Multicentre evaluation of the new ORTHO VISION® analyser

E. Lazarova,1 Y. Scott,2 A. van den Bos,3 P. Wantzin,4 R. Atugonza,5 S. Solkar5 & N. Carpio6

1 Transfusion Laboratory, CUB Hôpital Erasme, Brussels, Belgium, 2 Transfusion Laboratory, Freeman Hospital, Newcastle Upon Tyne NHS Trust, Newcastle Upon Tyne, UK, 3 Transfusion Laboratory, Radboud University Medical Centre, Nijmegen, the Netherlands, 4 Blood Bank Department, Rigshospitalet, Herlev Hospital, Herlev, Denmark, 5 Haematology & Blood Transfusion, Royal Free London NHS Foundation Trust, Royal Free Hospital, London, UK, and 6 Health Research Institute, Hospital Universitari I Politècnic La Fe, Valencia, Spain

Received 6 February 2017; accepted for publication 1 June 2017

SUMMARY

Background: Implementation of fully automated analysers has become a crucial security step in the blood bank; it reduces human errors, allows standardisation and improves turnaround time (TAT).

Objectives: We aimed at evaluating the ease of use and the efficiency of the ORTHO VISION® Analyser (VISION) in comparison to the ORTHO AutoVue® Innova System (AutoVue) in six different laboratories.

Methods: After initial training and system configuration, VISION was used in parallel to AutoVue following the daily workload, both automates being based on ORTHO BioVue® System column agglutination technology. Each participating laboratory provided data and scored the training, system configuration, quality control, maintenance and system efficiency. A total of 1049 individual samples were run: 266 forward and reverse grouping and antibody screens with 10 urgent samples, 473 ABD forward grouping and antibody screens with 22 urgent samples, 160 ABD forward grouping, 42 antibody screens and a series of 108 specific case profiles.

Results: The VISION instrument was more rapid than the AutoVue with a mean performing test time of 27.9 min compared to 36 min; for various test type comparisons, the TAT data obtained from VISION was shorter than that from AutoVue. Moreover, VISION analysed urgent STAT samples faster. Regarding the ease of use, VISION was intuitive and user friendly.

Conclusions: VISION is a robust, reproducible system performing the most types of analytical determinations needed for pre-transfusion testing today, thus accommodating a wide range of clinical needs. VISION brings appreciated new features that could further secure blood transfusions.

Key words: automation immunohematology, blood bank, efficiency, pre-transfusion testing.

The top priority for the transfusion service worldwide is to provide safe and appropriate blood products to the right patient at the right time and for the right reasons. Even if pre-transfusion testing is only one step in the entire transfusion procedure, it is crucial that potential errors are as low as possible. In order to improve pre-transfusion testing safety and efficiencies, new testing technologies and automated instrument platforms have been developed in the past decade (Butch, 2008). Implementation of fully automated analysers in the blood bank have facilitated human error reduction, technique standardisation workflow and improved turnaround time (TAT). Even if workload increases, it is imperative to maintain TAT and cost-effectiveness (South et al., 2012). Additionally, in order to assure urgent release of blood on demand, the latest generation of automated blood bank analysers should improve its workflow speed according to the current needs.

There are several published studies (Sandler et al., 2000; Shin et al., 2008; Schoenfeld et al., 2010; Taylor et al., 2010; Shin et al., 2013; Chang et al., 2014; Cheng & Wilkinson, 2015; Roback et al., 2015) comparing the efficiency of different automated platforms or automated and manual methods. Although all these automated methods have significantly contributed to the improvement of test performance and finally to the patient’s safety, none has been proven to be superior to others. To our knowledge, there are no studies published so far that compare the same automated method in a next-generation automated platform. The ORTHO AutoVue® was originally introduced in 1997, fully automating the previous ORTHO BioVue® Systems test. In 2004, a major update to the ORTHO AutoVue® was completed, and the ORTHO AutoVue® Innova System was introduced. The next-generation ORTHO VISION® Analyser was recently introduced; it was CE marked in 2015 and received FDA 510 K clearance in 2016.
The aim of this study was to conduct multicentre immunohaematology testing on the next-generation ORTHO VISION® Analysers (VISION) in different clinical settings and to compare it with the previous ORTHO AutoVue® Innova System (AutoVue). Additionally, we focused on evaluation of the ease of use and efficiency of VISION throughout the whole workflow process.

