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AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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(54) **Title:** CENTRAL PRESSURIZED CADAVER MODEL

(57) **Abstract:** Provided are methods for creating a pressurized cadaver model used for surgical procedure training. In the method the internal jugular veins, common carotid arteries, brachial arteries, superficial femoral arteries and femoral veins thereof of a cadaver are exposed. One internal jugular vein is ligated and a drainage tube is disposed in the other internal jugular vein. An arterial catheter is inserted into one brachial artery and connected to a pressure transducer and an arterial cannula is placed in a carotid artery and connected to a fusion pump. Fluid is injected into the artery through the cannulated carotid artery. A representative example of the surgical procedure includes resuscitative endovascular balloon occlusion of the aorta.



CENTRAL PRESSURIZED CADAVER MODEL

5

Cross-Reference to Related Application

This international application claims benefit of priority under 35 U.S.C. 119(e) of provisional application U.S. Serial No. 62/051,331, filed September 17, 2014, the entirety of which is hereby incorporated by reference.

10

BACKGROUND OF THE INVENTION

Field of the invention

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The present invention generally relates to the field of medical equipment. More specifically, the invention relates to a central pressurized cadaver model for the Resuscitative Endovascular Balloon Occlusion of the Aorta procedure.

Description of the Related Art

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The use of endovascular technology in the treatment of injury has steadily increased over the last several decades. Most recently, resuscitative endovascular balloon occlusion of the aorta (REBOA) has emerged as a potentially lifesaving technique for severely injured patients that do not respond to volume as a bridge to hemostasis. Many case series of resuscitative endovascular balloon occlusion of the aorta have proved that this technique could be critical for patients in shock due to non-compressible hemorrhage.

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Resuscitative endovascular balloon occlusion of the aorta involves passing a vascular sheath through a common femoral artery and inflating a balloon to occlude blood flow. The location of the balloon is selected based on the type of injury and a three-zones principle. Generally, a patient's body portion is divided into three zones as shown in FIG. 1. Balloon occlusion is performed in zone 1 for abdominal injuries and zone 3 for pelvic injuries. Zone 2 is considered a no-occlusion zone.

In a traumatic emergency, the execution of the resuscitative endovascular balloon occlusion of the aorta is highly complicated, thus requires extensive training. More often than not, resuscitative endovascular balloon occlusion of the aorta may not be in the standard armamentarium of many hospital privileges. Therefore, it is imperative that Acute Care Surgeons have gone through adequate training and each individual surgeon has demonstrated competence in this new technique before they start performing such a vascular procedure.

Currently, there are 3 main options for endovascular training. Virtual reality simulation (VRS) is a well-established method for skill development and its use in medical training has increased exponentially. Advantages for VRS include automated objective assessment and haptic feedback, no radiation exposure, and the ability to document and store progress development for each user. However, the absence of percutaneous cannulation and/or open exposure of the groin, which are essential considerable components of resuscitative endovascular balloon occlusion of the aorta, hindered the application of virtual reality simulation in resuscitative endovascular balloon occlusion of the aorta trainings. Animal testing provides dynamic blood flow and hemorrhage, but it lacks similarity to the access anatomy that is critical for mastering the resuscitative endovascular balloon occlusion of the aorta. In addition, animal testing can be subjected to ethical concerns for reasons of animal welfares.

Cadaver models provide real human anatomy and allow percutaneous and open arterial access through which the resuscitative endovascular balloon occlusion of the aorta procedure is performed. In real-life setting, the success of resuscitative endovascular balloon occlusion of the aorta is heavily dependent on correct and safe arterial access. The resuscitative endovascular balloon occlusion of the aorta may be performed exactly as in the resuscitation suite with x-ray capability and required equipment using cadaver models. However, the most challenging aspect of using cadaver model for this training is the lack of pulsatile blood flow, which is essential to simulate traumatic injuries.

Thus, there is a recognized need in the art for a cadaver model that provides pulsatile blood flow used in surgical training. Particularly, the prior art is deficient in this aspect. The present invention fulfills this long standing need and desire in the art.

SUMMARY OF THE INVENTION

The present invention is directed to a method for creating a pressurized cadaver model. In this method, a cadaver is first selected and internal jugular veins, common carotid arteries, brachial arteries, superficial femoral arteries and femoral veins thereof are exposed via incision. One internal jugular vein is ligated and a drainage tube is disposed in the other jugular vein. The common carotid arteries, the brachial arteries, the superficial femoral arteries and femoral veins of the cadaver are ligated. An arterial catheter is inserted in one brachial artery, proximal to the ligation thereon and a tube connected with a pressure transducer is subsequently attached to the arterial catheter. An arterial cannula is placed in a carotid artery and connected to a pressurized perfusion pump. A fluid is injected into the artery through the cannulated carotid artery.

The present invention is also directed to a training system for a surgical procedure that involves hemorrhagic shock. The training system comprises a cadaver and means for ligating veins of the cadaver. The training system also comprises a drainage tube disposed in an internal jugular vein of the cadaver and pressure tubing in a connecting relationship with the arterial catheter and an arterial catheter disposed in a brachial artery and a pressure transducer attached to the pressure tubing. One or more cannulas are disposed in a carotid artery, a common femoral artery or a combination thereof where one or more pressurized perfusion pumps are in a connecting relationship with the cannula. A blood replacement liquid is in a connecting relationship with the perfusion pumps.

