HHS Public Access

Author manuscript

Catheter Cardiovasc Interv. Author manuscript; available in PMC 2016 July 01.

Published in final edited form as:

Catheter Cardiovasc Interv. 2015 July ; 86(1): 136–143. doi:10.1002/ccd.25774.

A Two-in-One Aortic Valve Sizing and Valvuloplasty Conductance Balloon Catheter

Mark C. Svendsen, PhD[1,2], **Anjan K. Sinha, MD**[3], **Zachary C. Berwick, PhD**[1,2], **William Combs, MS**[1], **Shawn D. Teague, MD**[4], **Thierry Lefevre**[5], **Vasilis Babaliaros, MD**[6], and **Ghassan Kassab, PhD**[1,7,8]

[1]Department of Biomedical Engineering, Indiana University Purdue University Indianapolis, Indianapolis, IN

[2]3DT Holdings LLC, Indianapolis, IN

[3]Department of Cardiology, Indiana University Purdue University Indianapolis, Indianapolis, IN

[4]Indiana Institute for Biomedical Imaging Sciences, Indiana School of Medicine, Indianapolis, IN

[5]Institut Cardiovasculaire Paris Sud, Moassy, France

[6]Division of Cardiology, Emory University School of Medicine, Atlanta, GA

[7]Department of Surgery, Indiana University Purdue University Indianapolis, Indianapolis, IN, 46202

[8]Department of Cellular and Integrative Physiology, Indiana University Purdue University Indianapolis, Indianapolis, IN, 46202

Abstract

Background—Inaccurate aortic valve sizing and selection is linked to paravalvular leakage in transcatheter aortic valve replacement (TAVR). Here, a novel sizing valvuloplasty conductance balloon (SVCB) catheter is shown to be accurate, reproducible, unbiased, and provides real-time tool for aortic valve sizing that fits within the standard valvuloplasty procedure.

Methods & Results—The SVCB catheter is a valvuloplasty device that uses real-time electrical conductance measurements based on Ohm's Law to size the balloon opposed against the aortic valve at any given inflation pressure. Accuracy and repeatability of the SVCB catheter was performed on the bench in phantoms of known dimension and ex vivo in 3 domestic swine aortic annuli with comparison to computed tomography (CT) and dilator measurements. Procedural workflow and safety was demonstrated in vivo in 3 additional domestic swine. SVCB catheter measurements had negligible bias or error for bench accuracy considered as the gold standard (Bias: −0.11 ± 0.26 mm; Error: 1.2%), but greater disagreement in ex vivo versus dilators (Bias: −0.3 ± 1.1mm; Error: 4.5%), and ex vivo versus CT (Bias: −1.0 ± 1.6 mm; Error: 8.7%). The dilator versus CT accuracy showed similar agreement (Bias: −0.9 ± 1.5 mm; Error: 7.3%). Repeatability was excellent on the bench (Bias: 0.02 ± 0.12 mm; Error: 0.5%) and ex vivo (Bias:

Corresponding author current address: Ghassan S. Kassab, Ph.D., California Medical Innovations Institute, 11107 Roselle St., San Diego, CA 92121, 858-249-7418 (Office), 858-999-5235 (Cell).

−0.4 ± 0.9 mm; Error: 4.6%). In animal studies, the device fit well within the procedural workflow with no adverse events or complications.

Conclusions—Due to the clinical relevance of this accurate, repeatable, unbiased, and real-time sizing measurement, the SVCB catheter may provide a useful tool prior to TAVR. These findings merit a future human study

Keywords

TAVR; annular dimensions; paravalvular leak; CT; Ohm's Law

INTRODUCTION

Balloon aortic valvuloplasty (BAV) before, or after independent of transcatheter aortic valve replacement (TAVR) has become a common procedure for patients with aortic stenosis. Anatomical, symptomatic, and functional improvements are sometimes seen with BAV independent of TAVR, which are the result of stretching of the valve leftlets and/or annulus and the breakage of valvular calcifications and commissural fissures.[1] Patient quality of life (QOL) is typically improved following BAV, but unchanged long-term mortality and restenosis following the procedure have limited its widespread, stand-alone usage.[2–4]

The emergence of TAVR has led to a resurgence in BAV.[5] Prior to TAVR, balloon valvuloplasty is used to pre-dilate the native aortic valve and in some cases also to post-dilate the implanted valve if significant valvular regurgitation or valve misplacement occurs.[6–7] Initial TAVR outcomes have been favorable with long-term mortality equivalent to surgically implanted valve controls.[8–9] Nevertheless, numerous multi-center randomized trials using both the Edwards SAPIEN valve (Edwards Lifesciences, Irvine, CA) and CoreValveReValving® system (Medtronic, Minneapolis, MN) have cited even mild degrees of paravalvular leakage as an independent predictor related to long-term mortality (i.e., leakage in as high as 67% of patients at 1–3 years post-implant).[9–13] This paravalvular leakage, among other factors, has been shown to be related to inaccurate valve sizing and valve size selection.[14–16]

Aortic valve size is determined prior to or during TAVR procedures using multi-detector computed tomography (MDCT), transesophageal echocardiography (TEE), and transthoracic echocardiography (TTE).[17–22] Since MDCT provides 3-dimensional images to visualize eccentricities in valvular area that cannot be seen by 2-dimensional echocardiographic slices, measurements made with MDCT can be different than TEE/TTE.[17] A diameter underestimation of 1–1.7mm is reported between echocardiography and MDCT/surgical measurements which would have resulted in a different choice for a TAVR valve size or resulted in no valve selection (i.e., outside the manufacturer range) in up to 44% of the cases.[18–22] Although, MDCT is seemingly more accurate, it requires an added procedure, requires user interpretation of the images, and exposes the patient to high doses of x-ray and contrast dye. Therefore, a tool that fits well within the current TAVR workflow and provides safe, accurate, and unbiased aortic sizing measurements may be valuable. Here, we provide bench, ex vivo, and in vivo validation of a novel aortic sizing valvuloplasty conductance balloon (SVCB) catheter that fits well within the clinical TAVR

workflow to provide real-time, accurate, and unbiased (no image interpretation) dimension (cross-sectional area, CSA; or diameter) of the balloon sizing at any inflation pressure or volume.

