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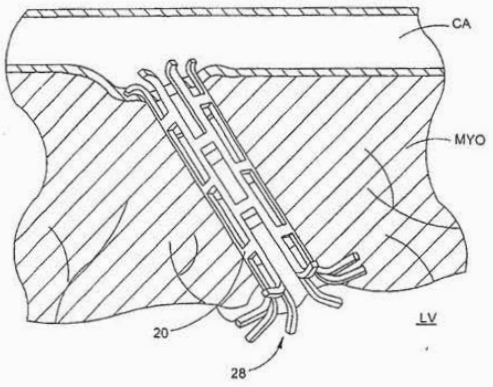

(57) Abstract

A conduit is provided to provide a bypass around a blockage in the coronary artery. The conduit is adapted to be positioned in the myocardium or heart wall to provide a passage for blood to flow between a chamber of the heart such as the left ventricle and the coronary artery, distal to the blockage. The stent is self–expanding or uses a balloon to expand the stent in the heart wall. Various attachment means are provided to anchor the stent and prevent its migration. In one embodiment, a conduit is provided having a distal top which is more preferably a ball top, wire top, flare top or flip–down top. These top configurations anchor the shunt at one end in the coronary artery.

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TMR SHUNT

Field of the Invention

The present invention relates to an apparatus for bypassing a blocked blood vessel segment, and, more particularly, to a conduit or stent positioned between the coronary artery or other blocked vessel and a chamber of the heart, such as the left ventricle of the heart, to bypass a blocked segment of the coronary artery or other blood vessel.

Background of the Invention

Coronary artery disease is a major problem in the U.S. and throughout the world. Coronary arteries as well as other blood vessels frequently become clogged with plaque, which at the very least impairs the efficiency of the heart's pumping action, and can lead to heart attack and death. In some cases, these arteries can be unblocked through non-invasive techniques such as balloon angioplasty. In more difficult cases, a bypass of the blocked vessel is necessary.

In a bypass operation, one or more venous segments are inserted between the aorta and the coronary artery. The inserted venous segments or transplants act as a bypass of the blocked portion of the coronary artery and thus provide for a free or unobstructed flow of blood to the heart. More than 500,000 bypass procedures are performed in the U.S. every year.

Such coronary artery bypass surgery, however, is a very intrusive procedure that is expensive, time-consuming and traumatic to the patient. The operation requires an incision through the patient's sternum (sternotomy), and that the patient be placed on a bypass pump so that the heart can be operated on while not beating. A vein graft is harvested from the patient's leg, another highly invasive procedure, and a delicate surgical procedure is required to piece the bypass graft to the coronary artery (anastomosis). Hospital stays subsequent to the surgery and convalescence are prolonged.

As mentioned above, another conventional treatment is percutaneous transluminal coronary angioplasty (PTCA) or other types of angioplasty. However, such vascular treatments are not always indicated due to the type or location of the blockage, or due to the risk of emboli.

Thus, there is a need for an improved bypass system which is less traumatic to the patient.

Summary of the Invention

The preferred embodiments of the present invention address the need in the previous technology by providing a bypass system that avoids the sternotomy and other intrusive procedures normally associated with coronary bypass surgery. These embodiments also free the surgeon from the multiple anastomoses necessary in the current process.

The preferred device provides a shunt for diverting blood directly from a chamber in the heart, such as the left ventricle, to the coronary artery, distal to the blockage, therefore bypassing the blocked portion of the vessel. The shunt comprises a stent or conduit adapted to be positioned in the heart wall or myocardium between a chamber in the heart such as the left ventricle and the coronary artery that allows for the direct passage of blood therethrough. As used herein, the terms "stent" and "conduit" are interchangeable, and refer to a device that allows for the passage of blood therethrough. The terms "myocardium" and "heart wall" are also used interchangeably. In addition, although the left ventricle is referred to throughout the description, it should be understood that the conduit described herein can be used to provide a passageway for the flow of blood from any heart chamber, not only the left ventricle.

The stent device is delivered either externally or internally through the coronary artery to a position distal to the blockage. At that position, the coronary artery, the myocardium and the wall of the left ventricle are pierced to provide a channel completely through from the coronary artery to the left ventricle of the heart. The stent is then positioned in the channel to provide a permanent passage for blood to flow between the left ventricle of the heart and the coronary artery, distal to the blockage. The stent is sized so that one open end is positioned within the coronary artery, while the other open end is positioned in the left ventricle. The hollow lumen of the stent provides a passage for the flow of blood.

The stent can be self-expandable or expanded by means of a balloon or similar device, and can be provided with various means to anchor it in position, such as expandable legs, hooks, barbs, flanges, collars, loops, wires, flares, suture holes and the like. The anchoring means can be adapted to anchor the conduit in the heart wall, or alternatively, in the coronary artery. The stent can be formed from a plurality of rings, which can be connected to provide stability. The stent can include a valve in its interior, and can also be used to deliver drugs or other pharmaceutical compounds directly into the myocardium and the coronary circulation.

Briefly stated, the methods and apparatus described and illustrated herein generally relate to direct coronary revascularization, wherein a conduit or opening is provided from the left ventricle to the coronary artery, oftentimes the left anterior descending (LAD), to provide blood flow directly therethrough. The conduit of the preferred embodiments has a distal top which is more preferably a ball top, wire top, flare top or flip-down top. These top configurations anchor the shunt at one end in the coronary artery.

Brief Description of the Drawings

FIGURE 1A is a cross-sectional view of a human heart, aorta and coronary artery.

FIGURE 1B is a side view of one embodiment of an expandable stent and the balloon catheter used for stent delivery.

FIGURE 2 is a side view of the stent of **FIGURE 1B** mounted on the distal end of the catheter for delivery into the myocardium, with the coronary artery and myocardium shown cut-away.

FIGURE 3 is a side view of the distal end of the stent/catheter assembly of **FIGURE 1B** positioned in the myocardium, with the coronary artery and myocardium shown cut-away.

FIGURE 4 is a cross-sectional side view of the stent of **FIGURE 1B** positioned within the myocardium after removal of the catheter used for delivery.

FIGURE 5 is a side view of another embodiment of the stent and the catheter used for stent delivery.

FIGURE 6 is a cross-sectional side view of the catheter and puncture device used to introduce the self-expanding stent of **FIGURE 5** into the myocardium.

FIGURE 7 is a cross-sectional side view of the stent/catheter assembly of **FIGURE 5** positioned in the myocardium.

FIGURE 8 is a side view of the self-expanding stent of **FIGURE 5** positioned within the myocardium after removal of the catheter and puncture device, with the coronary artery and myocardium shown cut-away.

FIGURE 9 is a perspective view of another embodiment of the stent having expandable legs, showing the stent mounted on the distal end of the introducer catheter.

FIGURE 10 is a perspective view of the stent of **FIGURE 9**, showing the distal end of the introducer catheter pushed forward to allow the legs of the stent to expand.

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