Investigation of the efficacy of an online diagnostic tool for improving the diagnosis of ocular fundus lesions imaged by Optical Coherence Tomography (OCT)

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Contents

Abstract

Background: Novel ocular imaging technology has proliferated within UK community optometry. Optical Coherence Tomography (OCT) is a pillar of ocular imaging, playing a central role in retinal disease management. As a non-invasive method for diagnosis and follow-up of patients with common retinal conditions such as age-related macular degeneration (AMD) and diabetic macular oedema, OCT is well suited to the primary care setting of community optometry.

The novel nature of OCT images presents considerable challenges for community optometrists. AMD prevalence will rise as a consequence of population growth and unprecedented life expectancy and, despite the emergence of novel treatment options, limited clinical capacity threatens access to potentially sight-saving treatment. Limited guidance exists for optometrists using OCT for diagnostic and referral decisions.

Objective: To measure the efficacy of a novel internet resource which, if proven to be efficacious, could not only aid in the use of OCT for diagnosis of retinal disease and subsequent patient management but could also play a role in ongoing training of optometrists.

Method: An online diagnostic tool (OCTAID) was designed for diagnosis of central retinal lesions using OCT. The effectiveness of OCTAID was evaluated by a randomised controlled trial comparing two groups of practitioners who underwent an online assessment (using clinical vignettes) of their diagnostic and management skills based on OCT images before and after an educational intervention. Participants' answers were validated against experts' classifications (the reference standard). OCTAID was randomly allocated as the educational intervention for one group with the control group receiving an intervention of standard OCT material.

Participants: Participants were community optometrists recruited through online optometry forums

Setting: Internet based application

Results: 53 optometrists (study group) and 65 optometrists (control group) completed the study (n = 118), forming the analysis population. Both groups performed similarly at baseline with no significant difference in mean exam 1 scores ($p = 0.212$). The primary outcome measure was mean improvement in exam score between the two exam modules. Participants who received OCTAID improved their exam score significantly more than those who received conventional educational materials ($p = 0.005$).

Conclusion: Use of OCTAID is associated with an improvement in the combined skill of OCT scan recognition and subsequent patient management. There is potential for this mode of educational delivery in optometric training.

Future work recommendations: With further development, OCTAID could become a collaborative learner-centred model of OCT education allowing optometrists to take responsibility for their own learning within a unique professional community.

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Chapter 1: Introduction

In this chapter the author will provide background information on:

- The motivation for the research
- The study hypothesis
- The aims of the research
- The anatomy of the eye with particular reference to the anatomic layers of the retina which are imaged by OCT
- Macular disease with particular reference to age-related macular degeneration
- The optometric eye examination, clinical methods of fundus examination and their limitations
- The new imaging technique of optical coherence tomography, its impact on clinical eyecare, the case for its use in optometric practice and its limitations

Motivation for the present research

Motivation refers to the reason or reasons that underlie behaviour and is characterised by willingness and volition. Broussard and Garrison (2004) provided a broader definition of motivation as "the attribute that moves us to do or not do something". Traditionally educators consider intrinsic motivation to be more desirable and to result in better learning outcomes than extrinsic motivation (Guay *et al*, 2010). The intrinsic motivation for this study evolved after the author introduced the imaging technology of OCT into his optometric practice in 2011. Limited guidance exists for optometrists using OCT for diagnostic and referral decisions.

Although OCT offers accurate and repeatable information in a qualitative and quantitative format, a full and accurate diagnosis and management decision by optometrists is not guaranteed. Limited guidance exists for optometrists using OCT for diagnostic and referral decisions and because high definition OCT scans reveal retinal detail previously unknown, it

is important to establish a general consensus to avoid confusion in daily practice (Gallego-Pinazo *et al*. 2013). For the author, the idea of a research question rising from the need to answer recurring clinical questions was particularly appealing.

Most patients seen in the British hospital eye service are referred by community optometrists and after such referrals most optometrists typically will continue to see the patient. Feedback from the ophthalmologist is therefore crucial for both educational purposes and for quality of care (Whitaker *et al*. 1999) but reply rates from ophthalmologists to referring optometrists can sometimes be very poor. In a study carried out at the Institute of Optometry (London) referrals from 2004 were audited and it was found that even when a reply was specifically requested (95% of cases) only 13% of these referrals received a reply and no relationship existed between the reason for referral and the likelihood of reply (Evans *et al*. 2005). Feedback has the effect of contributing to the professional development of optometrists and helping to ensure that inappropriate referrals from primary care optometry to secondary care ophthalmology are minimised over time (Ingram and Culham, 2001).

An optometrist may not reach a full and accurate diagnosis on every patient encounter but should maintain the ability to consistently recognise or monitor abnormalities. They should also be able to establish the urgency of referral and provide the ophthalmologist with good quality information. Providing accurate, high quality referrals will enhance the respect other professionals have for optometrists and increase goodwill within the primary and secondary care relationship. The successful introduction of OCT into optometric practice will require not only good training and regular use but also a healthy referral relationship between optometrists and ophthalmologists. Feedback from retinal experts to optometrists' OCT related referrals is an essential part of the steep learning curve facing community optometrists as they struggle to reach consensus.

There are capacity issues within specialist macular clinics and these clinics will be subject to further pressures. If optometric referrals into these clinics are to be timely and appropriate and if optometrists are to expand their role into co-management of AMD patients, they will require non-invasive imaging technology such as OCT and the skills to use it effectively.

Hypothesis

In the present era of rapidly evolving imaging technology, expanding treatment options for retinal disease and resulting changes in patient management plans (and referral protocols), today's optometric educators face the challenge of delivering knowledge and training to optometrists in an efficient and timely manner. We hypothesise that the internet delivery (e-learning) of such knowledge and training is the mode best suited to the delivery of OCT education and information can be revised and updated quickly in response to new research findings or expert opinion.

We further hypothesise that a diagnostic guide illustrating OCT images of retinal diseases (at various stages) commonly presenting to community optometrists along with patient management decisions should take the form of a website which takes account of current models of clinical reasoning. Such an internet resource has the potential to aid in OCT image interpretation and subsequent patient management. If proven efficacious, this resource could also play a role in ongoing training of optometrists in retinal disease.

Aims of the research

The aims of the research were to:

1. Develop and test an online diagnostic guide with the aim of improving the diagnosis and optometric management of central retinal lesions using OCT and monitor its use (as a secondary outcome measure) by the use of participant questionnaires and Google Analytics software.

2. Design an online assessment in the form of 'Visual Recognition and Investigation of Clinical Signs' (VRICS) and based on OCT images. The assessment adopted a stepwise approach for a diagnosis and management plan, similar to a clinical vignette, and questions were presented in multiple choice format. Participant questionnaire feedback on the overall value of the study to optometric practice (and on its value as an educational event) was also collected.
3. Conduct a randomised controlled trial comparing two groups of practitioners who took part in an online assessment of their diagnostic and management skills based on OCT images before and after educational intervention. The diagnostic guide was randomly allocated to one group with the control group receiving a control intervention.

Structure of the eye

Gross Anatomy

The adult eye is an asymmetrical globe about 22-25mm in diameter (Figure 1.1) (Bekerman *et al*. 2014). The front part of the eye (the part that we see in the mirror) comprises:

- The pigmented iris
- The cornea which is a clear dome over the iris
- The pupil which appears as a black, circular opening in the iris and allows light to enter the eye
- The sclera which is the firm outermost white coat
- The conjunctiva which is a thin layer of tissue covering the front of the eye except the cornea

Immediately behind the iris and pupil lies the lens. The lens focuses light on the back of the eye. Most of the eye is filled with a transparent gel called the vitreous. The retina is a light-sensitive tissue which lines the inside of the eye. It functions in a manner analogous to the film in a camera. The optical elements within the eye (cornea and lens) focus an image on to the retina initiating a series of chemical and electrical events within the retina.

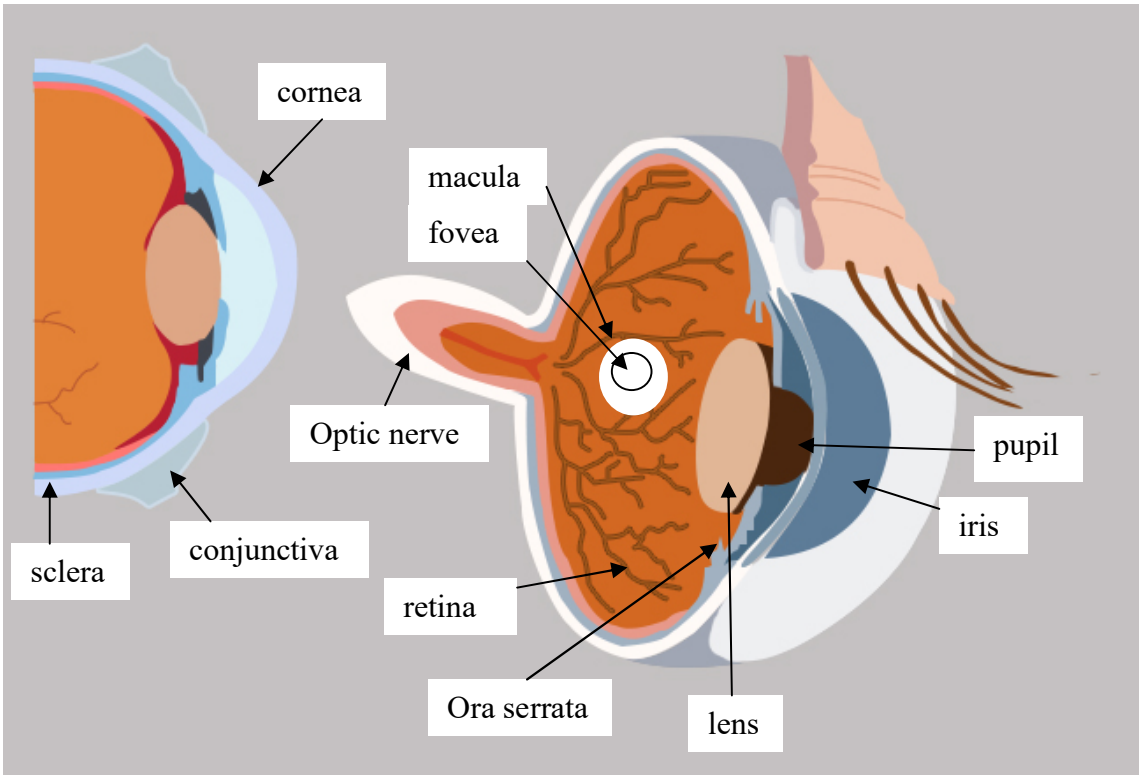

Figure 1.1 – Gross anatomy of the eye

The retina

The retina lines the inner surface of the posterior two thirds of the eye (with the exception of the optic nerve) and extends anteriorly to end at the ora serrata. The inner surface of the retina is adjacent (and in some places adherent) to the vitreous gel (Levison and Kaiser, 2014).

The neurosensory layers of the retina (which make up the bulk of the retinal thickness) are relatively transparent (Figure 1.2). The examiner will view the neurosensory layers against the background of the retinal pigment epithelium (which contains melanin) and the choroid (which is richly perfused by blood vessels). The neuroretina is only loosely attached to the underlying pigment epithelium, so the potential exists for a space to form between these two layers (Kang and Luff, 2008).

Nerve fibres within the retina send signals to the brain via the optic nerve. These signals are interpreted as images by the brain. The macula is a small but very specialised part of the central retina that processes high resolution, central vision. The macula contains the fovea

which is a small depression at the centre of the macula that has the greatest concentration of photoreceptors and thus provides maximum acuity (Provis *et al.* 2013).

The average healthy retina will vary in thickness depending on retinal location. The thickness immediately temporal to the optic disc is approximately 250 microns. The thickest part of the retinal is surrounding the fovea (400 microns approximately) and the thinnest part of the central retina is within the centre of the fovea itself (170 microns approximately) (Gella *et al.* 2015). The retina does however become thinner towards the periphery (80 microns at the ora serrata).

Cellular anatomy of the retina

The cells of the retina may be divided into three basic cell types: photoreceptor cells, neural cells and glial cells. Photoreceptor cells consist principally of rods and cones. Cones function best under bright (daytime; photopic) conditions and generate colour vision. Rods function mainly in dim light (scotopic) and deliver non-colour (black and white) vision. The human retina consists of approximately 120 million rods and 6 million cones (Hood and Birch, 1995). Each cone and rod cell contains photoreceptor elements and an axon. Each photoreceptor portion is divided into an inner and outer segment with the photoreceptor inner segment containing the cell nucleus. The central retina is cone-dominated, whereas the peripheral retina is rod-dominated. The centre of the macula contains the fovea. The fovea is a 'pit' where the cones are most densely packed and are arranged to provide the highest and most efficient optical density.

The retinal ganglion cells, which represent a third class of photoreceptors, are photosensitive cells involved in responses to light that do not relate to image formation such as contributing to the regulation of pupil size and synchronisation of circadian rhythms to the light-dark cycle (Fu *et al*. 2005).

The neural cells of the retina include:

- Bipolar cells, which are located entirely within the retina, connect the photoreceptors to the ganglion cells. They are perpendicular to the retinal surface and are therefore vertically orientated. Bipolar cells are post-synaptic to the rods and cones. There are at least 13 distinct types of bipolar cells, each of which transforms photoreceptor input in a different way (Euler *et al.* 2014).
- Ganglion cells terminate in dendrites which synapse with bipolar cells. Ganglion cell axons become the nerve fibre layer within the retina and become optic nerve fibres which terminate in the brain.
- Horizontal cells, which are oriented parallel to the retinal surface, connect bipolar cells with each other and are located in the outer plexiform layer of the retina.
- Amacrine cells, which function within the inner plexiform layer, connect bipolar and ganglion cells. Therefore, the inner plexiform layer represents the second synaptic layer of the retina. Most amacrine cells lack axons and are horizontally orientated. Both amacrine cells and horizontal cells serve to integrate and modulate the visual message presented to the ganglion cells (Kolb,1997).

The retina also contains cells such as Muller cells, astrocytes and microglial cells which perform a supporting matrix throughout the retina (Vecino *et al.* 2016). Muller cells are the principal glial cells of the retina. Muller cell bodies are located in the inner nuclear layer but their processes project in either direction to form the inner and outer limiting membranes.

Anatomic layers of the retina

There are ten named microscopic layers of the human retina (Figure 1.3) containing various structures. Starting with the innermost layer (adjacent to the vitreous), these layers are:

1. The inner limiting membrane – formed of astrocytes, footplates of Muller cells, and a basal lamina.

2. The nerve fibre layer – the ganglion cell axon fibres.
3. The ganglion cell layer – the nuclei of ganglion cells. Some of these ganglion cells are photosensitive.
4. The inner plexiform layer – contains the synapses between the dendrites of ganglion cells and amacrine cells. This layer also contains the axons of bipolar cells.
5. The inner nuclear layer – contains the nuclei of horizontal, bipolar and amacrine cells. This layer is thicker in the centre of the retina owing to the increased density of cone-connecting bipolar cells. Horizontal cells and amacrine cells concerned with cone pathways are smaller and more closely packed in the central retina. The nuclei of supporting Muller cells are also found in the inner nuclear layer.
6. The outer plexiform layer – contains the axons of the rods and cones. It also contains the dendrites of horizontal and bipolar cells and synapses occur among these structures within this layer. The outer plexiform layer is therefore sometimes referred to as the outer synaptic layer and in the macular area it is termed the fibre layer of Henle.
7. The outer nuclear layer – consists of the cell bodies of rods and cones. In the central retina the cone cell bodies outnumber the rods whereas the reverse is true of the peripheral retina.
8. The outer limiting membrane (OLM) – this layer separates the inner segment portions of the photoreceptors from their cell nuclei.
9. The rod and cone layer – this layer consists of the inner and outer segments of the rod and cone photoreceptor cells.
10. The retinal pigment epithelium (RPE) - this is the most external layer of the retina and consists of a single layer of supporting cells for the neural retina. RPE cells contain melanin which absorbs light and minimises light scatter within the eye.

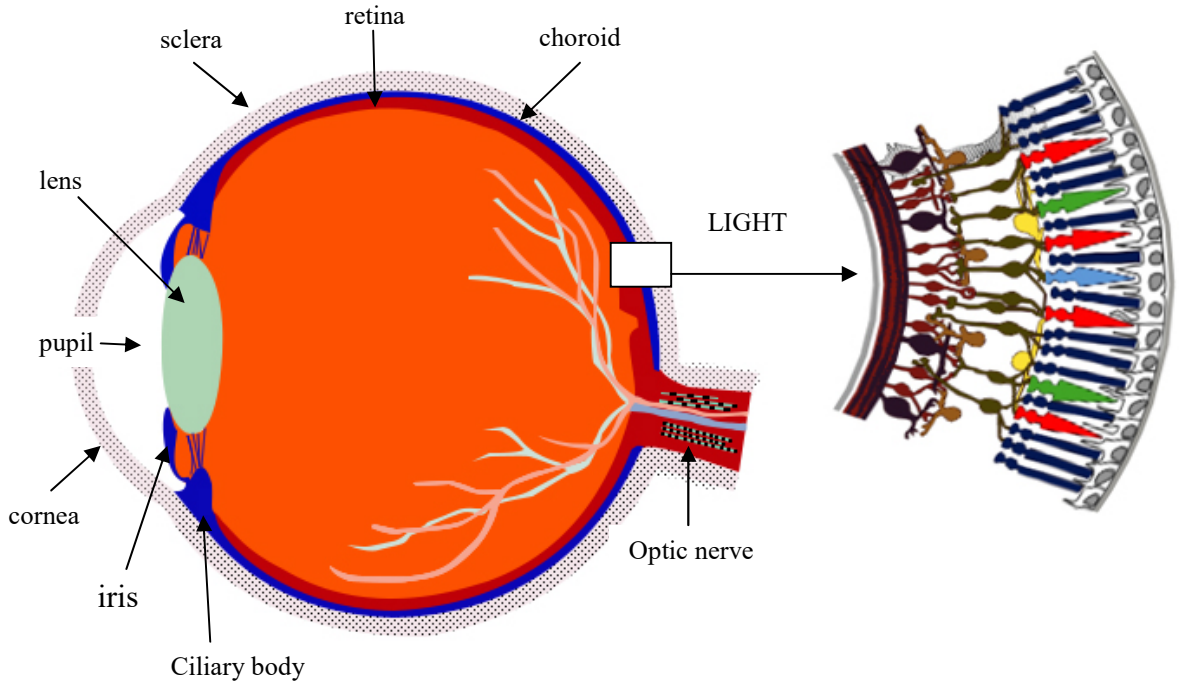

Figure 1.2 (anatomy of the retina)

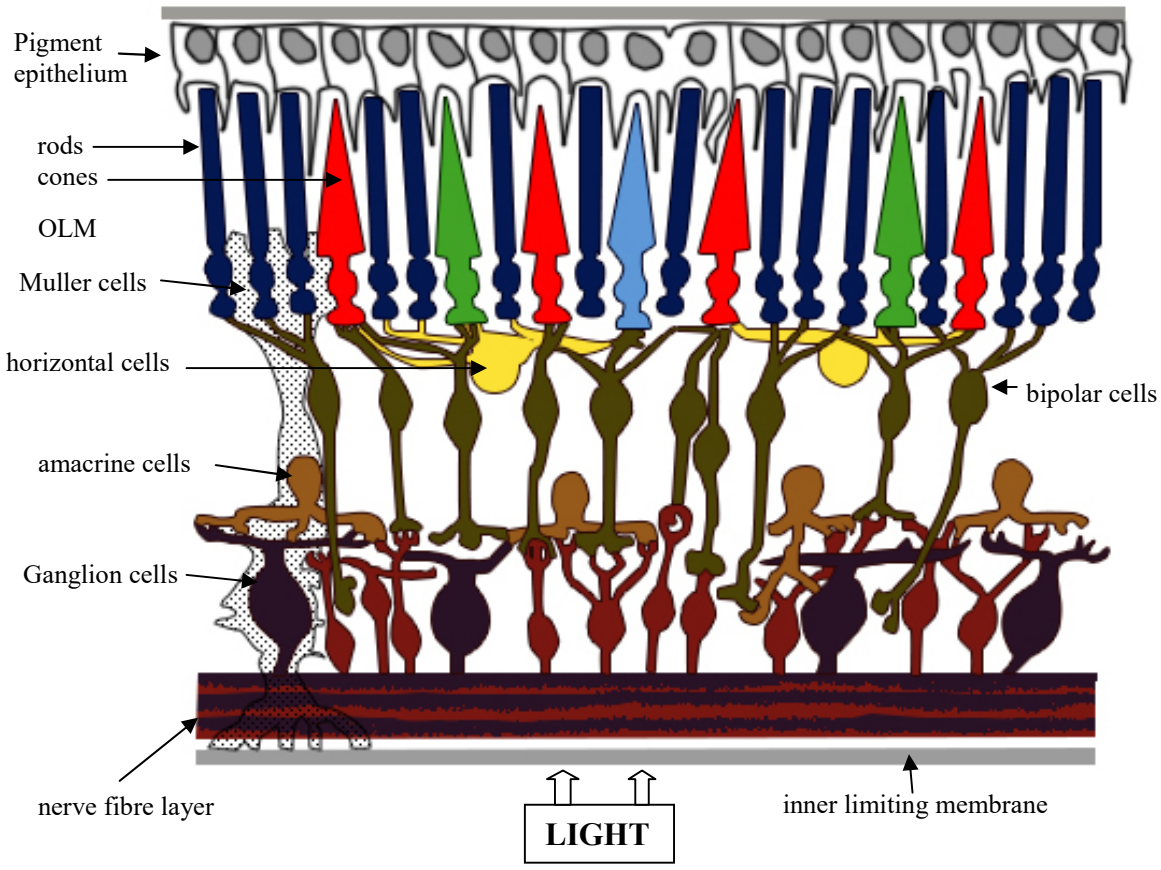

Figure 1.3 Cellular anatomy of the retina

Photoreceptive cells lie outer-most in the retina. Therefore, light must pass through and around the ganglion cells and through the thickness of the retina before reaching the cones and rods. Light does not pass through a healthy RPE or choroid as they are opaque.

There are about 120 million rods and 6 million cones in the retina (Koenekoop, 2009). The macula is the central 3mm of the retina. The fovea is found in the centre of the macula and measures about 500 microns in diameter. It is the thinnest part of the retina. The fovea does not contain any bipolar or ganglion cells so light will strike directly at the photoreceptors.

Macular disease

Because the macula is a delicate region, rich in photoreceptor nerve cells, macular dysfunction will impair our ability to see fine detail and colour. Symptoms associated with macular dysfunction include:

- Impairment of central vision (a blurred patch or an obstruction to central vision)
- Metamorphopsia (distortion of images, notably straight lines)
- Distortion of image size. This occurs less commonly. Objects may appear smaller (micropsia) or larger (macropsia)

The macular function can be affected by a range of pathologies including infection, trauma, degeneration, vascular disorders and inflammation. Macular disease may be further subdivided into those with and without choroidal neovascularisation (CNV). CNV involves the abnormal growth of new blood vessels into or beneath the retina. Some of the more common causes of macular disease (not associated with CNV) are:

- Dry Age-related macular degeneration (AMD)
- Diabetic macular oedema

- Macular hole
- Epiretinal membrane
- Central serous chorioretinopathy

Some of the more common causes of macular disease (associated with CNV) are:

- Wet age-related macular degeneration
- Macular degeneration associated with high myopia
- Idiopathic CNV
- Polypoidal choroidal vasculopathy
- Choroiditis (which may have a variety of underlying causes)

Macular disease has a widely variable clinical presentation and a sometimes unpredictable natural history and these are important confounding features when making a correct diagnosis (Ferrara *et al.* 2008). An accurate and specific diagnosis is important due to the high variability in visual prognosis and treatment options among the different disease entities. Differential diagnosis can be challenging and quite often impossible on a clinical basis. For example, AMD is the leading cause of blindness in the developed world (Carneiro and Andrade, 2017) but many other disease entities have similar clinical signs and manifestations. New imaging techniques such as optical coherence tomography are helpful in identifying fundamental diagnostic features of AMD and the conditions that can mimic AMD.

Age-related macular degeneration

The term ‘retinal disease’ describes a range of conditions affecting the retina. Age-related macular degeneration (AMD) is a serious retinal disorder which results in progressive loss of central vision. AMD accounts for more than half of all blind registrations in England and Wales (Bunce and Wormald, 2006). In an update to these figures (based on data collected

between April 2007 and March 2008), Bunce, Xing and Wormald (2010) state that AMD is still by far the leading cause of certified visual loss in England and Wales and that data based on certification only documents people who are sufficiently sight-impaired to warrant support (these figures are not estimates of the total numbers of newly blind people because not all people are offered or accept certification). Wilde *et al.*(2017) suggest that advanced AMD occurs more commonly in the UK Caucasian population than previously reported because significant asymmetry occurs between the two eyes in patients with unilateral advanced AMD. This results in visual impairment statistics not representing true prevalence of advanced AMD.

AMD is classified into 'dry' and 'wet' forms of disease, the wet form being more aggressive and destructive to vision. There are approximately 26,000 new cases of wet AMD each year in the UK (Amoaku *et al.* 2012). The dry type affects approximately 85 to 90% of individuals with AMD and tends to progress more slowly than the wet type (Michalska-Malecka *et al*. 2015). Wet AMD is caused by growth of abnormal blood vessels (which bleed and leak fluid) under the retina. It affects approximately 10 to 15% of AMD sufferers but accounts for 90% of all cases of severe visual loss from AMD (Soubrane *et al*. 2007).

Wet AMD can lead to a significant loss of vision within a very short period of time and such visual loss can have a profound impact on an individual's quality of life and independence (Mitchell and Bradley, 2006). The combined demographic impact of population growth, population aging and unprecedented life expectancy seems certain to ensure an increase in AMD prevalence (Michalska-Malecka *et al.* 2015). These changing demographics are illustrated in Figure 1.4.

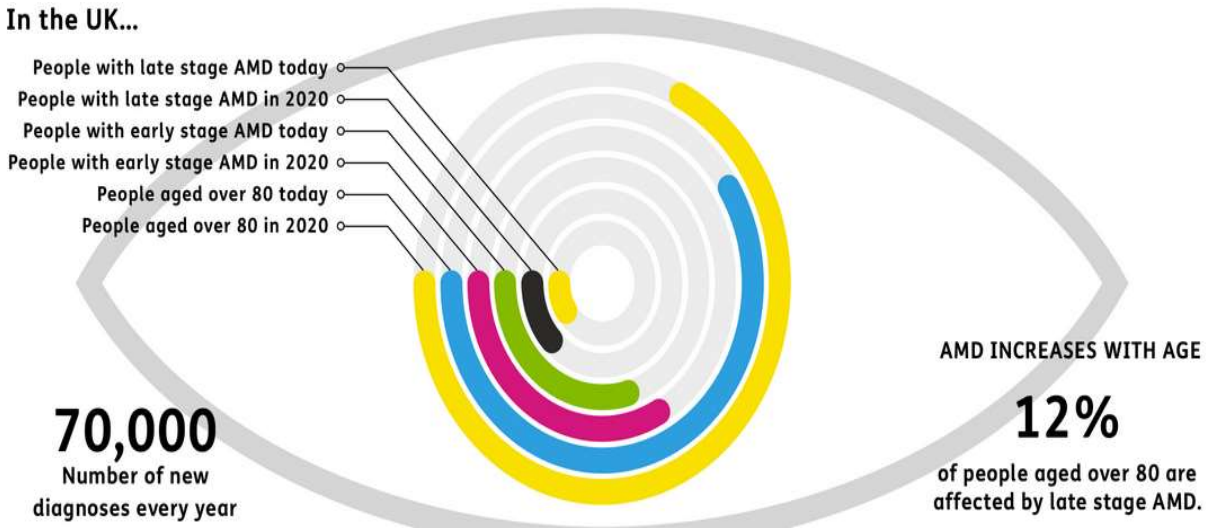

Figure 1.4 The burden of AMD and changing demographics. Reproduced with the kind permission of the Macular Society

Visual loss in AMD is associated with the degeneration of retinal pigment epithelium (RPE) cells and of the light-sensitive photoreceptor cells that they support. Healthy RPE cells form a tightly interconnected sheet of cells which are located between the photoreceptors and the choroid, which is a richly vascularised layer. This tight cellular structure forms a semi-permeable barrier that permits the RPE to transport nutrients selectively from the choroidal blood supply to the outer retinal layers. Degeneration of RPE cells in AMD appears to begin with impaired clearance of cellular waste material (Forest *et al.* 2015). This leads to a state of chronic localised inflammation, and eventually to the formation of abnormal deposits called drusen, which impair the function of RPE cells. Drusen are insoluble, extracellular aggregates.

The early stage of dry AMD (which is often asymptomatic) is characterised by the accumulation of drusen (Figure 1.5). The late stage of dry AMD is characterised by degeneration of the RPE and overlying photoreceptors which rely on the RPE for trophic support. These areas of degeneration may be scattered or confluent.

The other late stage of macular degeneration (wet) is characterised by neovascularisation (CNV). In this form of the disease immature blood vessels grow towards the inner retina from the underlying choroid and leak fluid, lipids and blood into or beneath the retina (Figure 1.5). This leads to distortion and fibrous scarring. It is the presence of fluid that led to the description as "wet". AMD patients usually develop the dry form of the disease first so wet AMD occurs on a background of dry AMD (Ambati and Fowler, 2012). Dry AMD is therefore considered a risk factor for wet AMD.

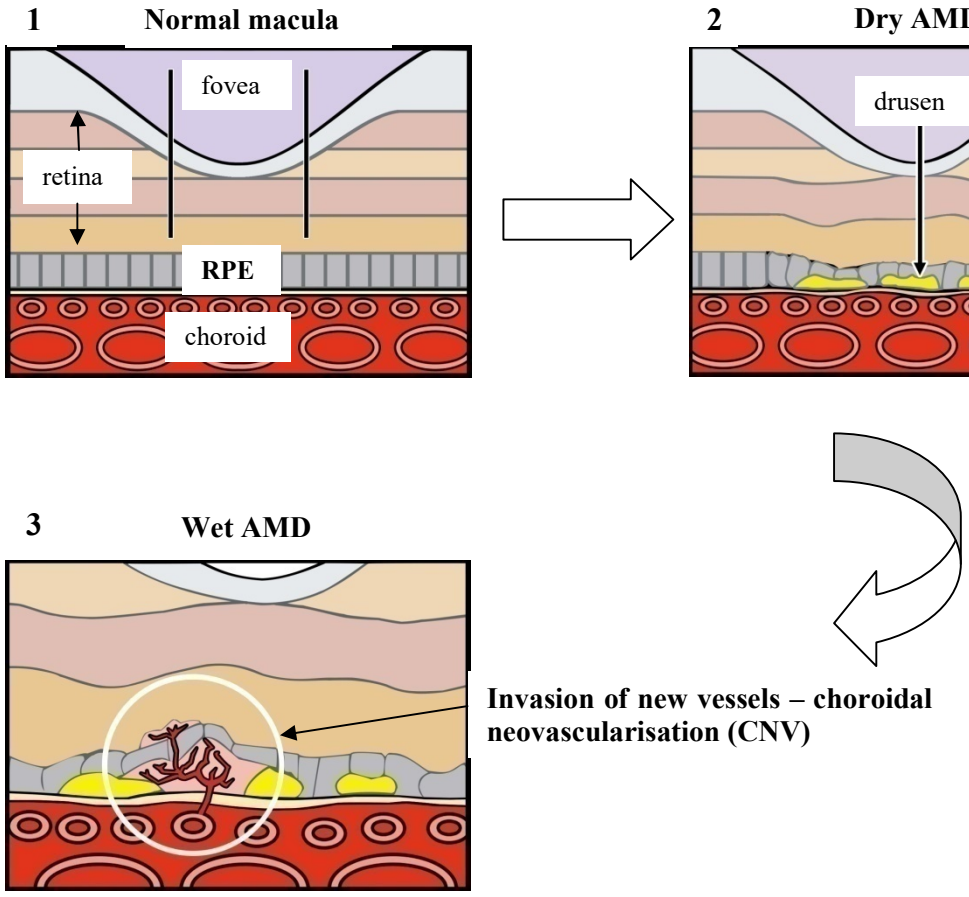

Figure 1.5 (1) The normal retina, (2) Drusen deposition in dry AMD, (3) New vessel invasion in wet AMD

Community optometrists are a common source of referral of patients with treatable AMD to the Hospital Eye Service (HES) (Creer *et al.* 2010).

Eye examination

Components of eye examination

Periodic eye and vision examinations are considered part of preventative health care and a complete eye examination involves a series of tests to evaluate the vision and detect eye diseases. Many eye and vision problems have no obvious signs or symptoms and individuals are often unaware that problems exist. The routine eye examination is an important tool in the detection of asymptomatic eye disease and optometrists check opportunistically for disease of the eye and elsewhere (Blakeney, 2012). Early diagnosis and treatment of vision problems are important not only for maintaining good vision and prevention of visual loss but also for the maintenance of good eye and general health (Grover, 2017).

Most eye examinations will commence by the examining optometrist asking the patient if there is a specific reason why they are attending or if the consultation is simply routine. Accurate history taking is as important in optometry as in any other field of medicine and if a patient is experiencing problems, the optometrist will need to know what symptoms the patient has, how long they have been experiencing them and whether any changes have happened suddenly or gradually. The optometrist will also require information on the patient's general health and any medications they may be taking. The patient will also be asked about close relatives who may have a history of eye diseases such as glaucoma.

According to the College of Optometrists guidelines, the exact format and content of an eye examination is determined by both the professional's personal judgement and the minimum legal requirements but as a minimum, a full eye examination should always include an internal examination of the eye (College of Optometrists, 2017). This is legally underpinned by the Opticians Act of 1948 which states that a key function of the eye examination is "to perform, for the purpose of detecting signs of injury, disease or abnormality in the eye or

elsewhere, an intra-ocular examination, either by means of an ophthalmoscope or by such other means as the doctor or optometrist considers appropriate".

The retina is the only part of the central nervous system visible from the exterior and the ocular fundus is the only location where the internal vasculature may be visualised. Much of what can be seen in internal medicine is related to the vasculature so viewing the fundus is an ideal way of getting a sense of the patient's overall vascular health (Abramoff *et al*.2010).

In a letter to the British Medical Journal, Clarke (2014) opines that ophthalmology receives more outpatient NHS referrals than any other speciality except trauma and orthopaedics and a significant underlying reason for this lies in the model of eyecare under which optometrists practice and are regulated in the UK. Under section 26 of the Opticians Act (revised in 1989), an optometrist carrying out an NHS sight test must "perform such examinations of the eye for the purpose of detecting injury, disease or abnormality in the eye" and "immediately following the test to give the person whose sight he/she has tested a written statement – (i) that he has carried out the examinations that the regulations require and (ii) that he is or is not referring the patient to a registered medical practitioner". Clarke believes that this is often interpreted to mean that an optometrist conducting an NHS sight test has a responsibility to refer any patient in whom an ocular disorder is detected to a medical practitioner and that optometrists are "unconstrained by any disincentives to refer patients". Clarke claims that as a consequence, the work of optometrists consumes a considerable amount of NHS resources. Clarke goes on to state that these so called "eye health checks" have never been subject to the scrutiny of the UK National Screening Committee. However, it should be noted that optometrists do not screen for disease in the true sense of the word but rather "case find" in that they only examine people who present to their practices rather than all those at risk in a population.

There is undoubtedly some benefit for patients with asymptomatic disease who may have their eye disease detected early but Clarke cites a high rate of false positive referrals as the price often paid (in terms of societal cost and patient anxiety) for the current model of NHS optometric eyecare. A false positive is a test result which wrongly indicates that a particular condition or attribute is present.

Clarke also suggests that General Practitioners may now feel less able to exercise their usual gate-keeping function for patients referred by optometrists because of increasing specialisation in optometry marked by new technology and terminology (GPs often have minimal formal training in ophthalmology) (Baker *et al.* 2016).

The current study is centred on the need to minimise any waste which might be generated by unnecessary referrals from 'scattergun' case finding of patients attending for OCT imaging at optometric practices.

Clinical methods of fundus examination

Examination of the ocular fundus is an essential skill for all eye clinicians and a basic fundus examination may be carried out with an ophthalmoscope. Although many practitioners have become familiar with some form of indirect ophthalmoscopy and biomicroscopy, the direct hand-held ophthalmoscope is still a common instrument of choice for fundus examination. The process of indirect ophthalmoscopy is so-called because the fundus is viewed through a hand-held condensing lens. The image formed is close to the principle focus of the lens, between the lens and the observer. The merits of direct versus indirect ophthalmoscopy are summarised in Table 1.1.

Feature	Direct ophthalmoscopy	Indirect ophthalmoscopy (20D lens)
Magnification	X14	X3
Field of view (without movement)	2 disc diameters (DD)	9DD
Illumination	Low	High
Depth of focus	Small	Large
Stereopsis (perception of depth)	Absent	Present
Peripheral fundus view	Limited	Extensive

Table 1.1 Features of direct v indirect ophthalmoscopy

Myint *et al.* (2011) found that in a national survey of diagnostic tests reported by UK community optometrists, the direct ophthalmoscope was the only fundoscopic examination method performed by a quarter of respondents. However, Probert (2016) observed that the increasing breadth of practice afforded by the evolution of shared-care schemes means that knowledge of different forms of fundus examination is now essential.

The direct ophthalmoscope is portable, easy to use compared to other methods and provides an erect image with a useful level of magnification (about X15 times in an emmetropic eye). The most important weakness of the direct ophthalmoscope is a narrow field of view (about two disc diameters which approximates to 7 square millimetres of retina simultaneously in focus). This view may be further limited by pupil size, patient refractive error, and the presence of media opacities. This limitation should also be viewed in the context of the surface area of the average human retina which is 1204 square millimetres (Panda-Jonas *et al*. 1994). Stereopsis (depth perception) is not afforded by the direct ophthalmoscope.

Slit lamp binocular indirect ophthalmoscopy (BIO) is an increasingly used method of fundus examination and provides a stereoscopic, wider view of the fundus. It is less affected by the

presence of media opacities but the image provided is inverted and reversed and more difficult to visualise through small pupils. This technique is more difficult to perform and requires a slit lamp microscope (therefore not portable). An even wider field of view can be achieved (at the expense of magnification) by binocular indirect ophthalmoscopy if the source of illumination is head-mounted. This technique is particularly useful when the peripheral retina needs to be examined for signs of detachment.

Contact lens ophthalmoscopy is an additional method of observing the peripheral retina but is mainly practiced by hospital clinicians. Fundus examination can be greatly enhanced for all techniques by the use of topical mydriatics (drugs which dilate the pupil).

Ocular imaging technology is now common in optometric practices but thorough fundus examination remains a key component of an eye examination. Macular disease and other posterior pole pathologies are leading causes of visual impairment and blindness worldwide. In some cases, prompt ophthalmological care may be required. However, inefficient and inappropriate referrals between primary eye care practitioners and ophthalmologists may inhibit timely access to ophthalmology treatment centres. Ly *et al*. (2016) suggest that if optometrists with a special interest in macular disease were to form an intermediate-tier optometric imaging clinic, they would be well placed to better refine referrals and recommend best management plans for patients with suspected macular disease.

Optical coherence tomography (OCT)

Technology

This section describes the optical imaging technique of optical coherence tomography.

Most pathological conditions elicit changes in the tissue optical response that may be investigated by one or more imaging modalities (Park *et al.* 2010). OCT is an optical imaging technology which relies on the penetration and backscattering of light into tissue to construct

cross-sectional, tomographic images. Tissue is relatively opaque for visible light wavelengths but is somewhat less absorbing at wavelengths of light near infrared (Fujimoto *et al.* 1995). Imaging depth in OCT is limited by optical scattering rather than absorption because scattering causes attenuation of the light signal (Schmitt *et al*. 1994). Scattering of light is also strongly dependent on wavelength. The use of optimised wavelengths (1300nm) can achieve imaging depths of 1 to 2mm in most tissues (Medina *et al*. 2014). This is shallow compared to other imaging modalities such as ultrasound but is sufficient for many clinical diagnostic applications such as ophthalmology. Because of the high transmissivity of ocular media, depth penetration is considerable and this explains why OCT is used mainly in eyecare. For instance, the corresponding application in dermatology is hindered by strong scattering of light by epidermal tissue (Sudheendran *et al*. 2010). For tissue imaging, radiation source wavelengths are restricted to the visible red and near-infrared (600 to 1300nm). This is referred to as the 'therapeutic window' where tissue absorption is limited (Gambichler *et al*. 2010).

OCT is often described as the optical analogue of ultrasound because it generates images using the time delay and magnitude of light echoes (Fujimoto and Swanson, 2016). Ultrasound terms such as A-Scan and B-Scan have exact analogues in OCT. In simple terms, A stands for amplitude and B stands for brightness. In an A-Scan the energy reflected back to a probe will give a curve or amplitude. Higher peaks or waves correspond to more energy or signal. In a B-Scan, the more energy returned the brighter the peak (or spot) displayed. The two are often combined to give more information. This results in a repeating wave form that also has brightness making it easier to read and interpret.

OCT is based on an optical technique known as Michelson low coherence interferometry which measures echo delay and intensity of back-reflected or back-scattered infrared radiation (800nm approx) from internal ocular microstructure. Differences in echo time and intensity between the reflected light signal and that from a reference path are measured and converted

into high resolution images. The resolution can be as fine as 3 microns (Medina *et al*. 2014) and OCT equipment achieving this level of axial resolution is now commercially available. Even early versions of OCT equipment were achieving levels of axial resolution which could not be achieved in living organisms by any other imaging modality (Fujimoto *et al*. 1995).

OCT images are based on the interference between a split (and later recombined) light signal. Figure 1.6 below is a schematic of a simple OCT system.

