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Vaginal film for prevention of HIV: using visual and tactile evaluations among potential users to inform product design

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Abstract

Topical prevention of HIV and other STIs is a global health priority. To provide options for users, developers have worked to design safe, effective and acceptable vaginal dissolving film formulations. We aimed to characterize user experiences of vaginal film size, texture and color, and their role in product-elicited sensory perceptions (i.e. perceptibility), acceptability and willingness to use. In the context of a user-centered product evaluation study, we elicited users' 'first impressions' of various vaginal film formulation designs via visual and tactile prototype inspection during a qualitative user evaluation interview. Twenty-four women evaluated prototypes. Participants considered size and texture to be important for easy insertion. Color was more important following dissolution than prior to insertion. When asked to combine and balance all properties to arrive at an ideal film, previously stated priorities for individual characteristics sometimes shifted, with the salience of some individual characteristics lessening when multiple characteristics were weighted in combination. While first impressions alone may not drive product uptake, users' willingness to initially try a product is likely impacted by such impressions. Developers should consider potential users' experiences and preferences in vaginal film design.

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Disclosure statement

None of the authors have financial or other conflicts of interest to declare.

This user-focused approach is useful for characterizing user sensory perceptions and experiences relevant to early design of prevention technologies.

Keywords

Vaginal film; user-centered product design; initial acceptability; perceptibility; multipurpose prevention technologies; HIV prevention

Introduction

Vaginal films are currently available for contraception (i.e. spermicidal film) and lubrication and are under investigation (Ham et al. 2012; Akil et al. 2014; Zhang et al. 2015; Bunge et al. 2016) as potential delivery systems for the prevention of sexually transmitted infections, including HIV (Garg et al. 2010; Romano et al. 2013). Drug delivery is critical, but prevention technology effectiveness ultimately depends on user behaviors. Users' sensory perceptions and experiences (Morrow et al. 2014) of film properties are essential for understanding potential product acceptability and potential use patterns (Buckheit et al. 2010).

This project evaluated vaginal film prototypes varying as a function of size, texture and color. The visual and tactile perceptions elicited by these formulation attributes were discussed with participants to understand the role each might play (alone and in combination) in vaginal film acceptability and use.

Methods

Twenty-four mutually monogamous, HIV/STI-negative, heterosexual couples were enrolled. User sensory perception and experience (USPEs) evaluations of film application and use during intercourse were part of the broader study exploring perceptibility parameters of varying topical formulations (Morrow et al. 2014; Guthrie et al. 2016). All study procedures were approved by relevant human subjects safety boards and all participants provided written informed consent prior to study visit(s) initiation: the study was registered as required (clinicaltrials.gov).

Female participants had previously had a single experience with insertion of a 1"×2", translucent, textured/smooth quick-dissolving film prior to the film preference discussion. This report presents film preference interview data from 24 female participants.

Evaluation of film characteristics

Participants were asked to evaluate prototype films across three specific attributes: size, texture and color. Each attribute was presented on separate, specially fabricated trays, with film prototypes distributed between two sheets of clear Plexiglas®. Tray-1 held four sizes of film: 1"×1"; 1"×2"; 1"×3" and 2"×2". Tray-2 held three different film textures: both surfaces smooth, both surfaces textured, one surface smooth/one textured. Tray-3 held three different film colors: clear, translucent and opaque (Figure 1). Participants completed a qualitative in-depth film preference interview in which they first considered the attributes

separately, then combined characteristics, ultimately considering which combinations might optimize film design and use. Interviews lasted 20–50 min, were audio-recorded and transcribed verbatim for analysis.

Analysis

A framework matrix analysis (Green & Thorogood, 2013) was conducted on the interview data. A qualitative analyst reviewed each transcript, summarizing participant comments in the matrix. Each row represents an individual participant; columns represent each of the film sizes, textures and colors. Comments from every participant about each film characteristic were summarized in the corresponding cell. Additional cells tracked ideal characteristics, preferred combinations and illustrative quotes. This approach allows systematic review of all responses to a particular property (e.g., all responses to opaque color are captured in one column and can be compared and summarized). In addition, an individual participant's total responses are accessed by reading across that row.