METHODS

The SVCB catheter is a standard valvuloplasty balloon with a 0.035” over-the-wire exchange, a set of radiopaque electrodes inside the balloon, a proximal electrode connection, and a port for balloon inflation (Figure 1a). The outer electrodes placed inside either end of the balloon serve as standard fluoroscopic edge markers in addition to serving as excitation sensors for the balloon sizing measurements (Figure 1b – outer electrodes). When connected to the computer console via the proximal electrode connector, a small amount of alternating electrical current (136 μApp, 1–10kHz) is applied inside the balloon through the outer 2 electrodes. Based on the conductance measurements made by adjacent pairs of the middle electrodes (spaced ~1–2mm apart), the outer CSA and effective balloon diameter can be determined and displayed by the console in real-time (i.e., Figure 1b – the sizing measurement is made locally at several locations along the balloon length at the various adjacent electrode pairs – see Appendix for details on how the sizing measurements are calculated based on Ohm’s Law). The SVCB catheters used in this study had a 10 Fr body and a ~100 cm length (Figure 1) with a maximum balloon diameter of 25–30 mm.

Bench Validation

Accuracy and repeatability of the SVCB catheter using both compliant (urethane) and non-compliant (PET) balloons were performed on the bench using circular metal (steel), glass, and plastic rigid phantoms that covered all of the balloon (uniform) or a small part of the balloon at the measurement location (non-uniform). The phantoms ranged from 20–30mm in diameter and were independently measured to determine the true dimension using either a set of calipers or through microscopic measurement. The value for the electrical conductivity of the injected fluid in the balloon was determined using an independent set of phantoms and then randomized repeat measurements were made using a contrast/saline mixture inside the balloon (i.e., either an 8:1 or 4:1 saline/contrast mixture using 0.9% NaCl solution (Baxter Healthcare; Deerfield, IL) and Omnipaque contrast (350mgI/ml; GE Healthcare; Waukesha, WI)). The recorded voltage values along with the other known parameters were used to calculate the SVCB catheter sizing measurements (see Eqs. 1–2 in the Appendix).

The accuracy of the SVCB catheter measurements was determined by the difference between the SVCB catheter and the true phantom measurement (considered as the gold standard). Repeatability was determined as the difference between consecutive randomized repeat SVCB catheter measurements in the same phantom. The average, standard deviation (SD), and root mean square (RMS) error were calculated for the accuracy and repeatability measurements. A linear regression (forced through the origin in line with Ohm’s law) and Bland-Altman analyses were performed for the accuracy (SVCB catheter vs. true) and repeatability (SVCB catheter measurement #1 vs. #2) data as well.[23]

In vivo Procedural Workflow

SVCB catheter usage was demonstrated in vivo in 3 normal, domestic swine (57 ± 20 kg). Animals were initially sedated using an intra-muscular injection of telazol (2 mg/kg), ketamine (1 mg/kg), and xylazine (1 mg/kg) with anesthetic maintenance through intubation and ventilation with 100% oxygen and 1–2% isoflurane. The carotid and femoral arteries were accessed for the placement of a SVCB catheter across the aortic valve and a diagnostic catheter in the ascending aorta. High rate pacing (170–220 bpm) was established prior to balloon inflation through right atrial pacing (Medtronic CapSureFix 5568 bipolar lead). After placement of the middle electrodes in the center of the valve, inflation of the SVCB catheter occurred during high-rate pacing and fluoroscopic monitoring until the indentation of the balloon at the aortic annulus was visualized. Inflation of the balloon was made using a 4:1 to 8:1 saline/contrast mixture. The balloon was then immediately deflated and the high-rate pacing was stopped. The ECG and other vital signs were monitored during the procedure to ensure there was no cardiac arrhythmia risk due to the SVCB conductance recordings. All animal procedures followed were in accordance with institutional guidelines under an approved IACUC protocol.

Ex vivo Validation

A comparison of the SVCB catheter measurements were completed in explanted normal domestic swine hearts (weight = 224±117 gm; n=3). The hearts were taken following euthanization under deep anesthesia using an intra-venous injection of potassium chloride. All animal protocols were approved by the Institutional Animal Care Use Committee at Indiana University-Purdue University Indianapolis.

Size measurement of valve annulus using the SVCB catheter was compared with CT and dilator measurements ex-vivo. For the CT validation, the aorta was canulated retrograde and the pulmonary veins and proximal coronary arteries were closed off with suture. The hearts were pressurized to 100 mmHg with a saline/contrast mixture and placed in a saline bath. All scans were completed using a Philips Brilliance 64 CT Scanner and analyzed (Figure 2) for cross-sectional area assessment at the level of the aortic annulus by two users (Drs. S. Teague and V. Babaliaros). Following the CT scans, the SVCB catheter was placed in the aortic annulus and measurements were made using an 8:1 contrast/saline mixture inside the balloon (urethane). This procedure was repeated 4 times for each heart and the aortic annular size was determined (see Eqs. 1–2 in the Appendix). Following the SVCB balloon measurements in all hearts, the apex of the heart was cut and a set of uniform plastic dilators (3D Parts Manufacturing LLC; Indianapolis, IN), starting with the smallest, was inserted into the aortic annulus until the size of the valve was determined (i.e., the dilator just prior to the one in which the dilator could not advance was the recorded size). The differences between the SVCB catheter, CT, and dilator measurements were used for comparisons between the measurements.

RESULTS

The accuracy of the SVCB catheter measurement compared to the true diameter for phantom measurements was −0.11 ± 0.26 mm with a RMS error of 1.2% (Figure 3a–b). For the

measurement range from 20–30mm, the phantom relationship between the SVCB measured diameter and the true diameter was $D_{measured} = 1.0*D_{true}$; $R^2 = 0.99$ (Figure 3a; where $D_{measured}$ is the SVCB catheter measured diameter and D_{true} is the true diameter). The mean difference between repeat bench measurements was 0.02 ± 0.12 mm with a RMS error of 0.5% (Figure 4a–b). The repeatability relationship on the bench was $D_{measured\#2} = 1.0*D_{measured\#1}$; $R^2 = 1$ (Figure 4a; where y is SVCB catheter measurement #2 and x is SVCB catheter measurement #1).

