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Australia and New Zealand Horizon Scanning Network

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TERRITORY GOVERNMENTS OF AUSTRALIA
AND THE GOVERNMENT OF NEW ZEALAND

Horizon Scanning Technology Prioritising Summary

Pulsed electron avalanche knife (PEAK-fc)

February 2008



**Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures -
Surgical**



**Royal Australasian
College of Surgeons**

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PRIORITISING SUMMARY

REGISTER ID S000070

NAME OF TECHNOLOGY PULSED ELECTRON AVALANCHE KNIFE (PEAK-FC)

PURPOSE AND TARGET GROUP TO AVOID COLLATERAL DAMAGE CAUSED BY CONVENTIONAL DISSECTION TECHNIQUES USED IN INTRAOCULAR SURGERY, PARTICULARLY IN PATIENTS AT RISK OF RETINAL DETACHMENT

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

- | | | |
|---|-------------|----|
| <input type="checkbox"/> Yes | ARTG number | NA |
| <input checked="" type="checkbox"/> No | | |
| <input type="checkbox"/> Not applicable | | |

INTERNATIONAL UTILISATION

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

IMPACT SUMMARY

Dissection using the Pulsed Electron Avalanche Knife during intraocular microsurgery in patients with an ocular condition is an alternative to mechanical segmentation and delamination. This technology is yet to emerge in Australia.

BACKGROUND

Intraocular microsurgery, in particular retinal and vitreous surgeries, is increasingly being used for the prevention and treatment of various eye conditions, including cataract, retinal detachment and infection (Palanker 2004). Untreated eye conditions may lead to severe vision loss or blindness, therefore it is necessary to identify and treat these complaints in a timely manner to optimise patient outcomes. The majority of treatments are surgical and due to the delicate nature of the eye, it is important to use precise and safe surgical equipment and techniques to prevent further damage to the fragile eye tissues (Palanker 2004).

Patients undergoing cataract extraction have a 1.5% chance of incurring an iatrogenic retinal tear which may lead to retinal detachment (Patalano 2004). A retinal tear allows vitreous liquid to enter and pool under the retina causing separation of the retina from the choroid (Patalano 2004). As detachment occurs, vision is lost, usually occurring at the perimeter of the retina first, resulting in peripheral vision loss, progressing until entire retinal detachment occurs and vision is completely lost (Patalano 2004).

Conventional vitreoretinal surgery involves the removal of vitreoretinal membranes by mechanical segmentation and delamination using a significant amount of traction to the underlying retinal tissue (Palanker 2004). This methodology often results in damage to internal retinal layers, tears, and bleeding (Palanker 2004). The Pulsed Electron Avalanche Knife (PEAK-fc) is a new electric cutting device for intraocular microsurgery (Priglinger et al. 2007). This electrosurgical instrument uses 'cold' cutting and traction free dissection in a liquid medium to reduce damage to the eye (Priglinger et al. 2007). The first generation PEAK-fc had limited surgical applicability due to the shape of its probe (Palanker 2004). The device used very short pulse length (nanoseconds) and high voltages (3 to 6 kV), sometimes resulting in perforated (instead of clean) incisions which meant revision of the incision was often necessary, resulting in increased damage and longer operations (Palanker 2004).

The second version of the device incorporates a varied probe structure with greater cutting efficiency. This device uses lower voltages (300 to 600 V) and a shorter pulse length (approximately 100 μ s) with each pulse consisting of a burst of several tens of biphasic 'minipulses' (1 - 2 μ s duration) (Priglinger et al. 2007). Cutting is established as the electrical pulse rapidly vaporises and ionises liquid and tissue in close proximity to the electrode (Priglinger et al. 2005). The addition to the original PEAK-fc probe structure is a protruding tungsten wire 'cutting piece' (0.6 mm length, 50 μ m diameter) as well as an integrated 'hot' coagulation mode to seal vascular abrasions and eliminate bleeding (Palanker 2004). Because PEAK-fc uses short duration electrical pulses to cut through tissue there is little collateral damage caused from heat diffusion through the tissue from the incision site (maximum heat diffusion 7 μ m) (Priglinger et al. 2007). The advantages of PEAK-fc over conventional methods include sharply defined transection and incision of epiretinal membranes, fine coagulation of vascularised epiretinal tissue and traction free dissection (Priglinger et al. 2007).

CLINICAL NEED AND BURDEN OF DISEASE

Eye disorders are a common health complaint among many Australians, particularly the elderly. Data from 2005 reports that of people aged 65 years and older, approximately 90% have experienced some form of eye disease (ABS 2006). In 1995, 47% of the population reported an eye problem as a source of their long term illness (ABS 1997). In 2006, 52% of Australians reported eye sight problems (ABS 2006). Compromised visual acuity often leads to an increased risk of falls, motor vehicle accidents, household injuries (e.g. scalding burns) and impaired quality of life.

