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Pilot study on functional performance and acceptability of two new synthetic adhesive male condoms (Wondaleaf): a randomized cross-over trial☆,☆☆

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ABSTRACT

Objectives: This study compared the condom failure rate, safety and acceptability of two new synthetic adhesive male condoms, Wondaleaf-Cap® (WLC) and Wondaleaf-On-Man® (WLM), with a marketed latex external condom Durex®-Together (DT).
Study design: We enrolled healthy married, monogamous, heterosexual condom users in a randomized controlled, cross-over, pilot trial in Malaysia. We randomized participants to six groups with different condom use-orders of the experimental WLC and WLM and control latex condom for four episodes for vaginal sex over 1 month for each condom type. We summarized the clinical and non-clinical failure rate, safety and acceptability of each condom type using descriptive statistics. We tested differences in condom failure and acceptability using generalized estimating equations and repeated measure ANOVA respectively.
Results: We screened 75 couples and randomized 50 eligible couples. Two couples withdrew before receiving any condom. The remaining used 576 condoms with 192 uses for each condom variant. Clinical failure rates of WLC, WLM and DT were 1.04%, 0% and 0.52%, respectively. Non-clinical failure rates of WLC, WLM and DT were 2.08%, 3.12% and 1.04%, respectively. Removal was found more painful with Wondaleaf products than the DT. Preferences of participants for WLC, WLM and DT were 33.3%, 29.2% and 25%, respectively. Overall, WLC and DT had greater acceptances among male participants than WLM.
Conclusion: Results of this pilot study support that use of synthetic adhesive male condoms is associated with failure rates similar to those seen with existing latex, and with greater acceptability. A larger study to ascertain non-inferiority is underway.
Implications: The availability of synthetic adhesive male condoms may increase the acceptability of condom use. However, removal pain and clinical performance requires further study.

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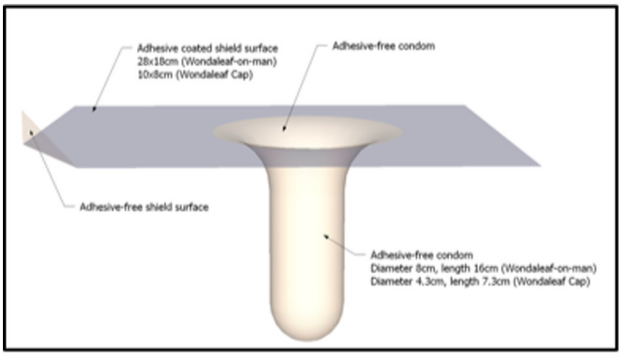
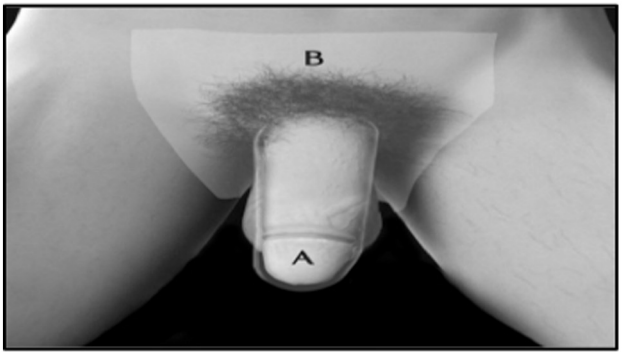
1. Introduction

