

May 30, 2002

Gynecological speculum for obese women

Matt Barra
Northeastern University

Randy Berger
Northeastern University

Caroline Finlay
Northeastern University

Brian Gallagher
Northeastern University

Dan Tully
Northeastern University

See next page for additional authors

Recommended Citation

Barra, Matt; Berger, Randy; Finlay, Caroline; Gallagher, Brian; Tully, Dan; and Waclawik, Elizabeth, "Gynecological speculum for obese women" (2002). *Mechanical Engineering Undergraduate Capstone Projects*. Paper 62. <http://hdl.handle.net/2047/d10011626>

Author(s)

Matt Barra, Randy Berger, Caroline Finlay, Brian Gallagher, Dan Tully, and Elizabeth Waclawik

Gynecological Speculum for Obese Women

MIM 1501-1502

Gynecological Speculum for Obese Women

Final Report

Design Advisor: Prof. John Rossettos

Design Team

**Matt Barra, Randy Berger,
Caroline Finlay, Brian Gallagher
Dan Tully, Elizabeth Waclawik**

May 30, 2002

**Department of Mechanical, Industrial and Manufacturing Engineering
College of Engineering, Northeastern University
Boston, MA 02115**

Table of Contents

List of Figures-	-	-	-	-	-	-	-	-	2
List of Tables	-	-	-	-	-	-	-	-	3
Copyright	-	-	-	-	-	-	-	-	4
Abstract	-	-	-	-	-	-	-	-	5
Introduction	-	-	-	-	-	-	-	-	6
Gynecological Exam	-	-	-	-	-	-	-	-	6
Design Requirements and Criteria	-	-	-	-	-	-	-	-	7
Existing Specula Designs	-	-	-	-	-	-	-	-	8
Initial Design Concepts	-	-	-	-	-	-	-	-	10
Final Design	-	-	-	-	-	-	-	-	12
Testing	-	-	-	-	-	-	-	-	15
Mathematical Modeling	-	-	-	-	-	-	-	-	16
Finite Element Analysis	-	-	-	-	-	-	-	-	20
Ergonomics	-	-	-	-	-	-	-	-	21
Recommendations	-	-	-	-	-	-	-	-	22
Conclusion	-	-	-	-	-	-	-	-	22
References	-	-	-	-	-	-	-	-	23

List of Figures

Figure 1:	Female Reproductive Anatomy	-	-	-	-	-	-	7
Figure 2:	Graves Speculum	-	-	-	-	-	-	9
Figure 3:	Welch-Allyn Speculum	-	-	-	-	-	-	9
Figure 4:	Patton Speculum	-	-	-	-	-	-	9
Figure 5:	Design I	-	-	-	-	-	-	10
Figure 6:	Design II	-	-	-	-	-	-	11
Figure 7:	Final Design	-	-	-	-	-	-	12
Figure 8:	Exploded View of Final Design	-	-	-	-	-	-	13
Figure 9:	Speculum Test Fixture	-	-	-	-	-	-	15
Figure 10:	Vaginal Wall Collapse	-	-	-	-	-	-	16
Figure 11:	Pinching	-	-	-	-	-	-	16
Figure 12:	Open Beam Geometry	-	-	-	-	-	-	17
Figure 13:	Closed Beam Geometry	-	-	-	-	-	-	17
Figure 14:	Blade Cross-Section	-	-	-	-	-	-	18
Figure 15:	Hump Deflection with Closed Collar	-	-	-	-	-	-	18
Figure 16:	Blade Deflection with Simulated Body Forces	-	-	-	-	-	-	19
Figure 17:	Ribs to Minimize Beam Deflection	-	-	-	-	-	-	20
Figure 18:	Beam Deflection Analysis	-	-	-	-	-	-	20
Figure 19:	von Mises Stress Concentration	-	-	-	-	-	-	21

List of Tables

Table 1:	List of Design Criteria	-	-	-	-	-	8
Table 2:	Properties of Acrylic	-	-	-	-	-	14
Table 3:	Properties of PFA	-	-	-	-	-	14

Copyright

“We the team members,

Matt Barra

Randy Berger

Caroline Finlay

Brian Gallagher

Dan Tully

Elizabeth Waclawik

Prof. John Rossettos

Hereby assign our copyright of this report and of the corresponding Executive Summary to the Mechanical, Industrial and Manufacturing Engineering (MIME) Department of Northeastern University.” We also hereby agree that the video of our Oral Presentations is the full property of the MIME Department.

Publication of this report does not constitute approval by Northeastern University, the MIME Department or its faculty members of the findings or conclusions contained herein. It is published for the exchange and stimulation of ideas.

Development and Design of a Gynecological Speculum for Obese Women

Design Team

Matt Barra, Randy Berger,
Caroline Finlay, Brian Gallagher
Dan Tully, Liz Waclawik

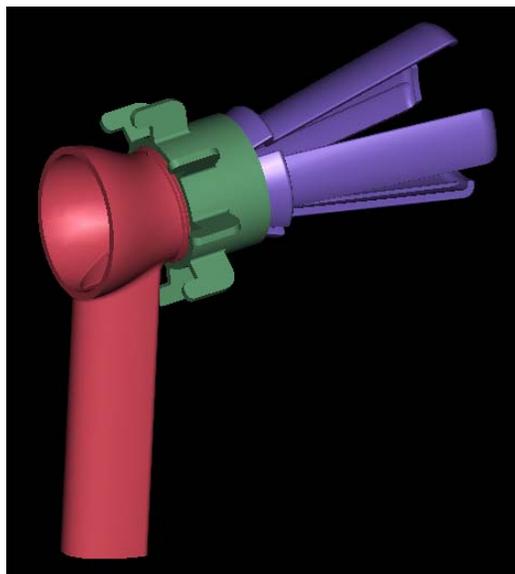
Design Advisor

Prof. John Rossettos

Abstract

Current gynecological specula on the market are not optimal. They do not adequately open obese women's vaginas and can be uncomfortable for all women. These specula lack lateral support for the vaginal sidewalls, and allow them to collapse inward during examination, obstructing the examiner's view of the cervix. Existing specula can pinch, so the practitioner must use it skillfully to prevent patient discomfort. Few specula open incrementally, a feature that facilitates universal use. Additionally, reusable specula are the most common, but they are expensive to buy and to sterilize. Today's medical market demands an inexpensive, disposable and comfortable speculum that is effective for all women.

