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Balloon-based measuring system for compliance investigations

Abstract: For the development of new stent designs, the compliance of the surrounding biological tissue has to be considered. We expect to obtain parameters for simulation, stent dimensioning, and the forces acting on the stent after implantation.

Starting point of the investigations is the commercially available Metricath system allowing cross-sectional lumen area measurements of arteries. Its working principle is based on the pressure-volume relationship using a balloon catheter, which is inflated to a specific pressure of about 250 mmHg and conforms to the shape and size of the lumen. However, for compliance charts multiple pressure levels and a larger pressure range are needed. To overcome this technical limitation, the Metricath balloon catheter is combined with a new inflation device, called pV-Monitor. The presented cross-sectional lumen area measurements in rigid tubes and compliance investigations of elastic tubes demonstrate the feasibility of the pV-Monitor system.

Keywords: compliance, pressure, volume, balloon, catheter

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1 Introduction

The knowledge of physiological *in situ* conditions is essential for the development of new cardiovascular stent designs but also numerous different fields of medical application. In addition to the geometric dimensions of the implantation site, the diameter compliance of the surrounding tissue is an important factor for stent dimensioning. It provides knowledge of the forces acting on the stent after implantation and can also be used for simulation of implants under physiological conditions.

One option for determination of the required information in the organism are measuring systems using a balloon catheter that can be advanced to the target location, e.g. the Metricath system (Angiometrx Inc., Canada). It allows the measurement of the cross-sectional lumen area and diameter of arteries before and after stent implantation at a specific balloon pressure of about 250 mmHg [1]. However, for compliance charts multiple pressure levels with a larger pressure range are needed. To overcome this technical limitation, we combine the Metricath balloon catheter with a new inflation device, called pV-Monitor.

In this study the new measuring system is described together with the calibration procedure and the basic mathematical model for pressure-diameter determination. Furthermore, the results of test measurements, including pressure-volume curves, initial diameter and compliance charts, are presented to confirm feasibility and plausibility of the pV-Monitor measurements.

2 Material and methods

2.1 Balloon Catheter

The balloon catheter Metricath Libra RX184060 (Neovasc Inc., Canada) used in this study is a part of the Metricath system for vascular measurements. Its semi-compliant balloon with a length of 6 mm is mounted on the distal tip, as seen in **Figure 1**. To specify artery lumen diameter, the nominal measurement range is between 1.8 and 4 mm. For accuracy reasons the Metricath system is limited to 40 measurements with the same balloon.

Because the working pressure in the Metricath system is 250 mmHg the balloon catheter was tested for its maximum pressure load. It was found to burst at about 4 bar. For safety reasons, our studies were limited to a maximum pressure of 2.4 bar which might cover most expected vascular conditions.

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2.2 Balloon inflation device

For this study we improved an inflation device that was originally developed for monitoring coronary balloon angioplasty. **Figure 1** illustrates the pV-Monitor with pressure unit, manually operated pump and a close-up view of the measuring balloon. The pressure range is user selectable between 2.4 or 10 bar full scale. Unless otherwise noted, all tests were carried out with a full scale of 2.4 bar and an effective resolution of about 10 mbar.

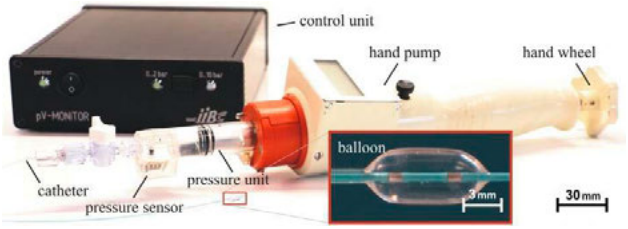

Figure 1: pV-Monitor with measuring balloon

Pressure unit: The pressure unit represents the connection between balloon catheter and pV-Monitor. A Luer-lock fitting connects the balloon catheter to the fluidic part. The pressure unit consists of several components and was originally designed as an interchangeable part due to sterilization reasons. Its cylindrical pressure chamber is fitted with a tight-fitting, frictionless piston. With a cross-sectional area of 150 mm² and a piston travel distance of about ±13 mm the available volume to inflate and deflate a balloon is ±2 ml. An integrated pressure sensor is specified to operate in a range from -1 to 10 bar for monitoring the balloon pressure.

