4-5-2012

MODEL-BASED SYSTEMS AND METHODS FOR ANALYZING AND PREDICTING OUTCOMES OF VASCULAR INTERVENTIONS AND RECONSTRUCTIONS

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US 20120084064A1

(19) **United States**

(12) **Patent Application Publication**

Dzenis et al.

(10) **Pub. No.: US 2012/0084064 A1**

(43) **Pub. Date: Apr. 5, 2012**

(54) **MODEL-BASED SYSTEMS AND METHODS FOR ANALYZING AND PREDICTING OUTCOMES OF VASCULAR INTERVENTIONS AND RECONSTRUCTIONS**

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(21) Appl. No.: **13/200,719**

(22) Filed: **Sep. 29, 2011**

Related U.S. Application Data

(60) Provisional application No. 61/387,775, filed on Sep. 29, 2010.

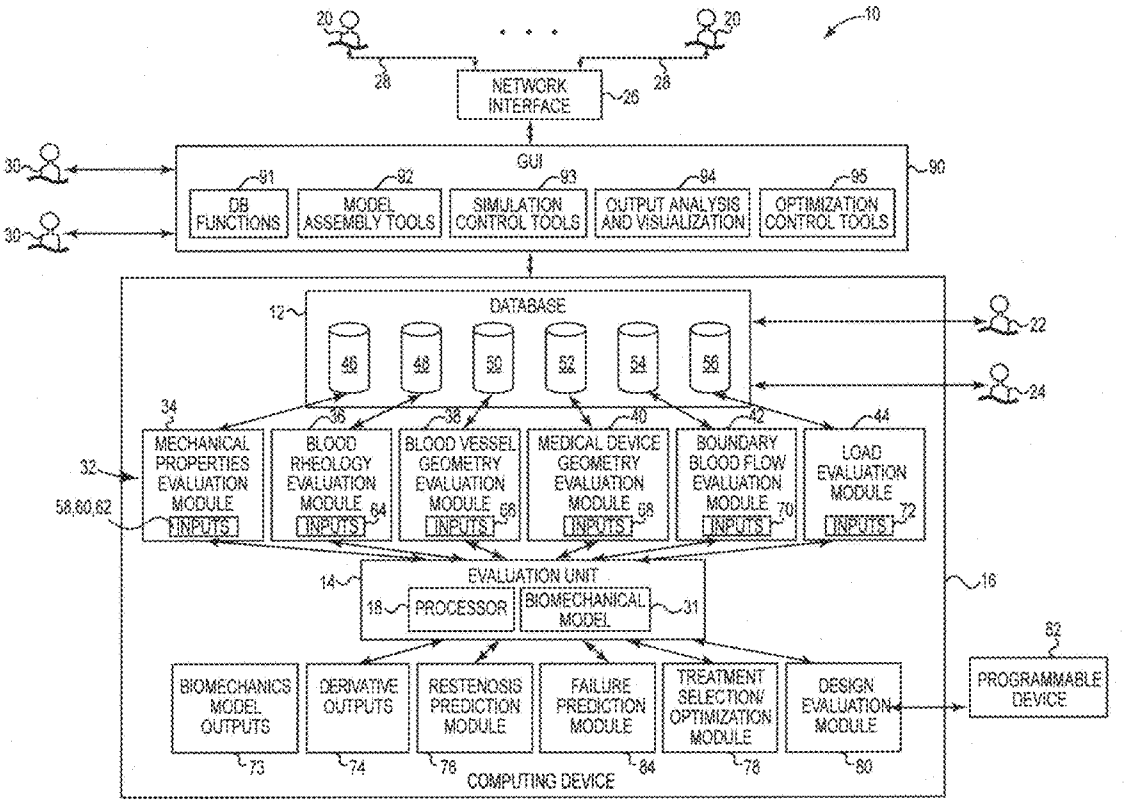
Publication Classification

(51) **Int. Cl.**
G06G 7/60 (2006.01)

(52) **U.S. Cl.** **703/11**

(57) **ABSTRACT**

Systems and methods for analyzing and predicting treatment outcomes of medical procedures such as vascular interventions and reconstructions are disclosed. An illustrative system for analyzing and predicting therapeutic outcomes of medical procedures comprises a relational database configured for classifying and storing patient specific input data for multiple patients, a fluid-solid interaction biomechanical model configured for performing a biomechanics simulation and generating biomechanics data, and a graphical user interface.



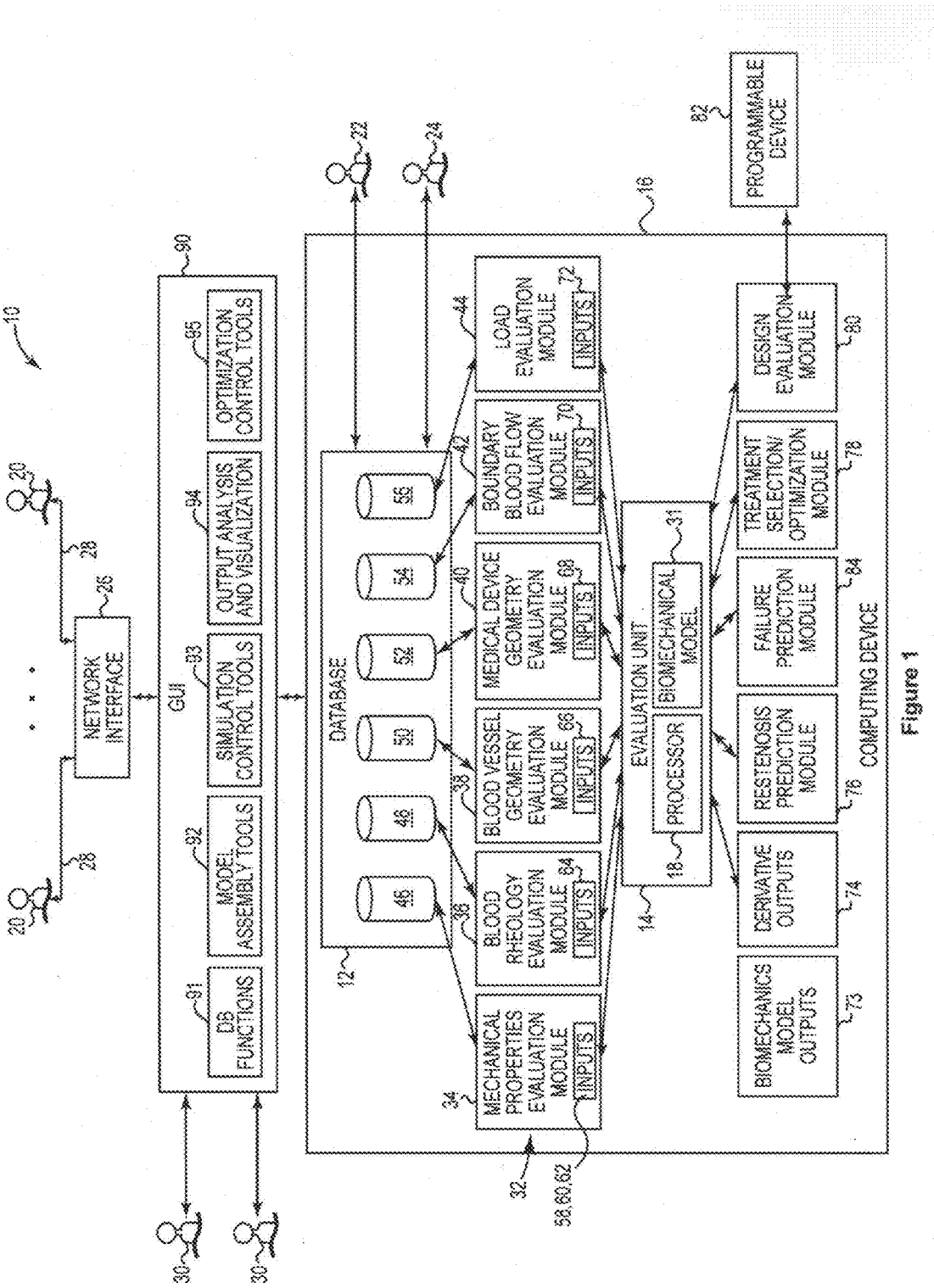

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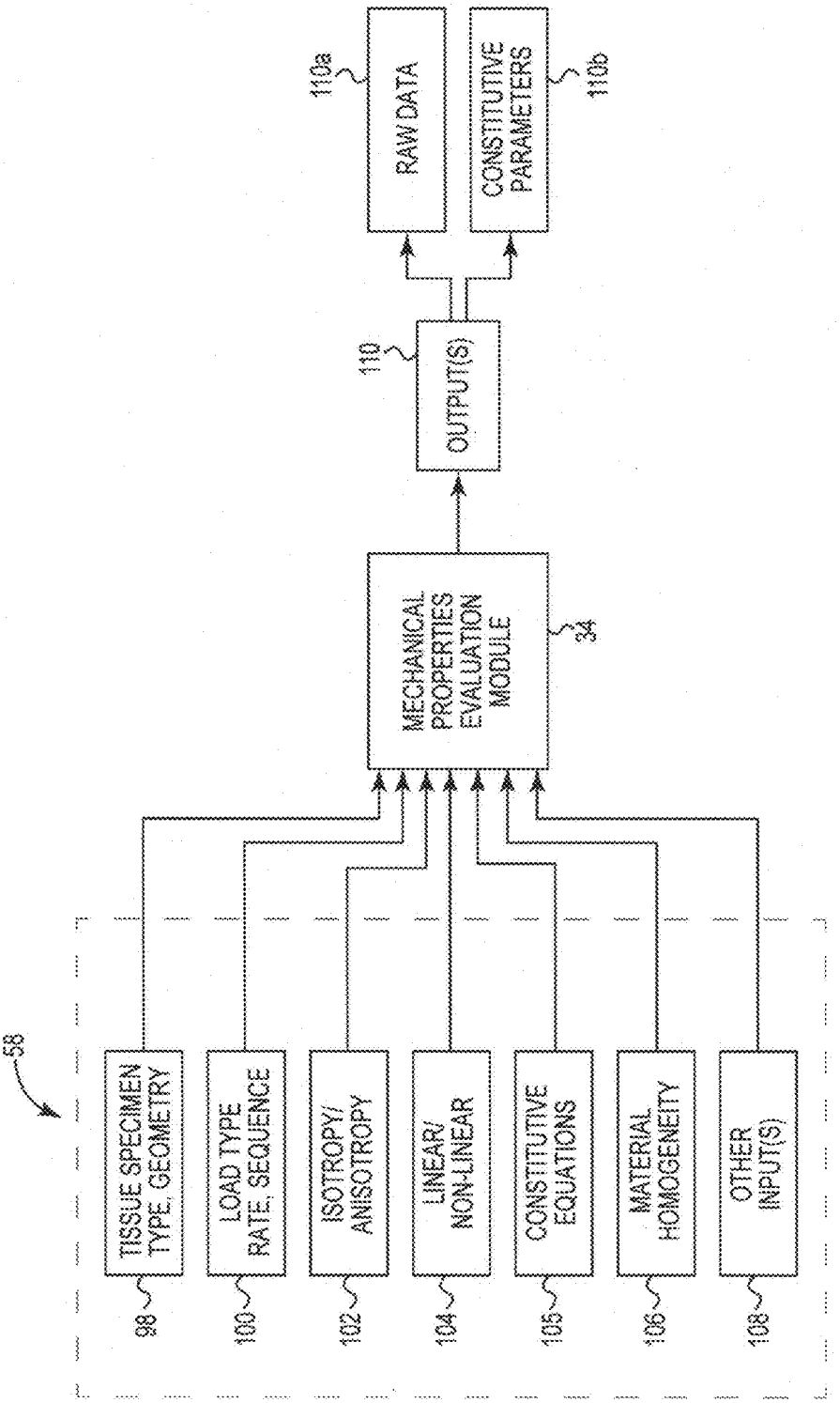
Figure 1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100
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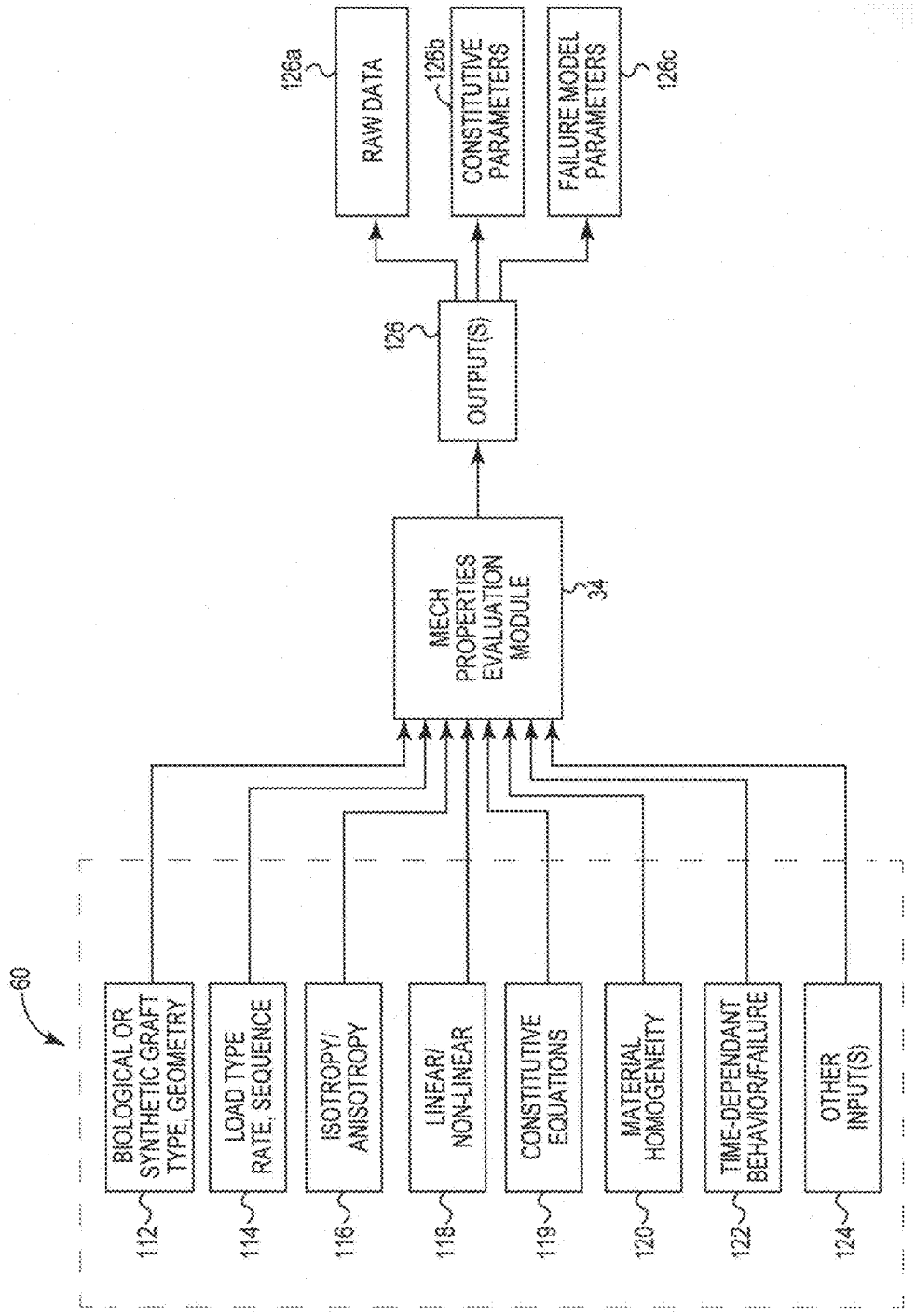
Figure 2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112
LOAD TYPE RATE, SEQUENCE
114
ISOTROPY/ ANISOTROPY
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LINEAR/ NON-LINEAR
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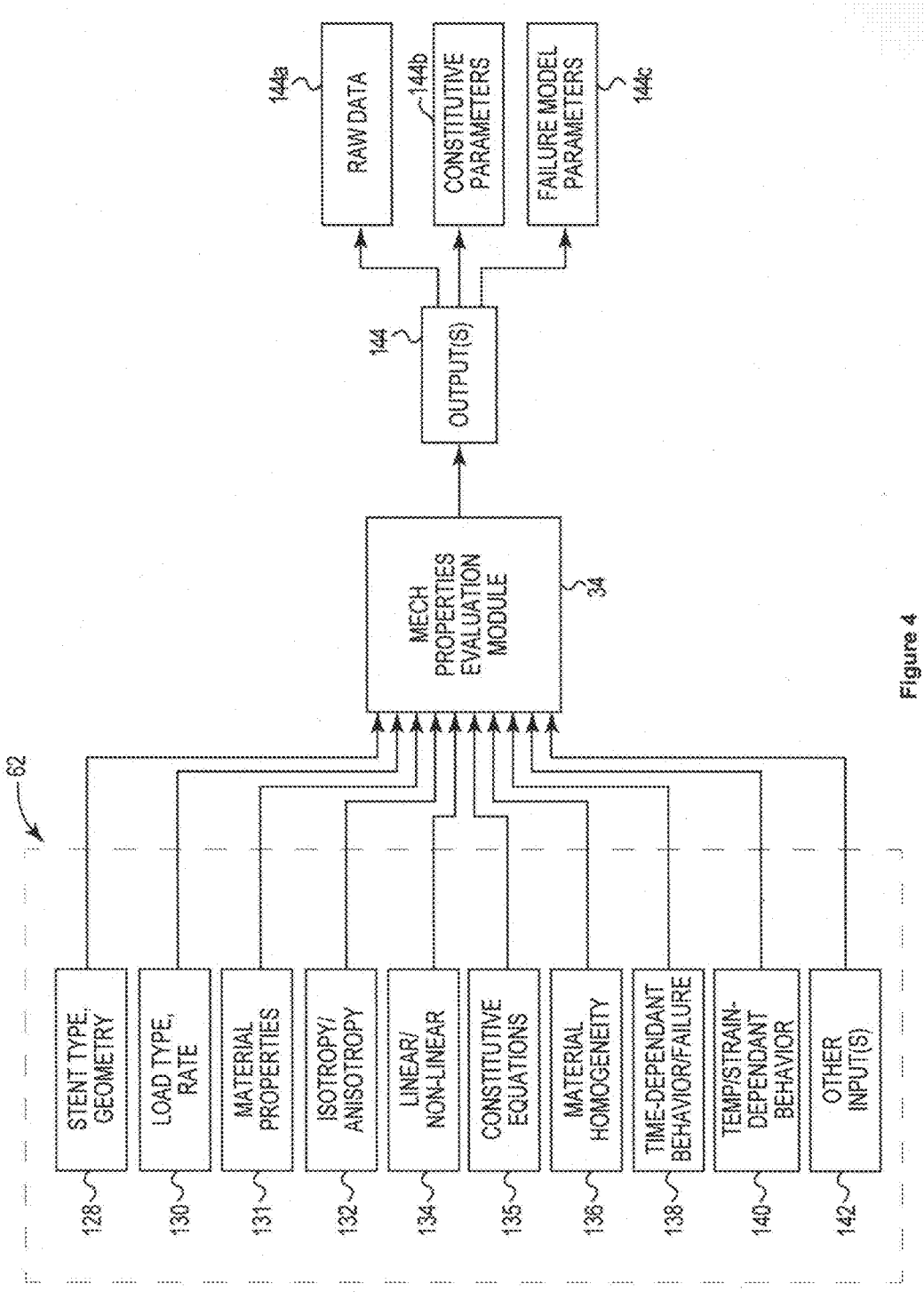
Figure 3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34
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RAW DATA
144a
CONSTITUTIVE PARAMETERS
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Figure 4

