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2018
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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

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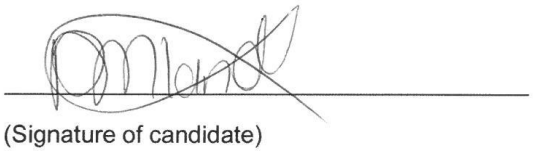
THIS IS A RESEARCH REPORT SUBMITTED TO THE UNIVERSITY OF THE WITWATERSRAND IN COMPLIANCE WITH THE MASTERS OF MEDICINE DEGREE

DECLARATION

I Yandisa P Mlandu declare that this dissertation is my original work and it is being submitted to the University of the Witwatersrand in fulfilment for the requirements of the Masters of Medicine Degree.



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13th day of December 2018 at Johannesburg

ABSTRACT

Introduction

Deliveries by caesarean section are increasing and so is the morbidity and mortality associated with this procedure. It is therefore important to consider strategies to reduce the mortality and morbidity. The Alexis-O abdominal wall retractor is a single use device that offers good visibility of the abdominal cavity. It has the added benefit of making it easy to suture the uterus without having to exteriorise it and has been associated with reduced wound sepsis in bowel surgery.

The primary outcomes of this study were to assess the operators' assessment of the ease of the operation when using the Alexis-O abdominal wall retractor and to determine difficulties experienced by the surgeon and to describe these difficulties.

The secondary outcomes were; to assess the frequency with which it was not possible to place the Alexis-O abdominal wall retractor or the operator was forced to abandon its use, the duration of the operation, the estimated blood loss, the patients' maximum perception of post-operative pain on an analogue scale, the incidence of immediate post-operative pyrexia, the length of hospital stay and the incidence of post-operative wound complications as reported by the discharging doctor and through a telephonic interview with the patient three weeks after discharge from the hospital.

Methods

This was a case series of caesarean sections performed at the Chris Hani Baragwanath Academic Hospital designed to be a 'pilot study' in which the Alexis-O abdominal wall retractor was used.

The Alexis-O abdominal wall retractor is a disposable, single-use device that consists of a flexible polymer transparent membrane formed into the shape of a cylinder. Attached to each end of the cylinder are two semi rigid polymer rings.

There are two obstetrics theatres running concurrently for 24 hours where elective and emergency caesarean sections are performed. A convenience sample of a 100 women undergoing both elective and emergency caesarean sections was taken. The

surgeons completed a questionnaire after the surgery, other details were taken from hospital notes and the patients were assessed by a discharge questionnaire and again telephonically three weeks after the surgery.

Results

A total of 39 surgeons took part in the study. There were five consultants, 31 registrars and three medical officers. A total of 106 patients were enrolled. Ten caesarean sections were performed by consultants, 83 were performed by registrars and 13 by medical officers.

In 82.2% of cases the surgeons preferred the Alexis-O abdominal wall retractor over the standard retractor which they had previously used and in 88% of cases the surgeons found the Alexis-O abdominal wall retractor easy to use. In 97.1% of cases the surgeons indicated that they would use the Alexis-O abdominal wall retractor again.

There were a total of 12 cases, performed by 11 surgeons, where the surgeons found the Alexis-O abdominal wall retractor difficult to use. In 11 of these cases the surgeons had used the Alexis-O less than 20 times and in seven of these cases the surgeons indicated that they preferred the standard abdominal wall retractor above the Alexis-O abdominal wall retractor.

In three cases the surgeons were unable to insert the Alexis-O abdominal wall retractor due to dense adhesions. In six cases the surgeons abandoned the Alexis-O abdominal wall retractor either due to adhesions or poor visibility of parts of the operating field. There were no complications from the removal of the Alexis-O abdominal wall retractor.

Of the 106 patients who were enrolled in the study, 18 had wound complications. One patient had puerperal sepsis and a hysterectomy was performed, the other 17 patients had wound complications that did not require surgery. Of these complications, eight patients were treated with oral or intravenous antibiotics, removal of sutures, draining of pus and dressing of wounds. No control group was available for comparison. Sixteen patients were lost to follow up.

Conclusion

The Alexis-O abdominal wall retractor was preferred by the majority of surgeons, the majority of whom found it easy to use. Since this is a case series, it is not possible to ascertain if this device is superior to standard abdominal wall retractors. A randomised control trial would be ideal to assess these outcomes.

ACKNOWLEDGEMENTS

1) God almighty

2) The Chris Hani Baragwanath Academic Hospital obstetrics theatre staff

3) The doctors who helped by participating in the research and reviewing patients in the post delivery wards

4) Dr Edridge my supervisor

5) Dr Maswime for her assistance and encouragement

6) Mrs Astrid Du Plessis

7) The patients who agreed to take part in the study

8) My family for their encouragement

TABLE OF CONTENTS Page

DECLARATION.....II
ABSTRACT.....III
ACKNOWLEDGEMENTS.....VI
TABLE OF CONTENTS.....VII
LIST OF FIGURES.....IX
ABBREVIATIONS.....X

CHAPTER 1

1.1 Introduction.....1
1.2 Problem Statement.....2
1.3 Research Question.....2

CHAPTER 2

2.1 Literature Review.....3
2.1.1 Operative mortality in South Africa.....3
2.1.2 Experience with the Alexis-O in general surgery.....4
2.1.3 Experience with the Alexis-O in other surgeries.....5
2.1.4 Experience with the Alexis-O in obstetric surgery.....5
2.2 Summary..... 6

CHAPTER 3

3.1 Objectives.....8
3.2 Methodology.....8
3.2.1 Study design.....8
3.2.1.1 Study population.....8
3.2.1.2 Sample size.....10
3.2.2 Study setting.....10
3.2.2.1 Operators and surgical training with the Alexis-O.....11
3.2.2.2 Surgical technique and operative process.....11
3.2.2.3 Post-operative follow up.....12
3.2.3 Ethics approval.....12
3.2.4 Data Collection.....12

3.2.5 Funding.....13

CHAPTER 4

4.1 Data Management.....14

4.2 Data Analysis.....14

4.3 Results 14

4.3.1 Patient Demographics.....14

4.3.2 Surgeon Demographics.....15

4.3.3 Indications for CS.....17

4.3.4 Primary Outcomes.....17

4.3.5 Secondary Outcomes.....23

CHAPTER 5

5.1 Discussion.....29

5.1.1 Primary Outcomes.....29

5.1.2 Secondary Outcomes.....31

5.2 Limitations.....34

5.3 Advantages.....34

5.4 Conclusion.....34

5.5 Recommendations.....35

References.....36

APPENDIX A: Patient Information Sheet.....40

APPENDIX B: Patients Consent Form.....41

APPENDIX C: Surgeon Consent Form.....42

APPENDIX D: Surgeon Data Sheet.....43

APPENDIX E: Patient Data Sheet.....44

APPENDIX F: Patient Discharge Letter.....45

APPENDIX G: Telephonic Questionnaire after 3 weeks.....46

APPENDIX H: Ethics Approval.....47

APPENDIX I: Turnitin report.....48

LIST OF FIGURES PAGE

Figure 1: Number of times the surgeon had used the Alexis-O prior to the current surgery.....15

Figure 2: Cases where the surgeon had used the Alexis-O less than 20 times.....16

Figure 3: Indications for CS among the patients who took part in the study.....17

Figure 4: Surgeons' assessment of the ease of the surgery as a whole.....18

Figure 5: The surgeons' experience on the use of the Alexis-O.....19

Figure 6: The preferred retractor among all the surgeons in the study.....20

Figure 7: The preferred retractor in cases where the surgeons had used the Alexis-O less than 20 times.....21

Figure 8: Duration of the caesarean section.....23

Figure 9: Patients' pain perception on a pain analogue scale from 1-10.....25

Figure 10: Number of patients who experienced wound complications.....26

Figure 11: Wound complications 3 weeks post discharge as per telephone interview.....27

ABBREVIATIONS

Alexis-O	Alexis-O abdominal wall retractor
AOL	Augmentation of Labour
BMI	Body Mass Index
CS	Caesarean Section
CPD	Cephalopelvic Disproportion
CHBAH	Chris Hani Baragwanath Academic Hospital
EBL	Estimated Blood Loss
Fig	Figure
HIV	Human Immunodeficiency Virus
Hr	Hour
IOL	Induction of Labour
IQR	Interquartile range
kg	Kilograms
Min	Minutes
Ml	Millilitres
MO	Medical Office
PI	Primary Investigator
RCT	Randomised Controlled Trial
SLE	Systemic Lupus Erythematosus
SSI	Surgical Site Infection
WITS	University of the Witwatersrand
Yr	Year

CHAPTER 1

1.1 INTRODUCTION

Caesarean section is a procedure performed daily in South Africa with a national rate of 23.1% according to the sixth report on the Confidential Enquiries into Maternal Deaths in South Africa 2011-2013 Saving Mothers Report, this number increased to 25.7% in the 2014-2016 triennium[1-2]. Caesarean sections are performed in a variety of medical facilities throughout South Africa by people of varying skills. The consequences of surgical complications can result in serious morbidity and mortality. In the 2008-2010 National Saving Mothers Report, the number of deaths associated with haemorrhage and CS with no other risk factors other than the CS itself (e.g. placenta accreta, abruption) was 26.2% and this increased to 32.3% in the 2011-2013 Saving Mothers Report[1,3] but this is currently on a downward trend with 30.7% in the 2014-2016 Saving Mothers Report[2].

One factor that influences the safety of CS is the accessibility and visibility of the intra-abdominal structures for the surgeon and the assistant. Hinkson et al[4] performed a study in Berlin and demonstrated that the Alexis-O provided better visualisation of the field, more freedom of surgical movement and easier removal when compared to the Collins retractor, and use of the Alexis-O has been shown by Theodoridis et al[4], in a study performed in Greece, to have a rapid learning curve.

Abdominal wall complications during or after the surgery include excessive bleeding, surgical site infection (SSI) and loss of wound integrity. The Centre for Disease Control and Prevention classifies SSIs into three categories namely superficial, deep and organ/space infection[6]. SSI is associated with longer hospital stay, emotional distress for the patient and an increased cost of care for the patient and the hospital[7]. Post-operative sepsis in its severe form may lead to multi-organ failure and death.

There is a steady increase in the incidence of obesity worldwide and obesity alone is associated with an increased risk for CS delivery and SSI[8]. Obesity also results in difficulty accessing the abdomen and compromises surgical technique[9]. A retrospective study to determine predictors of wound complications in massively obese patients (BMI>50kg/m2) showed that there was a higher incidence of wound

complications, at 30%, but these were mostly wound disruptions and the SSI rate was not reported[10]. The incidence of SSI post CS varies between different studies and is reported at 3-18.4%[8-9, 11-12]. A cohort in Norway also showed that an operating time of more than 38 minutes was associated with a higher risk of SSI in CS patients[7].

The Alexis-O is a disposable, single-use device that consists of a flexible polymer membrane formed into the shape of a cylinder. Attached to each end of the cylinder are two semi rigid polymer rings. It is available in two sizes for obstetric use: large (for 9- to 14-cm incisions) and extra-large (for 11- to 17-cm incisions).



Research has been performed on the Alexis-O assessing different outcomes under different circumstances with varying results.

1.2 PROBLEM STATEMENT

Considering that the rate of CS is increasing and that there is associated morbidity and mortality with the procedure, it would be prudent to find means of reducing CS complications and improve the ease of operating[13].The CS rate at CHBAH from August 2015 to July 2017 ranges from 33-50% per month.

