

**CROSPON™**

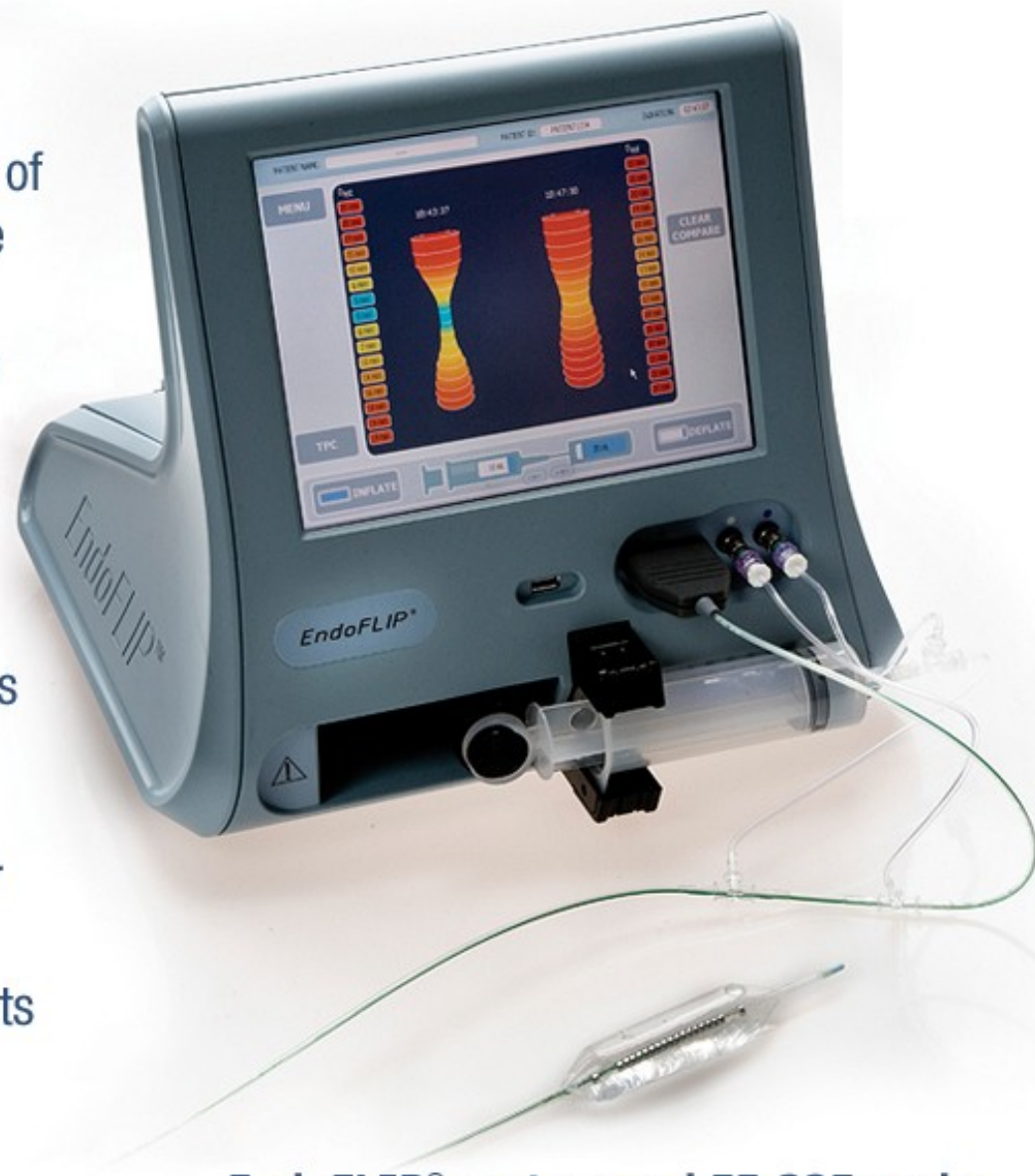


# Measuring the Diameter of the Aortic Valve Using the EndoFLIP® Endolumenal Measurement Catheter

*EndoFLIP*®   
Endolumenal Functional Lumen Imaging Probe

## Introduction

There exist challenges in the accurate sizing of percutaneous arterial valve prostheses, since standard valve sizers can no longer be used for such procedures, leading to a reliance on non-invasive techniques such as TEE and CAT which give conflicting results. We have used EndoFLIP® (Crospon, Galway, Ireland), a new endolumenal measurement catheter, to measure the diameter of the aortic annulus of embalmed cadaver hearts. We sought to investigate the ability of the EndoFLIP® catheter to accurately measure this diameter by comparing the diameter measurements recorded using EndoFLIP® with measurements taken using traditional mechanical sizers.



EndoFLIP® system and EF-325 probe

## Method

11 human embalmed cadaver hearts were selected for this study. An EndoFLIP<sup>®</sup> model EF-325 balloon catheter was used, which has a solid state pressure sensor and 16 diameter measurement electrodes. Diameter is measured electrically using the principle of impedance planimetry, which permits the balloon pressure to be independently set to a desired distending pressure, and the valve diameter to be measured at that pressure. The balloon was inserted through the aorta into the right ventricle and positioned so that it was centred at the valve cusps. The balloon was then successively inflated to pressures between 30 and 130mmHg to obtain the annulus diameter at each pressure. The valves were then measured using the mechanical sizers. The sizers were capable of giving measurements in 1-mm increments.

