The Heart Surgery Forum #2004-1175
8 (4), 2005 [Epub July 2005]
doi:10.1532/HSF98.20041175

Online address: http://cardenjennings.metapress.com/link.asp?id=112496

Experimental Stenting of the Posterior Mitral Leaflet to Correct Prolapse in Mitral Valve Insufficiency

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ABSTRACT

Objective: This study investigated the use of a new concept of mitral valve reconstruction using a novel device to stent the posterior mitral leaflet in combination with semicircular annuloplasty. Modern mitral valve repair is an accepted modality and a routine procedure for treatment of degenerative mitral valve insufficiency. One of the most common mechanisms of mitral valve insufficiency is leaflet prolapse. In the majority of cases the posterior leaflet is dysfunctional and therapeutic reconstruction of the PII flail leaflet segment involves quadrangular resection which is usually combined to mitral annuloplasty with a ring. A new time-saving concept of mitral valve reconstruction by stenting the posterior mitral leaflet in combination with semicircular annuloplasty is presented.

Methods: The new mitral valve reconstruction device (Shelhigh MitroFast(tm), Shelhigh, Inc.^{TM}, Union, NJ, USA) was implanted in four adult sheep. It is constructed as an annuloplasty ring in combination with a posterior leaflet stent. The device has the shape of a closed posterior leaflet and forms a "buttress" against which the anterior leaflet can coapt.

Results: Every implantation of a MitroFast^{TM} device could be performed in less than 30 minutes. After implantation of the device, all animals could be successfully weaned from CPB. Invasively measured left atrial pressure was below 12 mm Hg in all animals. After chest closure, transoesophageal echocardiography revealed a competent mitral valve in all animals, without any inflow restriction in three animals, and suspected mild stenosis in one animal.

Conclusions: In this experimental model, implantation of the newly designed annuloplasty ring with stenting the posterior mitral leaflet avoids extensive and time-consuming reconstructive surgery on a flail posterior leaflet. Implantation of the device resulted in favorable short-term hemodynamic effects. Implantation technique of the device is simple, the potential for minimal invasive implantation of a conceptual similar device will be further investigated.

Received December 29, 2005; received in revised form April 3, 2005; accepted April 28, 2005.

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INTRODUCTON

Modern mitral valve repair with implantation of a prosthetic ring was first performed in the late 1960s by Carpentier [Carpentier 1969]. Results following mitral valve repair are superior [Gillinov 2001, Grossi 2001] to those of standard mitral valve replacement without saving the subvalvular apparatus. Therefore repair is nowadays a routine procedure for treatment of degenerative mitral valve insufficiency. One of the most common mechanisms of mitral valve insufficiency is leaflet prolapse due to chordal elongation, ruptured chordae or papillary muscle. In the majority of cases the middle part (P II) of the posterior leaflet is dysfunctional and reconstruction of the PII flail leaflet segment involves quadrangular resection. This is usually combined to mitral annuloplasty with a ring. Resection of the middle segment is performed and the resulting gap sutured with single interrupted sutures to reconstruct a competent valve. Echocardiographic assessment following mitral valve repair commonly shows a rather shrinked and remaining posterior leaflet with decreased motility.

We investigated a new concept of mitral valve reconstruction using the Shelhigh MitroFast(tm) (Shelhigh, Inc.^{TM}, Union, NJ, USA) device to stent the posterior mitral leaflet in combination with semicircular annuloplasty. This technique allows substantial time saving compared to a classical reconstruction procedure.

MATERIALS AND METHODS

Description of the Shelhigh MitroFast(tm) Valvuloplasty Device

The Shelhigh MitroFast(tm) valvuloplasty device is made of medical grade polymer and covered with bovine pericardium fixed in a .35% buffered glutaraldehyde solution and has been treated with a proprietary "detoxification" process called "No-react$^{(c)}$" [Abolhoda 1996]. The device is constructed as an annuloplasty ring in combination with a posterior leaflet stent. It has the shape of a closed posterior leaflet

