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(54) Title: INTRAVENOUSLY IMPLANTED METAL ALLOY STENT AND A NEW METHOD FOR THE PRODUCTION OF THIS STENT

(57) Abstract: The invention is related to a permeable, tubular metal alloy stent, which is placed intravenously and ensures continuity of flow inside the vessel at necessary rate by being expended by a certain extent just after the placement, wherein Fe-Mn-X-Y alloy is used for producing biodegradable stents, X contains at least one elements selected from the group that is composed of Si, Co, Mo and Y contains at least one elements selected from the group that is composed of C and Pd., in such alloy Fe is characterized as 47-75%, Mn is 20-35%, Si is 1-6%, Co is 1-4%, Mo is 1-4%, C is 1-2% and Pd is 1-2% by weight. The invention is a method of production of a permeable, tubular metal alloy stent, which is placed intravenously and ensures continuity of flow inside the vessel at necessary rate by being expended by a certain extent just after the placement, wherein - the production is performed with 3D printer, - a laser source with 200-400 W power is used during production, - powders forming the alloy are laid properly on a tray inside the production pool, - the laser source is located stationary at mid-top point of the tray and in a way that it is distant from the tray at focal length, - mirrors are used for ensuring directing laser beams into desired point, - process steps contain scanning of each layer by directing laser beams by means of mirrors during production and combining them in a manner that desired geometry is achieved mean powder size is 5-20 microns, laser power is 200-400 W, scanning rate is 10 m/s - 20 m/s, diameter of laser beam is between 80 μm – 150 μm and layer height is between 20 μm – 200 μm during the production and argon or nitrogen gas is used as a protective atmosphere during production.

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Intravenously Implanted Metal Alloy Stent and A New Method For the Production of This Stent

Field Of The Invention

This invention is related to stents used for expanding narrowed vessels in body.

Background Of The Invention

Medical devices, which are commonly used for expanding narrowed vessels in the body, are called stent. Stents are permeable, tubular structures, which are placed intravenously and ensure continuity of flow inside the vessel at necessary rate by being expended by a certain extent just after the placement. Stents can either be made of metal or plastic.

Stents can be classified depending on different characteristics. Generally; stents are classified as bare metal stents, drug eluted stents, soluble stents by structure; cylindrical, grill, circular, multiple design and special type stents by design and carotid, coronary, renal and peripheral stents by the area of application. Stents are classified under two groups as self-expandable stents, balloon expandable stents depending on the application systems.

Among the stent types, stents that can be soluble in body, have become more important in recent years. Studies in this field are in progress both in our country and around the world. Plastic stents that can be soluble in body are commercialized and started to be applied on humans.

Production methods used for stent production in current art involve techniques that contain complex and multiple operations and production takes

longer. Furthermore, it is difficult and sometimes impossible to make custom fabrication with these methods. In addition to that, production time and cost of the stent is high. If production with 3D method is used for producing metal stents that can be soluble in body, it will be possible to solve aforesaid problems as well as to produce both commonly used and standardized stents and custom stents which are not standard and used in limited numbers, rapidly and economically.

Stents that are used currently are the ones that are made of corrosion resistant metals and stay in the body permanently. Bare metal stents are generally made of 316L stainless steel, nitinol and cobalt-chrome alloy. Thanks to stent application, re contraction of the vessel after the angiography is reduced with structural effect of the metal stent. On the other hand some disadvantages of fixed metallic implants limit their widespread use. These limitations include low thrombogenecity, continuous physical pain, chronic inflammatory local reactions, mechanical behavioural disharmony between vessel with and without stent, growth adaptation failure in young patients and unavailability to further surgical vascular operations or problems caused during the application.

Since fundamental effect of stent implantation is ensured by structural effect of the stent, 6 to 12 months are needed for reshaping and recovery of the vessel. After that period, presence of stent inside the body does not have any benefit. Metal stents inhibit restenosis but they stay in the body for an unnecessarily long period after they perform their functions. Permanent presence of stent inside the body causes problems such as long term endothelial dysfunction, delayed re-endotalization, thrombogenecity, permanent physical irritation and chronic inflammatory local reactions.

A bio-degradable and shape memory material is used within the scope of the invention. Similar materials are also used in prior art.

A bioerodable stent is mentioned in European Patent document No. EP2398521 available in current art. This stent is formed by a composition that is

composed of Fe, Mn, Si and C. This material does not have shape memory feature. It can only be used in balloon expansion method.

