



Accuracy comparison study of new smartphone-based semen analyzer versus laboratory sperm quality analyzer

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Purpose: This study aimed to test the clinical efficacy of a portable smartphone-based App assisted semen analysis (SA) system, O'VIEW-M PRO[®] to clinically accurate in comparison with results of laboratory-based conventional semen analyses including manual microscopic and computer-assisted semen analysis (CASA) for self-evaluation of seminal parameters.

Materials and Methods: From January to May 2021, a total of 39 semen samples were analyzed for the sperm concentration and motility with new smartphone-based App assisted semen analyzer, O'VIEW-M PRO[®], and results compared with those from laboratory-based manual microscopic SA with Makler Counting Chamber and CASA.

Results: The coefficient factors among the results of the measurement with Makler chamber and laboratory-based CASA comparing to O'VIEW-M PRO[®] were 0.666 and 0.655 for sperm density, 0.662 and 0.658 for sperm motility, respectively. There were no particular problems with clinical use of the O'VIEW-M PRO[®]. Device performance in classifying samples is positive (<15×10⁶ sperm/mL) and negative (>15×10⁶ sperm/mL) for sperm concentration criteria, and positive (<40%) and negative (>40%) for sperm motility criteria. The smartphone-based App assisted SA O'VIEW-M PRO[®] showed a sensitivity of 92.6%, a specificity of 66.7%, and overall accuracy rate of 84.6%.

Conclusions: This study shows a novel smartphone-based App assisted SA system. O'VIEW-M PRO[®] can easily obtain semen parameter information through self-diagnosis at home and induce infertile men's treatment and help patients after receiving infertile men's treatment before receiving treatment.

Keywords: Male infertility; Semen analysis; Smartphone; Sperm count

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INTRODUCTION

Infertility is a global health issue affecting approximately 15% to 20% of reproductive-aged couples and approximately 50% of these cases are attributed to the male partner [1-3]. Men are less concerned about male fertility than their female partners. With men's stress, embarrass-

ment, and tight timetables, they are hesitant to seek medical evaluation, delaying diagnosis of male infertility, prolonging the course of treatment for infertility in couples, and performing unnecessary interventions on female partners [4]. Semen analysis (SA) is an important key tool for evaluating male fecundity potential and male infertility and can help figure out the cause of male infertility [3]. SA is reported as

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Table 1. The developing history of commercially available smartphone-based semen analyzer

Generation	Commercial name	Manufacturer	Market launching (year)
1st	Tenga Men's Loupe®	Tenga Co. (Tokyo, Japan) https://tengahealthcare.com	2000
2nd	Seem®	Recruit-Lifestyle Co. (Tokyo, Japan) https://seem.life	2010
	YO Home Sperm Test®	Medical Electronic Systems (Los Angeles, CA, USA) https://mes-global.com	2017 ^a
	O'VIEW-M PRO®	Intin (Daegu, Korea) https://intin.kr/	2020

^a:1st U.S. Food and Drug Administration (FDA) cleared.

normal or abnormal was based on the criteria established by the World Health Organization (WHO). Nevertheless, 15% of normal SA can be infertility, whereas abnormal SA can lead to problems leading to conception. It is recognized that most men must attend a clinic or other hospital facility for SA.

Once at the clinic, the traditional laboratory-based SA is performed using both manual microscopic analysis and computer-assisted semen analysis (CASA). However, conventional semen analyses have several problems due to time-limiting, space limitation, costly and labor-intensive by skilled technician in aspect of clinical setting [1-3,5]. Also, there are many problems that it is difficult to obtain or not receive semen from infertility clinics [1]. Especially, manual SA results are much subjective depending on the testing procedure of technician and difficult to compare results from different clinics [5]. On the other hand, CASA system, which is based on image analysis, also requires bulky microscope-based image analysis systems that limit point-of-care applications in small fertility clinics.

In response to the growing awareness of SA at home, several home sperm tests have been introduced to consumer market allowing to attractive solution with privacy convenience, and lower cost with providing a valuable diagnostic tool for men who suffer from male factor infertility than conventional SA [6]. In particular, in the recent COVID-19 crisis, it is no wonder that the governments around the world are attempting the telemedicine in the name of 'untact care' in the name of providing consultation, doctor's judgment, and prescription over the phone or the Internet. In the circumstances of these times, the medical, cultural and social background requires a new paradigm in SA to accurately assess male fertility without visiting a fertility clinic equipped with high-resolution camera systems, conventional manual microscope-based analysis of SA.