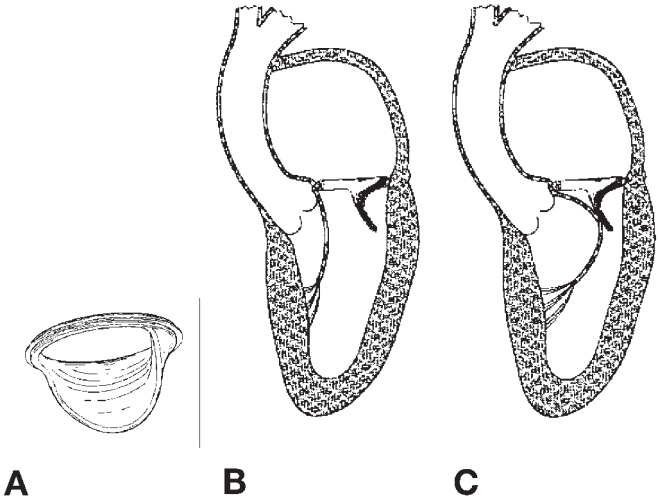

Figure 1. Schematic view of the Shelhigh Automatic Mitral Valvuloplasty Ring MitroFast(tm) with a scalloped stent mimicking the posterior leaflet (a). After implantation in the mitral position functional status is shown with open anterior (b) and closed anterior leaflet (c).

(Figure 1a) and forms a "buttress" against which the anterior leaflet can coapt (Figure 1b, c). Prior to implantation of the MitroFast(tm) device the competence of the mitral valve is assessed with a special sizer. The sizer used is also a very novel concept; it has the same shape of the device itself and has a relatively large luer which can be connected to a flashing syringe via a flexible tube. It has also a holder. The surgeon places the sizer at the posterior leaflet and the assistant can flash certain amount of saline to fill the left ventricle in order to close the anterior leaflet against the sizer. This method assures that the anterior leaflet coats perfectly before the surgeon commits to the kind of repair he will perform (or replacement) (Figure 2). The results are a priori validated, especially in doubtful cases or very difficult ischemic mitral regurgitation or in cases of rheumatic disease. The sizer allows choosing the most appropriate size of the device. Two 2/0 Ethibond(c) (Ethicon GmbH, Norderstedt, Germany) single interrupted sutures are placed at both trigones. Six additional sutures are placed along the fibrous annulus of the posterior leaflet. All sutures are fixed to the MitroFast(tm) ring which thereafter is slided down into the ventricle and the sutures are tied and cut.

Animal Model

All animals were studied in compliance with the Principles of Laboratory Animal Care according to the National Institute of Health guidelines for the use of experimental animals. The protocol was approved by the Animal Care Committee of the Canton of Berne, Switzerland. Four young adult, healthy, female sheep were included in this study. Their health was previously assessed through physical examination, blood biochemical values and a complete blood cell count. They were premedicated with ketamine (4 mg/kg) and midazolam (1 mg/kg) intramuscularly 30 minutes before anesthetic induction. Anesthesia was induced with slow intravenous (right jugular vein) injection of propofol (3-6 mg/kg). Anesthesia was maintained at first with a continuous intravenous infusion of propofol (.3-1 mg/kg/min). After instrumentation, surgical preparation and moving of the sheep into the operating theater, anesthesia was maintained with isoflurane in oxygen and a continuous intravenous infusion of fentanyl (.3-6 µg/kg/min). The sheep were mechanically ventilated to maintain end-tidal carbon dioxide partial pressures between 35 and 45 mm Hg.

For pressure measurements and infusion therapy a central venous line was placed in the left external jugular vein and an arterial catheter was placed in one auricular artery. All animals were placed in right lateral recumbency and left thoracotomy was performed to expose the heart. After heparinization with 100 IU/kg, left femoral artery and right atrium were cannulated. After initiation of car-

