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Peer Review File

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Reviewer A:

The authors describe the IDEAL approach to evaluating surgical innovation.

It adds no new insights into why IDEAL is not more widely adopted nor identified any novel solutions to the current recognised limitations of the IDEAL. Framework. Such as selection biases and inability to account for individual surgeon expertise and performance. Unlike a pharmaceutical trial surgery has many more variable, the largest being the surgeon. RCTs in robotic surgery such as the Lacey paper by Yaxley et so have not been able to show benefits from robotics and yet that institution no longer does open surgery as a routine.

Reply: We thank the reviewer for their comments. We agree that accounting for surgeon skill is a challenging component of formal evaluation in surgical studies. Thankfully progress is being made in this area. We have added a paragraph discussing these points on Pages 11-12, lines 229-237.

Minor comment, proctor for an attending surgeon is an outdated term. Preceptor is more commonly accepted and indicates someone who gives advice and can take over when/if required. The Oxford English definition of a proctor is someone who is an adjudicator and therefore oversees and assesses but does not give assistance or help.

Reply: The word proctor has been revised to preceptor throughout the manuscript (Page 8, line 158; Page 10, line 208).

Reviewer B:

This provides a summary of the current thinking around how surgical innovation occurs. It seems more like a review article than an original piece of research. Whilst in the context of robotic surgery - specific detail for a named procedure and maybe some flow diagrams summarising the pathway would help

Reply: We thank the reviewer for their constructive comments. The reviewer is correct that this is a review article and not an original piece of research. We modified the article throughout to describe development and implementation of a robotic distal pancreatectomy (Page 6, lines 108-111; Page 8, lines 162-165; Page 9, lines 168-169 and lines 184-188; Page 10, lines 195-198; Page 12, lines 244-246). We will also update the table to the 2019 IDEAL framework for additional clarity on the pathway (Page 4, line 78).

Reviewer C:

In this review article, the authors presented the surgical innovation process of a hypothetical robotic approach using the IDEAL framework. It is very well organized. However, there were several issues to be addressed to meet the criteria of this journal.

Comment 1:

To the best of my knowledge, the 2009 version didn't include the 'Pre-clinical Stage'. The mentioned stages in the manuscript come from the 2019 version (PMID: 29697448).

It is ok that the authors cite the 2009 version in this sentence "The most well-cited framework, the IDEAL framework, consists of multiple stages describing surgical innovation and proposes methods, interventions, and outcomes that should be utilized at each stage to assure patient safety and innovation efficacy", as the authors are reviewing the history.

However, please cite the 2019 version in this sentence "With these considerations in mind, we will discuss the innovation life cycle of a hypothetical new robotic approach using the IDEAL framework to highlight issues of patient safety and efficacy".

Meanwhile, I see the note in the file mentioned "Have an email out to get permission to use this table (will get a clearer version)". Since table 1 is from 2009 version, and the full text is organized according to the 2019 version, the current version of table 1 no longer needs to seek copyright. I suggest the author replace it with the 2019 version of the table and re-claim the copyright.

Reply: We thank the reviewer for their comments. The reviewer is correct that the 2009 IDEAL report did not include the pre-clinical stage. We added the 2019 IDEAL reference on Page 4, line 78 and to the concluding sentence of the introduction section (Page 5, line 95). Further, we have submitted a formal request for permission to use the 2019 IDEAL framework for table 1 (Page 4, line 78).

Comment 2:

The authors wanted to describe the implementation of robotic surgery example to present the innovative process of surgery. This is very nice. However, after reading through the entire text, I found that the content did not go into detail about the 6 stages of innovation in the context of robotic surgery. The content reads up with very little about robotic surgery and more of a generic description. I would suggest that examples could be used in each section to go into detail on how robotic surgery exemplifies these

ideas and if there are some particular areas that need attention.

Reply: We have revised the article and have provided more specific references to robotic surgery/distal pancreatectomy throughout the manuscript (Page 6, lines 108-111; Page 8, lines 162-165; Page 9, lines 168-169 and lines 184-188; Page 10, lines 195-198; Page 12, lines 244-246).

Comment 3:

Surgical innovations must be cost-effective and justifiable from an economic point of view. As for robotic surgery, it may need a high level of expertise and has elevated costs that have limited its widespread use. In addition, training for the surgeon planning to perform the new procedure also may be costly. The authors could kindly describe the cost considerations in Stage 3.

Reply: This is an excellent point and we added content to address this topic. In the IDEAL framework, cost-effectiveness studies should initially be included in the pre-clinical evaluation stage. A comment on this has been added to the pre-clinical stage section (Page 7, lines 136-142) and the stage 3 section (Page 11, lines 219-220).

Comment 4:

Surgical innovation is critical to advances in surgery. However, surgical innovation also raises a series of ethical issues that challenge the professionalism of surgeons. The authors mentioned in Stage 1 (institutional review board approval). Meanwhile, the other ethical issue, including the potential conflicts of interest (between surgeons and industry) should also be considered.

Replay: We added a brief discussion of conflicts of interest between industry and surgeons on Page 9 lines 147-152 and lines 156-157. A more in-depth discussion of the ethical issues surrounding surgical innovation is outside the scope of this article and discussed further in another article within the journal series on surgical innovation.