

FORM 2
THE PATENTS ACT, 1970
(39 OF 1970)
&
The Patent Rules, 2003
COMPLETE SPECIFICATION
(see sections 10 & rule 13)

1. TITLE OF THE INVENTION

**A SELF-SUPPORTING SURGICAL DEVICE AND ITS USE IN CREATION OF
ARTERIO VENOUS FISTULA**

2. APPLICANTS (S)

| NAME | NATIONALITY | ADDRESS |
|---|-------------|--|
| MAHAKALKAR, Chandrashekhar Chintaman | IN | Jawaharlal Nehru Medical College, Sawangi (Meghe), Wardha-442004, Maharashtra, India |
| KAPLE, Meghali Narayan | IN | Jawaharlal Nehru Medical College, Sawangi (Meghe), Wardha-442004, Maharashtra, India |

3 PREAMBLE TO THE DESCRIPTION

COMPLETE SPECIFICATION

The following specification particularly describes the invention and the manner in which it is to be
performed

A SELF-SUPPORTING SURGICAL DEVICE AND ITS USE IN CREATION OF ARTERIO VENOUS FISTULA

FIELD OF INVENTION

5 The present invention relates to a system for arterio venous fistula (herein after AVF). More particularly, the invention relates to surgical device which can be used as a self-supporting device to hold the artery and vein during arterio venous fistula creation.

BACKGROUND OF THE INVENTION

10 An arterio venous fistula is a communication between an artery and a vein. Such connections are created surgically for the purpose of hemodialysis. The blood flows from artery to veins side, from high velocity to low velocity, causing dilatation of the vein. Such AVF are used for maintenance hemodialysis in patients of chronic kidney disease.

The various for creation of AVF are at wrist (Radial Artery), elbow (Brachial Artery) or very rarely above this level. The blood flowing across the AVF determines the rate and time required for dialysis. The adequate lumen of anastomosis between artery and vein, the blood flows rapidly and dialysis time is shortened.

TECHNICAL PROBLEM

20 The procedure of AVF creation involves the surgically exposure of artery and vein, and dissection of artery and vein to create an anastomosis between artery and vein. During anastomosis, the blood flow from artery and vein is required to hold by applying the vascular clamps. These vascular clamps are bulldog's vascular clamps to clamp the artery and vein and consequently the blood flow from artery and vein. These clamps are to be hold and supported
25 by an assistant during the procedure of AVF creation. As these are hold by an assistant, these are likely to be disturbed and alignment of anastomosis (suture line) may be deviated or shifted. This is a human error, not under control of operating surgeon. Therefore, to overcome this human error, it was a need of hour to develop a device where no assistant is required to hold the clamp during the procedure of AVF creation. More particularly a need exists in the
30 field of AVF is a self-supporting or self-retaining device which holds the artery and vein at the time of anastomosis for stable positioning and secure anatomising during AVF creation. Applying such an instrument to artery and vein, positions of artery and vein can be kept stable and constant. This reduces the operating time and improves the quality of anastomosis.

Another need exists for the device that prevents rotation or twisting of venous wall during anastomosis as against in manually operated bulldogs clamps, the vein may rotate or twist and compromise the anastomosis and flow across the fistula.

At the conclusion, the vascular anastomosis needs to be done with very stable position of the patient's part and with a highly secure way, so that no compromise of lumen could be there. Simple application of bulldogs clamps may gradually shifts their positions because of repeated handling and come closer to the anastomosis site. This can compromise the anastomosis. For this, we have to adjust the bulldogs clamp every time during the procedure and cause efflux of blood into the lumen. To avoid this, a self-supporting or self-retaining device is needed in the field of AVF which would help to maintain the position of bulldog clamps at a fixed place and as a result, operation procedure can be done fast with stable position of artery and vein.

No prior art or prior arts highlighting the aforementioned problem and solution over such problem. An instant invention is required in the field to the meeting of aforementioned needs.

