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Automation of human semen analysis using a novel artificial intelligence optical microscopic technology

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Abstract

Current semen analysis still commonly depends on a manual microscopy method in clinical laboratories worldwide. However, some of the major disadvantages of this technique are that it is labour-intensive, subjective, laboratory-based and time-consuming. Although computer-assisted semen analysers (CASAs) have enabled partial automation of routine semen analysis, they lack wider acceptance due to their complicated operation. Therefore, the development of an accessible, rapid and standardised method for semen analysis is urgently needed. Here, we describe the development and clinical testing of a novel, automated, artificial intelligence optical microscopic (AIOM)-based technology, LensHooke™ X1 PRO (X1 PRO), designed for the quantitative measurement of sperm concentration, motility and seminal pH. We observed high degree of correlation in the results of concentration, progressive motility and progressively motile sperm concentration between the X1 PRO semen analyser and manual method using 135 clinical semen samples. In addition, the seminal pH results obtained by X1 PRO and manual methods were comparable (p = .12). In summary, our results showed that new X1 PRO semen analyser is a reliable diagnostic tool for routine semen analysis providing clinically acceptable results based on World Health Organization (WHO) 5th Edition guidelines.

KEYWORDS

automated semen analysis, computer-assisted sperm analysis, LensHook™ X1 PRO, sperm concentration

1 | INTRODUCTION

Infertility is an increasing medical and social problem from which 8%–12% of couples suffer worldwide (Kumar & Singh, 2015). Male factor infertility is an important cause of infertility, and approximately 40%–50% of all infertility cases are due to male infertility (Brugh & Lipshultz, 2004; Hirsh, 2003). Furthermore, the fertility rate among men younger than 30 years has decreased by 15% worldwide (Martin et al., 2006). A proper diagnosis of male factor infertility in an infertility workup is dependent on an accurate measurement of semen quality. Semen quality analysis is the most frequently used diagnostic option and fundamental investigation in an infertility workup. In addition to evaluating male infertility, semen analysis may also be used for post-vasectomy screening, and anyone who plans to preserve or donate sperm is expected to undergo such an examination. However, the shortcomings of conventional manual semen analysis (MSA), including that it is laboratory-based, labour-intensive and subjective in nature, producing inconsistent reports that can cause misdiagnosis or delayed infertility treatment, have promoted the development of semi-computerised and computerised semen measuring devices, known as computer-assisted sperm analysis (CASA; Barratt, Tomlinson, & Cooke, 1993; Holt, Watson, Curry, & Holt, 1994; Mahmoud et al., 1998).

The conventional CASA systems are semi-automated sperm-tracking computer-aided devices, essentially focusing through the microscope to provide successive images of spermatozoa within

a static field of view. These systems use special software to extract desired information and produce the desired output. If appropriate protocols are followed, high precision and provision of quantitative data on sperm kinetics are two major advantages of CASA over MSA. In addition, CASA systems reduce the burden of measuring sperm tracks when individual tracking data are needed. Another advantage is that any test samples can be analysed in a short time.

Most CASA systems allow partial automation in routine sperm analysis, but they have also shown limited success due to poor accuracy at low and high sperm counts and the high cost of virtually all CASA devices. Moreover, different CASA systems use different mathematical algorithms to calculate various sperm quality parameters, leading to the greatest disadvantage in the clinical application of CASA, with unreliability of comparative parameters across all devices (Akashi, Mizuno, Okumura, & Fuse, 2005; Amann & Waberski, 2014; Dearing, Kilburn, & Lindsay, 2014; Kanakasabapathy et al., 2017; Lammers, Splingart, Barriere, Jean, & Freour, 2014). Although CASA provides quantitative data on sperm kinetics, most CASA systems still rely greatly on highly trained technicians and require an additional bulky component for data collection and computational units for data analysis. The factors influencing the accuracy of the results and the lack of quality control may lead to large variations between different CASA systems and laboratories.

To overcome these limitations, we integrated autofocus optical technology, artificial intelligence (AI) algorithms, electronic engineering and a mechanical system all in one compact device. Hence, the present study aimed to evaluate the clinical performance of the novel artificial intelligence optical microscopic (AIOM)-based technology, LensHooke™ X1 PRO, in semen analysis by comparing its results with those of the manual microscopy method.

2 | MATERIALS AND METHODS

2.1 | Study participants

This study was approved by the Institutional Review Boards of Chung Shan Medical University Hospital, Lin Shin Hospital, Lee Women's Hospital in Taichung, Taiwan, and Min-Sheng General Hospital in Taoyuan, Taiwan. Written informed consent was acquired from all subjects.

A total of 135 semen samples were obtained from the participants, aged 20–60 years, attending Chung Shan Medical University Hospital, Lin Shin Hospital, Lee Women's Hospital and Min-Sheng General Hospital of Taiwan. The exclusion criteria were as follows: a history of malignant tumours; systemic, pelvic chemotherapy or radiation therapy; treatment with hormones; and subjects diagnosed with mental illness. The samples were collected after an abstinence period of 2–3 days and were delivered to the laboratory within 1 hr following masturbation. Semen parameters, including concentration, motility and seminal pH, were determined by means of standard manual semen analysis and by the automated LensHooke™ X1 PRO semen quality analyser according to WHO 5th Edition (2010) guidelines. Samples with normal and poor sperm quality were included, and samples with severe agglutination were excluded from the study.

