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QUALITY INNOVATION OF THE YEAR 2015

QUALITY INNOVATION 2015

Maximum 2 pages or 5 pages with annexes. Please send the completed application to vbascones@euskalit.net

The official name of the organisation Fundación Centro de Tecnologías de Interacción Visual y Comunicaciones Vicomtech-IK4		
Address Paseo Mikeletegi 57. Parque Tecnológico MIramón	Postal code 20009	City Donostia-San Sebastián
Competition category (*Please, delete all the remaining categories. An innovation can just take part in a category.)* **Innovation in the social and health sector -For responsible innovations of organisations in the social and health sector.**		
Innovation title (max. 100 characters) Software for computer-assisted 3D endovascular planning for aortic aneurysms based on image analysis		
Short description of the innovation (max. 200 characters) Endovascular (abdominal) aortic aneurysm repair (EVAR) device planning tool through accurate quantification based on image analysis, optimizing workflows and reducing EVAR-related complications		

Innovation description (Explain the core of this innovation, the guiding principle, the steps taken, the resources used (people and economic resources) and a description of how the innovation has involved a difference at the economic and environmental levels).

Vicomtech-IK4, in collaboration with the doctors Mariano de Blas and Jose María Egaña from Donostia Hospital and Biodonostia Health Research Institute, detected the need for supporting the vascular surgeons in the decision process related to the endovascular aortic aneurysm repair, as most softwares did not provide intuitive, reliable, accurate and agile sizing tools (*see "Design of stents for aortic aneurysm exclusion treatment" video on youtube: https://www.youtube.com/watch?v=3wAu9fz7cDo).*

The aorta is the body's largest artery. An aortic aneurysm is the progressive dilation of the vessel's walls. It may start asymptomatically but their rupture may cause death in almost 85% of cases. Abdominal aneurysms larger than 5,5 cm should be repaired.

The endovascular therapy is an alternative to open repair introduced in the 90s that has become the standard procedure. It consists of introducing and deploying an endograft through the femoral artery in order to exclude the aneurysm from blood circulation. The device is anchored between both ends of the aneurysm, and reduces the pressure of the wall, preventing the rupture. The design of endografts must be adapted to the morphology of each patient. As the aneurysm becomes more complex, it is necessary to design personalised endografts with branches.

The planning is based on measurements taken from high-resolution computerised tomography (CT) images of the abdomen. The difficulty is to obtain precise measurements for the endograft design in 3D images shown as 2D slices. The innovation consists of the development of a tool, based on the semi-automatic analysis and visualization of the CT scanner images, which includes segmentation of the aorta, vascular image analysis, multiple synchronized views and reconstructions and an agile, intuitive workflow. It allows computing the design parameters (measurements), easing the design of an endograft which can be perfectly tailored for the patient. This may allow a reduction in intervention times by preventing problems in deployment of the endograft during the endovascular procedure due to inadequate sizing. This is important because aortic aneurysm patients' health is usually delicate, and the procedure involves irradiation, possible toxicity due to image contrast and lack of irrigation to vital organs. The new tool also provided a novel solution for sizing fenestrated endografts (f-EVAR), which requires the planning of fenestrations (holes in the fabric) for cases requiring fixation upwards beyond the renal arteries (i.e. short or degenerated aneurysm necks).

In Vicomtech-IK4, we have worked to develop a planning system for this kind of surgery. The collaboration of the doctors Mariano de Blas and José María Egaña from Donostia Hospital / Biodonostia has been essential. The aim is to simplify the measurement and design in order to obtain a greater accuracy. The process starts with the semi-automated analysis of the contrasted CT images. First, the aortic tree is isolated (segmented) from the rest of the data. This process is not manually feasible due to the volume and complexity of the imaging data, so we have developed an automatic algorithm which is also capable of dealing with contrast inhomogeneities along the aorta. Once isolated, we can generate a 3D model of the aorta and perform an advanced vascular analysis based on complex mathematical methods in order to obtain the relevant measurements. We first obtain the centerline of the vessels, getting an irregular curve that will be subsequently smoothed. Based on the points of this curve, we obtain sections that serve as a visual reference allowing an accurate measurement, and also manual corrections. We have developed a digital workflow tailored for specialists, adapted it to any scanner and in close collaboration with other specialists such as radiologists.

The exploitation rights have been transferred to the eMedica company, having a leading role in the adaptation and completion of the tool. Moreover, in 2015, eMedica has signed an international distribution agreement with an important company of the sector based in Germany and conversations with other interested endograft manufacturers interested in acquiring the software are taking place.