OBJECT OF THE INVENTION

Accordingly, the principle object of the present invention is to provide a cost effective, manually operated surgical device that holds the artery and vein at the time of anastomosis for stable positioning and secure anatomosis during AVF creation where no further assistant is required to hold the clamps.

Another object of the present invention is to provide a surgical device that avoids repeated shifting of bulldog clamps during AVF creation.

Yet another object of the present invention is to provide a surgical device which maintains the position of bulldog clamps at a fixed plated and subsequently makes it "self-supporting" or "self-retaining" device that offers faster operation procedure with stable position of artery and vein to the surgeon.

Yet another object of the present invention is to provide a self-supporting or self-retaining surgical device in which vessels are well supported by the plate to which bulldog clamps are attached that promotes the placement of sutures exactly at the correct positions.

Yet another object of the present invention is to provide a self-supporting or self-retaining surgical device that prevents rotation and twisting of the venous wall during anastomosis.

Further objective of the present invention is to provide a surgical device which is simple in design and easy to operate.

SUMMARY OF THE INVENTION

According to present invention is provided a surgical device for holding the artery and vein in creation of arterio venous fistula, comprising

5 a thin metallic plate having first end and a second end;

two bulldog clamps includes first bulldog clamp and second bulldog clamp;

the first end of the metallic plate attached to the first bulldog clamp and the second end of the metallic plate attached to the second bulldog clamp, respective bulldog clamp disposed to
10 respective end so that the bulldog clamps can be easily opened and closed;

the metallic plate having an opening on its side wall for an attachment;

a metallic rod horizontally attached to the metallic plate through the opening of the metallic
15 plate, the horizontally attached metallic rod finally fixed to a vertical metallic rod so as to form a metallic bar having a 'T' shaped structure;

a vertical rod and a weighed plate, the weighted plate having an opening at its top surface for
20 an insertion; the vertical rod inserted to the weighted plate through the opening of the weighted plate.

If accordance with these and other objects when will became apparent herein after, the instant invention will now be described with particular reference to the accompanying drawing.

25 BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS

Figure 1 illustrates the self-supporting device in accordance with the present invention;

Figure 2 illustrates the dimensional feature of part A (a thin metallic plate attached to bulldog clamps) of self-supporting surgical device in accordance with the present invention;

Figure 3 illustrates the dimensional feature of part B (a "T" shaped horizontally attached
30 metallic rod) of self-supporting surgical device in accordance with the present invention; and

Figure 4 illustrates the dimensional feature of part C (a vertical rod attached to a weighted plate) of self-supporting surgical device in accordance with the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The present invention provides a surgical device particularly self-supporting surgical device for holding the artery and vein at the time of anastomosis for stable positioning and secure anastomosis during AVF creation, said device is divided into following three parts:

- 5 (A) a thin metallic plate attached to two bulldog clamps;
- (B) a "T" shaped horizontally attached metallic rod;
- (C) a vertical support device,

In one preferred embodiment the present invention illustrates the self-supporting surgical device and its mechanism for holding the artery and vein at the time of anastomosis for stable
10 positioning and secure anastomosis during AVF creation. Referring now to Figure 1, after dissecting out the artery and vein, the present device is applied to both the artery and the vein. The instrument is adjusted such that the centre of the device is at the site of anastomosis of artery and vein. After testing the patency of both the vessels, the instrument is adjusted and now it is fixed and made stable. The artery and vein is supported with the thin metallic plate.
15 The artery and vein is taken over this thin metallic plate and then bulldog clamps are applied. The bulldog clamps are fixed to the metallic plate (part A). This is the platform for suturing the artery and vein. This thin metallic plate is then fixed to a metallic rod which is horizontally attached to the metallic plate (part B). This rod is adjusted over the stabilizer or vertical support device (part C). This support device stabilizes the whole instrument. This is a
20 type of self supporting instrument to hold artery and vein in place while suturing AVF.

