Received: 29 June 2019 | Revised: 8 October 2019 | Accepted: 27 October 2019

DOI: 10.1111/ppe.12612

SPECIAL ISSUE: LEVERAGING TECHNOLOGY

Paediatric and Perinatal Epidemiology WILEY

At-home sperm testing for epidemiologic studies: Evaluation of the Trak male fertility testing system in an internet-based preconception cohort

Greg J. Sommer[1] | Tanran R. Wang[2] | Jon G. Epperson[1] | Elizabeth E. Hatch[2] | Amelia K. Wesselink[2] | Kenneth J. Rothman[2] | Laura L. Fredriksen[1] | Ulrich Y. Schaff[1] | Barry Behr[3] | Michael L. Eisenberg[3,4] | Lauren A. Wise[2]

[1]Sandstone Diagnostics, Inc., Pleasanton, CA, USA

[2]Department of Epidemiology, Boston University School of Public Health, Boston, MA, USA

[3]Department of Obstetrics and Gynecology, Stanford University, Stanford, CA, USA

[4]Department of Urology, Stanford University, Stanford, CA, USA

Correspondence
Greg J. Sommer, Sandstone Diagnostics, Inc., Pleasanton, CA USA.
Email: gsommer@sandstonedx.com

Funding information
Eunice Kennedy Shriver National Institute of Child Health and Human Development, Grant/Award Number: R01HD086742 and R21HD072326

Abstract

Background: Semen quality assessment in population-based epidemiologic studies presents logistical and financial challenges due to reliance on centralised laboratory semen analysis. The Trak Male Fertility Testing System is an FDA-cleared and validated at-home test for sperm concentration and semen volume, with a research use only sperm motility test. Here we evaluate the Trak System's overall utility among men participating in Pregnancy Study Online (PRESTO), a web-based study of North American couples planning pregnancy.

Methods: US male participants aged ≥21 years with ≤6 months of pregnancy attempt time at study enrolment were invited to participate in the semen testing substudy after completing their baseline questionnaire. Consenting participants received a Trak Engine (battery-powered centrifuge) and two test kits. Participants shared their test results via smartphone images uploaded to online questionnaires. Data were then linked with covariate data from the baseline questionnaire.

Results: Of the 688 men invited to participate, 373 (54%) provided consent and 271 (73%) completed at least one semen test result. The distributions of semen volume, sperm concentration, motile sperm concentration, total sperm count, and total motile sperm count were similar to 2010 World Health Organization (WHO) semen parameter data of men in the general population. The overall usability score for the Trak System was 1.4 on a 5-point Likert scale (1 = Very Easy, 5 = Difficult), and 92% of participants believed they performed the test correctly and received an accurate result. Lastly, men with higher motile sperm count were more likely to report feeling "at ease" or "excited" following testing, while men with low motile sperm count were more likely to report feeling "concerned" or "frustrated." Overall, 91% of men reported they would like to test again.

Conclusions: The Trak System provides a simple and potentially cost-effective means of measuring important semen parameters and may be useful in population-based epidemiologic fertility studies.

1 | INTRODUCTION

The cornerstone of male fertility evaluation remains laboratory semen analysis—a microscopic evaluation of a man's ejaculate to measure important semen parameters associated with men's fertility status.[1-3] For the purposes of preconception epidemiologic studies of couples trying to conceive (TTC), conventional semen analysis presents several barriers for data collection including high cost,[4] participant apprehension and inconvenience,[5] logistics and scheduling, and inter-laboratory variation of semen analysis techniques.[6,7] As a result, male fertility studies are often limited to recruitment of men seeking infertility evaluation and treatment at a single site (often in a clinical setting) with retrospective assessment to environmental, health, and life style factors.[8,9] Thus, few prospective preconception studies have successfully collected semen data from a geographically heterogeneous population of men.[10-13] Furthermore, as studies continue to report strong associations between male fertility status and overall health,[14-16] there is an urgent need for improved data collection technologies to assess semen parameters more accurately and cost-effectively across a diverse male population.

Pregnancy Study Online (PRESTO) is an NIH-funded Internet-based preconception study in the United States (US) and Canada.[17] Its primary aim is to evaluate the association of selected life style, behavioural, and environmental factors with fertility and pregnancy outcomes among pregnancy planners.[18-21] PRESTO recruits women (aged 21-45 years) and their male partners (aged ≥ 21 years) who are not using any assisted reproductive technologies and who are actively trying to conceive. Female PRESTO participants complete a series of bimonthly online surveys for up to 12 months or until they report conception. Consenting male partners complete baseline surveys upon enrolment, typically within a few days of female partner enrolment (median: 1 day, interquartile range: 0-5 days). As of September 2019, PRESTO has enrolled more than 11 250 women and 2575 men, and recruitment is ongoing.

