Built to Spec?

The vaginal speculum as a case study of inadequate design

by Jennifer Stroud Rossmann

Consider the pelvic exam: a woman lies on an examining table with her feet in metal stirrups. Naked from the waist down, she is given (for modesty) a rectangular paper blanket not quite wide enough to wrap around her waist. She hears the clicking of the speculum blades being ratcheted into position and is told to "relax," so that the gynecologist can inspect her vagina and cervix, to take tissue samples. She may wonder: isn't there a better way?

The speculum—from the Latin, *specere*, to look—more or less begat modern gynecology with its reintroduction in the mid-19th century. The speculum's purpose is to retract the vaginal walls to allow a clinician to visually examine the cervix and obtain culture specimens for tests, such as the Pap smear. Despite its utility, the evolution of the vaginal speculum can be considered a case study in inadequate design. The so-called "modern" speculum in use today is little more than a crude proof-of-concept that has somehow gone mostly unimproved even as medical technology, manufacturing, and materials have advanced.

The Graves and Pederson "duckbill" specula—designed in 1878—are the most commonly used specula in gynecological practice. Each typically has three parts: a top blade, a bottom blade attached to a handle, and a screw that fixes the speculum in place once the top and bottom blades have been separated and positioned for a pelvic exam. It comes in three sizes: small, medium and large. Many patients are ill-served by this device, and many more patients (and practitioners) find it suboptimal. Yet newer alternatives to the 120-year-old duckbill design have not been widely adopted.

Out of the Red Tent and into Stirrups

The female body has historically been a taboo subject, obfuscated by both mysticism and protective propriety. These attitudes have stunted the development of women's health in general and of the speculum in particular—the design process is generally not enhanced by viewing one's client as an elusive enigma or a delicate flower. While vaginal specula were developed in ancient Pompeii and North Africa, women's anatomy was largely misunderstood.

It was American J. Marion Sims, the "father of gynecology," who developed the first rudimentary prototype of the modern vaginal speculum using a bent pewter spoon. Sims had performed many unsuccessful, unanesthetized surgeries on a number of slave women with a gynecological condition known as a fistula. Sims wrote of his first exam

Photos by Michael Kollin Smith

aided by his speculum: "I felt like an explorer in medicine who first views a new and important territory"—a sort of anatomical manifest destiny. The women who inspired his invention were apparently not subject to the prevailing sense of chivalrous restraint; the owners of the women, not the women themselves, were Sims' clients.

It's been documented that women have felt disenfranchised by the medical industry, having been in essence dragged out of the Red Tent (where in biblical times menstruating women were exiled to) and into the stirrups. The history of the speculum reflects the complicated nature of medical device design. A designer must satisfy two clients: the patient and the doctor. While the patient's comfort is a concern, it is the doctor or nurse practitioner performing the exam who must be convinced of, first, the need for an improved device and second, its efficacy, ease of use, and economic value. The historical sense of women as, alternately, inscrutable and corrupting, and innocent and modest, has no doubt compounded this problem for designers of gynecological instruments.

Sims' crude prototype persists: the vaginal speculum in current use was not developed according to a formal design process, in which constraints and objectives were considered, prioritized, and various means of achieving the desired functions analyzed. Instead, like many innovations, it was achieved by trial and error—the brute force result of necessity.

The speculum's evolution was constrained by societal needs, morals, and hierarchies. Attitudes toward women and their bodies caused the design process to stall out, and the design was not refined or improved. The modern speculum is little more than a proof of concept: it simply gets the job done.

Attitudes towards women and their bodies caused the design process to stall out. The modern speculum is little more than a proof of concept: it simply gets the job done.

A Better Speculum

A new speculum design recently developed and FDA-approved, the FemSpec, is made of soft plastic that conforms to a woman's body, preventing common problems like pinching of the vaginal walls between traditional speculum blades and "sidewall convergence," which can compromise the view of the cervix. The speculum is a clear plastic cylinder with air pockets that are inflated after the cylinder has been inserted. While the cylinder is a little larger than a tampon when inserted, the inflation of the air pockets uniformly retracts the vaginal walls.

