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# AN INNOVATIVE DESIGN FOR THE VAGINAL SPECULUM



Report by:  
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# ABOUT THE AUTHOR

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J.M. Bouquet provided substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data, drafting the article or revised it critically for important intellectual content; and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

**Disclaimers:** The views expressed in this submitted article are the author's own and not an official position of Rocky Vista University.

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**Disclosures of Relationships:** J.M. Bouquet is the owner and CEO of, Viospex, the company that owns the intellectual property for the Bouquet Speculum TM . He designed, patented (US and Canadian patents), and FDA-cleared the Bouquet Speculum TM . He is also the President and Chairman of the Board of Cure Cervical Cancer, Inc., a nonprofit that donates the Bouquet Speculum TM to low-resource countries for screen and treat cervical cancer clinics.

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## KEYWORDS

Vaginal speculum, cervical dysplasia, cervical cancer, visualization of the cervix, speculum exam and procedures, phantom vaginal model, pap test, gynecologic procedures.

# ABSTRACT



Cervical cancer kills over 311,000 women every year. [1] Most providers of women's healthcare have struggled at some point in their career with visualizing the cervix during a routine pap test or while performing treatments or other gynecologic procedures [7]. Continuing use of the traditional 2-bladed speculum creates an additional barrier to effective screening by failing to provide full cervical visibility due to anatomical variation or lateral vaginal wall collapse, and by causing patient discomfort and anxiety [7,8,9,10]. Because of its design the 2-bladed speculum has several limitations, making it difficult to adequately visualize the cervix and perform gynecologic procedures which can ultimately lead to the failure to properly diagnose cervical cancer or dysplasia.

A study was designed and carried out to test the superiority in adequately visualizing the cervix using a newly innovated, FDA-cleared [14], 5-petaled Bouquet Speculum TM developed by the author himself. This new speculum claims to be superior to the traditional 2-bladed speculum, by evenly distributing a radial dilation when being placed into the vagina and allowing excellent visualization of the cervix and demonstrating compatibility of this speculum with standard instruments and tools that are used in gynecologic procedures.

The in-vitro testing involves a simulated, phantom vaginal model suspended in ultrasound gel at various volumes to create different intravaginal pressures and simulate lateral vaginal wall collapse.

The findings were that the novel 5-petaled Bouquet Speculum TM was statistically better at visualizing the cervix than the existing 2-bladed speculum. Additionally, as the speculum was dilated within the vagina at increasing vaginal pressures, the speculum remained intact, and the forces were evenly distributed around the 5 petals. The Bouquet Speculum TM was able to accept and obtain samples from the cervical os with an 8" cotton-tipped, large applicator on 10/10 attempts. This innovation to the vaginal speculum is a long time in coming and should pave the way to expand screening and treatment to underserved and marginalized populations for the very preventable disease of cervical cancer and precancers.

Clinical studies are underway, including in developing countries such as Cameroon, Chad, Kenya, Malawi, Nigeria, Uganda and Zambia. In the US, NIH has registered a study on the Bouquet Speculum TM vs. the existing two-bladed "duck-billed" speculum (<https://clinicaltrials.gov/ct2/show/NCT05254756?term=Bouquet+Speculum&draw=2&rank=1>).