2.2 | Manual analysis of semen samples

Manual semen analysis was performed by at least two professional technicians or licensed medical technologists of the hospital. Sperm concentration ($\times 10^6$/ml) was assessed by counting a minimum of 200 spermatozoa in duplicate using a Makler counting chamber after liquefaction of the semen sample in a water bath at 37°C for 30 min. Sperm motility (%) was evaluated at room temperature by counting at least 200 spermatozoa in duplicate using a phase-contrast microscope at 400× magnification. At least five fields of view for each sample were examined, and spermatozoa were classified as progressively motile, locally motile and nonmotile as suggested by the WHO 5th Edition (WHO, 2010). The seminal pH was manually measured 60 min after ejaculation with the pH paper (Merck Colorfast pH strip, 6.5–10.0). Since pH measurements could not be conducted at the Lee Women's Hospital, the data of only 58 patients were recorded for pH measurement from the rest of the institutions.

2.3 | Automated analysis of semen samples

Automated semen analysis was performed using the LensHooke™ X1 PRO semen quality analyser (Bonraybio Co., Ltd) for sperm concentration, motility and seminal pH in compliance with the World Health Organization (WHO) 5th Edition (WHO, 2010). The LensHooke™ X1 PRO technology is based on a built-in high-resolution and autofocus optical lens in combination with an artificial intelligence autocalculation system (Figure 1a). The rationale for using the autofocus optical lens to replace the laboratory's microscope is based on the concept of the use of an automatic optic inspection (AOI) system. In the context of the application of the AI algorithm, we use a predefined database to standardise the analysis and avoid subjective identification. The X1 PRO can further analyse sperm morphology based on the captured images. The LensHooke™ X1 PRO detects the shapes of the target sperm and partitions the images of the sperm into head, neck and tail portions by methods such as the active contour model, and the lengths and widths of each portion of sperm are calculated accordingly. An image classifier can be intelligently prepared using a training database that includes predefined samples. After the detection, the parameters of the various portions of the sperm can be fed into the classifier to determine whether the sperm has a normal morphology. Briefly, 40 μl of semen sample was firstly applied into the specimen holding area of the proprietary disposable specimen carrier after liquefaction (Figure 1b). Second, upon inserting the specimen carrier into the slot of the analyser, sperm images or videos are captured by the autofocus optical lens with a rate of 15 frames per second (FPS). The easy-to-use procedure is illustrated in Figure S1.

Seminal pH was measured by the X1 PRO device according to the CIE 1976 colour scales system $L^*a^*b^*$, where the L^* value designates

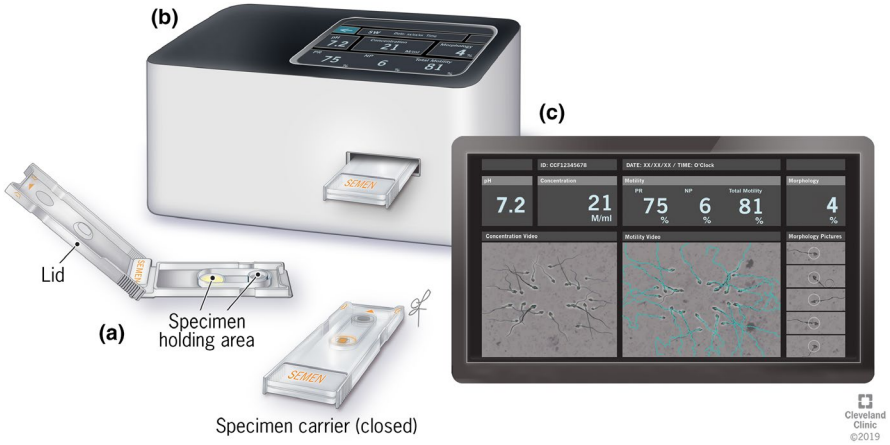

FIGURE 1 Diagram showing (a) the exterior of the LensHooke™ X1 PRO semen quality analyser, (b) a disposable specimen carrier LensHooke™ CS0 and (c) an HDMI screen displays a real-time test report, including sperm dynamic image, concentration, motility, morphology and semen pH value

lightness, whereas a^* and b^* are colour coordinates ($+a^*$ = redness, $-a^*$ = green, $+b^*$ = yellow, $-b^*$ = blue). By analysing the colour of the pH strip in the specimen carrier with the AIOM system, the device can automatically determine the pH value of the semen.

For quality control, the three known concentrations of LensHooke™ X QC beads were analysed according to the manufacturer's instructions. Figure 1c shows a real-time report, including a sperm dynamic video, pH value, concentration ($\times 10^6$/ml), motility (%), and morphology (%) displayed on a HDMI screen. In the motility section, the green line indicates sperm with progressive motility, the blue line indicates sperm with nonprogressive motility, and the yellow line indicates sperm without motility.

