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 (54) Title: LIBRARIES AND DATA STRUCTURES OF MATERIALS REMOVED BY DEBULKING CATHETERS

(57) **Abrégé/Abstract:**

Material removed by a debulking catheter from a body lumen can be preserved. Materials can be controlled from many different patients and/or from multiple procedures on individual patients. Data which describe the properties or qualities of the removed material and/or the patient and/or the patient's family or environment can be stored on computer readable media. The stored data can be used to draw correlations, to stratify groups of patients, to provide risk assessments, to provide diagnoses and/or prognoses. Further tests can be done on the stored materials at later times after the procedures have been completed.

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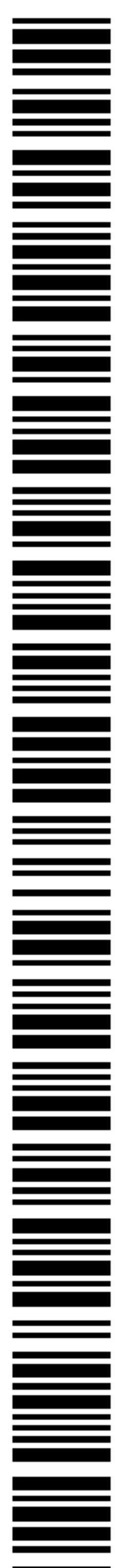
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**WO 2007/035909 A2**



# LIBRARIES AND DATA STRUCTURES OF MATERIALS REMOVED BY DEBULKING CATHETERS

## CROSS-REFERENCES TO RELATED APPLICATIONS

The present application claims priority to U.S. Patent Application No. 11/230,924, filed  
5 September 21, 2005, the complete disclosure of which is incorporated herein by reference.

## TECHNICAL FIELD

The present invention relates generally to computer readable media for storing data relating  
to patients and tissue samples excised from their vascular or other lumens. The data may be  
used to analyze current, past, or future patient health, to assess treatments, to evaluate drugs,  
10 to evaluate risk factors, and to determine proposed treatments or assessments.

## BACKGROUND OF THE INVENTION

Cardiovascular disease frequently arises from the accumulation of atheromatous material on  
the inner walls of vascular lumens, particularly arterial lumens of the coronary and other  
vasculature, resulting in a condition known as atherosclerosis. Atherosclerosis occurs  
15 naturally as a result of aging, but may also be aggravated by factors such as diet,  
hypertension, heredity, vascular injury, and the like. Atheromatous and other vascular  
deposits restrict blood flow and can cause ischemia which, in acute cases, can result in  
myocardial infarction. Atheromatous deposits can have widely varying properties, with some  
deposits being relatively soft and others being fibrous and/or calcified. In the latter case, the  
20 deposits are frequently referred to as plaque.

One conventional treatment for cardiovascular disease is the use of stents. Endoluminal  
stents are commonly used to treat obstructed or weakened body lumens, such as blood vessels  
and other vascular lumens. Once deployed in the blood vessel, the stent can remain in the  
body lumen where it will maintain the patency of the lumen and/or support the walls of the  
25 lumen which surround it. One factor impeding the success of stent technology in  
endoluminal treatments is the frequent occurrence of in-stent restenosis, characterized by  
proliferation and migration of smooth muscle cells within and/or adjacent to the implanted  
stent, causing reclosure or blockage of the body lumen.

Atherosclerosis and restenosis can be treated in a variety of ways, including drugs, bypass surgery, and a variety of catheter-based approaches which rely on intravascular debulking or removal of the atheromatous or other material occluding a blood vessel. Of particular interest to the present invention, a variety of methods for cutting or dislodging material and removing  
5 such material from the blood vessel have been proposed, generally being referred to as atherectomy procedures. Atherectomy catheters intended to excise material from the blood vessel lumen generally employ a rotatable and/or axially translatable cutting blade which can be advanced into or past the occlusive material in order to cut and separate such material from the blood vessel lumen.

10 While the tissue is readily available, methods for analyzing the tissue in a manner that compares and contrasts qualities of the tissues and the patients from whom they are derived do not yet exist.

Thus, there is a need in the art for methods and tools for managing and storing materials removed from body lumens. There is a need in the art for methods and tools for managing  
15 and storing information related to and/or derived from materials removed from body lumens.