Existing specula provided the starting point for a new and innovative design. The most common disposable speculum is the Welch-Allyn. It has incremental opening and is operable with one hand, but it does not retain the vaginal sidewalls, making it useless when examining obese women. Non-disposable specula are widespread and are usually made of uncomfortably cold stainless steel. Using information from patients, the project sponsor, pediatric gynecologist Dr. Estheranne Grace, and from preliminary concept drawings from Children's Hospital, the design team came up with two speculum designs. The most important other factor that affected speculum design was material selection. Testing was also performed to learn about speculum operation forces, internal vaginal pressure, and stress concentrations the speculum's pivot point. These two new designs combine the best features in existing specula with new and innovative components, and the better of these two was prototyped. The new speculum is easy to operate, comfortable, and usable on obese women.



Introduction

Specula facilitate dilation of the vaginal opening during gynecological exams. During a routine gynecological exam, the practitioner visually inspects the cervix and vaginal walls and samples cervical cells. Standard, or duckbill, specula have two flat blades that open the vagina vertically. This design has undergone few perturbations over the past one hundred years. Current specula vary little from one another, and although many come in three standard sizes, none accommodate obese women.

Gynecological practitioners cannot easily view obese women's cervixes during pelvic examination because of the excess skin and tissue in the vagina. The sidewalls of the vagina collapse inward because of the duckbill specula's lack of lateral wall support. This obstruction restricts an examiner's access to the cervix for routine cell sampling, leading to inadequate gynecological care for obese women. Additionally, duckbill speculum blades can pinch obese women's excess vaginal tissue upon closure.

Current gynecological exams on obese women require two practitioners. One inserts and opens the standard duckbill speculum while the other inserts a second, smaller speculum and opens it laterally. This is a working solution, but it is uncomfortable for patients and impractical for physicians. The new speculum design allows a single physician to perform a thorough gynecological exam on any woman. The new speculum provides both vertical opening and lateral vaginal wall retention, so pelvic exams can be easy for practitioners and comfortable for patients.

Currently, there are 23 million obese women in the United States. When combined with overweight women, this represents 50.7% of the female population. Unfortunately, obese women often have higher percentages of cervical cancer and other uterine diseases because they cannot get thorough gynecological exams. The new speculum has the potential to improve the health of a large number of women. More information regarding obesity and related statistics can be found in Appendix A.

Gynecological Exam

In order to maintain reproductive health, women must undergo routine vaginal and pelvic exams and a speculum is a standard piece of exam equipment. Physicians use these exams to detect cancer and to diagnose sexually transmitted diseases. Gynecologists recommend that women of reproductive age be examined yearly. Also, pregnant women, those in labor and those who have recently given birth have more frequent gynecological exams.

The vaginal cavity is about 3 inches long and extends from the female external genitalia to the tip of the uterus, of cervix, as seen in Figure 1. The internal vaginal walls are mucus membranes. Bacteria living in the vagina ferment secreted mucus, producing sterile acids, which prevent harmful infection. During pregnancy, the vagina and surrounding tissues change, allowing vaginal expansion during birth.

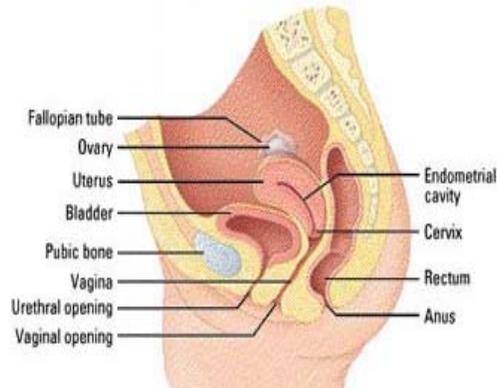


Figure 1: Female Reproductive Anatomy

During an exam, the patient lies on her back with her legs in stirrups that are attached to the exam table. The practitioner first inserts the speculum and dilates the vagina, allowing him or her to view the cervix, which is thoroughly inspected. Then s/he takes a swab of the cervix or vaginal cells, which are later tested for infection or cancer. Lastly, the practitioner inserts his or her finger in to the vagina to palpate the patient's reproductive organs.

Design Requirements and Criteria

The new gynecological speculum must outperform current specula many ways. Determining design specifications was the first part of the new speculum design process. Most of the design requirements came from Dr. Estherann Grace of Children's Hospital, the project sponsor. The design requirements are listed below:

The new speculum must -

1. Be operable with one hand
2. Have minimal insertion size
3. Retain vaginal walls in all directions
4. Allow for maximum visibility of vaginal walls and cervix
5. Include fiber-optic capability for lighting
6. Be disposable (at least in part)
7. Be comfortable for all women
8. Be able to be temporarily locked into open position

The requirement list provided a foundation upon which to build the design. Design requirements were fine-tuned as the design progressed. The establishment of end-design criteria drove design development. These design criteria are outlined in the following table. The table includes initial qualitative criteria and each criterion's quantitative corollary. The design team strove to meet all of these criteria and have done so successfully.