A number of smartphone-based home sperm testing devices have been developed for male factor infertility screening and can be used to distinguish sperm concentration, and

motile sperm count (Table 1). In particular, it is possible to induce infertile men to visit a hospital by introducing the smartphone-based home sperm analyzer including high-definition image recording, computational power, and Internet communication, so that early diagnosis and treatment are possible, and self-examination is also possible before or after the patient receives specific treatment or visits the hospital. Therefore, this technological system is expected to contribute to reducing the mental and physical burden of pregnant women before infertility management, shortening the pregnancy period, and reducing medical expenses.

In the present study, we verified the clinical efficacy of newly developed smartphone-based App assisted semen analyzer, O'VIEW-M PRO® (Intin Korea Co., Daegu, Korea) and compared the results with those from laboratory-based manual microscopic SA with Makler Counting Chamber (SEFI Medical Instruments, Tel Aviv, Israel) and CASA.

MATERIALS AND METHODS

1. Study design and semen preparation

After approval by the Pusan National University Hospital Institutional Review Board (approval number: 2101-021-093), human semen samples were collected from healthy male donors who visited the outpatient Department of Urology or the Public Sperm Bank of Pusan National University Hospital from January to May 2021. Written informed consent was obtained from all the donors. Here, we tested semen samples containing more than 15 million sperm/mL to minimize extensive data variability according to the WHO's lower reference limits. After an abstinence period of 2 to 3 days, a total of 39 human semen samples were collected from healthy male donors in this study and each semen sample was collected. Our evaluation was performed this study using fresh, unwashed, unprocessed donor semen.

After liquefying the semen samples for 30 minutes, semen samples were mixed well and were divided into three

equal aliquots to evaluate semen concentration and motility on three devices in a blinded manner.

Sperm concentration and motility results of O'VIEW-M PRO[®], a portable smartphone-based App-assisted SA system, were compared with manual microscopic SA with Makler[®] Counting Chamber and laboratory-based automated CASA SAIS plus Sperm Analysis Imaging System[®] (Medical Supply, Seoul, Korea) which is based on the detection of electro-optical signals combined with spectroscopy, interpreted by built-in algorithms. SA was performed by one tester who was well trained technician with the clinical pathology license in outpatient andrology laboratory of Pusan National University Hospital and SA results were obtained as an average value after three evaluations by the above three methods for each sample.

2. Components of O'VIEW-M PRO[®] device and testing procedure

The components of O'VIEW-M PRO[®] are packaged in a kit that is sufficient to run three complete tests (Fig. 1A-C). The kit consisted of one main body with clip, three chambers, semen collection cups, and sticks. Before testing, O'VIEW-M PRO[®] application was downloaded from the

Google Play Store of the Android operating system and this study was conducted on Galaxy[™] S8 smartphone (Samsung Electronics Co, Ltd, Suwon, Korea).

To begin test, firstly, one drop of liquefied semen is loaded into the chamber semen inserting slot, and then make sure that the semen seeps into the opposite site through the air hole by the capillary effect. Secondly, the chamber was inserted the slip of the main body in the direction of the arrow marked on the chamber bottom entrance. If insert correctly, the light at the bottom could be checked. Finally, after simple observation of the sperm with the naked eye is through the lens of the main body, then the lens part of the main body is attached to the front lens of the smartphone, and the fitting attachment of the body are fixed with clips to allow for proper image magnification and observed the sperm on the high-definition screen of the smartphone (Fig. 1D). After taking the actual screen shot window image, the sperm density and motility data were read and automatically displayed on the smartphone screen, and general WHO standards of semen parameters were displayed and analyzed.



