Acceptability of the Reality® Female Condom and a Latex Prototype

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ABSTRACT We report on the comparative acceptability of a prototype latex female condom and the polyurethane Reality® female condom. We also identified factors associated with acceptability, measured via a composite index with domains related to ease of insertion, noise, and comfort during insertion and use. There were 135 couples in this randomized crossover trial. The average age was 30 years; more than 60% had education beyond high school; 40% were married; and participants were at low risk for sexually transmitted disease and pregnancy (due to the investigational status of the prototype). Participants were asked to use three of each of the study condoms during a 6-week period. Acceptability ratings on 12 items were summed into a composite index for each participant by condom type. The index midpoint (range) for females was 48 (12–84), and it was 32 (8–56) for males, with lower scores indicating higher acceptability (men completed only a subset of the acceptability questions). Both condoms were equally acceptable: Mean scores were 37 and 40 for the women’s ranking of the prototype and Reality, respectively (P = .07) and 29 and 30 for men’s rankings, respectively (P = .35). Multiple regression models to predict acceptability scores by gender were somewhat uninformative (most R² values were less than 0.10). Nevertheless, minority ethnicity (African American or Hispanic vs. white) was associated with higher acceptability by both genders for both condom types. Among women, for both condom types, less education (less than high school compared with high school or beyond) was associated with higher acceptability. Female condom acceptability may not be equally distributed across demographic groups, which is important for health educators to keep in mind when promoting the female condom.

KEYWORDS Acceptability, Barrier methods, Female condom, Prevention.

INTRODUCTION

Women are at particularly high risk of sexually transmitted diseases (STDs), including the human immunodeficiency virus (HIV), due to issues of biological susceptibility, economic inequalities, and power imbalances between the genders.1 The Reality® female condom is a barrier method designed to give women more control in protecting themselves from pregnancy and disease since it is used at the initiative of women. The US Food and Drug Administration (USFDA) approved the Reality female condom in 1993 for protection against pregnancy and STD/HIV. Unlike the majority of male condoms, Reality is made of polyurethane, a form of plastic. Acceptability studies of the device have shown that couples enjoy the heat-transmit-
ting properties of polyurethane and report that sex with Reality feels natural.\textsuperscript{2-4} However, polyurethane also makes the device expensive—up to 20 times the cost of a male condom. The current high price of Reality may contribute to women’s reluctance to purchase, and donors’ lack of enthusiasm to provide, the device throughout the developing world where HIV/AIDS (acquired immunodeficiency syndrome) is endemic. New barrier methods that capitalize on the female-initiated strengths of Reality but are more price competitive have the potential to increase the range of barrier methods available for women and may improve the demand for, and acceptance of, these products.

The Reddy female condom (manufactured by Medtech Products, Ltd., Chennai, India) is a prototype female condom made of latex and therefore will be significantly less expensive than Reality, the only marketed product. The Reddy female condom has not been approved for use by the USFDA or any foreign regulatory agency. It is classified as an investigational device and is not sold commercially. The device is a latex pouch with a V-shaped plastic stiffener attached to the rim of its open end. Similar to the outer ring of Reality, the stiffener remains outside the body during intercourse and covers the external genitalia. A polyurethane sponge is located at the closed end of the device and is meant to anchor the device during intercourse. The device is packaged with the sheath rolled up similar to a male condom and is prelubricated with silicone. It is inserted by pushing the sponge into the vagina. This action causes the sheath to unroll and extend to the end of the vaginal cavity.

Data for this article are from two randomized crossover trials with the primary objective of testing the slippage and breakage rates of the latex prototype. Results from these studies have been previously reported.\textsuperscript{5} This article has the following separate aims. First, we report on the use and acceptability of the latex prototype compared with the polyurethane Reality female condom so that, if possible, design changes can be made to improve the performance of the latex prototype. Second, we identify factors associated with female condom acceptability.

\textbf{METHODS}

We conducted two randomized crossover trials using the same study protocol to evaluate the acceptability of a latex prototype female condom and the currently marketed Reality female condom. Results from the first trial led to three minor changes to the latex prototype. These modifications included attaching the outer stiffening rim more securely to the latex sheath, stamping the word “top” on the top of the outer ring to assist with proper orientation of the device during insertion, and shortening the sheath by 8 mm. The second study was conducted using the same protocol and the slightly modified latex prototype. These two studies provide information on the acceptability of both the existing and the prototype female condom.

\textbf{Study Subjects}

For the first study, couples were enrolled in equal proportions at two sites: a primary health care facility located in the Bronx, New York City, and the general population of Norfolk, Virginia. In the second study, subjects were recruited from a family planning clinic in Los Angeles, California, or from the general population via advertisements. Both studies assembled a convenience sample of volunteers, and participants were eligible to participate if they were in a monogamous, heterosexual