A stent made of an iron based allot is mentioned in Chinese Patent document No. CN103974728 available in current art. Such alloy contains Fe-X-Y. X is at least one austenite balancing element selected from the group that is composed of Co, Ni, Mn, Cu, Re, Rh, Ru, Ir, Pt. Y is at least one corrosion activator selected from the group that is composed of Pd and Au.

In known applications of the art, production of bio-degradable (soluble in body) metal stents with 3D printer technology by using shape memory alloys, which are types of smart materials, does not involve.

Objective of Invention

Purpose of the invention is to develop a bio-degradable (soluble in body) metal stents by using shape memory alloys, which are types of smart materials.

The stent developed for achieving such purposes contain Fe-Mn-X-Y alloy. Wherein, X contains at least one element selected from the group that is composed of S, Co and Mo. Wherein, Y contains at least one element selected from the group that is composed of C and Pd. Production is performed with 3D printer.

Detailed Explanation of the Invention

Stents that are planned to be produced within the scope of the invention are under balloon expandable stents.

Metal stents that can be soluble inside the body, dissolve during blood flow and removed with blood. The stent integrates with the vessel short time after its

implantation and settles inside the vascular tissue. The stent, after performing its function for the first 6 months, will be absorbed by the vascular tissue and cover mineral need of the body. It does not have any harmful effect for the body but it is very important in covering minerals (iron, manganese etc.) needed by the body during the dissolution.

Thanks to the invention, aforesaid problems will be resolved substantially and additional benefits will be obtained.

There is no existing study related to metallic stent production with 3D printer method. Material to be used in production is produced with mechanical alloying. Changing the alloy will change all parameters related to production with 3D printer. Changing the laser power will affect production speed. As the laser power increases, production time decreases. Furthermore sintering temperature varies depending on the material (alloy) to be used in production. No complete melting occurs during production with 3D printer. Achieving melting that will allow integration of materials will be sufficient. On the other hand, parameters such as progress rate, laser focus diameter and layer thickness are determined and used depending on the material used.

Material to be used in production is a material that is in shape memory materials class and can be soluble (by absorbing inside tissue) inside the body. Defining production parameters of this material for a 3D printer is a very important innovation. Thus, this bio-degradable material can be used in areas such as implant production.

There are studies on using shape memory materials in stent production but there are no applications on metal sent production with 3D printer method.

If this material is used in stent production; the stent will be absorbed inside the body and removed after completing its function or it will be possible for the body to cover its mineral needs from the stent. Depending on the period of

completion of the function of the stent or implant inside the body, period for the dissolution and corrosion of the stent can be adjusted or changed. In vivo dissolution periods of the product will be determined by means of corrosion tests to be performed. It will be possible to delay or move this dissolution period to an earlier time by means of new additives to be added.

Restenosis can be reduced or prevented thanks to mechanical features of the stent manufactured. Restenosis is one of the most commonly encountered problems in existing stents.

The material offered is a bio-degradable and shape memory material. As the result of the investigations made, similar material ingredients have been encountered. However use of production with 3D printer method in stent production is an innovation. Therefore, it will be possible to perform custom made stent production in very short time. Production in desired diameter, geometry and size depending on the condition of the vessel and occlusion will be able to be performed.

Thanks to the invention, post application problems caused by permanent stents are eliminated. In addition to that, it will be possible to test stents that are new and have different geometries in a very short time and try them on practice models or human body.

In current art, stent production technique involves highly complex and tough processes. On the other hand, it is possible to produce stents fast, economically and custom made with 3D printer method.

Implants that can be soluble in body can be produced by fully defining use of the alloy developed in 3D printer. Thus; inconveniencies arising from prolonged existence of implants completing their functions in the body are eliminated and complications that may arise during the operations made for removing the implant can be avoided.

Stent production in traditional method is performed by sensitive casting of the alloy in desired combination in tubular form and laser processing following it. Another method used in production of shape memory alloys is the power metallurgy (PM) method. PM method has advantages over other production methods such as high raw material-product return, low energy consumption, suitability for mass production, fine grain size and high mechanical characteristics. PM method's "net-shape" feature, which allows obtaining final product with a shorter process (with less process steps) is another factor that is considered while choosing this method.

The biggest cost item in Powder Metallurgy (PM) method is composed of the moulding expenses. Both in traditional PM method (Press-Sinter) and power injection method, there is a need for a different mould for every product. Mould cost is eliminated by application of articulating production methods to metal powders and it becomes possible to produce complex shaped parts which are difficult or not possible to be produced.