Fig. 1. Device and components of O'VIEW-M PRO[®] system. (A) Components of O'VIEW-M PRO[®] is consisted of main body with clip, chamber, semen cup, and stick. (B) Main body is consisted of cover, clip line, chamber inserting slip, lens, and built-in LED light source. (C) The liquefied semen sample is dropped into the sperm inserting slot. (D) Assay procedure with smartphone-based App assisted semen analysis, O'VIEW-M PRO[®]. After semen collection, liquefaction and stirring, semen loaded on 0.05 mL (1 drop) in the sperm inserting square slot of chamber and insert the chamber into the chamber inserting slip of main body. Sperm can be observed through the lens of main body by the naked eye. After fixing the attachment of the lens and body of the smartphone with a clip, the sample test result with concentration and mobility is shown as a screenshot.

3. Laboratory-based manual microscopic and automated-computer-assisted semen analysis

Laboratory-based manual microscopic SA with Makler Counting Chamber and CASA were performed and evaluated according to standard protocol and normal criteria for successful natural pregnancy on SA by WHO 2010 [7] and the manufacturer’s guidelines. Semen variables assessed were sperm concentration and motility. In brief, in manual microscopic SA, ten fields per chamber were counted and averaged for each sperm count and motility data according to a conventional SA method; this procedure was then repeated triplicate independent times for each specimen and was calculated as the final result. For CASA counts, samples were well mixed and transferred with a glass capillary into a chamber. All chambers were allowed to settle, and sperm cells were counted by use of phase-contrast microscopy. CASA counts were obtained by continuously repeating a one second video of a random single field of view. All CASA counts were performed at 200× magnification.

4. Statistical analysis

Descriptive statistics were used to explore the characteristics of the sample. Continuous data are expressed as the mean. Statistical analyses were performed using R 4.0.2 software (R Foundation for Statistical Computing, Vienna, Austria) with the calculation of Pearson correlation coefficient between 2 different analyzed data and classification accuracy reported for sensitivity and specificity. Significance was set for all tests at two tails and p-values less than 0.05 were considered to indicate statistical significance.

RESULTS

1. Characteristics of semen sample

In all, 39 males were recruited for this study. The underlying causes of 17 cases (43.6%) of varicocele, 12 cases (30.8%) of male infertility, 3 cases (7.7%) of male erectile dysfunction, 2 cases (5.1%) of vasectomy reversal status, 1 case (2.6%) of chronic prostatitis, urinary tract infection, and late onset hypogonadism in each, and 2 cases (5.1%) of voluntary semen donors. Subjects were aged 29.5±8.8 years on average (range, 20–55 y) (Table 2). We analyzed sperm concentration and motility by use of three different methods: manual microscopic analysis, laboratory-based CASA (L-CASA), and smartphone-based APP assisted SA with OVIEW-M PRO®.

Table 2. Summary of demographics of the consumer clinical study

Parameter	Result
Age (y)	29.5±8.8 (20–55)
Case	
Varicocele	17 (43.6)
Infertility	12 (30.8)
Erectile dysfunction	3 (7.7)
Voluntary semen donors	2 (5.1)
Post-vasectomy reversal	2 (5.1)
Chronic prostatitis	1 (2.6)
Urinary tract infection	1 (2.6)
Late onset hypogonadism	1 (2.6)

Values are presented as mean±standard deviation (min–max) or number (%).