1.3 RESEARCH QUESTION

Do surgeons consider the Alexis-O easy and user friendly which might be referenced to the standard abdominal wall retractors of which they have experience? Is usage of the Alexis-O associated with favourable patient outcomes post operatively?

CHAPTER 2

2.1 LITERATURE REVIEW

The national CS rate from The Saving Mothers Report was 20% in the 2008-2010 triennium, this rate increased to 23.1% in the 2011-2013 triennium and a further increase to 25.7% in the 2014-2016 triennium. This was a total increase of 91 415 more CS deliveries[1-3].

2.1.1 Operative maternal mortality in South Africa

2.1.1.1 Mortality due to haemorrhage

Maternal mortality due to obstetric haemorrhage was 26% in the 2008-2010 triennium; this increased to 32.3% in the 2011-2013 triennium but reduced to 22% in the 2014-2016 triennium. From the 2008-2010 triennium obstetric haemorrhage was the most common avoidable cause of maternal death. Bleeding during or after CS was the largest category. The largest percentage of these deaths was in secondary level hospitals followed by tertiary level hospitals with primary hospitals having the lowest rates[1-3].

Deaths from uterine atony and retained placenta have declined; deaths from placental abruption and ruptured uterus have remained the same and from bleeding during and after CS have reduced in the last triennium. The greatest concern with the latter is that the management may have been incorrect or suboptimal; the patients either were not taken to theatre to stop the bleeding or the decision was made too late or they died while waiting to be transferred or en route. The recommendation therefore is to improve the medical knowledge and surgical skills of health care workers in order to prevent bleeding occurring at CS and to timeously diagnose and appropriately manage these patients. There needs to be an improvement in the health care system as well i.e. emergency transport and availability of blood products[1].

2.1.1.2 Mortality from sepsis

From the 2011-2013 triennium it is noted that bleeding during and after CS was just as frequent a cause of death as pregnancy related sepsis. Pregnancy related sepsis as a cause of maternal death is declining in numbers. Pregnancy related sepsis is ranked fifth on the top five causes of maternal mortality in the last three Saving Mothers Reports[1-3]. This however does not mean that more cannot be done to further reduce its incidence – for example, operation related sepsis mortality may also be related to operative technique.

An unpublished study performed at CHBAH looking at relook laparotomies for puerperal sepsis after a CS reported 40 cases in four years, between 2009 to 2012.

2.1.2 Experience with the Alexis-O in general surgery

The outcomes on the SSI favour the use of the Alexis-O retractor in bowel surgery and there was a significant reduction of superficial SSI in this group of patients, however there was no difference in the incidence of intra-abdominal sepsis[14,15-16]. Different studies showed different rates of superficial SSI but differences between the Alexis-O retractor and standard abdominal wall retractors have been statistically significant: 0% vs. 8%, P=0.0021[14]; 4.7% vs. 22.7%, P=0.004[15]; and 1.6% vs. 14.6%, P=0.028[16] respectively.

Cheng et al[17] performed a RCT on 60 patients undergoing colorectal surgery. They showed no difference in post-operative pain between the two arms, but demonstrated a reduction in surgical site infection (0% vs. 20%, P=0.006); however the sample size was small in this study.

A study performed in colorectal surgery by Reid et al[15] where the Alexis-O was compared to standard abdominal wall retractors showed a significant difference in the SSI between these two arms (4.7% vs. 22.7%, P=0.004). In a study performed by Mohan et al[18] in colorectal surgery using a similar plastic wall retractor, organisms were cultured on the inside and outside of the retractor post-surgery. Enteric organisms were cultured twice as often from the inside surface of the retractor than the outside surface (49% vs. 26%, P<0.0001).

2.1.3 Experience with the Alexis-O in other surgeries

There are studies performed using the Alexis-O in other surgeries including urological, surgical and gynaecological procedures. These studies showed that the Alexis-O reduces the need for a larger incision, reduces trauma to the abdominal wall tissues and improves visibility and is safe to use[4, 6, 19-20]. In one study the Alexis-O was used during a total laparoscopic hysterectomy when removing the bulky multi fibroid uterus vaginally. In this study they showed that less assistance was needed to hold all the standard retractors in place and there was less trauma to the surrounding tissue[21].

2.1.4 Experience with the Alexis-O in obstetric surgery

Research has been performed looking at the impact of the Alexis-O or other devices similar to it during CS deliveries. The outcomes of these studies include duration of the CS, need to exteriorise the uterus when repairing the hysterotomy, blood loss at CS, SSI, post operative pain, and length of hospital stay[4, 6, 21].

The results are contradictory. Hinkson et al[4] performed a RCT on 198 patients undergoing their first planned CS at the Charite University Hospital in Berlin. They excluded patients with diabetes, chronic autoimmune diseases e.g. SLE, immune deficiency diseases (e.g. HIV), known bleeding disorders, patients receiving full anti-coagulation therapy, patients with a history of wound healing problems, patients who had a previous CS, patients who had previous major abdominal surgery, patients in the active phase of labour and patients with suspected or confirmed chorioamnionitis. The Alexis-O was compared only to the Collins metal self-retraining retractor. The surgeons reported that Alexis-O application was easier (86% vs. 18% p=0.001), operation field visualisation better (84% vs. 19%, p=0.001), freedom of surgical movement better (84% vs. 21%, p=0.001), need to exteriorise the uterus less (77% vs. 31%, p=0.001), estimated blood loss less (EBL<500ml, 19% vs. 3%, p=0.006) and removal of retractor easier (86% vs. 18%, p=0.001), when compared to the Collins retractor. Postoperatively patients who were on the Collin's retractor arm had more scar pain on discharge (P=0.001) and required more analgesia (P=0.001).Their study also found a reduction in SSI (1% vs. 8%, p = 0.035) in

patients on whom the Alexis-O was used and this reduction was statistically significant.

Nakad et al[22] performed an RCT on 536 patients in Texas, each arm comprised of 268 patients who were randomised either to the Alexis-O or standard abdominal wall retractors. There were no significant differences in gestational age at delivery, pre-pregnancy BMI, race, or maternal age. There were no differences in time to delivery, total operative time, EBL, or post-operative pain. There were seven (2.7%) wound infections in the Alexis arm versus three (1.1%) in the routine arm (P =0.20). There was a lower need to exteriorize the uterus in the Alexis-O group (61.3% vs. 91.2%, P<0.0001).

Scolari Childress et al[6] performed an RCT on 301 obese patients (BMI>30kg/m2) undergoing a non-emergency CS in Saint Louis University School of Medicine in the United States. They did not demonstrate a difference in SSI rate between the patients in the Alexis-O arm and the standard abdominal wall retractor arm. This study also showed no difference in total surgical time, antiemetic use, EBL and the length of hospital stay. There was however a reduced need to exteriorise the uterus during hysterotomy repair, 55.6% vs. 88.5%, P<0.001.
In situ repair of the uterus has been shown to reduce the incidence of uterine atony (3.8% vs. 9.1%, P=0.001)[23], nausea (18% vs. 38%, P=0.04)[24], tachycardia (3% vs. 18%, P=0.03)[24] and post-operative pain (first night 66.7 vs. 43.5, P < 0.001; second night 44.6 vs. 23.9, P < 0.001)[23-25]and is currently recommended by the NICE guidelines[26].

2.2 SUMMARY

Caesarean section deliveries are on the increase and every attempt should be made to make this procedure safer with fewer complications. These measures include the surgeon and the facilities available to patients. In colorectal surgery the Alexis-O does reduce SSI; however, this is not clear in patients undergoing a CS; the two published RCTs[4, 6] have different population groups (low risk patients undergoing an elective CS versus a group of obese women undergoing a CS). The study by Hinkson et al[4] only has a population study group of specially selected patients and

certainly does not reflect our population and their standard metal retractor (Collin's retractor) is different to the ones we use (Morris, Doyen, Cherney, Deaver, Langenbec). The evidence is inconclusive and does not indicate if the Alexis-O is superior to the standard abdominal wall retractors for reducing SSI in patients undergoing a CS. The evidence does however demonstrate that the Alexis-O is easier to apply, improves visualisation of the operating field, provides better surgical movement, reduces the need to exteriorise the uterus, and is associated with less blood loss and less scar pain on discharge

CHAPTER 3

3.1 OBJECTIVES

Primary

1. To assess the operators' assessment of the ease of the operation when using the Alexis-O.
2. To determine difficulties experienced by the surgeon and to describe these difficulties.

Secondary

1. To assess the frequency with which it was not possible to place the Alexis-O retractor or the operator was forced to abandon its use.
2. To assess the duration of the operation.
3. To assess the estimated blood loss.
4. To assess the patients' maximum perception of post-operative pain on an analogue scale.
5. To assess the incidence of immediate post-operative pyrexia.
6. To report on the length of hospital stay.
7. To assess the incidence of post-operative wound complications as reported by the discharging doctor and through a telephonic interview with the patient three weeks post discharge.

3.2 METHODOLOGY

3.2.1 Study design

The study is a case series, a 'pilot study' designed to assess the favourability of the Alexis-O retractor in our setting.

3.2.1.1 Study population

Patients who were awaiting a CS (elective or emergency), were not distressed, were willing and where there was ample time to speak to them were approached and requested to participate in the study. The intention of the research was explained to

them in a language they understood and the patients were offered an opportunity to read through the information sheet (Appendix A). If the patient agreed to take part, she signed a consent from (Appendix B). The operating surgeon, if she/he had consented to take part in the research, was requested to use the Alexis-O if possible and complete the surgeon's data sheet thereafter. On day two post operatively the PI, or in a few cases the other registrars who were willing to assist, would see the patients and the patients' data sheet was completed and the patients were given the discharge form. Three weeks later the patients were phoned and the telephonic questionnaire was completed. This group consisted of patients undergoing emergency and elective CS at CHBAH for any indication. The indication for CS was not a deciding factor except for cases where it would not be possible to speak to the patient i.e. cord prolapse, eclampsia, sudden collapse etc. Cases in which extreme difficulties were anticipated i.e. 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.

The PI approached women who were booked for either an emergency or an elective CS, been consented and booked for the CS. Due to the long list of emergencies there is ample time to counsel and consent a patient even if she is waiting for an emergency operation.

The research and its aims were explained to each patient and then the patient was given the opportunity to also read the information sheet. The information sheet and consent form were in English but explanations were given to the patient in the patient's preferred language (isiXhosa, isiZulu, Sotho, Setswana, Afrikaans) unless the PI was unable to speak the language (Venda, Tsonga, Portuguese). Patients who could not understand English or any other language that the PI could speak were excluded from the study. If the patient was willing to participate in the research, she then signed the consent form. In 15 cases, when the PI was absent, other surgeons consented the patients, English or an indigenous language was used.

Inclusion criteria

Any patient, who was older than 18 years, was not too distressed to allow the PI to explain the research and was willing to participate in the study.

Exclusion criteria

Any patient who was not willing to participate, did not understand English or the languages spoken by the PI or those representing the PI or was under the age of 18 was excluded. The indication for CS, unless it precluded the possibility of speaking to the patient as stated above, was not an exclusion criteria.

3.2.1.2 Sample size

The researcher chose a convenient sample size of 100, however, ten more patients were included in case some would be excluded and a total of 106 were reported on.

