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REVIEW ARTICLE

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Do sperm and lubricants *gel* well with each other? A systematic review

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ABSTRACT

Vaginal lubricants are commonly used to aid sexual pleasure and/or to help combat vaginal dryness and dyspareunia. Several studies have reported their impact on sperm function, however there are no published guidelines to help healthcare professionals and couples select a vaginal lubricant that is 'sperm-safe'. To address this, we conducted a literature search using both PubMed and Scopus to identify and appraise manuscripts that reported the impact of lubricants on sperm function. We did not restrict the literature search by year of publication, and we only included manuscripts that looked at the impact of vaginal lubricants on human sperm. The quality of the eligible studies was assessed using the Björndahl et al., (2016) checklist for semen analysis, as most of the studies reported the findings of a basic semen analysis. A total of 24 articles were eligible for analysis with a total of 35 vaginal lubricants (that were available to buy over the counter) being included, 2 of which studied the effect of vaginal lubricants on sperm function *in vivo,* and 22 being conducted *in vitro*. KY Jelly, PreSeed and Astroglide were most studied, with most manuscripts focussing on their impact on sperm motility. A paucity of data on most lubricants combined with methodological variations between studies and limited/no reporting on pregnancy outcomes means greater efforts are required before an evidence-based guideline can be published.

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Vaginal lubricants; sperm function; systematic review; recommendations

Introduction

Problems with vaginal lubrication have been identified as a factor leading to dyspareunia, which has been shown to impact natural conception (Ellington et al., 2003). Vaginal lubricants (VLs) are commonly used to help mitigate against this, but may also be used by couples to enhance pleasure during intercourse, and in fertility clinics during semen collection. Steiner et al. (2012) surveyed 296 women in the US who were actively trying to conceive (TTC) and found 25% had stated that they used a VL whilst trying to conceive. Whereas in the UK, a survey estimated ~10% of the 1,549 women who participated in the survey reported that they used a VL when TTC, but only 3% of the women would use it explicitly when experiencing vaginal dryness (Johnson et al., 2016).

Whilst VLs are commonly used worldwide, are easily accessible for most couples, and are considered relatively safe to use, there is little to no official guidance or recommendations by healthcare professionals regarding the knowledge and understanding of VL use, as illustrated by in previous studies (Mackenzie & Gellatly, 2019). The authors surveyed UK-based healthcare professionals in fertility clinics and found the majority responded with 'rarely or never have asked patients about lubricant use during a clinical history'. It was also identified that most of the respondents (>80%) would not recommend lubricant use for couples trying to conceive a pregnancy unless it is to help with vaginal dryness during intercourse. Whilst it was not highlighted by the participants of the survey why did they not recommend VL use for couples TTC, this can be attributed to two factors: (i) the general lack of knowledge or awareness surrounding common lubricant use and impact on fertility, specifically male fertility, or (ii) due to personal professional opinions the healthcare practitioners may have of lubricant use

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during intercourse. Wilhite (2018) has reviewed and provided appropriate recommendations for clinicians when dealing with patients struggling with vaginal dryness and what kind of VL to choose or recommend, however there was no mention or consideration for the impact the VLs may have on sperm.

Although several studies have reported the impact of VL on sperm function, there has yet to be a robust synthesis of evidence from these studies. Given the prevalence of VL usage among couples and limited knowledge surrounding their impact on sperm function among healthcare professionals (HCPs), this review was urgently required to help the development of an evidence-based guidance to prevent trying-to-conceive couples and HCPs from choosing an inappropriate VL. Therefore, the aim of this study was to perform a systematic review of the available data on the effect of VL on sperm function to see whether there is sufficient evidence to formulate evidence-based guidelines for couples and HCPs.

Materials and methods

Literature review strategy

A systematic literature search was performed following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Moher et al., 2009). PubMed and Scopus databases were searched (start date of March 2022) to identify peer-reviewed, English language manuscripts reporting the impact of VLs on human sperm function. No restrictions on the year of publication were imposed at the time of data collection.

For PubMed, the keywords, and Boolean operators (AND/OR) used were *('lubricants'[Title/Abstract] AND 'sperm'[Title/Abstract]) AND ('sperm motility' OR 'sperm function' OR 'DNA integrity' OR 'DNA fragmentation' OR 'glycerine' OR 'glycerol')*. For Scopus, the keywords and Boolean operators used were *(TITLE-ABS-KEY ('lubricants' AND 'sperm') AND KEY ('sperm motility' OR 'sperm function' OR 'DNA integrity' OR 'DNA fragmentation' OR 'glycerine' OR 'glycerol'))*.

All manuscripts identified in our search were subsequently downloaded using Endnote X9.3.3 (Clarivate, Philadelphia, PA) to pool the records together prior to manuscript screening. Following the removal of duplicates ($n = 19$), titles and abstracts were screened for their relevance to the present review's aim: Vaginal lubricants' impact on human sperm function, *in vivo* or *in-vitro*. After abstracts were screened, the remaining articles ($n = 28$) were eligible for full-text review to assess their suitability using our inclusion and exclusion criteria. Our inclusion criteria were as follows: the article had to primarily investigate the human spermatozoa; the article had included a vaginal lubricant(s) as part of the study's main treatment for analysis; the manuscript was a primary research manuscript or a short communication; the manuscript included testing against sperm functional parameters such as motility, DNA damage, vitality, sperm toxicity, or sperm quality; the manuscript was either an *in-vivo* or an *in-vitro* study; the manuscript was written in English as the main text; and the manuscript was published as either final print or ahead of print. We excluded manuscript based on the following: the manuscript primarily focused on animal spermatozoa or was an animal-based study; the manuscript did not discuss the resultant impact on sperm function(s) after VL treatment or use; the manuscript was exclusively investigating the effects and use of spermicidal or contraceptive lubricants against human spermatozoa; the manuscript was a review or a commentary; or the manuscript was not written in English as the main text. Figure 1 illustrates the flow chart of the PRISMA guidelines and reasons for exclusion of records for this review.

Following identification of eligible manuscripts, compounds that were studied or tested as 'vaginal lubricants' were quantified and then sub-divided into three main categories: (i) *Over the Counter* (OTC) refers to products that would be easily accessible for an individual or couple to purchase and find them, (ii) *non-OTC* refers to products that are more likely to be used in clinical and healthcare settings, such as gynaecological examinations or in laboratories and are not usually purchased by the general public, and (iii) *Discontinued* refers to those products that are currently unavailable in the market, either OTC or Non-OTC, since their time of study. A review protocol was not previously prepared and is not registered.