In the literature, there are studies on producing Fe-Mn based bio-degradable alloys with PM method. Hermawan et al. alloyed elemental Fe and Mn powders and sintered them either under argon or reductive Ar+H2 atmosphere at temperature of 1200 C as a part of their study. They performed cold rolling in order to increase density and obtained characteristics close to 316 L stainless steel. Furthermore, the biodegradation speed they obtain is higher than pure iron. Same researchers performed mechanical alloying of elemental Fe and Mn powders in a way that creates Fe-XMn (X=20,25,30,35) alloy and obtained highest resistance in Fe-20 Mn and Fe-25 Mn alloys and highest ductility in Fe-30 Mn and Fe-35 Mn alloys after sintering. They reported that all alloys formed had higher corrosion rates than pure iron and indicated that Fe-30 Mn and Fe-35 Mn alloy was the most suitable alloy for a stent. In another study (Harjanto 2012), Fe-25Mn-1C and Fe-35Mn-1C alloys created with PM method were examined and it was indicated that pores emerging as the result of PM process would have a

positive impact on biodegradation rate. In the only study (Chotu et al.,2013) on producing Fe-Mn based biodegradable materials with a 3D printer by using alloy powders other than production with traditional PM method, Fe-30Mn alloy was used and the technology used was based on spraying the material called 3D Inkjet Printing. In the method subject to the invention on the other hand, apart from this method, sintering-melting of biodegradable and shape memory metal alloys are planned.

Purpose of the Invention is to develop a method of production for biodegradable (soluble in body) metal stents with 3D printer technology by using shape memory alloys, which are types of smart materials, which are very hard to produce with traditional methods.

Fe-Mn-X-Y (X=Si, Co, Mo), (Y= C, Pd) (Fe %47-75, Mn = %20-35, Si = %1-6, Co = %1-4, Mo = %1-4, C = %1-2, Pd = 1-2% by weight) smart alloys have been developed for producing biodegradable stents. Optimum Mn and Si values have been determined for the production of a stent with the most suitable physical and mechanical characteristics. Using of optimum values, which will maximize X and Y values, poses great importance. Specificity of alloys in this composition is that they are biodegradable and have shape memory feature. The likes of alloys developed were produced with traditional methods and it was seen that alloys with limited number of combinations were studied in the literature.

After determining the layer heights for alloy powders with sizes varying between 5 to 20 microns, the laser power required for combining this alloy by means of melting method is determined. Laser power varies depending on the composition of the stent material and alloy ratios.

A laser source with 200-400 W power is used during production. Then, powders forming the alloy are laid properly on a tray inside the production pool. Laying of the material as a smooth layer affects measurement accuracy and surface quality. The laser source is located stationary at mid-top point of the tray

and in a way that it is distant from the tray at focal length. Mirrors are used for ensuring directing laser beams into desired point. Process steps contain scanning of each layer by directing laser beams by means of mirrors during production and combining them in a manner that desired geometry is achieved. Determination of the melting temperature and focal length regarding to the alloy constitutes great importance. Melting temperature is determined as the result of the tests to be applied on the alloy. Impact created by the laser on the material may vary depending on the focal height, diameter of the laser beam and layer thickness. If these values are not optimum, resistance of the material decreases and a suitable combination cannot be performed.

Technical specifications of the 3D printer are as follows:
Mean powder size: 5 micron to 20 micron (weighted average ~15 micron)
Laser power: 200-400 W
Scan rate: 10 m/s - 20 m/s (scan rate varies depending on the laser power and layer thickness used.)
Laser beam diameter: 80 μm – 150 μm
Layer height: 20 μm – 200 μm

The invention is related to a permeable, tubular metal alloy stent, which is placed intravenously and ensures continuity of flow inside the vessel at necessary rate by being expended by a certain extent just after the placement, wherein Fe-Mn-X-Y alloy is used for producing biodegradable stents, X contains at least one elements selected from the group that is composed of Si, Co, Mo and Y contains at least one elements selected from the group that is composed of C and Pd., in such alloy Fe is characterized as 47-75%, Mn is 20-35%, Si is 1-6%, Co is 1-4%, Mo is 1-4%, C is 1-2% and Pd is 1-2% by weight.

The invention is a method of production of a permeable, tubular metal alloy stent, which is placed intravenously and ensures continuity of flow inside the vessel at necessary rate by being expended by a certain extent just after the placement, wherein

- the production is performed with 3D printer,
- a laser source with 200-400 W power is used during production,
- powders forming the alloy are laid properly on a tray inside the production pool,
- the laser source is located stationary at mid-top point of the tray and in a way that it is distant from the tray at focal length,
- mirrors are used for ensuring directing laser beams into desired point,
- process steps contain scanning of each layer by directing laser beams by means of mirrors during production and combining them in a manner that desired geometry is achieved.

mean powder size is 5-20 microns, laser power is 200-400 W, scanning rate is 10 m/s - 20 m/s, diameter of laser beam is between 80 μm – 150 μm and layer height is between 20 μm – 200 μm during the production and argon or nitrogen gas is used as a protective atmosphere during production.

