Patient discomfort with a novel suction based cervical retractor compared to the traditional cervical tenaculum

Protocol Summary

IRB Approval Date:	2/20/2014
University of Utah IRB #:	IRB_00070910
Sponsor:	
Principal Investigator:	David Turok
Internal Staff and Sub-Investigators:	Vineela Maddukuri Ivana Thompson Pamela Royer Jessica Sanders Amy Orr Jessica Barlow
External Sub-Investigators:	Erica Torres Maurisa Pitzer Veronica Galinda Kathy Burke

Background and Introduction

Progress is being made in the effort to reduce unintended pregnancies in the U.S. A significant portion of this progress is due to the increased use of highly effective methods of contraception, especially the IUD. Placement of the IUD requires traction of the uterine cervix with a cervical tenaculum, an instrument that has not been improved upon for many decades. The cervical tenaculum is a sharp, pronged tool similar to a forceps that is used to pierce and grasp the tissue of the female cervix. This tool is used primarily to straighten and align the cervical canal and endometrial cavity with the vagina to ease entry of other devices into the endometrial cavity. It is used in many gynecological procedures including but not limited to intrauterine device insertions, endometrial biopsies, dilation and curettage, manual/electric vacuum aspiration, hysterectomies, and others. The tenaculum is an effective tool in engaging the cervix by using two sharp, pointed opposing points that pierce through the tissue of the cervix. However, the device can be painful for some patients and alternatives are limited. The tenaculum has been in use since at least the 1950's and little, if anything, has been done to innovate on this instrument or on the ability to engage the cervix in a different manner. The most commonly used tenaculum penetrates 2 sharp opposing points into the cervical stroma. The Bioceptive suction based cervical retractor adheres to the cervical tissue with suction but does not penetrate the tissue.

This study will test a suction-based method of engaging the cervix. Bioceptive has developed a device that more gently and atraumatically attaches to the cervix with no bleeding. This novel attachment mechanism may diminsh pain and discomfort. Pre-clinical testing has been performed on the device including testing on synthetic uterine models, human cadavers, and human uteri immediately post-hysterectomy (Utah IRB # 00059096). Results from these efforts have shown effective attachment to the cervix and the ability for the device to maintain suction throughout a procedure atraumatically. This study proposes to introduce this minimal risk device in a clinical setting to determine the response of women undergoing gynecologic procedures.

The study includes 2 phases. Phase 1 will be a baseline assessment of acceptability and measure of 100 mm visual analog scale (VAS) pain scores with the novel device. The 100 mm VAS has been used in many studies assessing pain in a variety of gynecologic procedures including a study performed by this group of investigators.[1] Phase 2 will be a RCT of pain scores in women randomized to a traditional tenaculum or the novel cervical attachment device.

Device:

Bioceptive's work on a novel IUD inserter, which includes the cervical suction retractor to be assessed in this protocol, received grant support from the Saving Lives at Birth program supported by USAID, the Bill and Melinda Gates Foundation, UKAID, Grand Challenges Canada and Norwegian Ministry of Foreign Affairs. (http://savinglivesatbirth.net/news/13/07/31/press-release-round-3-award-nominees-announced)

The cervical suction retractor is manufacturd by the Avant Garde Group, a design and manufacturing company located at 3F,NO.66, CHUNG CHENG RD., HSIN-CHUANG, TAIPEI, TAIWAN, R. O. C.

[1] **Swenson C**, Turok DK, Ward K, Jacobson JC, Dermish A. Self-administered misoprostol or placebo before intrauterine device insertion in nulliparous women: a randomized controlled trial. Obstet Gynecol. 2012 Aug;120(2 Pt 1):341-7.

Purpose and Objectives

This study will test a suction-based method of engaging the cervix.

The study has two aims.

Aim #1: To observe and measure a patient's reaction and perception to the application of the Bioceptive Cervical Retractor.

Aim #2: To measure the pain perceptions of the Bioceptive Cervical Retractor versus the single-toothed cervical tenaculum and the atraumatic tenaculum.

Study Population

Age of Participants: Women ages 18-45

Sample Size:

At Utah:	35
All Centers:	35

Inclusion Criteria:

There are two phases of the study and inclusion and exclusion criteria are the same for both phases of the study.

The Inclusion Criteria are:

·Subjects presenting for IUD insertion or endometrial biopsy

·Age 18 - 45

·Able to consent for study in English or Spanish

Exclusion Criteria:

Exclusion Criteria:

·Post-menopausal

·Current pregnancy

·Cervical abnormalities (cervical polyp, cervical lesion, or irregularity)

·Use of narcotics or Benzodiazepines prior to procedure

Design

Prospective Clinical Research

Study Procedures

Recruitment/Participant Identification Process:

We plan to review patient appointment logs at participating clinics in an effort to identify potential participants who are scheduled for an IUD insertion or endometrial biopsy. Providers from approved Planned Parenthood and University of Utah sites may refer patients who are scheduled for an IUD insertion or endometrial biopsy to study staff for an explanation of the study and verification of inclusion/exclusion criteria. We will confirm initial inclusion/exclusion criteria in order to confirm that patients meet appropriate criteria before approaching them for participation in the study.

