SPECIAL FEATURE: FEMALE-INITIATED METHODS OF STI/HIV PREVENTION

Female-Initiated Barrier Methods for the Prevention of STI/HIV: Where Are We Now? Where Should We Go?

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ABSTRACT *The female condom has been on the US market for over 8 years and was hailed as a method that would allow women greater control in protecting themselves against unwanted pregnancy and sexually transmitted infections. However, since its launch, promotion of the female condom has met with challenges that vary from provider bias against the device, concerns about efficacy, and doubts about whether it will be used. While daunting, many of these challenges are not unique to the female condom. In fact, they parallel those of the tampon when it was first promoted in the US for menstrual hygiene in the early 1930s. Many providers were initially opposed to the tampon; early users found the tampon inadequate. Ten years after the introduction of the tampon and despite mass marketing, acceptability was mixed and use was modest (25% prevalence in a 26-city survey). Similar to female condom use observed in current-day prospective studies, users did not use the tampon exclusively or even predominantly. The story of the tampon demonstrates that a method does not have to be adopted by all users immediately to play an important role, and that even initially controversial methods can become widely accepted as mainstream. The early history of the tampon sheds perspective, and hope, on where we stand with the female condom. While much-needed work is under way to develop microbicides, we should take advantage of the fact that the female condom is already available and promote it to those in need now.*

KEYWORDS *Acceptability, Female condom, Female-initiated methods, Prevention, Tampon.*

This issue of the *Journal* focuses largely on recent developments in the field of female-initiated methods (such as the female condom and spermicidal formulations) for the prevention of heterosexual transmission of the human immunodeficiency virus (HIV) and other sexually transmitted infections (STIs). The need to expand on current research into female-initiated methods is fueled by the increase in heterosexual transmission of HIV in the US¹ and internationally. Heterosexual transmission is having a devastating impact in sub-Saharan Africa—the region of the world hit hardest by the acquired immunodeficiency syndrome (AIDS) epidemic.²

Prevention efforts early in the AIDS epidemic promoted careful partner selection,³ reduction in the number of one's partners,⁴ and use of the male condom.^{4,5}

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Advocates soon noticed that, for women, these prevention strategies were ineffective or unrealistic. They were ineffective in terms of partner reduction since many women in areas with high HIV prevalence^{6–8} or found through high-risk settings in the US^{9–12} do not themselves have multiple partners. They were unrealistic in terms of promoting male condom use to women since, for a couple, the ultimate decision to use a male condom rests with the male, not the female, partner.

Given these realities, public health professionals have increasingly advocated for female-initiated options such as the female condom and microbicides, which women can use to protect themselves against STI/HIV. The female condom, approved by the US Food and Drug Administration (FDA) in 1993, was enthusiastically hailed as a female-initiated prevention method that would allow women greater control in protecting themselves against unwanted pregnancy and STI/HIV. However, since its launch in the United States and in more than 60 countries, promotion of the female condom has been met with challenges that vary from doubts in the popular press regarding whether women would use it,^{13–15} its high cost,¹⁶ concerns about the lack of data on its efficacy to prevent infection,¹⁷ to indirect evidence of provider bias against the method.^{18,19}

While daunting, many of these challenges are not unique to the female condom; in fact, they parallel those of the tampon when it was first widely promoted in the US for menstrual hygiene in the early 1930s. Reviewing the early history of the tampon sheds perspective, and hope, on where we stand with the female condom. The story of the tampon demonstrates that even initially controversial methods can become widely accepted as mainstream.

This article first briefly reviews the early history of the tampon and then draws parallels to the first 8 years in the evolution of the female condom. The article then discusses how this issue of the *Journal* advances the agenda to overcome some of the challenges related to the female condom and to promote more widespread adoption of female-initiated methods. The article concludes with suggestions for future prevention strategies to protect couples from the heterosexual spread of HIV.