3.2.2 Study setting

The study was conducted at Chris Hani Baragwanath Academic Hospital which is situated in Soweto, Gauteng. CHBAH is a referral centre for clinics, primary and secondary hospitals. There are, however, patients who self refer to CHBAH and some of them are low risk patients. There are two operating theatres in obstetrics and they operate 24 hours a day for seven days a week. Both elective and emergency CS are performed in these theatres, even though there are more emergency CS performed versus elective CS. There are occasions when CS are performed in the gynaecology emergency theatre because of the high number of patients that could be waiting and the long waiting period.

There are two shifts for doctors per day: the first shift starts at 07:30 in the morning until 16:00 at which point the ‘on-call’ team takes over until 07:30 the following morning. The registrars and medical officers are the ones who perform most of the CS deliveries. Consultants operate in one theatre from Monday to Friday starting at 07:30 till 13:00 when they hand over to a registrar or medical officer.

3.2.2.1 Operators and surgical training with the Alexis-O

The Alexis-O was already in use at CHBAH. There were, however, 14 surgeons who had never used it before. After approaching the surgeons to take part in the study, there was a demonstration and training provided for those who had never used the retractor before. The surgeons who agreed to participate in the study signed a consent form (Appendix C).The surgeon, if he/she had signed the consent form to take part in the study, was then requested to use the Alexis-O during a CS performed on a patient who had consented. All surgeons were told that this did not commit them to using the Alexis-O retractor on a particular patient, nor to continue with its use if they wished to remove it.

Surgeons were informed that if they could not place the Alexis-O or where it was impeding access to the operating field they could remove it, and if they were unable to place it or if they abandoned it to state the reasons.

3.2.2.2 Surgical technique and operative process

The skin was cleaned either by using 0.5% chlorhexidine gluconate in alcohol skin preparation or 10% povido-iodine solution depending on what was available. Intra-operative antibiotics were administered as per the anaesthetists' choice and availability according to the departmental protocol and international standard. Post-operative antibiotics were given according to the surgeons' prescription in the file for specific indications i.e. pre-operative chorioamnionitis, strong smelling/offensive liquor, patient pyrexia. The Alexis-O was placed after entry into the abdominal cavity if there were no dense adhesions that prevented proper placement. After insertion of the internal ring the outer ring was rolled until the polymer membrane was taut. The surgeon then had to digitally feel between the internal ring and the anterior abdominal wall to assess for bowel entrapment. If the surgeon found that using the Alexis-O was challenging, he/she was freely permitted to abandon it and use a standard retractor (Morris, Doyen, Cherney, Deaver, Langenebec retractors). At completion of the CS the surgeon was requested to complete the surgeon data sheet (Appendix D). In this form the surgeon was asked to answer questions including: indication for CS, previous laparotomy, duration of surgery, EBL, the surgeon's grading (medical officer, registrar or consultant), how many times the surgeon had

used the Alexis-O before, the surgeon's experience with the Alexis-O, if the surgeon prefers the Alexis-O or standard abdominal wall retractors and the ease of the surgery as a whole.

3.2.2.3 Post-operative follow up

A proforma (Appendix E) was completed detailing the post-operative period and experience of the patient by the PI. In the absence of the PI there were three registrars who completed the proforma. Information gathered included: weight, height (if available), HIV status, antibiotic use intra-operatively and post operatively, heart rate, highest temperature recorded in the post-operative period, wound assessment on discharge and if a patient had a relook laparotomy. The patients were asked to scale their post-operative pain experience on a scale of 1-10[27].

Upon discharge the patients were given a letter which they were asked to present to the consulting doctor should they experience problems with their wound. This letter requested the consulting doctor to contact the PI if the patient presented with complications from the CS (Appendix F).

After three weeks the PI called the patients and asked them questions regarding the state of their wound, if they had experienced any problems with their wound and if they had consulted a health care worker or received any medical intervention in the preceding three weeks. The telephonic questionnaire was completed at this time (Appendix G).

3.2.3 Ethics approval

The study was approved by the Human Research Ethics Committee at the University of the Witwatersrand. Clearance certificate no: M150813 (Appendix H).

Alexis-O were donated by the distributing company Surgical Innovations who had no influence whatsoever on the findings, recording of data, transferring of data, data analysis or conclusions.

3.2.4 Data collection

Data collection was performed between 14th December 2015 and 31st March 2016.

3.2.5 Funding

Surgical Innovations offered someone to train surgeons on the use of the Alexis-O, sponsored the Alexis-O retractors, and offered assistance with the expenses of performing the study (the PI paid for these expenses and is still in the process of recuperating them).They gave no inducement to the surgeons and had no influence in data collection or statistical analysis.

CHAPTER 4

DATA MANAGEMENT AND STATISTICAL ANALYSIS

4.1 DATA MANAGEMENT

Data was entered into a database using Research Electronic Data Capture (Redcap) software and was exported to an Excel spreadsheet. Data was analysed using the SAS Enterprise Guide version 7.1.

4.2 DATA ANALYSIS

Frequencies and their percentages were determined for categorical variables while means and standard deviation were determined for continuous measures. For purposes of statistical analysis, the ease of operation scale was categorised into easy, challenging and very difficult groups. Proportions were compared by the Chi-square test of proportions while continuous measures between groups were compared by the analysis of variance (ANOVA) test using the Bonferoni test. All statistical analysis was performed under the assumption of a 5% significance level using SAS Enterprise Guide 7.1 (SAS Institute, Cary NC, USA).
In instances where numbers were too small for statistical comparison a descriptive analysis was performed.

4.3 RESULTS

This was a pilot study to assess the performance of the Alexis-O retractor and there was no comparison group.

4.3.1 Patient Demographics

A total of 106 patients with a mean age of 28.6 years (SD 6.2), were enrolled.
The mean weight of the patients was 77.0 (SD 18.8) kilograms (BMI was not used since the height was not available for some of the patients), their median gravidity

was 2 (IQR 2) and median parity was 2 (IQR 2), the parity was assessed post delivery. Of those enrolled, 40 (38%) were HIV sero-positive.

4.3.2 Surgeon Demographics

There were 39 surgeons who took part in the study; five consultants, six 4th year registrars, six 3rd year registrars, six 2nd year registrars, 12 1st year registrars, one register did not state year of training and three medical officers.
The number of cases done by each category was ten (9.4%) by consultants, 13 (12.3%) by medical officers and 83 (78.3%) by registrars.

The number of times the Alexis-O had been used prior to the index operation is depicted in Figure 1.

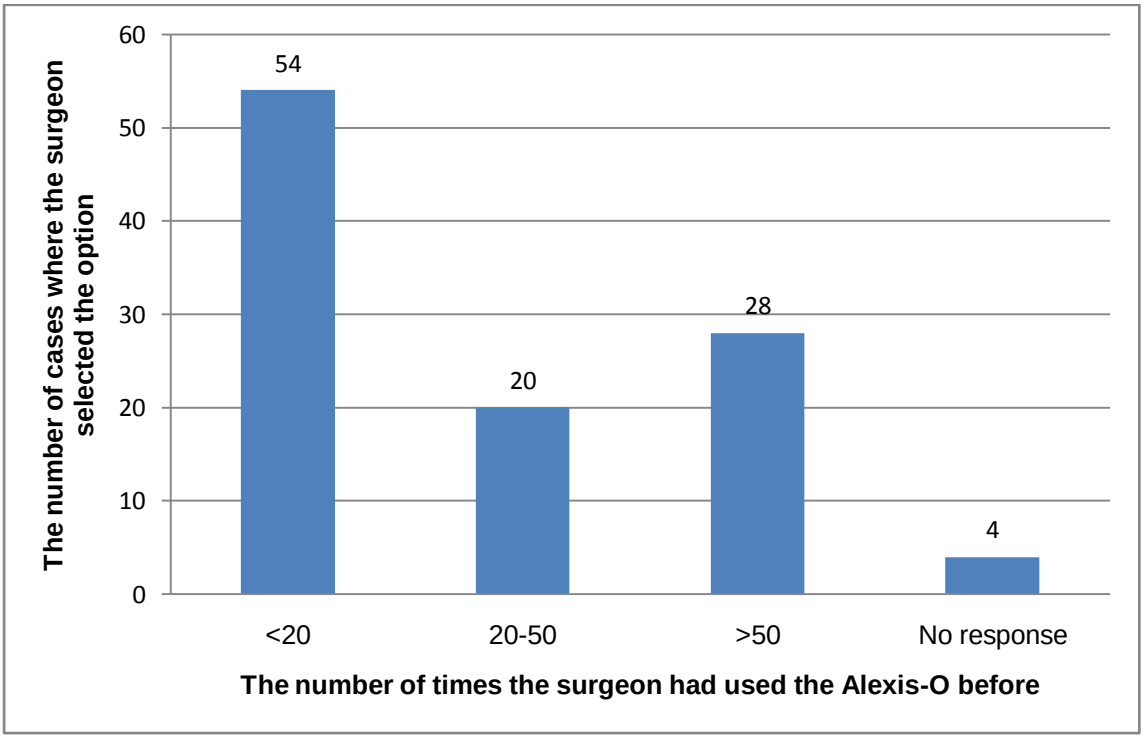

Figure 1: Number of times the surgeon had used the Alexis-O prior to the current surgery

Most of the surgeons (51%) had used the Alexis-O less than 20 times. Figure 2 further elaborates on the number of times the Alexis-O had been used among the

surgeons who had used it less than 20 times. In 63% of these cases, the Alexis-O had been used ten times or less prior to the surgery.

