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Design, manufacture and in-vitro evaluation of a new microvascular anastomotic device.

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Abstract—**Introduction: Many microvascular anastomoses have been proposed for use with physical assisted methods, such as cuff, ring-pin, stapler, clip to the anastomose blood vessel. The ring-pin type anastomotic device (e.g., 3M Microvascular Anastomotic System) is the most commonly used worldwide because the anastomotic procedure can be conducted more rapidly and with fewer traumas than using sutures. However, problems including vessel leakage, ring slippage, high cost and high surgical skill demand need to be resolved. The aim of this study is to design and manufacture a new anastomotic device for microvascular anastomosis surgery and validate the device functions with in-vitro testing. Methods: The new device includes one pair of pinned rings and a set of semi-automatic flap apparatus designed and made using computer-aided design / computer-aided manufacture program. A pair of pinned rings was used to impale vessel walls and establish fluid communication with rings joined. The semi-automatic flap apparatus was used to assist the surgeon to invert the vessel walls and impale onto each ring pin, then turning the apparatus knob to bring the rings together. The device was revised until it became acceptable for clinical requires. An in-vitro test was performed using a custom-made seepage micro-fluid system to detect the leakage of the anastomotic rings. The variation between input and output flow for microvascular anastomoses was evaluated. Results: The new microvascular anastomotic device was convenient and easy to use. It requires less time than sutures to invert and impale vessel walls onto the pinned rings using the semi-automatic flap apparatus. The in-vitro test data showed that there were no tears from the joined rings seam during the procedures. Conclusions: The new anastomotic devices are effective even with some limitations still remaining. This device can be helpful to simplify the anastomosis procedure and reduce the surgery time.**

INTRODUCTION

Microvascular anastomosis is a critical procedure in free tissue transfer and replantation surgery. It is almost universally performed by manual suturing. This remains technically sensitive and is often time consuming because of the difficult execution resulting from the current microscopic suturing techniques. However, a short ischaemia time is essential in this kind of surgery. In the search for faster and simpler methods, a variety of other techniques have been investigated. These include various anastomotic coupling devices, non-suture external cuff techniques and adhesive techniques. None of these methods have gained widespread popularity in microsurgery with the exception of the 3M Precise Microvascular Anastomotic System (3M MAC System, 3M. Healthcare, St. Paul, MN), which has found its way to an increasing number of microsurgical units in the last few years. The 3M MAC System consists of 2 metal rings with 6 pins and 6 holes evenly spaced around the surface of each ring. The vessel ends are delivered through the ring, inverted onto the pins, the rings are then mechanically approximated, opposing the vessel tissue. Although the procedure for mounting the vessels onto the device is much faster than suturing the vessel walls, surgeons must still manually insert the metallic pins into the vessel walls. Surgeons prefer to perform the procedure automatically.

The Semi-Automatic Microvascular Anastomotic System (SaMAS) presents a mechanical change in the principle and device structure that solves this problem. The SaMAS uses a semi-automatic flap mechanism to assist the surgeon to invert and fix the vessel walls. The device will semi-automatically attach the vessel walls to the pin-rings.

MATERIALS AND METHODS

A. Design and manufacture of SaMAS

The SaMAS is designed for end-to-end anastomosis of vessels with diameters smaller than 3.0 mm. The system consists of two elements: a couple of polyether ether ketone (PEEK) rings containing stainless steel pins, a set of semi-automatic flap apparatus that invert and fix the vessel walls onto pins following aligning approximates the vessel ends for anastomosis performance.

The PEEK rings contains six stainless steel fixing pins (Fig. 1(a)) which can be bend to fix the exerted vessel walls (Fig. 1(b)). The rings can be joined together tightly with corresponding positioning pins and holes.

The semi-automatic flap apparatus contains two parts, a holder and driver.(Fig. 2)

The microvascular anastomosis surgery concept using SaMAS is shown in Fig. 3. The first step in this anastomotic technique is to rotate the stopper forward and draw either the distal or proximal end of the vessel through the lumen of one of the anastomotic rings. The ends of the vessels are then placed onto the stopper micro-cylinder. The knob of the driver is then turned clockwise to bring the rings toward the stopper. The fixing pins will penetrate the vessel walls and bend to invert and fix the vessels. The driver knob is then turned counterclockwise to bring the rings away from the stopper and rotate the stopper backward. The driver knob is then turned clockwise again to bring the rings close to each other until the vessels join together tightly and eject the rings from the device.