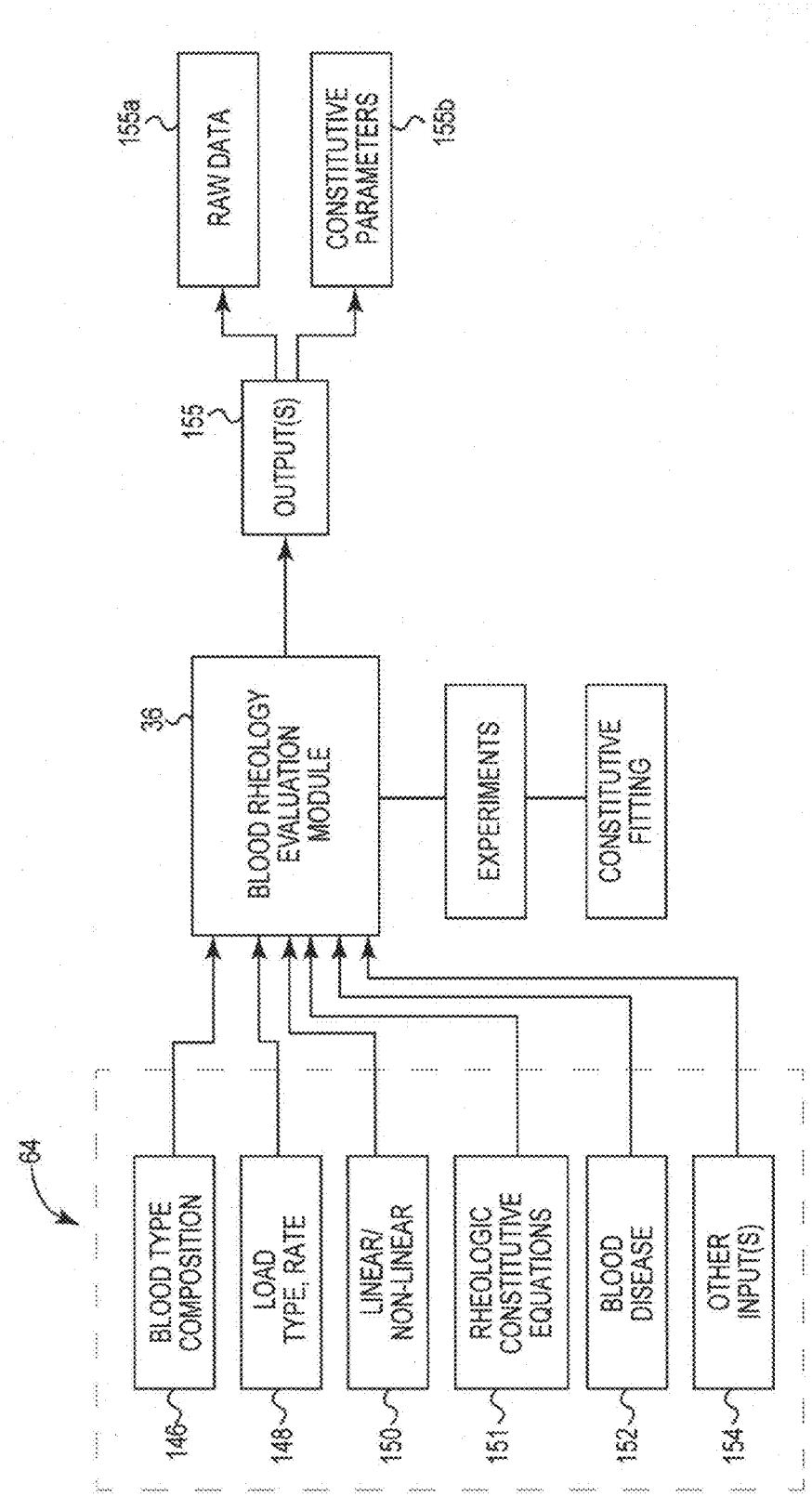
64
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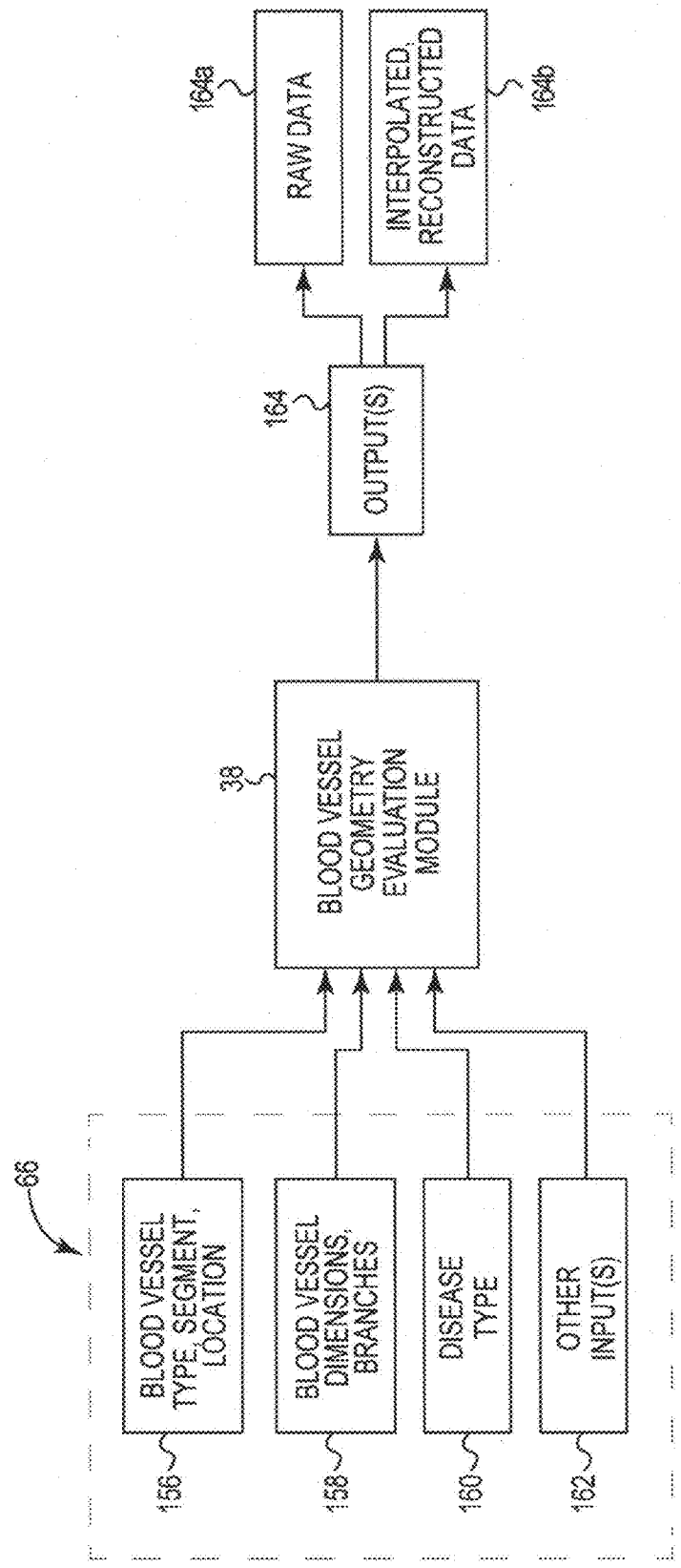
Figure 5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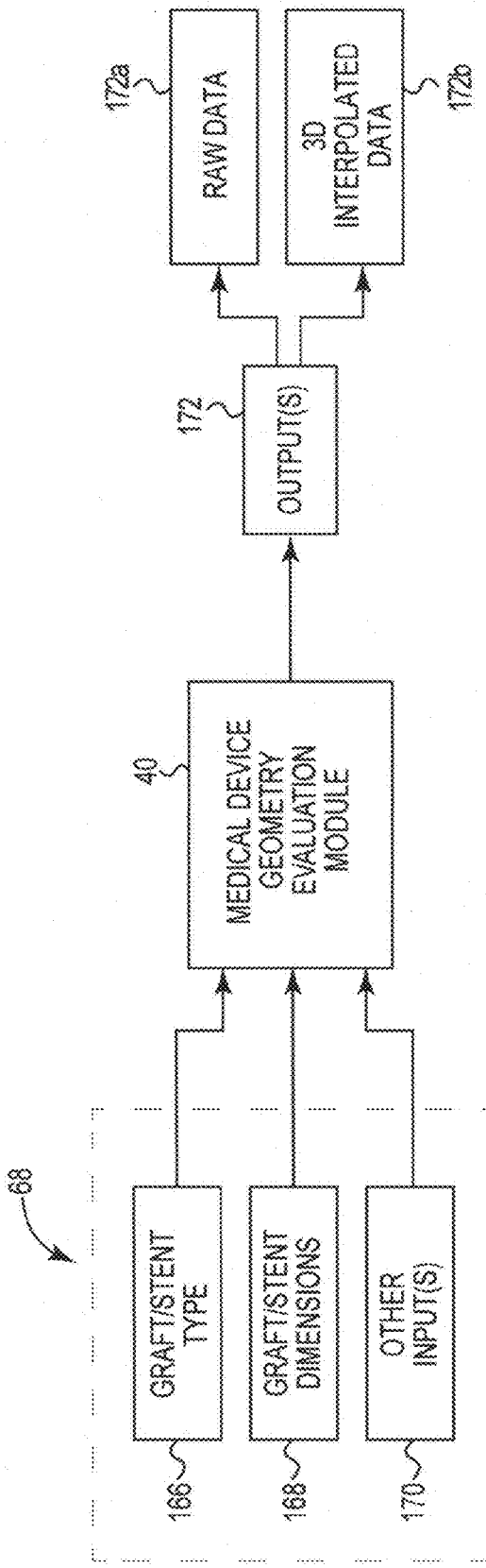
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Figure 7

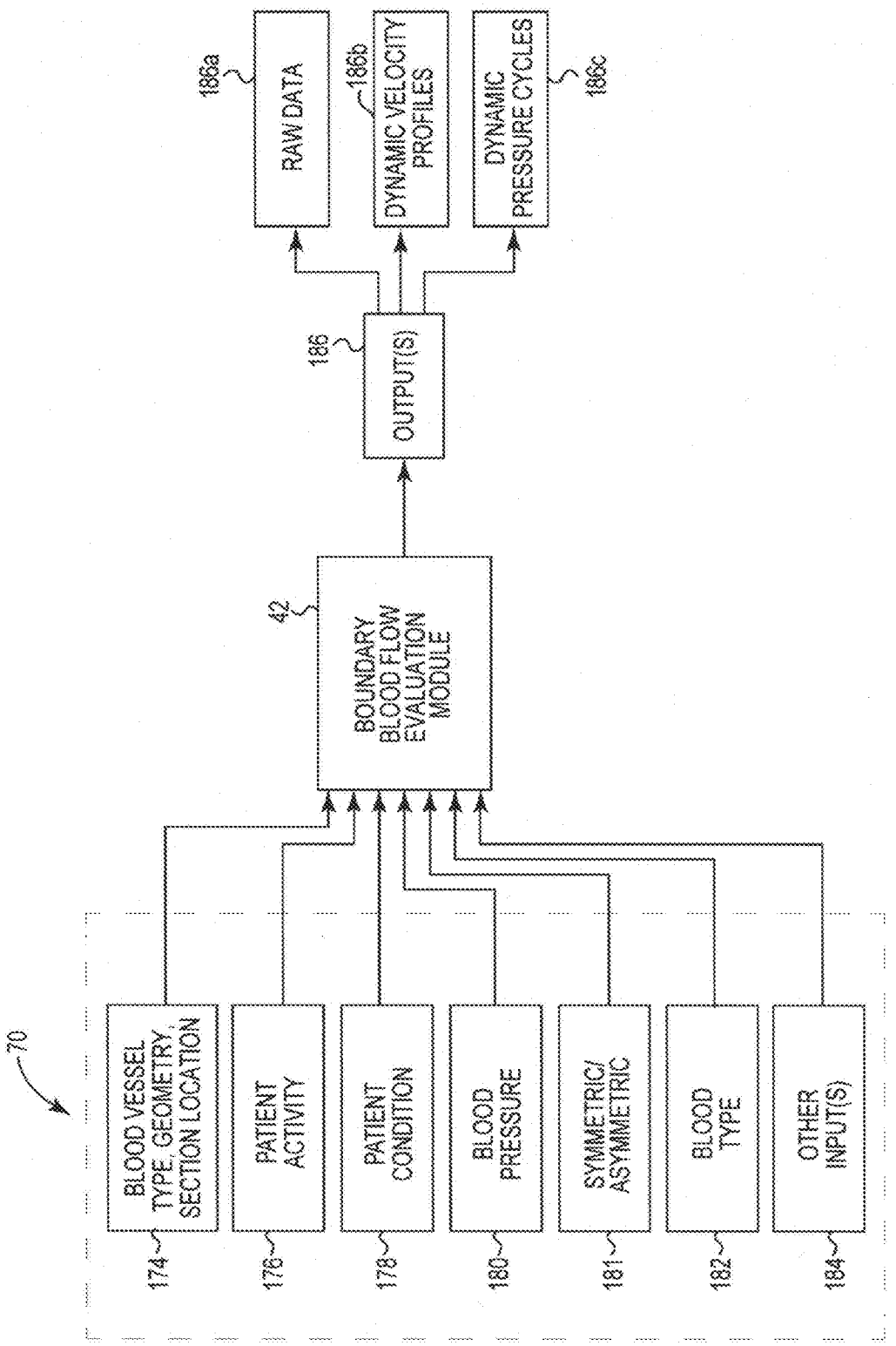
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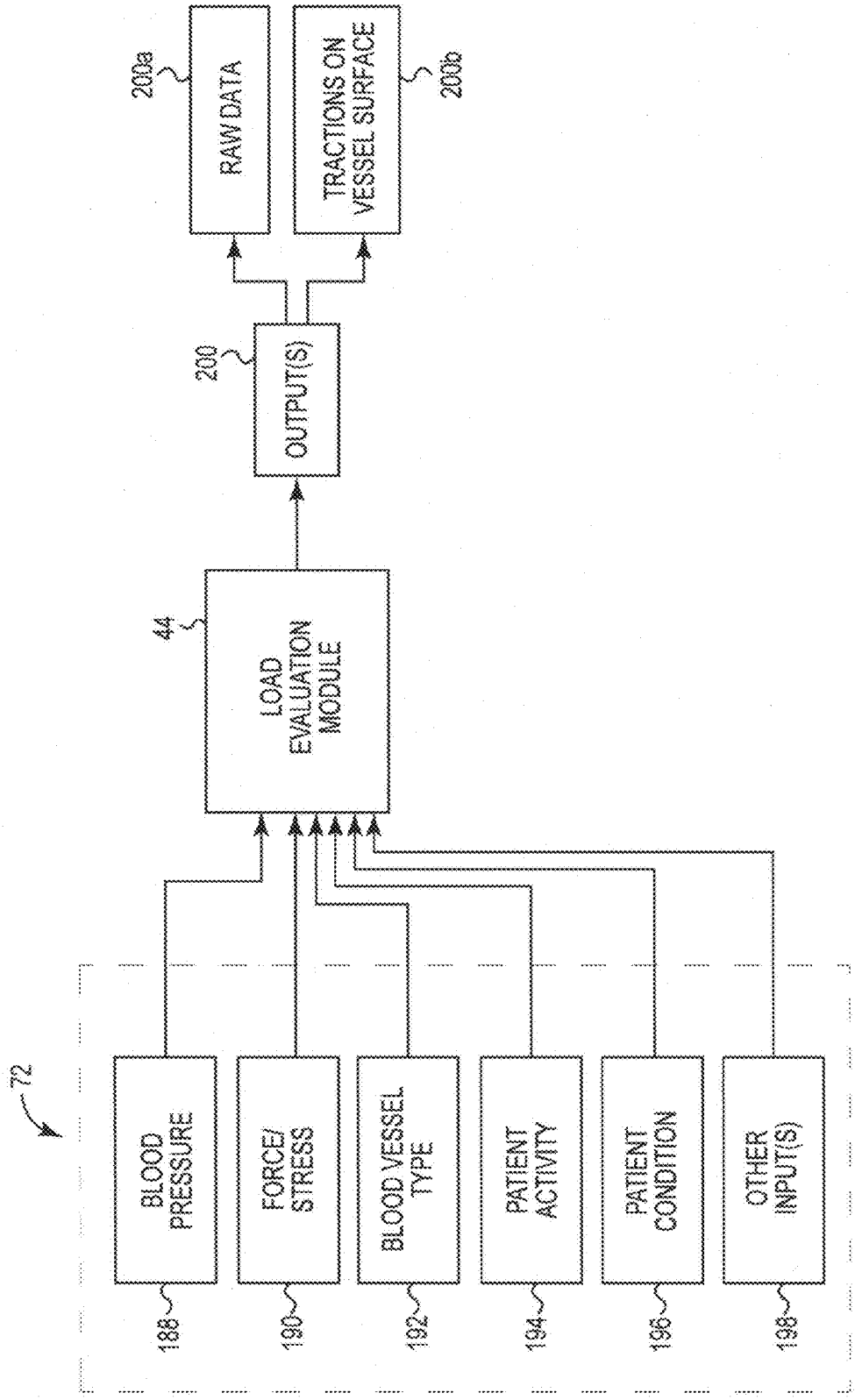
Figure 8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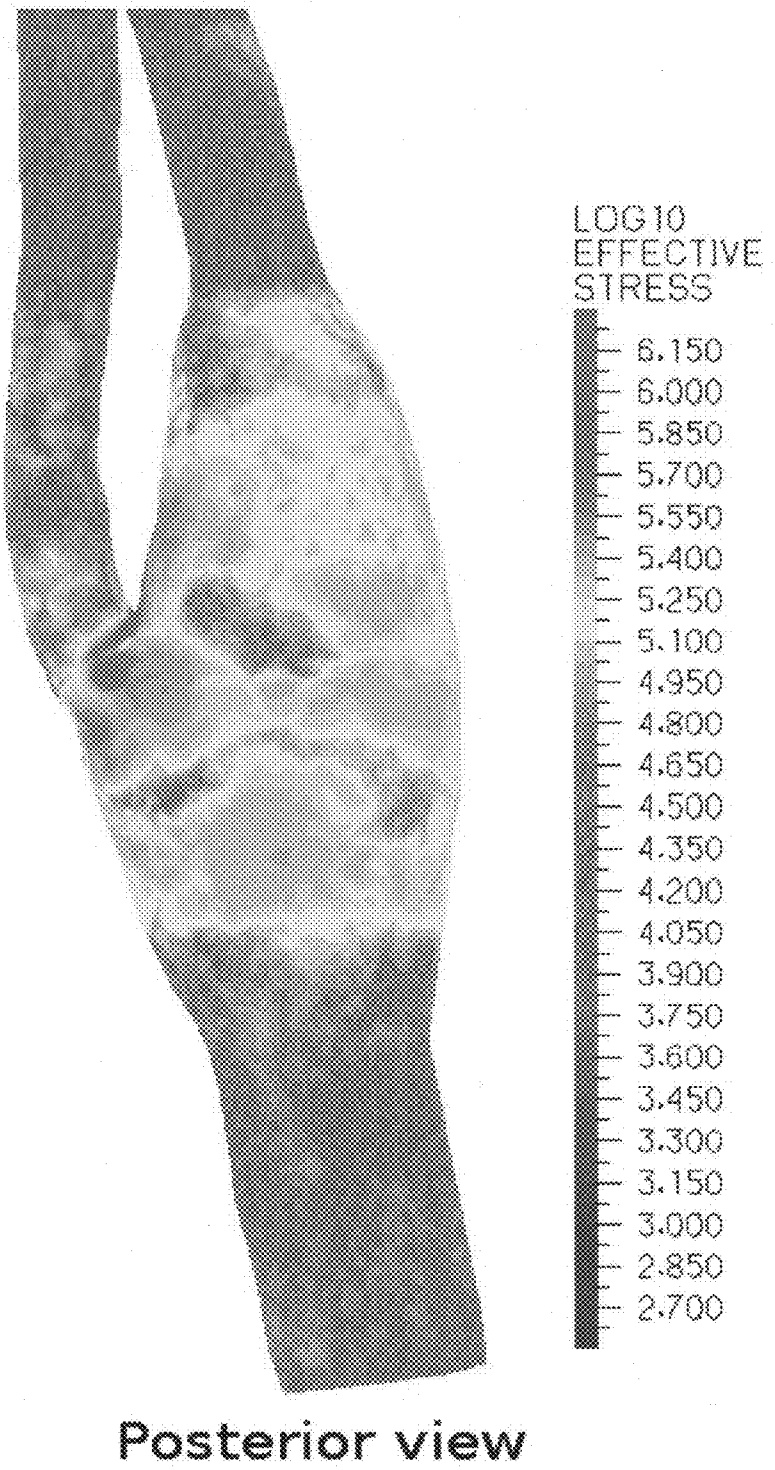
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EFFECTIVE
STRESS
6.150
6.000
5.850
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5.250
5.100
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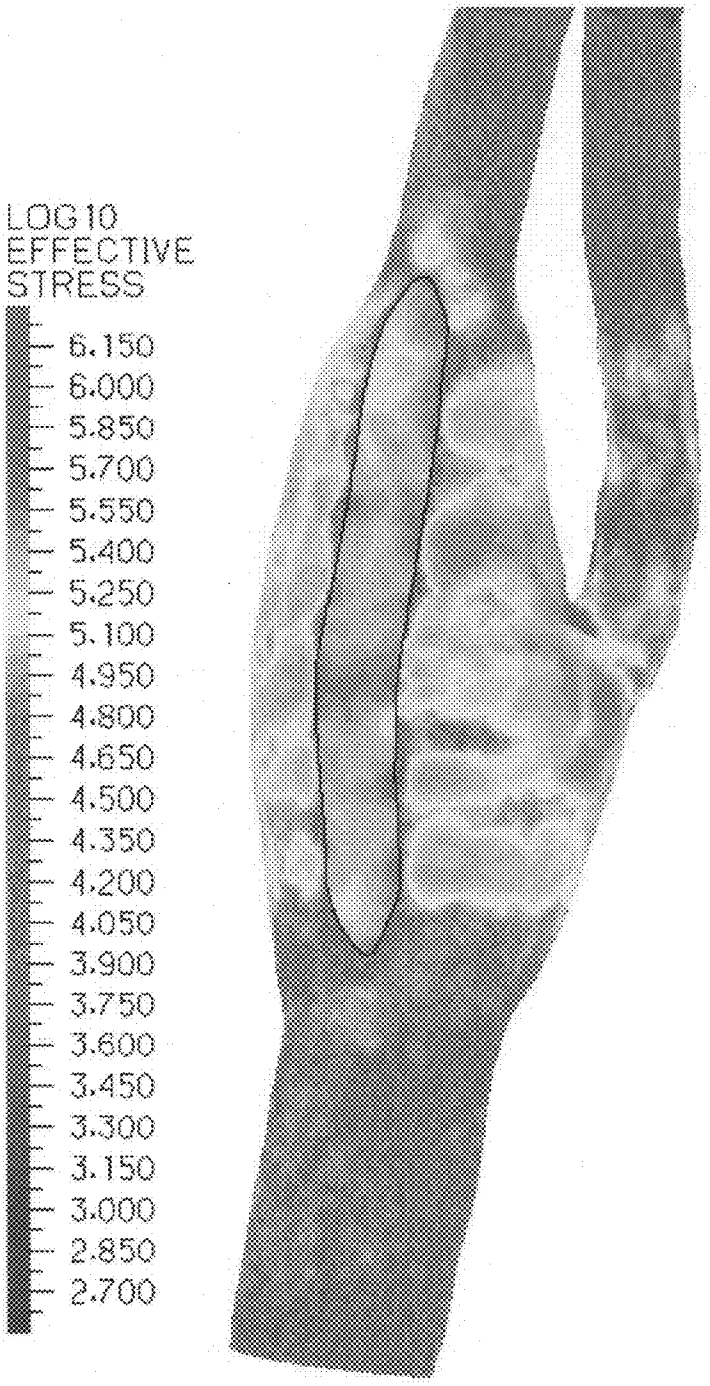
4.650
4.500
4.350
4.200
4.050
3.900
3.750
3.600
3.450
3.300
3.150
3.000
2.850
2.700
Posterior view