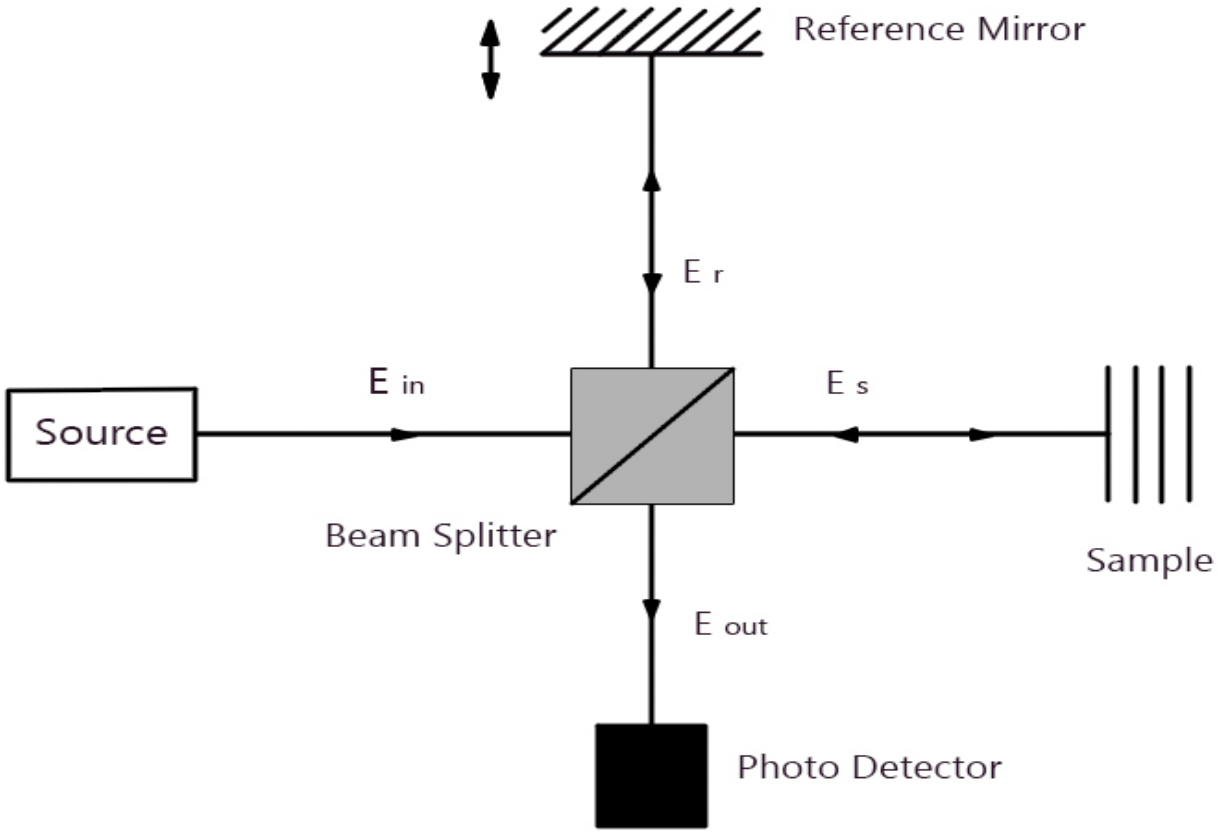

Figure 1.6. A typical OCT system. E = OCT signal in and out via the reference mirror (r) and the sample(s)

The light signal from the source is directed through a beam splitter and travels in two paths. One light beam travels towards a moving reference mirror and the other to the tissue sample being imaged. Light reflected from the tissue sample and the reference mirror is directed to a photo detector to observe the interference pattern. Retinal tissue samples will contain layers with different refractive indices. Variation between adjacent refractive indexes cause intensity peaks in the interference patterns detected by the photo detector. The resulting image will be a

line scan (sometimes referred to as an A-scan) of depth of the 3D volume to be analysed. Multiple A-scans may then be used to construct 2-D cross-sections and 3-D volumes of the tissue being imaged.

In its most basic form there are two types of OCT imaging system, namely the time-domain OCT (TD-OCT) and the Fourier-Domain (sometimes referred to as Spectral-Domain) OCT. In TD OCT a reference mirror is translated to match the optical path from reflections within the sample (Figure 1.6). The range of depth is sampled one point at a time by moving the reference mirror to produce an axial scan (A-Scan). This kind of serial sampling imposes limits on the speed and sensitivity of imaging. The new Spectral-domain OCT (SD-OCT) is faster and more efficient than TD-OCT because it detects reflections from the entire tissue depth range simultaneously by employing a spectrometer in the receiver. The spectrometer analyses the spectrum of reflected light signal and transforms it into information about the depth of cellular structures within the tissue sample (Chen *et al*. 2005). The SD technology eliminates the need to mechanically move the reference arm of the system with a resulting increase in the speed with which images are received and the axial resolution achieved. Because of not having any moving parts, the speed of SD-OCT systems in acquiring images is very high in comparison to TD-OCT and this increase in resolution and scanning speed permits high-density raster scanning of retinal tissue while minimising eye movement artefacts (Schuman, 2008).

The arrival of modern ocular medical imaging technologies has enhanced both the diagnosis and management of eye disease and the landscape of clinical eyecare is continuously being affected by the broadening frontier of technology used in ocular imaging (Nadler *et al.* 2012). With increasingly sophisticated technologies, eyecare professionals have never been better placed to offer the highest standards in eye healthcare. One of the most exciting developments in retinal imaging in recent years has been optical coherence tomography (OCT).

OCT was first described by Huang *et al*. (1991). It has since become a key diagnostic technology in the ophthalmic subspeciality area of retinal disease. OCT is used widely in the healthcare field, but particularly in eyecare because of the high transmissivity of healthy ocular media. Costa *et al.* (2006) suggested two properties of OCT data which explained its widespread adoption:

- The results are accessible to the non-specialist where microscopic defects are grossly and easily noticeable
- Results are reproducible and quantitative in the hands of the specialist

In modern time-domain OCT technology, two or three dimensional cross-sectional tomographic images of optical reflectivity are captured by this non-invasive, non-contact technique thus delivering a micrometer-scale, cross sectional image through the retinal tissue. This resembles a histological section (Chen and Lee, 2007) without the need for removal and processing of tissue samples as in conventional histology.

Changes in optical reflectivity are illustrated by computer-generated colour coding. Warm colours such as red, yellow and white indicate high reflectivity and cold colours (blue and green) indicate low reflectivity. Images may also be illustrated in greyscale which is preferable as false colours can be misleading. In greyscale, brighter shades replace warm colours to indicate high reflectivity. Absence of reflection will therefore appear black.

OCT images are comparable to ultrasound B-mode sections. Both technologies present serial or radial cross-sectional images in the same plane and produce data on the amplitude of echoes scattered from the tissues at measured depths (Restori, 2008). Imaging by ultrasound and radar is also reflectometry-based but several advantages are gained by the fact that OCT employs light. The wavelength of light is around 0.001mm, which is shorter than that of ultrasound (0.1mm) and radiowaves (greater than 10mm). As a result, the spatial resolution of OCT is much higher. Light passes through the air-tissue interface easily. Therefore, unlike

ultrasound, OCT does not require probe-tissue contact or an immersion fluid (Costa *et al*. 2006).

Optical coherence tomography of the retina

OCT images demonstrate reproducible patterns of retinal morphology that correspond well with the location of retinal layers seen on light microscopy. Horizontally aligned retinal structures such as the nerve fibre layer, plexiform layers and retinal pigment epithelium show high reflectivity whereas nuclear layers and photoreceptor inner and outer segments show a relatively lower level of reflectivity (Tofli *et al.* 1997) (refer to cellular anatomy of the retina on page 12). A typical OCT scan of the normal retina is shown below (Figure 1.7 and 1.8). Visibility of the distinct retinal layers is slightly enhanced when viewed in greyscale. It is important to be familiar with the appearance of the OCT scan of the normal retina as a comparator and to have an appreciation of normal variation.

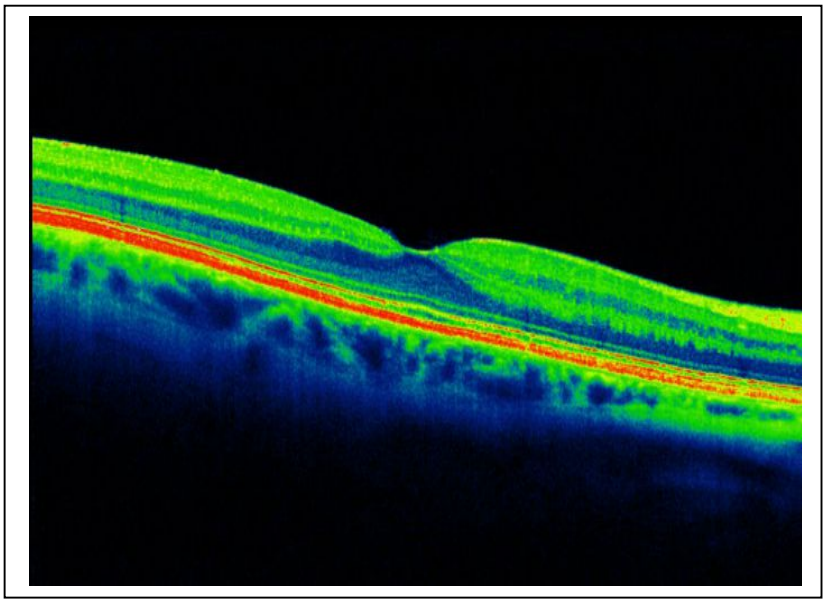

Figure 1.7. OCT scan of the normal retina

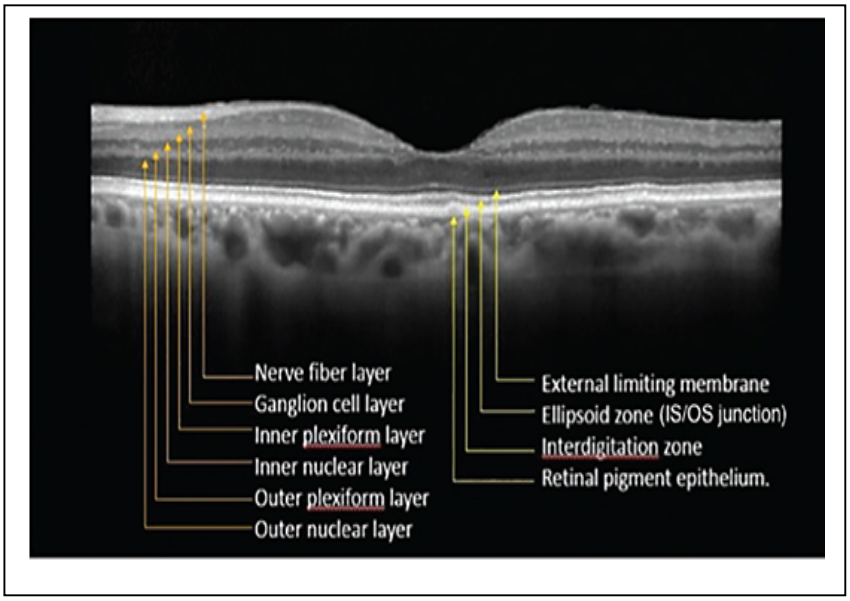

Figure 1.8 Layers of the normal retinal as represented by OCT (Ophthalmology Management, 2015)

The anterior hyperreflective band originates from the inner limiting membrane and retinal nerve fibre layer. There is a characteristic central dip at the fovea (the foveola). Moving posteriorly from the retinal surface there are alternating hyper and hyporeflective bands representing the ganglion cell layer, the inner plexiform layer, the inner nuclear layer, the outer plexiform layer and the outer nuclear layer. Posterior to the outer nuclear layer there are three adjacent hyperreflective lines which represent the outer limiting membrane (OLM), the photoreceptor inner and outer segment junction. There is a weak and patchy OCT signal from the choroid which is located posterior to the retinal pigment epithelium.

Developments

The in-vivo structure of the choroid is only partially visualised by SD–OCT but the more recent development of swept-source OCT (SS-OCT) has led to an increased visualisation of the choroidal anatomy (Mrejen and Spaide, 2013). SS-OCT has the following advantages over SD-OCT:

- Higher imaging speed. This means that high-resolution images may be obtained while reducing the negative impact of the patient's eye movement on the OCT scan quality
- The use of a longer wavelength OCT signal source provides clearer images of deeper ocular structures such as the choroid by overcoming scattering by the RPE
- The longer wavelength SS-OCT means less light scattering by lens opacities. Therefore SS-OCT delivers clearer images in patients with cataract compared to SD-OCT

Optical coherence tomography angiography (OCTA) is a new imaging technique. It has a potentially wide general applicability for retinal vascular disease because it provides a highly detailed view of the retinal vasculature. It can detect changes in choroidal blood flow and blood perfusion at the optic disc. It therefore has potential in the evaluation of common ocular conditions such as choroidal neovascularisation and glaucoma. OCT angiography can in fact image all layers of the retinal vasculature without the injection of dye (Spaide *et al. (1)* 2015).

The value of OCT in optometric practice

Impact on clinical eyecare and the case for OCT in optometric practice

Hermann van Helmholtz is credited by most for the invention of the ophthalmoscope, a hand-held instrument for viewing the ocular fundus, more than 150 years ago. Most eyecare practitioners perform ophthalmoscopy in some form, every day. All forms of fundus photography, even with ultra-wide field imaging, do nothing more than accurately capture what we can view directly with the ophthalmoscope. Diagnostic imaging by ophthalmoscopy offers magnified visualisation of the fundus but this simple optical device is unable to image subsurface features which may be of crucial diagnostic value.

As discussed before (page 17), there are two types of AMD: dry (atrophic) and wet (neovascular or exudative). Diagnosis and a decision to treat a patient suspected of having a sight-threatening condition such as 'wet' age-related macular degeneration (AMD) is often based on an invasive test, fundus fluorescein angiography (FFA), undertaken in the hospital setting. Until recently fluorescein angiography (FA) was regarded as the reference standard imaging modality used to detect the presence of 'wet' AMD and other macular lesions. FFA is an invasive technique and some serious, albeit rare, side-effects of allergy, anaphylaxis, and cardiac complications have been reported (Chen and Lee, 2007). Adverse reactions (most commonly nausea and vomiting) occur in under 5% of cases (Butner and Mc Pherson, 1983). Overall, FA is a relatively safe procedure but safeguards need to be in place to manage potential serious adverse reactions (Kwan *et al*. 2006). With FFA, a hospital setting is required with a clinician such as a nurse required to inject a dye and a specialist photographer required to identify and record the leaking of dye as it moves through the retinal and choroidal vascular network (Cameron *et al.* 2011). Therefore, identifying patients whose retinal lesions fulfil treatment criteria is time-consuming and imposes demands on hospital resources.

Although FA provides evidence of leakage in wet AMD it does not provide any anatomical information about the precise retinal layer implicated (Regatieri *et al.* 2011). Unlike FFA, OCT is a technique used to examine structures inside the eye non-invasively (Thomas and Duguid, 2004).

There is a need for advanced diagnostic imaging technology in optometric primary care but many other available imaging modalities (ultrasound, x-ray, CT, MRI) have significant constraints that make them difficult to adapt to the primary care setting. Even in a cost-conscious healthcare system, there is a need to introduce new imaging and quantitative methods to ensure appropriate patient referral to subspecialists to improve diagnostic outcome for every patient encounter. The evolution of OCT creates new opportunities to detect and analyse changes in the retina earlier and with greater accuracy than has been previously possible.

Clinical applications of OCT in optometric practice

Although this study focuses on the use of OCT for macular and central retinal pathologies, OCT is also utilised in anterior segment evaluations and other posterior pole evaluations, in suspect glaucoma and numerous optic nerve pathologies. In all these investigations OCT affords us a highly accurate, quantifiable, and repeatable technology (Drexler *et al.* 2001).

Macular disease

Before the use of OCT in clinical practice, mainly qualitative methods were used to detect changes in macular thickness such as slit lamp biomicroscopy and stereoscopic fundus photography. The appropriate management of conditions associated with changes in retinal thickness requires a quantitative method for analysing retinal thickness (Dobos, 2010). OCT scanning can identify or confirm the presence of macular thickening and this is particularly important when combined with other clinical findings such as retinal haemorrhages (superficial and deep) and exudates or the subjective reporting of blurred vision or metamorphopsia (distortion). On the other hand, a finding of reduced macular thickening in neovascular age-related macular degeneration may be related to the success of intravitreal anti-VEGF therapy. Documenting changes in macular thickening provides helpful insight into guiding therapy and follow-up decisions (repeat injection versus monitoring). For example, a reduction in macular thickening may be a sign of focal diabetic macular oedema which has been responsive to focal laser photocoagulation (Salem *et al*. 2012). The clinical utility of OCT has also been greatly enhanced by the development of normative databases and progression analyses for retinal parameters. A normative database permits the clinician to establish if the clinical parameters fall within normal limits.

Several retinal conditions are related to macular distortion caused by oedema such as diabetic retinopathy, central serous chorioretinopathy and cystoid macular oedema. The retinal

integrity of the post-treatment patient may be co-managed by an optometrist using OCT who can identify signs of resolution or exacerbation.

The vitreo-retinal interface

OCT scanning provides structural evidence of deviation from the normal retinal architecture and OCT is an increasingly important tool for diagnosing and monitoring a wide range of vitreoretinal diseases (Chen and Lee, 2007) and in guiding surgical decisions (Do *et al.* 2006). Visual distortion may be caused by a common phenomenon of the aging eye called posterior vitreous detachment (PVD). The vitreous is a clear jelly-like substance that fills the eye, taking up the space behind the lens and in front of the retina. The vitreous changes with age by becoming more liquefied in the middle and shrinking. The vitreous is attached to the retina (more strongly in some places than others) and as it shrinks, it comes away from the retina. Tractional forces may be exerted on the macula by persistent vitreomacular adhesions (Figure 1.9).

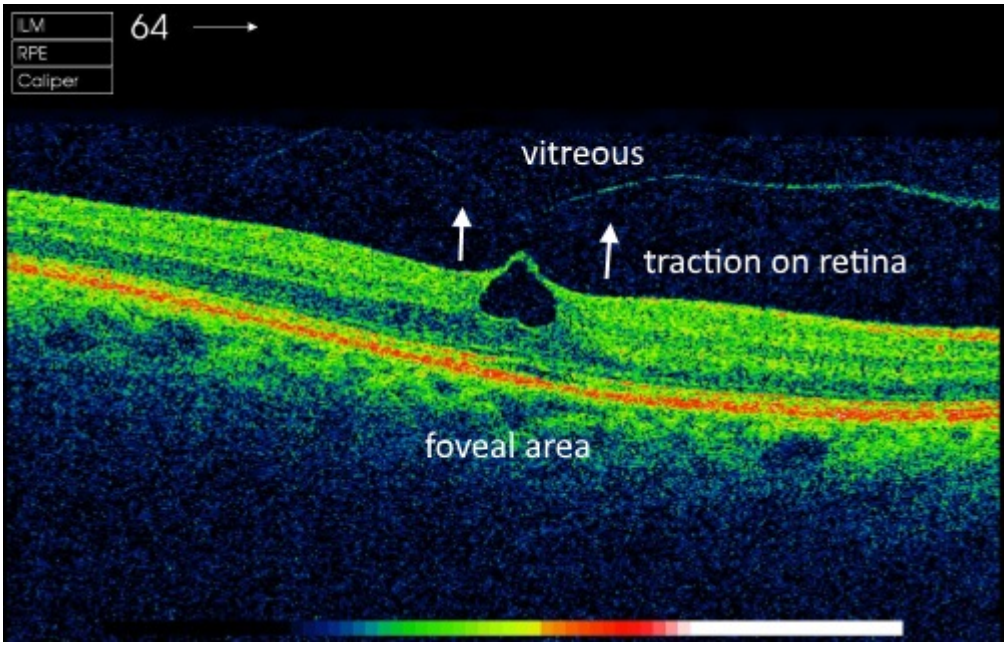

Figure 1.9 OCT scan showing traction on the retina from the vitreous gel

Vitreomacular traction syndromes may progress from preretinal fibrosis (epiretinal membranes) through classic vitreomacular traction syndrome to finally a macular hole. OCT may more easily visualise macular holes, differentiate their various stages and define their

characteristics to facilitate referral and treatment decisions (Steel and Lotery, 2013). It is important to differentiate between retinal thickening caused by vitreoretinal traction syndromes and other causes of retinal thickening which may be intraretinal or subretinal in origin.

Retinal vascular occlusion

A useful insight into the various manifestations of acute retinal ischaemia is provided by OCT. The form of presentation of retinal ischaemia will depend on the type and location of the vascular event. Clinically, visible retinal whitening may occur in retinal locations not affected by cotton wool spots (accumulations of axoplasmic material within damaged nerve fibres which are markers of ischaemia). The spectrum of retinal ischaemia from various causes manifests itself in the inner nuclear layer causing thickening and hyperreflectivity on OCT. This provides insight into the pathological processes involved (Coady *et al.* 2015).

OCT has provided new insights into the morphological changes that occur in patients with macular oedema secondary to retinal vein occlusion. By measuring retinal thickness, OCT has become an invaluable tool in assessing response to treatment (Trichonas and Kaiser, 2014).

Glaucoma

Glaucoma is a group of eye conditions which result in damage to the optic nerve and visual loss. It is characterised by a particular form of optic nerve damage and visual field loss in which elevated intaocular pressure is thought to be a risk factor. Glaucoma is a leading global cause of irreversible blindness (Pomorska *et al*. 2012) with many of these cases undiagnosed (Tielsch *et al.* 1991, Mitchell *et al.* 1996).

OCT provides high resolution, quantitative and objective assessment of the retinal cellular layers affected by glaucoma (Schuman, 2008). Some early reports (based on histology and glaucoma modelling) suggested that significant loss of retinal ganglion cells of up to 50%

may occur before a field defect is significant enough to be detected (Quigley *et al.*1989, Sommer *et al.* 1991, Kerrigan-Baumrind *et al.* 2000, Nouri-mahdavi *et al.* 2011, Harwerth *et al*. 1999).

Although it is a commonly held belief that structural damage precedes functional loss in glaucoma, more recent evidence suggests that the two occur concurrently throughout the progression of the disease (Denniss and Henson, 2009). In many patients structural measures achieve statistical significance before functional measures but in some patients the opposite is true. It is therefore optimal to measure both structure and function whenever possible. OCT technology may therefore quantify nerve fibre and structural damage earlier than visual field testing in some cases and some studies have already suggested that ganglion cell mapping and pattern analysis improve diagnostic accuracy and demonstrate a potential for tracking glaucoma progress (Tan *et al.* 2009).

OCT instruments show normative values for optic disc parameters and retinal nerve fibre layer (RNFL) thicknesses from very wide population-based studies. This information helps to report values and associations that can inform retinal physicians about normal variations within the wider population (Tariq *et al.* 2012). Figure 1.10 shows an OCT analysis of retinal nerve fibre layer (RNFL) thickness in a glaucoma sufferer in which this parameter falls below the normative data (in green within which 95% of normals lie) into the red zone (the thinnest nerve fibre thickness that is only found in 1% of normals) suggesting a loss of nerve fibres (and subsequent thinning of this layer).

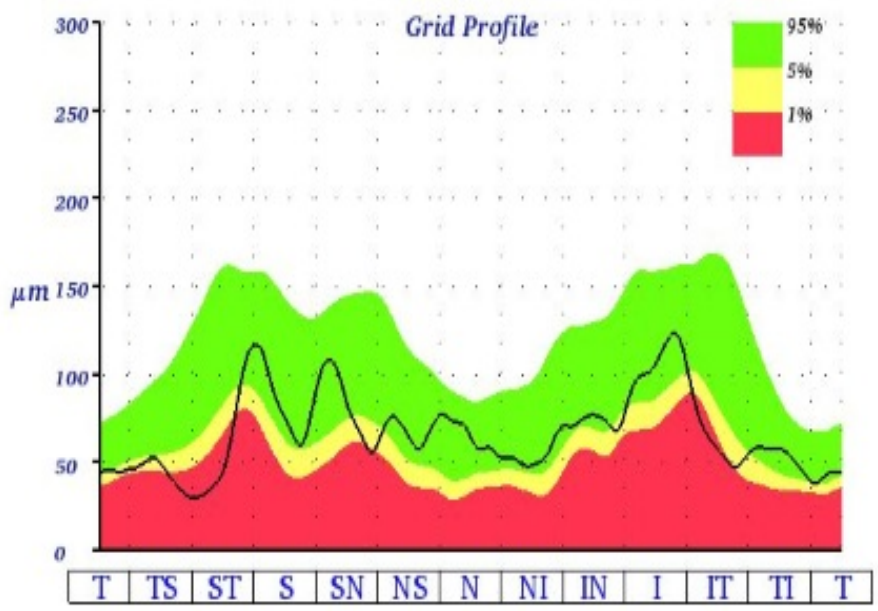

Figure 1.10 OCT RNFL thickness analysis (black line) for a glaucoma sufferer falling outside the normative data (green) and into the red zone. (T = Temporal. N = Nasal. S = Superior. I = Inferior).

OCT can provide valuable information on other optic nerve abnormalities such as optic nerve drusen (Johnson *et al.* 2009), optic pits (Doyle *et al.* 2009) and optic nerve oedema (Kardon, 2014). For example, retinal nerve fibre analysis may be helpful in assessing optic nerve fibre thickening in a patient with suspected benign intracranial hypertension or in the follow-up of such a patient after treatment has begun (Rebolleda and Munoz-Negrete, 2009).

Anterior segment assessment

OCT has a role in anterior segment evaluation by providing an objective method of assessing the eye's anterior segment (Salim, 2012). It is helpful in identifying narrow anterior chamber angles, shallow anterior chambers (Doors *et al.* 2010) and iris thickness and surface profile (Izatt *et al*. 1994). OCT can differentiate between solid and cystic defects. This is important when investigating pathologies which cause iris thickening such as cysts and melanomas. Anterior segment OCT (AS-OCT) is superior to ultrasound B scan for imaging small lesions on the anterior iris (Hau *et al.* 2014).

OCT for communication

Great potential exists for the use of OCT for clinician to clinician communication. OCT can provide crucial information in the co-management of cases where a cause of reduced visual acuity has not been clearly identified or in the many cases where eye diseases co-exist. For example, in cases of macular oedema, macular hole or macular degeneration in the presence of cataract, it may not be clear which of these conditions (cataract versus retinal disease) is having the greater impact on visual function. This information, when it passes from the primary care practitioner to secondary or tertiary care providers, may help predict surgical outcomes. OCT may also identify macular disease which is not visible using the ophthalmoscope or photography through dense cataract. Preoperative and postoperative OCT assessments in eyes at high risk (diabetes, uveitis) of cystoid macular oedema (CME) may be warranted and in any case, OCT has become a useful tool to detect and monitor CME after cataract surgery (Kim and Bressler, 2009).

Detection of subtle macular abnormalities by conventional clinical methods (ophthalmoscopy and biomicroscopy) through a cataract is challenging. A study by Creese *et al.* (2011) suggested that the routine use of OCT before cataract surgery improves the accuracy of the preoperative diagnostic process and plays an important role in avoiding misdiagnosis and postoperative macular surprises. This study involved 162 patients (232 eyes with cataract) with an average age of 73 years who were scheduled for cataract surgery. All the patients were diagnosed with visually significant cataract and were listed for cataract surgery. The study team selected consecutive patients attending the preoperative assessment clinics on days (which were chosen at random) during the study period (May to September 2010). Macular examinations were conducted using spectral domain OCT. Fourteen eyes (of 13 patients) were excluded from the study because of the difficulty in obtaining good quality OCT scans. Patients with clinically evident maculopathy were also excluded. Macular pathologies were detected in 10 out of 218 eyes (4.6%). Treating ophthalmologists were able to defer 5 cataract surgeries based on these OCT findings and refer these patients for medical retinal

consultations. In the other five patients, the OCT information facilitated a revision of the prognostic aspect of the informed consent for cataract surgery. Creese *et al.* also remind us that cataract surgery accounts for most malpractice claims in ophthalmology in the United States with unrealistic patient expectations being a common underlying factor.

OCT presents an excellent opportunity for optometrists to communicate with ophthalmologists, resulting in more effective referral, earlier diagnosis and clinical decision making. Some studies have identified substantial benefit to patient, optometrist and retinal specialist with the adoption of ocular telemedicine (Hanson *et al*. 2008, Cameron *et al.* 2009, Kelly *et al*. 2011). These studies showed that patients benefited from a reduction in the number of unnecessary visits to the retinal specialist. Optometrists benefitted from the provision of a more comprehensive eye examination and an immediate referral when needed. The retinal physician benefited from a reduction in the number of visits from patients who did not require further investigation or treatment while testing time and efficiency were improved for those who did.

Teleophthalmology

Teleophthalmology involves the process of transmission and remote viewing of ocular images via a web browser. A literature search has not found any randomised controlled trials of teleophthalmology between primary and secondary care although teleradiology is a more developed area of telemedicine which has led to the development of comprehensive teleradiology guidelines by the Royal College of Radiologists for those who wish to deliver teleradiology services (Royal College of Radiologists, 2010). Such a process involves the sharing of patient-identifiable information within and between organisations and perhaps across international boundaries. The Royal College of Radiologists (2010) suggest that the changing methods of diagnostic imaging services and the increasing commercialisation of aspects of healthcare including telemedicine means that there will be increased fragmentation

of where and how services are delivered. These changes will be mirrored in ophthalmology which will require the setting of standards for sharing of patients' ocular imaging data via teleophthalmology. Attention to guidelines and standards will maintain high-quality standards of reporting, thereby ensuring patient safety and confidentiality.

Patient education

OCT may be used for illustrative purposes and has an important place in patient education. The patient may gain a greater understanding of his or her disease process or reason for referral. OCT technology allows patients to view the images that illustrate their ocular condition in comparison to normal results. This has the potential, with a suitable explanation, to provide a clearer understanding of why their ocular condition is being monitored, leading to increased patient confidence about the value of care provided. Educating patients about the visual complications, risk factors and treatment options associated with their eye condition plays an essential role in ongoing patient care.

The future

An investigation into the current and anticipated use of equipment in community optometric practice in the UK in 2013 showed that 15 percent of respondents were using OCT, up from 2 percent in 2007 (Dabasia *et al.* 2014). More notably, Dabasia *et al.* also observed that 43 percent of those anticipating purchasing specialist equipment in the next 12 months, planned to buy an OCT. Such rapid changes in imaging technology and its application to practice will have a bearing on the future clinical practice of optometry. OCT provides a diagnostic facility which will function as an extension of optometric clinical practice and enable community optometrists to provide better care for their patients. If optometrists are to be the focus for community case finding of eye diseases such as AMD and diabetic retinopathy they will need to have access to the latest technology so that they can detect and monitor treatment and share in patient care. This has the potential to create a genuinely functional health-care team approach to eye care in the current context of a high risk, aging population and a scenario of capacity issues within specialist clinics. A question remains about whether the obstacles of the

cost and life cycle of new technology will be outweighed by the efficacy of the new diagnostic facility of OCT.

The use of OCT images in research and data protection issues

Various settings on OCT instruments can ensure that OCT images are not identifiable to a particular patient. Therefore OCT images can be exported without containing any patient details, achieving anonymity. This approach can be justified because an OCT image is of 0.35mm of the internal structure of the eye and it would be impossible to identify a person from their OCT image. This no doubt explains why it is commonplace for clinicians to disseminate and discuss OCT images that have been anonymised without explicit consent from the patient. A clear statement supporting this commonplace practice can be found in the guidelines for authors seeking to publish in BMJ journals: "Images - such as x-rays, laparoscopic images, ultrasound images, pathology slides or images of indistinct parts of the body - may be used without consent so long as they are anonymised by removal of any identifying marks and are not accompanied by text that could reveal the patient's identity through clinical or personal detail" (BMJ, 2013). Mavroforou *et al*. (2010) note that images of internal organs are one of five categories of anonymous recordings and note that both the UK Data Protection Act (1998) and the US Privacy Rule do not restrict the use of this type of de-identified information. They go on to state that the Court of Appeal in the UK has noted that the protection of patients' privacy is safeguarded if private information has been used anonymously.

Limitations of OCT

Image interpretation relies on a comprehensive understanding of the theoretical background of image generation. A recent paper on the classification of retinal and choroidal layers visible on OCT has suggested that the definitions for various retinal layers have changed frequently in the literature and have often been inconsistent with retinal anatomy and histology (Staurenghi *et al*. 2014). Whilst there is no doubting the fact that OCT can resolve intracellular structures and interfaces between the different cellular and nerve fibre layers of

the retina, these do not exactly correspond to microscopy findings (Ferreras *et al.* 2015). Layers may easily be highlighted by stains in microscopy but may not necessarily be seen as reflective structures in OCT. Interpretation of OCT results and their implications in clinical situations must be tempered by the fact that some of these images are subject to artefacts which may lead clinicians to wrong diagnoses or inappropriate management.

The use of ocular imaging for documentation and diagnosis of eye disease is rising. OCT is one of a range of ocular imaging devices used to document baseline characteristics of the optic nerve head (ONH) and for diagnosing glaucoma and glaucoma progression secondary to loss of retinal nerve fibre layer (RNFL). Some of these data will fall outside normal limits relative to normative databases. As a result, OCT imaging may provide artefacts which do not represent genuine ocular disease but occur secondary to limitations of imaging technology and its normative databases (Chong and Lee, 2012).

Care must be taken to ensure that OCT images have sufficient quality and the best OCT images are captured when a cooperative patient with good fixation is correctly aligned with the examining beam. OCT image signal degradation may be caused by media opacity (corneal opacity, vitreous opacity or cataract). Dry eye is another source of artefact leading to reduced signal and misidentification of retinal boundaries. Misalignment artefacts may be the result of a patient with poor vision, poor fixation or simply poor attention.

Structures which appear hyperreflective on OCT scanning, such as normal retinal vessels, haemorrhages and exudates, cause shadowing of underlying retinal structures with the loss of potentially important underlying morphological detail (Puzyeyeva, 2011).

Artefacts may arise from the OCT image acquisition, intrinsic characteristics of the eye, eye movement or computer image processing and display strategies (Spaide *et al.(2)*. 2015). Artefacts are not uncommon in OCT scanning. Interpretation of OCT images may be

qualitative or quantitative. Artefacts are more important for quantitative interpretation but may be difficult to detect. OCT retinal thickness measurements are useful in guiding treatment and re-treatment decisions in clinical trials and in monitoring response to treatment.

OCT possesses a wide range of image processing algorithms that can be used to obtain quantitative information from OCT scanning, thus providing a sensitive and reproducible way to monitor changes in retinal architecture and even retinal thickness (Arevalo *et al*. 2009). Quantitative OCT analysis is based on the fact that OCT software can measure the distance between the inner retina and outer retina reproducibly. OCT segmentation lines are automatically drawn to the inner limiting membrane (ILM) by all available machines and the retinal pigment epithelium (RPE) or the IS/OS junction (depending on the instrument) to determine retinal thickness and create a topographic map. The definition of retinal boundaries used by the automated segmentation algorithms differs between OCT devices (Talu, 2013), even for normal eyes. If different machines use different anatomical lines as the outer measurement, there will be inter-instrument inconsistencies in retinal thickness estimates.

A study by Puzyeyeva *et al.* (2011) reported on the clinical application of SD-OCT using a series of case reports of patients with clinically defined common and/or classic eye diseases to highlight the clinical utility and some of the potential limitations of OCT technology. In cases of macular oedema secondary to diabetic retinopathy and choroidal neovascular membrane where retinal thickness was greater than 400 microns, it was hard to discern the underlying retinal detail (and therefore the pathology) and the choroid. Retinal thickness measurements by SD-OCT in eyes with branch retinal vein occlusion were compromised by a significant rate of segmentation errors in a study by Matt *et al.* (2011). Macular thickness measurements in eyes with neovascular AMD did not approach the theoretical resolution of SD-OCT in a study by Tah *et al.* (2014). Automatic segmentation procedures also gave rise to substantial limitations in identifying areas of geographic atrophy (a common retinal disease) in current SD-OCT devices in a study by Schutze *et al.* (2011). It is therefore important that image-

processing and measurement algorithms should only be applied where image data are of sufficient quality.

Sadda *et al.* (2006) noted that significant errors in retinal thickness measurement occurred in eyes with more severe subretinal pathology (although these lesions were, in general, detected by OCT). This observation was supported by Menke *et al.* (2011) who found that although reproducibility of 3D-OCT retinal thickness measurements was good in both wet and dry AMD, reproducibility was significantly better in dry AMD. Patel *et al.* (2011) also found that OCT-generated retinal thickness measurements were subject to measurement variability in patients with active wet AMD. Figure 1.11 shows a failure of OCT to correctly identify the inner and outer retinal boundaries in a case of wet AMD where profound subretinal haemorrhage was a significant feature.

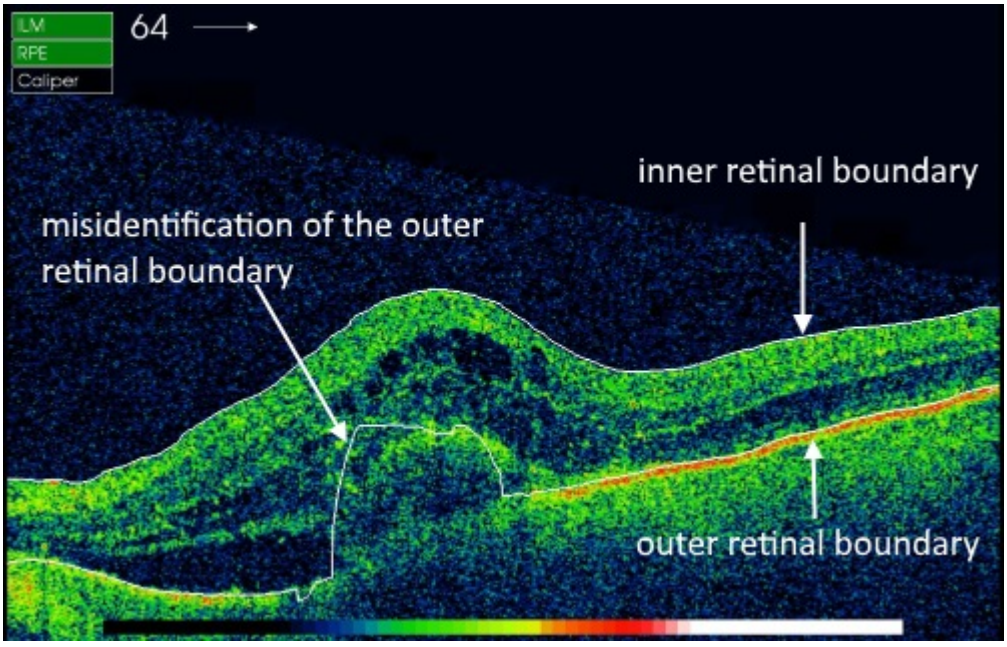

Figure 1.11 A segmentation error caused by failure of OCT to identify the outer retinal boundary because of the presence of sub and intraretinal haemorrhage

Some OCT instruments combine an OCT scan with a colour digital retinal photograph and the presence of colour information within the photograph may be beneficial. OCT uses a narrow spectrum of wavelengths thus providing limited colour information. For example, in the case of central retinal artery occlusion, conventional digital retinal photography will show the

typically pale retina suggestive of the presence of infarction more effectively than OCT. OCT will however facilitate recognition of the acute and chronic stage of arterial occlusion (Falkenberry *et al.* 2006).

Baranano *et al.* (2012) observed that the use of scanning protocols with reduced sampling densities resulted in decreased detection of key features of wet AMD. Therefore, with the increasing availability and use of OCT systems, there could be some benefit in optimising and standardising OCT scanning protocols.

In ophthalmic oncology it is important to recognise a limitation of OCT, namely its relatively poor penetration into deeply pigmented tissue. This limits its use for the detection of common intraocular tumours (Medina *et al.* 2014). The horizontal and depth resolution of OCT have significantly improved following the development of high-speed photodetectors and wide-bandwidth tuneable light sources. The arrival of spectral domain OCT (SD-OCT) has further enhanced image resolution (Sayanagi *et al.* 2008). As a result, error and artefact are less frequently reported in more recent studies on OCT technology and significant benefits have been reported for SD-OCT over the older time-domain OCT technology (Ericksson *et al.* 2011). Recognition of these artefacts is still important and will refine diagnosis thereby preventing faulty treatment decisions (Ray *et al.* 2005).

OCT is unlikely to eliminate the need for a careful fundus examination, digital retinal imaging, visual fields, and tonometry. Instead it will provide additional objective and quantifiable data that are not available from other diagnostic sources. It is not always possible to use diagnostic measures interchangeably; complementary use may be of higher clinical value (Aschliesser *et al*. 2014).

Chapter 2: Literature review.

Overview

This chapter describes a comprehensive literature search with the aims listed below:

- Identify the challenges faced by community optometrists in correctly diagnosing diseases of the central retina and accurately refining subsequent referrals to ophthalmology services
- Identify the need for a valid, sensitive and non-invasive method such as OCT for the diagnosis and follow-up of patients with common retinal conditions such as AMD and diabetic macular oedema (DMO) which is suited to the primary care setting of community optometry
- Discuss the burden of macular disease, capacity issues within specialist retinal clinics and the likely increasing role of optometrists in co-management of macular disease using OCT
- Discuss the lack of resources specifically aimed at community optometrists who wish to use OCT in practice to diagnose and manage patients with macular disease
- Discuss current models of diagnostic reasoning and how these might apply to optometric practice. Non-clinical influences on clinical decision-making are also discussed.
- Discuss the methods of assessing the diagnostic skills of practitioners and the potential value of e-learning versus conventional teaching
- Identify the current approaches to OCT training for optometrists
- Discuss the potential of an internet-based resource to assist optometrists with diagnostic and management decisions based on OCT scans

Search mode and resources

The following section also provides an overview to position the research question in context, review what other work has been done, identify gaps in knowledge and propose a rationale for

a new study to bridge these gaps. Most of the author's literature searches were conducted using Scopus and PubMed although some literature was also accessed using OpenAthens (via the College of Optometrists library). A summary of the literature resources available to the author are listed in Appendix 8. Searches for relevant literature began in November 2014 and the search was last updated in June 2017.