BRIEF DESCRIPTION OF THE DRAWINGS

So that the matter in which the above-recited features, advantages and objects of the invention, as well as others that will become clear, are attained and can be understood in detail, more particular descriptions of the invention briefly summarized above may be had by reference to certain embodiments thereof that are illustrated in the appended drawings. These drawings form a part of the specification. It is to be noted, however, that the appended drawings illustrate

preferred embodiments of the invention and therefore are not to be considered limiting in their scope.

FIG. 1 depicts the three zones associated with REBOA blood occlusion.

5 **FIG. 2** is a flowchart that lists the steps for making one example pressurized cadaver model of the present invention.

FIG. 3 illustrates the placement of the cadaver in one exemplary configuration.

FIG. 4 illustrates the location of the drainage tube that is placed in the internal jugular vein in one example embodiment;

10 **FIG. 5** shows the placement of the arterial cannula that is located in the right carotid artery.

FIG. 6 depicts the arterial catheter that is placed in the left brachial artery and is attached to a pressure transducer.

15 **FIG. 7** shows one example perfusion pump that can be used with the cadaver model.

FIG. 8 illustrates the proper placement of percutaneous cannulation of the right common femoral artery.

FIG. 9 depicts the step of making an incision to cannulate the contralateral common femoral artery.

20 **FIG. 10** is an exemplary image from a C-arm that depicts the location of an occlusive balloon following REBOA.

DETAILED DESCRIPTION OF THE INVENTION

25 As used herein in the specification, "a" or "an" may mean one or more. As used herein in the claim(s), when used in conjunction with the word "comprising", the words "a" or "an" may mean one or more than one.

As used herein "another" or "other" may mean at least a second or more of the same or different claim element or components thereof. Similarly, the word "or" is intended to include "and" unless the context clearly indicates otherwise. "Comprise" means "include."

30 As used herein, the term "about" refers to a numeric value, including, for example, whole numbers, fractions, and percentages, whether or not explicitly

indicated. The term "about" generally refers to a range of numerical values (e.g., +/- 5-10% of the recited value) that one of ordinary skill in the art would consider equivalent to the recited value (e.g., having the same function or result). In some instances, the term "about" may include numerical values that are rounded to the nearest significant figure.

In one embodiment of the present invention, there is provided a method for creating a pressurized cadaver model. The method comprises the steps of selecting a cadaver; incising the cadaver to expose internal jugular veins, common carotid arteries, brachial arteries, superficial femoral arteries and femoral veins thereof; ligating one internal jugular vein; disposing a drainage tube in the other jugular vein; ligating the common carotid arteries, the brachial arteries, the superficial femoral arteries and femoral veins of the cadaver; inserting an arterial catheter in one brachial artery, proximal to the ligation thereon; attaching a tube to the arterial catheter, the tube is connected with a pressure transducer; placing an arterial cannula in a carotid artery; connecting the cannula in the carotid artery to a pressurized perfusion pump; and injecting fluid into the artery through the cannulated carotid artery.

In this embodiment, the method further comprises a step of cannulating a right common femoral artery. In an alternative aspect of this embodiment, this method further comprises a step of cannulating a contralateral common femoral artery.

In a preferred embodiment, an arterial flushing is performed on the cadaver after the selecting step. Preferably, the arterial flushing is performed using boric acid solution. In this embodiment, the arterial catheter is an 18 gauge catheter. Preferably, the length of the arterial catheter is about 15 cm to about 16 cm. A representative example of the fluid injected in the artery includes a normal saline colored with red dye.

In this embodiment, the fluid courses through the cadaver in a pulsatile pattern to simulate hemorrhagic shock. Preferably, the pressure transducer reads a systolic blood pressure of about 40 mmHg to 80 mmHg.

In this embodiment, the cannulation of the right common femoral artery is performed using the Seldinger technique and a catheter is placed in the right common femoral artery. In an alternative aspect of this embodiment, the cannulation

of the contralateral common femoral artery is performed using the Seldinger technique and a catheter is placed in the contralateral common femoral artery.

In another embodiment of the present invention, there is provided a training system for a surgical procedure that involves hemorrhagic shock. The training system comprises a cadaver; means for ligating veins of the cadaver; a drainage tube disposed in internal jugular vein of the cadaver; arterial catheter disposed in a brachial artery; pressure tubing in a connecting relationship with the arterial catheter; a pressure transducer attached to the pressure tubing; one or more cannulas disposed in a carotid artery, a common femoral artery or a combination thereof; one or more pressurized perfusion pumps in a connecting relationship with the cannula; and a blood replacement liquid in a connecting relationship with the perfusion pumps.

In this embodiment, the representative surgical procedures include but are not limited to resuscitative endovascular balloon occlusion of the aorta, device testing for large vessel occlusion, or a combination thereof. Preferably, an arterial flushing is performed on the cadaver.

In this embodiment, the length of the catheter is about 10 cm to about 20 cm. Preferably, the size of the catheter is about 14 gauge to about 22 gauge. In this embodiment, the arterial catheter is disposed proximal to a ligation of common carotid arteries, the brachial arteries, or common femoral arteries of the cadaver.

In a preferred embodiment, a representative example of the blood replacement liquid is a normal saline colored with red dye. The pressure transducer reads a systolic blood pressure of about 40 mmHg to about 80 mmHg to simulate a hemorrhagic shock.