2.4 | Statistical analysis

The data were statistically evaluated using MedCalc® version 18.2 (MedCalc Software). After testing for normal distribution, nonparametric tests were employed and Spearman's rank correlations were calculated. Subsequently, the two methods were compared using Passing–Bablok regression analysis (Passing & Bablok, 1983) and Bland–Altman plots (Bland & Altman, 1986). Agreement between two methods was analysed through concordance correlation coefficient analysis, and therefore, the precision and accuracy were calculated. The p-value of $p < .05$ was considered as statistically significant.

3 | RESULTS

3.1 | Seminal pH

Measurement of pH in the ejaculate is an important part of basic semen analysis. While secretions from seminal vesicles are basic in nature, prostatic secretions are acidic. The mean pH values of 58 ejaculates determined by manual reading (7.86 ± 0.21) versus the X1 PRO (7.8 ± 0.20) are comparable (p = .12; Figure 2a and Table 1). In addition, pH measurement of the two methods was

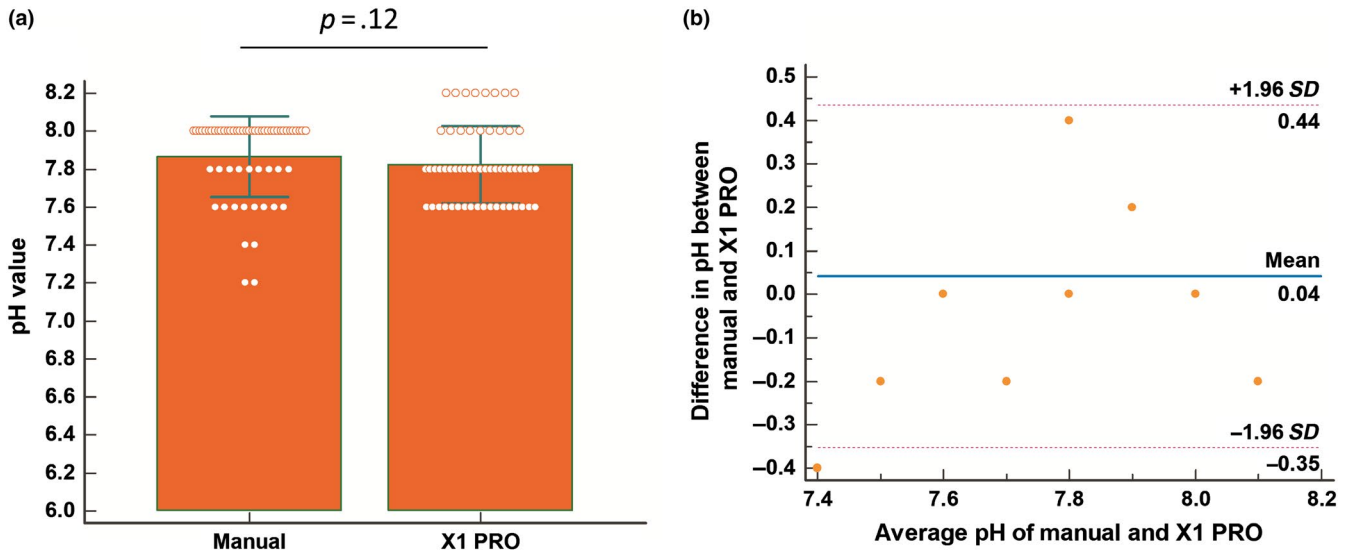

FIGURE 2 Comparing the seminal pH value between the automated X1 PRO semen quality analyser and manual microscopy method. (a) Each dot in the graph represents a value of pH and is shown as the means ± *SD*. (b) Bland–Altman analysis of the pH deviation results between the X1 PRO analyser and a manual microscope method. The solid black line represents the mean of the two methods, and the black dashed lines are the 95% confidence ranges

TABLE 1 Summary results of sperm parameters obtained by the manual method and the X1 PRO device

		Manual			X1 PRO			Paired *t* test
Parameter	*n*	Mean ± *SD*	Median	Range	Mean ± *SD*	Median	Range	*p* value
pH	58	7.86 ± 0.21	8.0	7.2–8.0	7.8 ± 0.20	7.8	7.6–8.2	.122
Concentration ($\times 10^6$/ml)	135	50.69 ± 39.84	48.35	0–212.5	49.15 ± 38.87	44.9	0–195.0	.052
Total motility (%)	135	56.56 ± 29.76	63.0	0–94	50.98 ± 27.92	59.4	0–95	<.0001
PR motility (%)	100	49.60 ± 20.23	53.45	0–82	52.64 ± 19.48	57.5	0–85.80	.088
MSC ($\times 10^6$/ml)	135	36.41 ± 34.46	32.2	0–199.8	31.24 ± 28.72	26.6	0–162.2	<.0001
PMSC ($\times 10^6$/ml)	100	33.28 ± 26.72	26.2	0–161.2	33.19 ± 24.14	29.3	0–141.6	.545

compared by the Bland–Altman analysis and shows a mean bias of 0.04, with a mean *SD* of 0.2 (95% limits of agreement: 0.43 to −0.35; Figure 2b).