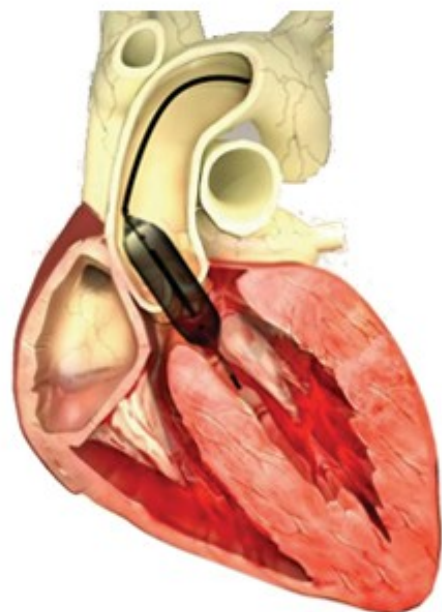
## Results

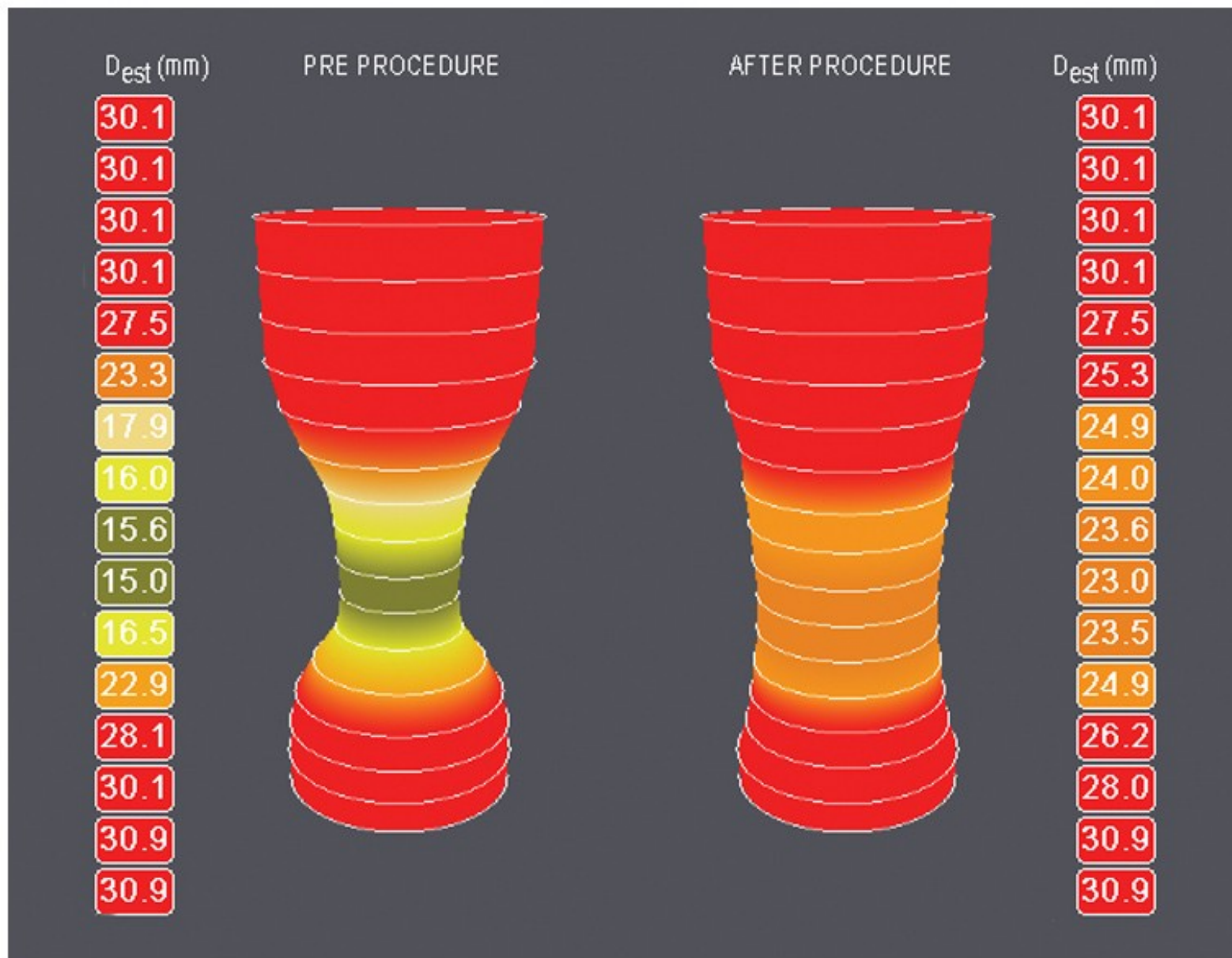
An analysis of the data, at each pressure tested, produced the following table:

Pressure (mmHg)	Mean Difference (EndoFLIP® - Sizer) (mm)	95% Confidence Interval	Standard Error
30	-4.33	-6.474 to -2.192	0.9827
50	-2.492	-4.297 to -0.686	0.8289
70	-1.221	-2.809 to 0.367	0.7287
90	-0.891	-2.368 to 0.586	0.6779
95	-0.674	-2.105 to 0.757	0.6566
100	-0.652	-2.078 to 0.775	0.6546
105	-0.638	-2.059 to 0.784	0.6523
110	-0.546	-1.922 to 0.830	0.6316
115	-0.164	-1.61 to 1.282	0.6569
120	0.066	-1.358 to 1.491	0.6394
130	0.255	-1.143 to 1.652	0.6271

## Conclusion

At pressures of 90mmHg and above the difference between the EndoFLIP<sup>®</sup> measurements and mechanical sizer measurements is not statistically different. Optimum accuracy is obtained at 120mmHg balloon inflation pressure. Current efforts are being directed at integrating the EndoFLIP<sup>®</sup> technology into the balloon valvuloplasty apparatus such that the optimal valve diameter can be selected once the valvuloplasty has been completed.





## Disclosures

D. Nolan, Crospon Ltd., Company/Organization, A. Employment;

J. O'Dea, Crospon Ltd, Company/Organization, A. Employment;  
Crospon Ltd, Company/Organization, E. Ownership Interest;

R. Reilly, None.