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Utilization and Perceptions of a Novel Cervical Visualization Tool, The Callascope, For Home-Based Self-Cervical Examinations

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Abstract

Background: Cervical visualization is critical for a wide array of reproductive health maintenance procedures. Yet, it has largely been limited to clinical providers, who utilize the speculum to access the cervix for diagnostic or treatment purposes. Self-cervical visualization, using the speculum and a mirror, has been attempted, but is often characterized as painful, awkward, and uncomfortable. We have developed a novel speculum-free device, the Callascope, that enables self-cervical visualization and image capture without clinician assistance. Self-cervical visualization has immense potential for increased confidence in knowing one's body, seeking help from a provider, and feeling empowered to take charge of one's own reproductive health. Additionally, self-cervical visualization could enable access to home-based basic reproductive health applications, such as intrauterine device placement monitoring, and eventually preliminary self-cervical cancer screening using contrast-agent application in combination with HPV self-sampling.

Methods: This mixed-methods study involved training healthy volunteers (n=12) to use the Callascope at home to assess ease-of-use and feasibility of imaging their cervix without clinician guidance. This involved (1) on-site training at the study site, followed by initial self-imaging of the cervix, (2) self-imaging at home, and (3) an optional audio reflection.

Results: The on-site training examinations resulted in 83% of participants (10 out of 12) visualizing their cervix, upon their first attempt. During the home examinations, 92% (11 out of 12) participants visualized their cervix. Overall, all participants captured at least one image of their cervix and would recommend the Callascope to others. Audio reflections showed high acceptability with participants described the Callascope experience as "comfortable", "easy to use", "empowering", and "fascinating".

Conclusion: We have shown high acceptability and feasibility of the Callascope for person-centered, home-based, comfortable, and cost-effective self-cervical visualization and image capture.

Keywords: Cervix Imaging; Speculum-Free; Home-Based; Cervical Cancer

Introduction

Cervical visualization is a critical component of reproductive health maintenance. Healthcare providers use the speculum for cervical visualization in a wide variety of clinical evaluations [1-5]. While the speculum is an important tool in obstetric and gynecologic care, it is associated with pain and discomfort leading to fear of pelvic examinations [6]. Fear of the speculum is an evident component of non-adherence to cervical cancer screening recommendations. Though cervical cancer is preventable with regular screening and the HPV vaccine, half a million women are diagnosed and a quarter million dies annually [7]. One of the main deterrents to screening is pain due to the speculum- based examination, which leads to a four-fold decrease in adherence to screening [8,9]. The barriers the speculum poses to health-seeking behavior creates a need for alternative approaches of viewing lower internal reproductive anatomy. Additionally, lack of awareness about reproductive anatomy significantly decreases women's reproductive health-seeking behavior [10]. Several studies conducted in socioculturally diverse settings found that educating women on their cervix and cervical cancer increased screening rates more than two-fold [11-15]. These studies suggest that women are more likely to advocate for their reproductive healthcare when educated on the subject.

We developed the Callascope, a low-cost cervical visualization device, to comfortably view internal lower reproductive anatomy and potentially substitute for the speculum (Figure 1) [16,17]. In our previously published studies, we evaluated clini-

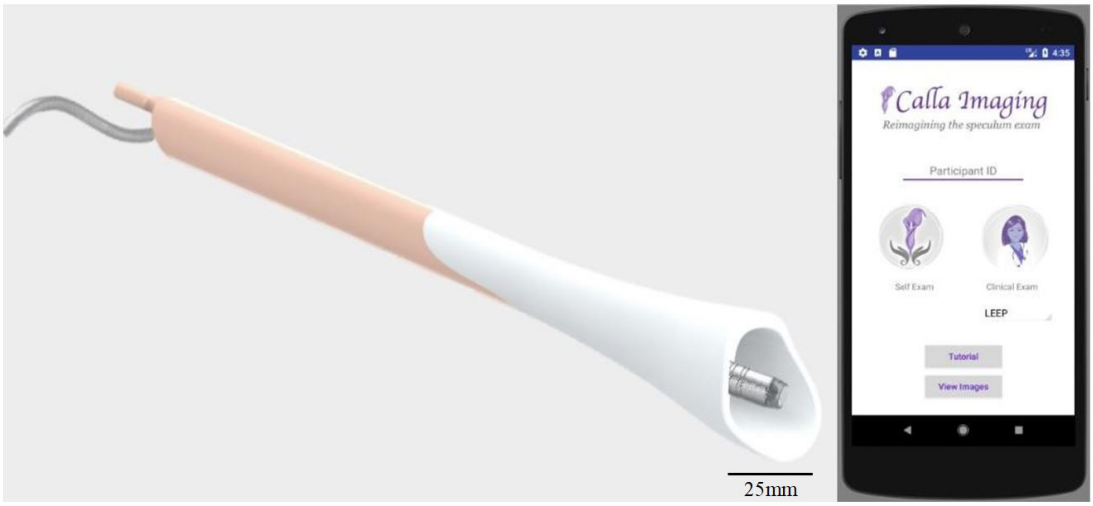


Figure 1: Illustrates the Callascope's slender introducer with a Calla Lily shaped tip (left), a light source and camerawithin it, and a custom-built Calla Imaging mobile application (right). The Callascope's tip pushes the vaginal walls away from the cervix and nudges the often off-centered cervix into the field of view of the camera. The Callascope connects to a cell-phone camera app that gives visual cues to navigate with real-time guidance without the aid of a clinician. The slender introducer replaces the speculum; a camera embedded in the stem of the introducer and connected to an application on a mobile phone for real-time visualization

cian-based cervical imaging, and self-cervical imaging using the Callascope under clinician guidance [16,17]. In this study, we investigated the utilization of the Callascope for self-cervical imaging outside of a clinical setting to assess the Callascope's potential for future use in home-based reproductive health applications and reproductive health education programs.

Methods

Healthy volunteer studies

This study was approved by Duke University's institutional review board (IRB) and was performed with an approved protocol, informed consent process, and data storage system (Pro00008173). Participants were healthy, between 21 to65 years old, had a history of at least one pap smear, and were not pregnant or not in 2nd or 3rd trimester of pregnancy(n = 12). Volunteers were recruited from the general Durham community using flyers and online on the Craigslist platform (Supplemental Figure 1). During the first phase of the study, participants completed the training module, and independently performed an on-site training examination. In the second phase, which consisted of a home examination, participants were given the Callascope in their homes for one week (Figure 2). In the last phase, the participants had the option of doing an audio reflection using the Calla imaging phone application.