Optical coherence tomography is used in several areas of medicine so literature searches were conducted using a variety of combinations of key terms (detailed below) such as "optical coherence tomography", "optometrists" or " optometry", "macular disease" (used interchangeably with "age-related macular degeneration"). Optical coherence tomography was not in common use in optometric practices in the UK prior to 2010 so most searches for OCT literature were limited to the last 7 years.

A PubMed search using the search terms "optical coherence tomography" and "optometrist/optometry" produced 22 documents. Only five of these papers were relevant to the scope of the review and these were chosen for detailed study. All 5 papers were used in the literature review but only one of these papers looked at optometrists' accuracy in interpreting OCT scans and this paper was focussed on a single retinal disease.

A PubMed search using the terms "Age-related macular degeneration" and "optometrist/optometry" produced 28 documents. Six of these documents were relevant to the scope of the review and were studied in more detail. Four were chosen for use in the literature review.

A PubMed search using the terms "macular disease" and "optometrist/optometry" produced 58 documents. Eleven were studied in more detail and one was suitable for use in the literature review. The term "age-related macular degeneration" and "macular disease" were used interchangeably but did not produce additional relevant papers.

A Scopus search using the same search terms and parameters was conducted resulting mostly in duplication of search results. Searches were also conducted using the resources listed in Appendix 8. and in all searches, some relevant publications were identified from the bibliographies of these papers.

This chapter includes a wide-ranging discussion on current models of diagnostic reasoning and clinical decision-making. An awareness of these models was thought to be crucial in the design of an effective diagnostic guide. The author's literature searches suggest that diagnostic reasoning in optometry has not been widely investigated but this subject appears to have been more widely studied in medicine, and other health professions. A combination of the search terms "diagnostic reasoning" and "optometry" produced only three results only one of which was suitable for review.

Pubmed or Scopus search terms such as "diagnostic reasoning" or "clinical decision-making" produced multiple results and required to be significantly refined by searches within specific medical specialities by the addition of keywords such as "radiology", "dermatology", "nursing", and radiography, to name but a few. Most searches for literature were concentrated on the visual recognition domains (for example, interpretation of medical imaging scans). This was thought to be most relevant to the current study. The term "theory of diagnostic reasoning" produced useful background information on the models of clinical reasoning but involved more exhaustive review of the many papers produced by this search.

The method of exam delivery (multiple choice questions linked to clinical vignettes) was also subjected to literature review. Search terms included "multiple choice questions" and "medical education" or "clinical vignettes" and "medical education" but produced multiple results which required filtering (mostly limited to the past 7 years). The subject of E-learning

within medical education was again limited to more recent years because of the nature of such wide search terms.

Optometric diagnosis and management of macular disease

A study by Ly *et al.* (2016) assessed the optometric referral patterns of patients with suspected macular disease to The Centre for Eye Health (CFEH) which was an intermediate-tier optometric imaging clinic in Australia (comprising optometrists with a special interest in macular disease). A retrospective review of patient records and referrals was performed for patients who were examined at the CFEH over a 12 month period from 1/7/2013 to 30/6/2014 (n = 291). Data were analysed under the following headings: primary reason for referral; patient demographic characteristics; diagnosed/suspected condition; CFEH diagnosis and recommended management plan. Signs specified by the referring optometrist were typically determined by funduscopic examination (such as drusen or pigmentary changes) although some referrals were based on other factors such as reduced visual acuity, symptoms of distortion or other ocular or family history.

Standard CFEH protocol required that all patients referred for macular assessment undergo ocular imaging by optical coherence tomography. In this cohort of patients 84% were recommended ongoing optometric care and only 16% required referral to an ophthalmologist thus corroborating the conclusion that many cases of ocular disease may be managed by optometrists. Ly et al. also note that OCT has emerged as an indispensable tool and its pattern of rapid uptake by community optometrists (30% and rising in Australia) has led to speculation that OCT will change its status from specialist imaging technique to a core test. It is also noted that referring optometrists benefit from referring to an intermediate-tier imaging optometry clinic by receiving direct feedback on the case diagnosis and associated best practice management.

A comprehensive search of literature has identified a lack of research on the optometric detection and diagnosis of AMD in practice. This is now more important owing to the recent emergence of anti-vascular endothelial growth factor (anti-VEGF) drugs, expanding the treatment options for all types of 'wet' AMD lesions.

In a UK-based study of the quality of optometry referrals to a neovascular age-related macular degeneration clinic, Muen and Hewick (2011) found that optometrists performed to a less than satisfactory standard in correctly identifying the clinical signs of 'wet' AMD and especially in identifying subretinal fluid. This doctoral student's literature search (conducted several times between 2014 and 2017) suggests that this small study by Muen and Hewick is the first to evaluate the quality of referrals to a wet AMD clinic using the quick access (RARF) protocol. OCT technology was not widely available to optometrists during the period of the study (2006 - 2009) and it must be assumed that participants to this study did not have access to OCT and were not trained in this area by the consultant ophthalmologist. The study does however highlight the challenges faced by community optometrists in identifying important clinical signs of AMD (and conditions which may appear similar) in the absence of effective imaging technology.

This prospective study was based in the Highlands NHS Trust and gathered data from all optometry referrals using the standard Rapid Access Referral Form (RARF) from the College of Ophthalmologists between the periods of December 2006 to August 2009. RARF forms are used to refer patients suspected of having neovascular (wet) AMD directly to a retinal specialist. Participants in the study (all of whom were community optometrists) previously attended an educational event on wet AMD conducted by a consultant ophthalmologist with special interest in macula disease. Participants were also instructed on how to correctly complete the RARF. RARF forms were analysed for recorded history, clinical signs and the final diagnosis. These findings were compared to the history findings, clinical signs and final diagnosis recorded by an expert (a consultant ophthalmologist with special interest in macula

disease). Points recorded in the history were quite specific and were reduction of vision, distortion, and central scotoma (blind spot). Participants also had to record if any of the following clinical signs were present: haemorrhage, exudates and drusen.

Fifty-four RARFs were received during the period of the study and all patients were seen within 2 weeks of receipt of the referral. In terms of history findings, optometrists scored well on reduction in vision (85.2%) and distortion (88.9%). However, optometrists appeared less able to elicit the symptoms of central scotoma (61.1%). The overall agreement between the specialist ophthalmologist and the optometrists on all three history findings was 57.4%. Optometrists performed less well when correlating history with clinical signs (haemorrhage 83.3%, exudates 66.7%, drusen 51.9% and subretinal fluid 44.4%).

A low level of accuracy is indicated by the total number of patients who received a correct diagnosis of wet AMD (20 patients or 37%) and this resulted in a high proportion of patients (63%) who did not have wet AMD being seen unnecessarily at the rapid-access specialist clinic. The bar chart in Figure 2.1 shows the percentage correct diagnosis of each clinical sign by participating optometrists. Optometrists had particular difficulty recognising subretinal fluid (SRF) and drusen.

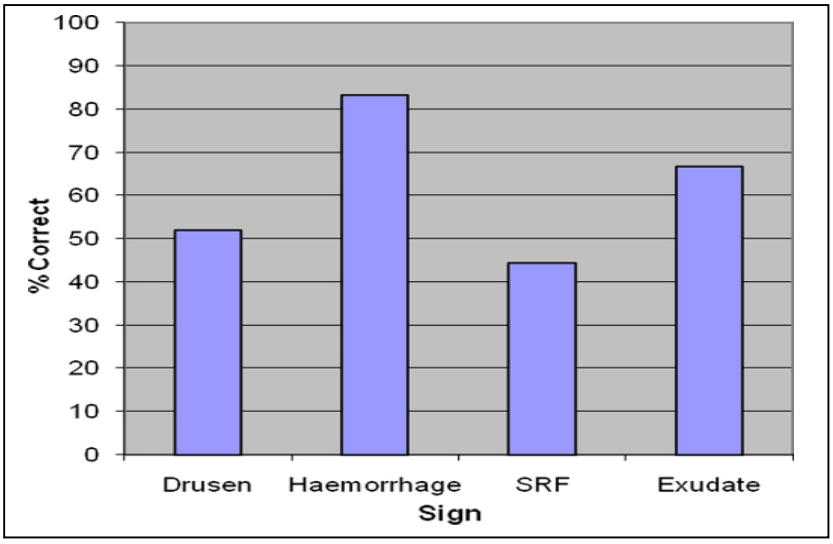

Figure 2.1 A bar chart showing the percentage correct diagnosis of each clinical sign by the optometrist (Muen and Hewick, 2011).

The extent to which other retinal diseases can mimic the signs and symptoms of wet AMD is illustrated in Table 2.1 which shows the diagnosis frequency of all patients referred to the rapid access clinic by optometrists on suspicion of having wet AMD.

Diagnosis	Patients (n, %)
Exudative AMD	20 (37.0)
Dry AMD	10 (18.5)
ERM	5 (9.3)
BRVO	4 (7.4)
CSR	4 (7.4)
Macular scar	3 (5.6)
PVD	2 (3.7)
Retinoschisis	1 (1.9)
Adult foveo-macular dystrophy	1 (1.9)
Macular hole	1 (1.9)
Vitreomacular traction	1 (1.9)
Glaucoma	1 (1.9)
Diabetic maculopathy	1 (1.9)

Table 2.1 Diagnosis for all patients referred to wet AMD clinic (Muen and Hewick, 2011)

AMD = age-related macular degeneration; ERM = epiretinal membrane; BRVO = branch retinal vein occlusion; CSR = central serous retinopathy

A limitation of this study was the small number of participants (n = 53). This represented a low yield given the large geographic area served by the specialist macula clinic (population of 250,000). The authors suggest that optometrists lacked confidence in recognising the clinical signs and diagnosing wet AMD and this might account for why the RARF was not commonly used. This suggests that some patients might instead have been referred to eye casualty and general ophthalmology thereby making their way to the specialist macula clinic via a different (and less appropriate) route.

A further limitation is the number of patients incorrectly diagnosed as not having wet AMD was not known. It was therefore not possible to assess the specificity accurately. However, the

authors concluded (based on the ocular conditions referred) that optometrists in the study had a low threshold for referring any abnormality but that the accuracy of referral could possibly be improved by the creation of a telemedicine system with the ability to send pictures and OCT scans with the referral.

The ECHOES trial compared the ability of ophthalmologists versus optometrists (optometrists in the community and ophthalmologists in the Hospital Eye Service) to correctly identify retinal lesions due to neovascular age-related macular degeneration. Regular review is an important part of the long-term care of patients with neovascular AMD and this even applies to patient in whom the disease is quiescent. Such reviews are costly and burdensome to health services, patients and carers (Reeves *et al* 2016). Participants were asked to classify lesions from vignettes which comprised clinical information, colour fundus photographs and OCT scan images. The primary aim of this study, which involved 155 participants (96 completed all assessments and formed the analysis population) was to compare the proportion of correct lesion classifications made by community optometrists and ophthalmologists from clinical vignettes. All participants received the same training which comprised attending two online webinars and assessment by way of training vignettes.

In addition, an estimate was made of the cost-effectiveness of community follow-up by optometrists compared with follow-up by ophthalmologists in the hospital eye service (HES). The views of patients (and their representatives), optometrists, ophthalmologists and clinical commissioners on the proposed care model were also collated.

The decision-making of optometrists was found to be non-inferior to ophthalmologists' with respect to the pre-specified limit of 10 per cent absolute difference. Most importantly, the frequencies of sight-threatening errors (although small at 5.7% for optometrists and 6.2% for ophthalmologists) were similar for both groups.

Although there was consensus that optometrist-led monitoring had the potential to reduce clinical workload and be more patient-centred, some barriers for the implementation of this model of shared care for AMD were identified in this study. The study questioned the ability of the two professions to work collaboratively with ophthalmologists perception of optometrists' competence being identified as a potential barrier along with the financial feasibility of shared care for Clinical Commissioning Groups (the mean care-pathway cost for assessment was very similar by group).

The ECHOES study is the only study identified by the author's literature search in which the OCT diagnosis and management skills of optometrists were evaluated, albeit in a single disease-focussed study. It should also be noted that all patients in the study already had a confirmed diagnosis of wet AMD and optometrists were simply being assessed in terms of their ability to detect and monitor macular changes from a "quiescent" disease baseline.

In a study into the optometric referral of suspect 'wet' AMD cases into a specialist retinal clinic, Creer *et al.* (2010) usefully highlighted some of the conditions which mimic the signs and symptoms of AMD and for which this mode of referral was not appropriate.
Manchester Royal Eye Hospital (MREH) ran an optometry-led fast-access direct referral clinic, the Macular Assessment Referral Refinement Clinic (MARRC).It was established in 2006 to speed up the referral pathway for patients with suspect wet AMD. Patients with suspect wet AMD could bypass consultant-led clinics and be referred for appropriate treatment within a short time period. This novel approach was designed to improve AMD prognosis, and screen out any patients who were not suitable for treatment.

This study was a retrospective audit based on the first 129 patients seen at the clinic between October 2006 and October 2008 and although most patients (63%) were diagnosed with wet AMD, 24% were diagnosed with dry AMD and the remaining 13% were given alternative diagnoses (Table 2.2).

Table 3. Diagnoses of patients seen in the Macular Assessment Referral Refinement Clinic

Lesion type	Number	Percentage (%)
Wet AMD (including PED)	78	63
Pigment epithelial detachment (PED)	22	18
Dry AMD	30	24
Macular hole	5	4
Central serous retinopathy	1	1
Macular dystrophy	2	2
Epiretinal membrane	1	1
Branch vein occlusion	2	2
Vitreous haemorrhage	1	1
Cataract	1	1
No significant ocular pathology	5	5

Table 2.2 showing some of the conditions which mimic the signs and/or symptoms of wet AMD based on the audit by Creer *et al.* (2011)

A study by Jaqadish and Dalziel (2015) looked at the discharge outcomes of patients referred to a specialist clinic from diabetic retinopathy screening (DRS) services in Northland, New Zealand (n = 98) and found that 45% of patients were enrolled back into DRS without treatment or need for specialist follow-up. Given the fact that such a significant proportion of patients were re-referred back to DRS after OCT at the specialist clinic, a consideration was to include OCT in the screening pathway.

A small study by Kelly *et al*. (2011) looked at fifty patients with suspected macular disease who were managed via telemedicine consultation over one year at a single optometric practice. Responses were provided by the hospital eye service to the referring optometrist or patient within the next day in 48 cases (96%) and in 33 patients (66%) on the same day.

Thirty-three patients (66%) required further "face to face" investigation and were therefore triaged on clinical urgency. Seventeen cases were managed in the community and the author identifies this as a potential cost improvement. Despite the limitation of small sample size this important study highlighted the significant potential of OCT in telemedicine.

There are relatively few ophthalmologists in the UK per head of population and many more optometrists (Violato *et al*. 2016). In recognising this fact, the author can see the potential for community optometrists performing a diagnostic role during the acquisition and interpretation of OCT images rather than burdening hospital eye services with this task, with teleophthalmology links being used for more unusual or atypical cases.

The prognosis for an increasing number of patients with wet AMD has improved due to recent developments in anti-vascular endothelial growth factor (anti-VEGF) AMD treatments. This has resulted in an influx of new patients into specialist retinal clinics (Creer *et al.* 2010). The timing of such referrals is crucial in the case of wet AMD as a delay in diagnosis and treatment is associated with severe visual loss (Oliver-Fernandes *et al.* 2005; Sickenberg, 2001). Ideally, treatment of confirmed wet AMD should be within two weeks of initial development of symptoms or detection of a treatable lesion (Royal College of Ophthalmologists, 2009).

It has been recently reported that fewer than half of people suffering from AMD are receiving treatment within the recommended two week timeframe. Furthermore, 41.8% of patients wait between two and four weeks with 8.8% waiting more than eight weeks for an appointment (Macular Disease Society, 2012). Capacity issues within specialist macular clinics will be subject to further pressures as intravitreal injections are extended to other groups of patients with macular oedema secondary to causes other than AMD such as diabetic macular oedema and retinal vein occlusion (Ford *et al.* 2014).

AMD services in the NHS have had to adapt to increases in demand and there have been improvements in rapid access and fast track processes for new patients but limited or inadequate clinical capacity continues to threaten access to potentially sight-saving treatment (Amaoku *et al.* 2012). Rapid access clinics exist for the provision of early assessment of patients with suspect wet AMD lesions or sudden onset of symptoms. The success of such a service depends on appropriate and timely referrals into the clinic, principally from community optometrists. Patients attending specialist retinal clinics require appointments both for regular treatment and also disease monitoring (Creer *et al.* 2010). Substantial workload is associated with intravitreal injection of anti-VEGF agents because of the need for frequent follow-up of these patients and according to the Royal College of Ophthalmologists (2013), staffing of these clinics is well below expected levels. A particular difficulty centres round the inability to discharge patients in order to accommodate new ones and most AMD specialists agree that capacity problems are caused by the increased and recurrent long term follow-up clinic visits required for wet AMD patients (RNIB, 2014). It has been suggested that, in the absence of adequate ophthalmic medical manpower to staff AMD clinics, the potential for recruiting non-medical staff (for example optometrists) should be explored. The overall workload might therefore be contained if some roles within AMD clinics (such as clinical assessments, re-treatment decisions and even intravitreal drug delivery) were undertaken by other clinicians or technicians. In identifying some key capacity issues within AMD clinics Amouku *et al*. (2012) suggested that in some HES facilities pressure on OCT clinical imaging services is being aggravated by the increasing use of OCT imaging for other ophthalmic disorders such as glaucoma. More demand on OCT imaging technology is likely to follow the implementation of the NICE recommended treatments of retinal vein occlusions and some forms of diabetic retinopathy with intravitreal therapies. The role of optometrists (and other health professionals such as nurses and pharmacists) in primary care is expanding as they now take on aspects of care such as prescribing. An extended role for optometrists in specialist retinal clinics is a distinct possibility but this will require educational support, safe guidelines

for practice and mentoring in the particular practice area will be required to embed newly acquired skills (Jarvis and Ker, 2014).

Community follow-up of previously treated and stable AMD patients by suitably trained optometrists (under the supervision of a medical retina specialist) may reduce the burden on hospital based AMD services and also carries the advantage of bringing the services into the community, closer to the patient. If optometrists hope to be able to accurately refine their referrals into specialist retinal clinics and expand their role into the co-management of AMD patients, they will require non-invasive imaging technology such as OCT and the skills to use it effectively.

Philosophies of educational practice

Diagnostic reasoning and clinical decision making

If we are to embrace the principles of diagnostic medicine we must understand the cognitive processes involved in diagnostic reasoning. Furthermore, we must identify weaknesses in these processes and define how to employ the best teaching strategies on clinical diagnosis, thereby reducing diagnostic errors.

Diagnosis is the cornerstone of the healthcare sciences (Body and Foex, 2008; Haynes and Wilczynski, 2004) and clinical practice would be impossible without some form of diagnosis. Diagnosis comes at the end of a process of using the history, physical examination, laboratory findings, imaging studies and other investigations to identify the disease responsible for the patient's illness or complaint. Clinicians can then make a more informed decision about treatment and prognosis. By diagnosing patients, practitioners also infer an understanding of the anatomical and pathophysiological mechanisms behind the disease process (Body and Foex, 2009).

Body and Foex (2008) also suggest that the traditional concept of diagnosis derives from the philosophical concept or paradigm of "positivism". Positivist physicians, having a preference for empirical data (based on what could be observed, measured and quantified) adopt a neutral position thereby making objective observations and generating hypotheses which could be subjected to verification. Doctors may recognise disease by objectively investigating it using a particular method and presenting the diagnosis as a fact. However, according to Body and Foex (2008) the positivist paradigm becomes untenable when subjected to closer scrutiny as according to the positivist paradigm every physician who observes the same piece of reality will see the same thing. Body and Foex (2008) remind us that we intuitively know this to be untrue and go on to suggest that a range of studies have demonstrated less than optimal interobserver reliability when two independent physicians conduct basic techniques such as taking a patient history or eliciting clinical signs. Body and Foex note that this is even true among experts, an example being interobserver variation among radiologists reporting chest radiographs (Albaum *et al*. 1996).

Errors which occur in medical diagnostics may include failure to generate the correct hypotheses; misperception or misreading of the evidence (especially visual clues); and misinterpretations of the available evidence (Bordage, 1999, Elstein and Schwarz, 2002). The description and analysis of the psychological process employed in identifying and solving complex diagnostic problems by expert physicians could be aimed at improving the diagnostic performance of novices. Croskerry (2009) suggested that both systemic and individual factors contribute to diagnostic error (missed or delayed diagnosis) and among the many factors that impact clinical performance of the individual physician, the calibre of cognition is the most relevant and merits most attention.

Elstein and Schwarz (2002) reviewed current understanding of the cognitive processes involved in diagnostic reasoning in clinical medicine and suggested that the earliest psychological formulation viewed diagnostic reasoning as a process of hypothesis testing.

They suggested that solutions to diagnostic problems were arrived at by the generation of a limited number of hypotheses early in the diagnostic process. These hypotheses are then used to guide subsequent data collection. Each hypothesis may be used to predict what additional findings ought to be present if it were true. The diagnostic process will then become a guided search for these findings. Elstein and Schwarz also suggested that the experienced physician forms hypotheses and diagnostic strategies early and the quality of the hypotheses is superior to that of a novice. They remind us of the fact that it is feasible to collect data thoroughly but it is then possible to ignore and/or misinterpret some of these findings. It is also possible for a clinician to be overly economical in collecting data but then to go on to accurately interpret what is available. In other words, "Accuracy and thoroughness are analytically separable".

Dual processing theory

According to Kulatunga-Moruzi *et al.* (2011), two complementary processes are thought to be involved in medical diagnosis, similarity-based and analytic. However, a debate exists about which of these two processes define expertise. Much of the early literature views the diagnostic process as hypothetico-deductive in which a clinician will advance multiple hypotheses and test them by gathering additional evidence. However this account of expert diagnosis assumes a single type of reasoning process. Kulatunga-Moruzi *et al.* suggest that this view is overly simplistic and propose that in reaching a diagnosis, at least two sources of information are used. These proposed sources are formal, analytical knowledge (rules of diagnosis, knowledge of causal mechanisms, symptom-disease probabilities) and episodic memory of specific cases (Figure 2.2)

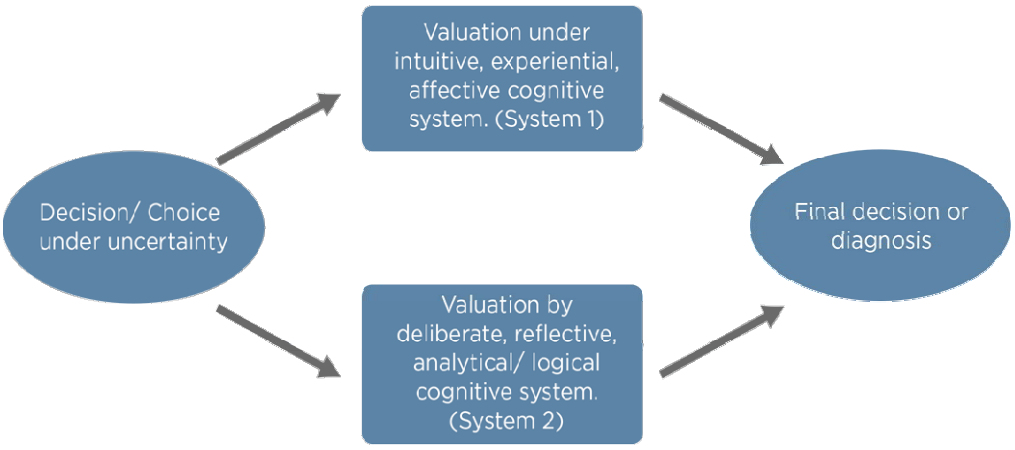

Figure 2.2 Dual processing theory

They hypothesise that the balance in the use of these two sources of information may change with experience. It is assumed, although not verified, that novice clinicians with limited clinical experience would be more reliant on formal rule-based knowledge. On the other hand, experienced clinicians can draw on years of experience and may rely more heavily on exemplar-based knowledge. The relative balance of these two strategies may also depend on the nature of the case or its degree of complexity. There is a common acceptance that some form of dual processing theory provides an explanation of the cognitive processes that characterise human decision-making (Crosskery 2009, Elstein and Schwartz 2002, Djulbegovic *et al.* 2012).

Interestingly, much of the evidence for these theories derives from experimental studies of diagnosis in visual domains such as dermatology and electrocardiology (Brooks *et al.* 1991; Kulatunga-Moruzi *et al.* 2001; LeBlanc *et al.* 2002). The recognition of OCT scans is an example of diagnosis in a visual domain. In another visual domain of cytopathology, Evered *et al.* (2013) observed that analytic strategies required trainees to base their interpretive decisions on carefully considered and often exhaustive cytomorphologic feature lists and that this process could be less efficient and time-consuming. In contrast, non-analytic pattern

recognition strategies were not often encouraged during the training period, even though this approach is characteristic of expert diagnostic behaviour.

In 2012 Djulbegovic *et al.* (2012) also described a model of clinical decision-making based on dual processing theory which postulated that reasoning and decision-making can be described as a function of both an intuitive, experiential, affective system (system 1) and/or an analytical, deliberative processing system (system 2). This paper highlights a growing recognition of the importance of system1 (fast, intuitive) and system 2 (slow, deliberate) at different times, but few investigators have examined how to harness both types of processes towards better clinical decision making and medical education.

Elstein and Schwartz (2002) argue that not all 'expert' clinicians perform to the same standard and that expertise is dependent on the clinician's mastery of their particular domain. Elstein and Schwarz (2002) argue that this assertion challenges the hypothetico-deductive model of clinical reasoning and that the accuracy of a diagnosis will not depend as much on strategy as on mastery of content. They also suggest that the clinical reasoning of experts in familiar situations often does not involve explicit testing of hypotheses. The speed, efficiency and accuracy of expert physicians implies a different reasoning process than that used by novices. So, expert physicians are thought to be more likely to use a hypothetico-deductive strategy only when faced with more challenging cases and the clinical reasoning of experts is more a case of pattern recognition or direct automatic retrieval. Elstein and Schwartz (2002) suggest that this theory signals a shift from the study of judgment to the study of the organisation and retrieval of memories.

Although most diagnostic errors are suspected to arise from cognitive biases associated with rapid and unconscious reasoning or intuitive judgement (Croskerry, 2009), Norman *et al.* (2014) demonstrated that simply encouraging slowing down and increasing attention to

analytical thinking is sufficient to increase diagnostic accuracy. In their words, “unexamined intuitive judgements should be submitted to verification”.

Each situation is unique and may invoke different types of reasoning. Whilst an algorithmic approach may be used in conditions where the information we collect from patients is discrete and accurate, primary care clinicians may also use pattern recognition for the diagnosis of common conditions. In situations where other modes of decision-making have failed, a more exhaustive approach may be appropriate. However, such exhaustive approaches may not be the most efficient or appropriate in the primary care or emergency setting.

Elstein and Schwartz (2002) identified and labelled some specific issues in problem solving and decision making. Problem solving was rationalised into a dual system:

- Hypothesis selection: a small number of hypotheses generated early in the diagnostic process which are used to guide subsequent data collection. Additional findings are predicted by each hypothesis
- Pattern recognition or categorisation: experts, when in familiar situations, may not form hypotheses (Brooks *et al.* 1991; Norman *et al.* 1992) but may instead employ a form of clinical reasoning which simply involves pattern recognition or direct automatic retrieval. A new case may be categorised by the extent to which it resembles or evokes the memory of a previous case (Brooks *et al.* 1991). Alternatively clinical experience may facilitate the construction of mental models, abstractions or prototypes. In other words, a network of links is formed between clinical features and diagnostic categories (Lemieux and Bordage, 1992).

Elstein and Schwartz (2002) suggest that an awareness of common types of cognitive errors may help clinicians recognise and avoid them. Cognitive errors may be classified as those

concerned with pre-test probability (overestimation or underestimation of disease likelihood) and failure to consider (in a meaningful way) all relevant possibilities. Probability errors include:

- Availability - clinicians wrongly estimate the prior probability of pathology because of recent experience. Croskerry (2002) described availability as the tendency for things to be judged if they come easily to mind. Things that are common are easily recalled or experience may lead to overestimation of probability when there is memory of a case that was dramatic (rare cases or cases that receive media attention). Elstein (2002) also suggests that errors in the estimation of disease probability may be linked to the perceived cost of mistakes. Croskerry (2002) defined non-availability as something that might occur when insufficient attention is paid to that which is not immediately present and suggested that novice clinicians are driven by availability (more likely to bring common prototypes to mind). Experienced clinicians are more willing to raise the possibility of an atypical variant.
- Representation error – Elstein (2002) suggested that clinicians may judge the probability of a disease based on how closely the patient's findings match classic manifestations of the disease or disease category. In the case of representation error, no account is taken of disease prevalence.
- Support theory - this theory proposes that the subjective probability of an event is inappropriately influenced by how detailed the description is. In clinical terms support theory predicts that long, detailed case descriptions will be assigned a higher subjective probability of the index disease than a brief description of the same case.
- Anchoring errors – Croskerry described anchoring as a tendency to fixate on specific features of a presentation too early in the diagnostic process. In other words, these errors occur when clinicians steadfastly cling to an initial impression (jumping to conclusions). In this type of diagnostic error, Elstein (2002) suggests that diagnostic possibilities are not revised as much as they should be and instead diagnostic options

are revised up or down from the starting point (the "anchor") even as conflicting and contradictory data accumulate. Confirmation bias occurs when physicians selectively accept clinical data that supports a preferred diagnosis and ignore data that do not (cherry-picking).

Elstein and Schwarz (2002) note that final opinions can sometimes be affected by the order in which data are presented. For example, information presented later in a case may be afforded more weight than information presented earlier.

The ultimate goal of all stages of medical education is to improve the health and health care of the population. The models discussed so far have important practical applications for medical decision-making and Croskerry (2009) suggests that they may be used as a template for teaching decision theory. Specific operating characteristics of the models may explain how diagnostic error occurs. A debate exists on how best to teach clinical diagnosis and thereby reduce diagnostic errors. To arrive at a diagnosis, information of various types must be considered and integrated. Croskerry (2009) also states that the recent model of reasoning and decision-making (Dual Process Theory) has an immediate application in medical decision-making and may provide some insight into the variety of theoretical approaches that have been utilised in the past.

Clinical reasoning in optometric practice

Clinical reasoning as the core of medical competence has been the subject of many research studies since the 1970's (Pelaccia *et al.* 2014) but despite this, it has rarely been referred to within the discipline of optometry. Faucher *et al.* (2012) state that because the clinical reasoning processes engaged in by optometrists have not previously been investigated, it is not known whether models of clinical reasoning from other health professions can be transposed to optometry. However, Faucher *et al.* do not indicate why they think that clinical reasoning in optometry may be different to other health professions. It is important to

understand the cognitive activities that lead an optometric practitioner to make a diagnosis and whereas there are a range of theories of clinical reasoning, the context in which a clinician is making decisions may impact on reasoning. The concepts described and explained above have been studied in a range of health professions. Models of reasoning may not legitimately be applied universally to all situations and environments in which clinical practice takes place. It is important to improve our understanding of how optometrists reach a diagnosis so that the cognitive source of errors can be identified and remedial strategies formulated. This could also inform optometric education and training strategies.

A thorough literature search on this subject matter has revealed that the clinical reasoning strategies engaged in by optometric practitioners had not previously been investigated until a small study by Faucher *et al*. (2012). This study was designed to make explicit the clinical reasoning processes of optometrists at the "competent" and "expert" level. These processes were compared to highlight characteristics of clinical reasoning expertise. Only four competent-level and four expert-level optometrists participated in the study during which they verbalised their reasoning during a complete eye examination on preselected patients. Consultations were recorded on DVD and played back during feedback sessions when optometrists could describe their mental processes. Although the researchers identified analytical and non-analytical modes of reasoning amongst optometrists, these results should be viewed within the context of significant study limitations which were readily acknowledged. All participants were trained at the same school of optometry (all four competent-level optometrists were from the same graduating class) so some of their similarities may have been caused by their training. Also, optometrists' behaviour and reasoning may have been influenced by filming of patient encounters (and feedback sessions) and the presence of an optometrist observer.

Although this small study is likely to have been the first to investigate the clinical reasoning of optometrists, it may pave the way for further research in this field. There is perhaps a need to investigate clinical thinking and its related concepts specifically for the profession of optometry. Optometric educators may be able to adapt their teaching and assessment methods to the specific context of optometric practice. In this writer's opinion, clinical reasoning amongst optometric clinicians is unlikely to be different from other health professionals. However, a distinct set of circumstances does exist within the current model of primary eyecare and the impact of this model on diagnostic accuracy and patient management requires further investigation.

Medical algorithms

Diagnostic and therapeutic algorithms are used across all professional boundaries and are widely used to help minimize surgical intervention (Stoval and Ling, 1993), in areas of child development (Wing *et al.* 2002), in screening for mental illness (Das *et al.* 2005) and in predicting disease risk in individuals (D'Agostino *et al.* 2008). The use of algorithms is becoming more widespread because computers have increasingly important roles in many aspects of our lives. Modern computers go beyond explicitly programmed instructions and are now capable of learning on their own. For example, some computer algorithms can facilitate machine learning. The word algorithm is commonly used in computer science to refer to a plan or strategy for solving a problem. A medical algorithm is a computation, formula or look-up table used in healthcare and may take the form of a decision tree. Medical decisions occur in many areas of medicine including medical test selection, diagnosis, and treatment/management. A medical algorithm is often presented as a protocol. It is strengthened if its contents are centred on evidence based medicine, regularly reviewed, and compared with (and tempered by) expert opinion. Medical algorithms will usually indicate appropriate history, physical examination, and laboratory tests (data) required. They will make precise recommendations for diagnosis and treatment/management based on data

obtained. They include branching logic which carries the advantage of allowing recommendations to be individualised.

Komaroff (1982) observes that over the past 50 years there has been an increasing attempt to "transform the 'art' of medical decision-making into a science" with the purpose of "supplementing what was recognised as a spontaneous, informal and implicit set of judgments with the conclusions of a predetermined, formal and explicit scheme of logic". Indeed, Van den Ende (2005) notes that in developing countries medical algorithms have become the main diagnostic and therapeutic strategy and suggests that the development of algorithms was highly influenced by computer logic. However, Van den Ende (2005) also suggests that algorithms may not always find favour among clinicians because of their counter-intuitive logic.

Gill *et al* (2005) describes two approaches to draw statistical inferences: 'frequentist' and Bayesian, and suggests that Bayesians do not interpret test results as a categorical probability but as the degree to which positive or negative results adjust the probability of a given disease. Validity can be afforded to both approaches even though they differ methodologically and philosophically but the 'frequentist' approach is dominant in medical literature and is increasingly applied in the clinical setting. Gill *et al.* (2005) suggest some irony in the fact that clinicians apply "Bayesian reasoning in framing and revising differential diagnoses" and use tests as opinion modifiers.

Komaroff (1982) suggests that the reasoning behind this 'frequentist' philosophy has been the perception that clinicians make decisions in an idiosyncratic manner and therefore risk compromising the quality of care or wasting valuable medical resources. Feinstein (1974) states that as input data are converted to output conclusions, diagnostic reasoning must navigate its way through a complex series of intermediate decisions and each decision will preferably identify and explain entities cited in preceding stages. Feinstein reasons that

intermediate decisions are disregarded during the formulation of some statistical theories linked to the diagnostic process. Feinstein therefore suggests that calculations of statistical probability may not deliver the precise diagnosis.

Arriving at decisions by compressing individual details into the formulation of a general case (despite the fact that individual details are often the essentials of clinical reasoning) is a statistical approach. Errors may occur if a clinician makes decisions based on general formulations whilst ignoring the uniqueness of individual patients. At the same time, clinicians must eventually arrive at certain general formulations and Feinstein (1974) reminds us that a clinician cannot practice medicine at all if he/she "regards each case as so unique that no general principles of decision can be established". Algorithms may be more effective if combined with experience, sensitivity, and compassion. Feinstein (1974) suggests that there is a risk that "strict adherence to an algorithmic standard might well lead to regimented and uninspired decision-making".

Komaroff (1982) quotes a clinician as saying, "I am being regimented if you give algorithms to me but I am being systematic if I develop algorithms for myself". Algorithms may continue to play a role in medical decision-making and hypothetical benefits may continue to outweigh theoretical risks.

Non-clinical influences on clinical decision-making

Hajjaj *et al* (2010) suggested that non-clinical influences could have a profound impact on clinical decision-making within medicine and that this critically important aspect of daily clinical practice is seldom formally considered. The optometry profession is undergoing a technology revolution within an environment of ever-increasing competition. Advanced imaging techniques are chargeable items (not funded by the NHS sight test) so, additional

diagnostic tests could be considered as a way of raising profits. A potentially serious ethical problem of for-profit eyecare may be the incentives and organisational controls that may adversely affect the optometrist-patient relationship thus creating conflicts of interest which may diminish the quality of eyecare. Decision making within optometry may have additional levels of complexity due to the expectations of the patient. Patients may request testing or treatments that are not supported by guidelines and/or are not medically indicated. Such requests may be based on misinformation, misunderstanding or anxiety.

Ocular imaging is used in optometric practice on patients with (or suspected of having) a range of ocular conditions but also increasingly on normal patients. This highlights a problem arising from the discovery of incidental abnormalities or findings. An incidental finding is a finding which has potential health importance and is unknown to the patient. It is discovered unexpectedly during an eye examination but is unrelated to the purpose or aims of the examination.

Advances in modern imaging techniques now enable the detection of very minor abnormalities that might have previously gone unnoticed. Incidental and clinically insignificant findings may create a new challenge for optometrists. Such findings may also raise ethical and legal issues which may not be addressed explicitly in guidelines. Growth in use and perhaps overuse of diagnostic imaging may significantly impact on the quality and costs of health care services. There may be modifiable factors involved in the unnecessary use of ocular imaging but these factors are not easily identified and not enough is known about their relative impact.

Evidence based medicine should form the basis of optometric management decisions but the wide range of influences that optometrists are subjected to (consciously or subconsciously) during the diagnostic and decision-making process should not be ignored. A lack of

understanding of non-clinical influences on optometric patient management could potentially lead to suboptimal individual patient care.

VOMIT – "An acronym for our times"

Richard Hayward (consultant neurosurgeon) first described the concept of 'victim of medical imaging technology' (VOMIT) in a BMJ personal view in 2003 (Hayward 2003). He cited two hypothetical cases of 'innocent pathology' found on magnetic resonance imaging (MRI) which caused worry and anxiety in patients and their families. Hayward also suggested that this anxiety may be further fuelled by internet searches and considerable time on the part of the specialist would be needed to allay fears. McCoubrie and Reid (2013) suggest that the term VOMIT has now passed into common medical parlance to describe all patients who suffer physically and/or mentally as a result of false positive scan findings (including those who are subjected to further unnecessary investigations for what turns out to be benign pathology. McCoubrie and Reid (2013) however remind us that not all incidental findings are trivial and that anxiety-inducing false positives can be prevented by good practice. Although McCoubrie and Reid were commenting on radiological imaging modalities, they suggested that this debate also applied to all investigations which were highly sensitive but not particularly specific.

Hayward also suggested that the rise of clinical imaging (and reducing invasiveness) has resulted in an exponential rise in volume and accuracy of information and this has caused these investigations to move from being symptom driven to non-symptom driven. He further suggested that the information flowing from these investigations and our knowledge of how to deal with it may be several years out of step.

Lysdahl and Hofmann (2009) conducted a survey of 374 radiologists'(members of the Norwegian Medical Association) perceptions of the causes of increasing and unnecessary use

of radiological investigations. The highest rated causes of increased use of radiological investigations were the arrival and availability of new technology, patients' demands, clinicians' intolerance for uncertainty (defensive medicine), expanded clinical indications and availability.

These theories have particular resonance in the present research which centres round the proliferation of a novel ocular imaging technology within community optometry.

E-learning versus traditional teaching

E-learning refers to the use of internet technologies to deliver a broad array of solutions that enhance knowledge and performance (Ruiz *et al.* 2006). E-learning is employed by medical educators to improve the effectiveness of medical interventions. Web-based delivery of education (e-learning) has revolutionised the modes of exchanging information and optometric educators are unlikely to ignore this trend.

The evaluation of web-based applications versus conventional instruction in optometric education has not been widely investigated and although 'notes' were the preferred learning tool for optometry students in a survey study by Herse and Lee (2005), much has changed in medical education since then. Text books also remain a corner stone for medical students but the internet represents an important aid to support learning needs (Guarino *et al.* 2014).The web is rapidly becoming an important clinical tool for doctors (Tang and Ng, 2006). Guarino *et al.* (2014) also note that among the websites cited, Google and Wikipedia significantly surpassed their peer-reviewed medical databases for the 368 medical students surveyed in their study. It has been suggested that web-based delivery of identical content results in less overall studying time as compared to textbook delivery in a specialisation within dentistry (Ramseier *et al.* 2012). Ramseier *et al.* (2012) state that there is a difficulty in defining e-learning as it may vary from simple text documents presented on a website to virtual

environments using sophisticated 3D simulations, all of which are very different. He also reminds us that controlling for some confounding variables is a particular challenge when comparing web-based with conventional learning as there may be more complex cognitive or practical reasons underlying the various experimental outcomes.

Computerised devices such as tablets contain many technological features that are not found in conventional print textbooks. Tablets offer backlighting for reading in low light. They have search options and built-in dictionaries. Learner motivation and engagement with study materials can be increased using videos and interactive diagrams. E-text books or papers can be updated instantly with new information which is most important within a rapidly changing healthcare system. The use of mobile devices by health care professionals has transformed many aspects of daily clinical practice and this has led to a growth in the development of medical software applications tailored to these devices which assist clinicians with many important tasks including decision-making, education and training (Lee Ventola, 2014).