EARLY TAMPON HISTORY

The first 15 years that the tampon was on the market in the United States were characterized by an initially sluggish uptake; medical provider resistance; a flurry of research to investigate its safety, efficacy, and acceptability; and the ultimate modest use of the product (Fig. 1). In 1933, a tampon design was patented (which soon became the Tampax[®] brand), and a major marketing campaign was launched in 1936.²⁰ Yet, through the late 1930s, tampon users were few. During this time, two different studies of women attending a general medical practice found that only 4% to 6% used the tampon.^{21,22} According to the 1939 Census of Manufactures, sales of the tampon were so small that they were grouped together with those of other sanitary products.²⁰

Nevertheless, tampon use was prevalent enough to gain the attention of the medical community. In the late 1930s and early 1940s, a debate among providers occurred, as evidenced by numerous commentaries and studies of the tampon's safety, efficacy, and acceptability in the medical literature. The majority of providers did not approve of the tampon. In one provider survey, 74% “definitely opposed” the use of the tampon, and only 14% were “completely favorable.”²² This led the authors of the article, who were themselves medical providers, to express dismay about the recent, albeit small, trend toward tampon use:

FIGURE 1. Early history of the tampon for menstrual hygiene in the United States.

It is our opinion that inefficacy of the method, common sense, and fear would limit the use of this procedure to a relatively small number, and that the fad should soon die of its own weight, were it not for the constant new crop of neophytes in schools and colleges gullible to attractive advertising and sampling.^(p148)

At least five studies were published during the late 1930s and early 1940s evaluating the safety, efficacy, and acceptability of the tampon. The tampon was found to be safe, but results from efficacy studies were mixed. Early safety studies of the tampon involved samples ranging in size from 21 to 110 women and employed various clinical assessments, including pelvic examinations, vaginal biopsies, and tests for vaginal pH and bacterial discharge.^{23–27} None of the studies found evidence of vaginal or cervical irritation or disturbances to the vaginal pH or flora. Regarding the mixed efficacy findings, in one study, 92% of the sample found the tampon inadequate in some way²⁸; another reported that the majority of women found it effective.²³

Studies of acceptability and use showed that it took about a decade for tampon use to reach modest proportions. A large survey ($n = 569$) of college students and nurses in the early 1940s found 28% had used the tampon at least once.²⁹ Of these individuals, 46% found the tampon quite acceptable as they had been using it for over 1 year, while 34% of those surveyed had tried it, but had discontinued use for various reasons. In a 26-city survey conducted in 1944, 25% of women surveyed reported using tampons. Of these women, one third used them exclusively, while two thirds used them in alternation with the sanitary napkin.³⁰ It was not until 1947—11 years after a major marketing campaign—that sales of the tampon were high enough to warrant a separate category in the Census of Manufactures.²⁰

COMPARATIVE TIME LINE OF THE TAMPON AND FEMALE CONDOM: WHERE ARE WE NOW?

Drawing parallels from the early history of the tampon provides perspective when thinking about the current state of affairs for the female condom. For example,

FIGURE 2. Comparative time lines: the tampon and female condom.

despite the seemingly indolent uptake of the tampon during its first 15 years on the market, and despite initial resistance from the medical community, over the course of time the tampon became a mainstream product. To keep the current challenges associated with promoting the female condom in perspective, it is helpful to remember that we are only in its first decade of existence, which is in contrast to 70 years since the introduction of the tampon for menstrual hygiene (Fig. 2).

It is reasonable to think that the historical challenges faced by promoters of the tampon apply to the female condom given the many parallels between the two products in terms of context, initial uptake, patterns of use, and the response of providers and the research community. Regarding context, both the tampon and the female condom came on the market when another method was available: the tampon was preceded by the sanitary napkin, the female condom by the male condom. In addition, both products are used for the two private matters of menstruation and sexual intercourse. However, it is likely that the additional intersection of gender relations, reproductive implications, and the emotional, cultural, and sometimes economic meaning of sex add unique complications to female condom promotion.

