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A study to assess the acceptability of the alexis retractor and a brief description of post operative wound complications associated with its use

Mlandu, Dr Y P

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MMED EXAMINERS' CORRECTIONS

STUDENT: Yandisa Philiswa Mlandu

STUDENT NO: 742314

RESEARCH TITLE: A STUDY TO ASSESS THE ACCEPTABILITY OF THE ALEXIS RETRACTOR AND A BRIEF DESCRIPTION OF POST OPERATIVE WOUND COMPLICATIONS ASSOCIATED WITH ITS USE

EXAMINER 1

- *I am confused by the way the study was conducted*

The study is a case series. It was a 'pilot study' to assess the suitability of the Alexis-O retractor in our setting. Surgeons were asked to identify whether they favoured the retractor, its ease of use/difficulty of use (comparing favourability with their own previous experience of standard retraction), and the study assessed immediate pain scores, and early wound complications. The study design was at the request of the University of Witwatersrand Post Graduate Committee. The study was initially presented to them as a randomized controlled trial (RCT) which was rejected because the Committee decided that it could not be an RCT as only the primary investigator personally could consent all participants and the Committee decided that the retractor would only be safe to use by specific surgeons individually instructed rather than any attempt to instruct all surgeons. A new protocol was therefore sent to the committee conforming to their wishes which was accepted.

- *Literature review is not clear, specific or well written*

This was re-written

- *Objectives not aligned with the study design and methods used*

There is no doubt that the study design severely limits the study's ability to compare standard retraction and the Alexis-O retractor. Surgeons are

essentially describing their favouring or ease of use of the retractor in comparison to their own previous experience with standard retraction which is not entirely valid. Widespread satisfaction does suggest that the retractor may be beneficial. Complications, although an essential part of the study, cannot confidently be assessed with small numbers and without a comparison group of patients undergoing standard retraction.

- *Inclusion criteria/exclusion criteria for surgeons who were conducting the study*

No surgeons were excluded at the grade of medical officer, registrar or above. All surgeons operating in the Maternity Theatres of Chris Hani Baragwanath Hospital at the time of the study were approached (by presentations and individually) and were asked if they would participate. This was not made clear and has been made clearer. All surgeons were allowed to participate if they agreed to do so. Hence surgeons of a wide background of experience were represented. The only inclusion criteria was willingness to participate.

- *Patient inclusion/exclusion characteristics....not clearly defined*

There were no patient inclusion/exclusion characteristics other than the exclusion of those patients who could not be communicated with by the principal investigator or those under 18 years. All willing patients who were above 18 years and could understand the consenting languages were included. It might be thought that precipitous caesarean sections rapidly performed might be excluded but no cases were intentionally or actually excluded; excepting cord prolapse, caesarean sections are not prepared so quickly for theatre at Chris Hani Baragwanath Hospital that consent for such a study is not possible. It is made clear that the primary investigator speaks the majority of S African languages but some with whom communication was not possible, were excluded.

Cases in which extreme difficulty were anticipated – placenta previa, multiple previous procedures, were not excluded as it was recognised that the Alexis-O retractor could be easily introduced and easily removed if unfavourable just as retractors are exchanged in other circumstances. It was considered that since anterior wall adhesions can make insertion of the

Alexis-O more difficult that it might be removed or unsuccessful in such cases, but previous surgery or anticipated difficulty were not in themselves exclusions for enrolment.

- *The assessment of post-operative pain threshold is rather not clear as there is no known diagnostic tool used*

Though mentioned in the text as a possible confounding variable (pain threshold) there was no deliberate attempt to assess this. The patients' own perception of pain, not an entirely standardisable entity, was assessed on an analogue scale.

EXAMINER 2

POINT 2: Has the student demonstrated that they have read, understood and analysed the appropriate literature

- *Include 2014-2016 Saving Mothers report*

Report included: reference no 9

- *P7 para1 '...numbers were too small' for?*

Has been changed to 'the sample size was too small in this study'

- *P7 para2 line3-7 what is the significance?*

To demonstrate that a plastic retractor similar to the Alexis-O protects the skin from bacterial colonisations and subsequent wound infection.

POINT 3: Does the research report reveal adequate acquaintance with methods of research?