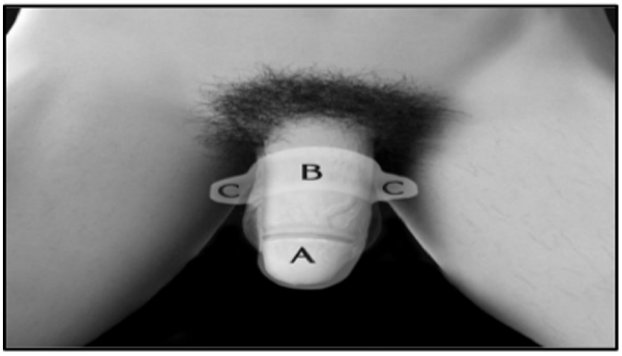
The latex external condom has long been a cornerstone of family planning and public health in preventing sexually transmitted infections (STIs). Despite its relative effectiveness, issues remain due to possibility of slippage, breakage and allergenic potential. To address these, synthetic-adhesive male condoms (SAMC) were first developed in the 1980's, with only two examples to our knowledge ever being commercially available: the first by the Mentor Corporation, and another by Galatic Cap. Nonetheless, SAMCs have yet to see significant commercial success, and as such neither products have been well studied. To the best of our knowledge, there are no studies on the functional performance and acceptability of SAMC compared to latex external condoms in the literatures. Past studies comparing the functional performance of non-adhesive SMC with latex external condom had mixed results [1–7]. While some studies [1–4] found that clinical breakage rate of polyurethane SMC is significantly higher than latex external condom, other studies [5–7] found no significant difference between them. Likewise, while some studies found SMC has significantly greater clinical slippage than latex external condom [2–4,7] some did not [1,5,6]. To



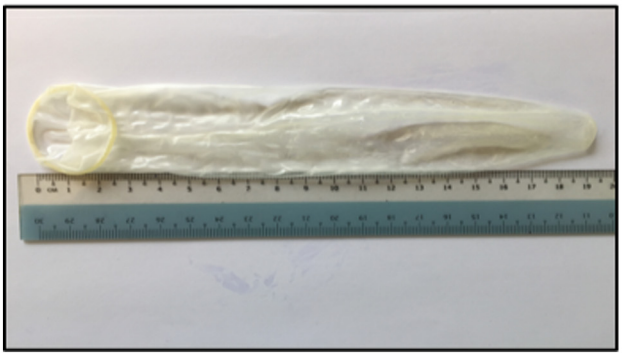
a) The layout of Wondaleaf-On-Man and its smaller version, Wondaleaf-Cap. The thickness of both condoms is 0.02mm.



b) Wondaleaf-On-Man duly deployed on the penis. The condom portion (A) loosely covers the penis, while the integral adhesive shield (B) sticks onto the entire groin region (including testicles).



c) Wondaleaf-Cap duly deployed on the penis. The loose-fitting condom (A) covers the glans penis, while the adhesive shield sticks onto the penile shaft (B) and onto itself (C) to form the proximal part of the condom (B) and two lateral tabs (C) respectively. The tabs that protrude laterally are soft and thin.



d) Durex-Together expanded and laid flat. It has nominal width 52.5mm, length 190mm, and thickness 0.07mm. It is pre-lubricated, and features an easy-on shape.

Fig. 1. Illustrations of study condoms (Wondaleaf-On-Man, Wondaleaf-Cap and Durex-Together).

the best of our knowledge, there are no studies on the functional performance and acceptability of SAMC compared to latex external condoms in the literatures.

The two new SAMCs in this study were branded as "Wondaleaf-Cap®" (WLC) and "Wondaleaf-On-Man®" (WLM). The former had an adhesive coating at the condom opening to stick onto the penile shaft, while the later had an integral adhesive shield that sticks onto the pelvis of the user. Both designs are different from the Galactic Cap, which sticks onto the glans penis. The adhesive coated shield design of the Wondaleaf external condoms allows users to put on the device without the need of penile erection, thus allowing pre-emptive deployment prior to sexual activity. The loose-fitting design with an adhesive rim at the open end of the condom also prevents spillage of the seminal content regardless of the state of the penile erection, thus achieving the goals of contraception and sexually transmitted infections preventions. Both Wondaleaf external condoms involved in this study have recently received patents and marketing approval in Malaysia (www.wondaleaf.com).

A previous study has investigated the characteristics of WLM in its original role as a female condom though there have not been any studies on WLM as a male condom [8]. We sought to better understand the functional characteristics of WLC and WLM as well as to obtain estimates of effects and variances for future larger studies. Thus, we conducted a pilot study by comparing the clinical failure rate (CFR), non-clinical failure rates, acceptability and safety of WLC and WLM during penile-vaginal intercourse with a commercially available condom, Durex®-Together (DT).

