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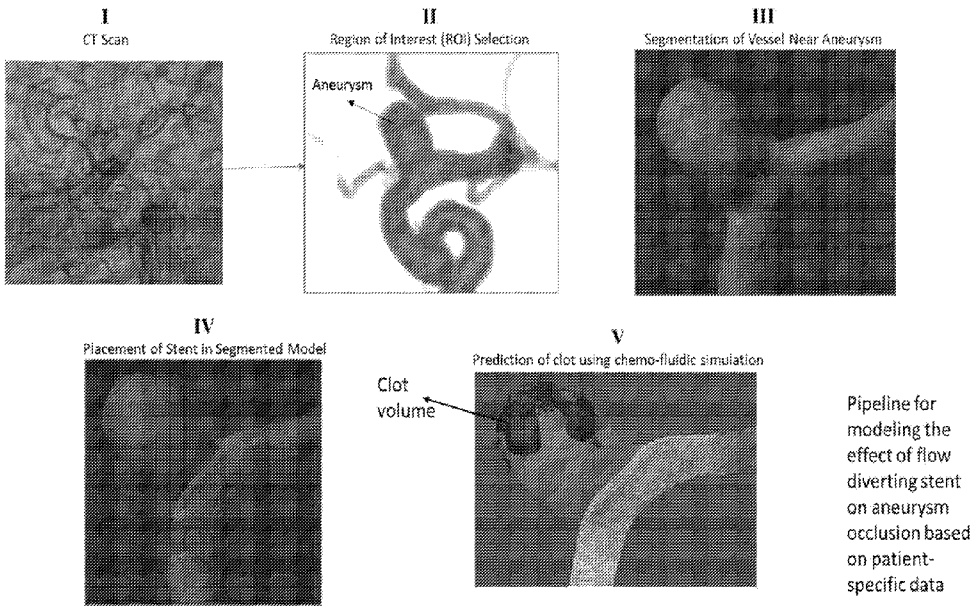

FIG. 5

(57) Abstract: Aneurysmal occlusion prediction resulting from stents, and flow diverting stents in particular, is determined using the system and the method of the present invention. The system utilizes existing or new patient data, such as imaging data, vitals, heart rate, and medications, in conjunction with a vessel segmentation algorithm to model outcomes for the patient. The system can be used to evaluate a specific stent choice for the patient, evaluating anticoagulation therapy for a patient with a flow diverter, and evaluating optimal stent design for a patient.

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A METHOD AND SYSTEM FOR PREDICTING ANEURYSMAL OCCLUSION RESULTING FROM FLOW DIVERTING STENTS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 63/600,193 filed on November 17, 2023, which is incorporated by reference, herein, in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates generally to medical devices. More particularly, the present invention relates to a method and system for predicting aneurysmal occlusion resulting from flow diverting stents.

BACKGROUND OF THE INVENTION

[0003] Endovascular treatment of intracranial aneurysms (IAs) has evolved considerably over the past decades. The technological advances have been driven by the experience that coils fail to completely exclude all IAs from the blood circulation, the need to treat the diseased parent vessel segment leading to the aneurysm formation, and expansion of endovascular therapy to treat more complex IAs.

[0004] Stents were initially developed to support the placement of coils inside wide neck aneurysms. However, early work on stent-like tubular braided structures led to a more sophisticated construct that then later was coined as a flow diverter (FD) and found its way into clinical applications.

[0005] Although FDs were initially used to treat wide-neck large and giant internal carotid artery aneurysms only amenable to surgical trap with or without a bypass or

endovascular vessel sacrifice, its use in other types of IAs and cerebrovascular pathology promptly followed and lead to an explosion in the application of FDs and subsequently endovascular therapy.

[0006] The primary intention of FD is to optimally alter the flow between the parent vessel and the aneurysm while providing an endovascular scaffold for the vessel to heal the defect that is responsible for the aneurysm to form in the first place. The FD provides impedance to the flow into the aneurysm resulting in increased stasis in the aneurysm that promotes thrombosis.

[0007] The degree to which these objectives are met is based on a complex interaction between the FD properties, parent vessel anatomy, aneurysm size, side branches.

[0008] Early in vivo and in vitro studies showed that the most relevant FD properties during this process are porosity and pore density. Porosity is defined as the ratio of the metal-free surface area to the total surface area of the device, whereas pore density is the number of pores per unit surface area.

[0009] Bench top studies using laser induced fluorescence (LIF) imaging and particle image velocimetry (PIV), computational fluid dynamics (CFD) as well as experiments in the rabbit elastase aneurysm model demonstrated that a maximum of 70% porosity and a minimum pore density of 18 pores/mm^2 were ideal parameters to achieve a high rate of stable aneurysm occlusion and yet preserve side branches covered by FDs.

[0010] Other combinations of porosity and pore density achieved similar stable aneurysm occlusion at longer time periods of 3 to 6 months. Translating these properties to in vivo models, while interacting with the underlying parent vessel anatomy aneurysm and vessels arising from the aneurysm neck, represents a key feature for an FD to be successful in clinical practice.

[0011] Another factor to consider for the success of an FD is the predictability of the device behavior on deployment. The intravascular change in the length of an FD, known as foreshortening, could represent an issue in the clinical practice if the change is not as expected, leading to an under- or overestimation of the size of the FD.

[0012] However, with the introduction of virtual simulation tools, operators now have the advantage of anticipating the FD behavior prior to the procedure. (Sim & Size). However, no tools currently exist for predicting the final outcome of the procedure – the thrombotic occlusion of the aneurysm.

[0013] Accordingly, there is a need in the art for a method and system for predicting aneurysmal occlusion resulting from flow diverting stents.

SUMMARY OF THE INVENTION

[0014] The foregoing needs are met, to a great extent, by the present invention which provides a system for modeling including at least one computer system. The at least one computer system is configured to receive patient-specific data. The at least one computer system is further configured for generating a geometric model of a vessel of interest of a vessel of a patient from the patient-specific data. The at least one computer system models an implantation of a stent into the geometric model of the vessel of interest to form a stented vessel model and models hemodynamics and thrombosis in the stented vessel model. The at least one computer system is configured for evaluation of occlusion in the stented vessel model and generating a visual output including images of the stented vessel model and metrics.

[0015] In accordance with an aspect of the present invention, the patient-specific data takes the form of at least one selected from a group of imaging data, vital data, heart rate,

medication, and platelet count. Imaging data includes at least one selected from a group of computed tomography data, magnetic resonance data, echo data, and fluoroscopy data. The system is further configured for modeling hemodynamics and thrombosis with anticoagulation treatments applied to the modeling. Additionally, the type of stent, size of stent, and coating on the stent can be varied for modeling.