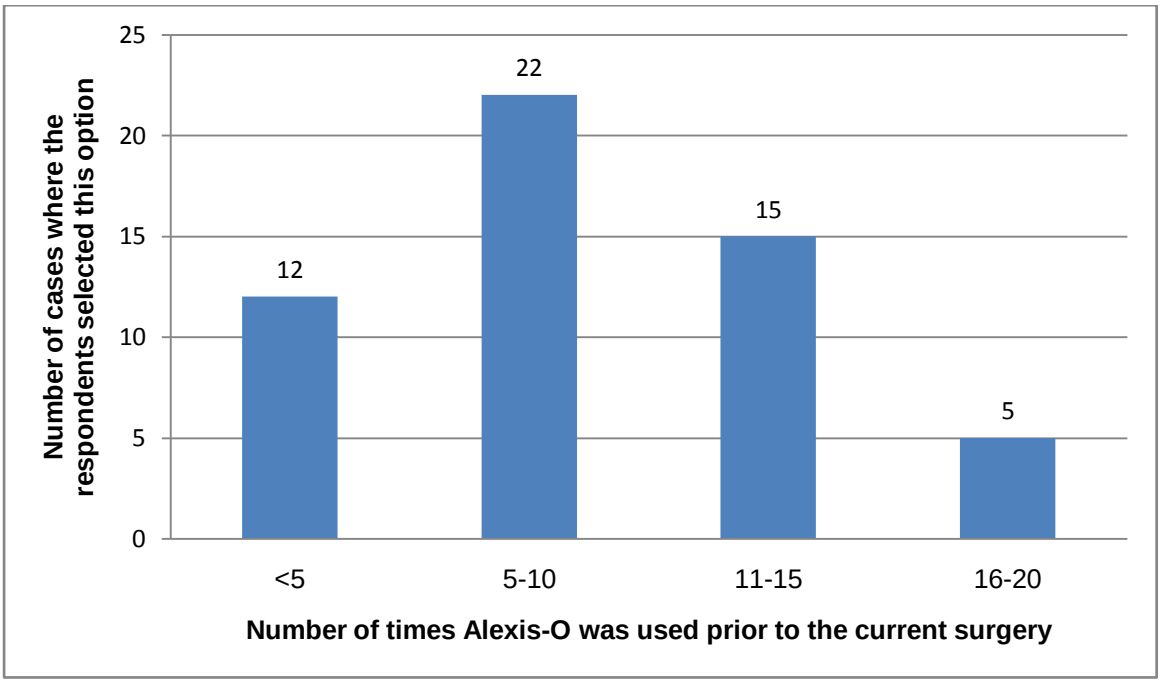

Figure 2: Cases where the surgeon had used the Alexis-O less than 20 times

4.3.3 Indications for CS

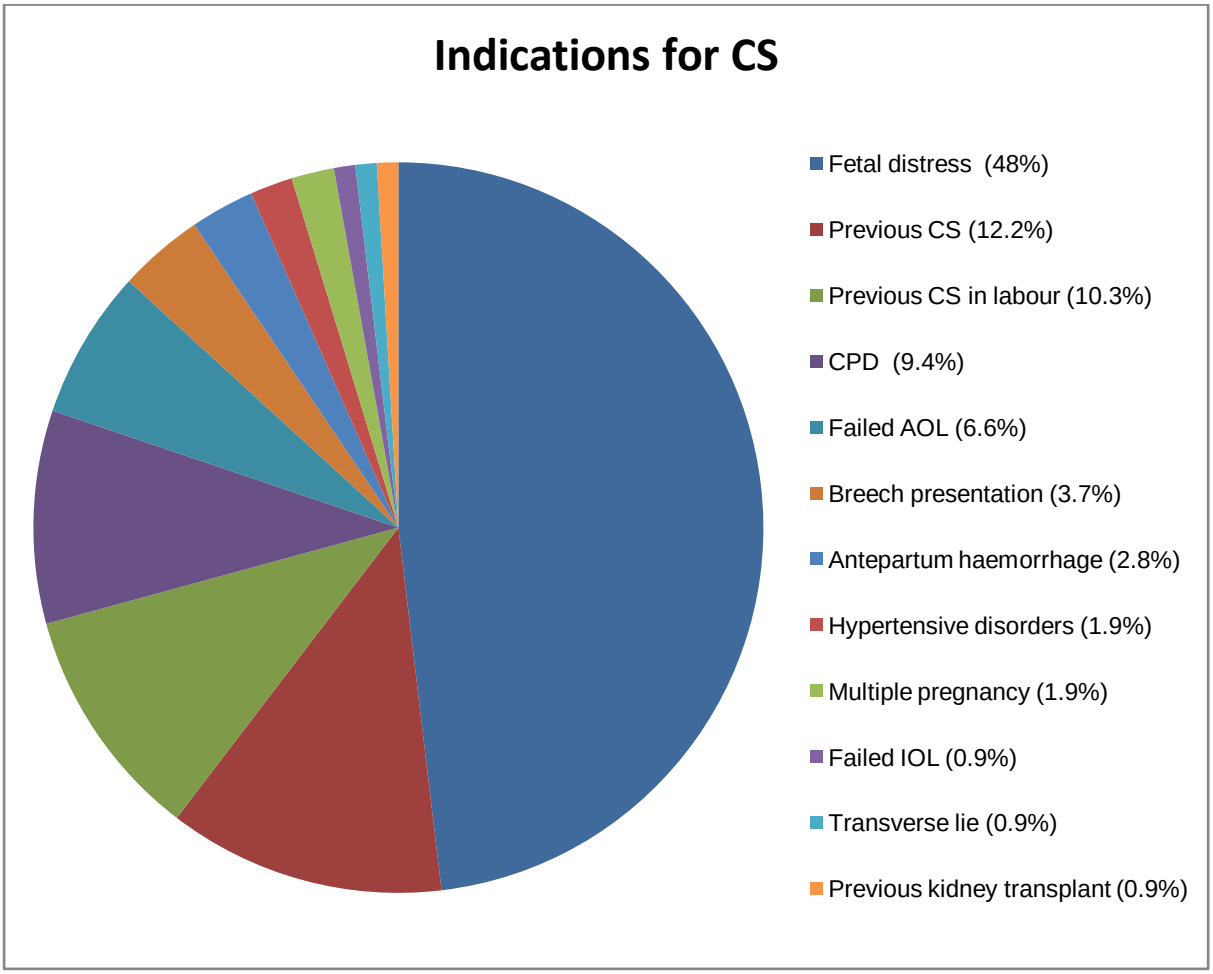

Figure 3: Indications for CS among the patients who took part in the study

Indications for CS are summarised in Fig 3. Thirteen of the CS were electives and 93 were emergencies.

4.3.4 Primary Outcomes

4.3.4.1 To assess the operators' assessment of the ease of the operation when using the Alexis-O

Ease of the surgery

Of the 106 operations, in 100 surgeries the surgeons responded to the question on the ease of the surgery. The surgeons were requested to grade the ease of the surgery (separate from the ease of use of the Alexis-O) from a scale of 1-10, 1 being

easy and 10 being difficult. This was the surgeon's assessment of the surgery (Fig 4). For statistical analysis the responses were grouped into 1-3 (assessed as easy), 4-7 (assessed as moderate), and 8-10 (assessed as difficult). In 82 (77.3%) cases the surgeons selected 1-3, in 15 (14.1%) cases the surgeons selected 4-7, in three (2.8%) cases the surgeons selected 8-10 and in six (5.6%) cases the surgeons did not complete this part on the questionnaire.

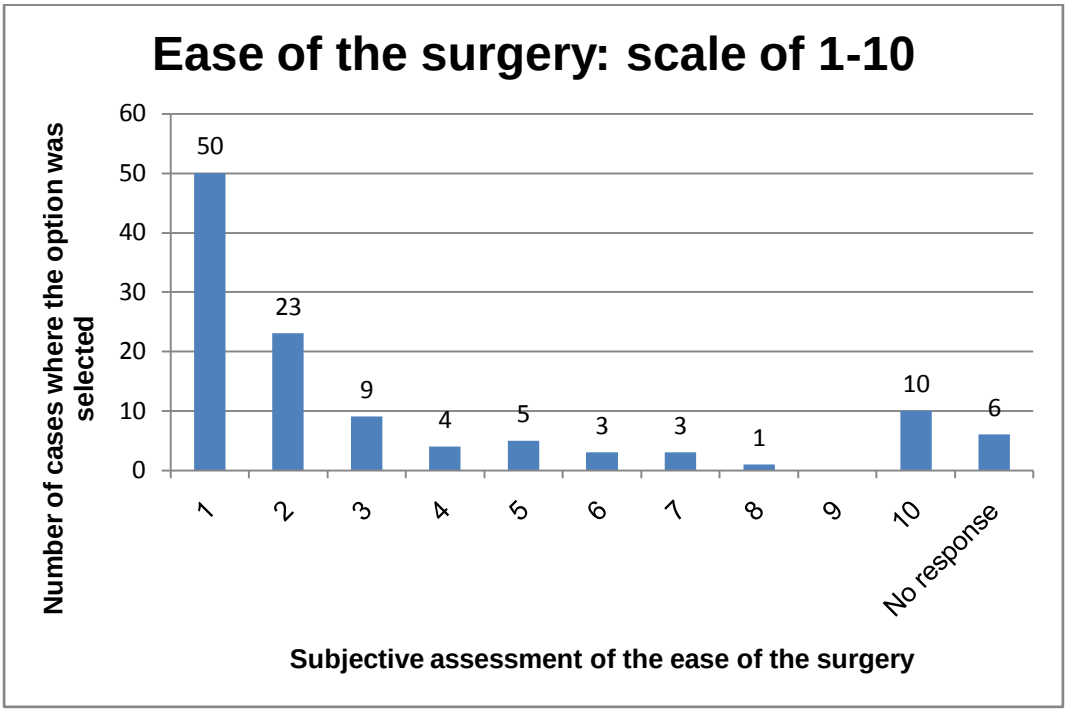

Figure 4: Surgeons' assessment of the ease of the surgery as a whole

Ease of use of the Alexis-O

The surgeons were also asked if they found the Alexis-O easy to use or not; in 90 cases the surgeons said it was easy to use, 12 said it was difficult and four did not respond (fig 5) .In the 12 cases where the surgeon said the Alexis-O was difficult to use; the surgeon had used the Alexis-O less than 20 times in 11 of them and in one case the surgeon had used it more than 50 times. In the one case where the surgeon had used the Alexis-O more than 50 times there were dense adhesions and as such the surgeon was unable to place the retractor in the abdominal cavity.

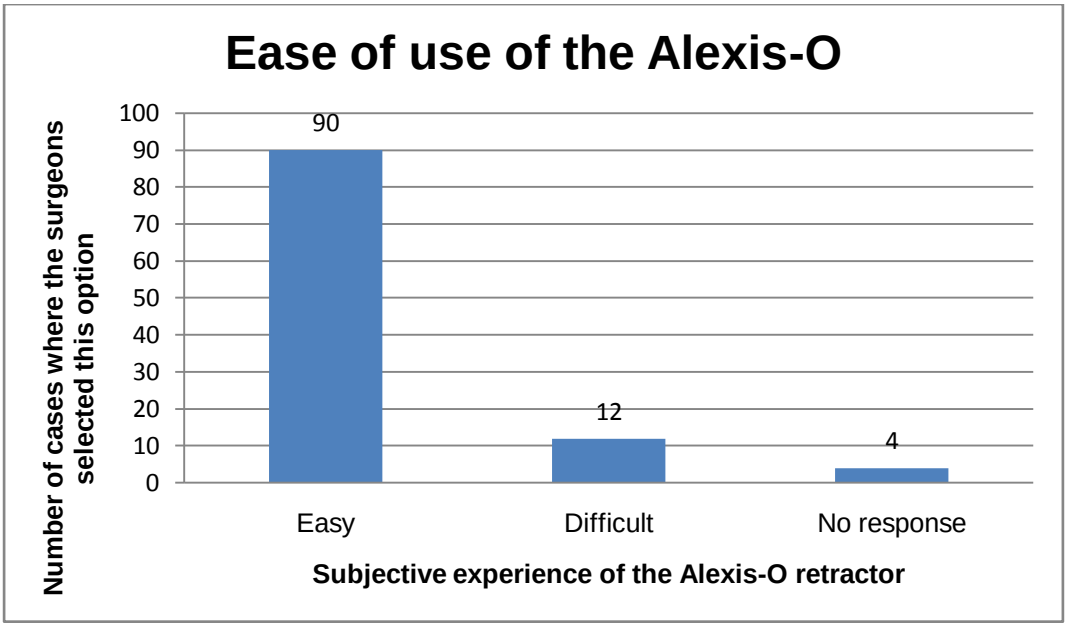

Figure 5: The surgeons' experience on the use of the Alexis-O

The surgeons selected easy to use in nine out of ten cases in the consultant group, 71 out of 83 cases in the registrar group and ten out of 13 cases by the medical officers.

The proportion of surgeons who reported use of the Alexis-O as easy was significantly higher than the surgeons who reported challenging use (76/81, 93.8% vs. 10/15, 66.7%, p=0.0016).

In 99/102 cases (97.1%) the surgeons indicated that they would use the Alexis-O retractor again, in three cases the surgeons said they would not use it again and four did not give a response. Of the 99 cases, 10/10 cases were performed by consultants, 77/83 by registrars (16 by fourth year registrars, 15 by third year registrars, nine by second year registrar, 35 by first year registrar and two by registrars who did not indicate their grade) and 12/13 by medical officers, and there was no statistical significance when the groups were compared.

