STAGED IMPLANTATION OF VENTRICULAR ASSIST DEVICES

The present invention relates to systems and devices for the implantation of ventricular assist devices and, more particularly, to such systems and devices suited to a staged regime.

BACKGROUND

Blood pumps are known for the purpose of assisting the pumping function of a heart in a mammal.

In one particular form a class of pumps known as "ventricular assist devices" assist, by pumping, the action of the left ventricle of the heart.

Blood pumps suited for this task include those disclosed in US6,227,797 (Watterson et al) and US5,470,208 (Kletschka).

At the present time such pumps are relatively expensive, partly due to current relatively low production runs and partly because of the relatively expensive materials which must be utilized for the task of pumping blood so as to maximize reliability of the pump and minimize the possibility of blood damage.

It has been observed that, in some patients, the "assist" function provided by a ventricular assist device permits the heart to recover function to the point where

the ventricular assist device can be removed and the patient's own heart takes over full pumping function.

Unfortunately, to date, no way has been found to predict the likelihood of a temporary assist leading to satisfactory or sufficient recovery of heart pump function.

It is an object of the present invention, in at least preferred embodiments, to provide a cost effective regime for the use of blood pumps and which takes into account the abovementioned problems.

BRIEF DESCRIPTION OF INVENTION

Accordingly, in one broad form of the invention there is provided an implantation regime for a ventricular assist device comprising:

(a) providing a first ventricular assist device for connection via a first ventricular assist device first connector and a first ventricular assist device second connector to a heart so as to assist heart function for a first predetermined period of time;

(b) providing a second ventricular assist device for connection via a second ventricular assist device first connector and a second ventricular assist device second connector to a heart so as to assist heart function for a second indeterminate period of time

commencing immediately and contiguously following said first predetermined period of time.

Preferably said first ventricular assist device is adapted for short term use.

Preferably said first ventricular assist device is adapted for short term use comprising a period extending in the range 0 to 6 months.

Preferably said first ventricular assist device is adapted for short term use comprising a period extending in the range 0 to 3 months.

Preferably said second ventricular assist device is adapted for long term use.

Preferably said second ventricular assist device is adapted for long term use comprising a period of 1 to 20 years.

Preferably said second ventricular assist device is adapted for long term use comprising a period of 1 to 10 years.

Preferably said first ventricular assist device is made by a low cost process.

In a particular preferred form components of said first ventricular assist device are made by an injection moulding process.

In an alternative preferred form components of said first ventricular assist device are made by a vacuum casting process.

Preferably said first ventricular assist device includes a pump casing made from plastic components.

Preferably said first ventricular assist device includes a pump rotor made from a plastic material.

Preferably said second ventricular assist device includes a pump casing made from a metallic material.

Preferably said second ventricular assist device includes a rotor made from a metallic material.

Preferably said second ventricular assist device includes a pump casing made from a ceramic material.

Preferably said second ventricular assist device includes a rotor made from a ceramic material.

In an alternative particular form said device comprises a sac-type device.

Preferably said heart is connectable to said first ventricular assist device by means of a respective first cannula and second cannula interposed between said heart and said first connector and said heart and said second connector respectively.

Preferably said second ventricular assist device is connectable to said heart via said first cannula and said

second cannula by means of said second ventricular assist device first connector and said second ventricular assist device second connector respectively.

In a further broad form of the invention there is provided a test procedure comprising the connection of a first ventricular assist device so as to assist a diseased heart for a first predetermined period of time; monitoring operation of said heart over said predetermined period of time so as to determine whether said heart can operate without the further assistance of said first ventricular assist device.

Preferably said first ventricular assist device incorporates short term life features (necessitated by reduced cost of manufacturing) which render said first ventricular assist device suited to operation over a short life span.

Preferably said short term life features include use of plastic materials in one or more of the pump casing and pump rotor of said first ventricular assist device.

Preferably said short life span comprises a period of up to 6 months.

Preferably said short life span comprises a period of up to 3 months.

In yet a further broad form of the invention there is provided a method of mechanically assisting a heart to pump blood; said method comprising releasably, sealingly connecting via a first cannula and a second cannula a first ventricular assist device so as to at least assist said heart to pump said blood; during a first predetermined period of time, ascertaining if mechanical assistance continues to be required and, if so, substituting a second ventricular assist device for said first ventricular assist device at the end of said first predetermined period of time.

In yet a further broad form of the invention there is provided, in combination, a first ventricular assist device adapted for short term use and a second ventricular assist device adapted for long term use.