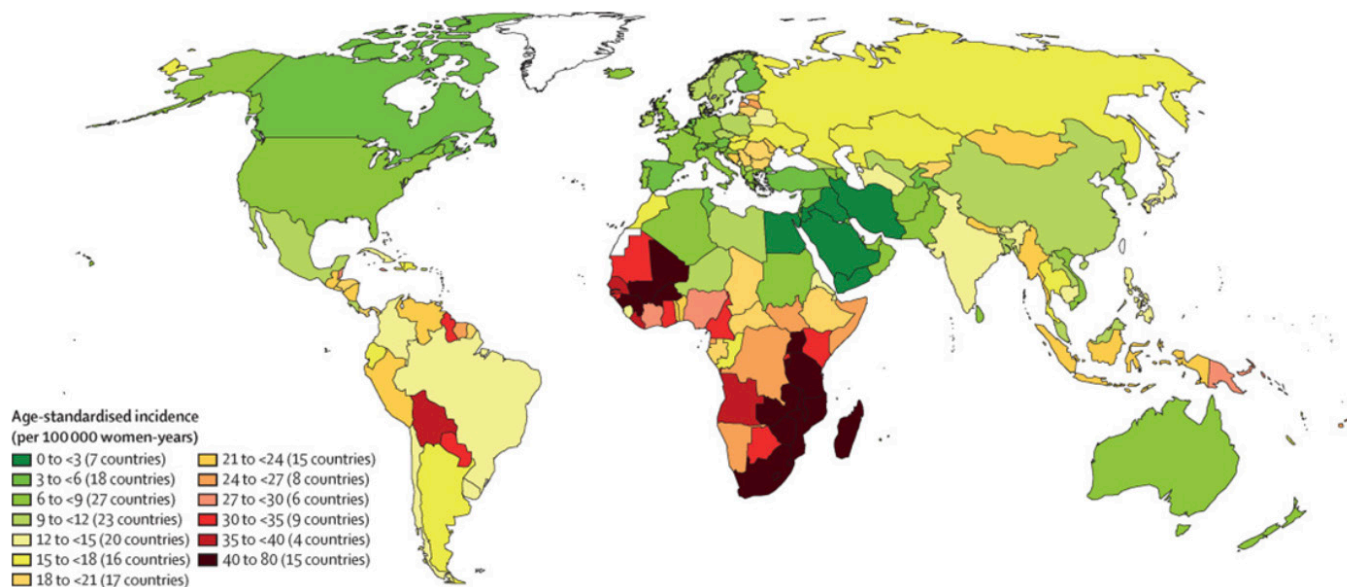
Additional head-to-head studies involving obese and multiparous women are being planned in the US. This study supports the hypothesis that this new vaginal speculum design will provide better visualization of the cervix, a more efficient exam, and less discomfort for the patient. The expected outcome from this innovation is better diagnosis and treatment of cervical dysplasia and potential cancers in populations all over the world.

# INTRODUCTION

Cervical cancer kills over 311,000 women every year [1]. It is the second most common cancer affecting women in developing countries and results in significant morbidity and mortality as well as negatively impacting these communities in many ways [2]. Human Papilloma Virus (HPV) is the single most important risk factor for cervical cancer and precancers, responsible for 99.7% of the incidence [3]. Routine gynecological screenings are effective in detecting and preventing cervical cancer, with a high cure rate with early detection [4]. Unfortunately, there is a significant lack of screening in developing countries and certain vulnerable and marginalized populations in the United States for a variety of reasons. Some of the reasons include lack of knowledge and awareness about cervical cancer and dysplasia, inaccessibility to health clinics and/or female providers, and the fear of embarrassment, pain, and discomfort from the pap test or procedure [5,6]. In some instances, the existing speculum creates an additional barrier to effective screening by

failing to provide full cervical visibility due to anatomical variation or lateral vaginal wall collapse, and by causing patient discomfort and anxiety [7,8,9,10]. The traditional, 2-bladed vaginal speculum is the oldest instrument in the history of obstetrics and gynecology. Its design goes back to 79 A.D. where a 2-bladed bronzed speculum was found preserved in the ashes of Pompeii when Mt. Vesuvius erupted [10, 11].

According to the American Cancer Society, in 2021, 14,480 new cases of cervical cancer were reported in the United States with 4,290 of these cases resulting in death. The global incidence rate, according to the World Health Organization (WHO), in 2018, was 570,000 women diagnosed with cervical cancer and about 311,000 women died from the disease. Most of these incidences and cases of death occur in underdeveloped, low resource areas around the globe [12]. (Figure 1)



**Figure 1:** Incidence of Cervical Cancer Around the World (2018)

## PROBLEM STATEMENT

The current, traditional, 2-bladed vaginal speculum has three apparent limitations. First, in some women where there is vaginal wall laxity, the 2-bladed design allows for lateral vaginal wall collapse thus impeding the view of the cervix and making the diagnosis of cancer or dysplasia difficult. Even experienced clinicians have difficulty with lateral vaginal wall collapse that may obscure the view of the cervix. Secondly, women with anatomic differences such as ante and retroversion and/or flexion present another challenge to the 2-bladed speculum [9]. This adds to the patient's and provider's stress as repositioning of the speculum and the patient may be necessary and results in an extended, uncomfortable, and frustrating exam. Finally, the current 2-bladed speculum, opens in a predominately vertical fashion creating forces in an anterior-posterior direction.

