Original Paper

Modular Catheter Systems in Minimally Invasive Interventional Medical Procedures: Case Study

Bradley Beach[1], MSc; Brian A Scansen[2], DVM, MSc

[1]Covellus LLC, Belmar, NJ, United States

[2]Department of Clinical Sciences, Colorado State University, Fort Collins, CO, United States

Corresponding Author:
Bradley Beach, MSc
Covellus LLC
822 13th Ave
Belmar, NJ, 07719
United States
Phone: 1 7328597270
Email: bbeach@covellus.com

Abstract

Background: Medical device catheters that are used in minimally invasive interventional medical procedures all follow the same integrated design and use paradigm. The features and elements of any catheter device are combined in a single unitary construction. A modular approach to the design, construction, and use of these types of interventional catheters may provide significant advantages and benefits not available with an integrated design paradigm.

Objective: This paper aimed to present the design of a modular catheter system and the findings from an initial veterinary use as a case study for the potential of modular catheter systems in general.

Methods: A modular catheter system was designed using commercially available angioplasty balloon dilatation catheters as one module in the system and a custom designed scoring adapter as the other module. The scoring adapter incorporates wires to add scoring features to the angioplasty balloon catheter to improve the dilatation performance during a pulmonary valvuloplasty procedure. The scoring adapter also includes a novel attachment mechanism to couple the scoring adapter to any 0.035-inch guidewire–compatible angioplasty balloon catheter.

Results: The modular catheter system was successfully designed, manufactured, and used in an initial minimally invasive veterinary cardiovascular intervention to treat a case of canine subvalvular pulmonary stenosis. The scoring adapter and angioplasty balloon catheter were successfully combined *tableside* in the operating room at the time of the procedure and used to successfully dilate the subvalvular obstruction.

Conclusions: The successful design and use of the presented modular catheter system demonstrates the feasibility and potential advantages of this type of paradigm to enable physicians to create interventional catheter devices at the time of a procedure guided by the procedural needs.

(JMIR Biomed Eng 2019;4(1):e14443) doi: 10.2196/14443

KEYWORDS

catheters; angioplasty; balloon valvuloplasty; medical device design; minimally invasive surgical procedures; endovascular procedures

Introduction

Interventional Catheters

Minimally invasive surgical procedures are a relatively new development in medicine. These procedures began with the development of cardiac catheterization, percutaneous angioplasty, and endoscopic procedures as an alternative to open surgery. During its short history, the use of medical device catheters in minimally invasive procedures has grown dramatically, expanding to include treatments for conditions throughout the body. Today, millions of these procedures are performed each year. Even though the number and type of catheters has grown to create new and improved diagnostic and therapeutic procedures, their basic construction paradigm has remained the same, exclusively that of an integrated design approach. With integrated catheter designs, each variant of a

catheter device type is a unique design and stock keeping unit (SKU).

Expanding the product family within an integrated design paradigm to include new configurations of an existing type or to add a new feature requires a unique design and SKU. Given the development and regulatory burden, as well as the carrying cost of inventory for both a manufacturer and hospital, expanding integrated catheter product families and creating new ones can be prohibitive. It is theorized that a modular approach to designing and using medical device catheters for certain interventions could improve access to appropriate devices and lower the overall cost.

The fundamental concept of a modular system is that complex products can be built from subsystems (modules) that are designed independently yet function together as a whole. Design changes made in one module do not affect other modules in the overall product. The interface shared among modules is standardized to allow for greater reusability among product types and adaptability of design [1]. The proposed modular catheter system enables physicians to combine 2 modules (a parent module with an adapter module), via a universal interface (attachment mechanism), to create interventional device catheters at the time of the procedure to meet specific procedural needs.

A modular catheter system of this nature represents a new way to approach the design and use of minimally invasive medical catheters for interventional procedures. A modular system would enable a physician to combine diagnostic, therapeutic, and structural elements to *build* a device catheter to meet a specific need. Examples include the relatively simple combination of a balloon dilatation catheter and scoring elements, as described in this case study. However, the idea could be extended to combine variants of other structural elements or incorporate more sophisticated elements such as advanced imaging sensors, drug delivery elements, ablation electrodes, pressure transducers, and many others. A new modular system paradigm can be used to develop new interventional techniques and therapies by giving physicians the tools to create devices tableside to meet evolving procedural needs.

Scoring and Cutting Balloon Dilatation

Scoring and cutting balloon catheters use scoring elements integrated with an angioplasty balloon to preferentially create dissections along the length of a lesion. There is evidence that adding the scoring element can improve the dilatation efficiency of the balloon, allowing effective dilatation to occur at lower balloon inflation pressures, or improve the dilatation result of resistant lesions [2-4].

A technique has been developed in veterinary medicine that utilizes commercially available cutting balloons to improve the dilatation of subvalvular aortic stenosis in dogs. The technique consists of scoring the fibrotic subvalvular tissue with a cutting balloon and then dilating the scored lesion with a larger, high-pressure balloon to complete the procedure. The idea is that the smaller cutting balloon will score the lesion to make the subsequent high-pressure ballooning more efficient. The scoring step of the procedure creates preferential dissections but does not completely dilate the stenosis. The second inflation with a larger-diameter balloon is intended to complete the dilatation for the final result [5].

This technique appears to be effective; however, the commercially available sizes of the cutting balloons are sometimes too small for these procedures or analogous pulmonary stenosis interventions. The lack of available balloon variants is an opportunity to demonstrate the above-mentioned modular catheter system to create scoring balloon variants using any size of commercially available angioplasty balloon catheters and a single scoring adapter module. The use of a scoring balloon modular system during a cardiovascular intervention of a canine subvalvular pulmonary stenosis has been described.

