(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
24 April 2025 (24.04.2025)

(10) International Publication Number
WO 2025/083523 A1

(51) International Patent Classification:
A61B 34/10 (2016.01) *A61F 2/07* (2013.01) *G06T 17/20* (2006.01)

(21) International Application Number: PCT/IB2024/059966

(22) International Filing Date: 11 October 2024 (11.10.2024)

(25) Filing Language: Italian

(26) Publication Language: English

(30) Priority Data:
102023000021822 19 October 2023 (19.10.2023) IT

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CV, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IQ, IR, IS, IT, JM, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY,

(54) Title: METHOD TO ESTIMATE IN REAL TIME THE FINAL POSITIONING OF A DEVICE IN A MINIMALLY INVASIVE INTERVENTION FOR VASCULAR AND/OR VALVULAR PATHOLOGIES

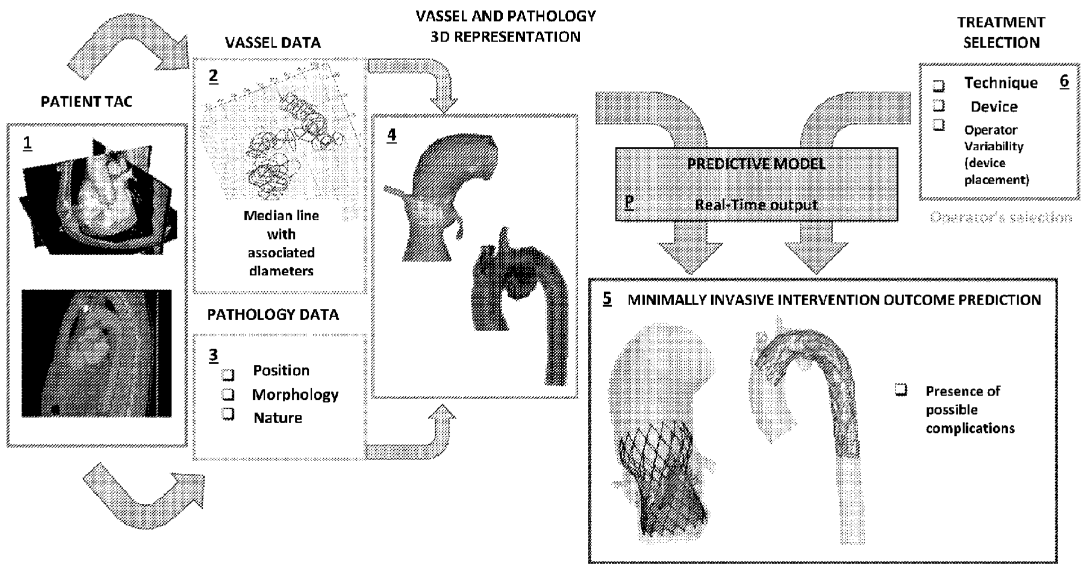

Fig. 6

(57) Abstract: Method to estimate in real time the final positioning of a stent-graft and/or a percutaneous valve in a minimally invasive intervention for vascular and/or valvular pathologies, comprising the following steps: creating a database of data generated by models of minimally invasive procedures and training a predictive algorithm (P) with these data; acquiring clinical images (1) relating to vessels of a patient affected by vascular and/or valvular pathology and extracting from these clinical images geometric parameters (2) of the vessels affected by the pathology and morphological parameters (3) of the pathology; generating a three-dimensional model (4) of the affected vessels and the pathology by processing the geometric parameters (2) and the morphological parameters (3); selecting indicator parameters relating to minimally invasive intervention by processing the three-dimensional model (4) of the affected vessels and the pathology; calculating an estimate of the final positioning (5) of a stent-graft and/or a percutaneous valve following the intervention by processing the indicator parameters using the predictive algorithm (P), wherein the predictive algorithm (P) is expected to be trained

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MA, MD, MG, MK, MN, MU, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, CV, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SC, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, ME, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:
— *of inventorship (Rule 4.17(iv))*

Published:
— *with international search report (Art. 21(3))*
— *in black and white; the international application as filed contained color or greyscale and is available for download from PATENTSCOPE*

by processing the data through machine learning techniques on a predefined number of numerical simulations of the finite elements of minimally invasive procedures of stent-graft implantation for vascular pathologies and/or percutaneous valve implantation for valvular pathologies.

Method to estimate in real time the final positioning of a device in a minimally invasive intervention for vascular and/or valvular pathologies

DESCRIPTION

SCOPE OF APPLICATION

The present invention relates to a method to estimate in real time the final positioning of a biomedical device in a minimally invasive intervention for vascular and/or valvular pathologies.

In more detail, the present invention relates to a method which allows to calculate the probability of success of a stent-graft and/or percutaneous valve implantation intervention, or in other words the probability that complications occur downstream of the stent-graft and/or percutaneous valve implantation, for example by means of a certain procedure performed with a respective biomedical device.

Description of the prior art

It is known in the art to perform a vascular and valvular interventional procedure, that is, a minimally invasive intervention which involves the insertion of a device formed by metal mesh, stent, stent-graft or stented valve, in an arterial or venous vessel or in the cardiac valve site, and finds application for example for large arterial vessels such as the aorta, the arteries of the lower limbs or heart valve.

The insertion of a stent-graft is a minimally invasive procedure for the treatment of pathologies affecting large vessels, such as the aorta, pathologies that occur when a part of the blood vessel has a deterioration of the wall of the vessel itself. The insertion of a percutaneous valve is a minimally invasive cure for the treatment of heart valve occlusions or dilatations. The procedures can employ a biomedical device such as a stent-graft (Figure 1a), i.e., a metal mesh generally in nickel-titanium alloy, sutured onto a polymeric material conduit, or a stent-valve, i.e., a metal mesh sutured onto polymeric and/or biological materials (Figure 1b). The procedures involve accessing the patient's vascular network usually from the femoral artery with a catheter, which is positioned up to the site to be treated. In the event of treating valvular pathologies of the heart valve, the percutaneous valve is forced inside the catheter and positioned at the heart valve site (Figure 2a). The catheter is then removed (Figure 2b), freeing the percutaneous valve, which tends to recover its expanded shape or which is plastically deformed, replacing the functionality of the pathological valve (Figure 2c).

In the event of treating large vessel pathologies, the stent-graft is constrained inside the catheter (Figure 3a) and positioned at the pathology (Figure 3b). The catheter is then removed (Figure 3c), releasing the stent, which tends to recover its expanded shape, restoring a physiological diameter excluding the pathology (Figure 3d).

A method to estimate in real time the probability of success of a thrombectomy surgery is described in the document HOLSWILDER GHISLAINE ET AL.: “The prognostic value of extracranial vascular characteristics on procedural duration and revascularization success in endovascularly treated acute ischemic stroke patients”, EUROPEAN STROKE JOURNAL, vol. 7, no. 1, 8 February 2022. The predictive model proposed in the aforesaid document is based on the analysis of some geometric parameters of the cerebral vessels and trained on retrospective clinical data of patients with acute ischaemic stroke undergoing a thrombectomy procedure.

Problem of the prior art

In the prior art, finite element analyses are used in the development of biomedical devices and related procedures to be used in minimally invasive interventions for vascular and valvular pathologies. In fact, finite element computational modelling is used to simulate the behaviour of devices and procedures to evaluate intervention situations. However, these are very expensive computational systems which require high computational costs, and therefore can be used in the research, development and optimisation phase of devices and related procedures, but not to evaluate intervention strategies immediately before the intervention is carried out. In practice, the interventionist must have time to process the patient’s data and explore different planning strategies to identify the optimal device and procedure for the specific patient.

