Reviewer’s report

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

Version: 0 Date: 03 Dec 2018

Reviewer: Stephen Chapman

Reviewer's report:

Many thanks for the opportunity to review this manuscript, which I enjoyed reading. A multi-centre, observational study of Novosyn® suture material in adult and paediatric populations is presented.

The manuscript is well reported and aligns well with the prospective study protocol (NCT02680886). There are no identified ethical concerns and the topic is clinically important.

I have several comments and suggestions, which you may wish to consider and clarify in your revisions:

1) As with any new surgical device, a period of familiarisation/learning curve is important. Did the surgeons (n=1 for adult population; n=7 for paediatric population) have the opportunity to familiarise themselves with the suture handling prior to using it in the study? Please describe this process further.

2) I note that the method of suturing (continuous & interrupted) was not standardised. Similarly, the assessments of cosmesis in the paediatric group were done by a mix of parents and children. The pooling of these data without appropriate sub-analyses is problematic. Although the current study size would likely not permit a reliable sub-analysis, the potential for confounding should be acknowledged.

3) Adverse events: were standardised definitions used to define key events such as surgical site infection, "inflammation", dehiscence? Please describe these fully in the Method section.

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).
5) Please confirm that emergency/urgent surgical procedures were excluded (in the adult population, sigmoid diverticulitis is included as an indication for surgery).

Steve Chapman
Academic Clinical Fellow in General Surgery, UK

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.

No

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

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

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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