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AN INITIATIVE OF THE NATIONAL, STATE AND
TERRITORY GOVERNMENTS OF AUSTRALIA
AND THE GOVERNMENT OF NEW ZEALAND

Horizon Scanning Technology

Prioritising Summary

**Triggerfish[®] continuous intraocular
pressure monitoring system for the
improved management of glaucoma
patients**

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PRIORITISING SUMMARY

REGISTER ID: 000506

NAME OF TECHNOLOGY: TRIGGERFISH[®] INTRAOCULAR PRESSURE MONITORING SYSTEM

PURPOSE AND TARGET GROUP: CONTINUOUS MONITORING OF INTRAOCULAR PRESSURE FOR IMPROVED MANAGEMENT OF GLAUCOMA PATIENTS

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- | | |
|---------------------------------------------------|-------------------------------------------------------------------------------------------------|
| <input checked="" type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- Yes
- No
- Not applicable

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Switzerland		✓	
Germany	✓	✓	

IMPACT SUMMARY

Sensimed (Lausanne, Switzerland) provides the Triggerfish[®] system with the aim of continuous monitoring of intraocular pressure (IOP). The technology would feasibly be offered through existing ophthalmological service providers for the improved management of persons with glaucoma, or those at high risk of developing the disease.

BACKGROUND

Glaucoma is a condition in which progressive destruction of the optic nerve results in gradual impairment of vision and ultimately complete blindness. The damage to the optic nerve is usually attributed to increased pressure inside the eye, or ocular

hypertension. Under normal circumstances, clear fluid flows in and out of the anterior chamber of the eye, leaving at the angle where the cornea meets the iris through a drain-like spongy meshwork (see Figure 1). Open-angle glaucoma, the most common form, occurs when this fluid passes through the meshwork too slowly. As the fluid builds up, the IOP increases to levels that have potential to damage the optic nerve. As the level of pressure an eye can withstand varies from person to person, a diagnosis of glaucoma requires the presence of optic nerve damage rather than ocular hypertension alone. In some instances, damage to the optic nerve may occur without elevated pressure within the eye (low tension or normal tension glaucoma), and is rather the consequence of poor blood supply to the nerve or a structural weakness within the nerve fibres (NHMRC 2008).

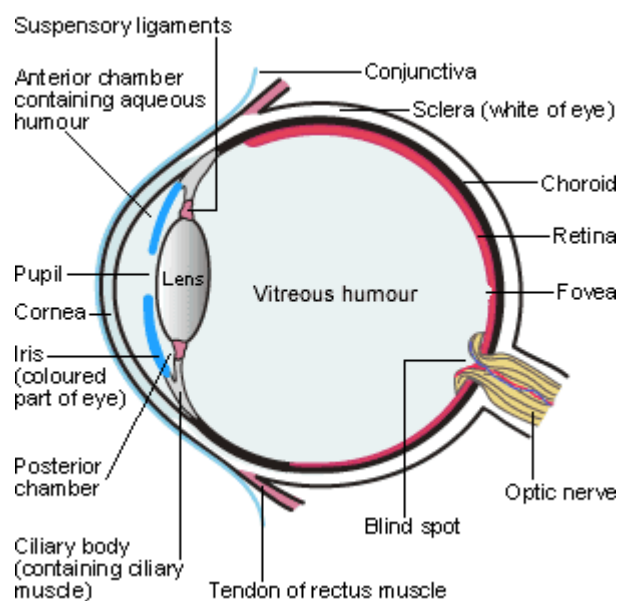


Figure 1 The structure of the eye (Retina Australia Victoria 2010)

When glaucoma first develops, vision is normal and there is no pain. If the glaucoma remains untreated, the vision begins to be first compromised at the periphery, and if treatment is further delayed, a sudden loss of side vision may ensue, giving the effect of looking through a tunnel. Over time, forward vision deteriorates to the point of complete blindness (CERA 2004; NHMRC 2008).

Given there is no cure for glaucoma, early diagnosis and treatment are vital in delaying the onset and/or progression of the disease. Typically, glaucoma is detected through visual acuity and field testing, optic nerve examination and tonometry, the measurement of tension or pressure, for which a number of commercial devices using various techniques are available. The current practice of monitoring of glaucoma with periodic tonometry during office hours is a suboptimal approach because of fluctuations in IOP and the common occurrence of nocturnal pressure peaks. The only way of assessing nocturnal IOP using standard tonometry is by overnight admission of a patient to a sleep laboratory or in-patient facility for periodic measurements and it

is controversial as to whether the need to awaken patients for nocturnal IOP measurements provides accurate representation of sleeping IOP. Determination of more complete IOP profiles is the rationale behind the development of contact lens embedded devices with the ability to communicate with a central processing unit (Sit 2009; Wikipedia 2010).