Goal of the Case Study

The aim of this case study was to demonstrate the potential of a new modular system paradigm in minimally invasive interventional catheters. This paper presents the design of a 2-module catheter system utilizing commercially available angioplasty balloons as one of the 2 modules. The paper further presents the results of using the system in treating a single case of canine subvalvular pulmonary stenosis. The initial use in a veterinary cardiovascular intervention is meant to demonstrate the feasibility of the proposed modular catheter system and not the efficacy of pulmonary valvuloplasty; therefore, only the acute results of the intervention are presented.

The study of medical devices and interventional techniques has long been done in animal models to approximate clinical conditions and demonstrate safety. There is also a historical precedent for treating veterinary patients, dogs, using new interventional surgical techniques before use in humans [6]. The case study presented here follows in that tradition.

Methods

Design Overview

To demonstrate the potential of such a system, a scoring adapter module (scoring adapter), which includes a universal interface (attachment mechanism), was designed to be combined with any commercially available over-the-wire percutaneous transluminal angioplasty (PTA) balloon dilatation catheter that has a maximum guidewire compatibility of 0.035 inches, considered the parent module. The scoring adapter includes nitinol wires, which when combined with the parent module balloon catheter creates a device that combines balloon dilatation with the wire scoring elements to improve dilatation performance, analogous to integrated scoring and cutting angioplasty balloon dilatation catheters.

Modular System Design Strategy

The use of existing stock catheter devices as the parent module was explored as an efficient means to test the concept of modular systems in catheter design and to streamline the development process.

It is recognized that many devices and catheters used in interventional procedures include a lumen for the purpose of employing a guidewire during the procedure. This catheter lumen, which has been designed to be compatible with a

standard guidewire size, can be leveraged to develop a standard interface for a modular catheter system. Commercially available 0.035-inch guidewire PTA balloon catheters come in a variety of balloon sizes and performance characteristics that make such devices an ideal parent module candidate for this case study.

Many challenges exist in designing a modular catheter system, including a robust, secure interface, or attachment mechanism, between the parent module and the adapter module (adapter). This design challenge becomes more difficult with the decision to use commercially available 0.035-inch PTA balloon catheters as the parent module. Although the standardization around a maximum guidewire compatibility of 0.035 inches provides some uniformity in the catheter lumen, there is still variation among brands and models. To accommodate this variation in lumen geometry, a nitinol coil element was designed as the interfacing element on the attachment mechanism integral with the scoring adapter module to interface with the 0.035-inch catheter lumen and connect the scoring adapter with the 0.035-inch PTA balloon parent module.

The attachment mechanism consists of a central tube as the main body with the aforementioned nitinol coil elements bonded to the outer surface of the central tube. To couple the 2 modules together, the central tube of the adapter module is inserted into the distal end of the catheter guidewire lumen of the parent module. As this insertion occurs, the nitinol coil elements, which have been designed to be slightly larger than the guidewire lumen of the 0.035-inch catheters, compress to interface with the 0.035-inch catheter guidewire lumen and anchor the adapter module to the parent module. The adapter module includes a distal tip that remains distal to the end of the 0.035-inch catheter parent module once the attachment mechanism has been fully inserted into the parent module guidewire lumen. Once the adapter module is attached to the parent module, the 2 modules cannot be separated and function as an integrated catheter.

Figure 1 shows an adapter module variant (not the scoring adapter) before attaching to a balloon catheter illustrating the elements of the universal 0.035-inch attachment mechanism. Figure 2 shows sequential images of the interfacing nitinol coil element as it is inserted into the distal end of the 0.035-inch PTA balloon catheter guidewire lumen. It should be noted that the nitinol coil compresses as it is inserted into the parent module. Figure 3 shows the adapter and attachment mechanism of Figure 1 after it is inserted into a PTA balloon catheter.

Figure 1. Adapter module elements.

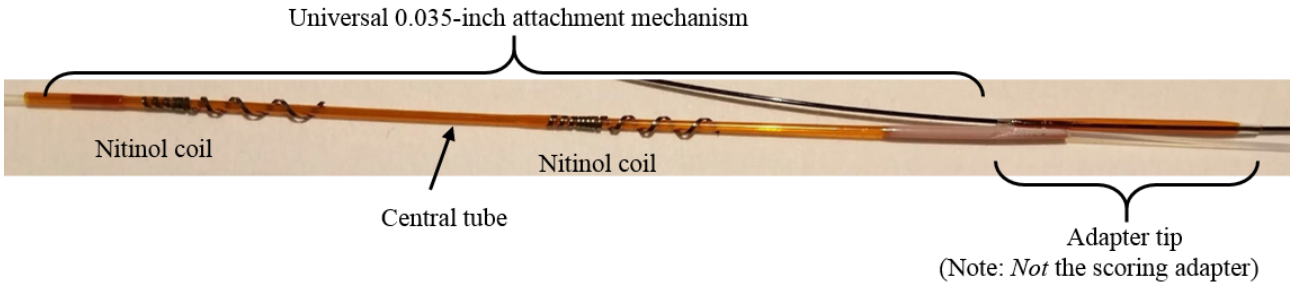


Figure 2. Nitinol coil element during adapter insertion.