In yet a further broad form of the invention there is provided a first cannula having a proximal end for connection to the aorta; a second cannula having a proximal end for connection to a ventricle; said first cannula having a distal end including connection means for releasably, sealingly connecting said distal end of said first cannula to either an inlet of a first ventricular assist device or an inlet of a second ventricular assist device; a second cannula having a distal end including

connection means for releasably, sealingly connecting said distal end of said second cannula to either an outlet of said first ventricular assist device or an outlet of said second ventricular assist device; said second ventricular assist device adapted for substitution for said first ventricular assist device following a first predetermined period of operation of said first ventricular assist device.

In yet a further broad form of the invention there is provided an embolisation device adapted for insertion into either said first cannula or said second cannula; said embolisation device including a stem having an end adapted to deliver a coagulating material to a sealing position within said proximal end of said first cannula or said second cannula.

In yet a further broad form of the invention there is provided a percutaneous lead for carriage of power to said device; said lead having a surface; said surface including regions which permit incorporation of the percutaneous lead surface into the surrounding tissue and a region or regions which will not allow incorporation. The region allowing incorporation may extend the entire length of the percutaneous lead or none of it or it may extend over regions near the ventricular assist device sufficient only

to help anchor the device in place or near to the site where the percutaneous lead exits the body and provide good closure to the wound so as to prevent or reduce the occurrence of infection. In addition other areas on the surface of the percutaneous lead may have properties which prevent incorporation so as to facilitate easy removal of the lead at the end of the predetermined period of implantation of the first ventricular assist device.

BRIEF DESCRIPTION OF DRAWINGS

One embodiment of the present invention will now be described with reference to the accompanying drawings wherein:

Fig. 1 is a flow diagram illustrating steps in an implantation regime in accordance with a first preferred embodiment of the present invention.

Fig. 2 is a side section view of cannulae and an embolisation tool in accordance with a particular embodiment of the present invention.

Fig 3 is a cross-section through a patient's chest and abdomen showing the ventricular assist device in place and the path of the percutaneous lead from the exit site in the skin to the ventricular assist device.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENT

With reference to Fig. 1 comprising sub-diagrams 1A, 1B, 1C and 1D there is illustrated steps in an implantation regime 10 according to a first preferred embodiment of the present invention.

In Fig. 1A a patient 11 having a heart 12 in need of at least an assisted pumping action is fitted with a first ventricular assist device 13 arranged, in this instance, to provide a pumped blood flow "in parallel" across left ventricle 14 of heart 12.

In this instance the fluid connection is effected by first cannula 15 and second cannula 16 as illustrated in Fig. 1.

More particularly first cannula 15 sealingly connects via first connector 17 to ventricular assist device 13 whilst second cannula 16 sealingly connects to ventricular assist device 13 by way of second connector 18.

In this instance the length of cannulae 15, 16 is such as to permit first ventricular assist device 13 to be placed in the abdomen 19 of patient 11.

As will be discussed further below the intention is that first ventricular assist device 13 is to be utilized for a relatively short predetermined period of time, typically up to approximately 3 to 6 months. This

predetermined period of time will be sufficient to monitor the function of heart 12 so as to determine whether the assistance provided by first ventricular assist device 13 is sufficient to allow full or substantial recovery of heart 12 to the point where no ventricular assist device is required.

In this event, as shown in Fig. 1B, at the end of the predetermined period of time 20 the first ventricular assist device 13 is removed from the abdomen 19 and first connector 17 and second connector 18 sealed.

In a particularly preferred form, as illustrated in Fig. 2, cannulae 15, 16 are sealed internally at a point sufficiently close to the heart 12 that there is no need to remove cannulae 15, 16 at the time that first ventricular assist device 13 is removed.

Sealing can be effected by use of a first embolisation tool 21 and a second embolisation tool 22 for respective first cannula 15 and second cannula 16.

Each tool 21, 22 comprises an elongate stem 23, 24 respectively having sealing caps 17A, 18A respectively at a first end (refer Fig. 2) and a carrier surface 25, 26 at respective second ends.

The carrier surfaces 25, 26 are adapted to carry a coagulating material 27. The sealing caps 17A, 18A are

adapted to be sealingly connected to first connector 17 and second connector 18 respectively upon insertion of the entire length of stems 23, 24 into cannulae 15, 16.

The length of stems 23, 24 is selected so that when tools 21, 22 are entirely inserted within cannulae 15, 16 the carrier surfaces 25, 26 are positioned so as to deliver coagulating material 27 to sealing positions 28, 29 which are sufficiently close to the heart 12 that, upon sealing of cannulae 15, 16 at positions 28, 29 there is no requirement to remove cannulae 15, 16 from the body.