MATERIAL AND METHODS

Participating centres

The present study was simultaneously performed at six sites: Freeman Hospital (FH), Newcastle upon Tyne (United Kingdom); Radboud University Medical Center (RUMCN), Nijmegen (The Netherlands); Hospital Universitari I Politècnic La Fe (HLF), Valencia (Spain); Rigs Hospital (RH), Copenhagen (Denmark); Royal Free Hospital, HSL Analytics, LLC, London (United Kingdom); and Hôpital Erasme (ULB), Brussels (Belgium). The participating centres present annual immunohaematological test volumes ranging from 16,000 to 64,000. All participating centres use a standard process for pre-transfusion tests, using AutoVue automation, whereby a Type & Screen (T&S) is performed based on the Laboratory Information System (LIS). The type and screen is defined as the automated determination of an ABO/Rh (D) typing or an ABd control typing (in case ABO/Rh (D) type is already known based on two independent samples) and an antibody screening for clinically significant antibodies.

Study design

After the initial VISION installation, the local custom system configuration, maintenance protocols and quality controls were designed. Afterwards, the staff member(s) were trained on the system and were asked to evaluate training methods and materials. The training consisted of online (pre-course e-learning module) and in-person training. Each participating laboratory provided data and feedback through questionnaires (79 total questions across all questionnaires) and daily activity reports for the following test cases: training, system configuration, quality control, maintenance and system efficiency. Each questionnaire had an overall rating with regards to user satisfaction, level of proficiency or level of ease for the tasks in the test cases. The rating scale ranged from 1 to 5, with 5 being very high, very good or very easy and 1 being very low, not good or very difficult. Additionally, each question allowed for participant commentary.

The immunohaematology tests were defined and performed by both analysers. The VISION testing was configured following the AutoVue configuration at each centre. Each site executed test cases of its own typical activities in addition to testing of newly introduced functionalities in the system, e.g. serial dilutions and remote result review. The VISION analysers were used only for this study, and each VISION analyser and all unused supplies were removed from every participating centre at the conclusion.

It took an overall of 4–6 weeks for VISION analyser installation, training and completing the study.

Ethics approval was received in each participating centre from the local ethics committee before the beginning of the study.

ORTHO VISION® Analysers

Both ORTHO AutoVue® Innova Analysers (AutoVue) and the ORTHO VISION® Analysers (VISION) are automated in vitro immunohaematology instruments that use ORTHO BioVue® (Biovue) System column agglutination technology (CAT) with digital image processing to perform testing. They integrate automation in multiple steps in the testing process, such as liquid pipetting, reagent handling, incubation, centrifugation, reaction grading and interpretation by digital image processing and data management. Both can be used as a stand-alone instrument or interfaced with the laboratory information system (LIS).

Recent technical improvements presented on the VISION instrument include dedicated reagent loading area and an independent review rack; partial cassette usage and re-usage; the ability to use selected cells in antibody identification; temperature-controlled (~18°C) on-board reagent storage; automated quality inspection of each cassette prior to use; cap detection at the time of sampling; serial dilution tests availability; remote result review function; and the introduction of the Intellicheck® function, e.g. complete automated audit of each sample processing step, providing total comprehensive understanding of the sample processing through the system.

Reagents

The test procedure is based on the principle of agglutination. Normal human red cells that possess the appropriate antigens will agglutinate in the presence of antibodies directed towards the antigen.

The BioVue utilises column agglutination technology (CAT), comprised of glass beads and reagent contained in a column, that, upon centrifugation of the cassette, traps agglutinated red blood cells and allows non-agglutinated red blood cells to travel to the bottom of the column. Red cells are separated from the serum proteins prior to exposure to reagent. The density of the reagent allows the red blood cells to pass through the column, whereas the less dense serum proteins remain above the glass bead/reagent interface.