Fig. 10a


LOG10
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6.000
5.850
5.700
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5.100
4.950
4.800
4.650
4.500
4.350
4.200
4.050
3.900
3.750
3.600
3.450
3.300
3.150
3.000
2.850
2.700
Anterior view

Fig. 10b

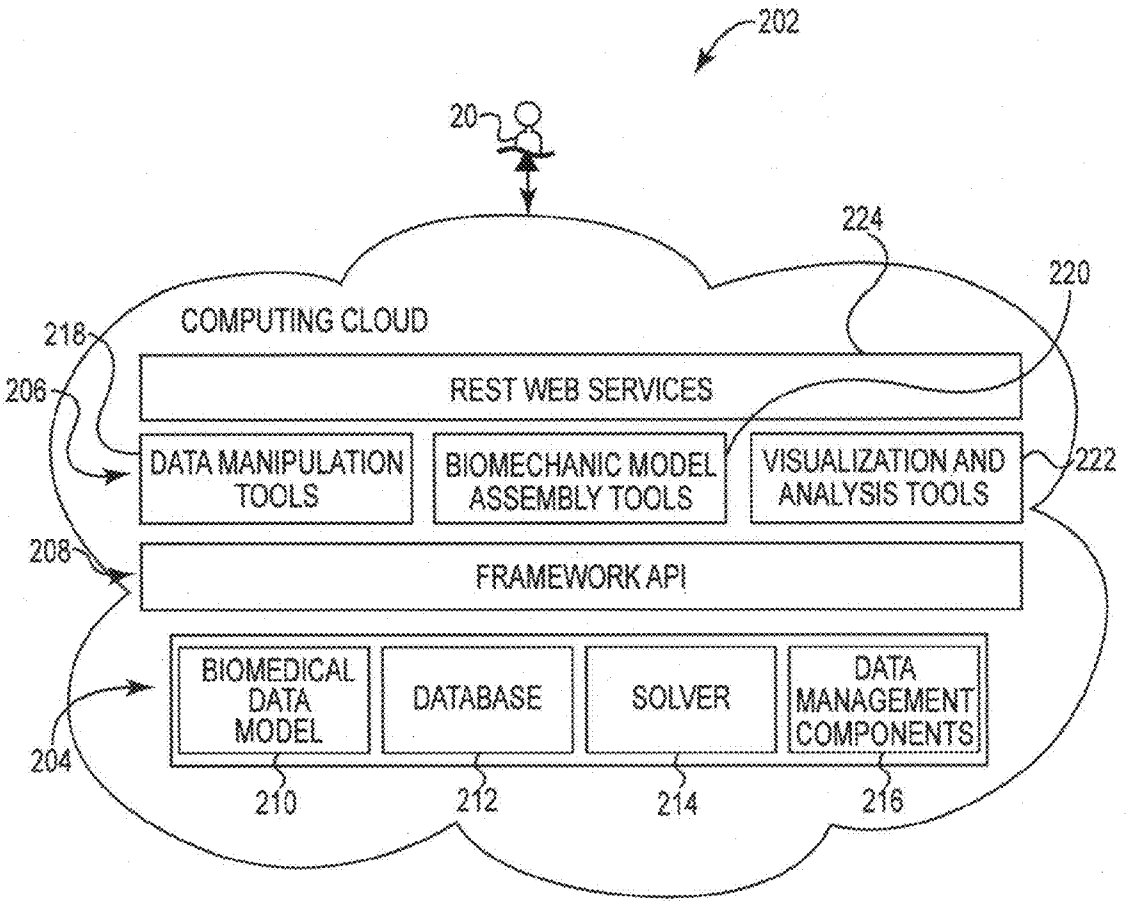
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Fig. 11

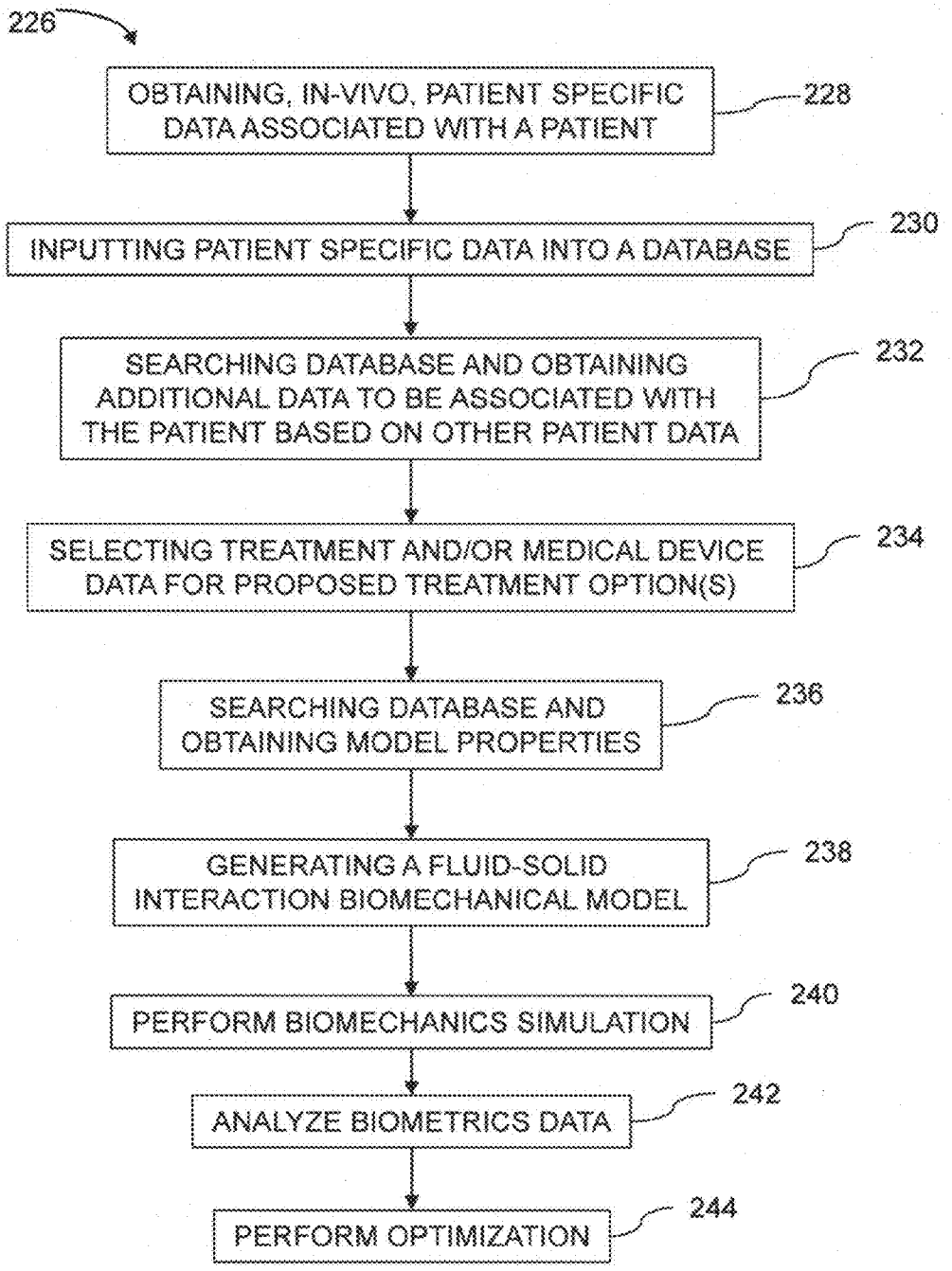
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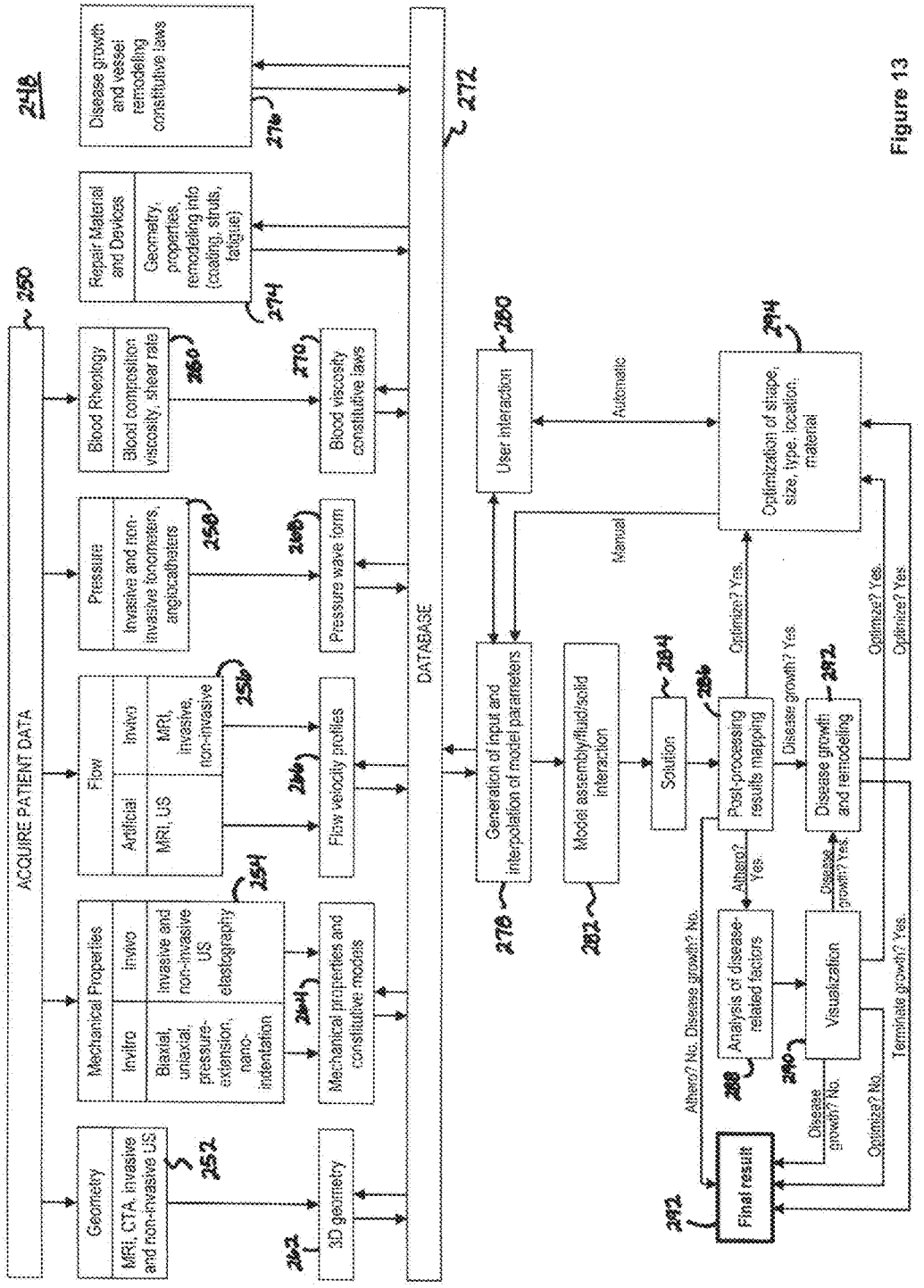
Fig. 12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Disease growth? Yes
Atherol? Yes.
Atherol? No. Disease growth? No.
Disease growth? No.
Optimize? No.
Terminate growth? Yes.
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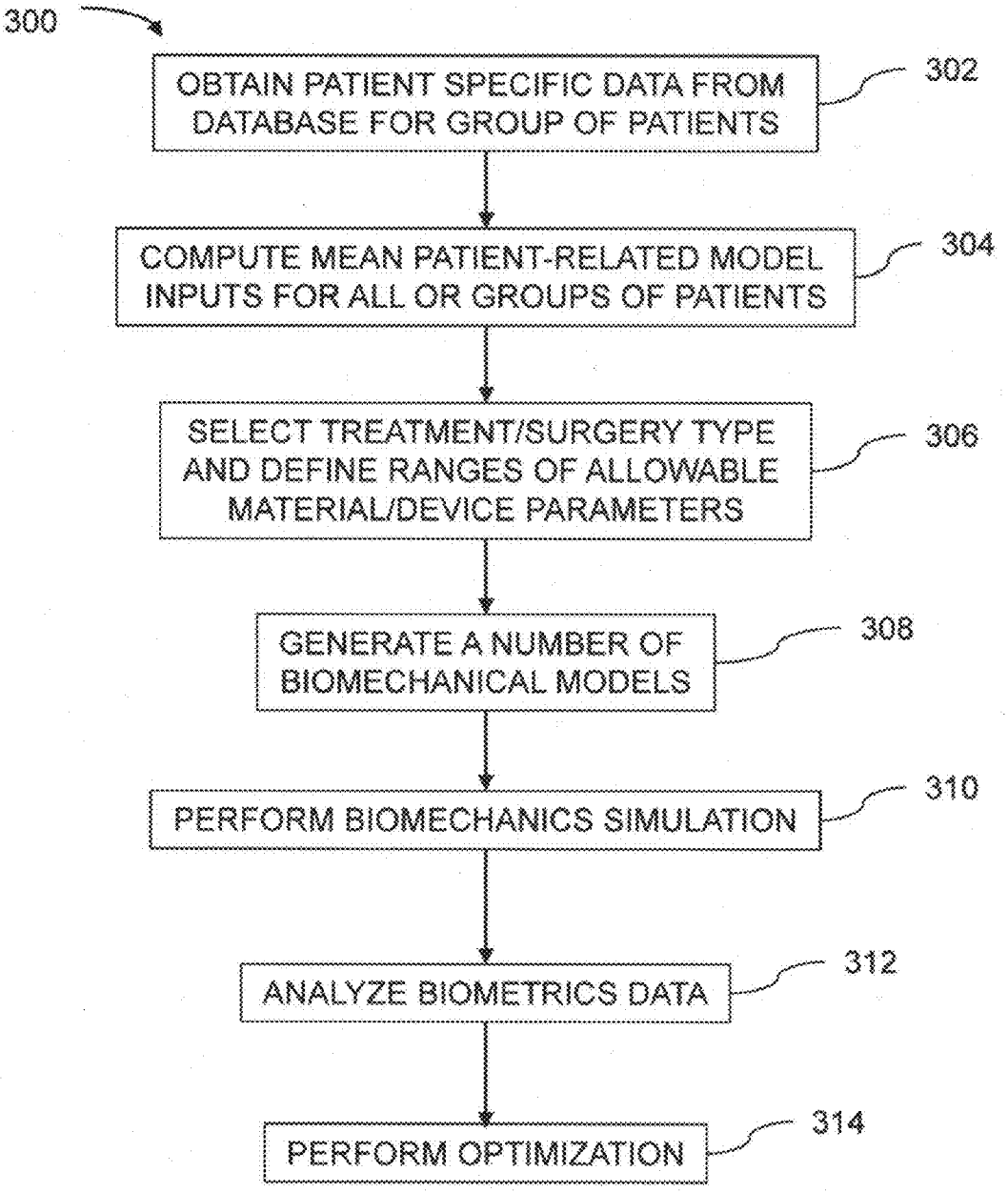
Figure 13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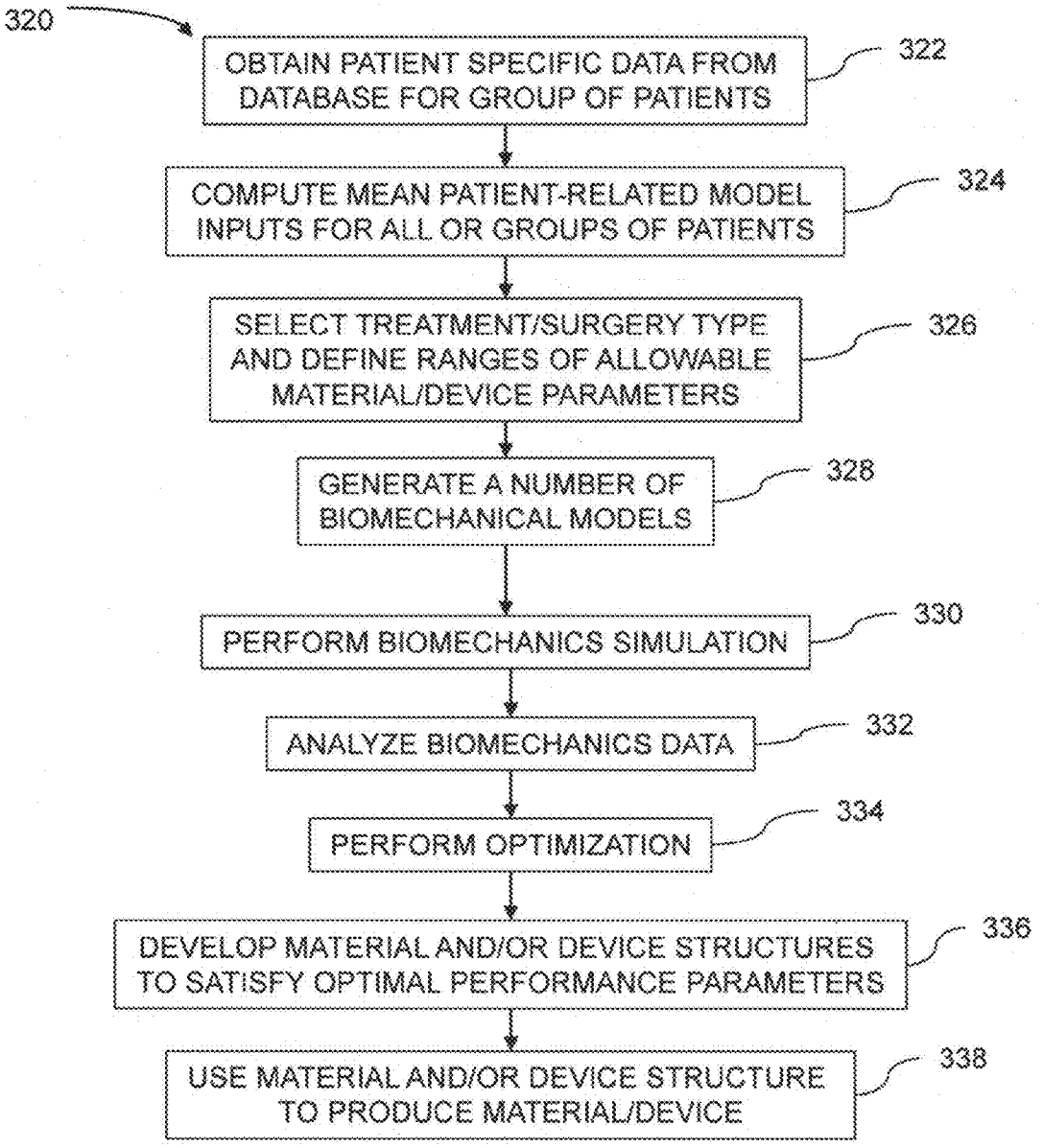
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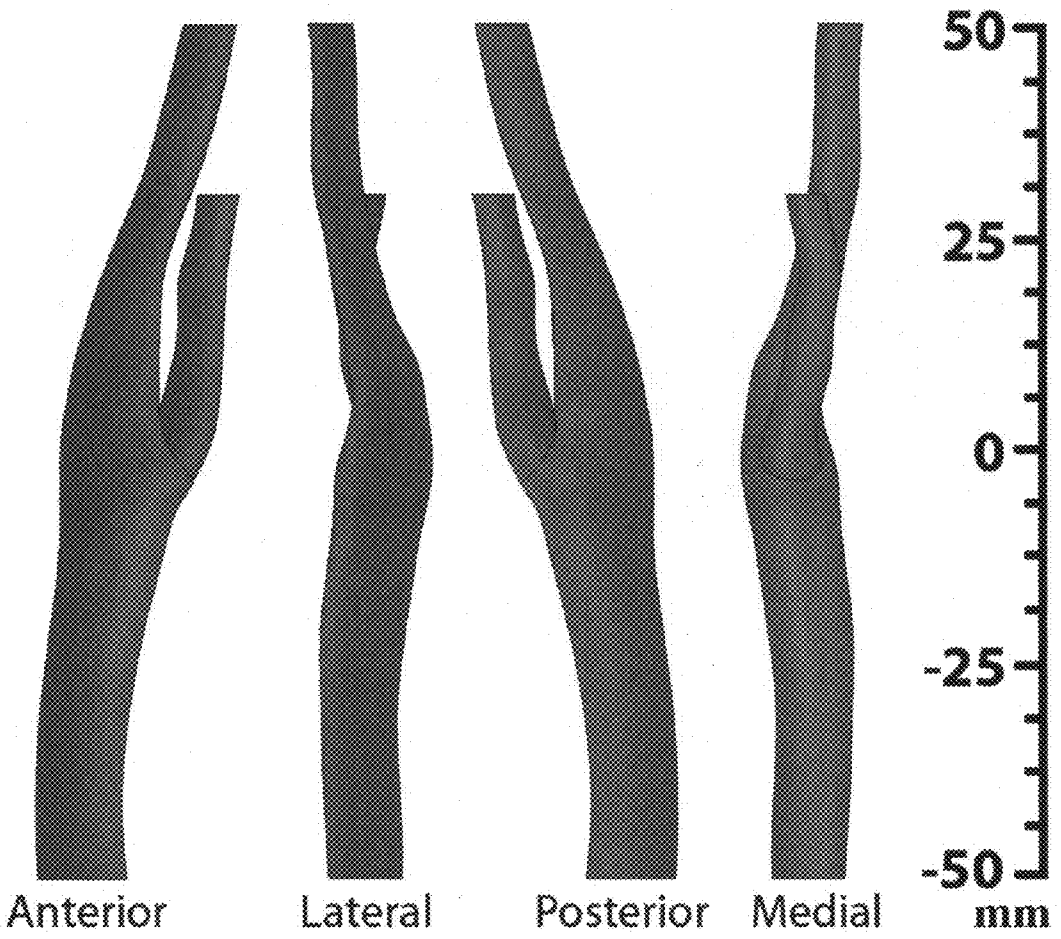