The FemSpec, marketed by San Francisco company FemSuite, entailed a two-year development-to-market process which began in 2003. The inflatable, disposable speculum is the result of a more thoughtful design process, involving doctors and a design team of one male and two female gynecologists. The designers were inspired by their own experiences, those of their patients, and by research showing that women who put off regular pelvic exams due to discomfort, or whose exams were compromised by sidewall convergence, have disproportionately high cervical cancer morbidity rates. While obese women and women who had given birth more than four times were most likely to be in this group,

Revealing Moments in the Speculum's History

1845

Physician J. Marion Sims repairs a patient's fistula by fashioning a crude retractor from the bent handle of a spoon.

79 AD

Early speculum artifacts found at Pompeii consist of dovetailing blades that open and close via a screw mechanism.

Mid-19th Century

Over 400 slight variations on Sims' design are patented. From those inventions, the Graves duckbill design prevails.

the team felt that all women could benefit from a more carefully designed speculum. Questionnaires were used to get patients' opinions on the current speculum and pelvic exam protocol; volunteers also underwent pelvic exams using early prototypes and offered feedback that was used to refine the designs. FemSpec's designers also worked with Planned Parenthood to ensure that a wide, diverse range of women were used as test subjects.

Resistance to Change

However, FemSpec is not in widespread use. Why not? The medical profession is notoriously reluctant to embrace new techniques and devices. HMOs, the usual suspects for thwarting common medical sense, may resist covering the added expense of these newer devices. Then again, since it could improve the treatment of obese and multiparous women, even obstinate HMOs should be convinced of its utility. Even without HMO buy-in, many patients would likely pony up themselves for the opportunity to avoid the Kubrickian experience of the usual pelvic exam.

In a 2006 radio interview, Jerry Sanders, FemSuite's CEO, blasted the duckbill speculum as "primitive, lacking in innovation and concern for the patient." Sanders believed his company's "long overdue" product would lead to better clinical outcomes, "since it won't cause women to put off their annual exams." Sanders said: "Younger gynecologists, many of whom are women, are embracing this new technology." Also, he noted, women could purchase a FemSpec for less than $4 from the FemSuite web site and bring it to their doctors' offices. This D.I.Y. approach appears to have been the crux of FemSpec's marketing strategy.

The bad news: even if doctors were receptive to patients who brought in their own medical equipment, the FemSpec is no longer available. Annie Legomsky, FemSuite's Director of Marketing, says that the "poor reception by doctors" was its death knell. She laments: "Doctors and nurses would see it and praise it, but then they didn't want to take the time to learn something new," or spend the marginally extra exam time FemSpec required or the money it cost. She notes that the FemSpec was well-suited to "niche populations," such as gynecologic oncology patients, and that "to this day we get emails from women who want one," but that as a small company it was not cost-effective to keep it in stock."

Despite the problems with the current speculum, many physicians feel it is adequate, or at least "good enough" for a clientele not inclined to protest. "It's comfortable for most people," says Dr. Lisa Oldham, a gynecologist at Rush University Medical Center. An informal survey of 12 gynecologists conducted by Catherine Herchenroder and myself at Lafayette College suggests otherwise. Eleven gynecologists in New York and San Francisco reported having problems with the current design, and all eleven cited inadequate support of vaginal walls by the speculum. Other problems mentioned were speculum size incompatibility with patients and the rigidity of the speculum itself, which made the pelvic exam uncomfortable for the patient and difficult for the practitioner to perform. Two doctors described fitting a condom or a latex glove over the speculum to prevent sidewall convergence.

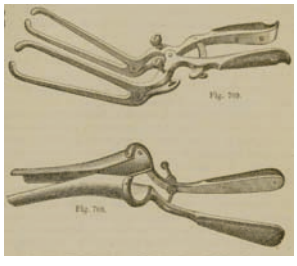
For now, kluged proof-of-concept specula are still winning out in the medical marketplace. But Herchenroder, who as an undergraduate designed and built three innovative specula, and her peers, are ready for a fight. It'll be a humdinger, as they battle taboos, stigmas, and women's historically-reinforced sense that they must simply lie back and relax.

courtesy of Historical Collections & Services, Claude Moore Health Sciences Library, University of Virginia & FemSuite

Photos

1960s - 1980s

The women's health movement starts a large-scale conversation among increasingly well-informed Western women. The speculum becomes an unlikely icon of female power.



2005

FemSpec, created following a user-centered design approach, hits the market. It is later pulled off and is no longer available due to being poorly received by doctors.