

## 랙과 피니언방식의 새로운 기계식 혈관문합기 개발

### Development of New Mechanical Anastomosis Device by Rack & Pinion Drive

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#### 1. Microvascular Mechanical Anastomosis

The microvascular anastomosis to use the suture needs not only the advanced surgery technique to require the long training time but also the long intraoperation time.<sup>(1,2)</sup> When the needles passed through the intravascular wall, it could damage it. It could cause the thrombus after the post-operation. If the ischemia takes long time, the risk of the complication due to the ischemia-reperfusion injury can be increased. It was reported that the fail rate of the microvascular anastomosis by the suture was about 2~5% due to these difficulties.<sup>(2)</sup> The common aims of the microvascular anastomosis are 1) to decrease the ischemia time by the quick operation, 2) to anastomose the micro-vascularity easily, 3) to minimize the damage of the blood vessel. Many anastomoses such as adhesives, mechanical anastomosis device, laser and so on, have been developed to increase their successful rate. The most popular microvascular anastomosis is to use the mechanical anastomosis device. After Nakayama *et. als.* developed the microvascular coupler in 1962, which consisted of both two metallic rings and twelve interlocking pins, the modified microvascular couplers have been developed and

their clinical results to test the animals have been reported. Despite of many advantages, they have not become the general microvascular anastomoses since the operator did not rely on the device method of the microvascular anastomosis (which needs the skillful suture techniques and many experiences) and the economic burden of the mechanical anastomosis device was charged to the patients. Therefore, the microvascular anastomosis of the suture was regarded as the most general method. This research is going to accomplish three aims mentioned before by the self-design and self-development of the microvascular coupler. Microsurgeons use the microvascular anastomotic coupler to connect extremely small blood vessels, safely and in less time than hand suturing. The coupler is the primary product in the microsurgery product line, and it is rapidly becoming the standard of care in micro-and reconstructive surgery. The flow coupler, connects blood vessels and measures blood flow in the connected vessels, is in the late development stage. The Microvascular Anastomotic COUPLER System in Fig. 1 is a mechanical method for anastomosis of small vessels ranging in size from 0.8 mm to 4.3 mm in outer diameter. Quick and reliable, the COUPLER is ideal for use in end-to-end vessel anastomosis, end-to-side anastomosis and arterial/venous interpositional vein grafts. In addition to saving time and money the COUPLER provides an intima-to-intima anastomosis with no foreign material exposed to the flow surface. The vessel is also stented open at the anastomotic site, which offer less

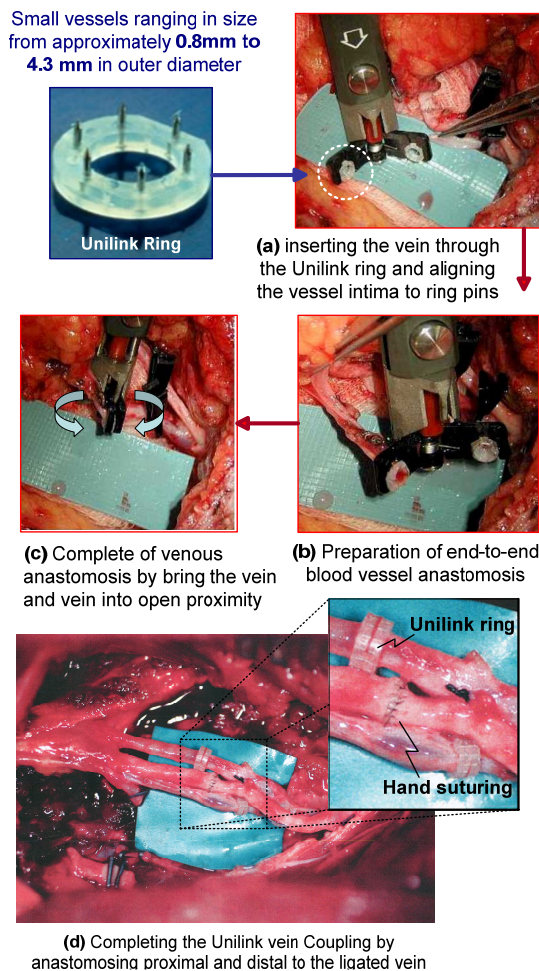


Fig. 1 Mechanical anastomosis system by Microvascular anastomotic Unilink COUPLER system