Triggerfish[®] is currently the only commercialised alternative to the expensive, inconvenient and limited approach to IOP monitoring by serial tonometry. The Triggerfish[®] sensor is a soft single-use contact lens with embedded strain gauges to measure fluctuations in IOP at the junction between the cornea and sclera. Also embedded are the telemetric chip and micro-loop antenna for wireless reception of power and data output (Figure 2). The signal sent from the micro-antenna is directly correlated to changing IOP (Sensimed 2010).

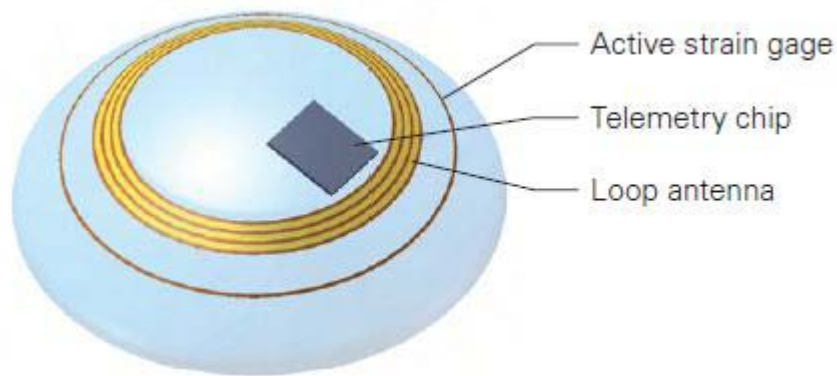


Figure 2 The Triggerfish[®] sensor (Sensimed 2010)

Effective monitoring involves wearing the Triggerfish[®] system for up to 24 hours during which the patient carries out normal activities, including sleep. The system comprises the contact lens sensor, a flexible adhesive antenna which fits around the eye and a recorder which is connected to the antenna via a thin, flexible data cable (Figure 3). At the conclusion of 24 hours, data are uploaded wirelessly via Bluetooth connectivity to a practitioner's computer for assessment (Sensimed 2010).

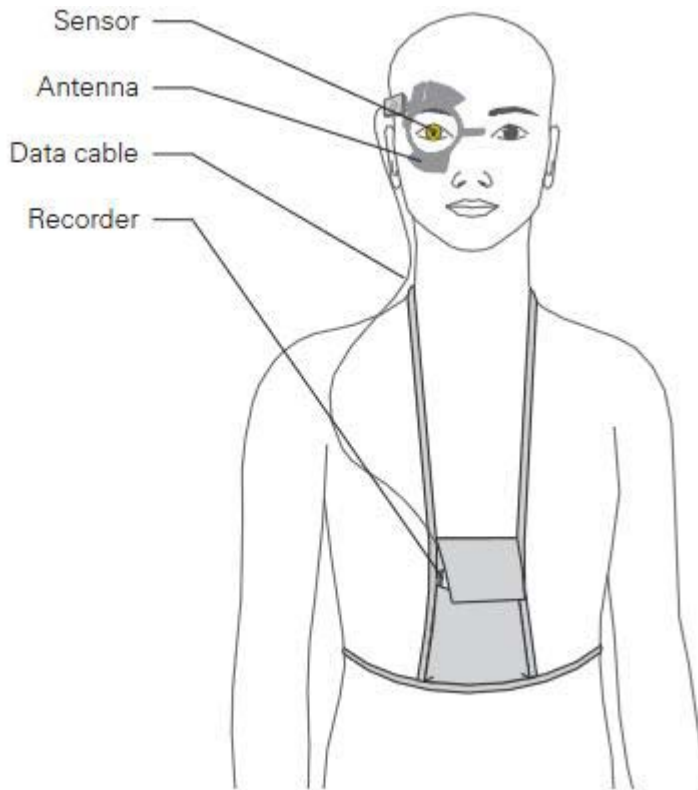


Figure 3 Wearing of the Triggerfish® system (Sensimed 2010)

CLINICAL NEED AND BURDEN OF DISEASE

Glaucoma is estimated to account for 2.3 per cent of the visually impaired population in Australia and is the fourth most prevalent eye disease, following cataract, age-related macular degeneration and diabetic retinopathy. Since glaucoma is a disease associated with ageing, one source has estimated that it is responsible for 14 per cent of all blindness in individuals aged over 40 years. From age 55 years, this figure rises to 16 per cent. Due to Australia’s ageing population, it can be expected that the prevalence of glaucoma will increase (CERA 2004; NHMRC 2008).

