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Short Communication

Shape of vaginal suppositories affects *willingness-to-try* and preference

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ABSTRACT

HIV and other sexually transmitted infections (STIs) are a global threat to public health that may be countered, in part, by microbicides. A successful microbicide must be both biologically efficacious and highly acceptable to users. Sensory attributes have a direct influence on product acceptability. We created a series of vaginal suppositories appropriate for use as microbicides to investigate the influence of shape on women's *willingness-to-try*. The influence of perceived size and firmness on acceptability was also assessed.

Sexually-active women ($n = 99$) were invited to participate in an evaluation of vaginal suppositories in 5 different shapes including: Bullet, Long Oval, Round Oval, Teardrop and Tampon. The volume (3 mL) and formulation for these five prototypes were identical. After manipulating prototypes *ex vivo* (in their hands), participants rated their *willingness-to-try* on a 100-point visual analog scale. The appropriateness of size and firmness were evaluated using 5-point just-about-right (JAR) scales. Each participant evaluated all five prototypes individually. Samples were presented in a counterbalanced monadic sequence using a Williams design.

Mean *willingness-to-try* varied by shape, with Bullet and Long Oval receiving significantly higher scores. This was consistent with JAR data for size, as 70% and 65% of women indicated these shapes were 'just-about-right', respectively. In contrast, a minority of women endorsed the other 3 shapes as having a size that was 'just-about-right'. The proportion of women who felt the firmness was 'just-about-right' was uniformly high, irrespective of shape, suggesting prior attempts to optimize the formula were successful. Perceptions of size and firmness were influenced by the physical length and width of the prototypes, in spite of having constant volume. Women showed high *willingness-to-try* when asked to assume they were at risk. These results are relevant for behavioral and formulation scientists working on microbicides, to better understand the influence of sensory attributes on acceptability, as acceptability and compliance ultimately impact effectiveness.

HIV and other sexually transmitted infections (STIs) are a global threat to health; in spite of current prevention efforts, there were 2.7 million new infections world-wide in 2010 (UNAIDS, 2011). Topical microbicides are a promising solution, as they empower women to protect themselves (Morrow et al., 2007; Stone, 2002). More than 50 microbicide candidates are under development (AMD, 2009). A successful microbicide must be biologically efficacious and highly acceptable to users (Elias and Coggins, 2001; Mantell et al., 2005; Severy et al., 2005). Acceptability impacts user adherence to microbicide use and thus real world effectiveness (Abdool Karim et al., 2010; Masse et al., 2009; Nel et al., 2011). User acceptability must be considered along with pharmacokinetics and toxicity if efficacious prototypes from controlled trials are to be effective in the field (Morrow and Hendrix, 2010).

Microbicide acceptability involves myriad factors, including user characteristics, context, and product attributes (Morrow and Hendrix, 2010). At the pre-clinical level, microbicide characteristics are critical for product acceptability (Morrow and Ruiz, 2008); colorless and odorless microbicide gels may be more appealing (Morrow et al., 2003). Lubrication may be a positive feature of microbicides (Whitehead et al., 2006), although sexual pleasure may be reduced due to the messiness from a microbicide gel (Giguere et al., 2012). Perceptual attributes (e.g. ropiness, graininess, and slipperiness) that are best quantified with human assessors (Mahan et al., 2011) may also be important. Indeed, sensory attributes may critically influence user acceptability, but their effects have not been well investigated.

In the packaged goods industries, the influence of sensory attributes on acceptability is frequently assessed with just-about-right (JAR) scales (Popper and Kroll, 2005; Rothman and Parker, 2009). A

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JAR scale is a bipolar instrument with semantic anchors at each end, reflecting appropriateness of a low and high intensity, respectively. The midpoint is labeled 'just-about-right', indicating this attribute is at an appropriate level in the product. According to American Society of Testing and Materials guidelines, most researchers use five categories (e.g. 'much too small', 'somewhat too small', 'just about right', 'somewhat too big', and 'much too big') (Rothman and Parker, 2009). Hedonic and intensity scales are typically used separately, but JAR scales intentionally combine these two measurements to assess attribute appropriateness (Stone and Sidel, 2004); attribute quality is evaluated relative to a theoretical ideal. JAR scales are popular for product reformulation or optimization (Xiong and Meullenet, 2006) because they are easy to use and generate actionable data. Practically, attempts are made to improve an attribute when more than 20% of the responses are 'too-little or 'too-much' (Meullenet et al., 2007).

In previous qualitative research, most women (45 of 57) preferred semisoft ovoids over spheres or teardrops, but preferences for size and firmness were less clear (Zaveri et al., 2012). Consequently, we conducted a larger quantitative study on oval prototypes using a factorial design and response surface modeling, identifying an optimum near 3 g and firmness (G′) of 25 kPa (Li et al., 2013). As part of an iterative optimization process, the current study investigated a second generation of suppository shapes at constant physical firmness and volume.