Note. More information about the competition and about how to fill in the form in www.euskalit.net

INNOVATION

Auto evaluation of the innovating features of the innovation. ¿How does the innovation satisfy and/or overcome the needs of customers, society or environment in a new way or significantly revised?

The innovation is a result of a close, multi-disciplinary collaboration and is based on the observation of the workflow of the clinicians, detection of pitfalls and difficulties of existing softwares in performing the required tasks, comparison with existing solutions and provision of adequate solutions to these problems.

The product is designed so as to satisfy the needs of a majority of users performing standard endograft sizing, requiring a fast and intuitive, guided workflow. Advanced users performing complex surgeries (fenestrated endografts) or requiring a greater degree of freedom are provided with specific advanced workflows. The interaction between surgeons and device manufacturers is improved by the provision of a content-rich report of the device design.

The software reduces the uncertainty in the selection/design of devices and accelerates the design processes, benefiting patients that are at risk. A better endograft sizing may reduce intervention time in complex procedures involving irradiation, potential toxicity from image contrast and lack of irrigation to key organs in delicate patients during surgery.

Auto evaluation of the utility. ¿How is the innovation applied in practice? ¿Is it done in a systematic way and in accordance to the organisation plan? ¿Is the innovation usable?

The innovation is being distributed. Thanks to the knowledge of eMedica, it is perfectly adapted to the workflows of the vascular surgeons, so its specialisation is high. With the software, clinicians perform endograft sizing with a higher degree of security, but also in a very agile manner, thus decreasing planning times. Content-rich generated reports, including visual screenshots avoid the need of creating complex drawings and completing forms. Endograft manufacturers find the solution as a tool to be used by their commercial force in close contact with end-users (vascular surgeons, interventional radiologists) offering an added value in the clinician–manufacturer interaction. Currently, the tool is being adapted to each manufacturer's needs, i.e. including brand names and models. In order to improve this joint collaborative user experience in the endograft design cycle, we are developing, in close collaboration with eMedica, an online collaboration platform for the collaborative review of cases planned with the software.

Learning. ¿Is the innovation based in a new idea or discovery? ¿Is the innovation based in a systematic development process? ¿Does the innovation applies an existing knowledge or practice?

The idea comes from the need of reducing the uncertainty in the endograft choice, by researching the possibility of making accurate measures with medical image analysis and visualization technologies beyond currently existing solutions which are not so specific. It is an open innovation case, in which agents of different nature (vascular surgeons of a public health entity, researchers of a nonprofit private foundation and a start-up company) have been able to find a common language and a cooperation environment where everybody's interests have been satisfied. Innovation exchange mechanisms include meetings, generation of exchange spaces, demonstration of planning of cases, clinical sessions, live interventions, etc. All this is boosted by the establishment of Biodonostia Institute as a focal point of the health and innovation system. Potential improvements and future lines of work are being detected and considered with some new developments already taking place, such as specific workflows for thoracic or thoraco-abdominal aortic aneurysms and thoracic aortic dissections.

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Customer orientation auto evaluation. ¿How the innovation matches with the current and future needs of the customers? ¿How the innovation satisfies and overcomes the requirements and expectations?

This innovation is a small step for the tailored medicine. It is a cost-effective solution, which contributes to reduce the average cost and uncertainty of the surgery planning and endograft choice or design. It is also a solution aiming to reduce intervention time, allowing a systematic workflow that may prevent problems in intervention procedures due to an incorrect endograft sizing.

Efficacy auto evaluation. ¿Which are the results and success indicators of this innovation related to customers, people, society or environment?

Measurements have been demonstrated to be consistent with current medical practice and the user feedback, both from clinicians and endograft manufacturers, is that the solution provides a combination of automation degree, speed and intuitiveness that is not found in other softwares, besides some specific features, such as the fenestrated endograft sizing, that makes it unique. We do not have information about any improvement in intervention times or outcomes due to the short time span. In accordance with the distribution agreement achieved by a small start-up company such as eMedica, with a German multinational of this sector, and the interested raised by other similar companies, it could be considered as a benefit indicator resulting from the use of this tool.