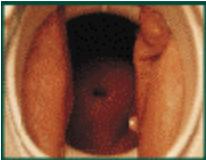
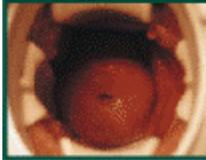
<u>Qualitative</u>	<u>Quantitative</u>
<p>The new speculum must hold the vagina open, allowing the practitioner to examine the cervix.</p> <div style="display: flex; justify-content: space-around; align-items: center;">   </div> <p style="display: flex; justify-content: space-around; align-items: center;"> Two bladed view Four bladed view </p>	<p>It must open the vagina in at least 4 directions.</p> <p>The maximum internal dilation diameter of the speculum blades must be greater than or equal to 2 inches.</p> <p>The blade length must be greater than or equal to 2.5 inches.</p>
<p>The new speculum must allow the physician to examine the vaginal walls.</p> <p>It must also conduct the light emitted by an optical fiber.</p>	<p>The material must have a haze of 3-4%</p> <p>The material must have visible transmission of 86-88%.</p> <p>The material must have a refractive index greater than 1.52.</p>
<p>The new speculum must be comfortable to insert.</p>	<p>The closed diameter of the tip of the speculum must be less than ¾ inch.</p> <p>The closed diameter of the base of the speculum must be less than 1 inch.</p>
<p>The speculum must be disposable, which is more hygienic.</p>	<p>Our speculum must cost less than \$8 to manufacture and must sell for less than \$10.</p>
<p>The new speculum must be one handed, allowing one physician to perform tests on the vaginal walls and cervix during the exam.</p>	<p>Our speculum can be used with either hand, and the opening/closing of the blades is performed with the thumb of the same hand that grasps the handle.</p>

Table 1: List of Design Criteria

Existing Specula Designs

A thorough gynecological exam is crucial in maintaining women’s reproductive health, so specula must perform as needed. A few specula address some of the issues surrounding the examination of obese women. Unfortunately, none addresses all of the design requirements.

The Graves speculum is a standard metal duckbill speculum. Its two blades open vertically and a screw and wing nut lock them in place. This is a two-handed speculum, so it takes longer to examine patients, increasing patient discomfort. Metal specula feel cold; they must be warmed prior to use and their opaque metal blades prevent visual inspection of the vaginal walls. Additionally, the speculum must be disassembled, sterilized, and reassembled after each use, which is labor intensive and costly.



Figure 2: Graves Speculum

The Welch-Allyn speculum is one of the first plastic disposable specula. It is better than metal specula because it has low thermal conductivity and does not feel cold upon insertion. Because it is disposable, it need not be sterilized, which is time-consuming and requires expensive equipment. This speculum's blades are transparent, so they do not obstruct the view of the vaginal walls. The most unique feature of the Welch-Allyn speculum is its fiber optic illumination tube, which illuminates the vaginal cavity and creates better visibility. Product and patent information on the Welch Allyn Speculum can be found in Appendix B.



Figure 3: Welch Allyn Speculum

The Patton speculum is four-bladed, but it is not a suitable speculum for obese women's gynecological exams. It is operable with one-hand, but does not have accurate incremental control. Although the four blades dilate the vagina, they are made of opaque plastic, disallowing the visual inspection of the vaginal walls. This is significant because there are four blades blocking the view of vaginal walls as opposed to just two, so the practitioner still cannot give a thorough exam. Refer to Appendix C for additional speculum designs.



Figure 4: Patton Speculum

Initial Design Concepts

Before coming up with a final design, a few design concepts were examined. All of the initial design concepts addressed the design criteria. Of these, two were carried to the modeling stage and one was chosen to be prototyped.

Design I

The first design concept is an improvement of the Welch-Allyn speculum. It has two clear, rigid plastic blades, which open vertically and are controlled by a ratchet arm. A squeeze handle controls two additional horizontally opening blades. When a force is applied to the squeeze handle, the two horizontal blades arch outward, preventing the vaginal sidewalls from collapsing inward. This is capable of housing a fiber optic light source, and features a light tube that then conducts light into the vaginal cavity. This design is made out of acrylic, so it will be cheap and disposable. The addition of the squeeze handle increases speculum functionality without compromising one-handed use. This speculum design is shown below in figure 5, and more detailed pictures can be found in Appendix D.

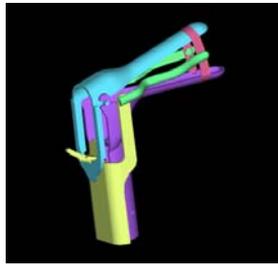


Figure 5: Design I

The design has five main components: the lower blade and handle, the upper blade, the squeeze handle, the two side blades, and the retainer band. The lower blade and handle is shaped like that in the Welch-Allyn speculum, but handle's contour was improved to give the doctor a better grip, and to allow him or her to depress the squeeze handle. It contains a slot for the existing light source and a light conducting tube. Four locating holes on the rear surface of the handle to connect it to the squeeze handle, while guiding the squeeze handle's motion. A cut and indentation near the tip of the lower blade houses the retainer band. The upper blade snaps into the lower blade's attachment hinge.

The upper blade is nearly identical to that of the Welch-Allyn. The hinge posts on either side of the upper blade snap into attachment hinge on the lower blade. The upper blade narrows at the tip and had a thumb lever at the rear. A notch within the thumb lever clicks into the ratcheting mechanism extending from the squeeze handle. A cut and indentation feature at the tip of the blade, identical to that on the lower blade, also houses the retainer band.

The squeeze handle makes this design innovative. This half of the handle has four posts, which travel in the four holes in the lower blade and handle. Springs provide static sliding resistance for each post. An arm that stems outward from the back face of the squeeze handle has ratchet teeth that control the upper blade opening. Arms extending upward from the front of the squeeze handle provide hinge support for the side blades.

The side blades are molded from flexible plastic, and follow the outside curves of the upper and lower blades. They attach to the arms extending from the squeeze handle with a snap-in hinge. Notches cut out of the outside of the blades create a living hinge, which allows the blades to bow outward along the horizontal plane when the squeeze handle is compressed. The tips of each side blade are held in place by the retainer band. These side blades support the lateral vaginal walls, giving the gynecological practitioner a clear view of the cervix.

The retainer band is a molded rubber housed in the notch in the upper and lower blades. The tips of the side blades will snap into two holes in the retainer band. The band holds and provides compression resistance to the tips of the side blades when the upper and lower blades are open.

This design satisfies our design criteria by providing horizontal support for the vaginal walls, having the capability of incremental opening, and by providing for fiber optic capability. It works from an existing speculum, but the two additional horizontal blades prevent vaginal sidewall collapse. Unfortunately, this speculum is difficult to prototype because the both side blade and the retainer materials must have a specific elastic moduli.