#### BRIEF SUMMARY OF THE INVENTION

One aspect of the invention provides one or more computer readable media having a data structure stored thereon. The data structure comprises a first data field comprising a value corresponding to a property of a first tissue sample excised from a vascular lumen of a patient  
20 and a second data field comprising data identifying the patient. Optional additional data fields include, but are not limited to, a third data field comprising a value corresponding to cardiac health of the patient, a fourth data field comprising a value corresponding to a characteristic of the patient's blood, a fifth data field comprising a value corresponding to family history of the patient, a sixth data field comprising a value corresponding to the  
25 patient's medical history, a seventh data field comprising a value corresponding to a property of a second tissue sample excised from a vascular lumen of the patient at a distinct time in relation to the time the first tissue sample was excised, an eighth data field comprising a value corresponding to a property of a second tissue sample excised from distinct vascular lumen of the patient on the same day as the first tissue sample, a ninth data field which  
30 comprises a value which links a labeled storage container comprising excised tissue with a value in the second data field, a tenth data field which comprises a value which links the



labeled storage containers comprising a component extracted or processed from an extracted tissue with a value in the second data field. These can be used separately or cumulatively, and in any order. These data fields are not an exclusive list of possible useful data fields.

5 The data fields are filled by converting information about tissue to a format that is computer readable, and usable for analyzing, comparing and contrasting the tissue data with data on the physical symptoms of the patient from whom the tissue was retrieved. The data fields can be further used for comparing and contrasting the tissue data and physical symptoms between patients and/or among populations of patients.

10 The tissue can be modified by methods described herein, generating new data to be input into the data fields for further analysis.

For a further understanding of the nature and advantages of the invention, reference should be made to the following description taken in conjunction with the accompanying figure.

#### BRIEF DESCRIPTION OF THE DRAWINGS

15 Figure 1 shows relevant markers for which the excised vascular material can be tested for expression, and about which data can be stored.

#### DETAILED DESCRIPTION OF THE INVENTION

Data collected related to samples of materials removed from body lumens can be stored in data structures. The stored data can be used to draw correlations, to stratify groups of patients, to provide risk assessments, to provide diagnoses and/or prognoses, among other  
20 uses. Libraries of samples can be assembled to be used for studies of drugs, candidate drugs, toxins, therapeutic treatments, etc. The samples can be preserved according to any method known in the art. Samples may be frozen, for example, in liquid nitrogen. They may be preserved in paraffin, dried, freeze dried, etc. Samples may be treated to achieve a purified or semi-purified component of the sample. Samples may be treated, for example, to extract  
25 DNA or protein. Samples may be treated to extract mRNA and to preserve it or "convert" it to cDNA. Desirably, samples are stored in a consistent and systematic way so that patient information remains associated with the samples so that patient outcome or other data collected at a later time can be associated with the sample concurrently or at a later time.



Samples within a library can be stored and associated with information related to the sample itself, *e.g.*, its properties, and the patient from whom the sample was excised. Other information that can be associated with the sample includes, but is not limited to, results of analyses of the sample, patient history information, patient outcome information, drug efficacy information, therapeutic efficacy information, family history, factors of the patient related to cardiac disease, and factors of the patient related to non-cardiac disease. In some cases this information may be stored without association with the physical samples. Patient identifying information may be coded so that confidentiality can be maintained while still permitting correlation of various patient attributes with the samples.

10 One or more aspects of the invention may be embodied in computer-usable data and computer-executable instructions, such as in one or more program modules, executed by one or more computers or other devices. Generally, program modules include routines, programs, objects, components, data structures, etc., that perform particular tasks or implement particular abstract data types when executed by a processor in a computer or other device.

15 The computer executable instructions may be stored on a computer readable medium such as a hard disk, optical disk, removable storage media, solid state memory, RAM, etc. As will be appreciated by one of skill in the art, the functionality of the program modules may be combined or distributed as desired in various catheters. In addition, the functionality may be embodied in whole or in part in firmware or hardware equivalents such as integrated circuits,

20 field programmable gate arrays (FPGA), and the like. Particular data structures may be used to more effectively implement one or more aspects of the invention, and such data structures are contemplated within the scope of computer executable instructions and computer-usable data described herein.

Data fields which are present in the data structures of the present invention may include one or more of those discussed below. A first data field comprises a value corresponding to a property of a first tissue sample excised from a body lumen of the patient. The body lumen is often a vascular lumen. The property may be, for example, level of a marker in the tissue, composition of the tissue sample, histologic characterization, immunochemical characterization of the tissue, a genomic characteristic of the tissue, level of an mRNA in the tissue, location of the vascular lumen from which the tissue was excised, or volume or mass of the excised tissue. Any property of the tissue may be stored in this data field. A second data field may comprise data identifying a patient. The patient data may be anonymous or

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identify a person. If anonymous, the code will uniquely identify a patient's characteristics, without actually identifying the patient. Thus data can be used for studies, without divulging identities of the patients.