A positive reaction is defined as agglutination, represented by red cells retained in or above the glass bead column. A negative reaction is defined as absence of agglutination, represented by a button of packed cells at the bottom of the column. The positive reactions are graded between 1+ and 4+ based on the strength of the agglutination and according to manufacturer’s instructions, 4+ being the presence of agglutinated cells as a band on the top of the bead column, 3+ being the image of the most agglutinated cells remaining in the upper half of the bead column, 2+ being the image of agglutinated cells observed throughout the length of the bead column and 1+ being the image of most agglutinated cells remaining in the lower half of the bead column.
ORTHO BioVue® Cassettes (Ortho-Clinical Diagnostics, Pencoed - United Kingdom) employed are as follows:

- ABD Confirmation, ABO-Rh/Reverse, Newborn or ABO-Rh Grouping cassettes
- Anti-IgG or antihuman globulin (AHG) Polyspecific and Neutral cassettes
- Reverse Diluent or Anti-IgG cassettes
- Rh/K cassettes
- Neutral cassettes
- Direct antiglobulin test (DAT) cassettes (anti-IgG, anti-C3b, C3d).

Reagent Red Blood Cells (RRBC) utilised are as follows:

- 0.8% Surgiscreen
- 0.8% or 3% Affirmagen
- ORTHO Resolve® Panel C Reagent Blood Cells

Blood samples

The samples for the study were selected from the residual waste volume of daily workload. These samples were unlinked from all patient-identifying information, and results were not used for patient diagnosis or evaluation.

Test types

Because of varying regulation requirements in different EU countries, some tests of the same type can be executed with different combinations of reagents. All sites used the ORTHO BioVue CAT technology, but different cassette types and reagent red cell combinations were used to obtain results for the different test types (ABO, D, Antibody Screen) across sites on both analysers. Within each site, test types were set up identically to allow for direct comparison of the TATs on the AutoVue and VISION analysers.

**ABO and D typing.** Three different types of ABO and D typing were performed across all sites:

- ABO/D typing for patients with Forward (FWD) and Reverse (RVS) testing
- FWD + RVS: 4 + 2 columns and 6 + 2 columns
  - Anti-A, Anti-B, Anti-D, A1 cell, B cell, Ctrl
  - Anti-A, Anti-B, Anti-AB, Anti-D, Anti-CDE, Ctrl, A1 cell, B cell
  - ABD confirmatory testing for known patients or donors (ABO and D forward typing only)
  - FWD: 3 columns: anti-A, Anti-B, Anti-D
  - ABO/D typing for New-borns (Forward typing only)
  - FWD: 6 columns:

Rh and K phenotype typing. All sites that performed the Rh/K phenotype test used a 6-column cassette.

Antibody detection testing. All sites performed a three-cell screen test in a Polyspecific (Anti-IgG, -C3d) or Monospecific (Anti-IgG) AHG cassette for type and antibody screen or antibody detection only.

Cross-matching (XM) and direct AHG testing. Three sites performed Major XM testing in a Polyspecific (Anti-IgG, -C3d) or Monospecific (Anti-IgG) AHG cassette and DAT testing in a Polyspecific (Anti-IgG, -C3d) or Differential DAT (Anti-IgG, -C3d, ctrl) AHG cassette.

Test combination in different centres

The test types listed above were combined in a variety of 26 different profiles depending on the needs of each centre. Profiles used in each site on AutoVue were identical on the VISION platform in order to allow for direct comparison of the TAT and system efficiency.

Data collection and analysis

Data were collected from both the VISION and the AutoVue electronically using e-Connectivity® by Ortho. Those data were then analysed, and data sets were returned to the participating centres for review.

System Efficiency testing

For the System Efficiency evaluation, each centre ran a subset of their daily AutoVue workload on the VISION, repeating the AutoVue sample loading pattern. This loading pattern varied between the centres based on their individual practices. The samples were loaded in different batch sizes, up to as many as 20 samples at a time. In addition, STAT (urgent) sample TAT was evaluated in three centres as follows: in a daily workload setting, a STAT sample of type and screen was introduced on a 10–15-min basis. In addition, a total of 1049 samples tested against a variety of 26 different profiles were run in parallel on AutoVue and VISION.

Result reproducibility testing

Two of the participating centres (Erasme Hospital ULB and University Hospital La Fe) performed comparison tests between AutoVue and VISION on five different work days using the same operator. A total of 102 ABO/D typings with ABO and D Forward and Reverse testing, Rh and Kell typing and antibody screen (ABS); 38 ABD confirmatory testing for known patients combined with ABS; 34 ABO/D typing for New-borns; 97 ABS
alone; and 61 complete ABO/D typings with ABO and D Forward and Reverse testing, Rh and Kell typing without ABS were performed on AutoVue and repeated on VISION within 1 h.