Synopsis

Study question

Is the Trak At-Home Male Fertility Testing System a useful tool for collecting semen quality data in population-based epidemiologic studies?

What's already known

Few prospective preconception studies have successfully collected semen data from a geographically heterogeneous population of men due to the logistical challenges associated with centralised laboratory semen analysis. Trak tests have been previously validated against gold standard semen analysis methods.

What this study adds

Trak kits were sent to 373 US male participants in the web-based Pregnancy Study Online (PRESTO). Two hundred and seventy one (73%) completed at least one semen test. User survey scores and the semen parameter population distribution (sperm concentration, motility, and semen volume) suggest Trak provides a simple and potentially cost-effective tool for collecting semen data in epidemiologic studies.

The Trak® Male Fertility Testing System is an FDA 510(k)-cleared class II medical device enabling men to measure their sperm concentration and semen volume at home (Figure 1).[22,23] The Trak System comprises a battery-powered mini-centrifuge (Engine), single-use plastic cartridges for measuring sperm concentration (Props), and sample collection cups that also measure semen volume (Volume Cups).[24] Based on CentriFluidic

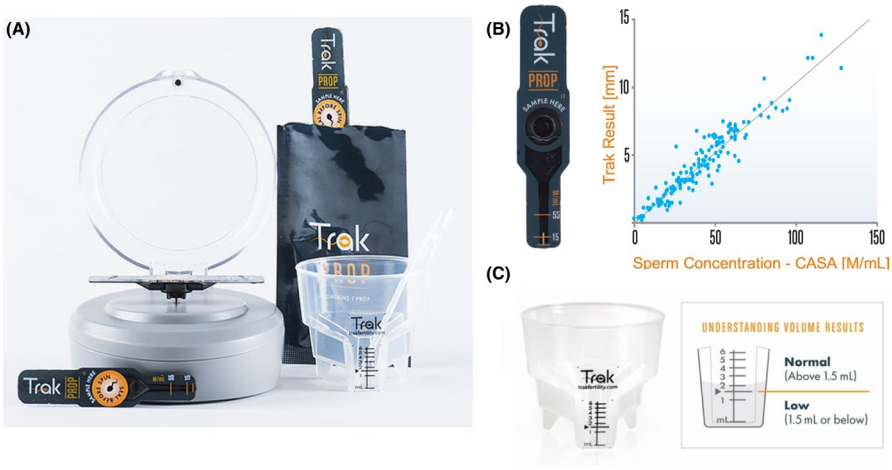

FIGURE 1 Trak Male Fertility Testing System overview. A, Trak Engine, Prop, Volume Collection Cup, and Sample Dropper. B, Sperm concentration results—sperm cells concentrate in the outer measurement window of the Prop during the 5-minute spin in the Trak Engine. The visual height of the white sperm cell pellet directly correlates with sperm concentration, as shown in the plot comparing Trak results with gold standard laboratory measurements via computer-aided semen analysis (CASA). C, The Trak Volume Collection Cup provides a measurement of semen volume between 0 and 6 mL by funnelling the sample into the graduated volume measurement window

technology from Sandstone Diagnostics, Trak users collect their sample into the cup, measure their semen volume (in millilitres, mL), load approximately 0.25 mL of semen into the Prop, and spin the Prop for ~6 minutes in the Trak Engine. Upon completion of the spin sequence, Trak provides a visual measurement of sperm concentration measured in millions of sperm cells per millilitre semen (M/mL). The Trak sperm concentration assay has been validated against gold standard laboratory semen analysis, including a 3-site, 239-patient blinded clinical trial in which lay users collected and tested their semen using the Trak System in a simulated home environment, in parallel with analysis via computer-aided semen analysis (CASA) in the laboratory as well as by Trak by a trained technician.[22] The study demonstrated that Trak's test meets the accuracy of the laboratory test, that results are linear when comparing Trak results with CASA results, and that lay users can use and interpret the test appropriately as per FDA's guidelines around home use diagnostic devices.