3.2 | Sperm concentration

To evaluate the performance of the artificial intelligence optical microscopic (AIOM) technology-based semen quality analyser on sperm concentration, we tested 135 semen samples using both the manual microscopy method and the X1 PRO analyser. Passing–Bablok regression analysis (n = 135) showed an intercept value of 0.0 and a slope of 1.05 (95% CI = 1.01–1.08), with a Spearman rank correlation coefficient of r = .97 (Figure 3a and Table 2). The cusum test for linearity demonstrates no significant deviation from linearity with p = .38. Overall limits of agreement between the two methods were also compared using the Bland–Altman analysis. Figure 3b shows a mean bias of 1.5 × 10^6/ml, with a mean *SD* of 9.18 × 10^6/ml (95% limits of agreement: 19.5 to −16.4 × 10^6/ml). Moreover, agreement analysis showed a concordance correlation coefficient of r = .97 (95% CI = 0.96–0.99) and Bias correlation factor C_b of 0.99 (Table 3). These results demonstrate a strong agreement and accuracy when comparing sperm concentration results obtained by the automated X1 PRO analyser to those obtained manually.

3.3 | Sperm total motility and progressive motility

In addition to sperm concentration, we also evaluated the performance of the X1 PRO analyser in sperm motility detection compared to the manual method. For total sperm motility, Passing–Bablok regression analysis (n = 135) showed an intercept value of 2.50 and a slope value of 1.07 (95% CI = 1.00–1.12), with a Spearman rank correlation coefficient of r = .93 (Figure 4a and Table 2). Figure 4b shows a mean bias of 5.6%, with an *SD* of 8.16% (95% limits of agreement: 21.6% to −10.5%).

For progressively motile sperm, Passing–Bablok regression analysis (n = 100) showed an intercept value of −4.26 and a slope of 1.07 (95% CI = 0.98–1.19), with a Spearman rank correlation coefficient of r = .81 (Figure 4c and Table 2). Figure 4d shows a mean bias of

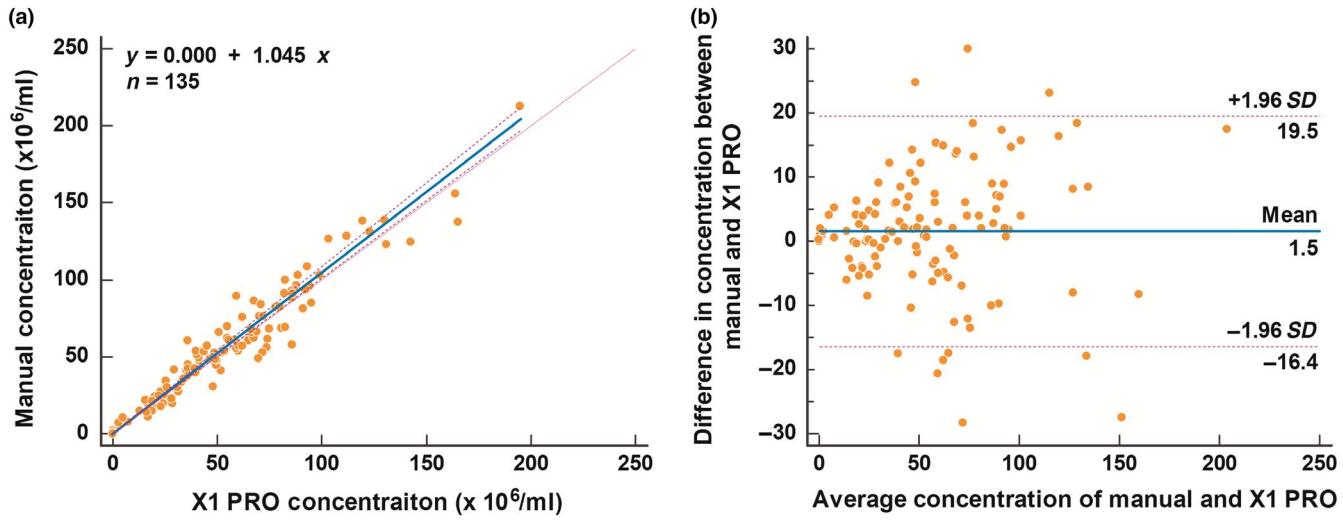

FIGURE 3 Comparing the sperm concentration results between the automated X1 PRO semen quality analyser and manual microscopy method. (a) Passing–Bablok regression plots comparing automated (X1 PRO) versus manual readings. The solid blue line represents the regression line, the red dashed line represents the diagonal line, and the black dashed line represents a confidence band (n = 135). (b) Bland–Altman analysis of the concentration deviation results between the X1 PRO analyser and a manual microscope method. The solid black line represents the mean of the two methods, and the black dashed lines are the 95% confidence ranges

TABLE 2 Passing–Bablok regression analysis of test results obtained by the X1 PRO and manual method on sperm concentration, motility and seminal pH