Design II

The second speculum concept adheres to our design criteria in a more novel way. It has four equally sized blades, which open the vaginal walls both vertically and laterally. Like design one, it is made of clear, disposable plastic and incorporates the fiber-optic tube used in the Welch-Allyn speculum. It is operable with one hand and has reduced pinch points. It also has a small insertion size and rounded blade tips, so it is comfortable for the patient. Figure 6 below depicts this design.

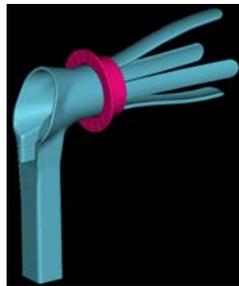


Figure 6: Design II

The concept two speculum has two vertically opening blades. These blades open to a maximum of 2.68in, the same as in the Welch-Allyn speculum. There are also two lateral blades that retain the vaginal sidewalls at a maximum opening of 1.25in. The four blades do not move independently because they are attached to the speculum handle. Vaginal depth and blade length both determine insertion, so the blades in the concept two speculum are the same length as the blades in the Welch-Allyn speculum. A threaded collar circles the base of the blades controls blade opening. The speculum handle has vertical ridges to give the user a better grip.

The four blades naturally spread because they are molded in the open position. Rotating the collar counterclockwise moves it forward on the blades and forces them to close. The user assembles this speculum by squeezing the blades closed and fitting the collar over them. The collar can then be screwed into the base of the blades. The speculum is now ready for insertion. Once the speculum is in place in the vagina, the practitioner rotates the collar clockwise with his or her thumb while holding the handle. This releases the blades, which spring open against the vaginal walls. When the exam is completed, rotating the collar counterclockwise again closes the blades for comfortable removal.

Material choice is particularly important for the concept two speculum. The material must be clear plastic with a high index of refraction so that the fiber optic tube will properly channel the light. Also, the plastic must be elastic enough to accommodate the opening and closing of the blades. The blades must not be too pliable, or they will bow too much in the middle, obstructing the examiner's cervical view. Lastly, since disposability is a design requirement, the material must be inexpensive and easily molded. Disposability had advantages, though, because fatigue and stress concentrations are not large considerations. This design was modified and became the final design. More detailed pictures of Design II can be found in Appendix E.

Final Design

The final design is a four bladed speculum that satisfies all the design criteria, and is easy to prototype and manufacture. The four blades support the vaginal walls in all four directions, giving an unobstructed view of the cervix. The speculum is comfortable to use because the four blades have a small insertion diameter. This design also incorporates the fiber-optic light pipe, which illuminates the vaginal cavity. This design (Figure 7) is disposable and also allows for one-handed operation. Detailed drawings of the Final Design are located in Appendix F.

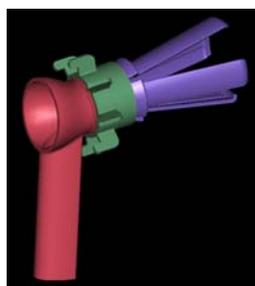


Figure 7: Final Design

The final design is similar to design two, except it has three injection-molded parts instead of two. These parts are the handle, the collar, and the blades. Having three parts makes the speculum easier to assemble because the collar could not fit over the blades of the design two speculum. So, the blades and handle were separated into two parts, which snap together inside the collar. It was impossible to find one material that would satisfy the design

criteria for both the handle and blades, so the handle and blades are made from different materials. A seemingly more complicated three-part design actually simplifies both material choice and assembly.

The final design speculum is easy to use. The gynecological practitioner will receive the speculum in the open position. S/he will grip the handle will use his/her thumb to rotate the collar. The mating threads between the collar and the handle will guide the collar forward, where it will apply even pressure to the base of the blades and cause them to close. Once completely closed, the examiner will insert the speculum into the vagina. The practitioner will then rotate the collar backwards to relieve the pressure on the blades, allowing them to spring open into the vaginal walls. The four blades will provide the examiner with a completely unobstructed view of the cervix. Once the exam is complete, the doctor will rotate the collar forward, again closing the blades. Then the doctor can remove the speculum and dispose.

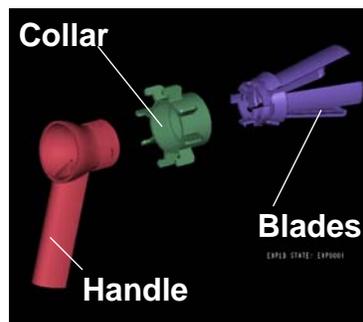


Figure 8: Exploded View of Final Design

Figure 8 above is an exploded view of the disassembled speculum's three components. The assembly of the three parts is simple. First, the assembler takes the collar and threads it onto the threaded portion of the handle. There is no possibility for error here because there is only one way that they can mate. Then, the blades simply snap into the catches on the handle. This is also error proof since any of the snaps can be aligned with any of the catches and the four blades are identical. The speculum is now ready for use. For more detail on the assembly please refer to the assembly drawing in Appendix F.

The first of the three parts is the handle (shown above), which is comprised of two separate sections. The first is the ergonomic grip, which is both a comfortable way for the doctor to hold the speculum and a housing for the light source. The second portion of the handle is the access cylinder, which is a semi-conically shaped loop at the top of the handle. This section provides enough room for the examiner to view the vagina and cervix as well as take samples. This part also houses the fiber-optic light pipe, which redirects the light from the light source into the vaginal opening. Also, there are threads that mate with the collar on the outer surface of the access cylinder. Lastly, the catches for the snaps are on the forward part of the access cylinder. For more detail on this part please refer to the drawings in Appendix F.

The second of the three parts is the collar (shown above). The collar is a cylinder with half of the inner surface threaded to mate with the handle. A travel-limiting flange is located on the inner surface of the non-threaded half of the collar. This flange mates with a similar feature on the blades, preventing excess travel of the

collar and full closure of the blades. This will prevent pinching. The final features on the collar are the thumb tabs. The doctor will use his/her thumb to push on these tabs to rotate the collar. These thumb tabs are located every forty-five degrees along the rear half of the outer surface. For more detail on this part please refer to the drawings in Appendix F.