The temporal change in conductance/diameter was displayed on the computer/console screen for the ex vivo and in vivo analyses (Figure 5). The simultaneous and multiple diameter measurements along the catheter length in a 20.4mm phantom (Figure 5a) are shown during inflation (i.e., increase in the conductance signal) and deflation (i.e., decrease in the conductance signal). The real-time measurement of middle electrodes during an in vivo measurement (Figure 5b) also shows an increase during inflation and a decrease during deflation. The dynamic changes in the balloon dimension are seen during high rate pacing oscillations in the in vivo tracing (Figure 5b). The catheter and measurement electrodes are clearly seen in vivo under fluoroscopy (Figure 6a) and the balloon is easily visualized during inflation (Figure 6b). There were no arrhythmias, adverse events, or complications during SVCB usage.

The mean difference between the ex vivo SVCB vs. dilator, SVCB vs. CT, and dilator vs. CT measurements for aortic valve measurements was −0.3±1.1 mm, −1.0±1.6 mm, and −0.9±1.5 mm with a RMS difference of 4.5%, 8.7%, and 7.3%, respectively. The mean aortic valve size for these measurements was 20.9±2.4 mm.

DISCUSSION

The novel SVCB catheter produced highly accurate and repeatable sizing measurements in phantoms and ex vivo in swine hearts and demonstrated procedural workflow and safety in vivo. A highly significant linear relationship (the slope and R^2 both between 0.99–1) was observed for the accuracy and repeatability measurements across the full sizing range (20–30mm) as shown in Figures 3–4. There was excellent agreement in the phantoms and ex vivo for accuracy (accuracy: 1.2% bench and 4.5% ex vivo SVCB vs. dilators) and repeatability with virtually no bias (phantoms = 0.02 mm; ex vivo = −0.4 mm). Such exceptional accuracy and repeatability is rooted in Ohm's Law (see Appendix Eqs. 1–2) where CSA is directly proportional to changes in the measured conductance. Since the balloon serves as an insulator, the fundamental principle applies regardless of the surrounding environment, as confirmed by the translation of the excellent results from metal, plastic, or glass phantoms to the swine hearts. The slightly larger accuracy in the ex vivo versus the bench analysis is likely due to the non-simultaneous nature of the SVCB, dilator, and CT measurements and due to the fact that the hearts were non-diseased and had compliance. Future efforts will be to validate the device in diseased human aortic valves, which should have even greater accuracy due to the reduced compliance similar to rigid phantoms.

In addition to sizing accuracy, the SVCB catheter performed seamlessly within the standard clinical workflow. The valvuloplasty balloon serves the original intended purpose for dilatation, but also provides accurate sizing that can be used prior to implant procedures. The results displayed are both the CSA (the direct measurement regardless of geometry) and the effective circular diameter based on the CSA measurement. The use of multiple electrodes allows for multiple sizing measurements to be made along the catheter length to provide a profile of the annulus. Since the balloon will expand slightly larger on either end in the left ventricular outflow tract and ascending aorta, the minimum sizing measurement along the length provides the annular dimension.

Currently, two valvuloplasty methods have been used to size the aortic valve in conjunction with a contrast injection[25] or intra-balloon pressure measurement.[26] For the contrast injection method, a balloon of known diameter is inflated in the aortic valve during a contrast injection made in the ascending aorta.[25] This method has shortcomings, however, for several reasons including: 1) contrast injections are made against the flow of blood in an already stenotic valve, 2) visual interpretation of contrast leakage is required around an inflated balloon (i.e. high resistance), 3) multiple balloons of various sizes may be needed to perform the measurements, and 4) balloon sizes are based on manufacturer ex vivo pressure compliance charts which fail to achieve the same dimensions in vivo, thus making balloon size assessment sub-optimal.[25,27] The intra-balloon pressure based sizing method requires the clinician to perform several added steps by inflating the balloon, manually measuring the dimension with a caliper, connecting to an indeflator, and deflating the balloon prior to usage.[26] This method is not ideal because additional inflations and measurements may be required to size accurately and an increase in intra-balloon pressure, which can be slight and difficult to measure, is used as a correlate for the sizing measurements. The SVCB catheter described here addresses the majority of these limitations, since conductance measurements are made and displayed in real-time, require no interpretation or contrast injections, and no calibration of the device by the clinician during the procedure; and do not depend on a pressure surrogate for sizing, but instead utilize a fully validated physical principle (Ohm's Law -Eqs. 1–2) to directly size the valve with unprecedented repeatability and accuracy.

Mis-sizing of the aortic valve prior to TAVR implantation has been an important factor linked to paravalvular leakage and mortality, as seen in the PARTNER and CoreValve trials.[14–16] Although currently the standard imaging modalities for aortic sizing, both MDCT and TEE suffer from limitations (additional procedures, image interpretation, >1mm difference between the two modalities, high amounts of x-ray exposure (MDCT), and measurement inaccuracy (TEE/TTE)). MDCT and TEE do not probe the annulus under the distension states which occur with TAVR and thus, MDCT and TEE may under size a compliant annulus.[17–22] The SVCB catheter adds no additional procedure time (when BAV is performed prior to TAVR) and does not require image interpretation or calibration. While, MDCT, TEE, and TTE usage will likely continue to be utilized for various TAVR functions, like proper valve positioning, the need for these imaging modalities can be supplemented, reduced or eliminated with the use of the SVCB.

The electrical signals generated in the SVCB catheter were extremely safe (no major arrhythmias, events, or complications) due to the isolated environment created by the

balloon and the small, high-frequency nature of the current. Further assurance of the current safety has already been proven in catheters and guidewires where there was no balloon to provide insulation and the current was injected directly into the coronary and peripheral arteries of humans (no safety concerns or adverse events) and animals.[28–32] Hence, even if the balloon were to rupture, this would pose no electrical risk to the patient. While a saline/contrast mixture of 4:1 to 8:1 was used in this study, other fluid ratios can be used in the future with equally accurate and repeatable results. SVCB catheter was highly versatile across various diameters (20–30 mm) and can be extended to smaller and larger diameters if necessary for this and various other applications including: pulmonary, tricuspid, or mitral valvuloplasty, TAVR post-dilatation, coronary and peripheral post-dilation, stent delivery, drug delivery (i.e. drug eluting dilation balloon), cutting balloons, cryoplasty, and/or any type of compliant, semi-compliant, or non-compliant balloon for vascular or medical applications in which sizing information during inflation is needed.

