

45th CIRP Conference on Manufacturing Systems 2012

Personalised Trachea Stent Designer: A Knowledge Feature

D. Ugarte^{a,*}, A. Izaguirre^a, A. Rosell^b

^aFaculty of Engineering, Mondragon Unibertsitatea, Mondragon 20.500, Spain

^bPneumology Department, Bellvitge Hospital, Bellvitge 08907, Spain

* Corresponding author. Tel.: +34-943-739-666; fax: +34-943-791-536. E-mail address: dugarte@mondragon.edu

Abstract

Modelling of anatomical parts is usually tackled through triangulated models with specialised Bio-CAD applications. If features beyond anatomy are required, geometry is usually translated into NURBS geometry for further modification in parametric feature based design CAD systems. But, they remain quite unmanageable yet. The authors present, validate and implement into a knowledge feature a methodology that generates an anatomically personalised trachea stent based a point cloud data extracted from a Computerised Axial Tomography with an open-source medical data visualisation application.

© 2012 The Authors. Published by Elsevier B.V. Selection and/or peer-review under responsibility of Professor D. Mourtzis and Professor G. Chryssolouris. Open access under [CC BY-NC-ND license](https://creativecommons.org/licenses/by-nc-nd/4.0/).

Keywords: Bio-CAD; Knowledge Based Engineering; Personalised trachea stent; Design Automation; Unigraphics – NX; Knowledge Fusion

1. Introduction

When a patient develops a tracheal stenosis that begins to narrow his airways, pneumologists implant a tracheal stent to keep his airways open. Current stents are a family of topologically equal tube-like geometries with varying dimensions in order to enable some fit to the patient. However, these stents do not consider any of the personal anatomical features of the patient as: pitch in between tracheal rings, angulations, non-circular section, and so on. This design approach shows the following limitations:

- Sudden overloads, as coughing, after the stent is in place can migrate the stent along the trachea and leave it misplaced, making necessary another medical intervention to place it back correctly.
- As the shape of the stent does not completely fit to the patient's trachea, the stent obstructs the airways more than necessary.

In the research under development a new design methodology is being defined to overcome these

limitations by creating a system that personalises the stent to the patient's features.

The development process of such a personalised stent follows these steps:

1. It typically starts by acquiring patient's geometry data through a Computerised Axial Tomography (CAT) by radiologists. Typically, the output is a file in DICOM format that contains among others, the linear attenuation coefficient of the material present on patient's body at each point for the whole body area of interest. As each point must represent a volume, they are actually voxels, with a resolution that can be set by the radiologist, with a maximum of around 0.8mm on both directions on the plane normal to the CAT machine axis and 0.5mm in the axial direction.
2. The Region Of Interest (ROI) must be aisled from the remaining voxels based on a threshold of their linear attenuation coefficient (typically measured in Hounsfield units (HU)), i.e., material. Once, the ROI is aisled, the current anatomical geometry is assumed to be obtained.

3. If the anatomical geometry requires additional geometric modification in order to perform its medical function, modification must be undertaken in order to define the stent.
4. Finally, due its complex geometry and one of a kind production, it is manufactured by means of rapid manufacturing techniques.

From a technical perspective, step 3 should naturally be undertaken with geometry modelled in voxels, as in [1] and because input comes in voxels and output must be given slices. However, as little to none voxel based modelling tools are available out in the market and the modification of voxel based model is neither parametric nor feature-based, they are rarely used on industrial practice.

Industrial practice has focused on converting voxels into triangulated models (e.g. STL) as in [2] and [3], through probably three dimensional convex hull algorithms. Therefore, many medical data visualisers can be found in the market (3D Doctors, Analyse, Anatomics, Julius, Mimics, Simpleware, Tomovision, Velocity Pro, Vworks, ...), that provide functionality to convert ROIs into triangulated models. Once more, even though software that can modify triangulated models easily in the market is increasing, all of the above plus many reverse engineering applications (Geomagic, Rapidform, Imageware, ...), their user-base is limited and so it becomes an specialised task. Therefore, both medical data visualiser and reverse engineering applications provide automatic functions to best fit nurbs patches over the triangulated models in order to export them as STEP or IGES files that could be more easily modified in the more widely used and more capable to easily modify geometry parametric feature based solid modellers like: CATIA, NX, Pro-E, Solid Edge, SolidWorks, etc. However, even though the possibility to modify geometry improves, as the NURBS are simple best fit patches with no modelling strategy, they are yet fairly hard to modify.

