

Repeated Use

In a five-month follow-up study of female sex workers in the Dominican Republic, functionality issues such as the penis slipping between the FC and vagina became increasingly rare as participants developed experience with the method [32]. A survey of 290 sexually active women in monogamous relationships was completed in China, dividing the women into two groups to test the acceptability of the FC2 and Phoenurse [27]. Group A used 10 Phoenurse female condoms, then 10 FC2s, while Group B used 10 FC2s, then 10 Phoenurses. For both groups, all types of clinical failure decreased with repeated use, including breakage, invagination, misdirection, and slippage. Another study among heterosexual couples in China using the Woman's Condom [31] showed that couples' abilities to successfully use the FC generally improve after several uses. This trend is also seen among female sex workers in Nicaragua and El Salvador, with most of them stating they needed to try the FC 3 to 10 times before deciding whether they liked the device [30]. While many found it difficult to use at first, nearly every participant said it was easy to insert, and comfortable to use, once they had enough practice.

Supportive Attitudes

Many of the studies demonstrate that once potential users have tried the FC, they feel positively about it, and report willingness to use it again. This was especially true for older female sex workers, as well as sex workers with older clients [22, 32, 33]. In a study in China [22], low-fee female sex workers were more likely to accept the device, and these workers tend to have older clients with a higher prevalence of erectile dysfunction. Unlike the male condom, the FC does not require an erect penis to function. Among female sex workers in the Dominican Republic, 54% of the workers reported liking the FC, especially those above the age of 25 years [32]. Among female sex workers in two rural towns in China, most of the FC users were slightly older, married, and had families to support [33].

Sex workers in Nicaragua and El Salvador appreciated the amount of lubrication on the FC [30]. Participants noted that the male condom is drier, which can lead to urinary tract infections and irritation. These supportive attitudes about the amount of lubrication was also seen in studies in Uganda [26].

Protection Confidence

In numerous studies, participants expressed confidence in the ability of the FC to prevent unwanted pregnancies and STIs. In a study of the Wondaleaf FC in Malaysia, most participants affirmed that the device protected against pregnancy and STIs [23]. Among female sex workers in China [34], FC users tended to use the device to prevent HIV infection. Studies among female South African university students also demonstrated a protection confidence with FC use, along with greater intention to use FC in the future [29]. Protection confidence is also used to negotiate FC use [24]. In El Salvador and Nicaragua, many sex workers believed the FC offered better protection against pregnancy and STIs than the male condom [30], including better protection for the labia.

Reproductive Control

Several studies found that women appreciated the greater sense of reproductive control that the FC afforded them. In a study in Malaysia, most participants believed that the FC promoted a greater sense of control over their health and personal hygiene [23]. Female sex workers in El Salvador and Nicaragua appreciated being able to insert the device prior to the initiation of sexual activity [30]. One participant explained that “[We] can put it in ahead of time. For example, if a client arrives and we already know that he does not like to use a condom, we can go to the bathroom a half-hour ahead of time, and put it on.” With the FC, they can protect themselves even with male partners who refuse to use male condoms. Compared to the male condom, there seems to be less concern among women about their male partners tampering with the FC, or removing the FC during sexual intercourse.

Decades after the introduction of the FC, and despite concerted efforts by the global health community to promote uptake of the only available method for preventing STIs and unintended pregnancies, as initiated by the receiving partner, the FC only accounts for less than 2% of total condom distribution worldwide [17]. In nationally representative household surveys that looked at FC practices and behaviors, ever-use of FC among women of reproductive age was less than 1% in most developing countries, with the exception of Zambia, Malawi, Guyana, Swaziland, and South Africa, which ranged from 1–7% [35]. The results of our systematic review shed more light on the many facets of this underutilization challenge, and provide the basis for recommendations to improve acceptability and use of the FC for improved sexual and reproductive health in LMICs.