SUMMARY OF THE INVENTION

The object of the invention in question is to be able to have a method which allows to provide in little time an accurate and reliable assessment of the probability of success of a minimally invasive intervention for vascular and/or valvular pathologies in order to decide the best intervention strategy for the patient to be operated on.

The technical task mentioned and the objects stated are substantially achieved by a method comprising the technical features set out in one or more of the appended claims.

Advantages of the invention

Thanks to an embodiment, it is possible to obtain a method which allows to provide a real-time estimate of the final positioning of the implanted device and the presence of any complications of a minimally invasive intervention for vascular and valvular pathologies, offering a surgeon the possibility of selecting the procedure and the biomedical devices which offer the greatest chances of success, before the intervention.

BRIEF DESCRIPTION OF THE DRAWINGS

The features and advantages of the present invention will become apparent from the following detailed description of possible practical embodiments thereof, illustrated by way of non-limiting example in the accompanying drawings, in which:

- Figure 1 shows some examples of a) stent-graft and b) percutaneous valve, i.e., known biomedical devices,

- Figure 2 shows an example of a computational model of the known procedure for percutaneous valve implantation for valvular pathologies: a) positioning at the site of interest of the constrained percutaneous valve, b) gradual release of the stented valve, c) complete reopening of the valve.

- Figure 3 shows an example of a computational model of the known procedure for stent-graft implantation for vascular pathologies: a) constraint of the stent-graft, b) positioning at the site of interest, c) gradual release of the stent-graft, d) complete reopening of the stent-graft.

- Figure 4 shows an example of application of a step of the method of the invention for the treatment of valvular pathologies,

- Figure 5 shows an example of execution of a step of the method of the invention for the treatment of vascular pathologies,

- Figure 6 shows a flow chart of an application example of the method of the present invention,

- Figure 7 shows an example of finite element numerical simulation to replicate the implantation of a biomedical device in the case of patient-specific anatomies,

- Figure 8 shows an example of execution of a step of the method of the invention for the treatment of vascular and/or valvular pathologies,

- Figure 9 shows an example of application of a step of the method of the invention for the treatment of vascular and/or valvular pathologies,

- Figure 10 shows an example of correct positioning of a biomedical device inside the vessel,

- Figure 11 shows an example of incorrect positioning of a biomedical device inside the vessel.

DETAILED DESCRIPTION

The present invention relates to a method to estimate in real time the final positioning of a stent-graft and/or a percutaneous valve in a minimally invasive intervention for vascular and/or valvular pathologies, which therefore also allows to provide an estimate of any complications following a minimally invasive procedure of stent-graft and/or percutaneous valve implantation. Figure 2 shows an example of application of the method of the invention in a percutaneous valve implantation intervention for the treatment of valvular pathologies. Furthermore, Figure 3 shows an example of application of the method of the invention in a stent-graft implantation intervention for the treatment of aortic pathologies.

The method comprises the step of creating a database of data generated by models of minimally invasive procedures for stent-graft implantation for vascular pathologies and/or percutaneous valve implantation for valvular pathologies and training a predictive algorithm P with such data by means of a processing unit associated with the database. In other words, the method includes training the predictive algorithm P according to machine learning techniques on the basis of precalculated data from the models of minimally invasive procedures of stent-graft and percutaneous valve implantation, preferably comprising one or more of clinical images, data regarding the geometry of the vessels concerned, the geometry of the pathology and its nature, the biomedical devices and the procedures used in the minimally invasive intervention and the outcome of such an intervention.

The step of creating a database of data generated by means of models of minimally invasive procedures for stent-graft implantation for vascular pathologies and/or percutaneous valve implantation for valvular pathologies and training a predictive algorithm P with such data by means of a processing unit associated with the database provides for training the predictive algorithm P by processing the data by means of machine learning techniques on a predefined number of numerical simulations of the finite elements of minimally invasive procedures of stent-graft implantation for vascular pathologies and/or of percutaneous valve implantation for valvular pathologies.

It should be noted that, in a preferred form, the database of data which is generated comprises a matrix which, for each simulation within the predefined number of simulations, has significant parameters of the procedure, data relating to the geometry and morphology of the vessels concerned, the geometry and nature of the pathology, the biomedical device concerned, the procedure used for the minimally invasive intervention and the outcome of such an intervention. In particular, the predefined number of simulations preferably depends on the machine learning (ML) technique adopted and on the number and nature of the results to be predicted.

For example, the morphological parameters 3 of the patient's vessel and of the pathology can be analysed, as will be explained in detail below in the present description, by means of median line analysis or by level set or statistical shape modelling techniques. Regarding the type of intervention, whether it is related to the treatment of valvular or vascular pathologies, this datum is preferably indicated by the user. The biomedical device concerned is preferably selected in accordance with both the type of intervention identified and the geometric assessment of the (valvular or vascular) anatomy concerned. Finally, the data relating to the outcome of the clinical procedure comprised in the database depends on the type of outcome to be predicted.

The method comprises the step of acquiring, in real time, clinical images related to vessels of a patient affected by vascular and/or valvular pathology. The method involves extracting from such clinical images both geometric parameters 2 of the vessels affected by the pathology and morphological parameters 3 of the pathology (Figure 4 and 5). Figure 4 shows an execution example of this step to extract from the clinical images of a patient geometric parameters of the affected vessels and morphological parameters of the valvular pathology. Figure 5 instead shows an execution example of this step to extract from the clinical images of a patient geometric parameters of the affected vessels and morphological parameters of the vascular pathology.

The method then comprises the step of generating a three-dimensional model 4 of the affected vessels and of the vascular and/or valvular pathology, by processing the geometric parameters 2 and the morphological parameters 3 by means of the processing unit.

The method also comprises the step of selecting indicator parameters relating to minimally invasive intervention for vascular pathologies with stent-graft and/or valvular implantation with percutaneous valve implantation by processing the three-dimensional model 4 of the affected vessels and the pathology.

The method comprises the step of calculating an estimate of the final positioning 5 of a stent-graft following the minimally invasive intervention for vascular pathologies with implantation of a stent-graft and/or of a percutaneous valve following the minimally invasive intervention for valvular pathologies with percutaneous valve implantation by processing the indicator parameters using the predictive algorithm P. It should be noted that the estimate of the final positioning 5 of the implanted biomedical device, i.e., stent-graft and/or percutaneous valve, has a certain margin of error. In other words, this step also allows to estimate the probability that the device will be positioned in a certain end position, indicating the estimated end position which could occur with greater probability.

It should be noted that, with regard to the predictive algorithm P, different machine learning architectures and techniques can be used. Preferably, an architecture of regression, classification and/or clustering problems can be used depending on whether one wants to predict a numerical result or whether one wants to group the cases according to predefined criteria. For example, a criterion can be defined relating to the risk of developing complications downstream of the procedure.

With reference to the example of Figure 6, it should be noted that the method makes it possible to extract from clinical computed tomography (CT) images of cardiac vessels or valves affected by pathologies geometric parameters of the affected vessels and the pathology which, provided in input to a predictive model P, allow to provide an estimate of the final positioning of a stent-graft and/or percutaneous valve following a minimally invasive intervention. The method finds application for pathologies involving large vessels and heart valves. For example, the method also finds application in estimating the probability of success of an intervention in cases of aneurysms and dissections of the aorta and of stenosis and insufficiency of a heart valve.