In the present paper, the authors will present a Knowledge Based Engineering (KBE) application, that taking the ROI from a medical data visualisation software, will automatically build a parametric feature that will stand on the parametric tree of Siemens PLM Software NX, that models the necessary tracheal stent. Thus, it makes easier not only to add further features to the anatomical geometry, but also adjusting the anatomical geometry itself, whenever necessary.

In order to present the development, first the main geometrical features that a personalised trachea stent must fulfil will be presented. Next, the overall design process will be introduced. Then, the implemented algorithm will be presented. Following, obtained results will be validated against software used in industry and finally, major limitations and future research lines will be outlined.

2. Features of personalised trachea stent

A personalised trachea stent should follow the following geometrical features:

- It must anchor itself to prevent migrations. Thus, in order to have a tight fit, the outer surface must be an “offset” of the inner surface of the trachea, i.e., the anatomical geometry present in the ROI.
- It must avoid necrosis on the supporting tissue. Thus, all edges must be blended.
- It must withstand some side loads during, e.g., eating. Therefore, it must have some thickness.
- It must provide as much airway as possible to the patient. Thus, inner surface should be an “inner offset” of the outer surface.

3. Design process

In order to enable pneumologists be closer to the medical prescription they provide through the personalised trachea stent, different medical data visualisation applications were screened and the most affordable and valid software was chosen. Amide is an opensource application available at <http://sourceforge.net> developed by a radiologist that enables users to define and export ROIs as point clouds, among many other features.

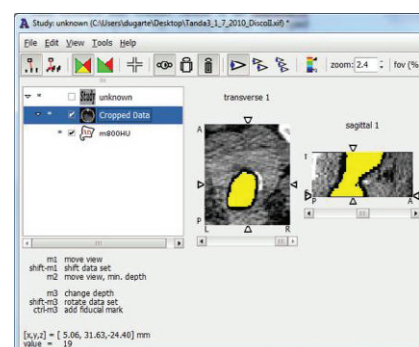


Fig. 1. Point cloud data collection in Amide.

This point cloud is then used as an input in NX. The Personal Trachea Stent knowledge feature is integrated into the menus and toolbars of NX, and brings up a dialog. The dialog allows the user to import the point cloud. The knowledge feature, processes the point cloud, and allows the user to change the fit size, length, thickness and blend radius of the personalised stent. Finally, once the user is satisfied, the personalised stent appears as a feature on the feature tree of NX, for future modification.

Following any feature could be added to the personalised trachea stent if required by the user.

4. Algorithm

As a general idea, the personalised trachea stent knowledge feature, models the stent by finding out the boundary points of each section in Z, create an spline for each section, offset it to generate the outer and inner sections of the stent at that level, generate corresponding NURBS surfaces, and finally blend both ends and make it a solid.

The point cloud provided by Amide is a tab separated value text file, composed by a header with identifying data, and the list of points with HU, weight and XYZ coordinates of the point sorted in increasing order of HU. Thus, first all points are sorted and arranged in sets based on their Z coordinate. Following, each Z point set goes through an edge filtering that finds out the boundary points of the set (see red points in Figure 2 (a)) and a spline going through the boundary points is created (see green curve in Figure 2 (b)).

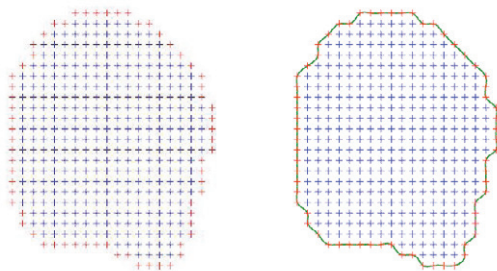


Fig. 2. (a) Z point set with its edge points; (b) corresponding spline.

A close look into Figure 2 (b), clearly unveils sharp edges due to the rather coarse resolution of the CAT for these purposes. Besides, the starting point of each spline is not aligned, which results in heavily twisted NURBS surface if used as are. Therefore, taking into account the medical description of tracheas, a set of rings roughly

perpendicular to airway path, a new alignment algorithm is implemented. The airway path is modelled by finding out the centre point of 60 points lying on the initial spline of every Z section (see Figure 3 (a)). Following, in order to solve alignment and aliasing issues, a variable amount of points are extracted from the initial spline. These are calculated by intersecting the spline by a plane that contains the centre point and Z direction, and form uniformly spaced angles with the X axis.