Regarding uptake, widespread use of the tampon did not occur immediately, and a similar crescendo in use is also occurring with the female condom. A survey among STI clinic patients 2 years after the introduction of the female condom in the US found that, while 77% had heard of it, only 3% had used the female condom.³¹ Patients cited insufficient knowledge and lack of awareness about where to obtain the female condom as reasons for nonuse. However, studies have shown that, with careful education about the female condom, couples will try it, and a subset of couples will adopt it as their prevention method.^{32–35} The tampon was not used exclusively, or even predominantly, and instead was used in alternation with the sanitary napkin. Similar patterns of mixed use of the female and male condom are seen today in prospective studies among couples.^{32–35}

The early attitudes of medical providers to the tampon and the female condom also have parallels. Medical providers were initially opposed to the use of the tampon, but they nevertheless played a critical role in researching it and eventually promoting its use.²⁰ Provider bias against the female condom was foreshadowed by early focus group research in which, in contrast to their enthusiastic clients, provider attitudes were neutral about the device.³⁶ Studies that directly investigate pro-

vider attitudes about the female condom are limited, despite the fact that providers play a pivotal role in its introduction.

The flurry of research on the safety, acceptability, and efficacy of these two products even after they were on the market (and, in the case of the female condom, even after it had undergone rigorous safety and efficacy testing to meet FDA approval)³⁷ was also similar. A Medline key word search of “female condom” at press time resulted in a listing of 123 articles on various aspects of safety, acceptability, and efficacy. While the first two have been well established^{38,39} and rigorous studies on the contraceptive efficacy of the female condom have been done,^{40–42} data on the efficacy against STI are limited,^{43,44} and more studies, especially those involving long-term follow up, are needed.

Given the many parallels between the early history of the tampon and our current understanding of the safety, acceptability, and efficacy of the female condom, it is reasonable to expect that the female condom also will become a more widely accepted product. This will happen in time, but not without continued efforts to overcome barriers of distribution and potential provider bias, effective outreach to potential users, and reduction of the high cost of the female condom relative to other barrier methods. Subsequent innovations in the tampon’s design (i.e., associations of a new design with toxic shock syndrome) also remind us of the need for research as innovation continues. Further investigation is also needed on other female-initiated methods that may hold promise in reducing the heterosexual transmission of HIV and on other innovative strategies to promote these multiple methods to those in need. The need for simultaneous promotion of existing methods is urgent since the HIV/AIDS epidemic has put millions of lives at risk.

IN THIS ISSUE

Articles in this issue of the *Journal* increase our understanding about how to overcome some of the major obstacles in the way of widespread acceptance of the female condom and provide insight into additional strategies needed to protect the reproductive health of women and men. The research presented in this issue comes from diverse samples, including adolescents, young women, commercial sex workers, and couples in stable relationships. Samples were drawn from both the US and the parts of Africa where HIV is endemic. Almost all articles in this issue involve women at high risk of either acquiring or transmitting HIV. These reports highlight the need for diverse prevention approaches to meet the needs of the range of women at risk for STI/HIV. Reports from Ray et al. and Raphan et al. show that the female condom will be used by women who find themselves at risk for STI/HIV for very different reasons—in the former report, as commercial sex workers in Zimbabwe, and in the latter, as urban adolescents in the US. The article by Jones et al. demonstrates that HIV-positive women will supplement male condom use with a variety of female-initiated methods, such as the female condom and spermicidal formulations, but that preferences differ by ethnic background. The article by Latka et al. suggests that couples at low risk for STI, but who are interested in being protected from pregnancy, find the female condom acceptable. The article by Minnis and Padian shows that reproductive histories of young women vary greatly by ethnicity and place of birth, suggesting that different pregnancy prevention strategies may be needed to reach these groups effectively.

