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ARTICLE

New microvascular anastomotic device for end-to-side anastomosis using negative pressure; a preliminary study

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ABSTRACT

We previously developed a device for end-to-end anastomosis powered by negative pressure and demonstrated that using the device allow the operator to anastomose semi-automatically with little stress. Here, we sought to build a device for and demonstrate that negative pressure can also be used in end-to-side anastomosis which is clinically popular as end-to-end anastomosis through animal experiment using rats. The devices were constructed with a laser lithographic/3D-printing machine. Nine SD rats were used. Each of the nine rats underwent end-to-side anastomosis between the superficial epigastric vein and the femoral vein using the device. Rat was anesthetized one week later and the anastomotic site was inspected through operative microscope for patency. The anastomotic site was harvested with the device and the rat was euthanized. The anastomotic site was embedded in epon, sectioned, stained with toluidine blue, and analyzed with light microscopy. Eight of the nine anastomoses were patent immediately after the procedures, and two of the nine were patent at 1 week after the procedures. In the failed cases, the vessels dislocated from the device because the clamps loosened during the observation period after the operation. The experiments have shown that the device using negative pressure can also be applied to end-to-side microvascular anastomosis. The patency rate is low and further improvement is required.

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Device; microvascular anastomosis; lymphatico-venular anastomosis (LVA); negative pressure vacuum

Introduction

Several microvascular anastomotic devices have been introduced [1–10]. Among them, the ring-pin-type anastomotic device (e.g. the Unilink device [8]) is the most commonly used worldwide and has been reported in many papers to be superior to conventional hand-sewn anastomosis [11–15]. Although the Unilink system is considered the best ring-type device, the system has not been updated since its release and has limitations that must be overcome. A ring-pin device has metallic pins that remain permanently, and surgeons still manually insert the metallic pins into the vessel walls.

We found that negative pressure is an ideal method of fixing vessel walls onto the device, replacing the use of metallic pins, and we previously reported a device using negative pressure for end-to-end anastomosis (the Vacuum-Assisted Microvascular AnastoCoupler) [16]. We believe that negative pressure is very suitable for four reasons. First, negative pressure is a non-traumatic force for fixing vessel walls instead of traumatic metallic pins. Second, because the device that uses negative pressure can be built without metallic pins, it could potentially be built using biodegradable materials in the future. Third, negative pressure works as an ideal actuator to place the vessel walls onto the device, allowing semi-automatic anastomosis, which will shorten the operative time. Fourth, negative pressure is available in most medical facilities and costs little.

In this study, we built a device using negative pressure as actuator to work on the vessel walls to be anastomosed, and evaluated whether the negative-pressure system could be applied to end-to-side anastomosis as well as end-to-end anastomosis in microsurgery.

Materials and methods

Development of micro-vacuum-device

The device was designed using 3D-CAD software (SolidWorks 2011–2012; Dassault Systèmes). Nine sets of the device were produced. One set was made from polymers (KC1257; JSR; Japan), including epoxy acrylate, using a laser lithographic machine (ACCULAS; Laser Solutions; USA). The other eight were made from polymers (VisJet Crystal; 3DSystems; USA), including urethane acrylate, using a 3D printing machine (ProjetHD3500plus; 3DSystems). The polymer details are proprietary and not available from the company.

The system consists of the device complex and the vacuum delivery system. The device complex consists of two main parts for the side vessel, one main part for the end vessel, and one clamp for the end vessel (Figure 1(a)). The negative pressure generated in the vacuum pump is delivered to the solenoid valve complex (VX2331G-1TLR1; SMC; Japan) and switched to the appropriate port; this pressure is regulated by the microprocessor (Arduino Uno; Italy) with the controller (Dual Shock2; Sony; Japan) and then consecutively distributed to the vacuum holes through the rubber tube, the vacuum conduit (for the main part of the

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Supplemental data for this article can be accessed here.