Provided in this invention is a method for creating a central pressurized cadaver model that provides for training endovascular procedures, particularly REBOA. The flowchart **10** for this method is shown in FIG. 2. Although FIG. 2 describes integral steps in an order for purposes of illustration, the one or more steps, in other embodiments may be performed in a different order, or overlapping in time, in series or in parallel, or are omitted, or one or more additional steps are added, or the method may be changed in some combination of ways. In FIG. 2, the methods includes the steps of selecting a cadaver at **11**; exposing the internal jugular veins at **12**; ligating one internal jugular vein and placing a drain in the other

at **13**; exposing and ligating the common carotid arteries, superficial femoral arteries and femoral veins at **14**; placing an arterial cannula in one carotid artery at **15**; inserting an arterial catheter in one brachial artery, proximal to the ligation at **16**; attaching a tube to the arterial catheter that communicates with a pressure transducer at **17**; connecting the cannula in the carotid artery to a pressurized perfusion pump at **18**; and injecting fluid into the artery through the cannulated carotid artery at **19**.

The method may further comprise cannulating one of the common femoral arteries which may be performed by the Seldinger technique. Proper placement of the cannula in the common femoral artery may be confirmed by observing the return of the injected fluid in a minimally pulsatile function. This method may further comprise cannulating the contralateral common femoral artery which may be performed using the Seldinger technique. Again, verification of proper placement of the cannula may be confirmed by observing the return of the injected fluid.

The drainage tube may be placed in either internal jugular vein. However, in certain embodiments, the right internal jugular vein is preferred. Likewise, the arterial cannula may be placed in either carotid artery. However, in certain embodiments, the right carotid artery is preferred.

The arterial catheter that is placed in the brachial artery may be placed on either side. The catheter may be about 10 cm to 20 cm in length. More particularly, in some embodiments, the catheter is about 16 cm long. Also, the size of the catheter may range about 14 gauge to about 22 gauge, but in certain embodiments, an 18 gauge catheter is preferred. The pressurized perfusion pump may also be placed on either common carotid artery.

Any non-toxic fluid may be infused into the model. Saline is one exemplary fluid that may be used. In certain embodiments, it may be preferred to dye the injected fluid to provide additional contrast. Red dye may be used to give the model a more realistic feel.

EXAMPLE 1

Preparation of the Cadaver Model

Fresh cadavers are refrigerated at 36 °F with no embalming performed. Arterial flushing is performed prior to refrigeration with boric acid solution (B4, Hydrol

Chemical Co, Yeardon, PA) to keep the body at a pH of 7.4. A body that has no, or minimal history of, severe peripheral vascular disease or vascular reconstruction is selected.

The selected cadaver is placed on a fluoroscopy table with the head at the sink to allow easy drainage of perfusion fluid, as shown in FIG. 3. The bilateral internal jugular veins, common carotid arteries, brachial arteries, superficial femoral arteries, and femoral veins are exposed through appropriate incisions. A drainage tube **21** for intermittent drainage is placed in the right internal jugular vein as shown in FIG. 4. An arterial cannula **22** for perfusate is placed in the right carotid artery (FIG. 5). The left internal jugular vein and the carotid arteries are ligated, as are the bilateral superficial femoral arteries, femoral veins, and brachial arteries in order to maximize perfusion to the central vasculature. A 18 gauge arterial catheter **23**, about 16cm, is placed in the left brachial artery proximal to the ligation, and attached to pressure tubing **24** and a portable pressure transducer **25**, as shown in FIG. 6.

The right common carotid artery cannula is connected to the pressurized perfusion pump shown in FIG. 7, and 0.9% normal saline colored with red dye **26** is infused until the pressure transducer reads systolic blood pressure of about 50 mmHg to about 80 mmHg. Percutaneous cannulation of the right common femoral artery is performed using the Seldinger technique, and the arterial catheter is placed in the common femoral artery. Correct needle **27** access is confirmed by the red-colored fluid **26** return in a minimally pulsatile fashion (FIG. 8), as in the case of a patient in hemorrhagic shock. Open cannulation of the contralateral common femoral artery can also be achieved through the appropriate incision (FIG. 9). The arterial line is placed using the Seldinger technique and once again luminal access is confirmed with return of red-colored fluid. Once cannulation is achieved, either percutaneously or by open groin cut-down, procedures such as the REBOA may be performed.

EXAMPLE 2

Training Procedure of Resuscitative Endovascular Balloon Occlusion of the Aorta

The Amplatz wire is advanced through the arterial catheter after approximation of insertion length by external landmarks. The arterial catheter is removed and a 12Fr sheath is inserted to allow access for the CODA balloon. The

systolic blood pressure prior to inflation is about 40 mmHg to 80mmHg, and infusate is pumped in a pulsatile fashion and titrated to this systolic blood pressure goal. If the systolic blood pressure rises about 80mmHg, and infusate is pumped in a pulsatile fashion and titrated to his SBP goal. If the SBP rises above about 80mmHg, prior to aortic occlusion, removal of fluid can be accomplished by venting the internal jugular cannula to allow drainage out of the central vasculature. A C-arm performs the function of a portable or digital X-ray machine by providing an image of the chest with wire **28** at the proximal descending thoracic aorta, as well as an image of the occlusive balloon **29** after inflation if necessary (FIG. 10).