APPENDIXES – VICOMTECH- SOFTWARE FOR COMPUTER ASSISTED 3D ENDOVASCULAR PLANNING FOR AORTI ANEURYSMS BASED ON IMAGE ANALYSIS

ANNEX I

I Macía, M de Blas, JH Legarreta, L Kabongo, Ó Hernández, JM Egaña, JI Emparanza, A García-Familiar, M Graña (2015). "Standard and fenestrated endograft sizing in EVAR planning: Description and validation of a semi-automated 3D software". Computerized Medical Imaging and Graphics (in press). Summary:

An Intuitive and Versatile Tool for 3D Endograft Sizing in EVAR Planning

I. Macía[a,b,g], M. de Blas[d,b], J.H. Legarreta[a,b], L. Kabongo[a,b], O. Hernández[c], J.M. Egaña[e,b], J.I. Emparanza[f,b], A. García[e], Manuel Graña[g]

[a]*VicomtechjK4 Foundation, Donostia / San Sebastián, Spain*
[b]*Biodonostia Health Research Institute, Donostia / San Sebastián, Spain*
[c]*eMedica S.L., Zamudio, Spain*
[d]*Radiology Service, Donostia University Hospital, Donostia / San Sebastián, Spain*
[e]*Vascular Surgery Service, Donostia University Hospital, Donostia / San Sebastián, Spain*
[f]*Clinical Epidemiology, Donostia University Hospital, Donostia / San Sebastián, Spain*
[g]*Computational Intelligence Group, Computer Engineering Faculty, University of the Basque Country Donostia / San Sebastián, Spain*

Abstract

Abdominal aortic aneurysm (AAA) is a pathological dilation of the abdominal aorta that may lead to a possible rupture with fatal consequences. Endovascular Aneurysm Repair (EVAR) is a minimally invasive surgical technique consisting of the deployment and fixation of a stentgraft that isolates the damaged wall from circulation. The technique requires adequate surgical planning for endovascular device sizing, which may be performed by vascular analysis and quantification of Computerized Tomography Angiongraphy (CTA) scans. This paper presents a novel 3D CTA image-based tool for AAA inspection and EVAR planning, *eVida Vascular*. We provide a description of the system, including the underlying vascular image analysis and visualization technology, functional modules and user interaction. Furthermore, an experimental validation for standard endograft sizing in a group of 14 patients of the tool is described.

Keywords: Computed Tomography (CT), abdominal aortic aneurysm (AAA), endovascular repair (EVAR), image segmentation, vascular analysis, surgical planning, software

1. Introduction

An abdominal aortic aneurysm (AAA) is a pathological condition consisting of an abnormal dilation of the abdominal aorta, exceeding more than 50% its normal diameter (Johnston et al., 1991). Aneurysms tend to grow, and eventually may rupture, resulting in a potentially fatal scenario with a high mortality rate. Elective surgery is usually performed when the diameter exceeds 5.5 cm (Lederle et al., 2002). Endovascular aneurysm repair (EVAR) is a minimally invasive technique involving the deployment and fixation of a stent graft that excludes the damaged arterial wall from circulation.

Email address: imacia@vicomtech.org (I. Macía) *URL:* http://www.vicomtech.org (Manuel Graña)

EVAR has lower perioperative morbidity and mortality than the traditional open repair approach, but presents other problems derived from the fact that the aneurysm is not removed but excluded. Incorrect sealing, either due to inadequate endograft sizing, retrograde flow, or device wear or rupture, may cause persistent blood flow into the aneurysm sac, a phenomenon known as *endoleak* (White et al., 1996), which may require reintervention.

EVAR requires pre-procedural planning consisting of aortic anatomy quantification on Computerized Tomography Angiography (CTA) images for endograft selection and sizing. It has been recently demonstrated (Sobocinski et al., 2013) that planning technology may have an impact on the intervention outcome.

In this paper, we present a 3D EVAR endograft sizing tool, named *eVida Vascular*, first mentioned in Macía et al. (2013), which includes advanced visualization and analysis tools for managing standard as well as complex cases, including the provision of fenestrations in the endograft fabric, while providing a tradeoff between the required degree of automation, robustness, usability, intuitiveness and flexibility. We also present the results of an experimental validation study for standard endograft sizing in eVida Vascular performed in a group of 14 patients.

2. EVAR Planning in eVida Vascular

The eVida Vascular application consist of a full-featured, cross-platform medical imaging workstation with an specialized module for vascular image analysis and endograft sizing. eVida Vascular includes a DICOM-standard study browser, a diagnostic module with advanced 2D/3D visualization capabilities, including Multi-Planar Reformatting (MPR) and Curved Planar Reformatting (CPR), and an endograft planning module, consisting of a segmentation module, a vessel analysis module, and reporting capabilities.

One of the key aspects of the eVida Vascular application is the vascular image analysis process incorporated. The set of 3D models, and geometric and topological descriptors featured, enables a straightforward quantification for endograft design purposes.