Limitations

Since the technology measures the balloon size at any inflation pressure, it requires apposition of the balloon against the valve leaflets and aortic annulus for sizing of the valve. When the balloon is fully opposed to the wall, the sizing measurement provides a CSA reading for any valvular size, shape, or disease condition. Since the SVCB catheter fundamentally measures CSA and not diameter (although an effective diameter is derived), the device can be accurately used to size any shape of aorta, including elliptical. The assurance of wall apposition can be gained by using a more compliant SVCB balloon catheter that will more easily conform to the shape of the aorta and by observing the plateauing of the conductance/CSA reading on the console screen during usage. Future work will include information about compliance (change in CSA per change in pressure) and radial force (product of pressure and CSA) that provide even further confirmation of full balloon expansion to help prevent overexpansion and to determine the propensity for valve rupture.

Although accurate valve sizing alone may not completely eliminate paravalvular leakage (since other factors like valve positioning can impact this), it may significantly reduce those cases in which improper sizing and valve selection play a role in less optimal implanation.[11,13] Furthermore, the technology is limited in those cases where BAV is not recommended or in cases where BAV is not required/typically used. Finally, the body of the current catheter is 10Fr in diameter, but the technology is highly adaptable and has already been mounted and validated on smaller peripheral[24] and coronary balloon catheters (3.7 Fr).

CONCLUSION

A standard valvuloplasty balloon catheter with additional sizing functionality provides an accurate, real-time, and unbiased measurement in phantom and ex vivo swine hearts. Future bench and in vivo stenosis studies will test the ability of the technology to become a therapy delivery tool that may improve the outcome of TAVR and eliminate the need for user-dependent sizing procedures under TAVR-like conditions.

Acknowledgments

FUNDING SOURCES

3DT Holdings LLC provided funding for the manufacture of the balloons and console systems, the bench testing, and the animal testing. This work was funded in part by NIH R43HL123186.

DISCLOSURES

Drs. Svendsen, Babalarios, and Berwick have received compensation from 3DT. Dr. Kassab is the founder of 3DT.

REFERENCES

1. Letac B, Gerber LI, Koning R. Insights on the mechanism of balloon valvuloplasty in aortic stenosis. Am J Cardiol. 1988; 62:1241–1247. [PubMed: 3195485]
2. O'Neill WW. Predictors of long-term survival after percutaneous aortic valvuloplasty registry. J Am Coll Cardiol. 1991; 17:193–198. [PubMed: 1987226]
3. Otto CM, Mickel MC, Kennedy JW, Alderman EL, Bashore TM, Block PC, et al. Three year outcome after balloon aortic valvuloplasty: insights into prognosis of valvular aortic stenosis. Circulation. 1994; 89:642–650. [PubMed: 8313553]
4. Safian RD, Berman AD, Driver DJ, McKay LL, Come PC, Riley MF, et al. Balloon aortic valvuloplasty in 170 consecutive patients. N Engl J Med. 1988; 319:125–130. [PubMed: 3386691]
5. Tamburino C, Capodanno D, Ramondo A, Petronio AS, Ettori F, Santoro G, et al. Incidence and predictors of early and late mortality after transcatheter aortic valve implantation in 663 patients with severe aortic stenosis. Circulation. 2011; 123:299–308. [PubMed: 21220731]
6. Grube E, Buellesfeld L, Mueller R, Sauren B, Zickmann B, Nair D, et al. Progress and current status of percutaneous aortic valve replacement: results of three device generations of the CoreValveRevalving system. Circ Cardiovasc Interv. 2008; 1:167–175. [PubMed: 20031675]
7. Webb JG, Chandavimol M, Thompson CR, Ricci DR, Carere RG, Munt BI, et al. Percutaneous aortic valve implantation retrograde from the femoral artery. Circulation. 2006; 113:842–850. [PubMed: 16461813]
8. Smith CR, Leon MB, Mack MJ, Miller DC, Moses JW, Svensson LG, et al. for the PARTNER Trial Investigators. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med. 2011; 364:2187–2198. [PubMed: 21639811]
9. Ussia GP, Barbanti M, Petronio AS, Tarantini G, Ettori F, Colombo A, et al. on behalf of the CoreValve Italian Registry Investigators. Transcatheter aortic valve implantation: 3-year outcomes of self-expanding CoreValve prosthesis. Eur Heart J. 2012; 33:969–976. [PubMed: 22240494]
10. Kodali SK, Williams M, Smith CR, Svensson LG, Webb JG, Makkar RR, et al. for the PARTNER Trial Investigators. Two-year outcomes after transcatheter or surgical aortic-valve replacement. N Engl J Med. 2012; 366:1686–1695. [PubMed: 22443479]
11. Moat NE, Ludman P, Belder MA, Bridgewater B, Cunningham AD, Young CP, et al. Long-term outcomes after transcatheter aortic valve implantation in high-risk patients with severe aortic stenosis. J Am Coll Cardiol. 2011; 58:2130–2138. [PubMed: 22019110]
12. Tamburino C, Capodanno D, Ramondo A, Petronio AS, Ettori F, Santoro G, et al. Incidence and predictors of early and late mortality after transcatheter aortic valve implantation in 663 patients with severe aortic stenosis. Circulation. 2011; 123:299–308. [PubMed: 21220731]
13. Gilard M, Eltchaninoff H, Iung B, Donzeau-Gouge P, Chevreul K, Fajadet J, et al. for the FRANCE 2 Investigators. Registry of transcatheter aortic-valve implantation in high-risk patients. N Engl J Med. 2012; 366:1705–1715. [PubMed: 22551129]
14. Detaint D, Lepage L, Himbert D, Brochet E, Messika-Zeitoun D, Iung B, et al. Determinants of significant paravalvular regurgitation after transcatheter aortic valve: implantation impact of device and annulus discongruence. J Am Coll Cardiol Interv. 2009; 2:821–827.
15. Takagi K, Latib A, Al-Lamee R, Mussardo M, Montorfano M, Maisano F, et al. Predictors of moderate-to-severe paravalvular aortic regurgitation immediately after CoreValve implantation

and the impact of postdilatation. Catheter Cardiovasc Interv. 2011; 78:432–443. [PubMed: 21793168]