[0016] In accordance with an aspect of the present invention, the geometric model of the vessel of interest includes a segmented vessel model. The system provides a user with a menu of stent features, such that a stent with those features can be modeled by the system. Stent features can include one or more selected from a group consisting of stent type, stent size, and stent material. The system can provide the user with a menu of commercially available stents. Modeling hemodynamics and thrombosis further includes extracts metrics and data on aneurysmal occlusion and stent thrombosis.

[0017] In accordance with another aspect of the present invention, the system includes generating a score sheet of stent success. The score sheet includes at least one selected from a group consisting of visual representations of the stented vessel model showing stent placement, and comparison with other potential stents. The score sheet can be interactive and can allow the user to alter different metrics in real time. The system of claim 1 further includes modeling various positions for the stent within the stented vessel model. The system includes modeling anticoagulation therapy.

[0018] The system includes providing a user with a preset list of anticoagulation therapies to select for modeling. The stent includes a flow diverter (FD). The system includes

modelling position of the FD with respect to an aneurysm. The system further includes measuring thrombotic occlusion of the aneurysm. The system includes scoring the thrombotic occlusion of the aneurysm. The system includes flow modeling an aneurysm within the vessel model.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] The accompanying drawings provide visual representations, which will be used to more fully describe the representative embodiments disclosed herein and can be used by those skilled in the art to better understand them and their inherent advantages. In these drawings, like reference numerals identify corresponding elements and:

[0020] FIG. 1 illustrates a flow diagram of a system for evaluating a specific stent for a patient, according to an embodiment of the present invention.

[0021] FIG. 2 illustrates a flow diagram of a system for evaluating anticoagulation therapy for a patient with a flow diverter, according to an embodiment of the present invention.

[0022] FIG. 3 illustrates a flow diagram of a system for choosing an optimal stent for a patient, according to an embodiment of the present invention.

[0023] FIG. 4 illustrates a flow diagram of a system for evaluating stent design, according to an embodiment of the present invention.

[0024] FIG. 5 illustrates a model of the effect of a flow diverting stent on an aneurysm occlusion based on patient-specific data.

[0025] FIG. 6 illustrates a flow diagram of key components and steps in the chemo-fluidic modeling of an aneurysm thrombosis, according to an embodiment of the present invention.

[0026] FIG. 7 illustrates an exemplary output, according to an embodiment of the present invention.

DETAILED DESCRIPTION

[0027] The presently disclosed subject matter now will be described more fully hereinafter with reference to the accompanying Drawings, in which some, but not all embodiments of the inventions are shown. Like numbers refer to like elements throughout. The presently disclosed subject matter may be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will satisfy applicable legal requirements. Indeed, many modifications and other embodiments of the presently disclosed subject matter set forth herein will come to mind to one skilled in the art to which the presently disclosed subject matter pertains having the benefit of the teachings presented in the foregoing descriptions and the associated Drawings. Therefore, it is to be understood that the presently disclosed subject matter is not to be limited to the specific embodiments disclosed and that modifications and other embodiments are intended to be included within the scope of the appended claims.

[0028] The present invention is directed to a system and method for predicting aneurysmal occlusion resulting from flow diverting stents. The system utilizes existing or new patient data, such as imaging data, vitals, heart rate, and medications, in conjunction with a vessel segmentation algorithm to model outcomes for the patient. The system can be used to evaluate a specific stent choice for the patient, evaluating anticoagulation therapy for a patient with a flow diverter, and evaluating optimal stent design for a patient.

[0029] The mechanism of action of FD can be divided into three stages: hemodynamic, thrombus formation, and endothelialization. The *hemodynamic stage* happens immediately after FD placement, which exerts a disruption of blood flow into and out of the aneurysm

from the parent artery related to the resistance (impedance) created by the mesh. This impedance is a complex function of the porosity and pore density of the deployed FD in the neck region of the aneurysm, as well as the features of the vessel and aneurysm anatomy that affect the interaction of the blood flow with the stent.

[0030] This is followed by immediate activation of platelets via a complex pathway with progressive formation of a stable thrombus (*thrombus formation stage*) over days to weeks. The thrombosis and subsequent occlusion of the aneurysm depends on the shape and curvature of the parent vessel, the hemodynamic properties (heart rate, flow rate) of the parent vessel, the (neck) size of the aneurysm, the shape of the aneurysm, impedance of the FD, which depends on the porosity and pore density properties of the FD, the subject's blood rheology, and the platelet response of the patient to antiplatelet medication.

[0031] The *endothelialization stage* represents the transformation of the amorphous thrombus to its final collagen stage and the simultaneous and progressive endothelialization of the can take several months to years. The FD acts as a scaffold for neo-endothelization and remodeling of the artery. Time-sensitive intra-aneurysmal thrombus transformation to collagen leads to a final reduction in aneurysmal mass.

[0032] Given the metallic properties of the FD, dual antiplatelet therapy (DAPT) is required to reduce the risk of thromboembolism. Aspirin and clopidogrel are the most used antiplatelets; however, due to the rising variability in clopidogrel platelet inhibition, platelet function testing (PFT) has been increasingly used to ensure therapeutic inhibition and mitigate the risk of thrombotic/hemorrhagic complications.

[0033] Nevertheless, PFT has been the subject of controversy, with association of harmful outcomes in FD patients, as observed in a meta-analysis. Yet, the utility of PFT to prognosticate complications may have become more meaningful in recent years, as observed in a meta-analysis, in which platelet hypo-responders and hyper-responders were associated with thrombotic and hemorrhagic events, respectively, following FD.

[0034] Due to the complexity of the physico-chemical process associated with the formation of the thrombus in a FD treated aneurysm as well as the dependence of this process on many factors, non-optimal outcomes are not uncommon. Non-optimal outcomes may include incomplete occlusion of the aneurysm or the formation of an in-stent stenosis.

[0035] The data from a study (Briganti, F., Leone, G., Marseglia, M., Mariniello, G., Caranci, F., Brunetti, A. and Maiuri, F., 2015. Endovascular treatment of cerebral aneurysms using flow-diverter devices: a systematic review. The neuroradiology journal, 28(4), pp.365-375) shows that parent artery thrombosis and stenosis occur when the aneurysmal thrombosis extends into the parent artery, and this occurs at an average rate of 3.8 – 6.8% (acute and late setting respectively). Ischemic complications are often associated with parent artery stenosis, and these occur at an average rate of 4.1%. The overall rate of complete aneurysm occlusion averages to about 81.5% indicating that incomplete aneurysm occlusion occurs at a rate of 18.5%.

[0036] The incidence rate of in-stent stenosis in patients treated with these devices was about 5% in one study (Wang, T., Richard, S.A., Jiao, H., Li, J., Lin, S., Zhang, C., Wang, C., Xie, X. and You, C., 2021. Institutional experience of in-stent stenosis after pipeline flow diverter implantation: a retrospective analysis of 6 isolated cases out of 118 patients.