## SOLUTION STATEMENT

To provide a novel speculum design that will allow healthcare providers to detect and subsequently treat cervical cancer and pre-cancers more efficiently and accurately while improving the patient experience. The Bouquet Speculum TM is a newly designed, 5-petaled vaginal speculum that claims to overcome these limitations of the existing, traditional speculum. The 5-petals open as the dilator is advanced and the ends of the petals lightly cup the cervix, ensuring that only the cervix is visualized, without vaginal wall collapse. The radial opening of this newly designed, 5-petaled speculum distributes the forces symmetrically and evenly reducing the discomfort experienced by the vertical forces of the existing speculum. (Figure 2).



**Figure 2:** Visual comparison of the Bouquet Speculum TM to the Existing 2-bladed Speculum

# STUDY

The purpose of this study was to compare the existing, 2-bladed speculum to the Bouquet Speculum TM in terms of visualizing the cervix under various simulated, intrapelvic pressures, use of instruments through the devices, and the relative forces exerted on the speculum [13,14].

## METHODS

### VAGINAL PHANTOM TEST

A vaginal phantom was designed and fabricated to simulate the female reproductive system's uterus, fallopian tubes, ovaries, cervix, and vaginal wall opening. The phantom is composed of a vaginal organ model that was placed in a plastic container with an opening on the side corresponding to the vaginal opening and was suspended for testing. The plastic container was filled with ultrasonic gel at different heights to simulate different pressures. (Figure 3).

- SynDaver Labs™ synthetic uterus sealed to an outward vulva model.
- Uterus model is held up by supporting wire to simulate a natural biological system.
- Sealed Acrylic case, allowing for the introduction of liquid (of a known density) into the container.



Figure 3: Synthetic Vaginal Model in a sealed acrylic case [15]

## METHODS

### PRESSURE TEST

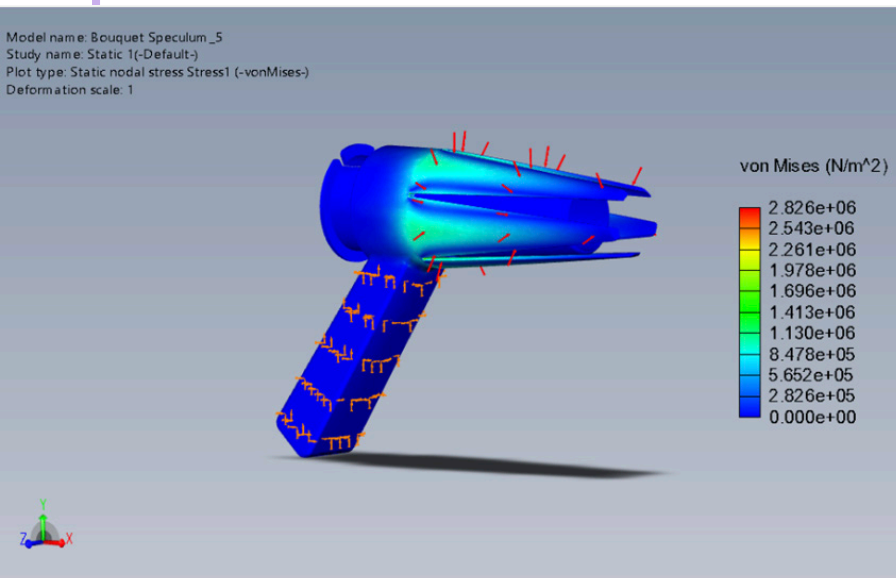
Different gel heights represent different pressures as given by the formula