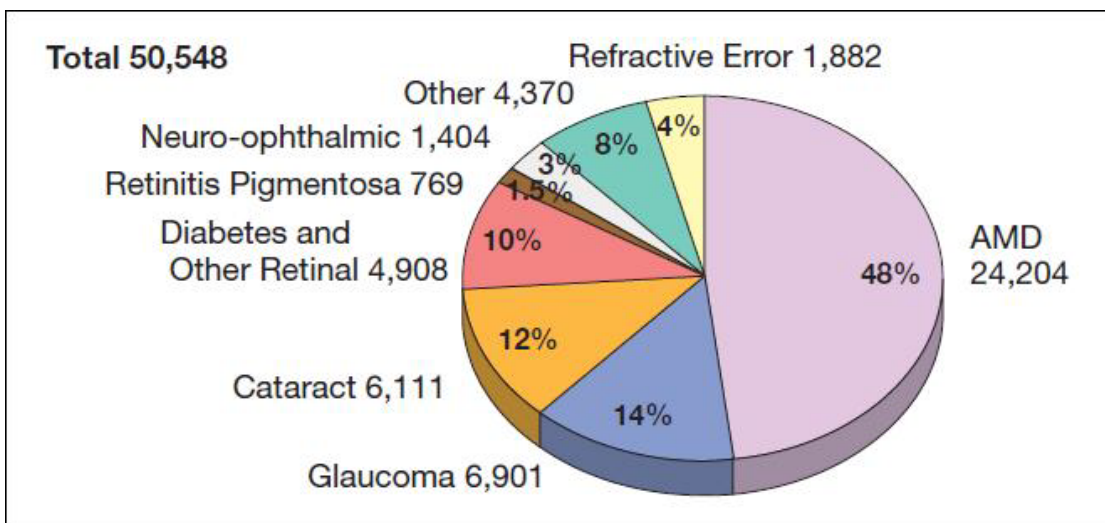


Figure 4 Estimated blindness by cause in Australians aged over-40 years, 2004 (CERA 2004)

Projected data for prevalence of visual impairment due to glaucoma stratified by age group emphasise the association between glaucoma and age (Table 1) (CERA 2004).

Table 1 Visual impairment from glaucoma by age, Australia, 2004-2024 (CERA 2004)

Age group	% Population with VI	Prevalence				
		2004	2010	2014	2020	2024
60-69	0.1	1,191	1,487	1,853	2,083	2,225
70-79	0.3	3,069	3,259	3,653	4,793	5,616
80-89	1.4	8,669	10,268	10,924	12,387	14,176
90+	1.2	813	1,081	1,229	1,359	1,489
VI						
Total pop		13,741	16,096	17,658	20,623	23,507
Pop >40 yrs	0.15%	0.16%	0.16%	0.18%	0.19%	
Blind						
Total	6,901	8,561	9,890	11,289	12,595	
Pop >40 yrs	0.077%	0.086%	0.092%	0.097	0.103%	

VI=visual impairment

The AIHW National Hospital Morbidity Database recorded 3,416 public hospital separations due to glaucoma during 2007-2008 (AIHW 2010). In New Zealand, Ministry of Health data indicated there were 518 public hospital separations during 2006-2007 (MoH 2010).

DIFFUSION

Triggerfish[®] has not diffused into Australian use and at the time of preparing this summary it was found that commercialisation was limited within Europe.

COMPARATORS

The current gold standard in measuring IOP is applanation tonometry. This technique is based on the force required to applanate (flatten) a constant area of the cornea to the point where the meniscal forces of the tear film become equivalent to the rigidity of the cornea. The instrument most widely used for applanation is the Goldmann tonometer. There are several other tonometrical techniques in use, including dynamic contour tonometry, which uses contour matching rather than applanation, and non-contact tonometry, which does not require the tonometer to come in contact with the cornea. All of these indirect methods have a degree of inherent imprecision as measurements are taken from the outside of the eye, representing a *function* of the true pressure on the inside (Sit 2009; Wikipedia 2010).