The SaMAS was designed with 3D-CAD software (Creo Elements/Pro 5.0, Parametric Technology Co, Needham, MA). Then the data were sent to a Computer Numerical Control (CNC) lathe machine, and the SaMAS prototype was built automatically by the machine.

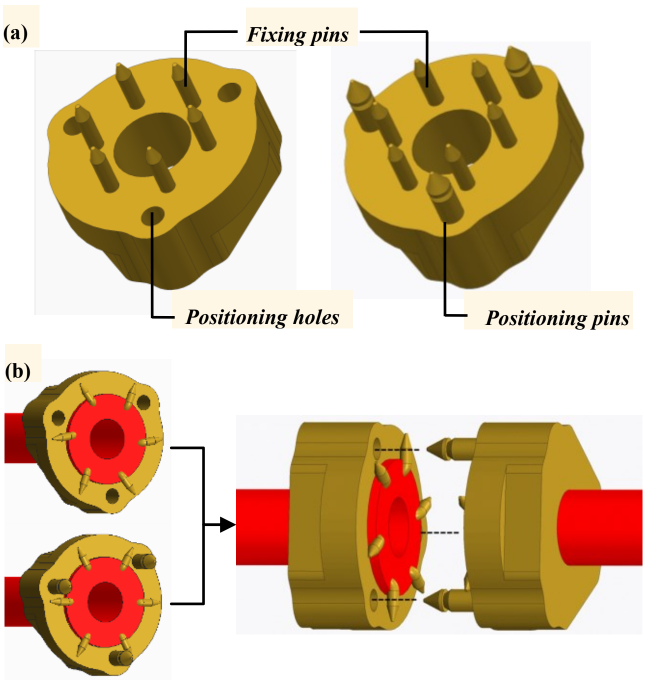


Figure. 1 (a) The structure of the anastomosis pinned rings; (b) The concept of the couple pinned rings used to fix the vessel walls and align them to each other.

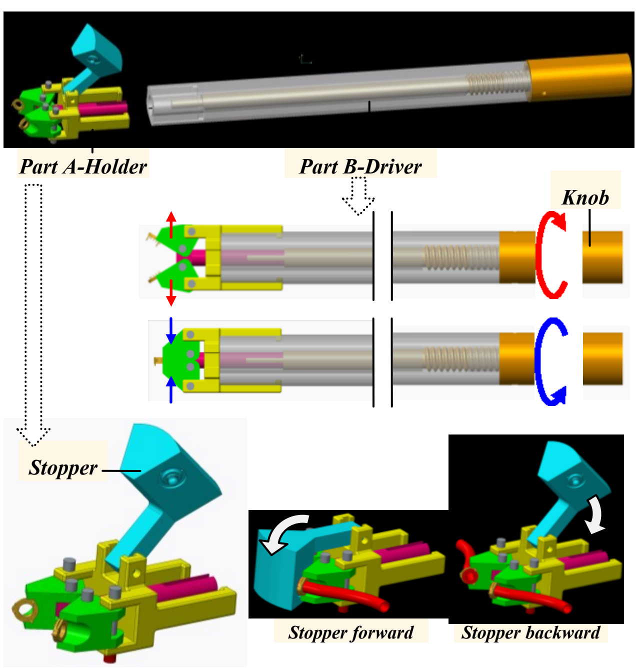


Figure. 2 (a) The structure of the semi-automatic flap apparatus contains: Part A-The holder is used to assist surgeou to exert vessel walls and to align the anastomosis rings to each other semi-automatically. Part B-The driver with knob and inner lead-screwis used to driver the grips of holder to bring rings open or close.