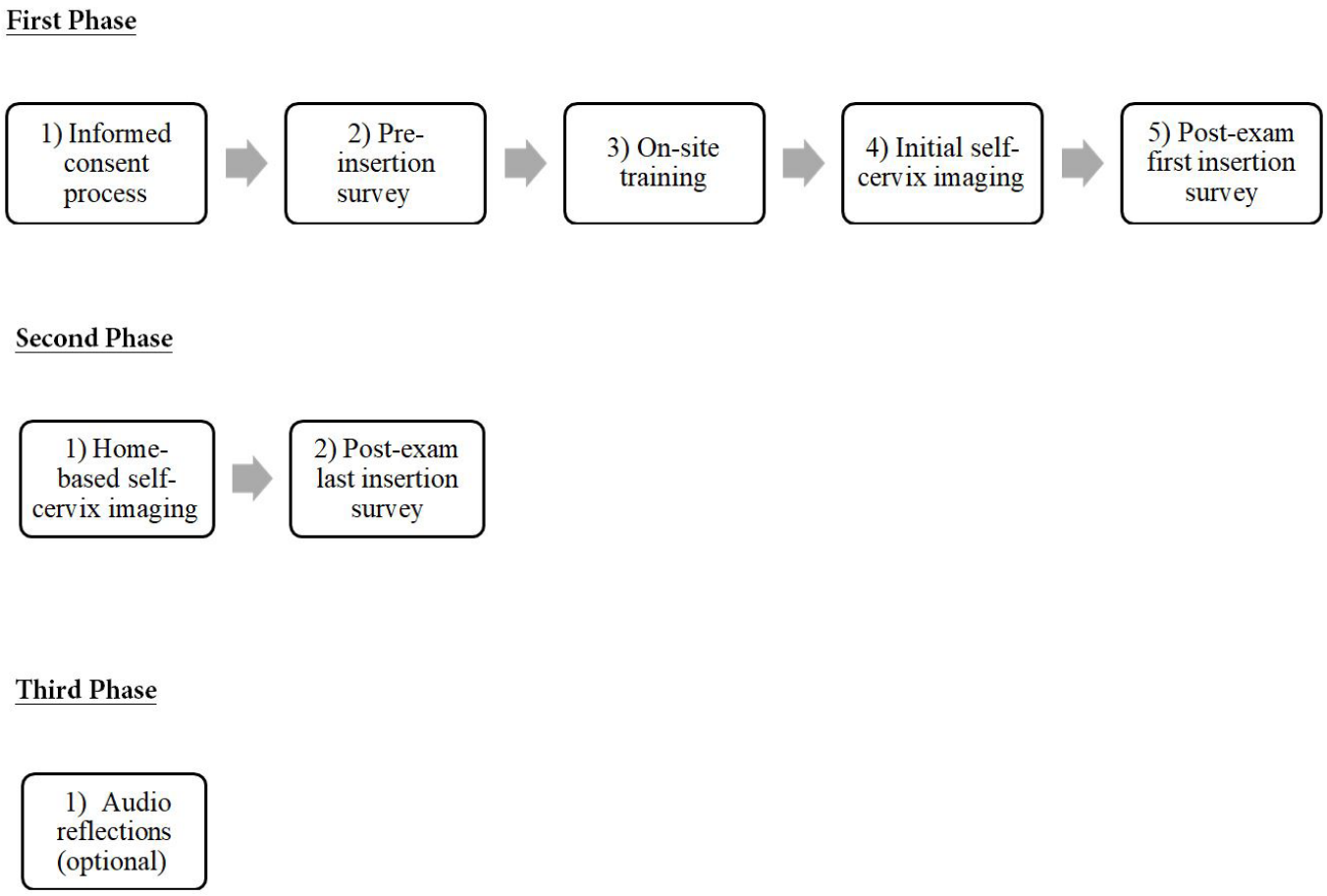


Figure 2: Flowcharts depicting the sequence of study procedures in the first, second and the third phases of participant engagement in the on-site examination, home-examination, and the audio reflections

On-site training and initial cervix imaging

Participants were seen at an initial visit to the Duke University Medical Center (DUMC) research study site during which they provided written informed consent for the study. Following informed consent, participants completed a pre-insertion baseline survey to assess their demographics, prior experiences with the standard speculum, and initial impressions of the Callascope (Supplementary Figure 2.1-2). Participants were then given a user kit containing a Callascope, an android phone and phone charger, Sani wipes, vaginal wipes, lubricating jelly, a printed user guide (Supplementary Figure 3), and an audio reflection guide (Supplementary Figure 2.3). Participants watched a video tutorial (this is the video tutorial link) available on the custom Calla mobile application consisting of information on the assembly and use of the Callascope. After watching the tutorial, participants were allowed to ask the study coordinators, who were well-versed with the Callascope design and function, any questions they had related to the Callascope. Participants were then privately allowed to capture an image of their cervix with the Callascope in a reserved room at DUMC. A study nurse confirmed whether the images captured were that of the cervix. If the imagewas not that of the cervix, the volunteers were given additional opportunities to capture an image of their cervix beforeattempting the home-examination part in the second phase of the study. Upon completion of the on-site exam, participants were asked to complete a survey to assess the comfort and ease-of-use of the Callascope, when used for the first time, using a Likert scale.

Home self-examination

After completing the initial examination in DUMC, participants were provided with the Calla user kit to take home for a week. At home, participants were asked to perform a self-cervix visualization examination one to three times and to capture images of their cervix. At the end of the one week period, participants completed a final survey to assess the ease-of-use and comfort level after using the Callascope upon their last attempt at home. Participants also completed an optional audio reflection guide to share their thoughts on exploring their inner reproductive parts and togive feedback on the study. Before the distribution of the Callascope user kit to the participants, the Callascope, and the phone were disinfected using high-level disinfection procedures [18-19].

Quantitative analysis

Since this study was exploratory, no power analysis was performed. Quantitative data is represented as a mean with standard deviation indicated. Additionally, Likert scale responses of participants regarding discomfort and ease-of- use of the Callascope were analyzed quantitatively. The percentage of the unobstructed cervix area visualized was calculated using a circular grid that was superimposed on cervix images captured by participants (Supplemental Figure 3) to standardize comparison of cervix images [17]. The percent cervix visualization area (PVA) was calculated by dividing the total number of squares within the cervix area visualized by the total number of squares in the grid(equation 1).

$$PVA = \frac{Total\ number\ of\ squares\ within\ cervix\ area\ visualized}{Total\ number\ of\ squares\ in\ the\ circular\ grid} \times 100\% \qquad \text{(Equation 1)}$$

Qualitative analysis

Audio reflections which were recorded on phones provided in the user kit were transcribed and then de-identified. The audio reflection guide (Supplemental Figure 1.3) was optional for all participants, it consisted of questions focusing on the acceptability and feasibility of self-imaging with the Callascope in a home-based setting. The recordings were analyzed using a validated qualitative data analysis platform, NVivo v11 (QSR International, London,UK) to organize, manage, and code the data. Three authors (JSA, MNA, MED) read all the transcripts, discussed thetranscripts as a group and conducted content analysis[20]. Codes were developed deductively (*a priori*) from topics in the audio reflection guide, and inductively (emergent themes) from transcripts. Deductive codes were developed based on the feedback on the Callascope from volunteers in prior clinical studies under clinician guidance [16-17]. Deductive codes included comfort and ease-of-use of Callascope and change in awareness of reproductive anatomy experience. Inductive codes were obtained from the analysis of audio reflections recorded after home-based examination with theCallascope. Three researchers (JSA, MNA, MED) independently coded the transcripts and agreed on coding decisions that were then applied to all transcripts. Authors (JSA, MNA, MED) met to review and revise the codes, resolve discrepancies, and agree on the final organization of the thematic structure.