An optional third data field comprises a value corresponding to cardiac health of the patient. Such values may, for example, relate to past infarct history, past angioplasty procedures, or past cholesterol values. A possible fourth data field may comprise a value corresponding to a characteristic of the patient's blood. The blood may have been withdrawn at the time of or before tissue excision. The blood characteristic may be any known in the art, including but not limited to, sedimentation rate, red blood cell count, white blood cell count, amount of triglycerides, and C-reactive protein level.

An optional fifth data field comprises a value corresponding to family history of the patient. Thus a value can be assigned to family history events based on degree of relatedness of the family member and the severity of the event. An optional sixth data field comprises a value corresponding to the patient's own medical history. This history includes but is not limited to cardiac related events. Thus other medical history events can be recorded which may not be currently known to be associated with vascular occlusion, but which may in fact have a correlation. Such data will make the data structure useful for discovering new associations, risks, and mechanisms. Such data may also be useful in stratifying patients for treatment regimens and for drug trials.

An optional seventh data field comprises a value corresponding to a property of a second tissue sample excised from a vascular lumen of the patient at a distinct time from the first tissue sample. The second tissue sample can be excised from the same vascular lumen as the first tissue sample or from a different vascular lumen of the patient. An optional eighth data field comprises a value corresponding to a property of a second tissue sample excised from a distinct vascular lumen of the patient on the same day as the first tissue sample. Further data fields can also be employed to comprise other properties of the second tissue sample.

The computer readable media can optionally be associated with one or more excised tissue samples in labeled storage containers. Labeled storage containers include storage containers that are in fixed positions or parts of a machine or apparatus which positions are themselves labeled. If such stored tissue samples are associated with the data structure, an optional ninth data field can be used which comprises a value which links the labeled storage containers



with a value in the second data field. Alternatively, the labeled storage containers may be labeled with a value in the second data field. Alternatively or optionally the data structure can be associated with labeled storage containers in which one or more samples comprise a component extracted or processed from an excised vascular tissue from a vascular lumen of the patient. Such extracted or processed components include, but are not limited to, DNA, RNA, cDNA, lipid, carbohydrate, and protein. In such a case, the data structure can optionally comprise a tenth data field in which a value which links the labeled storage containers with a value in the second data field is present. Alternatively, such labeled storage containers can be labeled with a value in the second data field. There is no significance to the numbers of the data fields as used herein. Data fields with sequential numbers need not be used. Thus, for example, a structure can comprise data fields with fields 1, 2, 5, and 6 without data fields 3, 4, 7, 8, 9, and 10. The number of data fields is limited only by the availability of data and the ability to process the data.

Catheters can be used to debulk atheroma and other occlusive material from diseased body lumens, and in particular coronary arteries, *de novo* lesions, and in-stent restenosis lesions. Catheters are also suitable for treating stenoses of body lumens and other hyperplastic and neoplastic conditions in other body lumens, such as the ureter, the biliary duct, respiratory passages, the pancreatic duct, the lymphatic duct, and the like. Neoplastic cell growth will often occur as a result of a tumor surrounding and intruding into a body lumen. Debulking of such material can thus be beneficial to maintain patency of the body lumen. The debulked material is typically a continuous strip of tissue removed from the lumen interior wall that ranges from about 1 mg to about 2000 mg; it retains the structure of the tissue prior to removal. The continuous strip or strand of tissue removed will typically have a length that is longer than a length of the cutting window. The data storage and access structures of the present invention can be applied to a variety of occlusive, stenotic, or hyperplastic material in a variety of body lumens.

Apparatuses will generally comprise catheters having catheter bodies adapted for intraluminal introduction to the target body lumen. The dimensions and other physical characteristics of the catheter bodies will vary significantly depending on the body lumen which is to be accessed. In the exemplary case of atherectomy catheters intended for intravascular introduction, the proximal portions of the catheter bodies will typically be very flexible and suitable for introduction over a guidewire to a target site within the vasculature.



Generally, the smooth muscle cells of the stenotic material show a range of phenotypes, but most of the cells contain myofilaments as well as a relatively high amount of synthetic organelles, such as rough endoplasmic reticulum, Golgi apparatuses and mitochondria. One can determine how much stenotic tissue is retrieved in an access procedure. One can  
5 determine presence or absence of inflammatory cells in excised tissue. One can determine the presence of inflammatory cells within critical areas of plaque. Determination of the location and degree of inflammatory cells present may facilitate a more informed characterization or diagnosis.