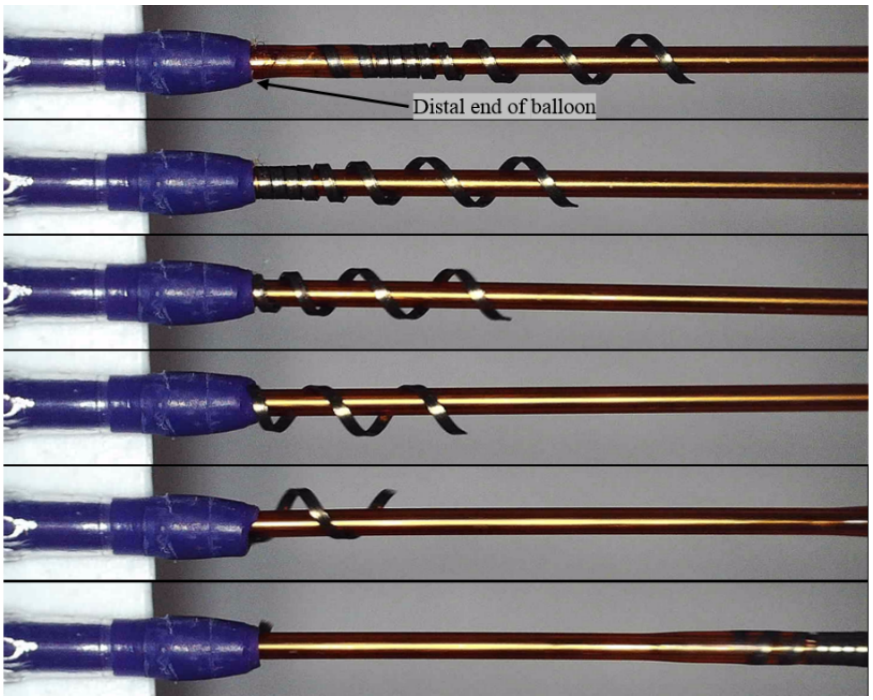
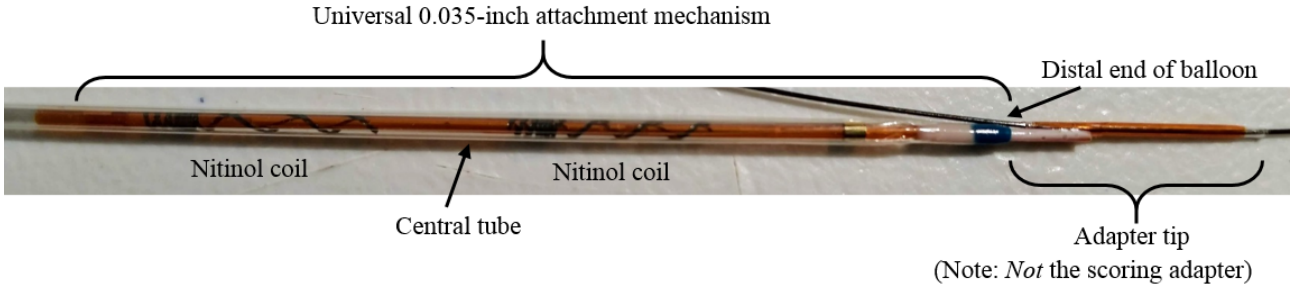


Figure 3. Adapter module attached to parent module (balloon).



Development for Veterinary Use

The veterinary scoring adapter was developed cooperatively by Covellus LLC, a privately held medical device company developing the modular catheter system, and BAS, associate professor of cardiology at Colorado State University. BAS is a diplomate of the American College of Veterinary Internal Medicine, specialty of cardiology, and has completed a fellowship in interventional radiology and endoscopy at the University of Pennsylvania and the Animal Medical Center (New York). The development of the scoring adapter was targeted as a tool to allow the use of the described cutting or scoring followed by high-pressure ballooning technique in congenital pulmonary or aortic stenosis where the stenosis is larger than can be effectively treated with commercially available cutting or scoring balloons. Currently, commercially available scoring and cutting balloons have a maximum diameter of 8 mm.

The scoring adapter design chosen for initial trial veterinary use included 4 nitinol wires 0.006 inches in diameter that are embedded into the scoring adapter tip as the scoring elements. The scoring wires extended proximally about 100 cm, such that the wires would extend proximally out of the access site for the procedure and remain under the control of the operator throughout the procedure. The 4 scoring wires were positioned approximately uniformly around the circumference of the scoring adapter tip. The scoring adapter tip that remains distal to the parent module balloon catheter is composed of a thermoplastic elastomer and has a tapered shape similar to a distal tip of a PTA balloon catheter, with a maximum diameter of 0.063 inches and a length of 0.23 inches. The scoring adapter tip also includes 2 embedded 3-mm-long sections of 0.25-mm tungsten wire, to add extra radiopacity for tip visualization during the procedure. Figure 4 is a partial schematic representation of the scoring adapter module illustrating the tip and position of the scoring wires. Figure 5 shows an image of the scoring adapter module attached to a 0.035-inch balloon catheter, with the adapter elements labeled to further illustrate the described design elements.

Figure 4. Schematic representation of the scoring adapter.