In accordance with a first preferred solution of the invention, the step of extracting indicator parameters involves calculating morphological parameters of the vessels by analysing the median line of the affected vessels and of the relative diameters. This step also involves calculating morphological parameters of the pathology by geometry analysis, for example of length, diameter and nature of the pathology itself. Still preferably, the characteristic parameters of the vessel concerned comprise one or more parameters chosen from the radius of curvature of the vessel, the winding of the vessel, the size of the valve plane, the angles with the bifurcations.

Figure 8 shows an example of extracting geometric parameters from the median line of the vessels. In such a case, the morphological parameters of the vessels preferably comprise one or more parameters among radius of curvature of the aortic arch, length of the arch, winding angles, diameters in relevant sections, for example in the landing zone of the device and at the level of the pathology. Other parameters can comprise, for example, the angle of the supra-aortic branches with respect to the median line, height of the coronary origin with respect to a reference point, and/or other relevant lengths for the endovascular procedure.

In accordance with a second embodiment alternative to the previous one, the step of extracting indicator parameters involves calculating characteristic parameters of the geometry of the vessels by analysing the entire geometry of the vessels affected by the vascular and/or valvular pathology using the level set technique. This step also involves calculating morphological parameters of the pathology by geometry analysis, for example of length and diameter, and nature of the pathology. This second embodiment does not aim to extract geometric parameters as required by the first embodiment. Instead, it involves analysing the entire geometry of the vessel. Preferably, the step of calculating characteristic parameters of the geometry of the vessels involves defining a fixed volume scaled so as to be able to contain all the possible vascular geometries of the patients. This step also involves discretising the volume with a grid according to a sensitivity analysis and placing each reconstructed vascular geometry into the grid in the three-dimensional model of the vessels concerned and of the pathology and calculating a matrix of the same size as the number of grid points by measuring the distances between each grid point and the nearest point of the vascular geometry. Such a step also involves calculating the characteristic parameters of the geometry of the vessels by processing the matrix using the technique of principal component analysis.

The level set technique consists of defining a fixed volume of appropriate dimensions so as to be able to contain all the patients' vascular geometries, once they are aligned with each other. The volume is then discretised, according to a sensitivity analysis, generating the grid. Each vascular geometry reconstructed as explained above, is inserted into this grid and the distances between each point of the grid and the nearest point of the vascular geometry are measured. A large matrix is thus obtained, equal to the number of grid points, which contains all the information on the examined vascular geometry. This matrix is subjected to a principal component analysis (also called PCA), a method to efficiently reduce the size of a system, maintaining a high percentage of the information contained. Thereby the geometry of the vessel is reduced to a low number of parameters. Unlike the first embodiment, the parameters thus obtained do not have a clear and unique physical value, but can represent a set of characteristics.

Figure 9 shows two examples of application of level set technique, one for thoracic aorta and one for aortic root, for measuring the distances between the points of the grid, which is fixed for all vascular geometries, and the reconstructed outer surface of the vessel.

An advantage of this solution is that the parametrisation is not done according to parameters established a priori, but by choosing the best reduced representation of the geometry through the PCA. As is also the case for the first embodiment solution, the parameters thus extracted, together with the characteristics of the pathology, are provided in input to the predictive algorithm P, for the calculation of the probability of success of the minimally invasive vascular and/or valvular implantation procedure, and even better of the estimate of the final positioning 5 of the stent-graft and/or percutaneous valve.

According to the preferred solution of the invention shown in Figure 6, the clinical images 1 comprise images obtained by computed tomography and/or magnetic resonance imaging.

Always preferably, the geometric parameters of the vessels 2 comprise median line and diameter for each vessel concerned. Still preferably, the morphological parameters 3 comprise nature, position and geometric characteristics. In accordance with the preferred solution just disclosed, the step of extracting geometric parameters of the vessels 2 and morphological parameters 3 from the clinical images, provides for processing the clinical images by means of a greyscale analysis algorithm to extract the parameters of interest relating to the morphology of the pathology.

In the example illustrated in Figures 4 and 5, the method involves automatically deriving from clinical images, such as computed tomography or magnetic resonance imaging, the patient-specific geometry of the vessel and district affected by the vascular and/or valvular pathology. For the vessel, the median line and diameters are identified, from which an automatic procedure allows the patient-specific three-dimensional reconstruction of the vessel to be obtained. The images also determine the position, morphology and nature of the pathology based on the grey scale. By positioning the pathology reconstruction in the vessel, the 3D representation of the vessel and patient-specific pathology is obtained.

Preferably, the step of calculating an estimate of the final positioning 5 of a stent-graft following the minimally invasive intervention for vascular pathologies with implantation of the stent-graft and/or of a percutaneous valve following the minimally invasive intervention for valvular pathologies with implantation of the percutaneous valve by processing the indicator parameters by means of the predictive algorithm P, comprises the sub-step of: calculating the probability that complications occur downstream of the implantation by processing the indicator parameters by means of the predictive algorithm P. Preferably, a model of possible complications is also included in the model of the finite elements of the minimally invasive intervention. By collecting the results of a certain number of simulations of minimally invasive procedures with a model of possible complications, it is possible to train a predictive model that, based on indicators such as vascular geometric characteristics, the morphology of the pathology and the stent-graft and/or percutaneous valve implantation technique used, provides the probability that possible complications will occur.

It should be noted that, for example, the accuracy in predicting the probability of developing complications involves using a population which represents a validation set in which specific patient anatomies are considered in terms of pre- and post-operative clinical images and results of numerical simulations of the finite elements, in which complications have, or have not, developed. It should be noted that the prediction confidence interval of the predictive algorithm P is proportional to the number of patient-specific real data. That is, the greater the number of patient-specific real data, the greater the confidence interval of the predictive algorithm P.

Figure 11 shows an exemplary case of incorrect positioning of the biomedical device inside the vessel, i.e., stent-graft on the left and aortic valve on the right. In this case, the stent-graft has a kinking complication, while the valve is not properly attached to the wall of the vessel.

With reference to Figure 6, it should be noted that the method of the invention allows to calculate the probability that a stent-graft and/or percutaneous valve implantation intervention, performed with one or more biomedical devices using a certain minimally invasive procedure, can be successfully performed with a correct positioning of the stent-graft and/or percutaneous valve with respect to the pathology, as shown in Figure 10, for example in terms of correct opening of the device inside the vessel. On the other hand, the method also allows to estimate the probability that the minimally invasive intervention may fail, optionally specifying what the reason for such failure could be.

In accordance with a preferred solution of the invention, the step of training the predictive algorithm P by processing the data through machine learning techniques on a predefined number of numerical simulations of the finite elements of minimally invasive procedures of stent-graft implantation for vascular pathologies and/or percutaneous valve implantation for valvular pathologies envisages that the minimally invasive procedure employs at least one implantation procedure of a respective stent-graft and/or a respective percutaneous valve.

Furthermore, before the step of calculating the estimate of the final positioning 5, it provides for the further step of selecting 6 at least one minimally invasive procedure and at least a respective stent-graft and/or a respective percutaneous valve to be employed in the minimally invasive intervention. This is possible because the predictive algorithm P is trained with databases obtained with finite element computational simulations of different types of minimally invasive procedures, i.e., using different biomedical devices, such as different stent-graft designs and/or percutaneous valves, and different intervention techniques. For example, the user/surgeon can select a biomedical device, such as a stent-graft and/or percutaneous valve and a respective procedure for the minimally invasive intervention of the vascular and/or valvular pathology from those available in a special list (or library) stored in the database. The library comprises a plurality of biomedical devices and respective intervention procedures for which the predictive algorithm P is suitably trained. The method will result in an estimate of the final stent-graft and/or percutaneous valve positioning following the minimally invasive procedure to be performed on the patient under examination in real time, should the selected device (or devices if more than one) and the respective minimally invasive procedure be used. The selection of device/devices and procedure can be performed before the calculation of the estimate of the final positioning 5 of the device, so that the calculation is focused on the combination selected by the operator with reduction of the computational cost and calculation time. Alternatively, the method can calculate the estimate of the final stent-graft and/or percutaneous valve positioning 5 for all the combinations of devices and procedures in the library for which the predictive algorithm P has been appropriately trained, so as to automatically identify the device-procedure combination which offers the best probability of success for the patient under examination.