Fig. 16

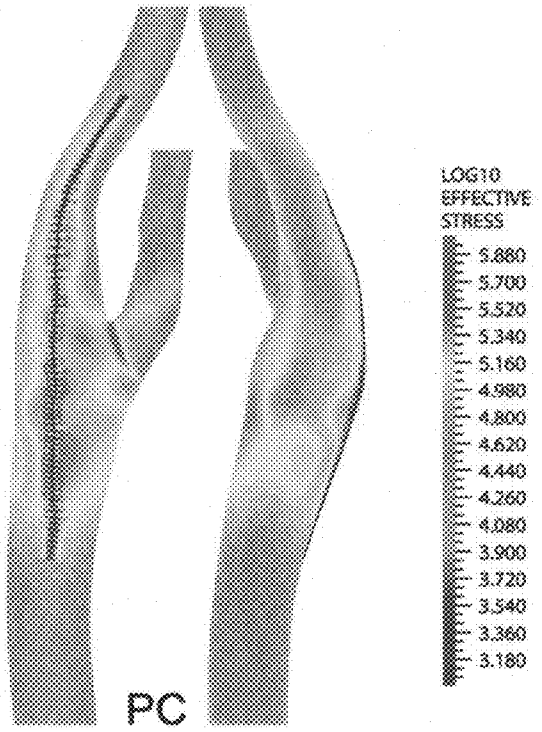


Fig. 17a

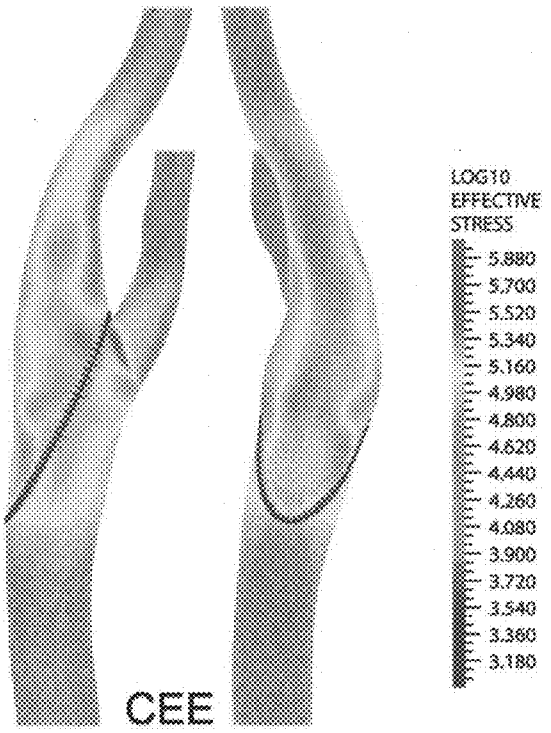


Fig. 17b

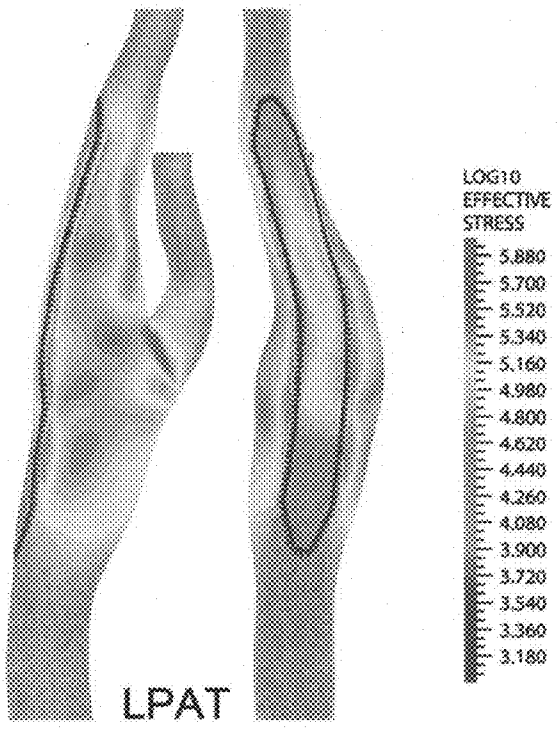


Fig. 17c

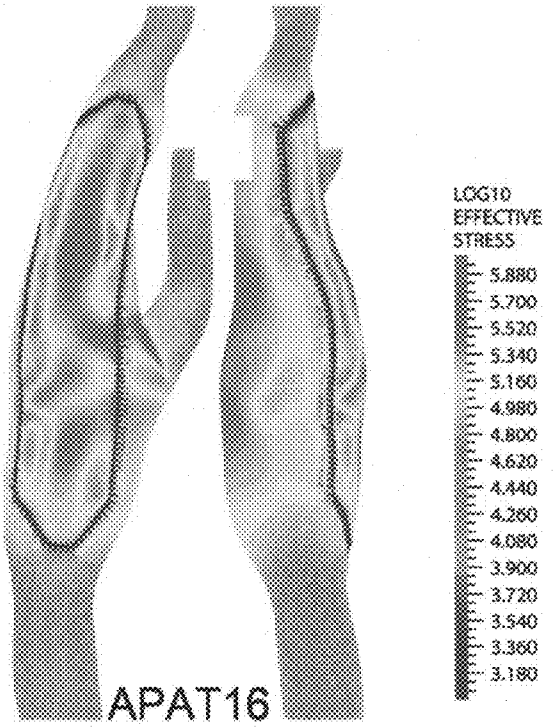
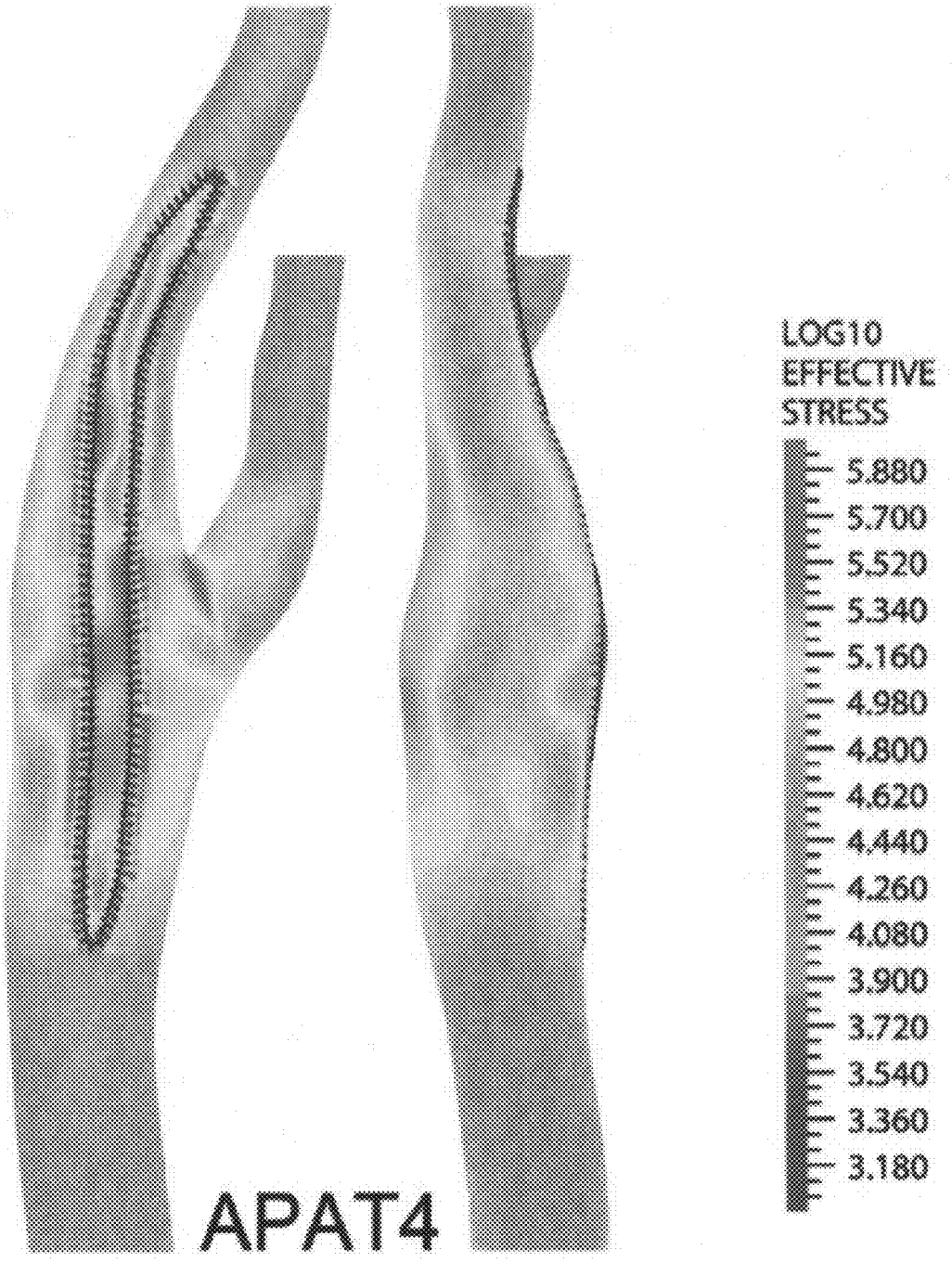


Fig. 17d


LOG10
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3.900
3.720
3.540
3.360
3.180
APAT4

