Author’s response to reviews

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

Authors:

Stefan Gfroerer (stefan.gfroerer@kgu.de)

Petra Baumann (petra.baumann@aesculap.de)

Anne-Kathrin Schwalbach (anne-kathrin.schwalbach@kgu.de)

Alexandre Smirnoff (alexandre.smirnoff@ch-larochelle.fr)

Version: 2 Date: 11 Mar 2019

Author’s response to reviews:

Stefan Gfroerer, MD

Department of Paediatric Surgery and Paediatric Urology

University Hospital Frankfurt

Theodor-Stern-Kai 7, 60590 Frankfurt am Main, Germany

Marco Petrillo

Associate Editor

BMC Surgery

Frankfurt/M., February 18th, 2019

Re-Submission of the revised manuscript "Prospective international multicenter observational study of Novosyn® Quick for skin closures in adults and children (SKINNOQ)" (BSUR-D-18-00429R1)
Dear Prof. Petrillo,

Herewith we wish to submit the revised manuscript "Prospective international multicenter observational study of Novosyn® Quick for skin closures in adults and children (SKINNOQ)" for consideration for publication in BMC Surgery.

We thank for the valuable comment of the reviewer.

We wish to answer all questions and comments raised point-by-point in this letter.

The changes have also been marked in the revised manuscript.

Reviewer reports:

Stephen J Chapman (Reviewer 1): 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.

Again, thank you very much for your valuable comment. We corrected this issue by deleting or exchanging effective/efficacy in all affected passages in the abstract and full-text.
effective -> reliable (revised manuscript page 2, line 23).
deleted: and effective (revised manuscript page 7, line 20).
efficacy -> performance (revised manuscript page 11, line 25).
efficacy -> performance (revised manuscript page 13, line 4).
Our results show, that, in consideration of the selected parameters, Novosyn® Quick can be regarded as safe. (revised manuscript page 15, line 8).
deleted: and effective (revised manuscript page 15, line 8)

We hope that we were able to respond appropriately to the reviewers’ comments and questions.

Sincerely,

Stefan Gfroerer, M.D.