In accordance with the method of the present invention, according to an application example, once the morphological parameters characterising the vascular pathology have been identified, by means of the median line analysis or the level set technique, a numerical model is recreated by means of finite element discretisation configured to reproduce the morphological characteristics identified above. Then, the vessel considered is preferably assigned boundary conditions which reflect the selected clinical procedure, and thereafter, the biomedical device which is to be implanted inside the vessel is identified. The aforesaid parameters represent the simulation input. Such a simulation is then solved by means of numerical techniques of the finite elements disclosed above, according to which, in relation to the result to be predicted with the predictive algorithm P, results are extracted in terms of displacement maps or stress/strain maps. The extraction of parameters which allow to predict the procedural outcome and the estimate of the final positioning of the biomedical device is based on these results.

Based on the above, Figure 7 shows several examples of finite element numerical simulations to replicate the implantation of stent-graft (left) and percutaneous aortic valves (right) in the case of patient-specific anatomies.

In more detail, the first line of Figure 7 shows the pathological patient-specific anatomies reconstructed from clinical images. Geometric analyses are performed on such anatomies by means of median line evaluation or by means of the level set technique previously described.

The second row instead shows the results of the numerical simulation in terms of the final configuration of the device inside the vessel. From this result of the numerical simulation, the results are subsequently extracted in terms of displacement maps or stress/strain maps. The extraction of parameters is based on the latter, thus making it possible to predict the procedural outcome and estimate the final positioning of the device.

The third and last line, which is carried out as long as post-operative data is present, shows a simulation validation process. In fact, it consists of comparing the result of the finite element numerical simulation with the reconstruction of the device from post-operative clinical images. These results are preferably part of a validation set adapted to evaluate the accuracy of the prediction of the predictive algorithm P.

It should be noted that the parameters resulting from the patient-specific vessel and pathology analysis are used to interrogate the predictive model of the outcome of a selected stent-graft or percutaneous valve implantation intervention. In the example disclosed and illustrated, the predictive model is a surrogate model, i.e., a model built with machine learning techniques on a large number of finite element numerical simulations of the stent-graft or percutaneous valve implantation procedure in patients suffering from vascular or valvular pathologies, so as to learn to recognise the relationship between a set of input parameters, in this case geometric parameters of the vessel and characteristics of the pathology, and the output of interest. The model provides the probability of success of the intervention procedure in real time, in terms of final positioning and probability of complications occurring downstream of the implantation. As mentioned before, the predictive model includes a library of possible minimally invasive techniques for vascular and valvular pathologies and models and sizes of devices. It also includes the possibility of considering a non-optimal use of the devices, such as a non-optimal positioning of the stent-graft or percutaneous valve by the operator. The model can have two different uses. In the first mode, the operator must indicate the type of procedure he/she intends to use on the patient and the model will provide the probability of success. In the second mode, the operator can ask the model to compare the probabilities of success of all the procedures and related devices contained in the library or a subgroup thereof, so as to identify the one with the best probability of success in the patient under examination.

Advantageously, the method of the invention is particularly useful in the optimisation phase of a device and/or procedure but above all as a support for the interventionist to choose the optimal device and/or procedure for the specific patient before the intervention.

Advantageously, the method involves acquiring images and data of the patient from diagnostic tools such as CT and magnetic resonance to build a 3D model of the vessels and pathologies, with specific data on their morphological conformation. The artificial intelligence system based on the predictive algorithm, trained on real cases, knows certain intervention devices and procedures. As explained above, the surgeon can choose the devices and procedures to be used in the intervention to know the probability of success thereof, or the system determines the device-procedure combination which has the best probability of success among those available, i.e., for which the artificial intelligence system has been trained.

Advantageously, on the basis of a limited number of anatomical measurements, the method is able to faithfully reconstruct the geometry of the patient-specific anatomical district and the position, size and conformation of the pathology.

Advantageously, the predictive model employed in the method of the invention is trained, verified and validated with real clinical data using finite element numerical simulations. Furthermore, the estimate of the probability of success is based on the interrogation of a reduced or surrogate predictive model which provides the result in real time. The method therefore makes it possible to evaluate the performance of a biomedical device, such as a stent-graft or percutaneous valve, but also which is the best device to use for the patient considered and the best implantation technique.

CLAIMS

1. Method to estimate in real time the final placement of a stent-graft and/or a percutaneous valve in a minimally invasive intervention for vascular and/or valvular pathologies, comprising the following steps:

- creating a database of data generated by models of minimally invasive procedures for stent-graft implantation for vascular pathologies and/or percutaneous valve implantation for valvular pathologies and training a predictive algorithm (P) with these data by means of a processing unit associated with the database;

- acquiring clinical images (1) relating to vessels of a patient affected by vascular and/or valvular pathology and extracting from these clinical images geometric parameters (2) of the vessels affected by the pathology and morphological parameters (3) of the pathology;

- generating a three-dimensional model (4) of the affected vessels and of the vascular and/or valvular pathology, by processing the geometric parameters (2) and the morphological parameters (3) by means of the processing unit;

- selecting indicator parameters relating to minimally invasive intervention for vascular pathologies with stent-graft and/or valvular implantation with percutaneous valve implantation by processing the three-dimensional model (4) of the affected vessels and the pathology;

- calculating an estimate of the final positioning (5) of a stent-graft following the minimally invasive intervention for vascular pathologies with implantation of the stent-graft and/or of a percutaneous valve following the minimally invasive intervention for valvular pathologies with percutaneous valve implantation by processing the indicator parameters using the predictive algorithm (P),

characterised in that the step of creating a database of data generated by means of models of minimally invasive procedures of stent-graft implantation for vascular pathologies and/or of percutaneous valve implantation for valvular pathologies and training a predictive algorithm (P) with such data by means of a processing unit associated with the database provides for training the predictive algorithm (P) by processing the data by means of machine learning techniques on a predefined number of numerical simulations of the finite elements of minimally invasive procedures of stent-graft implantation for vascular pathologies and/or of percutaneous valve implantation for valvular pathologies.

2. Method according to claim 1, wherein the step of selecting indicator parameters comprises the sub-steps of:

- calculating morphological parameters of the vessels by analysing the median line of the vessels and their diameters;
- calculating morphological parameters of the pathology by geometry analysis.

3. Method according to claim 1, wherein the step of selecting indicator parameters comprises the sub-steps of:

- calculating characteristic parameters of the geometry of the vessels by analysing the entire geometry of the vessels affected by the vascular and/or valvular pathology using the level set technique;
- calculating morphological parameters of the pathology using geometry analysis.

4. Method according to claim 3, wherein the step of calculating characteristic parameters of the vessel geometry comprises the sub-steps of:

- defining a fixed volume scaled to accommodate all possible patient vascular geometries;
- discretising the volume in a grid according to a sensitivity analysis;
- placing each reconstructed vascular geometry into the grid in the three-dimensional

model (4) of the affected vessels and of the vascular and/or valvular pathology and calculating a matrix of the same size as the number of grid points by measuring the distances between each grid point and the nearest point of the vascular geometry;

- calculating the characteristic parameters of the geometry of the vessels by processing the matrix using the technique of principal component analysis.