Results

Participant Demographics

Participant demographics are presented in Table 1. Participants represented different races and ages, vaginal birth experiences, and BMIs. Participant ages ranged from 22 to 56 years (median of 28.5 years). Most of the participants,66.7% (8 out of 12) of participants, identified as non-Hispanic white, with 25.0% (3 out of 12) of participants identifying as Black, and 1 participant identifying as Asian. Slightly more than half of participants, 58.3% (7 out of 12) were in a normal BMI range (18.5 – 24.9). Additionally, 16.7% (2 out of 12) were underweight, and 25.0% (3 outof 12) of participants were either overweight or obese. The majority, 75% (9 out of 12) of participants, were both nulliparous and regular users of tampons/menstrual cups. Half of the participants had more than 6 prior speculum examinations.

Table 1: Participant Demographics (n = 12)

Age (years)	Median Range	28.5 22-56
Race	Asian	1 (8.3%)
	Black	3 (25.0%)
	Hispanic white	0 (0.0%)
	Hispanic unknown/other	0 (0.0%)
	Non-Hispanic white	8 (66.7%)
	Unknown	0 (0.0%)
BMI	Underweight (<18.5)	2 (16.7%)
	Normal (18.5 - 24.9)	7 (58.3%)
	Overweight/ Obese (> 25)	3 (25.0%)
Number of vaginal births	0	9 (75.0%)
	1	2 (16.7%)
	2	1 (8.3%)
	3	0 (0.0%)
	5	0 (0.0%)
Regular use of Tampon/Menstrual cup	Yes	9 (75.0%)
	No	3 (25.0%)
Prior number of speculum examinations	1-2	3 (25.0%)
	3-5	3 (25.0%)
	> 6	6 (50.0%)

Pre-Insertion Survey

Pre-insertion survey responses collected prior to cervix visualization are summarized in Table 2. Fifty percent of participants found the speculum to be a barrier to cervical cancer screening. Based on appearance only, more participants were willing to use the Callascope over the speculum. 25% (3 out of 12) reported being 'extremely willing' or 'very willing' to use the speculum based on appearance alone compared to 100% (12 out of 12) who reported being 'extremely willing' or 'very willing' to use the Callascope. 75% (9 out of 12) reported being 'not willing' or 'slightly willing' to use the speculum based on appearance alone compared to 0% (0 out of 12) who reported being 'not willing'or 'slightly willing' to use the Callascope.

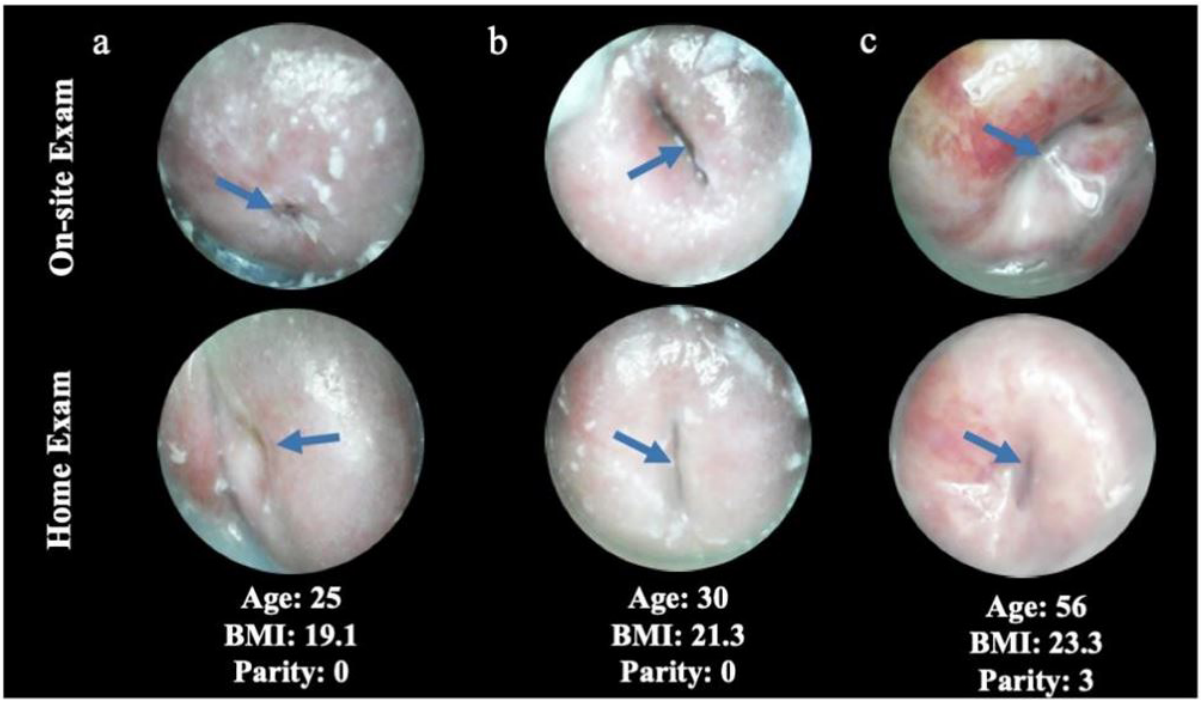
Participants ranked comfort as one of the top three factors impacting their experience with cervical cancer screening (cost and adequate assessment of cancer risk ranked higher). Procedure and travel time were least important for participants in the self-examination group.

