










A semi-automatic computer-aided method for personalized Vacuum Bell design

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ABSTRACT

Pectus Excavatum, one of the most frequent chest wall deformities, is characterized by a depression of the sternum and costal cartilages. Patients with mild deformities are generally treated conservatively by using the so called Vacuum Bell (VB) i.e. a suction cup to be placed on the patient's sternal region. Three different sizes, as well as a model fitted for young women, of VB are available on the market. Unfortunately, the variability of the surface to be treated, the possible asymmetry of the caved-in area and the prolonged use, can make the device uncomfortable and, in some cases, ineffective for the patient. In order to cope with these issues, the present paper proposes a computer-aided method for customized vacuum bell design to be used by non-expert user, e.g. by medical staff. In particular, the present work entails the development of a system comprising: 1) a dedicated software capable of acquiring the 3D chest geometry - by using a low-cost range sensor, i.e. Kinect v2 - and of processing the point cloud so to generate NURBS surfaces of the chest; 2) a procedural CAD modeling of a personalized VB implemented within Siemens NX 11 CAD environment. Using the devised method, the medical staff is required only to use the 3D scanning system for acquiring the patient chest and to sketch, in a CAD-based interface, the boundary of the area to be treated. Once these tasks are performed, the system automatically builds the personalized VB model, ready to be manufactured.

KEYWORDS

Procedural CAD modeling; reverse engineering; design customization; vacuum bell

1. Introduction

Chest wall deformities, i.e. abnormal development and appearance of the chest, may be congenital or acquired and may be divided into different categories [16]. 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 [4, 21, 23]. PE is characterized by an abnormal overgrowth of sternal and costal cartilages which results in a depression of the sternum and costal cartilages [9] as shown in Fig. 1(a).

Though PE is an asymptomatic disease in most cases (95% of cases according to [8]), 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 [14].

Worst severe deformities can be repaired surgically via, for instance, Ravitch or Nuss procedures [15]; 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 [10]. The body is made of a silicone ring and a transparent polycarbonate window (for inspection). 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. 1(b). [11].

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 [11]), can make the device uncomfortable, and in some cases

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Figure 1. Chest picture of an adolescent affected by a moderate/severe form of pectus excavatum [23] (a) and Different sizes of the vacuum bell [11] (b).

ineffective, for the patient. In fact, clinicians report complications and relevant side effects from VB treatment including scalded pressure wound, subcutaneous bleeding, dorsalgia, transient paresthesia of the upper extremities, wearing discomfort and pain during the application [11]. These side effects may play a role on patient compliance to the treatment schedule thus reducing the therapeutic outcome.

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 proven 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 involves a procedural CAD modeling 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.

2. Personalized VB design

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

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

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 acquisition system in order to minimize artifacts caused by patient movement (e.g. caused by breathing).

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 [6]: 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 [1, 18, 22], they prove to have the potential to be used as a 3D scanner [12, 24]. 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 [5].

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 [7].

The sensor has been placed centrally over the thorax of the patient (standing up straight against a wall),

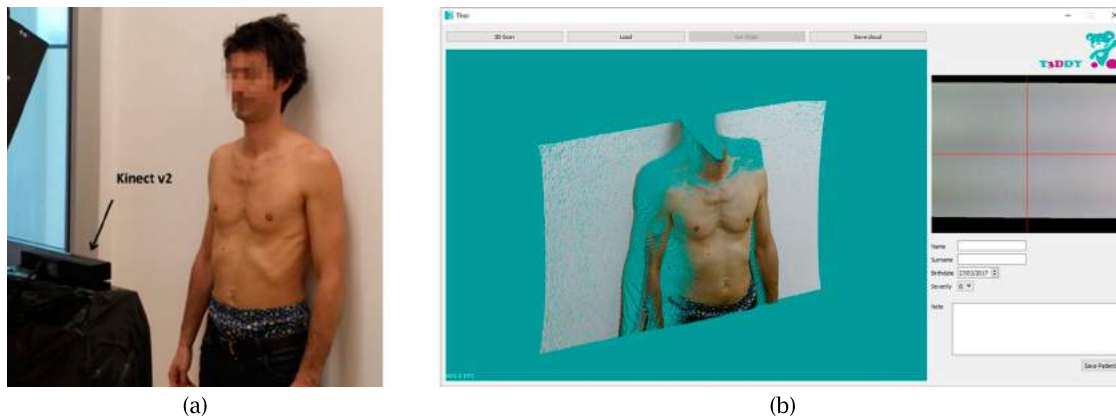


Figure 2. Kinect v2. Setup (a) and devised tool for the acquisition and the processing phases (b).

approximately orthogonal to the wall and at a distance of about 65 mm (see Fig. 2(a)).