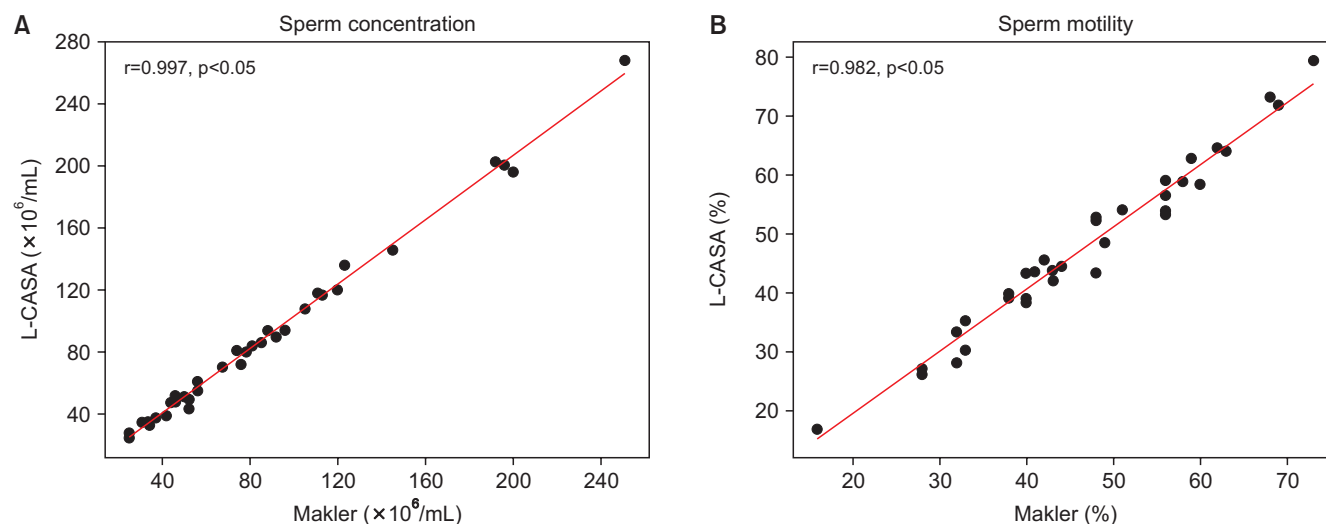


Fig. 2. Comparison data between manual microscopic semen analysis with Makler chamber and L-CASA for sperm concentration (A) and sperm motility (B). L-CASA, laboratory-based computer-assisted semen analysis.

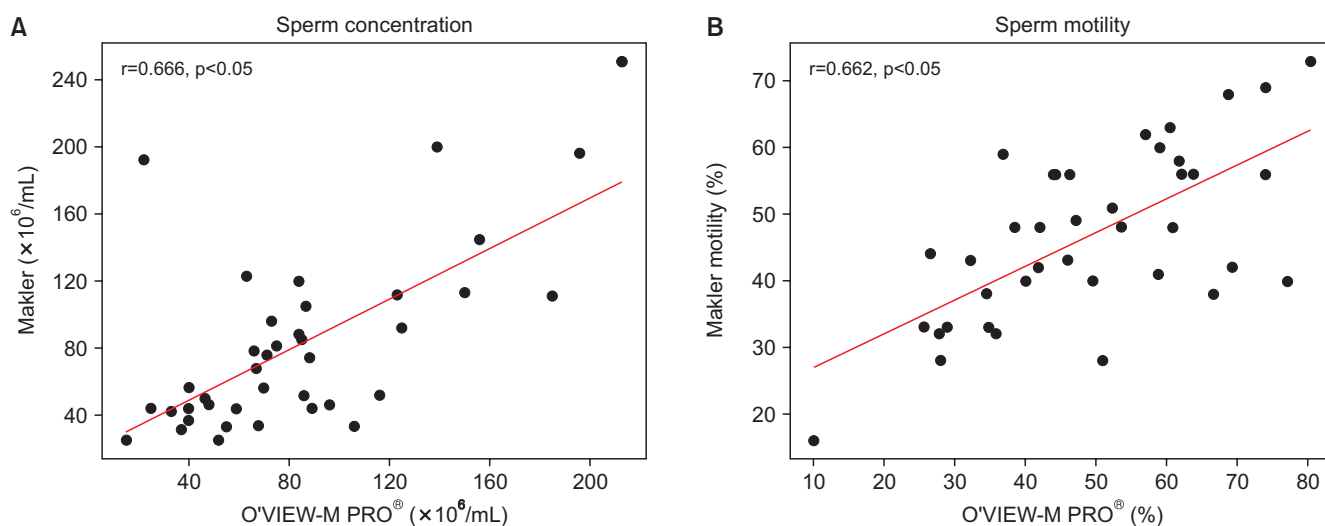


Fig. 3. Comparison data semen analysis between manual microscopic semen analysis with Makler chamber and smartphone-based App assisted semen analysis with O'VIEW-M PRO® for sperm concentration (A) and sperm motility (B).