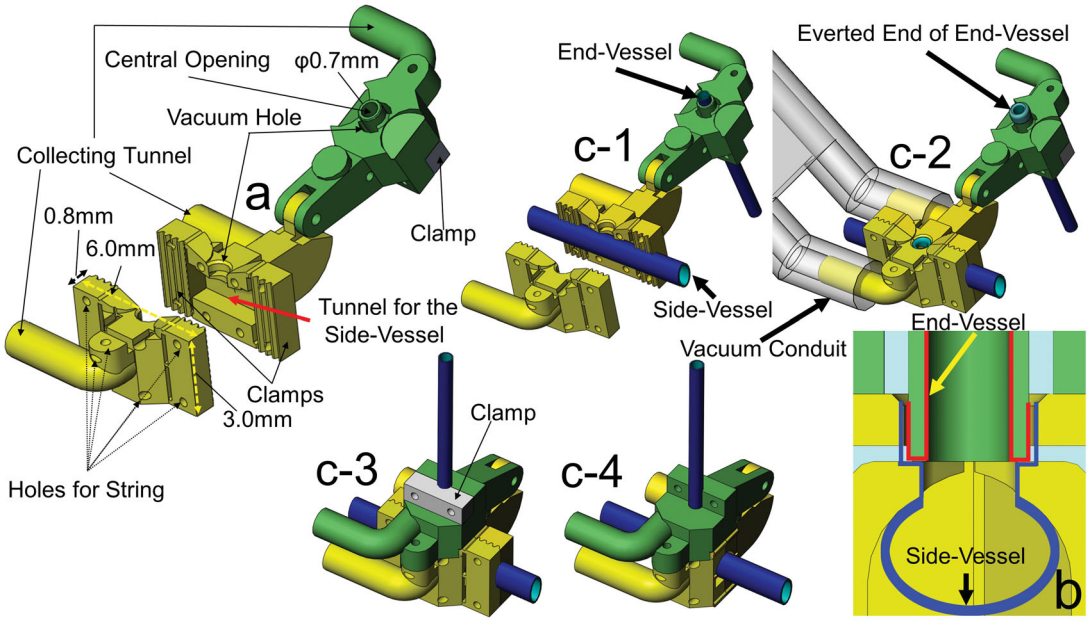

Figure 1. The device complex consists of two main parts for the side vessel, one main part for the end vessel, and one clamp for the end vessel. The main part for the side vessel has two clamps. The junction between the clamp and the other parts are designed to be weak so that they can be removed after assembly (a). Cross-sectional view: the vessel wall in the anastomotic site is everted 90° from the original position in the side vessel and 180° in the end vessel (b). The side vessel is clamped and fixed by the device. Negative pressure is delivered to the main parts for the side vessel through the vacuum conduit. All clamps are removed after the anastomoses are complete (c-1,2,3,4).

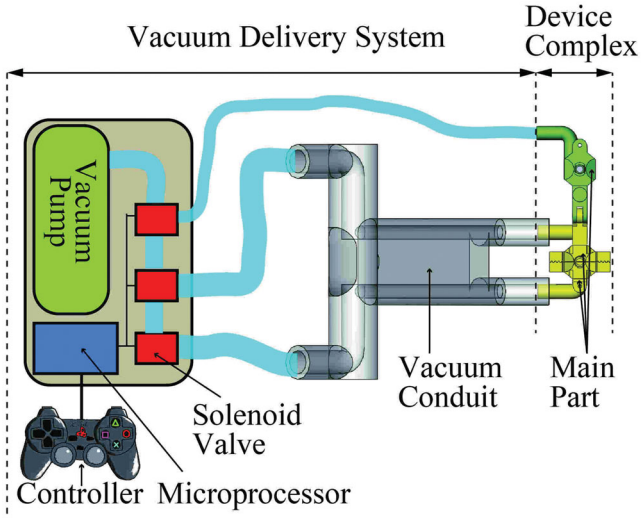

Figure 2. Outline of the vacuum delivery system. The negative pressure generated in the vacuum pump is delivered to the solenoid valve complex and switched to the appropriate port, which is regulated by the microprocessor with the controller. The negative pressure is then consecutively distributed to the vacuum holes through the rubber tube, the vacuum conduit (only in the main part for the side vessel), the collecting tunnel, and the hollow chamber inside the main part.

side vessel), the collecting tunnel, and the hollow chamber inside the main part (Figure 2).