The handle and the collar will be made from the same material. This was necessary because mating threads should be made of the same material to reduce friction. The requirements for the handle became the governing factors since the collar did not have strict material needs. The most obvious material need came from the fiber-optic light pipe. The material needed to have the proper refractive index and visible transmission. Acrylic was chosen because it is the material in the Welch-Allyn speculum, which also contains a fiber-optic light pipe. Table 2 lists the properties of Acrylic. Full listing of the properties of acrylic can be found in Appendix H.

	Mechanical Properties			Visible Properties		
	Elastic Modulus (ksi)	Yield Stress (psi)	Shrinkage (in/in)	Visible Transmission	Haze	Refractive Index
Acrylic	319 - 551	7980 - 12300	0.00650	80 - 93%	1%	1.49

Table 2: Properties of Acrylic

The final part is the blades (shown above). This is the most complicated and innovative part. The four blades join into a cylindrical shape at their base. This part will be molded so that the blades are in the open position. The blades themselves each have curved cross-sections that are one quarter of insertion diameter profile. At the rear end of each blade is a hump that mates with the collar. The hump sits at an appropriate angle to gradually close the blades as the collar moves forward and applies pressure. At the hinge point of each blade, a cutout has been made to reduce the cross-sectional area of that section to reduce the blade closing force. The flange that mates with the collar's travel-limiting flange sits behind these cutouts. For insertion comfort, the tip of each blade is curved for a less intrusive entry. Finally, there are four one-way snaps that connect to the catches located on the handle at the rear cylinder of the blades. For more detail on this part please refer to the drawings in Appendix F.

The blades will be made from a different material than the handle and the collar. To make the blades flexible enough so that the doctor can easily close them, yet resilient enough to spring out into the vaginal walls, a material with the desired Elastic Modulus was chosen. The material is PFA (polyflouroalkoxyethylene), which is a synthetic polymer that has the ideal range of Elastic modulus. It also has high chemical resistance, low shrinkage characteristics, and high moldability, while meeting FDA regulation 21 CFR 177.1640: Suitable for Food Contact. Table 3 lists the properties of PFA. Full listing of the properties of PFA are located in Appendix H.

	Mechanical Properties			Visible Properties		
	Elastic Modulus (ksi)	Yield Stress (psi)	Shrinkage (in/in)	Visible Transmission	Haze	Refractive Index
PFA	10 - 435	2180 - 4350	0.05	93%	4%	1.35

Table 3: Properties of PFA

Testing

The design team built a test fixture that simulates the vagina to easily observe speculum function. While operating a speculum inside the vaginal model, the user can note the severity of pinch points and observe the range of forces that the vagina may exert during a pelvic exam. Also, the vaginal sidewall collapse that occurs with the Welch-Allyn speculum in obese women is clearly visible in the vaginal model.

Test Fixture

The test fixture is a watertight Lexan box with hole in the top for addition and removal of fluid, and a female condom suspended across the width. The box measures 6 inches deep, by 6 inches long, by 4 inches wide. The ends of the female condom are fastened to the outside of the box over two holes, so that the inside of the condom is open to the outside. The female condom (Reality Female Condom) is made from clear, non-elastic plastic and simulates the vagina. When the box is filled with water, the constituent of 75% of the human body, the female condom collapses radially in on itself, occluding the view through it. The plastic vagina is both deeper and has a greater diameter than actual vaginas, so it creates a worst-case scenario for pinch points. Cutting the sealed end of the female condom enables entry into the model vagina from two ends with two different diameters, which simulates differences in female pelvic bone size. Changing the depth of water in the box changes the pressure on the model vagina's walls. The model accurately represents the tightness of the vaginal opening as well as the folds of skin that are present within the vagina. Figure 9 shows a diagram of the test fixture.

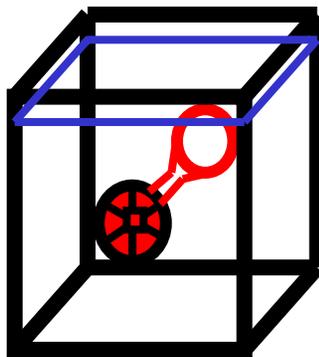


Figure 9: Speculum Test Fixture

Test Procedure

It was easy to observe and compare speculum function in the vaginal model. To better see pinch points within the model vagina, the model was filled with colored liquid. The Welch-Allyn speculum was inserted in the model and slowly opened, while observing vaginal behavior. Later, the new four-bladed speculum was inserted into the vaginal model to prove that it would properly open skin folds and not pinch.

Vaginal and speculum force testing comprised of varying the internal vaginal pressure while measuring the force required to open the speculum. Changing the water depth changes the pressure inside the model vagina, so force measurements were taken at four depths, measured from the box' bottom: 4½, 5, 5½, and 6 inches. Changing

the amount of blade opening will also affect opening force, so measurements were taken for four blade opening distances, measured at the tip of the blades: ½, 1, 1½ inches, and at maximum blade opening, just less than 2 inches.

To find the opening force, a speculum was inserted into the smaller hole of the female condom and the speculum handle was depressed with a digital force gauge so the blades stationary. The blade opening distance was measured with pieces of precut cardboard that were ½, 1 and 1½ inches long. This experiment produced vaginal wall pressure data and force data. The forces required to open the speculum to various distances at various vaginal pressures were now known.

Observations

When fully inserted and opened, the Welch-Allyn speculum opens the top and bottom vaginal walls, but does not retain the vaginal sidewalls. The sidewall collapse is visible in Figure 10. Also, the Welch-Allyn speculum trapped folds of the female condom upon closure. In a patient, this could be painful pinching. The extent of the pinching is visible in Figure 11.