Parameters	Intercept	Slope	95% CI of slope	Spearman's rank correlation coefficient (*r*)	Cusum test for linearity (*p*)
Concentration (×10^6/ml)	0.0000	1.0450	1.0124–1.0814	.974	.38
Total motility (%)	2.5027	1.0676	1.0083–1.1273	.926	<.01
PR motility (%)	−4.2602	1.0664	0.9770–1.1985	.814	.38
MSC (×10^6/ml)	0.0000	1.2033	1.1422–1.2456	.977	.10
PMSC (×10^6/ml)	−1.1795	1.1218	1.0350–1.1753	.938	.26

TABLE 3 Concordance correlation coefficients of different sperm parameters obtained by the X1 PRO device and the manual approach

Parameter	*n*	Concordance correlation coefficient ρ_c	95% CI	Pearson's ρ (precision)	Bias correlation factor C_b (accuracy)
Concentration (×10^6/ml)	135	.9721	0.9611–0.9800	.9731	0.9989
Total motility (%)	135	.9421	0.9211–0.9577	.9618	0.9796
PR motility (%)	100	.8632	0.8042–0.9054	.8741	0.9875
MSC (×10^6/ml)	135	.9400	0.9212–0.9544	.9684	0.9707
PMSC (×10^6/ml)	100	.9314	0.9012–0.9526	.9362	0.9949

Note: Concordance correlation coefficient analysis was used.
Abbreviation: CI, confidence interval.

−3.0%, with a mean *SD* of 9.94% (95% limits of agreement: 16.5% to −22.6%). Agreement analysis on total motility and progressively motile sperm showed concordance correlation coefficients of *r* = .94 (95% CI = 0.92–0.96) and *r* = .86 (95% CI = 0.80–0.90), respectively. High accuracy for total motility and progressive motility between the two methods was revealed by Bias correlation factor of C_b = 0.97 and C_b = 0.98, respectively (Table 3). These results demonstrate good agreement and accuracy in sperm total motility measurement between the two methods. However, there is still room for improvement with respect to the progressively motile sperm.

3.4 | Motile sperm concentration (MSC) and progressively motile sperm concentration (PMSC)

Regarding the MSC analysis, Passing–Bablok regression analysis (*n* = 135) showed an intercept value of 0.00 and a slope value of 1.20 (95% CI = 1.14–1.24), with a Spearman rank correlation coefficient of *r* = .97 (Figure 5a and Table 2). Figure 5b shows a mean bias of 5.2 × 10^6/ml, with an *SD* of 9.7 × 10^6/ml (95% limits of agreement: 24.3 to −14.0 × 10^6/ml). For PMSC analysis, Passing–Bablok regression analysis (*n* = 100) showed an intercept value of −1.18 and a slope of 1.21 (95% CI = 1.03–1.18), with a Spearman rank correlation coefficient of *r* = .94 (Figure 5c and Table 2). Figure 5d shows a mean bias of 0.1 × 10^6/ml, with a mean *SD* of 9.44 × 10^6/ml (95% limits of agreement: 18.6 to −18.4 × 10^6/ml). Agreement analysis on MSC and PMSC showed concordance correlation coefficients of *r* = .94 (95% CI = 0.92–0.95) and *r* = .93 (95% CI = 0.90–0.95), respectively. Bias correlation factor of C_b = 0.97 and C_b = 0.99 for MSC and PMSC, respectively (Table 3). Beside, Pearson (ρ) for MSC (ρ = .97) and PMSC (ρ = .94) indicates that both methods have a high precision. The X1 PRO shows good agreement with the manual method in measurement of MSC and PMSC.

4 | DISCUSSION

Semen analysis is performed to help evaluate the quality of male sperm, whether for those seeking pregnancy or verifying the success of a vasectomy. The increasing prevalence of male infertility, sperm donation, an ageing population, changing lifestyles, shortage in medical personnel, the rise in awareness about advanced fertility methods, such as in vitro fertilisation (IVF), and high adoption of advanced semen analysis methods, such as computer-assisted semen analysis (CASA), are further increasing the demands of semen analysis.

Over the last two decades, automated sperm analysers for routine semen analysis have gradually been accepted as they have several advantages over manual semen analysis, including standardisation, precision, low inter-laboratory variability and efficiency in terms of time and labour (Agarwal & Sharma, 2007; Tomlinson et al., 2010). Based on sperm detection technology, two major categories of automated sperm analysers are available on the market, the SQA-V system and the CASA system (Akashi et al., 2005; Moruzzi, Wyrobek, Mayall, & Gledhill, 1988). However, these bulky devices largely limit their application of point-of-care and home-based semen analysis. An important lesson learned from the evolution of CASA is that, as technology advances into a new biomedical era, there must be robust incorporation of the different disciplines involving medical, engineering and artificial