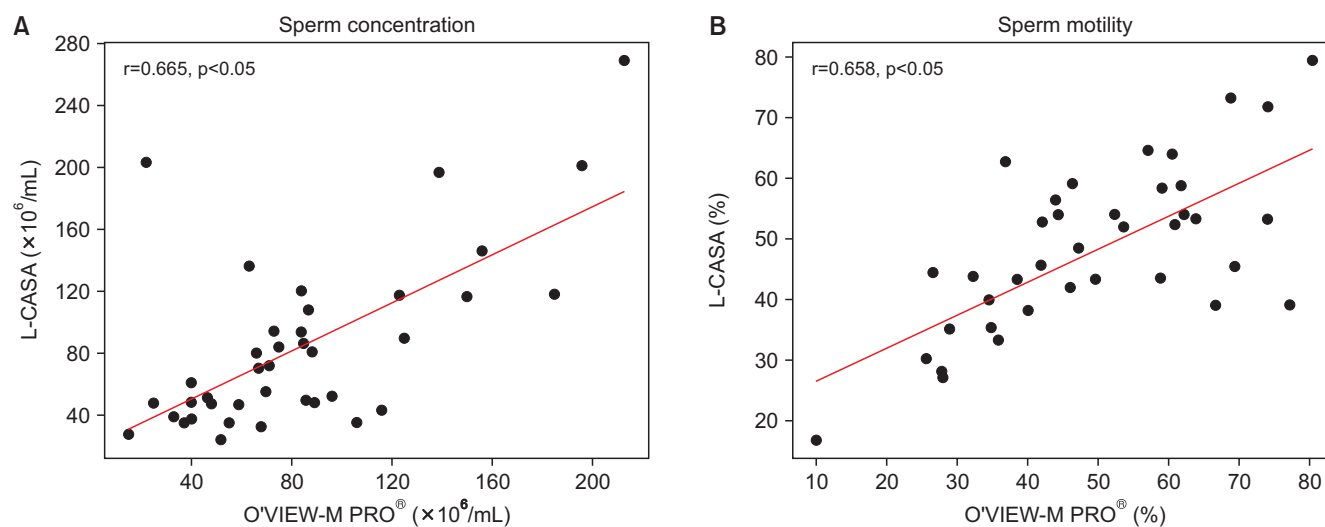


Fig. 4. Comparison data between L-CASA and smartphone-based App assisted semen analysis with O'VIEW-M PRO® for sperm concentration (A) and sperm motility (B). L-CASA, laboratory-based computer-assisted semen analysis.

2. Comparison of sperm concentration and motility among 3 groups

The relationship of each sperm concentration and motility in the manual microscopic (Makler) method and L-CASA resulted in Fig. 2. The coefficient factors on the results of sperm concentration and motility between manual microscopic SA with Makler chamber and L-CASA were 0.997 and 0.982, respectively ($p<0.05$) (Fig. 2) and resulted in highly statistically significant. Agreement between the Makler and L-CASA methods in measuring concentration and motility indicated overall accuracy.

Comparison of the results of sperm concentration and motility with use of manual microscopic SA with Makler chamber and smartphone-based App assisted SA with

O'VIEW-M PRO® was also statistically significant and showed positive correlation in the regression, with coefficients of 0.666 and 0.662, respectively ($p<0.05$) (Fig. 3). There was statistically significant and positive correlation between L-CASA and smartphone-based App assisted SA with O'VIEW-M PRO® for sperm concentration and motility with coefficients of 0.665 and 0.658, respectively ($p<0.05$) (Fig. 4). There were no particular problems with clinical use of the smartphone-based App Assisted SA system with O'VIEW-M PRO® to run sperm test.

3. The device performance in classifying samples

The contingency table in the scatterplots represents the quantitative accuracy of the assay results for measuring