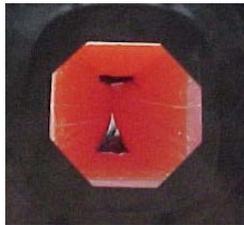


Figure 10: Vaginal Wall Collapse

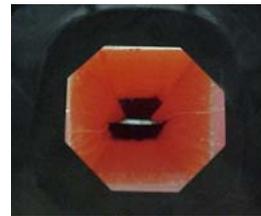


Figure 11: Pinching

Mathematical Modeling

Calculation of Speculum Dimensions

To set the final design dimensions, speculum operation was taken into account. With the help of Dr. Grace and industry standards, proper blade length and insertion size were chosen. A small closed diameter was chosen to minimize the blade insertion size, while still preventing pinch points and allowing proper blade operation. The blade length was taken from existing specula, and 0.10in spacing between the blades was chosen further reduced to eliminate pinch points. With these constraints specified, all other necessary dimensions were calculated.

Once the length of the blades (L) and the opening diameter (δ), shown in Figure 12, were defined, the geometry of the blade and hump were calculated. The angle (α) is the angle of blade opening, and the angle (β) dictates the proper operation of the hump. Using the geometry calculations, the travel distance of the collar section could then be calculated, as shown in Figure 13. This travel distance is an integral part in all calculations to follow; it will determine the point of applied load as well as the pitch of the threads that mate with the collar. Many of these dimensions were calculated, but some had to be set in order to simplify the design process. The blade and hump

thickness was set to 0.10in for the entire cross-section. A uniform thickness made calculations and possible future adjustments easier. Blade and hump geometry gave a starting point for force calculations.

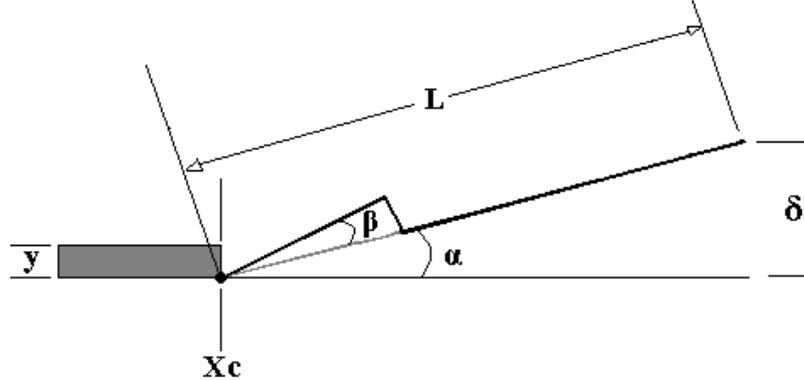


Figure 12: Open Beam Geometry

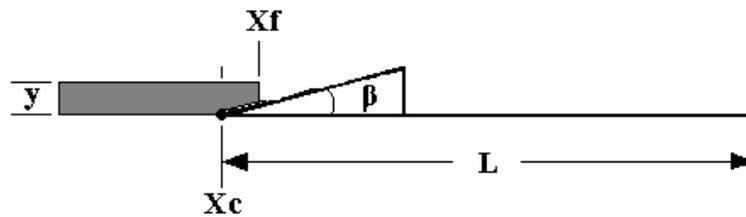


Figure 13: Closed Beam Geometry

$$\text{Beam Deflection equation: } \delta = [(PL^3) / (6EI)] * ((3X_c) - L)$$

Beam Calculations: Hump

After the final overall dimensions were determined, the following were calculated:

1. Moment of Inertia (I) of the cross section
2. Location of point force
3. Maximum allowable deflection of blades
4. Modulus of Elasticity (E) required for proper operation.

The hump was modeled as a cantilever beam fixed at one end to understand its reaction under force, shown in Figure 15. This is a conservative estimate since there are circular cutouts between each blade and a change in blade thickness, which reduce the cross-section at the base of the blade and act as a living hinge. Beam calculations require a known Moment of Inertia (I) about the cross section of the blades and hump. The cross-section used (shown below) is that of a parabola.

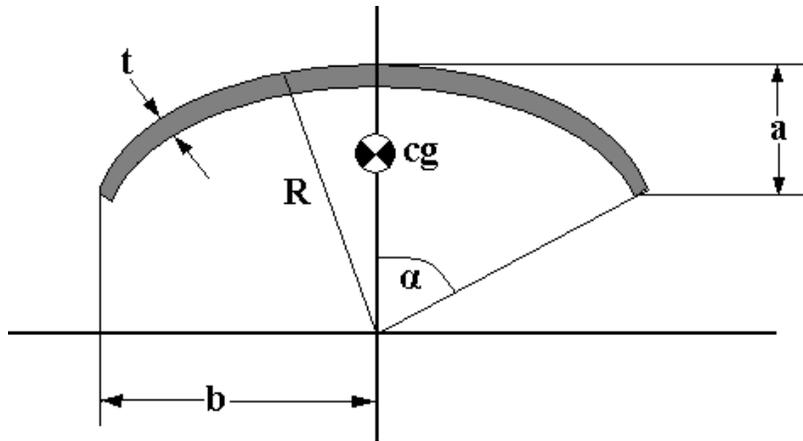


Figure 14: Blade Cross-Section

All dimensions of the parabolic cross-section are necessary to determine the Moment of Inertia (I). These dimensions are: the parabola's radius (R), the blade section angle (α), the arc length, the height (a), the width (b) of the section, and the thickness (t), shown in Figure 14. From these the magnitude and location of the center of gravity (cg) was calculated, and from this I was calculated. The remaining variables are the magnitude of the force acting on the blade and the Modulus of Elasticity (E). The force on the blade relates directly to the coefficient of friction between the blade and collar materials and to the torque applied by the physician.

The force applied to the mathematical blade model was varied within reason to find an acceptable range for E, which ended up being between 6 and 35ksi. This is a worse case scenario because it ignores the living hinge at the base of the blades. This range of E reduced the number of possible blade materials to several thermoplastic copolymers. Of these, the best choice was Polyperfluoroalkoxyethylene (PFA), described in the Final Design section.