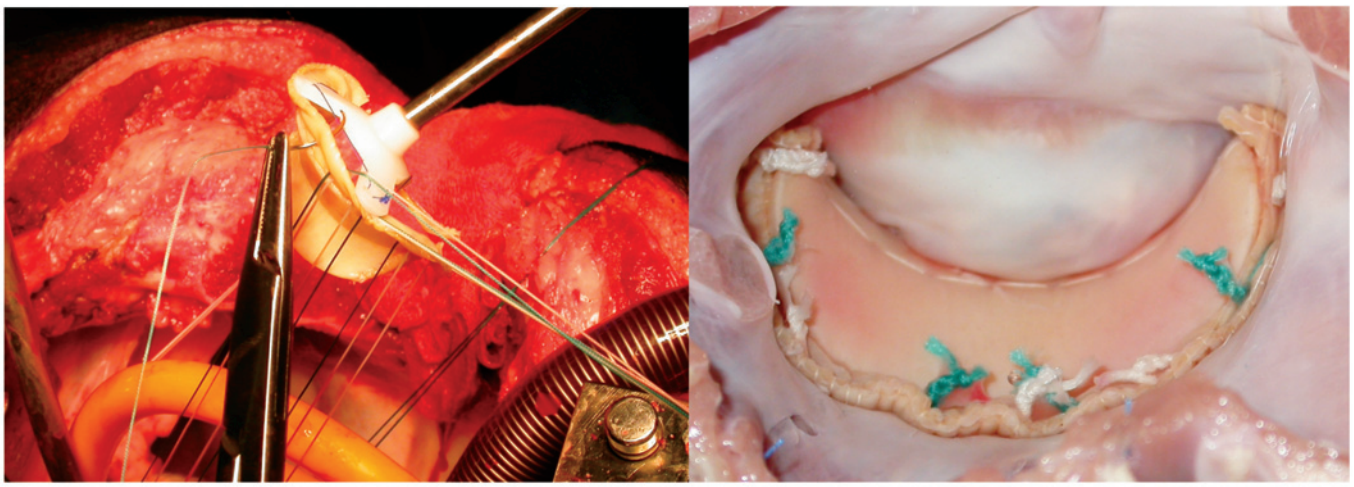

Figure 2. Placing the sutures through the ring of the MitroFast™ device (a) and after final implantation (b) while pressurizing the ventricle leading to perfect coaptation of the anterior leaflet without any leakage (ex vivo for better visualization).

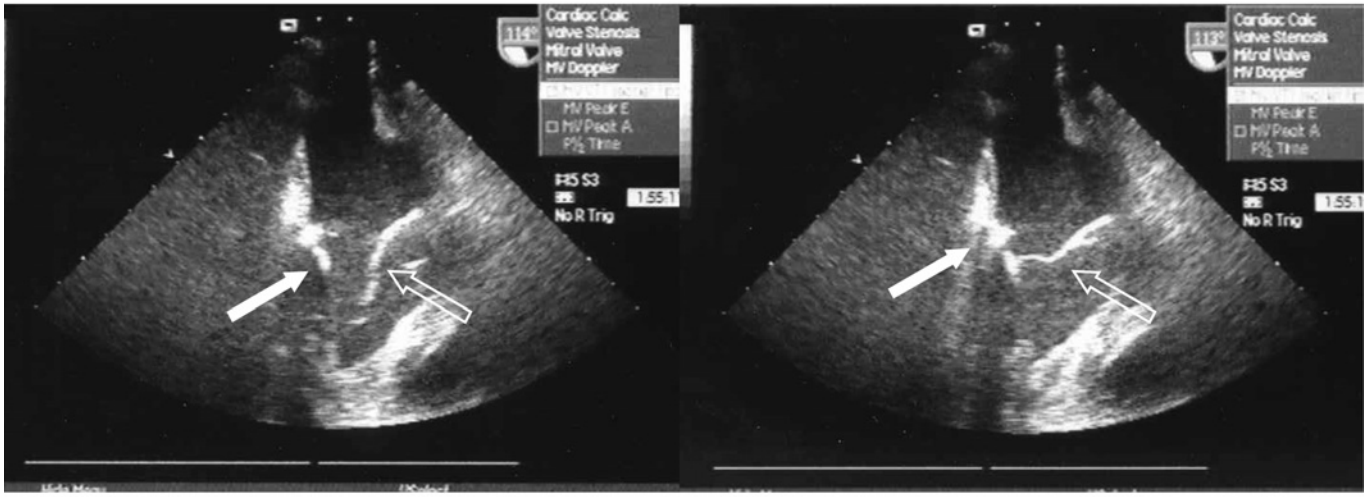

Figure 3. Transesophageal echocardiography showing posterior leaflet stenting with the MitroFast™ device (white arrow) with open (a) and closed coapting (b) anterior leaflet (transparent arrow).

diopulmonary bypass (CPB) the implantation of the MitroFast™ device was performed while the heart was beating. The left atrium was opened and mitral valve insufficiency was created to avoid arterial air embolism. The mitral valve was exposed and an appropriate sized device was tested by the special measuring tool described above. 2/0 Ethibond(c) (Ethicon GmbH, Norderstedt, Germany) single interrupted sutures were placed around the posterior annulus to fix the MitroFast(tm) device. Once implantation was completed, the ventricle and atrium were de-aired and the left atrium was closed with a running 5/0 Prolene(c) suture (Ethicon GmbH, Norderstedt, Germany). After reperfusion and successful weaning from CPB, complete hemodynamic assessment was performed in every animal. After chest closure transesophageal echocardiography was performed to evaluate the function of the device and the performance of the reconstructed valve.

RESULTS

Every implantation of a MitroFast™ device could be performed in less than 30 minutes despite the fact that all operations were performed in more difficult beating heart condition. After implantation of the device all animals could be successfully weaned from CPB. Arterial pressure of 100/60 mm Hg was achieved with minimal inotropic support (Dopamine, 10-20 µg/kg/min). Invasively measured left atrial pressure was below 12 mm Hg in all animals. The chest was closed in routine fashion and transesophageal echocardiography was performed. Echocardiography (Figure 3) revealed a competent mitral valve in all animals without any inflow restriction in three animals (transvalvular gradients below 3 mm Hg) and suspected mild stenosis in one animal (transvalvular peak gradient up to 6 mm Hg).