Motile sperm concentration is measured using a Trak Prop containing a modified liquid density medium engineered to separate motile cells from immotile cells. The Trak motility assay is currently for research use only, but it has been calibrated against gold standard laboratory semen analysis using serial dilutions of highly motile semen samples.[25] At ~$45/kit, comprising the Trak Engine and 2 tests ($22.50/sample), Trak is highly cost-effective relative to clinic testing ($250-$350/sample) and freeze-and-send methods ($300/sample).[12] In September 2015, PRESTO initiated a substudy in which a subset of male participants were mailed a research-grade Trak® System to measure and report their semen parameters at home. In this report, we evaluate the device's utility for epidemiologic applications among substudy participants who enrolled from 25 September 2015 through 9 September 2019.

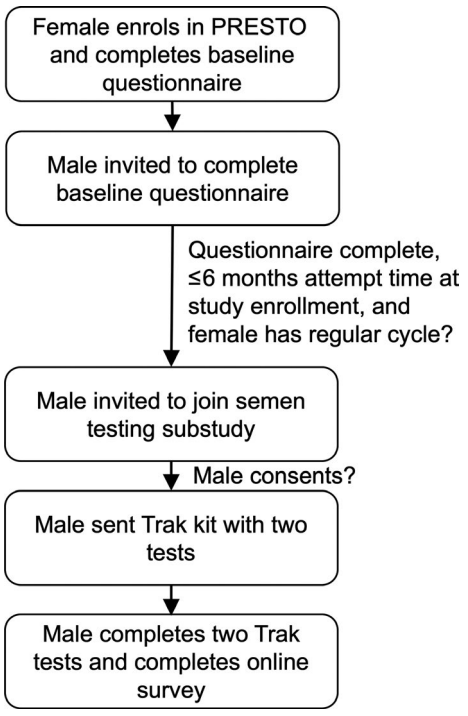

FIGURE 2 PRESTO/Trak semen testing substudy design

2 | METHODS

US male PRESTO participants with ≤6 months of pregnancy attempt time at study enrolment, and whose female partners reported a regular menstrual cycle ("regular in a way that you can predict about when your next period will start?"), were invited to participate in the semen testing substudy (Figure 2). Within 1 day of completion of the male baseline questionnaire, an email was sent to male participants inviting them to enrol in the substudy. Consenting participants were mailed a Trak Engine, two test kits, and instructional guide. Participants were asked to complete both Trak tests within 7-10 days of each other during their partner's luteal phase. Participants were instructed to abstain from ejaculation for 2-7 days before testing and to collect the entire sample in the provided collection cup via masturbation and without the use of condoms or lubricants. Participants were also asked to aim for a consistent abstinence time before both tests. Figure 3 illustrates the steps that users take to complete each test. As shown in step 4, the participants were instructed to capture smartphone photographs of their test results using a supplied "Test Card" to enable results quantification via image analysis. Users uploaded the photographs via an online questionnaire, which also included questions about test usability, feedback on the product, their emotional response to their test results, and their feelings about next steps, including their willingness to perform additional testing. Upon successfully uploading their second set of test results, users were emailed a $20 gift card for their participation. The semen substudy was reviewed and approved by the Boston University Medical Campus Institutional Review Board (protocol number: H-31848).

Three different versions of the Trak System hardware were deployed over the course of the substudy (25 September 2015 through 9 September 2019) as new tools and features became available. The two revisions to the original device included (1) addition of the Trak Volume Cup, a semen collection cup that also measures semen volume (previously, users measured semen volume by transferring their sample from a conventional sample cup to a 10 millilitre graduated tube) and (2) addition of the investigational sperm motility test enabling measurement of motile sperm concentration alongside total sperm concentration.

Participants shared their test results by completing self-administered online questionnaires and uploading smartphone images of the visual Trak results. Individual results were averaged for those participants who uploaded both test results between 25 September 2015 and 9 September 2019. Trak provided users with direct results on semen volume, sperm concentration, and motile sperm concentration. Upon receiving these results, investigators then calculated per cent motility, total sperm count, and motile sperm count as follows:

Motility (%) = Motile sperm concentration (M/mL)/sperm concentration (M/mL)

Total sperm count (M) = sperm concentration (M/mL) × semen volume (mL)

Total motile sperm count (M) = motile sperm concentration (M/mL) × semen volume (mL)

Data were then linked with covariate data from the PRESTO baseline questionnaire.

3 | RESULTS

3.1 | Study participation and compliance

Table 1 shows the number of men who were invited, consented, and participated in the semen testing substudy. Note that recruitment and testing remain ongoing as of submission of this manuscript, so the percentages listed in Table 1 for completing the first and second tests may likely increase as new results are collected. During 29 months of total recruitment, 373 of the 688 men (54%) invited to the substudy completed the online consent form and were mailed a Trak kit. Two hundred and seventy one of those 373 men (73%) submitted their first test results and completed the online survey, and 195 of the 271 men (52%) successfully completed and reported both tests to fulfil their study obligation and were emailed the $20 e-gift card.