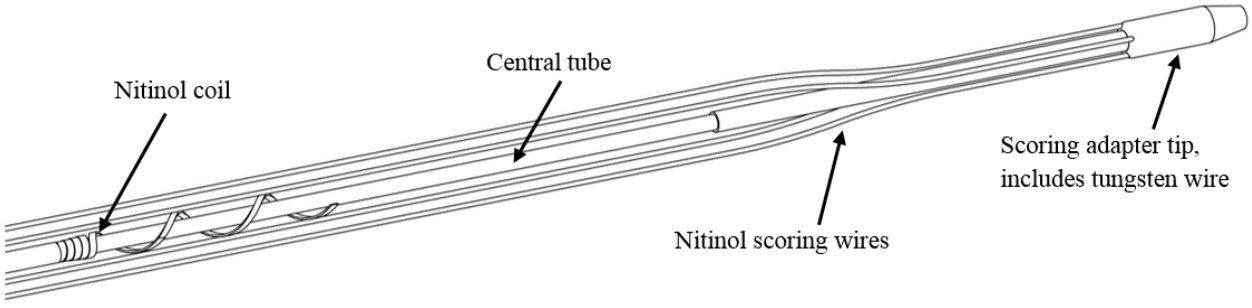
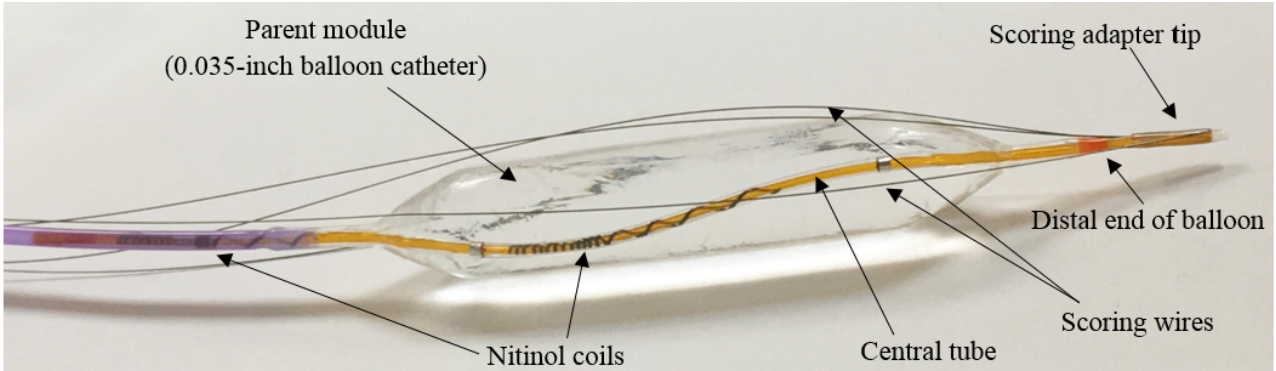


Figure 5. Scoring adapter modular system.



Manufacturing Veterinary Use Scoring Adapter

Covellus LLC manufactured a small lot of scoring adapters for use in this initial veterinary application. Along with the small lot of scoring adapters, Covellus manufactured adapter test samples and attachment mechanism test samples to verify if the manufactured batch of scoring adapters will function as intended, provide adequate securement between the parent module balloon and scoring adapter, and give assurance of sterility of the manufactured scoring adapters. The scoring adapter was packaged in a conventional Tyvek pouch system and radiation sterilized using electronic beam methods.

Results

Preoperative Evaluation

A 7-month-old female Vizsla dog was referred to BAS for balloon pulmonary valvuloplasty. The patient was previously diagnosed with a subpulmonary obstruction on echocardiography following detection of an asymptomatic murmur by the primary care veterinarian. Before the valvuloplasty intervention, the patient underwent a preoperative echocardiogram, where the peak transpulmonary pressure gradient across the obstruction was measured to be 74 mmHg. Figures 6 and 7 show images from the preoperative echocardiogram representing the subvalvular obstruction and the peak transpulmonary pressure gradient measurement. In addition, right ventriculograms during diastole and systole were performed to visualize the subvalvular obstruction as shown in Figure 8.

Figure 6. Preoperative echocardiogram showing the subvalvular obstruction.