First, the two main parts for the side vessel are set to catch the side vessel. Then, nylon strings are inserted in the holes and knotted to secure the assembly. As a result, the clamp on each end of the main part catches the side vessel not only to stop the flow from the vessel, but also to prevent the vessel from slipping off the device. A window is made on the side vessel.

The end vessel is put inside the central opening from the back, pulled out to the front, and clamped. The vacuum pump is turned on, and each vessel edge is everted and fixed to the device. The pressure on the vacuum hole is 394 mmHg while the vessel edge is set on it. Then, the two veins are pulled together facing each other by knotting the strings laced through the two holes such that an intima-to-intima coaptation is obtained (Figure 1(b)). Finally, the clamps are detached. The junction between the clamp for the side vessel and the rest is purposefully made weak, so that the clamp is removed by breaking the junction. Then, new blood flow is established (Figure 1(c)). The device complex is embedded, and the rest is removed(Supplementary Material: Video).

Experimental study

Ethical approval was obtained from the University of Tokyo Animal Ethics Committee (Med.P10-041) before beginning the experiments. Nine end-to-side anastomoses were performed with the devices on nine male Wistar rats weighing 450–535 g. The superficial epigastric veins (diameter: 0.75–0.95 mm) were used as end-vessels, and the femoral veins (diameter: 1.1–1.5 mm) were used as side-vessels (Figure 3). The rats were anesthetized with intraperitoneal administration of sodium pentobarbital (3.0 mg/100 g body weight). A cutaneo-adipose flap, which depends on the superficial epigastric artery, was elevated and assumed to be useful as a monitor of the patency of the anastomosis. The epigastric vein was dissected from the junction with the femoral vein, peripherally to the point where it had its first large branch. The femoral vein was dissected and exposed from the inguinal ligament to the junction with the superficial epigastric vein. All small branches of these vessels were ligated and divided. The device was placed on the femoral vein, 8 mm proximal to the junction. The superficial epigastric vein was transected a little distal to the junction and placed in the device. The femoral vein was clamped on both ends using the two clamp parts of the device for the side vessel. A window was made on the femoral vein through the central opening. The lumen of the vein was irrigated

