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Australia and New Zealand Horizon Scanning Network

ANZHSN

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

Horizon Scanning Technology Prioritising Summary

Sutureless, wedge-shaped, self-sealing pars plana sclerotomy

June 2004



ASERNIP(S)

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



**Royal Australasian
College of Surgeons**



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The production of this Horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

This Horizon scanning prioritising summary was prepared by staff from the Australian safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).

**NAME OF TECHNOLOGY:**

Sutureless, wedge-shaped, self-sealing pars plana sclerotomy.

PURPOSE & TARGET GROUP:

This sutureless, wedge-shaped technique has been developed as an alternative treatment for patients undergoing pars plana vitrectomy. Wound leakage and suture irritation associated with conventional suture techniques may be avoided leading to reduced recovery time.

STAGE OF DEVELOPMENT (IN AUSTRALIA): Yet to emerge in Australia.

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use

INTERNATIONAL UTILISATION:

| COUNTRY | LEVEL OF USE | | |
|-----------------|-----------------|-------------|-----------------|
| | Trials underway | Limited use | Widely Diffused |
| The Netherlands | | ✓ | |

IMPACT SUMMARY**Background:**

This technique can prevent vision loss by treating many different retinal disorders including complications or bleeding from diabetic eye disease, retinal detachment, clouding of the vitreous jelly (due to bleeding, inflammatory debris or infection), macular hole, epiretinal membrane, foreign bodies which have entered or passed through the eye, intraocular infections (endophthalmitis) or vitreous changes following cataract surgery.¹

Fluctuations in intraocular pressure (IOP) can occur during vitrectomy. This is due to the exchange of intraocular instruments through the sclerotomies and subsequent closure, resulting in intraocular fluid or gas leaks; this may cause intraocular haemorrhage and retinal incarceration. Suture-related complications include wound leakage, scleral pigment changes and suture irritation.²

Using this new technique, the microvitorectal blade is radially introduced 3.5 mm from the limbus at a 30-degree angle of entry, with the tip turned away from the surgeon. At the infusion site, an additional incision is made in the opposite direction to create a scleral wedge. The infusion is then placed through the initial cut and the tube fixed with adhesive tape onto the sterile drape. After vitrectomy, counter incisions at the remaining



sclerotomies are performed and openings checked for leaks. The infusion line is removed and also tested for leaks.³

Clinical need and burden of disease:

The self-sealing sutureless technique for vitrectomy, first described by Chen in 1996⁴, may allow for sutureless closure of sclerotomies, better maintenance of IOP and reduced incidence of suture-related complications. Since its development, modifications of the technique have been developed to make this operation safer and more effective.³ In Australia data from the Australian Institute of Health and Welfare (AIHW) National Hospital Morbidity Database indicates that 6,334 patients were admitted to public and private hospitals for chorioretinal inflammation, retinal detachments and breaks, retinal vascular occlusions and other retinal disorders between 2001-2002 (<http://www.aihw.gov.au/hospitaldata/datacubes/index.html>).

Estimated speed, geographic and practitioner use patterns of diffusion in the health system:

This technique was developed in the Netherlands by Theelan and other surgeons; results for 18 patients undergoing this procedure were published in June 2003. This technique has already been used by the one of the authors in more than 80 patients.³

Existing comparators:

- sutured sclerotomies
- sutureless sclerotomies (original⁴ and modifications^{2,5,6,7})

Estimated cost impact:

The cost of vitrectomy in Australia is not available. The Medicare Benefits Schedule reimbursement fee for vitrectomy (procedure only) would be approximately A\$1,112.⁸ The costs associated with this new procedure are not available, however costs may be lower than the conventional procedure due to possible reduced surgical time and the procedure not requiring sutures (M. Goggin (surgeon), pers. comm., 2 April 2004).

Efficacy and safety issues:

Short-term safety and efficacy data exist from one comparative study (quasi-randomised controlled trial).³

Between January and March 2002, 21 patients scheduled for pars plana vitrectomy of one eye were alternatively assigned to either:

- The new sutureless sclerotomy, n=14 patients (wedge technique)
- Conventional sutured sclerotomy, n=7 patients (radial stab incisions technique).

Patients were excluded if they presented with severe ocular trauma, previous vitreoretinal surgery or risk of postoperative ocular hypotony. In addition to standard clinical examination, changes of intraocular structures at the sclerotomy sites were longitudinally studied by high-frequency ultrasound biomicroscopy (UBM) on day one, and six to eight weeks postoperatively to compare clinical aspects and characteristics of UBM in eyes operated on by both techniques.



Due to losses at follow-up (two patients in the sutureless group and one patient in the conventional suture group), complete analysis was performed on 18 eyes in total. Results for eleven females and seven males, with a mean age of 65.6 years (range 19-86 years) at a mean follow-up of 6.5 weeks (range 6-8 weeks) were reported.