Due to the continuous pressurized perfusion, the systolic blood pressure rises by about 20 to about 35 mmHg with corresponding improvement in arterial waveform after aortic occlusion. Once the improvement in systolic blood pressure is observed, the balloon is deflated and removed from the sheath. The rise in systolic blood pressure of about 20 to about 35 mmHg following arterial occlusion is slightly lower than that found in clinical series of about 55 ± 20 mmHg. However, the increase and improvement in waveform is analogous. The procedure may be repeated several times, the exact number depends on cadaver edema, which can be minimized by pausing inflow during times of inactivity.

The subsequent removal of the 12Fr sheath requires surgical repair which can be performed at the completion of the procedure, or immediately on the side of the open groin as the exposure is already complete. Removal of the sheath and repair of the common femoral artery is an integral part of the REBOA procedure, and has the potential to incur severe injury, such as thromboemboli, dissection etc., if arterial repair is not performed correctly. Until technology provides lower profile devices which do not require open surgical arterial repair, training must include this final step of the REBOA procedure which cannot be obtained with VRS.

The present invention is well adapted to attain the ends and advantages mentioned as well as those that are inherent therein. The particular embodiments disclosed above are illustrative only, as the present invention may be modified and practiced in different but equivalent manners apparent to those skilled in the art. Furthermore, no limitations are intended to the details of construction or design herein shown, other than as described in the claims below. It is therefore evident that the particular illustrative embodiments disclosed above may be altered or

modified and all such variations are considered within the scope and spirit of the present invention. Also, the terms in the claims have their plain, ordinary meaning unless otherwise explicitly and clearly defined by the patentee.

WHAT IS CLAIMED IS:

1. A method for creating a pressurized cadaver model, comprising:
selecting a cadaver;
5 incising said cadaver to expose internal jugular veins, common carotid arteries, brachial arteries, superficial femoral arteries and femoral veins thereof;
ligating one internal jugular vein;
disposing a drainage tube in the other jugular vein;
ligating the common carotid arteries, the brachial arteries, the superficial
10 femoral arteries and femoral veins of said cadaver;
inserting an arterial catheter in one brachial artery, proximal to the ligation thereon;
attaching a tube to said arterial catheter, said tube connected with a pressure transducer;
15 placing an arterial cannula in a carotid artery;
connecting the cannula in the carotid artery to a pressurized perfusion pump;
and
injecting fluid into said artery through the cannulated carotid artery.
- 20 2. The method of claim 1, further comprising a step of cannulating the right common femoral artery.
3. The method of claim 1, further comprising a step of cannulating a contralateral common femoral artery.
25
4. The method of claim 1, wherein an arterial flushing is performed on the cadaver after the selecting step.
5. The method of claim 4, wherein said arterial flushing is performed
30 using boric acid solution.
6. The method of claim 1, wherein said arterial catheter is an 18 gauge catheter.

7. The method of claim 1, wherein said arterial catheter has a length of about 15cm to about 16 cm.

8. The method of claim 1, wherein said fluid is a normal saline colored
5 with red dye.

9. The method of claim 1, wherein said fluid courses through the cadaver in a pulsatile pattern to simulate hemorrhagic shock.

10. The method of claim 1, wherein the pressure transducer reads a
10 systolic blood pressure of about 40 mmHg to 80 mmHg.

11. The method of claim 2, wherein the cannulation of the right common femoral artery is performed using the Seldinger technique, and an arterial catheter is
15 placed in the right common femoral artery.

12. The method of claim 3, wherein the cannulation of the contralateral common femoral artery is performed using the Seldinger technique, and a catheter is placed in the contralateral common femoral artery.
20

13. A training system for a surgical procedure that involves hemorrhagic shock, comprising:

a cadaver;
means for ligating veins of said cadaver;
25 a drainage tube disposed in internal jugular vein of said cadaver;
arterial catheter disposed in a brachial artery;
pressure tubing in a connecting relationship with said arterial catheter;
a pressure transducer attached to said pressure tubing;
one or more cannulas disposed in a carotid artery, a common femoral artery
30 or a combination thereof;
one or more pressurized perfusion pumps in a connecting relationship with said cannula; and

a blood replacement liquid in a connecting relationship with said perfusion pumps.

14. The training system of claim 13, wherein said surgical procedure
5 comprises resuscitative endovascular balloon occlusion of the aorta, device testing for large vessel occlusion, or a combination thereof.

15. The training system of claim 13, wherein an arterial flushing is
performed on said cadaver.

10 16. The training system of claim 13, wherein a length of said catheter is about 10 cm to about 20 cm.

17. The training system of claim 13, wherein a size of the catheter is about
15 14 gauge to about 22 gauge.

18. The training system of claim 13, wherein said arterial catheter is
disposed proximal to a ligation of common carotid arteries, the brachial arteries, or
common femoral arteries of said cadaver.

20 19. The training system of claim 13, wherein said blood replacement liquid is a normal saline colored with red dye.

20. The training system of claim 13, wherein said pressure transducer reads a
25 systolic blood pressure of about 40 mmHg to about 80 mmHg.