5. Method according to any of the preceding claims, wherein the clinical images (1) comprise images obtained by Computed Tomography (CT) and/or Magnetic Resonance Imaging (MRI).

6. Method according to any of the preceding claims, wherein

- the geometric parameters of the vessels include median line and diameter for each vessel affected by the vascular and/or valvular pathology;

- the morphological parameters (3) of the pathology include nature, position and geometric characteristics.

7. Method according to claim 6, wherein the step of extracting from the clinical images (1) geometric parameters (2) of the vessels and morphological parameters (3) of the pathology provides for processing the clinical images using a greyscale analysis algorithm to extract the morphological parameters of the pathology.

8. Method according to any of the preceding claims, wherein the step of calculating an estimate of the final positioning (5) of a stent-graft following the minimally invasive intervention for vascular pathologies with implantation of the stent-graft and/or of a percutaneous valve following the minimally invasive intervention for valvular pathologies with implantation of the percutaneous valve by processing the indicator parameters by means of the predictive algorithm (P) comprises the sub-step of:

- calculating the probability that complications will occur downstream of the implantation of the stent-graft and/or of a percutaneous valve by processing the indicator parameters using the predictive algorithm (P).

9. Method according to any of the preceding claims, wherein:

- the step of training the predictive algorithm (P) by processing the data through machine learning techniques on a predefined number of numerical simulations of the finite elements of minimally invasive procedures of stent-graft implantation for vascular pathologies and/or percutaneous valve implantation for valvular pathologies provides that the minimally invasive procedure employs at least one procedure of implantation of a respective stent-graft and/or a respective percutaneous valve;

- before the step of calculating the estimate of the final positioning (5), provides for the further step of:

    - selecting (6) at least one minimally invasive procedure and at least one respective stent-graft and/or a respective percutaneous valve to be used in the minimally invasive intervention.