Today's optometric educators face different challenges than their predecessors in teaching tomorrow's optometrists. Advances in ophthalmology and optometry and changes in eye care delivery have increased demand on academic faculties. Also, changes in sites of eye care delivery from acute eye care hospitals to community-based settings (including community optometric practices) for chronic eye care will require adaptations in educational delivery.

Assessing the efficacy of clinical skills training

Assessing practitioners diagnostic skills

The performance of clinicians in their day-to-day practice has emerged as an area of intense public interest. Health care purchasers and patients want an effective means of identifying excellent clinicians (Landon *et al*. 2003). In all phases of medical education, measurement of a clinician's performance is necessary to determine the effectiveness of teaching methods and

evaluation of the educational process should be consistent with the goals of the particular educational intervention (Barrows and Abrahamson, 1964)

The General Optical Council (GOC) oversees a mandatory continuing education and training (CET) scheme and CET is a statutory requirement for all fully-qualified optometrists. It states that all registered optometrists in the UK are encouraged to extend their professional competence and to enhance their level of practice. CET is intended to sustain and maintain professional knowledge and skills utilising a range of modalities and covering an appropriate range of optometric competencies. Modality refers to the way in which CET is delivered. Provision of CET must be in a GOC specified core competency area(s). The delivery method (modality) must be appropriate to the competency(ies) which the CET aims to achieve and modalities must be approved by a panel of experts using guidelines and criteria provided for an acceptable provision (GOC, 2012 www.optical.org).

Visual recognition tests are a GOC approved modality. Digital imaging of the anterior and posterior segments of the eye has found its way into optometric practices over recent years and visual recognition of ocular pathologies has become an established modality for the delivery of CET to optometrists. The term VRICS (visual recognition and identification of clinical signs) is a term used in UK optometry journals to describe an assessment/educational tool which combines the skill of visual recognition of ocular pathology (presented as a high resolution ocular image) and the knowledge of associated clinical signs, symptoms, and management/treatment options (Figure 2.3).

Figure 2.3 VRICS CET event in Optometry Today (Association of Optometrists)

The domains of diagnosis, referral decision, urgency, likely treatment, and review interval are usually covered and questions are presented in multiple choice format. A literature search did not find evidence of the term 'VRICS' used outside of UK optometry although visual recognition tests are widely used as an educational tool across all clinical areas.

Attree (2006) reminds us that healthcare evaluators not only need valid and reliable methods of assessing knowledge acquisition but also need to be able to assess the application of knowledge to practice. There are complex relationships between educational inputs and outcomes especially within healthcare contexts where resources are scarce and confounding variables are difficult to control.

Current approaches to OCT training for optometrists

Given the proliferation in use of OCT in optometric practice, questions remain on the quality and availability of OCT training for optometrists who embrace this rapidly changing technology. Optometrists' scope of practice will change over time and the activities of experienced optometrists will become more focussed and specialised. Ocular images

constitute a core portion of the information an optometrist uses to render diagnostic and patient management decisions. OCT is one of the pillars of ocular imaging and plays a central role in the management of a range of retinal diseases. Accurate interpretation of OCT is rendered largely useless if it is followed by inappropriate patient management decisions. Defining what is 'normal' (and an appreciation of normal variation) is a very challenging part of the OCT learning curve for optometrists. Minor pathologies and other clinically insignificant findings may not appear to significantly change the retinal surface when viewed by conventional methods but may appear quite dramatic on OCT scanning. Optometrists using OCT in daily practice should ideally have a working knowledge of the common retinal diseases regularly presenting in optometric practice and their differential diagnosis. This should include knowledge of: the signs and symptoms; the natural history and impact on vision; the available treatments; the location of treatment centres and local referral protocols. Practitioners should also be alert to the possibility of OCT instrument artefact. The science of OCT scan recognition therefore needs to be matched to an understanding of an appropriate patient management plan.

Accredited courses

Optometrists may study at a small number of approved learning institutions across the UK which provide higher qualifications within the higher qualifications framework of the College of Optometrists (a modular approach to achieving College of Optometrists professional qualifications). One of the courses available is the Professional Certificate in Medical Retina which "provides community and hospital-based optometrists with knowledge of common medical retina conditions and includes topics covering screening, referral and treatment pathways with an emphasis on OCT interpretation and diabetic retinopathy grading" (College of Optometrists, 2017).

OCT manufacturers offer staff training at the time of installation. Companies have also exploited current technology (including the internet to offer webinars) to make training more accessible and convenient for users. A clinician's understanding of how the technology works needs to match their understanding of what needs to be imaged and why. Whilst vendor training is important, improving OCT competence should not stop with in-practice training. OCT technology continues to evolve so the difficulty of keeping pace with innovation is increasing.

Chapter summary

This chapter has discussed the challenges faced by community optometrists in correctly diagnosing retinal disease and appropriately refining subsequent referrals to ophthalmology services. It has identified the strengths and limitations of current methods of ocular fundus examination and suggested the need for a valid, sensitive and non-invasive method of fundus examination such as OCT which is suited to the primary care setting of community optometry. The role of optometrists in co-management of macular disease is likely to expand owing to capacity issues within specialist retinal clinics and the increasing burden of macular disease. The lack of resources specifically aimed at community optometrists who wish to use OCT in practice to diagnose and manage patients with macular disease has also been discussed.

The chapter has also outlined current approaches to OCT training for optometrists and the potential value of internet delivery of education including the potential value of an internet-based resource to assist optometrists with diagnostic and management decisions based on OCT scans. Current models of clinical reasoning and methods of assessing diagnostic skills are important in the design of educational resources and exam delivery, so they have been discussed in detail.

Chapter 3: Methods

This chapter will describe:

- The experimental design of the study
- The position of the researcher – ontology and epistemology
- The outcome measures
- An overview of statistical methods
- The participants and recruitment process
- The process of randomisation
- The strategies used to maximise recruitment and minimise attrition
- The method of vignette presentation – the exam host and exam format
- The pilot study
- The use of questionnaires and Google Analytics to measure some secondary outcomes

Study design

1. The methodology chosen to evaluate OCTAID was a randomised controlled trial (RCT) comparing two groups of practitioners who underwent an online assessment of their diagnostic and management skills based on OCT images before and after an educational intervention. Participants were randomly allocated to one of two possible educational interventions which were designed to assist in OCT interpretation. If they were allocated to the first intervention (the control) they received a link to a conventional OCT guide in addition to those resource/s they would normally use in practice when interpreting an OCT image. Some materials are freely and readily available via a Google search, but it was not assumed that all participants would have access to such materials or would have sufficient background knowledge of OCT to be able to conduct an effective search for relevant resources/materials. For this reason, the control group were given access to an OCT paper (with permission from the

copyright holder) to provide an introduction to OCT of sufficient relevance to the vignettes and quality to enable further searches for the information required to answer questions within the assessments. If participants were allocated to the OCTAID intervention group they were also permitted to use whatever resources they would normally use but additionally they received access to the OCTAID website. Participants' usage of the interventions was monitored by use of questionnaires and an overall assessment of the extent to which participants used the OCTAID site was provided by the use of Google Analytics software. The RCT is widely considered to be the most robust of research designs because the decision of randomising participants to receive or not receive an intervention ensures that any differences in outcome between the two groups can be attributed to the interventions and not to any other unidentified external factors (Sibbald and Roland, 1998).

2. An expert panel was recruited to play an advisory role in the design of the diagnostic algorithm and to act as a 'reference standard' in assessing practitioners' diagnostic and patient management skills by forming a consensus opinion on diagnosis/management based on OCT scans.
3. The lead researcher invited optometrists to participate in the study as described in the next section. A study information leaflet in PDF format was specially designed and attached to the invitation email sent to the forums. Interested practitioners then emailed the lead researcher to request a participant information sheet and a consent form. A questionnaire was designed and circulated to establish participants' previous level of OCT experience. Participants were not excluded on the basis of previous experience of OCT but the study co-varied for their level of experience in the analysis of results. The lead researcher also provided a telephone number for those practitioners who may have wished to ask further questions about the study. Participant information sheets and consent forms were returned in pre-paid, addressed envelopes to the lead researcher.

The main objective of the statistical analysis was to compare the change in vignette performance before and after intervention.

The RCT is a rigorous way of determining whether a cause-effect relation exists between intervention and outcome and was thought to the best match to the study title, research aims and objectives and data collection methods. Outcomes were easily quantifiable (exam scores expressed as numbers). Randomisation ensured that known and unknown baseline confounding factors would balance out in the treatment and control groups.

Other study designs (including non-randomised controlled trials) may also detect associations between intervention and outcome but the possibility that an association was caused by a third factor (or factors) linked to both intervention and outcome, cannot be ruled out. Random allocation ensures no systematic differences between intervention and control groups (known and unknown) that might affect outcome.

An observational study would not have been useful in testing a novel educational intervention. A cross-over design study (conducting an RCT using the same group twice) would have involved having a group of participants in the study group and then the same group crossing over into the control group (whilst randomly allocating them as to which group they went into first) This approach would have required a smaller number of participants. However, in the current study there would have been the logistical problem of the 'carry over' effect whereby participants who were crossing over groups would still have been experiencing the effect of the first educational intervention. Other quantitative experiments (where one or more requirements for RCT classification are missing) employing a 'pre-post' design would not have eliminated the possibility of confounding in the baseline characteristics of the study and control groups.

Participants and researchers ideally should remain unaware of which intervention was given until the study is completed. However, such double blind studies are not always feasible or appropriate and this will be discussed in the context of this study later in this section.

Ontology and epistemology – the position of the researcher

Researchers have a choice about their philosophical approach to a study but the importance of being reflexive is not always acknowledged and once a researcher accepts a particular epistemology, they tend to adopt methods that are characteristic of that position (Mauthner and Doucet, 2003). Ontology and epistemology both act as anchors in the approach to a research question. Each researcher will filter for preferences in their own world. These preferences are derived from previously held beliefs or principles, motives or perhaps constraints imposed by the research subject or question. As researchers filter for information they may decide on the evidence to be collected and the evidence to be set aside when building an argument. This can impact on the research methods and data-gathering techniques.

This student author approached the research question from a positivist stance (a deductive and more scientific view – "counting and measuring" quantitative research method). The researcher is aware of the risk of bias in that the choice of view in the research field is linked with the preferences of the researcher (and the variety and validity of what is already known). Whilst all possible approaches to the study design were considered, a design was chosen that was appropriate to the research question and the objectives of the researcher.

Main outcome measures

The first outcome measure was practitioners' diagnostic and management skills compared to the opinions of an expert panel. Each exam task consisted of 8 sets of questions (3 questions in each set) presented as clinical vignettes and including OCT images. This was followed by a further 8 questions which tested the participant's general OCT knowledge. All questions were in multiple choice question (MCQ) format. One assessment was presented before and another after the educational intervention. Some of the questions for each OCT image tested the participants' diagnostic skills (image interpretation) with the remaining questions testing the participants' management skills (referral decision, review period, likely treatment). The questions were structured in a stepwise fashion similar to a clinical vignette. The maximum score available for each assessment was 32.

The second outcome measure was the change in vignette score, compared before and after intervention in the two study groups.

Overview of statistical methods

Participants' score in the first assessment was used as a measure of the participants' baseline knowledge (knowledge-checker). Although the primary outcome measure was the change in exam score between exam 2 and exam 1 (score gain), a pass mark of 60% was set for each assessment. The pass mark was purely for the CET regulators and the participants were allowed (and indeed encouraged) to continue in the research even if they did not achieve the pass mark for the first exam.

Data were checked to determine if they were normally distributed—that is, bell-shaped, symmetrical about the mean. All data closely approximated a normal distribution so

parametric methods were used (appendix 10). Non-parametric methods are typically less powerful and less flexible than their parametric counterparts.

Categorical data were summarised as numbers and proportions. Participants' pass/fail rate was described and groups formally compared using Chi-square tests. Chi-square tests were used to compare proportions between two independent groups and the data were presented as a contingency table with one of the variables as rows and the other as columns. In the case of the second exam assessment, there were low numbers in one cell (only 3 fails in exam 2 for the OCTAID group). Because of these low numbers Fishers Exact test was the appropriate test to use for the 2x2 table for the second exam results and to maintain consistency, was therefore also used for comparing groups in the first exam assessment. Fisher's exact test is used when analysing two nominal variables. Fishers' exact test is most commonly used in 2x2 tables and it is thought to be more accurate than the chi-squared test of independence when expected numbers are small (Mc Crum-Gardner, 2008).

The Difference Score (the score in exam 2 minus the score in exam 1) or score gain reduced the two measurements for each participant into one so in this analysis one measurement in each of the two groups was compared using standard unpaired t-tests.

Secondary outcome measures

The main outcomes are the essential and most relevant outcomes for decision-making and those that form the basis of the summary of findings in any study. A pass mark was set for each exam module and the difference in the pass rate between the study and control groups was used as a secondary outcome measure.

Participants were asked (using short electronic questionnaires linked to the online study modules) how long it took them to complete each exam task and how long they spent studying the OCT educational tools provided for the study. The overall use of the OCTAID

website was monitored using Google Analytics software. The quality of the study in terms of its value to OCT education and relevance to optometric practice (from the participants' perspective) was also measured using a short feedback questionnaire.

Participants

Recruitment

Participant recruitment is often a significant challenge in research studies. Successful recruitment to the current study involved a number of activities including:

- Identifying suitable and sufficiently motivated participants
- Marketing the research study effectively
- Adequately explaining the study to potential participants
- Recruiting an adequate sample based on study goals and design
- Obtaining informed consent and retaining participants until study completion
- Maintaining ethical standards

All participants to this study were community optometrists with an interest in OCT but with varying levels of OCT experience including those who may not have had access to OCT equipment. Much of the recruitment effort was focussed on a number of online optometry forums. The Optix OCT forum is provided by Optix Software as a free service for the profession and is co-sponsored by Nidek (a leading supplier of OCT equipment). It is open to all optometrists for the exchange of ideas and advice relating to the use of any brand of OCT and interpretation of the results.

The optom.com is an online forum and chatroom for optometrists and has 7762 registered users.

The University of Manchester Listserv service is an email –based server that allows users to create, manage and control electronic mailing lists. Listserv manages list subscriptions and archives of posted messages and optimises mass mail. Listserv allows any networked user to subscribe to lists, receive postings and access list archives.

In a previous study design, a leading supplier of OCT equipment had indicated a willingness to assist with recruitment to the study by making customers (both new and established) aware of the study. This strategy would have entailed the supply of the study promotional leaflet (appendix 3) to mainly new OCT users (by the training team) when they took delivery of their equipment or during the initial training session. The author and research team did not request (and were not supplied) with information about the OCT supplier's clients.

The author (in consultation with supervisors) decided against this mode of recruitment for the following reasons:

- The Research Ethics Committe at LSBU expressed some reservations about recruitment via an OCT supplier in their initial review of the study's ethics application on the grounds of the potential for recruitment to the study to be perceived as part of a sales process.
- It was felt that the recruitment task would be quite onerous and something of a distraction for an OCT sales team striving to maximise sales opportunities in a highly competitive market
- There are several OCT suppliers in the UK and the research team did not wish the study to be associated with one company. This might have been an inhibiting factor for potential recruits and other OCT suppliers who may have felt less inclined to recommend the study as a training resource

An opportunity for recruitment also existed during a series of optical trade shows. The author attended a number of these shows to identify recruitment opportunities but did not recruit for the reasons already outlined. A summary of the range of methods considered for recruitment to the current study are summarised in Table 3.1.

Potential sources of recruitment	***Advantages***	***Disadvantages***
OCT manufacturer	Exposure to many optometrists of all levels of experience Cost effective Focussed on motivated subjects (recent and established OCT users)	Potential for ethical issues raised by study being perceived to be linked to sales process Independence of OCTAID and the overall study possibly compromised by its association with a single OCT manufacturer Heavily dependent on good will of OCT manufacturer Recruitment among new OCT users might have been slow (in pace with OCT supply)
Optical press	Exposure to large number of optometrists of all levels of experience	Expensive Lead researcher had no prior relationship with potential participants (less trust)
Local optical societies	Cost-effective	Possible regional bias Exposure to smaller pool of recruits Risk of lead researcher being known to potential participants
Optical trade shows	Exposure to large numbers of potential recruits	Expensive (travel, accommodation, trade stand) No prior trust established with potential participants Need for recruiter to be present (shows usually extend over 3 days)
Direct mail	Addresses available via GOC website	Expensive Not focussed on OCT users Unsolicited mail – no trust established with potential recruitments
Optometry conferences	Exposure to small to medium sized pool of participants	Only useful for OCT-focussed conferences Permission required to promote

		research
Optometry and OCT online forums	Exposure to very large pool of potential participants Cost effective Focussed on OCT users (new and established) Opportunity to establish prior relationship and trust with forum members (by contributing to the forum debate) Potential for forum members to recommend participation to other forum members (online chat giving "snowballing effect")	Risk of over-exposure (exam host was limited to 200 users) Risk of the study receiving poor feedback in online chat – potential recruits de-motivated

Table 3.1 The range of recruitment methods considered for the current study

The author contacted potential participants via the mailbase of the forums mentioned above. The email contained a short introduction to the research (appendix 1). A more detailed description of the study in a summary of the research (appendix 2) was electronically attached along with a leaflet designed to promote the study (appendix 3). All potential participants were requested to respond by email if they were interested in participating in the study or if they simply required more information. Those who expressed an interest in participation were posted a participant information sheet (appendix 4), a consent form (appendix 5), a short questionnaire designed to estimate their prior OCT experience (appendix 6) and an information sheet describing what will happen after the study is completed (appendix 7).

A non-probability (random simple) sampling method was used. This convenience (whoever is available) method permits limited choice and judgement to the researcher but was essential in maximising the number of participants.

Process of randomisation

Participants were given a unique identification code and divided into 3 groups depending on their prior level of OCT experience. Both the unique ID and level of OCT experience were

written on a piece of paper, folded and placed in one of 3 boxes based on OCT experience. The contents of each subgroup box was further divided in half by a third party randomly choosing half of the pieces of paper. Half of each subgroup was allocated to the study (OCTAID) group with the other half being allocated to the control group. The author played no part in allocating participants to study groups but a pragmatic approach to masking was adopted thereafter because the author needed to load participant details onto the LearnUpon platform to assign them to the correct subgroup (ensuring that they were assigned to the correct intervention and subgroup analysis). The author also needed to register an email address for each participant in preparation for automated invitations and reminders from LearnUpon. The author needed to have access to the participants email throughout the study, not only to answer queries, deal with IT issues, and ensure correct allocation of CET points but also to keep participants engaged, focussed and motivated.

LearnUpon hosted two courses for this study (OCTAID and Control) which were identical in every way except for the educational intervention following completion of the first exam task. Once assigned to a course on LearnUpon (and a subgroup for more detailed analysis), participants could not be moved to another group, even in the event of withdrawal, failure to register or enrol or failure to start or finish. The integrity of the original process of randomisation was therefore preserved at the risk of attrition affecting one study group disproportionately.

Sample size considerations

A sample size calculation was considered (Prajapati, Dunne, Armstrong, 2010), but the absence of previous data concerning an educationally significant improvement in the OCT exam, and the absence of data on the standard deviation of the exam results make such a calculation less plausible. One possibility is to use pilot data or data from the first participants to complete the study to obtain these measures but clearly the accuracy of these estimates will

be less than ideal. After discussion with the supervisory team it was concluded that a sample size calculation may not be required in this study for two additional reasons. First, there is a finite group of clinicians with OCT equipment. Second, the computerised nature of the exams and of the interventions means that there is no practical ceiling on the number of participants. It was decided to adopt a pragmatic approach to sample size and concentrate efforts on recruiting the maximum possible number of participants in the time available. In circumstances where effect size data are unavailable or considered less reliable, Cohen has determined standardised effect sizes described as “small”, “medium” and “large” (Prajapati, Dunne, Armstrong, 2010) and appendix 11 contains a sample size calculation based on primary outcome data (mean values and standard deviations) from the current study.

Procedure

The study procedure is summarised in Table 3.2

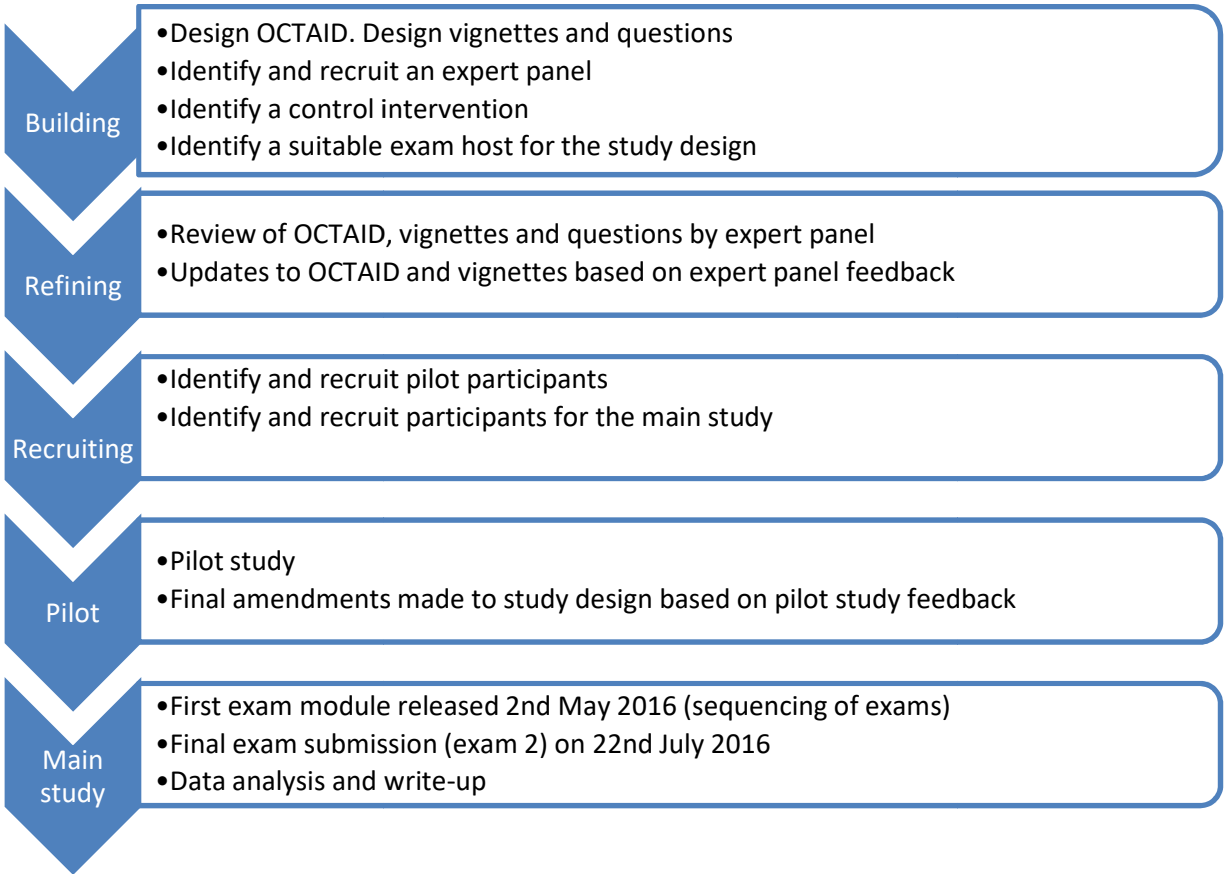

Table 3.2 Study procedure

Ethics approval

This study received LSBU Ethics Committee approval on 06/06/2013 and Institute of Optometry REC approval on 27/02/13.

Incentivising study participants

Early on in the study design it became clear that participants were to be asked to give a significant amount of their time to this project and it was decided to apply for continuing education and training (CET) points that could be provided as an incentive to optometrists who participated in the study. The vignettes/MCQs were submitted and approved for CET by the General Optical Council (GOC) for the 2016-2019 CET cycle. The General Optical

Council is the regulatory authority responsible for the registration of optometrists and overseeing continuing educational development. The GOC oversee a mandatory CET scheme. CET is a statutory requirement for all fully-qualified optometrists. The scheme is a points-based scheme that runs over a 3 year cycle and works on the principle of one learning hour earns 1 CET point.

GOC approval of the online assessments (signified by the presence of the GOC logo) added an additional layer of quality control to the assessment process and ensured that the questions within the two exam modules were set at an appropriate level.

Two CET points were awarded for successful completion of each of the two exams within the study. Prior to approval, exam questions are subjected to review by an expert panel of CET approvers. By definition, approved CET is that which has demonstrated it is relevant to the CET competency frameworks and standards and anything which is unrelated to CET standards of CET competence and professional conduct will not be approved. (https://www.optical.org/en/Education/CET/cet-requirements-forregistrants.cfm).

All participants to the study (from the study and control groups) were given free and open access to the OCTAID site on completion of the study. Participants were also invited to assist in the future development of the OCTAID site with their contribution (and scans from their personal practice archive) being fully acknowledged on the site.

Strategies to maximise recruitment and minimise attrition

Practitioners who responded positively to the study and expressed an interest in participation were asked to provide a postal address to which recruitment forms and information literature was posted. The information pack also included an addressed, pre-paid envelope for returning the consent form and questionnaire (on prior OCT experience). All practitioners selected

email as their preferred method of communication throughout the study and understood that their email would only be used for enrolment with the online exam host and for ongoing study support from the author. Practitioners who returned their signed recruitment documents were registered with the exam host (LearnUpon) and were then invited (using their preferred email) by the exam host to the LearnUpon portal. Practitioners who did not return their recruitment documents were reminded (twice only) by the author to return their documents after which time they did not receive any further communication. This process is summarised below in Figure 3.1.

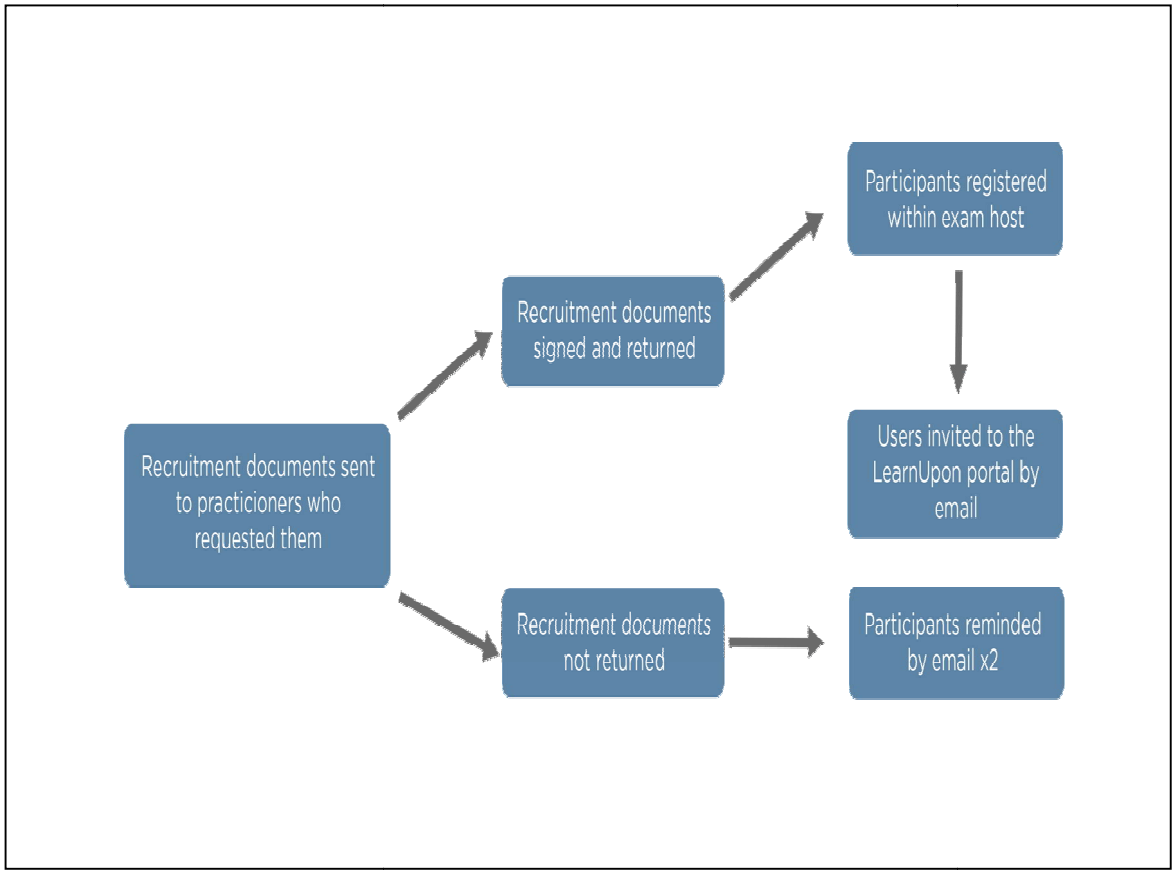

Figure 3.1 The recruitment and enrolment process

A number of strategies were adopted in order to avoid attrition from this study. A high rate of attrition had the potential to introduce bias and reduce the overall power of the study in terms of its validity, generalisability and validity of results.

Automated reminders within the LearnUpon system were triggered at various stages and this is described in the next section on the exam host. The course administrator (the author) was

able to monitor the progress of each participant and send a personal email when required. This was done at the following important junctures:

1. If a practitioner did not acknowledge (by clicking on the link) the invite email from LearnUpon (pending users)
2. If a practitioner registered but did not then go on to enrol for the exam modules (pending user enrolments)
3. If a practitioner enrolled for the exams but did not commence.
4. The author emailed users on completion of each exam module and thanked them for their participation. This was thought to be particularly important in the case of users who were not successful in achieving a passmark as this group of practitioners might have been the least motivated to proceed to the second exam task. These practitioners were reminded that exam results were treated confidentially and that other opportunities to do the exams (and earn CET points) would be made available after the study was completed.
5. The author emailed participants who appeared to have disengaged from the LearnUpon host at any point. This was found most often to be due to a loss of login password details. Password reset was simple and straightforward.

Participants were reminded (within the course modules and by direct email from the author) that access to the OCTAID site would be made available to all participants who completed the study regardless of their score. All participants were emailed by the author on completion of each exam module and thanked for their participation.

This process is summarised below in Figure 3.2

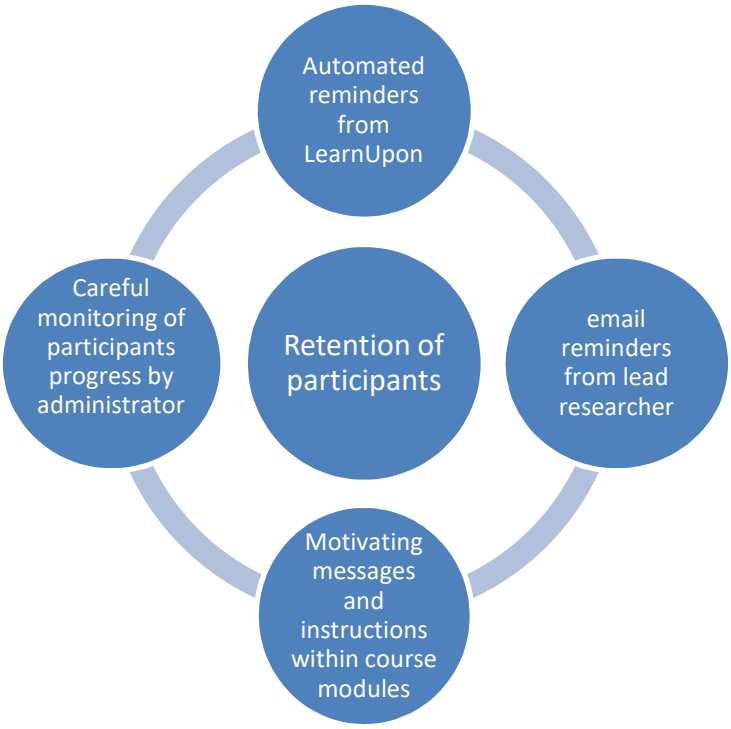

Figure 3.2 Strategies for the retention of participants

The method of vignette presentation - the exam host

The research assessed the performance of OCTAID compared with a control educational intervention using clinical vignettes/MCQs. The clinical vignettes/MCQs were hosted online by LearnUpon which is a learning management system designed for the delivery of online training and examinations. LearnUpon is a multi-award winning company with over 1.5 million users worldwide. LearnUpon provides excellent flexibility for all formats of examination design along with statistical analysis software.

The author invested considerable time and effort in identifying a suitable online host for the vignette exams. Some of the current popular choices in the online survey market such as Survey Monkey and the Bristol Online Survey were very limited in terms of:

- Hosting exams which included high resolution images with large file sizes
- Presenting exam questions in the sequenced fashion of a clinical vignette with the option to prevent return to a previously answered question
- Statistical analysis software and generation of charts

- Online support for participants and administrators
- Creation of separate course modules and sequencing of these modules

Some Learning Management Systems (LMS) were found to be suitable but prohibitively expensive and therefore not viable for small research projects with limited numbers of participants. LearnUpon had a tiered pricing structure which suited small projects with less than 200 participants. LearnUpon provided 24 hour online support to exam users and administrators.

Potential users were invited into the LearnUpon portal by email. Invited users appear in the Pending users section until such time as they accept the email invite they received and confirm their account. It was possible to resend an invite at any time by simply clicking the resend button. The date on which an invite was last sent to a user on the Pending User list was also included. The course enrolment screen (Figure 3.3) provides an overview of all enrolments, and the courses in which each participant is enrolled along with their subgroup (used when co-varying for a participant's OCT experience in statistical analysis), start and course completion dates.

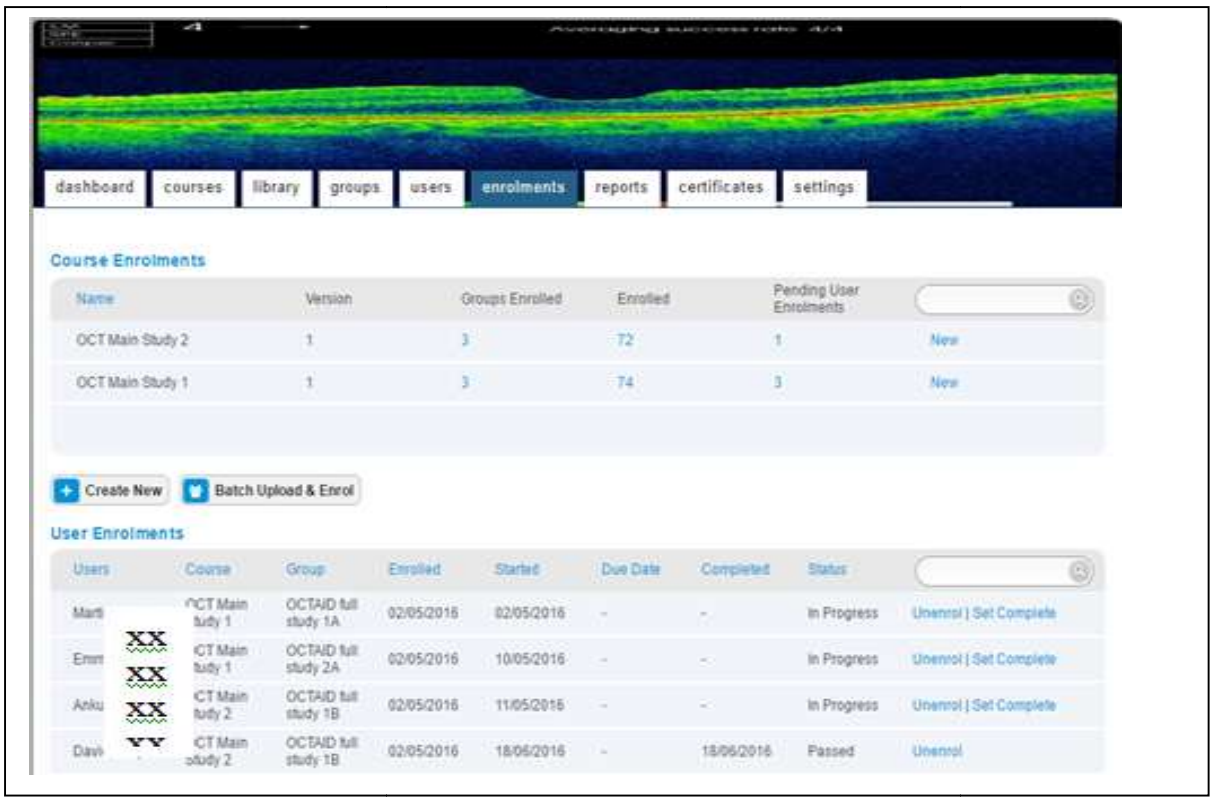

Figure 3.3 LearnUpon enrolment page. New users could be enrolled and assigned to their study group from this page and their status monitored

LearnUpon offers a user profile screen which provides administrators with a full overview of all the profile information relating to a particular registered user. It includes:

(i) A Details screen which gives an overview of the Learner including their custom user data, information for enabling/disabling their account, resetting their password, etc.

(ii) A current Training screen which shows details of all current enrolments for the user with the option to view the details of an enrolment, change the expiry date, manually mark them complete and unenrol them from the course (Figure 3.4)

(iii) A completed training screen which provides an overview of all course completions including date completed and scores achieved

(iv) A groups screen where you can see what groups the Learner in question is currently a member of

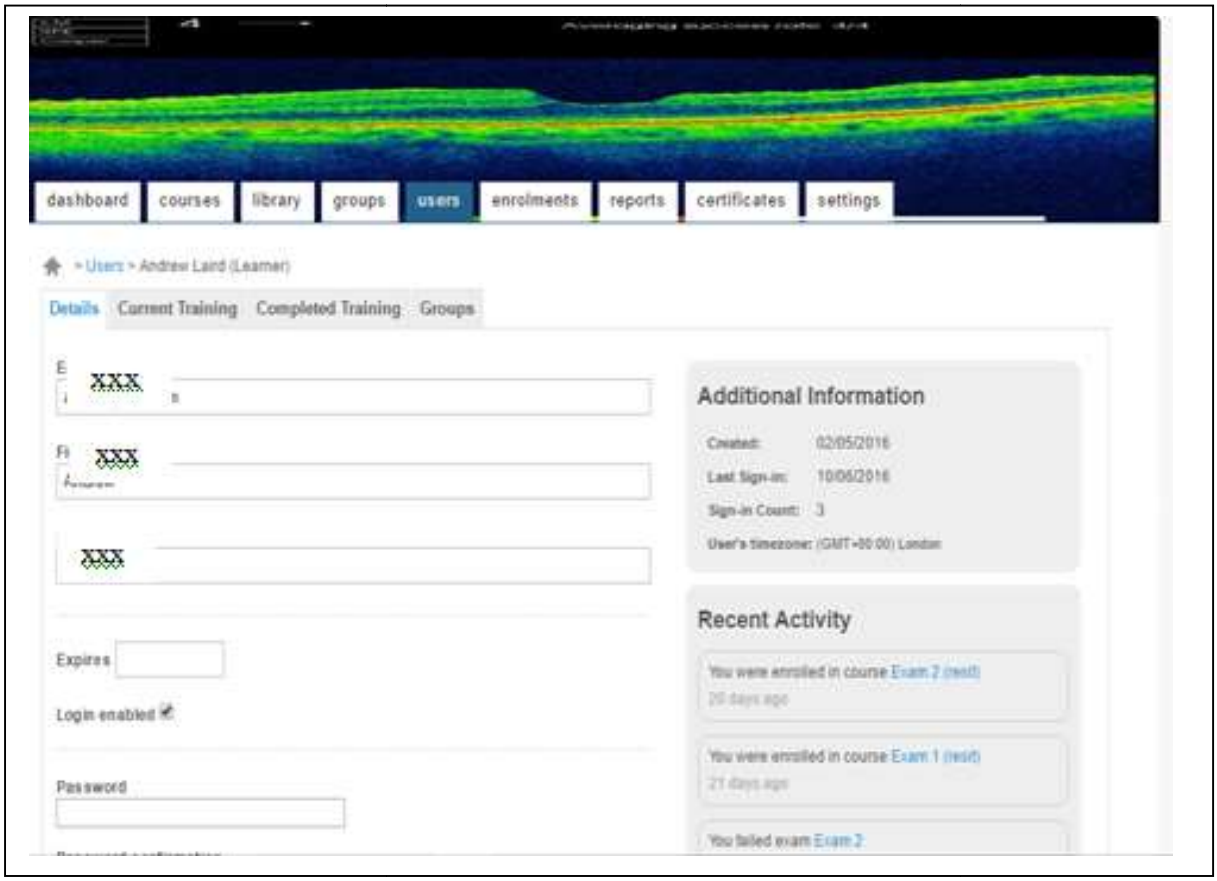

Figure 3.4 The current training screen

It was possible (and necessary in this study) to create Groups in LearnUpon, enabling the administrator to manage how courses were assigned to different groups of users (Figure 3.5).

Figure 3.5 The Groups page showing users allocated to various subgroups

Courses in LearnUpon can be made up of many different types of content such as videos, PDF documents, PowerPoint documents, SCORM courses, text and images, etc (SCORM stands for Sharable Content Object Reference Model and it is a set of technical standards developed for eLearning software products. Word, Powerpoint and PDF documents could be imported into the course. It was also possible to set various course options such as valid periods/due dates, exam options (for example, sequencing of questions/course modules, timing of exams and randomisation of questions).

An important function of LearnUpon was the option to send reminders of an upcoming due date to all participants who had not yet completed the course (i.e. everyone who was either "not started" or "in progress"). Completion reminders could also be sent up to 4 times (2 were chosen) to all participants who had not yet completed the course a set number of days after they were enrolled.

In LearnUpon, the concept of "question pools" allowed questions to be grouped together and then used across as many courses as required. This was important as it was necessary to create several courses using the same question pools (author and supervisor's version, pilot version, main study versions for the OCTAID and control groups, and resits for those wishing to repeat an exam). After an exam was added to a course, a list of all existing Question Pools in the content library could be imported (Figure 3.6).