The proportion reporting that they would use the Alexis retractor again was higher among those who reported that it was easy to use compared with those reporting it was challenging (80/81, 98.8% vs. 13/15, 86.7%, p=0.0134). In 13 cases in which its use was described as challenging, or the operation was difficult, the operator still favoured the Alexis-O.

Retractor Preference

Surgeons were asked if they preferred the Alexis-O retractor or the standard abdominal wall retractor. In 83/101 (82.2%) cases the surgeons preferred the Alexis-O retractor over the standard retractor; in 18/101 (17.8%) cases the surgeons indicated that they preferred the standard abdominal wall retractor and in five cases out of 106 the surgeons did not give a response (Fig 6). There were 54 surgeons who had used the Alexis-O less than 20 times, and among this group 39 (72%) still preferred the Alexis-O over the standard abdominal wall retractors.

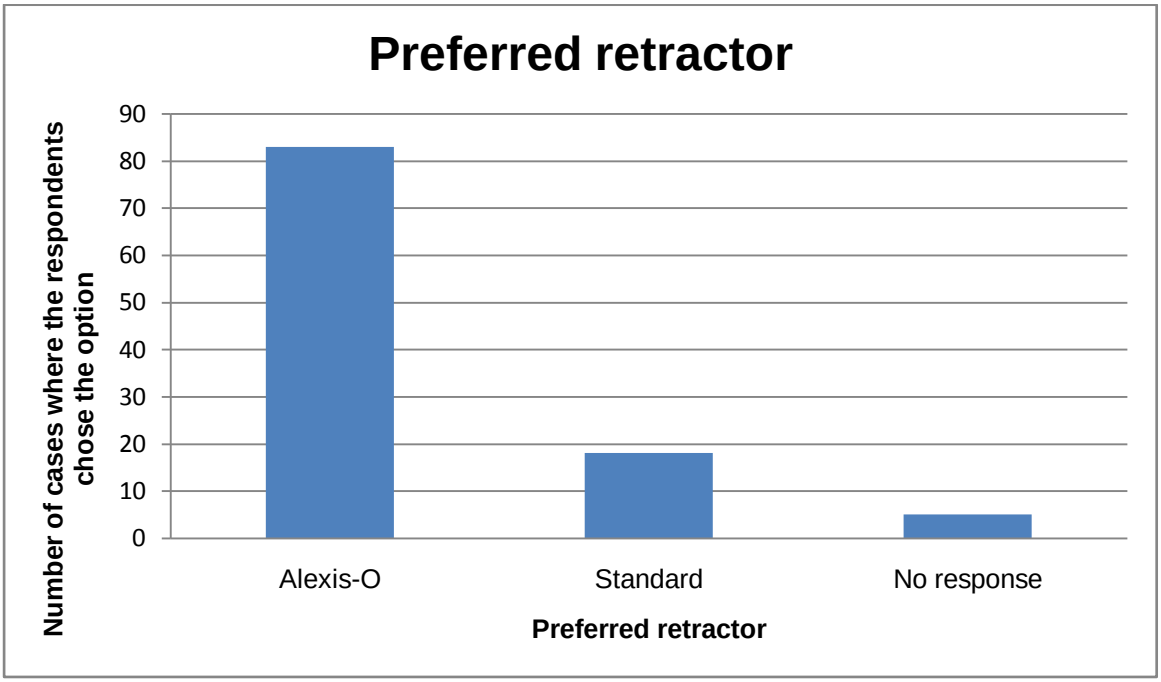

Figure 6: The preferred retractor among all the surgeons in the study

One surgeon (a consultant) indicated that she preferred both the Alexis-O and the standard abdominal wall retractor in two different surgeries. The rest of the surgeons did not change their preferences with different operations, even the ones who had difficulties in surgery still chose the Alexis-O if they had stated it as the preferred retractor.

In 9/10 (90%) cases performed by consultants, 66/83 (79.5%) cases performed by registrars and 8/13 (61.5%) cases performed by medical officers the surgeons indicated that they preferred the Alexis-O over the standard abdominal wall retractor.

There was no statistical difference in the proportion preferring the Alexis-O when comparing consultants vs. medical officers (90% vs. 61.5%, p=0.1233), consultants vs. registrars (90% vs. 79.5%, p=0.428) and medical officers vs. registrars (61.5% vs. 79.5%, p=0.1515), though this lack of difference may be a function of the size of the groups.

Figure 7 reflects the number of cases where the surgeons preferred the Alexis-O above the standard retractors among the surgeons who had used the Alexis-O less than 20 times.

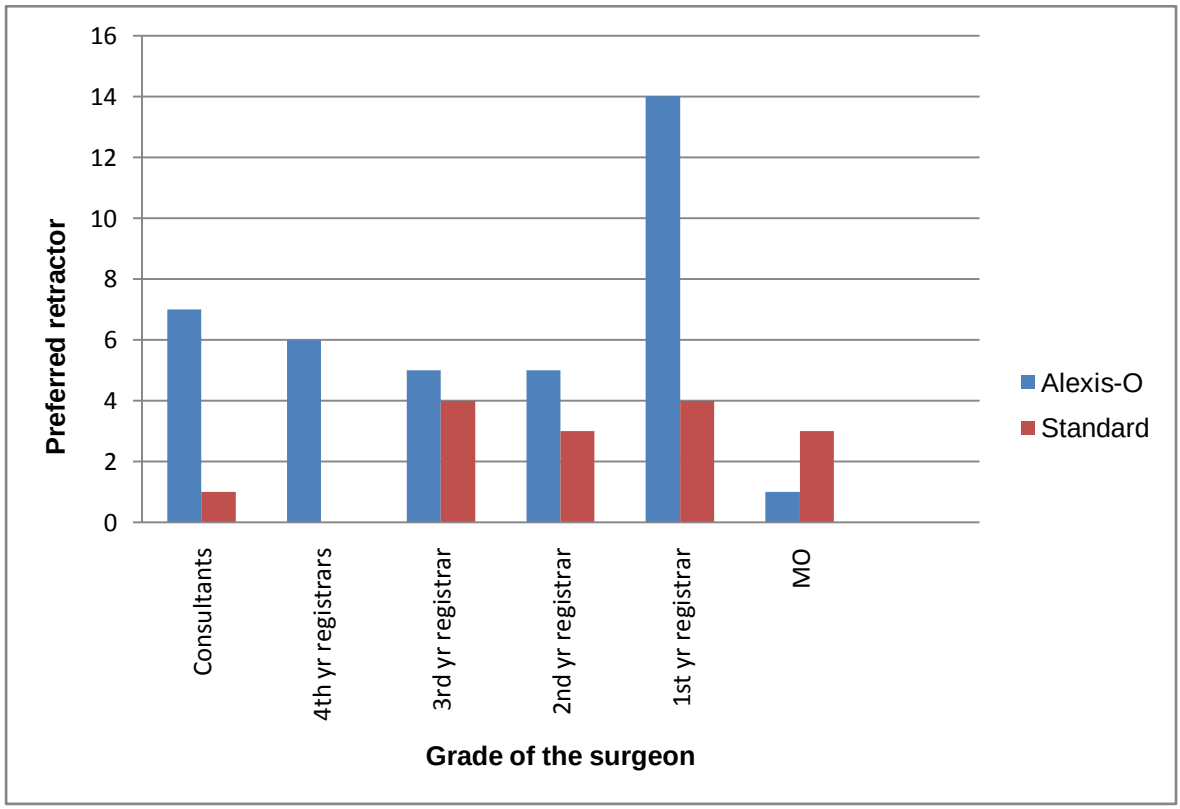

Figure 7: The preferred retractor in cases where the surgeons had used the Alexis-O less than 20 times

There were a total of 18 cases, performed by 11 surgeons, where the surgeons preferred the standard abdominal wall retractor. Of these 18 cases the surgeons found the Alexis-O difficult to use in seven cases. All of the seven cases were done by surgeons who had used the Alexis-O less than 20 times.

In three of the 18 cases the surgeons had used the Alexis-O between 20-50 times and in 15 cases the Alexis-O had been used less than 20 times.
The 11 surgeons who preferred the standard abdominal wall retractor were subdivided into grades of surgical experience. There was one consultant, one fourth year registrar, three third year registrars, two second year registrars, three first year registrars and one medical officer.

4.3.4.2 To determine difficulties experienced by the surgeon and to describe these difficulties

There were three cases in which the surgeons were unable to insert the Alexis-O due to dense adhesions. In 6/106 (5.7%) cases the Alexis-O was abandoned during the C/S; in 5/6 (83%) of these cases the reason for abandoning the Alexis-O retractor was the presence of dense adhesions and the one case had bilateral uterine tears where the surgeon could not visualise the apices, during the operation, with the Alexis-O in the abdomen.

There were 18 cases where the surgery was scored 4-10. Some of the surgeons, in 11/18 (61%) cases, explained the reasons for the operation being difficult but some did not. The reasons given for the difficulty of the surgery were varied and they included: dense adhesions 6/11 (54.5%), high BMI 2/11 (18%), bilateral uterine apical tears 2/11 (18%), impacted head 1/11 (9%) and forceps used to deliver baby 1/11 (9%). The variables in the other seven cases where the reason for the difficulty of the CS was not indicated were analysed. Three cases had a previous laparotomy (1 ectopic and 2 CS); CPD was the indication for CS in the other two cases. A possible reason in the remaining two cases was a raised BMI. Both cases were performed by senior registrars and the surgeons liked the Alexis-O in both cases. Out of the six cases there was one surgeon who did not like the Alexis-O retractor. In 6/106 (5.7%) cases the surgeons did not comment on the ease of surgery.

In our case series there was no prescribed manner of performing the CS and we only asked that the surgeons indicate if they exteriorised the uterus or not during

hysterotomy repair. There were 73/106 (68.9%) cases where the surgeon did not exteriorise the uterus, 30/106 (28.3%) cases where the uterus was exteriorised and 3/106 (2.8%) cases where the surgeon did not give a response. Of the 30 cases where the uterus was exteriorised; 20 scored the surgery as easy, in seven cases the surgery was scored as moderate, in two cases the surgery was scored as difficult and in one case there was no response given.

4.3.5 Secondary Outcomes

4.3.5.1 To assess the frequency with which it was not possible to place the Alexis-O or the operator was forced to abandon its use

The frequency in which it was not possible to insert the Alexis-O was three in 102 (0.029) and where the operator was forced to abandon it was six in 102 (0.058). In four cases the surgeons did not indicate if the Alexis-O had been abandoned or not.

