Title: Intrastromal corneal ring segments (ICRS) for keratoconus and corneal

ectasia

Agency: Medical Services Advisory Committee (MSAC)

Department of Health and Ageing

GPO Box 9848 Canberra ACT 2601 Australia **Reference:** MSAC Application 1083 Assessment Report

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Aim

To assess the safety, effectiveness, and cost-effectiveness of intrastromal corneal ring segments compared with penetrating keratoplasty (full thickness corneal graft), deep lamellar keratoplasty (partial thickness corneal graft) or continued treatment with contact lenses.

Conclusions and results

No comparative studies (either randomised or non-randomised were located). There were 18 included case series or case reports – 13 for keratoconus (considering altogether 412 eyes) and 8 for corneal ectasia (considering altogether 38 eyes).

Safety

ICRS implantation was associated with a range of complications including migration or extrusion of the ICRS segments, visual symptoms such as glare or halo and infections, including keratitis. The rate of complications depended on how they were defined. The rate of explantation ranged from 4% to 25% (median 10%) for eyes with keratoconus with reasons including dissatisfaction with vision, segment extrusion or decentration, chronic foreign body sensation and incorrect segment placement.

Effectiveness

ICRS implantation improved best corrected and uncorrected visual acuity for most patients with keratoconus and corneal ectasia. For keratoconus, a median of 67% and 81% of eyes improved for best corrected and uncorrected visual acuity respectively. The corresponding figures for iatrogenic corneal ectasia were 45% and 95%. However, a number of patients experienced no change in visual acuity and a small proportion experienced worsening visual acuity. ICRS implantation also resulted in flattening of the cornea and a reduction in irregular astigmatism with more normal keratometric values, spherical equivalence and refractive cylinder. Functional outcomes were only reported in two studies and patients reported reduced visual symptoms and improvements in subjective vision.

Durability of ICRS implantation, potential for delay in the need for corneal transplant and effect on progression of disease were not reported in any included studies.

Cost effectiveness

Cost effectiveness could not be assessed as there were no published comparative studies.

Recommendation

MSAC recommends that on the strength of evidence pertaining to Intrastromal corneal ring segments for ectasia and keratoconus public funding should not be supported for this procedure.

The evidence pertaining to this procedure is immature and small in volume. It is not possible to be confident that the benefits demonstrated are durable and the lack of published comparative clinical studies does not allow for any cost effectiveness analysis.

The Minister for Health and Ageing accepted this recommendation on 28 November 2005.