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RESEARCH LETTER

Computational Fluid Dynamics Analysis of a New Dissection Specific Stent Graft with the Aim to Prevent Distal Stent Graft Induced New Entry (dSINE)

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A major challenge in treating aortic dissection is unsatisfactory compliance of the distal portion of stent grafts in a dissected aorta. Distal stent graft induced new entry (dSINE), as a consequence of the aortic tissue injury around the distal end of the stent graft, is being reported increasingly.[1] To improve the compliance level of standard thoracic stent grafts (STSGs) in aortic dissection, a novel dissection specific stent graft (DSSG) was developed based on the Zenith Alpha Thoracic platform (Cook Medical Europe, Bjaeverskov, Denmark).[2] The first key feature of the DSSG is customisation of diameters and lengths with substantial tapering (usually $\geq$ 10 mm) to accommodate individual anatomy with no proximal barbs. Additionally, the second and third Z stents have reduced radial force (2.7 – 4.8 N compared with 7.0 – 7.6 N in the standard Alpha Thoracic platform) and are sited internally. Finally, the most distal stent is removed, leaving 30 mm of unsupported Dacron fabric ("endovascular elephant trunk"). As a result, only the DSSG fabric is in direct contact with the inner aortic wall at the distal part of the DSSG. All these features, while restricting the radial outward force at the distal end, contribute to the enhanced flexibility and conformability of the DSSG, thereby improving compliance of the DSSG compared with the STSG.

Sixteen chronic type B aortic dissection (cTBAD, defined chronic if $>$ 90 days from the inciting event[3]) patients, with maximum aneurysm diameter $\geq$ 6.0 cm or growth rate $\geq$ 1.0 cm over 12 months, were treated with the DSSG between January 2017 and January 2020. Use of DSSG was considered in the presence of risk factors for dSINE: (1) narrow true lumen of the distal landing zone; (2) documented connective tissue disorder; and (3) history of dSINE from a previous procedure. In a recent analysis of these 16 patients, the rate of dSINE (6%) was lower than the rate of dSINE with STSGs (up to 28%[1]), with satisfactory aortic remodelling during follow up. Based on this finding, it was hypothesised that differences in the DSSG geometry produce different local wall shear stress (WSS) distributions compared with those of the STSG, causing a reduction in dSINE occurrence. The hypothesis was then tested using computational fluid dynamics (CFD) simulation.

For the present study, 14 (out of 16) DSSG patients who had a good quality post-TEVAR and follow up imaging available for the analysis were enrolled. Three cTBAD patients treated at a different institution with a 4 mm tapered STSG (Valiant Captivia Thoracic Stent Graft; Medtronic, Inc., Santa Rosa, CA, USA), in whom dSINE was detected, were selected for comparison. The primary measurement from CFD analysis was the magnitude of the wall shear stress (WSS).

In all STSG patients at one month follow up, the uncovered aorta segment (in the region where the future dSINE was observed in the follow up imaging) yielded a higher WSS. The mean WSS gradient (WSS-G) in the transition zone (STSG distal end to uncovered native aorta) was 24.9 dyne/cm^2. In the DSSG group, however, the WSS values in the uncovered native aortic segment were lower than those in the most distal elephant trunk region. Instead, the high mean WSS-G of 20.2 dyne/cm^2 was observed inside the stent covered aortic segment between the reduced radial force segment and endovascular elephant trunk segment. Figure 1 shows differences in the occurrence site of high WSS regions between STSG (uncovered native aortic segment) and DSSG (covered aortic segment). After 12 months follow up, unchanged WSS and WSS-G patterns were found for both the DSSG and STSG groups.

Of note, the mean volume of the elephant trunk region increased from 9.02 cm^3 at one month follow up to 13.77 cm^3 at 12 months (p = .004). This finding implies that the elephant trunk region, which is an unsupported Dacron graft segment, is sufficient to keep the true lumen open and expanded, thereby improving stent graft flexibility and conformability that can help to decrease the risk of dSINE while promoting aortic remodelling.