PRIOR ART

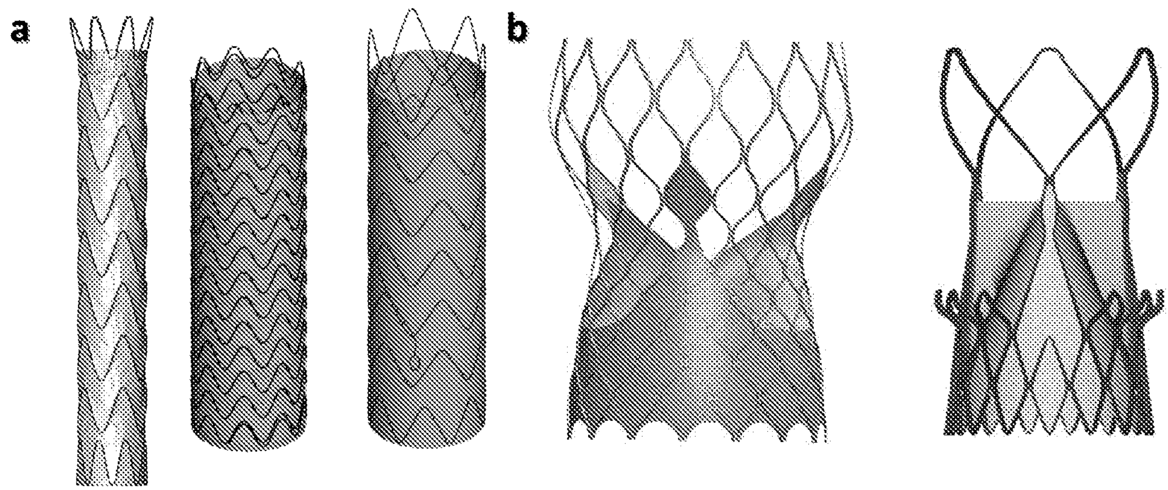

Fig. 1

PRIOR ART

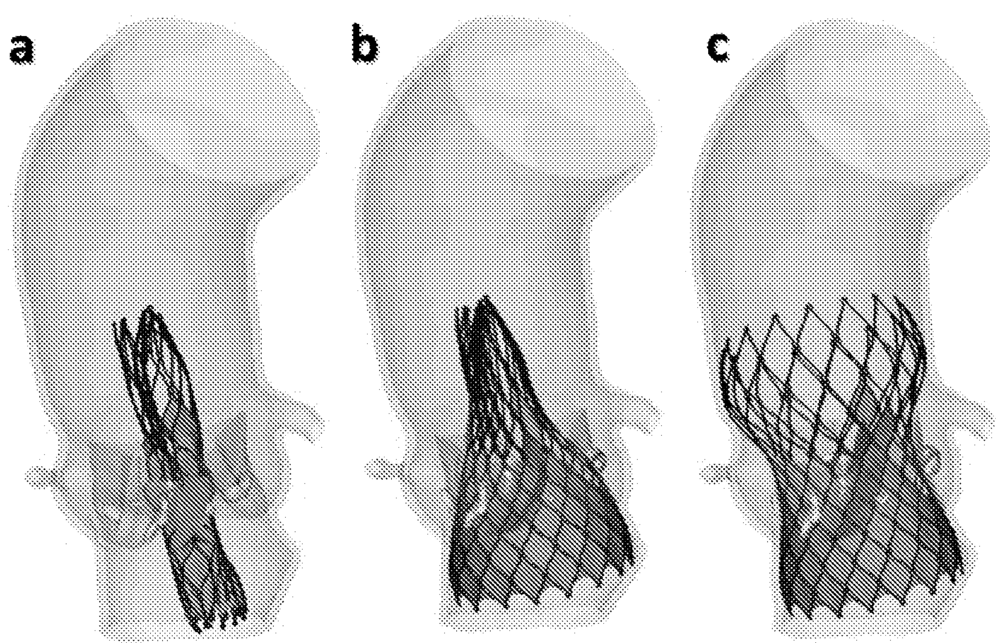

Fig. 2

PRIOR ART

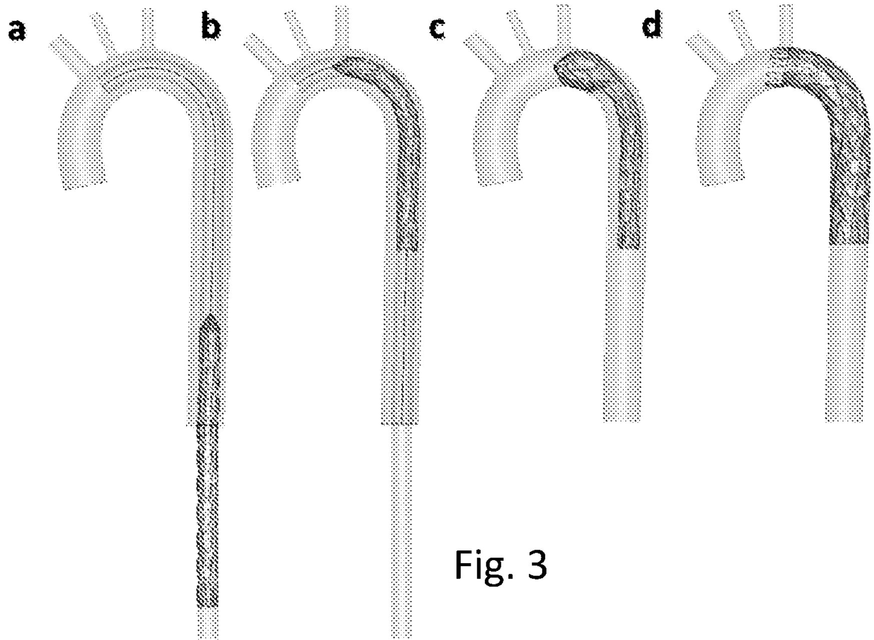

Fig. 3

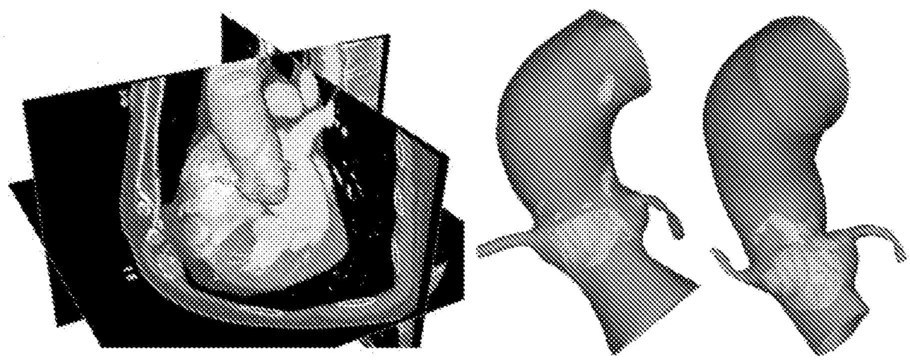

Fig. 4

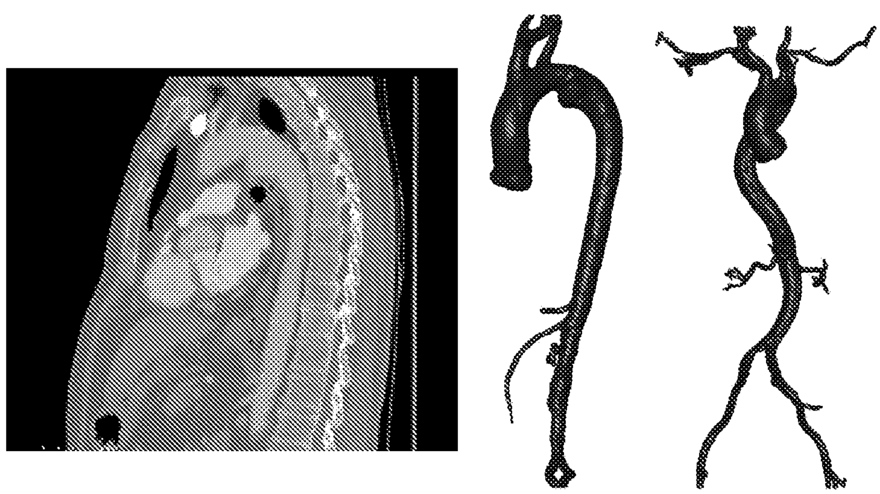

Fig. 5

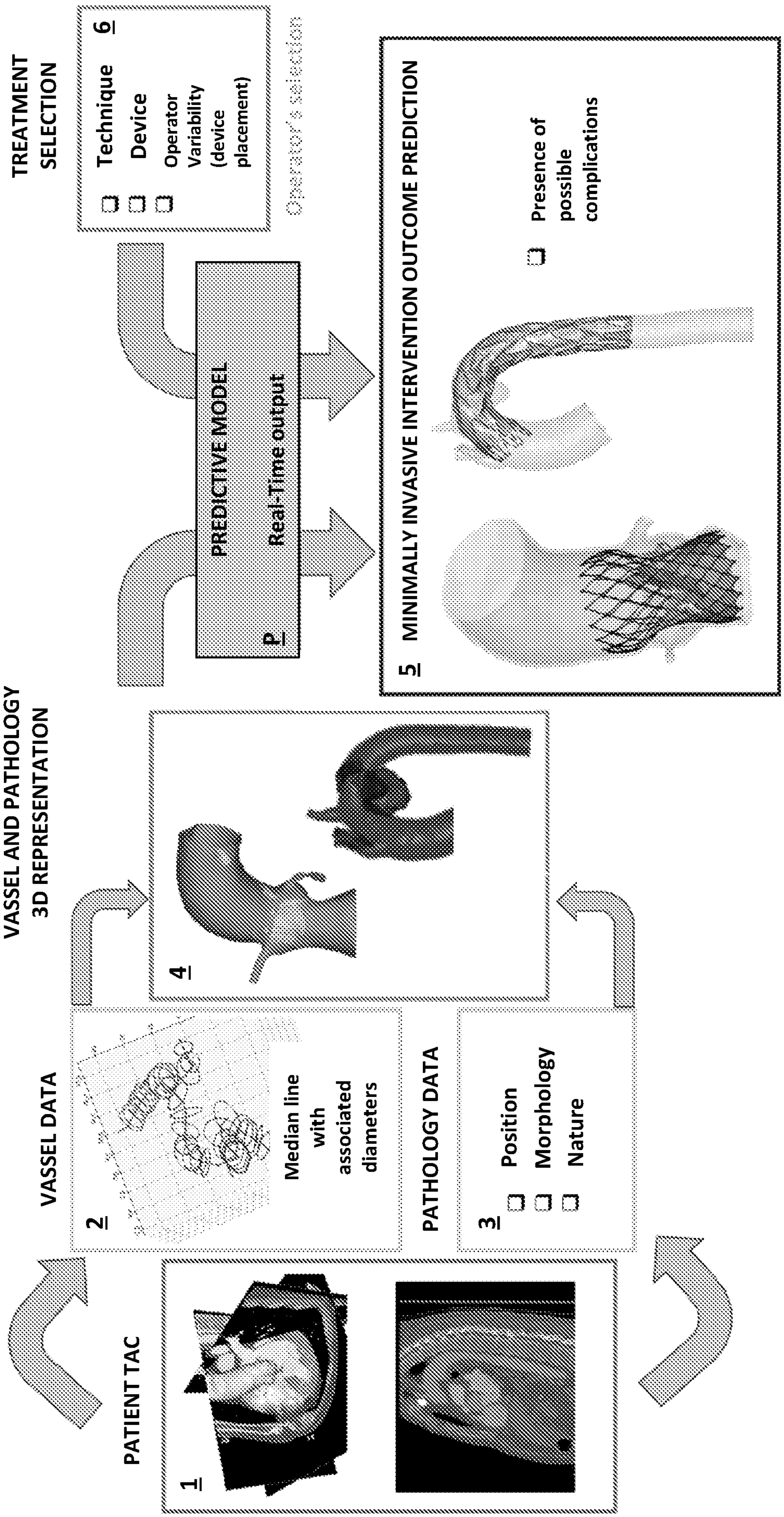
PATIENT TAC
1
VASSEL DATA
2
Median line with associated diameters
PATHOLOGY DATA
3
Position
Morphology
Nature
VASSEL AND PATHOLOGY 3D REPRESENTATION
4
TREATMENT SELECTION
6
Technique
Device
Operator Variability (device placement)
Operator's selection
P
PREDICTIVE MODEL
Real-Time output
5
MINIMALLY INVASIVE INTERVENTION OUTCOME PREDICTION
Presence of possible complications

