Reviewer’s report

Title: Prospective international multicenter observational study of Novosyn® Quick for skin closures in adults and children (SKINNOQ)

Version: 1 Date: 07 Feb 2019

Reviewer: Stephen Chapman

Reviewer's report:

Thank you for the opportunity to revisit this manuscript.

Most of the comments have been addressed very well. I thank and congratulate the authors.

The remaining concern still relates to my comment below:

4) In the statistical analysis section, a finding of equivalence to Vicryl® Rapide is prospectively used to indicate safety and effectiveness. I am afraid this is too strong. In the setting of a non-controlled, observational study, equivalence cannot be proven (to assess this reliably would implicate a non-inferiority RCT). I would suggest that this be toned down to reflect a more balanced conclusion (i.e. absence of excessive adverse events).

The justification of sample size has been appropriately adjusted - I agree that in a non-comparative, un-controlled, observational study, a sample of 100 is reasonable to explore safety. However, the conclusion of "effectiveness" in the abstract and full-text remains too strong. Effectiveness implies that a generalisable benefit has been statistically proven in an appropriately-powered trial. I refer the authors to the IDEAL Framework for stages of innovation in surgical procedures and devices: http://www.ideal-collaboration.net/framework/

From this data, the intervention appears safe. According to the framework, the next stage would be to embark on a randomised assessment.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Unable to assess
Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

No

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
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I am able to assess the statistics

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

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