

A COMPARISON OF VARIOUS HOME GLUCOSE
MONITORS AND THEIR SUBJECTIVE EASE OF USE
UNDER SIMULATED DIABETIC VISION LOSS CONDITIONS

J.GREGORY FORD
SENIOR INTERN

FERRIS STATE UNIVERSITY
COLLEGE OF OPTOMETRY

Blood glucose monitors have grown in popularity over the past ten years. With the advent of more sophisticated instruments, their reliability has increased. This trend is likely to continue indefinitely. As more and more patients elect to monitor their own blood glucose levels at home, there is likely to be an increase in the use among the visually impaired. It is the reason that this research herein was performed. Our goal is to determine the instrument best suited for the visually handicapped diabetic monitoring their own blood glucose levels.

Self monitoring of glucose levels leads to better control and therefore better individual health. While assisting in their own care, patients gain a desirable feeling of independence. According to the latest figures, approximately 6.14 million persons worldwide are visually handicapped diabetics. The use of a blood glucose monitor that is ideally suited to their vision loss situation would be a priceless asset to the patient's care. It is the hope of this research that we may find the instrument best suited for a particular vision loss situation.

RESEARCH PROTOCOL

As part of the research, six blood glucose monitors deemed practical for use by the visually handicapped were assessed. These instruments were tested under simulated vision loss conditions. The vision simulators were constructed from Sport safety goggles with crossed polaroid filters and varying degrees of overlying clear plastic strips. Along with decreased acuity and contrast, field losses were also represented by occluding certain portions of the lenses.

Simulator one was representative of Pan Retinal Photocoagulation encountered in the preproliferative or proliferative stages of diabetic retinopathy. Acuities tested through the simulator on a normal (20/20) subjects yielded acuities in the range of 20/30 to 20/40 O.U.. Contrast loss was encountered in the high spatial frequency range. Field losses for simulator one were minimal.

Simulator two represented proliferative diabetic retinopathy with extensive treatment. Field losses were simulated as scotomas including the macular area O.D. Acuities were reduced to the range of 20/80 to 20/100 O.U. Contrast sensitivity was again reduced in the higher spatial frequency as well as over the entire curve.

The third simulator with greatly reduced contrast over the entire curve and tubular (20 degree) fields represented advanced diabetic retinopathy with significant panretinal photocoagulation. Acuities with the simulator were 20/240 - 20/280 OU..

The fourth simulator was total occlusion OU., representing the non-light perception diabetic patient.

Subjects for this research were all correctable to 20/20 with normal intelligence and no physical handicaps. No subjects had previously used a home glucose monitor. Each subject was tested with only one vision simulator to insure pure subjective nature of the research. Each subject was made aware of the general principle of blood glucometers before donning the vision simulator. Each glucometer was presented on a level surface with a dark background. The subject, while wearing the vision simulator, was then made familiar with the controls on the machine and its general use. The blood glucose test strip was also presented at this time. A drop of artificial blood was placed on the medial edge of the index finger as testing commenced. The subject was then asked to place the sample blood onto the test strip at the proper time in the test sequence. The subject was prompted through the test sequence as necessary in a step by step manner. The subject was required to only do those steps required to test blood glucose on a daily basis. Subjects did not have to code or calibrate the instrument.

Upon completion of the test sequence for a unit, the subject was then briefed on the use of the following unit until all the units were tested. Units were presented in a random order to each subject as to reduce the learning factor error. After having used all the instruments the subject was then asked to complete a subjective questionnaire concerning the ease of use of various elements of the glucometers. Data was then compiled from this questionnaire.

INSTRUMENTS TESTED

Six blood glucose monitors were used for this research. These units were chosen on the basis of reliability, availability and use under vision loss conditions. The units for this evaluation were donated by their manufacturers or suppliers. Below are listed the instruments that were used for this research with a brief description of their use.

BOEHRINGER MANNHEIM ACCU-CHECK II WITH VOICE SYNTHESIS

The largest of the units tested, this instrument has a self contained carrying case. Also included in the unit is the AccuDrop mechanism (a guide for easier blood to strip application). The voice synthesis on this unit is very clear and concise. The testing sequence of this unit is 120 seconds. After placing the blood specimen on the test strip, the subject must press the TIME button. At 60 seconds the subject is to wipe the test strip and insert it in the monitor. The blood glucose level is displayed on the LED readout and is "called out" by the voice synthesis module.

BOEHRINGER MANNHEIM TRACER

A smaller unit of about 2 X 4 inches, the TRACER is a more compact and discreet unit. The instrument was one of the three instruments using audible signals and no voice synthesis. The timing sequence of the unit is also 120 seconds. Its general operation is much the same as the ACCU-CHECK II.

HOME DIAGNOSTICS DIASCAN S

This is an average sized unit of about 3 X 5 inches. The voice synthesis module used for this monitor is a separate unit of equal dimensions linked to the unit by an adaptor cord. The subject places the specimen on a test strip and pushes the time button at 30 seconds. At 70 seconds the monitor alerts the user to insert the test strip into the monitor. The results are displayed and called out at 90 seconds.

LIFESCAN GLUCOSCAN 3000

Glucoscan 3000 is similar in size to the DIASCAN unit. It utilizes the audible signal method of patient notification. The time sequence for this unit is 60 seconds. After placing the specimen on the test strip the subject presses the start button. At 20 seconds the subject must blot the test strip and insert it into the unit.

LIFESCAN ONE-TOUCH

This instrument is also similar in size to those previously mentioned. There are, however, some unique features of this monitor. This unit only requires 45 seconds to display a blood glucose reading and does not require the user to blot or wipe a test strip. The user places the test strip into the unit and then drips blood onto the strip. The unit senses the blood and begins the testing sequence automatically. The user need only wait for the results. This research project also made use of a voice synthesis module made available by the American Federation for the Blind.

EXACTECH FROM PHYSICIANS DIAGNOSTIC DIVISION OF BAXTER HEALTH CARE.

This is also an unique unit in that it is credit card sized and displays a reading in 30 seconds. This unit is the only one tested in the research which does not utilize reflectance and photometry. The user first inserts the test strip, or sample use enzyme electrode strip, which does not utilize reflectance specimen on the strip and presses the start button. A single use need not wipe the strip. A result is displayed within 30 seconds. No voice synthesizer is available for this unit.

RESULTS

RESULTS

Results from the questionnaire given to the subjects upon completion of the testing are contained below.

Question #1 - Operational Control Buttons - were they easy to locate and use

Subjects wearing simulator one (slight contrast and acuity loss) unanimously chose the LIFESCAN ONE TOUCH as the easiest to operate. The LIFESCAN has only one operational control button which only need be touched twice during testing. Chosen second by the group wearing simulator one was the TRACER unit. Subjects expressed that the contrast between the white unit and dark colored buttons made the TRACER's operational controls easier to locate and use. Surprisingly ranked last was the EXACTECH unit.

Subjects for group two (simulator with decreased acuity and several scotomas) chose the EXACTECH unit as their favorite in the operational controls category. The EXACTECH unit is a one step unit which requires the user to depress the one control button only once. Subjects from group two liked the fact that the control button was light grey on a dark background. The TRACER unit was ranked second by group two. The ONE TOUCH unit ranked number one by group one, was unaminously fourth for group two.

Those subjects wearing simulator three (tubular fields and greatly decreased acuity) chose the ONE TOUCH unit as their number one choice. The EXACTECH unit was ranked second by the group in this category, followed closely by the TRACER. Both these units have high contrast operational controls.

The DIASCAN S and GLUCOSCAN 3000 were consistantly ranked poorly by all three groups. These units each have three operational control buttons and low contrast backgrounds.

Question #2 - Digital Display - were you able to see and understand the display?

Group one thought the EXACTECH unit was the best in this category. The EXACTECH unit has a very high contrast LED display. Group one ranked the remaining in the following order: (2) TRACER (3)GLUCOSCAN (4) ONE TOUCH (5) DIASCAN (6) ACCUCHECK.

Group two felt quite differently about the ACCUCHECK units display and ranked it number one. Both the GLUCOSCAN unit and the EXACTECH unit were ranked closely behind.

Group three, on the other hand, felt the GLUCOSCAN unit offered the best display resolution for them. The EXACTECH and TRACER units were again rated highly. Consistently ranked poorly by this group were the DIASCAN and ONE TOUCH units. The latter uses a dot matrix system which was difficult for all simulated

vision losses to see clearly. The DIASCAN unit does not offer the high contrast display of the other units.

Question #3 - Audio Signals - Were they easy to hear and understand?

Consistently ranked in the top three for all simulators were the ONE TOUCH, ACCUCHECK, and TRACER units. Surprisingly, the DIASCAN, a voice synthesized model was ranked last by all groups. While the ACCUCHECK and ONE TOUCH units had very clear voice synthesis and well organized directions, the DIASCAN unit was difficult for most subjects to understand.

Question #4 - Test Strips - Were the strips easy to work with?

For this question, results were varied, much like the design of the test strips. The ONE TOUCH unit has a large, rigid test strip which is easy to visualize and grasp. The other strips are much like one another in that they are smaller and much less rigid than those of the ONE TOUCH. The ONE TOUCH strips were ranked first by all subjects. The strips for the EXACTECH unit are small but very rigid electrode strips which must be carefully inserted into the instrument prior to blood sample. It is important for the user to not contaminate the test strip. The area of insertion into the EXACTECH unit is very small and not well marked. Consistently subjects had much difficulty with the EXACTECH strip, and therefore consistently ranked it last in this category.

Question #5 - Instructions - Were the instructions included with the unit easy to see and understand with your simulated vision loss?

After a subject had completed testing all the units they were presented with the instruction manuals for each unit. The subject then ranked the instruction booklets according to the ability to see and understand the booklets. The ACCUCHECK booklet was consistently ranked above the rest. This fact is not a surprising one when one considers that the ACCUCHECK instruction booklet is a large spiral folder with high contrast, large print with symbols included. The rest of the instruction booklets were ranked as follows: (2) DIASCAN (3) EXACTECH (4) GLUCOSCAN (5) ONE TOUCH (6) TRACER.

Question #6 - General Use - Considering all factors, rank the glucometers according to overall ease of use considering your simulated visual loss.

This question is the most revealing of all questions. Subjects were asked to judge the devices on an overall basis which was often times much easier task than ranking the devices in a certain category. Subjects with simulator one chose the ONE

TOUCH unit as their unanimous favorite followed closely by the TRACER and ACCUCHECK in that order. The EXACTECH unit was rated a close fourth while the DIASCAN and GLUCOSCAN units followed behind.

Group two was also very impressed with the ONE TOUCH units ease of use as they also rated the unit in their top spot. The ACCUCHECK unit was rated second while the other voice synthesis model, the DIASCAN was third. TRACER, EXACTECH and GLUCOSCAN took the fourth through sixth positions respectively.

Group three, which represented the evaluations most profound visual defects, also chose the ONE TOUCH unit as the easiest to use. Group three rated the EXACTECH and ACCUCHECK units in a tie for second. The DIASCAN, TRACER and GLUCOSCAN units followed closely behind.

RESEARCH COMMENTS

In the beginning discussion of the research, it was stated that a total vision loss simulator would make up the fourth sample group. In fact, a total blind simulator was used on four subjects but the results were very poor. Normally sighted individuals who are placed in a total vision loss situation do not adapt well. Such was the case with this research. Subjects were unable to relate well with any instrument and found using the units extremely tedious. More importantly, no subjects could give subjective responses to the questionnaire. A simulated total blind situation caused too much confusion for any accurate research to be done in this area.

By the same token, it is important to realize that many subjects did not adjust well to any vision loss simulation. In order for the research to be more accurate, sample groups would need to be used with actual vision losses of the type researched. The constraints of this evaluation would make this type of sampling very difficult.

This research was confined to only those instruments by manufacturers or suppliers who responded to written inquiries before research commenced. Other glucometers may exist for the visually impaired which were not discussed in this research. The glucometers chosen for use were all considered acceptable in accuracy by Health Devices research.

CONCLUSIONS

Considering the subjective nature of this evaluation, drawing absolute conclusions is difficult. It is important, however, to point out some general trends and useful information generated by the survey.

In regards to operational controls; the instruments with high contrast controls were easier to use. For the most part, those with fewer controls were rated higher by subjects. The overall best in the operational control category to all subjects was the ONE TOUCH unit. Although the ONE TOUCH unit does not have a high contrast control, it is very easy to see and understand.

Contrast seemed to be the deciding factor also when considering the display of each unit. Those units which have large, high definition displays were preferred. Both the GLUCOSCAN and EXACTECH units did well in this area.

At the outset of the research, it seemed the obvious favorites in the audio signal category were to be the three voice synthesized units. However, there is one surprise in this area. The DIASCAN unit, a voice synthesized unit, finished disappointing sixth overall in this category. The Voice synthesis module for this unit was difficult for subjects to understand. Another drawback of the DIASCAN unit was its insufficient voice directions. Subjects often missed steps in the testing process. The glucometer chosen to have the best audio was the ACCUCHECK unit which was exceptionally specific and clear in directing the subjects.

As stated earlier, the results of the questions concerning the test strips were widely dispersed with the exception of the ONE TOUCH unit. This unit has a wide strip with a highly visible test area which most subjects found to be very helpful. The ONE TOUCH Touch strips, unlike others, is inserted into the instrument prior to placing the blood sample. Wiping is not required with this or the EXACTECH unit. An unfortunate drawback of the EXACTECH unit was the difficulty subjects had with placing the strip in the unit. This unit, like the ONE TOUCH, require that the user place the strip before placing the sample. During research, assistance often had to be given to the user of the EXACTECH unit to utilize the strip.

The rankings assigned to the instruction booklets were discussed earlier with the ACCUCHECK unit having the most beneficial instruction booklet.

The most revealing question on the survey, as discussed earlier, was the final summation question concerning overall ease of use the units tested. This question required the subjects to weigh out the pros and cons of each unit and choose their favorite considering their particular vision loss situation. Consistently ranked lowest overall was the GLUCOSCAN unit. The GLUCOSCAN is not a voice synthesis unit and had few distinctive features which may have led to its low ranking. The DIASCAN unit with its indistinct voice synthesis rated fifth overall. The difficulty people had with the test strip insertion on the EXACTECH unit left it ranked a surprising fourth. Other features made the EXACTECH a favorable unit, unfortunately visually

compromised individuals had great difficulty with the strip. The TRACER was another surprise, rated a high third with subjects most likely due its high contrast controls and well timed signals. Second overall was the ACCUCHECK unit. As discussed before, this unit is complete with voice module, carrying case, and the "Accudrop" attachment for assisting the visually impaired with sample placements. The overall highest ranking goes to the ONE TOUCH unit. This unit seems to combine all the positive features of the other units into one. The operational controls are easy to locate and use. The voice synthesis module provided by the AFB is clear and concise. The strips are easy to work with and require no wiping. Although the visual display is difficult to see under vision loss situations, the other advantages more than make up for any shortcomings. The preferred unit of this research, due to its outstanding ease of use in most all catagories, is the ONE TOUCH unit with the AFB Voice synthesis.