Medicine, 100). Several combinations of reasons may account for in-stent stenosis including sharp change of the FD, distal wall malapposition, inconsistent compliance between parent arteries, and as the FD occlusion due to intimal hyperplasia and vessel tortuosity. Currently, it is difficult for the surgeon to know ahead of time if the use of a particular FD device for a particular patient would be more likely to form an in-stent stenosis.

[0037] The *Pipeline Embolization Device* (PED, Chestnut Medical Technologies, Menlo Park, CA) was the first commercially available FD, which received the Conformité Européene (CE) mark in June 2008 and entered the US market after receiving Food and Drug Administration (FDA) approval on April 6, 2011. Since then, there has been a rapid growth in technological advancements and applications of several FDs.

[0038] Aside from their intrinsic features, the design of FDs is primarily based on the use of cobalt chromium (Pipeline and Surpass) or nitinol (all the others). Cobalt/chromium adds stiffness and radial force while nitinol brings flexibility and easy navigation and deployment. Cobalt/chromium implants allow a better answer to ballooning when an incomplete wall apposition is observed.

[0039] North America accounted for the largest market share of the global flow diverters in the year 2022. This is due to the high prevalence of intracranial aneurysm and rise in the demand for minimally invasive neurological procedures. For instance, according to the Brain Aneurysm Foundation, in the U.S. more than 6.5 million suffered from unruptured cerebral aneurysm. In the U.S., approximately, 30,000 people suffer intracranial aneurysm rupture every year. Rapid technological advancements are also among the factors contributing to the market growth in North America. Furthermore, supportive government initiatives, and

favorable reimbursements are also expected to fuel the market growth. [www.grandviewresearch.com]. The chart below summarizes the expected trend in US Flow Diverters Market.

[0040] Asia Pacific is expected to grow at a highest compound annual growth rate (CAGR) of 14.00% from 2023 to 2030. This is due to the presence of huge patient base suffering from neurovascular disorders in the emerging economies such as India, China, along with rising healthcare expenditures in this region. Moreover, mandatory healthcare insurance in some countries, rapid technological advancements, increasing government initiatives are high impact rendering drivers of the market. For instance, the China Intracranial Aneurysm Project (ICAP) is an observational, prospective, and multicenter registry study of risks, rupture, diagnosis, and treatment of intracranial aneurysm. Five studies are under ICAP. CIAP-1 is the observational study of unruptured intracranial aneurysm. This is anticipated to impel market growth over the forecast period.

[0041] In recent years, flow diverters are getting attention from neurosurgeons owing to their success rate in managing brain aneurysms. Several key players are focusing on research activities for addressing the pitfalls associated with the existing treatment options. For instance, in June 2022, Carmeda and a Stryker announced a partnership that will combine Stryker's flow diverter proven technology with Carmeda's coating active heparin for the treatment of brain aneurysms.

[0042] Furthermore, companies in the intracranial aneurysm market are undertaking this strategy for strengthening their product portfolio and offer diverse technological advanced

products to their customers. This strategy is the most prominently adopted strategy by the key market players for attracting more customers in the intracranial aneurysm market.

[0043] The thrombosis and subsequent occlusion of the aneurysm, which determines the success of the procedure, depends on the shape and curvature of the parent vessel, the hemodynamic properties (heart rate, flow rate) of the parent vessel, the (neck) size of the aneurysm, the shape of the aneurysm, properties of the FD, including the porosity and pore density of the deployed stent the subject's blood rheology, and the platelet response of the patient to antiplatelet medication.

[0044] All of the above features have significant variability within the patient population. Currently, the neurosurgeon relies primarily on his/her experience to determine the stent type and size to be used for a given patient and does not have any tools at his/her disposal that would provide patient-specific guidance on the effect of stent choice on the success of the procedure. A consequence related to this lack of tools is the rate of non-optimal outcomes from this procedure. Parent artery thrombosis and stenosis occur when the aneurysmal thrombosis extends into the parent artery, and this occurs at an average rate of 3.8 – 6.8% (acute and late setting respectively). Ischemic complications are often associated with parent artery stenosis, and these occur at an average rate of 4.1%. The average rate of incomplete aneurysm occlusion occurs is 18.5%.

[0045] In order to improve outcomes, the present invention was developed as a software program or application to predict the effect of stent choice on the successful occlusion of an aneurysm for a given patient. The software may take as input, imaging and other health data from the patient, the configuration of the stent(s), and predict the degree of thrombotic

occlusion in the aneurysm. The software will be developed into a product that users can license or a software-as-a-service (SAS) product to which users can subscribe.

[0046] FIG. 1 illustrates a flow diagram of a system for evaluating a specific stent for a patient, according to an embodiment of the present invention. As illustrated in FIG. 1, the system for evaluating a specific stent for a patient includes step 1 of receiving patient data. The patient data can take a number of forms, known to or conceivable to one of skill in the art. For example, the patient data can include imaging data, such as computed tomography (CT), magnetic resonance (MR), echo, and/or fluoroscopy data. The patient data can also include vitals, heart rate, medication, including anticoagulation, and complete blood count (CBC) data, including platelet count. In step 2, a vessel segmentation is performed. In this step, a vessel or vessels of interest are segmented from patient imaging data. A geometric model of the vessel of interest is generated. In step 3, the implantation of a stent is modeled. The implantation of the stent is modeled into the segmented vessel model. A stented vessel model is generated for further analysis. Additionally, during step 3, the user can input the type of stent, size of stent, material of stent, or any other suitable variable known to or conceivable to one of skill in the art. In some implementations, there may be a drop-down menu prepopulated with commercially available stents and their associated specifications, sizes, materials, etc. In some embodiments, the stent can be position adjusted within the vessel of the model. In step 4, hemodynamics and thrombosis are modeled using the stented vessel model. Hemodynamic and thrombosis simulations can be conducted for a set of patient specific models to generate data for further analysis. In step 5, occlusion is evaluated. The model extracts metrics and data on aneurysmal occlusion and stent thrombosis from the simulation data. In step 6, a score sheet of FD success is generated based on the metrics, data,

and other details from the user. The score sheet can include visual representations of the stented vessel model showing the ideal FD, placement, and comparison with other potential stents. The score sheet can be interactive and can allow the user to alter different metrics in real time.