To collect the necessary 3D data, a user interface has been realized using the C++ library Qt [20]. Such an interface is very simple and user-friendly, and hides to the final user (i.e. the medical staff) the logic behind data manipulation.

At application startup, the camera is open and the real time frame stream is shown to the user.

Both RGB and depth stream are considered for the acquisition [13] and aligned each other. The scanner data stream runs continuously and the 3D data together with the corresponding RGB image are stored instantaneously as the user press the *3D scan* button (see Fig. 2(b)). The grabbing process is instantaneous since the camera is already running when the button is pressed, thus eliminating initiation delays. This is a very important feature for a medical body scanner since it is very difficult for a human being to hold still for an extended period.

When the depth data is saved it is firstly transformed into a point cloud for further processing; specifically, the filtering process includes: a first definition of the region of interest, followed by a boundary removal and a moving

least squares smoothing, based on a weighted neighborhood, to remove the noise introduced during the acquisition process, without altering surface geometry. All the post processing filtering is performed using the open source Point Cloud Library (PCL [19]).

Once the point cloud is filtered, the next step is the alignment of the camera reference system with a convenient reference system to be used in the VB generation (see Section 2.2.). z axis of the camera is aligned with the normal vector of the plane where the patient lays (i.e. the wall). The plane identification is automatically performed by using the *sample consensus segmentation* [19], a randomized algorithm for robust model fitting. An example of the resulting cloud is shown in Fig 3(a).

In order to define the origin and the orientation of x and y axes a user guided procedure is necessary. In detail, the user is firstly required to manually click two points roughly corresponding to the areolas centres; the segment linking such points is then used to automatically rotate the point cloud so that the x axis lies on it.

Subsequently, the user has to manually select the chest area enclosing the pathology (see Fig 3(b).); this

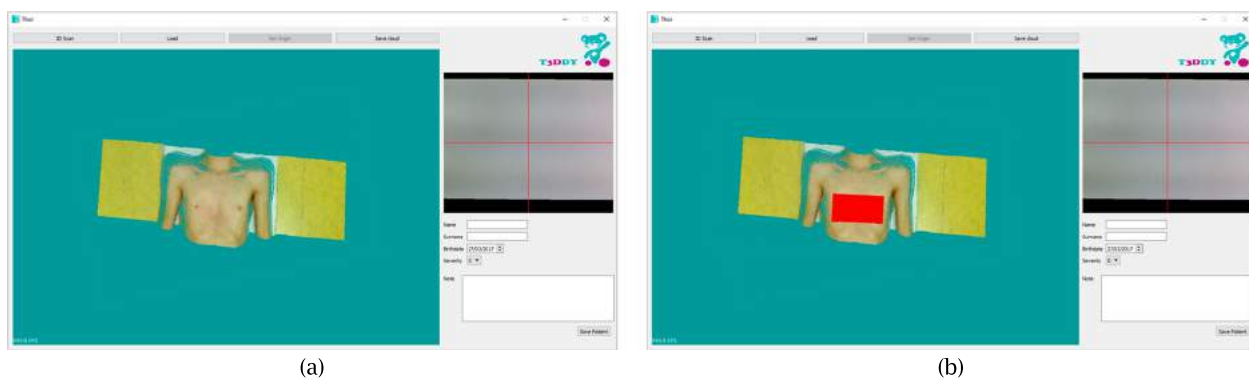


Figure 3. Point cloud with the z axis of the camera aligned with the normal vector of the plane where the patient lays (a); manually selected chest area enclosing the pathology (b).



Figure 4. Final result of the orientation phase.



Figure 5. Area to be treated sketched on the chest by the medical staff (a) and the same area drew using a spline in a CAD environment (b).

allows the developed procedure to detect the origin of the reference system as the point of surface maximum depression with respect to the wall. Finally, the point cloud is translated so that the origin of the camera system coincides with such a point (see Fig. 4.).