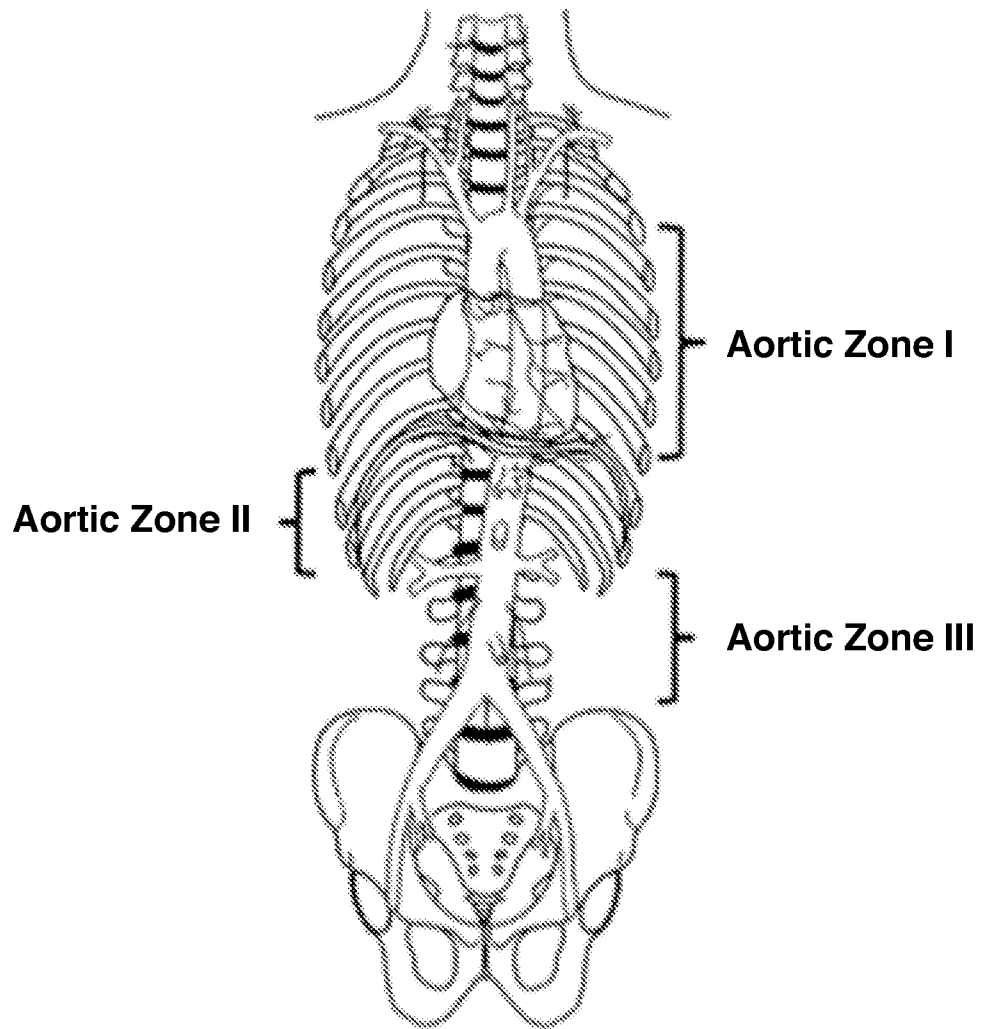


FIG. 1

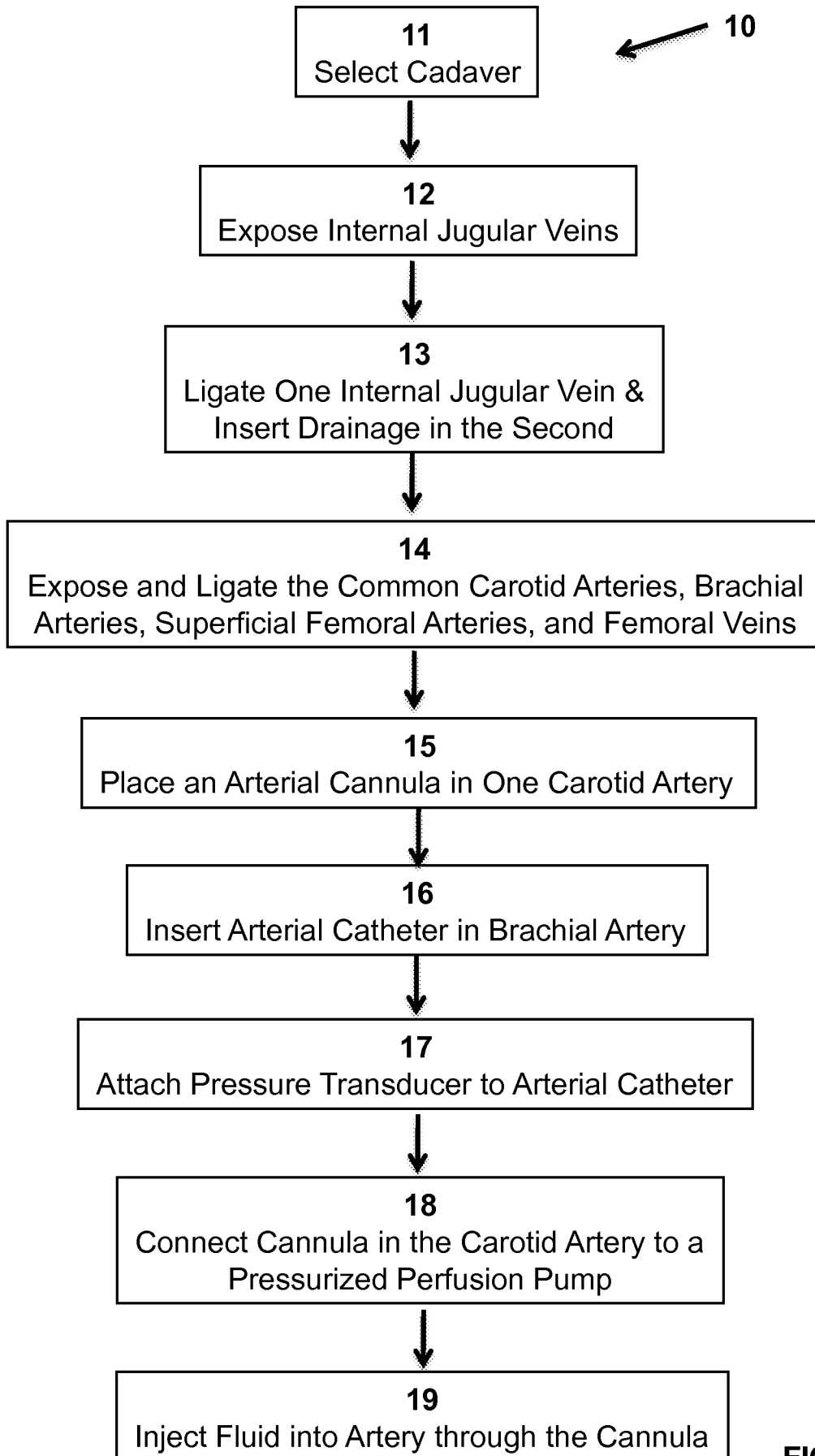


FIG. 2



FIG. 3