[0047] FIG. 2 illustrates a flow diagram of a system for evaluating anticoagulation therapy for a patient with a flow diverter, according to an embodiment of the present invention. The system illustrated in FIG. 2, follows the same general process as that of FIG. 1, but adds additional modeling analysis for anticoagulation therapy. As illustrated in FIG. 2, the system for evaluating a specific stent for a patient includes step 1 of receiving patient data. The patient data can take a number of forms, known to or conceivable to one of skill in the art. For example, the patient data can include imaging data, such as computed tomography (CT), magnetic resonance (MR), echo, and/or fluoroscopy data. The patient data can also include vitals, heart rate, medication, including anticoagulation, and complete blood count (CBC) data, including platelet count. In step 2, a vessel segmentation is performed. In this step, a vessel or vessels of interest are segmented from patient imaging data. A geometric model of the vessel of interest is generated. In step 3, the implantation of a stent is modeled. The implantation of the stent is modeled into the segmented vessel model. A stented vessel model is generated for further analysis. Additionally, during step 3, the user can input the type of stent, size of stent, material of stent, or any other suitable variable known to or conceivable to one of skill in the art. In some implementations, there may be a drop-down menu prepopulated with commercially available stents and their associated specifications, sizes, materials, etc. In some embodiments, the stent can be position adjusted within the vessel of the model. In step 4, hemodynamics and thrombosis are modeled using the stented vessel model. Hemodynamic and thrombosis simulations can be conducted for a set of patient

specific models to generate data for further analysis. Additional analysis can be added to step 4, to model the effects of different anticoagulation therapies. Step 4 can be repeated with different anticoagulation therapy selected by the user for modeling. In some embodiments, it is also possible that the system model the stent with a number of preset anticoagulation therapies to recommend an optimized therapy. In step 5, occlusion is evaluated. The model extracts metrics and data on aneurysmal occlusion and stent thrombosis from the simulation data. In step 6, a score sheet of FD success is generated based on the metrics, data, and other details from the user. The score sheet can include visual representations of the stented vessel model showing the ideal FD, placement, and comparison with other potential stents. The score sheet can be interactive and can allow the user to alter different metrics in real time.

[0048] FIG. 3 illustrates a flow diagram of a system for choosing an optimal stent for a patient, according to an embodiment of the present invention. In FIG. 3, the system for evaluating a specific stent for a patient includes step 1 of receiving patient data. The patient data can take a number of forms, known to or conceivable to one of skill in the art. For example, the patient data can include imaging data, such as computed tomography (CT), magnetic resonance (MR), echo, and/or fluoroscopy data. The patient data can also include vitals, heart rate, medication, including anticoagulation, and complete blood count (CBC) data, including platelet count. In step 2, a vessel segmentation is performed. In this step, a vessel or vessels of interest are segmented from patient imaging data. A geometric model of the vessel of interest is generated. In step 3, the implantation of a stent is modeled. The implantation of the stent is modeled into the segmented vessel model. A stented vessel model is generated for further analysis. Additionally, during step 3, the user can input the type of stent, size of stent, material of stent, or any other suitable variable known to or conceivable to one of skill in the art. In some implementations, there may be a drop-down menu

prepopulated with commercially available stents and their associated specifications, sizes, materials, etc. In some embodiments, the stent can be position adjusted within the vessel of the model. In step 4, hemodynamics and thrombosis are modeled using the stented vessel model. Hemodynamic and thrombosis simulations can be conducted for a set of patient specific models to generate data for further analysis. In step 5, occlusion is evaluated. The model extracts metrics and data on aneurysmal occlusion and stent thrombosis from the simulation data. In step 6, stent type, size, model, or other stent criteria can be changed and modeled again. In step 7, a score sheet of FD success is generated based on the metrics, data, and other details from the user for each of the stents selected. The score sheet can include visual representations of the stented vessel model showing the ideal FD, placement, and comparison with other potential stents. The score sheet can be interactive and can allow the user to alter different metrics in real time.

[0049] FIG. 4 illustrates a flow diagram of a system for evaluating stent design, according to an embodiment of the present invention. As illustrated in FIG. 4, the system includes step 1, where at least one stent is selected for evaluation. The system for evaluating a specific stent for a patient includes step 2 of receiving patient data. The patient data can take a number of forms, known to or conceivable to one of skill in the art. For example, the patient data can include imaging data, such as computed tomography (CT), magnetic resonance (MR), echo, and/or fluoroscopy data. The patient data can also include vitals, heart rate, medication, including anticoagulation, and complete blood count (CBC) data, including platelet count. In step 3, a vessel segmentation is performed. In this step, a vessel or vessels of interest are segmented from patient imaging data. A geometric model of the vessel of interest is generated. In step 4, the implantation of a stent is modeled. The implantation of the stent is modeled into the segmented vessel model. A stented vessel model is generated for

further analysis. Additionally, during step 4, the user can input the type of stent, size of stent, material of stent, or any other suitable variable known to or conceivable to one of skill in the art. In some implementations, there may be a drop-down menu prepopulated with commercially available stents and their associated specifications, sizes, materials, etc. In some embodiments, the stent can be position adjusted within the vessel of the model. In step 5, hemodynamics and thrombosis are modeled using the stented vessel model. Hemodynamic and thrombosis simulations can be conducted for a set of patient specific models to generate data for further analysis. In step 6, occlusion is evaluated. The model extracts metrics and data on aneurysmal occlusion and stent thrombosis from the simulation data. In steps 7 and 8, a score sheet of FD success is generated based on the metrics, data, and other details from the user. The score sheet can include visual representations of the stented vessel model showing the ideal FD, placement, and comparison with other potential stents. The score sheet can be interactive and can allow the user to alter different metrics in real time.

[0050] FIG. 5 illustrates a model of the effect of a flow diverting stent on an aneurysm occlusion based on patient-specific data. In FIG. 5, data is taken from a CT scan. A region of interest (ROI) is selected, generally surrounding the location of an aneurysm. The system segments the vessel near the aneurysm and a stent is placed in the segmented model. A chemo-fluidic simulation is done to predict clotting, flow, and effect of the FD on aneurysm occlusion. This chemo-fluidic simulation is done using additional patient-specific data.

[0051] FIG. 6 illustrates a flow diagram of key components and steps in the chemo-fluidic modeling of an aneurysm thrombosis, according to an embodiment of the present invention. FIG. 6 shows different input parameters for the thrombosis modeling used in flow modeling of the aneurysm.

[0052] FIG. 7 illustrates an exemplary output, according to an embodiment of the present invention. FIG. 7 shows modeling outcomes for different stents using the system of the present invention. A prediction from the system of the aneurysm occlusion resulting from stents with different porosities for a specific patient. The exemplary output provides both visualization of the modeling of the vessel, stent, and flow. In addition the output provides metrics on predicted occlusion for various selected stent models.

[0053] Function of the present invention can be carried out in conjunction with a computer, non-transitory computer readable medium, or alternately a computing device or non-transitory computer readable medium incorporated into the medical device associated with the present invention.