16. Willson AB, Webb JG, LaBounty TM, Achenbach S, Moss R, Wheeler M, et al. 3-dimensional aortic annular assessment by multidetector computed tomography predicts moderate or severe paravalvular regurgitation after transcatheter aortic valve replacement. J Am Coll Cardiol. 2012; 59:1287–1294. [PubMed: 22365423]
17. Jilaihawi H, Kashif M, Fontana G, Furugen A, Shiota T, Friede G, et al. Cross-sectional computed tomographic assessment improves accuracy of aortic annular sizing for transcatheter aortic valve replacement and reduces the incidence of paravalvular aortic regurgitation. J Am Coll Cardiol. 2012; 59:1275–1286. [PubMed: 22365424]
18. Gurvitch R, Webb J, Yuan R, Johnson M, Hague C, Wilson AB, et al. Aortic annulus diameter determination by multidetector computed tomography: reproducibility, applicability and implications for transcatheter aortic valve implantation. J Am Coll Cardiol Interv. 2011; 4:1235–1245.
19. Messika-Zeitoun D, Serfaty JM, Brochet E, Ducrocq G, Lepage L, Detaint D, et al. Multimodal assessment of the aortic annulus diameter: implications for transcatheter aortic valve implantation. J Am Coll Cardiol. 2010; 55:186–194. [PubMed: 20117398]
20. Schultz CJ, Moelker A, Piazza N, Tzikas A, Otten A, Nuis RJ, et al. Three dimensional evaluation of the aortic annulus using multislice computer tomography: are manufacturer's guidelines for sizing for percutaneous aortic valve replacement helpful? Eur Heart J. 2010; 31:849–856. [PubMed: 19995874]
21. Tzikas A, Schultz CJ, Piazza N, Moelker A, Van Mieghem NM, Nuis RJ, et al. Assessment of the aortic annulus by multislice computed tomography, contrast aortography, and trans-thoracic echocardiography in patients referred for transcatheter aortic valve implantation. Catheter Cardiovasc Interv. 2011; 77:868–875. [PubMed: 20824762]
22. Babaliaros VC, Liff D, Chen EP, Rogers JH, Brown RA, Thourani VH, et al. Can balloon aortic valvuloplasty help determine appropriate transcatheter aortic valve size? J Am Coll Cardiol Interv. 2008; 1:580–586.
23. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet. 1986; 1:307–310. [PubMed: 2868172]
24. Svendsen MC, Akingba AG, Sinha AK, Chattin B, Turner A, Brass M, et al. Conducance sizing balloon for measurement of peripheral artery minimal stent area. J Vasc Surg. 2014 In Press.
25. Cribier, A.; Eltechaninoff, H. Preimplantation percutaneous aortic balloon valvotomy (retrograde approach). In: Huber, C.; Feldman, T., editors. Transcatheter Valve Therapies. New York, NY: Informa Healthcare USA, Inc.; 2010. p. 161-170.
26. Babaliaros VC, Junagadhwalla Z, Lerakis S, Thourani V, Liff D, Chen E, et al. Use of balloon aortic valvuloplasty to size the aortic annulus before implantation of a balloon-expandable transcatheter heart valve. J Am Coll Cardiol Interv. 2010; 3:114–118.
27. Costa JR Jr, Mintz GS, Carlier SG, Costa RA, Fujii K, Sano K, et al. Intravascular ultrasonic assessment of stent diameters derived from manufacturer's compliance charts. Am J Cardiol. 2005; 96:74–78. [PubMed: 15979438]
28. Hermiller J, Choy JS, Svendsen M, Bigelow B, Fouts A, Hall J, et al. A nonimaging catheter for measurement of coronary artery lumen area: a first in man pilot study. Catheter Cardiovasc Interv. 2011; 78:202–210. [PubMed: 20939042]
29. Kassab GS, Choy JS, Svendsen M, Sinha AK, Alloosh M, Sturek M, et al. A novel system for the reconstruction of a coronary artery lumen profile in real time: A preclinical validation. Am J Physiol Heart Circ Physiol. 2009; 297:H485–H492. [PubMed: 19465543]
30. Kassab GS, Lontis ER, Horlyck A, Gregersen H. Novel method for measurement of medium size arterial lumen area with an conductance catheter: In-vivo validation. Am J Physiol Heart Circ Physiol. 2005; 288:H2014–H2020. [PubMed: 15734888]
31. Kassasb GS, Lontis ER, Gregersen H. Measurement of coronary lumen area using an conductance catheter: finite element model and in vitro validation. Ann Biomed Eng. 2004; 32:1642–1653. [PubMed: 15675677]

32. Svendsen MC, Choy JS, Ebner A, Bigelow B, Sinha A, Moussa I, et al. A lumen sizing workhorse guidewire for peripheral vasculature: two functions in one device. Catheter Cardiovasc Interv. 2014; 83:E85–E93. [PubMed: 23592431]

APPENDIX

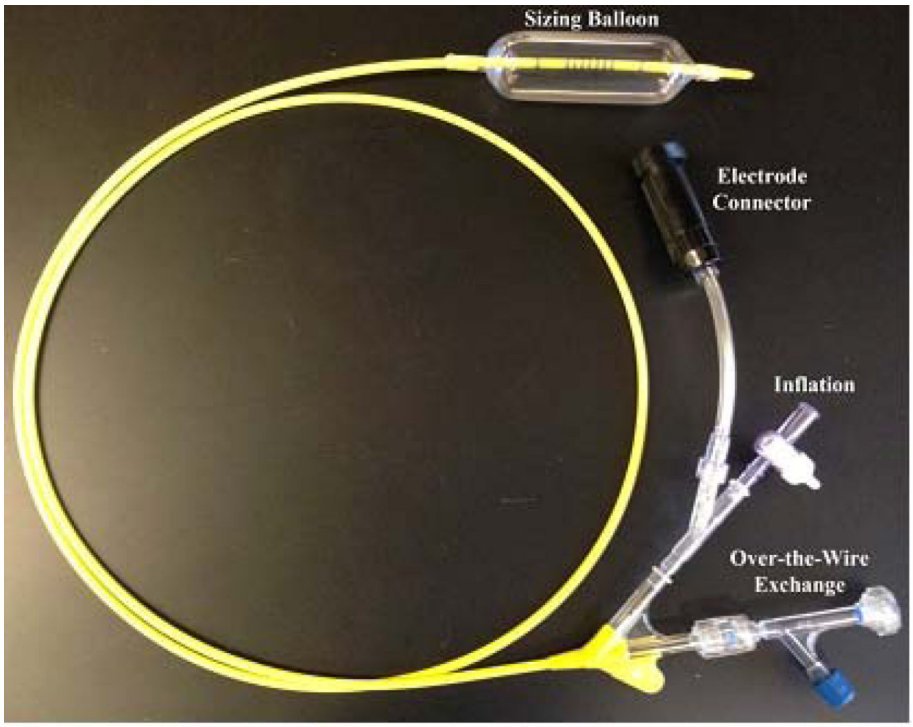
The balloon sizing measurements during inflation and deflation are determined based on a physical electrical law (i.e. Ohm's Law – Eqs. 1 and 2). According to Ohm's Law, the CSA inside the balloon, averaged across any of the adjacent middle electrode pairs, is determined by Eq. 1, where I is the known applied current inside the balloon, L is the known, fixed distance between adjacent electrodes, V is the measured voltage across the inner electrodes, and σ is the conductivity of the fluid inside the balloon. For the SVCB catheter, the contrast/saline mixture inside the balloon has an inherent σ that can be determined prior to sizing. Therefore, since I, L, and σ are known and V is measured in real-time, the balloon size is directly related to changes in V and the inner balloon CSA and effective diameter (D) are as follows:

$$CSA = \frac{IL}{V\sigma} \quad \text{Eq. 1}$$

$$D = \sqrt{\frac{4IL}{\pi V\sigma}} \quad \text{Eq. 2}$$

To obtain the outer balloon dimension (and thus the annular dimension during full inflation), twice the wall thickness of the balloon material is added in the calibration and/or calculations.

The value for σ is found by relating the measured V inside the SVCB catheter in various sized phantoms to the known CSA of the phantoms. The slope of that calibrated I/V versus CSA/L relationship in phantoms is the σ for the contrast/saline mixture.[28–31]



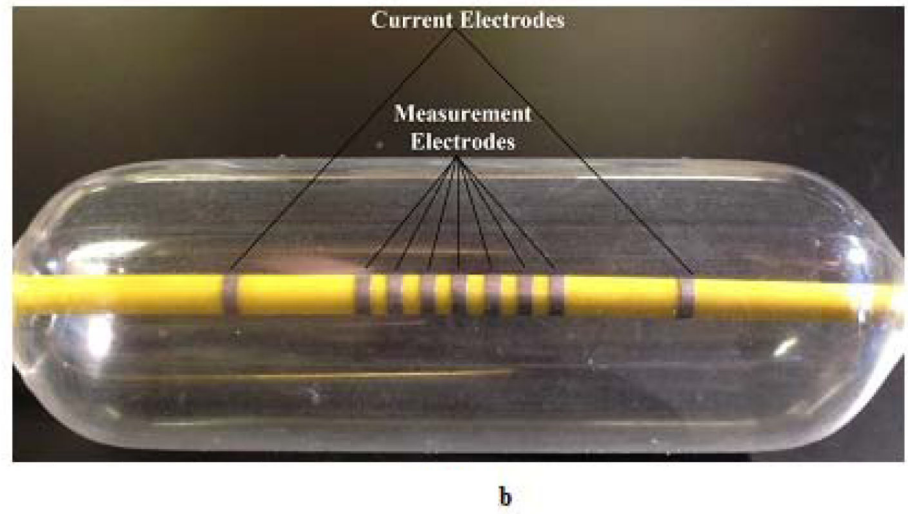


Figure 1.

The (a) SVCB catheter showing the balloon at the distal end and the electrode connector, inflation port, and over-the-wire exchange on the proximal end. The balloon (b) showing the outer electrodes used for the injection of the constant electric current and the middle electrodes used for the measurement of the balloon size through voltage measurements.

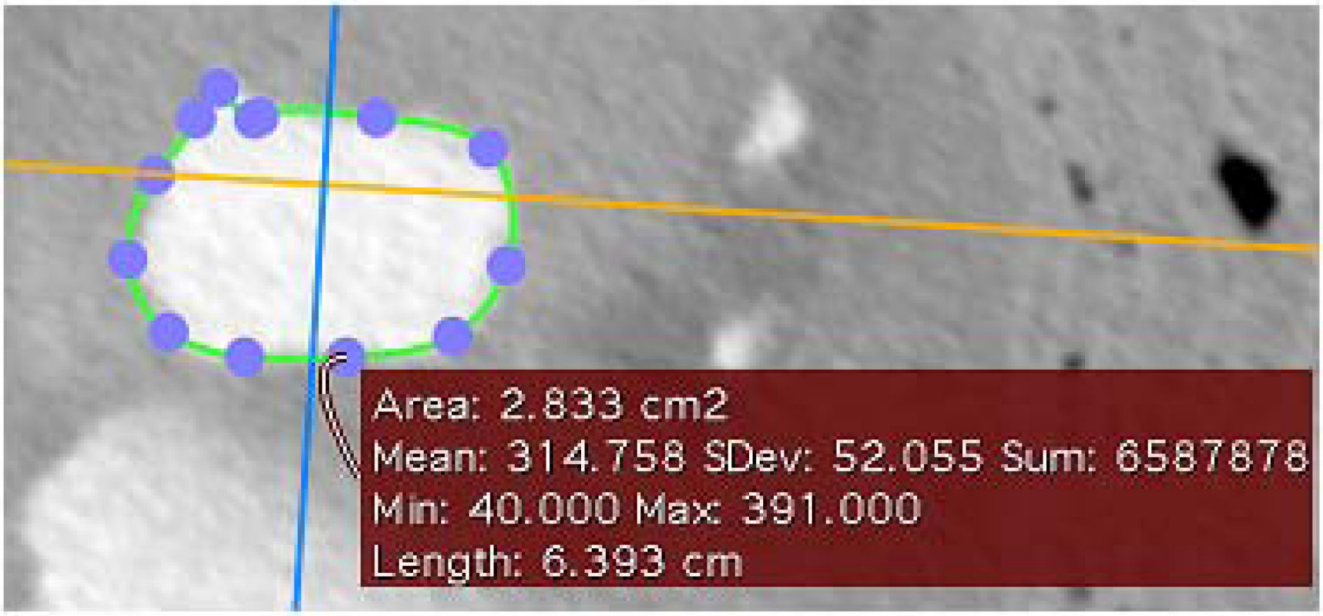


Figure 2.
CT measurement of one of the ex vivo swine hearts.