The diagram in figure 2shows the vascular image analysis steps in eVida Vascular application. The following vascular image analysis steps are considered:

1. *Aortic tree lumen segmentation*: the algorithm is based on a novel, 3D adaptive, seeded region growing approach. Complementary segmentation strategies have been developed to avoid leakages toward adjacent structures, and to overcome problems in undersegmented branches.
2. *Centerline extraction and regularization*: obtains the medial axis of the aorta and its subsidiary branches. It is the basis for most subsequent analysis and quantification processes. A distance-map-based homotopic thinning algorithm is at the core of this task. Continuity-ensuring regularization of the centerline is performed by means of a filtering process.
3. *Vessel graph creation*: a vessel graph is required to analyze the topological structure and properties of the extracted vessel tree. Some subsequent operations, such as spurious branch pruning or branch identification are based on graph operations.
4. *Diameter and length quantification*: these two measurements are performed on the basis of user selected points on the centerline: the diameter is measured over a centerline cross-section at the specified location, and the length is estimated as the distance between two points along the centerline.

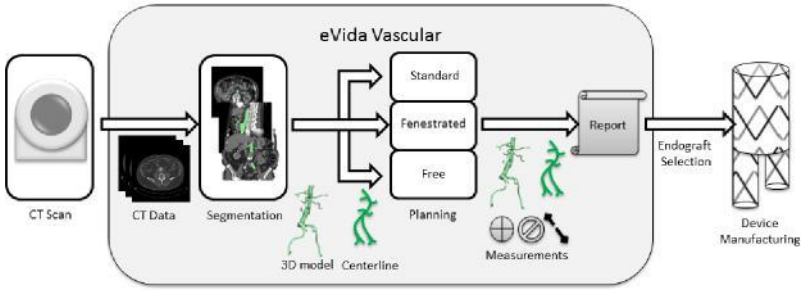

Figure 1: Vascular analysis of the eVida Vascular application.

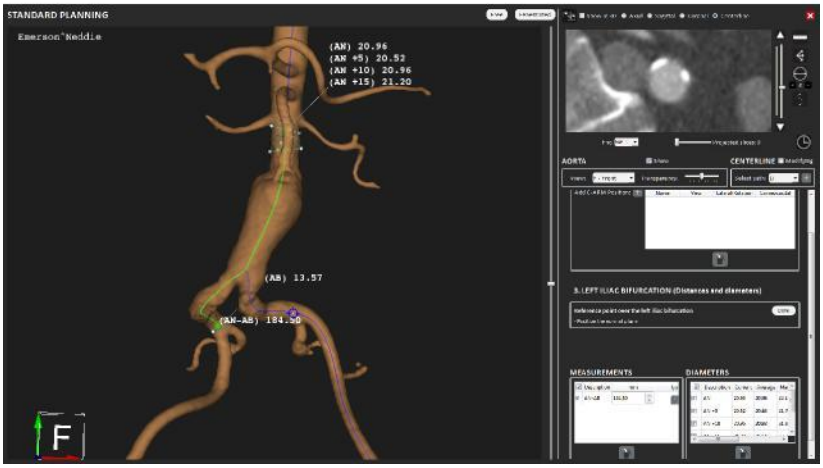

Figure 2: eVida Vascular standard endograft sizing view.

3. Validation

In order to assess the validity and accuracy of the tool, we performed a validation comprising a set of 14 patients requiring standard endograft EVAR. We compared the results of our eVida Vascular workstation (eVV) against a General Electric (GE) diagnostic workstation's vascular *VesselIQ Xpress* module used in clinical routine at the Donostia University Hospital.

3.1. Experiments

A set of 14 patients requiring EVAR with standard endograft sizing were selected retrospectively. Corresponding pre-surgery CTA datasets had been acquired with a GE LightSpeed VCT 64 slice CT scanner. For each patient, two sizing procedures were performed by two individual raters with each planning tool, eVV and GE.

The following measurements were performed on each patient with each application: (1) diameter distal to lowermost renal artery, corresponding to the aortic neck (D-AN); (2) diameter 15 mm below previous landmark (D-AN15); (3-4) diameter distal to primitive right iliac (D-RI) and left iliac (D-LI) artery, below the iliac bifurcation; (5-6) diameter of right iliac (D-RIB) and left iliac (D-LIB) 10 mm. above the bifurcation; (7) length from healthy aortic neck to aortic