Hand pump: The pressure unit is mechanically fixed to the hand pump. The pump is engineered to inflate the balloon with a known volume by manually rotating a hand wheel. The change of volume is 0.15 ml per revolution. Rotations and their direction are detected with incremental encoders with 360 steps per revolution. The pressure value is displayed on a small LCD display.

Control unit: The control unit is electrically connected to the hand pump. A controller is used for storing system parameters (sample rate, pressure range etc.), for preparing the pressure and volume values into digital information and for buffering the measuring data for serial data communication to the PC. For providing galvanic isolation, the control unit includes an optically isolated USB interface.

Software: The graphical user interface displays the recorded pressure over time and the balloon pressure-volume curve. For further offline analysis the data are stored in a text file. The effective sample rate is 1 Hz with an averaging of eight values per sample.

2.3 Mathematical model

Our mathematical model is based on the works of van der Giessen *et al.* [1-2]. At a specific pressure, the "Metricath equation" describes the calculation of the cross-sectional lumen area from volume calibration and measurement curves (see **Equation 1**).

$$\mathbf{A} = \frac{\pi \cdot \mathbf{BOD_{Metricath}}^2}{4} - \frac{\mathbf{CCFI - MCFI}}{\mathbf{L_{Metricath}}} \tag{1}$$

- $A = \pi \cdot (ID)^2/4$ = cross-sectional lumen area
- $BOD_{Metricath}$ = balloon specific diameter (manufacturer)
- CCFI = volume calibration curve (unrestrained)
- MCFI = volume measurement curve (restrained by the lumen)
- $L_{Metricath}$ = balloon specific length (manufacturer)
- ID = inside diameter of the lumen.

The shape of the thin-walled semi-compliant balloon in **Figure 1** is simplified in **Equation 1** to a cylindrical shell with a circular cross-sectional area. CCFI and MCFI describe the measured volume of fluid infused into the balloon catheter at a specific pressure with an unrestrained and restrained balloon, respectively. We assume that 250 mmHg is the specific pressure in the Metricath system.

2.4 Calibration cycle

Prior to measuring cross-sectional lumen area the balloon catheter is calibrated by recording the volume calibration curve CCFI in the unrestrained balloon.

The variables $BOD_{Metricath}$ and $L_{Metricath}$ in **Equation 1** are individual for each balloon catheter and were determined at 250 mmHg during manufacturing. Both variables are stored on a digital chip located at the electrical connector of the Metricath Libra balloon catheter [1].

Equation 1 also applies to other pressure ranges with pressure dependent BOD and L. To determine both variables, additional calibration steps were performed on rigid tubes (inner diameter ID < BOD) after recording CCFI. With two well-defined cross-sectional lumen areas **Equation 1** is rearranged by BOD and L as follows:

$$\mathbf{BOD} = \sqrt{\frac{4}{\pi} \cdot \frac{\mathbf{A_I \cdot (CCFI - MCFI_{II}) - A_{II} \cdot (CCFI - MCFI_I)}}{\mathbf{MCFI_I - MCFI_{II}}}} \tag{2}$$

$$\text{and } \mathbf{L} = \mathbf{4} \cdot \frac{\mathbf{CCFI - MCFI_{II}}}{\pi \cdot \mathbf{(BOD)^2 - 4 \cdot A_{II}}} \tag{3}$$

- BOD = balloon specific diameter, from calibration measurements
- L = balloon specific length, from calibration measurements
- A_I = cross-sectional area of calibration tube with ID_I

- A_{II} = cross-sectional area of calibration tube with ID_{II}
- $MCFI_I$ = volume measurement curve of calibration tube with ID_I
- $MCFI_{II}$ = volume measurement curve of calibration tube with ID_{II}

We preferred to use calibration tubes with diameters at the lower and upper end of the measurement range of the balloon. Tubes with $ID_I = 2.0$ mm and $ID_{II} = 3.5$ mm were used for calibrating Metricath Libra RX184060. **Figure 2** exemplarily shows CCFI, $MCFI_I$ and $MCFI_{II}$ calibration curves.