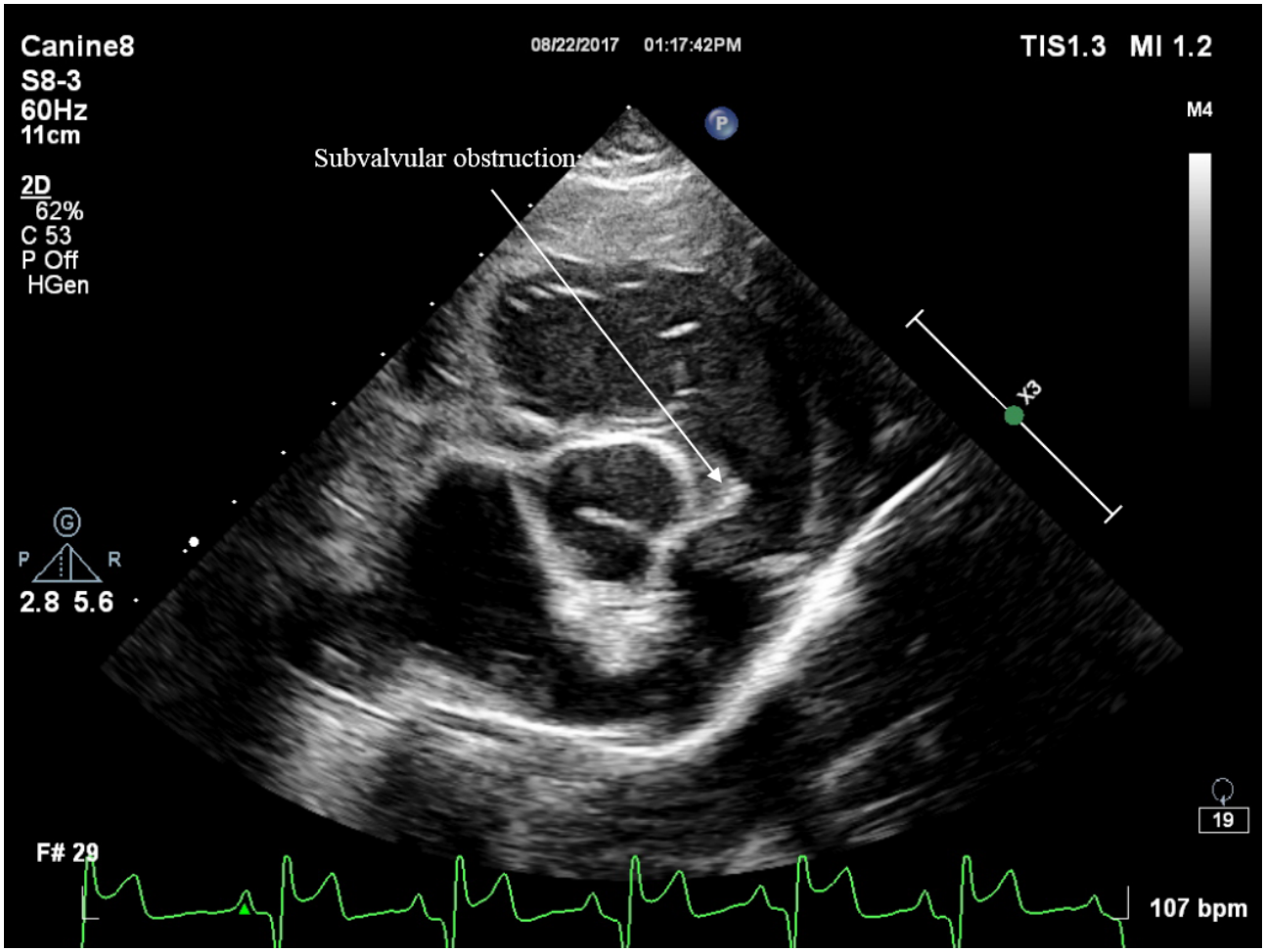


Figure 7. Preoperative peak transpulmonary pressure gradient.

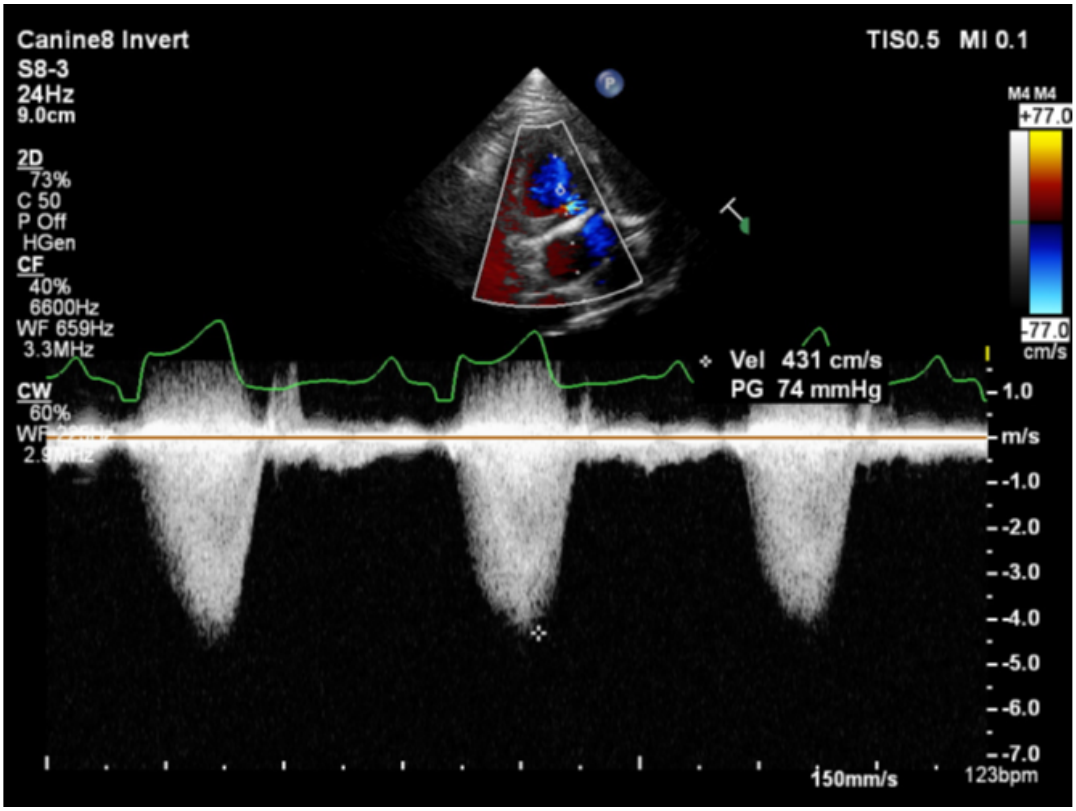
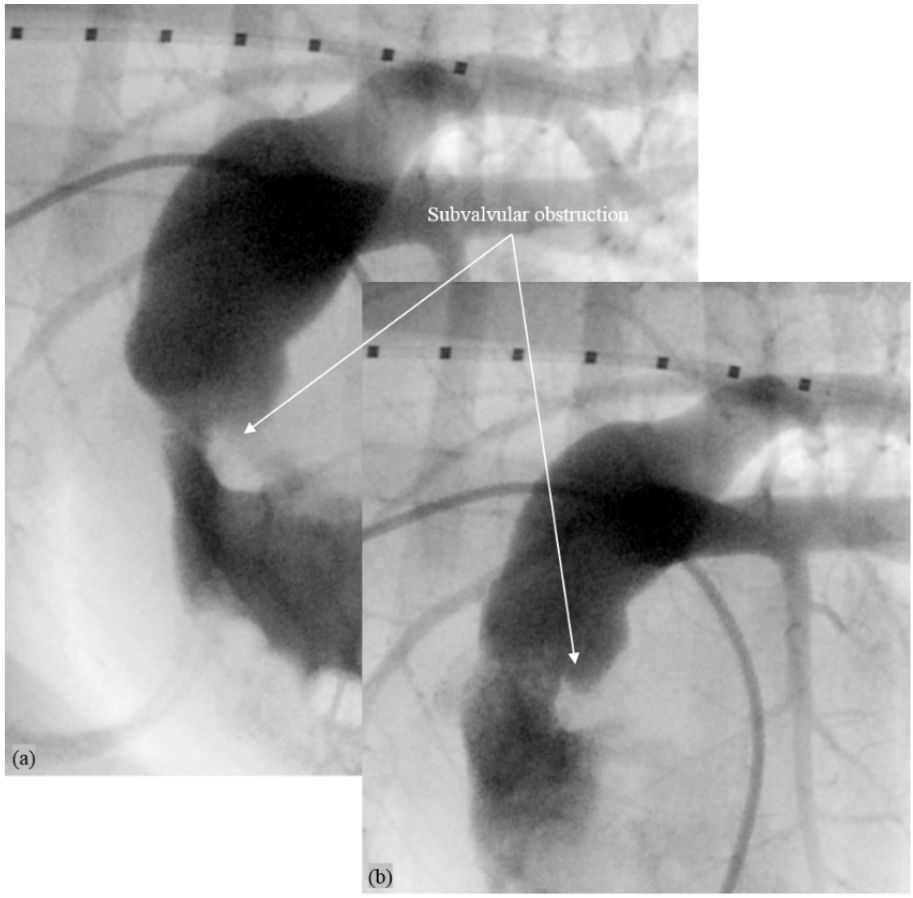