Traffic light system

A Red, Amber or Green (RAG) traffic light system was used to rate the effect of VL on sperm function, based on a similar approached that was created by the Human Fertilization and Embryology Authority (HFEA) for add-ons. Briefly, a red, amber or green colour rating is assigned to each VL identified in this review based on whether the evidence from the studies suggests that it affects sperm function. As most of the manuscripts had focused on sperm motility, we could only base the RAG traffic light system on this semen characteristic.

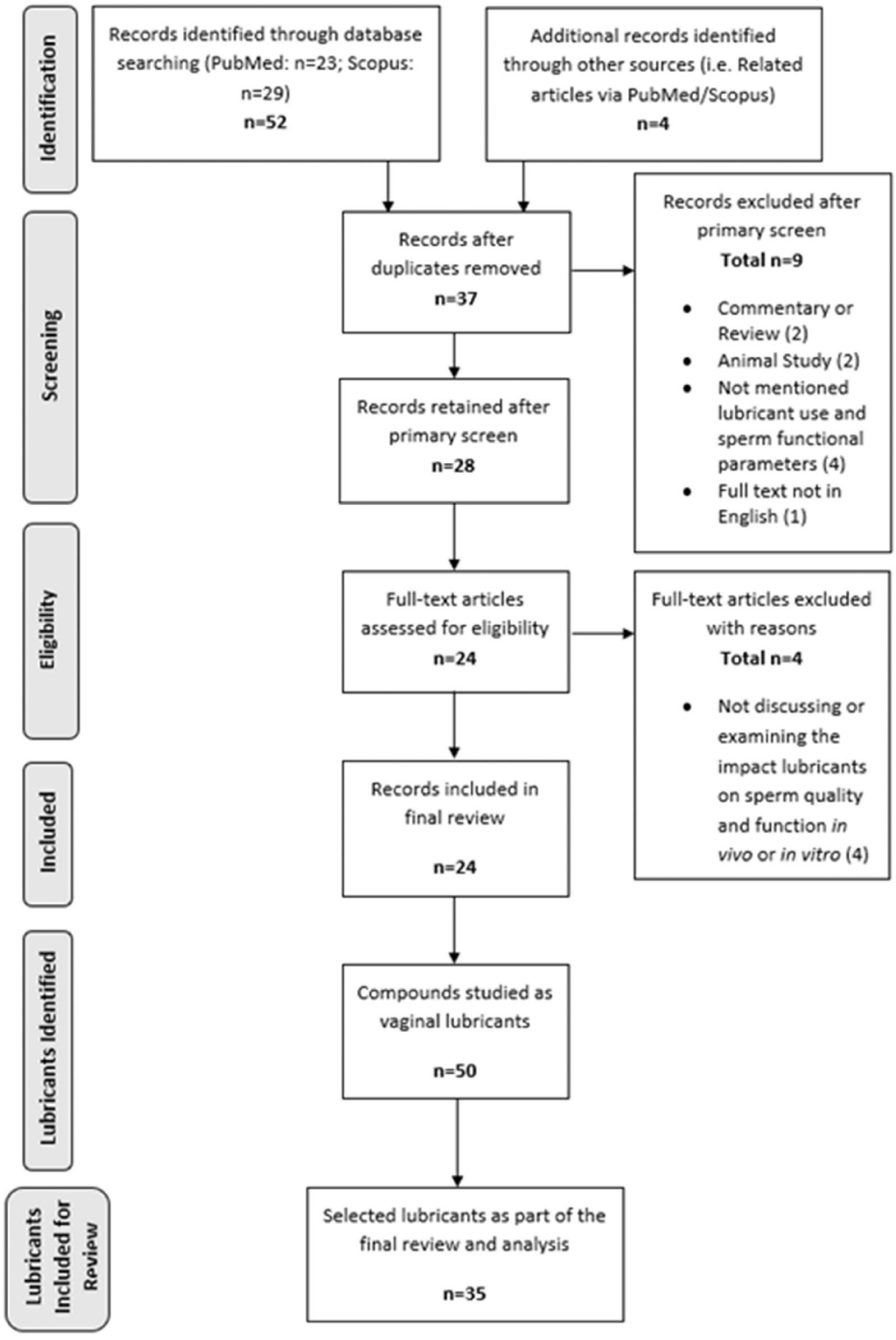

Figure 1. PRISMA flowchart for the identification and selection of studies investigating vaginal lubricants influence over sperm function in *in vivo* and *in vitro* settings.

VLs that had been studied more than once would need to have >50% of the publications report no statistically significant change or an increase in sperm motility to be placed as Green for 'Good', and those with >50% studies reporting a statistically significant decrease in sperm motility as Red for 'Bad'. VLs that have equal reports of positive and negative for sperm motility or were studied only once were placed as Amber for 'Inconclusive'.

Study checklist assessment

The reliability of the results of a semen analysis is dependent on the technical methods used to measure the different semen characteristics and authors being clear in their manuscripts which ones they used (Björndahl et al. 2016). We used the checklist provided by Björndahl et al. (2016) to score all included manuscripts ($n = 19$) for the extent to which they disclosed the technical methods they used when assessing the different semen characteristics. The parameters of interest that were scored for were sperm motility, sperm vitality and sperm morphology assessments from the studies without restricting the time frame of the study publication date. We quantified the total check points outlined under each assessment criteria within the checklist and used the total number to score against each manuscript by reviewing their methodologies. The total scoring achieved for each semen characteristic was 7 for motility, 3 for vitality, and 6 for morphology. For example, manuscripts that looked at the effect of sperm motility could only get a maximum of 7 points, if they have exclusively stated following each of the sperm motility assessment criteria. It is important to note that these scores are not enough to reveal the quality of laboratory assessment but the extent to which the manuscripts disclose the WHO recommended technical methods used to assess each of these semen characteristics.

Results

A total of 56 manuscripts were identified following PubMed and Scopus searching using the Boolean terminology and the keywords selected. Following removal of duplicates ($n = 19$) and articles which did not meet our inclusion criteria after a full text review ($n = 31$), 24 manuscripts were eligible for inclusion in our review (Figure 1, Supplementary Table 1). A total of 50 compounds that have been studied as VLs were identified among the 24 manuscripts (Supplementary Table 1 & 2), however this final review and analysis only focused on the OTC lubricants ($n = 35$) (Table 1). Only 2 manuscripts were identified as *in vivo*-based studies, and the remaining 22 articles were *in vitro*. Miller et al. (1994) examined the effects of Surgilube (Non-OTC) on sperm motility and compared them both *in vitro* and *in vivo* with and without the VL. Specifically, for the *in vivo* experiment, participants were enrolled for a standard post-coitus test to examine differences in sperm motility with and without the use of the lubricants. The second manuscript reported secondary analyses of couples TTC in which women were surveyed over their use of VLs and examined against the endpoint of them achieving a pregnancy, defined as a positive urinary pregnancy test, or not within 6 months (Steiner et al., 2012).