Fig. 17e

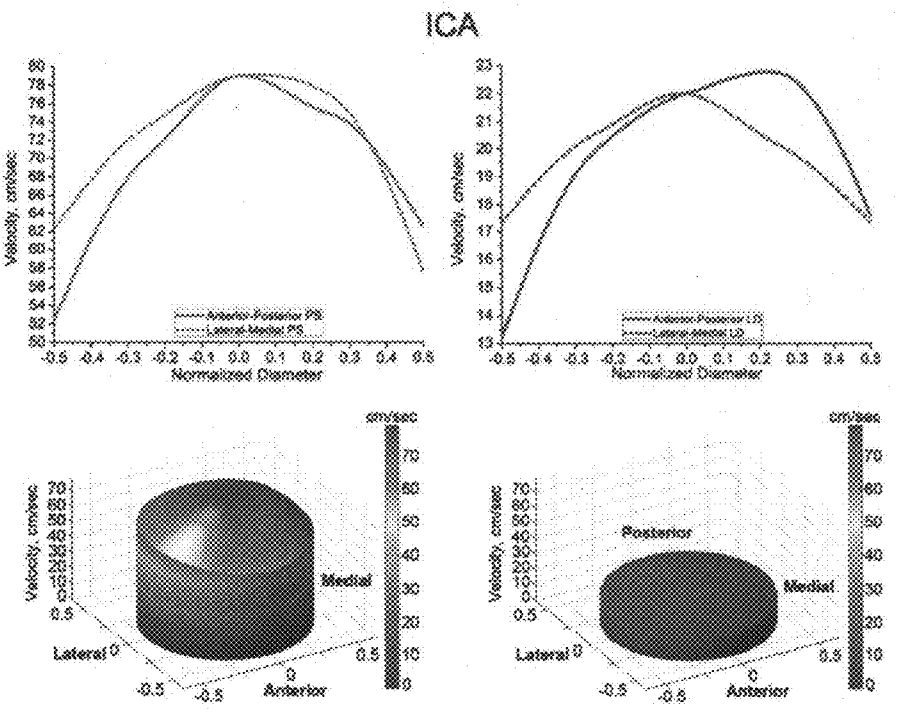

Fig. 18a

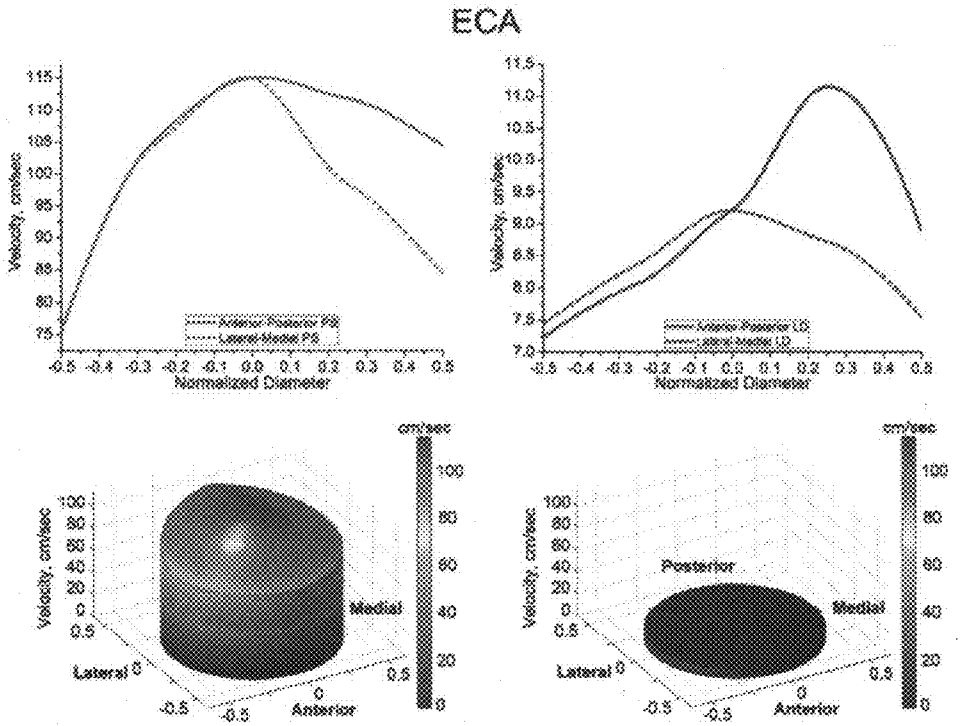

Fig. 18b

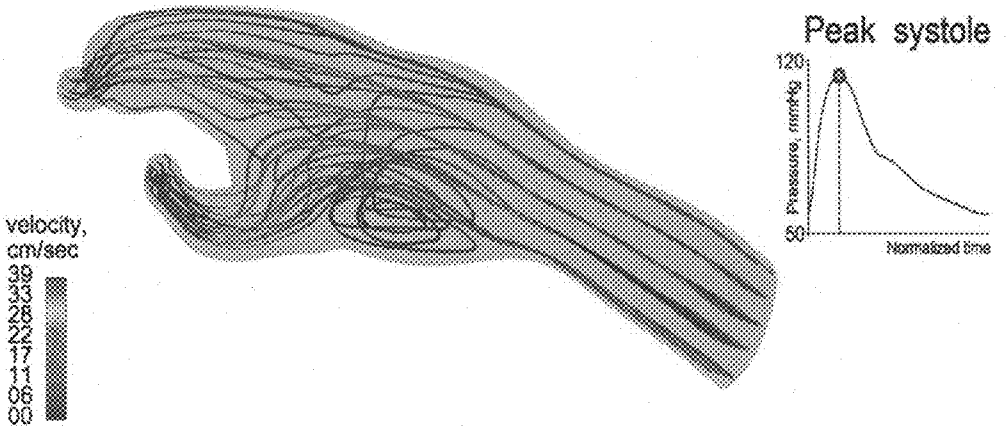

Fig. 19a

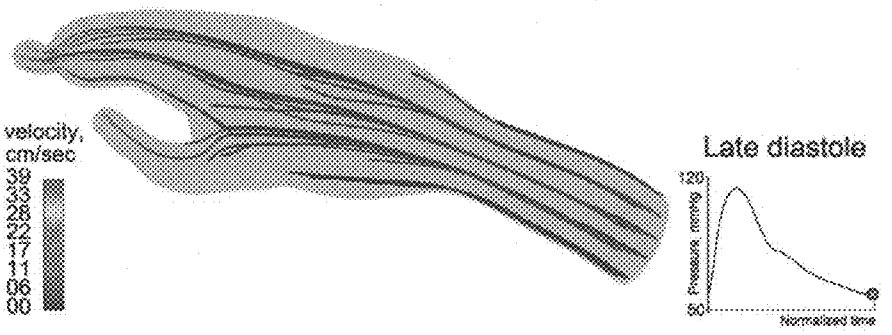

Fig. 19b

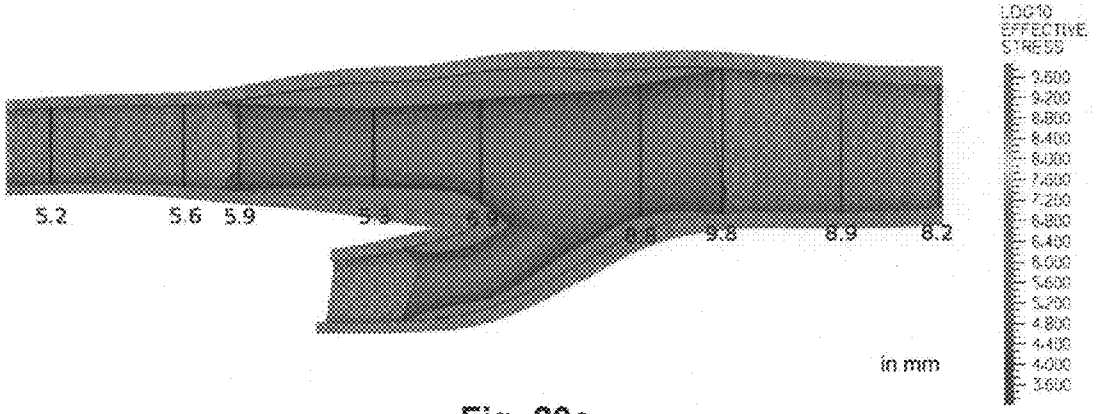

Fig. 20a

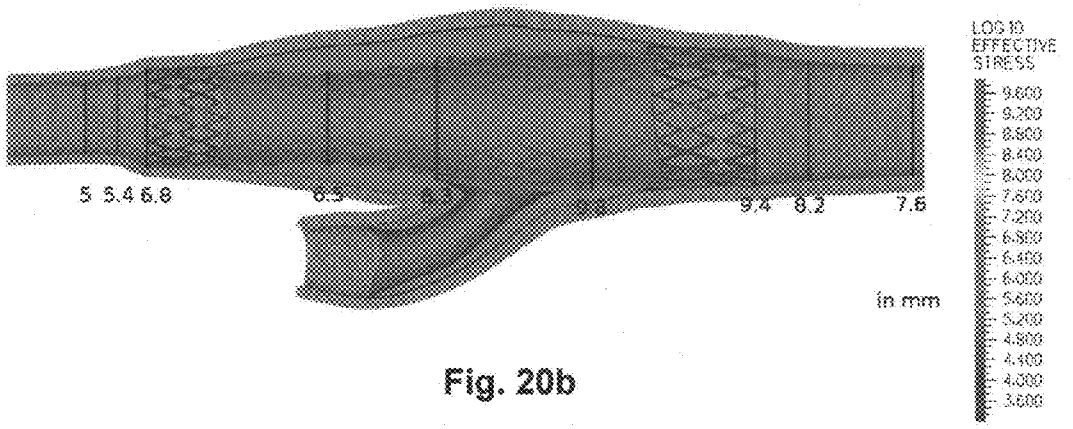

Fig. 20b

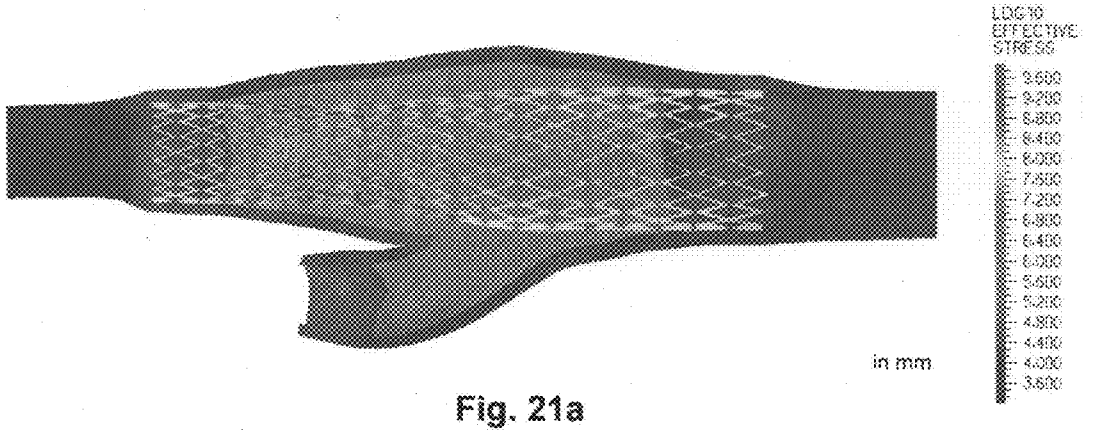

Fig. 21a

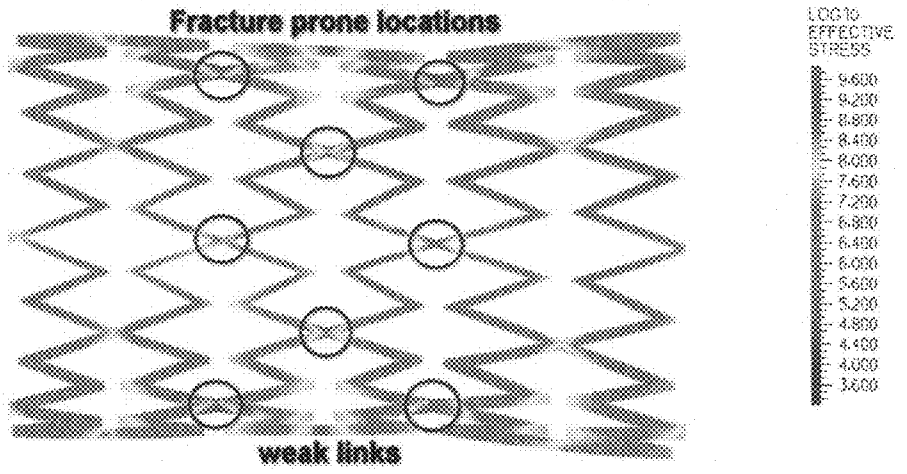

Fig. 21b

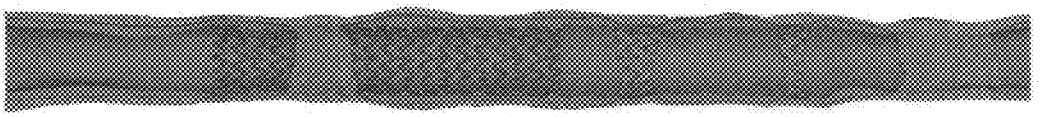

Fig. 22a

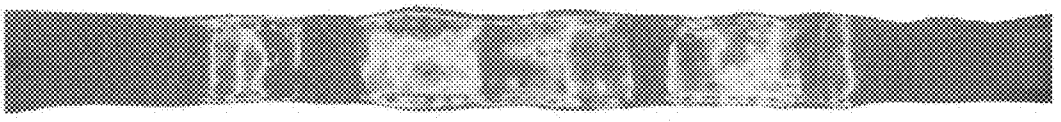

Fig. 22b

MODEL-BASED SYSTEMS AND METHODS FOR ANALYZING AND PREDICTING OUTCOMES OF VASCULAR INTERVENTIONS AND RECONSTRUCTIONS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to U.S. Provisional Application No. 61/387,775, entitled "Method For Selection of Patches For use In Vascular Interventions and Reconstructions," filed on Sep. 29, 2010, the contents of which are incorporated herein by reference in their entirety for all purposes.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] This invention was made with government support under NSF grant EPS-0701892. The government has certain rights in the invention.

TECHNICAL FIELD

[0003] The present disclosure relates generally to systems and methods for analyzing and predicting outcomes of vascular interventions, reconstructions, and other medical procedures.

BACKGROUND

[0004] Cardiovascular disease is the failure of the circulatory system to supply adequate amounts of blood to organs and tissue. Cardiovascular disease affects more than eighty million people in the United States alone, and is the single leading cause of death and disability for both men and women in the developed world. In many cases, cardiovascular disease is caused by atherosclerosis, or the narrowing of the arteries due to fatty build ups called atheromatous plaques. These plaques can also include scar tissue, cholesterol, calcium, and other substances contained in the blood.

[0005] In severe cases of the disease, reestablishment of blood flow in narrowed or blocked arteries can only be achieved with vascular interventions and reconstructions. Among blood vessels frequently repaired are the carotid, aortoilliac, peripheral, mesenteric, renal, and arm arteries. The surgical and interventional procedures used to treat severely affected blood vessels can be classified as either open or endovascular surgery. The former can be in the form of a bypass surgery involving synthetic or natural grafts or an endarterectomy procedure in which the atherosclerotic plaque is surgically removed through an incision on the side of the blood vessel. Endarterectomy procedures often involve the use of a patch of natural or synthetic material to close the incision formed in the vessel wall in order to maintain proper blood flow. Angioplasty is a minimally invasive, catheter-based vascular technique in which a small balloon is inflated inside a narrowed blood vessel, opening up the vessel for improved blood flow. After the angioplasty, a mesh-like stent is frequently deployed in the vessel to maintain long-term patency of the vessel after the procedure.

[0006] Other vascular diseases that can be treated with surgical procedures involving vascular grafts include abdominal and thoracic aortic aneurysms and peripheral arterial aneurysms (e.g., poplietal, femoral, carotid, arm, or visceral aneurysms). For aortic aneurysms, synthetic or natural grafts are typically used in the repair of the affected vessels. For peripheral aneurysms, bypass or replacement procedures are typically used. Endovascular stent-grafts or covered stents are sometimes used in the minimally invasive treatment of aneurysms.

[0007] Many of the treatment techniques used for treating cardiovascular disease have been shown to increase life expectancy and decrease the length of hospitalization and postoperative care. For example, endarterectomy procedures used for treating the carotid artery have been shown to reduce the risk of stroke in patients with moderate and high-grade symptomatic and high-grade asymptomatic carotid bifurcation stenoses. Cartoid endarterectomy followed by patch angioplasty has also been shown to decrease the incidence of early and late complications associated with the performance of carotid endarterectomy. A variety of synthetic and biological patches have been developed and are available for endarterectomy procedures. Alternatively, a variety of stents and stent-graft are also available.

[0008] One complication associated with some surgical and interventional procedures is the postoperative restenosis of the reconstructed vessel. Restenosis often starts as neointimal hyperplasia or abnormal growth of new tissue over or near the graft or stent. This is often followed by new atherosclerotic plaque build-up near or inside the graft or stent. Restenosis affects as many as 20 to 30 percent of all arterial reconstructions, and in some instances can affect a greater percentage of patients depending on the type of blood vessel being repaired and the characterization of the restenosis. Both neointimal hyperplasia and atherosclerosis have been linked to various forms of insult to the arterial wall. Such insult may be produced by the increased stresses and injury in reconstructed or treated blood vessels or by the atherogenic influence of the flow and oscillatory wall shear stress in the blood flow. Another possible complication is the mechanical failure of stents or stent-grafts.

[0009] The mechanical factors leading to restenosis or device failure cannot be imaged or measured using existing experimental techniques. However, they can be predicted using biomechanics modeling. The problem of accurately predicting these disease-related mechanical and flow factors in surgically repaired blood vessels is a complex non-linear fluid-solid interaction problem. The outcomes highly depend on the large number of inputs and data that are known to vary broadly based on the individual characteristics of the patient, stage and type of disease, and multiple other conditions. Currently, there are no known systems or methods to systematically evaluate, visualize, and optimize these mechanical and flow factors as a result of the reconstruction or treatment. Such optimization, however, could decrease the incidence of neointimal hyperplasia and atherosclerosis by selecting an appropriate medical device or a suitable course of treatment for a particular patient or group of patients. The optimization based on predictive modeling could also lead to new and improved repair materials and devices.

SUMMARY

[0010] The present disclosure relates generally to model-based systems and methods for analyzing and predicting outcomes of vascular interventions, reconstructions, or other medical procedures.

An illustrative method for analyzing and predicting treatment outcomes of vascular interventions and reconstructions comprises: inputting patient specific data associated with a patient into a database; searching the database and obtaining addi-

tional data to be associated with the patient, wherein the additional data is obtained based at least in part on patient specific data stored within the database for one or more other patients; selecting at least one of a treatment parameter or medical device parameter to be used in association with a proposed treatment option for treating the patient; searching the database and obtaining one or more model properties associated with the treatment or medical device parameter; generating a fluid-solid interaction biomechanical model based at least in part on the patient specific data, the additional data associated with the patient, and the model properties; performing a biomechanics simulation and generating biomechanics data using the biomechanical model; and analyzing the biomechanics data.

[0011] An illustrative system for analyzing and predicting therapeutic outcomes in medical procedures comprises: a relational database configured for classifying and storing patient specific input data for a plurality of patients; a means for obtaining and inputting patient specific input data to the database; a means for selecting additional data to be associated with the patient in the database; a means for inputting treatment related and medical device related parameters to the database; a means for selecting treatment type, inputting model parameters, and assembling a biomechanical model based on the selected treatment type, the patient specific data, the additional data associated with the patient, and the treatment and medical device related parameters; a processor and fluid-solid interaction biomechanical model configured for performing a biomechanics simulation and generating biomechanics data, the fluid-solid biomechanical model comprising time-dependent, three-dimensional solid and fluid equations; a means for evaluating the outcomes of the biomechanics simulation; and an interface configured for exchanging data between the database and a plurality of users.

[0012] While multiple embodiments are disclosed, still other embodiments of the present invention will become apparent to those skilled in the art from the following detailed description, which shows and describes illustrative embodiments of the invention. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

[0014] FIG. **1** is a schematic view of a model-based system for analyzing and predicting outcomes of vascular interventions and reconstructions in accordance with an illustrative embodiment;

[0015] FIG. **2** is a schematic view showing several example input parameters for use by the mechanical properties evaluation module of FIG. **1** in analyzing biological materials and anatomical structures;

[0016] FIG. **3** is a schematic view showing several example input parameters for use by the mechanical properties evaluation module of FIG. **1** in analyzing the behavior of synthetic grafts;

[0017] FIG. **4** is a schematic view showing several example input parameters for use by the mechanical properties evaluation module of FIG. **1** in analyzing the behavior of stents;

[0018] FIG. **5** is a schematic view showing several example input parameters for use by the blood rheology evaluation module of FIG. **1** in analyzing rheological behavior of blood;

[0019] FIG. **6** is a schematic view showing several example input parameters for use by the blood vessel geometry evaluation module of FIG. **1** in analyzing the geometry of blood vessels or vessel reconstructions;

[0020] FIG. **7** is a schematic view showing several example input parameters for use by the medical device geometry evaluation module of FIG. **1** in analyzing the geometry of medical devices such as grafts and stents;

[0021] FIG. **8** is a schematic view showing several example input parameters for use by the boundary blood flow evaluation module of FIG. **1** in analyzing blood flow;

[0022] FIG. **9** is a schematic view showing several example input parameters for use by the load evaluation module of FIG. **1** in analyzing dynamic and static loads exerted on blood vessels, reconstructions, or other anatomical structures;

[0023] FIGS. **10***a*-**10***b* are example plots showing posterior and anterior three-dimensional visualizations of blood vessel stresses that can be generated by the graphical user interface of FIG. **1**;

[0024] FIG. **11** is a schematic view showing an example software platform for use with the system of FIG. **1**;

[0025] FIG. **12** is a flow diagram of an example method for analyzing and predicting treatment outcomes of vascular interventions and reconstructions;

[0026] FIG. **13** is a flow diagram of another example method for analyzing and predicting treatment outcomes of a medical procedure such as a patch endarterectomy procedure;

[0027] FIG. **14** is a flow diagram of an example method for analyzing a medical device design for a group of patients;

[0028] FIG. **15** is a flow diagram of an example method for analyzing a medical device design for a specific patient;

[0029] FIG. **16** is a schematic view of three-dimensional mean carotid artery geometry generated for a group of sixteen patients;

[0030] FIGS. **17***a*-**17***e* are several plots showing the comparison of different surgical reconstruction techniques in terms of atherosclerosis-related mechanical parameters such as effective stress expressed in logarithmic values;

[0031] FIG. **18***a*-**18***b* are several plots showing complex, three-dimensional pulsatile velocity profiles in an internal carotid artery (ICA) and external carotid artery (ECA), respectively;

[0032] FIGS. **19***a*-**19***b* are several plots showing zones of blood flow recirculation and stagnation in a carotid bulb for systole and diastole, respectively;

[0033] FIGS. **20***a*-**20***b* are several plots showing a three-dimensional visualization of overlapping stents deployed in a superficial femoral artery, in which high stress concentrations are shown on the arterial wall along with the presence of atherosclerotic plaque;

[0034] FIGS. **21***a*-**21***b* are several plots showing the three-dimensional visualization of a carotid artery before and after angioplasty and stenting, respectively; and

[0035] FIGS. **22***a*-**22***b* are several plots showing the presence of zones of high stress concentrations in the arterial wall, plaque, and stent struts.

[0036] While the invention is amenable to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and are described in detail below. The intention, however, is not to limit the invention to the particular embodiments described.

On the contrary, the invention is intended to cover all modifications, equivalents, and alternatives falling within the scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION

[0037] Model-based systems and methods that utilize patient-specific physiological data and/or previously acquired data from other, similarly situated patients or cases can be used to analyze, and in some cases predict, various parameters for determining a suitable course of treatment for a patient. These systems and methods can also be used as a tool for selecting medical devices tailored to a patient's particular medical condition, or for developing new medical devices. In some embodiments, the patient-specific and/or previously acquired input data can be classified and stored in one or more computer databases that can be accessed by individuals over a computer or computer network. For example, the database or databases can be accessed by health care professionals over the Internet to perform preoperative or intraoperative evaluations of possible treatment options and/or to optimize a particular treatment plan, thus improving the clinical decision-making process and overall treatment outcome decisions. The database can also be used by medical device developers for researching and developing new medical devices and treatments.

[0038] In certain embodiments, the systems and methods can be used in open or endovascular surgery procedures in the treatment of cardiovascular diseases, including coronary artery disease, carotid artery disease and aortoilliac, peripheral, mesenteric, renal, and arm artery stenoses. The systems and methods can also be used in the treatment of various forms of arterial aneurysms, including abdominal and thoracic aortic aneurysms and peripheral arterial aneurysms (e.g., poplietal, femoral, carotid, arm, or visceral aneurysms) treated by repair, bypass, replacement, or endovascular stent-grafting. The systems and methods can also be used for developing new medical devices, or for developing medical devices customized for use in a particular patient or groups of patients.

[0039] The systems and methods disclosed herein can be implemented in hardware, software, or a combination of both. In some embodiments, the systems and methods can be executed as computer readable instructions on a programmable computer or processor comprising a data storage system with volatile and/or non-volatile memory. Although various example systems and methods are described herein with respect to vascular interventions and reconstructions, the systems and methods can be used to analyze and model other types of physiological conditions and can be used to evaluate other treatment options or to develop other types of medical devices. In some cases, the systems and methods can also be used to evaluate and predict possible medical device failures.

[0040] FIG. **1** is a schematic view of a model-based system **10** for analyzing and predicting outcomes of vascular interventions and reconstructions in accordance with an illustrative embodiment. The system **10** comprises a relational database **12** and an evaluation unit **14** operable on a computing device **16** such as a server, personal computer, or hand-held computing device. In some embodiments, the computing device **16** includes software and/or hardware functionality capable of executing various computer instructions via a processor **18**. Although the database **12** and evaluation unit **14** are shown as part of a single, integral computing device **16** in FIG. **1**, in other embodiments one or more components of the system **10** can be distributed across multiple computing devices or can be combined into a single unit.