2. Material and methods

2.1. Study population and design

We conducted the randomized cross-over pilot trial in accordance with ISO/WD 24493–1/2017 [9]. We registered the trial at ClinicalTrials.gov (NCT03324594) Ethics approval was granted to the trial by Malaysia Medical Research and Ethics Committee. We screened couples at Sarawak Family Planning Association and Sarawak Research Society and recruited those who met the following inclusion criteria: (1) couples who were in a married, monogamous and in heterosexual relationships; (2) couples who agreed to practice only vaginal sex using the condoms provided; (3) couples who were between 18 to 45 years; (4) couples who were not known to have STIs; (5) couples of which the men had used a minimum of 10 male condoms in the last 12 months; (6) couples of which the female partner was not pregnant upon recruitment and had been using an effective alternative method of contraception prior to study and would continue using it throughout their participation in the study; and (7) couples who agreed to use four condoms of each condom variant with 1-month interval for 3 months. We excluded couples who (1) were colleagues, friends or family of the research team and (2) who had known allergy or sensitive to latex, polyurethane, acrylic adhesive, or other residual chemicals used in the manufacture of latex condoms. All eligible couples had provided written informed consents prior to their participation in this study.

We applied the sample size rules of thumb cited by Browne [10], to recruit at least 30 subjects to estimate a parameter. Assuming a dropout r-

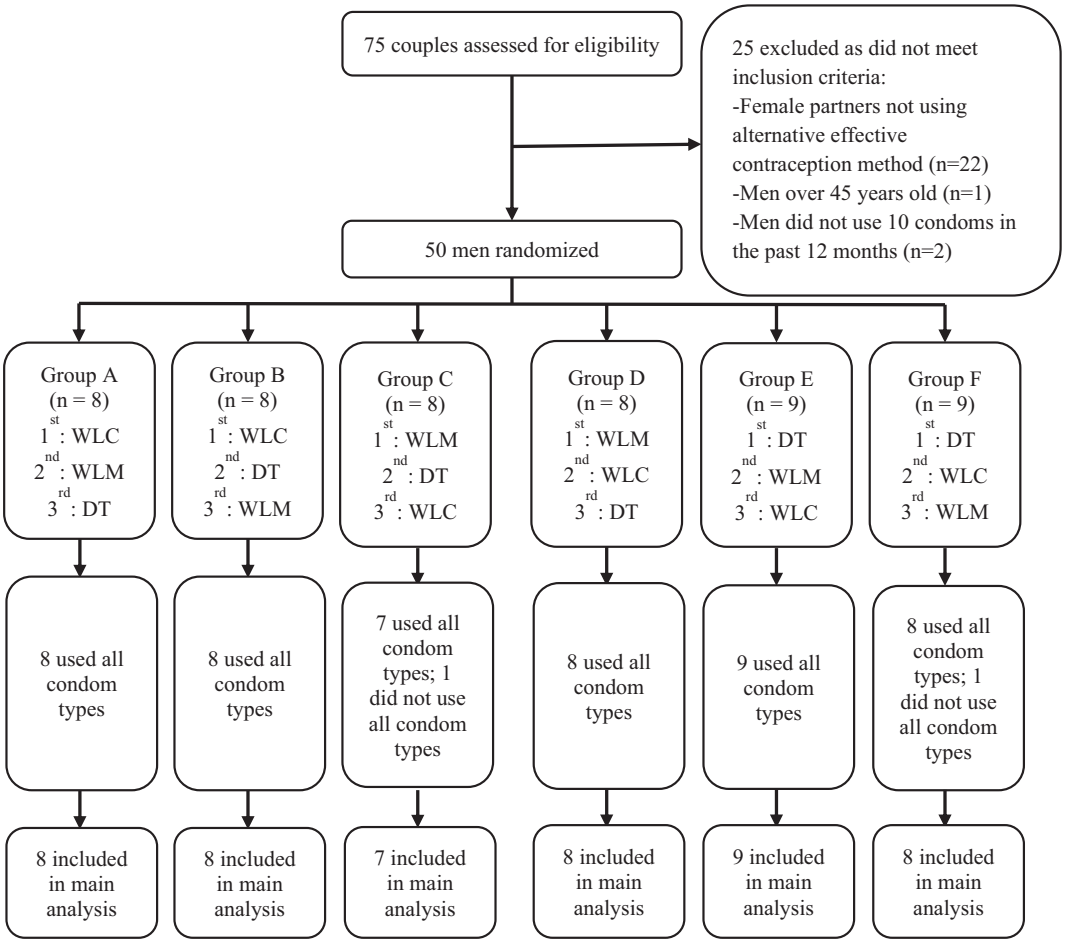


Fig. 2. Trial profile based on CONSORT 2010 statement. WLC = Wondaleaf-Cap; WLM = Wondaleaf-On-Man; DT = Durex-Together