Table 2 compares the baseline characteristics of men who consented to the semen testing substudy with those who were invited but did not consent, as well as to the full cohort of male PRESTO participants. Substudy participants resided in 44 of the 48 contiguous US states (Alaska and Hawaii residents were ineligible for inclusion). The median age of semen testing substudy participants was 31,

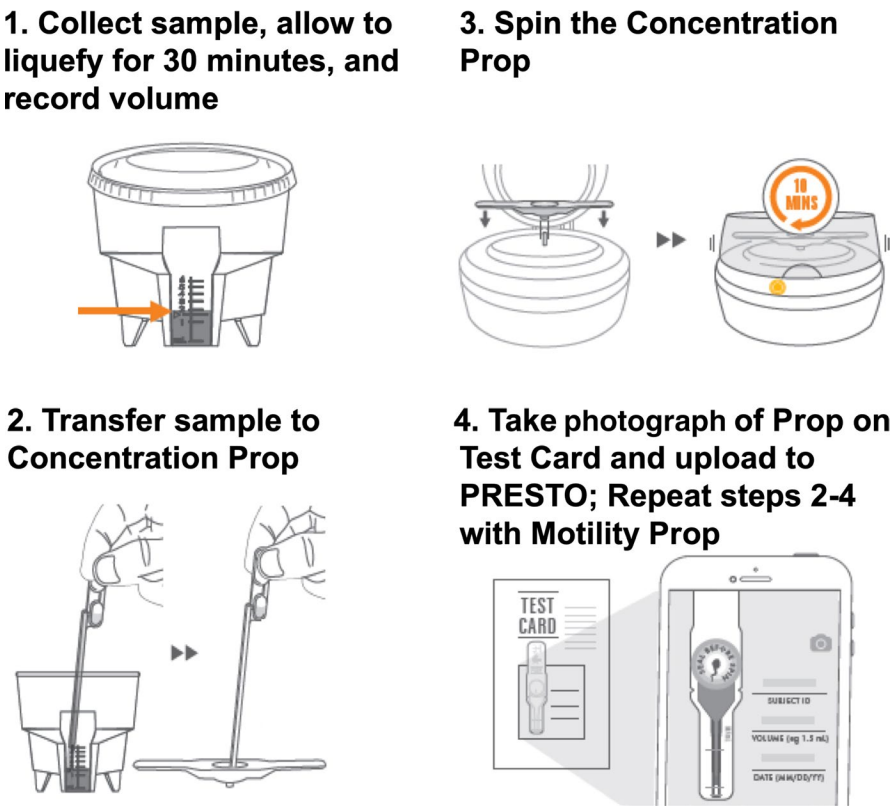

FIGURE 3 Trak System testing and reporting steps

TABLE 1 Male participants who were invited, consented, and successfully completed semen testing substudy

Trak system hardware variation	Invited to participate	Consented to participate	Successfully uploaded first result and completed survey	Successfully uploaded second result and received $20 e-gift card
1. Sperm count test + semen volume via graduated tube	84	44 (52.4%)	36 (81.8%)	26 (59.1%)
2. Sperm count test + semen volume via Volume Collection Cup	67	39 (58.2%)	27 (69.2%)	19 (48.7%)
3. Sperm count test + sperm motility test + semen volume via Volume Collection Cup*	537*	290 (54.0%)*	208 (71.7%)*	150 (51.7%)*
Totals	688	373 (54.2%)*	271 (72.7%)*	195 (52.3%)*

*This portion of the study is ongoing as of submission of this manuscript. Completion rates may increase as results are collected from men who recently consented but have not yet reported test results.

TABLE 2 Baseline characteristics of PRESTO participants, overall and by consent to semen testing study