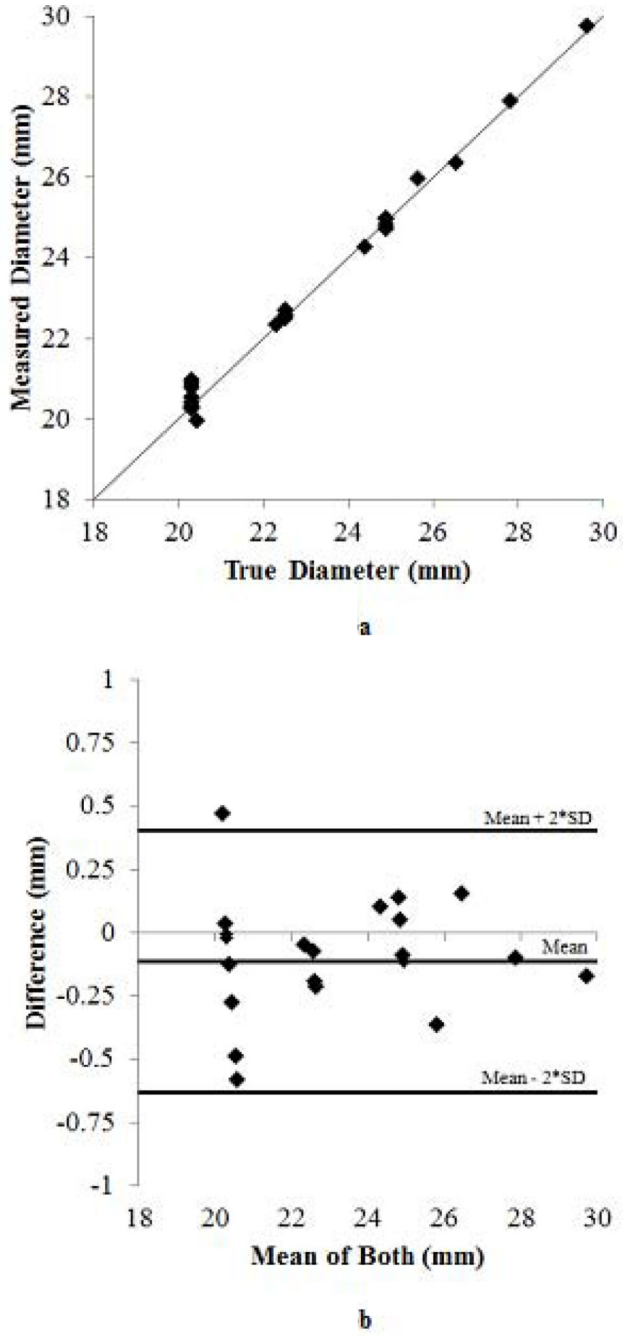


Figure 3.
SVCB catheter bench accuracy in phantoms from 20–30mm. Plot shows the (a) identity relationship between the balloon measurement and the true dimension (solid black line as the identity line) and the (b) Bland Altman analysis.

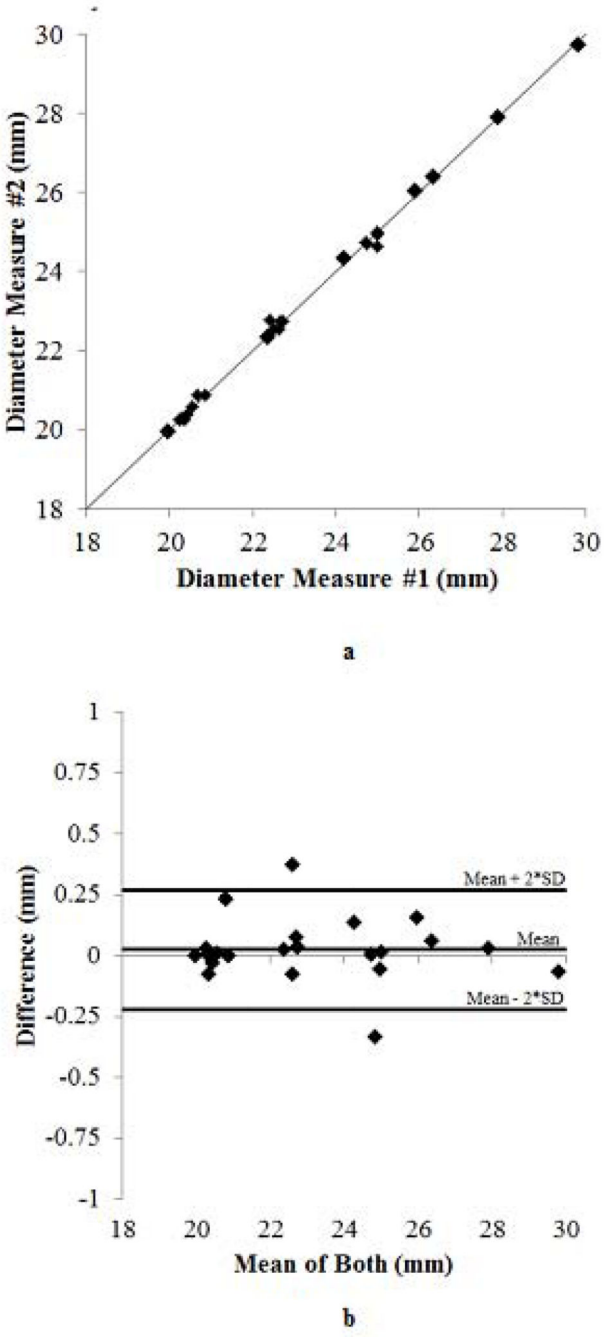


Figure 4.

SVCB catheter bench repeatability in phantoms from 20–30mm. Figure shows the (a) identity relationship between the balloon measurement and the true dimension (solid black line as the identity line) and the (b) Bland Altman analysis.