ate of 40%, 50 participants were recruited to achieve an estimated 600 condom uses (50 participants × 3 study condoms × 4 uses each type). We used a computer-generated randomization sequence to randomly assign participants to six groups with different condom use-orders of the experimental WLC and WLM and control latex condoms [11]. The participating couples, investigators, and research staffs were not blinded to the condom use-order assignment as there were observable differences on packaging and design among the condoms. The biostatistician, sponsor, and medical reviewers were blinded until the completion of final report to avoid biases during data analyses and results reporting.

Upon enrollment, we collected information including: (1) age; (2) spouse age; (3) highest education level; (4) ethnicity; (5) circumcision status; (6) monthly average frequency of sexual intercourse; (7) current alternative contraception method used by female partners; and (8) past condom use experiences. After enrollment, participants returned for three follow-up visits. During each visit, the men received a study package comprising (1) four units of either WLC or WLM or DT; (2) four sachets of water based lubricant 5 ml and 8 ml that comes only with WLC and WLM respectively; (3) written instructions for using the WLC or WLM (4) four copies of an "Individual Condom Use Data Collection Form"; and (5) an appointment slip with return visit schedule. Demonstrations on how to use WLC and WLM were done by viewing a video and donning the condom on a model penis. Upon assignment of each test condom, demonstration on how to use it was done by viewing a video and donning it on a model penis. Later, we required the men to apply the test condoms once by themselves at the study sites to ensure competency. For control condom, there was no demonstration and training on site.

2.2. Study condoms

WLM is made of 0.02 mm thick polyurethane film. Originally developed as a female condom, for use in men the pouch becomes a loose sheath over the penis and an extended adhesive shield that covers the entire groin area including testicles to provide potentially total protection against pregnancies and STIs. Neither the inner nor outer body of WLM is pre-lubricated. The WLM is intended for use with a lubricant, and an 8 mL sachet is included with each device.

In contrast, the smaller adhesive shield of the WLC is applied directly to the shaft of the penis forming the proximal part of the condom. The user removes the WLC by holding tabs on the side of the device and pulling the condom distally with counter pressure on the penile skin. The inner surface of the pouch that covers the glans penis is pre-lubricated, whilst the outer surface is not. A 5 ml lubricant is supplied with each WLC package, with instructions for use during every coital act.

The control condom, DT is made of latex and is pre-lubricated at the inner and outer body of the condom (Fig. 1). It has a nominal width 52.5mm, length 190 mm, thickness 0.07 mm, teat ended and easy-on shaped for comfort and fit (Fig. 1). We chose DT due to its relative commercial availability, known use of integrated quality systems, and its near global approval.

2.3. Condom use

The primary outcomes of the current study were frequency of clinical breakage, and frequency of non-clinical breakage and slippage. Participants were required to complete the coital log within 24 h after penile-vaginal intercourse, comprising (1) occasions of broken condoms; (2) location of breakage on condom, if any; (3) occasion of slipped condom; (4) reasons of breakage and slippage, if any; (5) timing of donning and removing of the condom; (6) product-related adverse events; and (7) difficulty in donning and removing the condom.

We defined clinical slippage as incidence when the study condom completely fell off penis during intercourse or withdrawal and clinical breakage as condom breakage occurred during intercourse or withdrawal. We summed up the percentage of clinical slippage and clinical breakage as clinical failure rate (CFR). On the other hand, we defined non-clinical breakage as condom breakage occurred before intercourse or after withdrawal of condom from vagina without potential adverse clinical consequences and non-clinical slippage as incidence when condom slipped partially but not completely off penis during intercourse or withdrawal. We summed up percentages of non-clinical slippage and breakage as non-clinical failure rate.