The manuscripts included in our final systematic review were published between 1972 and 2022. Of the 19 *in-vitro* studies, most did not fully disclose the technical methods they used to assess the different semen characteristics, and there was variation in how the samples were prepared, and how parameters were defined by the included manuscripts. Sperm motility was found to be a primary parameter evaluated among the manuscripts. Sperm vitality was studied 7 times, morphology was studied once, and DNA damage was examined by 3 separate manuscripts. Table 1 outlines the key findings for each of the 35 OTC compounds included against each manuscript included in the final systematic review ($n = 19$). 19 of the 35 OTC compounds were found to be specifically advertised and manufactured as 'vaginal lubricants' or 'vaginal moisturisers', 14 were either common household products or lotions, and the remaining 2 were manufactured as feminine hygiene cleansers. KY Jelly, PreSeed and Astroglide were identified as the top 3 studied lubricants. KY Jelly was consistently reported to decrease total or progressive sperm motility, with no observable impact on sperm DNA damage or vitality rates (Table 1). PreSeed was consistently reported to have no significant change to sperm motility, vitality, and morphology (Table 1). Whereas for Astroglide, all studies found sperm motility and viability to decrease following treatment (Table 1). The review identified common household products were also studied as lubricants, including plant-based oils (e.g. olive, peanut, canola, mustard, vegetable, safflower, and sesame), egg white, petroleum jelly, and lotions (Alpha-Keri, Keri lotion, Baby Oil, Skin lotion Searle, and Purity & Elizabeth Anne). However, it was noted that the majority were studied once, apart from olive oil, *Johnson's*® Baby Oil, canola oil, and egg white where they were studied at least two times (Table 1).

Based on the evidence reported regarding the impact the VL on sperm function, the 35 lubricants were categorized using the RAG rating to facilitate whether the lubricant should or should not be recommended based on their sperm motility assessments (Table 2). Four VLs were categorized as Green under the RAG rating as over half of the published manuscripts for each lubricant reported favourable outcomes on sperm motility (i.e. PreSeed, *Johnson's*® Baby Oil, canola oil, and egg white). Under the Red rating, 6 VLs (i.e. KY Jelly, Astroglide, Replens, olive oil,

Table 1. Key findings of 35 OTC lubricants investigated between 1972 to 2022.

Lubricants	Manuscripts	Reference	Key Findings	Type of Semen Samples Tested	Study Note
KY Jelly	10	Agarwal et al. (2008)	Reported statistically significant increase in sperm DNA fragmentation index (16.0 ± 9) against control (14.8 ± 8).	Raw semen sample	KY Jelly was used as a negative control for the sperm motility tests, so no data present for this.
		Anderson et al. (1998)	Reported reduced prog. motil. at 6.25% at all time points (5 to 30 mins), but not statistically significant. Kinematics VCL, VSL, ALH, and BCF were statistically significantly ($p < 0.05$) reduced against the control at the varying time points. Statistically significantly ($p < 0.001$) increased osmolality of semen samples after addition (530 ± 2.5 mosmol before vs 600 ± 3.7 mosmol after).	DGC prepared sample	
		Frishman et al. (1992)	Reported statistically significant reduction in prog. motil. against control ($p < 0.05$) at all concentrations except at 12.5% within 1 minute.	Raw semen sample	The study presented a graph but do not indicate the exact values found.
		Goldenberg and White (1975)	The qualitative assessment reported 0+ out of 4+ for motility at 15 mins and 2 hours after treatment.	Raw semen sample	
		Kutteh et al. (1996)	Reported statistically significantly reduced mean motility (0%) vs the Hams F-10 (68 ± 6%), the study control, at varying time points. Viability dropped to 62 ± 6% against 72 ± 5% for Control, and osmolality increased to 820 ± 15 mosmol vs control 333 ± 8 mosmol.	Raw semen sample	
		Mackenzie and Gellatly (2019)	Reported statistically significant loss of prog. motil. (0% motility) after 60 mins of treatment against itself by 0 mins of incubation. Study did not report differences in vitality against control with the HOS test. Osmolality increased to 1301.7 ± 2.7 mOsm against control 284.3 ± 1.2 mOsm.	DGC prepared sample	
		Mowat et al. (2014)	Reported over 70% for progressively motile cells but was statistically significantly less than PreSeed. DNA fragmentation rate was ∼2% but the relationship was not statistically significant against the control (∼0.75%).	DGC prepared sample	
		Soriano et al. (2021)	Reported average SMI as 0.83 and was not significantly different to the control (0.88), but after 1 hour incubation at 10% concentration the SMI was 0.69 ± 0.10.	DSUS prepared sample	Authors stated a score of SMI <0.75 is classed 'spermo-toxic'.
		Schoeman and Tyler (1983)	Reported drop in motility after 15 mins and 2 hours of incubations at 2.5%, 5.0% and 10% concentration of testing, however the reduction was not drastic. By 2 hours, 10% of treatment resulted in 71.6% for mean spermatozoa motility against 104.4% mean motility for Control. Similarly, at 2.5% concentration, the mean motility was 105.6% against 108.4% for the Control by 2 hours incubation. No statistical analysis was performed.	Raw semen samples	
		Tagatz et al. (1972)	Reported no motile cells found after 15 mins incubation in the 8 normal samples and no viable sperm found in 6 out of 8 samples using Blom staining. 1 sample had 2% of viable cells. After 30 minutes, cells were non-motile and non-viable. In abnormal samples, 10 out of 12 resulted in non-motility and non-viability after 15 mins.	Raw semen samples	Used donors from couples with diagnosed primary or secondary infertility.
PreSeed	8	Abadie and Lambert (2014)	Reported total motility 45.6% without PreSeed vs 44.2% with PreSeed. Forward progression without PreSeed was 47.6% w/o Pre vs 46.1% with PreSeed. Morphology of normal forms was 17.5% for both with PreSeed and without PreSeed conditions.	Raw semen samples	
		Agarwal et al. (2008)	Reported no statistically significant difference in sperm motility (64 ± 14%) against control (66 ± 12%); no statistically significant difference in percent DNA fragmentation index (15.5 ± 8) against control (14.8 ± 8).	Raw semen sample	
		Agarwal et al. (2013)	Reported no statistical significant differences for motility (57.3 ± 10.6% w/o PreSeed vs 58.6 ± 8.3% w/PreSeed), HOS test (67.1 ± 14.8% w/o PreSeed vs 67.4 ± 10.7% w/PreSeed), viability (58.1 ± 11.7% w/o PreSeed vs 53.3 ± 9.9% w/PreSeed), ROS test (157.5 ± 223.6 RLU/s/M sperm w/o PreSeed vs	Raw semen samples	

(*continued*)

Table 1. Continued.