No statistically significant differences were observed at baseline between both groups with regard to age, sex, ratio of right and left eyes, or lens situation.

Safety:

- no intraoperative complications reported in any case
- no patients had postoperative hypotony, leakage or any other complication that might be attributed to the sclerotomies

Efficacy: (see Tables 1 and 2)

- no visual loss reported
- in 1/12 (8%) patients in the sutureless group, two of the three sclerotomies had to be sutured at the end of surgery due to persistent fluid leakage. Due to proliferative diabetic retinopathy, complex vitreoretinal surgery with frequent change of instruments was necessary in this patient. In all other cases only few instrument changes were done
- no statistical significant intergroup differences according to pre- and post-surgical visual acuity and IOP were reported
- the mean grade conjunctival scarring six to eight weeks after surgery was higher in conventional suture group compared to the sutureless group, but the difference was not significant, $P=0.19$
- ultrasonography evaluation of the single sclerotomies did not show any significant differences accordant to vitreous incarceration, wound dehiscence and choroidal thickening
- no significant differences between patients with or without diabetic vitreous haemorrhage were reported. No significant intragroup change in the follow-up period
- the mean scleral dehiscence on the first postoperative day was significantly higher in the conventional suture group ($P=0.012$), after six to eight weeks of follow-up the difference was reduced
- on first day postoperative, choroidal thickening tended to be higher in the sutureless group on first postoperative day (no significant intergroup difference)
- at 6-8 week follow-up, no choroidal thickening was detected in either group. However, there was a significant decrease in choroidal thickening in the sutureless group ($P=0.015$) but not in the conventional suture group ($P=0.5$)



Table 1: Clinical features as mean and SD in patients undergoing pars plana vitrectomy

| Sclerotomy | Preoperative VA | Postoperative VA | Preoperative IOP (mm Hg) | Postoperative IOP (mm Hg) | Postoperative Conjunctival Scarring |
|------------|--------------------------|--------------------------|--------------------------|---------------------------|-------------------------------------|
| Sutureless | 0.20 [0.21] [†] | 0.50 [0.32] [†] | 15 [2] | 15 [3] | 0.50 [0.79] |
| Sutured | 0.24 [0.20] | 0.35 [0.24] | 16 [5] | 17 [3] | 1.50 [0.55] |

IOP intraocular pressure by Goldman applanation tonometry; VA visual acuity.

[†]P = 0.001, significant VA improvement (pre- to postoperative sutureless technique), Wilcoxon signed rank test.

Table 2: Ultrasound biomicroscopic grading as mean and SD in patients undergoing pars plana vitrectomy

| Sclerotomy | Vitreous Incarceration | | Scleral Dehiscence | | Choroidal Thickening | |
|------------|------------------------|-------------|--------------------|-------------|--------------------------|--------------------------|
| | Day 1* | Week 6 - 8* | Day 1 [†] | Week 6 - 8* | Day 1* | Week 6 - 8* |
| Sutureless | 0.58 [0.67] | 0.58 [0.51] | 0.33 [0.49] | 0.17 [0.39] | 0.50 [0.52] [§] | 0.00 [0.00] [§] |
| Sutured | 0.17 [0.41] | 0.33 [0.52] | 1.00 [0.00] | 0.67 [0.52] | 0.17 [0.41] | 0.00 [0.00] |

*No significant intergroup differences, Mann-Whitney U test;

[†]P = 0.012, significantly more scleral dehiscence in the sutured group, Mann-Whitney U test

[§] P = 0.015, significant decrease of choroidal thickening in the sutureless group, Wilcoxon signed rank test.

Ethical issues:

Not applicable.

Cultural or religious considerations:

Not applicable.

Other issues:

- Chen 1996⁴ first described a self-sealing technique for pars plana incisions; some modifications have been developed subsequently
- this technique should be avoided in eyes with weakened or thinned sclera

RECOMMENDATION:

Limited evidence exists on the safety and efficacy of sutureless, wedge-shaped, self-sealing pars plana sclerotomy. As there are some variations to the originally described self-sealing, sutureless sclerotomy, it is difficult to determine whether this new modification is of any benefit as an alternative method for vitrectomy.

HealthPACT decision:

Horizon Scanning Report

Full Health Technology Assessment

Monitor

Archive

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SEARCH CRITERIA:

A search of MEDLINE, PubMed and Cochrane Library, Current Controlled Trials metaRegister, UK National Research Register International, Network for Agencies for Health Technology Assessments, relevant online journals and the Internet was conducted in February 2004.

Search terms used were: self-sealing pars planar sclerotom*, vitrectom*, suture* sclerotom*, wedge shaped pars plana sclerotom*