- *Please number the objectives*

Objectives numbered

- *P8 last para – type of study under limitations and suggestion for ret under recommendations. Advice from the PG committee is not part of methodology*

Statement removed from methodology

- *P9 Expand study setting*

Study setting expanded see P10-P12

- *P10 Study design- the findings of the PG committee are not relevant – Please describe the study design of the research that was done as per the protocol*

Corrected as per recommendation: Please see pages 8-10 under study design

- *P11 1st para move to ethical considerations – not study design*

Done as per recommendation see pg 12 under ethics approval subheading

- *P11 surgical technique and post-op follow up procedure goes under study setting – make subheadings*

Corrected as per recommendation, and each under its numbered subheading see pgs 11 &12

- *P12 Funding – A copy of the agreement between Surgical Innovations and the PI should be in the Appendix, including a copy of the budget/expenses*

There was no written agreement, it was done verbally with the representative and the money is to be recovered from the WITS Health Consortium and still in the process of recovering it.

POINT 4: Has the student indicated that they understand their results? Are the results presented in an acceptable format?

- *Results section needs to be divided with subheadings, one for each objective. Noting that there was no objective stating that the demographic variables of the patients were to be described I would still*

include the paragraph so that there is some context. Similarly, a heading for the surgeons/indications – also not an objective but should be described. To aid in the explanation of the results, use of subheadings for each objective being answered is recommended. A clear distinction between the two primary objectives and the secondary objective can then be made. Thereafter the various correlations between the various objectives can be described.

Corrections made as per suggestion. Please see pgs 14-28

- *P13- Better to give median gravity and parity than mean – whole number.*

Corrected as per recommendation – pg 14-15

- *A description of the demographic variables at Bara should be in the study setting.*

Corrected – please see pgs 9-10

- *P14 – para1 lines 4-8 belong in methods*

Corrected – Moved to study population on pgs 8-9

- *P17 para 2 - answers objective 3 – needs to be expressed as a frequency as per the stated objective.*

Corrected - see pg 23 under secondary outcome 4.3.5.1

- *P17 para4 – figure 6-only found on page 20*

now on page 17 as figure 3

- *P19 – put figure 7 after para 3 – it is on p21*

Now on pg 20 as figure 6 under the relevant paragraph

- *P20- put figure 8 after para 2*

On pg 21 after the relevant paragraph as figure 7

- *P22 – put figure 9 after para 1.*

Corrected – on pg 25 after 1st paragraph

- *P22- Expand the results section on objective 8 – considering that 2 patients at least had a prolonged hospital stay, the range, interquartile ranges should be included*.

Expanded and ranges and IQR included, now on page 26 as outcome 4.3.5.5

- *P22 – last para then Fig 10*

Now on page 26 under outcome 4.3.5.6

- *P23 – Last sentence- since 12 of the patients were reporting the complication themselves – it is not possible to conclusively say how many had SSI. One can say as mentioned that 19/90 had a wound complication either self-reported (the clinic visit notes were not said to have been retrieved for the 6 and the 6 who did not seek help)*

Rewrote the report please see pg 28 both paragraphs.

- *P24 fig 11, last bar sought (spelling)*

Spelling corrected – now pg 27

POINT 5: Does the discussion indicate an adequate understanding of the results in relation to their own findings and to the literature?

- *P27 para4 sentence 1- unclear*

Clarified see pg 30 para 4

POINT 6: Are the conclusions appropriate and acceptable?

No corrections under this point

POINT 7: Is the reference section appropriately formatted?

- *Provide DOI and accessed dates for all journals accessed online and online resources e.g. NICE*

Could not find DOI for ref 5, but the rest have been included

Dates journal accessed added

- Please fix ref 26 and 27

Fixed, please see page 39

POINT 8: Is the literary presentation (grammar, formatting and use of the scientific language) of the research satisfactory?

1. *All whole numbers ten or less written in words*
   Corrected
2. *Abbreviation list in alphabetical order*
   Corrected
3. *Kg – correct abbreviation in small letters*
   Corrected
4. *ml or mL for millilitre*
   ml
5. *Mins - is min*
   Corrected

- *P1 para2 line 1 – correct the English*
  Corrected
- *P2 line1 – ref 16 is twice*
  Corrected
- *P2 last sentence – be clear when describing the Bara cs rate, versus the whole district including Bara and the clinics*
  The part in brackets was to state that some of the Bara CS patients are actually referrals from the clinics. I have opted to remove this part.
- *P5 line 1 – reference - ? personal communication/departmental stats*
  This was a personal communication with the PI who performed the study
- *P16 line 4 spelling – mines*
  Corrected now on P24 para 5 line 2
- *P25 para 4 line 4 – missing bracket*
  Corrected now on P29 para 4 line 4
- *P25 para 4 line 5 – 'in favour of'*

Corrected on P29 para 4 line 5

- *The advantages of a case series are not explored in the results and discussion.....*

  Please see advantages paragraph on page 34

- P37 the signed Ethics clearance certificate, and which was sent back to ethics, must be included

  Included on page 47 as appendix H