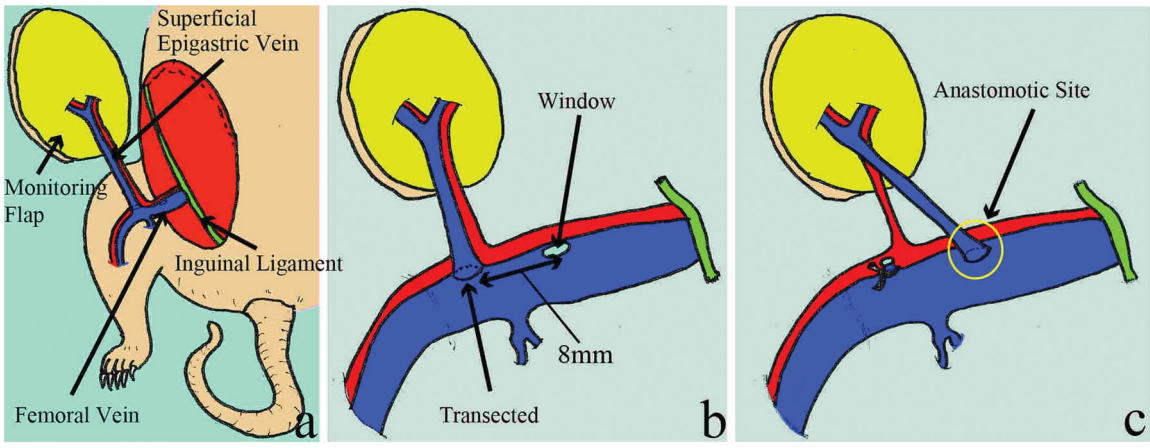

Figure 3. Rat femoral veins and superficial epigastric veins were used as the side vessel and the end vessel, respectively. A cutaneo-adipose flap that was dependent on the superficial epigastric artery was elevated to monitor the patency of the anastomosis (a). The superficial epigastric vein was transected a little distal to the junction (b). A window was made on the femoral vein 8 mm proximal to the junction where the end-to-side anastomosis was performed with the device (c).

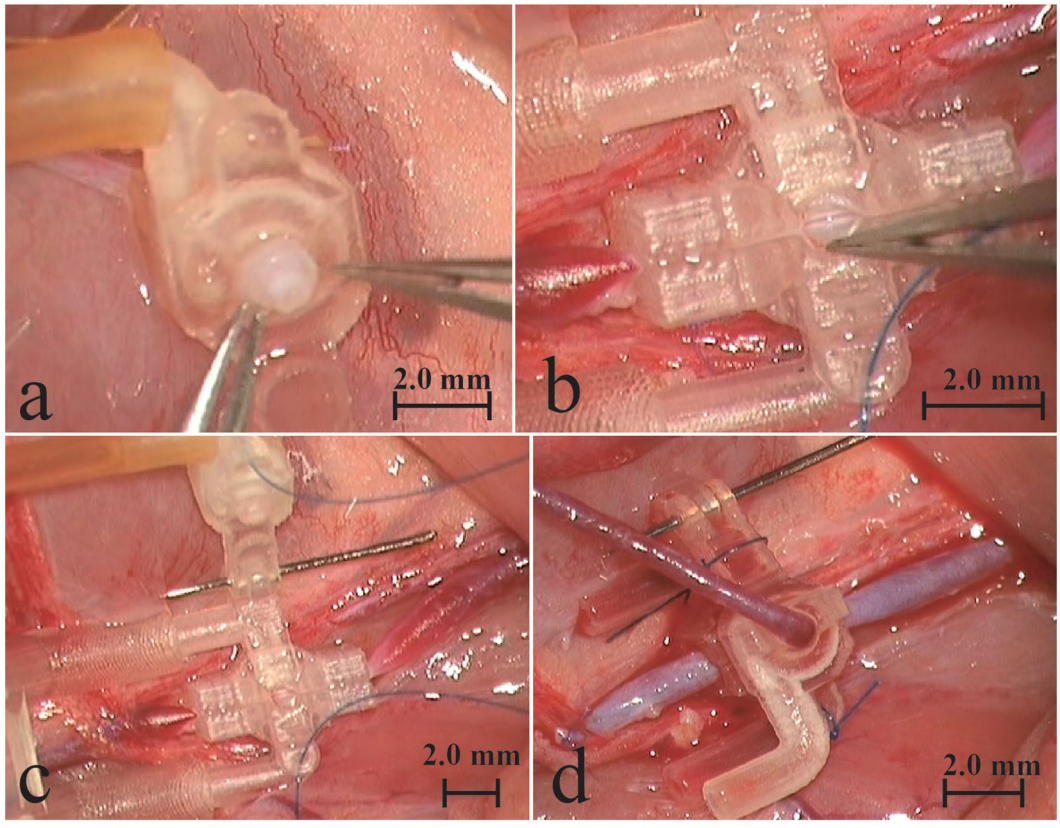

Figure 4. Views from the operating microscope. The vessel wall was everted and fixed on the device by negative pressure with the assistance of forceps (end vessel: (a), side vessel: (b)). After the vessels were set (c), the two-device complex was assembled (d).

with heparinized natural saline and prepared for the anastomosis. Each edge of the vein was installed in the device and assembled with the device (Figure 4). Right after the procedure, the patency was assessed by a distal squeeze test on the end vessel; when the blood flow came from the side vessel and filled the lumen of the end vessel after the forceps' clamping was released, the anastomosis was assessed patent.