Figure 3.6 Question pools could be created within the LearnUpon library and imported to a course

Images could be uploaded for all questions (crucial for vignettes). Multiple choice questions with only one correct answer were used in the current study but other question designs were available (for example, true/false, multiple correct answers, order lists, match list, fill in the blank etc.).

Another crucial feature of the LearnUpon exam option is the ability to prevent access to previously answered questions. This feature allowed the questions to be presented as clinical vignettes where questions relate to a previously posed question in a typical clinical scenario.

A participant could, at any time, click on their “Learning Paths” tab on their “Dashboard” to get an overview of their progress on each “Learning Path” they had been assigned. From the administrator’s (author’s) perspective, it was possible to view the progress for each participant by clicking on the Enrolments tab and selecting “Show Learning Paths”.

It is also possible to include surveys as part of a course in LearnUpon and this proved useful for some secondary outcome measures and feedback on the quality of the course as an educational experience for the study participants (Figure 3.7).

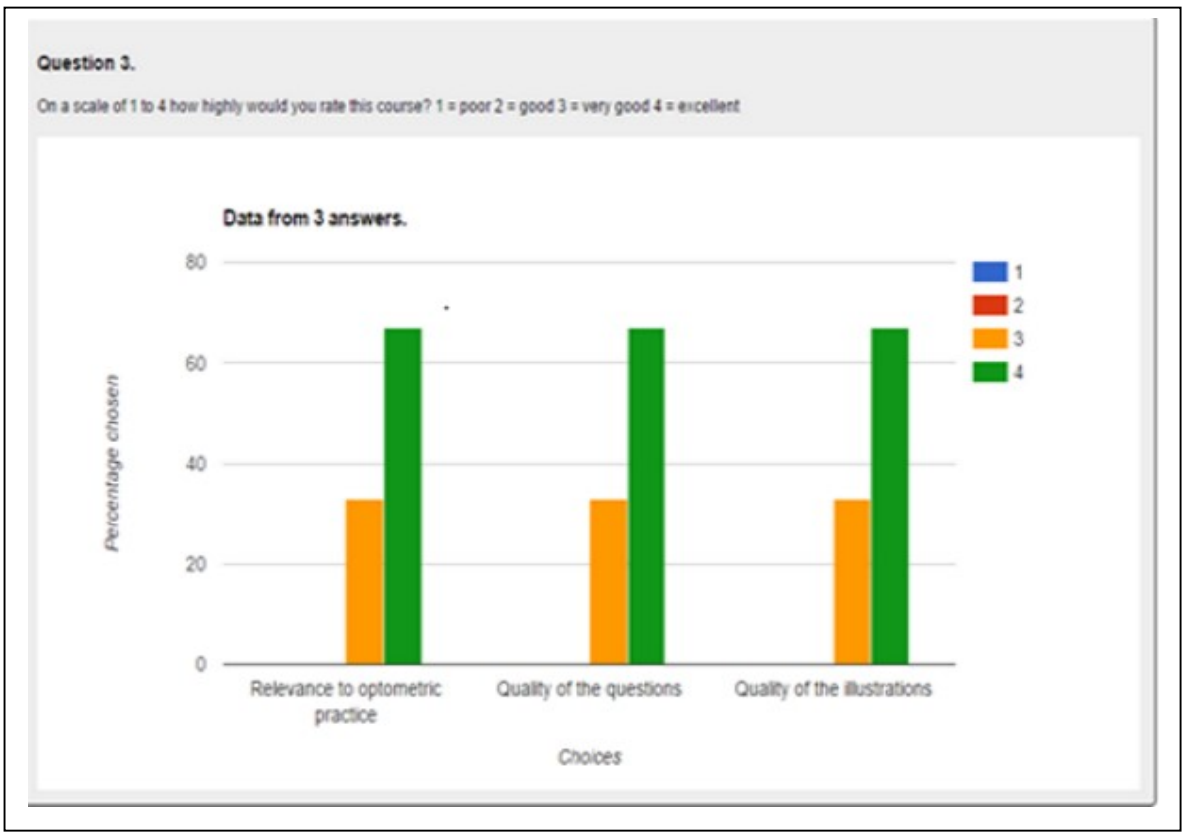

Figure 3.7 Survey report on the quality of the study from the perspective of participants

There are ten main types of reporting available in LearnUpon. The current study utilised two of these (exam report and survey report) for statistical purposes. These reports could be generated in the form of charts, Microsoft Excel spreadsheets and in full transcript format showing all answers to all questions for all participants. Reports could also be generated for each sub-group of participants separately.

Masking of participants

A pragmatic approach was taken to masking as it was not possible to mask participants for the entire study duration. Participants were not told which study group they would be assigned to and would not have been aware of this until after completion of the first exam task when they were provided with a live link to the OCT training tool (OCTAID or control). There was not a way of avoiding participants recognising the nature of the interventions they received. All participants were informed that they would have free access to the OCTAID site after completion of both exam modules. It was thought that this would help to avoid participant attrition from the control group.

The control intervention

The author and supervisors devoted much debate to the concept and selection of a control intervention. The study was measuring the efficacy of the OCTAID resource (in terms of vignette score improvement) by comparing it with conventional OCT resources available and accessible to community optometrists. It was difficult to identify a control intervention which could match OCTAID in terms of its scope and detail and the research team did consider the option of not giving the control group any additional resource (as they were permitted to use any OCT resource that they would usually refer to). However, a decision was made to provide the control group with an additional resource for the following reasons:

- It could not be assumed that all participants would have access to OCT resources when they decided to commence the exam modules

- Some participants in the control group would be likely to require an introductory level of OCT training. For example, some participants may have lacked sufficient knowledge of OCT technology and terminology to enable them to research effectively for OCT resources which might be helpful to them in the exam modules.
- It was thought important that all participants in the control group should be provided with a resource common to all of them.

The control intervention that was finally chosen had open access status (although permission for its use within the study was sought anyway and granted) and benefitted from the fact that it provided a comprehensive knowledge of OCT that would be useful to both novice and experienced OCT users. A live link to the control intervention is provided here: http://commons.pacificu.edu/cgi/viewcontent.cgi?article=1011&context=coofac

The "open book exam"

A challenging dilemma was whether to allow the participants to take the vignettes whilst they used their educational interventions or without access to these. The research team engaged in lengthy discussions about this topic and key relevant literature will now be briefly summarised.

Educators have long debated the usefulness of examinations and have striven to establish how a learner's experience of examinations might be more authentic and, in the process, more constructively tailored to the desired learning outcomes (Williams and Wong, 2009).

Participants to the current study used OCT resources supplied (and permitted) during the exam task. "Open book exams" are tests that allow text or materials being studied to be used during the exam. An open book exam still requires an understanding of the material to be able to interpret a question and provide a rational answer. In an open book exam the emphasis is on applying information rather than memorising it or interpreting information in the context of certain questions and scenarios rather than summarising it. A study by Theophilides and

Koutselini (2010) focussed on students' perceptions, study behaviour (prior and during exams), and exam performance in the open and closed book exam alternatives. Results indicated that participants preparing for a closed book exam tended to postpone their study until the end of a semester, concentrate their efforts on the assigned texts and try to memorise content. When taking exams, students who prepared for an open book exam faced exams with a greater degree of optimism. They felt that they had mastered course content and involved themselves more deeply in the learning process. They also reported that they used the knowledge gained in a more creative way.

In the opinion of the lead researcher and supervisors, the open book approach to the vignette task was thought crucial to the recruitment process, in that a perception that the exams presented a high level of difficulty would have been a disincentive to potential participants. This was particularly important after completion of the first exam as those participants who found the first exam challenging would need every motivation and encouragement to proceed to the second exam and so complete the study. Participants would not normally be limited to a "closed book" approach to other approved learning events and in any case it would have been impossible to measure the degree of compliance in a closed book non-invigilated exam setting.

OCTAID, in common with other OCT guides was designed as a quick reference guide to be used in practice to aid practitioners with diagnosis and patient management. Unlike a text book, quick reference guides are not designed to be 'revised' but are meant to be used in clinic. In this study we were measuring the efficacy of an online diagnostic guide versus a more conventional control guide in assisting the accurate diagnosis of retinal disease. The study was not designed to measure which of the two interventions was more likely to help participants to retain information for an exam task. The advantages and disadvantages of the open versus closed book approach to exams is summarised in Table 3.3.

Exam mode	Advantages	Disadvantages
Open book	Requires and encourages an understanding of the material rather knowledge recall Prior revision useful but not essential An incentive to participants with little experience or prior knowledge Participants may approach the exam task with a degree of optimism – the open book being similar to the "real world" situation when clinicians have access to resources when making referral decisions	Does not encourage commitment to a prior revision period Course materials not a constant for all participants Not possible to ensure compliance in a remote (online) setting
Closed book	A more exact measure of participants' revision and exam preparation Easier to ensure compliance in an invigilated exam setting	Disincentive to participants especially those with little experience or prior knowledge Less likely to encourage an understanding of the subject and less likely to test the application of knowledge Participants may approach the exam task with a degree of pessimism

Table 3.3 Open versus closed book approach to exams – advantages and disadvantages

Setting a pass mark

The choice of pass mark (60%) was not based on prior evidence but on the fact that participation in the study was approved for continuous education and training (CET) and this was the pass mark set for this type of CET event by the optometry profession's regulator, the General Optical Council. Therefore the difference in the pass rate between the study and control groups was used as a secondary outcome measure.

A question of timing

Imposing time limits on tests can serve a range of important functions in certain circumstances. For example, time limits are essential if speed of performance is an integral component of what is being measured. Limiting testing time may compromise a test's

validity, or the ability of the test to accurately reflect what the test was designed to measure. In this study the assessments were not intended to measure how quickly the participant could answer questions. Validity of the vignettes within this study lay in the ability of the assessments to provide a fair and accurate assessment of what had been learned. An educator, Graham Whisen, suggests that educators should replace phrases like "you have five minutes left" with phrases like "keep trying until you feel you have done all you can" (http://ideaconnect.edublogs.org/2011/01/19/should-tests-have-time-limits/).

Exam sequencing

The second exam was scheduled to be released 3 weeks after the release of the first exam. This was to prevent participants from proceeding to the second exam before familiarising themselves with the OCT educational interventions provided after completion of the first exam. Not all participants started the study at the same and therefore the interval between the availability of the first and second exam differed for each participant. Participants however were advised within the course modules (and by email on completion of the first exam) not to proceed to the second exam until after they had spent at least 2 weeks familiarising themselves with their assigned OCT aid (OCTAID or control intervention).

Avoiding bias in the design of OCTAID, clinical vignettes and exam questions

The lead researcher (and author) designed the OCTAID website, the clinical vignettes and exam questions. Several measures were taken to avoid the possibility of the OCTAID site having been specially tailored to the vignette task (or *vice versa*).These are summarised in Table 3.4.

The two study supervisors were asked to scrutinise the OCTAID site as well as the control educational intervention (as one of a range of resources available to participants) to ensure that exam questions were not biased to favour either intervention. Similarly, the expert panel

were asked to verify that exam questions were pitched at a reasonable level of difficulty and based on retinal conditions which community optometrists would commonly encounter in daily practice.

Potential source of bias	Action
OCTAID site specifically tailored to vignettes	OCTAID site and vignettes subjected to review by study supervisors, expert panel, and pilots
Clinical vignettes specifically tailored to OCTAID site with limited hope of researching answers within currently available (and accessible) resources.	Vignettes subjected to review by study supervisors, expert panel, and piloted to ensure that questions were pitched at a reasonable level and based on retinal conditions commonly encountered by community optometrists Vignette questions reviewed and approved by the General Optical Council as suitable for optometric education
MCQ exam format	Objective marking (only one correct answer in a well-designed question) – no marker bias Automated exam marking and reporting within the LearnUpon exam host

Table 3.4 Strategies to void bias in the OCTAID site, vignettes and exam questions

Pilot study

Moore *et al*. (2011) define pilot studies as "preparatory studies designed to test the performance characteristics and capabilities of study designs, measures, procedures, recruitment criteria and operational strategies that are under consideration for use in a subsequent, often larger, study". They are sometimes referred to as mini versions of a full-scale study or feasibility studies. Moore *et al.* (2011) suggest that pilot studies generally contribute to the design and development of future primary (and possibly more costly) studies by providing clarity to the research hypotheses being studied. More specifically, pilot studies identify potential barriers to subsequent study completion, evaluate the appropriateness of methods and procedures to participants and measure the time commitment required for study participation. Pilot studies can also provide reliable estimates of the expected rates of missing data and participant attrition (Moore *et al.* 2011). Leon *et al.* (2011) state that pilot studies are a requisite initial step in exploring a novel intervention, although pilot studies are not hypothesis testing studies because safety, efficacy and effectiveness are not evaluated in a

pilot. Leon *et al.* (2011) suggest that a pilot study does not provide a meaningful effect size estimate for planning subsequent studies due to the imprecision inherent in data from small samples. So, although pilot studies are a requisite initial step in exploring a novel intervention and a crucial element in a good study design, feasibility results do not necessarily generalise beyond the inclusion and exclusion criteria of the pilot design.

A pilot study was conducted to provide optimal information needed for the main study. It was considered important that the design of this pilot study should be guided by the aims of the main study and should therefore be similar to that of the larger subsequent study. So, the aims and methods of the pilot study were aligned with the goals of the main study. For example, the pilot study recruited participants from the same study population (UK optometrists with varying OCT experience). It was hoped that a pilot study would identify and address issues that might occur with respect to study design, sample selection, data collection/management and data analysis.

Pilot study methods

Informal enquiries among contacts of the author and supervisory team were made seeking suitable volunteers. The pilot study preceded the main study and involved 6 optometrists of varying degrees of OCT experience to reflect the range of experience of optometrists recruited to the study. The pilot participants were selected on the basis of their previous OCT experience as defined by the same questionnaire given to participants in the main study (appendix 6). So rather than make a self-declaration about their OCT experience, participants estimated how often they assessed OCT scans. It was thought that participants might struggle to accurately rank themselves as ‘novice’, ‘intermediate’ or ‘expert’. For example, an expert OCT users might be tempted to ‘downscale’ their level of experience when they are entering an exam situation because they may feel that assessors’ expectations of their exam performance might be high. For this reason, participants were asked how many OCT scans they assessed in a typical month.

Three of the participants were allocated to the study group and received a link to the OCTAID website after completing the first exam. One member of the study group had only very limited (novice) experience with OCT. Another had some 'intermediate' experience with OCT (had only started to use OCT or had only limited access to it). One member of the study group was an experienced (expert) OCT user. Those allocated to the control arm of the study were similarly divided into 'novice', 'intermediate' and 'expert' categories and were asked to complete the same exams but were given access to a conventional form of OCT education. This included a live link to an OCT guide used for the control group within the main study and pilot participants were also permitted to use other OCT resources they would normally use in practice when interpreting an OCT scan or answering a question on this topic. All of the course modules were sequenced and securely hosted online by LearnUpon.

Each exam module contained 40 MCQs. Thirty-two of these questions were in vignette format based on ocular images/OCT. The remaining 8 MCQ questions were designed to test participants' more general knowledge on OCT and retinal disease.

Pilot participants were asked to provide feedback on:

- The ease of access to the LearnUpon course platform (account login etc)
- The ease of navigation through the various course modules
- The level of difficulty and length of the exam modules
- The presence of any questions which seemed ambiguous or unfair
- The quality of the illustrations
- Access to the educational interventions via the live links
- Navigation through the educational interventions and how they might be improved

It should be noted that vignette questions were not changed once approved by the expert panel. Exam performance of the pilot participants was of interest to researchers as a measure of exam difficulty and as an insight into the likely spread of exam results in the main study.

Results of the pilot study

The research question can be directly addressed by comparing the improvement in the vignette score for participants receiving OCTAID with those who received the control intervention. Therefore, the vignette score improvement (VSI) was calculated for each participant as the percentage improvement in the vignette score.

The mean score improvement or score gain (the score in exam 2 minus the score in exam 1) in the OCTAID group was 15.7% compared with -3% in the control group. The greatest impact was within the 'novice' group where the OCTAID participant improved their score by 30%, whereas the control participant' score fell by 14% (-14%). The 'intermediate' participant from the pilot OCTAID group improved their score by 17% whereas the 'intermediate participant from the control group improved score by 5%. There may have been a 'ceiling effect' caused by the fact that this 'intermediate' control participant scored very highly in both exams (85% in exam 1 and 90% in exam 2). The least impact of the educational interventions was observed in the 'expert' group of participants. Although both participants passed both exams, their exam scores did not change between the two exams. The 'expert' participant from the OCTAID group scored 73% in each exam whereas the 'expert' participant from the control group scored 66% in each exam. The results of the pilot study are summarised in the bar chart in Figure 3.8.

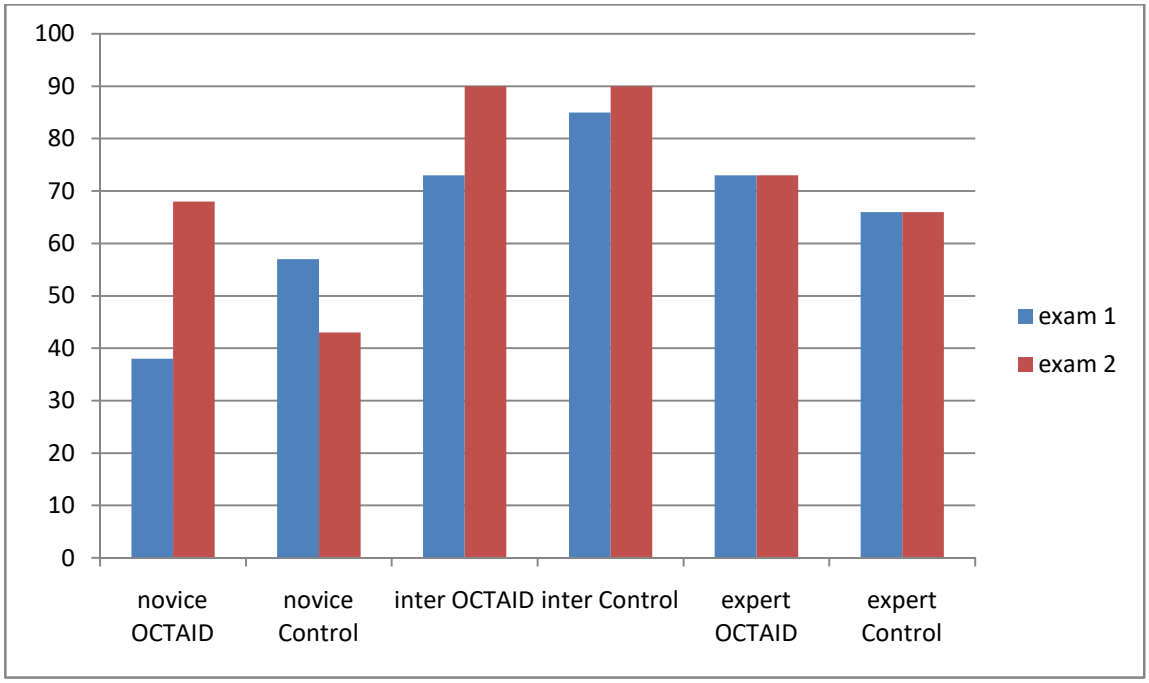

Figure 3.8 Bar chart showing pilot study scores in exam 1 (blue) and exam 2 (red) for each participant. Pilot participants were novice, intermediate or expert in their level of OCT experience

Feedback from the pilot study participants

Pilot participants reported favourably on their experience with the educational materials and vignette exam modules and reported no difficulties accessing course materials or navigating through the course modules. The original study contained 40 MCQ questions in each exam assessment. There was consensus and indeed concern among participants in the pilot study that the length of these exam modules might be too onerous for participants and a limiting factor in keeping participants enrolled in the study. A decision was made to enhance participant recruitment by reducing the overall participant burden. The number of questions in each exam was therefore reduced to 32. Questions were omitted which closely replicated issues and clinical scenarios already covered in other questions.

The pilot participants also advised that time-limiting the exams would likely pose a significant challenge to potential participants (especially inexperienced OCT users) and impact negatively in terms of recruitment and retention. A decision was taken not to limit the time allowed for the exam modules.

Monitoring the use of the OCTAID site using Google Analytics (main study)

Google analytics (GA) is a tool used mostly by advertisers to monitor and optimise 'traffic' to their websites. The world of online marketing is very dynamic so it is crucial that a reporting system provides actionable information on what is working and/or not working on a website. For example, high numbers of new visitors may suggest that a marketing campaign has successfully attracted new 'traffic' to the site whereas many repeat visitors may signal engagement of users who have been attracted back to the site.

The use of the OCTAID site was monitored over the duration of the study and beyond to ensure that participants had successfully accessed and used the website and that the number of visitors to the site was at least equivalent to the number of participants in the OCTAID study group. This number could only be approximate for the reasons outlined later in the results section and participants to the study were not prohibited from sharing links to the OCTAID site after they had completed their final exam module.

Chapter 4: Development of OCTAID

This chapter provides an insight into:

- The development of a new information resource, diagnostic algorithm and training platform for OCT interpretation (OCTAID) and the rationale behind its design and mode of delivery
- The use of an expert panel in the design of OCTAID

The dominance of the internet in everyday life has revolutionised the exchange of information and optometric educators have not ignored this trend. Slawson and Shaughnessy (2005) suggested that to encourage high quality patient care in contemporary medicine using the best evidence, it is not enough for medical schools to teach techniques for critically evaluating the medical literature. They suggested that incorporating the best evidence into the reality of busy clinical practice requires the applied science of information management. Hurwitz and Slawson (2010) went on to suggest that internet sources need to be created that have the readily available evidence-based answers to patient issues. In this way clinicians would not need to spend a large proportion of their time researching questions on their own. Ideally, information management would be built on a platform of EBM but would save the clinician time and improve accuracy by having experts validate the evidence and make it easily available.

For the present research, a new information resource, diagnostic algorithm and training platform for OCT interpretation was developed (OCTAID). The live link to the OCTAID site is www.octaid.co.uk and the details required are:

User name: user

Password: 0ptical1 (Note that the first character of the password is a zero)

When designing OCTAID the author took account of the two complementary processes thought to be involved in medical diagnosis, similarity-based and analytic, even though some

debate may still exist about which of these two processes define expertise. There does however appear to be consensus on the existence of a model of clinical decision-making based on dual processing theory (Ilgen *et al.* 2012) which postulated that reasoning and decision-making can be described as a function of both an intuitive, experiential, affective system (system 1) and/or an analytical, deliberative processing system (system 2).

The main diagnostic arm of the OCTAID site (Start Diagnosis) is organised with the branching logic of an algorithm. It was thought that novice OCT practitioners might choose this route when searching for a diagnosis as inexperienced clinicians often adopt an algorithmic approach to diagnosis as discussed in chapter 2. Experienced practitioners who have enough prior knowledge may instantly recognise a condition (pattern recognition) but may wish to confirm this. Their starting point might then be from the alternative diagnostic arm ("I know what this is"). This section of the OCTAID site contains the same type of branching logic of an algorithm (and in fact both sections are linked). At the conclusion of this diagnostic arm the user is invited to consider an alternative diagnosis. This is particularly important in the case of a diagnosis of 'wet' AMD which has a number of mimicking conditions for which the OCT appearance is very similar but the patient management decisions are markedly different. The OCTAID site also contains sections on scanning protocols, machine artefacts and the normal retina. The home page of OCTAID is illustrated in Figure 4.1.

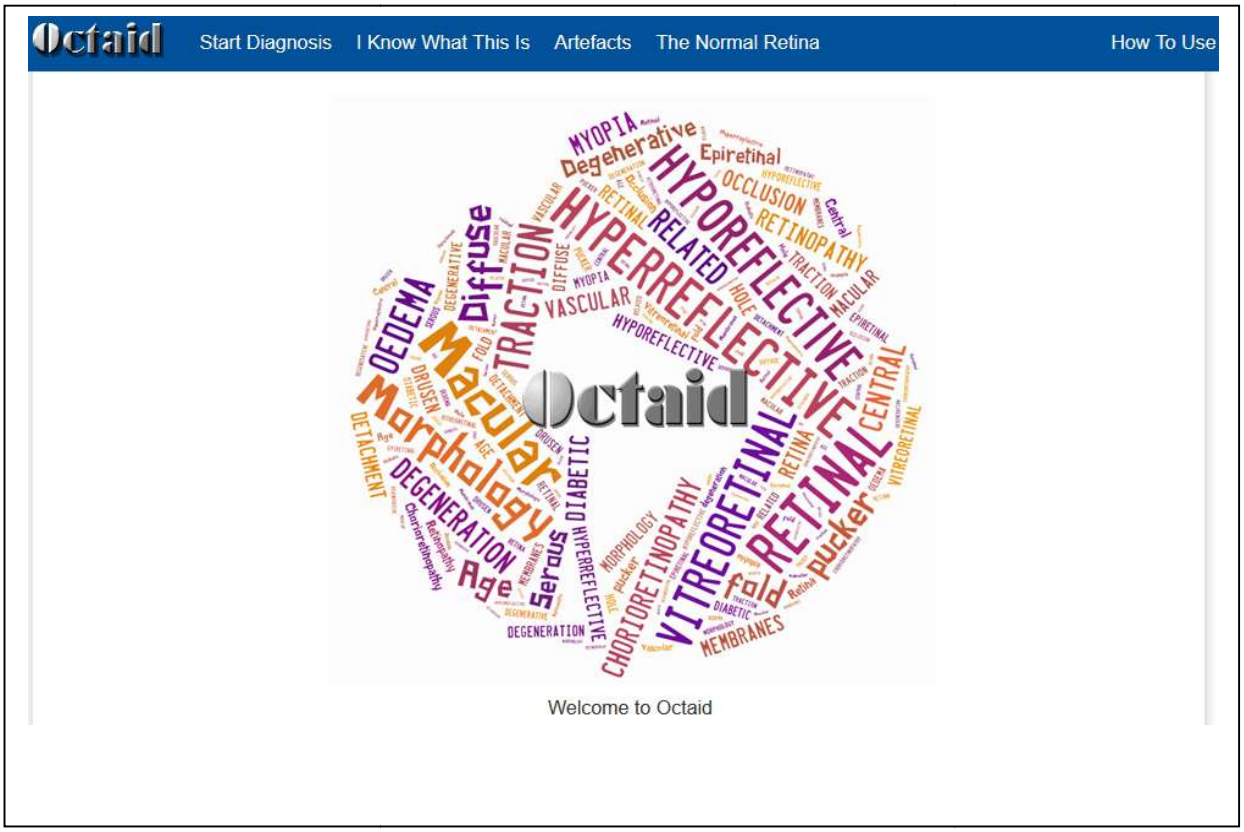

Figure 4.1 OCTAID front page showing the two main diagnostic arms i) Start Diagnosis and ii) I know what this is

Figure 4.2 below shows a typical pathway along the OCTAID algorithm to a possible diagnosis of retinal fibrosis and the underlying categories of disease associated with it.

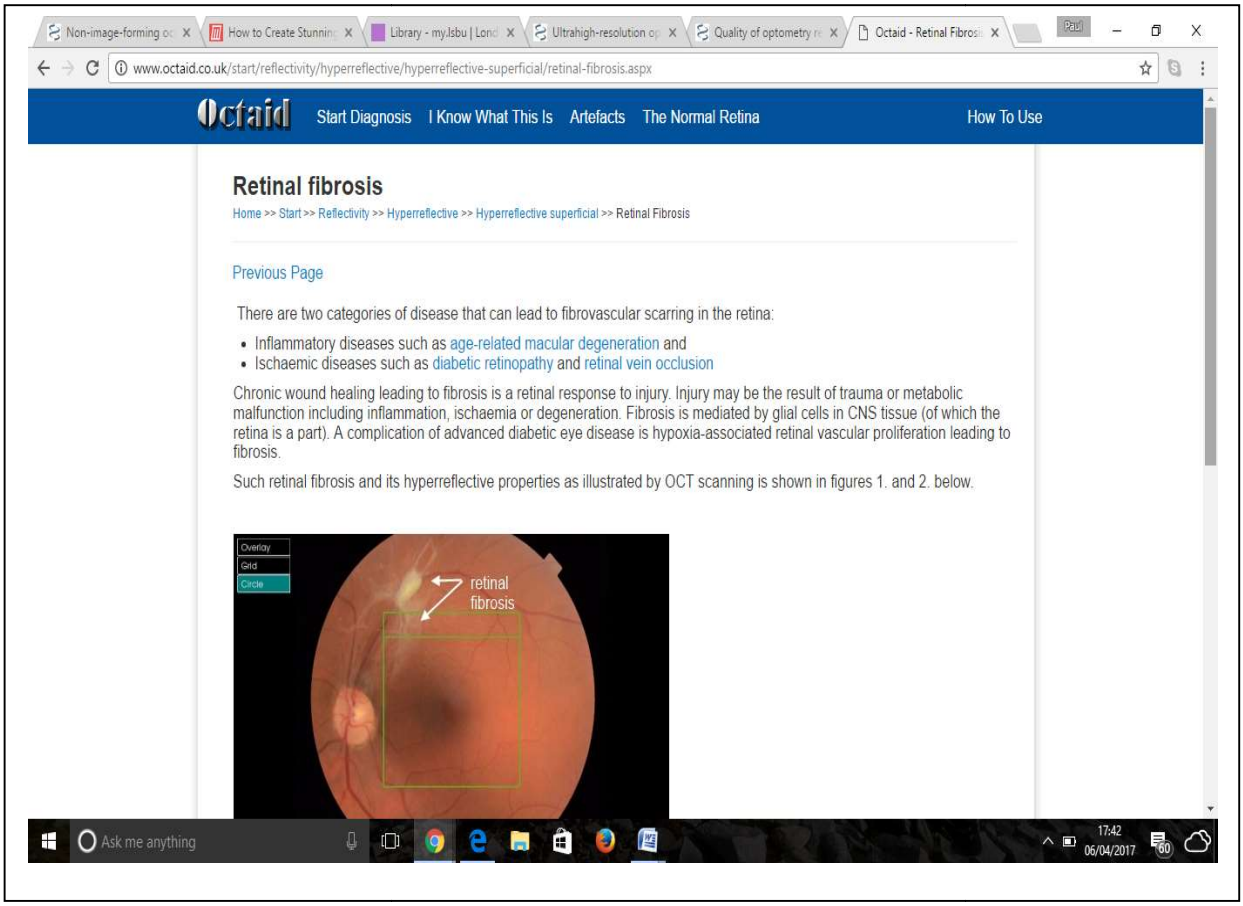

Figure 4.2 Home – Start diagnosis – Reflectivity – Hyperreflective – Hyperreflective Superficial – Retinal Fibrosis. Note that retinal fibrosis is only one of several diagnostic options (along with OCT images) OCTAID will offer to the user

OCTAID was developed over a 3 year period and currently consists of 28973 words over 184 web pages and 390 OCT scan images. It is securely hosted by Amazon Web Services and is password protected. It has been designed using the Umbraco software. Umbraco is an open source content management system (CMS) platform for publishing on the worldwide web. It is one of the most deployed web content management systems on the Microsoft tract (https://www.microsoft.com/web/umbraco/).

Back-up of OCTAID

Octaid is hosted on AWS (Amazon Web Services) on their EC2 (Elastic Compute Cloud) service which hosts a Windows 2008 cloud server running IIS (Internet Information Services) Umbraco which runs on the Asp.Net framework. It uses the open source database mysql to store its data.

To backup Octaid a scheduled task runs which does a mysql db export for that database along with a compressed password protected backup the entire web application folder for umbraco (containing application files and images). This is then sent to Dropbox.

An additional Amazon AMI (Amazon Machine Image) is also performed so that the entire Windows operating system and all data can be retrieved from Amazon S3 (Simple secure storage).

Expert panel

A single, error-free test that can be used as a reference (gold) standard may not exist in many diagnostic studies and the use of an imperfect reference standard may lead to errors in the final disease classification. There is also a risk in adopting new testing methods which may be inferior to existing methods. A widely used solution to the lack of a reference standard is "panel diagnosis" in which two or more experts will assess the results from multiple tests in a diagnostic study and reach a final diagnosis for each patient (Bertens *et al*. 2013).

Expert panels are an established consensus-finding method in clinical and health services research (Khodyakov *et al.* 2011) and often use a modified Delphi structure. Khodyakov *et al.* (2011) comment that although expert panels are a valuable tool for defining agreement on challenging subjects, they have some disadvantages. Firstly, it is necessary to identify a representative group of experts to form the panel and secondly, information-gathering must be co-ordinated around experts' schedules. Panel sizes are normally limited to ensure effective input from each member but at the same time panels should be large enough to reflect the diversity of opinion. Small panels of experts trained to a similar standard (who possess a general understanding in the field of interest) have been shown to provide effective and reliable responses that inform judgment and support effective decision making (Akins *et al*. 2005). Although panel diagnosis (also referred to in literature as consensus or expert

diagnosis) is often used as the reference standard, there is a lack of guidance on preferred methodology (Bertens *et al.* 2013). Available literature currently offers limited guidance on assembling and working with an expert panel for assigning a reference diagnosis for use in research (Handels *et al*.2014).

Handels *et al*. (2014) make a case for the use of a heterogeneous panel made up of experts with different backgrounds (although within the area of interest) and stated that heterogeneity of backgrounds could help prevent domination by a particular expertise. In the current study, expert panel members did not engage in dialogue with each other but rather with the author thus avoiding the possibility of individual experts dominating the debate.

The level of clinical experience of individual members of an expert panel may influence the degree to which each member might share in the exchange of feedback but the larger number of years of clinical experience attributable to each member of the panel recruited for this study might have been useful in preventing some panel members dominating the debate. Some difference might exist between the diagnostic accuracy of a panel made up of individuals with only a few years of experience and that of a very experienced panel but previous studies have not recommended a specific level of experience.

In this study an expert panel was recruited to play an advisory role in the design of the diagnostic algorithm and to act as a 'reference standard' in assessing practitioners' diagnostic and patient management skills by forming a consensus opinion on diagnosis/management based on OCT scans. The panel assisted in ensuring that the vignettes covered a suitable range of conditions and patient scenarios. The panel also helped to ensure that the two sets of vignettes had a similar level of difficulty and covered similar conditions. The panel consisted of two optometrists, two consultant ophthalmologists with special interest in medical retina conditions and a biomedical scientist. The biomedical scientist had a special interest in ocular imaging and technical expertise in OCT. All members of the expert panel were familiar with

OCT imaging and interpretation but it was thought that the strengths, limitations and artefacts of OCT scanning technology would be best known by an expert OCT technician. A shortlist of possible experts was drawn up based on: (i) a literature search of peer-reviewed publications of potential panelists, (ii) contribution to OCT forums, (iii) experience with OCT technology (in the case of a technician), and (iv) experience in OCT interpretation in a recognised specialist retinal clinic. Following consultation with the study supervisors an ordered list of preferred experts was made and the experts were approached in turn until the panel was filled.

The Delphi technique is a group process used to survey and collect the opinions of experts on a selected topic (Yousuf, 2007). The Delphi technique is not a single, clearly understood procedure but a family of techniques. It features a series of stages in which information is collected from panelists, then analysed and fed back to them as the basis for subsequent stages. An opportunity then exists for individuals to revise their judgments on the basis of this feedback. In conventional Delphi techniques there is some degree of anonymity for an individual's contributions whereas in conventional decision making, input is thought to be very subjective and might therefore risk marginalising an individual's critical judgment.
Myint *et al* (2010) developed a competency framework using a modified Delphi methodology for optometrists with a specialist interest in glaucoma and found that the application of such a consensus methodology allowed the development of a competency framework for glaucoma specialisation by optometrists thus helping to shape the development of a speciality curriculum.

A Delphi technique was initially considered in this study to collate expert panel feedback. There are a variety of methodological interpretations of the Delphi technique and many studies claiming to have used the technique have been widely published in nursing and allied health literature (Powell, 2003). However, the author and supervisors formed a consensus that normal Delphi methodology would not provide a practical solution to this study's aims and

within a reasonable timescale. Expert panel members were not blinded from the identity of other panel members or from each other's opinion in the exchange of feedback because it was thought that potential recruits to the expert panel would have been less likely to assist in the study if they did not know the status and credentials of fellow panel members. The sheer volume of work involved in a review of the OCTAID website and the clinical vignettes (80 questions in the pilot study) meant that repeated iterations after each amendment would have been asking too much of the panel. Furthermore, there may have been difficulties in ensuring adequate anonymisation of responses and the process of feedback recovery would have imposed considerable time delays in completing the study. The technique of blinding the experts from each other's opinion may have avoided the potential negative effects of individuals being swayed or intimidated by others. Although there existed in this study the potential for bias towards dominant experts, no evidence of this emerged during feedback exchanges.

This study's approach to obtaining expert feedback was designed to secure the opinion of experts without the need to bring them together face to face thus achieving a workable consensus within time limits. This approach still allowed panellists to reappraise their views in the light of the responses of the group as a whole but panel members were only required to correspond with the author.

As with the Delphi method, the limitations of this technique lie in the necessary process of selecting a suitable panel and the fact that the use of their views may limit the scope covered in the development of diagnostic/referral criteria (Harrington, 1994).

The author conducted two separate face to face meetings with the two consultant ophthalmologist members of the expert panel at Moorfields Eye Hospital. This method was suggested by the author as it was thought that the feedback task would be much less onerous

(in terms of time commitment) for these very busy clinicians and it was proving difficult to obtain replies to emails. All other expert panel members provided feedback by email.

Chapter 5: Development of vignettes to assess efficacy of OCTAID

This chapter describes:

- The clinical vignette format of assessment and the reasons why this exam format was chosen for this study
- The design of the clinical vignettes
- The multiple choice question format and its integration into the clinical vignettes
- The role of an expert panel in the design of the vignettes and exam questions
- The role of a pilot study in the design of the vignettes and exam questions

The author designed all of the questions within the two exam modules. Each exam module contained 8 sets of questions (3 questions in each set) presented as clinical vignettes and included OCT images. A further 8 questions tested participants' more general OCT and medical retina knowledge. All questions were in MCQ format and because questions within each vignette set were related to each other, it was not possible for participants to return to a question once answered.

In the current research it was decided that in order to take account of the range of knowledge required, the assessments should take the form of clinical vignettes covering the issues of scan interpretation and patient management but also including more general questions relating to OCT and retinal disease.

Clinical vignettes are a learning tool for medical students and other clinicians. Medical doctors are often assessed in 5 domains: history taking, physical examination, radiologic and laboratory testing, diagnostic accuracy and clinical treatment or management. Clinical vignettes commonly take the form of computerized case simulations and are frequently used by educators (Shah *et al.* 2007). They are designed to simulate patient consultations and

measure a clinician's ability to diagnose and manage medical conditions (Peabody *et al.* 2004). A clinical vignette is typically designed and scored by skilled experts, can simulate a range of medical conditions and will adopt a stepwise approach for diagnosis and the management plan (Shah *et al.* 2007). Vignettes are a valid and cost-effective way of measuring diagnostic skills and are therefore well suited to large scale assessments (Peabody *et al.* 2004). Peabody *et al.* (2000) identified some uncertainty over the question of whether vignettes reflect clinical practice or a practitioner's competence at the vignette task. Some research suggests that carefully designed computerised clinical vignettes can obtain valuable data in measuring a clinician's ability to diagnose and treat specific medical conditions although other researchers suggest that practitioners may respond differently in a vignette as they are in an assessment situation (Shah *et al.* 2007).

Optometric educators aspire to learning outcomes that produce competent practitioners. Online formative assessments are widely used and popular in higher education settings (Velan *et al.* 2008). Multiple choice questions (MCQs) were chosen as a method of assessment within this study for sound practical and educational reasons. MCQs can be designed that promote and measure critical thinking but significant thought commitment is required to design MCQs and examination formats that are reliable and consistent with learning objectives (Morrison and Free, 2001). MCQs are a well-established method of assessing factual knowledge and are considered to be both reliable and discriminating. Some assessors have questioned the use of MCQs in higher education because of their strong association with assessing lower order cognition such as the recall of discrete facts (Scouller, 1998). However, it is possible to design MCQ tests to test higher order cognition (such as synthesis, creative thinking and problem solving) but these questions need to be more carefully designed if they are to be valid and reliable (Palmer and Devitt, 2007).

MCQs are perhaps only one component in the assessment of clinical competence and perhaps should not constitute the only form of assessment (Moss, 2001). However, the majority of

MCQs within this study were integrated effectively into clinical vignettes. Other forms of clinical assessment involving extended writing would have placed a significant time burden on potential participants and could have been an inhibiting factor in recruitment.
Participants can typically answer an MCQ more quickly than an essay question. Extra validity may therefore be added to the MCQ exam format by the fact that a broader range of topics may be covered within a given time.

MCQs allow objective scoring (there can only be one correct answer in a well-designed question so marker bias is eliminated). In addition, MCQs are efficient and capable of discrimination and can be combined with other assessment strategies (Brady, 2005). The power of MCQs lies in the question design and the context within which the questions are used.

MCQs are less effective at testing a participant's ability to articulate an explanation or their ability to produce creative ideas. However, these weaknesses were thought to be less relevant in the context of this study.

Expert panel

The same expert panel who provided a consensus opinion on the OCTAID website also reviewed both of the vignette exam modules used in the research. Their task was to ensure that the questions within the clinical vignettes:

- Covered a range of retinal conditions and patient scenarios which would commonly be encountered in optometric practice
- Were not tailored to either OCTAID or the control OCT guide (or vice versa) in the case of the second exam assessment so that no unfair advantage was conferred upon either group

- Had a reasonable level of difficulty
- Were accurately presented and avoided confusion or ambiguity

In addition, the panel ensured that the same range of retinal conditions and patient scenarios were covered in both exams and with the same level of difficulty. The level of exam difficulty was an important measure. An exam that was too easy or too hard would not have produced an appropriate spread of results (too many subjects at the higher or lower end of the score range) thus making differentiation between participants more difficult. Also, a high level of difficulty would have served as a disincentive to many participants or resulted in a high attrition rate.

