Three dimensional optical reconstruction method for stent geometry characterisation; data validation using micro CT technique

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Introduction

In-stent restenosis remains an unsolved and important clinical problem due to the amount of neointimal hyperplasia in response to stent deployment and vessel wall injury [1]. The degree of restenosis has been suggested to relate to the magnitude of strain caused during stent implantation. Finite element models (FEM) allow researchers to investigate aspects that are difficult to solve with clinical or *in vitro* studies, but these results need to be validated with experimental data. In a previous experimental study of Walke *et al*. [2] two dimensional (2D) global characterisation of stent expansion within a polyethylene pipe was conducted. Changes in stent diameter and length were evaluated with increasing balloon pressures. Walke *et al*. showed correlation between experimental data and the results of a finite element model [2]. Deformation of the arterial surface after stent expansion *in vitro* and *in vivo* was measured by Squire *et al*. [3]. This study used 2D images of deformed reference points on the vessel to backproject onto a 3D cylindrical model for strain analysis. Recent reports have demonstrated that the study of vessel deformation in 3D is feasible [4, 5] but have not reported stent-vessel interactions. Optical 3D reconstruction techniques offer the potential to characterise vessel wall-stent interaction in high resolution and at high magnification in 3D. In our previous studies a stereo-photogrammetric 3D optical reconstruction technique investigated local strain variation in an elastic sheet under a tensile test with a field of view >30mm [6]. This paper reports the validation of the stereo optical method for full 3D reconstruction against volumetric data of expanded stents obtained using micro-CT.

Materials and Methods

Two balloon expandable 316L stainless steel alloy Taxus Express stents (Boston Scientific) were expanded to provide both partially expanded and fully expanded stent geometries. These stents had a rated inner diameter of 3.5mm and 4mm with 8mm length. The pressure in the balloon was incrementally increased in steps of 0.5atm. A clinical implantation device (Merit Medical Basix25, Ireland) was used for stent expansion. The first stent (3.5x8mm) was semi-deployed (SD) until a dog-boning effect was observed and the balloon was deflated. The second stent (4x8mm) was fully deployed (FD) and the balloon remained inflated during micro-CT scanning. Optical images of stent deployment are show in figure 1.

The 3D expanded stent geometry was assessed using both a stereo optical reconstruction method and by segmentation of stent geometry from a volumetric micro-CT dataset.

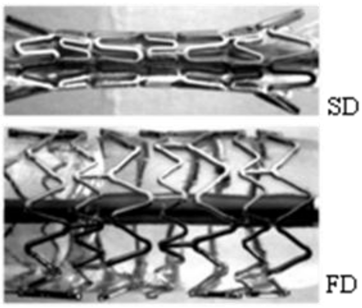
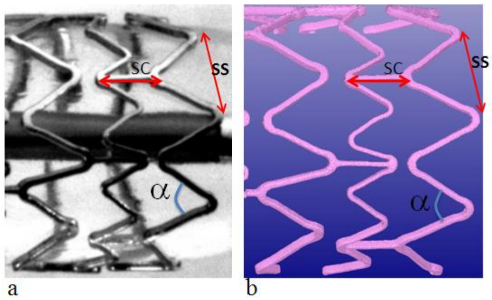


Figure 1. Left camera images of SD- semi deployed Taxus Express 3.5x8mm (p= 4.0atm) and FD- fully deployed Taxus Express 4x8mm

Stereo optical reconstruction: An experimental rig consisting of two stereoscopically positioned high resolution cameras operated with FlyCap2 software (Point Grey, Canada) was calibrated as described previously [6]. Calibration accuracy was determined through 3D reconstruction of a control object of known size. Stent expansion was imaged during balloon inflation and the calibration data was used to determine the 3D coordinates of landmark points in Matlab (Fig. 2a).

Micro-CT scanning of stent geometry: The micro-CT data was reconstructed (NRecon, Skyscan, Belgium) to provide a 3D volumetric data set for comparison with the stereo optical reconstruction. Regions of interest were selected using CTAn (CT data analyser) and 3D models were created by segmentation, using a binary threshold. The resulting surface was exported to Dimension Expert (DeskArtes) which was used to determine the 3D coordinates of the same landmark points as characterised using stereoscopic method (Fig. 2b).



a b

Figure 2. Fully deployed stent geometry. a) Optical image b) Segmented surface shown in Dimension Expert. α is inter-strut angle, SC is strut connector length, SS is strut separation distance.

The 3D coordinates of the landmarks derived from each method were used independently to calculate the length of the stent strut connections (SC), strut separation (SS) and the inter-strut angle α between the direction vectors along adjacent struts (Fig. 2a,b). The accuracy associated with hand picking of strut landmark points was estimated by repeating the measurements 7 times.