4.3.5.2 To assess the duration of the operation.

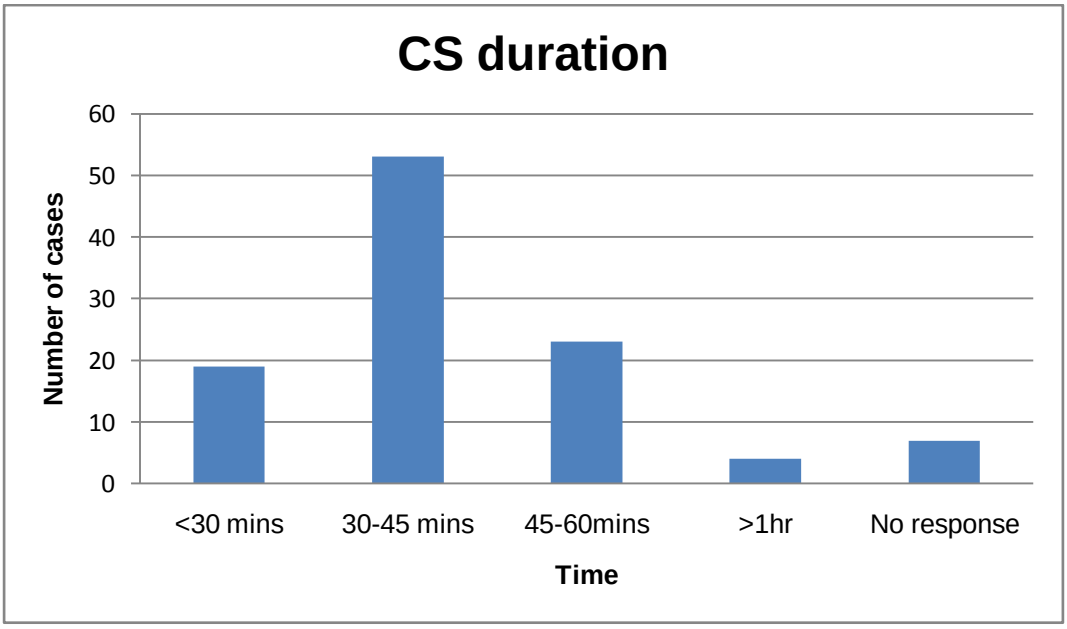

Figure 8: Duration of the caesarean section

The duration of the surgery has been tabulated in Figure 8. The most common duration of surgery was 30-45 minutes (n=53, 50%) followed by 45 min-1 hr (n=23,

21.7%), followed by <30 min (n=19, 17.9%) and then lastly >1hr (n=4, 3.8%). In seven cases the surgeons did not indicate the duration of the surgery. The proportion of registrars taking 30-45 min was significantly higher than consultants and medical officers combined (56.6% vs. 26.1%, p=0.0095) but there was no difference between them in the 45 min-1 hr CS duration.

4.3.5.2 To assess the estimated blood loss

Overall the mean (SD) EBL was 469.8ml (151.9). The mean (SD) EBL was 555ml (157.1) for surgeries carried out by consultants, 475.3ml (141.1) for registrars and 369.2ml (173.9) for medical officers. Consultants were likely to have a significantly higher EBL during surgery relative to medical officers ($p<0.05$) while there were no significant differences between consultants and registrars as well as registrars and medical officers.

Those with a previous CS or laparotomy had a significantly higher EBL compared with those without (500ml vs. 434ml, p=0.0187). There was no difference in EBL by weight of <80kg or ≥80kg.

The mean EBL for the levels of difficulty of the surgery was 447.6ml (136.5) for easy, 593.3 ml (200.8) for challenging and 533.3ml (57.7) for difficult. Those who reported the surgery as challenging reported a significantly higher EBL compared with those reporting easy ease of operation ($p<0.05$).

The mean (SD) EBL was 365.8ml (74.6) for duration <30 min, 474.5ml (112.9) for CS taking 30-45 min, and 538.9ml (184.1) for duration >45 min. Estimated blood loss for duration of CS >45 min ($p<0.05$) and 30-45 min ($p<0.05$) was significantly higher than <30 min.

4.3.5.3 To assess the patients' maximum perception of post-operative pain on an analogue scale

Patients were asked, two days post operatively, to grade the worst pain that they perceived post operatively by choosing a grade on a pain analogue scale (Figure 9).

Twenty-nine percent (29%) graded the pain they perceived as 6/10, 25.4% as 4/10, 14% as 10/10, 13.2% as 8/10, 10.3% as 2/10, 0.9% as 3, 0.9% as 7 and 5.6% of patients left before the PI had the chance to see them post operatively.

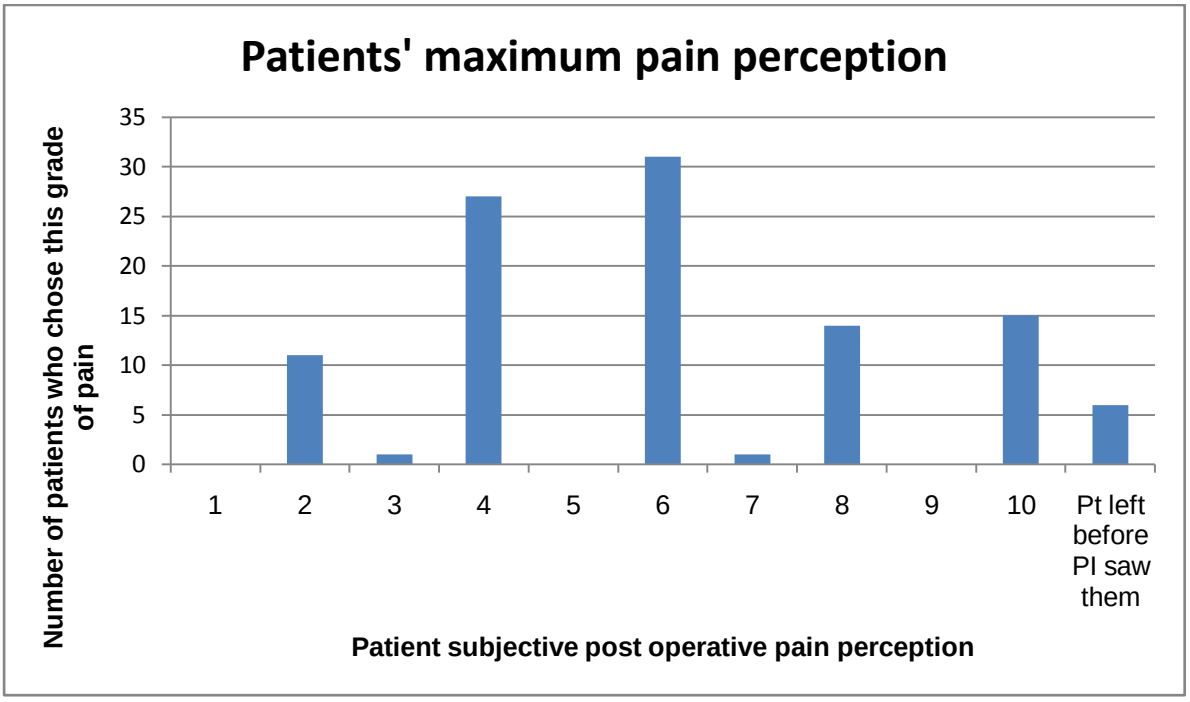

Figure 9: Patients' pain perception on a pain analogue scale from 1-10

4.3.5.4 To assess the incidence of immediate post-operative pyrexia

Confirmed use of intra-operative antibiotics was available in 93.9% of cases. In six cases no anaesthetic chart was available and in another six cases no proof of post-operative antibiotic use was available.

There were only two patients who had post-operative pyrexia. One patient had an emergency caesarean section for an antepartum haemorrhage, then had aspiration pneumonia and was admitted to ICU, she did not have any post-operative wound complications. The second patient, who had a caesarean section for previous CS in labour, had serous fluid oozing from her CS wound on day two. She later developed puerperal sepsis and went for a relook laparotomy. At laparotomy her uterine incision was noted to be necrotic and a total abdominal hysterectomy was performed.

4.3.5.5 To report on the length of hospital stay

The length of hospital stay was a mean 2.6 (2.9 SD) days, with a range of 27days (IQR =0). There were 102 patients who did not have major problems post-operatively. Of those 102, 88 were discharged on day two, ten were discharged on day three, three were discharged on day four and one was discharged on day five.

The remaining four patients had immediate complications. One patient was treated for wound sepsis and discharged on day seven. Another patient had aspiration pneumonia intra-operatively and was admitted to ICU, she was discharged on day 12.

The patient who had a previous kidney transplant sustained bowel injury on entry and she was admitted to ICU for post operative monitoring and subsequently discharged from the hospital on day ten. The patient who had a hysterectomy was discharged on day 29.

4.3.5.6 To assess the incidence of post-operative wound complications as reported by the discharging doctor and through a telephonic interview with the patient three weeks post discharge

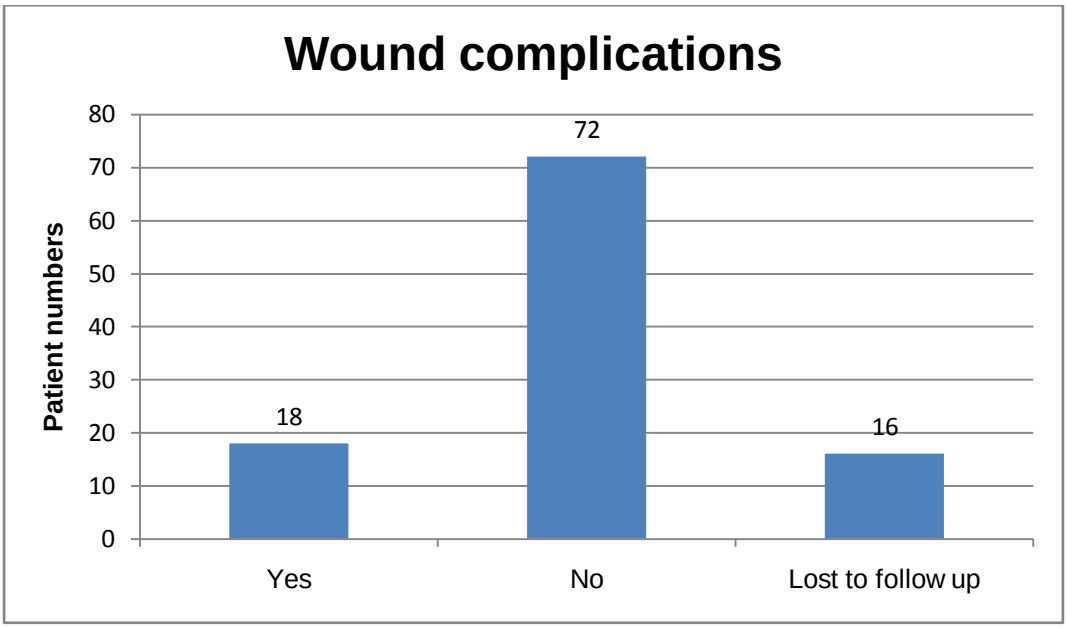

Figure 10: Number of patients who experienced wound complications

Patients were contacted by telephone three weeks after the operation. They were interviewed on their condition after discharge from the hospital. Sixteen (15%) patients were lost to follow up, either the cell phone number they gave was not working or they did not answer the phone on multiple occasions. Out of the 90 patients who had a telephonic interview, 18 (20%) had experienced wound complications (Figure 10).

Of the 18 patients who had wound complications, 12 of these patients had further interventions regarding their wounds (Figure 11). Two patients were re-admitted to CHBAH for wound sepsis, no relook laparotomy was done nor was any surgery performed and they were discharged after three days.

