TITLE: Artificial Iris Prosthesis for Aniridia: Clinical Effectiveness

DATE: 06 May 2016

RESEARCH QUESTION

What is the clinical effectiveness of artificial iris prosthetic devices for the treatment of aniridia in adult patients?

KEY FINDINGS

Two non-randomized studies were identified regarding the use of artificial iris implants in patients with aniridia.

METHODS

A limited literature search was conducted on key resources including PubMed, Ovid Medline, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2011 and April 25, 2016. Internet links were provided, where available.

The summary of findings was prepared from the abstracts of the relevant information. Please note that data contained in abstracts may not always be an accurate reflection of the data contained within the full article.

SELECTION CRITERIA

One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.
**Table 1: Selection Criteria**

<table>
<thead>
<tr>
<th>Population</th>
<th>Adult patients requiring iris replacement due to post-traumatic, congenital or iatrogenic aniridia (with or without aphakia)</th>
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<tbody>
<tr>
<td>Intervention</td>
<td>Customized artificial iris implant or prosthetic device (e.g., CustomFlex) with or without concurrent intraocular lens replacement (excluding solely cosmetic iris implants)</td>
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<td>Comparator</td>
<td>Simple iris prosthetic devices; Standard care (e.g., iris print contact lenses, sunglasses, patch); No comparator</td>
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<td>Outcomes</td>
<td>Clinical effectiveness (e.g., visual acuity [e.g., Snellen Visual Acuity, National Eye Institute Visual Functioning Questionnaire], best-corrected visual acuity [BCVA], intraocular pressure [IOP], reduced glare [brightness Snellen visual acuity], quality of life [Activities of Daily Vision Scale], patient satisfaction [Global Aesthetic Improvement Scale], reduced pupillary aperture); Harms (e.g., inner eye infection, retinal detachment, uveitis, glaucoma, darkening of iris tissue, procedural complications, need for re-surgery)</td>
</tr>
<tr>
<td>Study Designs</td>
<td>Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies</td>
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</table>

**RESULTS**

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials and non-randomized studies.

Two non-randomized studies were identified regarding the use of artificial iris implants in patients with aniridia. No relevant health technology assessments, systematic reviews, meta-analyses, or randomized controlled trials were identified.

Additional references of potential interest are provided in the appendix.

**OVERALL SUMMARY OF FINDINGS**

Two non-randomized studies\(^1,2\) were identified regarding the use of artificial iris implants in patients with aniridia. Patients were followed for up to 50 months.\(^1\) In both studies, visual acuity increased following artificial iris implantation.\(^1,2\) Reported complications included newly diagnosed glaucoma,\(^1,2\) low intraocular pressure,\(^2\) darkening of iris tissue,\(^1\) and corneal endothelial decompensation requiring corneal transplantation.\(^2\) In one study,\(^1\) adverse events were more commonly associated with the use of iris prostheses with embedded fiber mesh.
REFERENCES SUMMARIZED

Health Technology Assessments
No literature identified.

Systematic Reviews and Meta-analyses
No literature identified.

Randomized Controlled Trials
No literature identified.

Non-Randomized Studies


PREPARED BY:
Canadian Agency for Drugs and Technologies in Health
Tel: 1-866-898-8439
www.cadth.ca
APPENDIX – FURTHER INFORMATION:

Non-Randomized Studies

Cause or Extent of Iris Damage not Specified in Abstract


Case Reports and Case Series (fewer than 10 patients)


Review Articles


Additional References