[0054] A non-transitory computer readable medium is understood to mean any article of manufacture that can be read by a computer. Such non-transitory computer readable media includes, but is not limited to, magnetic media, such as a floppy disk, flexible disk, hard disk, reel-to-reel tape, cartridge tape, cassette tape or cards, optical media such as CD-ROM, writable compact disc, magneto-optical media in disc, tape or card form, and paper media, such as punched cards and paper tape. The computing device can be a special computer designed specifically for this purpose. The computing device can be unique to the present invention and designed specifically to carry out the method and operation of the present invention.

[0055] The many features and advantages of the invention are apparent from the detailed specification, and thus, it is intended by the appended claims to cover all such features and advantages of the invention which fall within the true spirit and scope of the invention. Further, since numerous modifications and variations will readily occur to those skilled in the

art, it is not desired to limit the invention to the exact construction and operation illustrated and described, and accordingly, all suitable modifications and equivalents may be resorted to, falling within the scope of the invention. While exemplary embodiments are provided herein, these examples are not meant to be considered limiting. The examples are provided merely as a way to illustrate the present invention. Any suitable implementation of the present invention known to or conceivable by one of skill in the art could also be used.

What is claimed is:

1. A system for modeling comprising:

at least one computer system configured to receive patient-specific data, wherein the at least one computer system is configured for:

generating a geometric model of a vessel of interest of a vessel of a patient from the patient-specific data;

modeling an implantation of a stent into the geometric model of the vessel of interest to form a stented vessel model;

modeling hemodynamics and thrombosis in the stented vessel model;

evaluation of occlusion in the stented vessel model; and

generating a visual output including images of the stented vessel model and metrics.

2. The system of claim 1 wherein the patient-specific data comprises at least one selected from a group consisting of imaging data, vital data, heart rate, medication, and platelet count.

3. The system of claim 2 wherein imaging data includes at least one selected from a group consisting of computed tomography data, magnetic resonance data, echo data, and fluoroscopy data.

4. The system of claim 1 wherein the system is further configured for modeling hemodynamics and thrombosis with anticoagulation treatments applied to the modeling.

5. The system of claim 1 wherein the type of stent, size of stent, and coating on the stent can be varied for modeling.

6. The system of claim 1 wherein the geometric model of the vessel of interest comprises a segmented vessel model.
7. The system of claim 1 further comprising providing the user with a menu of stent features, such that a stent with those features can be modeled by the system.
8. The system of claim 7 wherein stent features can include one or more selected from a group consisting of stent type, stent size, and stent material.
9. The system of claim 1 further comprising providing the user with a menu of commercially available stents.
10. The system of claim 1 wherein modeling hemodynamics and thrombosis further includes extracts metrics and data on aneurysmal occlusion and stent thrombosis.
11. The system of claim 1 further comprising generating a score sheet of stent success.
12. The system of claim 11 wherein the score sheet comprises at least one selected from a group consisting of visual representations of the stented vessel model showing stent placement, and comparison with other potential stents.
13. The system of claim 1 further comprising modeling various positions for the stent within the stented vessel model.
14. The system of claim 1 further comprising modeling anticoagulation therapy.
15. The system of claim 14 further comprising providing a user with a preset list of anticoagulation therapies to select for modeling.
16. The system of claim 1 wherein the stent comprises a flow diverter (FD).
17. The system of claim 16 further comprising modelling position of the FD with respect to an aneurysm.

18. The system of claim 17 further comprising measuring thrombotic occlusion of the aneurysm.

19. The system of claim 18 further comprising scoring the thrombotic occlusion of the aneurysm.

20. The system of claim 1 further comprising flow modeling an aneurysm within the vessel model.

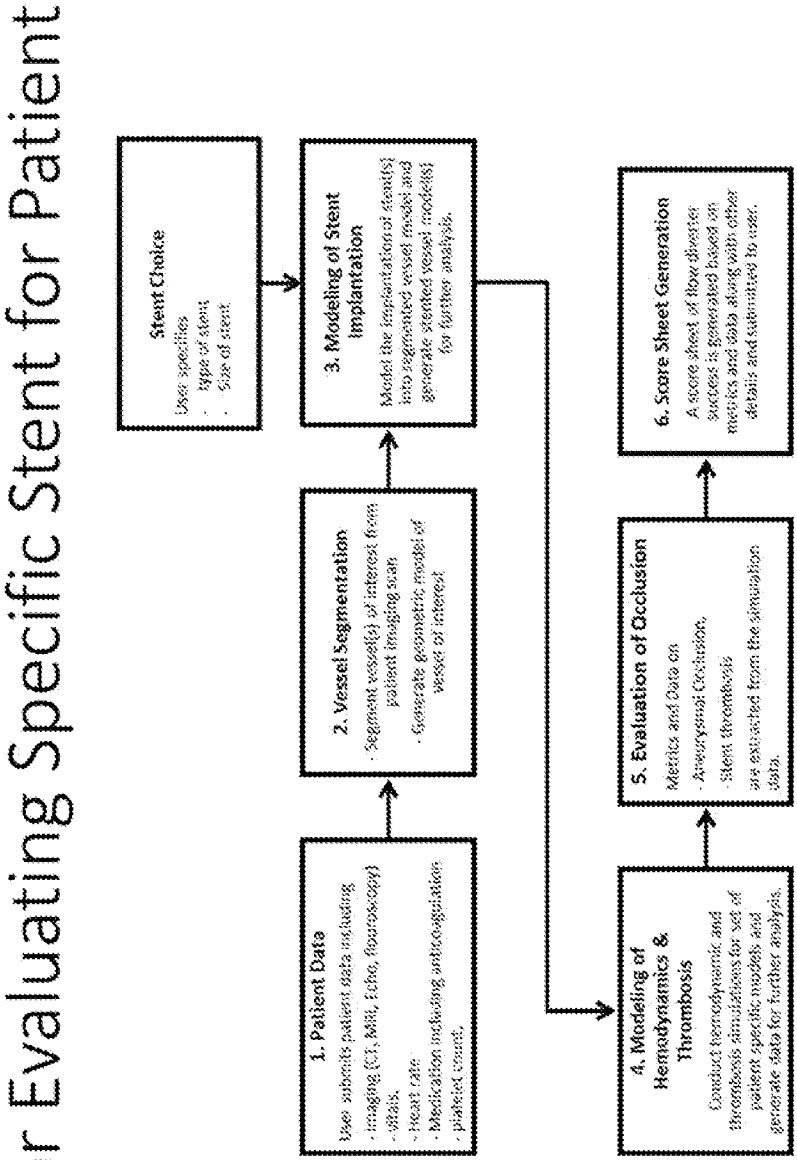
System for Evaluating Specific Stent for Patient
Stent Choice
User specifies
· type of stent
· Size of stent
1. Patient Data
User submits patient data including
· imaging (CT, MRI, Echo, fluoroscopy)
· vitals,
· Heart rate
· Medication including anticoagulation
· platelet count.
2. Vessel Segmentation
· Segment vessel(s) of interest from patient imaging scan
· Generate geometric model of vessel of interest
3. Modeling of Stent Implantation
Model the implantation of stent(s) into segmented vessel model and generate stented vessel model(s) for further analysis.
4. Modeling of Hemodynamics & Thrombosis
Conduct hemodynamic and thrombosis simulations for set of patient specific models and generate data for further analysis.
5. Evaluation of Occlusion
Metrics and Data on
· Aneurysmal Occlusion.
· Stent thrombosis
are extracted from the simulation data.
6. Score Sheet Generation
A score sheet of how diverse success is generated based on metrics and data along with other details and submitted to user.