Pilot study

Pilot study participants provided feedback on:

- The length and level of difficulty of the exam task
- The ease of navigation of the online exam

This is discussed in more detail in the methods section (pilot study results, page 110).

A dropbox link to the clinical vignettes is provided here:

https://www.dropbox.com/sh/uclppmkurvmjjbr/AADrCmy3Kfsc_JDsJWG6X9zsa?dl=0

Chapter 7: Results

This chapter will provide:

- A description of sample size, attrition rate and the study population
- A summary of the general descriptive data
- Comparative statistics (OCTAID v Control)
- Results for secondary outcome measures

Participants and sample size

One hundred and sixty signed consent forms were returned. Fifty percent (80) were randomly allocated to the OCTAID group with the other half allocated to the control group. All of these subjects were sent an automated email from the exam host (LearnUpon) which contained a live link. By clicking on this link participants acknowledged receipt of their invitation and were registered on the LearnUpon platform from where they were directed to enrol for the study. One hundred and fifty participants registered on the LearnUpon platform and ten did not. These 10 were termed "pending users". Four participants registered on the LearnUpon platform but did not then go on to enrol for the study. They were termed "pending user enrolments". One hundred and forty six participants fully enrolled for the study on the LearnUpon platform. One hundred and thirty four participants completed the first exam module (12 enrolled but did not start). Sixteen participants completed the first exam task but did not go on to complete the second exam task.

A total of 118 out of the 160 participants, who returned their signed consent forms (74%), participated fully in training and completed both assessments. They therefore formed the analysis population. There were strategies employed to maximise recruitment, retain participation and minimise attrition in this study and this has already been discussed in detail in the chapter on study methods.

Participants were randomly allocated to groups and enrolled before the beginning of the study (as described above) and therefore before the results of the first assessment were known. Fifty three participants formed the study (OCTAID) group and 65 participants formed the control group.

General descriptive data

Fifty three participants (n=53) from the study group (OCTAID) completed the course with a mean score of 67.2% in the first exam. Thirty eight participants passed the first exam (71.7%) by achieving a score of 60% or more and 15 failed (Table 6.1).

Sixty five participants from the control group completed the course achieving a mean score of 63.7% in the first exam (Table 5.3). Forty of these participants passed the exam (61.5%) and 25 failed to achieve the pass mark of 60% (Figure 5.1).

Exam 1

GROUP * PASSRATE Crosstabulation

Count

		PASSRATE		Total
		Fail	Pass	
GROUP	OCTAID	15	38	53
	Control	25	40	65
Total		40	78	118

Table 6.1 – Pass/fail rate for exam 1

The mean scores and distribution of scores in exam 1 are summarised in Tables 6.2 and 6.3 and the pass/fail rate for each group is further illustrated in the bar chart in Figure 6.1.

OCTAID

Exam 1 score

N	Valid	53
	Missing	0
Mean		67.17%
Std. Error of Mean		1.948
Median		66.00
Mode		66[a]
Std. Deviation		14.184
Variance		201.182
Skewness		-.775
Std. Error of Skewness		.327
Range		63
Minimum		25
Maximum		88

Table 6.2-Exam 1 results (OCTAID)

Control

Exam 1 score

N	Valid	65
	Missing	0
Mean		63.72%
Std. Error of Mean		1.905
Median		63.00
Mode		63
Std. Deviation		15.357
Variance		235.828
Skewness		-.481
Std. Error of Skewness		.297
Range		78
Minimum		16
Maximum		94

Table 6.3 – Exam 1 results (Control)

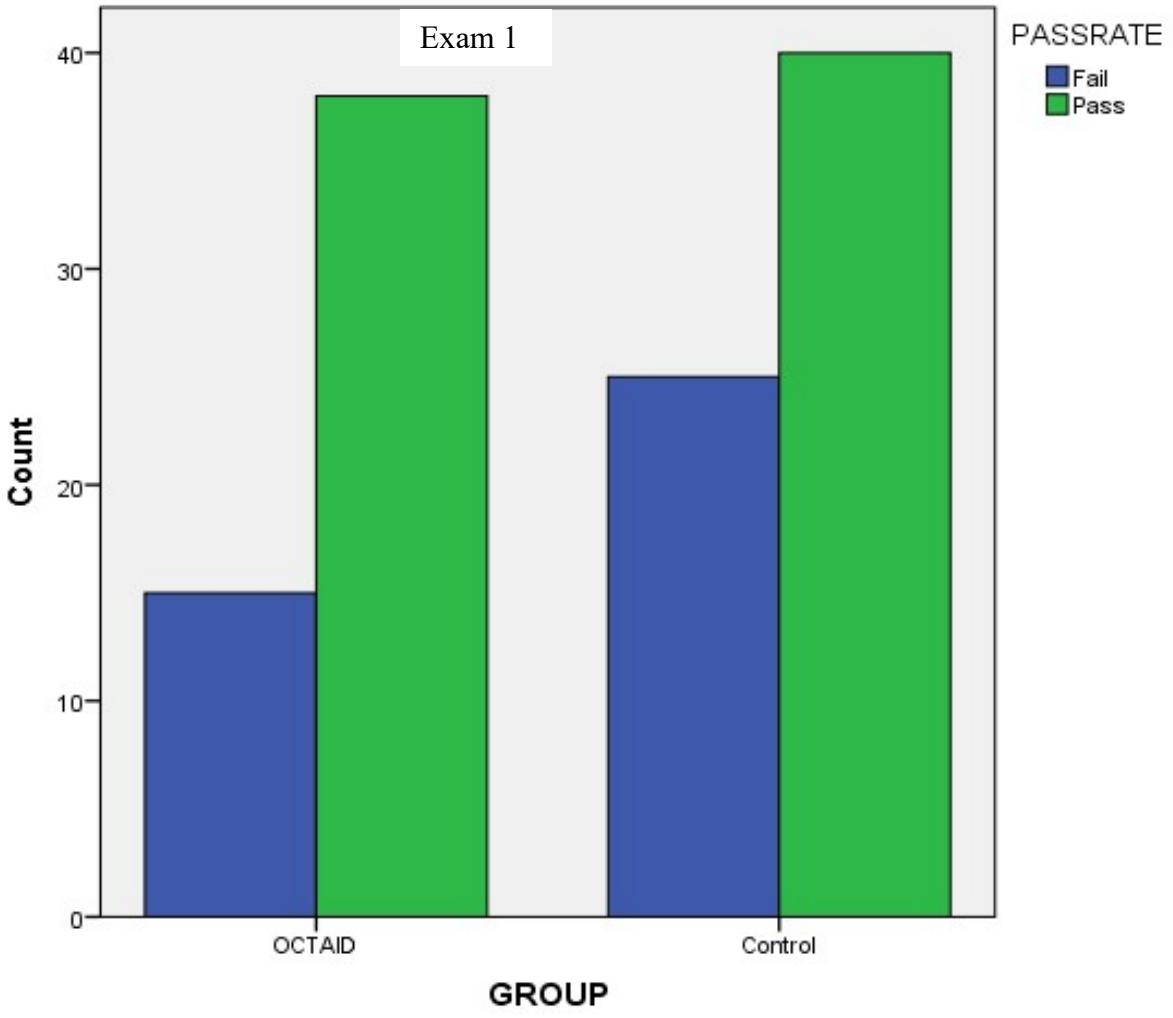

Figure 6.1 – Bar chart of pass/fail rate in Exam 1

When comparing exam performance in terms of the pass/fail rate, there was no statistically significant difference between the OCTAID and Control groups in the first exam (Fisher's 2 sided Exact Test, p = 0.328).

In the second exam, following the educational intervention (OCTAID in the case of the study group and conventional educational materials in the control group) 50 participants (94.3%) in the OCTAID group passed the exam (achieved more than 60%) and only 3 (5.7%) failed. Their mean score was 80.6%. Forty nine participants passed the second exam (75.4%) in the Control group and 16 (24.6%) failed. Their mean score was 70.9%. (Tables 6.4, 6.5 and 6.6).

PASSRATE * GROUP Crosstabulation

Count

Exam 2		GROUP		Total
		OCTAID	CONTROL	
PASSRATE	Fail	3	16	19
	Pass	50	49	99
Total		53	65	118

Table 6.4 – Table of pass/fail rate Exam 2

OCTAID

Exam 2 score

N	Valid	53
	Missing	0
Mean		80.57%
Std. Error of Mean		1.695
Median		81.00
Mode		91
Std. Deviation		12.337
Variance		152.212
Skewness		-1.845
Std. Error of Skewness		.327
Range		66
Minimum		31
Maximum		97

Table 6.5 – Exam score for Exam 2 (OCTAID)

Control

Exam 2 score

N	Valid	65
	Missing	0
Mean		70.89%
Std. Error of Mean		1.623
Median		72.00
Mode		63
Std. Deviation		13.084
Variance		171.191
Skewness		-.063
Std. Error of Skewness		.297
Range		56
Minimum		41
Maximum		97

Table 6.6 – Exam score for Exam 2 (Control)

The bar chart in Figures 6.2 illustrates the pass/fail rates in Exam 2 for the OCTAID and Control groups.

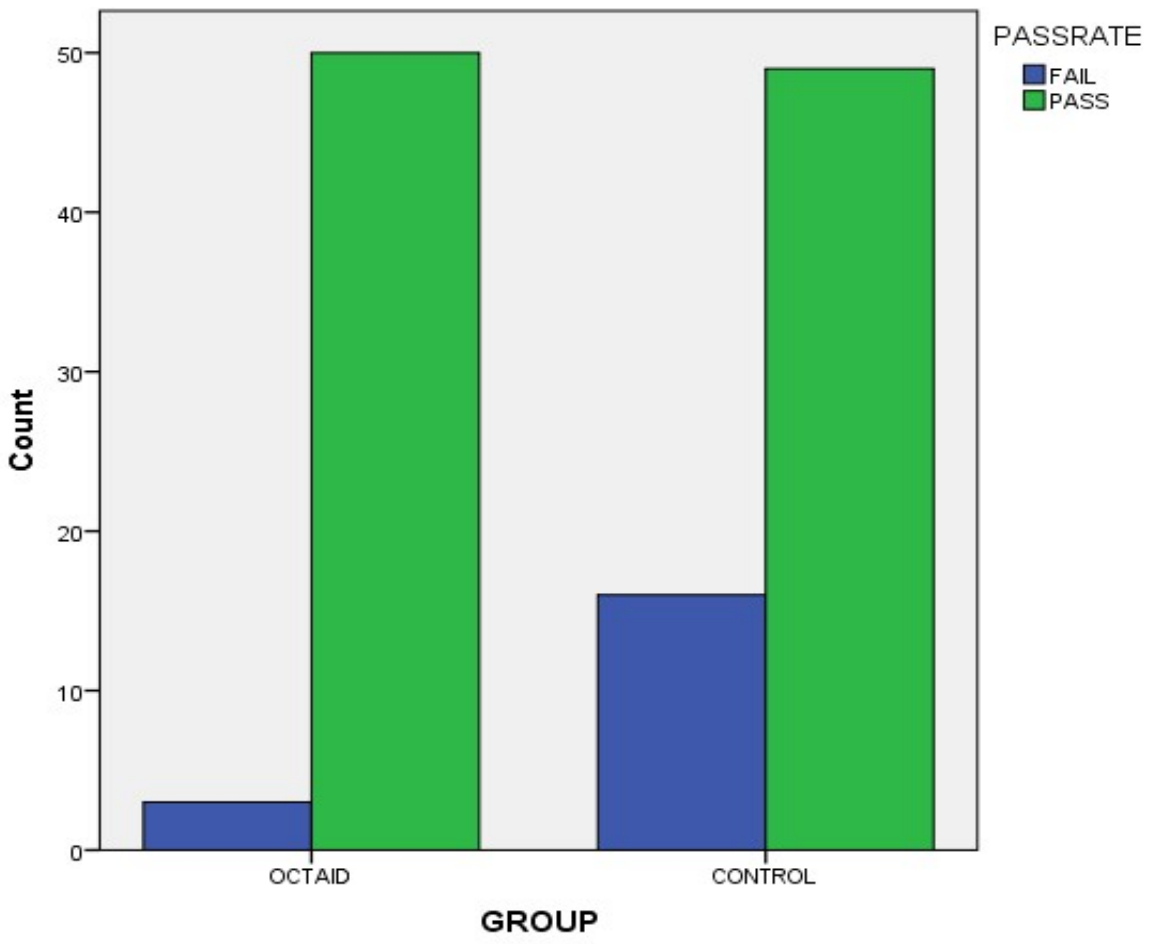

Figure 6.2 Bar chart of pass/fail rate in Exam 2

There was a statistically significant difference between the OCTAID and the Control group in their pass/fail rate in the second exam which followed the educational intervention (Fisher's Two Sided Exact test, p = 0.006).

The mean improvement in exam performance (the score gain) in the OCTAID group was 13.4% (score in exam 2 minus the score in exam 1 = 80.57 – 67.17 = 13.4%).

The mean improvement in exam performance in the control group was 7.17% (score in exam 2 minus the score in exam 1 = 70.89 - 63.72 = 7.17%).

Comparative statistics: OCTAID v control

The primary outcome measure was the change in exam score or improvement (score in exam 2 minus the score in exam 1). Participants were randomly allocated to OCTAID or Control groups and enrolled at the beginning of the study and therefore before commencing the first exam. Therefore, the scores in the first exam did not influence the allocation of participants to groups and there was no re-allocation of participants in response to withdrawals from the study. The score in the first exam was thought to be a reasonable measure of a participants baseline OCT knowledge. Although the allocation of participants to groups was random, statistical tests were conducted to test for possible differences between the groups in terms of their performance in Exam 1(their baseline knowledge) using the Independent Samples T-test. No statistically significant difference in mean exam 1 performance ($p = 0.212$) was identified between the two groups of participants (2-tailed).

However, when comparing the two groups in their second exam performance (after the intervention) a significant difference was found in their exam score. In each group the mean Exam 1 score was compared with the mean Exam 2 score by calculating the percentage improvement from Exam 1 to Exam 2. The OCTAID group improved by 13.4% compared with an improvement of 7.2% in the control group.

The primary outcome measure was the change in exam score or improvement (score in exam 2 minus the score in exam 1). The mean improvement in exam scores between exam 1 and exam 2 for each group is summarised in table 6.7 below:

Group Statistics

	GROUP	N	Mean	Std. Deviation	Std. Error Mean
improvement	OCTAID	53	13.62	12.662	1.739
	Control	65	7.17	11.828	1.467

Table 6.7 – Table showing score improvement

Applying the independent samples T test, a statistically significance difference between the OCTAID and control groups was demonstrated with the OCTAID group showing a significantly improved exam score compared with the control group (2-tailed p = 0.005).

This is further illustrated in the box/whisker chart in figure 6.5 below.

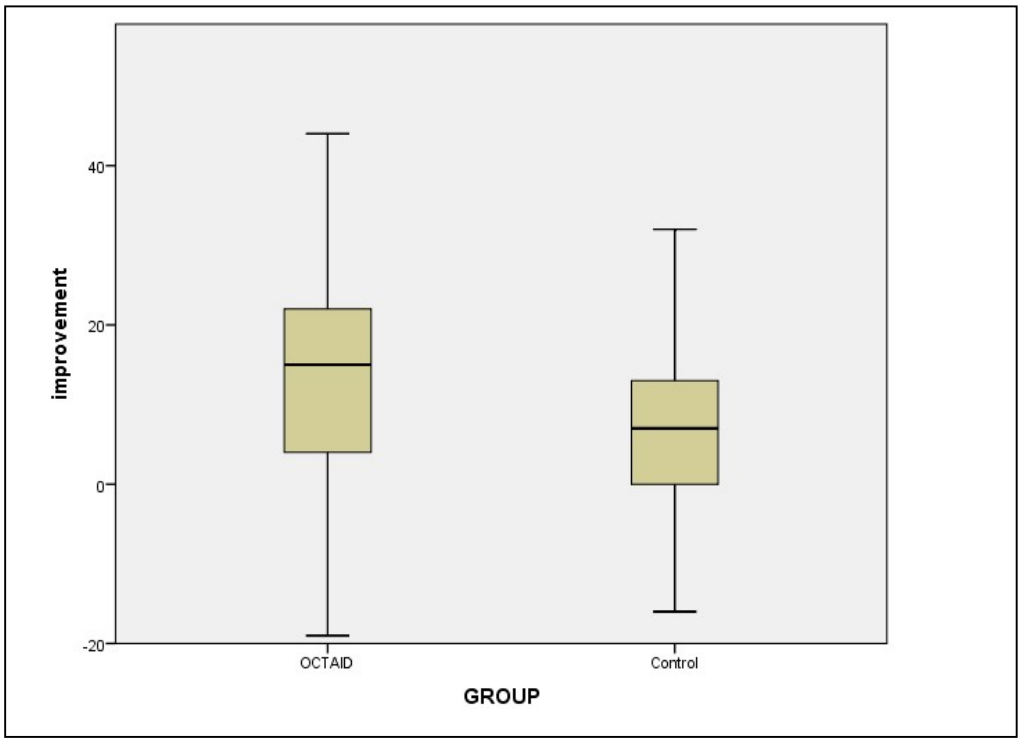

Figure 6.5 – Box whisker chart showing score improvement (OCTAID v Control)
(In a box whisker chart the ends of the box are the upper and lower quartiles so the box spans the interquartile range – the median is marked bythe horizontal line inside the box)

The scatter dot charts in Figures 6.6 and 6.7 illustrate the different impact of each educational intervention in terms of the improvement in exam score versus the participants' baseline OCT knowledge (exam 1 score).

OCTAID

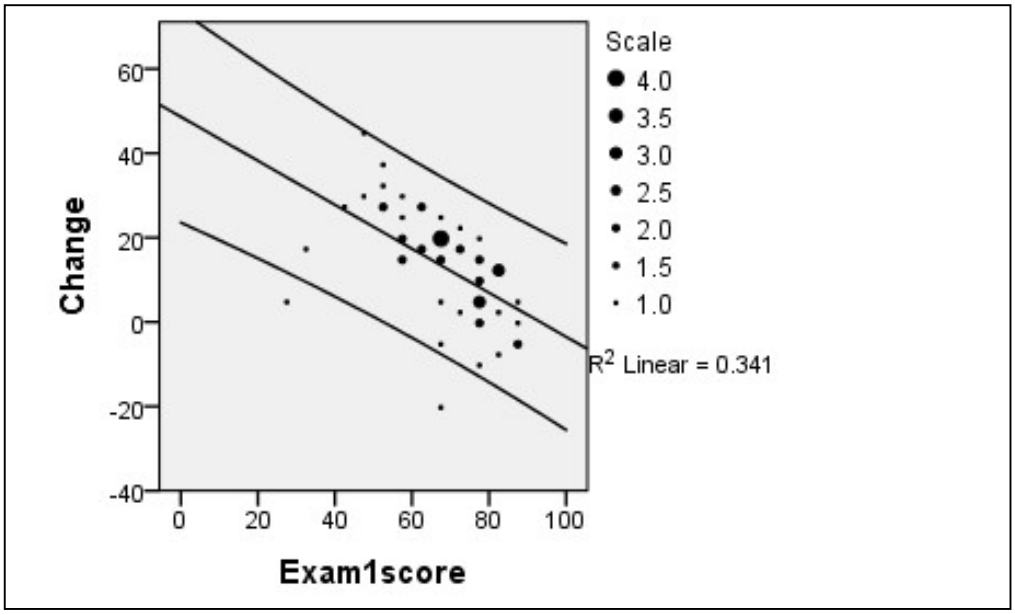

Figure 6.6–Scatter dot chart Exam1 score v change

Control

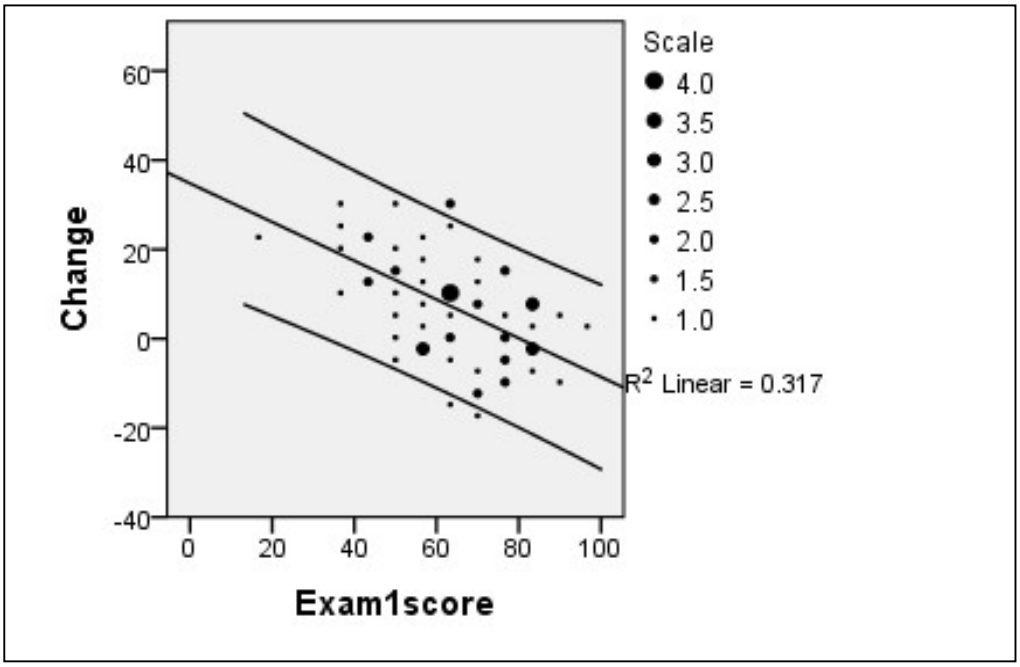

Figure 6.7-Scatter dot chart Exam1 score v change

These scatter dot charts show the impact of the OCTAID intervention in improving participants' score from their baseline knowledge (exam 1 score) compared to the control intervention. R^2 (coefficient of determination) is a statistical measure of how close data are to the fitted regression line.

Participants in both groups (OCTAID and control) showed improvement in their OCT knowledge following educational intervention. However, participants who received OCTAID

improved their exam score level significantly more than those who received conventional educational materials.

Co-varying for participants prior level of experience

Participants were asked about their prior OCT experience (in terms of how often they assessed OCT images) and three subgroups were formed for more detailed analysis. Participants' OCT experience ranged from inexperienced or 'novice' to experienced with an intermediate subgroup in between. This has been discussed in detail in the Methods chapter (pilot study methods). The intermediate subgroup members were small in number (6 in the control group and 3 in the OCTAID group) and their exam scores were not subjected to detailed analysis.

Novice subgroup

The 'novice' subgroups of participants (n = 21 for the OCTAID group, n = 19 for the Control group) performed similarly in their first exam score with a mean score of 57.7% for the OCTAID group and 57.95% for the Control subgroup (Tables 6.8 and 6.9).

OCTAID (novice subgroup)

Exam 1 score

N	Valid	21
	Missing	0
Mean		57.67%
Std. Error of Mean		3.040
Median		56.00
Mode		50[a]
Std. Deviation		13.930
Variance		194.033
Skewness		-.762
Std. Error of Skewness		.501
Range		53
Minimum		25
Maximum		78

a. Multiple modes exist. The smallest value is shown

Table 6.8 – Exam 1 scores (Novice OCTAID)

Control (novice subgroup)

Exam 1 score

N	Valid	19
	Missing	0
Mean		57.95%
Std. Error of Mean		3.836
Median		59.00
Mode		50[a]
Std. Deviation		16.721
Variance		279.608
Skewness		-.781
Std. Error of Skewness		.524
Range		68
Minimum		16
Maximum		84

a. Multiple modes exist. The smallest value is shown

Table 6.9 – Exam 1 scores (Novice Control)

There was no significant difference in the mean exam 1 score between the two novice subgroups when applying the independent sample T test (2 tailed p = 0.954). However, there was a significant difference between the two subgroups when comparing their mean exam score in the second exam. The mean exam 2 score for the OCTAID subgroup was 77.8% compared with 65.2% for the Control subgroup (Tables 6.10 and 6.11).

OCTAID (novice subgroup)

Exam 2 score

N	Valid	21
	Missing	0
Mean		77.76%
Std. Error of Mean		3.369
Median		81.00
Mode		69[a]
Std. Deviation		15.437
Variance		238.290
Skewness		-1.733
Std. Error of Skewness		.501
Range		63
Minimum		31
Maximum		94

a. Multiple modes exist. The smallest

Table 6.10 – Exam 2 scores (Novice OCTAID)

Control (novice subgroup)

Exam 2 score

N	Valid	19
	Missing	0
Mean		65.16%
Std. Error of Mean		3.648
Median		59.00
Mode		59
Std. Deviation		15.900
Variance		252.807
Skewness		.397
Std. Error of Skewness		.524
Range		50
Minimum		41
Maximum		91

Table 6.11 – Exam 2 scores (Novice Control)

Comparing the mean exam 2 scores by the independent samples T test, a statistically significant difference between the two novice subgroups was demonstrated (2 tailed p = 0.015). The OCTAID subgroup improved their mean exam score by 20.1% compared with a mean improvement of 7.2% in the control subgroup.

The secondary outcome measure of the exam pass/fail rate in the two subgroups is summarised in the tables below (Tables 6.12 and 6.13). In the first exam, almost equal numbers of participants passed and failed. Eleven failed and 10 passed (47.6%) in the OCTAID subgroup whereas 10 failed and 9 passed (47.4%) in the Control subgroup. In the second exam only 2 participants from the OCTAID subgroup failed with the remaining 19 passing (90.5%). In the control subgroup the pass/fail rate remained unchanged from the first exam with 10 participants failing the exam and 9 passing (47.4%).

PASSRATE * GROUP Crosstabulation

Exam 1 (novice subgroup)

		GROUP		Total
		OCTAID	Control	
PASSRATE	FAIL	11	10	21
	PASS	10	9	19
Total		21	19	40

Table 6.12–Pass/fail rate Exam 1 (Novice groups)

PASSRATE * GROUP Crosstabulation

Exam 2 (novice subgroup)

		GROUP		Total
		OCTAID	Control	
PASSRATE	FAIL	2	10	12
	PASS	19	9	28
Total		21	19	40

Table 6.13–Pass/fail rate Exam 2 (Novice groups)

Chi square analysis of the pass/fail rate showed no significance difference between the OCTAID and Control subgroups in Exam 1 (Fisher's 2 sided exact test, $p = 1.00$). However, a statistically significant difference was demonstrated between the two groups in their pass/fail rate in Exam 2 with the OCTAID subgroup outperforming the Control subgroup in their pass rate (Fisher's Exact test 2 sided $p = 0.005$).

The mean changes in exam score (exam 2 score minus exam 1 score) are summarised in the Table 6.14 below:

Novice subgroups

	GROUP	N	Mean	Std. Deviation	Std. Error Mean
IMPROVEMENT	OCTAID	21	20.10	12.596	2.749
	Control	19	7.21	10.952	2.513

Table 6.14 – Mean score improvement OCTAID v Control

The mean OCTAID subgroup exam score improvement was 20.1% compared with 7.2% in the control subgroup. Independent samples T test demonstrated statistically significantly better outcomes in terms of score improvement in the OCTAID subgroup (2-tailed p = 0.001). The primary outcome measure of exam score improvement is summarised in the box-whisker chart below (Figure 6.8).

Novice subgroups

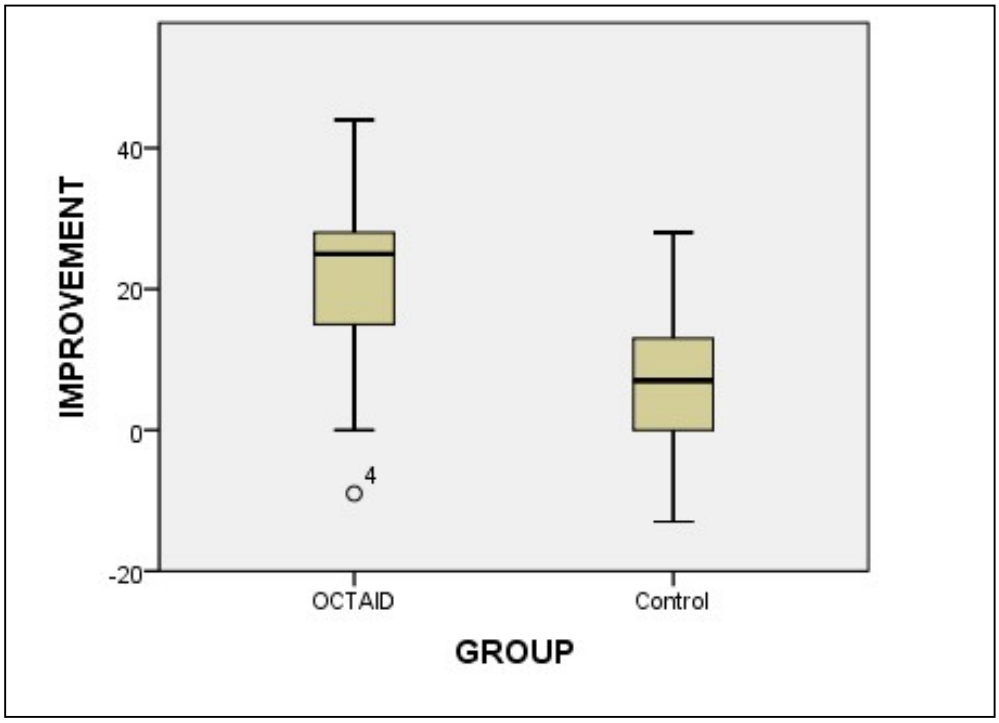

Figure 6.8 – Box whisker chart showing score improvement in exam scores OCTAID v Control

The scatter dot charts in figures 6.9 and 6.10 illustrate the different impact of each educational intervention in terms of the improvement in exam score versus the participants' baseline OCT knowledge (Exam 1 score).

OCTAID (novice subgroup)

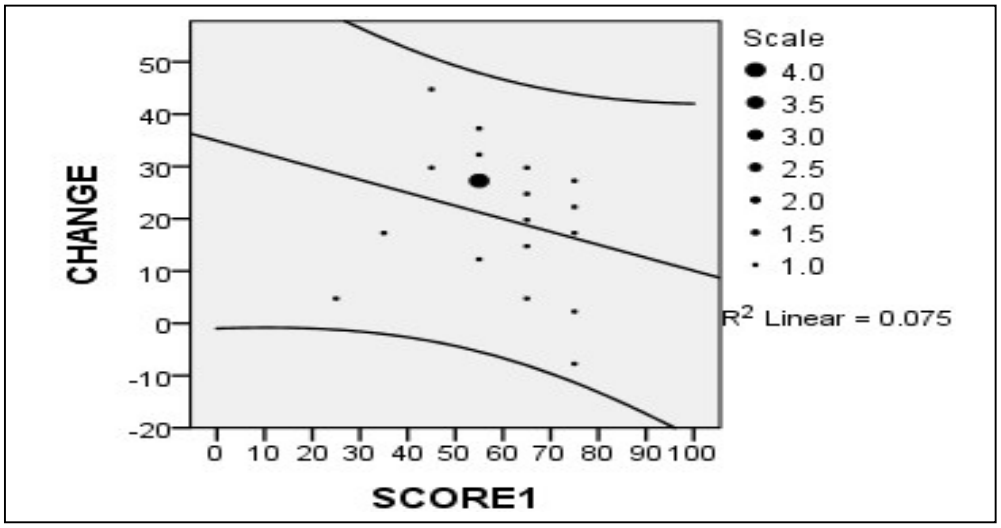

Figure 6.9–Scatter dot score 1 v change

Control (novice subgroup)

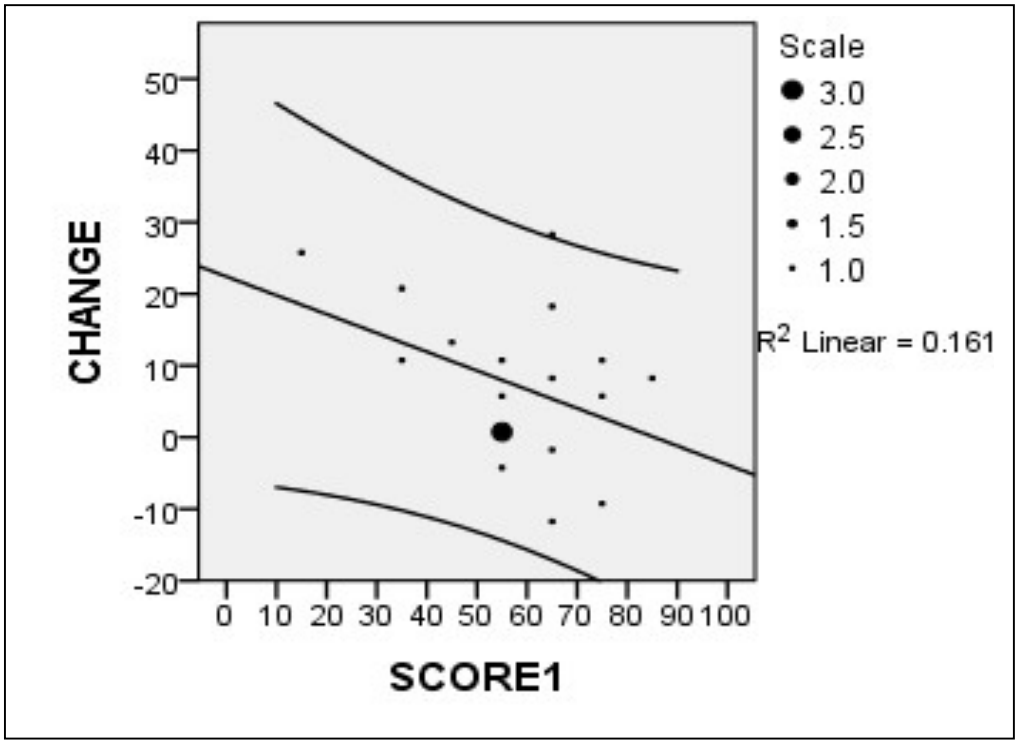

Figure 6.10 – Scatter dot score 1 v change

Expert subgroup

As expected, the 'expert' subgroups in the study performed best over the two exams with the OCTAID subgroup (n = 29) achieving a mean score of 73.5% in Exam 1compared with 68.7% in the control subgroup (n = 40; Tables 6.14 and 6.15).

OCTAID (expert subgroup)

Exam 1

N	Valid	29
	Missing	0
Mean		73.45%
Std. Error of Mean		2.035
Median		78.00
Mode		78
Std. Deviation		10.956
Variance		120.042
Skewness		-.496
Std. Error of Skewness		.434
Range		41
Minimum		47
Maximum		88

Table 6.14 Exam 1 score Expert OCTAID

Control (expert subgroup)

Exam1

N	Valid	40
	Missing	0
Mean		68.68%
Std. Error of Mean		2.100
Median		69.00
Mode		63[a]
Std. Deviation		13.283
Variance		176.430
Skewness		-.394
Std. Error of Skewness		.374
Range		60
Minimum		34
Maximum		94

a. Multiple modes exist. The smallest value is shown

Table 6.15 Exam 1 score Expert Control

No significant difference between the OCTAID and Control subgroups was demonstrated in the chi square analysis of the pass/fail rate in exam 1 (Fisher's Exact test, 2 sided p = 0.535). In the OCTAID subgroup, 25 participants passed exam 1 and 4 failed whereas 31 participants from the control subgroup passed exam 1 and 9 failed. Twenty eight participants from the OCTAID subgroup passed Exam 2 with only 1 failing. Thirty five participants from the Control subgroup passed Exam 2 with only 5 failing (Tables 6.16 and 6.17). Chi square analysis of the pass/fail results in Exam 2 also showed no significant difference between the two subgroups (Fisher's Exact Test 2 sided, p = 0.389).

GROUP * PASSRATE Crosstabulation

Expert subgroups

		PASSRATE		Total
		FAIL	Pass	
GROUP	OCTAID	4	25	29
	Control	9	31	40
Total		13	56	69

Table 6.16 OCTAID v Control pass/fail Exam 1

GROUP * PASSRATE Crosstabulation

Expert subgroups

		PASSRATE		Total
		Fail	Pass	
GROUP	OCTAID	1	28	29
	Control	5	35	40
Total		6	63	69

Table 6.17 OCTAID v Control pass/fail Exam 2

The scores in exam 2 are summarised in the tables 6.18 and 6.19 below. The OCTAID expert subgroup's mean exam score improved by 9.1% compared with 5.8% in the Control subgroup. Analysis of the mean raw scores in exam 1 showed no significant difference between the two expert subgroups (2 tailed, $p = 0.118$). However, a statistically significant difference in the mean scores between the two expert subgroups (82.6% for the OCTAID group vs 74.5% for control group) was demonstrated in exam 2 (2 tailed, $p = 0.003$).

OCTAID (expert subgroup)

Exam 2

N	Valid	29
	Missing	0
Mean		82.62%
Std. Error of Mean		1.847
Median		84.00
Mode		91
Std. Deviation		9.944
Variance		98.887
Skewness		-1.365
Std. Error of Skewness		.434
Range		47
Minimum		50
Maximum		97

Table 6.18 – Exam 2 scores (Expert OCTAID)

Control (expert subgroup)

Exam 2

N	Valid	40
	Missing	0
Mean		74.53%
Std. Error of Mean		1.776
Median		75.00
Mode		75
Std. Deviation		11.232
Variance		126.153
Skewness		-.093
Std. Error of Skewness		.374
Range		47
Minimum		50
Maximum		97

Table 6.19 – Exam 2 scores (Expert Control)

The mean score improvement for each subgroup is summarised in table 6.20 below:

Group Statistics

	GROUP	N	Mean	Std. Deviation	Std. Error Mean
IMPROVEMENT	1	29	9.1	11.000	2.043
	2	40	5.8	12.226	1.933

Table 6.20 Mean score improvements (OCTAID v Control)

Although the expert OCTAID subgroup improved their exam score by more than the control group, this did not reach statistical significance when applying the independent samples T test (2-tailed p = 0.25). This may have been the result of a 'ceiling effect' within this generally high-scoring subgroup which is discussed further in Chapter 5.

The primary outcome measure of score improvement is summarised in the box-whisker chart below (Figure 6.11).

Expert subgroups

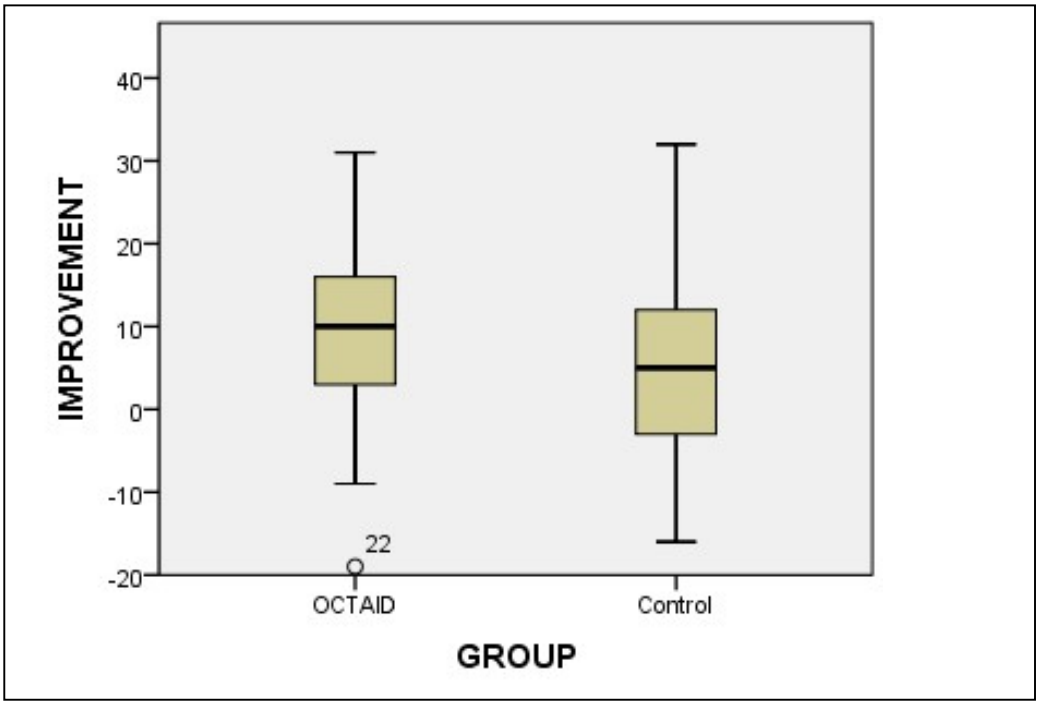

Figure 6.11 – Box whisker chart comparing score improvement for expert subgroups

The scatter dot charts in Figures 6.12 and 6.13 illustrate the different impact of each educational intervention in terms of the improvement in exam score versus the participants' baseline OCT knowledge (exam 1 score).