Characteristic	Full cohort (N = 2,552)	Invited to semen study (N = 688)	
		Consent (N = 373)	No consent (N = 315)
Age at baseline, years (median, range)	31 (20-65)	31 (21-54)	31 (20-47)
Attempt time at study entry, months (median)	2	1	1
≥16 y of education (%)	63.5	66.5	61.6
White, Non-Hispanic (%)	84.4	84.2	83.5
Northeastern United States (%)	24.2	24.9	19.1
Southern United States (%)	23.6	26.5	28.6
Midwestern United States (%)	21.9	26.3	34.0
Western United States (%)	16.2	22.3	18.4
Body mass index (BMI), kg/m^2 (median)	27.1	27.9	27.1
Current smoker (%)	8.9	7.5	7.0
Vigorous physical activity, hrs/wk (median)	1.5	1.5	1
Major Depression Inventory score (median)	8	8	7
Perceived Stress Scale-10 score (median)	15	15	14
Ever impregnated female partner (%)	45.6	45.0	50.5
History of infertility at study entry (%)	16.0	8.0	7.9

with 66% reporting at least a college education and 45% reporting a previous conception. The average BMI of substudy participants was 27.9 kg/m^2 (overweight according to current CDC guidelines[26]). In general, there were few differences between those who did and did not consent to participate in the semen testing substudy, and substudy participants broadly reflect the full cohort population, with the exception of a slightly shorter pregnancy attempt time at study entry (median of 1 month vs 2 months) and a lower percentage with past infertility (8.0% vs 16.0%). However, these differences were related primarily to the substudy restrictions (ie pregnancy attempt time of ≤6 months).

3.2 | Test ease-of-use ratings

Figure 4 shows a summary of participant responses to survey questions regarding the ease of use for each step of the testing process. Responses were gathered using a 1-5 Likert scoring scale (1 = Very Easy, 5 = Difficult).

The overall average rating across all participants and test steps was 1.4, with 92% of all responses rated either "Very Easy" or "Easy." The test procedure steps scored that received the most "Difficult" or "Very Difficult" ratings were "Collecting the sample into the cup" (5%), "Using the sample dropper" (7%), and "Interpreting the results" (9%). Because the response averages were nearly identical across versions of the test kit (as described in Figure 1), we report the overall scores only.

In addition, 91% of the participants reported they believed they performed the test correctly and received an accurate result.

3.3 | Semen parameter distributions

Table 3 shows the distribution of baseline semen parameter results for participants in the semen testing substudy (top row in bold). To evaluate the population results, we also show the distributions of two comparative datasets: (1) the reported 2010 WHO analysis of semen parameters in men in the general population (second row)[27] and (2) semen parameter data collected from 4467 male patients in the Stanford University Andrology Laboratory since September 2015 (third row). Comparing the population distributions suggests the semen parameter data collected via the Trak System were distributed as expected for a general population-based cohort of men aged 24-40 (semen volume (mL): median = 3.8, interquartile range (IQR): 3.0-4.8; sperm concentration (M/mL): median = 54, IQR: 30-88; total sperm count (M): median = 201, IQR: 104-315; motile sperm concentration (M/mL): median = 26, IQR: 12-46; motility (%): median = 52; IQR: 36-69; motile sperm count (M): median = 101, IQR: 44-174).

3.4 | Emotional response to test results

To better understand men's reactions to self-testing and learning their semen parameter results, we asked participants to select which

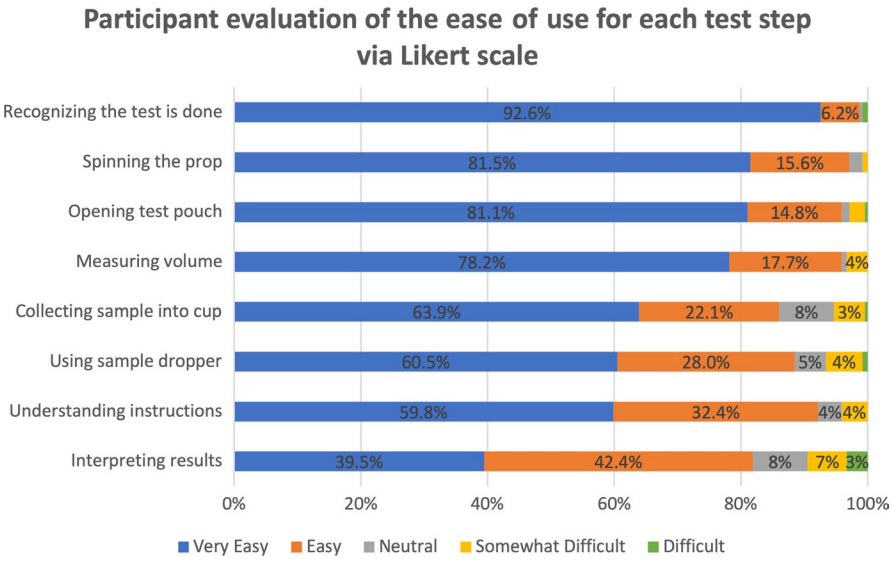

FIGURE 4 Participant evaluation of the ease of use for each test step via Likert scale