The material removed from a catheter collection chamber, or a portion thereof, can be placed  
10 in a preserving agent, a tissue fixative, and or a preparation agent suitable for a desired test prior to testing the material. The material removed from the patient by this method is typically at least one or more continuous strip(s) of material that maintains the structure of the material *in vivo*. The quantity of material removed by the method can be from about 1 mg to about 2000 mg. Typically the amount of material is about 1 mg to about 100 mg,  
15 about 100 mg to about 200 mg, about 200 mg to about 300 mg, 300 mg to about 400 mg, 400 mg to about 500 mg, 500 mg to about 600 mg, about 600 mg to about 700 mg, 700 mg to about 800 mg, or about 800 mg to about 2000 mg. In a typical procedure about 400 mg to about 600 mg of material is removed and available for testing and/or storage. Collection of one or more continuous strips of material from the inner surface of a lumen may be longer  
20 than a largest dimension of the cutting window of a catheter used to remove the material. In a particular example, the material can comprise plaque tissue. The material can be collected from a single site or at least one additional site in the same or a different body lumen.

Excised material can be stored to permit later confirmatory or additional testing without having to subject the patient to another percutaneous transluminal lumenectomy procedure.  
25 The material can be tested by genomic screening, DNA hybridization, RNA hybridization, gene expression analysis, PCR amplification, proteomic testing, drug efficacy screening, presence of one or more protein markers, presence of one or more DNA markers, presence of one or more RNA markers, histological testing, histopathology, cytopathology, cell and tissue type analysis, biopsy, and the like. Additionally, the material can also be cultured and/or  
30 tested to determine sensitivity to drugs, toxins, and the like. The material can be tested for the presence of DNA, RNA, or protein markers comprising a smooth muscle proliferative promoter, a smooth muscle proliferative inhibitor, a cellular marker, an apoptotic marker, a



cell cycle protein, a transcriptional factor, a proliferative marker, an endothelial growth factor, an adhesion molecule, a cytokine, a chemokine, a chemokine receptor, an inflammation marker, a coagulation factor, a fibrinolytic factor, an oxidative stress related molecule, an extracellular matrix molecule, an interleukin, a growth factor, a glycoprotein, a proteoglycan, a cell-surface marker, a serum marker, and/or an immune factor, and the like. Tests for each of these molecules and others are well known to the skilled artisan as are methods and preservatives, fixatives and preparation agents for adding to all or a portion of the material collected. The results of any of the tests for properties of the removed material can be stored in a data structure according to the invention.

The material produced by a lumenectomy comprises at least one continuous tissue stand collected *in vivo* from an inner surface of the body lumen of a subject. The body lumen can be an artery or other lumen or vessel of the circulatory system and the material can comprise arterial plaque and associated tissue. The continuous strand of tissue provided by the disclosed methods provides a sufficient amount of high quality material to successfully perform at least one or more tests comprising, for example, genomic screening, DNA hybridization, RNA hybridization, gene expression analysis (including serial analysis of gene expression), PCR amplification, proteomic testing, drug efficacy screening, a determination of the presence of one or more protein markers, a determination of the presence of one or more DNA markers, a determination of the presence of one or more RNA markers, histological testing, histopathology, cytopathology, cell type analysis, tissue type analysis, biopsy, and the like. Methods for performing each of the tests are well known to the skilled artisan. It is also well known that material collected from a patient can be added to a preserving agent, tissue fixative, or a preparation agent in order to prepare at least a portion of collected material for the desired test. Agents known in the art for preserving, fixing or preparing the material for later use include, for example, saline, heparinized saline, liquid nitrogen, formalin, a membrane lysis agent, an RNA or DNA preparation agent, and the like. Particular tests that can be carried out successfully on the excised lumenectomy material include, but are not limited to, histology techniques including hematoxylin and eosin staining, connective tissue staining, carbohydrate staining, and lipid staining, and the like. In addition, tissue array testing, enzyme histochemistry, transmission electron microscopy, immunohistology, immunocytochemistry, immunoassays, immunofluorescent assays, immunoprecipitation assays, ELISA, flow cytometry, fluorescent activated cell sorting, radioimmunochemistry, electrophoresis, two-dimensional gel electrophoresis, Western



blotting, protein sequencing, mass spectrometry, proteomic analysis, and protein microarray analysis can be carried out. Further, cytogenetic testing, Northern blotting, RNase protection assays, *in situ* hybridization assays, DNA microarray testing, reverse transcription polymerase chain reaction PCR (RT-PCR), Southern blotting, DNA sequencing, PCR amplification, single strand conformational polymorphism assays, single strand polymorphism (SNP) assays, and serial analysis of gene expression (SAGE) assays can be successfully carried out with the lumenectomy materials compositions. Other tests or procedures known in the art may also be used. The compositions can also be prepared for storage for later testing.