OCTAID (expert subgroup)

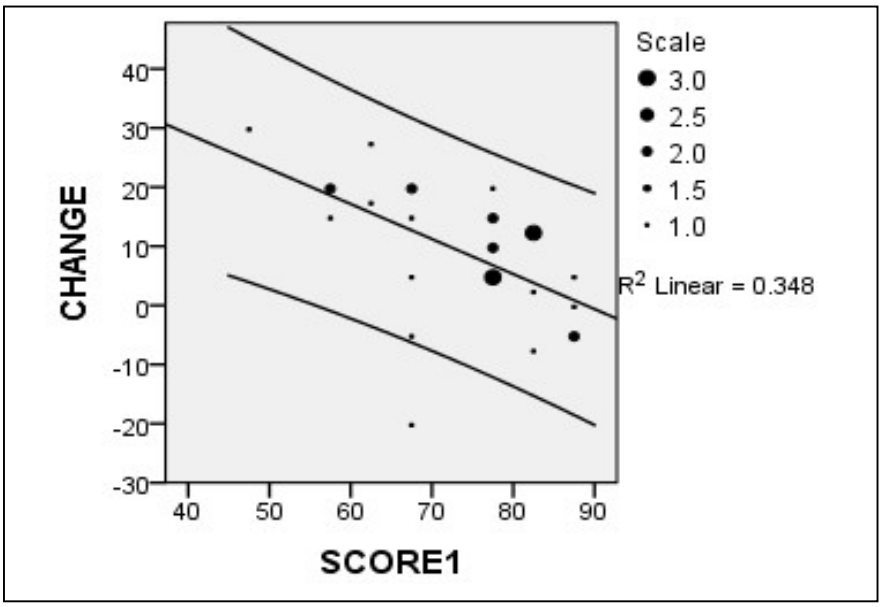

Figure 6.12 Scatter dot score 1 v change (OCTAID)

Control (expert subgroup)

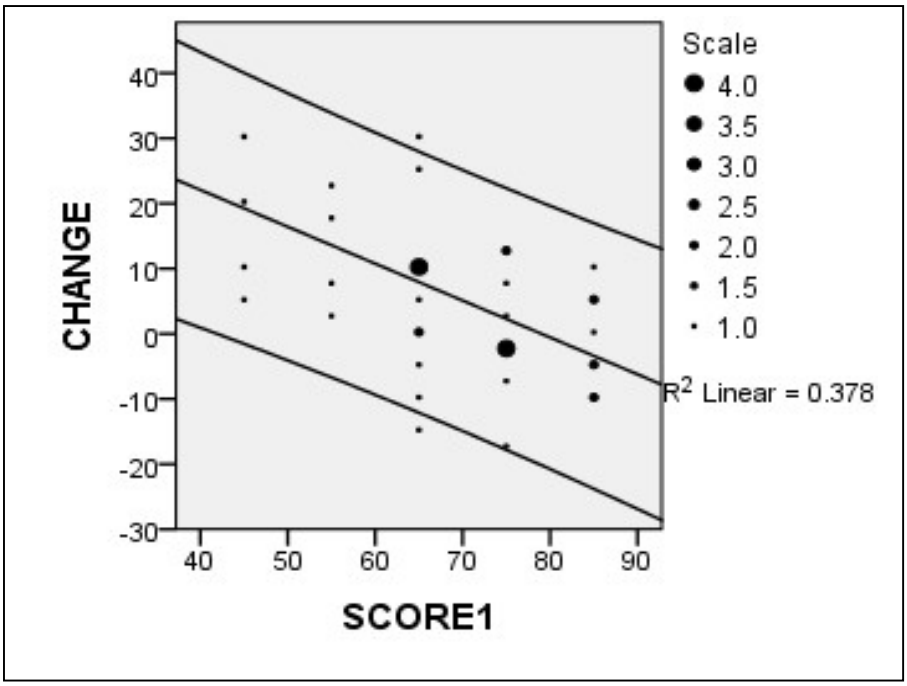

Figure 6.13 Scatter dot score 1 v change (Control)

Secondary outcome measures

Participants from both the OCTAID group and the Control group were asked how much time it took them to complete exam 1 and all 118 participants answered this question. The exam

modules were not timed and it is possible that participants who spent more time in researching the answers to questions might achieve a higher score. Based on feedback from the participants in the pilot study, it was estimated that most participants would complete each of the exam modules in less than 120 minutes. Four ordinal time categories were created for the tick-box replies of participants (less than 90 minutes, 90-120 minutes, 120 to 150 minutes, and more than 150 minutes). The results are summarised in Table 6.20 below.

GROUP * TIME Crosstabulation

Count

		TIME				Total
		Less than 90 mins	90 to 120 mins	120 to 150 mins	Over 150 mins	
GROUP	OCTAID	40	12	1	0	53
	CONTROL	54	10	0	1	65
Total		94	22	1	1	118

Table 6.20 Time spent completing exam 1 for OCTAID and Control

In view of the small numbers of participants in the 120-150mins and >150mins cells, the data were collapsed into two categories, namely <90 mins (94 participants across both groups) and > 90 mins (24 participants across both groups). This is represented in Table 6.21 below:

TIME * GROUP Crosstabulation

Count

		GROUP		Total
		OCTAID	CONTROL	
TIME	Less than 90 mins	40	54	94
	More than 90 mins	13	11	24
Total		53	65	118

Table 6.21 Time spent completing exam 1 for OCTAID and Control

Forty participants (76%) from the OCTAID group stated that they completed Exam 1 in less than 90 minutes compared with 54 (83%) participants from the control group.

Chi square analysis (Table 6.22) did not identify any statistically significant difference between the OCTAID and control groups in terms of time spent completing Exam 1 (Fisher's exact 2 sided, p = .361).

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	1.042[a]	1	.307		
Continuity Correction[b]	.626	1	.429		
Likelihood Ratio	1.037	1	.308		
Fisher's Exact Test				.361	.214
Linear-by-Linear Association	1.033	1	.309		
N of Valid Cases	118				

a. 0 cells (.0%) have expected count less than 5. The minimum expected count is 10.78.

b. Computed only for a 2x2 table

Table 6.22 Chi Square analysis of time spent on Exam 1 OCTAID v Control

Participants from both the OCTAID group and the Control group were also asked how much time it took them to complete exam 2 (with data analysed) using the same two time categories used for the exam 1 analysis (less than 90 minutes and more than 90 minutes). Eighty participants provided a response to this question (40 from each group).

GROUP * TIME Crosstabulation

Count

		TIME		Total
		Less than 90 minutes	More than 90 minutes	
GROUP	OCTAID	17	27	40
	CONTROL	27	13	40
Total		40	40	80

Table 6.23 Time spent completing exam 2 OCTAID v Control

For this question 17 participants (43%) from the OCTAID group stated that they completed exam 2 in less than 90minutes whereas 27 (68%) of the Control group stated that they had completed the exam in less than 90 minutes (Figure 6.23). In general the OCTAID group spent more time completing the second exam task than the control group (Table 6.24) and chi-square analysis showed that this difference in proportions was statistically significant (p = 0.042, Fisher's exact 2-sided test).

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	5.051[a]	1	.025		
Continuity Correction[b]	4.091	1	.043		
Likelihood Ratio	5.107	1	.024		
Fisher's Exact Test				.042	.021
Linear-by-Linear Association	4.987	1	.026		
N of Valid Cases	80				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 18.00.

b. Computed only for a 2x2 table

Table 6.24 Chi Square analysis of time spent on exam 2 OCTAID v Control

In another question participants from both the OCTAID group and the Control group were asked how much time they had spent studying the OCT resources (OCTAID or Control) provided by a live link after completion of the first exam.

Four ordinal time categories were created for participants to choose from in the questionnaire, completion of which immediately followed the second exam module (less than 2 hours, 2 to 4 hours, 4 to 6 hours, and more than 6 hours). The results are summarised in pie charts (Figures 6.14 and 6.15) and tables below.

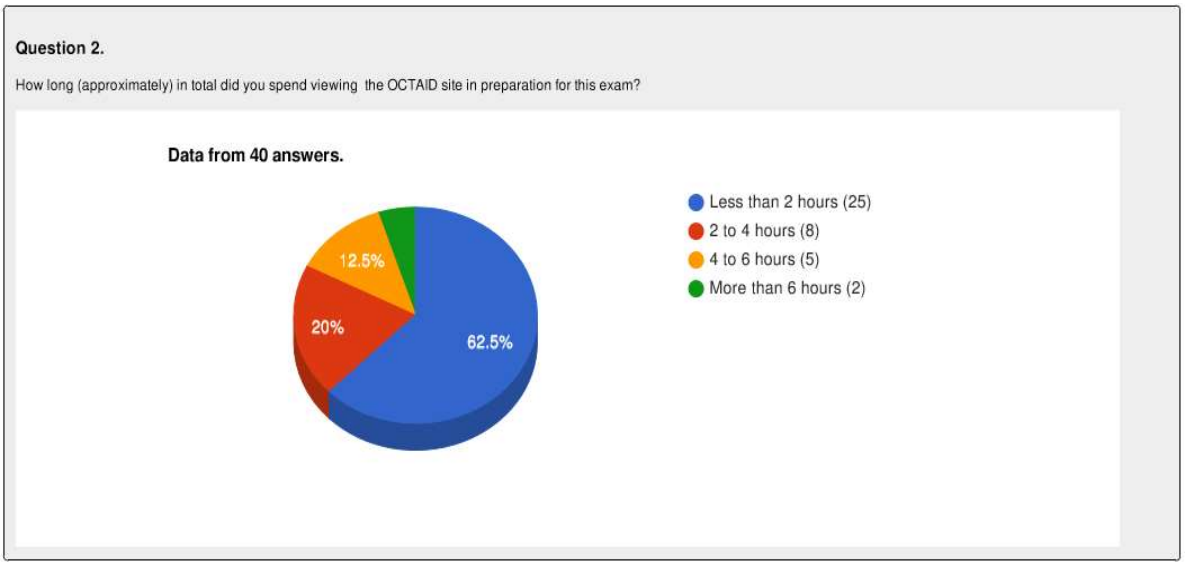

Figure 6.14 Pie chart showing the time spent studying (OCTAID) in preparation for exam 2

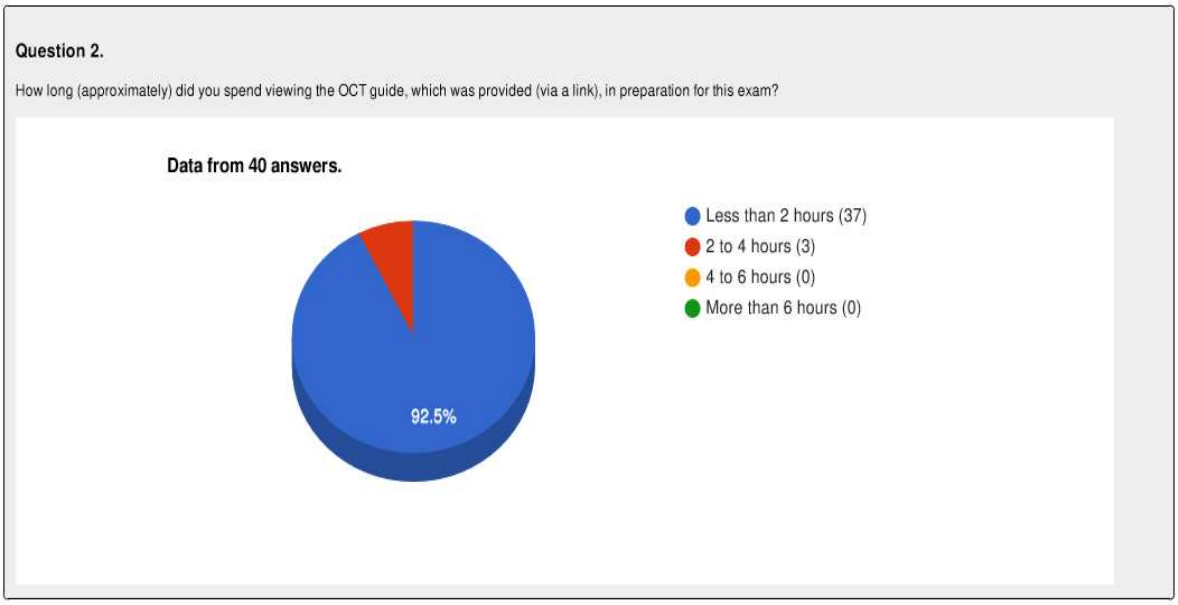

Figure 6.15 Pie chart showing the time spent studying (control resource) in preparation for exam 2

TIME * GROUP Crosstabulation

Count

		GROUP		Total
		OCTAID	CONTROL	
TIME	Less than 2 hours	25	37	62
	2 to 4 hours	8	3	11
	4 to 6 hours	5	0	5
	Over 6 hours	2	0	2
Total		40	40	80

Table 6.25 Time spent studying OCT resources (OCTAID v Control)

Participants in the study group spent more time reviewing the OCT resource (OCTAID) allocated to them than the control group spent reviewing the control resource. This time difference was statistically significant (p = 0.009). This is summarised in Table 6.26.

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	11.595[a]	3	.009
Likelihood Ratio	14.400	3	.002
Linear-by-Linear Association	10.918	1	.001
N of Valid Cases	80		

a. 4 cells (50.0%) have expected count less than 5. The minimum expected count is 1.00.

Table 6.26 Chi Square analysis of time spent studying OCT resources (OCTAID V Control)

Study evaluation from the participants' viewpoint

A course evaluation (in the form of a short electronic questionnaire) was presented to each participant on completion of both exam modules. The questionnaire required a selected response answer to measure the overall value of the study in educational terms. Participants were asked to rate the entire course (on a scale of 1 to 4) in terms of (1) the relevance to optometric practice, (2) the quality of the exam questions and (3) the quality of the illustrations within the exam modules and OCT resources. Both groups (OCTAID and

control) completed identical questionnaires. All participants (n=53) from the OCTAID group completed this questionnaire with only one participant from the control group failing to complete the questionnaire (n=64). Results from the questionnaire are illustrated in the bar charts below (Figures 6.16 and 6.17).

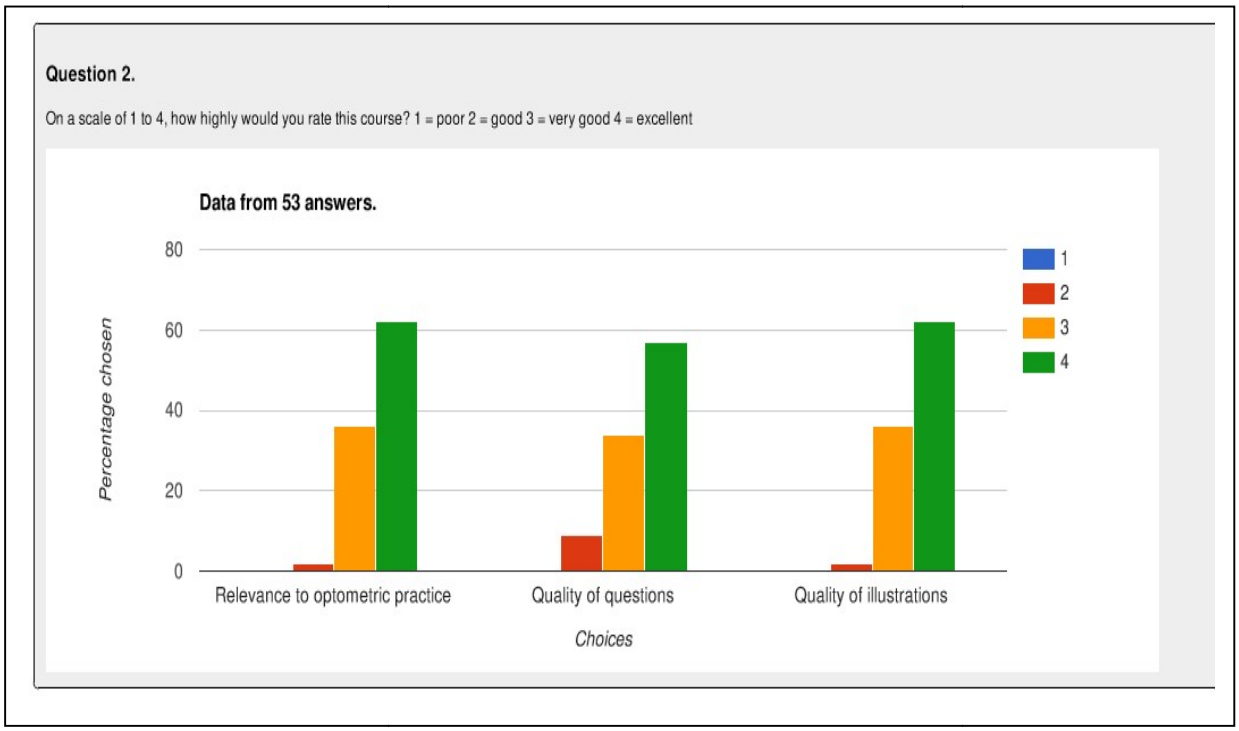

Figure 6.16 (OCTAID participants' feedback)

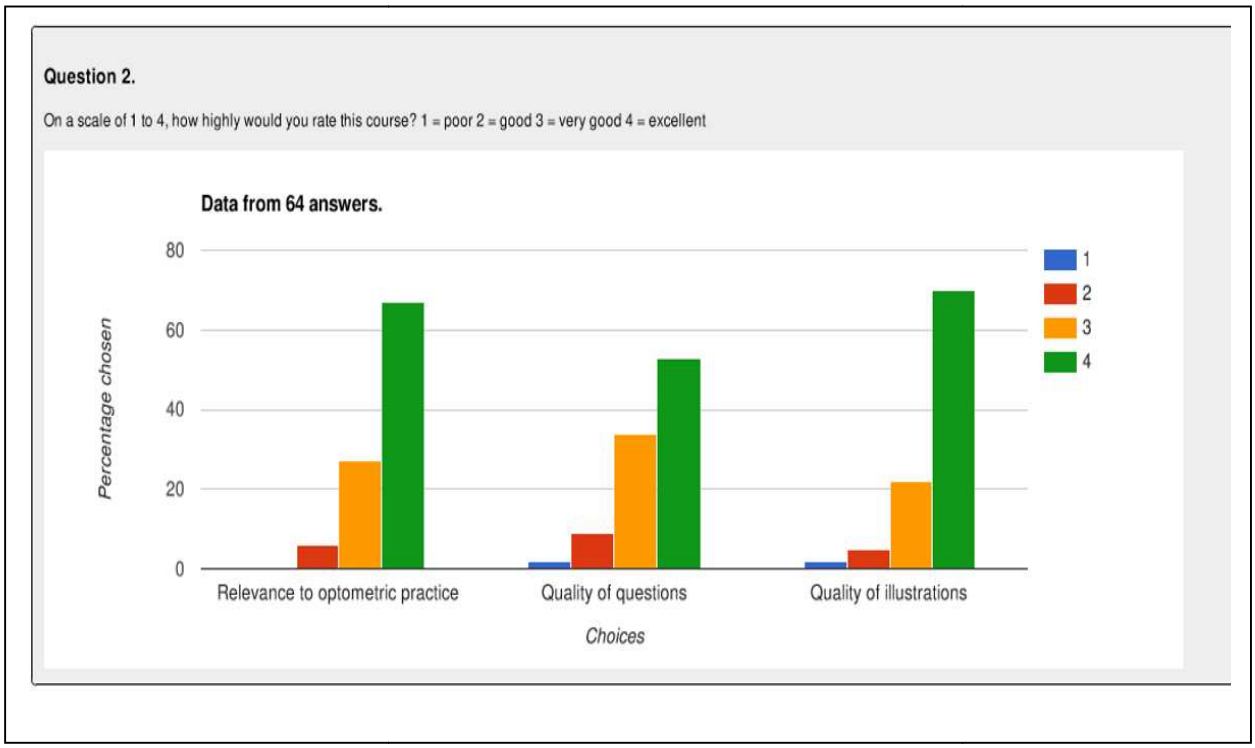

Figure 6.17 (Feedback from the control group)

Testimonials from some of the study participants are contained in Appendix 9.

The OCTAID site – user engagement measured by Google Analytics

A visit to the OCTAID site was the equivalent of a browser session although a single visitor may have generated several visits (each with multiple page views for several pages). Visits were ended after a period of 30 minutes of inactivity or when the browser was closed.

A relevant measurement was the Total Visitors which equated to the number of different people who viewed the site. Each visitor was only counted once by Google Analytics (GA) but it is important to appreciate that the total number of users was a measure of the number of unique devices that accessed the OCTAID site and not the number of people who visited the website. Each different device was counted by GA as a different user so the number of users may have seemed high as participants possibly accessed OCTAID from home computers, work computers, phones and other devices.

Other GA metrics included the Number of Sessions (a session equating to all of a user's activities within a given time period) and page views (how many pages were viewed on the site). The total number of page views would typically be higher than might be expected because it included multiple views of the same page (even during the same session).

Average Session Duration is a misunderstood metric because GA reports on how much time a user had spent browsing the OCTAID site. In other words, GA collects data by default on the page load and when the user visits another page. The user's true level of engagement is a mystery until they visit another page. It is a reasonable assumption that this measure would typically be lower than reported.

The Bounce Rate is the percentage of sessions on the OCTAID site that only completed one action. This typically means that users have arrived on the site and then left without performing any other action.

Data were collected between 2nd May 2016 and 22nd July 2016 as these dates represented the first and last exam submissions (Figure 6.18).

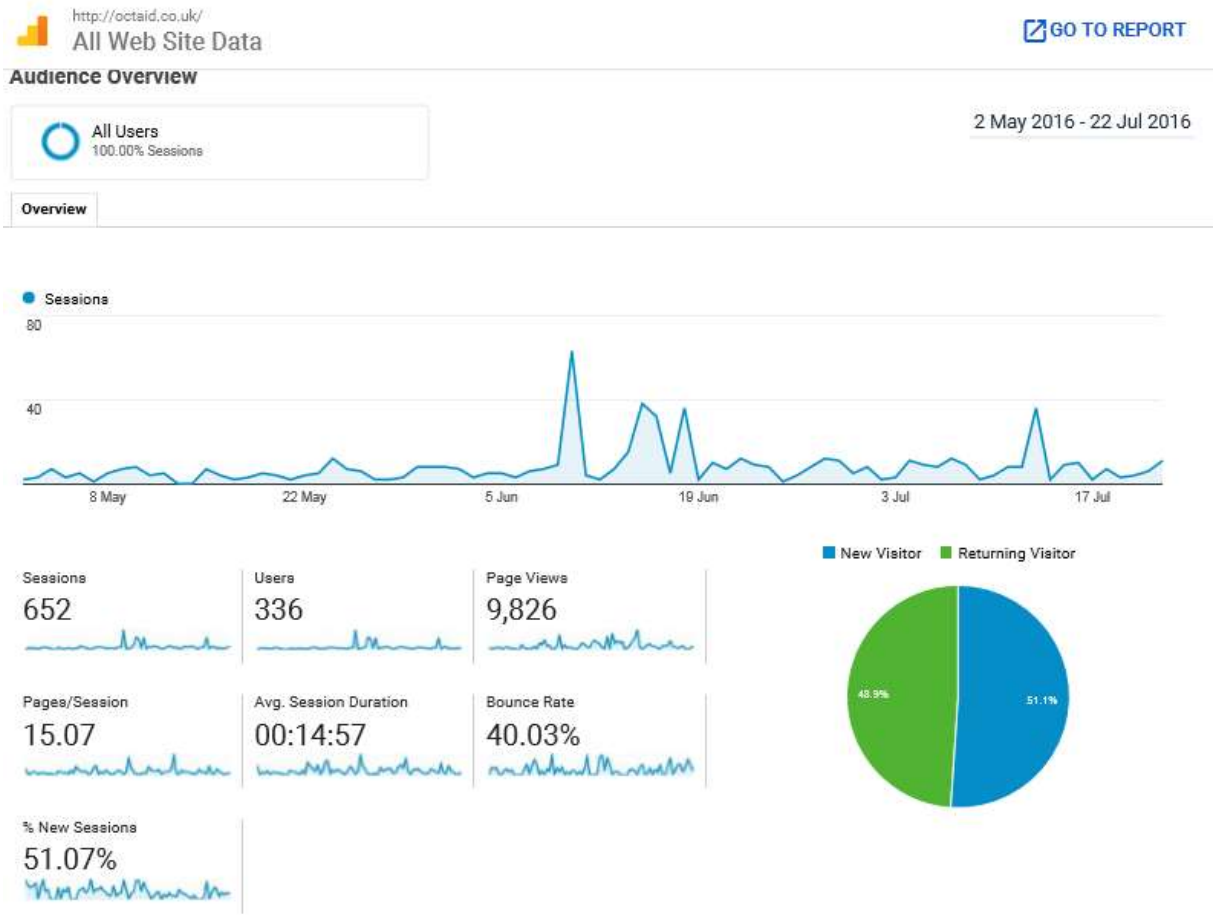

Figure 6.18 OCTAID website activity over the study period

Greatest website activity was recorded on 10th June 2016 when 61 users logged into the OCTAID site and generated 63 sessions. By the time the last exam module was submitted, OCTAID had 336 users suggesting that participants may have recommended and shared the OCTAID link with other colleagues. This number was fairly evenly split between new and existing users. There were 652 sessions over this time period with an average session duration of 15 minutes. Each session had an average of 15 page views. The high bounce rate (40%) is thought to represent users who were checking that user names and passwords were working (participants in the study were asked to check these links just after completion of the first

exam module (in the case of the OCTAID group) or on completion of the second exam module (in the case of the control group).

Comparative statistics controlling for confounding variables

The existence of confounding variables in research makes it more difficult to establish a causal link between intervention and outcome. Therefore, the potential for confounding should be considered in the design and implementation of a study.

Missing outcome data, due to attrition during the study, raise the possibility that an observed effect estimate is biased. To facilitate the complete and transparent reporting of the results of this study (and therefore aid in the critical appraisal and interpretation), the author has examined data relating to participants who did not complete the study.

Sixteen participants completed the first exam task but did not complete the second exam. They therefore did not form part of the analysis. Twelve of these participants failed (did not achieve 60% or more) this exam and this may account for their decision not to proceed to the next exam module. They may have found the vignette task difficult and time consuming and were perhaps poorly motivated for the second vignette task. Ten of these participants had been allocated to the OCTAID study group (there was no re-allocation of participants to groups once they had been assigned at the beginning of the study).

Twenty six participants failed to register for the study on the LearnUpon platform, failed to fully enrol, or enrolled but did not start. Seventeen of these participants had been allocated to the OCTAID study group and 9 had been allocated to the control group. The attrition rate disproportionately affected the OCTAID group in terms of the earliest stages of the study (registration and enrolment) but there was no re-allocation of participants to preserve the

integrity of the initial process of randomisation. Withdrawals after the first vignette task also disproportionally affected the OCTAID group. A possible explanation could be that this group of practitioners had been motivated only by the incentive of access to the OCTAID site after completion of the first exam task.

Chapter 7: Discussion

This chapter will provide;

- A summary of the results
- An appraisal of the results
- A comparison with other research in this area
- A discussion on the strengths and limitation of the study
- A conclusion and suggestions for further research

Summary of results

One hundred and sixty potential participants returned their consent forms and were enrolled on the LearnUpon platform (the online course and exam host). Eighty participants were randomly allocated to the OCTAID course on the LearnUpon platform and 80 were allocated to the control course. The two courses contained identical exam modules and differed only in the OCT resource provided by live link after completion of the first exam (OCTAID or Control). Participants were allocated to the OCTAID or Control groups and enrolled at the beginning of the study and therefore before commencing the first exam. Therefore, the scores in the first exam did not influence the allocation of participants to groups and there was no re-allocation of participants in response to withdrawals from the study. The score in the first exam was thought to be a reasonable measure of a participants baseline OCT knowledge.
Once allocated to a group and enrolled, participants remained within that group.

One hundred and eighteen optometrists fully participated in the study (n=118) by completing both exam modules. Fifty three participants (n=53) from the study group (OCTAID) completed the course with a mean score of 67.2% in the first exam. Thirty eight participants passed the first exam by achieving a score of 60% or more and 15 failed.

Sixty five participants from the control group completed the course achieving a mean score of 63.7% in the first exam. Forty of these participants passed the exam and 25 failed to achieve the pass mark of 60%. When comparing exam performance in terms of the pass/fail rate, there was no statistically significant difference between the OCTAID and Control group in the first exam (Fisher's 2 sided Exact Test, p = 0.328).

In the second exam, following the educational intervention (OCTAID in the case of the study group and conventional educational materials in the control group) 50 participants (94.3%) in the OCTAID group passed the exam (achieved more than 60%) and only 3 (5.7%) failed. Their mean score was 80.6%. In the Control group, forty nine participants passed the second exam (75.4%) and 16 (24.6%) failed. Their mean score was 70.9%. There was a statistically significant difference between the OCTAID and the Control group in their pass/fail rate in the second exam which followed the educational intervention (Fisher's Two Sided Exact test, p = 0.006).

The primary outcome measure was the mean improvement in exam score between the two exam modules. The mean improvement in exam performance (the score gain) in the OCTAID group was 13.4% (score in exam 2 minus the score in exam 1 = 80.57 – 67.17 = 13.4%).
The mean improvement in exam performance in the control group was 7.17% (score in exam 2 minus the score in exam 1 = 70.89 - 63.72 = 7.17%).

The OCTAID and control groups performed similarly in the first exam module. No statistically significant difference in mean exam 1 score (p = 0.212, 2-tailed) was identified between the two groups of participants. However, when comparing the two groups in their second exam performance (after the intervention) a statistically significant difference was found in their exam score.The OCTAID group improved by 13.4% compared with an improvement of 7.2% in the control group. An analysis of the improvement (difference score)

in the 2 groups using the independent samples T test (2 tailed), showed a significantly greater improvement in the OCTAID group ($p = 0.005$).

Participants in both groups (OCTAID and control) showed improvement in their OCT knowledge following educational intervention. However, participants who received OCTAID improved their exam score level significantly more than those who received conventional educational materials. These findings are summarised in Table 7.1.

Group	Percentage Pass Rate Exam 1	Percentage Pass Rate Exam 2	Mean Exam 1 Score	Mean Exam 2 Score	Improvement
OCTAID n =53	71.7%	94.3%	67.2%	80.6%	13.4%
Control n = 65	61.5%	75.4%	63.7%	70.9%	7.2%

Table 7.1 Summary of results for OCTAID and Control groups

The 'novice' subgroups of participants (n = 21 for the OCTAID group, n = 19 for the Control group) performed similarly in their first exam score with an almost identical mean score (57.7% and 58% respectively). However, there was a significant difference between the two subgroups when comparing their mean exam score in the second exam. The mean exam 2 score for the OCTAID novice subgroup was 77.7% compared with 65.2% for the Control subgroup.

Comparing the mean exam 2 scores by the independent samples T test, a statistically significant difference between the two novice subgroups was demonstrated (2 tailed $p = 0.015$). The OCTAID subgroup improved their mean exam score by 20.1% compared with a mean improvement of 7.2% in the control subgroup. These results along with the percentage pass rate in both exams and for both subgroups are summarised in Table 7.2.

Subgroup	Percentage Pass Rate Exam 1	Percentage Pass Rate Exam 2	Mean Score Exam 1	Mean Score Exam 2	Improvement
Novice OCTAID n = 21	47.6%	90.5%	57.7%	77.8%	20.1%
Novice Control n = 19	47.4%	47.4%	58%	65.2%	7.2%

Table 7.2 Summary of mean scores, mean score improvement and percentage pass rate for both novice subgroups

Chi square analysis of the pass/fail rate showed no significant difference between the OCTAID and Control subgroups in Exam 1 (Fisher's 2 sided exact test, p = 1.00). However, there was a statistically significant difference between the two groups in their pass/fail rate in Exam 2 with the OCTAID subgroup outperforming the Control subgroup in their pass rate (Fisher's Exact test 2-sided p = 0.005).

Comparing these 2 subgroups, the independent samples T test demonstrated statistically significantly better outcomes in terms of score improvement in the OCTAID subgroup (2-tailed p = 0.001).

As expected, the 'expert' subgroups in the study performed best over the two exams with the OCTAID subgroup (n = 29) achieving a mean score of 73.5% in Exam 1 compared with 68.7% in the control subgroup. No significant difference between the OCTAID and Control subgroups was demonstrated by the chi square analysis of the pass/fail rate in exam 1 (Fisher's Exact test, 2 sided p = 0.535). These results, including the percentage pass rate for each subgroup, are summarised in Table 7.3.

Subgroup	Percentage Pass Rate Exam 1	Percentage Pass Rate Exam 2	Mean Score Exam 1	Mean Score Exam 2	Improvement
Expert OCTAID n = 29	86.2%	97%	73.5%	82.6%	9.1%
Expert Control n = 40	77.5%	88%	68.7%	74.5%	5.8%

Table 7.3 Summary of mean scores, percentage pass rate and mean score improvement for the expert subgroups

Chi square analysis of the pass/fail results in Exam 2 also showed no significant difference between the two subgroups (Fisher's Exact Test 2 sided, p = 0.389).

The OCTAID subgroup's mean exam score improved by 9.1% compared with 5.8% in the Control subgroup. Analysis of the mean raw scores in exam 1 showed no significant difference between the two subgroups (2 tailed, p = 0.118). However, a statistically significant difference in the mean scores between the two subgroups was demonstrated in exam 2 (2 tailed, p = 0.003). However, the primary outcome measure was the exam score improvement (rather than a comparison of the mean scores in exam 2). Although the OCTAID subgroup improved their exam score by more than the control group, this did not reach statistical significance when applying the independent samples T test (2-tailed p = 0.25).

Participants from both the OCTAID group and the Control group were asked how much time it took them to complete exam 1. Chi square analysis did not identify any significant difference between the OCTAID and control groups in terms of time spent completing Exam 1 (Fisher's exact 2 sided, p = 0.361). Participants in the study group spent more time reviewing the OCT resource allocated to them (OCTAID) in preparation for the second exam than the control spent reviewing the control resource.

Appraisal of results

If optometrists are to be the focus for community case finding of eye diseases such as AMD and diabetic retinopathy they will need to have access to the latest technology. This will improve detection of pathology, monitoring treatment and sharing in patient management. This will help to create a genuinely functional health-care team approach to eye care in the current context of a high risk, aging population and a scenario of workforce shortages and capacity issues within specialist clinics. The arrival of optical coherence tomography and the proliferation of its use in optometric practice has been a most important event for the profession of optometry.

As noted in Chapters 1 and 2, community optometrists need help in learning how to interpret OCT images and implement appropriate management. Advances in ophthalmology and optometry and changes in eye care delivery have increased demand on academic institutions. Also, changes in sites of eye care delivery from acute eye care hospitals to community-based settings (including community optometric practices) for chronic eye care will require adaptations in educational delivery.

E-learning is employed by medical educators to improve the effectiveness of medical interventions. Web-based delivery of education (e-learning) has revolutionised the modes of exchanging information and optometric educators are embracing this trend.

The author has suggested that it would be useful to have a diagnostic guide in the form of a website which includes a structured and illustrated explanatory algorithm for interpreting OCT images of retinal diseases (at various stages) commonly presenting to community optometrists along with patient management decisions. Such a resource (OCTAID) has been

designed and its efficacy tested using clinical vignettes. In the present research OCTAID is compared with conventional OCT educational material in a randomised controlled trial.

OCTAID users showed marked and statistically significant improvement in their vignette score when compared with the group using conventional OCT resources. This improvement was greatest in a subgroup of 'novice' OCT learners but not proven in a subgroup of participants who were more experienced. The 'expert' groups, as expected, performed well in both exams and both improved their scores between exams 1 and 2. These subgroups performed similarly in exam 1 (no significant statistical difference between them). The OCTAID expert subgroup outperformed the control group in the second exam but it was not possible to demonstrate a statistically significant difference between these two expert subgroups in terms of the score improvement from exam 1 to exam 2. There may have been a 'ceiling effect' in these generally high-scoring subgroups. The true extent of any difference between the two subgroups is therefore difficult to establish.

The OCTAID group as a whole generally performed better (in terms of exam score gain) than the Control group but took more time to complete the second exam task than the control group in what was an 'open book' approach to exam assessment. Whilst it could be argued that this may have been a factor in improving the exam score of the OCTAID group, participants from both groups were allowed to take as much time as they wished to complete the exam task. Participants using the OCTAID site may have felt more confident about finding answers to vignette questions and therefore spent more time exploring the OCTAID resource during the exam task. The OCTAID site may also have had novelty value and participants' curiosity may have incentivised them to explore the site for solutions to the vignette task.

Mean exam scores improved between exam 1 and 2 and across both groups (OCTAID and Control). Participant feedback ranked the study highly in terms of its contribution to OCT

education and the learning experience delivered.

Comparison with literature

There is a paucity of literature on the accuracy and appropriateness of optometrists' referrals to secondary care based on OCT scans. This may reflect the fact that OCT is a relatively new technology to optometric practice and that cost still represents a significant barrier to its acceptance on a universal scale.

A study by Muen and Hewick (2011) concluded that optometrists lacked confidence in recognising the clinical signs and diagnosing wet AMD and that optometrists in the study had a low threshold for referring any abnormality. They went on to suggest that the accuracy of referral could possibly be improved by the addition of OCT along the care pathway.

In a study into the optometric referral of suspect 'wet' AMD cases into a specialist retinal clinic, Creer *et al.* (2010) usefully highlighted some of the conditions which mimic the signs and symptoms of AMD and for which this mode of referral was not appropriate.

A study by Jaqadish and Dalziel (2015) looked at the discharge outcomes of patients referred to a specialist clinic from diabetic retinopathy screening (DRS) services in Northland, New Zealand (n = 98) and found that such a significant proportion of patients were re-referred back to DRS after OCT at the specialist clinic. A consideration was to include OCT in the screening pathway.

This doctorate student's literature review has identified only one study which has evaluated the effectiveness of optometric OCT users in classifying retinal lesions in patients with known macular disease. The ECHOES trial had a very specific disease focus and compared the

ability of ophthalmologists versus optometrists (optometrists in the community and ophthalmologists in the Hospital Eye Service) to correctly classify retinal lesions due to neovascular age-related macular degeneration.

The decision-making of optometrists was compared to that of ophthalmologists and was found to be non-inferior to ophthalmologists'. This study had some similarities to the current study. Sample sizes were similar (98 participants completed the study), OCT scan recognition was a key element in the study as was training, a randomised controlled study was the chosen method. The correct classification of the activity status of a retinal lesion based on a vignette was compared with a reference standard (an expert panel). The ability of optometrists to make wet AMD retreatment decisions from vignettes was found to be non-inferior to ophthalmologists' ability. The ECHOES study concluded that shared care with optometrists monitoring quiescent wet AMD lesions has the potential to reduce workload in hospital eye clinics.

The ECHOES study had a single disease focus (AMD) and in fact was concerned only with patients with a quiescent stage of disease, whereas the current study looked more broadly at the use of OCT for all macular lesions.

A useful insight into the potential value of ophthalmic OCT images being transferred between primary and secondary care has been uniquely provided by a small study by Kelly *et al.* (2011). This study focussed on the better management of patients with macular disease. Teleophthalmology consultations based on OCT findings reduced the time taken to manage the fifty patients under study compared to earlier methods. Ninety-six per cent of cases had referrals analysed and a working diagnosis/care pathway provided by the ophthalmologist to the community optometrist within the next calendar day.

Strengths and limitations

The randomised controlled trial is a scientifically rigorous methodology for evaluating the efficacy of an educational intervention but its success is contingent upon adequate sample size, adherence to study protocols and retention of research participants. This study attracted considerable interest from optometrist OCT users and those thinking of introducing this imaging technology into their eye examination routine. The study had a good sample size (n = 118) and strategies for maintaining research participation were very effective. There was an excellent sample retention rate (74%). The study was the subject of favourable appraisal by OCT expert panel members, pilot participants and main study participants. Vignette scores were reasonable with a balanced spread of results indicating that the exam questions had been pitched at the correct level of difficulty. The statistical test of item analysis, where the quality of individual questions are assessed by comparing participants' question responses to their total test scores, may provide additional insight if the examinations are used again in future educational events.

The OCTAID site, all its tabs and links worked efficiently with no negative feedback. The online exams were conducted and processed without difficulty. Overall, all IT utilities proved to be robust and efficient. There were several potential limitations of this study which will now be discussed.

Factors affecting recruitment to the study

Recruiting the required number of participants is vital to the success of any study. The lead researcher and supervisors spent some time identifying appropriate sources for recruitment and an early aim of this study was to identify the factors the researchers perceived as influential in the recruitment of participants to this OCT-focussed research. There was consensus among the research team that many individuals who might be willing to take part

in OCT-focussed research would value the potential benefits of participation, namely the opportunity to access additional OCT resources.

Infrastructure, nature of the research, recruiter characteristics and participant characteristics are all believed to influence the success of recruitment to clinically focused research (Newington and Metcalfe, 2014). Newington and Metcalfe also suggest that a recruiter's professional role, personality and knowledge of the research project are influential factors in the recruitment process.

Despite having had a good sample size and excellent sample retention, attrition through failure to register, enrol, start or complete the study disproportionately affected the OCTAID study group. A balance in numbers between the two study groups could have been better preserved if there had been a re-allocation of participants to groups in response to early withdrawals and non-starters. However, this would have interfered with the integrity of the original process of randomisation and made the study design less robust.

The position of the researcher

The author (and recruiter) is a community optometrist with special interest in medical retina and optical coherence tomography. The author is a known contributor to the Optix OCT forum which was a key source of recruitment to this study. This may have had some positive and also negative effects. By gaining some credibility with the forum, the author was able to legitimise the research study. However, some forum members may have been wary of their exam performance being known to a forum contributor and caused them to perform to a higher than normal standard in assessment. On the other hand some forum members may have been reticent to participate because their exam performance would have been known to a fellow forum subscriber.

The position of the participants

Researchers evaluate evidence to determine whether an intervention is directly responsible for an outcome. The resulting studies follow a hierarchy in terms of the quality of evidence that they can produce. Randomised double masked controlled studies are considered a reference or "gold" standard in terms of the most convincing research design to determine whether an intervention is directly responsible for an outcome (Sibbald and Roland, 1998).

In the current study, randomisation has aided the efforts to eliminate confounding by any baseline variables. Although masking of participants for the entire duration of the study would have gone some way towards eliminating confounding by co-interventions, it was not thought to be helpful or practical in the context of this study design.

A simple random sampling technique was used in the current study. A more systematic or stratified sampling technique may have helped to ensure that the sample included all representative groups of practitioners but given the fact that there are a limited number of practitioners using OCT, a sampling technique which maximised the number of participants was thought to be a priority.

The author needed to communicate with participants (by email) at numerous stages in the study for IT support related to the online exams and links to the educational interventions used for the study. Participants' progress was monitored as they made their way through the various course modules to (1) allocate CET points on completion of an exam module in a timely fashion, (2) identify participants who appeared to have forgotten to start or progress through the course (forgetting login and password details was a common problem), (3) identify participants who were unsuccessful in achieving a pass mark in the first exam module. It was thought that these participants might have lacked the motivation to attempt the second exam and were therefore reassured that their exam result remained confidential and that the purpose of the first exam was a "knowledge checker" to test their baseline knowledge.