***Pressure = density x acceleration due to gravity x height.***

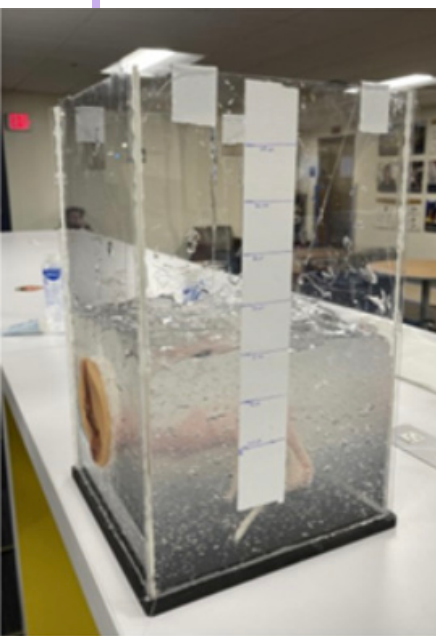
The speculum was inserted in the closed position and was opened once inside the phantom to test that it would fully open (and remain open as needed) and withstand these pressures without failure (breaking/shattering).

This test was repeated at increasing pressures to ensure that the breaking point of the speculum petals was above the known average vaginal wall pressures. (Figure 4 and Figure 5).

$$\text{Pressure (P)} = \text{Density (p)} \times \text{acceleration due to gravity (g)} \times \text{height (h)}$$



**Figure 4:** Stress plot. Stress applied = 1500 Pa (Maximum recorded vaginal pressure)



- Recorded vaginal pressures in supine position range from 0.1cm H<sub>2</sub>O - 15cm H<sub>2</sub>O (equivalent to 10 - 1471 Pa)
- The Bouquet Speculum was subjected to vaginal pressures within and above average range:
  - ◇ 0.1cm H<sub>2</sub>O
  - ◇ 4cm H<sub>2</sub>O
  - ◇ 8cm H<sub>2</sub>O
  - ◇ 12cm H<sub>2</sub>O
  - ◇ 16cm H<sub>2</sub>O (extreme case)
  - ◇ 18cm H<sub>2</sub>O (extreme case)

**Figure 5:** Simulating increased intrapelvic pressure by the addition of ultrasound gel

## METHODS

### VISIBILITY TEST

The visibility area of the cervix was observed by inserting the speculum in the phantom model in the same way as for the pressure test (closed, then opened), and a camera was placed at the opening of the speculum to take photos of the cervical region. The area was calculated from the percent visual area given by: (number of pixels within cervix region/ total number of pixels) \*100. This was also observed at different gel heights to observe how the visibility varies with different pressures. **(Figure 6).**

#### Calculating Percent Visual Area (PVA) of Cervix via MATLAB

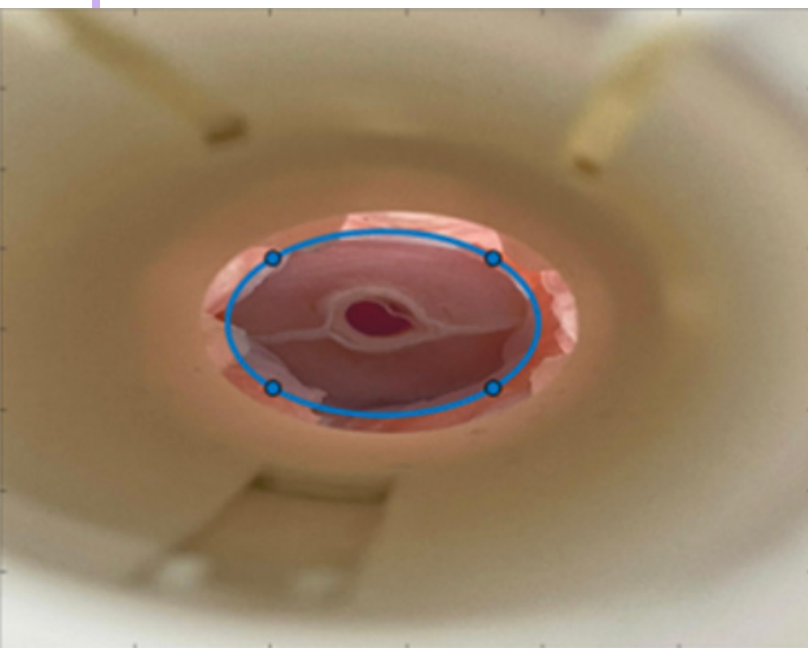
1. Estimate pixel area (cm<sup>2</sup>/ pixel) using known diameter of speculum
2. Segment unobstructed cervical region
3. Segment total cervix region
4. Calculate percent visual area (PVA):

