# A New Titanium Vascular Anastomotic Device's Biocompatibility and Patency

#### Daculsi Guy\*

Department of Materials Science and Engineering, Tel Aviv University, Israel

#### Editorial

This study aimed to evaluate the biocompatibility and patency of our newly developed Titanium Vascular Anastomotic Device (TVAD) in a pig jugular vein. TVAD was made of commercially pure grade 2 titanium. The patency and anastomotic time were simultaneously confirmed in an ex-vivo system developed by the authors and in vivo using pig jugular veins. Five 8-month-old pigs, with body weights of 50-60 kg, underwent anastomosis of both jugular veins using the device. Graft patency was evaluated for 12 weeks by biplane angiography and sono graph. All tissue biopsy samples were analyzed by histology. In all 10 cases, the anastomosis was completed in <5 min. The vessel lumen was not damaged, and the inner vessel wall was completely endothelialised at the anastomotic site. No foreign body reactions were observed at the vessel lumen, vessels, and outer vessel walls by histo pathologic analysis. Patency and absence of leakage at the anastomotic site of the follow-up period were confirmed clearly by angiography and sonography. This preliminary animal study proved that our newly developed device is a very promising tool for intima-to-intima contact anastomosis. TVAD can be used as a feasible and safe medical tool for vessel anastomosis.

### Introduction

Traditional hand-suturing techniques require long operative time, high technical expertise, and use of complex instruments the reported anastomosis failure rate of 2-6% due to suturing errors may cause the failure of the whole reconstructive surgery and increase healthcare costs. Therefore, alternative anastomotic techniques are highly needed to improve the precision and efficiency of the anastomosis process. The last step in surgery is vascular anastomosis regardless of the types of procedures, including free flap or organ transplant. There could be anastomotic failures such as tearing, leaking, and narrowing of the lumen, through-stitching, and inclusion of the adventitia, although they decrease with improvement in the surgeon's skill due to the learning curve associated with anastomosis regarding anastomosis, veins are easy to fail due to their thin and fragile vascular wall. Various types of vascular couplers for anastomosis without the use of sutures to reduce tissue ischemicreperfusion injury and organ warm ischemic time as well as improve vascular patency and prevent life-threatening complications have been devised to overcome this failure Titanium has become popular as a structural material for many medical devices due to its strong durability, light weight, and corrosion resistance These features are beneficial when transplanting an organ that needs the stability of vascular anastomosis and can withstand the weight of large vessels with stiffness.

#### **Design and fabrication of TVAD**

TVAD was made of commercially pure grade 2 titanium because it is a

\*Address for Correspondence: Daculsi Guy, Department of Materials Science and Engineering, Tel Aviv University, Israel, E-mail daculsi@gmail.com

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good candidate for medical applications as it is strong and ductile enough to protect the blood vessels from tearing and results in less tissue reaction and fibrosis. TVAD is 0.21-inch thick and is designed to reduce the ischemic time and difficulty in performing the procedure, which may lead to a fast and less invasive vascular anastomosis the two important factors in designing a vascular anastomotic device are the part that secures each blood vessel to the device and the two devices are combined. The first manipulation is called 'hooking,' which is similar to a fish hanging on a hook. The important aspect in hooking is that the blood vessels are attached to the device and maintained well until the operation is completed. The second manipulation is called 'coupling'. At this time, the blood should not leak into the gap between the connected devices The TVAD comprises inner and outer rings. The inner ring is made by a Computer Numerical Control (CNC) machine, whereas the outer ring is made by a press machine. The inner ring has inclined projections on the body that connect with the connecting arm of the opposite outer ring, and both edges are rounded to prevent damage when blood vessels are joined. The outer ring comprises three connecting arms, and each arm has a triangular hook on the base that hooks the blood vessel. The triangular hook has a pointed end to penetrate the wall of the blood vessel and narrow the gap with the opposite inner ring to prevent the blood vessel from falling out during the operation. By combining these two rings, the final TVAD is created. In the case of coupling, if one TVAD is rotated 60°, the connection occurs at six locations at 60-degree intervals When the TVAD is initially connected to the vessel, the vessel is not rotated because the TVAD is already connected with the vessel in a 60-degree rotation state. Once the TVAD is combined, it can be removed using a specially designed instrument to ensure that the blood vessels are not damaged. Once removed, the TVAD cannot be reused again [1-5].

## **Conflict of Interest**

The authors declare that there is no conflict of interest associated with this manuscript.

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