The secondary outcomes were focused on acceptability which was answered via a questionnaire. Participants assessed the smell, noise made during intercourse, heat transfer, sense of safety, cleanliness, lubricant use, ease of application, ease of removal, messiness, sexual satisfaction and softness of the study condoms via the 7-point Likert scale items in the questionnaires. We administered the questionnaire during follow-up visits. On their last visit, we asked the participants to rank their preferences towards the three condom types. In term of safety, we asked the participants to report any incidences of product-related adverse events such as irritation, burning, itching and bleeding within 24 h, as well as pregnancies or sexually transmitted diseases during the study period and 1 month after the study completion.

2.4. Data analysis

The results of the primary outcomes (clinical vs nonclinical failure rates) were presented descriptively. The results of the secondary outcomes (condom acceptability and preference) were analyzed using different methods. Generalized estimating equations (GEE) were used to detect differences in condom failures among study condoms due to

Table 1
Baseline characteristics provided by male participants (n=48).

Demographic*	Participants
Age	
Participants	34.9 (5.5)
Spouse (Female)	32.3 (5.1)
Ethnicity	
Malay	33 (68.8)
Iban	5 (10.4)
Bidayuh	6 (12.5)
Chinese	2 (4.2)
Others	2 (4.2)
Highest educational level	
Primary school	1 (2.1)
Secondary school	32 (66.7)
Tertiary	15 (31.2)
Circumcised	
Yes	46 (95.8)
No	2 (4.2)
Average monthly sexual intercourse	8.2 (4.3)
Current alternative contraception method used by female partner	
Oral contraception pill	37 (77.1)
Depo Provera injection	10 (20.8)
Sterilization	1 (2.1)
Past experience of condom breakage	
Yes	6 (12.5)
No	42 (87.5)
Past experience of condom slippage	
Yes	8 (16.7)
No	40 (83.3)
Satisfied with current condom type	
Yes	33 (68.8)
No	15 (31.2)
Brand of condom currently used	
Durex®	38 (79.2)
Family planning	8 (16.7)
Others	1 (2.1)
Not sure	1 (.21)

* There were no significant differences in all demographic characteristics among the six randomization groups ($p>.05$).

the repeated measure and dichotomous nature of the outcome [12]. Repeated measure ANOVA was employed to examine the acceptability of each condom type as the items were in Likert scale with repeated measures. Assumption for RM ANOVA was assessed using Mauchly's test of sphericity. The Condom preference was recorded as categorical data and therefore, z test was used to test the difference in preference towards the three study condoms. Z test was applied instead of GEE as the preferences were measured only once after the participants had tried all three condom types. All the statistical analyses were two sided and p value less than .05 was considered statistically significant. These analyses were performed using Stata version 14 (StataCorp LP, College Station, TX, USA).

3. Results

We screened 75 couples and 50 were eligible. Out of these 50 couples, two had withdrawn from the study before using any study condoms as they could not commit to the research timeframe (Fig. 2). We excluded these two couples who were prematurely randomized into the trial from the analyses, according to the post-randomization exclusions criteria [13]. Most of the participants were Malay (68.8%), circumcised (95.8%), and secondary school graduates 190 (66.7%). Most of the participants (77.1%) had their female partners taking oral contraceptive pills as an alternative method. (Table 1). Most of the men (95.8%) had used Durex® condoms prior to the study. About 10% and 17% of the parti-

Table 2
Self-reported characteristics of condom use and failure in coital logs (n=192).