Lubricants	Manuscripts	Reference	Key Findings	Type of Semen Samples Tested	Study Note
			115.6 ± 140.9 RLU/s/M sperm w/PreSeed), TAC test (1,936.8 ± 366.2 μM of Trolox w/o PreSeed vs 2,112.7 ± 424 μM of Trolox w/PreSeed) and DNA damage (16.9 ± 7.3% w/o PreSeed vs 17.7 ± 8.8% w/PreSeed).		
		Mackenzie and Gellatly (2019)	Reported no statistically significant difference in prog. motil. ($p > 0.05$) over time (0, 10, 30 and 60 mins) and was comparable to the control conditions. Reported no statistically significant difference in cell vitality. Osmolality increased to 287.0 ± 0.6 mOsm from 284.3 ± 1.2 in control.	DGC prepared sample	
		Markram et al. (2022)	Reported median forward progression as 1 (non-progressively motile) and statistically significantly reduced vs the Control (raw sample) and egg white at 2–4 hrs incubation period. Progression dropped to 0 after 24 hrs incubation.	Raw semen sample	Followed a Sperm Progression Rating System
		Mowat et al. (2014)	Reported statistically significant higher vitality rate at 91% against other lubricants and the media control, prog. motil. was statistically significantly greater than other lubricants with >85%. DNA fragmentation rate using the SCSA test was at 2% but was not statistically significant against the control (~0.75%) or other lubricants.	DGC prepared sample	
		Sandhu et al. (2014)	Reported no statistically significant decline in total sperm motility after 60 mins ($p > 0.229$); but there was a minimal and statistically significant reduction ($p < 0.01$) in progressive sperm motility of 4% and 7% after 30 minutes and 60 minutes, resp.	DGC prepared sample	Examined lubricants in a time-dependent manner and compared within the treatment samples. No control present.
		Vargas et al. (2011)	Reported no statistically significant reduction in the SMI value between 1 hr (SMI = 1.05) and 24 hr (SMI = 0.93) of incubation.	DGC prepared sample	Authors stated a score of SMI <0.75 is classed 'spermo-toxic'.
		Kutteh et al. (2008)	Reported reduced total motility and prog. motil. vs the media control at different time points. By 1 hour, motility was 60% (control) to 47% (PreSeed) and progression was 3+ (control) to 2.5+ (PreSeed).	Raw semen sample	
Astroglide	5	Kutteh et al. (2008)	Reported reduced motility (0%) and progression (0) vs the media control for motility (60%) and progression (3+) by 1 hour.	Raw semen sample	
		Agarwal et al. (2008)	Reported statistically significant decrease in total motility (2 ± 1%) against control (66 ± 1%).	Raw semen sample	
		Frishman et al. (1992)	Reported statistically significant reduction in prog. motil. against control ($p < 0.05$) at all concentrations within 1 minute.	Raw semen sample	The study did not indicate the exact values other than the graph
		Kutteh et al. (1996)	Reported reduction in mean motility (0%) vs the Hams F-10 control (68 ± 6%) and motility dropped to 0% by 15 minutes. Viability was 0% against 72 ± 5% for control, and osmolality was 1700 ± 38 mosmol vs control 333 ± 8 mosmol.	Raw semen sample	
		Sandhu et al. (2014)	Reported statistically significant reduction ($p < 0.001$) in total and prog. motil. in a time-dependent manner. The motility has dropped below 60% and 50% by 60 minutes incubation for total and prog. motil., respectively.	DGC prepared sample	Examined lubricants in a time-dependent manner and compared within the treatment samples. No control present.
Replens	4	Agarwal et al. (2008)	Reported statistically significant decrease in sperm motility (25 ± 12%) against control (66 ± 12%).	Raw semen sample	
		Kutteh et al. (2008)	The authors of the study mention studying the lubricant, however no data was presented against the lubricant.	Raw semen sample	
		Kutteh et al. (1996)	Reported reduction in mean motility (0%) vs the Hams F-10 control (68 ± 6%) and motility dropped to 0% by 30 minutes. Viability was 0% against 72 ± 5% for control, and osmolality was 7030 ± 16 mosmol vs control 333 ± 8 mosmol.	Raw semen sample	
		Vargas et al. (2011)	Reported loss of motility at 0.83% concentration and at 1 hr incubation SMI was 0.03 that then increased to 0.12 at 24 hrs. Reported as the only	DGC prepared sample	Authors stated a score of SMI <0.75 is classed 'spermo-toxic'.

(*continued*)

Table 1. Continued.