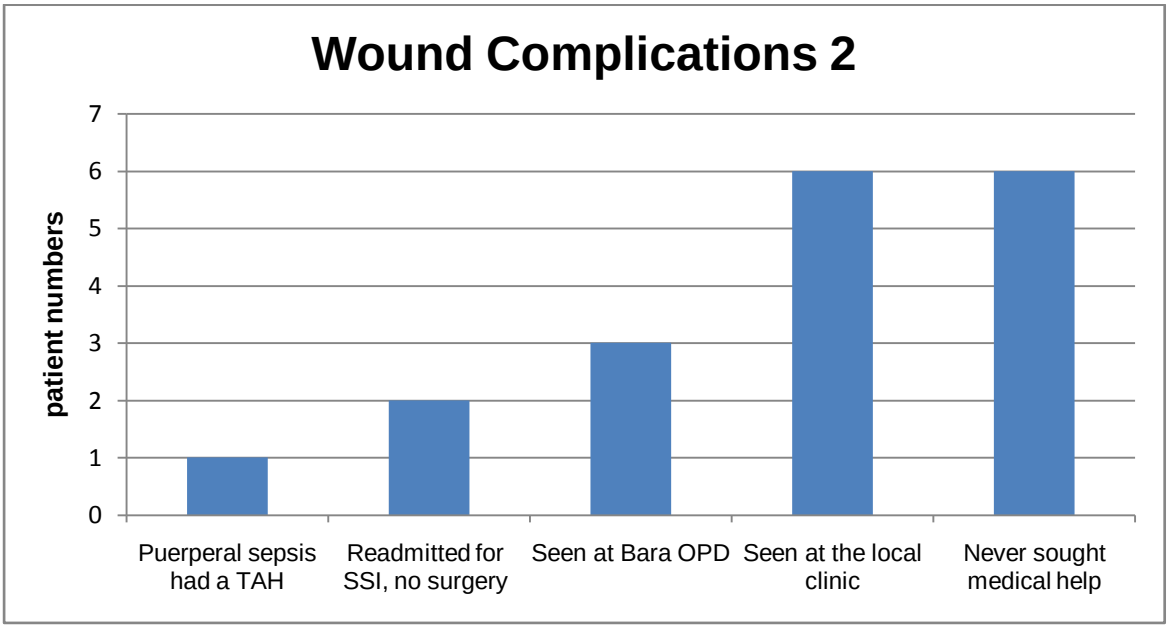

Figure 11: Wound complications 3 weeks post discharge as per telephone interview

Three patients were seen at CHBAH as outpatients, given treatment and discharged. One patient's stitches were partially removed at the local clinic and on presentation she had pus draining from the wound. Two of the patients presented with a section of the skin of the wound that had dehisced but there was no obvious infection on examination.

Six patients went to their local clinic when experiencing problems. The notes from the clinic were not available and the report is based on what the patients informed

the PI telephonically. Three patients had pus oozing from the wound; one of these patients was the patient who was discharged on day seven because she had been diagnosed with wound sepsis before discharge, the second patient went to remove sutures three weeks post discharge as she did not have anyone to look after the baby while she went to the clinic. The third patient had been told by the nursing staff that she had superficial skin infection and was given antibiotics, the forth patient had a small area of dehiscence and the sixth patient had serous fluid oozing from the wound.

The last six patients never sought any medical help but reported problems when questioned telephonically. Three had blood oozing from the wound, one had pus oozing from the wound, one had serous fluid oozing from the wound and the last patient had a small area of dehiscence. It is not possible to state how many of these wound complications were sepsis since six of the patients never sought help and the PI did not have access to the clinical notes of the patients who went to the local clinic.

CHAPTER 5

5.1DISCUSSION

5.1.1Primary outcomes

This is a case series looking primarily at the surgeons' experience of the Alexis-O retractor. In 88.2% of cases the surgeons reported that the Alexis-O was easy to use; in 97.1% of cases the surgeons indicated that they would use it again and in 82.2% of cases the surgeons preferred the Alexis-O over the standard retractor. In 82/106 (77.3%) cases, the surgeons assessed the operation as easy and they did not give a response in 5.7% of cases.

Hinkson et al[4] reported easier application of the retractor, better visualisation of the operating field, superior freedom of movement and easier removal of the retractor in the Alexis-O group versus the Collin's retractor group, 86% vs. 18% (P=0.001), 84% vs. 14% (P=0.001), 84% vs. 21% (P=0.001), 84% vs. 18% (P=0.001) respectively . In our case series we only asked if the surgeons liked the Alexis-O and if they found it easy to use. The question on ease of use was a subjective overall opinion of the surgeons.

In 51% of the cases the surgeons had used the Alexis-O less than 20 times, but even among these cases 72% of the surgeons preferred the Alexis-O. Theodoridis et al[5] showed a quick learning curve in applying the Alexis-O, with a median insertion time of 18 seconds.

There was no statistical difference in the proportion preferring the Alexis-O retractor when comparing consultants vs. medical officers (90% vs. 61.5%, p=0.1233), consultants vs. registrars (90% vs. 79.5%, p=0.428) and medical officers vs. registrars (61.5% vs. 79.5%, p=0.1515). The numbers suggest a possible difference in favour of the Alexis-O particularly when comparing consultants to medical officers, but the difference could be chance or the numbers are too small to achieve statistical significance.

Nakad et al[22] showed that the need to exteriorise the uterus during hysterotomy repair was significantly less in the Alexis-O arm compared to the routine retractor arm, 61.3% vs. 91.2% p<0.0001. Scolari Childress et al[11]also showed a similar difference of 55.6% vs. 88.5% respectively, p<0.001. In our case series there was no prescribed manner of performing the CS and we only asked that the surgeons indicate if they exteriorised the uterus or not during hysterotomy repair. There were 73/106 (68.9%) cases where the surgeon did not exteriorise the uterus, 30/106 (28.3%) cases where the uterus was exteriorised and 3/106 (2.8%) cases where the surgeon did not give a response.

There were a total of 12 cases where the surgeons did not like the Alexis-O. In 11 of these 12 cases the surgeons had used the Alexis-O less than 20 times and in seven cases the surgeons preferred the standard abdominal wall retractors. In 3/12 cases the surgeons were not able to insert the Alexis-O due to dense adhesions. In 2/12 cases use of the Alexis was abandoned; in one case the surgeon could not visualise the deep apical corners and in the other case no specific reason was given. Another surgeon, who did not actually abandon the Alexis-O struggled with deep tears of both uterine apices and the bowel had to be packed with additional swabs during the surgery. In one case there was deep pelvic impaction of the head and the surgeon stated that the Alexis-O made it more difficult to access the deeply impacted head.

Two surgeons stated an impression that the duration of surgery when using the standard retractor was less than when using the Alexis-O. The second surgeon contributed this longer duration of surgery to the fact that the assistance's glove got stuck while rolling the Alexis-O.

Among the cases where the Alexis-O was used less than 20 times, use of the retractor was difficult in 11 cases. There was one case where use of the Alexis-O was deemed difficult by a surgeon who had used the Alexis-O more than 50 times and there was no reported difficulty of use in the group that used it 20-50 times before. Lack of experience in its use does not necessarily mean the surgeon will have difficulty with it, but of those who had difficulty the majority had little experience in its use. Bar the cases where the surgeon was unable to use the Alexis-O due to adhesions, it is not possible to conclusively say if the difficulties experienced by the surgeon would not have been the same challenges had the standard retractors been

used. Even if there were randomization, the surgeon cannot at the same time use the two retractors on the same patients so even randomization has difficulties as a true comparison. In the studies that have been described (Hinkson et al[4], Scolari Childress et al[6] and Nakad et al[22]) the trials were done on women who were undergoing their first CS, there was also no mention of previous abdominal surgery or these patients were excluded and the researchers did not mention if the Alexis-O was abandoned during the CS or not.

In this study, most of the surgeons (50%) performed the operation in a time of between 30-45 min, 17.9% in less than 30 min, 21.7% between 45-60 min and 3.8% percent took more than an hour. A comparison of time taken with standard retractors was not possible since they were not used in the study.

Nakad et al[22] did not demonstrate a difference in operating time between the Alexis (59.9 min) versus the standard retractor (60.2 min, P=0.85). Scolari Childress et al[6] also did not demonstrate a difference in duration of surgery between the Alexis arm (64.5 min) versus the standard retractor arm (66 min P=0.74). Hinkson et al[4] did not compare the duration of the surgery.

5.1.2 Secondary outcomes

As mentioned above, in three cases the surgeons were not able to place the Alexis-O due to dense adhesions (2.8% of cases) and in six cases (5.6%) the surgeons abandoned the Alexis-O. In total, therefore, there were 9/106 (8.5%) cases where the surgeon was either unable to insert the Alexis-O or had to abandon its use during the surgery. The literature does not mention any cases where the Alexis-O was not used due to adhesions or where the surgeon had to abandon its use.

Hinkson et al[4] compared blood loss in the Alexis-O group compared to the Collin's retractor group; there were more patients who had EBL<500ml (19% vs. 3% p=0.006) in the Alexis-O group versus the Collin's retractor group, and less patients in the Alexis-O group had EBL of 500-1000ml (78% vs. 94%) versus the Collin's retractor group. The method of estimating the blood loss was not specified. Nakad et

al[22] did not demonstrate a difference in EBL in their trial, 1046ml in the Alexis arm versus 1048ml in the routine retractor arm, p=0.84. Scolari Childress et al[6] also demonstrated no difference in the EBL between the Alexis arm and standard retractor arm. In our case series we asked the surgeon to note their subjective estimation of blood loss. Overall the mean EBL was 470ml (SD 151.9). The mean EBL was 555ml (SD157.1) for surgeries carried out by consultants, 475.3ml (141.1) for registrars and 369.2ml (173.9) for medical officers. Consultants were likely to have a significantly higher EBL during surgery compared to medical officers ($p<0.05$) while there were no significant differences between consultants and registrars as well as registrars and medical officers. The reason for this could be that the consultants were better at estimating blood loss compared to medical officers, or that the medical officers underestimate blood loss. The EBL was higher in difficult and longer cases; those cases with a previous CS or laparotomy had a significantly higher EBL compared with those without (500ml vs. 434ml, p=0.0187). There was no difference in EBL by weight <80 kg or ≥80 kg. The mean EBL was 365.8ml (74.6) for CS duration of <30 min, 474.5ml (112.9) for CS taking 30-45 min, and 538.9ml (184.1) for duration >45 min. Estimated blood loss for duration of CS >45 min ($p<0.05$) and 30-45 min ($p<0.05$) was significantly higher than <30 min. The comparison with standard retractors was not possible since they were not used in the study.

Nakad et al[22] compared the patient's pain perception using a subjective scale analogue scoring the pain from 1-10, which was similar to the one we used. They found that there was no difference in the pain perceived post operatively by the patients comparing the Alexis with a standard retractor – in the Alexis arm the score was 6.4 (+/- 1.4) versus standard retractor at 6.2 (+/-1.5), P=0.14. The other studies did not have pain as an outcome. In our case series patients were asked to grade the worst perceived pain since the operation, this was done on day two post operatively. They were asked to grade this pain on a pain analogue scale from 0-10. Twenty nine (29%) graded the pain perceived as 6/10, 25.4% as 4/10, 14% as 10/10, 13.2% as 8/10, 10.3% as 2/10, 0.9% as 3, 0.9% as 7 and 5.6% of patients left before the PI had the chance to see them post operatively. There was no comparison group as this was a case series.

There were only two patients who had post-operative pyrexia during the time of admission, one patient had aspiration pneumonia and had no post-operative wound complications while the other one had puerperal sepsis.

At the three weeks post-operative telephonic follow up 18 patients reported that they had post-operative wound complications but it is difficult to know how many had SSI.