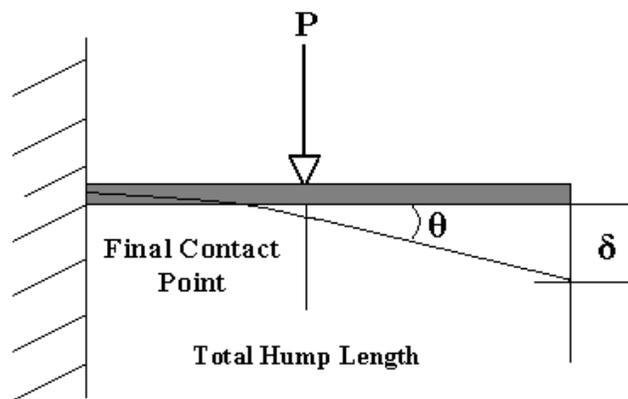


Figure 15: Hump Deflection With Closed Collar

Beam Calculations: Blades

Material and blade geometry were known, so the blade's exact reaction under stress was then determined. The most important part of the design is the proper operation of the collar and hump, which dictates blade behavior. The material dictated the value of E, but the magnitude and location of the force was determined through testing, as

discussed in the Testing section. The force (w) was assumed to be constantly compressive and to act over the final 1/3 of the blade. Modeling showed that the beam deflection fell in the acceptable range, verifying material and geometry choices. Figure 16 below shows the modeling of blade deflection with a distributed load simulating body forces.

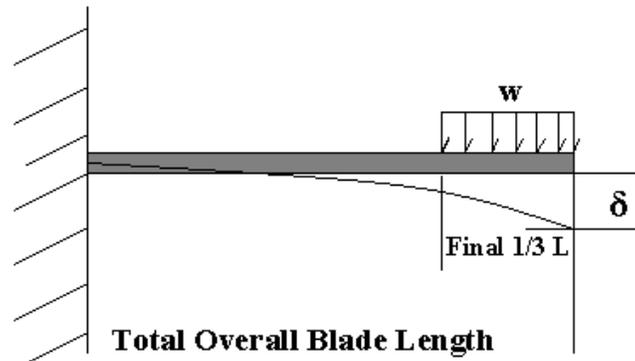


Figure 16: Blade Deflection with Simulated Body Forces

Other Concerns

Other factors can affect speculum function. Friction changes a material's range of elastic behavior because friction between parts, such as the handle and collar, creates heat, hastening plastic deformation. The same material was chosen for both parts to reduce this effect. Also, the blades must not plastically deform when they are closed for insertion, or they will not spring open and retain the vaginal walls. The possibility of deformation upon closure was investigated using the equation below, which relates the force applied over the cross-sectional area with the material's yield stress. Blade modeling determined that the blades remained in the elastic region while under stress from the collar.

$$\text{Plastic Deformation Investigation Equation: } \sigma = P/A_0 < \sigma_y$$

The calculations show that the stress applied is less than the yield stress and that the blades will function properly. Another concern is that the snaps used to mate the handle and the blade will undergo shearing stress, preventing proper operation. This was prevented by changing the snap geometry.

Further Testing and Recommendations

Once the design has been finalized and production has begun, testing will verify the material and geometry choices. The effects of friction on blade opening and closure will be tested to doubly ensure that the material does not plastically deform. If this is a problem, a fine surface finish can be added to the handle and collar, and the angle of chamfer on the collar can be increased, reducing stress in the hump.

If the blades bend too much under bodily forces, adding ribs or internal rings can strengthen them, as shown in Figure 17. The addition of internal rings will prevent blade compression, minimize blade flattening, and therefore reduce overall deflection.

Testing will determine whether or not the snaps can withstand the shearing force applied by the rotation of the collar. If this is a problem, more snaps can be added and/or the cross-section of the snaps could be altered to reduce the shearing stress per snap. Only final testing will determine the necessity of changes, but since all calculations were made based on a worst-case scenario, little change is anticipated.

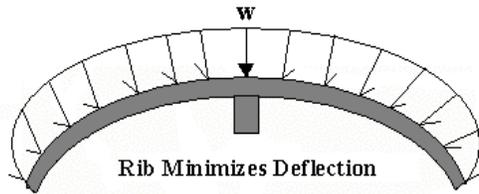


Figure 17: Ribs to Minimize Beam Deflection

Finite Element Analysis

With blade geometry defined and modeled in Pro/Engineer, finite element analysis (FEA) was used to accurately model the forces in the blades. Two FEA models were created, one to test blade deflection and another to test stress concentration at the cutouts at the base of the blades. The Modulus of Elasticity that was used in FEA was that of the blade material (PFA) after injection molding. There multiple factors, some unpredictable, that will effect exact deflection of the blades and the torque around the collar. Until the prototype is constructed out of PFA, the behavior of the speculum can only be mimicked by the SLA rapid-prototype. This is why FEA was necessary: to more accurately model blade behavior with the production material's Modulus of Elasticity. Please refer to Appendix G for high resolution FEA results.

The parameters for FEA analysis were changed systematically and applied to multiple blade geometries. Each blade type was imported into Pro/Engineer Mechanical and ANSYS 5.7 simultaneously, and was solved and analyzed in each program respectively. The deflections were slightly different in the two FEA programs, because of differences in mesh parameters, element type and node structure. This was not a problem because in each case the blade deflection was within the acceptable range and close to the deflection predicted by beam theory calculations made by hand. Figure 18 below is a picture of the beam, modeled in Pro/Engineer Mechanical, under the maximum possible force.