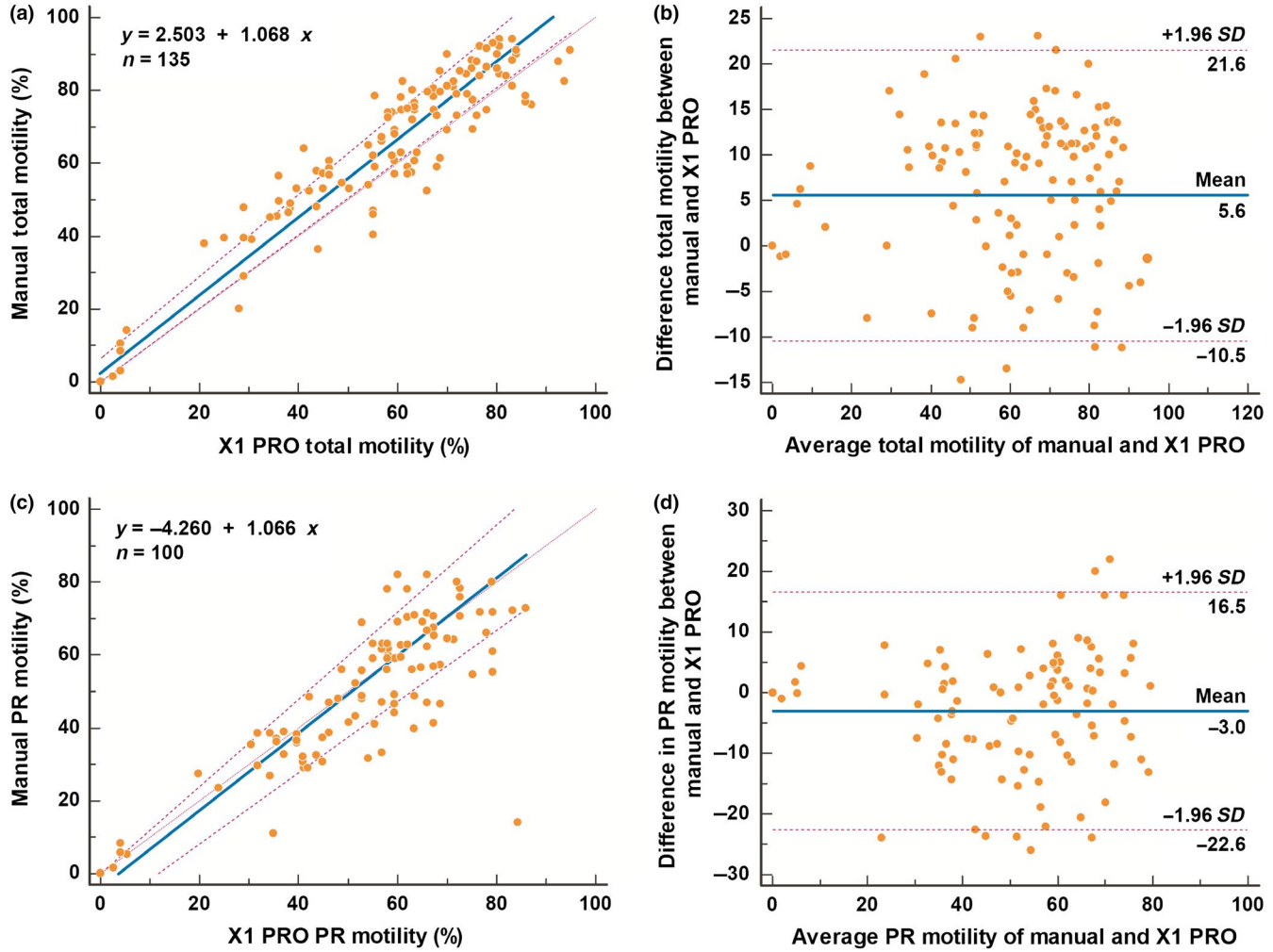

FIGURE 4 Comparing the sperm motility results between the automated X1 PRO semen quality analyser and manual microscopy method. (a) Passing–Bablok regression plots comparing automated (X1 PRO) versus manual readings. The solid blue line represents the regression line, the red dashed line represents the diagonal line, and the black dashed line represents a confidence band (n = 135). (b) Bland–Altman analysis of the total motility deviation results between the X1 PRO analyser and a manual microscope method. The solid black line represents the mean of the two methods, and the black dashed lines are the 95% confidence ranges. (c) Passing–Bablok regression plots comparing automated (X1 PRO) versus manual readings of progressive motility. The solid blue line represents the regression line, the red dashed line represents the diagonal line, and the black dashed line represents a confidence band (n = 100). (d) Bland–Altman analysis of the progressive motility deviation results between the X1 PRO analyser and a manual microscope method. The solid black line represents the mean of the two methods, and the black dashed lines are the 95% confidence ranges

intelligence. We have developed a novel AIOM technology-based semen quality analyser, LensHooke™ X1 PRO, addressing the issues of accessibility, simplicity, speed and portability. The X1 PRO analyser is an automated system that integrates the mechanical system, autofocus optical lens, AI algorithm and electronic platform in one compact device.