3 Results

3.1 Pressure-volume curves

Measurements in rigid tubes were obtained for pV-Monitor verification with predefined diameters (ID = 2.0 - 4.0 mm). **Figure 2** shows the recorded pressure-volume relationship from tubes with ID = 3.0 mm (red curve) and 3.8 mm (orange curve). The calibration curves are displayed in grey. **Figure 2** confirms the expectation that the larger the lumen diameter, the larger the measured balloon catheter volume. The upper balloon measuring limit is specified by CCFI and BOD.

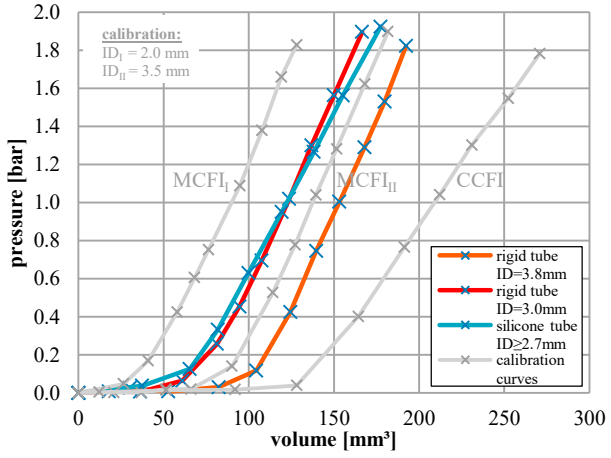

Figure 2: Pressure-volume curves of tubes including calibration

3.2 Initial diameter

The initial diameter describes lumen size as determined by imaging methods, such as intravascular ultrasound (IVUS) or quantitative coronary angiography (QCA). In order to estimate the initial diameter with the pV-Monitor, we examined the expansion of the balloon with a simple optical method in rigid tubes. A bright backlight shines through the tube and makes the state of unfolding visible. **Figure 3** illustrates two examples for the unfolding and complete filling of the tubes at low pressure.

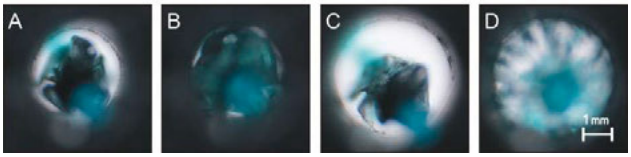

Figure 3: Estimation of initial diameters with backlight.
A&B: ID=3mm. C&D: ID=4mm. A&C: 0bar. B: 0.07bar. D: 0.09bar.

The pressure-volume curves are recorded in parallel to find the crucial pressure value when the balloon conforms to the tube size. **Table 1** lists the pressure and corresponding volume values for different diameters. The mean value is 0.08 bar and corresponds to the remarks regarding unfolding pressure (<50 mmHg) described by van der Giessen *et al.* [1]. Furthermore, **Figure 5** demonstrates the applicability of 0.08 bar for the estimation of the initial diameter with satisfactory results.

Table 1: Pressure and corresponding volume values for the estimation of the initial diameter (n = 1)

ID [mm]	pressure [bar]	volume [mm³]
2.0	-	<10
3.0	0.07	44
3.5	0.08	70
4.0	0.09	91
5.0	0.08	130
Mean ± SD	0.08 ±0.007	-

3.3 Compliance charts

Compliance investigations were performed on dip-coated and commercially available silicone tubes. The dip-coated tube in **Figure 2** and **4** (blue curve) with ID/OD = 2.7/3.0 mm is made of polycarbonate based silicone elastomer (Chronosil 80A, AdvanSource Biomaterials Corp., USA). For comparison, **Figure 4** also shows the curves of the two rigid tubes from **Figure 2**. **Equations 2** and **3** were used to calculate the lumen diameter in **Figure 4**.