	Percentile						
	5	**10**	**25**	**50**	**75**	**90**	**95**
Semen volume (mL)							
PRESTO	**1.5**	**2.1**	**3.0**	**3.8**	**4.8**	**6.0**	**6.0**
WHO	1.2	1.6	2.2	3.2	4.2	5.5	6.4
Stanford	0.8	1.0	2.0	2.5	3.6	5.0	6.0
Sperm concentration (M/mL)	**8**	**15**	**30**	**54**	**88**	**129**	**158**
	9	17	36	64	100	192	192
	4	11	26	51	88	123	148
Motile sperm concentration (M/mL)	**1**	**6**	**12**	**26**	**46**	**80**	**115**
	-	-	-	-	-	-	-
	1	1	5	18	46	80	98
Motility (%)	**13**	**23**	**36**	**52**	**69**	**85**	**90**
	36	45	55	62	70	85	85
	7	11	20	37	57	70	76
Total sperm count (M)	**27**	**45**	**104**	**201**	**315**	**503**	**623**
	20	45	101	196	336	619	619
	8	20	58	127	234	367	460
Motile sperm count (M)	**4**	**18**	**44**	**101**	**174**	**285**	**392**
	-	-	-	-	-	-	-
	1	3	12	44	121	219	295

TABLE 3 Semen parameter distributions in PRESTO semen testing substudy cohort (bold, top row) compared with the 2010 WHO distributions of men from the general population (second row) and sperm parameters in 4467 men tested at the Stanford University Andrology Lab since September 2015 (third row)

Note: that motile sperm concentration and motile sperm count results are not available in the WHO population.

emotions best captured their mindset after completing their first test. The results are shown in Table 4. The majority (59%) of participants reported feeling "at ease" while small numbers reported feeling "concerned" (17%), "frustrated" (5%), or "confused" (7%).

The participants' positive or negative reactions generally correlated with the magnitude of their test results. For example, participants who responded feeling "concerned" had a mean motile sperm count of 50 M, while those who responded feeling "at ease" had a mean motile sperm count of 152 M (mean difference: −102 M, 95% CI: −131, −73 M).

In addition, 91% of the participants reported that they would indeed test again if provided with additional test kits.

TABLE 4 Participants' emotional response upon completing their first test

		Mean semen parameter values					
	N	Semen volume (mL)	Sperm concentration (M/mL)	Motile sperm concentration (M/mL)	Motility (%)	Total sperm count (M)	Motile sperm count (M)
At ease							
Yes	143 (59%)	3.9	74	41	55	279	152
No	101 (41%)	3.8	45	24	47	158	88
Concerned							
Yes	42 (17%)	4.0	23	12	35	92	50
No	202 (83%)	3.8	70	39	55	258	143
Frustrated							
Yes	11 (5%)	3.6	25	14	40	95	59
No	233 (96%)	3.9	64	35	52	235	130
Confused							
Yes	18 (7%)	3.8	43	20	44	159	80
No	226 (93%)	3.9	63	36	52	235	132
Excited							
Yes	46 (19%)	3.6	87	53	59	298	169
No	198 (81%)	3.9	56	30	50	213	118
Want more information							
Yes	87 (36%)	3.9	56	29	51	209	111
No	157 (64%)	3.8	65	38	52	240	138
Eager to test again							
Yes	99 (41%)	3.7	64	36	51	227	122
No	145 (59%)	3.9	60	34	52	230	131
Do not want to test again							
Yes	5 (2%)	3.7	56	9	63	176	49
No	239 (98%)	3.9	62	35	52	230	127

4 | COMMENTS

4.1 | Principal findings

This study evaluated the use of a novel at-home semen testing technology to complement the PRESTO Internet-based fertility study. More than 50% of men who were invited to participate in the semen testing substudy provided consent, 73% of those men recorded at least one semen test result, and 52% completed both test results. The reported semen testing completion rates in previous preconception studies were 77% and 55% for the first and second samples, respectively, in the 1992-1994 Danish study of 430 couples trying to conceive,[13] and 93% and 80% in the 2005-2009 *Longitudinal Investigation of Fertility and the Environment* (LIFE) study of 501 couples trying to conceive in Michigan and Texas.[10] Completion rates in PRESTO were similar to those in the Danish study, but slightly lower than the LIFE study, which may relate to PRESTO being entirely virtual rather than involving in-person visits or interviews, and the added requirement that participants complete testing on their own.