Fig. 6

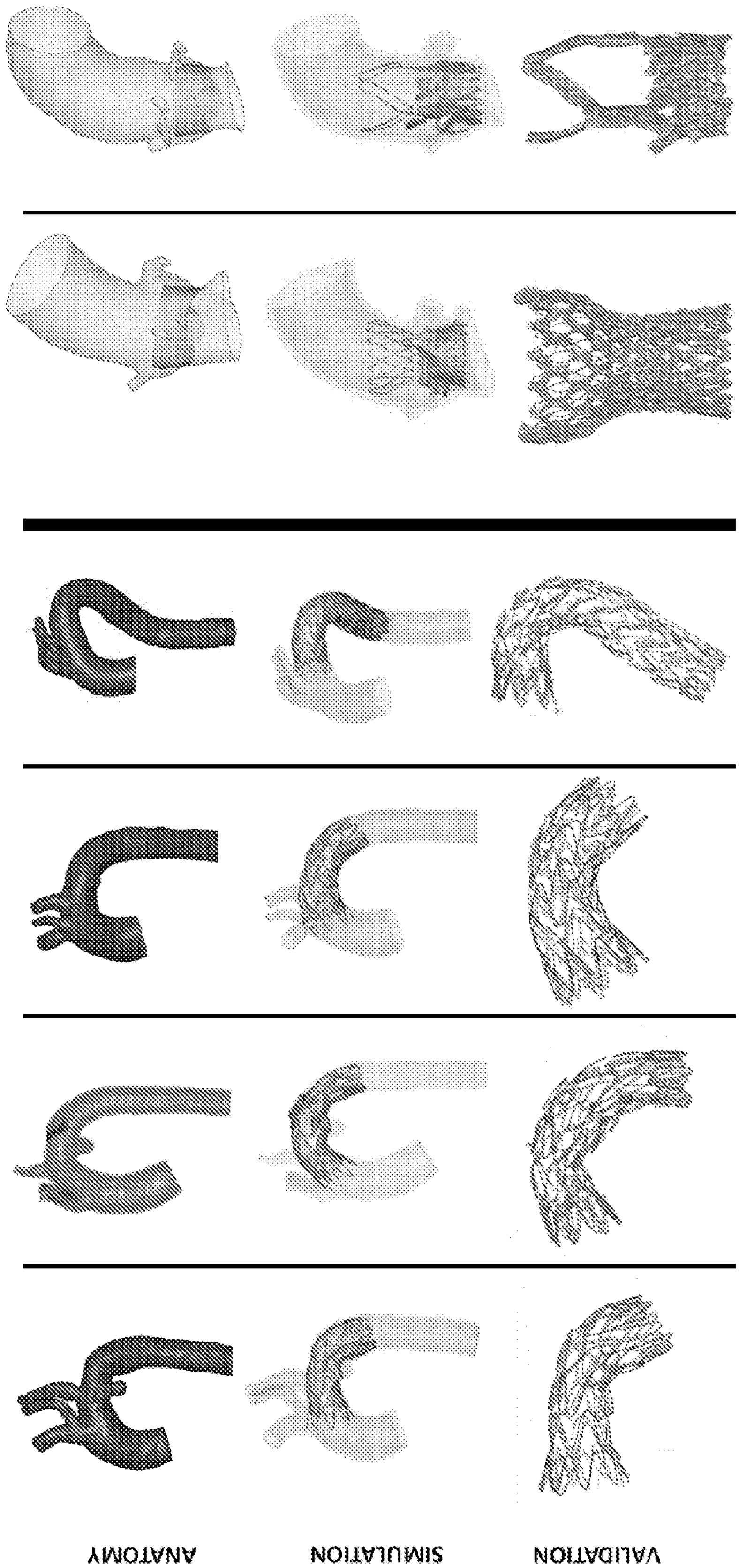

Fig. 7

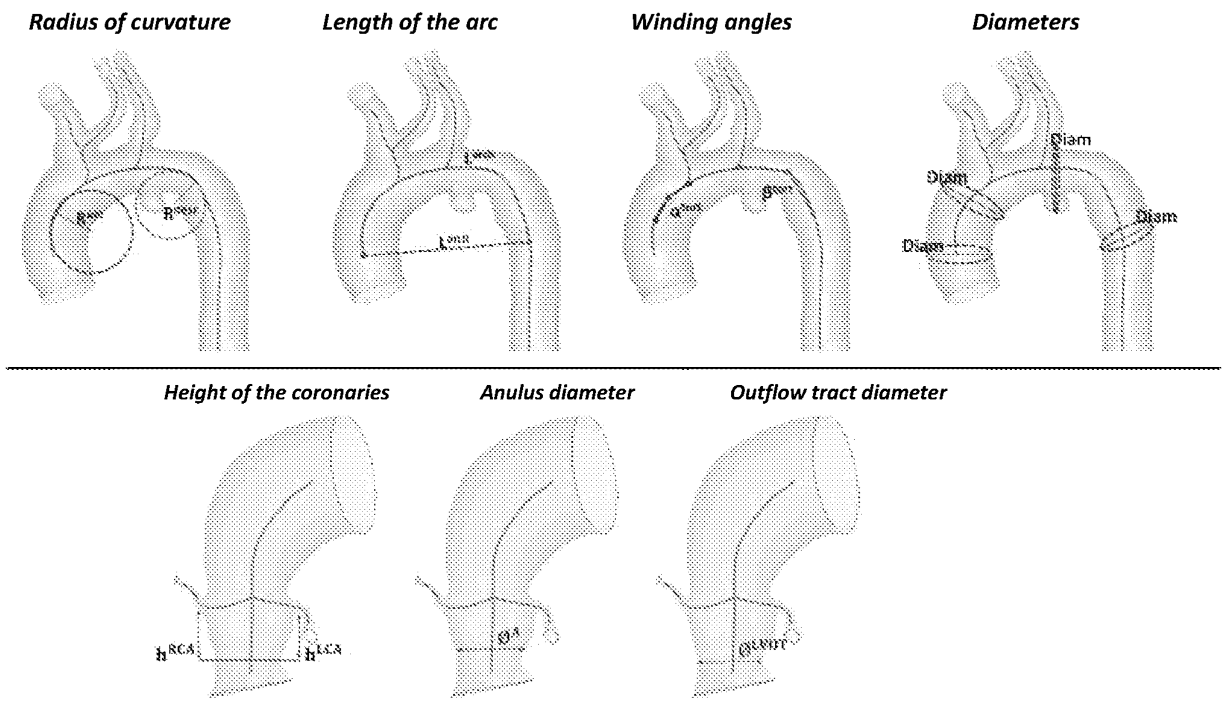
Radius of curvature
Length of the arc
Winding angles
Diameters
Diam
Diam
Diam
Diam
Height of the coronaries
Anulus diameter
Outflow tract diameter