		Frequency (%)			P value
		WLC	WLM	DT	
Condom use characteristics					
Person donning the condom	*Participants*	186 (96.9)	181 (94.3)	173 (90.1)	0.023[a]
	Spouse	6 (3.1)	11 (5.7)	19 (9.9)	
Ease of donning	*Very difficult*	5 (2.6)	18 (9.4)	0	<0.001[a]
	Difficult	18 (9.4)	41 (21.4)	8 (4.2)	
	Not sure	23 (12.0)	21 (10.9)	1 (0.5)	
	Easy	120 (62.5)	88 (45.8)	81 (42.2)	
	Very easy	26 (13.5)	24 (12.5)	102 (53.1)	
Timing of donning	*<1 min before penis erect*	42 (21.9)	38 (19.8)	29 (15.1)	<0.001[a]
	1–10 min before penis erect	61 (31.8)	35 (18.2)	29 (15.1)	
	> 10 min before penis erect	8 (4.2)	5 (2.6)	4 (2.1)	
	When penis was erect	81 (42.2)	114 (59.4)	130 (67.7)	
Timing of withdrawing penis from vagina	*When penis was still erect*	97 (50.5)	105 (54.7)	96 (50.0)	0.130[a]
	When penis was not erect	93 (48.4)	82 (42.7)	96 (50.0)	
Holding of condom upon withdrawal from vagina		64 (33.3)	70 (36.5)	91 (47.4)	0.009[a]
Person who removed the condom	*Participant*	186 (96.9)	182 (94.8)	183 (95.3)	0.212[a]
	Spouse	3 (1.6)	5 (2.6)	9 (4.7)	
Ease of removing the condom	*Very difficult*	0	8 (4.2)	1 (0.5)	<0.001[a]
	Difficult	27 (14.1)	28 (14.6)	7 (3.6)	
	Not sure	14 (7.3)	13 (6.8)	5 (2.6)	
	Easy	106 (55.2)	111 (57.8)	88 (45.8)	
	Very easy	43 (22.4)	27 (14.1)	91 (47.4)	
Timing of removing the condom	*While penis still erect*	78 (40.6)	65 (33.9)	91 (47.4)	0.046[a]
	While penis was not erect	112 (58.3)	122 (63.5)	101 (52.6)	
Pain experienced when removed the condom	*No pain at all*	120 (62.5)	90 (46.9)	176 (91.6)	<0.001
	Mild pain	48 (25.0)	50 (26.0)	8 (4.2)	
	Moderate pain	17 (8.9)	35 (18.2)	5 (2.6)	
	Painful	5 (2.6)	8 (4.2)	3 (1.6)	
	Very painful	0	4 (2.1)	0	
	Not relevant as did not use the condom after condom breakage	2 (1.0)	5 (2.6)	0	
Condom failure characteristics					
Number of clinical breakages reported		1 (0.5)	0	1 (0.5)	0.076[b]
Number of non-clinical breakages reported		2 (1.0)	5 (2.6)	0	0.064[b]
Timing of breakage happened	*Taking out of packet*	1 (0.5)	0	0	>0.950[b]
	During putting on	1 (0.5)	5 (2.6)	0	
	Noticed after withdrawal	1 (0.5)	0	0	
	During intercourse	0	0	1 (0.5)	
The sequence of condom uses when it broke	*First use*	1 (0.5)	1 (0.5)	0	>0.950[b]
	Second use	0	2 (1.0)	0	
	Third use	1 (0.5)	1 (0.5)	0	
	Fourth use	1 (0.5)	1 (0.5)	1 (0.5)	
Condition of breakage	*Tear, but still one piece*	3 (1.6)	5 (2.6)	1 (0.5)	0.314[b]
	Small hole	0	0	0	
Number of clinical slippages reported		1 (0.5)	0	0	>0.950[b]
Number of non-clinical slippages reported		3 (1.6)	1 (0.5)	2 (1.0)	0.875[b]
Condition of slippage	*Expose shaft of penis*	3 (1.6)	1 (0.5)	2 (1.0)	0.543[b]
	Expose glans of penis	1 (0.5)	0	0	
	Completely off the penis	0	0	0	
The sequence of condom uses when it slipped	*First use*	3 (1.6)	0	2 (1.0)	0.333 [b]
	Second use	1 (0.5)	0	0	
	Third use	0	1 (0.5)	0	
	Fourth use	0	0	0	

WLC = WONDALEAF-CAP®; WLM = WONDALEAF-ON-MAN®; DT = Durex®-Together.
[a] Pearson chi-square test;
[b] Fisher's Exact test.

cipants had experienced condom breakage and slippage, respectively. Thirty percent of them were discontent with their current condom use. These baseline characteristics did not differ statistically between the randomized groups.