The proportion of study participants (as reported by the authors of the articles included in our systematic review) who noted partner acceptability, or the lack thereof, as an issue that could constitute a barrier to FC uptake ranged from 27.1% to *greater than 50%*. While the goal of the FC is to give women greater control over their protection, studies have shown that partner acceptance and cooperation is critical for successful use of the FC [36, 37, 38]. Other studies have documented men's belief that the FC gives women too much power and control over sex [39, 40]. Further, functionality is another key element. Past studies have consistently shown insertion difficulties for FC users, with difficulties in insertion in as many as half of users in some studies [41, 42, 43, 44]. Difficulties in insertion have been associated with less consistent use of the FC in other studies [45, 46]. It is important to situate FC insertion difficulties within the intimacy context of sexual intercourse. Evidence shows how seemingly awkward or difficult moments in the lead up to sexual intercourse, or in the act itself, can discourage further acts of sexual intercourse [47] and even strain spousal relationships. To this end, it appears that our findings corroborate earlier findings that emphasize the importance for FC manufacturers, policy makers, and reproductive health program managers to improve training and other interventions that can aid user experience of the FC, in order to minimize the occurrence of difficulties.

Aesthetics also plays an important role in FC acceptability. Studies have shown that the appearance and large size of the FC have led to negative impressions and were often cited as reasons for rejection by male partners [48, 49, 50]. Our findings in this review show how aesthetics are important to both women and men, for similar or different reasons. For example, the relatively larger size of the FC, compared to the male condom, was found to be disturbing in two studies we reviewed. However, while some men found the wide spread of the FC on their female partner's vulva area as less erotically stimulating, women generally accepted the FC's protective ability to cover their labia, and reduce contact surface area, especially in the context of transactional sex. Also, access is a critical factor determining the acceptability, or lack thereof, of the FC. Past studies have highlighted that the high cost of the FC, in comparison to the male condom, has resulted in limited access, promotion, and sustained use of the method [16, 41]. A negotiated price point of 0.57 US\$ per FC was set for developing countries between UNAIDS and manufacturers; however, this is significantly more expensive than the cost of the male condom [16]. In our review, 5 out of the 14 studies we analyzed described poor or absent access as an important barrier to FC acceptability and use.

Despite these barriers, there are several key factors that facilitate the acceptability of the FC that have been noted in the literature. Repeated use has been shown to be a facilitator. Past studies have demonstrated that most users overcome initial difficulties associated with appearance, insertion and/or removal, and technical issues during sex, with practice and repeated use, and these have resulted in higher acceptability of the FC [44, 38, 51, 52]. Supportive attitudes have also been shown to play an important role in the acceptability of the FC. Studies have shown that positive perceptions related to lack of male responsibility and enhanced sexual pleasure, both from stimulation from the external ring and lubrication, were cited as key advantages to the FC [44, 52, 53, 54]. In addition, protection confidence was another factor highlighted in the literature. Past studies have shown that protection from STIs, including HIV, and unintended pregnancies were commonly cited as an advantage of the FC both by women in the general population and

female sex workers [53, 55]. Lastly, greater reproductive control was cited as a facilitator of FC acceptability among the articles assessed as part of this systematic review. Several studies note that the FC has been used as a protective tool that can help address gender inequalities and power imbalances, especially in scenarios where partners refuse male condom use [48, 56, 57, 58]. Overall, we see common themes across LMICs that affect acceptability and use of the FC. We strongly believe that this presents the opportunity for all stakeholders in sexual and reproductive health care, programming, and policy to better situate and operationalize their efforts at mitigating the burden of STIs (including HIV) and unintended pregnancies in LMICs.