Moreover, the mathematical surface of the area selected is extracted for the CAD modeling of the Vacuum Bell device. The parallel sections of the chest point cloud are obtained using the vtk Cutter functions of the VTK library (Visualization Toolkit [25]), as intersection with a set of N parallel planes (parallel to xz). Every plane will generate a set of points, and each one of the obtained point set is then transformed into a spline lying in the xz plane at different y value. Obviously, N should not be too low to avoid inconsistent chest geometry surface reconstruction; on the other hand, a too high number of planes makes the surface reconstruction more complex without significant benefits. Accordingly, a good compromise, considering also the variability of the chest dimensions, has been found equal to 40 planes. Eventually, each curve is used to obtain the surface using a loft function; such a

surface can be easily exported in IGES or 3dm format for the subsequent phase.

The main idea behind the semi-automatic generation of the personalized VB foresees the definition, directly by the medical staff, of the area to be treated (see Fig. 5(a.)). As already mentioned, 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 3D chest geometry (see Fig 5(b)).

In order to allow non-expert users (e.g. medical staff) to generate the personalized VB, a custom application (add-in) for Siemens[®] NX 11 CAD environment 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)[17].

Table 1. Default parameters.

Parameter	Tuned Value	Variation range
α	0.3	0.2–0.4
β	0.3	0.2–0.4
γ	0.7	0.65–0.75
δ	0.85	n.a.

The developed add-in is based on a procedural CAD modeling strategy [2, 3] and consists of the 16 steps described in Table 1.

- Step 1 - (user guided) import the chest geometry (NURBS surfaces) obtained in the acquisition task. According to the procedure defined in Section 2.1. the geometry is properly oriented and the origin of the reference system is located in the deepest point of the pectus excavatum (with reference to the wall). This reference system is the one used for building the VB model;
- Step 2 - (automatic) a plane (*Plane#1*) parallel to the wall (*W_Plane*, corresponding to the xy plane

in the global coordinate system) and passing through the point of the surface at the maximum distance from *W_Plane* is detected;

- Step 3 - (user guided) manually sketch a 2d spline (*2Dspline*) delimiting the area to be treated (see Fig. 5(b).) on *Plane#1*; an appositely developed GUI automatically opens the sketch using such a plane so as to avoid mistakes by the users on the correct positioning of the spline;
- Step 4 - (automatic) the spline defined in Step 3 is projected on the chest surface (*3Dspline#1*);
- Step 5 - (automatic) a plane (*Plane#2*) parallel to *Plane#1* at a distance equal to $(1 + \alpha)$ times the ratio between the area and the perimeter of the *3Dspline#1* is defined.
- Step 6 - (automatic) 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 β times the area defined by the *3Dspline#1* (see Fig. 6(a).);
- Step 7 - (automatic) a volume loft (*Loft#1*) between *3Dspline#1* and *Circ#1* (see Fig. 6(b).) is built;

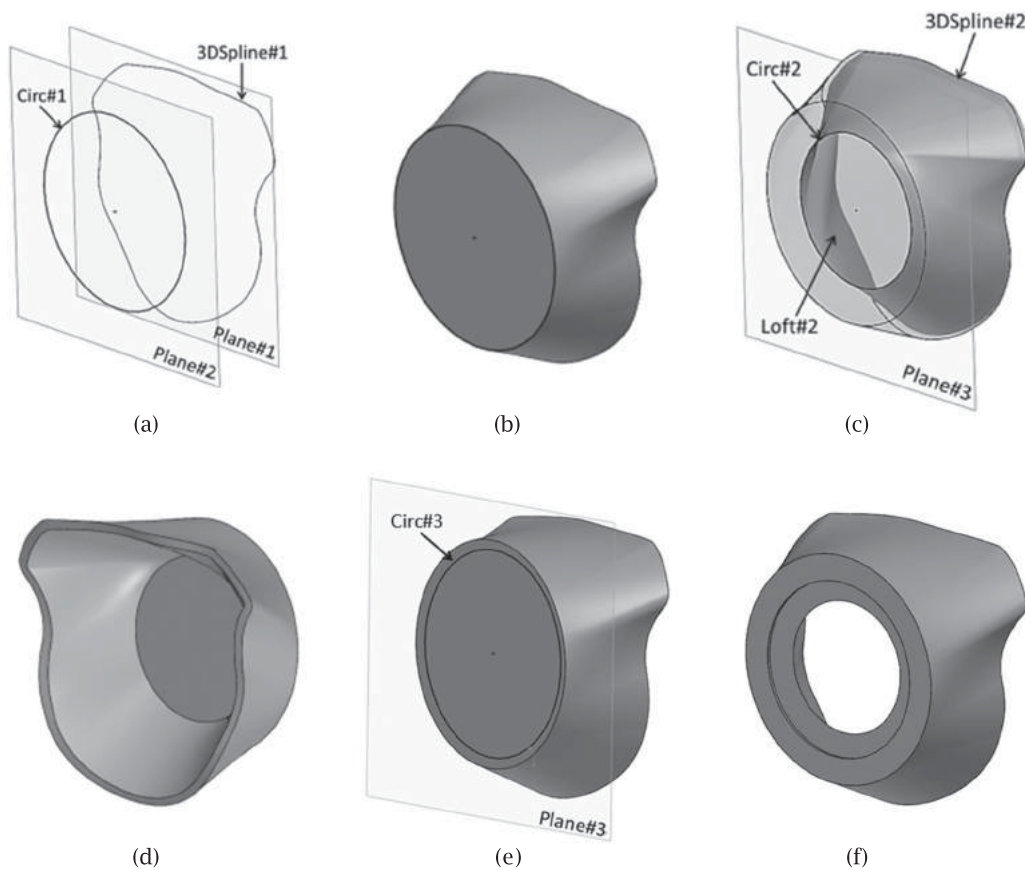


Figure 6. Some steps of the archetypal generation: (a) *3Dspline#1* obtained by projecting the 2D spline sketched by the medical staff onto the chest surface; (b) *Loft#1* between *3Dspline#1* and *Circ#1*; (c) *Loft#2* between *3Dspline#2* and *Circ#2*; (d) volume obtained by subtracting *Loft#2* from *Loft#1*; (e) cut-extrusion using *Circ#2* and *Circ#3* and (f) final result.

- Step 8 - (automatic) a plane (*Plane#3*) parallel to *Plane#2* and placed at a distance equal to 8 mm, directed towards the chest is defined.
- Step 9 - (automatic) a circumference (*Circ#2*) on *Plane#3* centered with *Circ#1* and with a diameter equal to γ times the diameter of *Circ#1* is drawn (see Fig. 6(c).);
- Step 10 - (automatic) the external surface of the *Loft#1* is offset to inside (5 mm) thus defining a surface *SLoft#1*; The newly defined surface is then extended for 20 mm in order to ensure it intersect with the chest geometry surface; the selected thickness value, equal to 5 mm, has been chosen on the basis of the value adopted for standard VBs;
- Step 11 - (automatic) the intersection between *SLoft#1* and the chest surface is evaluated so that to obtain a new 3D spline (*3Dspline#2*) (see Fig. 6(c).);
- Step 12 - (automatic) a loft (*Loft#2*) between *3Dspline#2* and *Circ#2* (see Fig. 6(c).) is built;
- Step 13 - (automatic) the subtraction between *Loft#1* and *Loft#2* is carried out (see Fig. 6(d).);
- Step 14 - (automatic) a circumference (*Circ#3*) on *Plane#3* centered with *Circ#1* and with a diameter equal to δ times the one defining *Circ#1* is drawn (see Fig. 6(e).);
- Step 15 - (automatic) a cut-extrusion of *Circ#3* (6 mm i.e. the thickness of the window that will be manufactured in transparent polycarbonate) is carried out;
- Step 16 - (automatic) a cut-extrusion of *Circ#2* passing through the body is carried out (see Fig. 6(f).).

The final result of the procedure described above consists of a 3D model of the “ring” that will be produced using silicone.

The procedural CAD modeling requires a number of parameters to be tuned (i.e. α , β , γ and δ) to work properly. On the basis of a trial and error approach by varying the chest surface and the *2Dspline*, defined in Step 3, the optimal values of the parameter are listed in Table 1. Such parameters were used for creating personalized VB for 28 patients each one characterized by her/his own anatomy and chest defect; therefore they can be considered reliable for a wide range of situations.

As mentioned above, though appropriate for most of the case studies the procedure has been tested on, these tuned values may occasionally fail to produce correct geometries due to particular conformation of the patient's chest (this case occurred only in 2 test cases obtained by manually modifying the original chest geometry of real patients so to “exaggerate” the chest deformities).



Figure 7. Final result of the procedure.

Therefore, they may have to be manually adjusted in order to overcome the specific problem when it arises. Since a specific indication for tuning the parameters is hard to be provided, the manual adjustment should be performed by a CAD user on a case-by-case basis. As a practical rule, in Table 1 a variation range for the parameters is suggested. Adjusting the parameters within the suggested variation range it was possible to obtain consistent geometries in all the studied configurations.

In order to finalize the personalized VB design, an additional part obtained by extruding *Circ#3* (6 mm) is performed so as to realize the inspection window. Obviously, in this step the new body has to be kept divided from the previously built one. Moreover, in such a body a small hole for a G 1/8" screw is also realized; the center position of the hole is located on a circumference whose diameter is equal to the half of the one of *Circ#2*. Such a hole is required in order to place the suction system.

The final model of the VB is shown in Fig. 7.

3. Graphical user interface

As mentioned above, one of the main aims of the devised procedure is to help medical staff in designing the personalized VB without the need of being aware on the procedural modeling strategy.

In other words, the medical staff is required only to choose the chest acquired with the Kinect and to sketch the 2D spline defining the contour of the area to be treated. Subsequently the devised application automatically builds the personalized VB. To this purpose a GUI, implemented as a new Tab of the Siemens NX 11 ribbon interface, has been developed (Fig. 8.). In detail the GUI is structured into a three-step procedure allowing to 1) import the chest surface, 2) draw the 2D spline) and 3) generate the personalized VB model.

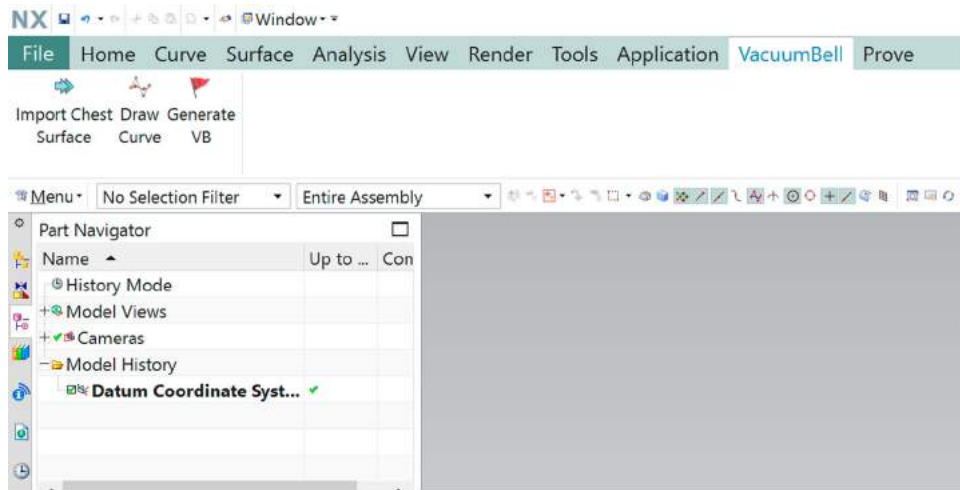


Figure 8. GUI implemented as a new Tab of the Siemens NX 11 ribbon interface.

The add-in is able to check and to prevent possible geometrical errors coming out during the generation of the VB model, with particular reference to the “hourglass effect” in loft generation (i.e. the erroneous loft reconstruction occurring when curves defining the loft are not consistently oriented). In fact, at the end of loft generation (e.g. Step 7) a pop-up window asks the user to confirm the correctness of the geometry (see Fig. 9.). In case the loft is not properly generated, the devised program automatically set the consistency of the two curves orientation.

In the same way the user is asked to change parameters α , β , γ and δ , set to the default value of Table 1, if required. It has to be noticed that, while errors in loft generation are probable (but easy to be treated also by

medical staff), the modification of α , β , γ and δ parameters is not straightforward for the medical staff. This is a drawback of the devised method. Fortunately, in all the case studies the procedure has been tested on, no failure related to such parameters has been detected. It is, however, expected that in a real-life environment a few cases may occur. Therefore, a training for the medical staff will be required in the near future to confront with this issue while, to date, the support of CAD modelers is still required.

4. Case study

In order to verify the appropriateness of the developed procedure a number of case studies provided by the

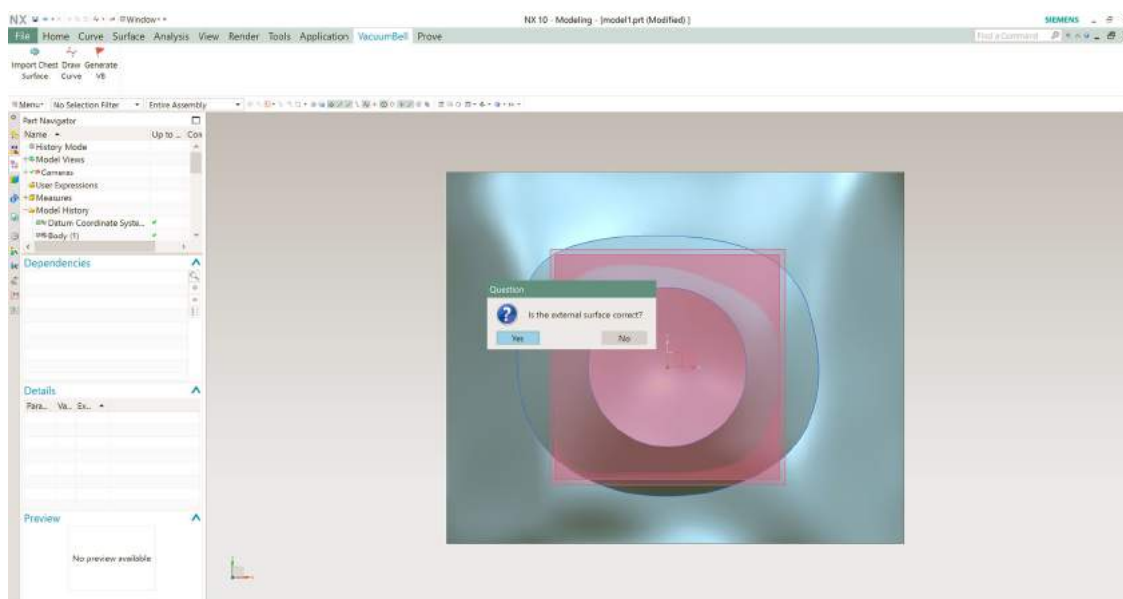


Figure 9. Pop-up window capable to correct possible “hourglass effect” in loft generation.



Figure 10. Personalized VB.

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 modeled. All subjects have been informed of the nature of the experimentation and written consent was obtained. The Ethical Guidelines of both the University of Florence and Italian law have been respected while performing the experimentation. Tests demonstrated the effectiveness of the method to create VBs whose geometry is adapted to different patients. From a CAD perspective, the procedure can be considered validated since it was able to reproduce consistent geometry (in other words no reconstruction error are reproduced by the CAD software package) and the shape of the obtained part correctly conforms to scanned patient chest without clearances or interferences.

An exemplificative case study is discussed in this section to demonstrate the potential of the developed procedure. The case study refers to a patient (male, age 40 years) with a mild pectus excavatum to be treated with VB device. The entire reconstruction procedure was carried out by the medical staff without any help from the engineers. 3D acquisition of the patient chest has been performed in less than 1s and, using the developed interface the medical staff was able to process the point cloud in a few minutes. The CAD model of the personalized VB has been easily designed in less than 5 minutes. Finally, the CAD model has been exported in STL format to allow the manufacturing of a physical prototype using manufactured by casting the silicone into a mold (created starting from the STL file mentioned above) as shown in Fig. 10. Since the material used (silicone) and (as already mentioned) the thickness of the personalized VB are almost the same used for standard VBs, the mechanical strength of the newly produced device has not been tested. Nonetheless, since the geometry is considerably

different, in future works a FE analysis (considering non-linear behavior of silicone) should be performed to verify the actual mechanical behavior under several working conditions.

5. Conclusion and future works

A semi-automatic computer-aided method capable to design personalized vacuum bells is proposed. The design relies on a semi-automatic procedure allowing also non-expert users (after a brief training) to quickly obtain a VB 3D model once the patient chest has been acquired using commercial 3D scanners. Tested against a set of 30 case studies, the devised procedure proves to be effective in quickly generating the 3D model of the VB compliant with the geometry of the patient chest.

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; therefore, a questionnaire-based analysis on a set of patients will be carried out in the future. Moreover, a comparison between the medical treatment using the standard VB device and the personalized one has not been performed yet. Consequently, a more deep 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 medical effectiveness of the treatment according to the UNI EN ISO 14155 normative (i.e the European Good Clinical Practice) and Helsinki declaration.

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.

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