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Novel Triangular Tube for Ischemia-free Organ Transplantation

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To solve the serious shortage of transplantation donors, the use of donors after circulatory death (DCDs) has been promoted in association with the recently developed normothermic machine perfusion.[1] Since Dr. Alex Carrel first reported the experimental vascular anastomosis surgical technique for organ transplantation in 1902, its clinical use has promoted the maintenance of organs in a warm ischemic state until reperfusion during transplantation. In cases requiring vessel anastomoses for the transplanted organs, ex vivo to in situ continuous machine perfusion is a novel technique that overcomes the need for intraoperative warm ischemia from put-in to resumption of blood flow in the recipient.[2] Herein, the authors propose a surgical technique that establishes in situ perfusion for vascular anastomoses and promotes ischemia-free transplantation.[3] Previously, hard wire-reinforced circular cannulas have been used in this setting. However, in this study, we introduce a newly developed soft triangular insertion tube for use with ex vivo machine perfusion that facilitates vascular anastomoses in the graft liver, thereby achieving ischemia-free transplantation.

This novel tube was manufactured using medical-grade soft silicone to avoid damage to inner vessel walls. To maintain good circulation from the standpoint of fluid dynamics, this new insertion tube, which maintains its triangular shape and circular lumen in blood vessel cross-sections, was developed based on the tri-stapled anastomosis performed by Carrel (Figure 1). The benefit of the triangular shape of the tube was tested by bending both triangular and cylindrical silicon tubes. The triangular tube showed excellent tolerance to kinking and maintained flow even with a 180° bend. The cylindrical tube was completely occluded and prevented all flow at bend angles ranging from 140° to 160° (Figure 2).

Our authors tested liver engraftments using this novel device by performing porcine orthotropic transplantations after cardiac arrest. Liver grafts from DCDs were maintained using subnormothermic perfusion with 10% red blood cells. Blood vessel anastomoses were created by inserting the newly developed triangular silicone tubes into blood vessels on the side of the organs undergoing anastomosis. After interrupted suturing at the bilateral ends, the flat bottom of the triangular tube allowed smooth and continuous suturing of the posterior wall (Figure 1). The anterior wall was sutured continuously from the bilateral ends while the tube was carefully avoided. These sutures were tied up immediately after removing the tube, and the vascular clamp was subsequently released. After reestablishing blood flow, hemostasis was confirmed and the vascular anastomoses were performed. Perfusion was maintained during the vascular anastomosis process and there were no excessive pressure fluctuations from the perfusion

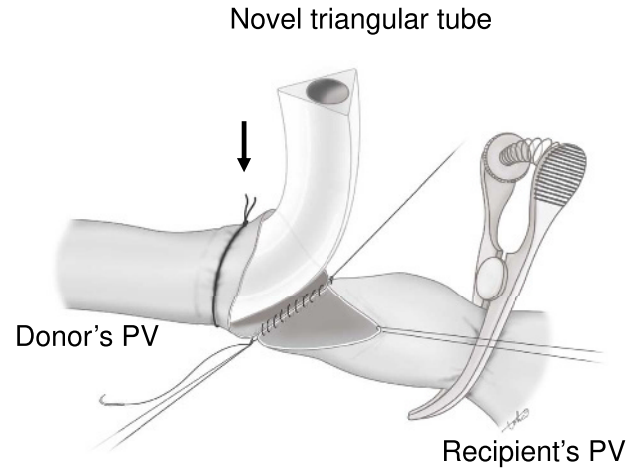

FIGURE 1. Method of using newly developed triangular insertion tube. The tube comprises an insertion head with 3 grooves for ligation (arrow head), a triangular tube with a triangular-shaped cross-section and an inner hole, and a connecting port. The inserted tube allows efficient and continuous suturing of the inferior segment of the vessel. PV, portal vein.

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E.K. and S.Y. designed the study and contributed to the analysis, collection, and interpretation of the data.

Both authors approved the final version of the manuscript and agree to be held accountable for all aspects of the work by ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Ethical approval: The pig experiments were conducted with the approval of the Ethics Committee of Medical Device Development Center (MEDDEC), Kobe, Japan (approval number: IVT1516).

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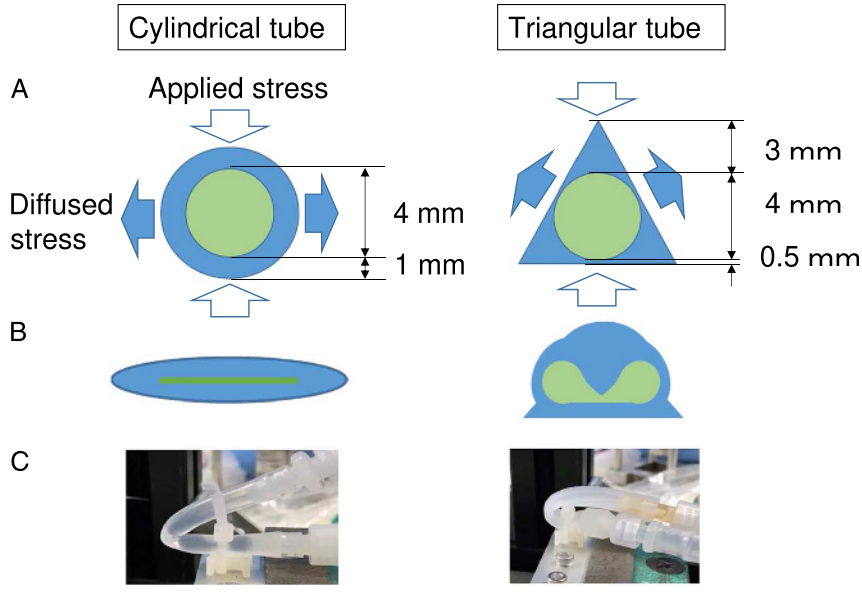

FIGURE 2. Rigidity mechanism of a novel triangle tube for portal vein. A, The diameter of the inner hole of the tube is about 4 mm. The thickness of the cylindrical tube wall is 1 mm and that of the triangular tube is 0.5 to 3 mm. White cursors show the direction of the applied stress when the tube kinks and blue cursors show the direction of the diffused stress. B, The cylindrical tube collapses into a flat shape and the triangular tube collapses into the shape that maintains gaps allowing continued perfusion flow. C, Bending test environment.

machine. Compared with previous blood vessel suturing methods, the anastomotic time using this technique was shortened for all 6 patients in each group.

Although the benefits of ischemia-free liver transplantation using a perfusion machine have been reported clinically, the strategies for transplantation using DCDs could be dramatically changed by maintaining continuous resuscitation in donor organs.[1,2] Herein, we present our novel tube device in a technical "Materials and Methods" communication.

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REFERENCES

1. Nasralla D, Coussios CC, Mergental H, et al. A randomized trial of normothermic preservation in liver transplantation. *Nature*. 2018;557:50–56.
2. Guo Z, Fung UE, Tang Y, et al. The era of "warm organ transplantation" is coming. *Am J Transplant*. 2018;18:2092–2093.
3. Kobayashi E. "In-site" perfusion technique for rinse solution in liver transplantation. *Transplant Direct*. 2017;3:e141.