Table 2: Pre-insertion survey responses (n = 12)

Perception of speculum as a barrier to cervical cancer screening	Not a barrier	6 (50.0%)	
	Small barrier	4 (33.3%)	
	Medium barrier	2 (16.7%)	
	Large barrier	0 (0.0%)	
Willingness to use Speculum/Callascope based on appearance		**Speculum**	**Callascope**
	Not willing	1 (8.3%)	0 (0.0%)
	Slightly willing	8 (66.7%)	0 (0.0%)
	Very willing	2 (16.7%)	9 (75.0%)
	Extremely willing	1 (8.3%)	3 (25.0%)
Top three important features for cervical cancer screening	Cost	9 (75.0%)	
	Adequate assessment of risk	9 (75.0%)	
	Comfort	8 (66.7%)	
	Clinician gender	4 (33.3%)	
	Travel time	3 (25.0%)	
	Procedure time	3 (25.0%)	

Cervical Visualization Examinations

During the on-site training (initial cervix imaging session), the study nurse confirmed that 10 out of 12 (83%) of the study participants could visualize their cervix upon their first attempt. 2 participants (17%) were not able to capture images of their cervix during their first attempt at the on-site training phase; they also were not able to capture images on their second attempt on-site. Of the two participants who were not able to capture images of their cervix on their first attempt, one had a BMI > 30, and the other had a normal BMI (18.5 – 24.9). The duration of the initial self- imaging sessions ranged from 4-15 minutes. Representative images of the cervix captured during the on-site training examination and the home-examination are shown in Figure 3a-c, and bar graphs of the cervix area visualized per participant is illustrated in Figure 3d. A representative video of the insertion of the Callascope, showing the vaginal wall and cervix manipulation, is shown at this link. The cervix percent area visualized was calculated via the number of cervix quadrants visualized as described in our previous work [17]. All participants were able to capture at least one image of their cervix either during the initial attempt (on-site training examination) or at home. Of the 12 participants,11 (92%) were also able to visualize and capture an image of their cervix at home. Nine participants (75%) performed one self- examination, and two participants (17%) performed two self-examinations at home. Of the two participants who performed the examination twice, both captured images of their cervix on each attempt. One participant (8%) was unable to do so due to a self-reported device failure with the camera of the Callascope at home. Overall, the images did not show any significant differences in percent cervix area visualization between the on-site examination and home examination. The mean percent cervix visual area in the images captured during on-site and home examination were comparable at 81% +/- 9%, and 82% +/- 7% respectively. There was no association between percentvisual area and BMI.



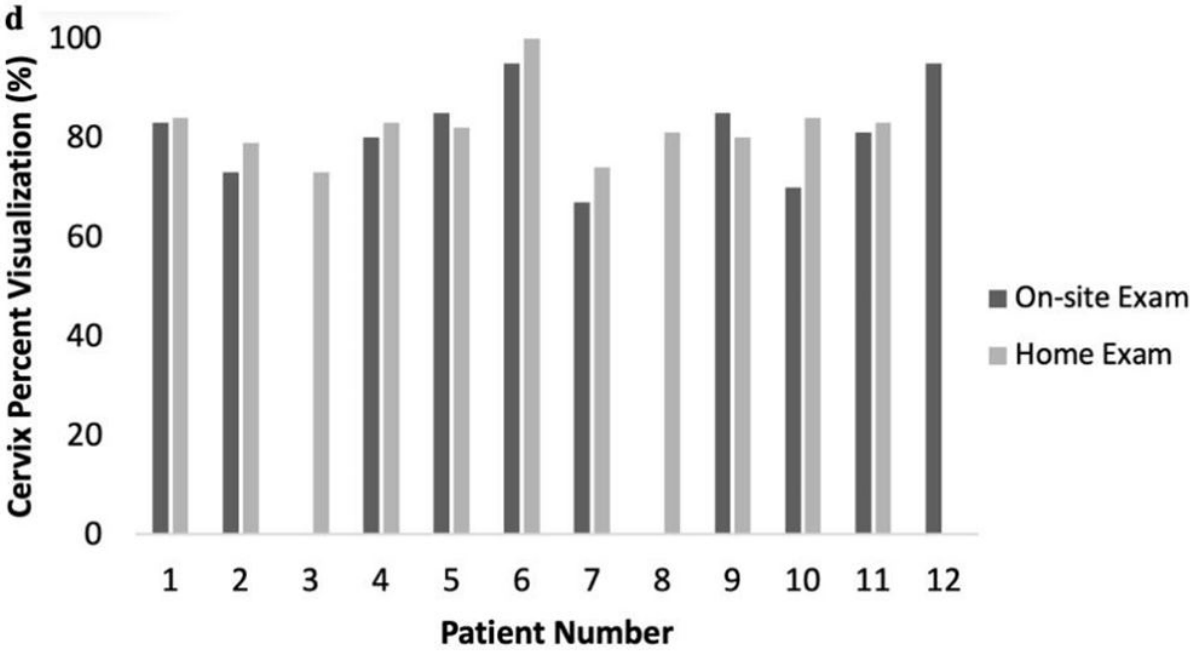


Figure 3: Representative images (a, b, c) were captured by three participants using the Callascope during the on-site examination and the home examination, respectively (with arrows pointing to the os, the opening of the cervix to the uterus). d) Bar graphs depicting percent cervix visualization of images captured by each participant

The results from the post-insertion questionnaire comparing the ease-of-use of the Callascope in terms of ease of understanding the instructions/tutorial materials (S3), and ease of use of the Callascope to visualize the cervix, are shown in Figure 4. Most of the participants found the instructions easy (extremely, very, or slightly easy) to use bothduring on-site (11 out of 12) and home use (11 out of 11) respectively. One participant did not complete this portion of the last insertion survey at home. Further, 67% (8 out of 12) of participants found it easy (extremely, very, or slightly easy) to visualize their cervix using the Callascope during their first attempt (on-site), compared to 33% (4 out of 12) who found it hard (extremely, very, or slightly hard). Of the participants who attempted to visualize their cervix twice on-site, due to inability to capture an image of their cervix on the first attempt, one participant found it extremely hard, and the other found it very hard. In terms of ease-of-use at home, 55% (6 out of 11) of participants found it easy, while 45% (5 out of 11) found it hard. There was some overlap between responses recorded during theon-site visit and home examinations. Specifically, 8% (1 out of 12) reported cervical visualization was extremely easy, 8% (1 out of 12) reported very easy, 33% (4 out of 12) reported slightly easy, 8% (1 out of 12) reported slightlyhard, and 8% (1 out of 12) reported extremely hard for both first and last post-insertion surveys. 8% (1 out of 12) of participants changed from reporting very hard on-site to extremely hard at home, 8% (1 out of 12) of participants changed from reporting very hard on-site to slightly hard at home, 8% (1 out of 12) of participants changed from reporting slightly easy on-site to slightly hard at home, and finally, 8% (1 out of 12) of participants did not complete this portion of the last insertion survey.

