METHOD AND APPARATUS FOR TREATING VENOUS INSUFFICIENCY

This is a divisional of U.S. patent application Ser. No. 09/483,969, filed on Jan. 18, 2000 (now U.S. Pat. No. 6,981,972), which was a divisional application of Ser. No. 08/811,820, filed on Mar. 4, 1997 (now U.S. Pat. No. 6,033,398).

BACKGROUND OF THE INVENTION

The invention relates generally to the treatment and correction of venous insufficiency, and more particularly, to a minimally invasive procedure and apparatus using a catheter-based system having an energy-delivery arrangement for providing energy intraluminally to shrink a vein to change the fluid flow dynamics, and to restore the competency of venous valves thereby restoring the proper function of the vein.

The human venous system of the lower limbs consists essentially of the superficial venous system and the deep venous system with perforating veins connecting the two systems. The superficial system includes the long or great saphenous vein and the short saphenous vein. The deep venous system includes the anterior and posterior tibial veins which unite to form the popliteal vein, which in turn becomes the femoral vein when joined by the short saphenous vein.

The venous systems contain numerous one-way valves for directing blood flow back to the heart. Venous valves are usually bicuspid valves, with each cusp forming a sack or reservoir for blood which, under retrograde blood pressure, forces the free surfaces of the cusps together to prevent retrograde flow of the blood and allows only antegrade blood flow to the heart. When an incompetent valve is in the flow path, the valve is unable to close because the cusps do not form a proper seal and retrograde flow of blood cannot be stopped.

Incompetence in the venous system can result from vein dilation. Separation of the cusps of the venous valve at the commissure may occur as a result, thereby leading to incompetence. Another cause of valvular incompetence occurs when the leaflets are loose and floppy. Loose leaflets of the venous valve results in redundancy which allows the leaflets to fold on themselves and leave the valve open. The loose leaflets may prolapse, which can allow reflux of blood in the vein. When the venous valve fails, there is an increased strain and pressure on the lower venous sections and overlying tissues, sometimes leading to additional valvular failure. Two venous conditions which often involve vein dilation are varicose veins and more symptomatic chronic venous insufficiency.

The varicose vein condition includes dilatation and tortuosity of the superficial veins of the lower limbs, resulting in unsightly discoloration, pain, swelling, and possibly ulceration. Varicose veins often involve incompetence of one or more venous valves, which allow reflux of blood within the superficial system. This can also worsen deep venous reflux and perforator reflux. Current treatments include surgical procedures such as vein stripping, ligation, and occasionally, vein segment transplant, venous valvuloplasty, and the implantation of various prosthetic devices. The removal of varicose veins from the body can be a tedious, time-consuming procedure having a painful and slow healing process. In addition, patients with varicose veins may undergo injection sclerotherapy, or removal of vein segments. Complications, scaring, and the loss of the vein for future cardiac and other by-pass procedures may also result. Along with the complications and risks of invasive surgery, varicose veins may persist or recur, particularly when the valvular problem is not corrected. Due to the long, technically demanding nature of the surgical valve reconstruction procedure, treating multiple venous sections with surgical venous valve repair is rarely performed. Thus, a complete treatment of all important incompetent valves is impractical.

Non-obstructive chronic venous insufficiency (CVI) is a problem caused by degenerative weakness in the vein valve segment, or by hydrodynamic forces acting on the tissues of the body, especially the legs, ankles and feet. As the valves in the veins fail, the hydrostatic pressure increases on the next venous valves down, causing those veins to dilate. As this continues, more venous valves will eventually fail. As they fail, the effective height of the column of blood above the feet and ankles grows, and the weight and hydrostatic pressure exerted on the tissues of the ankle and foot increases. When the weight of that column reaches a critical point as a result of the valve failures, ulcerations of the ankle begin to form, which start deep and eventually come to the surface. These ulcerations do not heal easily because of poor venous circulation due to valvular incompetence in the deep venous system and other vein systems.

Chronic venous insufficiency often consists of hypertension of the lower limb in the deep, perforating and often superficial veins, and may result in discoloration, pain, swelling and ulceration. Existing treatments for chronic venous insufficiency are often less than ideal. These treatments include the elevation of the legs, compressing the veins externally with elastic support hose, perforator ligation, surgical valve repair, and grafting vein sections with healthy valves from the arm into the leg. These methods have variable effectiveness. Moreover, invasive surgery has its associated complications with risk to life and expense. Similarly, the palliative therapies require major lifestyle changes for the patient. For example, the ulcers may recur unless the patient continues to elevate the legs and use pressure gradient stockings for long continuous periods of time.

Due to the time-consuming and invasive nature of the current surgical treatments, such as valvuloplasty or vein segment grafting, typically only one valve is treated during any single procedure. This greatly limits the ability of the physician to fully treat patients suffering from chronic venous insufficiency. Every instance of invasive surgery, however, has its associated complications with morbidity and expense.

Another type of treatment, the ligation of vascular lumina by cauterization or coagulation using electrical energy from an electrode, has been employed as an alternative to the surgical removal of superficial and perforator veins. However, such ligation procedures also close off the lumen, essentially destroying its functional capability. For example, it is known to introduce an electrode into the leg of a patient, and position the electrode adjacent the exterior of the varicose veins to be treated. Through a small stab incision, a probe is forced through the subcutaneous layer between the fascia and the skin, and then to the various veins to be destroyed. A monopolar electrode at the outer end of the probe is placed adjacent the varicose vein and the return electrode is placed on the skin. Once properly positioned, an alternating current of 500 kiloHertz is applied to destroy the adjacent varicose veins by electrocoagulation. The coagulated veins lose the function of allowing blood to flow through, and are no longer of use. For example, occluding or ligating the saphenous vein would render that vein unavailable for harvesting in other surgical procedures such as coronary by-pass operations.

An approach used to shrink a dilated vein involves the insertion of a catheter that provides RF or other energy to the vein tissue. The amount of energy imparted is controlled so that shrinkage occurs as desired. However, one such device is