CLAIMS

1. A permeable, tubular metal alloy stent, which is placed intravenously and ensures continuity of flow inside the vessel at necessary rate by being expended by a certain extent just after the placement characterised in that; Fe-Mn-X-Y alloy is used for producing biodegradable stents, X contains at least one elements selected from the group that is composed of Si, Co, Mo and Y contains at least one elements selected from the group that is composed of C and Pd.

2. An alloy mentioned in Claim 1 characterised in that; Fe is 47-75%, Mn is 20-35%, Si is 1-6%, Co is 1-4%, Mo is 1-4%, C is 1-2% and Pd is 1-2% by weight.

3. A method of production of a permeable, tubular metal alloy stent, which is placed intravenously and ensures continuity of flow inside the vessel at necessary rate by being expended by a certain extent just after the placement characterised in that;
   - the production is performed with 3D printer,
   - a laser source with 200-400 W power is used during production,
   - powders forming the alloy are laid properly on a tray inside the production pool,
   - the laser source is located stationary at mid-top point of the tray and in a way that it is distant from the tray at focal length,
   - mirrors are used for ensuring directing laser beams into desired point,
   - process steps contain scanning of each layer by directing laser beams by means of mirrors during production and combining them in a manner that desired geometry is achieved.

4. A stent production method mentioned in claim 3 characterised in that; mean powder size is 5-20 microns, laser power is 200-400 W, scanning rate is 10 m/s - 20 m/s, diameter of laser beam is between 80 μm – 150 μm and layer height is between 20 μm – 200 μm during the production.

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5. A stent production method mentioned in claim 3 characterised in that; argon or nitrogen gas is used as a protective atmosphere during production.

INTERNATIONAL SEARCH REPORT

International application No
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A. CLASSIFICATION OF SUBJECT MATTER
INV. A61L31/02 A61L31/14 B28B1/00 B29C64/135
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61L B28B B29C

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/217370 A1 (SCHEUERMANN TORSTEN [DE] ET AL) 26 August 2010 (2010-08-26) paragraph [0028]; claims; examples; table 1	1
X	US 2010/174367 A1 (JANKO GORDON F [US] ET AL) 8 July 2010 (2010-07-08) paragraphs [0011], [0022], [0023], [0043], [0045], [0054]; claim 3; example 2	1,2
X	US 2013/103161 A1 (GUO YA [US] ET AL) 25 April 2013 (2013-04-25) paragraphs [0024], [0026]; claims; table 1	1

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

[X] See patent family annex.

* Special categories of cited documents :

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

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 September 2017	10/10/2017

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/TR2017/050159

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 9 114 032 B1 (PULUGURTHA SYAMALA RANI [US]) 25 August 2015 (2015-08-25) column 1, lines 48-67 column 3, line 36 - column 4, line 2 column 7, line 12 - column 9, line 16 claims	3-5
X	US 2015/010422 A1 (NASH STEPHEN [IE]) 8 January 2015 (2015-01-08) paragraphs [0036], [0039], [0042], [0053]; claims; examples	3-5
A	HERMAWAN H ET AL: "Fe-Mn alloys for metallic biodegradable stents: Degradation and cell viability studies", ACTA BIOMATERIALIA, ELSEVIER, AMSTERDAM, NL, vol. 6, no. 5, 1 May 2010 (2010-05-01), pages 1852-1860, XP027039408, ISSN: 1742-7061 [retrieved on 2009-11-23] the whole document	1,2
A	DA-TREN CHOU ET AL: "Novel processing of iron-manganese alloy-based biomaterials by inkjet 3-D printing", ACTA BIOMATERIALIA, vol. 9, no. 10, 1 November 2013 (2013-11-01), pages 8593-8603, XP055411037, AMSTERDAM, NL ISSN: 1742-7061, DOI: 10.1016/j.actbio.2013.04.016 the whole document	1-5
A	XU ZHIGANG ET AL: "A comparative study of powder metallurgical (PM) and wrought Fe-Mn-S", MATERIALS SCIENCE AND ENGINEERING: A, vol. 630, 10 April 2015 (2015-04-10), pages 116-124, XP029146581, ISSN: 0921-5093, DOI: 10.1016/J.MSEA.2015.02.021 the whole document	1-5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/TR2017/050159

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☒ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/TR2017/050159

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