According to present invention the term 'stabilizer' or 'vertical support device' means a vertical rod attached to a weighted platform or a vertical rod attached to a weighted plate.

25 According to present invention the term 'weighted platform' or 'weighted plate' are herein interchangeable and could be used in the same way.

According to present invention the term "'T" shaped horizontally attached metallic rod' defines a metallic rod is horizontally attached to a thin metallic plate through an opening of the metallic plate and finally fixed to a vertical metallic rod so as to form a metallic bar having a
30 T shaped structure.

Fabrication of self-supporting surgical device of the present invention:

Part (A): Thin metallic plate attached to bulldog clamps

Part (A) consists of a thin metallic plate and two bulldog clamps. The thin metallic plate of the present invention acts as a platform for suturing the artery and vein wherein the length of the plate is 2.5 cm, the width of the plate is 1.0 cm and the thickness of the plate is approximately 2 mm (Figure 2). It is made tip of stainless steel. The bulldog clamps are fixed to both the ends of metallic plate. The bulldog clamps are fixed in such a way that they can be easily opened and closed. The distance between two bulldog clamps is 1.5 cm. The bulldog clamps fixed at both ends are chosen in such a way that the thickness will be around 4.0 mm. When both the bulldog clamps are applied to the vessels, a distance of 1.5 cm should be there between the inner margins of two bulldog clamps. This thin metallic plate has opening on the side wall in the centre for the attachment of Part B.

Part (B): "T" shaped horizontally attached metallic rod

Part (B) consists of a metallic rod which is horizontally attached to the metallic plate of part (A) and a vertically metallic rod. This metallic rod is "T" shaped with a long horizontal part of 8.0 cm, of which 6 mm is for fixation to thin metallic part (Part A) and remaining 7.4 cm is smooth surface and circular in shape. At the end it is attached with a vertical metallic rod of 4.0 cm in length. This joint is non-detachable. The thickness of this rod is 2.0 mm except at its fixing end to part A where it is 1.0 mm. At the junction of the metallic rod and vertical metallic rod, an opening of approximately 2.0 mm is kept to fix it to part (C). This opening is along the full thickness of the rod. It is made up of stainless steel (Figure 3).


Part (C): Vertical support device

Part (C) consists of a vertical rod and a weighted plate. The purpose of Part (C) is to support part A via part B. In part (C), both vertically rod and weighted plate have been kept on the flat surface of the operating table to balance the weight and adjust the height of the device. The rod at its upper end has screwed surface of 6 mm length and 1.5 mm diameter. The middle portion of the rod is smooth surfaced and lower end which is inserted in the whole of circular plate is screwed for last 4.5 cm. The diameter of the rod at its middle and lower part is 3.00 mm. The shape of the weighted plate at its base is circular. The diameter of the weighted plate at base surface is 5.0 cm and at top surface is 2.5 cm. The top surface of weighted plate has an opening in the centre of 3.0 mm diameter and 4.0 cm deep for insertion of the vertical rod. The total height of the weighted plate is 4.5 cm. The height of the base surface of the weighted plate is 3 cm and the height of the top surface of the weighted plate is

1.5 cm.

Although the foregoing description of the present invention has been shown and described with reference to particular embodiments and applications thereof, it has been presented for purpose of illustration and description and is not intended to be exhaustive or to limit the invention to the particular embodiments and applications disclosed. It will be apparent to those having ordinary skill in the art that a number of changes, modifications, variations, or alterations to the invention as described herein may be made, none of which depart from the spirit or scope of the present invention. The particular embodiments and applications were chosen and described to provide the best illustration of the principles of the invention and its practical application to thereby enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such changes, modifications, variations and alterations should therefore be seen as being within the scope of the present invention as determined by the appended claims when interpreted in accordance with the breadth to which they are fairly, legally and equitably entitled.

For MAHAKALKAR, Chandrashekhhar Chintaman et. al.



Tarun Khurana

Regd. Patent Agent [IN/PA-1325]

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