We investigated the effect of shape on *willingness-to-try,* and perceived appropriateness of size (*size*) and firmness (*firmness*). Shapes included Round Oval, Long Oval, Teardrop, Bullet and Tampon (Fig. 1). These names are provided for readability and discussion; they were never used with participants, who referred to samples using random 3-digit codes.

Women (n = 99) were recruited as described elsewhere (Li et al., 2013) to evaluate prototypes *ex vivo* (in their hands) at the Sensory Evaluation Center at Penn State. All procedures were approved by the local Institutional Review Board (protocol #36943). Participants reported race and ethnicity using categories in OMB Directive 15. Most were married, college-educated white women; complete demographics are provided in Supplemental Table 1, and vaginal product usage is summarized in Table 1. Of the 99 participants, 37 had participated in our previous microbicide studies.

Participants watched a short video about the product concept in our waiting room, which described how to evaluate a prototype: (1) take the sample and put it into her non-dominant hand; (2) gently stroke the sample with the index finger of her dominant hand; (3) put the sample between her fingers and pinch gently (hand not specified; shown as dominant hand in video); (4) finally hold the sample between her fingers and imagine she was trying to insert the sample into her vagina (hand not specified or shown). After watching the video, women deciding to participate provided written informed consent before entering individual test booths. Participants were reimbursed for their time.

Table 1
Product usage.

Products	Usage (%)
Menstruation products, such as tampons	64
Lubrication products such as KY® gels, liquibeads and vitamin-E suppositories	37
Yeast infection medicines, such as Vagisil® and Monistat®	28
Douche	8
Vaginal contraceptive products, such as Nuvaring®	4
Spermicidal gels and films	2
Decline to answer	9

Women rated *willingness-to-try* using a 100-point visual analog scale. Women were told these products would be used without an applicator. Sample presentation was counterbalanced in a Williams design. To avoid low *willingness-to-try* ratings due to low perceived STI risk, women were asked to assume they might need these products "to prevent potential infections, including Chlamydia, herpes and HIV". Appropriateness of size and firmness were assessed using 5-point categorical just-about-right (JAR) scales. (Here forward, we use *size* and *firmness,* in italics, to refer to appropriateness scores for these attributes). JAR is a global approach; specific contexts (e.g. insertion versus coitus) were not provided. Women ranked the shapes from most to least preferred after all samples had been evaluated. Demographics were collected at the end of the test.

Data were collected using Compusense Five v5.2 (Guelph, Ontario) and analyzed in JMP v9.0.2 (Cary, NC). Whether shape influenced *willingness-to-try* was tested via ANOVA, with participant as a random effect and shape as a fixed effect. Tukey's Honest Significant Difference was used for post hoc comparisons. Response distributions within a JAR scale category were compared using the Cochran–Mantel–Haenszel (CMH) test (Rothman and Parker, 2009). Exponential regressions characterized relationships between physical characteristics and percentage of "too-big" and "too-firm" responses using DataGraph v3.0 (Chapel Hill, NC). Ranking was analyzed via Friedman's test; rank-sums were calculated

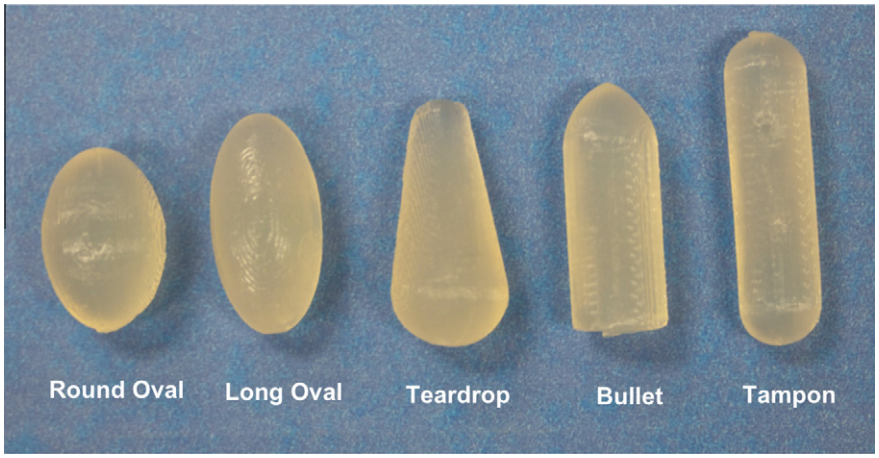

Fig. 1. Second generation microbicide prototypes. Volume is constant at 3 mL across all five shapes. Samples were prepared with kappa carrageenan, potassium chloride and water 1 day before evaluation, and stored in 1-oz transparent plastic cups at 16 °C with the lids tightly sealed until evaluation.