Another aspect worth mentioning here is the association between dSINE and landing aortic segment tortuosity,

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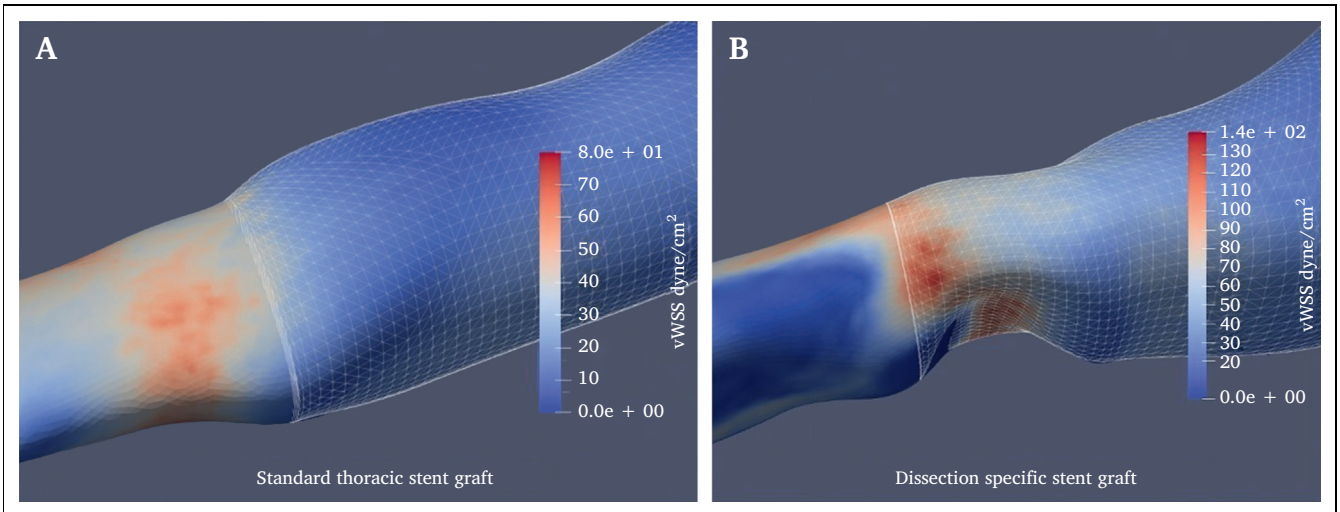

Figure 1. Wall shear stress (WSS) distribution map of standard thoracic stent graft (A) and of dissection specific stent graft (B), showing differences in the occurrence site of high WSS regions: uncovered native segment of the aorta (distal to the stent graft) in the standard thoracic stent graft cases *vs.* covered segment of the aorta in the dissection specific stent graft cases (inside the stent graft).

which was measured by the distal attachment zone angle (defined as the transition angle between stented aortic segment and native uncovered aortic segment). The only dSINE case of the DSSG group had a more acute distal attachment zone angle of 136°, whereas the median in the DSSG group was 167.9° (IQR 159.1°, 169.1°), suggesting greater angulation caused greater outward force on the aortic wall resulting in dSINE.

The main limitation of this study is small sample size, especially within the control group. Another important limitation is the lack of patient specificity for the boundary conditions, which may affect the accuracy of the simulations. However, as the current study focuses on probing the DSSG *vs.* STSG configurations in respect to their haemodynamic properties, the present authors believe that the reported WSS measurements provide validity evidence to support the effectiveness of DSSG. What can be noted from the present study is the potential use of this new DSSG as a platform upon which to build.

In conclusion, being geometrically enhanced with reduced radial force, the DSSG induces changes in shear stress distribution different from those with standard stent grafts, transitioning high WSS zones into the stent covered aorta. This transition may help prevent intimal injury and consequent dSINE development.

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