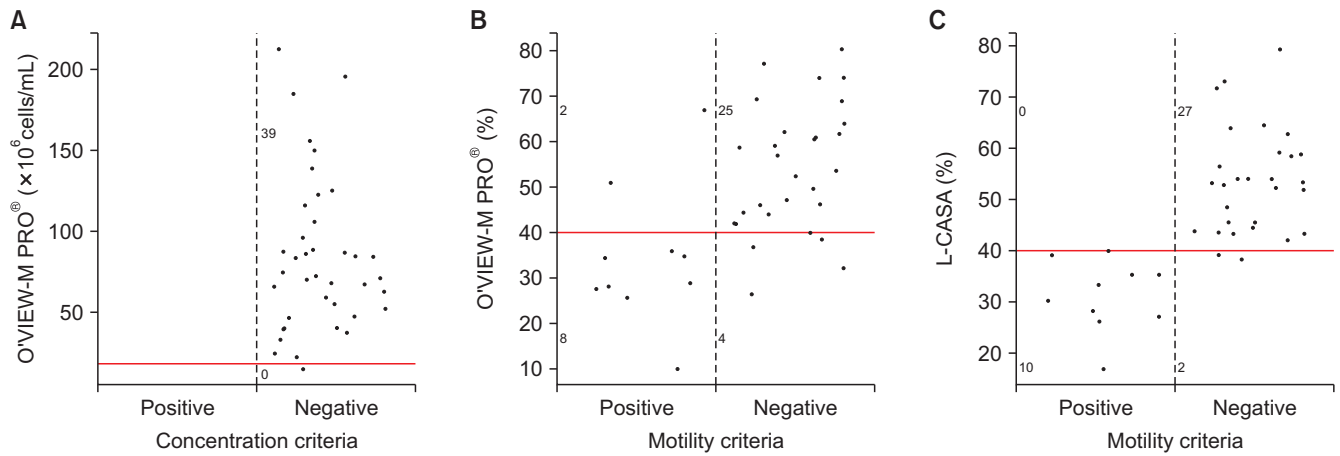


Fig. 5. Contingency table of scatter plots represent the high quantitative accuracy of the O'VIEW-M PRO® and L-CASA comparing to the manual microscopic semen analysis with Makler chamber in measuring concentration (A) and motility (B). The solid red bars represent the threshold values for each criterion. (C) Positive and negative threshold values are 15×10^6 sperm/mL for sperm concentration criteria and 40% for sperm motility criteria. L-CASA, laboratory-based computer-assisted semen analysis.

Table 3. Contingency table comparing L-CASA and O'VIEW-M PRO® in sperm motility

Predicted O'VIEW-M PRO®	Actual O'VIEW-M PRO®		Total
	Negative	Positive	
Negative	25	4	29
Positive	2	8	10
Total	27	12	39

Sensitivity=92.6%, specificity=66.7%, accuracy=84.6%. L-CASA, laboratory-based computer-assisted semen analysis.

sperm concentration and motility between the smartphone-based App assisted SA, O'VIEW-M PRO®, and the L-CASA (Fig. 5). In sample classification, device performance is positive ($<15 \times 10^6$ sperm/mL) and negative ($>15 \times 10^6$ sperm/mL) for sperm concentration criteria (Fig. 5A). Device performance is positive ($<40\%$) and negative ($>40\%$) for sperm motility criteria (Fig. 5B). As there was no positive value of the threshold for sperm concentration, only sperm motility was analyzed (Fig. 5C).

The sensitivity and specificity of O'VIEW-M PRO®-based analyzer according to the sperm motility criterion were 92.6% and 66.7%, respectively, and the accuracy was 84.6% (Table 3). A comparison of the results of devices performance for above and below 40% thresholds is presented in Table 4. More than 79.5% accuracy results in O'VIEW-M PRO®. And the accuracy of L-CASA analyzer was 94.9%. There were 4 ($<10\%$) false-positive cases of the O'VIEW-M®-based analyzer.

DISCUSSION

Sperm quality is crucial for couples preparing for natural pregnancy. In the context of a global issue of increasing

Table 4. PPA and NPA on sperm motility between the devices performance

Device	Criterion	n	PPA (%)	NPA (%)	FP cases	Accuracy (%)
O'VIEW-M PRO®	Makler	39	86.2	80.0	4	84.6
O'VIEW-M PRO®	L-CASA	39	85.2	66.7	4	79.5
L-CASA	Makler	39	93.1	100.0	2	94.9

PPA, positive percent agreement; NPA, negative percent agreement; FP, false positive.

male infertility, SA is always essential as the first step in evaluating male infertility because accurate information on sperm production as a primary source [2,8,9]. It is also important for those who want to check the success of various infertility treatments for men. Until recently, all SA techniques were recognized as laboratory settings available to trained technician. Conventional SA has several drawbacks, such as limitations on skilled technicians, labor intensive-ness, time and space limitations, and cost issues. From the patient's point of view, men who visit fertility center are not comfortable with this procedure, which they find stressful, embarrassing and time-consuming [3,7,10]. Therefore, to tackle this problem about conventional SA, several trials of home SA kits have been developed in the consumer market over the past few decades, by a growing awareness of convenient and valuable SA diagnostic tools for male factor infertility patients [6,11].