$$PVA = \frac{\text{Area of segmented cervix region}}{\text{Area of total cervix region}} \times 100$$

## METHODS

### GYNECOLOGICAL TOOLS TEST

The speculum was inserted into a vaginal model (closed, then opened) where an 8-inch cotton-tipped applicator was inserted in the speculum. The applicator was inserted inside the opened speculum and manipulated with different movements to ensure that it could efficiently be manipulated, and perform regular functions (i.e., reach the cervical os). **(Figure 8).**



**Figure 6:** How to calculate the Percent Visual Area (PVA)



## RESULTS

Better visualization of the cervix and the cervical os (sampling area for pap tests) was recorded with the Bouquet Speculum TM than the existing 2-bladed speculum at all intrapelvic pressures. (Figure 7)

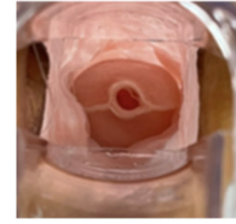
### Vaginal Phantom Test - Results

Pressure Value (in cm H <sub>2</sub> O)	0.1	4	8	12	16	18
Standard Speculum Mean PVA (%)	85.18	50.05	31.97	18.9	0	0
Bouquet Speculum Mean PVA (%)	88.18	87.44	65.45	56.16	27.67	18.72

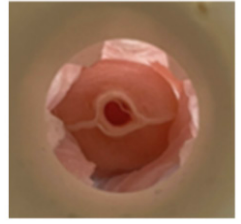
Statistical analysis using an independent t-test showed that the mean PVA for the Bouquet was statistically higher (i.e. better) than the standard speculum ( $p < 0.05$ ) for 4, 8, 12, 16 and 18 cm H<sub>2</sub>O.

0.1 cm H<sub>2</sub>O (10 Pa)

Traditional:

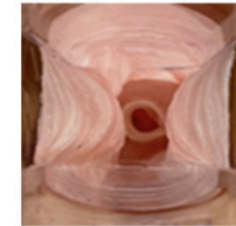


Bouquet:

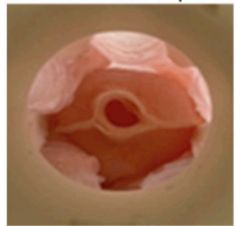


4 cm H<sub>2</sub>O (392 Pa)

Traditional:

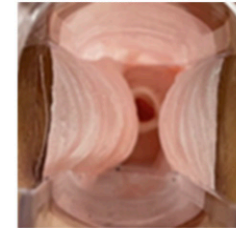


Bouquet:

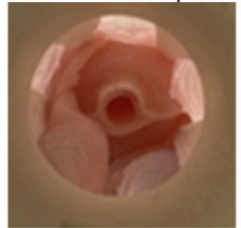


8 cm H<sub>2</sub>O (785 Pa)

Traditional:



Bouquet:



12 cm H<sub>2</sub>O (1177 Pa)

Traditional:

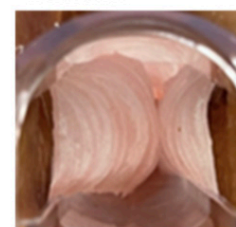


Bouquet:



16 cm H<sub>2</sub>O (1569 Pa)