Graphical and statistical analysis
Statistical analysis and frequency histograms of TAT comparisons for VISION and AutoVue were performed using Minitab® 17.1.0. The histograms curves assume a normal distribution. In all frequency distributions, the data utilised compared paired tests between VISION and AutoVue. A paired Student’s t-test was used to evaluate statistical significance for parameters with normal distribution, and the Wilcoxon paired non-parametric test was used for groups with non-Gaussian distribution. P value <0.05 was considered significant.

RESULTS
Tests performed
As the same cassette types and reagents were used on both analysers, the study focused on system efficiency rather than concordance of the results. In order to merge and analyse the data, the tests composing the case profiles, specific for each participating centre, were considered individually. The results from all 941 individual tests run on AutoVue and on VISION in the same local profile settings are presented in Fig. 1 and Table 1.

Fig. 1. Frequency histograms of VISION vs AutoVue. (a) Population distribution of the time to results in minutes (all paired profiles/all sites); (b) Frequency histograms, assuming normal distribution, of 941 paired tests, plotted together, time to results in minutes for VISION and AutoVue; P < 0.05.
These data include forward and reverse grouping (n = 266), ABD forward grouping and antibody screen (n = 473), ABD forward grouping alone (n = 160), antibody screen alone (n = 42), STAT ABD forward grouping plus Ab screen (n = 22), and STAT ABD forward and reverse grouping plus screen (n = 10). A series of 108 case profiles specific for only one or two local centres, e.g. DAT, new-born grouping with or without Rh/K, groups combined with DAT or with K antigen typing, cross-matches, antibody panel identification, serial dilutions, were also performed (data not shown).

TAT comparison

After analysing all paired data, the VISION instrument was revealed to be 22% more rapid than the AutoVue with a mean performing test time of 27.9 min compared to 36 min (P < 0.001), Fig. 1 and Table 1. Test combinations shared by more than two local centres were plotted in separate graphs in order to look into details in the global data presented in Fig. 1 and to perceive from which tests or group of tests the statistical differences come from. Figure 2a shows forward and reverse grouping (n = 266), Fig. 2b shows ABD forward grouping and antibody screen (n = 473), Fig. 2c shows ABD forward grouping alone (n = 160), and Fig. 2d shows antibody screen alone (n = 42). The mean time to results in minutes and the standard deviation of the mean obtained with AutoVue and with VISION platforms for all profiles tested or for different tests or combinations of tests are presented in Table 1. For all test type comparisons, the TAT data obtained from the VISION was shorter than that obtained with the AutoVue analyser (P < 0.05), with percentage change varying from 7% to 25%.

STAT TAT for the ABD forward grouping plus Ab screen (n = 22) and for the ABD forward and reverse grouping plus screen (n = 10) in a daily workload settings are shown in Fig. 2e,f, respectively. VISION accomplished these STAT samples for a mean of 24.45 min and 24.9 min, which were significantly statistically different from the TAT of 32.6 min and 30.5 min, respectively, obtained with the AutoVue analyser (P < 0.05).

Concordance of results

Comparison testing between AutoVue and VISION performed at Erasme and Hospital La Fe showed 100% concordance of all results, including the number of rejected results that needed manual revision, e.g. eight weak reactions (data not shown). However, we noted in 10% of the samples in the Reverse ABO testing one point weaker strength of the reaction by AutoVue than by VISION.

Ease of use

A summary of the answers of the participants received through the questionnaires regarding the training, system configuration, quality control, maintenance and system efficiency are presented in Table 2. A total of 79 questions were answered across the questionnaires. An example of the several questions with response rating is shown in Table 3.

New tests

VISION provides for the first time the possibility of automated serial dilutions testing for alloantibody and isohaemagglutinin titration, and five out of six participating centres tested this technical innovation; a total of 17 samples were run, and the ease of use was analysed (Table 2). Results were compared to the manual tube-based techniques; titration by VISION showed systematically two dilutions higher titration results than the manual tube technique (data not shown).