SAFETY AND EFFECTIVENESS ISSUES

The literature search for studies investigating the use of Triggerfish[®] found only one case series published in German (Faschinger & Mossbock 2010). The abstract reported that 24 hours of continuous IOP measurement revealed profiles with greatest variation during sleeping hours with subjects in the supine position. However, due to lack of validation of the results, it is unknown if intermittent spikes represented true

increases in IOP or artefacts. Tolerability of the device was reported to be good by all patients studied.

American researchers have described IOP measurement using an experimental contact lens embedded sensor in conjunction with a modified dynamic contour tonometer (Twa et al 2010) (level III-3 diagnostic evidence). The study involved repeated measurements of IOP in 12 eyes of 12 subjects with no history of eye disease (median age 25 years, range 23-35 years) in sitting and supine positions. Three configurations of a dynamic contour tonometer were used: conventional slit-lamp mounted (DCT), hand held (HH) and contact lens embedded sensor (CL), however, no supine measurements were taken with the DCT, as this standard configuration can only be used with the subject in an upright position. The main aims of the study were to determine if IOP measurements using the CL-based sensor were feasible, how these measurements compared to conventional DCT, and the effects of body position on IOP measurements made with this sensor.

The mean sitting IOP measured with DCT, the HH sensor and the CL sensor was 16.3mm Hg (95% CI [15.6, 17.1]), 16.6mm Hg (95% CI [15.6, 17.6]) and 15.7mm Hg (95% CI [15.0, 16.3]), respectively, $p=0.053$. Supine IOP measurements were taken using only the HH and CL sensors, 19.6mm Hg (95% CI [18.3, 21.0]) and 17.7mm Hg (95% CI [17.0, 18.4]), respectively, $p=0.003$. Supine measures of IOP were higher than sitting measurements with both the HH and CL sensors. The measured difference in IOP as a function of subject position using the HH sensor was 3.0mm Hg (95% CI [1.8, 4.3]), $p<0.001$. The difference in IOP observed for the CL sensor was 2.0mm Hg (95% CI [1.2, 2.8]), $p<0.001$ (Twa et al 2010).

These results indicate that IOP using a sensor embedded within a contact lens is possible and that sitting IOP measurements compare favourably with standard DCT tonometry. However, the investigators indicated that this experimental device used a hard contact lens which was swabbed with alcohol and re-used for each of the subjects, and that a wire directly connecting the embedded sensor with the stand of the tonometer required manual support to maintain the lens position for accurate measurements of IOP (Twa et al 2010). The Triggerfish[®] system, described by Faschinger and Mossbock (2010), has addressed these issues with development of a single use soft contact lens that has no connecting wires, but a clear indication of the clinical relevance of Triggerfish[®] for glaucoma detection and management awaits the emergence of prospective trials in English (see 'Other Issues').

A prototype of the Triggerfish[®] system has been evaluated in animal models (Leonardi et al 2009). Enucleated pig eyes, in which IOP was alternated between 11 and 14mm Hg to simulate ocular pulsation, were used to demonstrate the correlation between the contact lens embedded sensor measurements and true IOP. The IOP was artificially increased from 20mm Hg to 30 mm Hg in 1mm Hg increments and the sensor was found to measure the changing pressure with an accuracy of ± 0.2 mm Hg.

COST IMPACT

A request was made to Sensimed for cost information on the Triggerfish[®] system, however, no response was received.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

OTHER ISSUES

During the preparation of this summary, it was found that investigators in Germany are currently recruiting subjects for a prospective cohort study comparing Triggerfish[®] with Goldmann applanation tonometry in primary open-angle glaucoma (NIH 2010).

SUMMARY OF FINDINGS

The evidence supporting IOP measurement using contact lens embedded sensors is currently in a preliminary form. To date, only an experimental predecessor of Triggerfish[®] has been described in English. Further prospective trials are awaited.

HEALTHPACT ASSESSMENT:

Based on the limited availability of evidence which is preliminary in nature, and uncertain clinical impact at this stage, it is recommended that no further review of this technology be undertaken by HealthPACT at this time and that any further developments with the technology will be duly noted by future horizon scanning activity.

NUMBER OF INCLUDED STUDIES

Total number of studies	1
Level III-3 evidence	1

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SEARCH CRITERIA TO BE USED:

Glaucoma
Intraocular pressure, contact lens
Tonometry
Sensimed