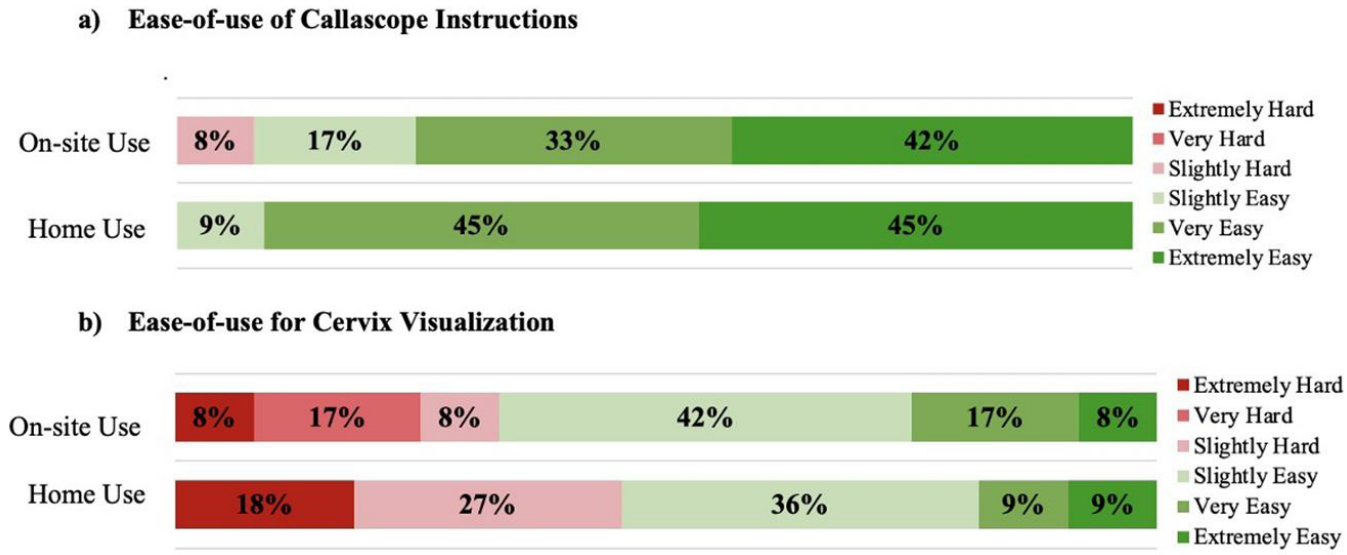


Figure 4: The ease-of-use of a) the Callascope instructions, and b) cervix visualization with the Callascope in both in- clinic and home use, using participant percent rating with the following terms: extremely hard, very hard, slightly hard, slightly easy, very easy, and extremely easy

The results from the post-insertion questionnaire comparing discomfort associated with insertion and removal of the Callascope during on-site versus home examination use are shown in Figure 5**.** 50% (6 out of 12) of the women hadslight to no discomfort inserting the Callascope during the initial use, 42% (5 out of 12) found insertion moderately uncomfortable, and only 8% (1 out of 12) had a lot of discomfort during insertion. In the case of final use, the same participant continued to report a lot of insertion discomfort (9% or 1 out of 11). Additionally, 73% (8 out of 11) reported slight to no discomfort, and 18% (2 out of 11) reported moderate discomfort. The majority of participants reported the same rating for discomfort with insertion for both on-site and home-based settings; 33% (4 out of 12) reported no discomfort, 17% (2 out of 12) reported slight discomfort, 17% (2 out of 12) reported moderate discomfort,and 8% (1 out of 12) reported a lot of discomfort respectively for both sessions. 8% (1 out of 12) of participants changed from reporting moderate discomfort on-site to no discomfort at home, 8% (1 out of 12) of participants changed from reporting moderate discomfort on-site to slight discomfort at home, and 8% (1 out of 12) of participantsdid not complete this portion of the last insertion survey. All participants found that removal of the Callascope posedno discomfort or only slight discomfort both in the on-site training and home-based settings; 75% (9 out of 12) reported no discomfort and 17% (2 out of 12) reported slight discomfort respectively for both settings; 8% (1 out of 12) did notcomplete

this portion of the last insertion survey. In the last post-insertion survey administered to participants, 100%of participants (12 out of 12) indicated that they would recommend the Callascope to others.

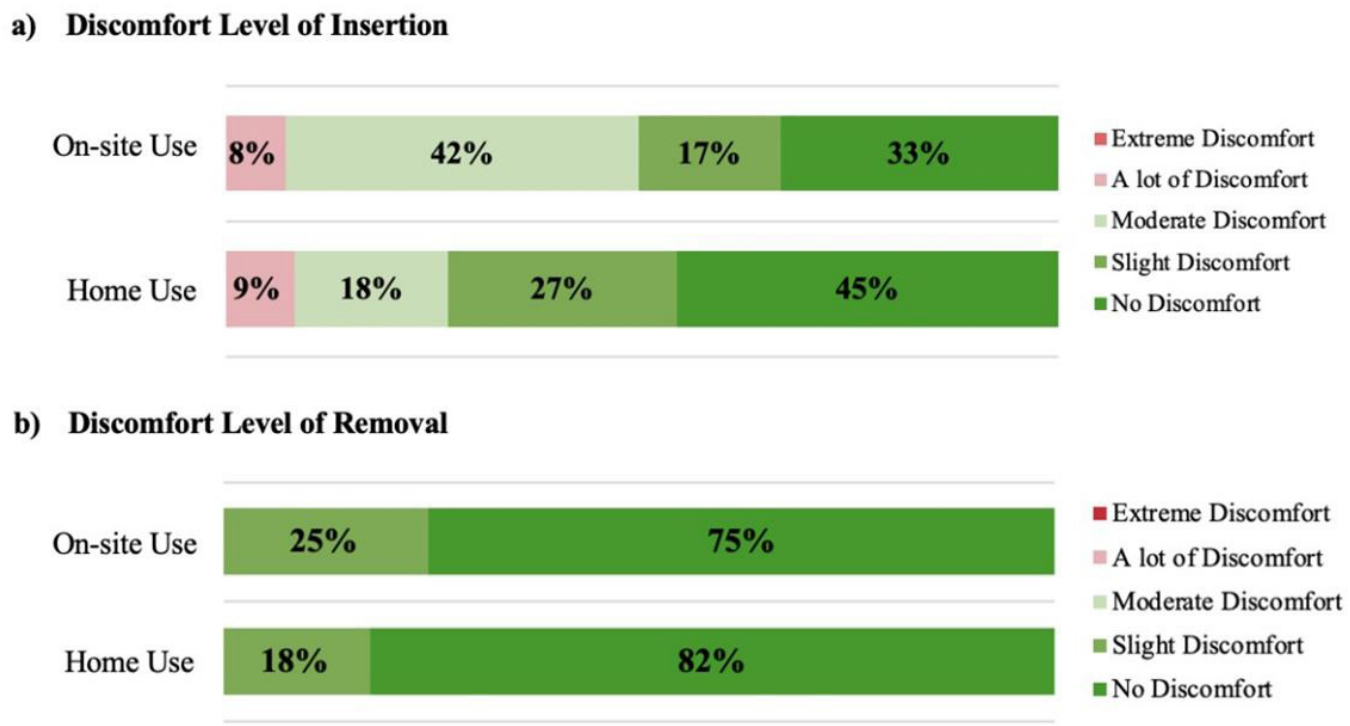


Figure 5: The discomfort level of a) insertion and b) removal of the Callascope in both on-site and home use, using participant percent rating with the following terms: no discomfort, slight discomfort, moderate discomfort, a lot of discomfort, and extreme discomfort

