Author's response to reviews

**Title:** Time-Action Analysis (TAA) of the Surgical Technique Implanting the Collum Femoris Preserving (CFP) Hip Arthroplasty TAASTIC trial Identifying pitfalls during the learning curve of surgeons participating in a subsequent randomized controlled trial (An observational study)

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**Author's response to reviews:**

To the editor,

Dear sir / madam,

Thank you for reviewing the manuscript entitled: “Time-Action Analysis (TAA) of the Surgical Technique Implanting the Collum Femoris Preserving (CFP) Hip Arthroplasty.”

We hereby send you the revised manuscript containing the alterations according to the reviewer’s and Journal’s comments.

**Reviewers comments**

We hereby provide you with a response to the reviewers comments:

**Concerning the sample size calculation:**

Thank you for the opportunity to clarify this matter.

The sample size of 20 cases for each surgeon was estimated based on previous studies on learning curves in total hip arthroplasty. The P x C rule is used as a stopping rule to determine whether 20 cases is enough or whether the Time-Action Analysis needs to be prolonged with another 5 cases or more.

To achieve more clarity and thereby facilitate easier replication of the design for future studies we altered the manuscript text:

“Based on these studies, we estimate the efficiency to reach a plateau between 10 and 20 cases. Therefore the first 20 cases of each surgeon will be analysed.
A learning curve can however differ between individual surgeons. It is therefore important to study multiple surgeons with different levels of experience and to define a stopping rule. The stopping rule defines whether the estimated number of 20 cases is sufficient to study an individuals learning curve and terminate the task analysis or whether additional cases are needed. The criterion for terminating the task analysis was previously determined through the probability of failure (P) multiplied by the cost of failure (C) to an acceptable level # the P x C. The role of the P x C rule is to save the analyst time in analysing tasks where the error variance would be inconsequential and to guide more exploration where the error variance would be intolerable. The cost of failure is inherent to the clinical consequence of a peri-operative complication which requires clinical interpretation. We defined three major peri-operative complications during total hip arthroplasty which determined C:

1. massive bleeding
2. fracture (femoral or acetabular)
3. evident neurological damage

This resulted in the following definition of the stopping rule: if a surgeon encounters a major complication (C) within the last five consecutive surgical procedures (P), the stopping rule is considered unacceptable and an additional five surgical procedures have to be analysed.

To facilitate comparison of different levels of expertise we suggest one surgeon less than five years board certification, two surgeons 5 to 15 years and 1 surgeons more than 15 years board certification. This justifies our total sample of 4 surgeons each performing 20 cases, resulting in a total of between 80 surgical interventions to be analysed.”

Journal comments

We hereby provide you with a response to the journal comments:

Ethics: we inserted the following text:

“Since the TAASTIC trial is an observational study, a formal ethical approval was waived for this study by the OLVG Medical Ethics Committee. The OLVG Medical Ethics Committee declared to have no objections to the TAASTIC trial.”

Abstract: an abstract will be provided. Since this manuscript concerns a study protocol, the abstract will not contain a conclusions section

Competing interest: the following text is added to address competing interest:

“The TAASTIC trial will receive financial contribution for an amount of less than €10.000,- from Link Nederland B.V. Prior to receiving any contribution an
Unrestricted Grant Agreement or financial disclosure will be signed by Link Nederland B.V. and the trial committee members. Link shall financially contribute to the study, but will not be considered a Sponsor of the study. Principal Investigator (RWP) shall be responsible for the general management and supervision of the study. Link Nederland B.V. is not involved with the study design; in the collection, analysis, and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication.”

Authors’ contributions:

We added the following text:

“JVO designed the protocol, will carry out the data acquisition, data analysis and data interpretation and wrote and edited the final manuscript.

MUS was involved with the design of the protocol, data acquisition, trial consultant and edited the final manuscript.

MB was involved with protocol design, was an important data analysis consultant and edited the final manuscript.

WCR was involved with the protocol design, will perform the surgical interventions and edited final manuscript.

RWP designed the protocol, is principal investigator, will perform the surgical interventions, edited the final manuscript.

All authors read and approved the final manuscript.”

Acknowledgements:

We added the following text:

“The authors would like to thank the following persons for their contributions:

• Inger N. Siereveld, data analysis consultant
• Elisa Rijk, data acquisition, assessment and analysis
• Jan Joost Wiegerinck, data acquisition, assessment and analysis”

• Dr. C.C.P.M. Verheyen, Orthopaedic Surgeon, for performing the surgical procedures
• Dr. C. van Egmond, Orthopaedic Surgeon, for performing the surgical procedures

Furthermore, we altered the manuscripts according to the BMC Authors’ checklist for manuscript formatting.

We hope the abovementioned alterations of the manuscript are in compliance
with the suggestions made by the reviewer and the Journal.

Kind regards,

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