In this study, we evaluated the performance of the X1 PRO analyser in semen quality analysis in comparison with the manual microscopy method. Our study shows that seminal pH, sperm concentration, progressive motility and PMSC results from the X1 PRO analyser are comparable with the manual readings (Table 1). For sperm concentration, both the Spearman rank correlation coefficient and concordance correlation coefficient are above 0.97, indicating a high agreement between the manual reading and X1 PRO.

On the other hand, a significant difference ($p < .01$) for total motility and MSC measurements was observed between the two methods. A small p-value ($p < .01$) of the cusum test for linearity was found for total motility indicating that there is no linear relationship between the two measurements, and therefore, the Passing–Bablok analysis is not applicable (Table 2). The concordance correlation coefficient for total motility above $r = .94$ suggests a good correlation between the two methods (Table 3). Passing–Bablok regression analyses and the consideration of the 95% confidence intervals of the slop point out a proportional difference between the two methods on MSC measurement. Nevertheless, a high Spearman rank correlation coefficient ($r = .98$) was observed.

A recent study has shown that the YO device (Medical Electronics Systems), a home-based semen testing, has a very high

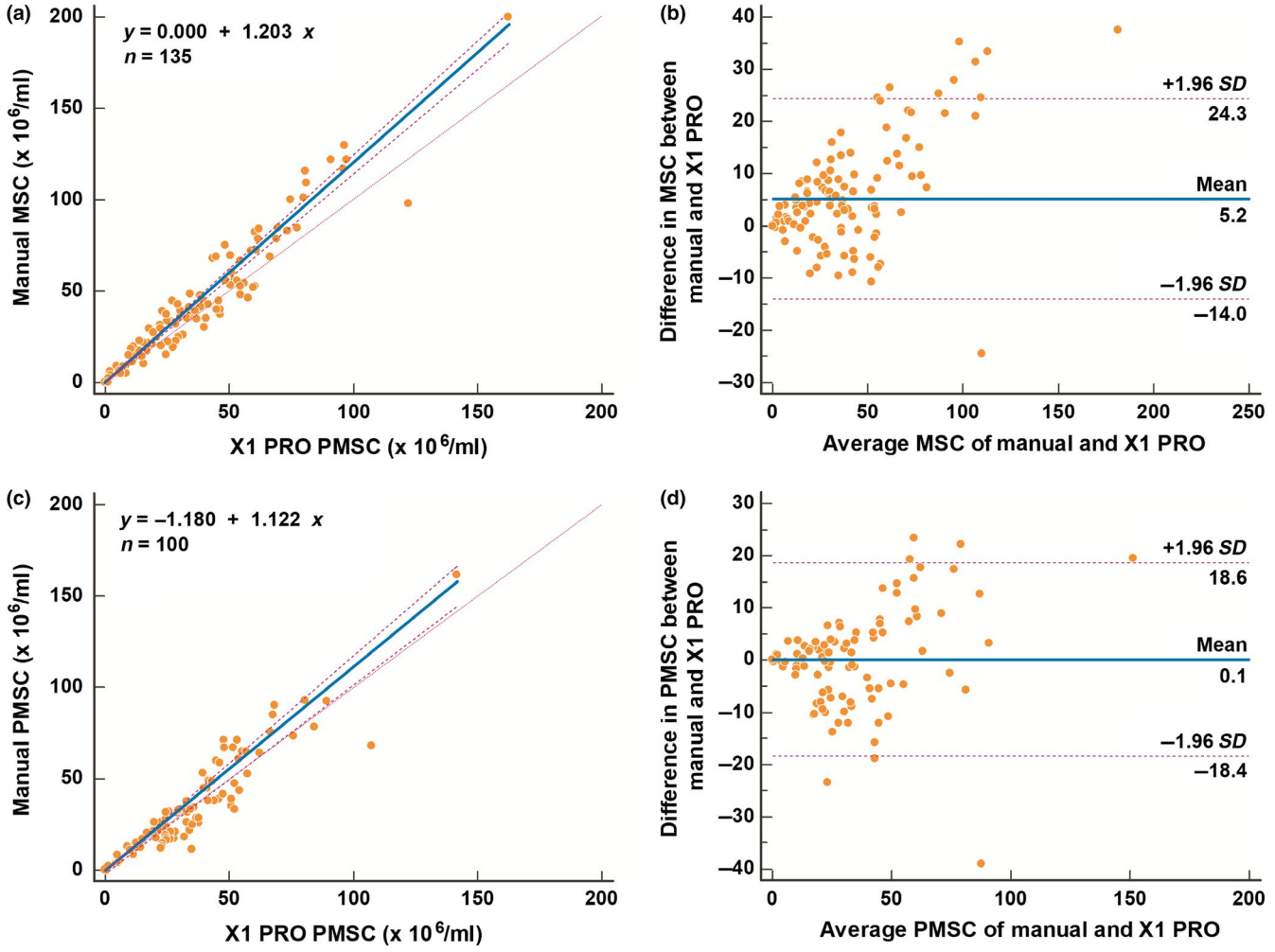

FIGURE 5 Comparing the sperm MSC and PMSC results between the automated X1 PRO semen quality analyser and manual microscopy method. (a) Passing–Bablok regression plots comparing automated (X1 PRO) versus manual readings of MSC. The solid blue line represents the regression line, the red dashed line represents the diagonal line, and the black dashed line represents a confidence band (n = 135). (b) Bland–Altman analysis of the MSC deviation results between the X1 PRO analyser and a manual microscope method. The solid black line represents the mean of the two methods, and the black dashed lines are the 95% confidence ranges. (c) Passing–Bablok regression plots comparing automated (X1 PRO) versus manual readings of PMSC. The solid blue line represents the regression line, the red dashed line represents the diagonal line, and the black dashed line represents a confidence band (n = 100). (d) Bland–Altman analysis of the PMSC deviation results between the X1 PRO analyser and a manual microscope method. The solid black line represents the mean of the two methods, and the black dashed lines are the 95% confidence ranges

level of sensitivity and specificity on MSC measurement (6 × 10^6/ml cut-off value) when compared to other methods (Agarwal et al., 2018). In the same fashion, the X1 PRO shows also a high level of accuracy with sensitivity and specificity above 96% (Table S1). In addition, the agreement of the methods illustrated by the Bland–Altman plots was poor, with a higher measurement of total motility and MSC in the manual reading revealed by a mean bias >5 (Figures 4b and 5b). Lammers et al. (2014) showed that manual reading of total motility was higher than those of two automated systems in a trial of 250 human samples. Recently, a study analysing 100 human ejaculates also showed a proportional difference for total motility measurements with a slope higher than 1.2 between the manual method and a commercially available automated device, SQA-V (Engel, Grunewald, Schiller, & Paasch, 2019).

For comparison of progressive motility, a low Spearman rank correlation coefficient (r = .81) reveals a poor agreement with manual reading and a significant systemic difference was observed with an intercept of −4.26 by Passing–Bablok analysis (Table 2). Engel and colleagues demonstrated systematic and proportional differences for progressive motility between the manual method and the SQA-V device with a large intercept (−18) and a slope higher than 1.2 as well as a low Spearman rank correlation coefficient (r = .86), indicating poor agreement between the two methods (Engel et al., 2019). This could be due to the fact that manual assessment of motility is subjective and generally overestimated because of the attraction of the eye to movement (Komori et al., 2006; Tomlinson et al., 2010). Therefore, manual assessment of sperm motility is often miscalculated.

