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Numerical models for assessing the risk of leaflet thrombosis post-transcatheter aortic valve-in-valve implantation

Romina Plitman Mayo, Halit Yaakobovich, Ariel Finkelstein, Shawn C. Shadden and Gil Marom

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Review timeline
Original submission: 18 October 2020
Revised submission: 18 November 2020
Final acceptance: 20 November 2020

Note: Reports are unedited and appear as submitted by the referee. The review history appears in chronological order.

Note: This manuscript was transferred from another Royal Society journal with peer review.

Review History

RSOS-201838.R0 (Original submission)

Review form: Reviewer 1

Is the manuscript scientifically sound in its present form?
Yes

Are the interpretations and conclusions justified by the results?
Yes

Is the language acceptable?
Yes

Do you have any ethical concerns with this paper?
No

Have you any concerns about statistical analyses in this paper?
No

Recommendation?
Accept as is

Comments to the Author(s)
All of my original concerns have been addressed by the authors.

Review form: Reviewer 2

Is the manuscript scientifically sound in its present form?
Yes

Are the interpretations and conclusions justified by the results?
Yes

Is the language acceptable?
Yes

Do you have any ethical concerns with this paper?
No

Have you any concerns about statistical analyses in this paper?
No

Recommendation?
Accept with minor revision (please list in comments)

Comments to the Author(s)
The authors proposed a revised version of their numerical work answering to the doubt and the criticisms made by the reviewer. Nevertheless, one aspect is still unclear.

If the reviewer has understood correctly for both the devices (i.e the Evolut and the Sapien valve) the leaflets open geometry is achieved through the same strategy,that is the application of a uniform pressure ramp onto the ventricular leaflet surface. The reviewer finds reasonable the geometry obtained for the Sapien valve, since the device geometry is symmetric. Nevertheless, some perplexities arise from the shape assumed by the leaflets of the Evolut device which is markedly not symmetric. Is this problem related to the deformed geometry of the stent or to the mechanical properties of the leaflets? Please add some comments also regarding the constitutive behavior prescribed in the model.

Decision letter (RSOS-201838.R0)

We hope you are keeping well at this difficult and unusual time. We continue to value your support of the journal in these challenging circumstances. If Royal Society Open Science can assist you at all, please don't hesitate to let us know at the email address below.

Dear Dr Plitman Mayo

On behalf of the Editors, we are pleased to inform you that your Manuscript RSOS-201838 "Numerical Models for Assessing the Risk of Leaflet Thrombosis Post-Transcatheter Aortic Valve-in-Valve Implantation" has been accepted for publication in Royal Society Open Science subject to

minor revision in accordance with the referees' reports. Please find the referees' comments along with any feedback from the Editors below my signature.

We invite you to respond to the comments and revise your manuscript. Below the referees' and Editors' comments (where applicable) we provide additional requirements. Final acceptance of your manuscript is dependent on these requirements being met. We provide guidance below to help you prepare your revision.

Please submit your revised manuscript and required files (see below) no later than 7 days from today's (ie 16-Nov-2020) date. Note: the ScholarOne system will 'lock' if submission of the revision is attempted 7 or more days after the deadline. If you do not think you will be able to meet this deadline please contact the editorial office immediately.

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Thank you for submitting your manuscript to Royal Society Open Science and we look forward to receiving your revision. If you have any questions at all, please do not hesitate to get in touch.

Kind regards,
Andrew Dunn
Royal Society Open Science Editorial Office
Royal Society Open Science
openscience@royalsociety.org

on behalf of Prof R. Kerry Rowe (Subject Editor)
openscience@royalsociety.org

Associate Editor Comments to Author:
Well done on thoroughly addressing the referees' concerns in this transferred paper - only one comment remains from one of the reviewers, and we would like you to tackle this before a final acceptance can be issued. Thanks in advance.

Reviewer comments to Author:
Reviewer: 1

Comments to the Author(s)
All of my original concerns have been addressed by the authors.

Reviewer: 2

Comments to the Author(s)
The authors proposed a revised version of their numerical work answering to the doubt and the criticisms made by the reviewer. Nevertheless, one aspect is still unclear.

If the reviewer has understood correctly for both the devices (i.e the Evolut and the Sapien valve) the leaflets open geometry is achieved through the same strategy,that is the application of a uniform pressure ramp onto the ventricular leaflet surface. The reviewer finds reasonable the geometry obtained for the Sapien valve, since the device geometry is symmetric. Nevertheless, some perplexities arise from the shape assumed by the leaflets of the Evolut device which is markedly not symmetric. Is this problem related to the deformed geometry of the stent or to the

mechanical properties of the leaflets? Please add some comments also regarding the constitutive behavior prescribed in the model.