Audio reflections and optional comments provided more in-depth reviews by participants

Participants from the home study provided optional comments in their final surveys as well as audio reflections of their experience with the Callascope. The audio recordings ranged in duration from 2 minutes to 26 minutes; the mean duration was 9 minutes, with a standard deviation of 7 minutes. Themes were developed based on both deductive and inductive methodologies. These themes were comfort and ease-of-use of Callascope, change in awareness of reproductive anatomy, excitement at future applications of the Callascope for gynecologic examinations, and feelingsof empowerment associated with the use of the Callascope and visualization of the cervix. Keywords associated with the use of the Callascope include "comfortable/easy to use", "excitement", "self-awareness", and "empowering" (Table 3). Briefly, self-examination participants mentioned that the device was easy to use at home and expressed excitement over being able to view their cervix themselves. Participants also mentioned feeling empowered and havingimproved cervix awareness by being able to visualize their reproductive anatomy themselves, which they had not beenable to do previously. Additionally, one participant mentioned uncertainty about whether her cervix looked healthy based on the image captured, and two participants stated that they would have preferred to have remote access to a healthcare provider to confirm whether their cervix, and its associated discharge, looked was normal. One participantdid not complete an audio reflection, hence was excluded from the qualitative analysis of the audio reflections.

Table 3: Themes and quotations from audio reflections and surveys after Callascope self-examination (n = 11)

Theme	Participants who mentioned theme	Representative Quotation(s)
Callascope easy/ comfortable to use	90.9% (n= 10)	"I thought it was really easy to use. I thought the instructions were straight-forward." "My Calla exam was very easy." "I think everything was done nicely. I felt comfortable the whole time."
Excitement at future applications of Callascope for gynecologic examinations	72.7% (n = 8)	"I think it has promising features, especially for screening in lower-middle income countries and places that don't have access to healthcare. I think this device has the potential to make a big difference in self-examinations." "I think it's an exciting project and I think this has the potential to do wonderful things for women's health both domestically and internationally."
Self-examination enabled exploration/ awareness of reproductive anatomy	63.6% (n = 7)	"Before the Calla study, it [gynecological examinations] use to be this dark, obstructed thing and I am one of those people who likes seeing what is being done to me." "I think normally, you know, you are in a medical setting whenever you have the opportunity to see the inner workings of your body, so it was really nice to be able to be in the relaxed setting of my own house to just explore and see what's going on. It was a unique view that I had never had before." "I feel interested and curious. It is strange to think that it [internal lower reproductive anatomy] is a part of myself. It makes me just feel curious to learn more."
Self-examination was empowering	36.4% (n = 4)	"The image of my cervix will stick in my head. It was interesting and empowering to know my body a little better. It feels very vagina monologues-ish." "My experience was empowering. I was able to see something more personal about myself and bond more with myself. It was an empowering and intimate experience with me." "It is a very empowering and fulfilling experience to be able to see my own cervix. It makes me feel like I know myself better."

Discussion

The Callascope is a portable, low-cost imaging device that enables cervical visualization by either a clinician in a clinic/hospital or by individuals themselves in the comfort of their home or within their community. In our prior work, we showed that healthy volunteers could undergo cervical visualization with the assistance of a healthcare provider and/or in a clinical setting [16-17]. In this study, we built upon our prior work by testing the feasibility of healthy participants to independently visualize their cervix without clinician assistance in both an in-person and at-home setting. Our results are consistent with studies of acceptability and feasibility of HPV-self-sampling at home [21,22]. For example, a study of 818 participants in Ontario, reported that 89.7% of participants found self-HPV testing acceptable, and 88% would recommend it to a friend; comparable to 100% who would recommend the Callascope to a friend in this study [21]. Another study of 878 Appalachian women (a region with lower income levels than our study site, Durham) found that 99% of those who collected self-specimens were able to obtain adequate samples; this is comparable to 92% (11 out of 12) participants who were able to obtain cervical images at home, and 100% who obtained at least one image during the study using the Callascope. However, it should be noted that the study reported in this manuscript had a much smaller sample size [23-25]. Overall, our results are comparable to studies of self-HPV testing and support future work pairing self-cervical visualization with HPV sample collection.

The need for travel associated with multiple hospital visits poses a significant challenge to receiving gynecologic examinations due the financial cost of transportation, childcare, and taking time off work to visit a healthcare center [26]. Since many rural areas lack well-established cervical cancer screening centers, women from these areas bear the burden of long travel times and significant costs for obtaining care [27]. The travel to screening sites poses a significant challenge for cervical cancer prevention and this has only been exacerbated in the era of COVID-19, which has brought to light the emerging and critical need for novel, affordable, and effective technologies for remote patient care [28-29]. In addition to challenges regarding travel, ethnic/racial minority groups [6,30-31], sexual minority groups [32], adolescents [33], obese women [34], victims of sexual assault and other trauma [35], and women with disabilities [36] have also cited emotional distress and fear of pain as reasons for non-adherence to cervical cancer screening. Speculum examinations are also especially painful for women with certain medical conditions that reduce elasticity, cause spasms or pain with manipulation of the labia or the vestibule, such as atrophic vaginitis [36-37], vaginal stenosis, vulvodynia and vaginismus [38]. International studies corroborate that the speculum is a barrier to cervical cancer screening for many across the globe [39,40]. One of the most successful approaches to increasing the accessibility of cervical cancer screening is the provision of tests that individuals themselves can perform such as self-collected HPV sampling tests [41]. While self-collected HPV sampling tests have been shown to be highly sensitive, they unfortunately have low specificity; only 10% of patients with high-risk HPV develop persistent infections that progress to cervical cancer [42-45]. Thus, the low specificity of HPV tests can lead to the unnecessary overburdening of already resource-limited healthcare facilities [42-45]. There is potential for a significant clinical benefit of combining self-collection of HPV samples with self-cervical imaging with the Callascope to increase the specificity of preliminary cervical cancer screening. Additionally, the increased privacy, comfort, and empowerment associated with self-cervical imaging could increase the acceptability of preliminary cervical cancer screening among patients with a prior history of pain or emotional distress associated with screening.