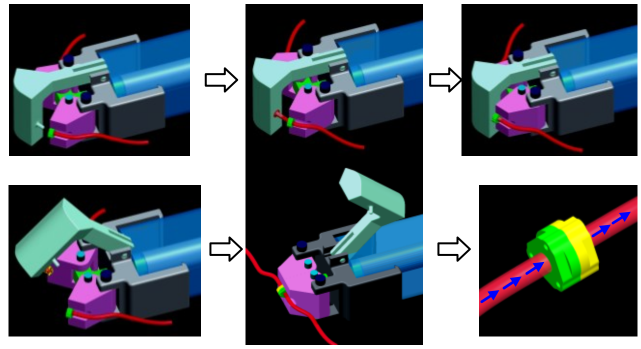


Figure. 3 The microvascular anastomosis surgery operating processs using SaMAS.

B In-vitro leakage test

An in-vitro test was performed using a custom-made seepage micro-fluid system to detect leakage in the anastomotic rings in our new device. The custom-made seepage micro-fluid system was developed to detect leakage in anastomosis rings. (Fig. 6) The system contains a quantitative pump for output fluid, a programmable logic controller (PLC) for controlling the pump frequency and power, two micro-flow meters to monitor and record the input and output mass flow rate, respectively. The variation between input and output flow for microvascular anastomoses was evaluated using the micro-flow meter. This system automatically records the data.

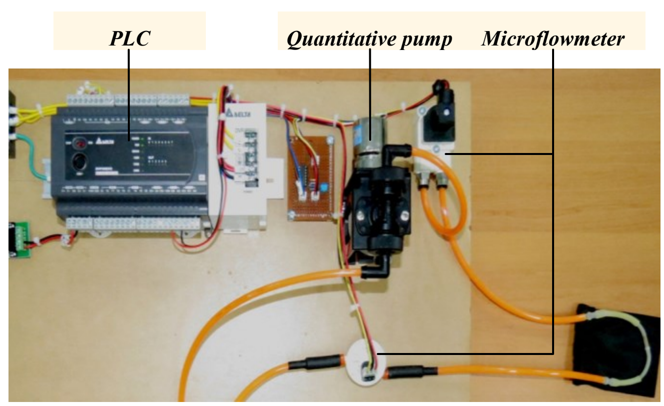


Figure. 4 The custom-made seepage micro-fluid system for detect the leakage of the anastomosis rings.

RESULTS AND DISCUSSION

All parts of the SaMAS including the pinned rings coupler (inner diameter φ 1 mm and φ 3 mm) and semi-automatic flap apparatus were manufactured and assembled as shown in Figs. 4 and 5. The basic operation was performed to check the system functions. The size of the pins greatly increased manufacturing and assembly difficulty. Beside the micro-features, traditional machining procedures are inadequate. Therefore a transition fit mechanism was applied for assembly with the pins and holes on the rings used to increase the retention strength and anastomosis. Most of the semi-automatic flap apparatus functions, including closing and opening the holder are obtained with a screw that moves when the knob is rotated. Only one mechanism, the stopper micro-cylinder should be correct for fixing the end of vessels tightly. This relates to whether the semi-automatic flap and vessel walls penetrated with the pins work. The geometry of the stopper micro-cylinder should be redesign and tested.

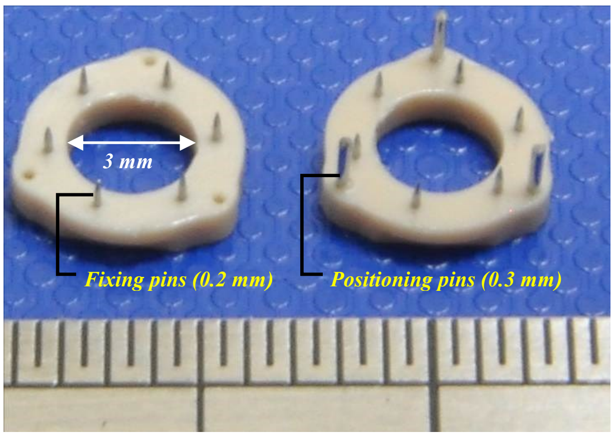


Fig 5. The prototype of pinned rings with fixing pins and positioning pins.