Dimension	ICC	CCC	Bias Mean Diff	UL agrmnt	LL agrmnt	Diff > 2 mm
D-AN	0.884 (0.806-0.932)	0.882 (0.816-0.926)	0.4	2.8	-2.1	82%
D-AN15	0.911 (0.776-0.958)	0.909 (0.854-0.945)	0.7	3.0	-1.6	77%
D-RI	0.935 (0.425-0.980)	0.934 (0.896-0.958)	1.2	3.2	-0.8	73%
D-LI	0.833 (0.704-0.904)	0.830 (0.731-0.895)	0.8	4.8	-3.2	71%
D-RIB	0.958 (0.903-0.979)	0.957 (0.929-0.974)	0.7	3.2	-1.8	88%
D-LIB	0.891 (0.655-0.953)	0.478 (0.263-0.648)	1.1	3.9	-1.8	77%
L-AN-AB	0.905 (0.844-0.943)	0.904 (0.842-0.942)	-1.1	10.3	-12.4	-
L-AN-RIB	0.962 (0.936-0.978)	0.708 (0.549-0.817)	-1.2	9.2	-11.6	-
L-AN-LIB	0.931 (0.885-0.959)	0.929 (0.883-0.958)	-1.0	12.5	-14.4	-

Table 1: Correlation and agreement between the GE workstation and eVida Vascular.

bifurcation (L-AN-AB) and (8-9) length from aortic neck to right iliac (L-AN-RIB) and left iliac (L-AN-LIB) bifurcation.

In order to measure the intra-observer variability and agreement with a single tool, we computed, for both eVV and GE tools separatedly, statistics based on two repeated measurements (diameter or length at a given location) on the same tool made by each observer. We computed the Intraobserver Correlation Coefficient (ICC), the Concordance Correlation Coefficient (CCC), the bias using the mean difference, and the upper and lower limits (UL; LL) of agreement with a confidence interval or 95%. In order to compare the agreement between both tools, we computed the same statistics, but comparing the measurements performed by each observer on both tools. In order to compare the limits of agreement with a clinical objective, a 2 mm threshold was established for diameter calculations so that the percentage of compared measurements lying within that range coud be verified.

3.2. Results

Table 1 shows the results for the comparison between the two tools. Most ICCs yield values close to or above 0.9. Similar values are obtianed for the CCCs. The percentage of diameters within the 2 mm error threshold ranged approximately between 75-80%. Taking into account the computed limits of agreement, and the presence of outliers, we can conclude that the agreement between both tools is reasonable enough, and that in the majority of situations and in absence of measurement errors, they would provide the same endograft choice.

4. Discussion

The eVida Vascular application, provides an agile, flexible, robust and full-featured solution for endograft sizing in EVAR. At the core of the application, a set of vascular image analys algorithms provides the necessary automation and robustness for this application. The semiautomatic segmentation algorithm has been designed in order to be fast, intuitive and reliable. Additional mechanisms, such as an automatic bone removal process, an erasing tool for oversegmented regions and an additional radius-constrained segmentation tool for missing vascular targets are provided. These allow, even in the worst case scenario, to perform a planning based on a set of centerlines obtained from an imperfect segmentation that covers the relevant vessels.

In the light of the experiments performed, we can conclude that there is a good agreement between the two tools tested. In a standard, non-fenestrated case, they would result in the same endograft choice, since most of the measurement differences both for diameter and lengths would lie in the range where identical endograft model size would be selected. We did not perform comparisons for fenestrated endografts, since they are special or custom designs, and there is no clinical evidence on what should be the limits of corresponding measurements.

5. Conclusions and Future Work

We have developed a novel 3D EVAR planning tool, eVida Vascular, based on advanced vascular analysis and visualization of the aortic tree. An easy-to-follow, step-by-step workflow is provided to complete endovascular plannig tasks. Thanks to the 2D and 3D vascular visualization and interaction tools, all necessary visual and quantitative feedback is provided to clinicians about the planning, reducing the degree of uncertainty of the design.

The system provides fast, intuitive and accurate measurements for standard endograft device design parameters. It also provides the ability to manage complex cases such as those requiring the provision of fenestrated endografts, a feature not present in the majority of EVAR planning softwares. Planning of such fenestrated endografts is performed in a novel manner, with the help of a set of virtual endograft and stents.

A validation establishing the degree of agreement of the eVida Vascular with a cleared commercial solution for standard endograft planning has been performed. Results indicate that eVida Vascular is valid for EVAR clinical practice: an adequate degree of agreement has been observed between the measurements obtained by both tools, and leading to the same endograft designs, taking into account the measurement tolerance in design parameters (diameters and lengths) used to select one model or another.

Future work includes fenestrated endograft planning validation, the extension of the system for planning thoracic (TAA), thoraco-abdominal aortic aneurysms (TAAA) and aortic dissections (TAD), and a long-term clinical study in order to assess the improvements in the outcomes of interventions using this type of advanced planning.

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