10 The material collected can be analyzed for a variety of factors, including the presence of DNA, RNA, or protein markers comprising smooth muscle proliferative promoters (platelet-derived growth factor (PDGF), and PDGF receptor, basic fibroblast growth factor (FGF) and FGF receptor, interleukin 1 (IL-1), or transforming growth factor  $\alpha$  (TGF $\alpha$ ), and the like), smooth muscle proliferative inhibitors (nitric oxide/endothelial-derived relaxing factors

15 (NO/EDRF), interferon  $\gamma$  (IF $\gamma$ ), transforming growth factor  $\beta$  (TGF $\beta$ ), or TGF $\beta$  receptor, and the like), cellular markers (including CD68, CD3, CD4, CD8, CD20, smooth muscle actin, or CD31, and the like), apoptotic markers (Bcl-x, Bcl-2, Bax, Bak, or P53, and the like), cell cycle proteins (cyclin A, cyclin B, cyclin D, or cyclin E, and the like), transcriptional factors (transcription factor NF $\kappa$ B, transcription factor E2F, transcription factor CREB, or

20 transcription factor KLF5/BTEB2, and the like), proliferative markers (Ki-67 or proliferating cell nuclear antigen (PCNA), and the like), endothelial growth factors (vascular endothelial growth factor (VEGF), and the like), adhesion molecules (intercellular adhesion molecule-1 (ICAM-1), CD11a/CD18 (LFA-1), CD11b/CD18 (MAC-1), vascular cell adhesion molecule-1 (VCAM-1), p-selectin (CD62P), or integrin, and the like), cytokines (interleukin 6 (IL-6) or

25 interleukin 8 (IL-8), and the like), chemokines and chemokine receptors (monocyte chemoattractant protein 1 (MCP-1) and its receptor CCR2, CX3C chemokine fractalkine and its receptor CX3CR1, or eotaxin and its receptor CCR3, and the like), inflammation markers (C-reactive protein, myeloperoxidase, or complement proteins, and the like), coagulation factors and fibrinolytic factors (fibrinogen, prothrombinogen, plasminogen activator, tissue

30 factor, or glycoprotein receptor on platelets (GpIIb-IIIa), and the like), oxidative stress related molecules (oxidized LDL and its receptor CD36, or lipoxygenase, and the like), extracellular matrix molecules (collagen, matrix metalloproteinase (MMP), FK506-binding protein 12 (FKBP12), endothelial differentiation gene receptors (EDG receptors), ephrins, elastin, lamin

- receptor, monocyte colony stimulating factor (M-CSF), tumor necrosis factor (TNF), or PDZ domain proteins, and the like), other interleukins (such as interleukin 1 (IL-1) and the like), growth factors, glycoproteins, proteoglycans (versican, hyaluronan, biglycan, or decorin, and the like), cell-surface markers, serum markers, and/or immune factors (stromal cell-derived factor 1a (SDF-1)), and the like). Analysis of the excised material by any of the above tests can be used for diagnosis of a condition in a patient, to design a treatment directive or protocol for a subject, to monitor progress of a treatment regimen, or if tests from a number of individuals are compared, the information can be used in a multi-patient analysis, such as a cardiovascular disease population study.
- 5
- 10 While all the above is a complete description of the preferred embodiments of the inventions, various alternatives, modifications, and equivalents may be used. Therefore, although the foregoing invention has been described in detail for purposes of clarity of understanding, it will be obvious that certain modifications may be practiced within the scope of the appended claims.



CLAIMS

1. One or more computer readable media having a data structure stored thereon, said data structure comprising:  
a **first data field** comprising a value corresponding to a property of a first tissue sample excised from a vascular lumen of a patient;  
a **second data field** comprising data identifying a patient.
2. The computer readable media of claim 1 further comprising:  
a **third data field** comprising a value corresponding to cardiac health of the patient.
3. The computer readable media of claim 1 wherein the property is a level of a marker in the tissue.
4. The computer readable media of claim 1 wherein the property is composition of the tissue sample.
5. The computer readable media of claim 1 wherein the property is histologic characterization of the tissue.
6. The computer readable media of claim 1 wherein the property is an immunochemical characterization of the tissue.
7. The computer readable media of claim 1 wherein the property is a genomic characteristic.
8. The computer readable media of claim 1 wherein the property is level of a mRNA.
9. The computer readable media of claim 1 wherein the property is location of the vascular lumen from which the tissue was excised.
10. The computer readable media of claim 1 wherein the property is volume or mass of the excised tissue.