One week after the procedure, the rats were again anesthetized. The flap was elevated in the same manner, and the anastomosed vein was dissected all the way from the inguinal ligament to the flap. The anastomotic site was exposed, and patency was assessed with a distal squeeze test as previously described. The femoral artery and vein were ligated and divided peripheral to the device. The femoral vein was cut proximal to the device to judge whether the venous blood had returned from the flap. If active venous blood was clearly observed, it was deemed to be patent. By elevating the flap, we could exclude the possibility that blood flow from the femoral artery and the femoral vein were due to other new blood vessels arising during the observation period. The vein on the anastomotic site was harvested with the device, and each rat was euthanized. Each specimen was fixed in 4% buffered formalin, embedded in epon, sectioned at 1.5 μm thickness, stained with toluidine blue, and examined with light microscopy.

Results

All rats survived the experimental period without complications. Eight of nine veins were patent immediately after the implantation procedure. Two of nine veins were patent after 1 week (Figure 5). At the anastomotic site of the patent specimens, the endothelial lining was restored (Figure 6). The time from the inset of the vessels to the removal of the clamps was 32 min in average (the standard deviation: 6.02). In most failed anastomoses, the edge of the side vessel around the window had detached from the device. A large, old hematoma was found in each failed case. In each specimen, a gap of approximately 300 μm was found between the main part of the end vessel and that of the side vessel, and was thought to be one of several causes of the vessels detaching from the device.

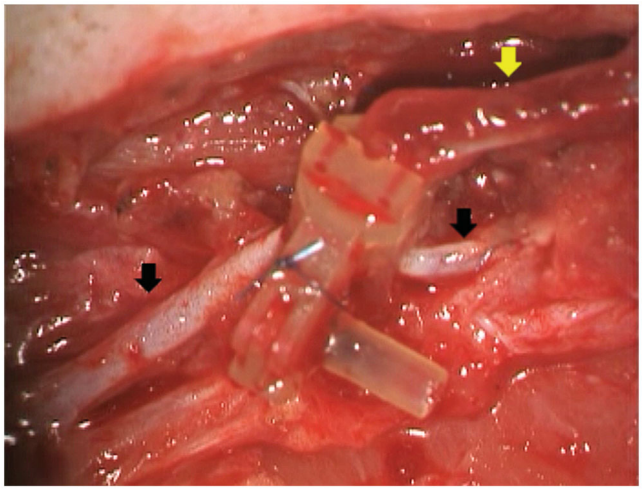

Figure 5. A view from the operating microscope: one week after the anastomosis before harvest of the anastomotic site. The vessels are patent. The black arrows indicate the side vessels, and the yellow arrow indicates the end vessel. The anastomotic site was covered with strong scar and granulation tissues.

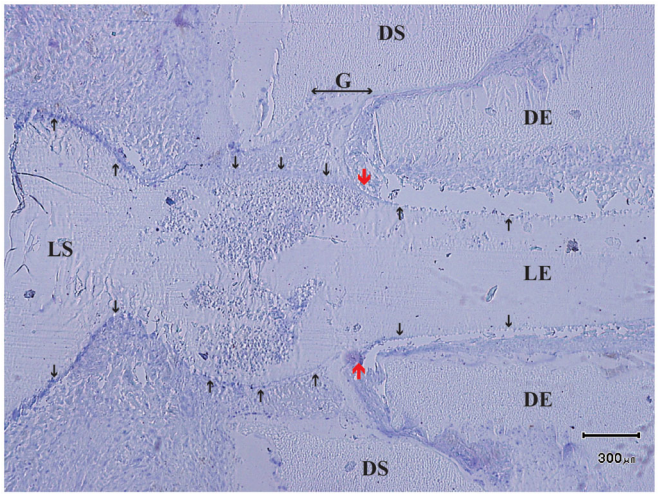

Figure 6. Image of a patent specimen under light microscopy (stained with toluidine blue). The endothelium was restored at the anastomotic site. The black arrows indicate the endothelial lining of the anastomotic site. The red arrows indicate the junction between the endothelial lining of the end vessel and the side vessel. LE: lumen of the end vessel. LS: lumen of the side vessel. DE: device for the end vessel. DS: device for the side vessel. G: gap between the two main parts.