Psychological factors, such as social stigma or embarrassment, may cause some men to hesitate to seek medical help, resulting in delayed male infertility treatment and unnecessary medical interventions for his female partner (Datta et al., 2016). If accessible semen testing could be carried out at home and provide meaningful preliminary data to the physician in advance, it would benefit a large portion of men suffering from infertility. Based on this rationale, Kanakasabapathy et al. (2017) developed a smartphone-based assay for at-home semen analysis that involves an optical attachment and a disposable microfluidic device for handling of the specimen. Similarly, a smartphone combined with a ball lens microscope and an LED flashlight has been developed for determining sperm concentration and motility (Kobori, Pfanner, Prins, & Niederberger, 2016). However, the specific model or restricted location setting between the camera of the cellphone and the additional optical device may limit convenience and consistency when using these smartphone-based semen testing.

Other home-based semen assays on the market, including FertilMARQ, SpermCheck and Trak, measure sperm concentration in a semi-quantitative fashion but do not measure motility (Schaff et al., 2017). Incomplete data, however, will give the user a false sense of security that their seminal parameters are normal, leading to potentially delayed infertility therapy, and vice versa. Products of this category of home-based semen testing may be best suited to post-vasectomy screening and may also be applicable for animal breeding, but they cannot eventually replace a full infertility examination by a specialist. Therefore, advertising these assays as at-home fertility assessments could be misleading and should rather be regarded as screening devices. In contrast to the above systems, the X1 PRO not only has an easy-to-use operational interface, but it is also able to produce test results along with a video of sperm dynamics in a few minutes (Figure S1). In this situation, the physician can immediately discuss the semen quality with patients in the clinic. This advancement largely saves the time waiting for the report as well as provides appropriate and secure male infertility testing in the hospital.

On the other hand, comparing the correlation of the measurement of normal sperm morphology obtained by the X1 PRO and the manual method was a limitation in this study. Since each hospital had its inherent operational procedure and criteria to determine normal sperm morphology, a proper correlation and agreement analysis of normal sperm morphology between the two methods were not possible. However, this analysis will be done in a separate study.

In conclusion, the advantages of using the LensHooke™ X PRO automated semen analyser are miniaturisation, standardisation, speed, objectivity, automated data saving and being easy-to-use. The portable X1 PRO device shows clinically acceptable agreement with the reference manual method and has the potential to be used as a home-based analysis for evaluation of semen quality.

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CONFLICT OF INTEREST

None of the authors have any conflict of interests to declare.

AUTHOR CONTRIBUTIONS

Chun-Chia Huang and Maw-Sheng Lee conceived the study and analysed the data. Ralf Henkel and Ashok Agarwal drafted the article. All authors approved the manuscript.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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