The leading reason of visual impairment and blinding in Australia is aging, with the most common cause being cataract (AIHW 2007). Although retinal detachment may lead to vision loss it is of relatively low incidence in Australia (personal communication 2008). In 2005, it was estimated that 9.4% of people aged over 55 years were visually impaired and 1.2% were blind (AIHW 2007). Other populations at particular risk of vision loss include: Aboriginal people, Torres Strait Islanders, people with a familial history of eye disorders, diabetics (15.3% have developed retinopathy) and people from lower socioeconomic communities (AIHW 2007).

DIFFUSION

The PEAK-fc is a novel approach in in-vivo human intraocular surgery. It has undergone several investigational studies in Germany, however it is yet to emerge elsewhere in the world.

COMPARATORS

The main comparator for PEAK-fc is conventional dissection through mechanical segmentation and delamination using intraocular scissors, forceps, myringotomy blades or diamond knives (Palanker 2004).

SAFETY AND EFFECTIVENESS ISSUES

The literature available regarding the use of the PEAK-fc device in human patients during intraocular microsurgery was limited. A total of three case series were retrieved.

Priglinger et al. (2007) recruited 20 consecutive patients (20 eyes, one per patient) for investigation of the PEAK-fc device. The patients included ten males and ten females with a mean age of 46 years (range: 2 – 81 years). The preoperative diagnoses of the patients included congenital cataracts in five children, advanced senile cataracts (n = 2), mature cataracts (n = 6, including three with posterior iris synechia), posttraumatic cataracts with zonulolysis (n = 3), posttraumatic intumescent cataract (n = 1), anterior capsule opacification after cataract surgery (n = 2) and massive fibrosis covering the iris, pupil and most of the trabecular meshwork (n = 1). Three surgical manoeuvres were carried out using PEAK-fc, including anterior and posterior capsulotomy, synechiolysis and dissection of anterior capsule phimosis/scar tissue. Complete ophthalmologic

examinations included visual acuity tests (Snellen), slit-lamp examination, intraocular pressure measurement and fundus biomicroscopy (Priglinger et al. 2007).

In an earlier study by Priglinger et al. (2006) two patients with cataracts were selected, including one child with congenital cataract and one adult with mature cataract.

Conventionally, continuous curvilinear capsulorhexis (CCC) is the preferred technique to achieve circular, stable anterior capsulotomy during cataract extraction; however this is often difficult and dangerous in some cases of congenital or mature cataract. This is because of an increased risk of radial tears due to either increased capsule elasticity and posterior pressure in pediatric eyes, or the lack of red fundus reflex or liquefied cortex in mature eyes (cortical cataracts). The PEAK-fc device is capable of dissection devoid of capsule traction and is potentially a more practical approach to cataract extraction. After one-year of failed amblyopia therapy, the two-year old child with congenital cataract in the left eye underwent anterior capsulotomy using the PEAK-fc device. A 45-year old man with mature cataract and impaired visual acuity (with history of trauma to the left eye six months prior to presentation) also underwent anterior capsulotomy with the PEAK-fc device (Priglinger et al. 2006).

In the earliest study of the PEAK-fc device, also reported by Priglinger et al. (2005), 18 patients (18 eyes, one per patient) were consecutively enrolled. The study included 10 men and eight women with a mean age of 64 years (range: 53 – 79 years). The preoperative diagnoses included tractional retinal detachment involving the fovea in patients with diabetic retinopathy (n = 6), proliferative vitreoretinopathy (n = 5), age-related macular degeneration with subretinal hemorrhage (n = 5), tractive epiretinal membrane with history of central retinal vein occlusion (n = 1) and posterior capsule fibrosis with prolonged proliferative diabetic retinopathy (n = 1). The study protocol allowed the use of PEAK-fc for one or more manoeuvres at the surgeon's discretion. The manoeuvres tested during surgery included drainage retinotomy for patients with subretinal hemorrhages, relaxing retinotomy for patients with prolonged retinal detachment, transection and incision of epiretinal membranes in proliferative diabetic retinopathy/proliferative vitreoretinopathy/macular pucker, surgical posterior membranectomy with posterior capsule fibrosis in prolonged proliferative diabetic retinopathy and retinal vessel coagulation (Priglinger et al. 2005).

In all three studies, the PEAK-fc parameters used were those obtained from in-vivo animal and in-vitro human testing. The parameters were increased until the desired human tissue effect was obtained. The initial parameters were set as follows: pulse repetition rate 40 - 100Hz, pulse duration 100 μ s and 60 'minipulses' per pulse (Priglinger et al. 2007; Priglinger et al. 2006; Priglinger et al. 2005).

a) Safety

The three studies included did not report extensive safety data.