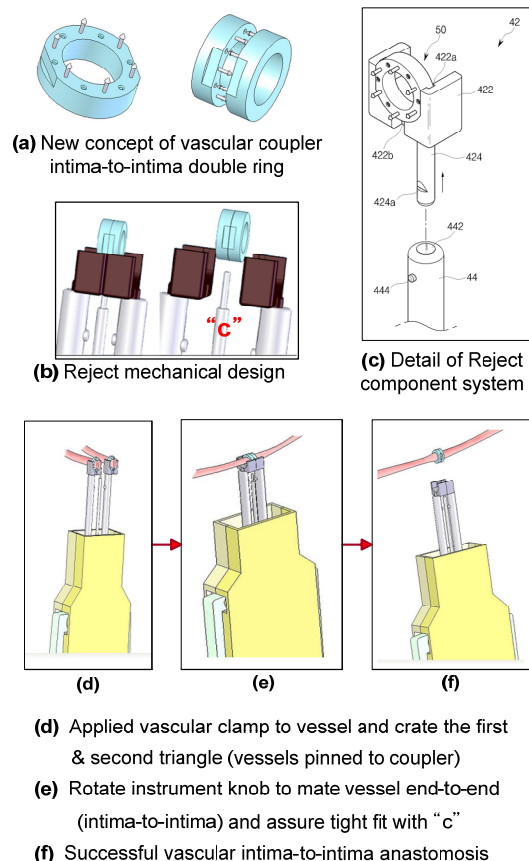


Fig. 2 Next generation device of new concept microvascular coupler patented by Triple-C Medical Corp.

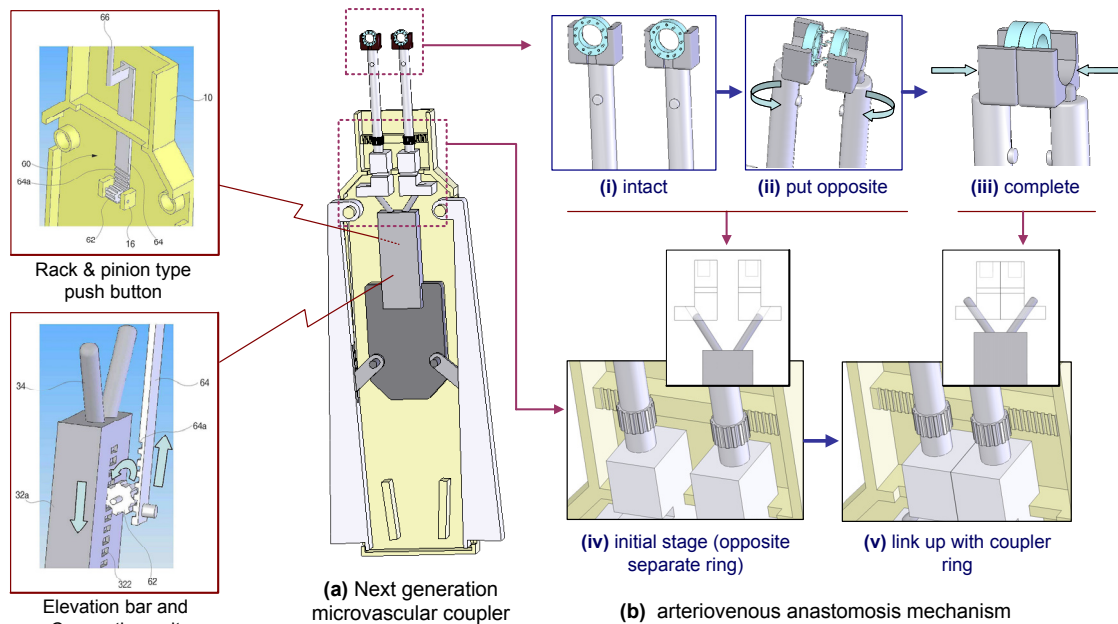


Fig. 3 Next generation mechanical anastomosis device of rack and pinion type by our research group of patents

