

Transcatheter Septal Myectomy Device for Hypertrophic Obstructive Cardiomyopathy (Tel Hashomer)
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Transcatheter Septal Myectomy Device for Hypertrophic Obstructive Cardiomyopathy

Elad Maor, Sheba Medical Center, Israel

Categories	Myectomy Device , Interventional Cardiology, Hypertrophic Obstructive Cardiomyopathy
Development Stage	Preclinical efficacy and initial design of prototype
Patent Status	Pending
THM Reference	2013019

Abstract

Hypertrophic cardiomyopathy (HCM) is the most common genetic cardiovascular disease. Dynamic left ventricular outflow tract obstruction is the hallmark of the disease and can lead to heart failure.

A significant proportion of patients require interventional strategy to relieve the obstruction, and surgical septal reduction therapy (myectomy) is the only recommended treatment. The surgical procedure is not suitable for high operative risk patients. ACC/AHA 2011 guidelines recommend that the surgery will be performed by experienced operators, and it is therefore limited to major medical centers worldwide. Alcohol septal ablation, the only non-surgical intervention, is considered a suboptimal alternative.

Risk factors for the development of end-stage HCM (manifesting as LV systolic dysfunction and LV dilation) include younger age of onset/presentation of HCM, a family history of HCM, increased ventricular wall thickness, along with the presence of certain genetic mutations in certain individuals.

The Need

Hypertrophic obstructive cardiomyopathy can cause outflow track obstruction

Myectomy is a major surgery

Alcohol ablation is sub-optimal solution

There is clinical need for minimally invasive non-surgical approach

The Technology

We have developed a novel transcatheter ablation approach. Our method induces cell death by creating pores in cell membranes. In contrast to all other available ablation modalities, it induces ablation within seconds and with no heat generation. Due to its non-thermal nature, the procedure does not damage extra cellular components. Our preliminary *in vivo* results show that we can achieve ablation of myocardium, ***without the need for open heart surgery***.

Our approach is based on a novel non thermal ablation approach that can damage only cellular components within seconds and with no damage to the extra cellular components.

It can induce significant ablation of biological tissue, and is currently under evaluation in clinical trials for the treatment of solid tumors. Our previous work demonstrated that our technology can be delivered in an endovascular approach, and that it can cause significant ablation of myocardial tissue in the beating heart.

Applications

Septal ablation for HOCM

Congenital heart disease

Tissue scaffolding

Cardiac arrhythmias

Endovascular drug delivery

Advantages

Method and device to attenuate left ventricular obstruction and heart failure in patients with HCM, without the need for open heart surgery.

The procedure has an extremely short duration (seconds).

It affects only the cell membrane and has the potential of sparing the tissue scaffold.

Short learning curve due to the simplicity of our transcatheter approach.

More patients can benefit from the treatment, since our transcatheter device therapy is not limited to low operative risk subjects

The Market

Hypertrophic Obstructive Cardiomyopathy:

The most common cardiac genetic disorder

Prevalence 1:500 adults (600,000 in the U.S.)

A major cause of sudden death and heart failure in young people.

2.5 Million individual worldwide with HCM

10% will benefit intervention

Estimated price target 5K-10K USD

1-2 B USD potential market

Tel Hashomer Medical Research, Infrastructure and Services

Tel: +972-3-5305998 Fax: +972-3-5305944 sylvie.luria@sheba.health.gov.il