Typically it will be clear within a predetermined period of between one and three months of use of first ventricular assist device 13 as to whether sufficient recovery of heart 12 will be made that the option of removal of first ventricular assist device 13 and appropriate sealing or removal of cannulae 15, 16 can take place as outlined in step B of Fig. 1.

Once the predetermined period 20 has expired and it is judged that heart 12 is unlikely to recover then, as per steps C and D in Fig. 1 first ventricular assist device 13 is removed and immediately replaced with second ventricular assist device 30.

The replacement is performed by disconnecting first connector 31 of first VAD 13 from first connector 17 of

first cannula 15 and disconnecting second connector 33 of first VAD 13 from first connector 18 of second cannula 16, withdrawing first ventricular assist device 13 from abdomen 19 and immediately substituting therein second ventricular assist device 30 and then connecting first connector 32 of second ventricular assist device 30 to first cannula 15 and second connector 34 of second ventricular assist device 30 to second cannula 16 by way of respective first connections 17, 18 of cannulae 15, 16.

Ideally, immediately prior to disconnection of first ventricular device 13, cannulae 15,16 are clamped so no air can enter or blood leak out. The clamps are maintained while second ventricular assist device 30 is connected to the same cannulae. The clamps are removed once connection is completed.

With reference to Fig. 3 there is illustrated an exemplary ventricular assist device 13, 30 having respective first connectors 31, 32 and respective second connectors 33, 34 for the passage of blood through the device.

The ventricular assist device 13, 30 requires power which is conducted through percutaneous lead 40 from outside of the body via exit site 44.

To facilitate the removal of the percutaneous lead 40 which carries electrical energy and control to the ventricular assist device 13 (and subsequently second ventricular assist device 30), the outer surface of the percutaneous lead 40 may be treated so as to prevent the incorporation into surrounding tissue 41 of the percutaneous lead 40. Such surface treatment may extend the entire length of the percutaneous lead 40, or may be terminated just below the surface 43 of the skin 42 so as to allow full incorporation at the exit site 44 and hence a barrier to infection. An example of surface treatment of the percutaneous lead 40 is the use of silicone rubber which naturally resists incorporation. Incorporation at or near the exit site 44 may be achieved through the use of adhesively bonded woven velour 45 or other material or surface treatment which will provide tissue ingrowth as the outermost surface of the percutaneous lead in this region. Alternatively the surface treatment can comprise texturing of surface 46 of lead 40.

As shown in inset 1 in Fig. 1b the texturing of surface 46 of lead 40 can be such that ingrowth of tissue 41 can be only mildly anchored, for example by the use of a pyramid-shaped texture whereby there is little anchoring of tissue to surface 46. Alternatively the texturing can include a

labyrinth arrangement such as illustrated in inset 2 of Fig. 3 wherein tissue 41 can follow a labyrinth path through the interstices 48 of labyrinth texture 47.

As previously stated the texture can extend the entire length of lead 40 within the body from the exit site 44 through to device 13, 30. In the alternative the texturing may be at selected and predetermined locations.

The texturing itself can be tailored whereby the degree of tissue ingrowth into the surface 46 is controlled and tailored as a function of displacement along the surface of lead 40.

The surface can be tailored to provide a high degree of ingrowth such as that provided by inset 2 or can be tailored to provide only minimal ingrowth as, for example, provided in inset 1.

It is to be noted that, because of the location of both first ventricular assist device 13 and second ventricular assist device 30 in abdomen 19, permitted by appropriate selection of cannulae 15, 16 it follows that the substitution of second ventricular assist device 30 for first ventricular assist device 13 may take place without patient ventilation or formal heart bypass during the procedure because there is no need to open the chest cavity of patient 11. This arrangement thereby may significantly

limit risk to the patient as compared with the situation where general anaesthesia or heart bypass is required.

Second ventricular assist device 30 is intended for long term operation which is to say for many years, ideally extending to beyond the expected lifetime of patient 11.

In particular both first ventricular assist device 13 and second ventricular assist device 30 will, ideally, share the same surgically created pocket in abdomen 19.

Broadly, it will be appreciated that first ventricular assist device 13 is intended for short term use and thereby can have its characteristics selected for short term use whilst second ventricular assist device 30 is intended for long term use and therefore can have its characteristics selected for long term use.

By way of example first ventricular assist device 13 can take the form of almost any blood pump including those disclosed in US6,227,797 (Watterson et al) and US5,470,208 (Kletschka) provided only that the blood pump is sized to fit in the pocket created in abdomen 19. In particular the first ventricular assist device 13 may comprise an axial or centrifugal pump, or sac-type device. Its impeller may be suspended in any number of ways including mechanically, magnetically and hydrodynamically or by a combination of these. In the case of a sac-type device urging of the

blood through the device may be caused by the reciprocating action of a pusher-plate or similar mechanism in a sac-type device.