Results

During the inflation process the proximal end of the 3.5x8mm stent began to inflate as the pressure was increased to 3.5atm, at 4.0atm a dog-boning effect was observed. The proximal end of the 4x8mm stent began to inflate at a pressure of 3.75atm, with expansion of all struts when the pressure reached 4.5atm. Balloon inflation was continued to a pressure of 9atm, causing an additional increase in stent diameter of approximately 0.34mm.

The results from calibration and reconstruction accuracy assessment using a control object suggest measurement accuracy of the order 25µm. The accuracy associated with hand picking of correspondence points was of the order 16µm (the max and min magnitude of this distance between points were 31µm and 6µm respectively).

A comparison of the optical and micro-CT measurements is shown in Table 1 and Figure 3. The change in inter-strut angle (α) around the stent circumference is plotted for both stents (SD and FD) (Fig.3a,b) with comparison between the methods (Fig.3c).

		Matlab [mm]	Dimension Expert [mm]	error [%]
SD	SC	1.03	1.036	0.6
		1.046	1.037	0.9
	SS	0.745	0.731	1.9
		0.618	0.66	6.2
FD	SC	1.067	1.055	1.14
	SS	1.53	1.51	1.32
		1.48	1.46	1.36
		1.53	1.52	1.32
		1.04	1.03	0.97

Table 1. Comparison of strut connections (SC) and strut distance (SS) evaluated using optical and micro-CT methods for both (SD) semi-deployed stent and (FD) fully-deployed stent

Discussion

Good correlation between results obtained from 3D optical reconstruction and micro-CT was observed. Independently determined measurements of the value of inter-strut angle around the circumference at one point along the length were compared between the two techniques. In all cases the calculation of inter-strut angle agrees to within 97%. A maximum difference of approximately 5° was computed for the SD stent. This variation occurs for a single measure where the strut is at an angle to the camera, resulting in reflections which compromise the ability to judge strut location. However, the average difference between the angles was approximately 2°. This comparison of the inter-strut angle calculated by both optical reconstruction and micro-CT confirms the accuracy of the data obtained from the stereo-photogrammetric method. Note a regression line (Fig.3c) indicates an agreement between the two techniques (R^2=0.9882). All optical measures of struts connection (SC) length agree to within +/- 1.5% of the micro-CT data. Larger errors are seen for the strut separation (SS) due to the difficulty in selecting the same landmarks in the curved surface using both techniques.

The results are encouraging given the additional uncertainty introduced when defining landmark points between two different reconstruction methods. This method has been shown to provide a full

3D description of stent geometry which agrees well with volumetric data. The advantage of the optical technique is that images can be collected dynamically throughout the stent expansion process.

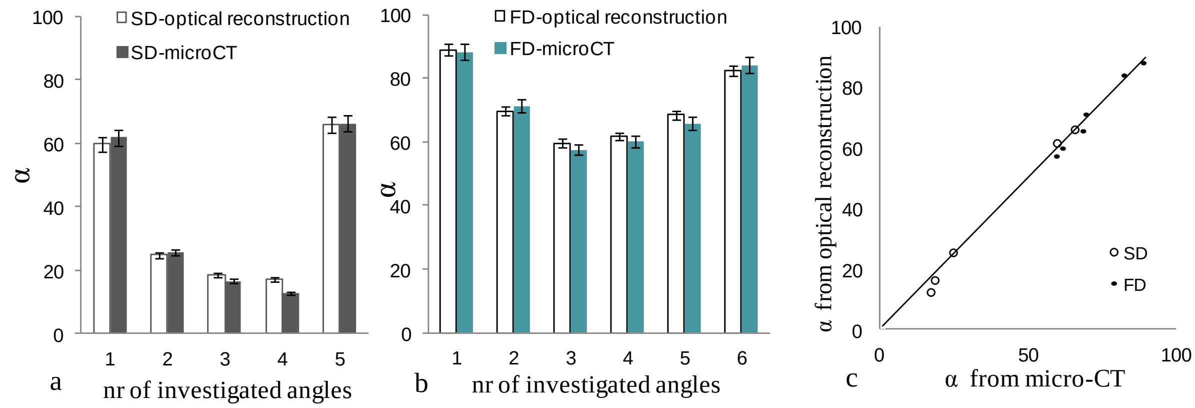


Figure 3. Variation of inter-strut angle (α) around the circumference of the stent for both a) the semi-deployed (SD) and b) fully deployed (FD) stents, evaluated using both optical and micro-CT measures of strut geometry; c) comparison of the inter-strut angle results calculated by both, optical reconstruction and micro-CT.

Conclusion

An optical method to measure 3D local stent geometry during *in vitro* expansion has been presented and compared with volumetric micro-CT data. The results demonstrated good agreement between the two techniques. Further improvement in accuracy may be achieved through automated detection of landmarks using image processing techniques. The methods have been employed at coronary stent length scales and hence are appropriate for extension to the study of stent-vessel wall interaction.

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