11. The computer readable media of claim 2 further comprising:  
a **fourth data field** comprising a value corresponding to a characteristic of the patient's blood.
12. The computer readable media of claim 11 wherein the patient's blood was withdrawn at the time of or before tissue excision.
13. The computer readable media of claim 11 further comprising:  
a **fifth data field** comprising a value corresponding to family history of the patient.
14. The computer readable media of claim 13 further comprising:  
a **sixth data field** comprising a value corresponding to the patient's medical history.
15. The computer readable media of claim 14 further comprising:  
a **seventh data field** comprising a value corresponding to a property of a second tissue sample excised from a vascular lumen of the patient at a distinct time.
16. The computer readable media of claim 15 wherein the second tissue sample is excised from the same vascular lumen as the first tissue sample.
17. The computer readable media of claim 16 further comprising:  
an **eighth data field** comprising a value corresponding to a property of a second tissue sample excised from distinct vascular lumen of the patient on the same day as the first tissue sample.
18. The computer readable media of claim 17 wherein said media are associated with one or more excised tissue samples in labeled storage containers, wherein the computer readable media comprise a **ninth data field** which comprises a value which links the labeled storage containers with a value in the **second data field**.
19. The computer readable media of claim 1 wherein said media are associated with one or more excised tissue samples in labeled storage containers, wherein the storage containers are labeled with a value in the **second data field**.



20. The computer readable media of claim 18 wherein said media are associated with one or more samples in labeled storage containers, wherein the one or more samples comprise a component extracted or processed from an excised vascular tissue from a vascular lumen of the patient, wherein the component is selected from the group consisting of DNA, RNA, cDNA, and protein, and wherein the computer readable media comprise a **tenth data field** which comprises a value which links the labeled storage containers with a value in the **second data field**.

21. The computer readable media of claim 1 wherein said media are associated with one or more samples in labeled storage containers, wherein the storage containers are labeled with a value in the **second data field**, wherein the samples comprise a component extracted or processed from an excised vascular tissue from a vascular lumen of the patient, wherein the component is selected from the group consisting of DNA, RNA, cDNA, and protein.

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## Markers upregulated in vascular disease

AA775616	osteopontin
AA682386	oxidised low density lipoprotein (lectin-like) receptor 1
AA969504	interferon, gamma
AA102526	interleukin 8
BU631490	tissue inhibitor of metalloproteinase 2
NM_002356	myristoylated alanine-rich protein kinase C substrate
NM_000930	plasminogen activator, tissue
NM_002117	major histocompatibility complex, class I, C
AI129421	interleukin 18 (interferon-gamma-inducing factor)
W51794	matrix metalloproteinase 3 (stromelysin 1, progelatinase)
AA143201	matrix metalloproteinase 1 (interstitial collagenase)
N94616	laminin, alpha 4
NM_021999	integral membrane protein 2B
NM_000584	interleukin 8
NM_002510	glycoprotein (transmembrane) nmb
N53447	integral membrane protein 2A
NM_002659	plasminogen activator, urokinase receptor
AL133111	SH3-domain binding protein 5 (BTK-associated)
NM_147780	cathepsin B
W46577	endothelial cell-specific molecule 1
AA857496	matrix metalloproteinase 10 (stromelysin 2)
NM_005502	ATP-binding cassette, sub-family A (ABC1), member 1
AI342012	macrophage scavenger receptor 1
AA490846	integrin, alpha 4 (antigen CD49D, alpha 4 subunit of VLA-4 receptor)
AA454999	hypothetical protein FLJ10111
AK093984	hypothetical protein MGC5618
AA666269	integrin, beta 3 (platelet glycoprotein IIIa, antigen CD61)
NM_005625	syndecan binding protein (syntenin)
BC014989	phospholipid scramblase 3
AI279830	protein phosphatase 1, regulatory (inhibitor) subunit 16B
AA936768	interleukin 1, alpha
NM_001920	decorin
AK055130	calmodulin 2 (phosphorylase kinase, delta)
NM_016497	mitochondrial ribosomal protein L51
AA451863	CD4 antigen (p55)
NM_058197	eyelin-dependent-kinase-inhibitor-2A
R10284	hyaluronan-mediated motility receptor (RHAMM)
AI309439	integrin, alpha M (complement component receptor 3, alpha)
AI334914	integrin, alpha 2b
AF001893	multiple endocrine neoplasia I
N36136	endomucin-2
AW772163	hypothetical protein FLJ20401
NM_001964	early growth response 1
AA454668	prostaglandin-endoperoxide synthase 1
NM_004530	matrix metalloproteinase 2

Fig. 1  
(continued)



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AK027663 stanniocalcin 2  
 AA057204 interleukin 2 receptor, beta  
 NM\_001444 fatty acid binding protein 5 (psoriasis-associated)  
 AA873792 small inducible cytokine A5 (RANTES)