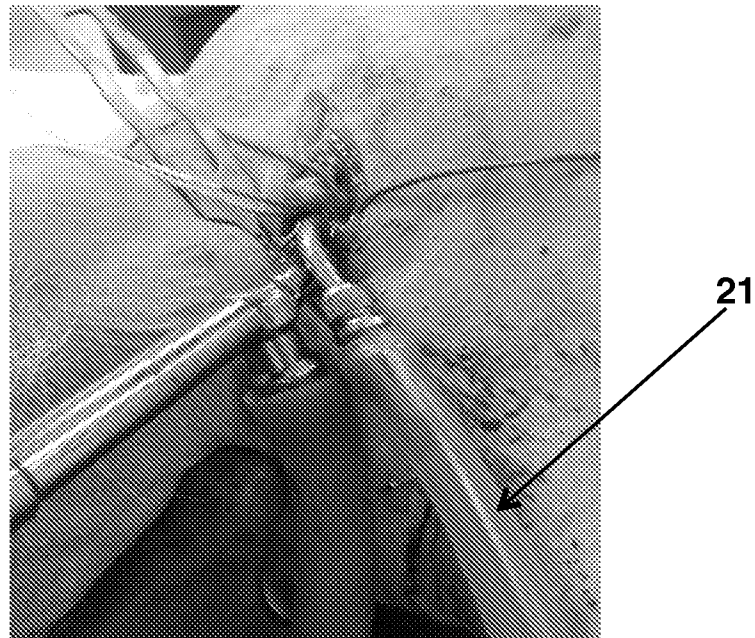
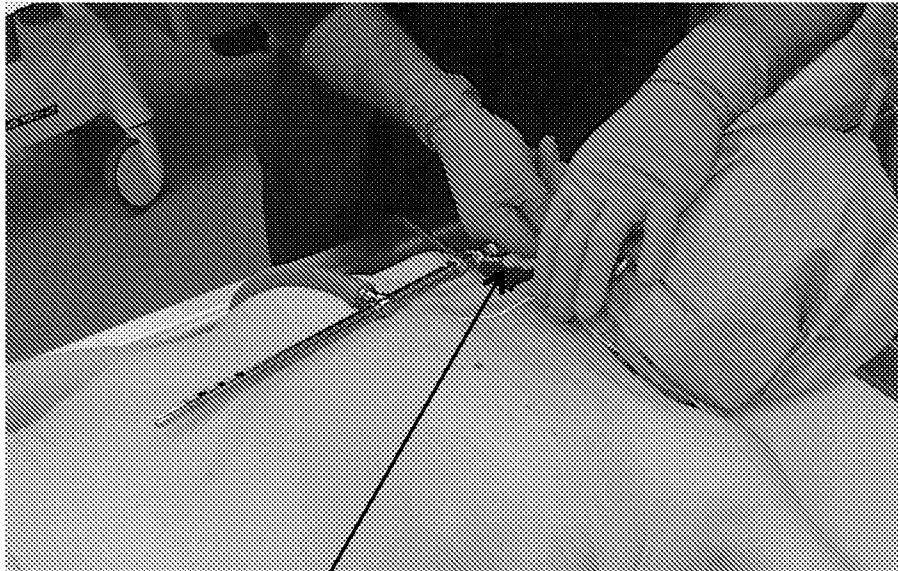
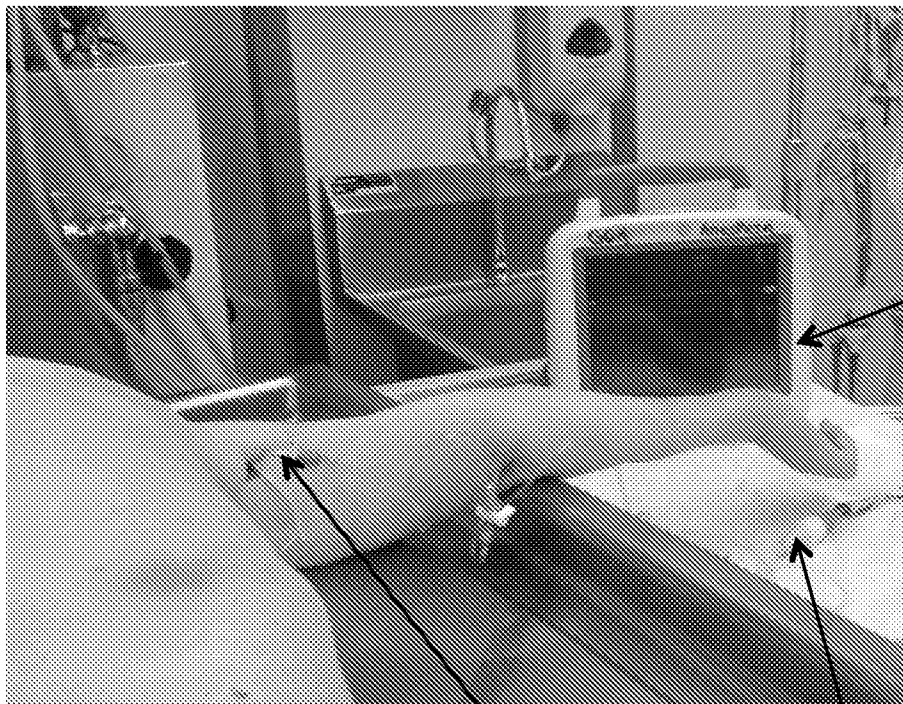