[0041] The database **12** is configured to store data inputted to the system **10** by one or more users **20**, **30**. In some embodiments, for example, the database **12** is configured to store raw and/or processed data associated with a group of current patients **22** to be treated or other individuals **24** such as past patients or cadavers. For example, the database **12** can be configured to store data obtained from an imaging procedure such as Magnetic Resonance Angiography (MRA) or Computerized Tomographic Angiography (CTA). The database **12** can also be configured to store simultaneous electrocardiogram (ECG) recordings, recordings of blood flow evaluations and other physiologic data acquired from the patients **22**, **24**. Examples of velocity data to be stored in the database and an example three-dimensional graphical representation of such data is shown, for example, in FIGS. **18***a*-**18***b*. Data relating to mechanical properties of materials such as blood vessel wall plaque and properties of patching materials, stents and/or stent-grafts can also be collected and inputted as data to the database **12**.

[0042] Other input data such as patient age, gender, race, cardiovascular risk factor profile, clinical history, medications, blood count, diet, lifestyle, as well as other clinical laboratory measurements can also be inputted to and stored within the database **12**. Typically, the type and format of the information inputted to the database **12** will vary depending on the type of patient, the patient's condition, the treatment options available for treating the patient, as well as other factors. In some embodiments, the database **12** contains average parameters computed for a particular patient or group of patients. In some embodiments, for example, the database **12** contains mean three-dimensional geometric data of a particular type of vessel (e.g., a carotid artery) computed from multiple patients.

[0043] The database **12** is expandable and scalable, allowing for the addition of new data such as tissue histology, tissue models, medical devices, and newly discovered medical record data. In some embodiments, the database **12** is implemented using a combination of relational and non-relational database schemas, allowing disparate data formats inputted by the users **20**, **30** to be integrated into a unified database **12** that can be accessed by other system users **20**, **30**.

[0044] In the embodiment of FIG. **1**, the database **12** and evaluation unit **14** are accessible by one or more users **20** over a network interface **26** with multiple network access portals **28**. In certain embodiments, for example, the network access portals **28** comprise Internet or intranet portals that can be accessed by users **20** over a computer. The database **12** and evaluation unit **14** can also be accessed directly (e.g., off-line) by some users **30** such as software end-users or a network administrator. The level of database access and functionality may vary depending on the type of user **20**, **30**. For example, users **20**, **30** such as health care professionals may be provided with security credentials greater than other users **20**, **30**, allowing these professionals to access confidential information about a specific patient or group of patients **22**, **24**. In contrast, other users **20**, **30** such as researchers or medical device developers may be given more limited access credentials to the database **12** in order to maintain patient confidentiality and anonymity.

[0045] The processor **18** is configured to run an algorithm or routine that combines data acquired from one or multiple evaluation modules **32** and generates various output param-

eters that can be used by the processor **18** and a biomechanical model **31** to analyze, and in some cases predict, various patient-based treatment outcomes associated with the use of a particular reconstruction technique or medical device. In the embodiment of FIG. **1**, the algorithm or routine comprises a coupled fluid-solid interaction biomechanical model **31** that uses, as model inputs, data that is measured and/or gathered by one or more of the evaluation modules **32**. Based on these model inputs, the biomechanical model **31** determines one or more parameters associated with a blood vessel under evaluation or in the selection of a particular medical device for use in treating a patient or group of patients. In certain embodiments, for example, the biomechanical model **31** uses input data obtained across several of the evaluation modules **32** to better understand the current condition of a patient's blood vessel, and from this information, selects a medical device (e.g., a patch or graft/stent) that is optimal for the patient. Example methods for evaluating potential treatment options for a patient using a fluid-solid interaction biomechanical model is further described with respect to FIGS. **12** and **13**.

[0046] In some embodiments, the biomechanical model **31** uses coupled solid and fluid mechanics equations as well as data stored within the database **12** in a numerical algorithm that employs finite difference, peridynamic, other meshless, and/or finite element analysis in calculating stresses in blood vessel walls and blood flow parameters within an existing or reconstructed blood vessel. The biomechanical model **31** can also be used to calculate various mechanical and hemodynamic parameters linked to restenosis, such as maximum stress or cyclic stress or strain, wall pressure, wall shear stress, oscillatory shear stress, blood viscosity, and spatial gradients such as wall pressure gradients and wall shear stress gradients. Example model inputs that can be used by the biomechanical model **31** to calculate these stresses comprise the material properties of the blood vessel (e.g., linear, nonlinear, isotropy, anisotropy, viscoelasticity), the deformation characteristics of the blood vessel (e.g., small versus large deformations), the blood flow characteristics of the blood vessel (e.g., laminar versus turbulent blood flows, Newtonian vs. non-Newtonian rheology), and the type of attachment and closure (e.g., closure with suture, stitching, frictional attachment).

[0047] The biomechanical model **31** can be used for predicting outputs associated with humans, animals, or both. In some embodiments, for example, the biomechanical model **31** employs an animal model for evaluating and predicting various outputs related to vascular interventions and reconstructions in animals such as rats, dogs, or pigs. Information acquired from the animal model may provide users **20**, **30** with information for researching both the underlying mechanisms of diseases such as atherosclerosis as well as assisting in the development of improved materials, devices, and treatment methods. The biomechanical model **31** can employ semi-destructive, destructive, or non-invasive techniques for evaluating animals, either in vivo or postmortem. Simulated results from the biomechanical model **31** can be compared to data obtained and stored in the database **12**. As with human data contained within the database **12**, the animal data can be categorized and stored for later analysis by animal type, age, condition, as well as other categories.

[0048] The suite of evaluation modules **32** can be accessed by the system users **20**, **30** to input and evaluate various physiologic parameters relating to current or past patients **22**, **24** as well as device-specific parameters relating to those medical devices (e.g., patches, stents, grafts) that are available for treating the patients **22**, **24**. In the embodiment of FIG. **1**, the suite of evaluation modules **32** includes a mechanical properties evaluation module **34** for inputting and evaluating data relating to the mechanical behavior of biological materials and medical devices such as patches, synthetic grafts, and stents; a blood rheology evaluation module **36** for inputting and evaluating data relating to the rheological behavior of blood, a blood vessel geometry evaluation module **38** for inputting and evaluation data relating to the geometry of a diseased or reconstructed blood vessel; a medical device geometry evaluation module **40** for inputting and evaluating data relating to medical device geometry; a boundary blood flow evaluation module **42** for inputting and evaluating data relating to blood flow properties, and a load evaluation module **44** for inputting and evaluating data relating to loads on the blood vessels. In some embodiments, each individual module **34**, **36**, **38**, **40**, **42**, **44** includes an associated module database **46**, **48**, **50**, **52**, **54**, **56** for storing module-specific data for later analysis and use. In certain embodiments, the module databases **46**, **48**, **50**, **52**, **54**, **56** are a part of the database **12**. In other embodiments, the module databases **46**, **48**, **50**, **52**, **54**, **56** are separate databases that interact with the database **12**.

[0049] The mechanical properties evaluation module **34** is configured for use in inputting and evaluating various input parameters **58** relating to the mechanical behavior of biological materials and specimens such as blood vessels and plaque as well as the behavior of natural and synthetic grafts and stents used for treating such vessels. The data inputted to the mechanical properties input module **34** can be classified within the database **46** into appropriate groups, depending on the particular blood vessel under evaluation, the particular treatment method performed (e.g., endarterectomy with a natural graft), as well as other classifications. Example data that can be classified within the database **46** comprise the type of artery, patient age, disease type, disease stage, plaque extent, plaque composition, and natural graft source. Several example input parameters **58** that can be input to the database **46** for use in analyzing blood vessels, plaques, and natural grafts are further described with respect to FIG. **2**.

[0050] For the analysis of the mechanical behavior of synthetic grafts and stents, the data can be similarly classified into appropriate groups within the database **46** for later analysis by the mechanical properties evaluation module **34**. Example data that can be classified within the database **46** comprise the type of material and coating, if any, the device manufacturer, U.S. Federal and Drug Administration (FDA) approval status, the frequency of use, and the percentage of known complications. Several example input parameters **60** that can be input to the database **46** for use by the mechanical properties evaluation module **34** in analyzing synthetic grafts are further described with respect to FIG. **3**. Several example input parameters **62** that can be input to the database **46** for use by module **34** in analyzing stents are further described with respect to FIG. **4**.

[0051] Different types of synthetic and natural grafts, stents, and other implantable devices can be evaluated using the mechanical properties evaluation module **34**, including those commonly used for vascular repair, bypass, replacement, and post endarterectomy patching. Example graft types that can be evaluated comprise polytetrafluoroethylene (PTFE) and other biocompatible polymer grafts, textile Dacron grafts, biodegradable polymer grafts, vascular grafts,

femoral vein/artery, aortoiliac artery, saphenous, external jugular and facial vein vascular grafts and allografts, bovine pericardium patches, tubular vascular conduits and prostheses, and v-shaped grafts. Example stent types that can be evaluated comprise shape memory alloys and steel stents, open cell and closed cell stents, self expanding stents, shape memory alloy stents, braided mesh stents, biodegradable stents, coated stents, and drug eluting stents.

[0052] The blood rheology evaluation module **36** is configured for use in inputting and evaluating various parameters **64** relating to the rheological behavior of blood. The data inputted to the blood rheology evaluation module **36** can be classified within database **48** into appropriate groups for later analysis by the module **36**. Example data that can be classified within the database **48** comprise blood composition parameters such as erythrocytes count and LDL/HDL cholesterol content, patient condition, and blood disease. Several input parameters **64** that can be input to the database **48** for use in analyzing rheological behavior of blood are further described with respect to FIG. **5**.

[0053] The blood vessel geometry input module **38** is configured for use in inputting and evaluating various input parameters **66** related to the geometry of a blood vessel being treated, or for bypass-type procedures involving diseased blood vessels, for evaluating input parameters **66** related to reconstructed vessels. The data inputted to the blood vessel geometry evaluation module **38** can be classified within the database **50** for later analysis by the biomechanical model **31**. Example data that can be classified within the database **50** comprise vessel type, patient condition, disease type, and disease stage. Several example input parameters **66** that can be input to the database **50** for use in analyzing blood vessel geometry are further described with respect to FIG. **6**.

[0054] The medical device geometry input module **40** is configured for use in inputting and evaluating various input parameters **68** related to the geometrical properties (e.g., size, shape, curvature, etc.) of a graft or stent. The data inputted to the module **40** can be classified within the database **52** into appropriate groups for later analysis by the biomechanical model **31**. Example data that can be classified within the database **52** comprise device type, manufacturer type, FDA approval status, frequency of use, and type and percentage of known complications. Several input parameters **68** that can be input to the database **52** for use in analyzing graft/stent geometry are further described with respect to FIG. **7**.

[0055] The boundary blood flow evaluation module **42** is configured for use in inputting and evaluating various input parameters **70** related to the flow of blood and blood pressure at the boundaries of a region under evaluation, such as, for example, at the boundaries of a diseased portion of a blood vessel to be treated or a reconstructed vessel. The data inputted to the boundary blood flow evaluation module **42** can be classified within the database **54** for later analysis by the module **42**. Example data that can be classified within the database **54** comprise vessel type, arterial geometry characteristics, flow profile, pressure waveform, patient condition, patient activity, blood type, and reconstruction type. Several example input parameters **70** that can be input to the database **54** for use in analyzing blood flow parameters are further described with respect to FIG. **8**.

[0056] The load evaluation module **44** is configured for use in inputting and evaluating various input parameters **72** related to dynamic and static loads exerted on a blood vessel or other anatomical structure resulting from blood pressure, body movements, adjacent tissue, forces from expanded stents/grafts, extension/contractions due to movement and residual stresses, as well as other factors. The data inputted to the load evaluation module **44** can be classified within the database **56** for later analysis by the load evaluation module **44**. Example data that can be classified within the database **56** comprise vessel type, arterial geometry characteristics, flow profile, patient condition, patient activity, and device or reconstruction type. Several example input parameters **72** that can be input to the database **56** for use in analyzing dynamic and static loads are further described with respect to FIG. **9**.

[0057] The evaluation unit **14** is configured to directly compute biomechanics data outputs **73** for analysis by the users **20**, **30**. Examples of biomechanics data outputs **73** comprise time-dependent, three-dimensional distributions of stresses within a vessel wall, time-dependent; three-dimensional distributions of blood velocities, pressure, and shear stresses in blood; medical device material; and medical device geometry. The evaluation unit **14** can also be used to compute one or more derivative parameter outputs **74** associated with the biomechanics data. Example derivative parameter outputs **74** comprise atherosclerosis-related parameters including cyclic stress, cyclic strain, wall shear stress and their maxima/minima, areas/volumes over threshold(s), prediction of potential restenosis locations/volumes, and prediction of mechanical failures. The derivative parameter outputs **74** can comprise quantitative values, qualitative data, or a combination of both. In some embodiments, the derivative parameter outputs **74** are computed using additional modules such as a restenosis prediction module **76** or a failure prediction module **84**, which contain additional models and model inputs.

[0058] The restenosis prediction module **76** can be used for predicting the likelihood that restenosis will occur within a particular blood vessel. In certain embodiments, for example, the restenosis prediction module **76** includes functionality that links computed parameters such as vessel wall stresses and blood flow parameters to tissue remodeling and restenosis using an appropriate atherogenesis theory, which describes growth of atheromas or plaques in the inner lining of arteries. Alternatively, or in addition, the restenosis prediction module **76** includes functionality that links parameters such as vessel wall stresses and strains and blood flow characteristics to tissue using a hemorheologic-hemodynamic theory of atherosclerosis. An example of such prediction for a carotid artery is shown in FIGS. **10***a*-**10***b*, which shows posterior and anterior three-dimensional visualizations of carotid artery stresses.

[0059] In some embodiments, the restenosis prediction module **76** comprises a model that links computed mechanical and hemodynamic parameters to atherogenesis. Various physiological and biochemical phenomena accompanying restenosis can also be incorporated into the restenosis prediction module **76**. For example, the restenosis prediction module **76** can model mechanotransduction and the effects of mechanical stimuli on migration of endothelial cells (e.g. via the wound-healing model), the effects of stresses and high uniaxial/biaxial strains on SMC signaling, alignment, or apoptosis, various biochemical processes triggered by stress and strain induced gene expressions, as well as other physiological and biochemical phenomena. The restenosis prediction module **76** can also be used to evaluate the effects of restenosis-suppressing drugs eluted from drug-eluting stents or grafts. In addition, the restenosis prediction module **76** can

also be used to evaluate various patient-specific factors known to affect atherogenesis such as, for example, morphological, genetic, metabolic, and hormonal factors as well as relevant diseases such as hypertension. In some embodiments, the restenosis prediction module **76** is configured to perform blood vessel remodeling to predict the development of stenotic-induced aneurysms resulting from a stenosis.

[0060] In certain embodiments, the restenosis prediction module **76** is configured to generate three-dimensional images of predicted restenosis localization and growth that can be compared with actual atherosclerosis localization using direct postmortem observations or a suitable imaging technique such as high-resolution CT, MRI, or ultrasound imaging. An example imaging technique for visualizing atherosclerosis localization includes hybrid PET-CT or PET-MRI imaging with appropriate biochemical atherogenesis markers. In some embodiments, and as further discussed herein, the restenosis prediction module **76** can be used in conjunction with an optimization evaluation module **78** to define various restenosis-related criteria and goals.

[0061] The treatment selection/optimization evaluation module **78** is configured for use in evaluating a range of available treatment options and for selecting a treatment that is best suited for a particular patient. Example treatment parameters that can be optimized via the module **78** comprise the type of treatment, the type of stent/graft material, the base geometry of the stent/graft, placement location, and attachment location/configuration. In use, the treatment selection/optimization evaluation module **78** employs a mathematical optimization routine using linear or non-linear programming techniques to automatically determine an optimized treatment plan based on the available data stored in the database **12**. In some embodiments, the treatment selection/optimization evaluation module **78** continuously varies one or more discretionary variables based on user input preferences. For example, one or more surgeon-defined variables can be used as inputs by the treatment selection/optimization evaluation module **78** to determine an optimized treatment option that takes into account the surgeon's experience and preferences. Example discretionary variables that can be inputted comprise patch or stent size, type and shape preferences, placement location, and attachment location. An example of such an evaluation for a carotid artery repaired with different surgical reconstruction techniques is shown in FIGS. **17***a*-**17***e*, in which "PC" represents a primary closure, "CEE" represents eversion endarterectomy, "LPAT" represents lateral patching, "APAT**8**" represents anterior patching with a standard 8 mm patch, "APAT**16**" represents anterior patching with a wide 16 mm patch, and "APAT**4**" represents anterior patching with a narrow 4 mm patch.

[0062] In some embodiments, the optimization of a particular treatment option can be performed by the treatment selection/optimization evaluation module **78** by visually evaluating the output from a graphical user interface (GUI) **90**. Furthermore, and in some embodiments, the treatment selection/optimization evaluation module **78** can also be used to quantitatively compare outputs from several possible treatment options based on appropriate selection criteria. The selection criteria can be based, for example, on absolute maximum or cycle stress or strain intensities in the vessel walls, relative (e.g., percentage) increases in such intensities, comparisons of the vessel before repair to a healthy vessel, blood flow velocity (e.g., stagnation points), and wall shear stress. Other inputs from one or more of the evaluation modules **32** can also be used as selection criteria for optimizing a particular treatment. An example visualization showing flow abnormalities in a carotid bulb during systole and diastole is shown in FIGS. **19***a* and **19***b*, respectively.

[0063] In some embodiments, the treatment selection optimization evaluation module **78** is configured to screen and rank specific user-selected treatment options for evaluation. Example options that can be screened and ranked comprise the type of treatment (e.g., angioplasty with or without stenting, endarterectomy followed by primary closure, eversion endarterectomy, endarterectomy followed by primary closure, and eversion endarterectomy with lateral or anterior patch closure), graft material (e.g., synthetic, biological, by comparison/ranking of FDA-approved patches), the graft or stent geometry (e.g., shape, size, diameter, length, open cell, closed cell), the graft or stent placement (e.g., implantation position, overlaps), and attachment/bonding to the vessel (e.g., stitching, self-expanded, balloon-expanded). Examples of such treatment screening for carotid and superficial arteries is shown in FIGS. **20**-**22**.

[0064] A design evaluation module **80** is configured for use in evaluating material properties, device geometries, and other design parameters for new materials or device designs. The design evaluation module **80** can be used, for example, by medical device developers or material developers in developing new materials or device geometries for improving, and in some case optimizing, treatment outcomes. In the context of endarterectomy procedures, for example, the design evaluation module **80** can be utilized as a guide for medical device developers to develop new materials and geometries for implantable devices such as grafts and stents. Various user-specified ranges of allowable material properties and device parameter combinations can be examined by the design evaluation module **80**, either manually, semi-automatically, or automatically. The design evaluation module **80** can utilize mean anatomic, physiological, and other patient-related data computing using the database entries for multiple patients such as, for example, patients belonging to a specific group. When computed for specific groups, the module outcomes will be related to that group. In other embodiments, the design evaluation module **80** can be used in conjunction with individual patient inputs, thus designing the materials and/or devices for that specific patient.

[0065] In some embodiments, the design evaluation module **80** uses pre-characterized design moduli stored within the database **12** for developing new materials and/or devices. In certain embodiments, the design moduli comprise optimization parameters contained within the database **12** that can be applied to a model used by the design evaluation module **80** to achieve a particular goal. For example, in developing new materials for synthetic grafts, the design evaluation module **80** can employ various micromechanics models of heterogeneous porous or composite synthetic graft materials to select an appropriate composition and structure to achieve a desired property such as anisotropy ratio, certain types of non-linearity, strength, fatigue resistance, or biocompatibility. In similar fashion, stent geometry and composition can be adjusted to achieve certain goals. In some embodiments, the design evaluation module **80** also uses individual patient measurements for individualizing the design and manufacturing of materials and/or structures to the patient's particular needs.

[0066] In some embodiments, the output results from the design evaluation module **80** can be fed to a programmable manufacturing device **82** capable of automatically producing

the new material or device based on the optimized material or structure. Example manufacturing devices **82** capable of automatically producing new materials or devices comprise automatic programmable devices for producing porous materials, automated programmable lay-up devices for producing composite materials, and automated laser cutting devices for programmable stent manufacturing.

[0067] A failure prediction module **84** is configured for use in evaluating potential failures associated with graft materials, stents, or other implantable devices. In addition to restenosis, implantable devices such as grafts and stents can also fail mechanically under long-term cyclic loading, typically through the gradual accumulation and propagation of cracks or other irregularities in the structure. In some cases, the mechanical failure of the device can lead to immediate artery blockage or thrombosis. Such mechanical failures can also lead to high wall stresses, abnormal flow shear stress and disturbed blood flow patterns at the location of the failure, which can result in a rapidly accelerated restenosis or other complications. The failure of implantable devices such as grafts and stents thus represents a specific modality of possible post vascular surgery complications which, in addition to restenosis, can affect long-term treatment outcomes. Examples of zones prone to potential failure of a repair device used to repair carotid and superficial arteries are shown in FIGS. **19-20**.