## Markers upregulated in diabetes

AA936768 interleukin 1, alpha  
 NM\_000600 interleukin 6 (interferon, beta 2)  
 N98591 interleukin 6 (interferon, beta 2)  
 AA156031 metallothionein 2A  
 NM\_001235 serine (or cysteine) proteinase inhibitor, clade H  
 BF131637 metallothionein 2A  
 NM\_006216 serine (or cysteine) proteinase inhibitor, clade E  
 NM\_001552 insulin-like growth factor binding protein 4  
 NM\_004530 matrix metalloproteinase 2  
 NM\_000088 collagen, type I, alpha 1  
 NM\_023009 MARCKS-like protein  
 NM\_003670 basic helix-loop-helix domain containing, class B, 2  
 T80495 Hs. clone 24707 mRNA sequence  
 NM\_002993 chemokine C-X-C motif, granulocyte chemotactic protein 2  
 NM\_006756 transcription elongation factor A (SII), 1  
 AI983239 Hs. cDNA FLJ32163 fis, clone PLACE6000371  
 NM\_005110 glutamine-fructose-6-phosphate transaminase 2  
 NM\_000584 interleukin 8  
 AK092836 Homo sapiens cDNA FLJ35517 fis, clone SPLEN2000698  
 NM\_000104 cytochrome P450, subfamily I (dioxin-inducible), peptide  
 NM\_004966 heterogeneous nuclear ribonucleoprotein F  
 AK025599 mannosidase, alpha, class 1A, member 1  
 NM\_002923 regulator of G-protein signalling 2, 24kDa  
 AW005755 macrophage migration inhibitory factor  
 AA873792 small inducible cytokine A5 (RANTES)  
 U72621 pleiomorphic adenoma gene-like 1  
 NM\_000358 transforming growth factor, beta-induced, 68kDa  
 AK054688 Homo sapiens cDNA FLJ30126 fis, clone BRACE1000114  
 BC007583 Homo sapiens, clone MGC:15572 IMAGE:3140342  
 NM\_000089 collagen, type I, alpha 2  
 NM\_004404 neural precursor cell expressed, developmental regulated 5  
 NM\_078467 cyclin-dependent kinase inhibitor 1A (p21, Cip1)  
 U97105 Homo sapiens N2A3 mRNA, complete cds  
 AI356451 CD19 antigen  
 BF732465 tissue inhibitor of metalloproteinase 2  
 NM\_001554 cysteine-rich, angiogenic inducer, 61  
 BQ890604 Homo sapiens URB mRNA, complete cds  
 NM\_002631 phosphogluconate dehydrogenase  
 N94503 pregnancy-associated plasma protein A  
 NM\_001710 B-factor, properdin

Fig. 1  
 (continued)

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## Markers upregulated in normal (non-diabetic) vessel segments

NM_000584	interleukin 8
N98591	interleukin 6 (interferon, beta 2)
AA936768	interleukin 1, alpha
BM803108	ESTs
NM_000600	interleukin 6 (interferon, beta 2)
AI359876	EST
AA156031	metallothionein 2A
BF131637	metallothionein 2A
NM_003670	basic helix-loop-helix domain, class B, 2
NM_001235	serine (or cysteine) proteinase inhibitor, clade H
NM_004530	matrix metalloproteinase 2
NM_002982	monocyte chemotactic protein 1
NM_002631	phosphogluconate dehydrogenase
NM_078467	cyclin-dependent kinase inhibitor 1A (p21, Cip1)
NM_152862	actin related protein 2/3 complex, subunit 2
NM_002923	regulator of G-protein signalling 2, 24kDa
AI983239	Hs. cDNA FLJ32163 fis, clone PLACE6000371
NM_005415	solute carrier family 20, member 1
AW772163	hypothetical protein FLJ20401
R21535	Hs. cDNA FLJ11724 fis, clone HEMBA1005331
NM_005110	glutamine-fructose-6-phosphate transaminase 2
AK092836	cDNA FLJ35517 fis, clone SPLEN2000698
NM_006216	serine (or cysteine) proteinase inhibitor, clade E

## Markers which are downregulated with statin treatment

NM000600	interleukin 6 (interferon, beta 2)
N98591	interleukin 6 (interferon, beta 2)
NM_005746	pre-B-cell colony-enhancing factor
NM_002852	pentaxin-related gene, rapidly induced by IL-1 beta
N92901	fatty acid binding protein 4, adipocyte
NM_005110	glutamine-fructose-6-phosphate transaminase 2
AK094728	cDNA FLJ37409 fis, similar to COMPLEMENT C3
NM_004000	chitinase 3-like 2
NM_002923	regulator of G-protein signalling 2, 24kDa
T80495	Hs. clone 24707 mRNA sequence
AA936768	interleukin 1, alpha
<del>NM_145791</del>	<del>microsomal glutathione S-transferase 1</del>
NM_006169	nicotinamide N-methyltransferase
AW007736	UDP-glucose ceramide glucosyltransferase
NM_005420	sulfotransferase, estrogen-preferring
NM_003670	basic helix-loop-helix domain containing, class B, 2
AA425102	monocyte chemotactic protein 1
NM_003254	tissue inhibitor of metalloproteinase 1
BF131637	metallothionein 2A
NM_000104	cytochrome P450, subfamily I (dioxin-inducible)
NM_001733	complement component 1, r subcomponent