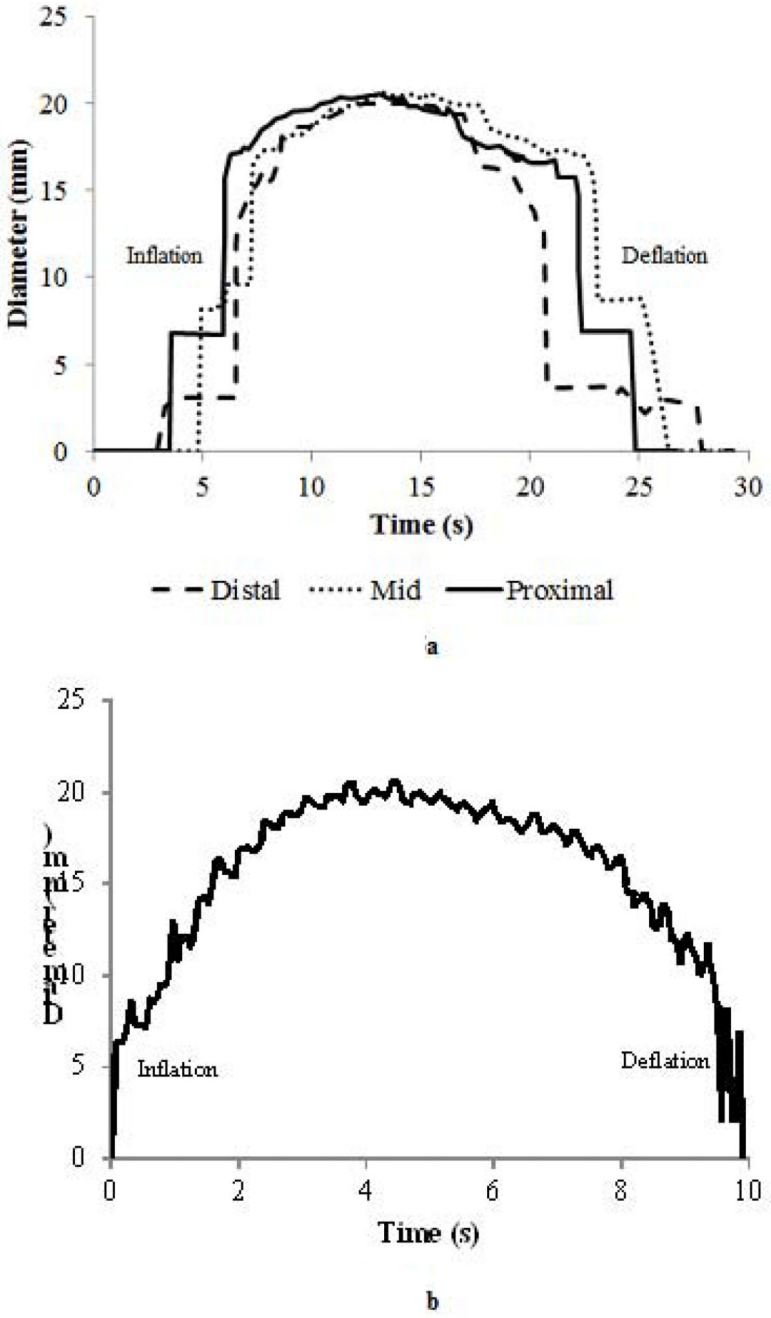


Figure 5.

Example of (a) ex vivo and (b) in vivo temporal course of the SVCB catheter diameter measurements. The ex vivo analysis (a) when making multiple measurements in a uniform 20.4mm phantom along the proximal, middle (mid), and distal portions of the catheter and the in vivo analysis (b) for a single middle measurement. Note that the oscillations shown in (b) are due to the changes in the balloon CSA due to the cardiac cycle during high rate pacing. Both the raw and processed data can be displayed in real-time.

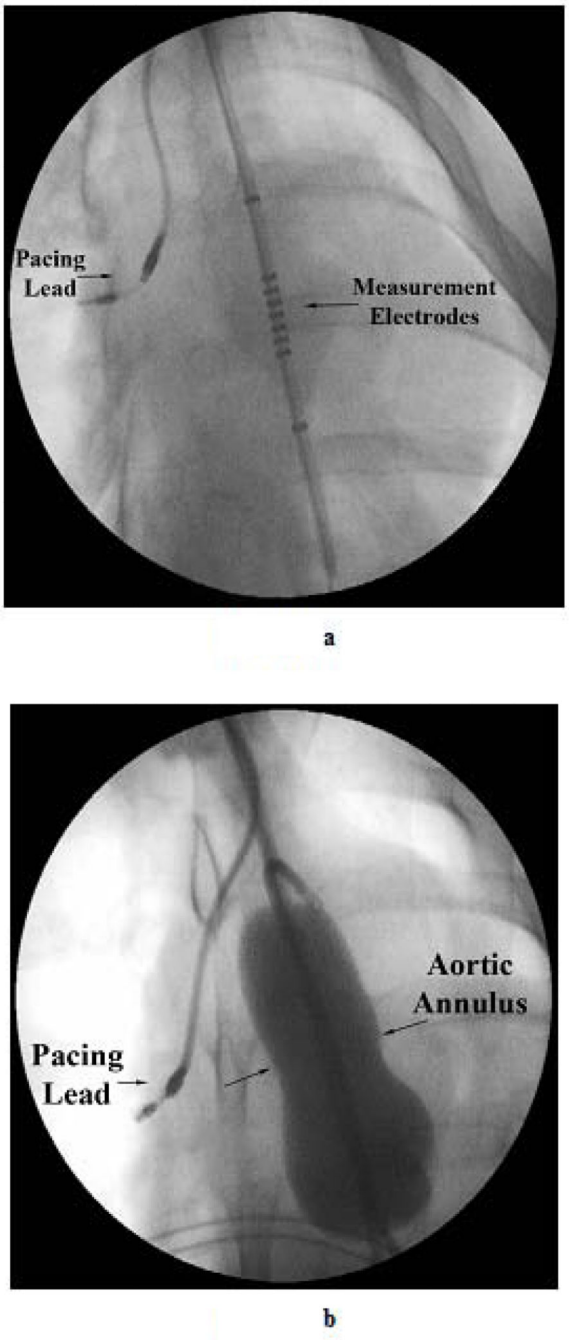


Figure 6.
SVCB catheter prior to (a) and after full inflation (b) in vivo in swine.