[0068] In some embodiments, the failure prediction module **84** applies measured input parameters to a failure prediction model that uses a combination of static and fatigue strength, damage, and fracture mechanics approaches typically employed for analyzing structural materials. Based on the measured input parameters, the failure prediction module **84** is configured to predict and track gradual failure progression in grafts and stents. The failure prediction module **84** also considers the effects of changes in the material properties of the graft or stent during fatigue degradation along with the associated changes in wall stresses and blood flow patterns along with the effects of restenosis. In some embodiments, the evaluated and predicted cyclic graft or stent durability can be used as a goal or criteria for designing improved grafts or stents that are less likely to fail or cause restenosis.

[0069] Other modules can also be utilized for evaluating other physiological parameters associated with a patient **22**, **24** or group of patients **22**, **24**, for evaluating material or structural parameters for devices to be used for treating patients **22**, **24**, or for performing other tasks. In addition, data acquired from one or more of the modules **32** can be analyzed by one or more other modules to evaluate, and in some cases predict, other parameters. Although each of the modules **32** are described functionally as separate modules, in other embodiments one or more of the modules can be combined together into a single module or groups of modules. Furthermore, one or more of the modules **32** can comprise an external module that is physically embodied on another computing device or multiple devices.

[0070] In those embodiments in which the system is accessible to multiple users **20**, **30** (e.g., as a software program operable over a network server or as a stand-alone software program), the number and type of modules made available to the users **20**, **30** may vary depending on the user type. Thus, while several example modules **32** are shown in FIG. **1**, the particular configuration of the system **10**, including the types and functionality of modules **32** available to a particular user **20**, **30**, may vary depending on the particular application. For health care professions, for example, the functionality provided by the modules **32** include features that assist in inputting potential treatment options for patients whereas the functionality provided by the modules **32** for researchers are focused on research-related functionality.

[0071] The system users **20**, **30** can interact with the database **12** and other system components either directly or via the network interface **26**. In some embodiments, an interactive graphical user interface (GUI) **90** can be used by the users **20**, **30** for analyzing data generated by the biomechanical model **31** and/or the various modules **32**. In certain embodiments, for example, the graphical user interface **90** can be used by surgeons and health care professionals for preoperative analysis, evaluation, and visualization of treatment outcomes for individual patients or groups of patients, or for optimizing potential treatment options. For example, the graphical user interface **90** can be used by surgeons in endarterectomy procedures for manipulating surgical outputs such as graft/stent size and placement location based on various physiological parameters assessed visually using MRA, CTA, or other suitable visualization technique, and based on patient ECG data.

[0072] The graphical user interface **90** includes database tools **91** for use in performing various database operations, model assembly tools **92** for use in generating models, simulation control tools **93** for use in performing biomechanics modeling and simulation operations, output analysis and visualization tools **94** for performing analyses on outputs generated by the evaluation unit **14**, and optimization control tools **95** for use in optimizing outputs generated by the evaluation unit **14**.

[0073] Example database operations that can be performed via the database tools **91** comprise importing data into the database **12** as well as formatting, reducing, labeling, storing, and/or performing other operations associated with such data. The database tools **91** can also include a search query module that can be used for searching the database **12**. In certain embodiments, for example, the search query module comprises a search bar or interactive interface displayed on the graphical user interface **90**, allowing the users **20**, **30** to search for data in the database **12** by inputting a text query or by answering a series of questions.

[0074] Example biomechanics operations that can be performed via the model assembly tools **92** comprise inputting patient data directly to the biomechanical model **31**, selecting additional data from the database **12** (e.g., via searching, comparing, selecting functions), assembling three-dimensional blood vessel models, and running biometric simulations.

[0075] Example visualizations that can be provided via the simulation control tools **93** comprise three-dimensional graphs with areas or volumes that are color or gray-level coded to indicate stress, strain, and velocity intensities, vector plots for indicating intensity and direction, three-dimensional geometry of regrown tissue due to remodeling, animation videos showing deformation and stress/velocity changes over time during cyclic or other dynamic loading or as a result of biodegradation or other long-term phenomena in vessels or grafts/stents, sectioning for still-graphs, and animated videos for representing complex three-dimensional distributions of parameters. The sectioning of items on the graphical user interface **90** can be pre-determined or made adjustable based on user input. An example three dimensional visualization of the stresses within a blood vessel is shown in FIG. **10**.

[0076] Example analyses and/or optimization operations that can be performed via the output analysis and visualization tools **94** and the optimization control tools **95** comprise computing derivative output parameters on biomechanics data outputs, visualizing anatomical structures for evaluation or comparison (e.g., via mapping color-coded parameters over pulsating blood vessel surface and/or section of a vessel), for performing side-by-side visual comparisons of multiple treatment options under consideration, for computing maxima/minima and/or areas/volumes over a threshold for quantitative comparison of multiple treatment options, for performing automatic or semi-automatic optimizations (e.g., using computational loops and/or non-linear programming methods), and for storing or exporting optimal treatment techniques, materials, devices, and adjustable parameters for further use by surgeons, materials developers, or medical device manufacturers.

[0077] In some embodiments, the graphical user interface **90** can be utilized for performing postoperative evaluations to assess the quality and patency of a completed therapy, or to evaluate possible reasons for detected or diagnosed anomalies or other complications. For complications such as restenosis, for example, the graphical user interface **90** can be used to perform research on the underlying cause or causes of the restenosis, and in some cases, can be used to individualize patient care. In some embodiments, the graphical user interface **90** can be used for performing real-time evaluations of a selected treatment option during an interventional procedure based on either real-time, intraoperative measurements obtained from the patient or based on a combination of real-time and preoperative measurements stored within the database **12**. The ability to analyze and predict outcomes based on such data may be of particular interest in the case of an emergency or when intraoperative complications may arise with little or no preparatory time.

[0078] The graphical user interface **90** can be used to quantitatively and/or qualitatively evaluate certain conditions based on appropriate selected criteria. The selection criteria can be based, for example, on absolute maximum or temporal mean or cyclic values of stress and/or strain intensities in the vessel walls, relative (e.g., percentage) increases in such intensities compared to the vessel before repair or to a healthy vessel, blood flow velocity characteristics (e.g., stagnation points), and wall shear stress. The processor **18** is configured to find critical spots, calculate their extent, and color-code them onto three-dimensional visualization outputs, such as graphs and videos, that can be displayed on the graphical user interface **90** for analysis. The users **20**, can select between one or multiple, pre-programmed, interactively adjustable threshold levels, and perform other tasks via the graphical user interface **90**. Three-dimensional geometric information obtained via an imaging system can be combined as a composite image on the graphical user interface **90** along with the localization of targeted biochemical events identified by markers. The resultant, calculated three-dimensional images containing marked critical locations can then be directly compared with restenosis occurring in treated patients **24** for further analysis.

[0079] FIG. **2** is a schematic view showing several example input parameters **58** for use by the mechanical properties evaluation module **34** of FIG. **1** in analyzing the behavior of biological materials and anatomical structures such as blood vessels, plaques, and natural grafts. As shown in FIG. **2**, the mechanical properties evaluation module **34** receives, as input parameters **58**, a specimen type/geometry input parameter **98**, a load type, rate, and sequence input parameter **100**, an isotropy/anisotropy input parameter **102**, a linear/non-linear input parameter **104**, a constitutive equations input parameter **105**, and a material homogeneity input parameter **106**. The specimen type input parameter **98** relates to the type of blood vessel to be evaluated. For example, if the specimen to be evaluated is a natural graft, the specimen type input parameter **98** can be used to select the type and source of the graft (e.g., natural graft: saphenous or external jugular vein) and its geometry. If the specimen to be evaluated is plaque, the specimen type input parameter **98** can be used to input data relating to the extent and composition of the plaque.

[0080] The load type input, rate and sequence parameter **100** relates to the loading conditions (e.g., uniaxial or biaxial, rate, sequence) in which blood vessel or graft measurements were acquired. The isotropy/anisotropy input parameter **102** relates to whether the blood vessel or graft is to be approximated by the biomechanical model **31** as either isotropic or anisotropic. The linear-/non-linear input parameter **104**, relates to whether the blood vessel or graft is to be approximated by the biomechanical model **31** as either linear or non-linear (e.g., hyperelastic), elastic, or viscoelastic. The constitutive equations input parameter **105** relates to the equations to be used by the module **34** in evaluating outputs. The material homogeneity input parameter **106** relates to whether the blood vessel or graft is to be modeled as a homogenous or heterogeneous material. For a heterogeneous material, the mechanical behavior can be approximated by a composite mechanical model that uses the measured behavior of multiple components or constituents. For example, blood vessel walls can be considered as a layered, heterogeneous structure consisting of the intima, media, and adventitia, each with distinct, measurable properties. Plaque, in turn, can be considered as a heterogeneous structure consisting of dense, relatively acellular fibrous tissue, calcified tissue, pultaceous debris (i.e., amorphous debris containing cholesterol clefts rich in extracellular lipid), and cellular fibrous tissue.

[0081] The mechanical properties evaluation module **34** can be further configured to receive one or more other measured or modeled input parameters **108** for analysis. Examples of other parameters **108** that can be input to the mechanical properties evaluation module **34** comprise chemical, mechanical, or electrical characteristics of the structure to be evaluated, data input to other evaluation modules, as well as the outputs generated by other evaluation modules.

[0082] Based on the input parameters **58**, experiments, constitutive fittings, and other factors are used by the mechanical properties evaluation module **34** to generate one or more outputs **110** associated with the condition of the blood vessel, plaque or graft. Examples of outputs **110** that can be evaluated comprise raw data **110***a* such as stress/strains and constitutive parameters **110***b* that describe blood, arterial wall, plaque and repair material or device behavior, tissue growth and remodeling conditions.

[0083] FIG. **3** is a schematic view showing several example input parameters **60** for use by the mechanical properties evaluation module **34** in analyzing the behavior of synthetic grafts. As shown in FIG. **3**, the mechanical properties evaluation module **34** receives, as input parameters **60**, a synthetic graft type and geometry input parameter **112**, a load type, rate, and sequence input parameter **114**, an isotropy/anisotropy input parameter **116**, a linear/non-linear input parameter

118, a constitutive equations input parameter **119**, a material homogeneity input parameter **120**, and a time-dependent behavior/failure input parameter **122**.

[0084] The graft mechanical properties can be either evaluated experimentally or by modeling. For synthetic grafts such as polytetrafluoroethylene (PTFE) grafts, the material can be modeled as a porous material whose behavior is approximated based on the behavior of PTFE and the volume fraction and shape of the pores. For textile grafts, the behavior can be predicted based on the fiber properties and textile structure. For biodegradable polymeric grafts, the mechanical properties evaluation module **34** is further configured to receive a time-dependent behavior/failure input parameter **122** that takes into account the degradation characteristics of the graft over time. One or more other measured or modeled input parameters **124** can also be received for analysis by the mechanical properties evaluation module **34**.

[0085] Based on the input parameters **60**, experiments, constitutive fittings, failure model fittings, and other factors are used by the mechanical properties evaluation module **34** to generate one or more outputs **126** associated with the synthetic graft. Examples of outputs **126** that can be evaluated comprise raw data **126***a*, constitutive parameters **126***b* (e.g., tissue remodeling laws that describe the tissue growth within and around the graft), and failure model parameters **126***c* (e.g., time-dependent change of graft material properties).

[0086] FIG. **4** is a schematic view showing several example input parameters **62** for use by the mechanical properties evaluation module **34** in analyzing the behavior of stents. As shown in FIG. **4**, the module **34** receives, as input parameters **62**, a stent type and geometry input parameter **128**, a load type input parameter **130**, a material properties input parameter **131**, an isotropy/anisotropy input parameter **132**, a linear/non-linear input parameter **134**, a constitutive equations input parameter **135**, and a material homogeneity input parameter **136**. The stent type and geometry input parameter **128** can be used to select the type and geometry of the stent to be analyzed. For example, the stent type input and geometry parameter **128** can be used to select between evaluating a quasi-homogenous solid shell stent or a wire-mesh type stent. In the context of homogenous type stents, the load type and rate input parameter **130** relates to whether the stent is to be modeled as axially loaded under tension or compression (i.e., uniaxial loading), or simultaneous radial expansion, axial tension/compression and torsion (i.e., biaxial loading including the effects of shear).

[0087] For biodegradable polymeric stents, the module **34** is further configured to receive a time-dependent failure/behavior input parameter **138** that is used for evaluating the degradation characteristics of the stent over time. For stents made from shape-memory alloys, the temperature and strain-dependent behavior of the alloy can be provided as an input parameter **140** to the mechanical properties evaluation module **34**, either as a measured value or approximated based on modeling. One or more other measured or modeled input parameters **142** can also be received for analysis by the mechanical behavior evaluation module **34**.

[0088] Based on the input parameters **62**, experiments, constitutive fittings, failure model fittings, and other factors are used by the mechanical behavior evaluation module **34** to generate one or more outputs **144** associated with the stent. Examples of outputs **144** that can be evaluated comprise raw data **144***a*, constitutive parameters **144***b* (e.g., tissue growth laws within the stent, degree of inflammation), and failure model parameters **144***c* (e.g., number and severity of developed cracks, stent migration, and alteration of stent and adjacent wall geometry).

[0089] FIG. **5** is a schematic view showing several example input parameters **64** for use by the blood rheology evaluation module **36** of FIG. **1** in analyzing rheological behavior of blood. As shown in FIG. **5**, the blood rheology evaluation module **36** receives, as input parameters **64**, a blood type and composition input parameter **146**, a load type and rate input parameter **148**, a linear/non-linear input parameter **150**, a rheologic constitutive equation input parameter **151**, and a blood disease input parameter **152**. The blood type and composition input parameter **146** relates to the specific blood type and composition of the patient's blood, and includes factors such as erythrocytes count and LDL/HDL cholesterol content. The load type and rate input parameter **148** relates to the loading conditions of blood. The linear/non-linear input parameter **150** relates to whether the blood is to be approximated by the blood evaluation module **36** as either a Newtonian or non-Newtonian fluid for purposes of modeling. The rheologic constitutive equation input parameter **151** relates to the rheologic equations to be used for modeling. The blood disease input parameter **152** relates to whether the patient has a particular blood-related disease or disorder, and if so, provides specific information related to that disease or disorder such as the disease stage. If, for example, the patient has Leukemia, the blood disease input parameter **152** can be used to input the type of Leukemia (i.e., lymphocytic or myelogenous) and the severity of the disorder (i.e., acute or chronic). One or more other measured or modeled input parameters **154** can also be received for analysis by the blood rheology evaluation module **36**.

[0090] Based on the input parameters **64**, experiments, constitutive fittings, and other factors are used by the blood evaluation module **36** to generate one or more outputs **155** associated with the patient's blood. Examples of outputs **155** that can be evaluated comprise raw data **155***a* such as blood viscosity, shape and size of erythrocytes and constitutive parameters **155***b* such as laws to describe the viscous properties of blood.

[0091] FIG. **6** is a schematic view showing several example input parameters **66** for use by the blood vessel geometry evaluation module **38** of FIG. **1** in analyzing the geometry of blood vessels or reconstructed blood vessels. As shown in FIG. **6**, the blood vessel geometry evaluation module **38** receives, as input parameters **66**, a blood vessel type, segment, and location input parameter **156**, a blood vessel dimensions and branches input parameter **158**, and a disease type input parameter **160**. The blood vessel type, segment, and location input parameter **156** relates to the type and location of the blood vessel to be treated. For reconstructed blood vessels using harvested vessels, the blood vessel type, segment, and location input parameter **156** relates to the type and location of the harvested vessel. The blood vessel dimensions and branches input parameter **158** relates to the dimensions and branches of the vessel being treated, or for vessel reconstructions, the dimensions of the vessel to be reconstructed. The disease type input parameter **160** relates to whether the patient has a particular blood vessel disease or disorder, and if so, provides specific information related to that disease or disorder such as the disease stage. If, for example, the patient has atherosclerosis, the disease type input parameter **160** can be used to input the type and the severity of the disease to the module **38**. One or more other

measured or modeled input parameters **162** can also be received for analysis by the blood vessel geometry evaluation module **38**.

[0092] Based on the input parameters **62**, experiments, medical imaging, border identification, and other factors are used by the blood vessel geometry evaluation module **38** to generate one or more outputs **164** associated with vessel geometry. Examples of outputs **164** that can be evaluated comprise raw data **164***a* and interpolated/reconstructed data **164***b* (e.g., arterial tortuosity, curvatures, branching angles, variable wall thickness, length of segment under consideration, three-dimensional shape).

[0093] FIG. **7** is a schematic view showing several example input parameters **68** for use by the medical device geometry evaluation module **38** in analyzing the geometry of a medical device such as a graft or stent. As shown in FIG. **7**, the medical device geometry evaluation module **40** receives, as input parameters **68**, a graft/stent type input parameter **166** and a graft/stent dimensions input parameter **168**. The graft/stent type input parameter **166** relates to the type and/or manufacturer of the device. The graft/stent dimensions input parameter **154** relates to the specific graft/stent length, the size or shape of a patch, or any other user-selectable geometric parameter. In some embodiments, the dimensions for various devices can be stored in the database **12**, or can be varied by the clinician. One or more other measured or modeled input parameters **170** can also be received for analysis by the medical device geometry evaluation module **38**.

[0094] Based on the input parameters **64**, three-dimensional imaging data/reconstructions and other factors are used by the medical device geometry evaluation module **38** to generate one or more outputs **172** associated with the graft or stent geometry. Examples of outputs **172** that can be evaluated comprise raw data **172***a* and three-dimensional interpolated data **172***b*.

[0095] FIG. **8** is a schematic view showing several example input parameters **70** for use by the boundary blood flow evaluation module **42** of FIG. **1** in analyzing blood flow. As shown in FIG. **8**, the boundary blood flow evaluation module **42** receives, as input parameters **70**, a blood vessel type, geometry, and section location input parameter **174**, a patient activity input parameter **176**, a patient condition input parameter **178**, a blood pressure input value **180**, a symmetric/asymmetric input value **181**, and a blood type input parameter **182**. The blood vessel type, geometry, and section location input parameter **174** relates to the type and location of the blood vessel to be treated. The patient activity input parameter **176** relates to the general activity level of the patient, such as "active," or "sedentary." The patient condition input parameter **178** relates to the general condition of the patient. In some embodiments, for example, the patient condition input parameter **178** relates to the patient's specific condition. The symmetric/asymmetric input parameter **181** relates to the symmetry of blood flow conditions. The blood type input parameter **182** relates to the specific blood type of the patient. One or more other measured or modeled input parameters **184** can also be received for analysis by the boundary blood flow evaluation module **42**.

[0096] Based on the input parameters **70**, experiments, interpolations, and other factors are used by the boundary blood flow evaluation module **42** to generate one or more outputs **186** associated with blood flow. Examples of outputs **186** that can be evaluated comprises raw data **186***a*, dynamic velocity profiles **186***b*, (e.g., three-dimensional pulsatile blood velocity profiles at various locations of an arterial tree, peak velocity values and their corresponding luminal locations), and dynamic pressure cycles **186***c*.

[0097] FIG. **9** is a schematic view showing several example input parameters **72** for use by the load evaluation module **44** of FIG. **1** in analyzing dynamic and static loads exerted on blood vessels, reconstructions, or other anatomical structures. As shown in FIG. **9**, the load evaluation module **44** receives, as input parameters **72**, a blood pressure input parameter **188**, a force/stress input parameter **190**, a blood vessel type input parameter **192**, a patient activity input parameter **194**, and a patient condition input parameter **196**. The blood pressure input parameter **188** comprises the patient's systolic and diastolic blood pressure during one heart cycle or across multiple heart cycles (e.g., an averaged blood pressure). The force/stress input parameter **190** relates to external forces applied to the vessel, including, but not limited to, forces from surrounding tissue, neighboring grafts and stents, extensions and contractions due to locomotion, and residual stresses. The forces can be measured and/or evaluated at particular times such as during a period of maximum load, at systole/diastole, or during peaks in cardiac activity. The forces can also be measured continuously through dynamic or cyclic activities. One or more other measured or modeled input parameters **198** can also be received for analysis by the load evaluation module **44**.