Fig. 1  
(continued)



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NM\_032849 hypothetical protein FLJ14834  
 NM\_005328 hyaluronan synthase 2  
 NM\_002009 fibroblast growth factor 7 (keratinocyte growth factor)  
 NM\_002615 serine (or cysteine) proteinase inhibitor, clade F  
 NM\_002658 plasminogen activator, urokinase  
 NM\_033439 DVS27-related protein  
 AA381343 interleukin 6 (interferon, beta 2)  
 AW780123 ribosomal protein S26  
 M14219 chondroitin/dermatan sulfate proteoglycan (PG40) core  
 AF495759 Homo sapiens unknown mRNA  
 NM\_001679 ATPase, Na<sup>+</sup>/K<sup>+</sup> transporting, beta 3 polypeptide  
 NM\_001029 ribosomal protein S26  
 NM\_002074 guanine nucleotide binding protein, beta polypeptide 1  
 NM\_001552 insulin-like growth factor binding protein 4  
 AF208043 interferon, gamma-inducible protein 16  
 AI268937 monocyte chemotactic protein 2  
 AA040170 monocyte chemotactic protein 3  
 AW131311 EST  
 NM\_005415 solute carrier family 20 (phosphate transporter), member 1  
 NM\_006988 a disintegrin-like and metalloprotease (reprolysin type)  
 NM\_006307 sushi-repeat-containing protein, X chromosome  
 NM\_000584 interleukin 8  
 D31887 KIAA0062 protein  
 NM\_002229 jun B proto-oncogene  
 NM\_002982 monocyte chemotactic protein 1

Markers downregulated with statin treatment

NM\_002615 serine (or cysteine) proteinase inhibitor, clade F  
 AK094728 Homo sapiens cDNA FLJ37409 fis, clone BRAMY2028516  
 NM\_001552 insulin-like growth factor binding protein 4  
 N92901 fatty acid binding protein 4, adipocyte  
 N98591 interleukin 6 (interferon, beta 2)  
 NM\_000104 cytochrome P450, subfamily I (dioxin-inducible)  
 NM\_006756 transcription elongation factor A (SII), 1  
 NM\_000600 interleukin 6 (interferon, beta 2)  
 AF506819 Homo sapiens URB mRNA, complete cds  
 NM\_145791 microsomal glutathione S-transferase 1  
 N39161 CD36 antigen (thrombospondin receptor)  
 M14219 Human chondroitin-sulfate-proteoglycan-core protein  
 NM\_031476 hypothetical protein DKFZp434B044  
 NM\_000186 H factor 1 (complement)  
 NM\_003254 tissue inhibitor of metalloproteinase 1  
 N98591 interleukin 6 (interferon, beta 2)  
 AJ318805 ESTs, Weakly similar to hypothetical protein FLJ20378  
 AA284954 colony stimulating factor 1 receptor  
 NM\_002923 regulator of G-protein signalling 2, 24kDa  
 NM\_001920 decorin  
 BI830199 likely ortholog of mouse Urb

Fig. 1  
(continued)

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AA451863	CD4 antigen (p55)
AA464526	interleukin 1 receptor, type I
AW192258	sprouty homolog 4 (Drosophila).
N68859	intercellular adhesion molecule 1 (CD54)
BC007552	Homo sapiens, clone MGC:15473 IMAGE:2967168, mRNA
NM_001733	complement component 1, r subcomponent
NM_006288	Thy-1 cell surface antigen
NM_000201	intercellular adhesion molecule 1 (CD54)
R22412	platelet/endothelial cell adhesion molecule (CD31 antigen)
NM_013417	isoleucine-tRNA synthetase
NM_004000	chitinase 3-like 2
R70506	growth factor receptor-bound protein 2
NM_030781	collectin sub-family member 12
NM_001710	B-factor, properdin
NM_006216	serine (or cysteine) proteinase inhibitor, clade E
NM_005110	glutamine-fructose-6-phosphate transaminase 2
AF506819	Homo sapiens URB mRNA, complete cds
NM_002074	guanine nucleotide binding protein, beta polypeptide 1
H26022	fractalkine, inducible cytokine subfamily D (Cys-X3-Cys)
AK092836	Homo sapiens cDNA FLJ35517 fis, clone SPLEN2000698
BQ890604	Homo sapiens URB mRNA, complete cds
AA057204	interleukin 2 receptor, beta
AI524093	myosin, heavy polypeptide 11, smooth muscle
AI655374	stromal cell-derived factor 1

Fig. 1