In the developmental history of SA, from sperm counting chambers to information and communications technology (ICT), there has been a continuous evolution to improve the diagnostic accuracy of SA [12]. Mobile phone use, which is emerging worldwide today, has expanded rapidly, with glob-

al smartphone use exceeding 96.8% in 2015 [10]. Smartphones have great potential as powerful platform for various home diagnostic testing because they are portable, contain excellent digital cameras, process information quickly, easily connected to the Internet and easily attached to a microscopic device and are already used in point-of-care devices [1,2,13-17]. Understandably, smartphones have recently become an integral part of the global healthcare system, using cameras to rapidly capture clinically relevant images. And, smartphone offer user-friendly data display, proper memory storage, faster data transfer in the form of application software. This technology is becoming an important part of home SA that is easy-to-use, fast, automated, and inexpensive [5]. Smartphone-based semen test kits available on the market are capable of self-testing, especially for embarrassed or busy booking men, and have several advantages of performing SA data to obtain preliminary data for screening while preserving the privacy. In particular, the younger generation familiar with smartphones and the Internet is currently observing sperm concentration and motility, continuously recording various SA data on a smartphone-based SA for long-term follow-up, and reporting male infertility directly to a doctor through the Internet. Besides, it can be done more cost-effectively. Eventually, it is expected that smartphone-based SA will be able to easily evaluate male reproduction of the young generation familiar with the recent 5G wireless network technology environment under the ubiquitous health care system.

In the history of the development of automated smartphone-based semen diagnostic assays, Kanakasabapathy et al. [5] first presented a novel device using a small amount of semen sample loaded into a disposable microfluidic device to measure sperm concentration and motility together. And lens free on-chip microscopy by Su et al. [17], single-ball lens microscopy by Kobori et al. [1] and digital photomicrography by Roy et al. [18] were introduced for an ideal, point-of-care portable smartphone-based SA. Although it did not automatically calculate sperm concentration and motility, it was first developed in late 2010 by SA Tenga Co., Ltd. (Tokyo, Japan), a video-based smartphone as a sperm image viewer (Table 5). The smartphone-based App-assisted SA system afterward developed SEEM® (Recruit Lifestyle Co., Ltd, Tokyo, Japan), which is able to automatically calculate and display sperm concentration and motility in real time according to the guidelines set by the WHO [10]. YO Home Sperm Test® (Medical Electronic Systems, Los Angeles, CA, USA) received U.S. Food and Drug Administration (FDA) approval (K161493) for the first time in the United States and entered the consumer market [2]. A recent comparison of the two

Table 5. Comparison characteristics of smartphone-based semen analyzer

Commercial name	Main measuring tool & measure variables	Analysis time (time of analysis result after taking video)	Sale price & characteristics
Tenga Men's Loupe®	Smartphone & magnifying plate based Sperm image viewer only	NA	<ul style="list-style-type: none"> • 25.7 USD/kit • Room light source
Seem®	Smartphone & App based sperm image viewer Sperm concentration & motility count	About 1 minute	<ul style="list-style-type: none"> • 37.2 USD/kit • Room light source • Accuracy rate: NA
YO Home Sperm Test®	Smartphone & App based sperm imaging viewer Sperm concentration & motility count	About 30 seconds	<ul style="list-style-type: none"> • Liquefaction powder (<5 mg α-chymotrypsin with eosin) • 79.95 USD/2 YO kits • Built-in light source • Overall accuracy rate iPhone vs. Galaxy: 97.8%
O'VIEW-M PRO®	Smartphone & App based sperm image viewer Sperm concentration & motility count	Time to capture about 20 seconds and time of analysis result about 20 seconds	<ul style="list-style-type: none"> • 49.9 USD/3 kits • Built-in LED light source • Accuracy rate 84.6% vs. Makler 79.5% vs. L-CASA
3rd generation under developing	Smartphone & APP based sperm image viewer Sperm concentration, motility count & morphology	Faster analysis time	<ul style="list-style-type: none"> • Cheaper price • Higher accuracy rate • Connection with big data cloud computing system

NA, not available; L-CASA, laboratory-based computer-assisted semen analysis.

systems, a prerequisite for a smartphone-based SA that provides high-quality evaluation results is a high-resolution camera, a built-in sperm counter with objective and an operating application program from the manufacturer [2,10].