FIG. 1

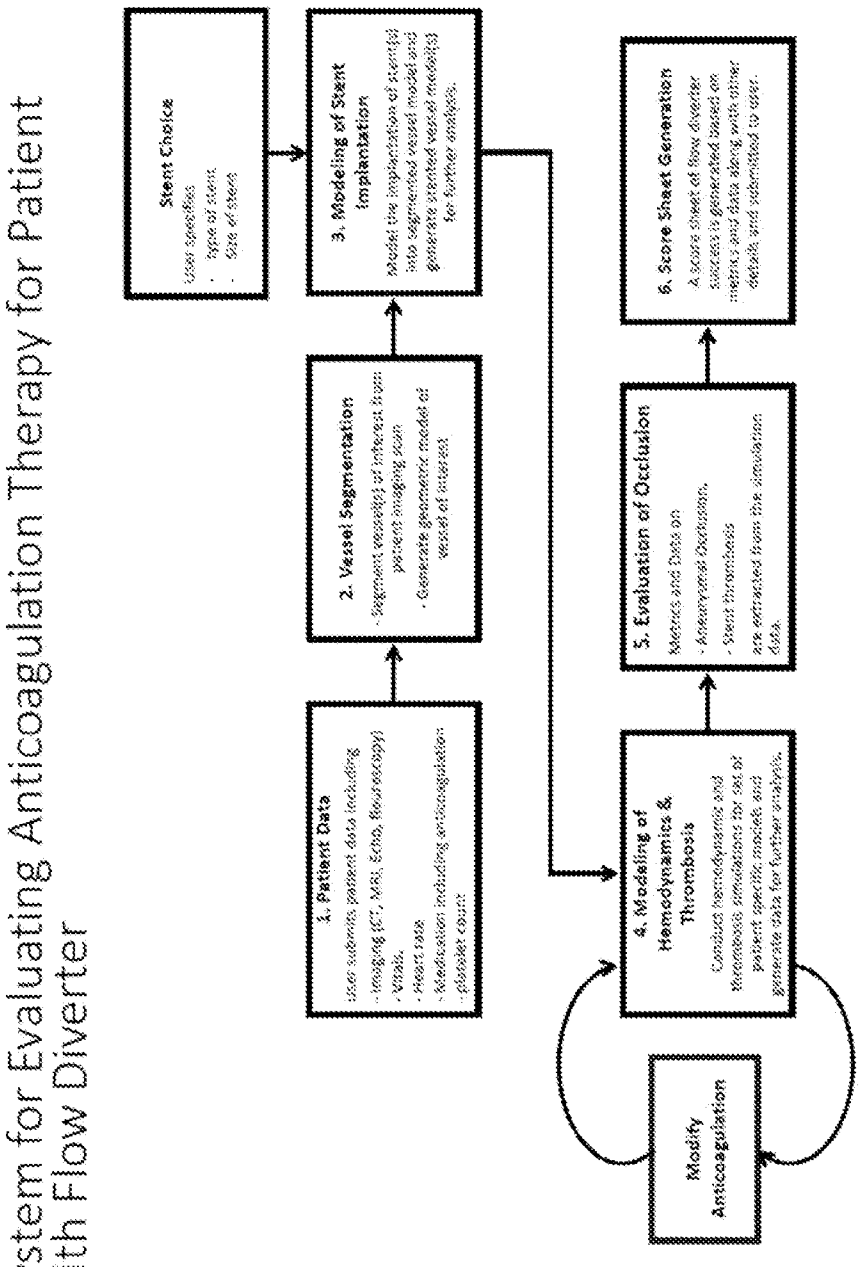
System for Evaluating Anticoagulation Therapy for Patient with Flow Diverter
Stent Choice
User specifies
- type of stent
- size of stem
1. Patient Data
User submits patient data including
- imaging (CT, MRI, Echo, Fluoroscopy)
- Vitals
- Heart rate
- Medication including anticoagulation
- platelet count
2. Vessel Segmentation
- Segment vessel(s) of interest from patient imaging scan
- Generate geometric model of vessel of interest
3. Modeling of Stent Implantation
Model the implantation of stent(s) into segmented vessel model and generate stented vessel model(s) for further analysis.
4. Modeling of Hemodynamics & Thrombosis
Conduct hemodynamics and thrombosis simulations for set of patient specific models and generate data for further analysis.
5. Evaluation of Occlusion
Metrics and Data on
- Aneurysmal Occlusion,
- Stent Thrombosis
are extracted from the simulation data.
6. Score Sheet Generation
A score sheet of flow diverter success is generated based on metrics and data along with other details and submitted to user.
Modify Anticoagulation