The distributions of semen volume, sperm concentration, motile sperm concentration, total sperm count, and motile sperm count were as expected for a population-based cohort of men aged 21-45 years and similar to those from the WHO normative population.[27] The Stanford population results generally fall lower than both the WHO and PRESTO results, which may be expected since the Stanford University Andrology Lab data primarily comprise men seeking fertility treatment.

Survey results regarding ease of use of the Trak System indicate that the device is simple to operate and interpret by lay users. Moreover, participants' emotional reactions to their test results support the Trak System as an effective method of conveying results to patients. At a cost of ~$45 per kit, which includes the Trak Engine and disposables for two tests, the Trak System provides a potentially cost-effective option for collecting semen parameter data in epidemiologic studies.

4.2 | Strengths and limitations

PRESTO's cohort of North American men aged 21-45 years who are trying to conceive provides a more geographically heterogeneous and racially/ethnically diverse population of users for

evaluating performance and usability of the Trak System than cohorts examined in previous semen studies.[11,13,28-30] Using Internet-based reporting and questionnaires removes the need for on-site recruitment, testing, and evaluation that has formerly presented challenges to epidemiologic studies involving semen analysis parameters.

Results are captured using smartphone photo capture and analysed by study staff, thus removing reliability concerns associated with self-interpretation by the participants. This method also does not incur costs and delays related to expedited direct mail services, refrigeration, and laboratory staff costs used for mail-in semen analysis options.

Lastly, semen testing substudy participants are monitored alongside the full PRESTO cohort such that the semen analysis results presented in this work can be studied in association with health and life style factors, along with fecundity and pregnancy outcomes in future analyses.

A limitation of this study is that it did not involve a comparison of participants' individual Trak results with clinical semen analysis results. Validation studies for the Trak System have been published elsewhere.[22,24,25] Furthermore, while the Trak sperm concentration and semen volume tests have been validated and 510(k) cleared by the FDA, the reliability and validity of the motility test have not yet been reviewed by the FDA. Lastly, the Trak System does not capture all semen parameters; other factors such as sperm morphology, progressive motility, round cell count, and DNA fragmentation are not available via this method.

5 | CONCLUSIONS

The Trak System provides a simple and potentially cost-effective means of capturing key semen analysis parameters via at-home testing and reporting. Semen analysis via Trak may be a useful tool in population-based epidemiologic studies of male reproductive health.

ACKNOWLEDGEMENTS

This work was funded by NIH grants R01HD086742 and R21HD072326, and by Sandstone Diagnostics. Sandstone personnel were involved in supplying a portion of the Trak test kits as in-kind donations and in analysing participants' de-identified photographic results.

ORCID

Greg J. Sommer https://orcid.org/0000-0002-3867-7100
Elizabeth E. Hatch https://orcid.org/0000-0001-7901-3928
Kenneth J. Rothman https://orcid.org/0000-0003-2398-1705
Laura L. Fredriksen https://orcid.org/0000-0002-1987-1549
Ulrich Y. Schaff https://orcid.org/0000-0002-4345-020X
Michael L. Eisenberg https://orcid.org/0000-0001-5482-0141
Lauren A. Wise https://orcid.org/0000-0003-2138-3752