Fig. 8

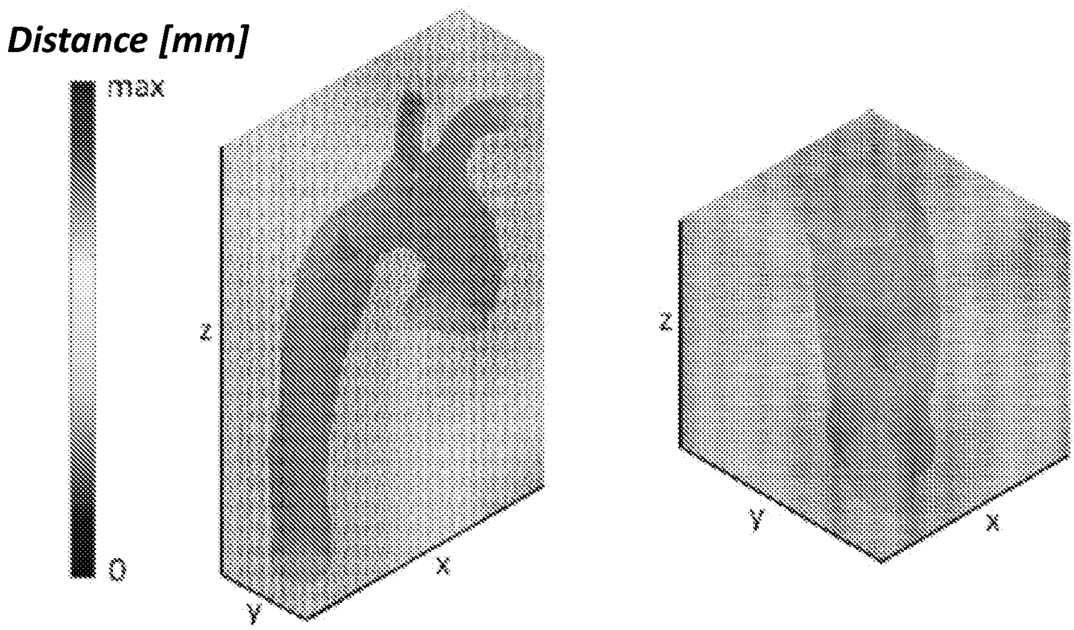
Distance [mm]
max
0
z
x
y
z
y
x

Fig. 9

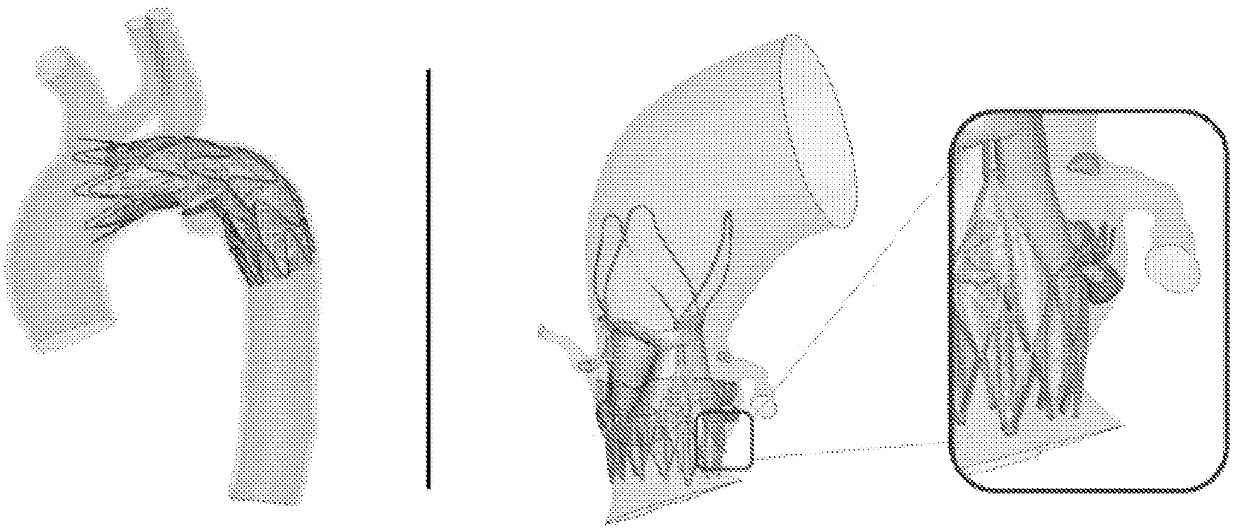

Fig. 10

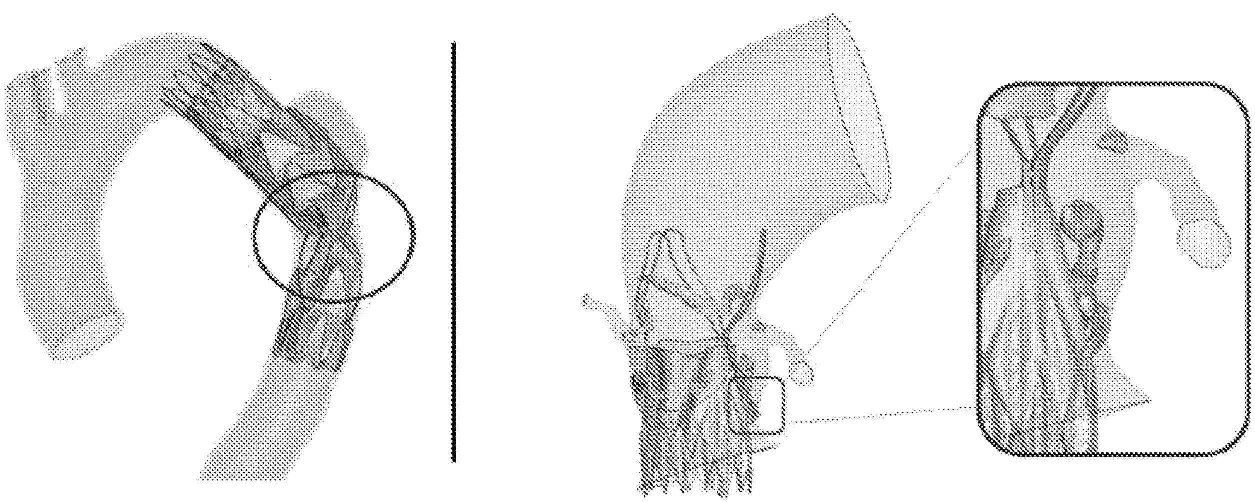

Fig. 11

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2024/059966

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B34/10 G06T17/20 A61F2/07
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61F G06T

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	BISIGHINI BEATRICE ET AL: "Machine learning and reduced order modelling for the simulation of braided stent deployment", FRONTIERS IN PHYSIOLOGY, vol. 14, 29 March 2023 (2023-03-29), XP093150695, CH ISSN: 1664-042X, DOI: 10.3389/fphys.2023.1148540 page 1 - page 10; figures 1-4 -----	1-9

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[X] Further documents are listed in the continuation of Box C.

[ ] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance;; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance;; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 January 2025	24/01/2025

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Roudaut, Tanguy

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	HOLSWILDER GHISLAINE ET AL.: "The prognostic value of extracranial vascular characteristics on procedural duration and revascularization success in endovascularly treated acute stroke patients", EUROPEAN STROKE JOURNAL, vol. 7, no. 1, 8 February 2022 (2022-02-08), XP055979691, cited in the application the whole document -----	1-9
A	BRIDIO SARA ET AL: "A low dimensional surrogate model for a fast estimation of strain in the thrombus during a thrombectomy procedure", JOURNAL OF THE MECHANICAL BEHAVIOR OF BIOMEDICAL MATERIALS , vol. 137 1 January 2023 (2023-01-01), page 105577, XP093150681, AMSTERDAM, NL ISSN: 1751-6161, DOI: 10.1016/j.jmbbm.2022.105577 Retrieved from the Internet: URL:https://pdf.sciencedirectassets.com/274145/1-s2.0-S1751616122X0012X/1-s2.0-S1751616122004829/main.pdf?X-Amz-Security-Token=IQoJb3JpZ2luX2VjEAsaCXVzLWVhc3QtMSJGMEQCIDZ40DgA3wg7sm4iiJE2vYOZdZpgdR5ukD4a6Xc4qzDnAiB81ApHvZ4yHJcv7e4qkkaNe6kPMaWs4GPugcgwE7cK9iqyBQhEEAUaDDA1OTAwMzU0Njg2NSIMiDDMFR29YM9M69tFK [retrieved on 2024-04-11] the whole document -----	1-9