DISCUSSION

Although Braunberger et al (2001) reported excellent long-term results after initial valve reconstruction in patients with nonrheumatic mitral valve insufficiency, Flameng et al (2003) reported in their series of 242 patients who had undergone mitral valve repair for degenerative valve incompetence a linearized recurrence rate of nontrivial mitral regurgitation (>1/4) of 8.3% per year and of severe mitral regurgitation (>2/4) of 3.7% per year. They concluded that the durability of a successful mitral reconstruction for degenerative mitral valve disease is not constant.

Mitral valve incompetence is mainly caused by prolapsing leaflet due to elongation or rupture of chordae with or without consecutive annular dilatation (Carpentier 1980). Although implantation of an annuloplasty ring is widely accepted, the ideal form of the ring is still under discussion as several designs with a closed, opened, semicircular, flexible, semirigid or even three-dimensional shapes are available (Dall'Agata 1998, Gorman 2003, Tibayan 2003). Annuloplasty ring dimension depends mainly on the width and the height of the anterior leaflet (Carpentier 1995) demonstrating the importance of the anterior leaflet compared to the posterior one.

In the majority of cases the posterior leaflet is affected and mitral valve repair is performed by a quadrangular resection of the posterior leaflet (PII) with or without sliding plasty and reattachment of the remaining leaflet edges. After reconstruction of the PII leaflet segment and additional implantation of an annuloplasty ring, the remaining portion of the posterior leaflet often shows reduced remaining mobility. Green et al (1999) demonstrated in normal ovine hearts that mitral annuloplasty even with conventional flexible and or semi-rigid ring types markedly reduced the mobility of the central posterior leaflet such that valve closure became essentially a single (anterior) leaflet process

with the frozen posterior leaflet serving only as a buttress for coaptation.

Complex mitral valve reconstruction is still time consuming and requires a great deal of training and three-dimensional power of imagination. We investigated a time-saving new concept of mitral valve reconstruction using a novel device developed by Shelhigh Inc. (Union, New Jersey, USA). The Shelhigh MitroFast(tm) mitral valvuloplasty device is based on a completely new concept to repair the flail posterior mitral valve leaflet. It can be implanted either as a complete ring or as used in this investigation as a semicircular enforcement of the posterior commissure. Long-term biocompatibility can be expected due to complete covering of the device by detoxificated bovine pericardium. The device acts as a fixed posterior leaflet stent to which the anterior leaflet can coapt. As the posterior leaflet stent covers the complete native flail leaflet there is no need for reconstruction maneuvers. Furthermore, when fixing a ruptured chordae the whole native subvalvular apparatus can be preserved. It does represent, however, a fixed stent without inherent possibilities for movement and care has to be taken for the majority of the opening area to be covered by the remaining anterior leaflet.

Sheep present the best animal model for experimental reconstructive mitral valve surgery as the ovine mitral valve is comparable to the human valve as far as asymmetrical structure and subvalvular apparatus are concerned. The present study has obvious limitations: we only evaluated the acute hemodynamic effects after implantation of this new device in an experimental model. Since the surface of the buttress is very smooth and there are no moving parts in this device we do not anticipate long-term effects. However, only long-term results can confirm this hypothesis. There is also a great deal of learning curves to identify the best indication and how this device will function in difficult cases of mitral valve disease, generally not amenable to successful repair; like in cases of rheumatic mitral valve disease and severe ischemic mitral regurgitation.

CONCLUSION

We present a completely new concept of mitral valve repair which consists in stenting the posterior mitral leaflet. This allows us to avoid extensive and time-consuming reconstructive surgery on a flail posterior leaflet. Open surgical implantation technique of the MitroFast(tm) device is simple; the potential for minimal invasive implantation of a conceptual similar device will be further investigated.

ACKNOWLEDGMENT

We thank Craig Miller, MD, Tomasz Timek, MD and Mary Zasio, BA, Department of Cardiothoracic Surgery, Stanford University, CA, USA, and James S. Harper 3rd, VMD, Brown University, Providence, RI, USA, for their advices and encouraging discussions to help establishing the animal model.

DISCLOSURES

This study was partially funded by Shelhigh, Inc.™, Union, NJ, USA.

The authors hereby state that they had full control of the design of the study, methods used, outcome parameters, analysis of data, and production of the written report.

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