Two articles in the *Journal* provide needed information that will help advance the agenda to reduce the cost of the female condom by providing information on

its potential for reuse. Polyurethane, the material from which the female condom is made, makes the device expensive,¹⁶ but also strong enough that the female condom can be considered for reuse.^{45,46} Before reuse can be promoted, however, additional questions related to safety and feasibility of reuse need to be answered. Safety studies are ongoing (C. Joanis, personal communication, July 2001), but virtually nothing is known about the feasibility of reuse under real-world conditions—especially in resource-poor settings in which reuse of the female condom would likely be promoted. Do women in these settings have access to adequate facilities and supplies to clean the female condom after use? Will women find the notion of reuse acceptable? In a special World Health Organization consultation in June 2000 on reuse of the female condom, such questions on feasibility loomed large in the debate, and the absence of published research on the feasibility of reuse was recognized.⁴⁷

This issue of the *Journal* contains two reports to help fill that gap. The article by Smith et al. provides information on the reuse practices of a small, but unique, sample of Zambian women who had reused the female condom of their own volition and therefore provides needed insight into existing notions that women have about female condom reuse. The article by Beksinska et al. reports on a systematic examination of the attitudes of South African women about reuse and describes washing and lubricating practices reported by women involved in a research study on female condom reuse.

The issue concludes with an article that highlights the pivotal role that providers have in promoting the female condom. The article by Mantell et al. is one of the first studies to document directly that medical providers can be skeptical about the female condom, and that this skepticism may lead them to be less than enthusiastic about promoting the female condom to their clients. Fortunately, in the current and a prior report,⁴⁸ the authors suggest that providers' attitudes can be positively shaped through well-designed training programs.

PROTECTING COUPLES FROM STI/HIV: WHERE SHOULD WE GO FROM HERE?

Reports in this issue of the *Journal* demonstrate the diversity of women at high risk for STI/HIV during sex. Prevention approaches should be just as varied to meet their needs. Diversity in both the need and the preferences across populations is not new in public health. Other models, such as the family planning approach, demonstrate the benefits of offering method choice.^{49–52} Studies for STI/HIV prevention show that most women make wise choices about protecting themselves when given full information on the risks and benefits of their options.^{32–35,43,53–54} While some concern is in order for the interaction of method choice and commercial sexual encounters,⁵³ on the whole, these studies show that the addition of the female condom method to the mix increases overall protection,³⁴ and that it meets unique prevention needs, such as when the male condom might fail⁴³ or for protection from steady partners.^{33,35,55} Thus, there is growing evidence in the STI/HIV prevention literature that providing method choice is good. Developers of STI/HIV prevention strategies should embrace it and give up on the notion that a “one-approach-fits-all” strategy is always best.

Promoting “one approach fits all” presumes that a single method can be used by all and assumes that only a highly efficacious method can stem epidemics. Regarding the former, lessons from the first two decades of the AIDS epidemic reveal

the difficulties in achieving high levels of male condom use across a variety of populations, despite its extensive promotion.⁵⁶ Regarding the latter, others have argued that multiple, imperfect methods must be used, rather than wait for one perfect solution that may not arrive.⁵⁷ Historic precedent illustrating the power of imperfect methods is suggested by the use of coitus interruptus—a contraceptive method generally held as ineffective—which has been proposed as the reason for dramatic decline in family size in the US at the end of the 19th century.⁵⁸ It is time to revisit our assumption that only methods with high use-effectiveness warrant extensive promotion in the fight against STI/HIV.

CONCLUSION

Realistic expenditures of time and effort are especially important when defining the successful uptake of female-initiated barrier methods so as not to conclude failure prematurely if they are not immediately used by 100% of the population targeted. Indeed, at times, our expectations for behavioral prevention programs in the public health community are unrealistic given that private-sector companies define successful marketing programs as those that achieve tiny shifts in market share after spending millions of dollars on advertising. Similar to the continued efforts to promote the male condom, which have had varied success across at-risk populations, we should not curtail efforts to promote the female condom, microbicides, and other female-initiated methods simply because they are not universally adopted in the short term. Extensive and much-needed work is under way to develop microbicides⁵⁹ and other female-initiated methods like the diaphragm to expand women's STI/HIV prevention options further. Nevertheless, there is work to do in the meantime to promote the female condom—a prevention option that is already available. We should take advantage of this good fortune and do our best to ensure that couples learn about, and have access to, the female condom now.

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