FIG. 4



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FIG. 5



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FIG. 6

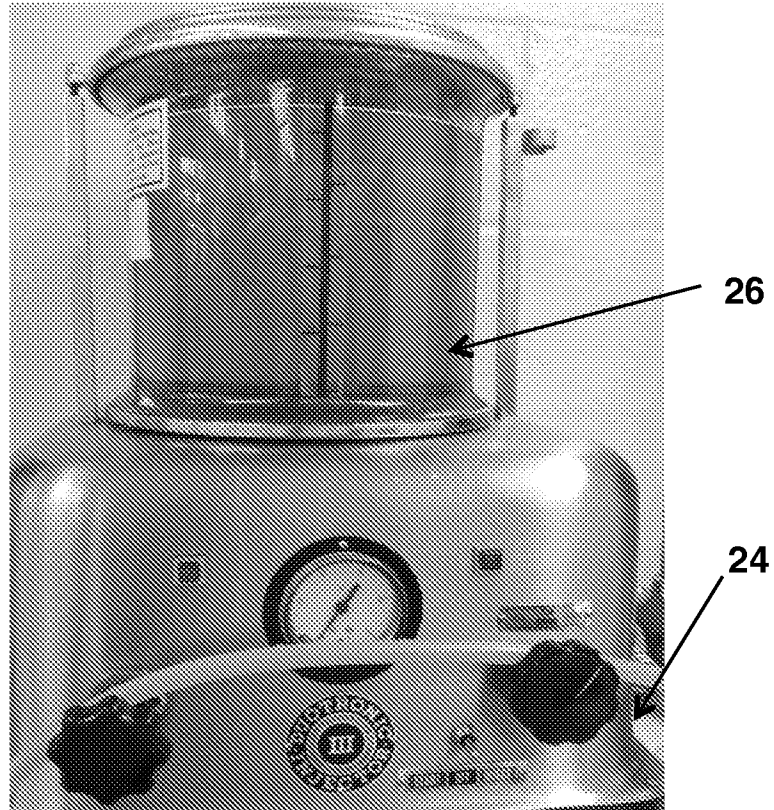


FIG. 7

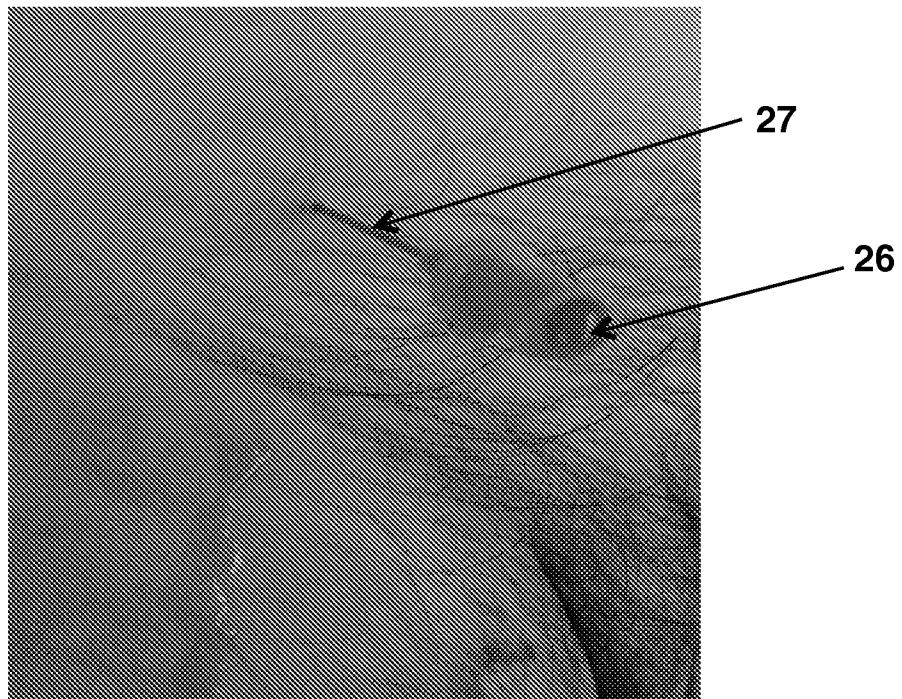


FIG. 8

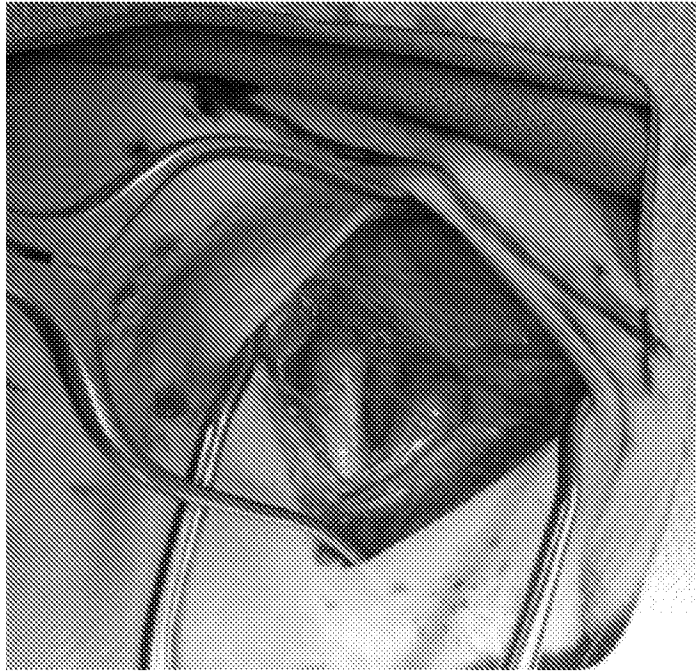


FIG. 9

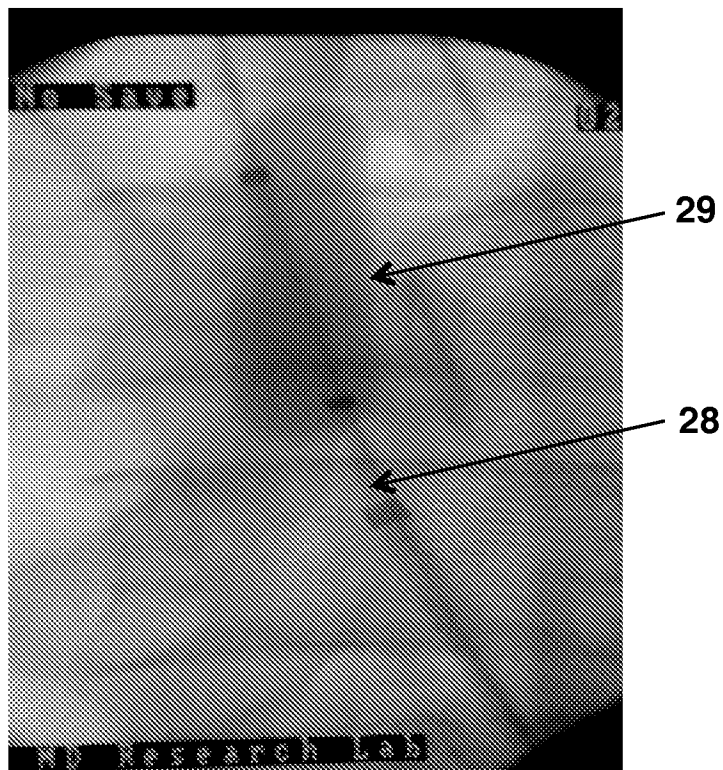


FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 2015/050660

A. CLASSIFICATION OF SUBJECT MATTER

G09B 23/28 (2006.01)

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)

G09B 23/28

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)

"Rossiyskaya meditsina", SCSML.RSSI.RU, NCBI (PubMed), Medline, EAPATIS, Patentscope, Espacenet, USPTO, CIPO (Canada PO)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/0186203 A1 (EMAD T. ABOUD) 02.10.2003, abstract, claims, paragraphs [0016] - [0018], [0028], [0041], [0051], [0061], [0063], [0066] - [0067], [0075], [0089], fig. 1-5	1-20
A	PHAM Martin et al. A Perfusion-based Human Cadaveric Model for Management of Carotid Artery Injury during Endoscopic Endonasal Skull Base Surgery. Journal of Neurological Surgery, 2014, part B, Vol. 75, No. B5/2014, pp. 309-313	1-20



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	"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
"A" document defining the general state of the art which is not considered to be of particular relevance	"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
"E" earlier document but published on or after the international filing date	"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
"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)	"&" document member of the same patent family
"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	

Date of the actual completion of the international search

23 December 2015 (23.12.2015)

Date of mailing of the international search report

11 February 2016 (11.02.2016)

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Berezhkovskaya nab., 30-1, Moscow, G-59,
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