Results

Of 91 females who completed prescreening for the parent study, 42 were preliminarily eligible with their sexual partners. Twelve couples declined to enroll in clinical screening; six couples were not interested or not eligible after clinical screening and/or film tolerance evaluation. Twenty-four (24) couples enrolled and were interviewed between June 2011 and June 2012.

Film preference evaluations

We present results for size, texture and color: the three vaginal film attributes specifically evaluated in this study. Several additional properties related to film perceptibility were identified during the discussion, including perceptions of thickness, flexibility, film edges and film shape. Illustrative quotes for each of these characteristics are provided in Table 1.

When asked to choose their ideal film size, relatively equal numbers of women chose each of the three sizes: six chose 1"×1"; four chose 1"×2", eight chose 1"×3", and six chose 2"×2" films. Some women perceived the larger films as easier to insert or as providing more protection (quote #1). Others felt the smallest film would insert more easily, dissolve more quickly and result in less leakage. These distinctions arose from individual experiences handling smaller versus larger films (quote #2), positioning during vaginal insertion and perceived volume postinsertion.

Participants indicated that films with texture could improve insertion by providing better grip on the film (quote #3). Approximately, half (13 of 24; 54%) preferred the film with one smooth side and one textured side over the film that was smooth on both sides. Many felt the smooth/smooth film too closely resembled plastic wrap, while others noted that the film that was textured on both sides felt thick and 'heavy.' Some participants suggested that the textured film would dissolve more quickly whereas the plastic-like smooth/smooth film would dissolve more slowly (quote #4). Quotes #8 and #9 illustrate how participants weighed both size and texture (inclusive of a sensation of thin/thick related to the presence/

absence of texture), trading off perceived benefits of each, to design an ideal HIV prevention product.

Color options were related to insertion self-efficacy and perceived product efficacy. The majority (79%) favored translucent (11) or opaque (8) films. Some participants were concerned that the translucent film looked too much like Scotch® tape (quote #5), while the clear film was considered discreet (quote #6). Yet, as quote #7 illustrates, others felt that it would be easier to tell if an opaque film was improperly inserted. This raised questions about both their own confidence in inserting the film properly and in its resulting effectiveness.

When asked to identify which of these attribute values would combine to make an ideal vaginal film, some participants simply listed each individual choice previously identified. With other participants, however, their previously stated individual priorities shifted, so that the salience of individual attributes were then balanced or weighted when in combination. Reasons were based on strong needs/desires for a particular characteristic (e.g. quick dissolution or easy insertion), anticipated consequences of combining characteristics and/or prior experience. Further, some women were amenable to changing certain characteristics, yet were inflexible about others. One participant, for example, said her ideal product would be a 1"×3, smooth/smooth, clear film. But of these preferred features, she said that, while she was willing to use a different size, she would not use anything other than a clear product because she wanted it to be invisible.

Discussion and conclusions

User perceptions of vaginal film are an important addition to the emerging field of perceptibility science and are essential for topical prevention product developers to consider during product design (Buckheit et al. 2010; Morrow et al. 2014; Guthrie et al. 2016). User evaluations of preuse (i.e. out of the package) characteristics may shape willingness to try a product, and sensations experienced as a function of product properties during actual use will likely shape effective use and adherence (Guthrie et al. 2016). User sensory perceptions and experiences of these properties demand further attention, especially as relevant to the development of multipurpose prevention technologies (MPTs) combining pregnancy, STI and/or HIV prevention targets (Romano et al. 2013; Buckheit et al. 2010; Guthrie et al. 2016). The current study provides insight into users' responses to key preuse characteristics of size, texture, and color, helping to guide future vaginal film design.