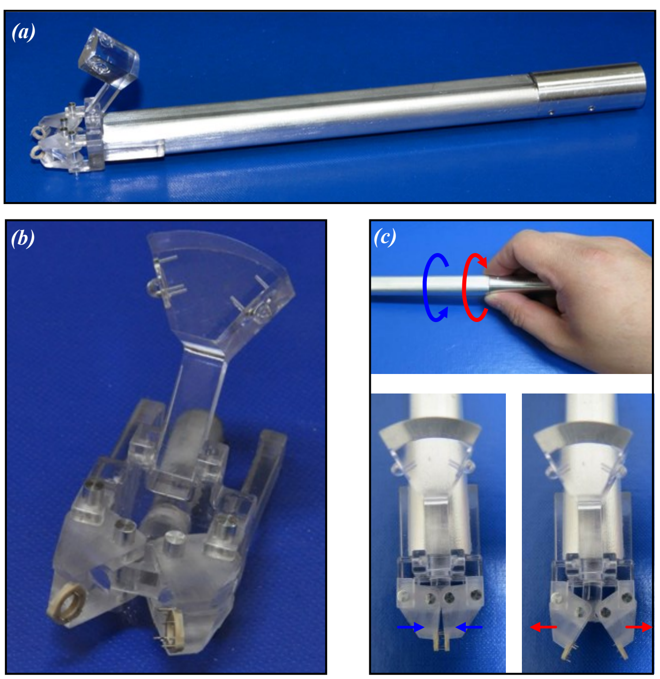
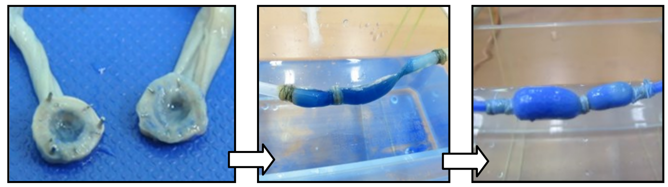
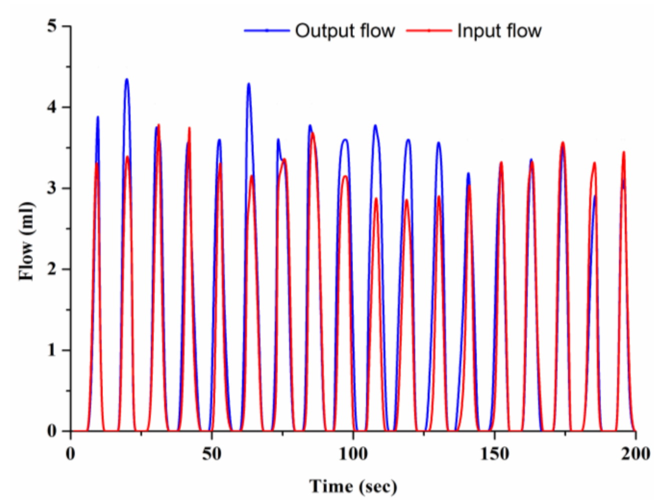


Fig. 6 The prototype of the semi-automatic flap apparatus: (a) the assembly of the apparatus; (b) the part A, holder, of the apparatus; (c) the part B, driver, of apparatus, and the operative test of the apparatus.

An in-vitro test was performed in this study to check whether the proposed anastomosis rings generate leakage. Two separated fish intestines were jointed together using the pinned rings (Fig. 7(a)). and the intestines were then connected to a micro-fluid system. After the frequency and cycle were set, the variation between the input and output flow for microvascular anastomoses was evaluated. Figure 7(b) plots the test results. According to the results the variation between the input and output was not obvious and visual leakage was also not found. This means that the anastomosis strength between the new anastomosis rings may be enough to adequately join separated vessels.



(a)



(b)

Fig. 7 (a) Fish intestines were fixed on the pinned rings and joined together and connected to a micro-fluid system. The right picture show the intestine expended due to the fluid pass through, (b) The input and output flow was recorded and plotted.

CONCLUSION

The SaMAS is a novel ring-type micro-vascular anastomosis device that uses a simple mechanism to semi-automatically attach vessel walls to the pinned rings. The devices were built and tested using a custom-made seepage micro-fluid system. The proposed anastomotic devices have some limitations yet remaining, but this device can be helpful in simplifying the anastomosis procedure and reduce the surgery time.

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