Lubricants	Manuscripts	Reference	Key Findings	Type of Semen Samples Tested	Study Note
			lubricant to have decreased the mean pH of the solutions at both 4.15% and 8.3% concentration.		
Olive oil	4	Anderson et al. (1998)	Reported statistically significantly reduced ($p < 0.001$) prog. motil. at 5 and 15 minutes at 6.25% concentration against control. At 12.5% concentration, no statistically significant difference in percentage prog. motil. against KY Jelly until 5 minutes. Kinematics VCL and VSL were statistically significantly ($p < 0.05$) reduced against control at varying time points. No change in osmolality in semen after addition.	DGC prepared sample	
		Markram et al. (2022)	The reported median forward prog. motil. score was 1 at the 2–4-hour period, and then further dropped to 0 by 24 hours.	Raw semen sample	Followed a Sperm Progression Rating System
		Goldenberg and White (1975)	The qualitative assessment reported 2+ out of 4+ for motility at 15 mins and 3+ at 2 hours after treatment.	Raw semen sample	
		Kutteh et al. (1996)	Reported reduction in mean motility (42 ± 3%) vs the Hams F-10 control (68 ± 6). Viability was 70 ± 6% against 72 ± 5% for control, and osmolality was 390 ± 2 mosmol vs control 333 ± 8 mosmol.	Raw semen sample	
Baby oil *Johnson's*	3	Anderson et al. (1998)	Reported no statistically significant differences in kinematics at 12.5% concentration at varying time points. At 6.25%, prog. motil., VCL, VSL, ALH, and BCF were not statistically significant from the control ($p > 0.05$) at varying time points. Reported reduced osmolality of semen after the addition but non-significant (422 ± 4.1 mosmol before vs 306 ± 4.9 mosmol after).	DGC prepared sample	
		Mowat et al. (2014)	The reported vitality rate was ~60% and not significant against other lubricants. Whereas prog. motil. was the 2nd highest (>80%) and was statistically greater against lubricants Yes, Forelife and Sylk, but not significantly different than the positive control (80%). The rate of DNA fragmentation was just below 2% and the relationship against other lubricants and control was not significant.	DGC prepared sample	
		Sandhu et al. (2014)	Reported statistically significant decrease in total motility (6% drop; $p < 0.02$) at 60 minutes and in prog. motil. (7% drop; $p < 0.001$) after 5 minutes against 0 minutes of incubation, but both the total and prog. motil. were >70%.	DGC prepared sample	Examined lubricants in a time-dependent manner and compared within the treatment samples. No control present.
Yes	2	Markram et al. (2022)	The reported median forward prog. motil. score was 0 at all incubation points, and from 24 hours showed 100% immotile. Reported statistically significantly reduced prog. motil. ($p < 0.001$) in comparison to PreSeed and control.	Raw semen sample	Followed a Sperm Progression Rating System
		Mowat et al. (2014)	The reported vitality rate was approx. 50% (third after Conceive Plus at ~50% and PreSeed at ~91%) but not statistically significant against other lubricants. It came third for least progressively motile at just below 60%, and was statistically less than PreSeed, Baby Oil, Culture Oil, Media, Conceive Plus, Maybe Baby and Glycerol. The DNA fragmentation rate was below 2% and the relationship against other lubricants and control was not significant.	DGC prepared sample	
Canola oil	2	Kutteh et al. (1996)	Reported increase in mean motility (70 ± 4%) vs the Hams F-10 control (68 ± 6). Viability was 70 ± 6% against 72 ± 5% for control, and osmolality was 378 ± 12 mosmol vs control 333 ± 8 mosmol.	Raw semen sample	
		Sandhu et al. (2014)	Reported statistically significant (P = 0.003) decrease in total motility (dropped ~6%) 30 minutes and in prog. motil. (dropped ~5%) at 5 minutes against 0 minutes incubation, but total and progressive motility were >70%.	DGC prepared sample	Examined lubricants in a time-dependent manner and compared within the treatment samples. No control present.
KY jelly warming	2	Kutteh et al. (2008)	Reported reduced total motility (0%) and progression (0) vs the media control for total motility (60%) and progression (3+) by 1 hour.	Raw semen sample	

(*continued*)

Table 1. Continued.

Lubricants	Manuscripts	Reference	Key Findings	Type of Semen Samples Tested	Study Note
		Sandhu et al. (2014)	Reported an immediate and statistically significant ($p < 0.001$) decline in total and prog. motil. within 5 minutes incubation, and a further decline by 60 minutes. Total motility reached <30% and prog. motil. <20% by 60 minutes incubation.	DGC prepared sample	Examined lubricants in a time-dependent manner and compared within the treatment samples. No control present.
Conceive Plus	2	Mowat et al. (2014)	Reported 2nd highest vitality rate (>70%) that was statistically significantly greater than the remaining lubricants (except for PreSeed and the media control (80%)). Reported 2nd highest vitality rate after PreSeed that was statistically significantly greater than ForeLife lubricant ($p < 0.05$), but not statistically different than the control. The DNA fragmentation rate was over 1.5% and non-significant against the control or other lubricants.	DGC prepared sample	
		Wilson et al. (2017)	Reported statistically significantly reduced prog. motil. vs control ($p < 0.05$). No difference between 5 and 20 minutes (13.25%) but it had dropped to 7.15% by 60 minutes and was shown as the second poorest performing lubricant (after Dischem).	Raw semen sample	
Egg white	2	Markram et al. (2022)	The reported median forward prog. motil. score was 2 for 2–4 hours of incubation, that dropped to +1 at 24 hours, and then further dropped to 0 by 48 hours and onwards. No significant difference was found between egg-white and Raw control.	Raw semen sample	Followed a Sperm Progression Rating System
		Tulandi and McInnes (1984)	Reported no statistically significant ($p > 0.05$) change in total and prog. motility at all incubation periods against the control.	Raw semen sample	
Alpha-Jeri	1	Goldenberg and White (1975)	The qualitative assessment reported 0+ out of 4+ for motility at 15 mins and 2 hours after treatment.	Raw semen sample	
Keri lotion	1	Goldenberg and White (1975)	The qualitative assessment reported 0–1+ out of 4+ for motility at 15 mins and 0+ motility at 2 hours after treatment.	Raw semen sample	
Peanut oil	1	Goldenberg and White (1975)	The qualitative assessment reported 3+ out of 4+ for motility at 15 mins and 2 hours after treatment.	Raw semen sample	
Safflower oil	1	Goldenberg and White (1975)	The qualitative assessment reported 3+ out of 4+ for motility at 15 mins and 2 hours after treatment.	Raw semen sample	
Skin lotion Searle	1	Goldenberg and White (1975)	The qualitative assessment reported 0–1+ out of 4+ for motility at 15 mins and 0+ motility at 2 hours after treatment.	Raw semen sample	
Vaseline or Petroleum jelly	1	Goldenberg and White (1975)	The qualitative assessment reported 2–3+ out of 4+ for motility at 15 mins and 3–4+ motility at 2 hours after treatment.	Raw semen sample	
Vegetable oil	1	Goldenberg and White (1975)	The qualitative assessment reported 3+ out of 4+ for motility at 15 mins and 2+ at 2 hours after treatment.	Raw semen sample	
Touch	1	Kutteh et al. (1996)	Reported decrease in mean motility (10 ± 2%) vs the Hams F-10 control (68 ± 6). Viability was 68 ± 5% against 72 ± 5% for control, and osmolality was 666 ± 13 mosmol vs control 333 ± 8 mosmol.	Raw semen sample	
ConceivEase	1	Kutteh et al. (2008)	Reported motility and progression was the most comparable and closest to the media control at all testing time points (ConceivEase: 60% motility & 3.0+ prog., 50% motility & 2.5+ prog., and 33% motility & 2.0+ prog. at 1 hr, 24 hrs, and 72 hrs, resp. Control: 60% motility & 3+ prog., 52% motility & 2.5+ prog., 35% motility & 2+ prog., at 1 hr, 24 hrs, and 72 hrs, resp.).	Raw semen sample	
ForeLife fertilitycare lubricant	1	Mowat et al. (2014)	Reported the least vitality rate at 27% and was second least prog. motile cells at 47%. The vitality rate was statistically significant against PreSeed ($p < 0.001$) and Conceive Plus ($p < 0.05$), only, whereas the motility rate was statistically significant ($p < 0.05$ and $p < 0.001$) against the rest of the lubricants and the media control (80%).	DGC prepared sample	
Maybe Baby	1	Mowat et al. (2014)	The reported vitality rate was ~50% but was not statistically significant against other lubricants or control. Prog. motil. was just below 80% and was	DGC prepared sample	

(*continued*)

Table 1. Continued.