Apart from the potential for routine gynecologic applications, the Callascope also offers immense potential as an educational tool for people with cervices to understand their internal reproductive anatomy and be empowered to explore their internal anatomy, often for the very first time. One strategy to empower individuals to advocate for their reproductive autonomy is the provision of self-exploration technology that facilitates visualization, understanding, and appreciation of their own bodies as expressed in audio reflections and comments from this study. There have been published studies concerning the utilization of self-examination as a learner-centered pedagogical methodology for health promotion. For example, a study in Brazil examined the use of self-eye examination as a method for health promotion reported improved awareness of eye care among 324 student participants46. In another study in Turkey, 174 men investigated the impact of testicular self-examination (TSE) on knowledge, performance, and health beliefs, in relation to testicular cancer and TSE, showing significantly improved positive beliefs towards TSE after performing a self-examination47. These studies of self-examination support future work to develop a reproductive health educational curriculum harnessing the pedagogical value of physical self-examination in the context of the cervix. To our knowledge, there have not yet been any published studies of self-examination as a learner-centered pedagogical tool for cer-

vical health. However, there have been public health initiatives, such as The Beautiful Cervix Project that promote cervical health through displaying images of cervices, captured at home using a speculum, mirror and phone, via an online platform [48]. Future studies will investigate the use of the Callascope with an online basic reproductive health educational program to increase knowledge, awareness, and health-seeking behavior with a focus on cervical health. This educational program would consist of multimedia content on basic reproductive health including images detailing a variety of pathological conditions of the cervix to educate users on the need to adhere to screening recommendations and warning signs for which to seek medical attention immediately with the knowledge that early diagnosis is essential for a positive prognosis.

This study was limited to a small participants size (n = 12) in this explanatory phase to prove feasibility before launching a larger scale study. In future studies, in addition to accrual from a larger and more diverse population, the user guide will be upgraded with trouble-shooting modules for the rare incidences of difficulties with camera use. Additionally, 2 out of 12 (17%) participants who were not able to capture images of their cervix on their first attempt, one had a BMI > 30 which may have contributed to difficulties with image-capture. In our previous clinical studies, we observed a correlation between increased BMI and failure to capture an adequate image of the cervix with the Callascope [16-17]. Thus, in future studies we plan to provide a variety of Callascope form-factors optimized for women with larger body masses by increasing the length of the introducer and enlarging the opening of the Callascope introducer tip. Additionally, we received feedback requesting more detailed educational resources on vaginal discharge. Therefore, we will include an extensive multi-media tutorial on expected discharge throughout the menstrual cycle as well as other reproductive experiences, so that participants have an increased understanding of what they observe with the Callascope. Finally, artificial intelligence and machine learning (AI/ML) combined with the Callascope device and mobile application could democratize reproductive health by vastly increasing accessibility [49]. Various data-based scenarios could be explored such as fertility/cycle prediction, and assessment for infections or preliminary cervical cancer screening based on cervix images. We are currently exploring the use of AI/ML for automated risk assessment of cervix images and plan to apply this to the Callascope in future studies

Limitations

Due to the exploratory nature of the study, a small sample size was used. This study however provides a foundation upon which to conduct a larger study. One of the challenges was accrual of a more diverse population in the sites where we posted flyers in the Durham community and online on Craigslist platform. Another continuing challenge was the inability to accrue additional patients owing to the COVID-19 pandemic.

Conclusion

This pilot study demonstrates feasibility of two novel scenarios for self-imaging of the cervix; (1) in a clinic setting, as an alternative to speculum-based imaging, patients can be given the Callascope imaging kit, with the training guide and provided a private room to take images of the cervix, which can then be used for clinical decision making (this is performed for self-HPV testing when testing at home is challenging or not affordable), and (2) in the home setting where users could purchase the Callascope to perform basic imaging of their cervix either for education and awareness or for health care in their homes. We have shown that the Callascope has the potential to positively transform access to gynecologic examinations through enabling a person-centered, home-based, and comfortable approach to viewing internal female reproductive anatomy. In future studies, we will increase efforts to recruit a more diverse cohort through collaborations with community health centers and minority women's health advocacy groups. In addition, these studies will also be conducted in low-resource settings to be more representative of populations most affected by cervical cancer. Finally, we will explore the use of the Callascope for more specific clinical and diagnostic applications beginning with IUD placement monitoring and eventually preliminary self-cervical cancer screening using contrast-agent application in combination with HPV self-sampling.

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Declaration of interests

MNA, MSK, and NR, have founded a company called Calla Health Foundation to commercialize the Callascope. They and JSA have developed technologies related to this work where the investigators or Duke may benefit financially if this system is sold commercially. For the concept of this system a patent has been awarded to JSA, MNA and NR with the title: "Colposcopes and mammoscopes having curved ends and flat ends, associated methods, and speculum-free imaging methods". U.S. Patent Application No. 16/089,522. This does not alter the authors' adherence to policies on sharing data and materials. Other authors declare no competing interests.

Author Contributions

Conceptualization: JSA MNA MK MH GS WH NR.

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Supplemental Materials

S1. Study Recruitment Flyer

IRB #: Pro00008173

DUKE CENTER FOR GLOBAL WOMEN'S HEALTH TECHNOLOGIES

Innovate with passion, deliver with compassion

Invitation to Participate in the *Calla* Study

Designed by women for women.

Calla is a new tool for cervical visualization which is being tested out as an alternative to the speculum.

You may be eligible if you are:

- Healthy
- 21-65 years old
- Not in 2nd or 3rd trimester of pregnancy
- Have had a pap smear
- Willing to perform a cervical self-exam

Participating as a volunteer allows you to:

- Contribute to global women's health! Specifically, research for the development of an affordable cervical cancer screening toolkit
- Explore your own reproductive anatomy
- Earn a gift card.

If you are interested in the study, email julia.agudogo@duke.edu.

S2. Volunteer study questionnaires

S.2.1. Pre-insertion survey

Calla Pre-Insertion Questionnaire

Date: _____
Site: _____
Participant ID: _____

1. What is your age? _____
2. How many times have you had a speculum exam?

☐ **1-2** ☐ **3-5** ☐ **6-10** ☐ **> 10**

3. Are you a regular user of Tampons/Menstrual Cups? Yes/No
4. How many vaginal births have you had? _____
5. How much of a barrier, if any, do you consider speculums to be to you getting screened for cervical cancer?