[0098] Based on the input parameters **72**, measurements, back calculation of tractions, and other factors are used by the load evaluation module **44** to generate one or more outputs **200** associated with loading. Examples of outputs **200** that can be evaluated comprise raw data **200***a* and tractions on the vessel surface **200***b* (e.g., maps of distributed loads on arterial walls and repair devices, boundary conditions, interactions with surrounding tissues).

[0099] The various input parameters supplied to the evaluation modules **32** can be measured in-vitro, in-vivo, or a combination of both. For example, geometry and in vivo mechanical properties of the patient's blood vessels and/or atherosclerotic plaque can be measured using invasive or non-invasive ultrasound, MRA, PET-CTA, or CTA while mechanical properties of the repair materials and devices can be determined using in vitro biaxial tests.

[0100] FIG. **11** is a schematic view showing an example software platform **202** for use with the system **10** of FIG. **1**. The software platform **184** may represent, for example, a service-orientated software architecture comprising a suite of software tools that can be used in a cloud-based environment with multiple, Web-based users **20**. The software platform **202** comprises a three distinct, distributed layers **204**, **206**, **208** that provide software functionality for communicating with the system components and with each user **20**. A data layer **204** provides access to the underlying data manipulation functionality and data repositories. In some embodiments the data layer comprises a biomechanical data model **210**, a database **212**, a solver **214**, and data management components **216**.

[0101] A tool layer **206** provides a suite of software tools to facilitate interaction with system users **20** via an Internet connection. Each of the software tools are modular, allowing functional elements to be easily incorporated into or removed from the system. In the embodiment of FIG. **10**, the tool layer **206** comprises a database manipulation tool suite **218** for importing new data into the database **212**, for performing queries to access data stored within the database **212**, for

reviewing data via three-dimensional representations, graphs, dynamic analyses (e.g., measuring dimensions, flow rates) and tabulating results, for performing side-by-side comparisons of patient data stored within the database **212** for multiple patients, and for performing statistical analyses to correlate medical records, risk factors, as well as other predetermined or user-definable criteria.

[0102] A model assembly tool suite **220** provides a suite of software tools for building and refining biomechanics models for modeling medical procedures such as cardiovascular interventions or reconstructions. In some embodiments, the model assembly tool suite **220** provides functionality for selecting model inputs based on information within the database **212** and/or based on user imported data, for assembling graphical interaction models (e.g., a graphical model for selecting between different repair techniques based on three-dimensional vessel geometry), for automating the input of device types, materials, mechanical properties, rheological blood properties, flow properties, boundary conditions, and other input parameters from each of the evaluation modules, for selecting the size, location, and other characteristics of the device and/or the anatomy to be treated, and for performing finite element meshing.

[0103] An output visualization and analysis tool suite **222** provides a suite of software tools for visualizing and analyzing data. In some embodiments, the output visualization and analysis tool suite **222** provides functionality for visualizing static and dynamic mechanical data (e.g., three-dimensional pulsatile vessel deformations or velocities, blood flow, density/color mapping, stress/strain), for interactively performing graphical manipulation of data (e.g., rotation, zooming, panning, highlighting), for computing and mapping other mechanical factors onto three-dimensional vessel geometry (e.g., by interactive sliding thresholds, computation of maximum or minimum values, visualization of volumes over thresholds), for performing both quantitative and qualitative side-by-side comparisons of different medical procedures and potential outcomes, and for storing selected data outputs in the database **212** and exporting data in a user-defined format for later analysis.

[0104] An application programming interface (API) layer **208** provides a framework for the various software tools to communicate and exchange information through the Internet. The system architecture allows the various tool suites and other tools to be deployed across multiple, different platforms. In some embodiments, a centralized server architecture is used for performing resource-demanding graphical rendering and analysis. For Internet-based applications, a Representational State Transfer (REST) protocol, Simple Object Access Protocol (SOAP), or other suitable Web-services protocol **224** is used for exchanging information in the implementation of Web-based services.

[0105] FIG. **12** is a flow diagram showing an example method **226** for analyzing treatment outcomes in vascular interventions and reconstructions using the system **10** of FIG. **1**. FIG. **12** may represent, for example, an example method for analyzing potential therapeutic outcomes in an endarterectomy procedure of a carotid artery using the system **10** of FIG. **1**. As shown in FIG. **12**, the method may begin generally at block **228** in which the user is prompted to input patient-specific data into the database for analysis. The patient data can include data obtained in-vivo from clinical measurements taken from the patient. The patient data can also include data such as the patient's age, gender, race, health condition, cardiac risk factor profile, as well as other patient-specific information. Once gathered, the patient specific data is then input to a database for later analysis (block **230**).

[0106] At block **232**, and in some embodiments, the user searches the database to obtain additional data to be associated with the patient based on patient data stored within the database. If, for example, patient-specific data at block **230** is not available, the data can be interpolated or extrapolated from the database based on other patient records that are searchable and stored within the database. For example, if data on blood viscosity is not readily available, it can be extrapolated from the database using viscosity data from patients with similar clinical records (e.g., blood count, stage of disease, lifestyle, risk factors, etc.).

[0107] The system next prompts the user to select treatment and/or medical device data to be associated with a proposed treatment option (block **234**). The user then performs a search of the database and obtains model parameters to be associated with the biomechanical model (block **236**). If, for example, the user desires to use finite element analysis to analyze the effects of pulsatile blood flow on an endarterectomized blood vessel, the user may select the model type from a display screen, and select from a number of finite element analysis options available for the modeling. An example finite element analysis model that can be used to evaluate endarterectomized and patched arteries is described, for example, in "Finite Element Model of the Patched Human Cartoid" published on Oct. 14, 2009 in the Journal of Vascular Endovascular Surgery, the contents of which are incorporated herein by reference in their entirety for all purposes.

[0108] From this information, the system then generates a coupled fluid-solid interaction biomechanical model and instructions (block **238**) to be used for analyzing the inputs and model data. The biomechanical model and instructions can be construed in both the fluid and solid domains using an appropriate system of equations for each. A biomechanics simulation can then be performed (block **240**) and an analysis performed on the biomechanics data (block **242**). Based on the modeling preferences supplied to the biomechanical model, the processor analyzes the data supplied to the database from each of the evaluation modules to determine at least one potential treatment outcome using the biomechanical model. In some embodiments, the evaluation unit combines both measured and modeled data obtained across multiple modules to analyze potential treatment outcomes and to suggest potential treatment options available for treating the patient. In some embodiments, an optimization is performed on the biometrics data to optimize the proposed treatment option (block **244**).

[0109] FIG. **13** is a flow diagram of another example method **248** for analyzing treatment outcomes in vascular interventions and reconstructions. FIG. **13** may represent, for example, an example implementation of the method **226** of FIG. **12** for analyzing potential therapeutic outcomes in an endarterectomy procedure using the system **10** of FIG. **1**. As shown in FIG. **13**, the method **248** may begin generally at block **250** in which patient-related data is acquired from one or more patients. In some embodiments, the process of acquiring patient data comprises acquiring geometry data associated with the vessel under evaluation (block **252**), acquiring mechanical property data associated with the vessel (block **254**), acquiring flow data associated with the flow characteristics of blood within the vessel (block **256**), acquir-

ing blood pressure data (block **258**), and acquiring blood rheology data (**260**). Other physiological data can also be acquired from the patient.

[0110] The process of acquiring geometry data at block **252** can be accomplished using MRI, CTA, invasive or non-invasive ultrasonography, and/or other suitable technique. In some embodiments, the three-dimensional geometry of the vessel under evaluation can be analyzed (block **262**), providing the clinician with information such as the size, shape, tortuousness, and/or other geometrical characteristics of the vessel. An example of mean reconstructed arterial geometry from data obtained from sixteen patients is shown in FIG. **16**.

[0111] The mechanical property data associated with the vessel can be acquired in-vitro, in-vivo, or using a combination of in-vitro and in-vivo techniques. For example, mechanical properties of patching materials that can be acquired in vitro using biaxial or tensile tests. Example of mechanical property data that can be acquired in-vivo comprises mechanical property data obtained using invasive and non-invasive ultrasonography and elastography. Based on these measurements, the mechanical properties of the vessel are obtained and constitutive models of the vessel are generated (block **264**).

[0112] The process of acquiring flow data associated with the flow characteristics within the vessel at block **256** can be accomplished artificially using MRI or ultrasonography and/or in-vivo using MRI or invasive or non-invasive ultrasonography. Based on these measurements, flow velocity profiles associated with the vessel is generated (block **266**).

[0113] The process of acquiring pressure data at block **258** can comprise measuring blood pressure using an invasive or non-invasive sensor, an angiocatheter, or other suitable technique. In some embodiments, the pressure measurements can be correlated with electrocardiogram measurements. Based on the sensed pressure data, a blood pressure waveform is generated (block **268**).

[0114] The process of acquiring blood rheology data at block **260** can comprise measuring the blood composition, viscosity, shear rate, and/or other characteristics of the patient's blood. Based on these measurements, blood viscosity constitute laws are generated, which describe the blood viscosity characteristics of the patient's blood (block **260**).

[0115] The three dimensional geometry data, mechanical properties and constitutive models, flow velocity profiles, pressure waveform data, and blood viscosity constitutive laws are stored within the database for further analysis by the evaluation unit (block **272**). In some embodiments, information regarding the medical devices and materials available for repairing the blood vessel as well as disease growth and vessel remodeling constitutive laws are also supplied to the database for further analysis by the evaluation unit, as indicated generally at blocks **274** and **276**, respectively.

[0116] Based on the data stored within the database, the evaluation unit is configured to generate inputs and interpolate model parameters to be used by the biomechanical model for analyzing the acquired patient data (block **278**). From this data, and guided by user interaction (block **280**), the system assembles a fluid/solid interaction model (block **282**) that can be used to generate a proposed solution (block **284**). In some embodiments, for example, the proposed solution generated by the model comprises the determination of which of the available medical devices and/or repair materials are optimal for a particular diseased vessel or patient condition. In another embodiment, the proposed solution generated by the model comprises the determination of a size or shape of a medical device (e.g., a stent) to be used in performing therapy on the patient. Other proposed solutions are also possible.

[0117] In some embodiments, post-processing and/or results mapping can be performed to confirm the efficacy of the proposed treatment and/or to further optimize the treatment (block **286**). In certain embodiments, for example, results mapping can be performed over a three-dimensional blood vessel or two or three-dimensional sections of the vessel to determine and visualize locations of maximum or minimum values of particular factors, regions where factors exceed the set thresholds, stream/streak path lines on the plots, display plots of stress and strain, and/or viscosity, to perform queries for particular vessel zones, display dynamic graphs and three-dimensional plots, and generate area evolution graphs. Other post processing can also be performed on the data.

[0118] If at block **286**, atherosclerosis potentially exists at the treatment site, the system can analyze the disease progression based on atherosclerosis growth models (block **290**). If the analysis confirms that the disease will not grow or if further optimization is not desired or possible, then the system outputs a final result to the clinician (block **292**). If, on the other hand, the disease is predicted to progress, the system performs additional treatment optimization (block **292**). When the disease growth is predicted to terminate, the system outputs a final result (block **292**) to the clinician.

[0119] In some embodiments, the system may perform an optimization on one or more criteria or goals (block **294**), which can be automatically provided as input to the generation of input and interpolation of model parameters at block **278**, or manually provided to the user. Examples of criteria or goals include the shape, size, type, location, and material. Such optimization can be performed at any time during the process, including at the post-processing and results mapping step (block **286**), during visualization (block **290**), and/or during the disease growth and remodeling step (block **292**). The process of assembling the model, providing a proposed solution, and performing post-processing and results mapping can then be performed again based on the optimized data to obtain another result.

[0120] FIG. **14** is a flow diagram showing an example method **300** for developing a material or device design using the system **10** of FIG. **1**. FIG. **14** may represent, for example, an example method for developing a stent or synthetic graft using the system **10** of FIG. **1**. As shown in FIG. **14**, the method may begin generally at block **302** in which the user obtains patient specific data from a database containing data for multiple patients. The patient data can include data obtained in-vivo from clinical measurements taken from the patient. The patient specific data can also be obtained in-vitro.

[0121] Based on the data stored in the database, the system next computes patient-related model inputs for all or groups of the patients (block **304**). The system next prompts the user to select the treatment or surgery type and define ranges of allowable materials and/or device properties (block **306**).

[0122] From this information, the system then generates one or more biomechanical models (block **308**) to be used for analyzing the inputs and model data. A biomechanics simulation can then be performed (block **310**) and an analysis performed on the biomechanics data (block **312**). In some embodiments, an optimization is performed on the biometrics data to optimize the proposed treatment option (block **314**).

[0123] FIG. **15** is a flow diagram showing an example method **320** for developing a material or device design using the system **10** of FIG. **1**. FIG. **15** may represent, for example, an example method for developing a stent or synthetic graft for a specific patient using the system **10** of FIG. **1**. As shown in FIG. **15**, the method may begin generally at block **322** in which the user obtains patient specific data from a database containing data for multiple patients. The patient data can include data obtained in-vivo from clinical measurements taken from the patient. The patient specific data can also be obtained in-vitro.

[0124] Based on the data stored in the database, the system next computes patient-related model inputs for all or groups of the patients (block **324**). The system next prompts the user to select the treatment or surgery type and define ranges of allowable materials and/or device properties (block **326**).

[0125] From this information, the system then generates one or more biomechanical models (block **328**) to be used for analyzing the inputs and model data. A biomechanics simulation can then be performed (block **330**) and an analysis performed on the biomechanics data (block **332**). In some embodiments, an optimization is performed on the biometrics data to optimize the proposed treatment option (block **334**). The optimization performance parameters that are obtained from the optimization are then used to develop the material and/or device structures (block **336**). The materials and/or device structures are then used to produce the final material or device (block **338**).

[0126] Various modifications and additions can be made to the exemplary embodiments discussed without departing from the scope of the present invention. For example, while the embodiments described above refer to particular features, the scope of this invention also includes embodiments having different combinations of features and embodiments that do not include all of the described features. Accordingly, the scope of the present invention is intended to embrace all such alternatives, modifications, and variations as fall within the scope of the claims, together with all equivalents thereof.

What is claimed is:

1. A method for analyzing and predicting treatment outcomes of vascular interventions and reconstructions, comprising:

inputting patient specific data associated with a patient into a database;

searching the database and obtaining additional data to be associated with the patient, wherein the additional data is obtained based at least in part on patient specific data stored within the database for one or more other patients;

selecting at least one of a treatment parameter or medical device parameter to be used in association with a proposed treatment option for treating the patient;

searching the database and obtaining one or more model properties associated with the treatment or medical device parameter;

generating a fluid-solid interaction biomechanical model based at least in part on the patient specific data, the additional data associated with the patient, and the model properties;

performing a biomechanics simulation and generating biomechanics data using the biomechanical model; and

analyzing the biomechanics data.

2. The method of claim **1**, wherein the patient specific data for the patient comprises data selected from the group of data comprising age, gender, race, risk factor profile, clinical history, medications, blood count, diet, and lifestyle.

3. The method of claim **1**, wherein the patient specific data for the patient includes three-dimensional vessel geometry properties.

4. The method of claim **1**, wherein the patient specific data for the patient comprises data selected from the group of properties comprising vessel wall tissue mechanical properties and blood rheologic properties.

5. The method of claim **1**, wherein the patient specific data for the patient comprises data selected from the group of properties comprising dynamic blood flow properties, blood pressure cycles, and boundary conditions.

6. The method of claim **1**, wherein the patient specific data and model properties associated with the treatment or method are obtained using a plurality of input evaluation modules.

7. The method of claim **6**, wherein the plurality of input evaluation modules are selected from the group of modules comprising a mechanical properties evaluation module, a blood rheology evaluation module, a blood vessel geometry evaluation module, a medical device geometry evaluation module, a boundary blood flow evaluation module, and a load evaluation module.

8. The method of claim **1**, wherein the additional data to be associated with the patient is selected from the database of data for other patients based on clinical data for the patient.

9. The method of claim **8**, wherein the clinical data for the patient is selected from the group of data comprising patient age, gender, race, risk factors, clinical history, medications, diet, lifestyle and pregnancy.

10. The method of claim **8**, wherein the clinical information for the patient includes laboratory or in-vivo tests on the patient.

11. The method of claim **1**, wherein selection of the treatment parameter or medical device parameter comprises selecting at least one parameter from the group of parameters comprising a type of surgery or intervention, the type of medical device, the geometry of the medical device, the material of the medical device, and the mechanical properties of the medical device.

12. The method of claim **1**, wherein generating the fluid-solid interaction biomechanical model comprises generating an algorithm for solving time-dependent, three-dimensional solid and fluid biomechanics equations with boundary conditions based on the patient specific and additional data associated with the patient and model properties associated with the treatment or medical device parameter.

13. The method of claim **12**, wherein generating the biomechanics data comprises generating at least one output selected from the group of outputs comprising a time-dependent, three-dimensional distributions of stresses and strains within a vessel wall or medical device, time-dependent, three-dimensional distributions of blood velocities, pressure, and flow shear stresses in blood.

14. The method of claim **1**, further comprising analyzing one or more derivative parameters associated with the biomechanics data.

15. The method of claim **14**, wherein the one or more derivative parameters comprises at least one derivative parameter selected from the group of parameters comprising atherosclerosis-related parameters, restenosis prediction parameters, and device mechanical failure parameters.

16. The method of claim **14**, wherein the derivative parameters are obtained by quantitatively and qualitatively analyzing the biomechanics data.

17. The method of claim **14**, wherein the derivative parameters are obtained by static or dynamic visualization and mapping.

18. The method of claim **1**, further comprising generating and repeatedly updating the fluid-solid interaction biomechanical model, performing a biomechanics simulation, generating biomechanics data, and analyzing the simulation and biomechanics data to optimize the proposed treatment option.

19. The method of claim **1**, further comprising computing mean patient data based on patient data for a plurality of patients.

20. A method for analyzing and predicting treatment outcomes of vascular interventions and reconstructions, comprising:

obtaining, in vivo, patient specific data associated with a patient;

searching a database and obtaining additional data to be associated with the patient, wherein the database is configured to classify and stored data for a plurality of patients, and wherein the additional data is obtained based at least in part on patient specific data stored within the database for one or more other patients;

selecting at least one of a treatment parameter or medical device parameter to be used in association with a proposed treatment option for treating the patient;

searching the database and obtaining one or more model properties associated with the treatment parameter or medical device parameter;

generating a fluid-solid interaction biomechanical model based at least in part on the patient specific data, the additional data associated with the patient, and the model properties, wherein the fluid-solid interaction biomechanical model comprises time-dependent, three-dimensional solid and fluid equations;

performing a biomechanics simulation and generating biomechanics data using the biomechanical model; and

analyzing the biomechanics data and determining the effectiveness of the proposed treatment.

21. A system for analyzing and predicting therapeutic outcomes in medical procedures, comprising:

a relational database configured for classifying and storing patient specific input data for a plurality of patients;

a means for obtaining and inputting patient specific input data to the database;

a means for selecting additional data to be associated with the patient in the database;

a means for inputting treatment related and medical device related parameters to the database;

a means for selecting treatment type, inputting model parameters, and assembling a biomechanical model based on the selected treatment type, the patient specific data, the additional data associated with the patient, and the treatment and medical device related parameters;

a processor and fluid-solid interaction biomechanical model configured for performing a biomechanics simulation and generating biomechanics data, the fluid-solid biomechanical model comprising time-dependent, three-dimensional solid and fluid equations;

a means for evaluating the outcomes of the biomechanics simulation; and

an interface configured for exchanging data between the database and a plurality of users.

22. The system of claim **21**, wherein said means for gathering input data comprises a plurality of input evaluation modules.

23. The system of claim **22**, wherein the plurality of evaluation modules are selected from the group of modules comprising a mechanical properties evaluation module, a blood rheology evaluation module, a blood vessel geometry evaluation module, a medical device geometry evaluation module, a boundary blood flow evaluation module, and a load evaluation module.

24. The system of claim **22**, wherein the plurality of evaluation modules further comprises a restenosis prediction module.

25. The system of claim **22**, wherein the plurality of evaluation modules further comprises a failure prediction module.

26. The system of claim **22**, wherein the plurality of evaluation modules further comprises a treatment selection and optimization module.

27. The system of claim **22**, wherein the plurality of evaluation modules further comprises a design evaluation module.

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