Lubricants	Manuscripts	Reference	Key Findings	Type of Semen Samples Tested	Study Note
			statistically greater against lubricants Yes ($p < 0.001$), and Forelife and Sylk ($p < 0.05$), but not significantly different than the media control. DNA fragmentation rate was below 2% and was not significant against other lubricants and the control.		
Sylk	1	Mowat et al. (2014)	Reported reduced vitality rate at ~60–70% but not statistically significant against the media control or other lubricants and had statistically significantly reduced prog. motil cells at 31% after treatment against other lubricants and the media control. The DNA fragmentation rate (<2%) was non-statically significant against other lubricants or the control.	DGC prepared sample	
Inclear [feminine vaginal cleanser]	1	Park et al. (2014)	Reported no statistically significant differences between Inclear and control at 0 and 30 minutes ($p > 0.05$) for concentration and motility, however sperm motility was reduced (49.51 ± 18.49 and 44.84 ± 20.52 at 0 and 30 minutes, resp.) against control (56.21 ± 15.80 and 50.62 ± 18.85 at 0 and 30 minutes, resp.).	DGC prepared sample (alternative method)	Whilst the authors do point out that this product is specifically made as a feminine hygiene product to improve pH, odour and minimize irregular discharge for women, they presume the product can also be used as a vaginal lubricant to 'promote healthy and comfortable sexual activity' because the product contained glycerine.
KY Jelly sensitive	1	Sandhu et al. (2014)	Reported immediate and statistically significant decline ($p < 0.001$) in total motility and prog. motil. within 5 minutes incubation, and further decline to 60 minutes.	DGC prepared sample	Examined lubricants in a time-dependent manner and compared within the treatment samples. No control present.
KY Jelly tingling	1	Sandhu et al. (2014)	Reported immediate and statistically significant decline in total and prog. motil. within 5 minutes incubation, and further decline to 60 minutes. By 60 minutes, total motility, and prog. motil. were near negligible levels (~0%).	DGC prepared sample	Examined lubricants in a time-dependent manner and compared within the treatment samples. No control present.
Mustard oil	1	Sandhu et al. (2014)	Reported no statistically significant effect on total and prog. motil., in which the levels were similar to control (mHTF). Authors noted that mustard oil induced persistent hyperactivation of sperm in all 22 donor samples.	DGC prepared sample	Examined lubricants in a time-dependent manner and compared within the treatment samples. No control present.
Sesame Oil	1	Sandhu et al. (2014)	Reported statistically significant decline ($p < 0.05$) in total and progressive motility after 5 minutes incubation and the decline continued to 60 minutes incubation.	DGC prepared sample	Examined lubricants in a time-dependent manner and compared within the treatment samples. No control present.
Durex (unspecified)	1	Soriano et al. (2021)	Reported average SMI 0.98 and was not statistically significant different to control.	DSUS prepared sample	Authors stated a score of SMI <0.75 is classed 'spermo-toxic'.
Vaginesil/Vagisil	1	Soriano et al. (2021)	Reported average SMI was 0.02 and was found to be 'toxic' at all concentrations after 0.5-hour incubation.	DSUS prepared sample	Authors stated a score of SMI <0.75 is classed 'spermo-toxic'.
Velastisa (ISDIN)	1	Soriano et al. (2021)	Reported mean SMI 0.85 and was found 'toxic' at 10% by 2 hours of incubation (SMI = 0.71).	DSUS prepared sample	Authors stated a score of SMI <0.75 is classed 'spermo-toxic'.
Felis lubricant	1	Vargas et al. (2011)	Reported reduced SMI from 1 hr incubation (SMI = 1.11) to 24 hrs (SMI = 0.52). Increased the mean osmolalities of the solution at 4.15% and 8.3% concentration to 511 mOsm/kg and 734 mOsm/kg.	DGC prepared sample	Authors stated a score of SMI <0.75 is classed 'spermo-toxic'.
Astroglide X	1	Wilson et al. (2017)	Reported statistically significantly reduced prog. motil. vs control ($p < 0.05$). There was no difference between at 5- and 20-mins incubation for prog. motil. (37.45%), but it declined by 60 minutes (29.10%).	Raw semen sample	
Dischem lubricating gel	1	Wilson et al. (2017)	Reported 0% prog. motil. at all timings (5, 20 & 60 mins) that was statistically significant against the control ($p < 0.05$).	Raw semen sample	Dischem is an online-retail store in South Africa. The authors have discussed 'Dischem Lubricating Gel' as a water-based lubricant with glycerine, but the exact name of the lubricant was

(*continued*)

Table 1. Continued.

Lubricants	Manuscripts	Reference	Key Findings	Type of Semen Samples Tested	Study Note
					unspecified. And, since the lubricant was water-based containing glycerine, the authors linked the impact was hypo-osmotic swelling with dissolving of the flagellar membrane.
Purity and Elizabeth Anne	1	Wilson et al. (2017)	Reported prog. motil. was close to the control (53.05% and 43.30% at 5 and 20, and 60 minutes respectively) but was statistically significant less ($p < 0.05$). There was no change in prog. motil. at 5 and 20 mins (42.30 %), but it reduced by 60 mins (31.70%).	Raw semen sample	The authors did not define the exact product used to analyse by Purity and Elizabeth Anne, however they have stated that progressive motility was not significantly detrimental because the lubricant was oil-based.

Where applicable, further information was provided regarding the lubricant and the manuscript. Abbreviations: *DGC – density gradient centrifugation; DSUS – direct swim-up from semen; prog. Motil – progressive motility*. Note: the units are reported as found in the original manuscript.

Yes, KY Jelly Warming) were placed since most of the published findings found detrimental impact on sperm motility following treatment. The remaining 25 VLs were placed under the Amber rating as the data appeared to be inconclusive for one lubricant (i.e. Conceive Plus) and the others had only 1 manuscript.

In addition to reporting the key findings of the lubricants studied, we highlighted if the lubricant was tested against raw semen samples or a prepared sample (see Table 1). Among the 35 OTC VLs, each were tested differently in each manuscript, either by using it as a fresh raw sample, prepared using density gradient centrifugation (DGC), or direct sperm swim-up (DSUS) preparation. 22 VLs were tested using raw semen samples across 11 different manuscripts, 19 VLs among 6 manuscripts were tested on samples after DGC preparation, and 4 VLs from 1 manuscript were tested using samples prepared with DSUS preparation.