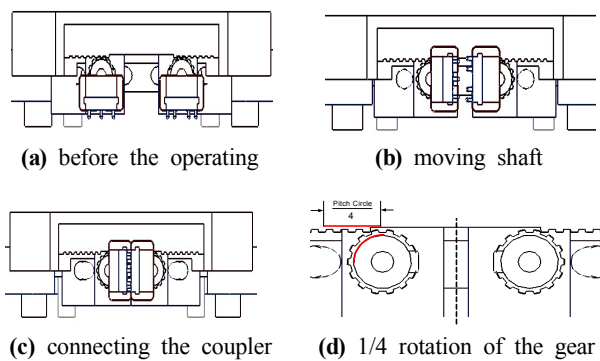


Fig. 4 Rack and pinion shaft control system

chance of thrombosis than traditional suturing. To develop the mechanical anastomosis device, the modelling such as Fig. 2 has been made by SolidWork using the collection of many informations and the design procedures. The most important point for the modelling is the mechanism that two rings to connect the blood vessels keep parallel accurately and are also combined. To parallel two rings, the transfer method from the longitudinal movement to the transverse one was chosen.

## 2. Development of Fancy Microvascular Anastomosis Device

To develop the next generation mechanical anastomosis device, the modelling such as Fig. 3 has been made by SolidWork using the collection of many informations and the design procedures. The most important point for the modelling is the mechanism that two rings to connect the blood vessels keep parallel accurately and are also combined. To parallel two rings, the transfer method from the longitudinal movement to the transverse one was chosen. The driving shaft moves longitudinally by the lever part in Fig. 3(a)(left figure). The connected part to join to the pin made the upper constant angle, moves transversely as long as  $y$ -axis length  $x \tan \theta$  in Fig. 3(b) and both rings are combined. At this time, the combined shaft with the rings which includes the pinion gear to connected to the part in Fig. 3(b), rotates by the rack. The rotation of the shaft has to be stopped at the mirror angle of the rings which is combined at the upper part and it moves to keep parallel. During the microvascular anastomosis, the initial ring position of the mechanical anastomosis device is confirmed by the operator's eyesight with the microscope and it has to be located at the front side to fit the ring pin to the blood vessels. When the shaft rotates and moves, the upper rings

have to keep the enough distance not to interfere each other. Simultaneously, the minimum moving distance to be able to operate the vascular anastomosis at the narrow space is required. It was known that the total size of the vascular anastomosis depends on this moving distance. Our group concluded that about 40 mm width and 20 mm thickness was adequate to operate it easily by one hand and designed the details of the gear. the tooth number of the gear and the pressure angle of  $20^\circ$  is determined. The distance between the shaft before the operating the anastomosis device in Fig. 4(a) and the shaft after 1/4 rotation in Fig. 4(b) (the moving distance from the shaft of Fig. 4(a) to the shaft in Fig. 4(b)), has to be long enough to rotate and not to interfere the upper rings each other when the shafts rotate. The thickness of the ring including the pin was less than 2 mm. Therefore, the distance of 2 mm to keep the gap of one ring size during moving, was remained in Fig. 4(b). Until the rings were faced during moving of the shaft from Fig. 4(a) to Fig. 4(b), 1/4 rotation of the gear is required and the pitch circle of the gear can be determined by this rotating distance. In the case of the mechanical anastomosis coupler using the ring, the join of the ring not to keep parallel is one of the failure reason for the microvascular anastomosis. When the length of the blood vessel was already subject to the ring pin and was decreased, the distance of the blood vessel is severely decreased since the failure of the vascular anastomosis results in the cut of the blood vessel and it is operated again. To overcome this shortness of the conventional microvascular anastomosis device, the mechanical microvascular anastomosis coupler has been developed and its details have been designed. The moving of the microvascular anastomosis coupler in the blood vessel with 0.5mm~1mm diameter should be minimized rather than that of the big blood vessels and the corresponding elements have to be the minimum. Summing up the above results, it is believed that the mechanical microvascular anastomosis is the good microvascular anastomosis to replace the conventional suture one.

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