Its components can be made using mass production techniques and utilising less expensive materials than for the long life second ventricular assist device.

In particular the components comprising the pump casing and internal surfaces and rotating parts can be made from plastic materials including polymeric materials.

Coatings (such coatings not necessarily having a significantly long life) can be applied so as to increase blood compatibility. It is noted that some plastic materials such as covalently bonded heparin are particularly suited to receive and support such coatings. The Carmeda process can be utilized to perform the covalent bonding of Heparin. In addition or alternatively the coating may constitute a slow-release antibiotic.

In a further particular form the first ventricular assist device 13 adapted for short term use need not be hermetically sealed. Instead it may comprise one or more components in respect of which slow permeation of body fluids is acceptable. Examples of slow permeation materials which may be suitable include polypropylene, epoxy or nylon.

Conversely, second ventricular assist device 30 is constructed for long term (which is to say much greater than 3 months and typically, of the order of many years) reliable operation and can embody, for example, the principles of rotor support described in US6,227,797 (Watterson et al) and US5,470,208 (Kletschka). In this instance, suitable materials from which to construct the pump casing and/or the pump rotor for reliable, long term operation include hermetically welded titanium alloy.

The above describes only some embodiments of the present invention and modifications, obvious to those skilled in the art can be made thereto without departing from the scope and spirit of the present invention.

CLAIMS

1. An implantation regime for a ventricular assist device comprising:

(a) providing a first ventricular assist device for connection via a first ventricular assist device first connector and a first ventricular assist device second connector to a heart so as to assist heart function for a first predetermined period of time;

(b) providing a second ventricular assist device for connection via a second ventricular assist device first connector and a second ventricular assist device second connector to a heart so as to assist heart function for a second indeterminate period of time commencing immediately and contiguously following said first predetermined period of time.

2. The regime of Claim 1 wherein said first ventricular assist device is adapted for short term use.

3. The regime of Claim 1 or Claim 2 wherein said first ventricular assist device is adapted for short term use comprising a period extending in the range 0 to 6 months.

4. The regime of Claim 1 or Claim 2 wherein said first ventricular assist device is adapted for short term use comprising a period extending in the range 0 to 3 months.

5. The regime of any previous claim wherein said second ventricular assist device is adapted for long term use.

6. The regime of Claim 5 wherein said second ventricular assist device is adapted for long term use comprising a period of 1 to 20 years.

7. The regime of Claim 5 wherein said second ventricular assist device is adapted for long term use comprising a period of 1 to 10 years.

8. The regime of any one of claims 1 to 7 wherein said first ventricular assist device is made by a low cost process.

9. The regime of any one of claims 1 to 7 wherein said first ventricular assist device are made by an injection moulding process.

10. The regime of any one of claims 1 to 7 wherein said first ventricular assist device are made by a vacuum casting process.

11. The regime of any one of Claim s1 to 7 wherein said first ventricular assist device includes a pump casing made from plastic components.

12. The regime of any one of Claims 1 to 7 wherein said first ventricular assist device includes a pump rotor made from a plastic material.

13. The regime of any one of Claims 1 to 7 wherein said second ventricular assist device includes a pump casing made from a metallic material.

14. The regime of any one of Claims 1 to 7 wherein said second ventricular assist device includes a rotor made from a metallic material.

15. The regime of any one of claims 1 to 7 wherein said second ventricular assist device includes a pump casing made from a ceramic material.

16. The regime of any one of claims 1 to 7 wherein said second ventricular assist device includes a rotor made from a ceramic material.

17. The regime of any one of Claims 1 to 7 wherein said device is a sac-type device.

18. The regime of any previous claim wherein said heart is connectable to said first ventricular assist device by means of a respective first cannula and second cannula

interposed between said heart and said first connector and said heart and said second connector respectively.

19. The regime of any one of Claims 1 to 17 wherein said second ventricular assist device is connectable to said heart via said first cannula and said second cannula by means of said second ventricular assist device first connector and said second ventricular assist device second connector respectively.

20. A test procedure comprising the connection of a first ventricular assist device so as to assist a diseased heart for a first predetermined period of time; monitoring operation of said heart over said predetermined period of time so as to determine whether said heart can operate without the further assistance of said first ventricular assist device.

21. The test procedure of Claim 20 wherein said first ventricular assist device incorporates short term life features which render said first ventricular assist device suited to operation over a short life span.