The participating couples used a total of 576 condoms, with 192 condoms for each variant in this study. Clinical failure rate of WLC, WLM and DT were 1.04% (breakage=0.52%; slippage=0.52%), 0% (breakage=0%; slippage=0%) and 0.52% (breakage=0.52%; slippage=0%) respectively (Table 2 and Supplementary Material 1). Non-clinical failure of WLC, WLM and DT were 2.08% (breakage=0.52%; slippage=1.56%), 3.13% (breakage=2.60%; slippage=0.52%) and 1.04% (breakage=0%; slippage=1.04%), respectively. None of these differences were statistically significant (Supplementary Material 1). Specific descriptions of the condom failure events were provided in Supplementary Material 2.

In terms of condom's acceptability, we found no significant differences between the test and control condoms on their smell, noise made during intercourse, heat transfer, sense of safety, cleanliness and lubricant use (Table 3). In terms of overall sexual satisfaction, there's no significant difference between WLC and DT, though the former scored highest among all three condoms. WLM scored significantly lower than DT in the domains of easiness in donning and removal, texture (soft and comfortable), not messy, and sexual satisfaction. Overall, DT and WLC had greater acceptances than WLM. The condom preferences of men for WLC, WLM and DT were 33.3%, 29.2% and 25% respectively (Supplementary material 5). Among the women, their preference for WLC, WLM and DT were 31.3%, 18.8% and 31.3% respectively. The condom preferences were not significantly different for both men and women.

Several participants reported moderate to severe pain upon removal of WLC (11.5%) and WLM (24.5%; Table 2). Of the participants, 24.5% and 11.5% described pain during the removal of the WLM and WLC group, respectively. Post hoc analysis revealed that WLM pain scores decreased with increasing familiarity with device, with number of participants who described "no pain at all" increasing from 27 (57.45%) to 31 (65.96%) after four uses. A similar trend was also noted for WLC with an increase from 21 (44.68%) to 25 participant (53.19%; Supplementary material 3) reporting "no pain at all". The ease of donning and removing the condom were inversely correlated ($p<.05$) with the pain experienced during removal of condoms (Supplementary Material 3). No pregnancy occurred during the study period and 1 month after the study completion.

4. Discussion

The results above showed that Wondaleaf male condoms have comparable functional performance to traditional condom such as Durex. WLM has the lowest clinical failure rates (0%) compared to the other two condoms (0.52–1.04%). In terms of clinical breakage, only one breakage case was reported for WLC and DT. When investigate further, the former incident was due to the tightness of WLC ("I stick the adhesive part too downward and cause the condom to be overly tight") and the later incident was due to the dryness of DT ("The condom was too dry and lack of lubricant. It broke at the head of the condom"). The only clinical slippage was reported in one of the WLC users due to improper application ("I squeezed the condom after withdraw penis from vagina and realized that the semen leak from the bottom of the condom. I found that the adhesive part wasn't closed tightly.")

Nevertheless, both Wondaleaf products suffered from non-clinical failures more frequently than DT. We speculate that these breakages were more in keeping with the participants' unfamiliarity of these devices rather than being due to the safety features of the condoms

Table 3
Repeated ANOVA testing on the acceptability items towards three condom variants among male participants ($n=48$).

Variables ($n=48$)	WLC		WLM		DT		RM ANOVA p value	Post hoc analysis	
	Mean*	SD	Mean*	SD	Mean*	SD		SMD	P value
Ease of donning	5.35	1.35	4.94	1.82	6.15	1.43	<0.001	DT > WLM	<0.001
								DT > WLC	<0.001
								WLC > WLM	0.013
Ease of removing	5.54	1.58	5.42	1.53	6.15	1.27	<0.001	DT > WLM	<0.001
								DT > WLC	0.002
Pleasant smell	6.25	1.06	6.17	1.12	5.96	1.07	0.370	nsd	
Least noise	4.85	1.98	5.02	1.62	5.31	1.79	0.125	nsd	
Feel soft	5.85	1.44	5.44	1.65	5.85	1.11	0.004	WLC > WLM	0.038
								DT > WLM	0.009
Feel comfortable	5.63	1.41	5.42	1.54	5.85	1.11	0.005	DT > WLM	0.011
Feel sensitive and stimulating	5.69	1.31	5.35	1.73	4.98	1.67	0.024	nsd	
Good heat transfer	5.23	1.63	5.35	1.51	5.06	1.76	0.253	nsd	
Feel safe	6.10	1.13	6.17	1.04	5.92	1.07	0.865	nsd	
Feel clean	6.17	1.04	6.06	1.12	5.94	1.04	0.940	nsd	
Not messy	5.77	1.06	5.21	1.60	6.00	1.15	<0.001	DT > WLM	<0.001
								WLC > WLM	0.013
Work well with lubricant	5.98	1.06	5.96	1.32	5.71	1.22	0.166	nsd	
Overall sexual satisfaction	6.00	0.97	5.63	1.41	5.81	1.30	0.007	WLC > WLM	0.003
								DT > WLM	0.032