RECOMMENDATIONS

Effective promotion and uptake of the FC in LMICs can be realized if novel strategies and approaches are implemented to tackle persistent barriers to acceptability. Contexts will vary across and within countries, and the acceptability of the FC to persons differing across sociocultural, economic, and demographic factors (such as age, education, relationship status, income, religion, and sexual orientation) will be most improved if such factors are considered in the development and deployment of FC interventions. Innovative approaches for developing novel solutions, such as human-centered design (HCD) which is based on an intentional engagement of would-be end-users, can be utilized to capture insights from women and men, across sociocultural, economic, and demographic groups, to improve the design and desirability of FCs. For example, the “Panty Condom” is an innovative design that combines the FC with lingerie, and has been shown to be highly acceptable from pilot studies [59]. Other approaches to improving the aesthetics of FCs include availability of a varied mix of shapes, contours, colors, and scents. Such wide varieties, even for the same brands of FCs, can be powerful in stimulating acceptability.

The prevention of STIs and unintended pregnancies are the primary functional aims of FCs. Other functions like increased sensation and pleasure are usually considered secondary. We recommend that FC manufacturers, as well as intervention programs and policies, carefully assess their manufacturing processes, to avoid an imbalance in a potential trade-off between pleasure and safety. The use of coloring and scents can potentially affect the tensile strength of latex materials. Beyond the material from which FCs are made, we also recommend the use of digital communications solutions to link comprehensive FC instructions and tutorials with end-users. For example, in settings with high mobile phone usage (as we are seeing in LMICs), the use of QR codes in packaging that links to videos of FC demonstrations and insertion techniques could pose a great potential in improving acceptability.

Targeting men in FC programming must be intentionally scaled up, involving both a demand-side and a supply-side component to the programming. Successful FC programs are those that involve information and demonstration campaigns that target both women and men, such as Pathfinder International’s FC program in Mozambique [60]. More nuanced research is recommended in order to understand the behavioral modalities that drive male acceptance of the FC, for heterosexual and same-sex relations. We recommend social and behavior change (SBC) programs in sexual and reproductive health and rights to consider expanding the “prestige” inherent in the act of male partners initiating the use of FCs, including through private procurement. Men should feel proud to suggest FCs to their partners – this needs to be conveyed as “manly” and “ego-boosting” for males. Other communication efforts can include building capacity among women, and men who have sex with men, to effectively negotiate with male partners, and this can be incorporated as part of every FC program, through primary healthcare facilities, community health workers, and voluntary counselling and testing centers for HIV and other STIs.

Manufacturing and procurement agencies should explore the economies of scale that are present when large amounts of FCs are produced. For this to succeed, we recommend that the global health community, including multilateral institutions (e.g., the WHO, World Bank, UNFPA), national governments, bilateral aid organizations (e.g., NORAD, USAID), donor/philanthropic foundations, and the private sector actively support advanced purchase orders of FCs. We recommend the provision of free FCs to targeted populations that have high levels of acceptability, such as female sex workers.

Our systematic review is possibly the first to examine LMICs as a group of countries (not limited to a geographical region, e.g., sub-Saharan Africa) when assessing factors associated with acceptability and use of the FC. However, these results all come from intervention studies which may not reflect the profile of the general population. A recent literature review of FC use in sub-Saharan African countries argued that non-intervention studies did not provide users an opportunity to experience the use of FCs firsthand, and therefore tended to rate overall acceptability negatively, due to preconceived ideas and beliefs about the FC [61]. While our systematic review addresses this concern, we also note that our results reflect the perspectives and experiences only of those who have actually used the FC.

Given the potential use of the FC as an internal condom by men who have sex with men (MSM), it is necessary to critically study FC use among this demographic. MSM are also at risk of STIs, including HIV. However, the behavioral and biological factors that affect acceptability of the FC in heterosexual intercourse is expectedly different in the context of MSM relationships. Further, due to the stigma against MSM in some LMICs, there is a critical lack of research on acceptability and usage of the FC among that demographic group. As such, our systematic review did not appraise acceptability of the FC within this important group of persons, due to lack of prior research in the area. This further limits the generalizability of our findings.

COMPETING INTERESTS

The authors have no competing interests to declare.

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