22. The procedure of Claim 21 wherein said short term life features include use of plastics materials in one or more of the pump casing and pump rotor of said first ventricular assist device.

23. The procedure of Claim 21 wherein said short life span comprises a period of up to 6 months.

24. The procedure of Claim 21 wherein said short life span comprises a period of up to 3 months.

25. A method of treatment of the surface of a percutaneous lead for a ventricular assist device utilised in the regime of any one of Claims 1 to 15; said method comprising applying a surface texture or treatment to predetermined portions of the surface of the percutaneous lead thereby to allow incorporation of portions of said lead into tissue surrounding the percutaneous lead thereby to facilitate subsequent removal of said ventricular assist device and percutaneous lead.

26. A percutaneous lead for use with the regime of any one of Claims 1 to 19 incorporating a surface treatment applied to predetermined portions of the surface of said lead whereby tissue ingrowth is controlled over said portions.

27. The lead of Claim 26 wherein said surface treatment comprises application of a material to said surface.

28. The lead of Claim 27 wherein said material comprises velour.

29. The lead of Claim 26 wherein said treatment comprises application of a surface texture.

30. The lead of Claim 29 wherein said surface texture is tailored as to the degree to which ingrowth is promoted therein.

31. The lead of Claim 30 wherein tissue ingrowth is controlled by the extent to which texturing produces a labyrinth arrangement in said surface.

32. The lead of Claim 31 wherein tissue ingrowth is controlled by selection of depth and shape of textures in said surface.

33. A method of treatment of the surface of a percutaneous lead for a ventricular assist device; said method comprising applying a surface texture or treatment to predetermined portions of the surface of the percutaneous lead thereby to allow incorporation of portions of said lead into tissue surrounding the percutaneous lead thereby to facilitate subsequent removal of said ventricular assist device and percutaneous lead.

34. A percutaneous lead incorporating a surface treatment applied to predetermined portions of the surface of said lead whereby tissue ingrowth is controlled over said portions.

35. The lead of Claim 34 wherein said surface treatment comprises application of a material to said surface.

36. The lead of Claim 35 wherein said material comprises velour.

37. The lead of Claim 34 wherein said treatment comprises application of a surface texture.

38. The lead of Claim 37 wherein said surface texture is tailored as to the degree to which ingrowth is promoted therein.

39. The lead of Claim 38 wherein tissue ingrowth is controlled by the extent to which texturing produces a labyrinth arrangement in said surface.

40. The lead of Claim 38 wherein tissue ingrowth is controlled by selection of depth and shape of textures in said surface.

41. A method of mechanically assisting a heart to pump blood; said method comprising releasably, sealingly connecting via a first cannula and a second cannula a first ventricular assist device so as to at least assist said heart to pump said blood; during a first predetermined period of time, ascertaining if mechanical assistance continues to be required and, if so, substituting a second ventricular assist device

for said first ventricular assist device at the end of said first predetermined period of time.

42. In combination a first ventricular assist device adapted for short term use and a second ventricular assist device adapted for long term use.

43. A first cannula having a proximal end for connection to the aorta; a second cannula having a proximal end for connection to a ventricle; said first cannula having a distal end including connection means for releasably, sealingly connecting said distal end of said first cannula to either an inlet of a first ventricular assist device or an inlet of a second ventricular assist device; a second cannula having a distal end including connection means for releasably, sealingly connecting said distal end of said second cannula to either an outlet of said first ventricular assist device or an outlet of said second ventricular assist device; said second ventricular assist device adapted for substitution for said first ventricular assist device following a first predetermined period of operation of said first ventricular assist device.

44. An embolisation device adapted for insertion into either said first cannula or said second cannula of Claim 43; said embolisation device including a stem

having an end adapted to deliver a coagulating material to a sealing position within said proximal end of said first cannula or said second cannula.

45. A percutaneous lead for carriage of power to a ventricular assist device; said lead having a surface; said surface including regions which permit incorporation of the lead surface into the surrounding tissue and a region or regions which will not allow incorporation.

46. The lead of Claim 45 wherein the region allowing incorporation may extend the entire length of the percutaneous lead or none of it or it may extend over regions near the ventricular assist device sufficient only to help anchor the device in place or near to the site where the percutaneous lead exits the body and provide good closure to the wound so as to prevent or reduce the occurrence of infection.

47. The lead of Claim 45 or Claim 46 wherein, in addition, other areas on the surface of the percutaneous lead may have properties which prevent incorporation so as to facilitate easy removal of the lead at the end of the predetermined period of implantation of the first ventricular assist device.