FIG. 2

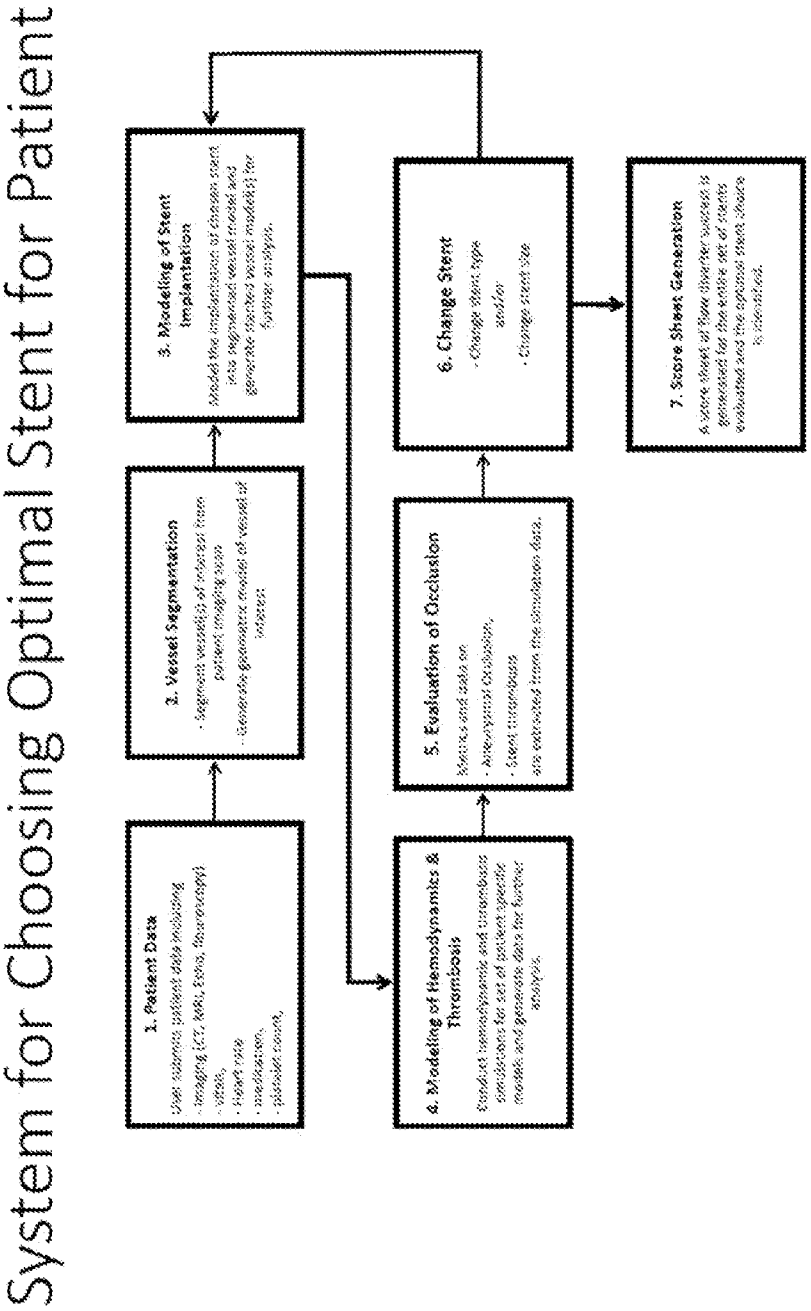
System for Choosing Optimal Stent for Patient
1. Patient Data
2. Vessel Segmentation
3. Modeling of Stent Implantation
4. Modeling of Hemodynamics & Thrombosis
5. Evaluation of Occlusion
6. Change Stent
7. Score Sheet Generation

FIG. 3

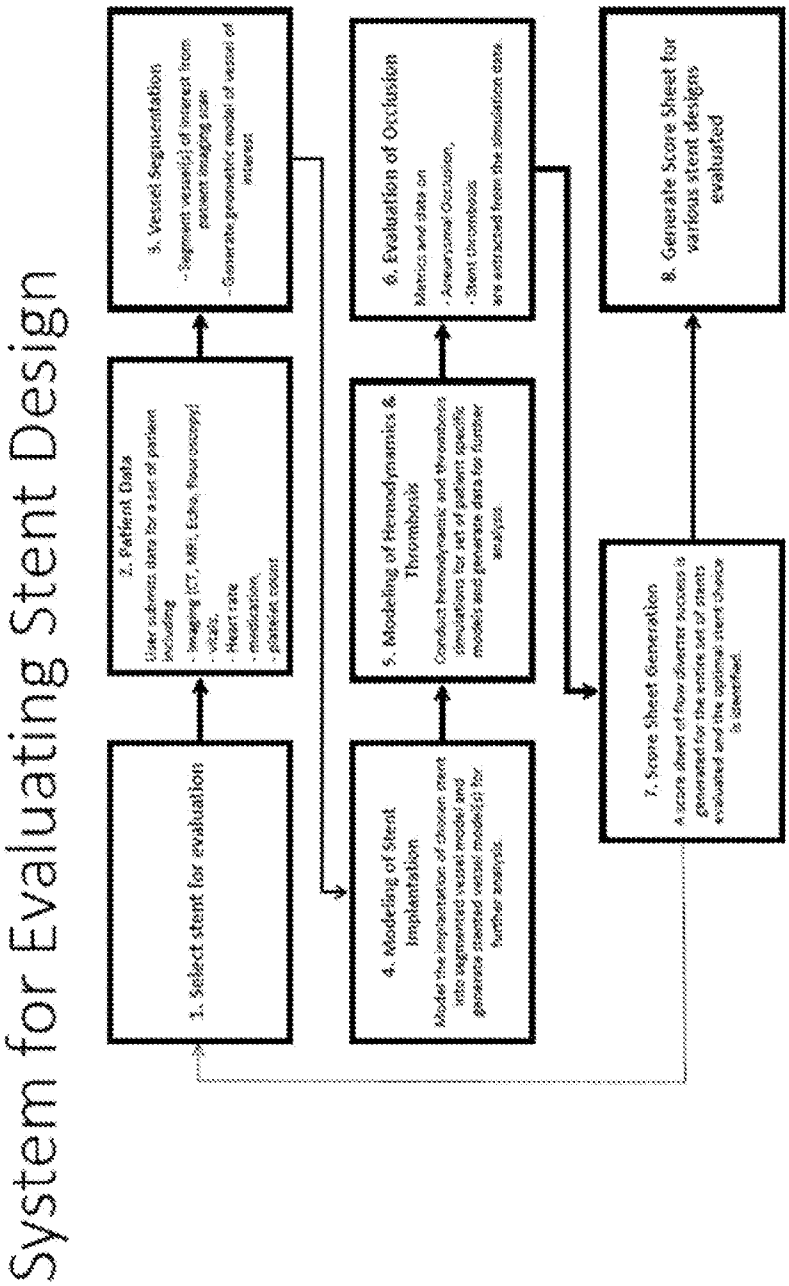
System for Evaluating Stent Design
1. Select stent for evaluation
2. Patient Data
User submits data for a set of patient including
- Imaging (CT, MRI, Echo, Fluoroscopy)
- vitals,
- Heart rate
- medication,
- platelet count
3. Vessel Segmentation
- Segment vessel(s) of interest from patient imaging scan
- Generate geometric model of vessel of interest
4. Modeling of Stent Implantation
Model the implantation of chosen stent into segmented vessel model and generate stented vessel model(s) for further analysis.
5. Modeling of Hemodynamics & Thrombosis
Conduct hemodynamic and thrombosis simulations for set of patient specific models and generate data for further analysis.
6. Evaluation of Occlusion
Metrics and data on
- Aneurysmal Occlusion,
- Stent thrombosis
are extracted from the simulation data.
7. Score Sheet Generation
A score sheet of flow diverter success is generated for the entire set of stents evaluated and the optimal stent choice is identified.
8. Generate Score Sheet for various stent designs evaluated

