Contraception

Contraception 91 (2015) 85–90

Original research article

The female condom learning curve: patterns of female condom failure over 20 uses☆,☆☆,★

Mags Beksinska[a,b,*], Jenni Smit[a,c], Ross Greener[a], Gilda Piaggio[b], Carol Joanis[d]

[a]MatCH Research (Maternal, Adolescent and Child Health Research), Department of Obstetrics and Gynaecology, Faculty of Health Sciences, University of the Witwatersrand, Durban, South Africa

[b]Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine, Keppel Street, London WC1E, UK

[c]School of Pharmacy and Pharmacology, Faculty of Health Sciences, University of KwaZulu-Natal, Durban, South Africa

[d]Joanis Consulting, 120 Chastain Road NW, Unit 1305, Kennesaw, GA 30144, USA

Received 28 May 2014; revised 29 August 2014; accepted 22 September 2014

Abstract

Background: Male and female condom (FC) functional performance failure declines with user experience. With the recent availability of a wider range of FCs, it is important to know if women with experience in using one type of FC are more proficient in using another type, even if the FC design is quite different.

Study design: A randomized, noninferiority crossover clinical trial assessed the function of four FCs (FC2, Woman's Condom, Cupid and VA w.o.w) among 300 women in Durban, South Africa. FC functional failure (breakage, slippage, invagination and misdirection) by condom type and use period was investigated in women using five FCs of each type (20 FC uses in total).

Results: Of the 5364 condoms used during intercourse by 272 women, 200 clinical failures occurred in 195 condoms (190 condoms had one failure, and 5 had two failures). Total clinical failure was comparable across FC types. Of the 195 condoms in which failures occurred, the number of failures in the first condom use period was 103 (7.7%), decreasing to 43 events (3.2%) in the second, 33 (2.5%) in the third and 16 (1.2%) in the fourth. Only 2 failures were reported in the 20th use of an FC compared to 29 in the first use, irrespective of condom type.

Conclusions: FC failure rates decreased markedly after use of the first five condoms regardless of FC type and continued to fall across the next three use periods.

Implications: FC failure rates decrease over 20 uses, regardless of FC condom type used. The decrease is higher at the beginning of use, indicating that improvement is greatest after the first five uses.

Keywords: Female condom; Function; Barrier methods; Experience

1. Introduction

Condoms have played a key role in tackling the HIV epidemic globally, with year-on-year distribution increases reported in many countries [1]. For maximum effectiveness against pregnancy and sexually transmitted infections (STIs)/HIV, condoms need to be used correctly with every sex act. Male condom (MC) breakage and slippage are commonly reported, with breakage rates ranging from 0.41% to 6.7% and slippage ranging from 0.6% to 5.4% [2]. Data for female condom (FC) functional performance failure in the general population are limited. However, data from FC functionality trials and acceptability studies show failures to be generally low [3]. It has been reported previously that, regardless of FC type used in randomized crossover studies, rates of failure decrease with increasing number of uses [4–7]. Less information is available on the extent of improvement over time or on the rates of improvement in individual failure modes, specifically. Only one trial has reported on the impact of use experience on FC failure. In

☆ There are no conflicts of interest known to the authors.

☆☆ This study was funded by the Universal Access to Female Condoms Joint Programme.

★ This trial is registered on the South African Clinical Trials database DOH-27-0113-4271.

* Corresponding author. MatCH Research (Maternal, Adolescent and Child Health Research), Department of Obstetrics and Gynaecology, University of the Witwatersrand, Durban, South Africa. Tel.: +27 31 0011904; fax: +27 31 267 0057.

E-mail address: mbeksinska@matchresearch.co.za (M. Beksinska).

http://dx.doi.org/10.1016/j.contraception.2014.09.011

this study in which 170 women used 15 FCs each (five uses each of three different FC types), rates of total clinical failure dropped from 7.0% to 2.1% between the first and third condom use periods [6].