Traditional:



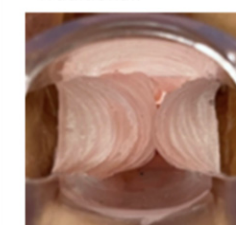
Bouquet:



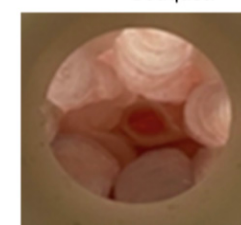
\*Full Obstruction

18 cm H<sub>2</sub>O (1765 Pa)

Traditional:



Bouquet:



\*Full Obstruction

## Benchmark testing - Gynecological Tools Compatibility

- Pass/ fail test: White stain represents cell sample from cervical tissue (as can be seen in developing cancer stages). Tool showed represents standard length for gynecological examination tools (8 in long).
- Sample was retrieved successfully in 10 consecutive trials = **Passed**



## DISCUSSION

The Bouquet Speculum TM is an innovative redesign of the traditional 2-bladed speculum. This new five-petaled, radially dilatable speculum showed statistically significant improvement in cervical visibility compared to the traditional speculum. It demonstrated low, symmetrically directed pressures when dilated. It was compatible with other gynecologic tools such as the cotton-tipped swab.

This speculum was designed to ultimately improve the diagnosis and treatment of cervical cancer and pre-cancers. This can also be applied to other general gynecological examinations and instrumentation.

Some of the limitations to this study include: this a simulated vaginal model and may not translate substantively to human subjects, the static nodal stress studies for breakage of the device and relative pressures were only tested on the Bouquet Speculum TM and other gynecologic tools (cytobrush, cryowand, IUDs) may need to be tested for compatibility with the speculum.

## CONCLUSION

The innovative design of the Bouquet Speculum™ provides improved visualization of the uterine cervix, less discomfort for the patient due to its radial distribution of forces and may result in greater efficiency for the provider due to localization of the cervix without repositioning of the patient or the speculum.

Additionally, the new design offers a handle that does not require a specialized gynecologic table with footrests. This is important in screen and treat clinics in low-resource countries. The Bouquet Speculum™ has the added benefit of having a universal fit and smaller insertive end for efficiency and patient comfort.

## DIRECTIONS FOR FUTURE RESEARCH

The future scope of the project will focus on moving forward with the preferred mass manufacturing method (injection molding), as well as finding healthcare providers interested in implementing the use of this design nationwide. RVU, in a separate study, is actively recruiting women to participate in a head-to-head clinical study. The Global Track at RVU is interested in using and studying the new speculum on their overseas trips. Megan Clarke, PhD, from NIH/NCI is proposing a clinical study, with her colleagues, on the use of the Bouquet Speculum™, in difficult to visualize cervixes such as obese, overweight, and multiparous women [9].

The future goal for this project is to have a low-cost and accurate program to screen and treat women in low-resource countries for cervical cancer and dysplasia. The Bouquet Speculum™, in conjunction with visual inspection with acetic acid (VIA) can yield a safe, efficient, practical, accurate and inexpensive method to screen for cervical cancer in communities where this treatment is needed the most [16]. Clinical studies are underway, including in developing countries such as Cameroon, Chad, Kenya, Malawi, Nigeria, Uganda and Zambia.