FIG. 4

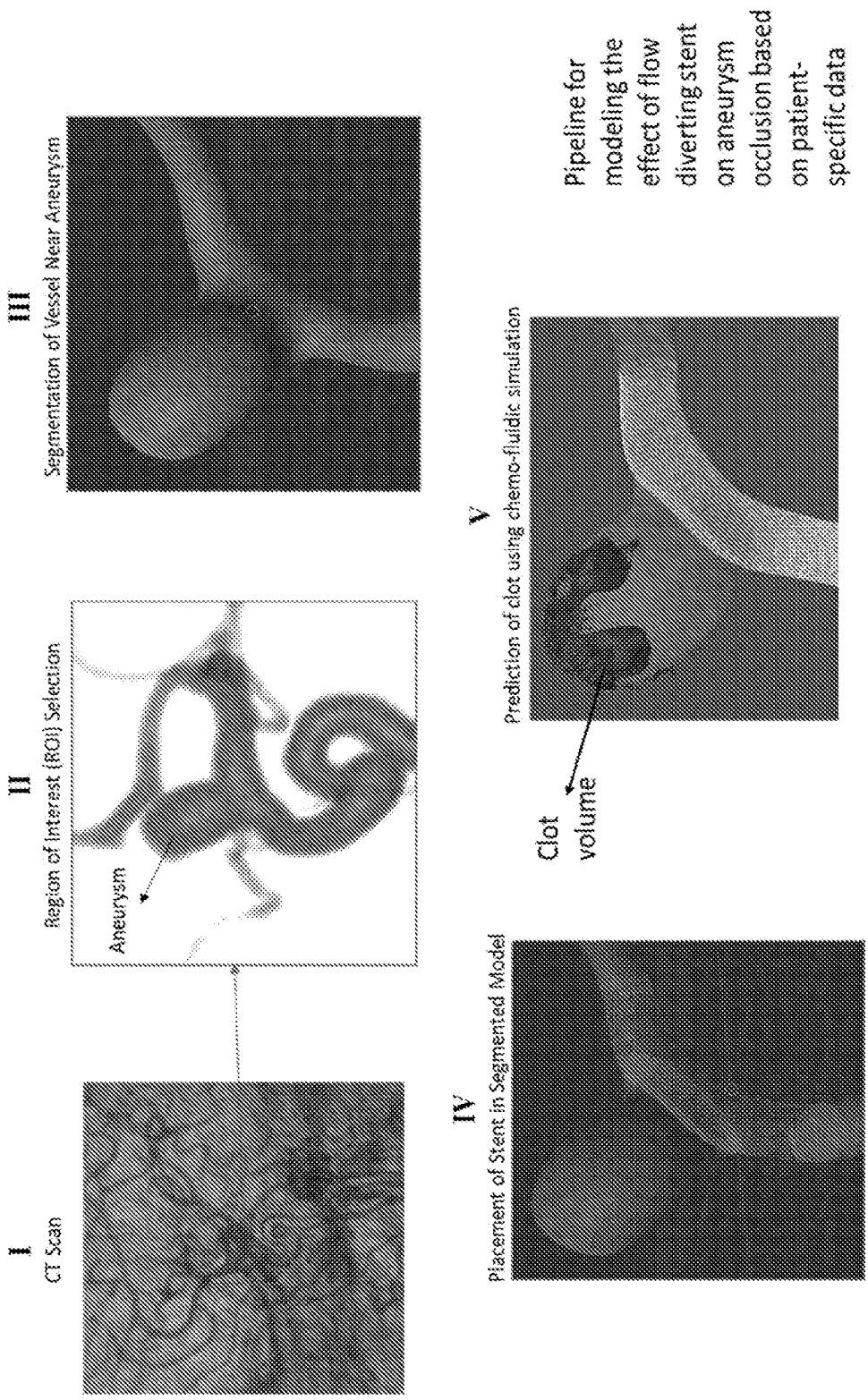
I
CT Scan
II
Region of Interest (ROI) Selection
Aneurysm
III
Segmentation of Vessel Near Aneurysm
IV
Placement of Stent in Segmented Model
V
Prediction of clot using chemo-fluidic simulation
Clot volume
Pipeline for modeling the effect of flow diverting stent on aneurysm occlusion based on patient-specific data

FIG. 5

FIG. 6

Key components and steps in the chemo-fluidic modeling of the aneurysm thrombosis.

Prediction from our system of the aneurysm occlusion

Resulting from stents with different porosities for a specific patient.

FIG. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2024/056395

A. CLASSIFICATION OF SUBJECT MATTER

IPC: ***A61B 6/50*** (2024.01); ***A61B 8/08*** (2024.01); ***A61F 2/82*** (2024.01); ***G06T 17/20*** (2024.01); ***G06T 7/00*** (2024.01); ***G16H 50/50*** (2024.01); *A61B 5/026* (2024.01); *A61B 5/055* (2024.01); *A61B 6/03* (2024.01); *A61P 7/02* (2024.01)

CPC: ***A61B 6/504; A61B 8/0891; A61F 2/82; G06T 7/0012; G16H 50/50; G06T 17/20; A61B 5/02007;*** *A61P 7/02; A61B 5/026; A61B 6/03; A61B 5/055; A61B 5/0071*

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)

See Search History Document

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

See Search History Document

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

See Search History Document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	CN 109473161 A (SHANGHAI UNITED IMAGING HEALTHCARE) 15 March 2019 (15.03.2019) see machine translation	1-3, 5-14, 16-18, 20
Y	US 2012/0041739 A1 (TAYLOR) 16 February 2012 (16.02.2012) entire document	1-3, 5-14, 16-18, 20
Y	CN 219803842 U (HOU et al.) 10 October 2023 (10.10.2023) see machine translation	5
Y	US 2017/0071671 A1 (SIEMENS HEALTHCARE GMBH) 16 March 2017 (16.03.2017) entire document	9
Y	US 2014/0046642 A1 (HEARTFLOW INC.) 13 February 2014 (13.02.2014) entire document	13

☑ 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
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"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
06 January 2025 (06.01.2025)	**15 January 2025 (15.01.2025)**

Name and mailing address of the ISA/US	Authorized officer
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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2009/0311675 A1 (HOSOKAWA) 17 December 2009 (17.12.2009) entire document	14
Y	US 2015/0235569 A1 (ARIZONA BOARD OF REGENTS ON BEHALF OF ARIZONA STATE UNIVERSITY et al.) 20 August 2015 (20.08.2015) entire document	17, 18
Y	US 2019/0099145 A1 (INFINITT HEALTHCARE CO. LTD.) 04 April 2019 (04.04.2019) entire document	18
A	US 2023/0326127 A1 (SINGAPORE HEALTH SERVICES PTE LTD et al.) 12 October 2023 (12.10.2023) entire document	1-20