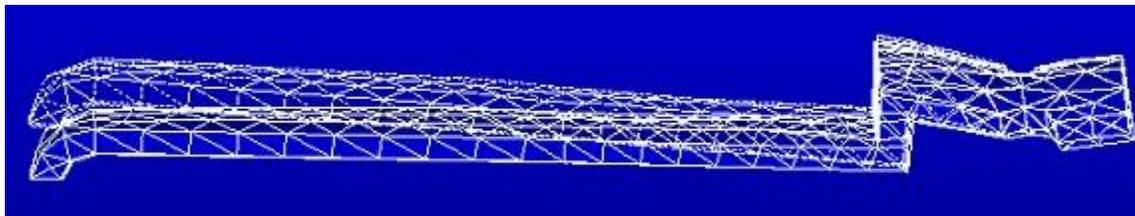


Figure 18: Beam Deflection Analysis

A von Mises stress analysis was used to determine whether or not the stress concentrations in the cutouts at the base of the blades would significantly weaken the speculum. When the speculum was modeled, the rounded cutouts were approximated with many sharp edges and the force applied to the blade was worst-case. Even with these two factors increasing stress concentration, adding to the possibility of plastic deformation, the stresses were still well within the material's strength. Lastly, since the speculum is disposable, fatigue will not be a concern at the stress concentration points. Figure 19 below shows that stress increases at the cutouts, but is tolerable given the properties of the material.

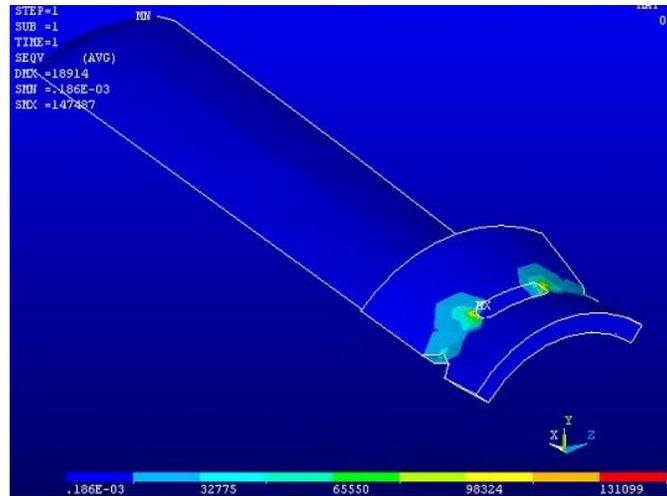


Figure 19: von Mises Stress Concentration

Ergonomics

Any tool requiring human interaction benefits from ergonomic design. Inventions are only useful when people of both sexes can use them. To design our speculum so that physicians can easily and comfortably use it, a few areas needed to be researched. These included hand dimensions, grip dimensions, and knob controls.

Data is available on hand dimensions for both men and women, for the 1st, 50th, and 99th percentile. The key number for our design is thumb length. The thumb of the gripping hand actuates the collar, so the thumb must be able to reach the extended tabs on the collar. The thumb length for men ranges from 1.9in to 2.7in from the crotch of the thumb to the tip. The thumb length for women ranges from 1.7in to 2.5in. The required thumb length to operate our speculum is 1.5in, short enough so that all people can comfortably use it.

To ensure that the speculum would be comfortable for the physician to use, the optimal grip angle, length, and diameter had to be identified. For a “pistol” grip style, the handle should be at an angle of 75° – 80° to the horizontal. The grip length to comfortably accommodate all four fingers should be between 3in and 3.5in. Recommended grip diameter is approximately 1.5in. The speculum was designed to these standards; it has an 80° pistol grip, a 3.5in grip length, and a grip measuring 1.0in by 1.0in.

Designing the extended tabs on the collar also involved ergonomic constraints. Spacing between the tabs had to be large enough to accommodate all thumb sizes, and yet small enough to allow for people with small hands to reach multiple tabs. The spacing between the thumb tabs is 0.75in. Not only does the speculum have a small insertion size for patient comfort, but it is designed for physician comfort as well.

Recommendations

There are a few things that need to be addressed before producing and marketing the new speculum. Extensive prototype testing is necessary to ensure the robustness of the new design. Gynecological practitioners who use specula prototypes in clinical trials will provide critical feedback. This combination of bench testing and clinical use will spur the fine tuning and polishing of the new speculum. Future steps also include a deeper investigation into the product market, including an analysis of the cost consumers are willing to pay. Preliminary data had been collected on existing speculum designs, and this data can be found in Appendix C. When all of the results are known from the bench tests and clinical trials, the speculum will be ready to market and sell.

Conclusion

The new speculum meets all of the design criteria and outperforms any existing speculum on the market. Its four blades open the vaginal walls completely and it is comfortable to insert. It has a fiber-optic light pipe to conduct light into the vagina and its clear blades allow vaginal wall examination. It is one-handed and easy to use, reducing uncomfortable examination time. The travel limiter minimizes the chances for pinching by restricting the blades from closing down completely. It is easy to assemble, and assembly could be automated. The new four-bladed speculum is an excellent alternative to both duckbill specula and to existing four bladed specula, which are expensive and uncomfortable. The medical community's interest in the new speculum is anticipated, and a provisional patent has been filed.

References

Cacha, Charles A., Ergonomics and Safety in Hand Tool Design, Lewis Publishers, New York, 1999.

Department of Mechanical Engineering, Northeastern University, Gynecological Speculum,
<http://www.coe.neu.edu/Groups/mimecap/Gyno.pdf>

Medical Instruments, Vaginal Specula, www.m-e-dical.com/english/vs.htm

National Institute of Diabetes and Digestive and Kidney Diseases: Weight Control Information Network, Statistics Related to Overweight and Obesity,
www.niddk.nih.gov/health/nutrit/pubs/statobes.htm

Patton Medical, Patton Speculum, www.patton-medical.com/products

Tilley, Alvin R., The Measure of Man and Woman: Human Factors in Design. Henry Dreyfuss Associates, New York, 1993.

US National Library of Medicine, Pap Smear,
<http://www.nlm.nih.gov/medlineplus/ency/article/003911.htm>

US National Library of Medicine, Pap Smears and Cervical Cancer,
<http://www.nlm.nih.gov/medlineplus/ency/imagepage/9440.htm>

Welch Allyn: Interactive Catalog, Kleenspec Disposable Vaginal Specula,
www.welchallyn.com/medical/products/catalog/type.asp?ID=25303