Figure 8. Right ventriculogram showing the subvalvular obstruction in systole (a) and diastole (b).



Procedural Details

To meet the needs of this particular case, BAS chose a 12-mm diameter by 40-mm long Armada 35 model (Abbott Labs) PTA balloon catheter to pair with the scoring adapter for the scoring step of the procedure. The scoring adapter was successfully attached to the Armada balloon in the operating room at the time of the procedure. Figure 9 shows the scoring adapter attached to the Armada 35 balloon (Abbott Labs); it should be noted that this picture was taken following the procedure, so the balloon has been previously inflated but otherwise illustrates the attached adapter.

The scoring adapter and balloon combination was tracked through a 40-cm, 8-Fr Flexor Balkin Sheath (Cook Medical) and over a 200-cm long V-18 control wire (Boston Scientific) to the target site and positioned across the obstruction. The balloon with scoring adapter combination was inflated to the rated burst pressure by BAS. Figure 10 shows the preinflation, midinflation, and peak inflation angiographic images.

Figure 9. Scoring adapter attached to percutaneous transluminal angioplasty balloon.

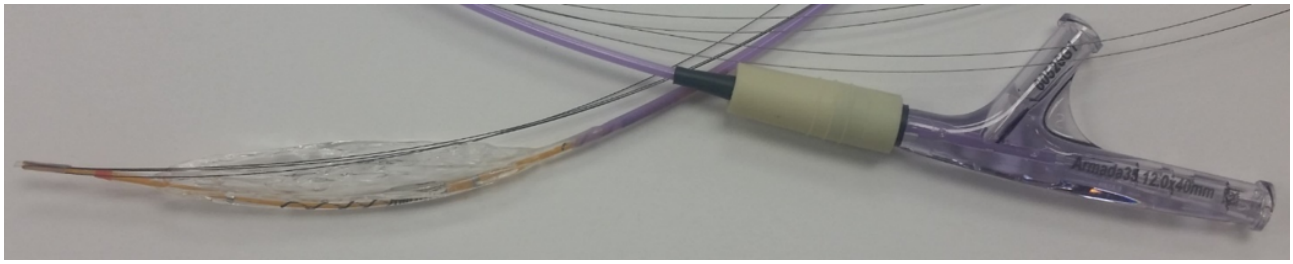


Figure 10. Angiographic inflation images.

