

MITRAL VALVE TRANSLOCATION DEVICE AND METHOD FOR THE TREATMENT OF FUNCTIONAL MITRAL REGURGITATION

Summary

There is currently no reliable, durable mitral valve repair option for patients with Functional Mitral Regurgitation (FMR).

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Field Cardiology

Technology

Surgical device and technique for the treatment of functional mitral regurgitation

Advantages

- More durable FMR repair
- Increases the surface of coaptation between the two leaflets
- Compensates for common FMR issues including annular dilation and flattening.

Status Available for licensing

Patent Status PCT/US2018/059253

UMB Docket Reference JG-2017-025 Table mitral valve repair option for patients with Functional Mitral Regurgitation (FMR). Replacing the mitral valve with a prosthetic tissue or mechanical valve is currently the most durable approach to the treating FMR. However, this procedure has a high perioperative mortality risk and carries the risk of thromboembolism and prosthetic valve infection and degeneration of bioprosthesis. Mitral valve replacement also requires anticoagulation of the mechanical valves. Another approach for the treatment of FMR is restrictive mitral annuloplasty (RMA). Although there are clear benefits to mitral valve repair over replacement, this approach results in a very high rate of recurrence of mitral regurgitation (~60% in two years). Use of a device like the MitraClip® is common and requires a surgical approach (the "Alfieri" stitch) that is known to be only variably effective. Results from treatment of FMR with the MitraClip® have been suboptimal, and a substantial number of patients have either residual or recurrent mitral regurgitation. Dr. Gammie has developed a novel device and method for the treatment of FMR that involves the apical translocation of the mitral valve within the ventricle. The technique should have several advantages over current FMR treatment approaches.

Technology

The proposed device allows for the translocation of the patient's mitral valve within in the ventricle. The positioning of the mitral valve at the apex of the patient's heart

compensates for the geometric issues of FMR, such as annular dilation, annular flattening, leaflet tethering, and increased interpapillary distances. The device reduces mitral regurgitation by improving the position of the mitral valve, increasing coaptation surface area between the leaflets, and decreasing the required amount of leaflet tethering. The technique improves the likelihood of a durable repair and provides for an effective and lasting treatment of FMR. The device can be used alone or in combination with other devices and



methods, including the placement of a circumferential band around the papillary muscles and the use of artificial tethers.

Market

There are approximately six million FMR patients in the United States and nearly as many in Europe. FMR exacerbates heart failure-related symptoms and is associated with increased hospitalization and mortality rates.

Technology Status

This surgical technique has been tested in acute and chronic ovine models.