Priglinger et al. (2007) reported PEAK-fc cuts to have sharp edges with very little visible whitening suggesting minimal collateral damage. This study reported no PEAK-fc related

complications. However, several cases of minimal bleeding which resolved spontaneously were reported following treatment with the PEAK-fc device. There were no cases of postoperative cystoid macular oedema during the follow up period (Priglinger et al. 2007).

Priglinger et al. (2006) reported no major intraoperative complications in the two patient sample. Again, PEAK-fc cuts appeared to be sharp with little whitening suggesting insignificant thermal damage (Priglinger et al. 2006).

Priglinger et al. (2005) reported retinal tears, bleeding and collateral damage as adverse surgical events. There was one case of minor self limited bleeding at the margin of one retinotomy. Three of the five patients operated on with sub macular bleeding associated with age related macular degeneration incurred extensive bleeding and required 180° retinotomy due to iatrogenic retina detachment. Intraoperative bleeding (caused by vascularised epiretinal membranes in proliferative diabetic retinopathy) was stopped using the coagulation mode of PEAK-fc (Priglinger et al. 2005).

b) Effectiveness

In Priglinger et al. (2007) anterior capsulotomy was successfully performed in 15 patients (15 eyes), even in extremely complicated cases, for example when massive pigment desposition occurred after the removal of iris synechiae. In two cases surgeons failed to complete a continuous curvilinear capsulorhexis with capsulorhexis forceps as the incision margins showed extensive radial rip which would eventually result in damage to the posterior capsule. PEAK-fc was able to complete the procedure and avoid further damage. In two cases PEAK-fc successfully separated posterior iris synechiae (after unsuccessful attempts using conventional instrumentation). After synechiae removal capsulotomy was successfully performed with PEAK-fc in all cases. PEAK-fc also allowed for selective tissue dissection without affecting the surrounding eye structures. Postoperative examination data suggests that endothelial cell counts were similar to those of patients who had recently undergone conventional cataract surgery and visual acuity improved by a mean \pm SD of 5.6 \pm 3.3 Snellen lines (Priglinger et al. 2007).

In Priglinger et al. (2006) anterior capsulotomy was successfully performed in both patients. Slow movement of the probe (approximate velocity 1mm/s) proved to be the best method of incision as it produced successful cuts with little collateral damage. The formation of gas bubbles, similar to those produced by conventional diathermy, resulted from the use of the PEAK-fc device, however at the set parameters used, these bubbles were able to be minimized at a level which did not significantly impair visualization during the procedure (Priglinger et al. 2006).

In Priglinger et al. (2005) PEAK-fc was successfully used in all 18 operative procedures. A bimanual approach facilitated precise cutting with minimal to no traction and avoided

potential complications. With the exception of strong adherent membranes and intraretinal proliferative vitreoretinopathy, membranes were easily removed in all cases. Subretinal bleeding and choroidal neovascularisations were successfully removed. Again, gas bubbles produced posed a potential threat to visualisation during surgery. Despite the fact the bubbles did not interfere in this case it is a possible limitation of the PEAK-fc system (Priglinger et al. 2005).

COST IMPACT

The Australian Institute of Health and Welfare described the financial and social costs of visual impairments as considerable (AIHW 2007). Visual impairment was found to shorten life expectancy, increase the risk of other conditions, restrict participation in social activities, decrease independence, and impair mental and physical health status (AIHW 2007).

People with visual impairment are also more likely to be reliant on social services and their admission to nursing homes is higher, both contributing to an increased financial burden (AIHW 2007). In 2004, the total financial cost of visual impairment was calculated at \$5 billion (AIHW 2007). In 2006, the Australian government allocated \$13.8 million over a four year period in the federal budget to the new National Eye Health Initiative, in order to raise public awareness of eye health and the importance of early treatment and to improve the status of eye health care (AIHW 2007).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified from the retrieved material.

OTHER ISSUES

No issues were identified from the retrieved material.

SUMMARY OF FINDINGS

The available literature suggests that the PEAK-fc device can be successfully used to carry out a number of surgical manoeuvres encountered during ocular surgeries.

Based on the quantity of literature available it is necessary that further studies be carried out, ideally these studies should compare the outcomes of conventional ocular surgery with surgery using the PEAK-fc device and include larger sample sizes.

HEALTHPACT ACTION

Based on the limited evidence available, the PEAK-fc will be monitored for 12 months.

NUMBER OF STUDIES INCLUDED

Total number of studies	3
Level IV evidence	3

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SEARCH CRITERIA TO BE USED

Pulsed electron

Avalanche knife

PEAK-fc

Cataract extraction

Intraocular microsurgery