INTRODUCTION

- Transcatheter heart valves function optimally when expanded to specific dimensions.
- Clinicians may sometimes wish to over-expand balloon-expandable valves to address specific clinical challenges.
- The implications of over-expansion have assumed considerable importance, and objective information to guide practice is limited.
- We assessed the effect of over-expansion beyond labelled size (diameter) of transcatheter heart valves through an ex-vivo bench study.

METHODS

- We evaluated SAPIEN 3 transcatheter heart valves (Edwards Lifesciences Inc., Irvine, California).
- Valves (23mm, 26mm and 29mm diameter) were expanded to nominal dimensions, and then incrementally over-expanded with balloons sized 1.2, and 3mm larger than the recommended diameter.
- Valves underwent visual, micro-CT, and hydrodynamic evaluation at various degrees of over-expansion.

Ex-vivo bench testing methodology

RESULTS

- SAPIEN 3 valves with labelled diameters of 23mm, 26mm and 29mm could be incrementally over-expanded to mid-valve diameters of 26.4mm, 28.4mm and 31.2mm, respectively.
- With over-expansion, there was visible restriction of the valve leaflets, which was particularly evident with the smaller valves.
- After maximal over-expansion of a 26mm valve a leaflet tear was observed.
- High speed video demonstrated impaired leaflet motion of the 23mm and 26mm valves and hydrodynamic testing documented a regurgitant fraction for the 23mm and 26mm valves above accepted international standards. The maximally over-expanded 29mm S3 still had relatively normal leaflet motion and excellent hydrodynamic function.

THVs expanded to nominal size and incrementally over-expanded with 1, 2, and 3mm larger diameter balloons

CONCLUSIONS

- Over-expansion of balloon-expandable valves is possible.
- Excessive over-expansion may be associated with impaired hydrodynamic function, acute leaflet failure, and reduced durability.
- Smaller valves may be at greater risk with over-expansion than larger valves.
- Over-expansion is best avoided unless clinical circumstances are compelling.