Three participating sites performed major cross-match (XM) testing in Polyspecific (Anti-IgG, -C3d) or in Monospecific (Anti-IgG) AHG cassettes. Seven samples were run in parallel on AutoVue, so these data are included in Fig. 1. Seven other
Fig. 2. Frequency histograms, assuming normal distribution. (a) Time to results in minutes for VISION (V) and AutoVue (AV) of 266 paired tests of ABD Group (forward/reverse) + antibody screen; \( P < 0.05 \); (b) Time to results in minutes for VISION (V) and AutoVue (AV) of 473 paired tests of ABD Group (forward) + antibody screen; \( P < 0.05 \); (c) Time to results in minutes for VISION (V) and AutoVue (AV) of 160 paired tests of ABD Grouping (forward); \( P < 0.05 \); (d) Time to results in minutes for VISION (V) and AutoVue (AV) of 42 paired tests of antibody screen; \( P < 0.05 \); (e) Time to results in minutes for VISION (V) and AutoVue (AV) of 22 paired STAT tests composed of ABD (forward) grouping and antibody screen; \( P < 0.05 \); (f) Time to results in minutes for VISION (V) and AutoVue (AV) of 10 paired STAT tests composed of ABD (forward and reverse) and antibody screen; \( P < 0.05 \).

samples were individually tested in one of the centres in order to test the ease of use (data not shown).

The remote results review, one of the new features introduced in VISION, was tested by one of the centres; data shown in Table 2.

DISCUSSION

In the present multicentre study, we conducted routine immunohaematology testing on the VISION Analyser in different clinical settings and evaluated the ease of use and the efficiency of this new automated analyser, compared to AutoVue. The VISION was tested in different hospitals settings in terms of bed size, workflow, testing practices, work volume and emergency demands for a period of 4–6 weeks. The participating sites span across multiple countries in the European Union and are guided by varying regulatory authorities, resulting in a wide range of combinations of tests and pre-transfusion practices.

Each participating centre possesses local pre-transfusion testing specificities and applies local test type combinations
in profiles instead of running stand-alone tests. This ‘profile’ approach provides an efficiency advantage as it allows the automated system to optimise the distribution steps of the different reagents. In this study, the test types were combined in a variety of 26 profiles, each of them used to address the local testing practices. Profiles used in each site on AutoVue were identical on the VISION platform, which allowed direct comparison of the TAT and calculation of the change in system efficiency. However, in order to analyse the TATs correctly, we combined the individual test results data from each profile.

The VISION instrument was more rapid than the AutoVue for all tested profiles, analysed as individual tests or in various testing groups according to the different profiles (Table 1). We documented an improvement in the testing time on the VISION regarding all tests as well as regarding different type of tests when analysed alone, which ensures better efficiency of VISION than of AutoVue.

Table 2. Overall ratings of a total of 79 questions asked through the questionnaires filled by 1 up to 6 participating centres. Each test case was accompanied by a questionnaire consisting of several questions that received a rating with regards to user satisfaction, level of proficiency or level of ease for the tasks in the test cases. The response rating scale ranged from 1 to 5, with 5 being very high, very good or very easy and 1 being very low, not good or very difficult

| Test case                        | Number of centres | Rating (mean) | Rating (range) |
|----------------------------------|-------------------|---------------|----------------|
| Training of general operator     | 5                 | 3-6           | 3-3–4-3        |
| Training of key operator         | 5                 | 3-3           | 1–4            |
| Quality control                  | 6                 | 3-4           | 1.5–4          |
| Maintenance                      | 6                 | 4-0           | 2–5            |
| System efficiency                | 6                 | 3-7           | 2–4            |
| Serial dilution                  | 5                 | 3-9           | 3–4-3          |
| Remote result review             | 1                 | 4             | 4              |

Assuring urgent blood release with adequate automated pre-transfusion testing is still one of the major concerns of the modern blood banks. In order to assess these performances of the VISION instrument, we analysed STAT samples of type and screen in three of the participating centres. When inserting STAT samples into a batch of routine samples, the VISION guaranteed faster sample processing and availability of results, thus granting faster time to result for laboratories working with sample batches as well as incoming emergency samples (Table 1).

We have shown that the VISION system has a complete concordance of results when compared with AutoVue. The differences seen in the agglutination intensity for the weak reaction did not change final results and may be due to the image processing system of the equipment. Besides, the possibility of performing new tests, such as automated alloantibody and iso-haemagglutinin titration, is a valuable advantage that improves monitoring of difficult patients like those who have undergone stem cell transplantation with ABO non-identical donor. Differences observed for the alloantibody and iso-haemagglutinin titration between VISION and manual tube-based techniques were probably due to the greater variability of the manual technique; these findings are in agreement with previously published data comparing tube and CAT technology (Kumlien et al., 2007; AuBuchon et al., 2008).

VISION analyser delivers more dynamic workflow management, providing better adaptability to respond to unpredictable laboratory demand. These features are based on recent technical improvements presented on the VISION instrument, e.g. minimising process interruptions with a dedicated reagent loading area and an independent review rack; maximised reagent utilisation by punching only the columns that are needed and allowing for reintroduction of partially used cassettes; the ability to use selected cells in antibody identification, combined with the improved analyser stability for the reagent red cells, enhances the efficient use of cassettes and reagent red cells; the quality

Table 3. Example of test case questions and respective rating scales

| Test case (rating scale)                              | Questions                                                                 |
|-------------------------------------------------------|---------------------------------------------------------------------------|
| Training (1 = low, 5 = high)                          | Overall rating of confidence and proficiency with the ORTHO VISION Analyzer after General Operator Training |
| Training (1 = not prepared, 5 = very prepared)       | How well did completing the on-line training module prepare you for training?  |
| Training (1 = not effective, 5 = very effective)      | How effective were the practice exercises?                                 |
| Quality control (1 = low, 5 = high)                   | Overall, how would you rate the QC functionality in terms of effectiveness and ease of use? |
| Quality control (1 = not proficient, 5 = highly proficient) | Please rate your level of confidence and proficiency in setting up QC lots in the ORTHO VISION Analyzer |
| Quality control (1 = high, 5 = low)                   | How effective was the reference guide for QC set up?                      |
| Quality control (1 = not likely, 5 = very likely)     | Would your laboratory use the QC functionality?                           |
| Maintenance (1 = low, 5 = high)                       | Overall, how would you rate the ORTHO VISION in terms of effectiveness and ease of use for maintenance activities? |
| System efficiency (1 = much worse, 5 = much better)   | How would you rate the overall efficiency of the VISION compared to your current system? |
inspections of each cassette prior to use increases the success rate on the first pass yield of tests; cap detection at the time of sampling reduces risk of downtime if caps are accidentally left on the sample tubes; the ability to run serial dilution tests further eliminates the need for manual testing and increases standardisation; and the remote review function allows for efficient management of results in today’s complex laboratory organisations. Additionally, the VISION analyser provides proprietary IntelliCheck® Technology, which verifies and documents diagnostic checks throughout sample processing, such as pre-qualification checking of each cassette; dispensing volumes; and processing parameters including temperature, times and centrifuge speed. This information provides the confidence and information support that each assay is processed under controlled conditions, which can be accessed through the InteliReport.

According to the answers of the questionnaires elaborated to evaluate the ease of use, VISION was very intuitive and user friendly. The quality of the training was appreciated as appropriate for operators who were already familiar with AutoVue (Tables 2 and 3). The overall opinion was that the maintenance was straightforward and easy to execute. The traceability of the operators was improved, and the touch screen afforded efficiency savings. The analyser performed with stability and robustness, with no technical problems encountered during the study. Main positive points are the great management of emergencies, the possibility of introducing an urgent Ab identification panel or a cross-match, the most efficient cassette use (no wastage) and selected cell testing capability, the needle strength and cap detection, the possibility of retrieving of the cassettes for review without stopping the routine processing of tests and the reflex function utilising the reflex function for differential DAT testing after finding a positive DAT screen.

CONCLUSION

The VISION analyser is new-generation transfusion automated analyser that brings appreciated new features like urgent sample management, cross-matches, identification panels and antibody titrations on board, maintaining and even improving the efficiency known with ORTHO AutoVue® Analyser. It is a robust, reproducible system and can perform the most types of analytical determinations needed for pre-transfusion testing today, accommodating a wide range of clinical needs. VISION provides monitoring technologies (IntelliCheck® Technology and e-Connectivity) that could further secure blood transfusions.

ACKNOWLEDGMENTS

Financial and equipment support for this study was provided by Ortho-Clinical Diagnostics, Inc.

E. L., Y. S., A. B. and N. C. designed the research study and analysed the data. E. L., Y. S., A. B., P. W., S. S., R. A. and N. C. contributed to data acquisition. E. L., Y. S. and N. C. wrote the paper.

CONFLICT OF INTEREST

The authors have no competing interests.

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