The technical methods used to analyse the different semen characteristics were not standardized across the included manuscripts. These technical methods were analysed for conformance to the Björndahl et al. (2016) checklist for reporting the results of sperm motility, vitality, and morphology assessments (Table 3). Overall, most manuscripts did not sufficiently outline the methodologies they used to assess these semen characteristics. Whilst 52.6% (10/19) cited that they followed the relevant WHO recommendations when performing the initial handling and analysis to select normozoospermic samples prior to VL incubation, only 21% (4/19) cited they used the WHO recommendations when assessing semen characteristics following the VL treatments. Of these 4 studies, only 1 outlined the technical method in full, as assessed using the Björndahl et al. (2016) checklist (See Table 3).

Discussion

At present there are no guidelines or recommendations for HCPs and couples TTC to consult to help them choose a VL that is 'sperm-safe'. To offer clarity on this, we have categorized all VLs identified in our literature search as Red, Amber or Green based not only on their reported effect on sperm function but also the number of manuscripts reporting these findings and how consistence their reported findings were, including how standardized their semen analysis methods were. Based on our analysis presented herein, we do not currently believe that there is sufficient evidence for a robust guidance or recommendation to be formulated. The majority of VLs were

Table 2. RAG traffic light system of the 35 OTC lubricant categorized according to what most studies reported their findings on sperm motility.

Lubricants	Total Articles	Positive Findings	Negative Findings
PreSeed	8	6	2
Baby oil Johnson's	3	3	0
Canola oil	2	2	0
Egg white	2	2	0
KY Jelly	10	3	7
Astroglide	5	0	5
Replens	4	0	3
Olive oil	4	1	3
Yes	2	0	2
KY Jelly Warming	2	0	2
Conceive plus	2	1	1
Alpha-Keri	1		
Astroglide X	1		
ConceivEase	1		
Dischem lubricating gel	1		
Durex	1		
Felis lubricant	1		
ForeLife fertilitycare lubricant	1		
Inclear [feminine vaginal cleanser]	1		
Keri lotion	1		
KY jelly sensitive	1		
KY jelly tingling	1		
Maybe baby	1		
Mustard oil	1		
Peanut oil	1		
Purity and Elizabeth Anne	1		
Safflower oil	1		
Sesame oil	1		
Skin lotion Searle	1		
Sylk	1		
Touch	1		
Vaginesil/Vagisil	1		
Vaseline/Petroleum jelly	1		
Vegetable oil	1		
Velastisa (ISDIN)	1		

Lubricants studied only once were excluded from categorizing as either positive or negative, instead they were placed into Amber as Inconclusive. The reason for this as there is insufficient data to begin making conclusions based on one study alone.

categorized as Amber due to there being an insufficient number of articles published to draw any conclusive results and undertake robust evidence synthesis, or because of heterogenous findings (*i.e.* Conceive Plus). The RAG rating is useful in its purpose to highlight how many manuscripts did find positive or negative outcomes of VLs against sperm motility, a very important functional parameter of the cell. Unfortunately, by having most manuscripts focus on sperm motility only, other functional parameters such as vitality, total count or concentration, morphology, the ability to fertilize a cell, or the overall function within the female reproductive tract following treatment could not be used to categorize VLs using the RAG rating. Sperm motility is known to be related to pregnancy rates (Barratt et al., 2011), and therefore any compound that lowers sperm motility may impact the success of couples actively trying to conceive. However, if a lubricant has no impact on sperm motility this doesn't necessarily mean that a lubricant can be labelled as 'sperm-safe' as it has been well noted that there are many other factors (for example, the ability of sperm to undergo the acrosome reaction or sperm hyperactivation) that impact the ability of a sperm to fertilize an oocyte. Henceforth, for VLs with no obvious impact on sperm motility, (i.e. PreSeed) further tests on their impact on other functional parameters of sperm are required before we can be certain whether they are fully safe to be used by couples actively trying to conceive. Furthermore, to the best of our knowledge, there is no published manuscript that has assessed whether the impact of lubricants known to decrease sperm motility can be reversed making it difficult at this stage to confidently label any VL as 'sperm-safe'.

As mentioned previously, the reliability of the results of a semen analysis are dependent on the technical methods used to assess the different semen characteristics, with the WHO recommendations providing up to date evidence-based recommendations to help laboratories standardize these methods. Interestingly, only one manuscript fully outlined the technical methods that they followed when assessing sperm motility (Mackenzie & Gellatly, 2019) with all other manuscripts only providing partial information regarding the technical steps they followed, or simply stating that they followed relevant WHO recommendations without providing specific details. For the latter manuscripts, we are currently not able to fully assess the quality of their semen analysis results and therefore the reliability of their results. Inconsistent outcome reporting and definitions of these outcomes makes the evidence synthesis challenging and a meta-analysis not possible at this stage, limiting the utility of these studies to inform clinical practice, a not uncommon finding in the field of male reproductive health (Rimmer et al., 2022). When reviewing the manuscripts, most focused on the impact of VLs on sperm motility in washed and prepared sperm, with most of these manuscripts detailing different experimental approaches (i.e. lubricant concentration and incubation time). *In vivo* sperm are most likely to encounter a VL when they are in semen, therefore a comparison of a VLs impact on sperm function in semen and washed and prepared samples is required in the future. Mortimer et al. (2013) recommended that in addition to performing a basic semen analysis to assess whether a compound is 'sperm-safe', further assays to measure a compound's impact on other markers of sperm function not assessed in a basic semen analysis should also be performed prior to

Table 3. Checklist of the publications looking at the OTC lubricants cross-checked against the (Björndahl et al., 2016) guidance when reporting technical methods used when performing a semen analysis.