The compliance as the slope of the pressure-diameter curve shows linear properties with 0.28 mm/bar for the elastic dip-coated tube. On the other hand and as expected, compliance is approximately zero for rigid tubes.

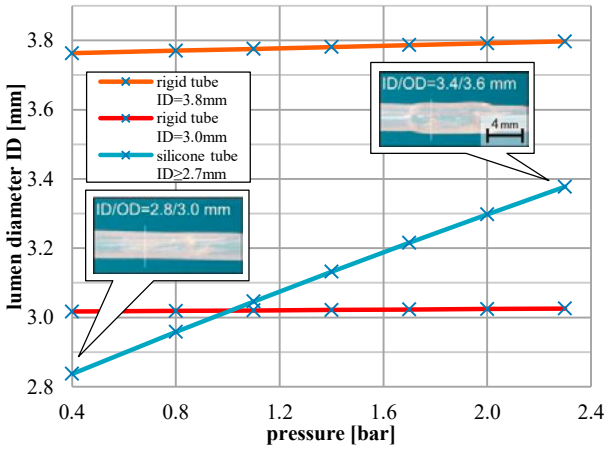

Figure 4: Compliance charts of elastic and rigid tubes

3.4 Reproducibility

The reproducibility of pV-Monitor measuring data was verified by tests on rigid tubes with several balloon catheters (n = 6). In addition, the results were compared with those obtained with the Metricath system using the same balloon catheters.

The lumen diameter of a rigid tube (ID = 3.0 mm) determined with the pV-Monitor is shown in **Figure 5** as a box plot for multiple pressure levels. Furthermore, **Figure 5** includes the diameter of the same tube analyzed with the Metricath system (at 0.33 bar). Comparison of the pV-Monitor measurements with Metricath shows relatively small differences. The median of pV-Monitor diameter measurements is about 3.02 ±0.015 mm (pressure range: 0.4-2.3 bar). However, lumen measurements show a maximum upper and lower deviation of +0.17 mm and -0.07 mm from actual ID value, respectively. This corresponds to 94 % accuracy. Lumen diameters determined by the Metricath system have a median of about 2.94 mm.

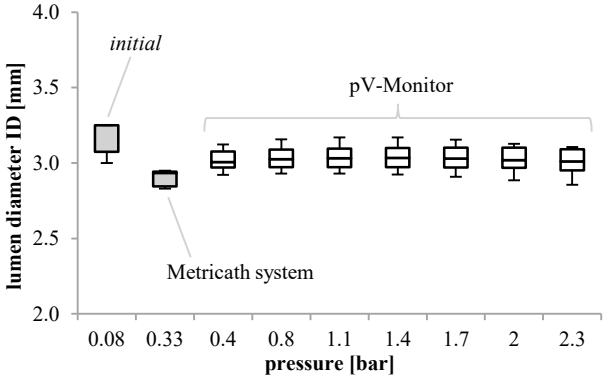

Figure 5: Diameter measurements as box plots (n = 6)

4 Discussion

This study investigated cross-sectional lumen area measurements with pV-Monitor analysis. Lumen diameter and compliance determination were feasible and reliable. We evaluated our technique with predefined lumen dimensions. Comparison of the pV-Monitor measurements with Metricath and the actual lumen diameter showed relatively small differences. In our experiments diameters determined by the Metricath system were slightly smaller than the actual value. This might be related to aging of the balloon catheter. Compared to Metricath, the presented pV-Monitor procedure performs a complete system calibration including the balloon specific variables BOD and L.

5 Conclusion

In future studies the pV-Monitor will be applied to determine the physiological compliance and dimensions of the Eustachian tube that is connecting the nasopharynx with the middle ear. These investigations will serve as a basis for the development of a Eustachian tube stent for the treatment of Eustachian tube dysfunction.

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Author Statement

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