# A novel bioprosthetic venous valve

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The authors describe their experience with a novel bioprosthetic valve to treat deep venous insufficiency.[1] Venous valve repair is still the holy grail of venous therapy. Surgical repair techniques such as internal or external valve repair or axillary vein transfer are technically demanding and associated with increased patient morbidity.[2-4] It is not the first time a company has tried to launch an artificial valve for deep venous repair but one of the very few trials that have progressed to a clinical study. From a laboratory that already has experience with cardiac valves, the Hancock valve features a stainless-steel frame with a porcine monocusp leaflet. The position of the valve in the femoral vein is not without problems. Stainless steel does not have memory capabilities compared with nitinol; thus, theoretically, external pressure can crush the stent's frame. Strut failure has been reported in cardiac valves and could be an issue over time with the VenoValve device.

The valve is placed surgically in the femoral vein, probably also for technical reasons because of the better accessibility of this venous segment than the popliteal vein. Some patients will have several reflux levels; thus, implantation of more than one valve might be necessary. In the iliac vein and popliteal vein, this would require an endovascular approach.

The porcine valve used in their study is preserved by glutaraldehyde crosslinking, a potentially thrombogenic material in a low flow area. Although long-term results are not yet available, we can assume that optimal valve function will require aggressive lifelong anticoagulation therapy, with all the side effects this can imply. In most cases, a bovine patch was added to the valve with its porcine leaflet, increasing the device's thrombogenicity.

Ablation of superficial reflux before valve implantation was one of the inclusion criteria for their study. After ablation of superficial varicosities, the timing of valve implantation must be clearly defined, and the necessity for prolonged compression therapy considered.

The authors have presented exceptional midterm results. We do not know whether these findings resulted from aggressive anticoagulation postoperatively, the valve design, or other factors. Ulcer healing and improvement of the venous severity score could also be a consequence of superficial reflux ablation alone. After the venotomy required for insertion of the valve, a patchplasty was performed. We do not know what influence this surgical adjunct to the valve implantation had on mid-term valve performance.

Improvement occurred even after occlusion of the device. Thus, theoretically, no deterioration in deep venous insufficiency will occur when the valve fails because reflux was blocked—another question that must be answered in controlled studies.

The technique described can only be performed by vascular surgeons. Broader applicability will require the transfer of this device to the endovascular world. If the results they have reported will be replicable using an endovascular procedure, this device could change how we treat patients with deep venous reflux. The technique described could be an evolutionary step in between. A larger group of patients with good follow-up data available will be necessary before vascular surgeons can evaluate such a device's clinical role.

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## REFERENCES

1. Ulloa JH, Glickman M. Human trial using the novel bioprosthetic VenoValve in patients with chronic venous insufficiency. J Vasc Surg Venous Lymphat Dis 2021;9:938-44.
2. Raju S, Fredericks R. Valve reconstruction procedures for nonobstructive venous insufficiency: rationale, techniques, and results in 107 procedures with two- to eight-year follow-up. J Vasc Surg 1988;7:301-10.
3. Gloviczki P, Merrel SW, Bower TC. Femoral vein valve repair under direct vision without venotomy: a modified technique with use of angioscopy. J Vasc Surg 1991;14:645-8.
4. Maleti O, Lugli M. Neovalve construction in postthrombotic syndrome. J Vasc Surg 2006;43:794-9.