Compared with SEEM[®] and YO Home Sperm Test[®], the O'VIEW-M PRO[®] evaluated in this study not only shows high-quality images captured with a built-in LED light source, but also has faster analysis time of sperm images and sperm test result. In addition, it has designed a set of more computationally intensive image analysis algorithms to perform sperm analysis based on the size of the sperm head to distinguish other larger cells. There is no limitation to discern sperm from white blood cells or seminal debris. This finding also was confirmed on preliminary study with samples of hemospermia or pyospermia. Additionally, the smartphone application, which can be downloaded for free both iOS and Android systems, is used to take a video of the semen and display the concentration and motility results. In this study, the performance of O'VIEW-M PRO[®] was evaluated by comparing the results of sperm concentration and motility obtained with a manual microscope and L-CASA. The results of sperm concentration and motility obtained with a smartphone-based SA show a strong correlation with results of manual microscopic and L-CASA.

In general, to optimize the interpretation of the results about sperm concentration or motility, specialized evaluations, such as analysis of higher sperm DNA fragmentation and normal semen with varicocele, are needed. In this study, routine semen evaluation was performed to determine the main cause of male infertility, varicocele, and azoospermia after vasectomy. As a result of this study, regardless of the characteristics of the semen sample, we evaluated a smartphone-based App-assisted SA system that allows patients to easily estimate the quality of semen regardless of the characteristics of the semen sample, not in a professional laboratory environment.

The correlation between O'VIEW-M PRO[®] and Makler or CASA is lower than the correlation between the conventional method Makler chamber and L-CASA, but it is significant and therefore can be used as a home sperm testing device. However, like other smartphone-based home SA kit, one of the main problems is sperm morphology and other important parameters that potentially affect fertility, such as redox potential and DNA fragmentation index, are not tested. Therefore, it is not recommended for infertile couples who have difficulty getting pregnant due to male factors. Another limitation is that general users were not included in this study because semen sample collection and processing could significantly affect the results. And consumer

usability and convenience, such as exposure temperature of samples, long time between collection and analysis, and incomplete liquefaction, were not investigated. Based on these results, it is expected to develop an advanced platform for assessing the quality of complete sperm by adding a new version of the new algorithm, including the evaluation of sperm morphology.

In the near future, it is expected that these technologies will evolve into a portable, easy, fast, and accurate home-based mode that caters to consumer needs by installing AI, IoT, and big data cloud computing on smartphones and allowing web access from anywhere. Emerging and rapidly evolving ICT contexts are expected to make so-called “contactless semen analysis” easier and enable free communication of semen data between patients and doctors or medical institutions in modern society.

Therefore, our results suggest that the development of a portable smartphone-based App-assisted SA system for male reproductive and infertility screening with various advantages as a diagnostic tool is technically well done. Therefore, it is expected to become one of the essential elements of the ubiquitous global health care system and telemedicine-based smart hospital.

CONCLUSIONS

This study demonstrates a novel smartphone-based APP-assisted SA system, O'VIEW-M PRO[®] not only serves to easily obtain semen information through self-examination at home, but also play a role in motivating infertile men to visit an early clinic. In addition, in infertile men, the treatment effect on sperm quality can be easily tracked by the patient before visiting the hospital after treatment.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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AUTHORS' CONTRIBUTIONS

Research conception and design: Nam Cheol Park. Data acquisition: Mi Young Lim. Statistical analysis: Nam Cheol Park. Data analysis and interpretation: Mi Young Lim. Drafting of the manuscript: Min Jung Park, Hyun Jun Park, and Nam Cheol Park. Critical revision of the manuscript: Min Jung Park and Nam Cheol Park. Administrative, technical, or material support: Nam Cheol Park. Supervision: Nam Cheol Park. Approval of the final manuscript: Min Jung Park and Nam Cheol Park.

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