There was no patient selection in our study; all patients who were approached and all that agreed were included. Of those enrolled, 40 (38%) were HIV positive. There were 16 patients who were lost to follow up. Of the 90 contacted after three weeks, 18 had wound complications. One patient had a total abdominal hysterectomy for puerperal sepsis and the remaining eight were treated with antibiotics or did not seek any help. The remaining nine patients had wound skin dehiscence or disruption. The wound complication rate was 18/90 (20%).The rate of wound complications seems relatively high. But it is not possible to compare this in this population to patients in whom a standard retractor was used. In the RCTs described, specific patients were selected to take part in the studies, preventing comparison with this group. Hinkson et al[4] excluded patients who were HIV positive, diabetic, emergencies, had a previous CS or laparotomy, had autoimmune diseases, had a bleeding disorder, in active phase of labour and suspected or confirmed chorioamnionitis. Some of these conditions i.e. chorioamnionitis, are risk factors for wound sepsis. Their results showed 1% SSI in the Alexis group versus 8% in the Collins retractor group, P=0.035. Nakad et al[22] excluded patients who were undergoing emergency CS, had a planned vertical incision, and had active skin infection and chorioamnionitis. They reported a SSI rate of 2.7% in the Alexis group and 1.1% in the standard retractor group, P=0.20. Scolari Childress et al[6] performed an RCT on obese patients (BMI>30kg/m^2) undergoing elective CS, some of the patients did however have an emergency CS. They did not show a difference in the rate of SSI between the Alexis group (20.6%) versus the standard retractor group (17.6%), P=0.62. These rates are closer to our own.

Patients stayed a mean of 2.6 days post operatively.

The cost of using the Alexis-O retractor was not assessed in this study.

5.2 LIMITATIONS

The study was limited by a lack of a randomized study format or a comparative group. The postgraduate committee recommended a case series citing that the number of patients that would be recruited for an RCT would be too much for the primary investigator to consent all and to perform the study without assistance. This was appealed and declined.

Ease of operation scale was not understood the same way by the different surgeons; some of the surgeons who abandoned or did not use the Alexis-O due to dense adhesions said the surgery was easy yet others said it was hard without describing hindrances. This was the surgeon's subjective understanding of difficulty, and unfortunately the PI did not explain to the surgeons the intended distinction of grading the difficulty and this is therefore a limitation in the study.

BMI could not be calculated in the study.

A number of patients were lost to follow up.

The type and frequency of analgesia and antibiotics given to patients were not noted.

5.3 ADVANTAGES

The studies that were analysed excluded women who had previous CS or laparotomy, or did not mention if patients had a history of previous abdominal surgery. We discovered a problem of difficulty of inserting the Alexis-O in patients who had previous abdominal surgery. This is a problem that has not been mentioned in the references assessed.

5.4 CONCLUSION

The Alexis-O is preferred by many surgeons. Most surgeons find it easy to use and its use has a rapid learning curve. Since this is a case series, it is not possible to deduce if this device is superior to the standard abdominal wall retractors with regards to the outcomes assessed. A randomised control trial would be necessary. In difficult cases with complications deep in the pelvis the Alexis-O may need to be removed and where dense abdominal wall adhesions that cannot be easily dissected the Alexis-O cannot be placed nor should be. The Alexis-O nonetheless provides excellent vision, may assist in diminishing operative complications and awaits further comparison.

5.5 RECOMMENDATIONS

A randomised trial, in our setting, should be performed comparing the Alexis-O to the standard abdominal wall retractors. The outcomes should include parameters included here relating to characteristics of the operation, peri-operative and immediate post-operative complications, SSI, and the cost of treating patients with SSI and intra-abdominal sepsis and the cost of using the Alexis-O.

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APPENDIX A – Patient Information Sheet

Dear Patient

My name is Dr Philiswa Mlandu

I am a doctor in the Maternity department of Chris Hani Baragwanath Hospital. Many patients in the Maternity department will have a Caesarean section. I would like to invite you to take part in a study I will be conducting at the Maternity department here at Chris Hani Baragwanath Hospital.

This study only involves patients who are going to deliver by caesarean section.

I want to find out if the use of a particular 'retractor', which is for holding back the layers of the patient's abdomen to help to see the womb during the operation, makes it easier for the doctor doing the operation and if it affects your wound after the operation. This retractor is called the 'Alexis'. This instrument for helping with operations has been used in many operations before and is safe and is being used throughout the world in many operations today.

We cannot say that the use of the Alexis is definitely going to help you or the surgeon or not. We are going to ask the surgeon after the operation how they found the use of the Alexis, we are going to check you and your charts after the operation and we are going to call you at home to see how you have been after the operation.

If you agree to take part in the study we request your permission to get information from your file that will relate to the caesarean section when and if necessary.

If however, you do not wish to take part in this study, you will still get all the necessary medical care and will not be discriminated against.

For those who do take part in the study, information about them will be entirely confidential. That is nobody will be able to identify them in any way in discussions about the study. Patients will be identified by their study identity number and no patient details will be used in any discussions.

Should you have any queries or complaints about this research please contact the Human Research Ethics Department.

Chairperson Prof P Cleaton-Jones, Tel 011 717 2301. Secretariat: Zanele Ndlovu and Langutani Masingi 011 717 1252/1234 zanele.ndlovu@wits.ac.za or Langutani.masingi@wits.ac.za.
Ethics clearance certificate no. M150813

Thank you
Dr Philiswa Mlandu, Department of Obstetrics and Gynaecology, Chris Hani Baragwanath Hospital

APPENDIX B– Patient Consent Form

I have read the Information Sheet about the Alexis Study and I understand the information that is explained there.

I understand that the purpose of the study is to find out the experience of the doctors in using the Alexis retractor and its effect, if any, on my wound healing.

I understand that no definite advantage will come to me if I do sign consent for the study.

I understand that no particular surgeon has been assigned to my operation and that this will not be different if I am in the study or not.

I understand that I may withdraw my consent to be in the study at ANY time.

Name:…… Hospital Number:……..

Signature :…… Date:……..

Witness 1:Name:…… Signature:……

Date:……

Witness 2: Name:…… Signature:……..

Date:……

APPENDIX C – Surgeon Consent Form

Surgeon's consent form

Dear doctor

My name is Dr YP Mlandu. I am a registrar in the department of Obstetrics and Gynaecology. I am doing research on the experience of the surgeon when using the Alexis abdominal wall retractor.

I am requesting your assistance in the trial by using the Alexis retractor on the patients who have been consented to take part in the study and by filling in forms one immediately after the caesarean section and one upon discharge of the patient.

I agree/disagree to assist in the study

Name:……

Signature :…… Date:……

APPENDIX D – Surgeon Data Sheet

A study to assess the acceptability of the Alexis Retractor and a brief description of post operative wound complications associated with its use (Ethics clearance certificate no. M150813)

Please complete the following (circle appropriate)

Study number:_____

1) **Date of C/S ___/___/____**
2) **Previous C/S or laparotomy (indicate which lap done)_____**
3) **Duration of the caesarean section (from incision to closure)_____**
4) **Indication for C/S_____**
5) **Elective / emergency**
6) **Transverse incision /SUMI**
7) **Surgeon: Registrar: year___ / Consultant**
8) **Was there oozing of blood from the anterior abdominal wall as you closed? Y / N**
9) **Diathermy used? Y / N**
10) **Any predisposition to haemorrhage (e.g. HELLP syndrome)?_____**
11) **Estimated blood loss:_____ml**
12) **Was the liquor malodorous? Y / N**
13) **Method of skin closure(e.g. clips, interrupted nylon, sub-cut)_____**
14) **Did you apply sutures to the adipose tissue? Yes / No**
15) **Uterus exteriorised repair? Yes / No**
16) **Your experience with the Alexis retractor**

a. **How many times have you used it?_____**
b. **Ease of use_____**
c. **Would you use it again? Y / N**
d. **Which retractor do you prefer? Alexis / standard retractors**
e. **If you abandoned it please state why _____**
   _____
f. **Any other comments _____**
   _____

17) **Ease of the operation**

Easy Challenging Very difficult

|----------|----------|----------|----------|----------|----------|----------|----------|----------|

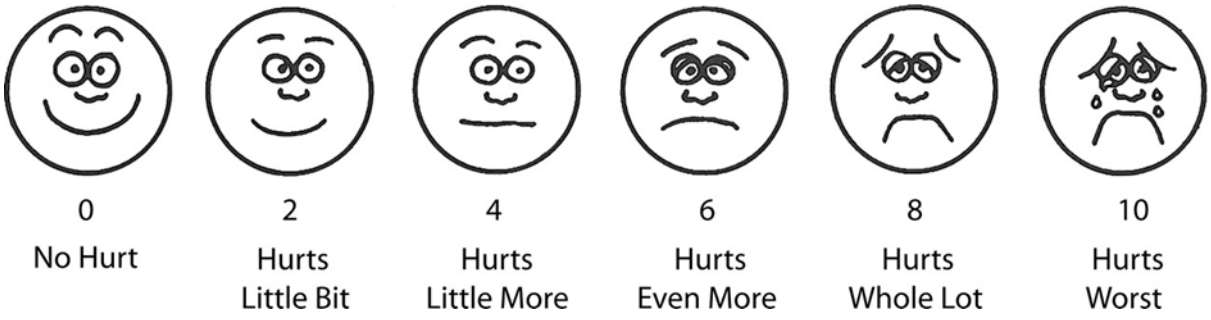
1 2 3 4 5 6 7 8 9 10

APPENDIX E – Patient Data Sheet

Please complete the following on discharge of the patient

Study Number:_____

1. **Age_____**
2. **Gravity____Parity____**
3. **HIV status R / NR**
4. **BMI or weight(if no height recorded)_____**
5. **Length of hospital stay since operation(days)_____**
6. **Prophylactic antibiotics use? Y / N If yes, which one?_____**
7. **Post-operative antibiotics given Y/N**
8. **Patient's reported worst perception of pain during the hospital stay (please choose a number as per analogue scale)**



9. **If antibiotics given - were they started for wound/other reason_____**
   _____
10. **Post op pyrexia Y/N Highest Temp: T°=_____**
11. **Pulse on discharge_____**
12. **State of wound: normal / oozing blood / oozing serous fluid / oozing pus**
13. **Did the patient have a relook laparotomy?_____**
14. **If you answered yes to the above, Indication_____**
15. **Intra-op findings_____**

APPENDIX F – Patient Discharge Letter

Dear Doctor

_____ is in a study to assess the acceptability and the operative wound complications associated with the use of the Alexis abdominal wall retractor.

She has been asked to come to the admissions ward if there are any problems.

Please contact Dr Mlandu when she presents.

Thank You
Dr YP Mlandu

APPENDIX G - Telephonic Questionnaire After 3 Weeks

Study Number_____

Date of original surgery_____

Date of discharge from Bara_____

1. **Have you had any problems with the wound since going home Y / N**
2. **If the answer is YES, what problems have you had? (bleeding/ draining clear fluid/ draining pus? To be asked specifically if nothing volunteered**

   _____
   _____
   _____
3. **After leaving the hospital have you been prescribed antibiotics for the wound from a doctor or at a clinic or hospital? Y / N**
4. **Have you had any procedures/operations since going home? Y / N**
5. **If YES, which?**

   _____
   _____
   _____
6. **Have you had any other problems after going home? Y / N**
7. **IF YES, what problems**

   _____
   _____
   _____
   _____
   _____
   _____
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   _____
   _____
   _____

APPENDIX H – Ethics Approval

R14/49 Dr Yandiswa Philiswa Mlandu

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M150813

NAME: (Principal Investigator)	Dr Yandiswa Philiswa Mlandu
DEPARTMENT:	Obstetrics and Gynaecology Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	A Study to Assess the Acceptability of the Alexis Retractor and a Brief Description of Post Operative Wound Complications Associated with its use
DATE CONSIDERED:	28/08/2015
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr William Edridge

APPROVED BY: Professor P Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 12/10/2015

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 10004, 10th floor, Senate House/2nd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report.**

Principal Investigator Signature

Date 23/08/2018

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX I - Turnitin report

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