Informed Consent:

Description of location(s) where consent will be obtained:

Consent will be obtained in a private examination room at the clinic where the patient is receiving care.

Description of the consent process(es), including the timing of consent:

Participants will have all questions answered prior to enrollment. Due to the timing of the procedures, extra time (e.g., days) may not be possible.

Procedures:

Eligible patients undergoing IUD insertion or endometrial biopsy who provide informed consent for participation in the study study will have their procedure performed using the novel Bioceptive suction based cervical retractor. Those interested in participation will be

consented prior to their scheduled appointment to permit testing during said visit.

Women will not need to be followed as this study only seeks immediate data. The procedures for this study will be performed by a limited number of providers with extensive experience in procedures involving passage of catheters trough the cervix.

Patients will be informed that the study is intended to determine several data points that will be used in the development of medical products that seek to make certain intrauterine procedures less painful and occur with fewer adverse events.

Study Design:

Patients will be asked to complete questionnaires at the beginning and end of the study visit. They will be asked about any pain medications they've taken prior to their procedure, as well as their feelings about the procedure, once it's over.

Participants will also complete questionnaires addressing pain by a validated visual analogue pain scale. Pain scores will be measured using a 100-mm visual analogue scale (anchors: 0- none, 100 mm- worst imaginable). Participants will be asked to complete a pain score with the 100 point VAS at 6 different points during the study visit: prior to placement of the speculum, with placement of the speculum, after 1 turn of the know of the cervical retractor, at the time of complete attachment of the cervical retractor, immediately after IUD insertion or endometrial biopsy, and after the speculum is removed.

The study is to be performed in two phases. Phase 1 is to be completed prior to the commencement of the second phase.

Phase 1: Patient Response to Bioceptive Cervical Retractor

1. Complete all regular examinations and/or procedures scheduled to take place during the visit.

2. Remove Bioceptive Cervical Retractor from container after Cidex disinfection.

3. Assure patient remains in normal gynecological examination position.

4. Prior to placement of the speculum Hand the tablet to the patient to hold and record her response on the 100 point visual analogue scale (VAS) on the screen (VAS #1)

5. Place the speculum in the vagina (VAS #2)

6. With the speculum still in place, position the distal end of the Bioceptive Cervical Retractor so that the rubber tip on the suction port enters the cervical os and the outer ring of the port contacts cervical tissue.

7. While placing gentle forward pressure toward the cervix, twist the knob on the Bioceptive Cervical Retractor ONE FULL TURN to generate suction. Record the patient's response on the VAS #3.

8. Continue to twist the knob slowly until it cannot be twisted any more, then record the

patient's response on the VAS #4.

9. Place traction on the cervix and perform the IUD insertion or endometrial biopsy per usual care. Follwing IUD placement or completing endometrial biopsy obtain VAS #5.

10. Twist the knob back in the opposite direction to release suction and remove the entire Cervical Retractor from the vagina.

11. Examine the cervix to determine the condition of the cervix post-application.

12. Document any changes in cervical tissue, deformities or lacerations.

13. Remove speculum and have patient document final VAS (#6).

Phase 2: Randomized Control Study of Cervical Attachment Methods: Bioceptive Cervical Retractor vs. Single-Toothed Tenaculum vs. Atraumatic Tenaculum.

Participants will be blinded to the type of cervical retractor. Randomization will occur in blocks of 4 via REDcap for a total recruitment of 24 participants.

1. Complete all regular examinations and/or procedures scheduled to take place during the visit.

2. With speculum still in place from normal examination, remove one of the cervical tools from its package without showing it to the patient or giving any indication as to which device is being used.

3. Record the patient's response on the VAS.

4. Make attachment to the cervix following the attachment technique appropriate to the tool used.

5. Measure the patient's response according to the VAS.

6. Place traction on the cervix with the tool and hold.

7. Measure the patient's response according to the VAS.

8. Remove traction and release the tool from the cervix.

9. Measure the patient's response according to the VAS.

**Note: Before starting to recruit for Phase 2 of the study we will submit an amendment to the IRB with the consent document that will be used for this 2nd phase. We will not begin recruitment for Phase 2 until we have received IRB approval.

Procedures performed for research purposes only:

Placement of the Tenaculum or suction cervical retractor as well as questionnaires and the VAS pain scale are part of the research. The placement of the IUD or endometrial biopsy pipelle is standard care for the service that people present for.

For the second phase of the study, randomization to either the Bioceptive cervical retractor or the standard single-toothed tenaculum will also be a research only procedure.

Statistical Methods, Data Analysis and Interpretation

The sample size was selected to meet the goals of initially testing this novel cervical attachment device in human subjects and creating a basis for further comparisons to the traditional instrument.