Discussion

For many years, the vessel has been hand-sewn during microvascular anastomosis because of its small size. Most efforts and struggles of surgeons have been directed toward improving the suturing technique, not making an "automatic sewing machine" for micro-vessels. The first and foremost device for microvascular anastomosis was the Unilink-Device, which has two ring pins that face each other to fix vessels walls, allowing the surgeons to easily anastomose the micro-vessels. The device has a simple and excellent design, but it has no actuator to work on the vessels, so surgeons still have to do all the tedious work of installing vessels onto the device. It is a simple "static" device, not a "dynamic" machine. We have been eager to power the device for automatic microanastomosis, and have found that negative pressure is the best power source to use as an actuator. Device-assisted microvascular anastomosis would require micro-actuators that are too small to be built. On the other hand, negative pressure is promptly conveyed to the destination through tiny tunnels inside a small device from a distant location, and even works as a formless actuator that allows the device to function automatically. In our experiment, the device was designed small (dimension of the two main assembled parts: height: 3.0 mm, thickness: 1.6 mm, length: 6.0 mm). The vacuum hole is 0.15 mm in height and 0.70 mm in diameter, and yet no occlusion occurred in the negative pressure airway during the experiment. Right after the pump was turned on, the device instantly attached the side vessel to its vacuum hole.

We previously built and reported that this device that is powered by negative pressure works well for end-to-end anastomosis [16]. This time, we have found that the negative-pressure system can also be applied to end-to-side anastomosis, which is as clinically popular as end-to-end anastomosis. The most important feature is that we built a "semi-automatic" microvascular anastomotic device that functions as an actuator and proved that the negative-pressure system works for both end-to-end and end-to-side anastomosis in rats. An additional advantage in using this negative pressure system is that during the anastomosis, surgeons often find blood and fluid at the anastomotic site that hinder the procedure. The device worked perfectly with suction, and the procedure was performed in a clean, fluid-free operative site with no stress.

On the other hand, one big problem remains to be solved. Because fixation using negative pressure is far weaker than fixation with metallic pins, the procedure carries a risk that the vessels will slip off the device during and after the procedure. In our previous experiments with devices for end-to-end anastomosis, the vessels sometimes slipped off the device during the assembly, which hindered the procedure. These situations become harder in end-to-side anastomosis because the side vessel has two intact ends that are embedded in the tissue, producing strong tension between the vessel and the bottom of the operative area. Thus, we improved the structure in two ways.

First, the shape of the vacuum hole of the main part was improved. In the previous end-to-end device, the vacuum hole was a tiny round hole that generated weaker negative pressure than expected. The end-to-side device has slit-shaped vacuum holes that are much larger than those in the end-to-end device which allowed the device to hold the vessel wall of the side vessel tight enough to prevent slip-offs during the procedure. Second, a pair of removable clamps was added to the main part. They held the side vessel firmly during the procedure and also worked as vessel clamps.

Although eight of nine anastomoses were patent right after the implantation procedure, only two of nine anastomoses were patent after 1 week. In each failed case, a large, old hematoma was found, and the side vessel had dislocated from the central opening in the specimen, as seen with light microscopy. The clamps worked perfectly and prevented the vessel from slipping off during the surgery. However, after the negative pressure was turned off, the device had to hold the vessel by itself with its small area to catch the vessel, which could not prevent the vessel's falling off. Acute movement of the rat just after the surgery may have been another cause of the dehiscence of the anastomosed vessels. If several additional small spicules are designed on the surface, they may increase the friction force and prevent the falling off. Ideally, all sets of the devices should have been made by laser lithographic machine using epoxy acrylate, which had higher manufacturing accuracy than that of the 3D printing machine. The cost which was extremely high in using laser lithographic machine made us use 3D printing machine, sacrificing the resolution of the devices. If all sets of the devices were made by laser lithographic machine, the loosening might have been lessened and the patency rate might have been improved.