They were also reminded that two further exam attempts were permissible after the study was completed.

This study compared two educational interventions and it would have been obvious to participants which of the two interventions was new and which one was conventional. As an incentive to participate, all participants to the study were, at the outset, also offered free access to the OCTAID site after completion of the study and invited to join a new professional community which would help to develop the OCTAID resource further.

Participants made a self-declaration about their previous level of OCT experience prior to enrolment in the study. It is possible that relatively experienced OCT users might 'downgrade' their level of experience when they know they are about to be assessed. There is always a difficulty in defining experience especially in terms of the use of new technology because optometrists are unlikely to have continually assessed and evaluated their level of experience. In asking participants about their previous level of OCT experience the question was framed in terms of how many OCT scans they would assess in a normal month as opposed to asking them if they were expert, novice or somewhere in between.

It could be hypothesised that studies like the present one are more likely to attract and recruit optometrists who are confident in OCT scan diagnosis and patient management decisions. Despite the assurances of confidentiality provided to all potential participants, those who were perhaps less confident may not have wanted gaps in their knowledge to be exposed.

Study participation was open to all optometrists regardless of their OCT experience. Participants were simply asked how many OCT scans they would have assessed in a typical month. This may have included those who had no access to OCT in practice but intended to introduce this technology to their practice in the near future. Their experience may therefore have been limited to participation in training events, demonstrations of OCT by suppliers or reading of OCT literature. This group of participants was therefore grouped with those who

had some access to OCT but perhaps only part-time or OCT may have been introduced to their practice very recently (less than 3 months). This was clearly a heterogenous group.

The exam modules were not timed so it could be argued that participants' scores may have been influenced by the amount of time spent on the exams. Although the time spent on the exam modules was not directly measured for each individual participant, a post-exam feedback questionnaire (at the end of each exam) did ask participants how many minutes they required to complete the exam. These answers may not have been an accurate reflection on how much time each participant devoted to the exam modules. Similarly participants were asked how much time they spent studying the OCT resources (OCTAID and control) in preparation for and during the exams. Their responses in the post exam feedback may not have accurately reflected the extent to which the resources were used. However, some data were collected on the overall use of the OCTAID site using Google Analytics software. It was not possible to collate such information on the use of the control intervention.

Participants' performance in the vignette situation may not accurately reflect their performance under clinical conditions in optometric practice.

The Control Intervention

When researching the answers to questions in the exam modules, participants in both the study group and the control group were permitted to use whatever resources they would normally refer to when making a diagnostic or patient management decision based on an OCT scan in their everyday practice. In addition to this the study group were provided with a link to the OCTAID website and the control group were provided with a link to a conventional OCT resource. Whilst it could be argued that the control intervention provided a less comprehensive knowledge of OCT than the OCTAID site, the study was testing the efficacy of the OCTAID site compared with conventional OCT resources of which the control

intervention was only one. We could not however be certain that the study and control groups were accessing resources of equivalent content.

The Exam Modules

Each exam module in the main study contained 32 questions. Twenty four of these questions were based on OCT scan recognition and patient management decisions based on these scans. Eight of the questions were based on more general OCT knowledge. This was more than would normally be required to qualify for 2 CET points in other optometric training events. Under GOC guidelines visual recognition tests earning a candidate 1 CET point and involving 1 hour of learning would typically involve 4 ocular image slides with 3 matching questions for each image (12 in total). The two exam modules, along with the educational interventions provided for study and reference, presented a high level of difficulty in terms of time and commitment and this may have accounted for the fact that some participants did not start or complete the study. The exam format (vignette) did not allow a participant to return to a question, once answered and unanswered questions were marked as incorrect. This format would have been unfamiliar to many participants who would normally be accustomed to being able to review their answers before submission in other CET events.

Another important potential limitation was that optometrists' self-reported practice in a vignette setting may not predict actual practice. A large scale prospective study of optometry referrals based on OCT images to the hospital eye service may provide more insight into optometrists' OCT knowledge in a variety of clinical settings.

The vignette exam modules were not timed although participants made a self-declaration of how much time they spent on each exam and this was used as a secondary outcome measure. The use of self-report data is widespread across diverse fields of research but open to criticism. It is difficult to determine the extent of agreement between subjective (a self-report

questionnaire) and objective (directly measured) measurements of time spent on an exam task. It is therefore possible that correlations between self-report and direct measures may have been low. The costs and benefits of direct measurement need to be considered in any study to determine if the added resources required justify the possible increase in precision of the results.

The OCTAID site

The OCTAID site was designed by the author who also designed the clinical vignette assessments. Several steps were taken to avoid the possibility of exam questions being biased to favour either OCT educational intervention and this has already been discussed in the chapter on methods.

The OCTAID site was designed and constructed by the author, based (almost entirely) on his own personal archive of OCT scans and retinal images. These images may not have illustrated retinal disease to best effect and therefore may not have been the best examples to use for the purpose of OCT education. OCT images from this personal archive may not have been sufficient in number to fully illustrate a disease stage and variability. Not all images in this personal archive were eligible to be used in the OCTAID site as a definitive diagnosis (a comprehensive report from the hospital ophthalmology service) was not always available. This was often because of a lack of feedback from the hospital eye service to which the patient had been referred.

However, the suitability of images was validated by supervisors and, ultimately, by the expert panel. One member of the expert panel, a consultant ophthalmologist commented that there was no such thing as a textbook example because individual variation and the stage of disease at presentation will always challenge clinicians at all levels of expertise. It was therefore thought that multiple images demonstrating the entire spectrum of disease in terms of stage

and variability may be of more value educationally than a 'perfect text book example'. In future versions of the OCTAID site, it is thought that this problem could be addressed by asking study participants to provide scans from their own archives after the completion of the study thus empowering participants to build their own diagnostic guide.

Limited resources exist on optometric management of OCT-detectable lesions in optical practice and this was a limiting factor in formulating patient management decisions on the OCTAID website. The expert panel input proved to be an invaluable resource for informing these decisions.

Confounding variables

This study was perhaps limited by the inability to control some potentially confounding factors. There may have been a novelty effect in the case of the OCTAID website where the study group would have been aware of the novel nature of this educational intervention. Consequently, the author could not be certain of the factors of most importance and was also unable to define the element that actually led to improved outcomes. This could have been an inherent quality of the educational methodology, the manner in which the content was delivered or related to the interactivity with the computer interface.

Double blinding would have gone some way in ensuring that the preconceived views of participants and researchers could not systematically bias the assessment of outcomes but this was not practical in the context of the current study (as already discussed in the Methods chapter).

Conclusions

Today's optometrists are increasing their utilization of non-invasive technologies like OCT to aid in the observation of retinal anatomy and physiology in health and disease. The world of diagnostic testing is highly dynamic with new tests being developed at a rapid rate and the technology of existing tests is the subject of continuous improvement. Optical coherence tomography is fast-becoming an invaluable tool in optometric practice where it is applied in the diagnosis and management of patients with a variety of ocular conditions, both congenital and acquired.

OCT has made substantial technological improvements over the years, removing many of the barriers to its application in evaluation of retinal anatomy. As OCT technologies and techniques continue to evolve, the challenge of keeping pace with innovation could be a barrier to the delivery of appropriate care to patients. It is therefore important to design accessible resources to bridge this gap.

OCT is a relatively new imaging technology and so the diagnostic accuracy of optometrists using OCT to discriminate patients with referable retinal conditions has not yet been fully established. The opportunistic finding of retinal lesions and subsequent patient management decisions remains a difficult task for optometrists despite the rapid advancement in the development of non-invasive imaging modalities such as OCT. Correct image interpretation depends on some degree of understanding of the theoretical background of image generation along with an awareness of the challenge presented by machine artefact. Optometrists using OCT will require a detailed knowledge of retinal disease as represented by OCT and an appreciation of normal variation. Incidental findings (especially findings of only minor clinical significance) will require appropriate management or referral decisions which are cognisant of the potential waste generated by unnecessary visits to ophthalmic services.

A rigorous evaluation process of the diagnostic accuracy of optometrists using OCT in every day practice would go some way towards defining the causality and exploring strategies to minimise diagnostic error in optometry. Studies to determine the diagnostic accuracy of optometrists who use OCT in practice would form a vital part of the evaluation process. The introduction of a resource such as OCTAID into optometric practice has the potential to reduce the number of unwanted clinical consequences relating to diagnostic error and also limit the health care costs relating to misdiagnosis and suboptimal patient management. There is a need for the development of standards and protocols that will serve to improve clinical application and interpretation. OCT needs to work synergistically with current models of eye care and fit within the ecosystem of innovation, clinical excellence, competition and practitioner education.

This thesis describes a method for improving the accuracy of OCT image-based diagnosis and patient management by providing optometrists with an online guide in algorithmic form. The data presented indicate benefits from this diagnostic tool, OCTAID, in improving the combined skill of OCT scan recognition and patient management. The potential exists for OCTAID to be used as a training tool for optometrists. There are potentially greater improvements in diagnostic accuracy that can be realised through the future development of the OCTAID site with the feedback and archive images of multiple users

These results illustrate the importance of designing accessible diagnostic aids to complement new and improving retinal imaging technologies whilst improving the understanding of retinal disease mechanisms. It is important to consider the applicability of the findings of this study to clinical practice and policy and when interpreting the results of this study, one should consider the diagnosis and treatment pathway to which the data could realistically be applied. The ultimate clinical value of using a new diagnostic tool depends on whether it improves patient outcomes beyond the outcomes achieved using older, more established OCT resources.

A failure to standardise the science of OCT and retinal anatomy in health and disease could undermine its value.

Recommendations for further work

Diagnostic reasoning

Whilst it might seem reasonable to assume that the clinical reasoning processes engaged in by practising optometrists are similar to those used by other health professions, there is little evidence in this domain (Faucher *et al* 2012). It also seems possible that clinical reasoning processes might be subjected to the unique influence of conditions within the optometric profession including the current model of eyecare, and the commercial pressures relating to this.

Further research on the diagnostic accuracy of optometrists using OCT imaging technology and the factors influencing its use may help to confirm, complement or challenge our findings.

The success of OCTAID may lie in aspects of its delivery rather than its content, the web being the delivery medium of the educational content for the OCTAID group. The dominance of the internet in everyday life has revolutionised modes of exchanging information. Participants who study content via a web based application may generally perform better than those who study identical content using more conventional (paper) resources. This requires further investigation across a range of subjects.

Further development of OCTAID – Collaboration as a process of shared creation

All participants in this study (including those in the control group) were provided free access to the OCTAID site after the study was completed. Furthermore, they will be invited to assist in developing the OCTAID site by providing feedback and supplying suitable OCT scans

from their personal archives which might better illustrate a broader range of retinal disease in terms of phenotype and disease stage. The author believes this collaborative approach to building a diagnostic guide to be unique.

Modern learning requires learners to be critical and independent thinkers but learners are also required to be collaborative and interdependent problem solvers. A clear component of collaboration is the ongoing interactions and communications that take place as learners work together toward a common goal. Educationalists often suggest that the provision of interactive learning opportunities is best practice because shared learning provides learners with an opportunity to get involved in discussion and develop the skills of critical thinking and reflection (Taylor and Parsons, 2011).

Diagnostic reasoning is a complex process and often takes place under conditions of uncertainty and limited time. Diagnostic errors are not uncommon and in considering how they might be avoided, Ely *et al.*(2011) observed that high-risk, high-reliability professionals such as airline pilots and nuclear plant operators have reduced errors by using checklists and that recently checklists have gained acceptance in medical settings and are now commonly proposed tools to reduce diagnostic error (Sibbald *et al*. 2013). Ely *et al.* proposed extending the checklist concept to diagnosis and describes three types of checklist:

- A general checklist that prompts physicians to optimise their cognitive approach. This could form the basis of the algorithmic approach to OCTAID
- A differential diagnosis checklist to help physicians avoid a common cause of diagnostic error - failure to consider the correct diagnosis as a possibility. OCTAID includes a differential diagnosis approach which may be expanded and refined.
- A checklist of common pitfalls

Ely *et al.* state that such checklists were developed informally and to date, have not been subjected to rigorous evaluation but suggest that because of the complexity of diagnostic reasoning, checklists might provide an alternative to reliance on intuition and memory in clinical problem solving. The potential exists for this approach to diagnostic reasoning to be applied to OCT scan interpretation and the OCTAID site is ideally designed to deliver such a study.

It is hoped that OCTAID will become a learner-centred model of OCT education, thus providing an opportunity for optometrists to take responsibility for their own learning within a unique professional community.

Appendices

Appendix 1 – Email to potential recruits who subscribe to online optometry forums

Dear forum members,

We were wondering if members of this excellent forum would be interested in participating in an OCT study for which we are currently recruiting. We would particularly welcome participation from practitioners with little or no OCT experience. Some forum subscribers may be thinking of introducing OCT into their practice in near future and may find this OCT focussed CET event very useful. Some of you may have already been contacted via other forums and indeed some have already agreed to participate. Thank you all for this.

The online exam host has limited capacity (200 participants max) and places on the study will be allocated on a first come first served basis. Further information about the study is attached.

If you are interested, the lead researcher may be contacted (off-line please) at:

paul@graceandoneill.com

Best wishes,

Paul Grace, Bruce Evans, David Edgar

An updated summary of the research is attached:

Appendix 2 – summary of research (email attachment)

Summary of research

Limited guidance exists for optometrists using OCT for diagnostic and referral decisions. The novel nature of OCT images presents considerable challenges for community optometrists in interpreting OCT images to reach an accurate diagnosis of macular lesions and so make appropriate referrals. We hypothesise that it would be useful to have a diagnostic guide in the form of a website which would show OCT images of retinal diseases (at various stages) commonly presenting to community optometrists along with patient management decisions.

The first goal of the research was to develop this online diagnostic algorithm (OCTAID) for the diagnosis of central retinal lesions using OCT and this is now complete. A second goal of the research is to evaluate the effectiveness of OCTAID in improving optometric diagnosis using OCT. We have done this by designing an online assessment. The questions are in multiple choice format so it should be possible to complete the task fairly quickly. Most of the questions will take the form of 'visual recognition and investigation of clinical signs' (VRICS) based on OCT images but some questions will test your broader OCT knowledge. The questions cover a range of common retinal conditions which participants are likely to encounter in optometric practice. We are comparing two groups of practitioners who will undergo an online assessment of their diagnostic and management skills based on OCT images both before and after one of two educational interventions. OCTAID will be randomly allocated to one group with the control group receiving a control intervention of standard OCT training materials.

We may ask about participants' existing knowledge and experience of OCT so that we can control for their level of experience. Participation will be open to any optometrist with an interest in OCT, whether or not they subscribe to the Optix OCT forum.

This study has been approved as a CET event by the General Optical Council. A total of 4 points are available for successful completion of both MCQ tests.

Participants (both in the study group and control group) who complete both legs of the study will have free access to the OCTAID website after the study is completed. It may also be useful (with consensus opinion) for subscribers to donate interesting, anonymised scans from their own personal archive in order to further develop the OCTAID site. For example, a 'scan of the month' could be created for OCT scans which have caused particular challenge or debate. This could be easily incorporated in a website. We believe that this novel and collaborative approach to building a diagnostic guide may prove useful to OCT practitioners.

We hope you will find this interesting. Paul Grace, Dave Edgar, Bruce Evans.

Appendix 3 – study promotional leaflet (email attachment)

Investigation of the efficacy of an online diagnostic algorithm for improving the quality of optometric referral and diagnosis of ocular fundus lesions detected with Optical Coherence Tomography (OCT)

Background

My name is Paul Grace. I am an optometrist from Northern Ireland and I have been a partner in an independent practice since 1990. Our practice purchased an OCT in 2011.

I am also a doctorate student at London South Bank University and the Institute of Optometry and am researching the optometric diagnosis and referral of ocular fundus lesions detected by OCT.

If optometrists are to take full advantage of OCT's enhanced capabilities, they must develop the skills required to interpret the data effectively and reach a consensus with retinal experts on the optimal diagnostic and referral criteria for patients with retinal disease (especially AMD patients), based on OCT findings in optometric practice.

OCT suppliers provide excellent onsite training and OCT reference manuals but limited clinical guidance exists for optometrists using OCT for diagnostic and referral decisions. In addition, the novel nature of OCT images presents challenges for community optometrists in interpreting the images to reach an accurate diagnosis of macular lesions and so make appropriate referrals.

Our study has the following aims/objectives:

- **To develop an online diagnostic algorithm to assist in the diagnosis and optometric management of central retinal lesions using optical coherence tomography (OCTAID).**
- **To conduct a randomised controlled trial comparing two groups of practitioners who will undergo an online assessment, using clinical vignettes, of their diagnostic and management skills based on OCT images before and after an educational intervention.**
  The two educational interventions will be randomly allocated each to one group and will be (a) OCTAID and (b) a control intervention.
- **To measure practitioners' diagnostic and patient management skills compared to an expert panel.**

We propose inviting optometrists with all levels of experience (including optometrists who have not yet used OCT but who would be interested in learning more about OCT scan interpretation), to participate in the research. Some OCT suppliers have kindly agreed to make OCT purchasers aware of the research and to provide the contact details of the lead researcher.

An expert panel has been recruited to play an advisory role in the design of the diagnostic algorithm and to act as a 'reference standard' in assessing practitioners' diagnostic and patient management skills by forming a consensus opinion on diagnosis/management based on OCT scans. The panel comprises two optometrists (David Bennett and Alison Blake), two consultant ophthalmologists with special interest in medical retina (Dhanes Thomas and Praveen Patel), and a biomedical scientist with special interest in ocular imaging (Gerry Mahon). All members of the expert panel will be familiar with OCT imaging.

This study is supervised by Prof. Bruce Evans (Institute of Optometry, London) and Prof. David Edgar (City University, London).

Will I benefit from participating in the study?

We hope that all participants will benefit from the material presented in the online algorithm. If you have been allocated to the control group, we will be sending you a link to the online algorithm after the second assessment. We hope that OCTAID may be further developed after the study with the addition of anonymised scans from optometrist OCT users who have participated in the study. We believe that a unique and collaborative approach such as this will benefit all OCT users.

A total of 4 CET points are available for successful completion of both assessments.
All educational interventions and CET will be provided free of charge.

Paul Grace MSc MCOptom Dip Tp (AS)

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Participant information sheet

Investigation of the efficacy of an online diagnostic algorithm for improving the optometric referral and diagnosis of ocular fundus lesions detected with Optical Coherence Tomography

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Feel free to ask me (the lead researcher) if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.
Thank you for reading this.

What is the purpose of the study?

The new imaging modality of optical coherence tomography (OCT) is now available to optometrists. However, if optometrists are to take full advantage of OCT's enhanced capabilities, they must develop the skill to interpret the data effectively. Although manufacturers provide helpful guidance for new users, interpreting OCT images presents challenges for practitioners particularly when making decisions around diagnosis and management of macular lesions.

What is the aim of the study?

The aim of the study is to test the usefulness of an online algorithm which we have developed to assist in the interpretation of OCT images. To test the algorithm we will conduct a randomised controlled trial comparing two groups of optometrists who will undergo an online assessment, using clinical vignettes ("virtual" patients), of their diagnostic skills based on OCT images of central retinal lesions. Some questions will also test more general OCT knowledge. Each group of practitioners will take the assessment both before and after receiving training (in technical terms an "educational intervention") in interpretation of OCT images. There will be two different educational interventions which will be randomly allocated, each to one group.

What will happen if I take part?

If you decide to participate, simply sign and return the consent form enclosed in the pre-paid addressed envelope provided. We will contact you again (by email) to provide you with further information on how to participate in the research and we will only contact you if it is necessary. You will be asked on the consent form if you prefer to be contacted by email, phone or letter. You are welcome to contact the lead researcher at any time if you have any questions. He can be contacted by email, telephone or at the postal address provided on this form.
The online assessments will mainly involve a series of multiple choice questions (MCQs) based on approximately 25 OCT images (in total for both exams). Some MCQs will test more general OCT knowledge. The assessment will follow a similar pattern to the Visual Recognition and Interpretation of Clinical Signs (VRICS)

assessments which will be familiar to many optometrists as an approved GOC modality for the delivery of Continuing Education and Training (CET). After the assessment you will be randomly allocated to one of two possible educational interventions which are designed to improve skills in OCT interpretation. The second assessment which will be in a similar format to the first will follow about 4 weeks later. All information will remain confidential and will only be used by the researchers.
Four CET points are available for successful completion of both assessments and these points will be applied to the new 2016-2018 CET cycle.
You are not required to conduct OCT scans for the purpose of this study and your patients are not part of this research. We are not asking you to change anything about when and how you use OCT in your day-to-day practice.

Why have I been chosen?

This study is aimed at all practitioners who have an interest in OCT. We wish to include those who regularly use OCT in daily practice and those who have some limited experience but perhaps feel the need for some guidance on OCT image interpretation and referral decision-making. We also welcome participation from practitioners who are not currently using OCT in practice but who are perhaps planning to use OCT in the near future and would like an introduction to OCT scan interpretation. You will be asked about your previous level of OCT knowledge.

Will I benefit from participating in the study?

We hope that all participants will benefit from the material presented in the online algorithm. If you have been allocated to the control group, we will be sending you the online algorithm after you complete the second assessment.

All data collected during the study will be anonymous and confidential. The results of the research may be presented at conferences or in research reports. However you will not be individually identified. All participants will be allocated a unique identifier on recruitment which protects their anonymity. They will only be referred to using this identifier throughout the study and in any subsequent study or publication.

Do I have to take part?

Your participation in this research is entirely voluntary. It is completely up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.

Confidentiality

All data will be held confidentially on an encrypted hard drive for 12 months after the study is completed and will then be securely erased. No individual will be identified in any subsequent thesis, reports or publications.

About the researcher

My name is Paul Grace and I am an optometrist and a Professional Doctorate student conducting research based at London South Bank University and the Institute of Optometry.
I hope that by participating in this research you will obtain useful insight into the interpretation of OCT images of central retinal lesions. The researcher has no financial interest in this study and the educational intervention will be made freely

available to all participants who complete the study. This study is self-funded and is scheduled to be published in 2016.
This study has been reviewed by the Institute of Optometry Research Ethics Committee and the Research Ethics Committee at London South Bank University. The study is supervised by Prof. Bruce Evans and Prof. David Edgar.

Contact for further information

Paul Grace (lead researcher)
30 Bristow Park
Belfast
BT96TH

Tel. 02838327437
Mob. 07885117997
Email. paul@graceandoneill.com

If you have any issue that you are unable to resolve with the research team you can contact the Chair of the University Research Ethics Committee at ethics@lsbu.ac.uk.

Appendix 5 – Participant consent form

CONSENT FORM

Title of Investigation:

Investigation of the efficacy of an online diagnostic algorithm for improving the optometric referral and diagnosis of ocular fundus lesions detected with Optical Coherence Tomography

I have read the attached information sheet on the research in which I have been asked to participate and have been given a copy to keep. I have had the opportunity to discuss the details and ask questions about this information.

The Investigator has explained the nature and purpose of the research and I believe that I understand what is being proposed.

I understand that my personal involvement and my particular data from this study will remain strictly confidential.

I have been informed about what the data collected in this investigation will be used for, to whom it may be disclosed, and how long it will be retained.

I understand that I am free to withdraw from the study at any time, without giving a reason for withdrawing.

I would prefer to be contacted by: (*tick one*)

1) Email
2) Telephone
3) Letter
4) Any

I hereby fully and freely consent to participate in the study.

Participant's Name: (Block Capitals) …….

Participant's Signature: …….

Date: ……..

As the Investigator responsible for this investigation I confirm that I have explained to the participant named above the nature and purpose of the research to be undertaken.

Investigator's Name: ……

Investigator's Signature: ……

.

Date: …….

Appendix 6 – participant OCT prior experience questionnaire

Please complete and return this form in the prepaid envelope provided to:

Paul Grace
30 Bristow Park
Belfast
BT96TH
Northern Ireland

Name:

Address:

Telephone number:

Email:

GOC number:

(Four CET points will be available for successful completion of both assessments and these points will be applied to the 2016-2018 CET cycle)

I would prefer to be contacted by: email.....post.....telephone (circle one)

We want to know about your prior knowledge and experience of OCT scan interpretation so we will ask you how often you view and assess OCT images in any context or situation*

*If you have access to OCT in practice (either full or part-time) you are likely to be viewing and assessing the OCT images of your own patients reasonably often.

If however you do not have access to OCT, you may still have some experience in OCT interpretation (for example in lectures, CET events, demonstrations by OCT suppliers).

How many OCT scans do you view and assess (in any context or situation) in a typical month? Please **circle** the most appropriate option:

1. **Less than 5**

2. **5 to 10**

3. **More than 10**

Appendix 7 – participant post-study information

What will happen after the study is completed?

A total of 4 CET points (for the new 2016-2018 cycle) will be available for successful completion of both assessments. After the study is completed only participants who have completed the study (from both the study and control groups) will be given free access to the OCTAID. Feedback will be invited only from these participants and this feedback will form the basis of the site's further development. Practitioners may be particularly interested in sharing some scans from their own archive especially when there is a full patient history and:

- A confirmed and definitive diagnosis and management plan, for example, when there is a HES reply to the referral
- A good quality scan illustrates a 'typical' example of a disease entity
- A good quality scan illustrates an 'atypical' example of a disease where optometrists may find the diagnosis/management challenging
- A good quality scan illustrates the staging of a disease (from early to advanced)

A mechanism will be formulated to measure consensus opinion on the content of the OCTAID site so that all participants can feel part of this collaborative venture. All scans/images will be fully acknowledged on the image captions.

Appendix 8 - Literature search (sources and search engines).

1. LSBU library using SCOPUS and Pubmed
2. College of Optometrists Library giving access to archive copies of peer reviewed College publications: Ophthalmic and Physiological Optics; Optometry in Practice
3. College of Optometrists OpenAthens login providing access to the following resources: **College Library Catalogue**; **Ebook Library (EBL); EBSCO A to Z service** (Acta Ophth; Am J of Ophth; Am Orthop J; BJO; BJVI; BMJ; Clinical & Exper Ophth; Clin & Exper Optom; Doc Ophth; Eye; J AAPOS; J of Cat & Ref Surg; Ophthalmology; Surv Ophth; Vision Research); **Nature Publishing group (Eye); Ovid Online** (Journals & e-books: Arch Ophth; Cornea; Eye & Contact Lens; Int Ophth Clin; Optom Vis Sci. E-books include Evidence-Based Eye Care and Shields Textbook of Glaucoma); **SAGE Journals Online** (Access British Journal of Visual Impairment); **ScienceDirect** (Journals and e-books: American Journal of Ophthalmology; Contact Lens & Anterior Eye; Journal of Cataract & Refractive Surgery; Ophthalmology; Optometry; Survey of Ophthalmology; J AAPOS; Vision Research); **VisionCite** (A database of journal article citations related to vision science, developed and maintained by the Illinois College of Optometrists Library); **Wiley InterScience** (Acta Ophthalmologica, Clinical & Experimental Optometry, Clinical & Experimental Ophthalmology); **British Journal of Ophthalmology**

Appendix 9 – Study participants' feedback (testimonials)

Hi Paul,

Please find attached feedback form. Thank-you for letting me take part in your study. I found it very interesting and educational.

Kind Regards

.....

I'm very glad I took part. My knowledge has increased significantly and I feel far more confident now. Thank you for giving me the opportunity to take part.

Kind regards

.....

Above average presentation of learning aid with genuinely thought provoking questions.

.....

Novel idea and very very useful. Excellent CET

.....

Well, I learnt all sorts of things...
Never heard of MacTel before, but have now thanks to OCTAID
Also the common artifacts and the causes, was oblivious before...
I could go on but sure you're very aware that there are loads of us v new to it all...too nervous to post on the Optix forum, (there are some of our local colleagues on there!!)....had v short intro from Topcon/other supplier....there is little out there to help...except Retina Revealed, I do look at that...College library has nothing on its shelves to borrow as everything out on loan....
So thank you for all your hard work
Best wishes

PS how about a 'search' feature on OCTAID?

.....

It definitely is a good aid when analysing images. Let me know when I can repeat the first exam

.....

Hi Paul

What you are doing seems some good work here…

I am already part of your OCT study and have completed the first part with a score of 75%. I signed up ages ago. I was wondering if it would be possible for me to have a Powerpoint of your case questions and images that I can use internally for my optoms, for me to run a training session aside from your study?

This would be completely separate from your study of course?

Won't be offended if you say no..

Regards

.....

A very useful tool that I shall continue to use in practice on a regular basis. Thank you very much

.....

Excellent. Best OCT CET ever

.....

The CET enabled me to reflect on my own and others practice.

.....

Well presented and very relevant to daily practice
I really enjoyed it, and learned a lot despite it being the introductory exam.
Above average presentation of learning aid with genuinely thought provoking questions.
More CET of this level / quality is what we should strive for

.....

Excellent thought provoking content.
I thought the questions were searching, and more challenging than I expected. I believe this will be very good for my personal development.

On the whole the presentation of this CET put me in a very realistic situation. Challenging scenarios but very relevant.
I think it is a very worthwhile exercise.

.....

Very good, and challenging, CET module – unlike so many in the domain. The questions (and the answers) caused me to go back to the training information and review what I'd "learned".
This was really helpful

.....

Very good quality material throughout, would highly recommend.

.....

A very useful tool that I shall continue to use in practice on a regular basis.
Thank you very much

.....

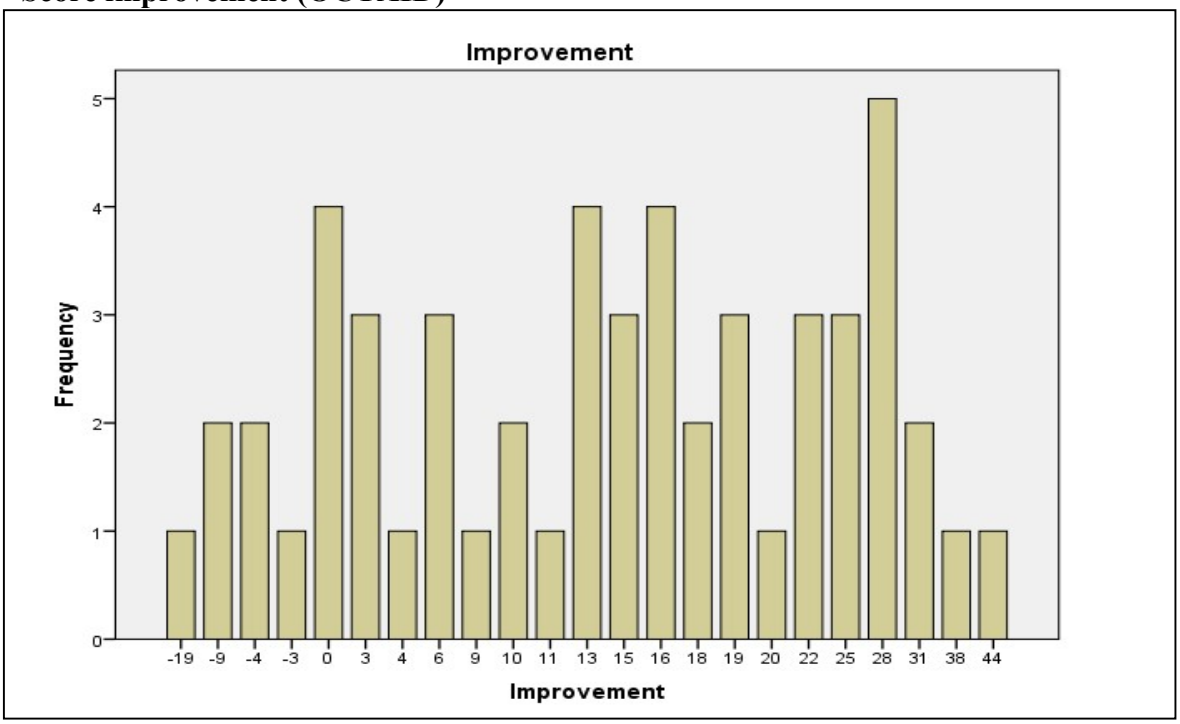
A very interesting and engaging way of learning.

.....

I found this CET extremely interesting, and very helpful. I would recommend anyone intending to use OCT in their practice to take part. It is extremely helpful for lone practitioners.
A novel approach to educating and highly usable in daily practice
Very enjoyable and thought-provoking

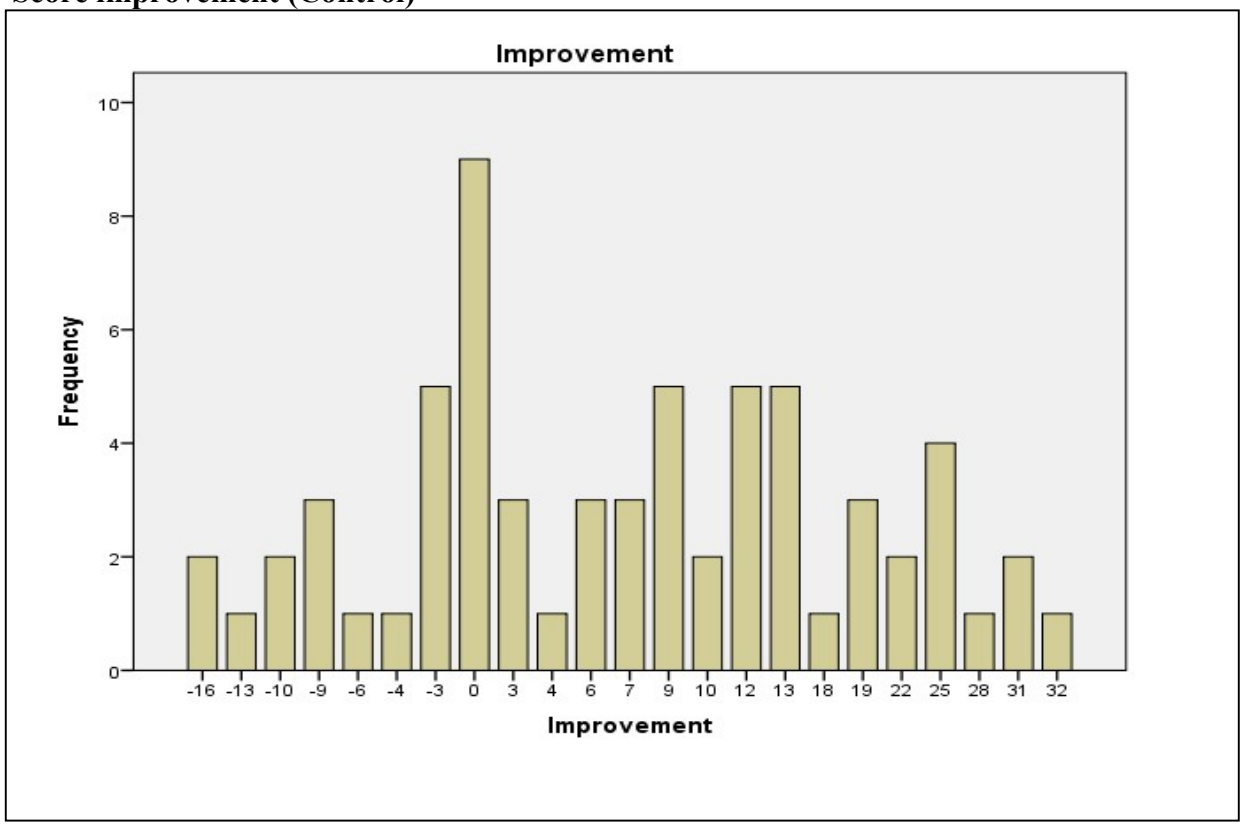
Appendix 10 – distribution of data and normality tests for main study outcome

Score improvement (OCTAID)



Frequency bar chart showing distribution of data for exam score improvement (OCTAID)

Score improvement (Control)



Frequency bar chart showing distribution of data for exam score improvement (Control)

Tests of normality (Improvement score OCTAID v Control)

Tests of Normality

	GROUP	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
		Statistic	Df	Sig.	Statistic	df	Sig.
Improvement	OCTAID	.084	53	.200*	.990	53	.943
	Control	.097	65	.200*	.977	65	.268

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

Appendix 11 – Sample size calculation

Cohen's d is a common way to measure effect size. The formula for Cohen's d is:

$d = M1 - M2 / S\text{-pooled}$

Where:

M1 = mean of group 1

M2 = mean of group 2

S-pooled = the pooled standard deviation for the two groups

$S\text{-pooled} = \sqrt{[(S1^2 + S2^2) / 2]}$

Some general "rules of thumb" guidelines (to be used cautiously) exist whereby:

Small effect size = 0.2

Medium effect size = 0.5

Large effect size = 0.8

Large effect isn't necessarily better than small effect especially in settings where small differences may have a major impact.

However we have utilised data (means and standard deviations) from the primary outcome measures of the current study (mean exam score improvement) and have estimated a suitable sample size:

Mean exam score improvement (OCTAID) = 13.62 S1 = 12.662 $S1^2 = 160.326$

Mean exam score improvement (Control) = 7.17 S2 = 11.828 $S2^2$ = 150.114

S-pooled = 12.252

So in the case of the current study Cohen's d = (13.62 - 7.17)/12.252 = 0.526

Sample size estimate based on a desired statistical power of 0.8 and a probability level of 0.05:

Minimum total sample size = 92 (1-tailed hypothesis)

Minimum sample size per group (1-tailed hypothesis) 46

Minimum sample size per group (2-tailed hypothesis) 58

Minimum total sample size (2-tailed hypothesis) 116

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Publications presentations

Post Graduate Research Summer School 2014. Conference poster competition.

Second prize

European Academy of Optometry and Optics 2016 (Berlin)

Poster presentation

London South Bank University
Faculty of Health and Social Care

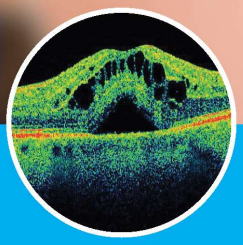
THE INSTITUTE OF OPTOMETRY

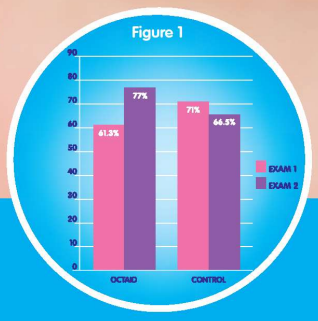
A randomised controlled trial of two approaches to improve diagnostic skills in Optical Coherent Tomography (OCT)

- Learn about OCT
- Test your OCT skills
- Earn free CET points

Paul Grace (London South Bank University, London)
Bruce Evans (Institute of Optometry, London)
David Edgar (City University London)

seeing beneath the surface is essential ...to the health of your eyes





If optometrists are to take full advantage of OCT's enhanced capabilities, they must develop the skills required to interpret scans so that they can make accurate diagnoses and make appropriate referrals of patients with retinal disease – especially Age related macular degeneration (AMD) patients.

We designed an online diagnostic algorithm (OCTAID) to assist in the diagnosis and optometric management of central retinal lesions using OCT.

The pilot study

- Six optometrists with varying degrees of OCT experience participated in the pilot study. We conducted a trial comparing two groups who underwent an online assessment, using clinical vignettes, of their skills in diagnosis and patient management (e.g., referral priority) based on OCT images before and after an educational intervention.
- The two educational interventions were randomly allocated each to one group and were: (a) OCTAID and (b) a control intervention comprising conventional OCT training materials.

An expert panel was recruited to advise on the design of the diagnostic algorithm and to act as a reference standard in assessing practitioners' diagnostic and patient management skills. The panel comprised two optometrists, two consultant ophthalmologists, and a biomedical scientist all with expertise in medical retina/ocular imaging.

- Pilot participants reported favourably on the educational value of the study, the ease of navigation of the OCTAID site and online exams.
- The participants consistently reported that the online exams took too long to complete.

Outcomes of pilot and conclusions

- The pilot data indicate that OCTAID improves OCT skills (see Figure 1).
- The online exams have been shortened in response to pilot feedback.

The main study has commenced following the successful pilot.

All eyecare professionals who would like to improve their OCT skills are invited to enrol by the closing date of 15.6.2016.

Research ethics committee documentation

Governance : Administration Of Research Ethics Committee <ethics@lsbu.ac.uk> 06/06/2013

to bjwe, Pamela, d.f.edgar, me

Dear Paul

Thank you for your revised documents for your application to the University Research Ethics Committee entitled:*Investigation of the efficacy of an online diagnostic algorithm for improving the optometric referral and diagnosis of ocular fundus lesions detected with Optical Coherence Tomography (OCT)* (UREC 1307). I can now give full Chair's Approval.

Best wishes for your research. A formal letter will be sent in due course.

Sincerely

Joan

Professor Joan Curzio
University Research Ethics Committee
London South Bank University
106 Borough Road
LONDON SE1 0AA

From: Paul Grace [bristowpark@googlemail.com]
Sent: 13 May 2013 08:56
To: Governance : Administration Of Research Ethics Committee
Subject: Paul Grace Prof Doc Allied Health Resubmission

Ronald Rabbetts, MSc, FCOptom, SMSA, DCLP 31 Warblington Street PORTSMOUTH, PO1 2ET Phone: 023 92816571 Email: ronald.rabbetts@virgin.net The Chair London South Bank University Research and Ethical Committee London 27 February 2013

Dear Sir/Madam Ref: Doctorate of Optometry application Paul Grace Investigation of the efficacy of an online diagnostic algorithm for improving the optometric referral and diagnosis of ocular fundus lesions detected with Optical Coherence Tomography (OCT)
As Chairman of the Institute of Optometry's Research and Ethical Committee, I report that this application together with its documentation has been reviewed by the Institute's REC, and that Paul Grace has reviewed and corrected as appropriate the various minor suggestions and criticisms suggested by my committee members.

Hence I confirm that the Institute of Optometry's Research and Ethical Committee now approves the application.

Yours sincerely

Ronald Rabbetts