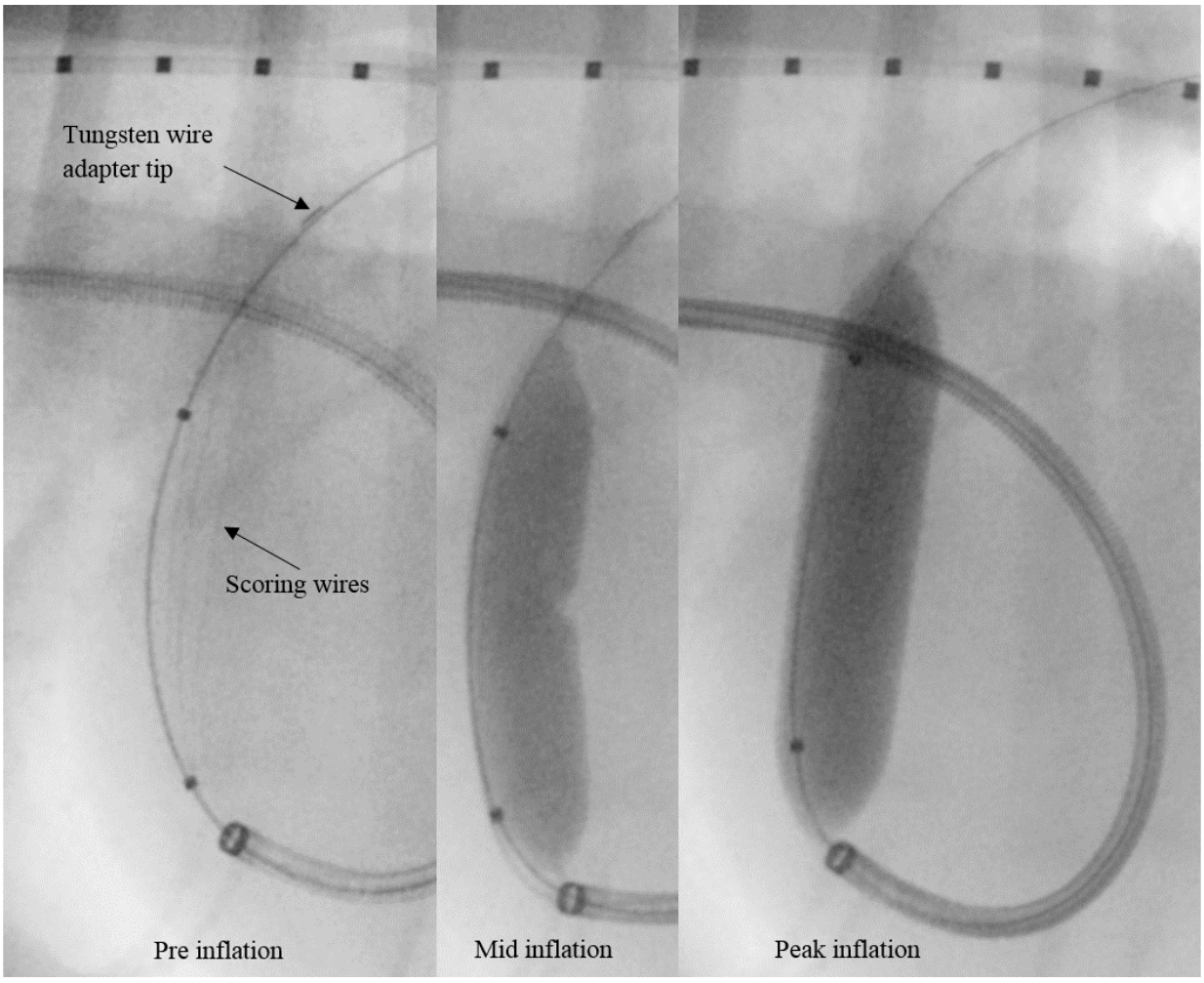
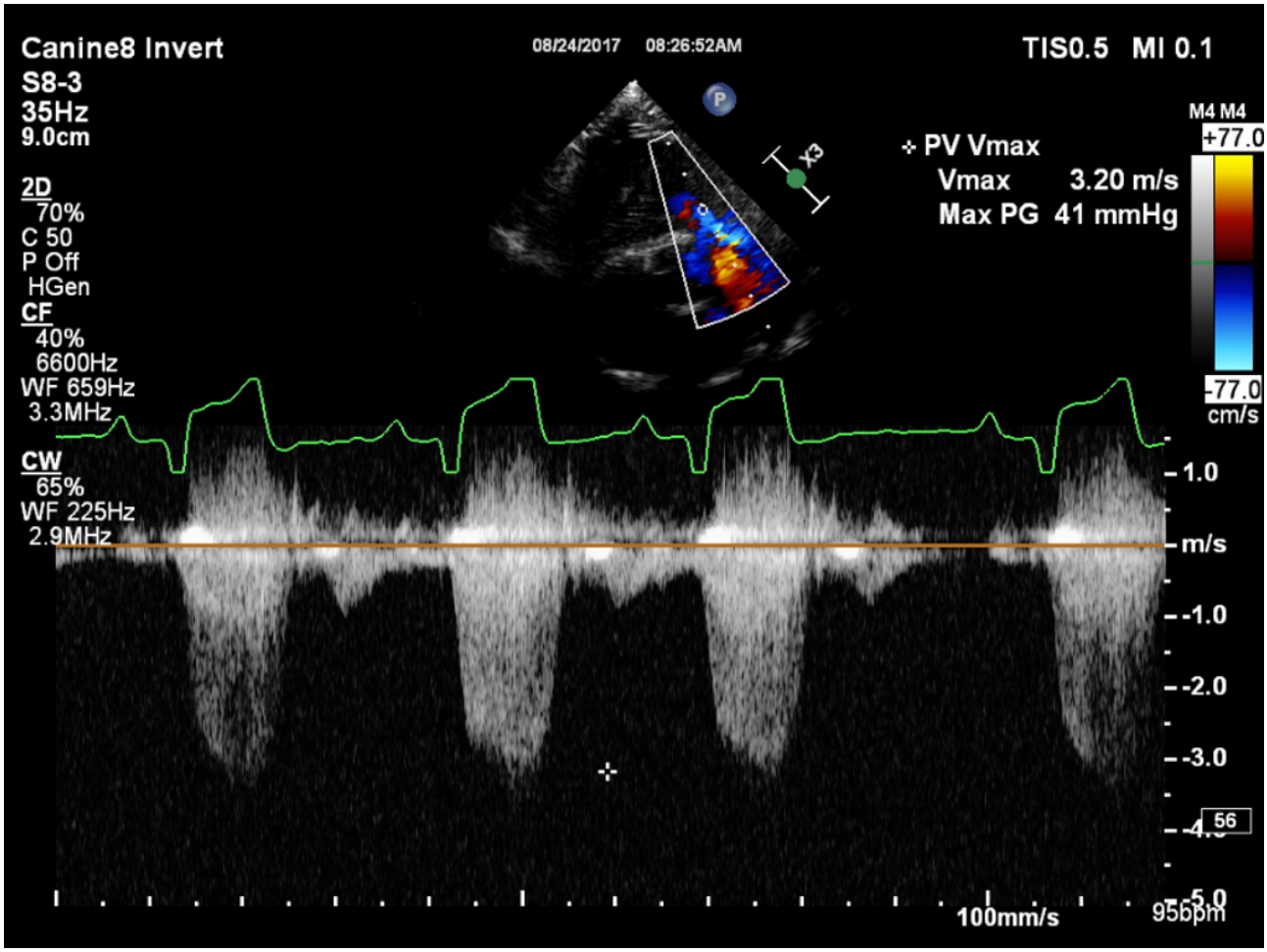