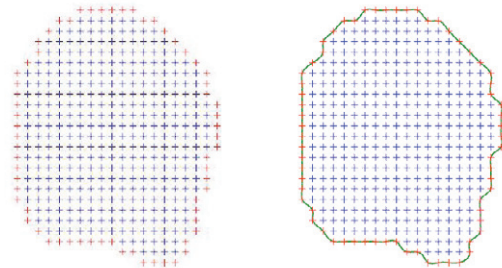


Fig. 3. (a) Z section centre calculus; (b) corresponding smoothing.

The spline that goes though these points (see blue points and red spline in Figure 3 (b)) has two properties: 1) is far smoother and 2) the airway direction curves of the NURBS surface derived out of these splines, will resemble the airway path

Following, as precise offsets of the red spline in Figure 3 (b) usually fail, the blue points in Figure 3 (b) themselves are radially offset inwards (see Figure 4 (a)) and outwards (see Figure 4 (b)) to generate the inner and outer sections of the personalised trachea stent knowledge feature.

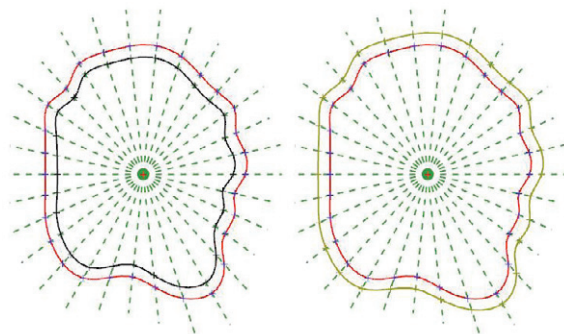


Fig. 4. (a) Smoothed Z section inner rough offset; (b) corresponding outer rough offset.

Figure 5 shows the comparison between the initial Z point set provided by Amide and the Z section of the personalised trachea stent knowledge feature. The outer

section clearly goes beyond the boundary points in order to provide the fit to anchor the stent to prevent migrations. The inner section is a rough offset of the outer, providing as much airway as possible. The thickness can be roughly controlled through the difference between inner and outer offset. Finally, the outer section has no sharp edges that could generate necrosis on the supporting trachea tissues.

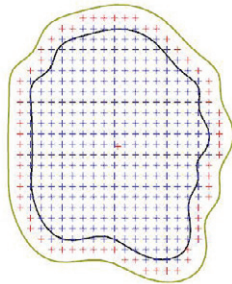


Fig. 5. Original Z point set and inner-outer sections.

Following, the inner and outer surfaces of the personalised trachea stent are generated by NURBS surfaces that go through the section curves (see Figure 6 (a)). Finally, the blends are generated as section surfaces that go through the start and end sections, remaining tangent to stent surfaces and with a given radius (see Figure 6 (b)).

Lastly, two bounded planes that close up the volume are generated, and a sewing operation that joins all surfaces in a solid body is performed.

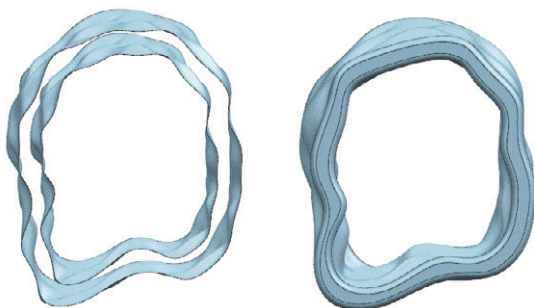


Fig. 6. (a) Stent surfaces without blends; (b) Blended stent.

All the modelling necessary knowledge to develop personalised trachea stents following the described methodology has been encapsulated into a Siemens PLM Software NX7.5 knowledge feature. This has been accomplished by programming in the embedded Knowledge Based Engineering engine Knowledge

Fusion. In order to increase its usability the graphical user interface shown in Figure 7 has been developed.

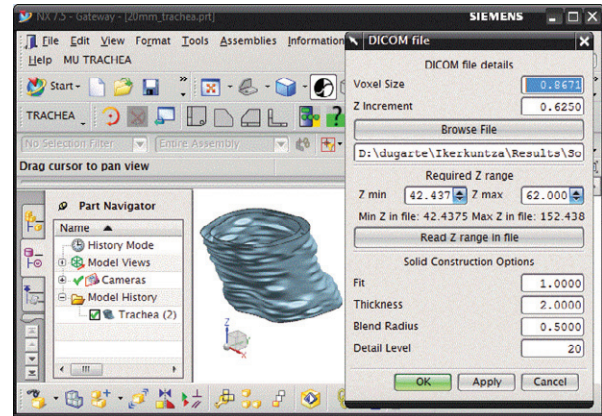


Fig. 7. Knowledge feature user interface in NX7.5.

5. Validation

In order to show the validity of the approach, authors sought the collaboration of a nearby research centre, namely Lortek, who had Mimics licenses and followed the mainstream industry practice to develop personalised stents and prostheses.

Thus, patient, DICOM file and HU threshold values were agreed and the same trachea surface was developed.

As shown in Figure 8, geometries matched very closely, considering there was a little offset in one of the directions.



Fig. 8. Validation of knowledge feature (in red) with Mimics (in blue).

Thus, the methodology and implementation of the proposed algorithm has been regarded as valid as the industrial practice with Mimics.

6. Results

The knowledge feature has been used to design six personalised trachea stents, based on CAT data from different patients. Results have been regarded as innovative by the pneumologist.

7. Limitations and discussion

Researchers clearly identify two limitations within the implemented modelling methodology:

1. Variable thickness: if the tangent to the initial spline goes through the section centre, the computed stent thickness becomes zero.
2. Partial solution: the knowledge feature is a partial solution to pneumologist needs, as its application to the point where trachea splits into bronchus remains unsolved.

The former has been neglected, as the natural shape of trachea is rings and thus, the case would be rare. The latter, requires some significant enhancement to algorithm but researchers consider that it would be possible to overcome it in the near future [4].

Beyond methodology constraints, researcher identify three further limitations to the real prescription of personalised trachea stents to patients:

1. Resolution of current CAT data is rather rough for this application.
2. HU threshold setting is rather iterative and qualitative in medical data visualisation applications like Amide or Mimics. Close research should be conducted with radiologists to define an adequate methodology for these purposes.
3. The stent should be manufactured in medical grade silicone for long stays. Currently, this can be achieved through silicone rubber moulding. However, this process is far too labour intensive to be cost effective. Ideally, it should be manufactured through Rapid Manufacturing techniques to directly get trachea stents as the one shown in Figure 9, plot in ABS plastic. However, even though some can directly manufacture on medical grade silicone, this is not adequate for long stays, yet, as far as researchers are aware.



Fig. 9. Plot ABS plastic trachea stent.

8. Conclusions

The presented methodology and personalised trachea stent knowledge feature, open up a way to directly model in Siemens PLM Software NX7.5, a parametric feature based design system, based on a point cloud data extracted in an opensource medical data visualisation application, namely Amide.

Thus, the results have been regarded as innovative by the pneumologist because they:

1. Add reliability on an opensource software that can decrease costs for the development of personalised prostheses.
2. Bring the stent design process closer to the pneumologists, as the stents are medical prescription.
3. Reduce the need of specialised CAD tools, making the user base far wider and related labour costs.

Acknowledgements

We extend our thanks to Itziar Tolosa from Lortek research centre for her cooperation in the validation process of this methodology and Andrew Loening for releasing as opensource an application as Amide. Finally, we acknowledge the financial support from the Spanish Ministerio de Ciencia e Innovación and European Union's FEDER funds through the (PSE-020000-2009-1) project.

References

- [1] Z. Fang, B. Starly, A. Shokoufandeh, W. Regli, and W. Sun, 2005. A Computer-aided Multi-scale Modeling and Direct Fabrication of Bone Structure, *Computer-Aided Design and Applications*, vol. 2, no. 5, pp. 627-634.
- [2] W. Sun, B. Starly, J. Nam, and A. Darling, 2005. Bio-CAD modeling and its applications in computer-aided tissue engineering, *Computer-Aided Design*, vol. 37, no. 11, pp. 1097-1114, Sep. 2005.
- [3] B. Starly, Z. Fang, W. Sun, A. Shokoufandeh, and W. Regli, 2005. Three-Dimensional Reconstruction for Medical-CAD Modeling, *Computer-Aided Design and Applications*, vol. 2, pp. 431-438.
- [4] R. Basagoiti, D. Ugarte, and A. Rosell, 2011. Use of Dynamic Time Warping for a Personalized Tracheal Stent Design, in *Soft Computing Models in Industrial and Environmental Applications*, 6th International Conference SOCO 2011, pp. 571-578.