. by building a loft (*Loft#2*) between *3Dspline#2* and *Circ#2* (Fig.4c);

13. by subtracting the *Loft#2* from the *Loft#1* (see Fig.4d);
14. by drawing a circumference (*Circ#3*) on *Plane#3* centered with *Circ#1* and with a diameter equal to 85% of the ones defining *Circ#1*;
15. by cut-extruding *Circ#3* of 6 mm (i.e. the dimension of the window that will be manufactured in transparent polycarbonate).

The final result of the procedure described above consists of a 3D model of the "ring" that will be produced using silicone. In order to finalize the personalized VB design, an additional extrusion of 6 mm of *Circ#3* is performed so as to realize the inspection window. In this last step the new created body has to be keep divided from the previously built one.

The archetype of the VB is shown in Fig4e. In order to verify the appropriateness of the proposed procedure the model has been tested using different chest surfaces and different areas (i.e. splines) to be treated. Tests demonstrated the effectiveness of the archetype to adapt to different patients.



(a) (b) (c) (d) (e)

Fig. 4: Some steps of the archetypal generation: (a) *3Dspline#1* obtained by projecting the 2D spline sketched by the medical staff onto the chest surface; (b) *Loft#1* between *3Dspline#1* and *Circ#1* ; (c) *Loft#2* between *3Dspline#2* and *Circ#2;* (d) volume obtained by subtracting *Loft#2* from *Loft#1* and (e) final result.

In order to allow non-expert users (e.g. medical staff) to generate the personalized VB, a custom application for NX has been developed using Visual Basic programming language with NXOpen (a collection of API which allows through an open architecture the access to NX methods using well-known programming languages).

The medical staff is required only to choose the chest acquired with the Kinect and to sketch the spline. Subsequently the devised application automatically builds the personalized VB.

Finally, the CAD model is exported in STL format to allow the manufacturing of a physical prototype using, for instance, Rapid Prototyping (RP) techniques or traditional manufacturing processes. An example of the personalized VB obtained using the above described procedure, manufactured by casting the silicone into a mold (created starting from the STL file mentioned above), is shown in Fig.5.

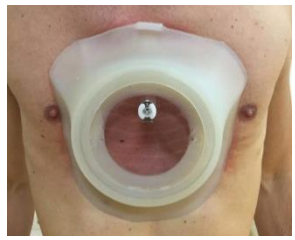


Fig. 5: Personalized VB.

Results and Conclusions:

In order to verify the appropriateness of the developed procedure a number of case studies provided by the Children Meyer Hospital of Florence (Italy) have been analyzed. More in particular, a set of 30 different chest surfaces and different areas (i.e. splines) to be treated have been considered and personalized vacuum bells have been modelled. All subjects have been informed of the nature of the

experimentation and written consent was obtained. The CAD models of the personalized VBs have been easily designed in less than 5 minutes for all the considered case studies.

The newly conceived VB promises to be more effective and comfortable with respect to traditional devices where only pre-defined sizes are provided. However, no ergonomics test has been performed on this device yet. Moreover, a comparison between the medical treatment using the standard VB device and the personalized one has not been carried out. Consequently, a deeper investigation is required to assure the promising benefits coming from this new device are actually confirmed. Accordingly, future works will be addressed to test the effectiveness of the treatment on a panel of patients.

Furthermore, there is room also for improving the manufacturing process by using, for instance, a series of Rapid Prototyping (RP) techniques so as to speed-up the physical realization of the device. To this end, a study on available materials capable of presenting both high deformability (like the silicone) and bio-compatible (i.e. not harmful when in contact with the patient skin) is mandatory.