The first FC (FC1) made by the Female Health Company (FHC) was approved by the US Food and Drugs Administration in 1993. Production of this device ceased at the end of 2009 and was replaced by the FHC's FC2 FC. New FCs have become available recently, or are in development, and are different in design, construction and materials used [8]. Many of these new FCs are progressing through various regulatory processes to obtain country regulatory and bulk procurement approvals from international donors. In some FC programs, more than one FC product is available, and in the future, this may increase.

In trials where several different products are evaluated, it is important to know if women learning to use one type of FC gain useful experience in using a different type, even if the design is quite dissimilar.

This paper reports in detail on the proportion of total and individual failure modes across four condom use periods among women attending a reproductive health clinic in Durban, South Africa. The data analyzed here are a subset of a randomized controlled noninferiority crossover trial that included women from China and was designed to determine device function, safety and acceptability of three new FC types compared with the currently available FC2 [9]. Noninferiority trials test whether a new product performs at a level that is not unacceptably worse than a product already approved and in use (i.e., new FC products will be compared to the FC2 control).

2. Materials and methods

This four-period, randomized noninferiority crossover clinical trial was conducted in Durban, South Africa, and Shanghai, China. Only South African data are included in this analysis, and the main two-country study results comparing the three new devices with FC2 have been reported previously [9]. The target population was 300 urban, sexually active women in each country who were either novice or experienced users of FCs. Women in South Africa were recruited from a large, urban sexual and reproductive health clinic in Durban. Potential participants had to be at least 18 years of age and no older than 45, literate, with no known allergies to the study products (latex, synthetic latex, polyurethane), using a reliable, nonbarrier method of contraception, and free of STIs, as determined by pelvic examination and a syndromic diagnostic tool. Pregnant women (according to urine pregnancy test) were excluded. Participants were required to be sexually active and monogamous, and could not be practicing sex workers. The participants were recruited directly from the clinic waiting area. Researchers informed women about the study, and if they were interested in volunteering, they were asked to report to the study room within the clinic after their medical consultation. On presentation at the study room, women were given an information sheet and told more about the study. Participants read and signed an informed consent form prior to screening and enrolment. In this study, each woman was asked to use five of each of the four FC types and to complete a condom log at home after each condom use. Women were trained in the use of each study product. Training involved demonstration of insertion and removal of the FC using a pelvic model, and participants were provided with verbal and written instructions in their preferred language (English or isiZulu). In addition, women practiced insertion and removal on the model. After completing use of each condom type, participants returned to the clinic where interviewer-assisted questionnaires were used to gather acceptability and preference data. Practically, the trial could not be blinded as all four condom designs are quite distinct, each requiring product specific training for correct use.

2.1. Study products

The four study FCs are described in Fig. 1.

Each FC product was shipped by the manufacturer to Family Health International (now FHI360) for quality assurance testing to ensure that study products were of the quality specified by the manufacturer and met ISO Standard 25841-2011 [10].

2.2. Ethical considerations

The study was approved by the institutional review boards of the University of Witwatersrand Human Research Ethics Committee (South Africa), protocol number M11021, and by the provincial, district and local Departments of Health in South Africa. This trial is registered, DOH-27-0113-4271.

The primary objective of this research was to compare the functional performance of four FC types. The FC2 served as the control device, since the predicate device (FC1) is no longer manufactured. The primary noninferiority end points were self-reported total clinical failure and total FC failure. Their component events (clinical breakage, non-clinical breakage, total breakage, slippage, misdirection and invagination) were assessed as well. Safety and acceptability data were collected also. FC failure events (modes) are recognized by the World Health Organization and other regulatory agencies. Definitions of each failure mode analyzed are shown in Box 1 [3].

For the trial, a randomization sequence for the crossover design was generated, and women were randomized to condom type use order or sequence using a William's design [9]. Randomization cards containing the allocated treatment sequence were used, where each code for a given FC type was concealed beneath a separate foil square. The development and use of the cards for this trial is reported elsewhere [11].