The device was supposed to be built from biodegradable or biocompatible materials, however because of the cost and technical reasons the device had to be made from non-biodegradable polymers which details were not available. We concluded that the tension between the vessels caused the dehiscence of the anastomosis and was the major cause of the failure.

Conclusions

A novel actuator-loaded microvascular anastomotic device for end-to-side anastomosis powered by negative pressure was designed, constructed and tested in rats. The idea and the mechanism have been introduced. The device needs further investigation.

Disclosure statement

All authors have and declare that: no support, financial or otherwise, has been received from any organization that may have an interest in the submitted work; and there are no other relationships or activities that could appear to have influenced the submitted work.

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References

[1] Galvao FH, Bacchella T, Machado MC. Cuff-glue sutureless microanastomosis. Microsurgery. 2007;27(4):271–276.
[2] Daniel RK, Olding M. An absorbable anastomotic device for microvascular surgery: experimental studies. Plast Reconstr Surg. 1984;74(3):329–336.
[3] Daniel RK, Olding M. An absorbable anastomotic device for microvascular surgery: clinical applications. Plast Reconstr Surg. 1984;74(3):337–342.
[4] He FC, Wei LP, Lanzetta M, et al. Assessment of tissue blood flow following small artery welding with an intraluminal dissolvable stent. Microsurgery. 1999;19(3):148–152.
[5] Holt GP, Lewis FJ. A new technique for end-to-end anastomosis of small arteries. Surg Forum. 1960;11:242–243.
[6] Inokuchi K. Stapling device for end-to-side anastomosis of blood vessel. Arch Surg. 1961;82(3):337–341.
[7] Nakayama K, Tamiya T, Yamamoto K, et al. A simple new apparatus for small vessel anastomosisi (free autograft of the sigmoid included). Surgery. 1962;52:918–931.
[8] Ostrup LT, Berggren A. The UNILINK instrument system for fast and safe microvascular anastomosis. Ann Plast Surg. 1986;17(6):521–525.
[9] Qu W, Muneshige H, Ikuta Y. An absorbable pinned-ring device for microvascular anastomosis of vein grafts: experimental studies. Microsurgery. 1999;19(3):128–134.
[10] Zhong C, Tang NX, Zheng CF, et al. Experimental study on microvascular anastomosis using a dissolvable stent support in the lumen. Microsurgery. 1991;12(2):67–71.
[11] Rad AN, Flores JI, Rosson GD. Free DIEP and SIEA breast reconstruction to internal mammary intercostal perforating vessels with arterial microanastomosis using a mechanical coupling device. Microsurgery. 2008;28(6):407–411.
[12] Berggren A, Ostrup LT, Lidman D. Mechanical anastomosis of small arteries and veins with the unilink apparatus: a histologic and scanning electron microscopic study. Plast Reconstr Surg. 1987;80(2):274–283.
[13] Ragnarsson R, Berggren A, Ostrup LT. Microvenous end-to-side anastomosis: an experimental study comparing the Unilink system and sutures. J Reconstr Microsurg. 1989;5(03):217–224.
[14] Spector JA, Draper LB, Levine JP, et al. Routine use of microvascular coupling device for arterial anastomosis in breast reconstruction. Ann Plast Surg. 2006;56(4):365–368.
[15] Yap LH, Constantinides J, Butler CE. Venous thrombosis in coupled versus sutured microvascular anastomoses. Ann Plast Surg. 2006;57(6):666–669.
[16] Tachi K, Furukawa KS, Koshima I, et al. New microvascular anastomotic ring-coupling device using negative pressure. J Plast Reconstr Aesthet Surg. 2011;64(9):1187–1193.