References:

[1] Carfagni, M.; Furferi, R.; Governi, L.; Volpe, Y.: A vane-motor automatic design procedure, International Journal on Interactive Design and Manufacturing, 7, 2013, 147-157. http://dx.doi.org/10.1007/s12008-012-0172-x

[2] Carfagni, M.; Governi, L.; Volpe, Y.: Development of a software platform for collaborative MCAD based shoe design, in: 2008 IEEE International Technology Management Conference, ICE 2008, 2008. http://ieeexplore.ieee.org/stamp/stamp.jsp?tp=&arnumber=7462081&isnumber=7461988

[3] Cobben, J. M.; Oostra, R.-J.; van Dijk, F. S.: Pectus excavatum and carinatum, European Journal of Medical Genetics, 57, 2014, 414-417. http://dx.doi.org/10.1016/j.ejmg.2014.04.017

[4] Corti, A.; Giancola, S.; Mainetti, G.; Sala, R.: A metrological characterization of the Kinect V2 time-of-flight camera, Robotics and Autonomous Systems, 75, Part B, 2016, 584-594. http://dx.doi.org/10.1016/j.robot.2015.09.024

[5] Grappolini, S.; Fanzio, P. M.; D'Addetta, P. G. C.; Todde, A.; Infante, M.: Aesthetic Treatment of Pectus Excavatum: A New Endoscopic Technique Using a Porous Polyethylene Implant, Aesthetic Plastic Surgery, 32, 2008, 105-110. http://dx.doi.org/10.1007/s00266-007-9025-6

[6] Haecker, F.-M.; Martinez-Ferro, M.: Non-surgical Treatment for Pectus Excavatum and Carinatum, in: Kolvekar, S. and Pilegaard, H. (Eds.) Chest Wall Deformities and Corrective Procedures, Springer International Publishing, Cham, 2016, 137-160. http://dx.doi.org/10.1007/978-3-319-23968-2_17

[7] Haecker, F.-M.; Mayr, J.: The vacuum bell for treatment of pectus excavatum: an alternative to surgical correction?, European journal of cardio-thoracic surgery, 29, 2006, 557-561. http://dx.doi.org/10.1016/j.ejcts.2006.01.025

[8] Haecker, F.-M.; Sesia, S.: Vacuum bell therapy, Annals of Cardiothoracic Surgery, 5, 2016, 440-449. http://dx.doi.org/10.21037/acs.2016.06.06

[9] libfreenect2. http://zenodo.org/record/50641 (accessed: 12/20/2016)

[10] Lopez, M.; Patoir, A.; Costes, F.; Varlet, F.; Barthelemy, J.-C.; Tiffet, O.: Preliminary study of efficacy of cup suction in the correction of typical pectus excavatum, Journal of Pediatric Surgery, 51, 2016, 183-187. http://dx.doi.org/10.1016/j.jpedsurg.2015.10.003

[11] Nasr, A.; Fecteau, A.; Wales, P. W.: Comparison of the Nuss and the Ravitch procedure for pectus excavatum repair: a meta-analysis, Journal of Pediatric Surgery, 45, 2010, 880-886. http://dx.doi.org/10.1016/j.jpedsurg.2010.02.012

[12] Nuss, D.; Kelly, R. E.: Chest Wall Deformities, in: Puri, P. and Höllwarth, M. (Eds.) Pediatric Surgery, Springer Berlin Heidelberg, Berlin, Heidelberg, 2009, 247-256. http://dx.doi.org/10.1007/978-3-540-69560-8_25

[13] PointCloudLib. http://pointclouds.org/ (accessed: 12/20/2016)

[14] QtLib. https://www.qt.io/developers/ (accessed: 12/20/2016)

[15] Sarwar, Z. U.; DeFlorio, R.; O'Connor, S. C.: Pectus Excavatum: Current Imaging Techniques and Opportunities for Dose Reduction, Seminars in Ultrasound, CT and MRI, 35, 2014, 374-381. http://dx.doi.org/10.1053/j.sult.2014.05.003

[16] Tocchioni, F.; Ghionzoli, M.; Messineo, A.; Romagnoli, P.: Pectus Excavatum and Heritable Disorders of the Connective Tissue, Pediatric Reports, 5, 2013, e15. http://dx.doi.org/10.4081/pr.2013.e15

[17] VTKLib. http://www.vtk.org/ (accessed: 20/12/2016)