☐ **Not barrier** ☐ **Small barrier** ☐ **Medium barrier** ☐ **Large barrier**

We would like to hear about your views on various approaches & tools for cervical cancer screening.

6. How willing are you to be screened for cervical cancer using:	**Not willing at all**	**Slightly willing**	**Very willing**	**Extremely willing**
a) Based on appearance only, the speculum				
b) Based on appearance only, the Calla				

7. In your opinion, what are the three most important features for your cervical cancer screening?	**Cost**	**Procedure time**	**Adequate assessment of cancer risk**	**Physician gender**	**How comfortable the screening procedure is**	**How long it takes to get to clinic**
a) Select three of the options						

8. Do you have any additional feedback/ comments?

_____

_____

_____

S.2.2. Post-insertion surveys (first and last attempt)

Calla First Insertion Survey

Participant ID:_____

A) Level of Discomfort	No Discomfort[1]	Slight Discomfort[2]	Moderate Discomfort[3]	A lot of Discomfort[4]	Extreme Discomfort[5]
1. How much discomfort, if any, did the Calla cause when you inserted it into your vagina?					
2. How much discomfort, if any, did the Calla cause when you removed it from your vagina?					

B) Ease of Use	Extremely Easy[1]	Very Easy[2]	Slightly Easy[3]	Slightly Hard[4]	Very Hard[5]	Extremely Hard[6]
3. How easy or hard was it to follow the instructions provided for the Calla?						
4. Using the Calla how easy or hard was it to view your cervix ?						

Additional Feedback

5. Was there any external event(s) or circumstance(s) that could have affected your experience? For example, did you use a tampon or have your period or sex in the last 24 hours prior to insertion?

_____

_____

6. Do you have any additional feedback/ comments?

_____

_____

Calla Last Insertion Survey

Participant ID:_____

A) Level of Discomfort	No Discomfort[1]	Slight Discomfort[2]	Moderate Discomfort[3]	A lot of Discomfort[4]	Extreme Discomfort[5]
1. How much discomfort, if any, did the Calla cause when you inserted it into your vagina?					
2. How much discomfort, if any, did the Calla cause when you removed it from your vagina?					

B) Ease of Use	Extremely Easy[1]	Very Easy[2]	Slightly Easy[3]	Slightly Hard[4]	Very Hard[5]	Extremely Hard[6]
3. How easy or hard was it to follow the instructions provided for the Calla?						
4. Using the Calla how easy or hard was it to view your cervix ?						

Additional Feedback

5. Was there any external event(s) or circumstance(s) that could have affected your experience? For example, did you use a tampon or have your period or sex in the last 24 hours prior to insertion?

_____

_____

6. Do you have any additional feedback/ comments?

_____

_____

7. Would you recommend the Callascope to others? Yes/No

S.1.3. Audio reflection survey

Calla Audio Reflection

Please take some time to freely record your thoughts. Get in a comfortable position, take some long centering breaths, turn off your personal phone, and give yourself permission to be fully present in this space for about 15 - 30 minutes. You do not need to share any information you are not comfortable sharing. Nothing will be shared without your permission. Without judging the thoughts and experiences that come forward, simply notice them. These questions are a guideline, you are free to answer any, all, or none of them. Begin audio recording in a quite space.

We would love to hear about your background and your views of the reproductive anatomy

- Please tell us a bit about yourself.
- What are the images, words, feelings, and thoughts that come to mind when you think about female reproductive anatomy?

Share your thoughts about your Calla self-exam

- How was your Calla self-exam? Did you learn anything new through the self-exam?
- Were you able to see your cervix? If so, what was helpful to find it and how did you know it was your cervix? If not, what difficulties did you experience?
- Take a look at the image you captured. Mention any questions that arise, physical sensations you experience, and thoughts that emerge.
- Are there any stories or events in your history that influenced your experience with the Calla?

We would love to hear your opinions on the Calla

- What suggestions would you give to a new user trying out the Calla?
- What suggestions do you have for the Calla team?

S2. Volunteer study tutorial

S.2.1. Paper tutorial (trifold – back and front)

Cleaning Procedure

Clean Calla, & Camera

Germicidal wipes

Wipe camera and phone with germicidal wipes and place back in the packet.

Calla Troubleshooting

Issue 1: Camera tip contacts mucus OR image appears hazy or foggy
Use anti-fog wipes to gently wipe the front end of camera.

Issue 2: The video/photo feed does not appear, the video/photo feed freezes, or there is some other problem with the video/photo feed
a) Unplug camera from phone.
b) Close USB Webcam Pro.
c) Re-plug camera in phone.
d) Re-launch USB Webcam Pro

If the above recommendations do not solve the problem or if any part of the device is damaged and/or consistently malfunctioning, contact the Center for Global Women's Health Technologies

GWHT Contact Information

GWHT Website Link:
https://www.globalwomenshealthtechnologies.com

Physical Address:
140 Science Drive
Durham, NC 27708

Mailing Address:
101 Science Drive
Box 90281
Durham, NC 27708

Calla Contact:
Júlia Sroda Agudogo, BSE
Associate in Research
Phone: (919) 519-1254
E-mail: julia.agudogo@duke.edu

Reference

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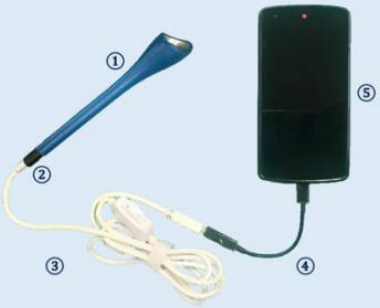
Duke Center for Global Women's Health Technologies (GWHT)

Calla User Guide

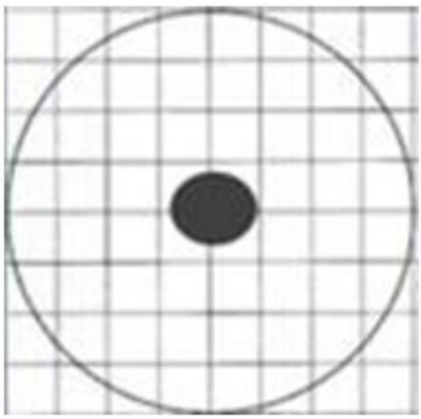


① **Calla**
② **Bayonet lock**
③ **2MP Camera**
④ **USB Connector**
⑤ **Android Phone**

The instructions and device described are to be used only by informed volunteers and trained, qualified medical professionals. The following content is intended as a guide for the use of the Calla.

Duke PRATT SCHOOL OF ENGINEERING
DUKE GLOBAL HEALTH INSTITUTE

S3. Circular visual grid



Supplemental Figure 3: Circular visual grid used to calculate cervix visual area [31]