Study	OTC Lubricant(s) Studied	Cited WHO manual for basic semen analysis	Used WHO manual for post-treatment testing	Motility	Vitality	Morphology	DNA Damage
Abadie and Lambert (2014)	PreSeed	No	No	0 / 7	N/A	0 / 6	
Agarwal et al. (2008)	KY Jelly, PreSeed, Astroglide, Replens	WHO 2010	No	0 / 7	N/A	N/A	X
Agarwal et al. (2013)	PreSeed	WHO 2010	WHO 2010	1 / 7	3 / 3	N/A	X
Anderson et al. (1998)	KY Jelly, Olive Oil, Baby Oil	WHO 1992	No	2 / 7	N/A	N/A	
(Frishman et al., 1992)	KY Jelly, Astroglide	WHO unspecified	No	0 / 7	N/A	N/A	
Goldenberg and White (1975)	KY Jelly, Olive Oil, Alpha-Keri, Keri lotion, Peanut Oil, Safflower Oil, Skin lotion Searle, Vaseline, Vegetable Oil	No	No	0 / 7	N/A	N/A	
Kutteh et al. (1996)	KY Jelly, Astroglide, Replens, Olive Oil, Canola Oil, Touch	WHO 1992	No	2 / 7	1 / 3	N/A	
Kutteh et al. (2008)	PreSeed, Astroglide, Replens, KY Jelly Warming, ConceivEase	No	No	1 / 7	N/A	N/A	
Mackenzie and Gellatly (2019)	KY Jelly, PreSeed	No	WHO 2010	7 / 7	1 / 3	N/A	
Markram et al. (2022)	PreSeed, Olive Oil, Yes, Egg White	WHO 2010	WHO 2010	4 / 7	N/A	N/A	
Mowat et al. (2014)	KY Jelly, PreSeed, Baby Oil, Yes, Conceive Plus, Forelife, Maybe Baby, Sylk	WHO 2010	WHO 1999	1 / 7	1 / 3	N/A	X
Park et al. (2014)	Inclear feminine cleanser	No	No	0 / 7	N/A	N/A	
Sandhu et al. (2014)	PreSeed, Astroglide, Baby Oil, Canola Oil, KY Jelly Warming, KY Jelly Sensitive, KY Jelly Tingling, Mustard Oil, Sesame Oil	WHO 2010	No	1 / 7	N/A	N/A	
Soriano et al. (2021)	KY Jelly, Durex, Vagisil, Velastisa (ISDIN)	WHO 2010	No	0 / 7	0 / 3	N/A	
Schoeman and Tyler (1983)	KY Jelly	WHO 1980	No	0 / 7	N/A	N/A	
Tagatz et al. (1972)	KY Jelly	No	No	0 / 7	1 / 3	N/A	
Tulandi and McInnes (1984)	Egg white	No	No	0 / 7	N/A	N/A	
Vargas et al. (2011)	PreSeed, Replens, Felis Lubricant	WHO 2010	No	0 / 7	0 / 3	N/A	
Wilson et al. (2017)	Conceive Plus, Astroglide X, Dischem lubricating gel, Purity and Elizabeth Anne	WHO 2010	WHO 2010	2 / 7	N/A	N/A	

labelling anything as 'sperm-safe' of sperm. Many manuscripts did not report on rates of conception or pregnancy outcomes, likely to be the primary motivation a couple are attending a fertility clinic, which limits these studies utility to inform clinical practice.

These findings call for concern since most of the manuscripts focused on the effects of VLs on sperm motility only, with the majority of them failing to outline the technical steps they used when assessing sperm motility, limiting our ability to judge the reliability of the results of all the other manuscripts (Björndahl et al., 2016; Vasconcelos et al., 2022; World Health Organization, 2021). Furthermore, some of the publications reported the sperm motility data with SMI values or a sperm progression rating system for either the impact on motility or vitality following lubricant treatment (Goldenberg & White, 1975; Markram et al., 2022; Soriano et al., 2021; Vargas et al., 2011).

Using SMI values or a sperm progression rating system is an alternative method to reporting sperm motility data, however the lack of reporting of the essential steps required when performing a standard motility analysis is not explained. For vitality assessments, there was noted similar compliance to reporting of the criteria as there was for motility assessments, with 1 out of 7 studies reporting 3 out of 3 criteria (Agarwal et al., 2013). Whilst progressive motility has both biological and clinical importance for *in vivo* and *in vitro* conception (Barratt et al., 2011; Björndahl et al., 2010), other aspects of sperm function also influence whether a progressively motile sperm is able to fertilize an oocyte (ability to undergo the acrosome reaction, sperm hyperactivation etc) and therefore should be taken more into account.

When reviewing the compositions of the OTC VLs tested, for some of them there were discrepancies between the ingredients noted by the manufacturer and those reported in the manuscripts. The differences were either missing or new compounds reported, or differently ordered lists. Products' ingredients can

change over time by the manufacturers, and whilst there is no present legislation preventing products from being altered, they still must adhere to the current regulations of different countries for accurately reporting their ingredients lists (European Commission, 2019; Medicines and Healthcare Products Regulatory Agency Delivery Plan 2021–2023, (2022); Office for Product Safety and Standards, 2021). Therefore, if we were to assume that at the time of publication and study of these lubricants the ingredients list was correct, this may provide additional explanation as to why there is such heterogeneity among the published data of the VL impact on sperm function. One example would be KY Jelly, a lubricant that was studied since 1972, yet 7 out of 10 studies found detrimental and negative effects on sperm motility, while the other 3 did not report statistically significant impacts, or the differences were non-significant compared to the control of the study for sperm motility. As this product has been commercially available for several decades, its formulation may have changed over time, and therefore changes to the composition of KY Jelly may explain slight difference in the results described in these different studies. For that reason, future studies attempting to demonstrate lubricants impact on sperm function should consider quantifying the exact ingredients and concentrations of the testing product to clearly outline if the reported ingredients are accurate.

Conclusions

Presently, there is insufficient evidence to formulate a robust guidance or recommendation for HCPs and couples regarding the impact of VLs on sperm function. Based on our results, we can only recommend and categorize lubricants based on their reported impact on sperm motility which is restrictive when considering the overall safety of any product, particularly for couples who are actively trying to conceive, as many other factors in addition to sperm motility can impact sperm's ability to fertilize an oocyte. The current recommendations should be taken with caution as the many of the included manuscripts did not fully illustrate that they performed the standardized method of assessing sperm motility, and the different manuscripts did not standardize the VL concentration or incubation time making comparison of manuscripts and drawing conclusions difficult. Despite what some of the identified studies may state regarding KY Jelly or Replens being 'spermo-toxic' based on their sperm motility assessments (Soriano et al., 2021; Vargas et al., 2011), further research is required and appropriate assays to be performed to understand if the product is truly 'spermo-toxic' (Mortimer et al., 2013). Furthermore, in the case of VLs shown not to impact sperm function further tests are required to assess their impact on other factors known to be important for fertilization, such as the sperm's ability to successfully complete the acrosome reaction, sperm hyperactivation, and other markers of sperm capacitation. The results reported, herein, are important as they allow us to gauge the gaps and shortcomings in current data regarding the impact of VLs on sperm function revealing clear evidence-based recommendations to guide future research.

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Authors' roles

EG and SAG performed the initial study design. EG performed the original data collection and data analysis as part of her MSc research project under School of Medicine, University of Dundee. The initial draft of the manuscript was written by EG and SAG, followed by discussions and further drafting by MPR. All authors contributed to the writing and editing of the final draft of the manuscript.

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Data availability statement

The data underlying this article will be shared on reasonable request to the corresponding author.

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