Prosthetic Venous Valves

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Veins are the vessels that carry blood back to the heart from the rest of the body. In the legs, the veins use muscle contractions to aid in the blood circulation process. When a person stops moving and stands still, the blood will stop flowing towards the heart and try to flow backwards. The venous valve is in place to block this backwards flow, called reflux.

A main problem for venous valves is a condition called chronic venous insufficiency. This condition is caused when there is an excess in high blood pressure in the veins. The increase in pressure can cause weakening of the blood vessels and even lead to damaged valves. When the valves are damaged, they will no longer close properly, which can lead to excess reflux from the valves. This reflux can lead to lower extremity problems, like discomfort, swelling of the affected areas and even changes in the skin's appearance.

There are many different treatments for CVI, both surgical and non-surgical. Most of these treatments only focus on decreasing the symptoms of CVI, and not actually curing the dysfunctional valves themselves. Compression stockings are elastic stockings that are used to restore some of the compression and sop excess reflux from the venous valves. Patients may need to wear these stocking for the rest of their lives. Sclerotherapy is a procedure where a damaging chemical is injected into the damaged vein. This causes the vein to die and the blood to find a new path. Antibiotic can be used to cure some symptoms and walking and constant movement can also be done to cure some of the excess reflux.

There are also some surgical measures that can be taken if the CVI is severe enough. Ablation is similar to sclerotherapy in that it destroys the damaged veins, but this procedure uses an electrode at the end of a catheter to do the damage. A bypass is for the most severe cases and it's where the damaged vein is bypassed with the use of either a healthy vein or a synthetic one. Valve repair can also cure the ailments of CVI. In valve repair, the surgeon will generally shorten the flaps of the valves to improve the valves functionality. A sleeve is then placed on the outside to squeeze the vein and make the valve closure complete.

Artificial venous valves are an alternative to other surgical means of repairing veins damaged due to CVI. There are currently no commercially available venous valves on the market today; this is largely due to high failure rates and biocompatibility issues. The valves are comprised of two parts, a solid frame and flexible leaflets. The solid frame is a circular base that is made out of a pho-activated polymer resin. Attached to this base is a flange which is where the flexible leaflets are attached. The flexible leaflets are handcrafted out of a polymer named BioSpan. The leaflets are made to mimic the flaps of the real valve and completely close the passage way to contain reflux.

A test was conducted with a prototype two times as large as the required valve. This was done to see if there were any flaws in the valve design. The model was placed in a water flow experiment and a few problems were found with the design. The tests showed that when the leaflets closed, they had undesirable sagging, and the bases of the valves were susceptible to breaking where the base and flange connected. These two problems were solved by adding and shoulder like protrusion and a beveled edge.

After the experiments were completed, the valves were then scaled down to normal size. Four valves of varying flange length were tested through four distinct tests. These tests were done to simulate four different motions in a person's leg. The tests were compared against a test with no valve at all. The two main tests that showed which flange length to choose, were percent reflux and energy retention. The study showed that the valves with 2.50mm and 3.75mm flanges worked the best.

In the future, scientists hope to incorporate drug reservoirs within the flanges themselves. The reservoirs could hold multiple drugs at once, and delivery these drugs to the veins through channels made of rate controlling materials. They also hope to find a suitable biocompatible material for the frame. A collapsible frame would also make it possible to deliver the artificial valve into the patients affected vein through the use of a catheter.

References

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