REFERENCES

1. American Urological Association. The optimal evaluation of the infertile man. (2010).
2. WHO. *WHO laboratory manual for the examination and processing of human semen*. 5th Edition. Geneva, Switzerland: WHO. 2010.
3. Bjorndahl L, Mortimer D, Barratt CLR, et al. *A Practical Guide to Basic Laboratory Andrology*. Cambridge: Cambridge University Press; 2010.
4. Yu S, Rubin M, Geevarughese S, Pino JS, Rodriguez HF, Asghar W. Emerging technologies for home-based semen analysis. *Andrology*. 2018;6:10-19.
5. Pottinger AM, Carroll K, Mason G. Male attitude towards masturbating: an impediment to infertility evaluation and sperm parameters. *Andrologia*. 2016;48:774-778.
6. Martín Rivera-Montes A, Rivera-Gallegos A, Rodríguez-Villasana E, et al. Estimate of the variability in the evaluation of semen analysis. *Ginecol Obstet Mex* 2013;81:639-644.
7. Filimberti E, Degl'Innocenti S, Borsotti M, et al. High variability in results of semen analysis in andrology laboratories in Tuscany (Italy): the experience of an external quality control (EQC) programme. *Andrology*. 2013;1:401-407.
8. Barratt CLR, De Jonge CJ, Sharpe RM. 'Man Up': the importance and strategy for placing male reproductive health centre stage in the political and research agenda. *Hum Reprod*. 2018;33:541-545.
9. Leung AK, Henry MA, Mehta A. Gaps in male infertility health services research. *Transl Androl Urol*. 2018;7:S303-S309.
10. Buck Louis GM, Schisterman EF, Sweeney AM, et al. Designing prospective cohort studies for assessing reproductive and developmental toxicity during sensitive windows of human reproduction and development–the LIFE Study. *Paediatr Perinat Epidemiol*. 2011;25:413-424.
11. Buck Louis GM, Sundaram R, Schisterman EF, et al. Semen quality and time to pregnancy: the Longitudinal Investigation of Fertility and the Environment Study. *Fertil Steril*. 2014;101:453-462.
12. Eisenberg ML, Kim S, Chen Z, et al. The relationship between male BMI and waist circumference on semen quality: data from the LIFE study. *Hum Reprod*. 2014;29:193-200.
13. Bonde JPE, Ernst E, Jensen TK, et al. Relation between semen quality and fertility: a population-based study of 430 first-pregnancy planners. *Lancet*. 1998;352:1172-1177.
14. Eisenberg ML, Li S, Behr B, et al. Semen quality, infertility and mortality in the USA. *Hum Reprod*. 2014;29:1567-1574.@@@
15. Walsh TJ, Schembri M, Turek PJ, et al. Increased risk of high-grade prostate cancer among infertile men. *Cancer*. 2010;116:2140-2147.
16. Eisenberg ML, Park Y, Hollenbeck AR, et al. Fatherhood and the risk of cardiovascular mortality in the NIH-AARP Diet and Health Study. *Hum Reprod*. 2011;26:3479-3485.
17. Wise LA, Rothman KJ, Mikkelsen EM, et al. Design and conduct of an internet-based preconception cohort study in North America: pregnancy study online. *Paediatr Perinat Epidemiol*. 2015;29:360-371.
18. Wise LA, Rothman KJ, Wesselink AK, et al. Male sleep duration and fecundability in a North American preconception cohort study. *Fertil Steril*. 2018;109:453-459.
19. Wesselink AK, Hatch EE, Rothman KJ, et al. Prospective study of cigarette smoking and fecundability. *Hum Reprod*. 2018;34:558-567.
20. Aschengrau A, Hatch EE, Rothman KJ, et al. Perceived stress and fecundability: a preconception cohort study of North American couples. *Am J Epidemiol*. 2018;187:2662-2671.
21. Hatch EE, Wesselink AK, Hahn KA, et al. Intake of sugar-sweetened beverages and fecundability in a North American preconception cohort. *Epidemiology*. 2018;29:369-378.

22. Schaff UY, Fredriksen LL, Epperson JG, et al. Novel centrifugal technology for measuring sperm concentration in the home. *Fertil Steril*. 2017;107:358-364.e4.
23. Sommer G, Wesselink A, Trinidad T, et al. Using an in-home semen testing system to evaluate total sperm count and time to conception: a pilot study. *Fertil Steril*. 2017;108:e79-e80.
24. Fredriksen LL, Epperson J, Hong K, et al. Design and validation of the trak® volume cup - a dual purpose semen collection and volume measurement device for diagnosing hypospermia. *Fertil Steril*. 2018;110:e275.
25. Fredriksen LL, Epperson J, Sommer G, Schaff U. Development of an at-home sperm motility assay. *Fertil Steril*. 2018;110:e306.
26. Centers for Disease Control and Prevention, S. for A. R. T. Defining Adult Overweight and Obesity. 2019.
27. Cooper TG, Noonan E, von Eckardstein S, et al. World Health Organization reference values for human semen characteristics. *Hum Reprod Update*. 2010;16:231-245.
28. Zinaman MJ, Brown CC, Selevan SG, Clegg ED. Semen quality and human fertility: a prospective study with healthy couples. *J Androl*. 2000;21:145-153.
29. Slama R, Eustache F, Ducot B, et al. Time to pregnancy and semen parameters: a cross-sectional study among fertile couples from four European cities. *Hum Reprod*. 2002;17:503-515.
30. Guzick DS, Overstreet JW, Factor-Litvak P, et al. Sperm morphology, motility, and concentration in fertile and infertile men. *N Engl J Med*. 2001;345:1388-1393.

How to cite this article: Sommer GJ, Wang TR, Epperson JG, et al. At-home sperm testing for epidemiologic studies: Evaluation of the Trak male fertility testing system in an internet-based preconception cohort. *Paediatr. Perinat. Epidemiol.*. 2019;00:1–9. https://doi.org/10.1111/ppe.12612