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## REFERENCES

1. Marc Arbyn, Elisabete Weiderpass, Laia Bruni, Silvia de Sanjosé, Mona Saraiya, Jacques Ferlay, Freddie Bray, Estimates of incidence and mortality of cervical cancer in 2018: a worldwide analysis, *The Lancet Global Health*, Volume 8, Issue 2, 2020, Pages e191-e203, ISSN 2214-109X.
2. Goldie SJ, Gaffikin L, Goldhaber-Fiebert JD, Gordillo-Tobar A, Levin C, Mahé C, Wright TC; Alliance for Cervical Cancer Prevention Cost Working Group. Cost-effectiveness of cervical-cancer screening in five developing countries. *N Engl J Med*. 2005 Nov 17;353(20):2158-68. doi: 10.1056/NEJMsa044278. PMID: 16291985.
3. Burd EM. Human papillomavirus and cervical cancer. *Clin Microbiol Rev*. 2003;16(1):1-17. doi:10.1128/CMR.16.1.1-17.2003
4. Carneiro SR, Fagundes MA, do Rosário PJO, Neves LMT, Souza GDS, Pinheiro MDCN. Five-year survival and associated factors in women treated for cervical cancer at a reference hospital in the Brazilian Amazon. *PLoS One*. 2017 Nov 16;12(11):e0187579. doi: 10.1371/journal.pone.0187579. PMID: 29145414; PMCID: PMC5690614.
5. Seng LM, Rosman AN, Khan A, et al. Awareness of cervical cancer among women in Malaysia. *Int J Health Sci (Qassim)*. 2018;12(4):42-48.
6. Thomas A, Weisberg E, Lieberman D, Fraser IS. A randomised controlled trial comparing a dilating vaginal speculum with a conventional bivalve speculum. *Aust N Z J Obstet Gynaecol*. 2001 Nov;41(4):379-86. doi: 10.1111/j.1479-828x.2001.tb01313.x. PMID: 11787909.
7. Bates CK, Carroll N, Potter J. The challenging pelvic examination. *J Gen Intern Med*. 2011 Jun;26(6):651-7. doi: 10.1007/s11606-010-1610-8. Epub 2011 Jan 12. PMID: 21225474; PMCID: PMC3101979.
8. Asiedu, M. N., Agudogo, J., Krieger, M. S., Miros, R., Proeschold-Bell, R. J., Schmitt, J. W., & Ramanujam, N. (2017). Design and preliminary analysis of a vaginal inserter for speculum-free cervical cancer screening. *Plos One*, 12 (5). doi: 10.1371/journal.pone.0177782
9. Clarke MA, Fetterman B, Cheung LC, Wentzensen N, Gage JC, Katki HA, Befano B, Demarco M, Schussler J, Kinney WK, Raine-Bennett TR, Lorey TS, Poitras NE, Castle PE, Schiffman M. Epidemiologic Evidence That Excess Body Weight Increases Risk of Cervical Cancer by Decreased Detection of Precancer. *J Clin Oncol*. 2018 Apr 20;36(12):1184-1191. doi: 10.1200/JCO.2017.75.3442. Epub 2018 Jan 22. PMID: 29356609; PMCID: PMC5908221.

## REFERENCES

10. Eveleth, R. Why no one can design a better speculum. *The Atlantic*, Nov. 7, 2014. Retrieved August 1, 2021 <https://www.theatlantic.com/health/archive/2014/11/why-no-one-can-design-a-better-speculum/382534/>
11. Sandelowski M. This most dangerous instrument: propriety, power, and the vaginal speculum. *J Obstet Gynecol Neonatal Nurs*. 2000 Jan-Feb;29(1):73-82. doi: 10.1111/j.1552-6909.2000.tb02759.x. PMID: 10660279.
12. Cervical Cancer - Statistics. (2021, January 12). Retrieved August 15, 2021, from <https://www.cancer.org/cancer/cervical-cancer/about/key-statistics.html>
13. Team #12: Carlos Armas, Rayyan Naji, Valentina Roldan, Shadi Selkhi  
Department of Biomedical Engineering, College of Engineering and Computing  
Florida International University. Poster Competition April 16th, 2021. (Used with permission, Rayyan Naji).
14. FDA Filings for the Bouquet Speculum. (Retrieved July 11, 2022) Bouquet Vaginal Speculum. Regulation Number: 884.4520
15. Synthetic uterovaginal model. (Retrieved July 31, 2021) from <https://syndaver.com/product/uterus/>
16. Bouquet JM, Chernau A, McLaughlin R, Choudhury Q (2019) A New Vaginal Speculum and an Inexpensive Kit to Screen and Treat Dysplasia and Cancer of the Cervix. *J Women's Health Care* 8.470. doi: 10.35248/2167-0420.19.8.470