Amount of lubricant	WLC		WLM		DT		p value
	n	%	n	%	n	%	
Too little	2	4.2	2	4.2	6	12.5	0.219
Just right	46	95.8	46	95.8	42	87.5	
Too much	0	0	0	0	0	0	
Size fitness							
Too small	2	4.2	1	2.1	1	2.1	<0.001
Just right	44	91.2	35	72.9	47	97.9	
Too big	2	4.2	12	25.0	0	0	

WLC = WONDALEAF-CAP®; WLM = WONDALEAF-ON-MAN®; DT = Durex®-Together; RM ANOVA = Repeated measure analysis of variance; nsd = no significant difference by comparing the test condoms with control condom.

* Score range=1–7, with 1 indicates strongly disagree and 7 indicates strongly agree.

themselves. For instance, a participant explained that breakage of WLC was due to difficulty in applying the adhesion part on his first attempt ("The condom broke during putting on as the sticky part meshed together and when I wanted to re-align it, it broke"). Another participant tore a WLC accidently while opening the packaging. One participant who also accidently broke WLM during donning also complained the WLM size was inadequate for his penis (this same participant repeatedly broke WLM during donning which accounts the high percentage of non-clinical breakage for WLM).

On the other hand, while both WLC and WLM have similar thickness made of adhesive synthetic material, WLC was found to provide significantly greater sexual satisfaction than WLM. The difference could be due to the degree of penile shaft exposure and fitness of size (Table 3). Wonderleaf products could continue to improve its acceptability based on this user's feedback. Although both adhesive condoms were rated as being significantly harder to be applied and removed (Supplementary Material 3), post hoc analysis revealed that easiness of donning and removal increased with practice (Supplementary Material 4). Thus, we suggested that a proper education on the device application and practices are imperative for SAMC to minimize non-clinical failure.

Lastly, the results of the current study should be interpreted with consideration of several limitations. First, majority of the male participants were circumcised, it is unknown of the generalizability of the study results to uncircumcised men. Second, the participants were given four condoms to be tested in a month as per recommendation of ISO 29943-1:2017 on the frequency of condom use for both test and control condoms [9]. However, at baseline they reported having eight coital acts per month on average. This means that adverse events of continuous or extended condom use might not be captured. Additionally, the participants might have selected situations in which the condom use might have been intrinsically more feasible. Future study is needed to investigate the effect of selective situational coital acts on the participants' reporting of the condom functional performance. Moreover, as majority of the participants (96.0%) were experienced Durex® condom users, their subjective perception on the ease of donning and removal of SAMC could be biased due to branding effect of DT and behavioral fluency with roll-on condom [14]. Nevertheless, 30% of participants were discontent with their use of condom prior to the study. Future study should also investigate the impact of prior condom satisfaction and pain experienced during condom removal on their acceptance towards the study condoms as well as the willingness-to-pay and cost-effectiveness [15] for the new SAMCs.

In conclusion, we noted that SAMCs were fundamentally different from traditional condoms in their adhesive nature, which claimed to obliviate the need for erection prior to application and reduces the risk of slippage. The preliminary findings in this study suggest that clinical failure rate of WLC and WLM were comparable to DT and did not incur serious product-related adverse events. A larger non-inferiority trial on the WLC and WLM versus non-adhesive male condom is warranted.

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