Figure 11. Postoperative echocardiogram.



Procedural Results

The scoring adapter and balloon combination was successfully removed with the 2 modules still completely attached, with no visible damage to the balloon or adapter elements. An 18-mm diameter by 40-mm long ATLAS GOLD PTA balloon catheter (BARD) was used for postscoring high-pressure balloon dilatation. The peak transpulmonary pressure gradient dropped to 41 mmHg, as measured during the postoperative echocardiogram (see Figure 11).

Discussion

Principal Findings

The transpulmonary pressure gradient was reduced from 74 mmHg preoperative to 41 mmHg postoperative. A transpulmonary pressure gradient of 41 mmHg is considered mild and should lead to an improved prognosis and long-term outcome. In addition, this is a better result than typically achieved with conventional ballooning for subvalvular pulmonary obstruction. The result indicates the modular catheter system design utilizing commercially available PTA balloon catheters as the parent module functioned like an integrated scoring balloon catheter in this procedure. This case illustrates how a modular catheter system can be used to create interventional catheters that are not otherwise available and, therefore, improve access to appropriate devices.

The objective of this case study was to demonstrate the feasibility of the proposed modular catheter system and not the efficacy of pulmonary valvuloplasty; therefore, only the acute results of the intervention are presented. Furthermore, the dog traveled to Colorado State University from another state, limiting our ability to obtain postoperative echocardiograms beyond the initial day 1 postoperative study.

Conclusions

The attachment mechanism and modular catheter system was successful. The attachment mechanism provided a means to combine the parent balloon module with the scoring adapter module at the time of the procedure, such that the procedural need guided the creation of a *new* scoring balloon of a diameter that would not have been available otherwise. This case study is proof of concept of a modular system that represents a new paradigm of device catheter construction and use for minimally invasive interventional procedures.

Acknowledgments

This work was funded by Covellus LLC, a privately held medical device company.

Conflicts of Interest

BB is the CEO of and a shareholder in Covellus LLC.

References

1. Gu P, Xue D, Nee AY. Adaptable design: concepts, methods, and applications. Proc Inst Mech Eng B J Eng Manuf 2016 Aug 9;223(11):1367-1387 [FREE Full text] [doi: 10.1243/09544054JEM1387]
2. Singh HS, Kirtane AJ, Moses JW. AngioSculpt scoring balloon catheter: an atherotomy device for coronary and peripheral interventions. Interventional Cardiology 2010 Aug;2(4):469-478. [doi: 10.2217/ica.10.51]
3. Kawase Y, Saito N, Watanabe S, Bao B, Yamamoto E, Watanabe H, et al. Utility of a scoring balloon for a severely calcified lesion: bench test and finite element analysis. Cardiovasc Interv Ther 2014 Apr;29(2):134-139. [doi: 10.1007/s12928-013-0232-6] [Medline: 24318791]
4. Bergersen L, Gauvreau K, Justino H, Nugent A, Rome J, Kreutzer J, et al. Randomized trial of cutting balloon compared with high-pressure angioplasty for the treatment of resistant pulmonary artery stenosis. Circulation 2011 Nov 29;124(22):2388-2396. [doi: 10.1161/CIRCULATIONAHA.111.018200] [Medline: 22042887]
5. Kleman ME, Estrada AH, Maisenbacher HW, Prošek R, Pogue B, Shih A, et al. How to perform combined cutting balloon and high pressure balloon valvuloplasty for dogs with subaortic stenosis. J Vet Cardiol 2012;14(2):351-361. [doi: 10.1016/j.jvc.2011.11.008] [Medline: 22578699]
6. Buchanan JW, Anderson JH, White RI. The 1st balloon valvuloplasty: an historical note. J Vet Intern Med 2002;16(1):116-117 [FREE Full text] [doi: 10.1892/0891-6640(2002)016<0116:tbvahn>2.3.co;2] [Medline: 11822800]

Abbreviations

PTA: percutaneous transluminal angioplasty
SKU: stock keeping unit

Edited by G Eysenbach; submitted 18.04.19; peer-reviewed by A Peña-Oscuvilca, NM Trofenciuc; comments to author 28.05.19; revised version received 03.07.19; accepted 08.07.19; published 29.07.19

Please cite as:
Beach B, Scansen BA
Modular Catheter Systems in Minimally Invasive Interventional Medical Procedures: Case Study
JMIR Biomed Eng 2019;4(1):e14443
URL: http://biomedeng.jmir.org/2019/1/e14443/
doi: 10.2196/14443
PMID: