ISSN 2055-1282
December 2020 / **Issue 15**

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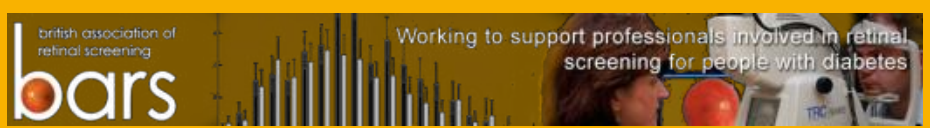

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DiabeticEyeJournal

What a year it has been so far. Not one of us could have imagined this time a year ago. The pandemic has not only disrupted lives, but has interrupted patients' care and the delivery of crucial services. It has also meant that production of the DEJ was suddenly thrown into disarray, some contributors were no longer able to commit to delivering their articles and timelines became less and less important. Meanwhile, health care professionals were redeployed to areas of urgent need in our hospitals. Nevertheless, the Autumn issue of the DEJ is here, not only with our usual columns, but with additional perspectives on what it's been like working through a pandemic.

What we had wanted to concentrate on in this edition was the 20th anniversary of BARS and its Annual Conference, which unfortunately had to be postponed and will kick off with an even louder bang in September 2021. The BARS organisation has been supporting the Retinal Screening Community for 20 years and began its journey hand in hand with the national delivery of diabetic eye screening services. You can find out how it all began in the article by Professor Roy Taylor and Lillian Lovelock, plus a personal perspective from Angela Ellingford. They were all members of the BARS Council when the organisation was founded in 2000.

Self-isolation, fear of infection and increased pressures on hospital eye services have meant that not all patients were able to continue with their regular care. This has led to the unmonitored progression of eye disease including Macular Degeneration. You can read about various imaging modalities used to monitor this condition in our section on other lesions by specialists from Wirral University Teaching Hospital.

Imaging has become an unmissable part of fundus examination, no more so than in Diabetic Retinal Eye Screening. But is it moving in the right direction? You can read about the quality of fundus cameras in an article by one of the members of the national DES Camera Assessment Group in the section on imaging.

Diabetes became ever important topic during this pandemic because many of those with the condition have had to take extra special care to avoid the virus. Our friends from DUK have been looking into how Covid affects those with diabetes, including its impact on DMO treatment.

And would it be safe to delay retinal screening during the pandemic for pregnant patients? Find out in a recent study by the team from Kings College, King's College Hospital and Guy's and St Thomas' Hopsital from London in our section on Diabetic Eye Disease.

We hope that you enjoy this issue and look forward to your feedback and contributions. Take good care, keep safe and carry on.

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DEJ content

RETINAL SCREENING AND BARS – How it all began

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The beginnings of an idea – Roy

In 1985, as newly appointed Consultant Physician, I found my Diabetes clinic had two young women – under 21 years – who were already blind due to their type 1 diabetes. 'Blind' was the accepted terminology then, and is appropriate to describe the brutal reality of two lives changed for ever. How could such tragedies be avoided in future?

Since the late 1970's, it had been possible to treat proliferative retinopathy successfully using laser therapy. The snag was that this was only effective before symptoms had developed. The concept of annual screening to detect early treatable retinopathy was already widely accepted, but the problem was that this had to be carried out using the ophthalmoscope. In busy clinics use of dilating eye drops was seen as unfeasible, and setting aside time to darken the room for ophthalmoscopy just impracticable.

The camera which could take Polaroid pictures of the retina had just been introduced. However, Ophthalmologists and most diabetes specialists all poured scorn upon the notion that this could be used for screening. But that opinion lacked any scientific basis.

The most important question in diabetes at that time was 'How to stop more people, especially young people, from losing their sight? I set out to find out whether this new-fangled retinal camera might be better than ophthalmoscopy in preventing repeats of the personal tragedies in my clinic.

Testing the idea

I went to see the Treasurer of the British Diabetic Association (now Diabetes UK). He was interested in the idea, gained support from other senior people in the organisation and awarded the requested £28,937 to fund the Mobile Retinal Camera Project.

If the retinal camera had just been placed in my clinic, it would have only been used two half days per week. Because of this I planned to mount it in the back of a suitable van, and to use it in diabetic clinics throughout hospitals of the Northern region.

We were fortunate in being offered a 7 year old ambulance. Although it had been destined for the scrap heap, it went on to serve the population of the North East for the next 7 years! This fantastic vehicle is shown in Plate 1. The back was converted into a darkened waiting area and a camera area (Plate 2). With the help of the Medical Physics department at the Royal Victoria Infirmary, Newcastle, we designed a vibration proofed mounting for this delicate instrument so that it would survive potholes and bumps!

There were 113 responses to the job advert for the first ever retinal screener/driver. Lilian Lovelock stood out then – and continued to stand out (Plate 3). She rose to the challenge of explaining to people with diabetes what it was all about, taking excellent photographs and making the research idea actually happen.

The results of the study were amazing. In 1990 we presented data proving that Polaroid photographs of the retina taken through undilated pupils were far superior to ophthalmoscopy carried out after dilation of the pupil and in a darkened room.

Plate 1:

The first mobile screening van with the Tyne Bridge in the background

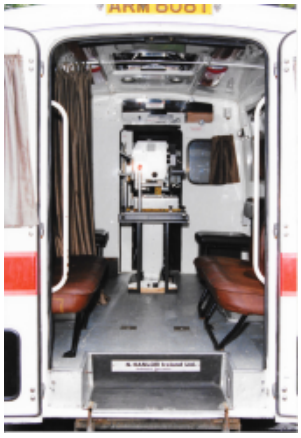
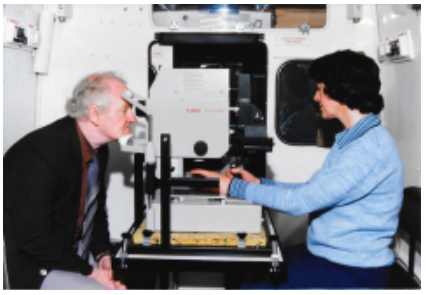


Plate 2:

The mobile unit contained the camera and a small darkened waiting area. In the early days, people would sit for 10 minutes to allow pupils to dilate prior to photography.

Plate 3:

Lilian taking a Polaroid photograph of the retina. She is looking at a small monitor to her right. During driving, the bolts holding the camera base were undone so that it was 'floating' on the foam mat, and 'ear muffs' were fitted to hold it still, using the holes in the upright bars.



Uproar!

Most ophthalmologists were outraged at the results. There was no way anything could be better than screening by the ophthalmoscope, they said. Photography would miss new vessel formation because these may be out of focus. The correspondence column of the BMJ glowed incandescently! Diabetes specialists too were lukewarm about the idea.

We made ourselves even more unpopular by demonstrating that retinal screeners using the Polaroid retinal camera could obtain and interpret images with greater accuracy than consultant ophthalmologists using fully dilated pupils and a slit lamp! Ophthalmologists are experts in managing severe retinal disease – but not good at meticulously searching for early disease in person after person. However, we had enormous support from Newcastle ophthalmologists from 1985 onwards, and that was vital.

There was only one thing to do. That was to persuade by gathering more hard data, especially using other centres throughout the UK. We kept the Northern Region Screening Service going with support from the IRIS fund. And then came a breakthrough - a £150,000 donation from the Allied Dunbar Foundation. This donation allowed us to purchase, fit out and run 11 other mobile units (Plate 4). All units performed well and some outstandingly, but I must mention Tayside, where Prof Ray Newton used one of the mobile units to build the foundations of the present fantastic Scottish Diabetes Information system, Norfolk where Dr Richard Greenwood derived data from a vast rural area, and Liverpool where Dr Deborah Broadbent and Prof Simon Harding used the mobile unit to carry out useful practical research on screening. From the 11 sites, plus Newcastle, we were able to analyse data on 64,000 screening episodes. This confirmed our original study.

The multicentre screening project was published in 1996. Suddenly it was game, set and match. We had National Eye Screening programmes in England, Scotland, Wales and Northern Ireland by 2002.

Plate 4:

The National Mobile Eye Screening Project vans lined up for the official start of the 12 centre Mobile Retinal Camera project in 1992. They are parked outside the old British Diabetic Association Headquarters in St Anne Street, London.

Retinal Screeners

It had become clear that we needed to invent a whole new type of diabetes health care professional. Lillian trained the retinal screeners initially, and I published some training resources. 'A Practical Guide to Polaroid Retinal Screening' was later updated and enlarged as 'The Handbook of Retinal Screening'. A CD Rom 'DR – a Dynamic Approach' - providing visual information and videos of procedures was widely used. Most recently, 'Life Without Diabetes' describing the new understanding of type 2 diabetes has been published for people with diabetes as well as Health Care Professionals. Other training centres were launched. In 1997 the first national workshop on retinal screening took place in Exeter; this was followed by three other national meetings, gradually putting together all the necessary consensus as to what was required.

On Thursday 5 October 2000, the first national meeting of BARS took place in Newcastle upon Tyne. Lillian Lovelock was elected as Secretary and I became the first President.

Lillian formalised the initial constitution with a lawyer friend. The early committee meetings were largely taken up with setting in place a recognised qualification, and after much work (especially by Dr Deborah Broadbent) this was adopted by City and Guilds. Since 2000, annual meetings of BARS have taken place, spreading good practice, providing education and creating a network of retinal screeners throughout the country. The organisation has achieved huge success in all respects.

Because of BARS, and every single retinal screener, diabetes is no longer the commonest cause of preventable adult blindness in the UK. Today in Tyneside, and possibly in the UK, there is no one under 21 years with loss of sight due to diabetes.

Lillian takes up the story…

I was appointed to the Newcastle Retinal Camera Screening in 1986 to establishing a brand new mobile patient care system. It covered an area within 35 miles of Newcastle, taking Retinal Screening Service into the community and successfully promoting shared care between hospital and general practitioner.

During the first 2 years of the service, an evaluation was carried out into the effectiveness of this system of screening. A person attending clinic would first have non-mydriatic retinal photography, then tropicamide would be instilled so that ophthalmoscopy could be performed by consultant or registrar. For this research, the photographs would remain hidden and were later reported by three experienced consultants. The person performing ophthalmoscopy filled in a proforma. Then the two sets of results were then compared - in over 2,000 patients. The non-mydriatic retinal photographs were shown to be as good as ophthalmoscopy with mydriasis at detecting new vessel formation whilst being significantly better at detecting exudative maculopathy. But we also found that of the 10% of people with poor quality images, half had been scored as having small pupils. From that time onwards, we used tropicamide eye drops routinely.

This led to many requests for advice from the newly appointed screeners, many of whom came to Newcastle for initial training. This made the need for a national training program very apparent to me. Retinal screeners needed a forum, to be seen as a respected professional body not merely a pressure group. All other professions had their own forums and retinal screeners needed an established organization that would represent and support them. This forum would also allow cross fertilization of ideas between all involved in providing retinal screening.

It was decided to organize a study day for retinal screeners in Newcastle. Various companies involved with retinal screening were invited to exhibit, speakers were arranged and a workshop organized. The day proved to be very successful and participants asked for it to become an annual event, and this did happen, at different centres across the UK. During this time a committee of retinal screeners was formed. It was this committee, after much deliberation and hard work that developed the British Association of Retinal Screeners (BARS).

This constitution was circulated to all known retinal screeners for approval. Voting in of the 1st BARS Council was to happen at the next National Meeting of retinal screeners. The meeting incorporated the Inaugural Meeting of BARS, on the first evening of the main meeting. This inaugural meeting, chaired by Lilian Lovelock and the (newly appointed) chair of BARS David Taylor, elected the required personnel for the committee. Members represented all areas of the UK. The afternoon session of that day was chaired by the 1st President of BARS - Prof. Roy Taylor. The day concluded with a Peking & Cantonese Banquet in the evening and great fun was had by all.

The following morning was filled with members presentations, setting the scene for the future ethos of BARS. After lunch we were fortunate to be given an insight into the deliberations of the National Screening Framework for Diabetes (then imminently due for release). This was followed by a talk from the President of the Royal College of Physicians, Prof. Sir George Alberti, entitled 'The National Screening Framework for Diabetes: will it help?' Twenty years on we can say "YES!" The lecture was followed by exhibitors demonstrating their latest developments for retinal screening. The day concluded with a Software & Hardware discussion.

The date of this inaugural meeting of BARS is engraved in my memory: Thursday 27th September 2001. That day realized a personal dream I had had for some time - to establish a body for retinal screeners that would represent them in the arena of health care provision, at the same time establishing a robust Training & Accreditation Programme for retinal screeners. I felt the foundation was laid on that day, and I slept well that night!

2021 bars

Conference in the City of Newcastle

Today I can say my dream has become a reality. BARS has moved from strength to strength since 2001 and is supporting retinal screeners on all fronts. As our journal states

'Working to support professionals involved in retinal screening for people with diabetes'.

Much to my surprise I was awarded an MBE in 2003 officially for 'Services to Retinal Screening'. This was something I had come to love and enjoy: Retinal screening!

I would like to wish you all every success in the future.

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Managing diabetic eye screening for pregnant patients during the COVID-19 pandemic

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Word Count: 976
Running title: **"Managing diabetic eye screening for pregnant patients…"**

Background

Pregnancy is known to increase the risk of diabetic retinopathy (DR) development and progression[1-3], which can lead to a visual loss[5]. Diabetic eye screening aims to identify referable retinopathy at an early stage allowing timely intervention and treatment.

The Diabetes in Early Pregnancy Study (DIEP) showed that progression of DR was more likely if retinopathy was present prior to pregnancy. In addition rapidly corrected, tight glycaemic control led to accelerated progression [2]. This was validated by other studies[6, 7], suggesting that ideally good glycaemic control should be achieved before pregnancy or should be optimised cautiously once pregnant.

DIEP also found that with a longer duration of diabetes (>15 years), 38% progressed to proliferative DR compared to 18% progression in those with diabetes ≤15 years [2]. Duration is unlikely to be the sole factor, another study found that 70% of women with diabetes >20 years did not have any DR progression, most likely due to a well-controlled HbA1c at presentation[8].

The level of pre-existing retinopathy is important as one study found that DR progressed in 77.5% of patients with pre-existing retinopathy compared to 26% of patients with no DR at the start of the study[9]. Morrison et al. analysed 14 studies and found that 30.2% progressed to proliferative DR where at baseline these patients had non-proliferative DR[10].

Current NICE guidelines are shown in **figure 1** [4]. During the COVID-19 pandemic, when lockdown was enforced from the 23rd March 2020, it was advised that patients should only attended essential appointments. There was additional fear amongst pregnant mothers who were considered more vulnerable, with possible risk to the foetus.

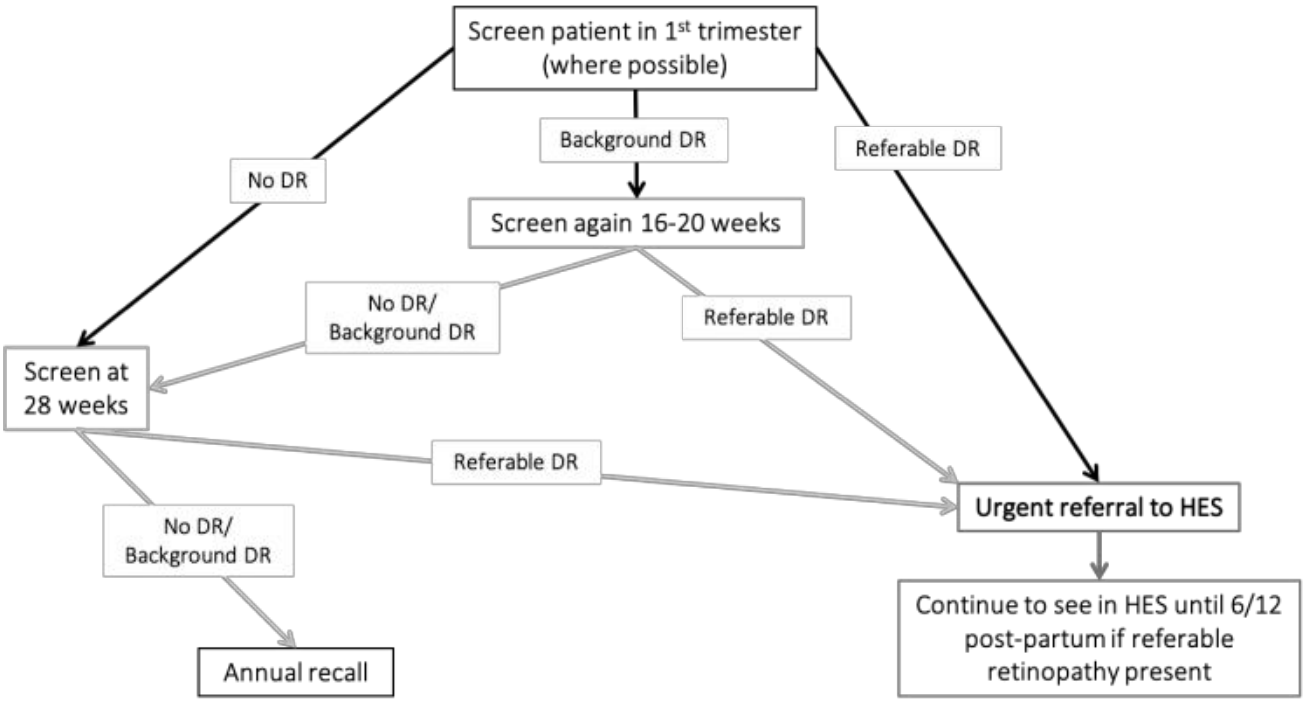

Figure 1. Schematic representation of the NICE guidance for diabetic eye screening in pregnant patients, adapted from NICE guidelines[4]. All pregnant patients with pre-existing diabetes should be screened initially for diabetic retinopathy within their first trimester and then again at 28 weeks if the first screen was graded as normal. If the first screen showed any retinopathy then a further screen at 16-20 weeks is indicated.

Changes to Diabetic Eye Screening during the COVID-19 pandemic

During the COVID-19 pandemic peak, the Royal College of Ophthalmologists recommended that routine Diabetic Eye Screening (DES) could be postponed, as these patients were deemed low risk. The college recommended continued eye screening for some higher risk groups including pregnant mothers with diabetes[11].

Methods - Continuation of Eye Screening Services

A centralised database was created to collate details of patients with pre-existing diabetes and pregnancy by the antenatal team. This allowed failsafe teams to monitor appointments, attendance, screening grades, and referrals.

As several community screening sites were temporarily closed, pregnant women were invited to Hospital Eye Service (HES) screening sites only particularly when co-located with antenatal appointments. This allowed further reduction of COVID-19 exposure. Additionally, if any pregnant mother required eye treatment, this could be carried out at the same time. Screening was carried out according to National guidance with mydriatic 2 field digital photographic screening per eye followed by grading of the images, or by slit lamp exam if photographic screening was not possible at HES sites. Towards the end of lockdown, community sites re-opened and adequate personal protective equipment (PPE) was available. Appointments were then booked at a wider range of community screening sites.

Failsafe mechanisms allowed the tracking of patients to ensure that these women were seen appropriately. Patients with more extensive retinopathy at baseline were prioritised. However, as women were invited at the same time as their antenatal appointments, they did not all have screening at precise time points. It was possible to invite women for their 16- and 28-week screen as needed at a community site once lockdown lifted.

Results of Screening

A total of 69 patients were seened during the period where routine diabetic eye screening was suspended. The majority of these were Type 2 diabetics (46) and 23 were Type 1 diabetics. **Table 1** shows the mean and range of HbA1c values in the patient cohort.

Table 1.

Mean, median, maximum, minimum and ranges of HbA1c for pregnant patients seen in this study (mmol/mol and DCCT %). The ranges show large variation within the patient's HbA1c. Non-diabetic values of HbA1c are less than 48mmol/mol or 6.5% (DCCT). Results were not available for n=28.

	HbA1c (mmol/mol)	% (DCCT)
Mean	54	7.1
Median	49	6.6
Maximum	112	12.4
Minimum	33	5.2
Range	79	7.2

The majority of patients did not show disease progression (80%), 20% of patients progressed. A total of 8 patients under routine DESP showed progression, 3 of these were at a level of referable disease (5.5%). One patient already under HES progressed to R3AM1 disease and was requiring laser treatment.

Table 2.

Number of patients with disease progression from last screen to current screen appointment. Yes – progression, No – No progression, miscarried, DNA – did not attend, TBC – to be confirmed (future appointments).

No progression	44
Progressed	11
Miscarried	5
Did not attend	4
To be confirmed	5
Total Screened	55
Total Invited	69

Antenatal clinics and screening scheduled at the same time and location meant that attendance levels were very high at 94%, with only 4 patients not attending. This proved to be a successful strategy through the pandemic.

A Case of Progression: A 33 year old Type 1 diabetic diagnosed in 2003 was under the care of ophthalmology, but had not attended appointments since 2017. Retinal images can be seen below in **figure 2**. This patient with multiple risk factors was successfully treated due to systems put into place during the COVID- 19 pandemic.

Figure 2. Retinal images of the patient's eyes taken on 08/07/2020. The patient fell pregnant and was referred urgently to HES in February 2020 with grade R2M1. Multiple appointments were offered from February to June. She attended in July 2020 and graded R3AM1; proliferative retinopathy in the right eye. Laser treatment was carried out on the same day with pan-retinal photocoagulation laser therapy. Images courtesy of Emma Richardson.

Conclusion

The COVID-19 pandemic poses uncharted challenges for healthcare systems. Patients at higher risk of DR, such as pregnant women were not failed by our Screening Programme that managed to adapt at the start of lockdown. Patients were booked into screening appointments on the same day as antenatal appointments. This helped to decrease unnecessary risk of COVID-19 exposure.

We demonstrated that although 20% progressed in their level of retinopathy during this time, only 5.5% (3 women) progressed to referable disease and only 1 required laser treatment.

This study has shown that it was safe to continue to screen pregnant mothers for diabetic eye disease at the height of the pandemic. There were no cases of any women contracting the virus within this setting. Screening at HES sites allowed treatment to take place at the same time, if required. This study also highlights the importance of failsafe procedures to ensure high attendance (94% and higher than pre-COVID levels). These mechanisms, which are less established in the HES setting, may prove invaluable in the future as we try to recover from the COVID-19 impact. Especially in the midst of an inevitable second wave and likely winter pressures.

Moreover, as healthcare systems gain knowledge and change behaviours, measures described in this study will gain value from additional resources.

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Diabetic Retinopathy Screening

A Personal Historical Perspective

Angela Ellingford
Former DRS Programme Manager, NHS Tayside

Diabetic Retinopathy Screening (DRS) has been a part of my professional life for over twenty five years. This historical account describes how NHS Tayside, with its advanced IT infrastructure was able to collaborate with the DRS programme to become an essential and integral partner both locally and nationally in Scotland.

In the mid-eighties, diabetic retinopathy was recognised as the leading cause of blindness within the working population in the UK affecting 1-2%. Several studies had been undertaken to improve the detection rate of retinopathy, but the ideal modality of screening had not been determined. At the time in Tayside, the ophthalmology diabetic retinopathy clinics were particularly busy, as Diabetologists would routinely undertake ophthalmoscopy during patients' annual review, often resulting in a referral to the eye clinic for ongoing assessment, to ensure no disease progression.

As an Ophthalmic Photographer, stereo fundus imaging was used primarily for assessment and record keeping for future comparison. The majority of people with diabetes in Tayside did not attend hospital diabetic clinics but were under the care of General Practitioners who, in many cases, were not proficient in the use of an ophthalmoscope. As a result retinopathy was often undetected. Furthermore, as ophthalmoscopy was ad hoc, there was much inconsistency over the region.

Dr Norman Waugh, a Senior Diabetologist, asked if I would be interested in testing two new non-mydriatic cameras. These were the Canon CR2-45NM and the Kowa Nonmyd + which enabled a single 45o image of the macula and disc without dilation. A study undertaken by a Cardiff group [1] found the sensitivity of non-mydriatic photography compared very favourably with ophthalmoscopy, consequently it was assumed a camera system would be sensitive enough to minimise false negatives and specific enough so as not to over refer people into ophthalmology clinics. Additionally, if camera systems were utilised for screening purposes, annual costs would be inexpensive in comparison to ophthalmoscopy. We concluded[2],a camera based system could meet the Wilson and Junger criteria for screening and suggested large scale population based randomised trials be undertaken to evaluate such cameras for screening purposes.

The St Vincent Declaration in 1989 agreed a series of recommendations and five year targets for diabetes care. The target for retinopathy being to reduce new blindness in diabetes by one third. As a result of the declaration, the British Diabetic Association (known today as Diabetes UK) had raised funds from donations to provide eleven mobile units and funding for a Screener for a period of two years. Professor Ray Newton, a Consultant Diabetologist, requested and received a fully equipped van complete with a Canon CR3-45NM with Polaroid camera back (**Figure 1**). The camera utilised Polaroid 600 prints which developed automatically and were much improved in Polaroid terms. Although small details such as IRMA were almost impossible to visualise resulting in reduced image quality by today's standards, nevertheless, this was acceptable at the time. The mobile unit came equipped (**Figure 2**) with four chairs for waiting patients and a blackout curtain divided the camera from the waiting area. Compared to now, patient confidentiality was not given the priority that it does today.

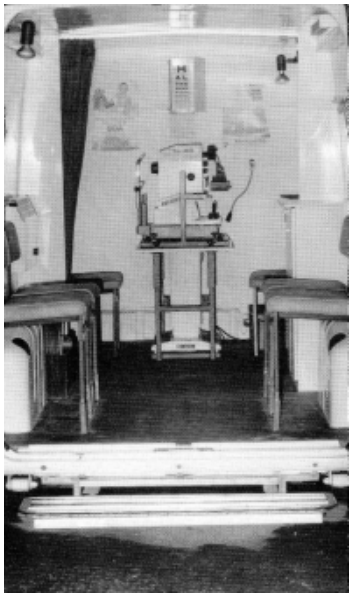

Figure 2:

Interior view of Mobile Unit

Figure 1:

Tayside Mobile Screening Unit Circa 1989

Professor Newton wanted to ensure General Practitioners were involved and called a region-wide meeting. He explained the wonderful opportunity being offered by the mobile unit at no cost, however, as the screening programme did not have access to patient records, it would be necessary for GPs to appoint eligible patients on their lists. Following discussions, a major breakthrough was achieved when GPs surprisingly agreed. Potential patients would be informed about the imminent launch of the screening service via their General Practitioners, advertising within diabetes clinics and local radio.

The DRS Service was launched in January 1990 with funding being secured for my salary one day per week and a full-time Screener. It was agreed the Screener did not require any photographic or nursing skills, but essentially needed good technical and people skills plus a clean driving licence. We concluded that a technician might be most suited for the post. Mobile screening proved to be ideal for the Tayside region as it covers an area of approximately 3,000 square miles. There were in excess of 70 general practices dispersed into two cities, Dundee and Perth and in practices in rural locations, the furthest health centre being an hour and a half drive from the base at Ninewells Hospital. The Screener would liaise directly with health centre staff several weeks prior to their visit letting them know of their arrival and departure time and health centre staff would arrange appointments.

Dr Norman Waugh successfully obtained funding for an IT audit initiative to support the screening programme which we called EYES. The database enabled the Screener to input patients' demographic data during the screening process. The patient's name and date would be written directly onto the Polaroid photographs and stapled to a screening card ready for grading. Diabetologists were responsible for initial grading and any images requiring a second opinion would be referred on to a Consultant Retinal Ophthalmologist. Graders followed a basic grading classification. All grading results were written on the screening form and the Screener would input the data into EYES and a report generated for the General Practitioner. Hospital protocol meant the screening service were prohibited from referring patients directly to the eye clinic as this was the GP's responsibility.

In 1996, Professor Andrew Morris, Diabetologist, working alongside an established team of computer experts, combined to launch an electronic diabetes register called the Diabetes Audit and Research Technology System (DARTS) [3].

The system operated via record linkage using a newly, mandatory community health index (CHI) number. This was a unique patient identifier given to anyone having contact with primary or secondary care services in Tayside. Patient records indicating possible diabetes, through various hospital diabetic clinics were linked via the CHI number. In order to connect retinopathy screening data to DARTS, the EYES database had to be updated to an Access based system we called EyeStore before migration could take place. To ensure accurate information within DARTS, all data collection had to be 'clean' therefore facilitators continuously validated parts of the database. The facilitator was the only link between the practice and the database, a process which continues to this day.

In 2000, Professor Morris launched the DARTS 2000 project which was an upgraded development of DARTS. This was an interactive NHS intranet web-based system allowing an unrestricted information gateway via a password login system to be allocated to personnel within primary and secondary care to enter clinical and administrative data. The website gave restricted access to patient and practice specific information and facilitated reporting and audit.

In addition, retinal images could now by displayed for General Practitioners' information (**Figure 3**). Some practices were uncomfortable inputting data directly into the website therefore completion of an optical character recognition (OCR) form was encouraged which would be submitted to the DARTS team, who in turn scanned the form. The system would be updated every evening with any input or scanned data being available on the website the following day. This was pivotal for the screening service. Until that time the programme had been reliant upon GPs appointing eligible patients however, as screening lists could now be sent from DARTS to EyeStore, patient appointments would be sent directly from the screening service.

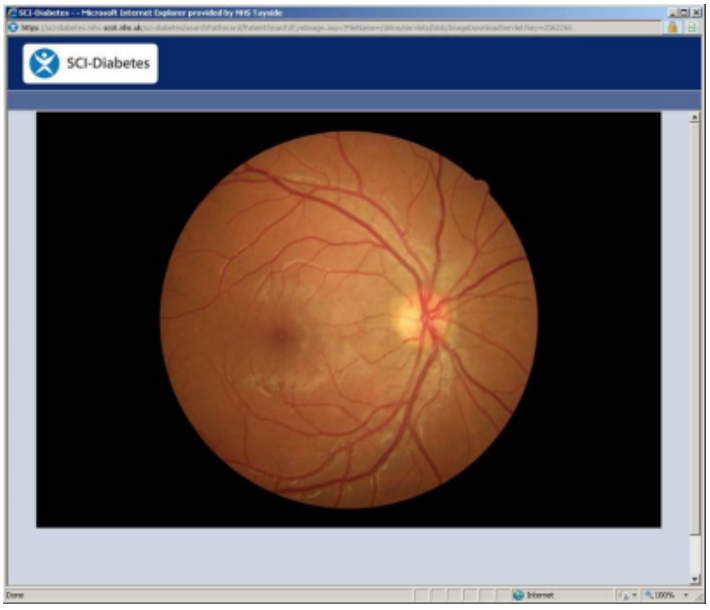

Figure 3:
Fundus image circa 2000.

Furthermore, it was crucial operationally that DARTS could immediately identify eligible or non-eligible patients. Essentially, newly diagnosed people with diabetes could be sent a screening appointment without delay and a registered death would immediately be removed from EyeStore resulting in an invitation letter not being sent out, thereby mitigating damage to the service and upsetting to relatives. Regular general practice overviews could be viewed and monthly reports were sent electronically to each practice giving details of various aspects of diabetes care and management including eye screening, any areas of concern would be highlighted in red enabling individual practices to develop appropriate management strategies. The DARTS team would produce data for region-wide audit and research. In addition, the website became a management tools for healthcare professionals giving access to eye screening information, departmental contacts and a diabetes handbook containing guidelines and protocols. Likewise, the introduction of an internet page facilitated patient access to information such as leaflets and the mobile screening timetable.

By 2000, a digital camera (Canon CR4-45NM) was introduced to the mobile unit and upgrades had to be made to EyeStore to facilitate a capture element. Direct connectivity allowed the Screener to input data into the system as well as visualising and saving captured images via a laptop which would be uploaded overnight into DARTS. A grading feature was also incorporated into EyeStore which used Paintshop Pro, an off the shelf image enhancing software package to assist when grading.

The Scottish Health Plan (2000) identified Diabetes as a priority resulting in establishing the Scottish Diabetes Framework in 2001, which was an appointed group of healthcare professionals. The Framework supported a National Diabetic Retinopathy Screening Programme as well as a National diabetes IT management system. Approval had been given for a collaborative approach between DARTS and the Lanarkshire Diabetes Hospital System, resulting in an initiative called the Scottish Care Information – Diabetes Collaborative (SCI-DC). Like DARTS, the system relied on linkage between primary and secondary care services, which fed into one centrally managed electronic record. By 2004, NHS Quality Improvement Scotland recommended all health boards in Scotland implement SCI-DC and move to a fully integrated web-based system which would provide standardised measuring of data for General Medical Services contacts and Quality Outcomes.

The Scottish Diabetes Framework developed to support improvements in diabetes services sanctioned the Health Technology Board for Scotland (HTBS) to produce a report (2002) regarding the setting up of a National Screening Programme which rolled out in 2003. A newly formed DRS Collaborative network consisting of representatives from each health board would form an executive group responsible for ratifying changes or proposed developments. The HTBS report had advised digital retinal photography be the modality for screening and the DRS Collaborative recommended National guidelines with respect to grading, staffing, training, software, monitoring and failsafe. Akin to the English National Programme, Scotland were to train Screeners to grade. The National Programme however, differed from the English National Programme in a number of ways, namely there was to be a three-stage approach to screening whereby single field, macular centred and non-mydriatic photography would be used in the first instance. Mydriasis would be used only if the image was of inadequate quality and a slit lamp assessment would be required.

Another difference between the English and Scottish programmes was the method of grading. Scotland adopted a three level approach. Screeners would be trained to grade images at level 1 and 2, each grading level would be determined by experience. Level 1 grading was the assessment of image quality and the presence or absence of pathology. Level 2 required the person to be able to identify possible sight threatening diabetic pathology. Level 3 grading was generally undertaken by an Ophthalmologist who would decide whether the person required referral to ophthalmology.

The Tayside Diabetic Retinopathy Screening Service was launched in 2003 as part of the National Programme with Professor Graham Leese being the clinical lead. The position of a full-time Programme Manager was advertised and I was successful in attaining the post, with the existing Screener being promoted to a senior position. It had been agreed Tayside would use a combination of static and mobile screening and therefore a second vehicle with camera had to be procured and a third camera purchased for use within the diabetes clinic. Due to anticipated increased capacity it was necessary to employ another three technician/screeners. As nationally agreed, mydiasis could be used, however as it would take a few months until appropriate changes to the UK regulations were made regarding Patient Group Directions, patients had to be screened without dilation during this time. Although the HTBS recommended all Screeners undertake a formal accredited course, none existed at the time and this prompted me to set up an internal training programme in conjunction with Diabetologists, Ophthalmologists and the Senior Screener. Due to demand a further five courses were subsequently organised for other Health Boards. The DRS Collaborative developed a handbook for screeners and graders (2003) which assisted greatly in training staff. However, it would take several years before Scotland joined the English National Training Programme, which set the Level 3 City and Guilds in Diabetic Retinopathy Screening, as the UK-wide qualification for Screeners.

Software for the National Screening Service was procured in 2005 from Siemens called Soarian, which facilitated image acquisition, call-recall, grading and quality assurance. Although the system was implemented across all health boards in 2006, NHS Tayside were the last region to implement so as to give Siemens and the SCI-DC team time to migrate all demographic data from EyeStore, ensuring continuous functionality of the screening programme. In line with National recommendations, SCI-DC populated the Soarian system with demographic data through an interface allowing results of the screening process, including images to be fed back into the local clinical management system (in most cases this was SCI-DC). Furthermore, as SCI-DC could identify and send eligible people with diabetes directly to Soarian, the call/recall process would be made more efficient.

The SCI-DC team continued to work extremely closely with DRS in Tayside and through a facilitator many data issues were resolved as well as providing any necessary audit and research information. By 2014, SCI-DC with Scottish Governmental support, completed the migration of all Scottish health board systems to a single IT management system for diabetes care which was renamed SCI-Diabetes[4]. Soarian remained the National DRS IT system until 2017 (the year following my retirement from DRS in 2016).

The development of the Tayside DRS programme was made possible with the collaborated efforts of a wide range of people including GPs, practice nurses, hospital consultants and many more. Good communication involving all stakeholders proved to be the strength of the DRS programme. NHS Tayside were extremely fortunate to have an excellent SCI-Diabetes team working alongside DRS which forged a close working relationship. A new era started with the launch of BARS of which I was privileged to part of its inception. BARS brought together a new group of professionals, some of whom became life-long friends. I also was appointed Council Member, Treasurer and Chairman and during this period gave me the opportunity to see how other programmes operated outside Scotland. As a result, I was able to incorporate some ideas locally and nationally within Scotland.

Special thanks to Ritchie McAlpine, Data Facilitator, SCI-Diabetes.

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NHS Diabetic Eye Screening Programme National Update

I was unsure what to write when I was asked for the National update for the Journal this time round as we have all been through such unprecedented times over the past 6 months. I would like to start by saying a huge thank you to everyone involved in the NHS Diabetic Eye Screening (DES) Programme for your hard work, perseverance, feedback and tolerance during the coronavirus response. We have all had to try and continue our lives under some incredibly strange and difficult times professionally and personally during the past 6 months. I thought I'd start by outlining where we are with the coronavirus response and then briefly touch on some business as usual topics.

Coronavirus Response in Diabetic Eye Screening

Coronavirus began impacting local services from early to mid-March when it was becoming clear that there were issues accessing venues, people were cancelling their appointments at short notice and there were higher than normal levels of people not attending. Following the lockdown announcement towards the end of March, screening and hospital eye service referrals were severely impacted across the UK.

In PHE Screening there was huge concern for those people with diabetes at the highest risk of sight loss, including those with pre-proliferative disease and pregnant women, not having timely screening which could lead to life changing sight loss for these individuals. Therefore, PHE Screening provided guidance to NHS England & Improvement (NHSEI) to ensure those most at risk should still be screened where possible. This became part of the original technical guidance which was cascaded to local services in early April. During April-July the continued and targeted screening of this group of individuals led to nearly 2000 referrals to hospital eye services during the lockdown, demonstrating the importance of keeping the service available for those most at sight loss. Again a massive thank you for persevering in very difficult times to continue screening these individuals.

To ensure a standardised and orderly restoration of diabetic eye screening, a 'Task and Finish Group' was set up by NHSEI including PHE screening and regional commissioners to oversee the restoration from a National perspective.

PHE Screening developed the restoration guidance which is now being utilised across England. The key principle of the restoration guidance is offering screening to those who are most at risk of developing retinopathy whilst allowing an extension of the screening interval for those least at risk of sight loss to a maximum of 24 months. This acknowledges the reduced capacity and capability that local services are experiencing due to reduced appointment slots, the additional personal protective equipment and infection control requirements, and ongoing social distancing and venue availability.

All 57 local screening services in England are now screening those most at risk of developing retinopathy and all services have plans in place for the other lower risk cohorts. All services can refer their screen positive patients to appropriate hospital eye services for urgent and routine treatment. This hard work must be acknowledged and we in the national team know how much work local services and commissioners have had to do to plan and initiate the restoration of DES.

PHE Screening will be producing monthly data reports for NHSEI, commissioners and local services that will include the numbers invited, proxy measures of uptake, DNA rates and referral to consultation tracking to help monitor and understand how screening services are managing in restoring screening. We will also use this data to provide guidance, support and quality assurance advice where necessary. PHE Screening will still be collating and providing the standard quarterly reports with caveats around the coronavirus restoration where applicable.

At the present moment, it is hoped that DES will be back to normal routine digital screening by April 2022, so we can then start the process of implementing 2 yearly screening intervals following this date. Appropriate guidance will be produced by PHE Screening and NHSEI to support services and commissioners with this development within the screening programme and will take into consideration the coronavirus restoration.

Optical Coherence Tomography Best Practice Guidance

PHE Screening, with the support of commissioners, local screening staff, key clinical stakeholders, the DES programme advisory group and the Royal College of Ophthalmologists, has developed best practice guidance for local screening services that want to commission OCT separately from the screening programme.

It was published in July 2020 and is available here on the DES GOV.UK pages:

https://www.gov.uk/government/publications/diabetic-eye-screening-optical-coherence-tomography-in-surveillance/optical-coherence-tomography-oct-in-diabetic-dye-screening-des-surveillance-clinics

The guidance which has been ratified as best practice by the RCOphth utilises the digital surveillance pathway in screening and includes;

- Clinical pathway/flowchart
- Training requirement for staff undertaking OCT
- Roles and responsibilities of screening service in OCT provision
- Cost effectiveness

PHE Screening are now looking at how to incorporate OCT formally in the pathway and are discussing with the UKNSC secretariat/evidence team how this is best achieved.

National Diabetes Audit

NHS Digital and PHE and the National diabetes audit (NDA) have been working closely to enable diabetic eye screening service providers to submit DES data to the NDA.

In previous years, the audit has only been able to report on 8 of the 9 National Institute of Health and Care Excellence (NICE) key processes of diabetes care. This is because the retinal screening outcomes are recorded in screening management systems that have not previously been able to export data to the National Diabetes Audit.

From April 2020 onwards, it will now be possible for diabetic eye screening providers to submit their data directly to NHS Digital for inclusion in the audit for the first time.

This year it has been been undertaken centrally by the 2 software providers for 2019/20 data with a system expected to be in place for 2020/21 to enable direct transfer of the data once a year. For 2019/20, more than 98% of local DES programmes successfully transferred data from screening to the NDA which is a huge accomplishment.

Patrick Rankin
National Programme Manager –Diabetic eye screening
PHE Screening

Digitalisation of Leaflets and Letter Changes

PHE screening has been assessing the usage of leaflets in screening programmes for the last 12 months to reduce spending and to ensure it is in-line with Department of Health and Social Care requirements for a digital first approach and meets the accessibility standard.

As part of this work, we have assessed the usefulness and number of leaflets we send out in the DES programme. We undertook a virtual focus group with a number of people with diabetes with support from Diabetes UK and this was central to the development of the new letter templates.

The PHE Screening comms team commissioned a piece of work to assess the impact of digitalisation on certain groups. Recommendations included a phased approach to the rollout of digital leaflets and that individuals should still be able to request and access paper copies to prevent inequalities occurring due to lack of access to digital formats.

Therefore, we decided to review the existing letters to transfer as much information from the leaflets onto the letters and have QR codes for digital versions of the leaflets. Individuals can also request a copy of a leaflet if required. New patients will continue to be sent a leaflet with their invitation letter.

The new letters have gone live on the GOV.UK webpages and local services are expected to have completed transition to these templates by the end of November 2020.

Northern Ireland DESP during the COVID-19

Professor Tunde Peto and Ms Susan Johnston
Consultant Ophthalmologists
Belfast Health and Social Care Trust

March 2020 brought unprecedented changes to day-to-day life and challenges on a previously unseen scale for health care provision. Overnight, rulebooks on safe care provision were metaphorically shredded, people's life took a completely new pattern, the roads went quiet and the skies went blue. With these changes, the Diabetic Eye Screening Programmes supposedly went quiet. But did they? It is absolutely true that patients were not being seen in huge numbers and that the current NSC standards are impossible to adhere to at present. But quiet the places were not!

The COVID-19 pandemic brought the health service nearly to its knees and in order to protect the UK's population and keep the health service running, every part of the country had to adapt. People contributed enormously to this effort: they stayed at home. It became clear from early on in the course of the pandemic that people with diabetes are at particularly high risk of poor outcome if they catch the disease and so many of them were self-isolating for up to 12-16 weeks, some not venturing out at all during that time! In addition to not many patients wanting to come to screening/clinic, many of the healthcare workers were re-deployed to essential services and wards, away from eyecare provision.

Against this backdrop, how could a diabetic eye screening and clinical service not be quiet? In Northern Ireland, the Diabetic Eye Screening Programme (DESPNI) and the Belfast Trust's Diabetic Eye Clinic (DEC) lead is the same person, enabling provision of joined-up care in most of the county, and working closely with her counterpart in the Western part of the NI. Once the decision was made to not-quite-pause the services, it was imperative that we communicated this to our staff and patients. Together with the Public Health Agency of NI, it was decided that as long as practicable, the Pregnancy pathway within DESPNI will continue to function. Fortunately, we had put this on a good footing the year before, all new pregnancies in diabetes in NI are reported to DESPNI using a common template, and the appropriate clinical pathway is decided by the clinicians working within DESPNI. Therefore this common pathway was easy to maintain, the major difference was that all patients were seen by a clinician who could immediately carry out treatment should this be needed. This complied with the guidelines that stated that only a clinician capable of immediately dealing with the problem should examine the patient in order to minimise patient contact and the need for the patient to travel. This change was immediately communicated to all Pregnancy in Diabetes Clinics, and set up so there was no pause in providing this service. Administrative staff was trained up to provide all the necessary information to the patient on the phone, and the clinical lead rang every patient who was unsure about coming to a hospital clinic. This was needed a fair few times as the Mater Hospital was the dedicated COVID hospital and so when patients saw the invitation, they were understandably worried!

Fortunately, the eye clinic is in a stand-alone portacabin and we were able to provide reassurance that patients do not have to go through the main hospital itself. We had an excellent attendance rate all throughout the pandemic and many beautiful babies were safely born! We are completely indebted to the whole of the Diabetes Team and to our patients and their families who helped us to maintain it safely!

Many of our personnel on all levels were re-deployed to COVID-related services and some were self-isolating; for those who were able to come to work, we had to find safe ways of carrying out their jobs. Of course the first week or so was spent on finalising the grading and making sure that all results letters were sent, but these traditionally high volume activities dried up after about 10 days! This is where our work on clearing up the different queues started in earnest: every patient in every suspended and excluded queue (other than the deceased queue) was checked against current guidelines. Hundreds of phonecalls to GPs and patients were made about their current state of health, about their diagnosis of diabetes and for those lost to follow-up, good detective work took place for finding them. Hundreds of nursing home questionnaires were posted and received back and these were carefully evaluated for eligibility of the different screening pathways, including making sure that those no longer able to come are not invited again. All through the pandemic the number of newly diagnosed patients rose, we had over 2000 newly diagnosed patients referred in the first 9 weeks, a truly remarkable number to deal with once we re-start screening in big numbers.

We have done a lot of training during the period of nearly-complete-pause: people finished their qualification and became screener/graders; new ways of distributing interesting cases were devised, iTATs were completed and several online courses were completed. We had training events for the whole team using Teams and all the other electronic platform we needed to use!

While these were ongoing activities, many patients rang in asking what would happen to their appointment, and so we worked with Diabetes UK and the Macula Society to distribute this information and we attended many virtual patient groups. The Macula Service (where injections take place) developed a youtube video so we can ask patients and their relatives to watch it before they come, and returned countless phone calls. If someone needed to be seen, there were emergency appointments all through the week when we could see them.

So what happened if the patients needed to be seen? Both DESPNI and DEC found themselves, like many other units, having to look at service provision and create a plan to continue to provide a service within the restrictions of Covid-19 related regulations regarding social distancing. If a patient needed a clinical appointment, the DEC team was the one providing the service.A greatly reduced workforce (due to some redeployment), provided 5-6 days worth of service and saw all emergencies. All the way through we provided face-to-face clinics, predominantly with the view to treat the patient (either by laser or by injection) with an excellent attendance rate during COVID. Of course not everyone agreed to the appointments, but of those who did, over 90% of them came or if circumstances changed, rang on time to cancel so we could use the appointment slot for someone else. In the remaining time, the team worked together to validate all waiting lists and stratify cases according to disease severity. This allowed us to identify our most vulnerable patients. We also reviewed the clinical space available and calculated the number of patients we could see per session. We reorganised staff timetables to maximise weekly capacity and created a weekly timetable consisting of treatment clinics, imaging clinics and face-to-face clinics. Face-to face clinics were utilised to see urgent reviews and pregnant patients.

When a member of medical staff was going to be absent from a clinic an additional imaging clinic was booked to insure no loss of capacity. We had a dedicated staff member who contacted each patient, by phone, prior to their appointment, to check that they were able to attend and to take them through the Covid-19 screening checklist. If a patient was unable to attend the appointment an alternative patient was offered the appointment. This was not only a great success with the patients as they were reassured about the processes, it also greatly reduced the DNA rate.

We had some fun as well! COVID took away the joy of celebrating Vision2020 the way we wanted to and so to celebrate sight, on the 6/6 2020, the date that stands for the two most commonly used notations of visual acuity, at 6.(0)6 pm we had an online celebration of sight, where we heard about Vision2020 from Professor Rupert Bourne and from our Vice Chancellor of Queen's University Belfast who talked about the significance of the day, and then, right on time at 6.(0)6 pm on 6/6/2020 we raised our glass to celebrate this never returning date! In parallel we ran an art review and many people sent in drawings, cakes and every other media to show the importance of the eye and sight! It was a remarkable event and showed the resilience of the team!

Overall, this was a busy period, and all contributed to enable us to provide service to the most vulnerable and most in-need. The Team has come together and produced a workable solution for the nation. I am immensely proud of everyone who contributed as without every cog in the wheel we would not have been able to treat so many patients and we would not have seen so many happy endings for our pregnant ladies. And for the future? It is going to be an immense challenge to re-build the service so that it complies with the Brave New World, but I am confident that after what we have all been through, we will be able to come up with a plan, especiallyif the 5-nations work together well and we can learn from each other.

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Dry, Wet, RAP and The Polyps – Low Down on Macular Degeneration and Imaging

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Introduction

Age related macular degeneration (ARMD) is one of the leading causes of central visual loss and legal blindness in elderly population around the world. It predominantly affects the macula.

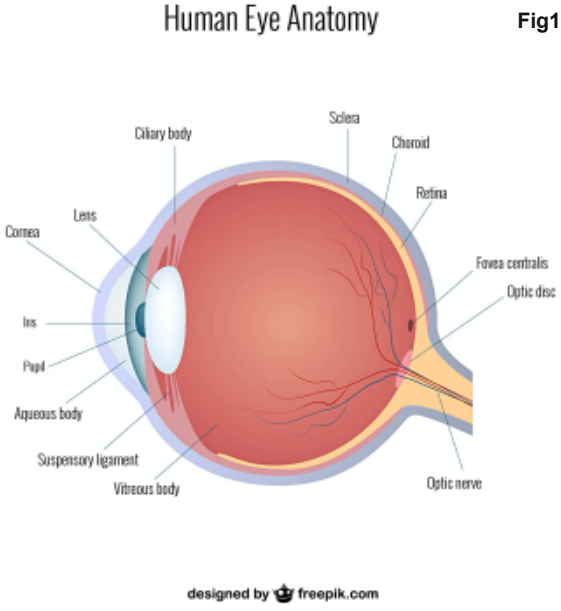


Fig1. Cross section of the human eye

As it is a degenerative process, it is considered to be a consequence of body's capacity to clear the metabolic by-products being slowed down with ageing and due to various other factors. This leads to accumulation and deposition of these toxic by-products into layers of retina (usually termed as Drusen) which over a period of time causes damage to the retinal layers and leads to formation of abnormal blood vessels into macula (usually referred to as Choroidal neovascular membrane or CNVM) causing leakage of fluid and blood into macula [1,2]. Untreated, this process would lead to significant loss of central vision.

Other Lesions

Age-related macular degeneration is commonly classified based on its characteristics into dry (non-exudative) ARMD and wet (exudative) ARMD and according the natural course of the disease, it is categorized into early, intermediate, and advanced ARMD.1, 2 While is it useful to have classifications of such nature, it is imperative to understand that these classifications are only varying stages of the same disease and patients can change from one to another over time. Also important to note that this is a disease of ageing and not curable as we know it.

Dry ARMD represents approximately 90% of diagnosed ARMD cases3. This type is distinguished by the drusen accumulation, the absence of choroid neovascularisation, and retinal pigment epithelium (RPE) atrophy.

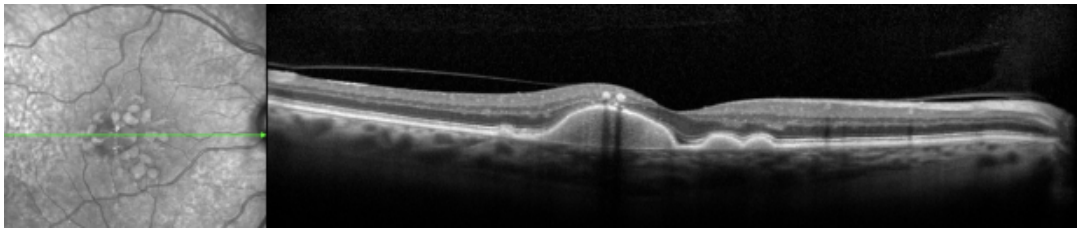
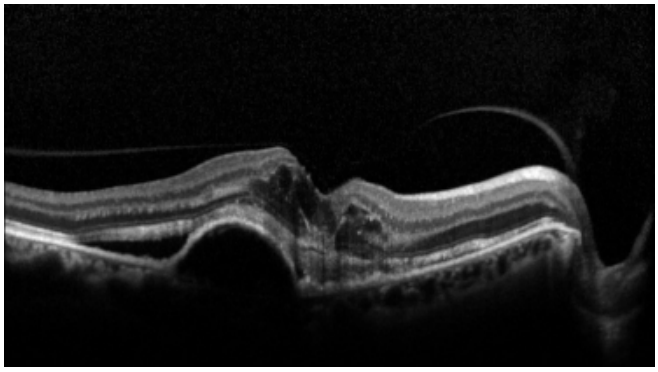


Fig 2.
OCT showing drusen & PED

The hallmark of wet ARMD is the development of choroidal neovascularisation, and this fragile new blood vessel tends to leak forming exudates. It counts for 10% of ARMD cases and has been linked with rapid deterioration toward loss of central vision and legal blindness.[3]

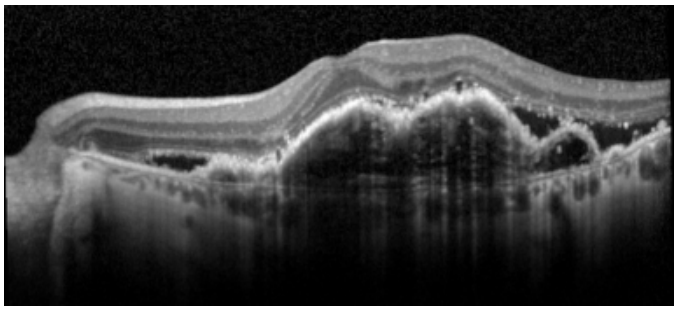
Fig 3.
OCT of typical CNVM appearance

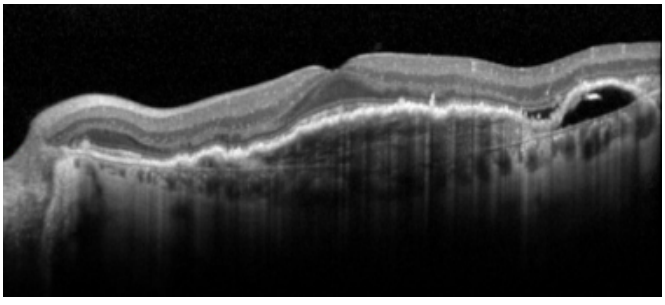


Beyond ageing process, smoking and ethnicity are the only consistent risk factors related with ARMD documented in studies. A cohort study of 65 years old or older patients found smoking doubles the risk of having ARMD in 5 years compared to non-smokers.[4]

While dry macular degeneration patients are being managed with anti-oxidant and Vitamin supplements in order to slow down the degenerative process[5], the last three to four decades have seen a drastic change in the management of patients with wet macular degeneration. The identification of a protein (Vascular Endothelial Growth Factor / VEGF) to be the main mediator of the many changes in wet ARMD, led to the development of medications that can be injected into the eye with very fine microscopic instruments on repeated intervals, in order to clear the leakage of fluid and blood from the macula of patients with wet macular degeneration.

Fig 4. OCT scan before anti-VEGF treatment (**left**), and the same eye after a course of treatment (**right**)**.**





Further research[6] into the types of wet macular degeneration has led to sub classifying the types of CNVM into

A. Classic type,

B. Occult type (or the not so classic type) and

C. other types including Retinal Angiomatous Proliferation (RAP) and Polypoidal Choroidal Vasculopathy or PCV.

More recently, PCV is being recognised a distinctly separate entity leading the separation of PCV from the Wet AMD group.

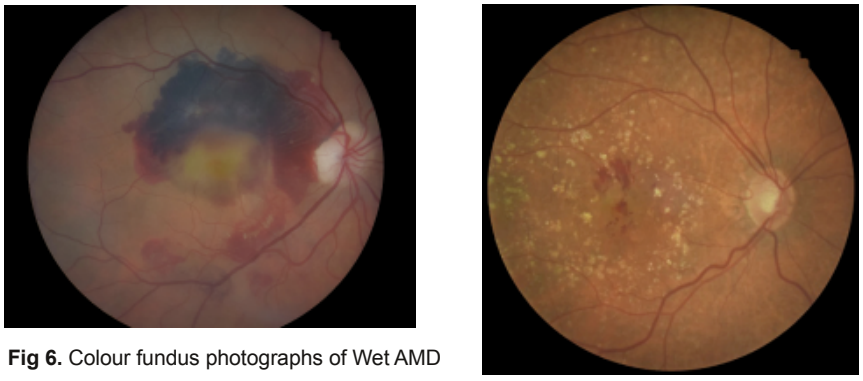


Fig 6. Colour fundus photographs of Wet AMD

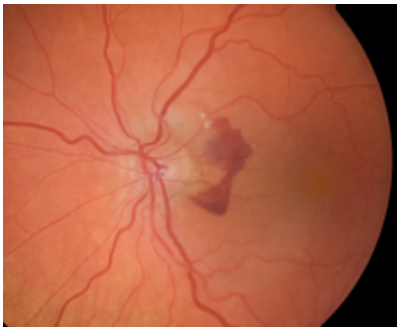


Fig 7. Colour fundus photograph of PCV

The identification of ARMD in patients is a crucial aspect in delivering early treatment. Elderly patients especially those aged above 50 years are more susceptible to develop ARMD. While binocular slit-lamp examination and fundus examination is needed to disclose the signs of macular degeneration, a comprehensive eye examination includes non-invasive and invasive imaging to detect any subtle changes in the retina structures.

Imaging not only holds an important position as a diagnostic tool in ARMD but also provides better understanding of ARMD pathophysiology, determines treatment options, and evaluates the treatment response and disease progression. Imaging aids clinicians to visualize abnormalities exhibited by ARMD such as lipofuscin, RPE atrophy, drusen deposits, choroidal neovascularisation, and sub retinal fluid. The characteristics found during the imaging determine the treatment options and prognosis of the patient.

Let us look at some of the imaging technologies that have been actively utilised in this process.

A) Colour Fundus Photograph

The ever green high quality colour fundus photo stands at the top of the imaging tools as a vital addition in diagnosis, documentation and follow up of patients with ARMD. Various ARMD abnormalities consisting lipofuscin, drusen as a yellow deposit, reticular pseudodrusen, well-defined area of RPE atrophy, and choroid neovascularisation can be well identified on fundus photography[7].

Some of the drawbacks of fundus photograph in management of patients with ARMD included the image created, which is in 2D and thus lacks depth and generates a problem in visualising small details. Any abnormalities in the refractive media such as cataract result in lower image clarity. When used as single imaging procedure, fundus photography has lower sensitivity to detect choroidal neovascularisation 78% compared to OCT 94% [8]. Fundus photography has better accuracy when in conjunction with other imaging modalities and hence the role of multimodal imaging has gained increasing importance in patients with ARMD.[9]

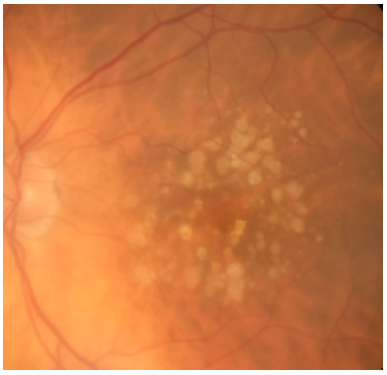


Fig 8.

Colour fundus photograph of drusen at the macula

B) Fundus Autoflourescence (FAF)

Fundus auto fluorescence (FAF) is an imaging method using a specific wavelength of light to trigger the fundus fluorescent characteristics without the need of contrast. This auto fluorescence characteristic is mainly due to lipofuscin, by-product of RPE.

Specific wavelength of light around 300–500 nm is used to excite the lipofuscin, which then emits 500–700 nm. FAF is done using fundus spectrophotometer, confocal scanning laser ophthalmoscope, or a fundus camera. Confocal scanning laser ophthalmoscope (cSLO) is more superior to others as it has capability to reduce the noise from other auto fluorescence sources commonly from anterior segment of the eye10. Both Dry and Wet ARMD shows specific features on FAF which helps in diagnosis, monitoring and prognosis.[11]

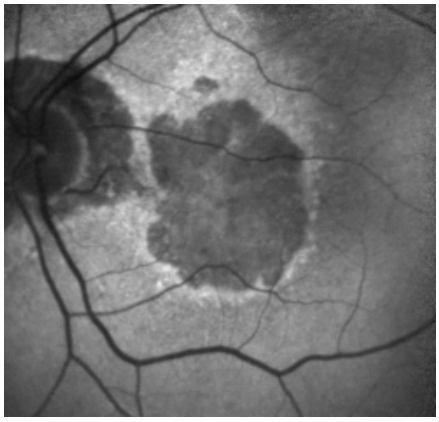


Fig 9.

Autofluoresence image of the macula, showing geographic atrophy

C) Fundus Fluorescein Angiography (FFA)

Compared to other modalities, FFA excels in detailing the state of choroidal neovascularisation in its structural and leakage state as it is a dynamic test. Based on the location of CNV, it is classified as extra foveal, sub foveal, and juxta foveal.[6]

Identification of the CNV location is a useful prognostic factor and treatment options.

FFA also provides leakage property of the CNV, which is then further classified into occult CNV, classic CNV, retinal angiomatous proliferation and PCV.

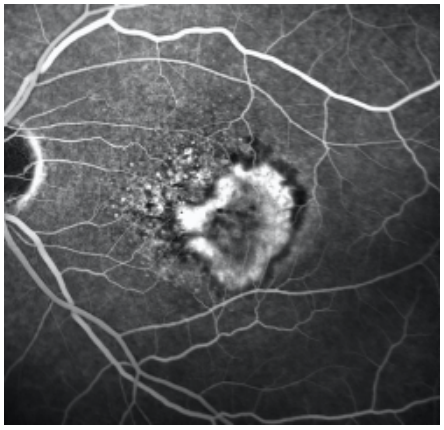


Fig 10.

FA image of the macula showing a classic type CNVM

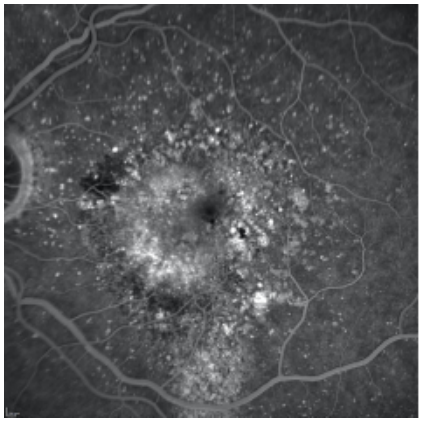


Fig 11.

FA image of the macula showing an occult type CNVM

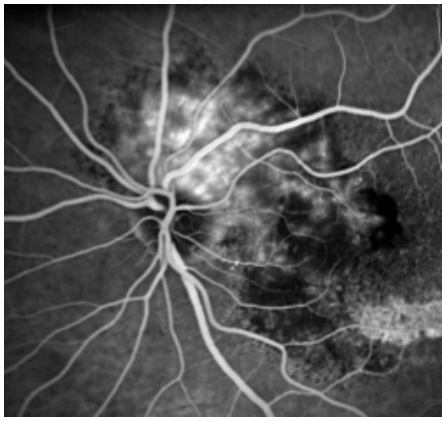


Fig 12.

FA image showing PCV

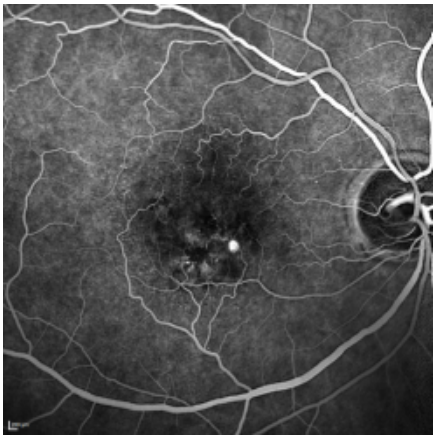


Fig 13.

FA image showing RAP

On FFA examination, sometimes it is difficult to detect deeper retinal and choroidal abnormalities in the presence of blood and exudation. Hence, another imaging technique such as indocyanine green angiography is needed to offer a better visualisation of the lesion.

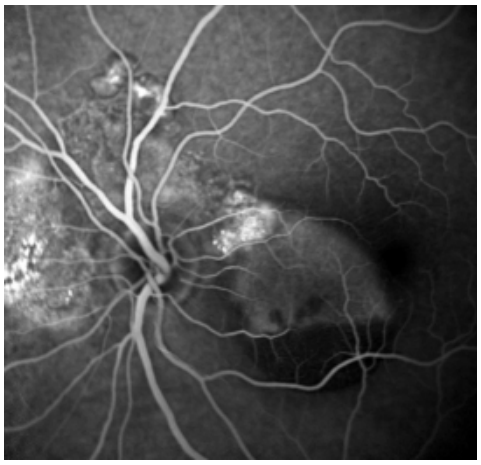
D) Indocyanine Green Angiography

Indocyanine green angiography (ICGA) uses indocyanine green dye, a high-molecular weight contrast (775kD), and projects 790 nm infrared light directed into the eyes that allows deep penetration to the RPE structure. The dye used in ICGA binds to plasma proteins and thus leaks less compared to FFA imaging.

ICGA is well suited in identification of type I CNV or occult CNV, PCV and RAP.

Polypoidal choroidal Vasculopathy (PCV) is described as branching of abnormal choroidal vascular network with aneurysmal dilatation (Polypoidal characteristics) at its edge. The exact origin of PCV is still in dispute; some suggest that PCV arises from choroidal abnormalities, while others speculate that PCV is another type 1 CNV modification. [12]

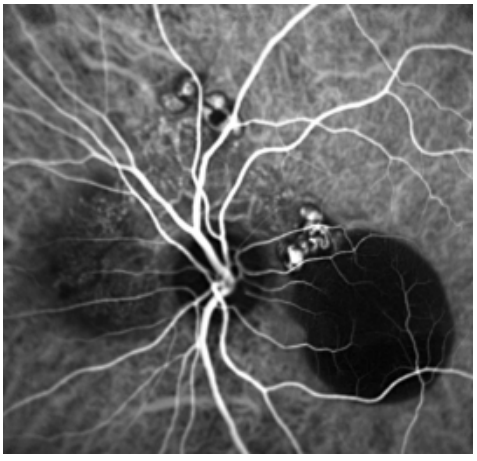
Upon FFA imaging, PCV often masks the appearance of occult CNV or classic CNV and thus ICGA serves as the gold standard in identification of PCV as its appearance masked by the RPE layers in FFA. On ICG angiography examination, PCV appears as hypercyanescent hot spot in the early angiogram with a grape-like/polypoid structure.



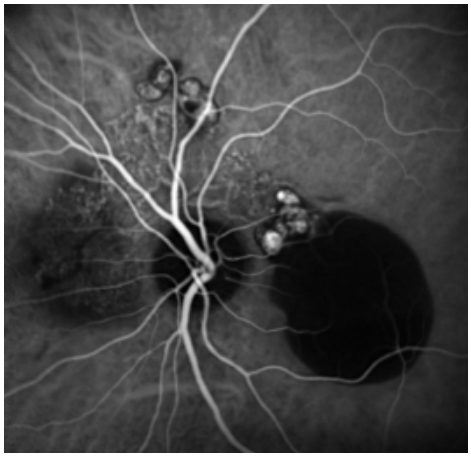
(FA image)

Fig 14.

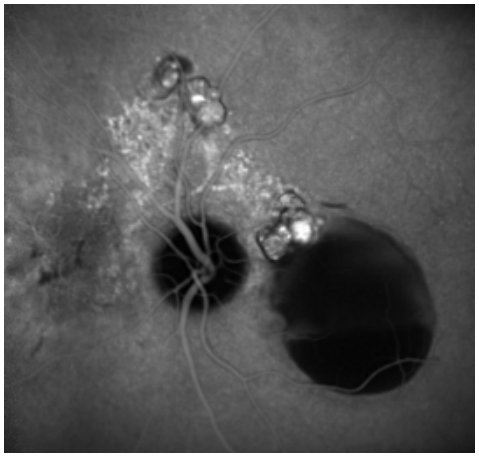
An example where PCV lesion masking an occult CNV on FFA and the ICGA examination revealed hypercyanescent hot spot with polypoid structure upon early, mid, and with “wash out” phenomenon in late-phase angiogram



(ICG image early)



(ICG image mid)



(ICG image late)

Retinal angiomatous proliferation (RAP) is also a type of CNV best visualised by ICGA. This lesion appears as early hyperfluorescence hot spot with apparent retinal artery communication into the CNV, followed by progressive increase in both size and intensity in the late phase. Identification of RAP on one eye has been linked with the increased chance of neovascularisation on the other eye reaching almost 100% within 3 years of follow-up [13].

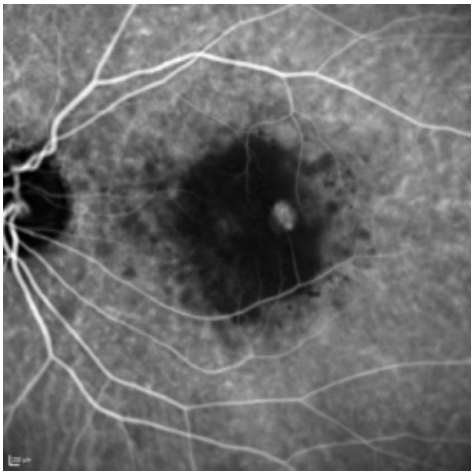


Fig 15.

RAP lesion on ICG

E) Optical Coherence Tomography (OCT)

Optical coherence tomography (OCT) is performed by projecting low coherence laser into retina. The image is a product of time delay and backscattered lights resulting in cross section of retina layers.

OCT is one of the most convenient imaging modalities to detect and monitor ARMD. It provides information of retinal changes without an invasive procedure and systemic complication as required in invasive angiographic imaging such as fundus fluorescence angiography (FFA) and indocyanine green angiography (ICGA).

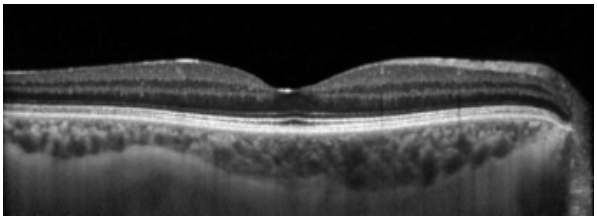


Fig 16. Shows a normal OCT scan of the macula

Image produced by OCT is in the form of hyperreflective and hyporeflective bands representing the layer of retina. In clinical practices, there are four hyperreflective bands that are observed in ARMD patients. These hyperreflective bands are presumed to represent external limiting membrane, inner/outer segment of photoreceptor, RPE, and Bruch's membrane. OCT is capable to exhibit ARMD abnormalities such as drusen deposits, pseudodrusen, subretinal fluid, RPE detachment, and choroid neovascularisation. In OCT, drusen deposits appear as low mounds underneath RPE layer.

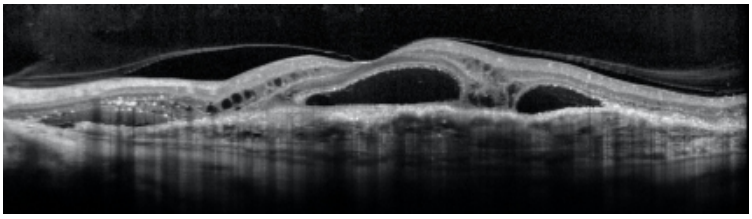


Fig 17.
Shows an ARMD case with sub retinal and intra-retinal fluid

In geography atrophy, the RPE atrophy exhibits a feathered-like pattern projected deep into the RPE due to laser beam penetrated into RPE. OCT images also exhibit a progressive loss of retinal bands, which includes external limiting membrane, inner/outer segments of photoreceptor layer, RPE membrane, and outer nuclear membrane.

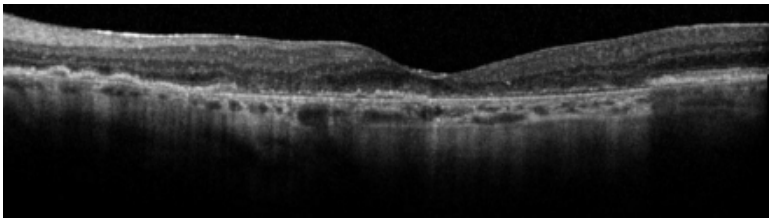


Fig 18. OCT showing geographic atrophy

Neovascularisation activity is visualised on OCT based on accumulation of fluid in various levels of retina. Subretinal fluid is described as hyporeflective lesion located above the RPE and beneath the retina. RPE detachment appears as dome shaped at RPE layer. The exudative activity is one of determining factors for neovascular ARMD treatment.

F) Optical Coherence Tomography Angiography

OCTA is a non-invasive imaging examination that allows visualisation of retina and choroid vascular structure. By utilizing the principle of OCT, it detects erythrocyte flow using sequential B-scans to detect the variable amplitudes and signal intensity gradients. This gradient is then processed through full-spectrum or split-spectrum processing. It can produce en face or cross-sectional image displaying neovascular network. En face OCTA is the most commonly utilised technique in clinical practices. This allows visualisation of vascular characteristics from retina, superficial vascular, deep vascular, avascular zone, choriocapillaris zone, and choroid zone. However, OCTA does not detect any leakage property of the vascular zone.

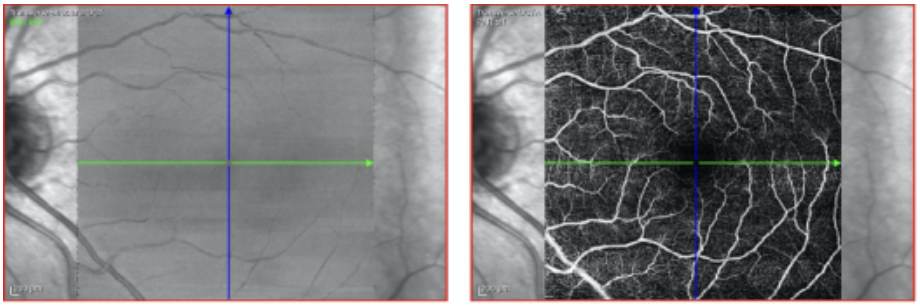
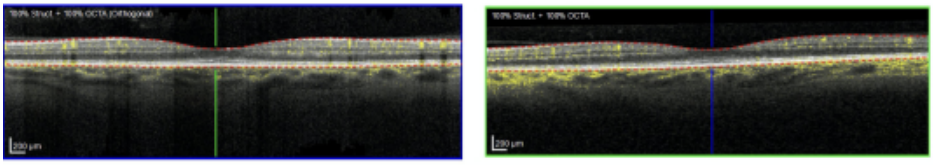


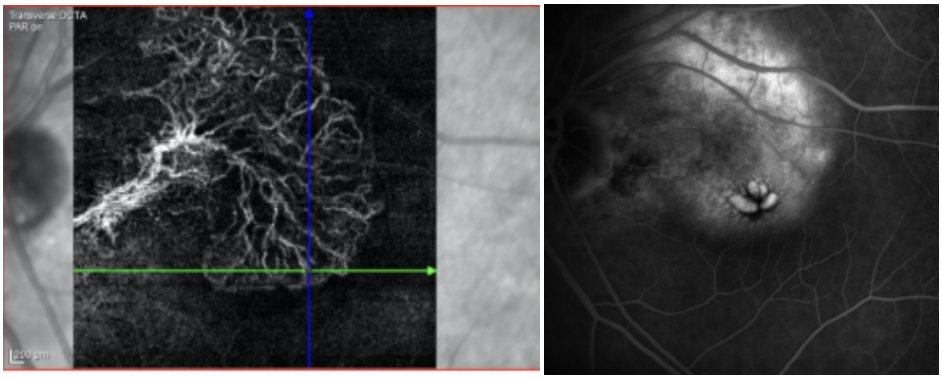
Fig 19.Standard OCTA of the macula, showing flow of the retinal layers



OCTA allows visualising the neovascular network and hence early detection and prompting treatment. CNV appears as hyper fluorescence high flow network varying on the depth of the retina involvement according to the degree of CNV. OCTA has been proven to have a comparable detection capability in visualising CNV compared to other imaging such as FFA and ICGA [15].

Fig 20.

OCTA image of the avascular complex revealing a CNVM (left), and on the right, the same eye showing a late stage leaking on the fluorescein angiogram.



Type I CNV appears on the choriocapillaris layer penetrating the Bruch's membrane and below the RPE. This CNV appears as a minimal vascularisation arising from choroid, choriocapillaris, and RPE with no evidence of neovascularisation in the outer retina.

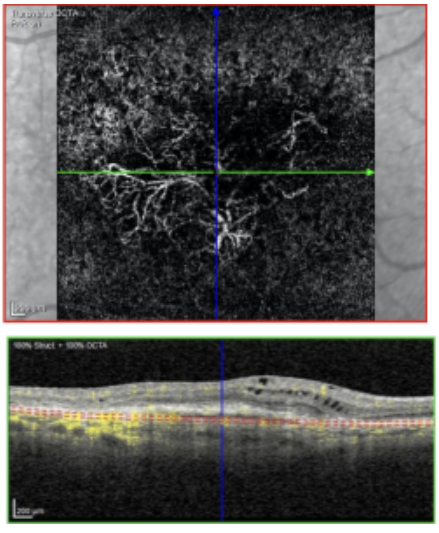


Fig 21.

OCTA image showing type I CNVM complex in the choriocapillaris

Meanwhile, a type II CNVM presents as choroidal neovascularisation arising into RPE and subretinal space. It appears as a sharp demarcated vascular changes at the choroid, choriocapillaris, RPE, and extending to outer retina.

Other Lesions

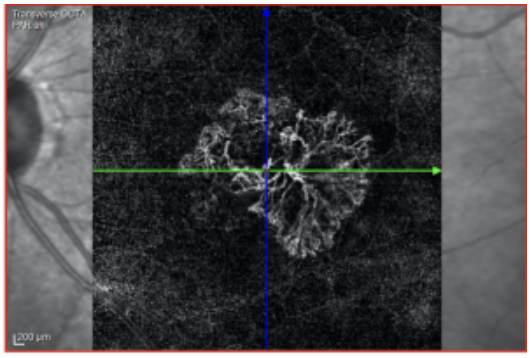
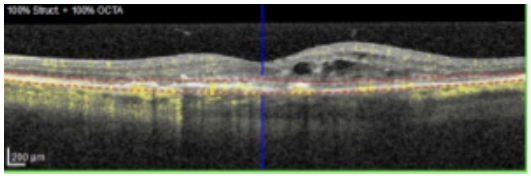
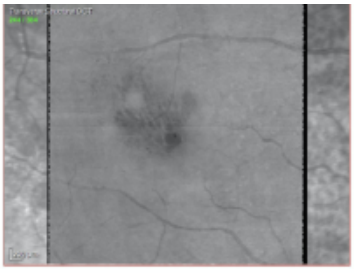


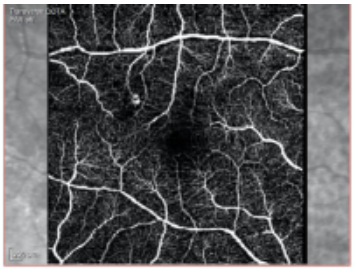
Fig 22.

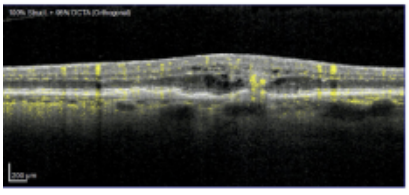
OCTA image revealing type II CNVM in the avascular complex

The appearance of RAP is hyper reflective cluster situated in outer retinal layer with interconnecting vessel with the inner retinal circulation .









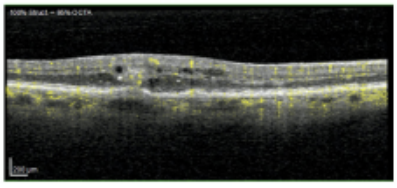
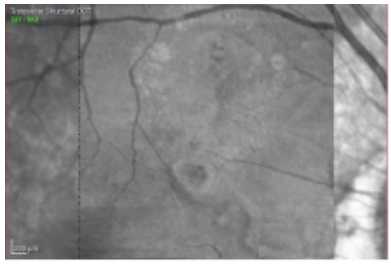
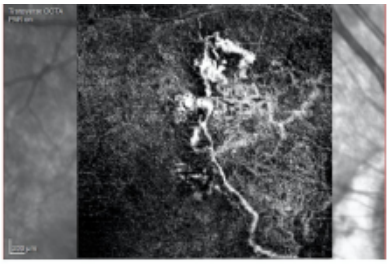


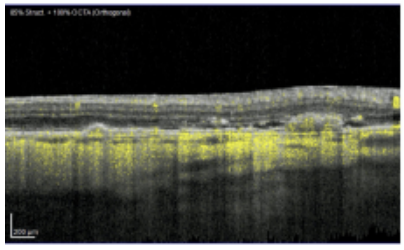
Fig 23.

OCTA image showing RAP (image courtesy of Heidelberg Engineering)

PCV also can be identified and analysed well on OCTA[16]. By using layer-by-layer analysis of OCTA, researchers demonstrated 3-D architecture of the PCV complex with actual flow signals. They provided flow-based support for the previous hypothesis that the PCV complex originates from the choroidal layer by a vascular stalk that ascends into sub-RPE space, becomes a flat tuft or tangle of branching vessel network lying in close apposition with the Bruch's membrane, and terminates even further toward the roof of the underside of the RPE detachment to form polypoidal structures.







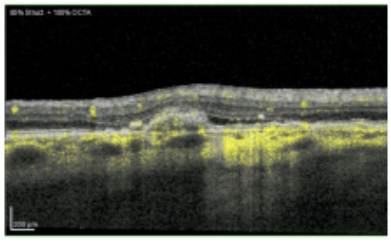


Fig 24.

OCTA image showing PCV (credit: Gabriella De Salvo, consultant ophthalmologist from Southampton NHS)

Conclusions

While the treatment of this visually devastating condition continues to improve with the availability of newer medication and treatment options, the explosion of imaging technology has hugely advanced the diagnostic capabilities. With the use of multimodal imaging, clinicians can now accurately locate, identify, classify and monitor treatment responses using the various imaging tools available now. This has clearly resulted in better patient care and improved visual outcomes.

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Covid-19 and diabetes – looking for answers

It became apparent during the early stages of the coronavirus pandemic that the virus has a bigger impact on people with diabetes compared with the general population. Since then there has been an ever-increasing volume of research published on Covid-19 and diabetes. Diabetes UK set up an urgent call for research proposals into this vital area and has recently awarded funding to four projects which will aid our understanding and improve care for people with diabetes at risk of, or with, Covid-19. Dr Susan Aldridge, Editor of Diabetes Update, the charity's magazine for healthcare professionals, introduces this new research.

Alarm bells began to ring when it was noted that people with diabetes were accounting for one-third of all deaths from Covid-19 in hospital in England (31.4% type 2 and 1.5% type 1). This prompted the rapid publication of two studies[1,2] from NHS England and Improvement and leading diabetes researchers around the country. These analysed mortality data from the National Diabetes Audit and the Office of National Statistics from all those with type 1 and type 2 diabetes in England from 1 January 2017 to 1 May 2020. They found a more than twofold excess of deaths from 3 April 2020 compared with the same period last year, which can be attributed to Covid-19. When in-hospital deaths were analysed, those with type 1 had a 3.5 times higher risk, those with type 2 double the risk of dying compared to people without diabetes. Further analysis showed that Black and Asian people with type 1 and Black people with type 2 were more at risk, as were men and older people in general and those with diabetes complications. Socioeconomic deprivation was another risk factor. The researchers also found that higher HbA1c and obesity were also risk factors for poor outcomes from Covid-19. Other published research, from the UK and around the world, addressed the unanswered questions around diabetes and Covid-10 – covering the underlying immunology and biology, caring for people with diabetes in hospital and how to tease out underlying factors like age, ethnicity, obesity and other influences.

Diabetes UK wanted to make its own contribution to the research effort so launched an urgent call for proposals back in April. We accelerated our usual funding process so that people with diabetes could benefit from the findings of the projects as soon as possible. After applications closed, a panel of scientific experts and people living with diabetes worked to select the most promising projects out of the 54 applications submitted. We, in partnership with JDRF and Moorfields Eye Charity announced the awards, totalling £313,072. The four selected projects are as follows:

Impact of coronavirus on DMO treatment

Firstly, and of special interest to readers of the DEJ, Mr Ranjan Rajendram at Moorfields Eye Hospital, will study people with diabetes whose treatments for diabetes-related loss of vision has been delayed by the lockdown, looking at the long-term effect on their eye health. The project specifically focuses on treatment of diabetic macular oedema (DMO) with anti-VEGF injections. This treatment is among those that have been delayed from March 2020, during the pandemic.

Mr Rajendram will invite people with type 1 and type 2 diabetes to visit him and his team six, 12 and 18 months after missing their planned treatment to have their vision assessed. This will reveal the consequences of missed treatments for DMO. This will help guide and improve the eye care people with diabetes receive during a lockdown situation and, hopefully, help to protect their sight in the long term. This project is co-funded by Moorfields Eye Charity.

Testing for antibodies

Professor Kathleen Gillespie at the University of Bristol will test 5,000 people with type 1 diabetes for coronavirus antibodies to see if they have been infected, using a new test. Although we know that people with type 1 have a greater risk of more severe symptoms, this information has come from people who have been hospitalised. We need to know more about how many of those with type 1 in the community have been infected and how the virus might affect the condition. Prof Gillespie and her team lead some of the longest-running and largest studies of type 1 diabetes, so they have the skills and facilities to roll out the antibody test to people with type 1 diabetes and their families. Participants are being drawn from those involved in these existing studies. Blood samples will be sent by post to researchers, so the study can be done under social distancing conditions.

Participants will also complete a questionnaire about how they managed during lockdown. This will include whether people have been shielding, how their blood glucose levels have changed and whether they have had any Covid-19 symptoms. This will provide valuable information about rates of coronavirus infection among those with type 1 diabetes, as well as revealing what impact having the virus has on the management of the condition. This work is co-funded by JDRF.

Who is most at risk of severe Covid-19 symptoms?

We don't yet know why people with all types of diabetes are more likely to become severely ill or die with Covid-19 compared with the general population. We urgently need to know more about how people with diabetes respond to the virus and how best to treat them.

Dr John Dennis at the University of Exeter will study large health databases to take a detailed look at various characteristics of people with diabetes, including age, blood glucose levels and diabetes subtype. The data include records from Public Health England, intensive care data from those with severe coronavirus and the UK Biobank, which follows the health of 500,000 people.

This will help identify those at greater risk of poor outcomes from Covid-19, which will help healthcare professionals target better care and advice to these individuals. Knowing how to spot high risk people with diabetes will also help inform decisions about who should shield, observe stricter social distancing or maybe be prioritised for vaccination, if one becomes available.

The pandemic and diabetes complications

There have been big upheavals in both people's way of life and diabetes care during lockdown and beyond. People with diabetes may find they are eating less healthily or exercising less, which could have an impact on their diabetes management, as could missing routine appointments.

Professor Naveed Sattar from the University of Glasgow is looking at the impact of the pandemic on risk factors for diabetes complications, including blood glucose levels, blood pressure and body weight. He and his team intend to examine health records to see how these risk factors and rates of complications develop over the next two years. They will also study how factors like age or ethnicity increase the risk of complications in order to reduce inequalities in treatment.

They will also look at how coronavirus infection affects blood glucose and whether it can actually trigger type 2 diabetes among those at high risk.

This work will be crucial to help determine what needs to be done to improve diabetes care, reduce health inequalities and minimise the potential negative impact of the coronavirus pandemic on the health and wellbeing of people with diabetes.

For a world where diabetes can do no harm

Diabetes UK says...

Commenting on the awards, Dr Elizabeth Robertson, Director of Research at Diabetes UK, said: "The coronavirus pandemic presents an especially challenging time for people living with diabetes. That's why we are delighted to partner with JDRF and Moorfields Eye Charity and commit funding to four new projects that will provide much needed insights about the impact of coronavirus on people with diabetes.

"By understanding how the virus affects people with diabetes and who might be more at risk of poor outcomes, we will be better able to provide the care, information and reassurance they need during this difficult time."

• Dr Faye Riley, Senior Research Communications Officer at Diabetes UK, writes about these projects and presents a special round-up on Covid-19 and diabetes research in the Autumn issue of Diabetes Update.

Check **www.diabetes.org.uk/update**

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Title

Reduction in Diabetic Macular Oedema on Optical Coherence Tomography after stopping Pioglitazone

Key words

Diabetic Macular Oedema, Pioglitazone, Optical Coherence Tomography.

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Manuscript word count: Short report: 579 words, Abstract: 155 words

No financial/competing interests

Abstract

Introduction:

Pioglitazone, an agent used for treatment of type 2 diabetes mellitus, can improve insulin sensitivity but has also been associated with diabetic macular oedema and withdrawing this drug may help resolve macular oedema.

Methods:

We assessed the patients with diabetic macular oedema presenting to our clinic that were already on pioglitazone for more than a year. By using optical coherence tomography, we measured the change in central retinal thickness after stopping pioglitazone treatment. The patients with significant change in HbA1C or systolic blood pressure or requiring ophthalmological intervention for diabetic macular oedema were excluded.

Results:

7/9 patients (77.8%) showed improvement in the form of reduction central retinal thickness of 69.6 + 26.1 um over a period of 12.4 + 6.6 months after discontinuing pioglitazone.

Conclusion:

Health care professionals involved in care of patients with diabetes mellitus need to be aware of the association of pioglitazone with macular oedema which may reverse on stopping the medication.

Introduction

Pioglitazone, an agonist of peroxisome proliferator-activated receptor gamma belonging to thiazolidinedione class, is known to improve insulin sensitivity, glycaemic control, hypertension, dyslipidaemia and microalbuminuria in patients with diabetes mellitus.[1] Recent studies have shown that pioglitazone can also reduce the risk of myocardial infarction, stroke and death compared to placebo in patients with type 2 diabetes mellitus.[2] Also studies have shown that in people without diabetes but with insulin resistance and having a recent history of ischaemic stroke or Transient Ischaemic Attack (TIA), the risk of stroke or myocardial infarction was lower in patients who received pioglitazone in comparison to placebo.[3] Pioglitazone use has also been associated with developing lower risk of diabetes but it does have its own range of side effects including weight gain, oedema, and fracture.[3] Presence of Diabetic Macular Oedema (DMO) in patients with type 2 diabetes mellitus treated with pioglitazone, has been documented previously and withdrawing this drug may help resolve DMO.[4] Optical Coherence Tomography (OCT) is the preferred modality to diagnose/classify DMO which may not be easily detected otherwise on digital retinal photography screening and grading.[5]

The aim of this study was to see whether the patients on pioglitazone who were found to have DMO had any improvement on stopping the medication.

Patients and Methods

This retrospective observational study was conducted at our joint diabetes and ophthalmology clinic at Royal Stoke University Hospital at University Hospitals of North Midlands where we assessed the patients with DMO already on pioglitazone to evaluate the change in central retinal thickness (CRT) measured by OCT after stopping pioglitazone treatment. All patients with type 2 diabetes mellitus who were referred to the tertiary eye clinic with DMO were screened, and patients who had been treated with pioglitazone for a minimum of 1 year, who were subsequently followed up in our clinic for a minimum of 12 months with OCT done on 4-6 monthly intervals were then included in our study. The patients with variation in HbA1C of > 10 mmol/mol or change of > 20 of mmHg in systolic blood pressure, or requiring macular laser photocoagulation and/or intra-vitreal injectable therapy for DMO were excluded from the study.

Results

A total 9 patients (6 males; 67%) were eligible for the study based on inclusion criteria with mean age of 64.7 + 7.8 (SD; 95%CI) years; mean duration of diabetes 13.0 + 4.4 years and mean duration of pioglitazone treatment 62.9 + 24.4 months. The initial mean CRT of the patients was 349 + 70 microns (um) which decreased after stopping pioglitazone to 329 + 59 um. Seven patients (7/9; 77.8%) demonstrated good improvement in CRT, with a reduction of 69.6 + 26.1 um over a period of 12.4 + 6.6 months after discontinuing pioglitazone. Even in the other two patients (2/9; 22.2%) there was mild improvement in the severity of DMO, though not fully resolved with amelioration of retinal thickness by only 6 + 1 um.

Discussion

The association between DMO and pioglitazone has been well established in previous studies, with one study by Idris et al, who reviewed a cohort of 103,368 patients in united Kingdom with type 2 diabetes with no DMO on baseline on thiazolidinedione, and found increased risk of DMO over 10-year period (HR 2.3; 95%CI 1.7-3.0).[4] Our study not only demonstrates the usefulness of OCT in monitoring the dynamic changes of DMO in patients with diabetic retinopathy/maculopathy but also shows that DMO may improve significantly on discontinuing pioglitazone therapy. Measurements in our study are based on OCT and offer further evidence to this documented phenomenon as retinal screening photography alone may not be able to provide this vital dimensional information which is a key to assessing the impact of medications used for diabetes control or retinopathy.

It is an important message for all the physicians, general practitioner and ophthalmologist dealing with patients with diabetes mellitus in either primary or secondary care, to recognise this association of pioglitazone with DMO in order to recognise and prevent this visual complication of diabetes.

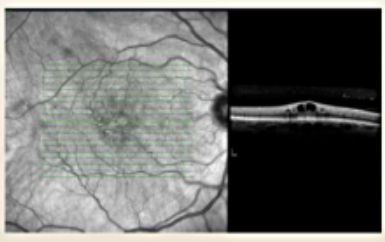

Figure 1:

OCT image and fundal photograph prior to stopping pioglitazone showing macular oedema.

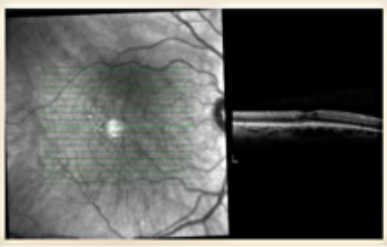

Figure 2:

OCT image and fundal photograph 8 months after stopping pioglitazone showing reduced macular oedema

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MAKING HEALTHCARE BETTER

Improving Fundus Camera Quality

Paul Galsworthy
Joint Programme Manager – Birmingham, Solihull & Black Country DESP
Member of CPG DES Camera Assessment Group & CPG DES Grading Group

Rationale

It is a privilege to be given the opportunity to write this article for DEJ following a presentation I gave under the same title at the 2019 BARS Conference in Liverpool.

I am the Joint Programme & Grading Centre Manager for the Birmingham, Solihull & Black Country (BSBC) DESP. I have been working within diabetic eye screening since 2006 where I was a trainee screener/grader for Medical Imaging UK, moving to Heartlands Hospital a year after. I have a degree in Photography and since completed a Post Graduate Diploma in Diabetes along with the mandatory City & Guilds Diploma. I am also a Visiting Lecturer for Aston University - School of Life Sciences (Optometry) and deliver talks for various Heartlands screening & grading courses.

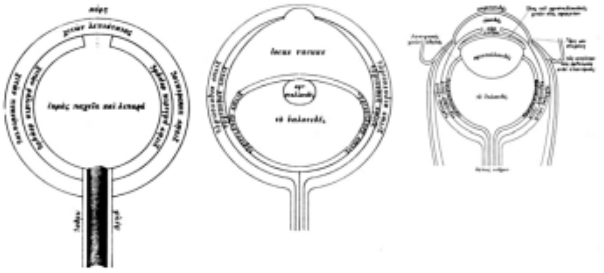
I have undertaken some paid work as a Referral Outcome Grader for Global Diagnosis (ROI DESP), previously I have undertaken product advisory roles for Health Intelligence and Zeiss Fundus Cameras. I am currently undertaking an advisory role for Sense Medical (Kowa Fundus Cameras) whereby Heartlands Hospital provide some testing of devices to improve device usability, connectivity and image quality. The BSBC DESP has approached many camera suppliers to also do similar work in an effort to improve the range of products available for eye screening purposes.

I have an number of voluntary roles within PHE, including being a member of the DES clinical and professional group for DES Grading, which oversees grading across the programme, I am a contracted professional and clinical advisor and undertake quality assurance visits at services across England. Another role I have is that of the DES Camera Assessments group. I have been working within this group for some years now and have tested and evaluated many of the currently approved fundus cameras available to buy for diabetic eye screening purposes.

It's really important at this point to state that the opinion and findings within this article are that of ones own and that of my programme's experiences using cameras and not of PHE, BARS or that of DEJ. It is through my experience of using cameras on a weekly basis within my own clinics, testing cameras for PHE/DESP and managing a large screening programme of 200,000 patients, team of 150+ screeners, 33 graders and a stock of 128 fundus cameras within the programme.

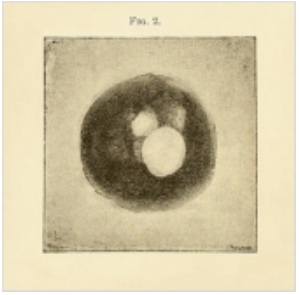
History of Fundus Imaging

Fundus imaging has been around for many years, some of the first images of the eye were illustrations from 400 BC as per diagrams below by Democritus. As time has gone on the detail has improved greatly with more anatomical features being documented and studied.

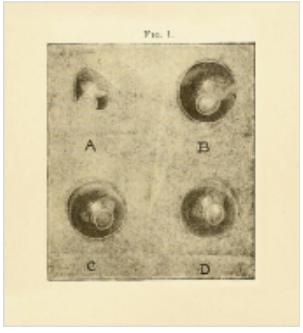


Democritus 400 BC - Celsus 400 years later, and Galen's eye from about 150 AD

The Ophthalmoscope was invented in roughly 1850 and the first attempt of fundus photography was attempted on animals a decade later however it was Jackman & Webster in 1886 who captured first human fundus photograph with a two and a half minute exposure for each image.



Over the next few decades the process was refined, apparatus became smaller, exposure times reduced and flash was introduced to freeze any eye movements. in 1926 Nordenson & the Zeiss Camera Company marketed a commercial device available for clinicians.



It was really not until the 1960s that fundus imaging techniques progressed to the use of fluorescein angiography (FFA) which involved injecting a contrast die into the bloodstream and the flow of blood is captured in a series of still images. However modern day imaging that has revolutionised diagnostics and aided the treatment of various eye conditions came into play within the 1990s when Optical Coherence Tomography was introduced allowing the layers of the retina to be imaged. That decade Optos wide field imaging was also introduced allowing far greater peripheral retina to be imaged within a single frame instead of jigsawing multiple overlapping images together.

In the last 5 years OCT Angiography and widefield OCT has been introduced into clinical practice. Regardless of these technological advancements, for the purpose of diabetic eye screening fundus photography has remained unchanged.

Rationale for This Article

As discussed above, one of my PHE roles is as a member of the camera assessment group. This small team assess, approve or reject potential fundus cameras to be used within the NHS diabetic eye screening programmes.

PHE screening staff currently oversee the camera assessment process and are present at camera assessment days to oversee the legal, contractual NHS supply chain side of things better than we do.

I have assessed almost every fundus camera approved on the DES approved list. I am joined in this process by a senior optometrist and recently we included a senior grader from a local service to provide additional expertise.

Despite the current process being used for many years there are limitations in terms of both assessment methods

Current Assessment Process

Suppliers/distributors are informed of a planned camera assessment date, the manufacturers apply to submit a camera for testing. Suppliers are sent an application pack including the current camera specifications to ensure the camera is fit for purpose and appropriate for testing. If the camera meets the specification it's added to the list of cameras to be tested on the assessment day. We will often will test around 4 cameras on a given assessment day, and do one or two a year.

Current Specification

All approved cameras must meet a large list of criteria however some key points are listed below:

- Camera must take 45-degree fields of view (the studies which provided the evidence base for a national screening programme were based on this)
- Camera must have both internal and external fixation aides
- Must incorporate a viewing screening to aid, focus and capture images
- Must be able to be operated manually if it also has automated functions
- Must be able to take the 4 DES standard colour images within 2 minutes
- Must be capable of taking an anterior chamber image plus additional peripheral fundus images
- Must be securely mounted and have a chin/head rest to support patient
- Must meet a minimum resolution (30 pixels per degree)
- Must be portable/manoeuvrable for transportation purposes (e.g. GP practice Screening)
- Must meet EU/CE quality standards and medical devices regulations

Two volunteers (usually PHE staff) have their eyes dilated. We try and use volunteers with different ethnicities, as this offers some reassurance that the camera can accurately record the fundus detail of a variety of ethnic backgrounds as the colour and flash intensity required can differ from person to person. Each supplier will set up their fundus camera, table and software (if required). The team will run through the camera specification and check all standards are met from a technical point of view before proceeding to test the image capture times and assess the images for quality.

The supplier will take their best 4 DES standard images i.e. 2x macula centered and two optic disc centered views. This is a timed assessment and images must be captured manually (no auto functionality allowed) within a two--minute period. The assessment team may wish to also test the operation of the product if it appears “unconventional” e.g. No joystick to operate, touch screen functionality etc.

Following the practical timed tests of all the devices and once the suppliers have left, the team discus the operation of each of the cameras and also assesses the image quality against one another and against previously approved cameras. Over a period of time we have collected a sizeable set of images of the same two people taken on many different cameras, this allows images from those currently being tested to be benchmarked against tried and tested already approved cameras that are being used within clinics around the country.

When reviewing images we will assess the exposure, checking if the camera can take an image that is correctly exposed to show the detail across the whole of the retina and include the fine detail at both the macula and the optic disc. We will look at the image with regard to how much digital noise (grain) is present and of course most importantly can the detail of smallest vessels be seen at both the fovea and OD.

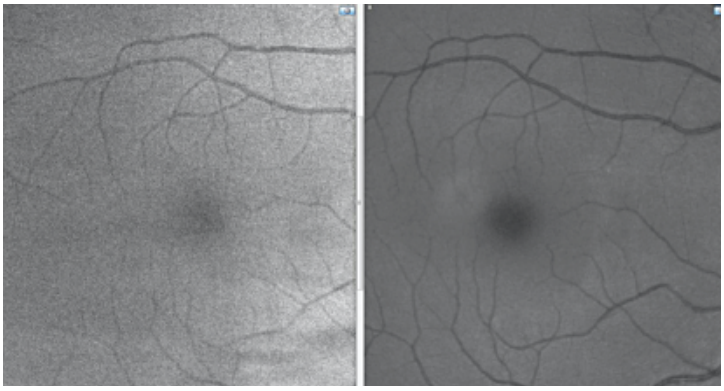
This method has been in-place since around 2006 and has served its purpose, however it does have limitations. I have experienced this myself in my own programme in which we have 128 cameras (eleven different models from five different camera suppliers). What this means is that my graders are used to seeing varying results from different cameras and we all have our own favourites in terms of ease of use and ones we prefer grading the images of. For example, a camera can be very easy to use but may give poor soft images whereas a camera that's technically more difficult and time consuming to use gives fantastic detail and clarity.

One of the greatest limitations that has become an issue in recent years is that of how the camera interfaces and connects to our DES approved software management systems. The current camera specification and assessment process does not involve a test of how the manufacturers equipment interfaces with the software. In reality this has meant that although a camera can output an image onto a computer, the means by which Optomize or Spectra locates the image is not tested by the assessment team. For example I have seen cameras that because they require the use of their own software to capture an image, you have to input many demographic data fields onto the camera device and then manually import the images from a shared folder on the computer to put the images into Optomize or Vector. This has led to the incorrect images being assigned to a patient because of human error and if in particular it is a first time screening it can slip through grading without noticing.

Findings

Image Quality:

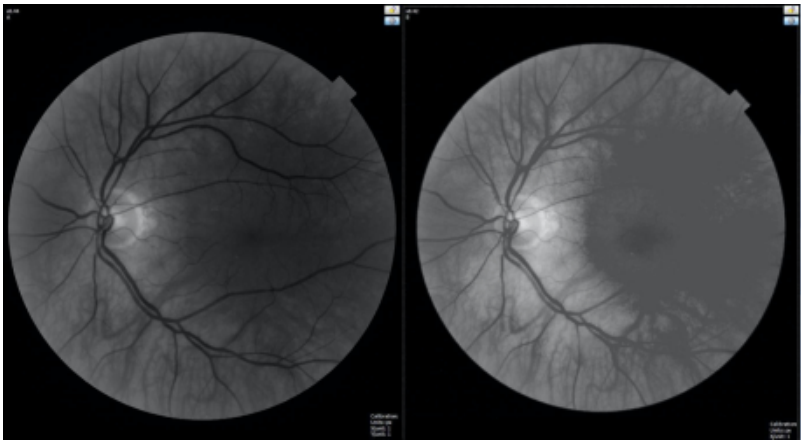
The greatest problem I encountered is that in general all of the camera suppliers new fundus cameras seem to have gone backwards in regards their image quality. Images do not appear as sharp as they once were. There also appears to be a recent shift towards using to what may be poorer quality internal sensors The amount of noise on images seems to be made worse by darker skin tones and any media opacities which makes differentiating between a microaneurysm and pixilation very challenging.



This is demonstrated to the left when two images of the same patient (same day) are enhanced in the software by the same levels. The left-hand side image is from that of a camera using a new internal sensor whereas the older same brand camera using a traditional SLR camera back is on the right-hand side. As you can see the image quality of the traditional SLR camera back is of higher quality especially once manipulation is applied to the image.

We found the same to be true with most internal sensor fundus cameras whereby the newer model with internal sensor gave a poorer quality image than the previous model which used a SLR back.

Another example of traditional SLR vs internal sensor camera can be seen to the right. The left image using an SLR camera and right same brand with internal sensor, where oddly some patients images also come out very wishy washy for no apparent reason. The internal sensors produce far greater levels of noise (grain) but also seem to struggle with the overall exposure of images. It was pretty common that optic disc detail was missing, so additional OD images were needed of both eyes with less flash to prevent the bleaching out of the fine vessels of the OD.



Please note that not all internal sensor fundus cameras produce noisy images, one particular internal sensor camera range produced images of a good image quality.

I appreciate that traditional SLR camera manufacturers are not producing SLR cameras in the volumes they once did as the demand has decreased with the popularity of mobile phone cameras. I also appreciate that bespoke SDK files which have to be written to allow SLR cameras to communicate with screening software is also challenging.

I can see why there should be advantages in manufacturers using an internal sensor; one of the most important being that an internal sensor should reduce the amount of artefacts on images as SLR backs are prone to getting internal dust onto the sensors which we see as dull lesions on all our images often being confused with diabetic eye disease and causing incorrect grading. However it does appear apparent that the internal sensors used at present are not up to the standards of SLR cameras and as a result the fundus images are of a poorer standard than previous models.

With the introduction of extended intervals in the future, the importance of accurate grading is paramount to the delivery of safe and appropriate patient care pathways, so image quality is the first step to ensure accurate grading can take place. Regardless of how accurate a grader maybe the images need to be of sufficient quality so you are not guessing if MAs are present or if the images are just noisy/grainy.

Automation & Operation:

New fundus cameras have many more bells and whistles; many cameras now have automated aides such as auto focus, eye tracking and even image capture. However, many of our diabetic eye screening population are technically difficult to screen and the devices have difficulty in responding fast enough to acquire the images. For example, a recent device put forward for testing took 6 minutes to capture the 4 standard DES images on a young compliant person in auto mode, it took me 40 seconds to acquire the images in manual mode.

The same can also be said with the move towards cameras that do not use joysticks to operate. Some manufacturers use touch screen commands to adjust focus, movement and capture - again these devices can be very cumbersome to use and sometimes results in misaligned images and taking far longer than the 2 minutes we use as a benchmark to acquire the 4 DES screening images.

Many new devices, because of the use of internal sensors, have to use their own software to capture the images instead of directly linking with screening software, viewing on a specific screen to capture. Instead having to use another intermediate capture software (sometimes hosted on another computer) again adds another unnecessary level of complexity into the screening test. Some of the devices require you to input demographic information into the camera for each patient before images can be captured even if the screening software has the individual's details already on the clinic list for the day. This not only slows clinics down but also adds the possibility of incorrect data input, incorrect images being assigned to patients and also possible GDPR issues of duplicating data etc.

Multiple Purpose:

The simple/humble fundus camera sadly seems to have become a thing of the past, with many suppliers opting to produce combined fundus and OCT into the one device. Again in principle this is a positive thing and with Optometry Practices looking to save space and possibly money a multifunctional device should be beneficial. However, again all the combined fundus and OCT devices tested thus far offer poorer image quality compared to the same supplier's standalone fundus cameras. It would appear that the added bonus of OCT comes at the cost of a loss in fundus image quality, this for the purpose of diabetic eye screening is not favourable as all grading is done on the fundus image and not the OCT scan.

The Future of Diabetic Eye Screening and Camera Testing

The current camera assessment process is being updated, simple plug and play joystick operated cameras have moved on so a new camera specification and assessment process is required to ensure that fundus image quality does not continue to decline and if fundus photography is to remain the prime screening mode, the camera devices approved for eye screening use need to be fit for purpose.

Large scale real life testing of devices, the use of different imaging modalities such as wide field imaging and OCT need to be explored by a large technology assessment study. Would these advancements in imaging a) pick up more disease and b) if so would it make a difference to clinical outcomes? We all know that photographing more of the retina is likely to pick up MAs and find other lesions however would more clinically significant or sight threatening disease be picked up?

At present there is not an objective, measurable method of testing lens/optical qualities of fundus cameras, their colour reproduction or ability to pick up consistently details found on the retina. Various measurable tests are being trialed at the moment - a "model eye" so all camera testing is against a "standard eye" allowing models to be tested against a set vascular pattern and some ability to see differences in image quality and clarity, however this does not test real life scenarios as listed previously in this article. The use of traditional camera and lens calibration charts used in the photographic industry is another option, although these are not designed to replicate the shape and anatomy of the eye.

The new DES camera specification and testing will also test the camera's connectivity to DES software packages and how images are manipulated within the software (as a grader would do so) for the testing panel to assess the quality of the images. In addition to the 2 minutes timed image capture element of the assessment it will also include the transfer of images to the DES software within the 2 minutes as well. It is my own personal view that some current cameras may not have passed the assessment process if these measures were previously in place.

Recommendations:

So, what you're all probably wanting to know is which new fundus camera(s) would I recommend?

With my role on the camera assessment group, it is not appropriate for me to recommend a specific camera. However due to the issues highlighted in this paper, I am currently trying to keep all my old fundus cameras working by good servicing and updating the SLR cameras backs. I do this simply because most new fundus cameras do not appear to be as good as previous models from the same supplier. I hope that this will change following the updated camera specification and approval process.

However, when a camera is no longer serviceable or cannot be repaired what are your options? Well first you should arrange a demo from the suppliers that on paper meet your needs and budget. Try a two-week clinical trial of your own, photograph a series of patients both on your exiting camera and on any potential new equipment so you can directly compare the images.

Ensure the camera connects to your computers and screening software seamlessly, there should be no manual moving of images and allocating them to patients records, you should not need to duplicate or input data on various systems - these things only slow clinics down and open the door to clinical incidents.

Summary

Over the decades there has been huge technological, medical & optical advancements in medical retina. The introduction of OCT and OCT A imaging along with ultra-wide field imaging has allowed greater diagnostic and treatment opportunities for patients and clinicians.

Sadly, the current 45-degree fundus photography image quality in my personal opinion is not as good as it once was. Manufactures are generally trying to produce one device that will do lots of things and the fundus photograph appears to have lost its importance.

With the move to extended screening intervals in the future, whereby a single MA is more important than ever before, the image quality required for diabetic eye screening needs to be of the highest quality.

There is a need for a more robust camera specification and assessment process which should result in greater image quality and therefore detection of disease. The screening programme has managed to reduce blindness rates by the prompt identification and appropriate treatment however this is only possible if we have the correct tools for the job.

My experience of Retinal Screening during the Covid-19 lockdown

Isla Knight Retinal Screener/ Grader Devon DESP

The last time I was shown how to wear Personal Protective Equipment (PPE) was on an isolation ward during the Swine Flu pandemic of 2009. I had just qualified from medical school and was working as a junior doctor. All staff on the isolation ward were taught in small groups how to apply PPE and then had a chance to practice.

The plan was if a patient presented to the hospital with symptoms, they would be taken straight to a room on the isolation ward. There, a senior doctor (Registrar) would clerk the patient in so they could be admitted. Despite the preparations I never met a patient with swine flu. I now work as a Diabetic Retinal Screener/Grader - So how did I find this current Covid-19 pandemic compares?

Pre-lockdown:

On the Thursday and Friday before lockdown I did two 'normal' clinics in rural Devon community hospitals. On the Thursday I did a double clinic with a colleague in Okehampton seeing up to 50 patients. At this point I had no PPE and the only thing out of the ordinary was that all the patients had neatly stood themselves along the corridor, rather than sitting next to each other in the waiting room. It looked like a GP surgery where everyone was patiently waiting for their Flu jabs.

On the Friday I drove to the town of Torrington, which serves a rural cohort. Overnight there seemed to have been a lot of changes, and the hysteria was justifiably rising in response to media coverage. Patients were staying in their cars and sending younger relatives in to check in. We had also received an email asking us to keep alcohol gel away from patients as there had been incidents where it had been stolen. Many of the patients rang to cancel; and those that did attend seemed confused on what to do. One asked if he had to remove his muddy shoes to keep rates infection down. Another was very distressed as his mother had been admitted to hospital with 'pneumonia'. Patients were also making comments to me about 'elderly patients' they had seen me call in and whether it was responsible that I was seeing them? I did not know what to reply to many of these comments. By the end of the day only half of my patients had come, and the hospital was nearly out of alcohol gel.

When Monday arrived, it looked like we would all be imminently working from home according to the BBC NEWS. Our Diabetic Eye Screening Programme (DESP) programme had been really organised – not only had they kitted all the screeners out with the correct screen, leads and mouse – but our Programme Manager had put a little 'survival pack' together for those graders still in the office which helped boost morale.

Lockdown:

My first day of working from home and lockdown – 24th March – was also my birthday. For most of us logging into Microsoft Teams for the first time was a bit daunting. My first experience was checking in to the group chat at 8.30am and there was my Programme Manager, Line Manager and Grading Manager all singing happy birthday to me (albeit with some people on mute or freezing – which we would get familiar with over the next 6 weeks!).

The rest of the week continued pretty much as normal: virtual team meeting at 8.30am, followed by either grading or phoning of patients to cancel their clinics. Getting the grading queue down to zero was a big milestone. It also allowed the programme to run some checks to see that there was no one stuck in the grading queue. Over the next month we all initially had jobs allocated to us to keep us busy – diploma, audits, teaching and volunteering to help with Covid-19 efforts…

InHealth staff redeployment to help NHS during lockdown

From the early stages our company InHealth Intelligence, part of the InHealth Group, was keen to support any staff wanting to help the NHS throughout the pandemic. Staff across the country were encouraged to volunteer for redeployment to help support a 24/7 CT service, NHS 111, London, Bristol, Manchester and Harrogate Nightingale Hospitals, and other local NHS trusts/providers. InHealth supported and celebrated its members of staff in the regular email staff updates. For example, in April the staff update celebrated stories of how staff members were being trained up to help in the ICU at Bristol's Nightingale Hospital.

In Devon, we were offered 2 main opportunities for redeployment. Firstly, InHealth offered its whole fleet of 15 mobile CT scanners to NHS England. They asked for volunteers to help fill the 120 CT healthcare assistant roles needed to run this service 24 hours a day. They designed an online training programme so any member of staff in any role could train to be a CT Healthcare assistant.

Secondly, they asked if we would help the Covid-19 drive-through testing service. I volunteered to do the latter. Every day I received a list of patients from Public Health England to ring and book in for Covid-19 testing at drive-through testing sites in Exeter, Plymouth, and Bristol. I had to check their eligibility, explain the process, and book them in. These tests were initially offered to healthcare/NHS staff who had been referred by their employer if they, or their family, displayed symptoms. For example, a GP had to isolate when his daughter had a cough but was anxious to be tested so he could return to work. Later testing was also opened to residential care home staff and other key workers. Some of the challenges that we faced was the BBC News kept announcing new guidelines every day to who was entitled for testing. This led to some confusion for the employers as who could be referred to the testing service. This job role ended when the Government opened testing to everyone and had an online system.

Preparing for coming out of lockdown:

Now 6 weeks into lockdown, I have finally been told that I will be doing one of our first clinics on Friday.

So how have we got to this point?

Firstly, our programme has had to identify the cohort we wanted to invite to these early clinics. Not an easy task with over 70000 people on our register. Our referral hospitals explained that they were only able to accept urgent referrals (i.e. Proliferative disease). This is because, like dentists, eye hospital staff must risk coming into very close proximity to patients to perform slit lamp examinations and laser. Our Failsafe Officer identified from her tracker the pregnant patients due to be screened. This is because pregnancy is a risk for rapid retinopathy disease progression. The 'second group' to be invited were patients with known proliferative disease but who had been discharged from the eye hospital due to non-attendance.

Our service had also been advised to review the images of known R2 (pre-proliferative) and R3s patients, due to be recalled between March and the end of May. It was felt these were the 'third group' of patients most at risk of developing proliferative disease. The images of each of these patients were given a score of 1 – 4 by the ROG (Referral Outcome) graders to help prioritize who to invite first. Points were awarded based on the presence of multiple blot haemorrhages, Intraretinal Microvascular Abnormalities (IRMA), and/or Venous Beading. The patients with the highest score were the first to be invited (2 points and over). Of most concern were patients with venous beading as this happens in response to severe ischaemia and is a precursor to new vessels. The maculopathy (R1M1) patients were not reviewed as they were less likely to have progress to R3a (proliferative disease). The screening manager and two ROG graders have since reviewed dozens of images for patients on 3 months recalls identifying the most ischaemic eyes at risk of developing New Vessels.

Next, we had to contact 4 clinics – one in Exeter, Plymouth, North and Central Devon to see if they would be willing to have the service. Once we got the go-ahead the management put together a protocol for inviting the patients. Each patient was rung up by the Failsafe officer or senior referral outcome grader (ROG). It was explained why they were at risk and booked in if they had no symptoms. They were then advised to come by car and to wait in the car until the screener rung them to come to the locked hospital door to be let in.

Figure 1. Testing the Camera Shield in the office

So how am I feeling about my first clinic?

Two of us were approached by our programme manager and asked if we would be happy to do screening clinics. I have since been provided with ample masks, goggles, wipes, spray, gloves, tissues, rubbish bags and aprons (**Figures 1 – 3**). I have received written and visual instructions (via YouTube training videos) on PPE. InHealth also arranged for a nurse to talk us through PPE in each stage of our day from setting up, to the clinic and packing up at the end of the day. This is more than I can remember receiving in 2009 when I was working on an infection control ward at the height of the swine flu scare when we received one teaching session on how to put PPE on.

I am confident that we will be able to protect patients from Covid-19, as I only have 14 patients booked and a clear protocol of what to do for each individual screening location.

My first clinic

My colleague and I have now completed two clinics each. I rang every patient on the morning to check no one in their household had Covid-19 symptoms. They were asked to stay in their car until their appointment time and then a volunteer walked them from the main entrance to the outpatient's reception where I greeted them in PPE and took them straight through to their appointment. Apart from the pregnant patients, everyone else said that it was an "adventure" to be there. So, did the risk of them going blind outweigh the potential risk of their attending and catching covid-19?

Figure 2. PPE supply provided for me to take to clinic

Figure 3. Before and after PPE

Case Study from Group One:

The pregnant patients

This group of patients were the most anxious about attending appointments when I phoned them on the morning of the clinic to confirm attendance. I encouraged them to attend as pregnancy can result in rapid progression of any retinopathy. This can be seen in the following cases that attended one of these early clinics:

Case 1: A 23-year-old in her first trimester attended for retinal screening at one of these first clinics. She had previously had background retinopathy in both eyes. It had now progressed to early R3a with small NVE (New Vessels Elsewhere) in both eyes. Despite this her vision was excellent and she had no symptoms. If the pregnant patients had had their screening delayed this would not have been picked up at the early proliferative stage. She was referred urgently to HES (Hospital Eye Service).

Case 2: The ROG grader had a dilemma about whether to refer a 36-year-old who was 32wk pregnant. Her vision was 6/5 in both eyes and she was graded R1M0. The ROG grader queried whether she needed a referral for a possible vein occlusion in the left eye. Normally if we have any uncertainties regarding a pregnant patient, we will refer to HES. However, her diabetes, renal failure and pregnancy make her high risk of complications if exposed to Covid-19 in the hospital eye services.

The ROG grader therefore asked the ophthalmologist to review her images. The ophthalmologist noted several retinal flame haemorrhages with excellent vision. As there was no treatable macular oedema or treatable neovascularisation visible, the ophthalmologist felt the risk of being exposed to Covid-19 outweighed any benefits of being referred. The ophthalmologist also noted that any planned follow up with HES (Hospital Eye Service) was likely to be 3 months and this might not be booked on time due to the current situation and backlog.

Outcome: It was agreed that it would be safer to rescreen the patient in Digital Surveillance in 3 months and refer it at that time if it had progressed or the vision reduced.

Case Study from Group Two:

Patients discharged from HES due to non-attendance.

This 60-year-old bus driver (**Figures 4 & 5**) had been under regular review for her diabetic retinopathy at HES. In October 2019, HES noted she now had new vessels on her left optic disc and requested a one-month review. She was discharged back to the screening programme as she failed to respond to 2 subsequent invites to HES.

When I screened the patient, she explained that during the Covid-19 lockdown she had noticed a sudden loss of vision in her left eye and had rung the eye unit to get an appointment. They told her she would need to be referred again. She was unsure whether to contact her GP due to the media regarding pressures on the NHS. When we rang her to offer an appointment with the DESP she was very relieved to able to attend my clinic the next day.

I asked her if she was worried about coming into the community hospital today for her appointment. She said that the whole lockdown period had been very frightening for her as she had continued working as a bus driver and had been provided with no screens or PPE. She had low expectations of what to expect today; she had taken her husband to the eye hospital several weeks before for injections and had been shocked at how busy the eye unit was. Today, she was surprised at how much room there was in the community hospital and that it was very well organised.

Her vision was 6/18 in her left eye. Her images demonstrated that her NVD (New Vessels at Disc) had now turned into fibrosis, pre-retinal haemorrhages and NVE. She has now been referred urgently to HES.

Outcome: She was seen urgently by HES. They noted significant vitreomacular traction in her left eye because of her NVD. They have referred her to the surgical team for management. The patient has also been advised regarding her vision and driving.

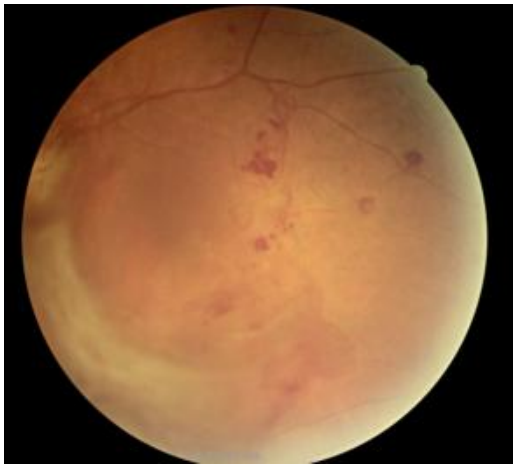
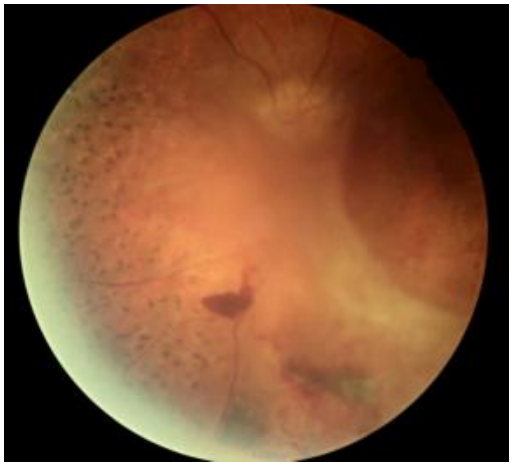


Figure 4. Left macula image May 2020

Figure 5. Left Nasal image May 2020



Case study from Group Three:

Patients scoring 2 points or above on their previous images

These patients were selected for screening because they scored 2 points or higher when their previous digital surveillance images were reviewed.

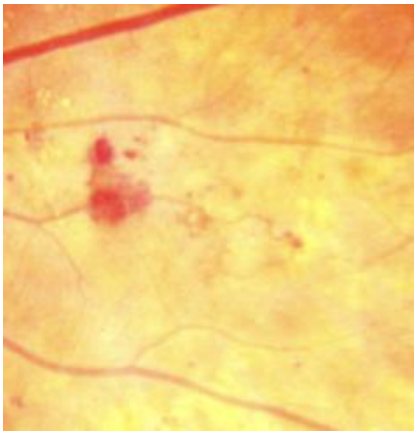
This 53-year-old driving instructor (**Figure 6**) had been seen in January 2020 and graded as R2M1 and placed on a 3-month recall.

When I screened him, he said he had no concerns about coming to his appointment and that it was all an adventure as he had not been out for weeks. His main concern was that during the lockdown he had been eating lots and that his sugars were 'sky high'. He said as soon as the pressures on the NHS had reduced, he was going to talk to his GP about his sugars.

He had good vision but was graded as R3a due to a small NVE that had developed (Figure 6) since his previous January images. He has been referred urgently to HES.

Outcome: He was seen by HES within 2 weeks. They also noted the cotton wool, haemorrhage, and queried IRMA or NVE next to it. The plan is for a for Fundus Fluorescein Angiography (FFA) within 2 weeks. The FFA will demonstrate if the abnormal vessel leaks. If it leaks this would be suggestive on NVE and the patient would then be booked in for Pan-retinal photocoagulation.

Figure 6. Portion taken from Right Nasal image May 2020



Summary

Overall, it was a positive experience and I feel the correct patients were identified. In the first 2 weeks our service did 4 clinics seeing 31 patients (including 11 pregnant patients). We referred 11 (35%) urgently for possible proliferative disease. Most importantly, the case studies demonstrated how we managed to identify early R3a in asymptomatic high-risk patients who were previously graded R1 and R2. It was beneficial that they attended as they should receive prompt treatment to save their vision.

I have found the organisation and hospitals are constantly looking to improve safety for both staff and patients. Even in the few weeks since my first clinic I have noticed further improvements by the hospitals based on staff and patient feedback. Many now hand out face masks to all patients and have digital thermometers at their entrances.

GLOUCESTERSHIRE RETINAL EDUCATION GROUP

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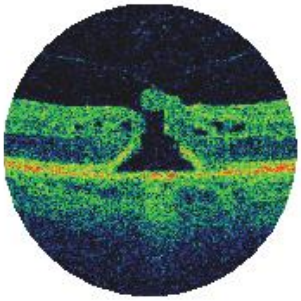

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