===PREPARING YOUR MANUSCRIPT===

Your revised paper should include the changes requested by the referees and Editors of your manuscript. You should provide two versions of this manuscript and both versions must be provided in an editable format:
one version identifying all the changes that have been made (for instance, in coloured highlight, in bold text, or tracked changes);
a 'clean' version of the new manuscript that incorporates the changes made, but does not highlight them. This version will be used for typesetting.
Please ensure that any equations included in the paper are editable text and not embedded images.

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===PREPARING YOUR REVISION IN SCHOLARONE===

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Attach your point-by-point response to referees and Editors at Step 1 'View and respond to decision letter'. This document should be uploaded in an editable file type (.doc or .docx are preferred). This is essential.

Please ensure that you include a summary of your paper at Step 2 'Type, Title, & Abstract'. This should be no more than 100 words to explain to a non-scientific audience the key findings of your research. This will be included in a weekly highlights email circulated by the Royal Society press office to national UK, international, and scientific news outlets to promote your work.

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2) A 'clean' version of the new manuscript that incorporates the changes made, but does not highlight them.

-- An individual file of each figure (EPS or print-quality PDF preferred [either format should be produced directly from original creation package], or original software format).
-- An editable file of each table (.doc, .docx, .xls, .xlsx, or .csv).
-- An editable file of all figure and table captions.
Note: you may upload the figure, table, and caption files in a single Zip folder.
-- Any electronic supplementary material (ESM).
-- If you are requesting a discretionary waiver for the article processing charge, the waiver form must be included at this step.
-- If you are providing image files for potential cover images, please upload these at this step, and inform the editorial office you have done so. You must hold the copyright to any image provided.
-- A copy of your point-by-point response to referees and Editors. This will expedite the preparation of your proof.

At Step 6 'Details & comments', you should review and respond to the queries on the electronic submission form. In particular, we would ask that you do the following:
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Author's Response to Decision Letter for (RSOS-201838.R0)

See Appendix A.

Decision letter (RSOS-201838.R1)

We hope you are keeping well at this difficult and unusual time. We continue to value your support of the journal in these challenging circumstances. If Royal Society Open Science can assist you at all, please don't hesitate to let us know at the email address below.

Dear Dr Plitman Mayo,

It is a pleasure to accept your manuscript entitled "Numerical Models for Assessing the Risk of Leaflet Thrombosis Post-Transcatheter Aortic Valve-in-Valve Implantation" in its current form for publication in Royal Society Open Science.

Please ensure that you send to the editorial office an editable version of your accepted manuscript, and individual files for each figure and table included in your manuscript. You can send these in a zip folder if more convenient. Failure to provide these files may delay the processing of your proof. You may disregard this request if you have already provided these files to the editorial office.

Due to rapid publication and an extremely tight schedule, if comments are not received, your paper may experience a delay in publication. Royal Society Open Science operates under a continuous publication model. Your article will be published straight into the next open issue and this will be the final version of the paper. As such, it can be cited immediately by other researchers. As the issue version of your paper will be the only version to be published I would advise you to check your proofs thoroughly as changes cannot be made once the paper is published.

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Thank you for your fine contribution. On behalf of the Editors of Royal Society Open Science, we look forward to your continued contributions to the Journal.

Best regards,
Lianne Parkhouse
Editorial Coordinator
Royal Society Open Science
openscience@royalsociety.org

on behalf of Professor R. Kerry Rowe (Subject Editor)
openscience@royalsociety.org

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Appendix A

Response to Decision Letter – Manuscript ID RSOS – 201838

Dear Prof. Rowe,

We thank you for accepting our manuscript in the Journal of the Royal Society Open Science. We have addressed the remained comment of Reviewer 2, our answer is given below and the changes are highlighted in the final submission draft. We also changed the reference style to Vancouver with DOI for all the journal articles.

Answer to Reviewer:

If the reviewer has understood correctly for both the devices (i.e the Evolut and the Sapien valve) the leaflets open geometry is achieved through the same strategy, that is the application of a uniform pressure ramp onto the ventricular leaflet surface. The reviewer finds reasonable the geometry obtained for the Sapien valve, since the device geometry is symmetric. Nevertheless, some perplexities arise from the shape assumed by the leaflets of the Evolut device which is markedly not symmetric. Is this problem related to the deformed geometry of the stent or to the mechanical properties of the leaflets? Please add some comments also regarding the constitutive behavior prescribed in the model.

We thank the reviewer for the comment. The deployed configuration of the Evolut is greatly influenced by the arch of the ascending aorta, leading to an asymmetric deployed configuration. As a result, the open configuration of the Evolut leaflets is also asymmetric. We have added a sentence clarifying this issue.

Additionally, we have added to the manuscript that the material model of the leaflets was defined as linear elastic.