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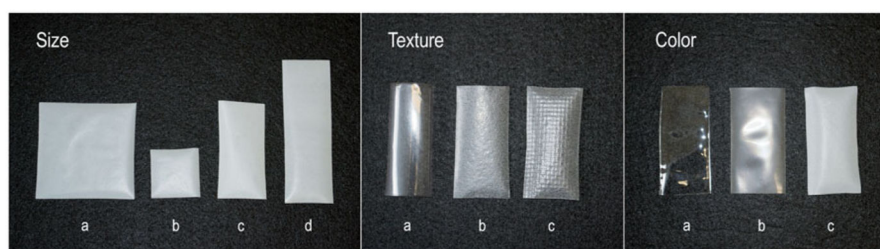


Figure 1. Prototype films: Size: (a) 2×2 , (b) 1×1 , (c) 1×2 , (d) 1×3 ; Texture: (a) smooth-smooth, (b) smooth-textured, (c) textured-textured; Color: (a) transparent, (b) translucent, (c) opaque.

Table 1

Illustrative quotes of participant responses to characteristics during film property evaluation interview.

Themes and participants' meaning making	Illustrative quotes*
Film size	
Size elicits perceptions of product efficacy	(1) [expressing preference]: [the 1"×2"] because ... the size of it looks big enough to be able to do the job.
Smaller films dissolve more quickly and elicit anticipations of stickiness and/or leakage	(2) [expressing preference]: Maybe [1"×1"] 'cuz it's smaller. I think [the 1"×3"] is too big 'cuz ... I had a hard time putting it in [in the clinic]. So this is definitely way too big ... because when it gets moist it sticks to your hands.
Film texture	
Texture impacts ease of insertion	(3) [smooth/smooth] I don't imagine that this consistency, both being light and being really slippery would lead to getting inside me easily. ... And [smooth/textured] is just—I feel like [it] might be too heavy, heavier than needed, unnecessary.
Texture impacts perceptions of dissolution	(4) [textured/textured], I think it would be easier to dissolve. ... if you were to fold it like this, it feels more easier to dissolve than—than [smooth/textured] and [smooth/smooth] would be because [smooth/smooth] feels like a piece of plastic.
Film color	
Degree of transparency versus opacity related to acceptability	(5) It reminds me of Scotch® tape [not deemed acceptable] [and] (6) Anything that's clear, that you can't see, is cool with me
Being aware/knowing the film is present: elicits perceptions of product efficacy and/or use confidence	(7) I feel like [opaque] works because you would know if it's coming out of you, like if you don't get it all in there, you could easily tell that it was the product and not just your vaginal fluids.
Other relevant attributes	
Texture elicits perceptions of thickness/thinness as well as anticipations of physical awareness	(8) I think you probably wouldn't feel [smooth-smooth] at all ... 'cause it is very thin. It's a lot thinner than [smooth-textured] and [textured-textured]. [textured-textured] I would think you would feel just a smidgen more 'cause it is thicker
Texture impacts comfort balanced with efficacy, but smaller sizes elicit perceived need for mass (i.e. thickness) to gain perceived product efficacy	(9) Like [smooth/smooth] I would prefer inside me, with a partner, ... if it was equally as effective, I would prefer [that]. But as a consumer, I feel like it's so little [size], that if you gave me the thin or the thick, and I'm trying to prevent HIV, I'm gonna go with thick
Flexibility related to acceptability, potentially comfort	(10) I would say the texture would actually be non-negotiable, because I like that it's light ... and I like how it feels ... it's light and it's flexible. ... Not so flexible as like a tissue, but, you know, not rigid like this piece of packing tape [smooth-smooth] over there.
Edges elicit concerns regarding sharpness and product effects	(11) [this one] seems a little bit hard, like the edges might be a little bit uncomfortable to put in (12) [my partner] might be worried about the sharp corners too ... he might be like, 'well how fast does it dissolve? Are the corners still gonna be there when we start having intercourse?' (13) The other thing I did was just kinda feel the edges to see if they felt like sharp ... and they don't seem too sharp
Shapes elicit perceptions of comfort on insertion	(14) It might be better if it was circular ...it would fit better if it was circular. And ... these little points on the side might not curl under ... And, it might just go in better.

* [Bracketed information] identifies editorial notations and/or the film property being referenced by the participant.