Literature search and clinical opinion on alternate keratoprosthesis (excluding Boston KPro).

May 2017

This literature review provides supplementary information to the following documents:

https://www.nice.org.uk/advice/mib91

https://www.nice.org.uk/guidance/ipg534

Introduction

Keratoprosthesis is a surgical procedure where a diseased cornea is replaced with an artificial cornea. Traditionally, keratoprosthesis is recommended after a person has had a failure of one or more donor corneal transplants (Akpek et al 2014). More recently, a less invasive, non-penetrating artificial cornea has been developed which can be used in more routine cases of corneal blindness. While conventional cornea transplant uses donor tissue for transplant, an artificial cornea is used in the Keratoprosthesis procedure. The surgery is performed to restore vision in patients suffering from severely damaged cornea due to congenital birth defects, infections, injuries and burns.

Keratoprotheses are made of clear plastic with excellent tissue tolerance and optical properties. They vary in design, size and even the implantation techniques may differ across different treatment centers. The procedure is done by ophthalmologists.

Although many keratoprostheses have been developed, only four models are currently have a CE mark. These include Boston keratoprosthesis, AlphaCor KPro, the KeraKlear Artificial Cornea and Legeais. According to Salvador et al (2016), AlphaCor has recently been discontinued after patients due to patients developing severe mid- and long-term complications. It is also believed that Legeais is no longer available as only one study have been published to date. The clinical community in England is unaware of implanted with Legeais.

This document presents literature search results and clinical opinion on the AlphaCor the KeraKlear Artificial Cornea and Legeais.
Literature search results

A literature search was undertaken for AlphaCor KPro, KeraKlear and Legeais in the PubMed database. The search dates applied to the search were from 1st May 2005 to 10th May 2017. All study designs reporting primary research published in English were included.

Eight studies were identified for AlphaCor KPro, three studies KeraKlear Artificial Cornea and one study for Legeais. References for each of the three keratoprosthesis are listed below.

**AlphaCor KPro (Argus Biomedical)**


**KeraKlear Artificial Cornea KPro (KeraMed)**


**Legeais BioKPro-III (FCI Ophthalmics)**


**Ahmed Syed**
Clinical Effectiveness Team
Specialised Services, NHS England

**Clinical Opinion:**

**Policy Working Group Clinical Opinion:**

The above papers were reviewed and summarised in the following table:

<table>
<thead>
<tr>
<th>AlphaCor</th>
<th></th>
<th>Patients</th>
<th>Follow-up</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>No.</td>
<td>Name</td>
<td>Type</td>
<td>Patients</td>
<td>Follow-up</td>
</tr>
<tr>
<td>1</td>
<td>Hoffart</td>
<td>Case series</td>
<td>12</td>
<td>2-38 mths</td>
</tr>
<tr>
<td>2</td>
<td>Jiraskova</td>
<td>Case series</td>
<td>15</td>
<td>12-67 mths</td>
</tr>
<tr>
<td>3</td>
<td>Holak</td>
<td>Case series</td>
<td>6</td>
<td>13-36 mths</td>
</tr>
<tr>
<td>4</td>
<td>Ngakeng</td>
<td>Case series</td>
<td>6</td>
<td>14-38 mths</td>
</tr>
<tr>
<td>5</td>
<td>Chalam</td>
<td>Case report</td>
<td>1</td>
<td>10 mths</td>
</tr>
<tr>
<td>6</td>
<td>Hicks</td>
<td>Case series Multi-site</td>
<td>322</td>
<td>15-89 mths</td>
</tr>
<tr>
<td>7</td>
<td>Bleckman</td>
<td>Case series</td>
<td>4</td>
<td>6 months</td>
</tr>
<tr>
<td>8</td>
<td>Crawford</td>
<td>Case series</td>
<td>2</td>
<td>12 months</td>
</tr>
</tbody>
</table>

**KeraKlear**
<table>
<thead>
<tr>
<th>No.</th>
<th>Name</th>
<th>Type</th>
<th>Patients</th>
<th>Follow-up</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Studen</td>
<td>Case series</td>
<td>3</td>
<td>6-24 mths</td>
<td>3/3 implanted. 2/3 achieved 6/60 vision or better after 1 year (1 died)</td>
</tr>
<tr>
<td>2</td>
<td>Alio</td>
<td>Case series</td>
<td>15</td>
<td>7-21 mths</td>
<td>9/15 good anatomical results, 6 complications. No eye better than counting fingers vision.</td>
</tr>
<tr>
<td>3</td>
<td>Alio</td>
<td>Case report</td>
<td>1</td>
<td>1 month</td>
<td>Aim of paper to demonstrate surgical technique.</td>
</tr>
</tbody>
</table>

**Legeais**

<table>
<thead>
<tr>
<th>No.</th>
<th>Name</th>
<th>Type</th>
<th>Patients</th>
<th>Follow-up</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Hollick</td>
<td>Case series</td>
<td>7</td>
<td>12-48 mths</td>
<td>1 successful case, vision 6/12 6/7 were extruded after 2-28 months</td>
</tr>
</tbody>
</table>

**Clinical Opinion:**

**AlphaCor**
- This has been the most widely used alternative to the Boston KPro. All papers listed consist of case series, mostly single centre, with few patient numbers and clinical follow-up.
- The first 5 papers listed (published within the last decade) present results for a total of 32 patients. The most useful paper is Hicks (2006), reporting outcomes for 322 cases. Taking this paper alone, the incidence of complications is frequent. Unfortunately visual outcomes are not clearly expressed.

*Taking account of these published results coupled with the fact that this device is no longer in production, clinical opinion is that there is insufficient evidence to recommend this device for commissioning by the NHS*

**KeraKlear**
- The KeraKlear is designed for use in patients in whom standard grafts are likely to fail. It differs from other keratoprotheses in that it is implanted in the stroma without anterior chamber penetration.
- The few cases published have short follow-up and poor visual outcomes in almost all cases and frequent complications.

*Taking account of these published results clinical opinion is that there is insufficient evidence to recommend this device for commissioning by the NHS.*

**Legais**
- This device was used in a small case series, with universal poor outcomes.

*Taking account of these published results clinical opinion is that there is insufficient evidence to recommend this device for commissioning by the NHS.*
Conclusion: Clinical Opinion

Having reviewed NICE MIB91 (2017), NICE IPG534 (2015) and the supplementary literature listed this paper, it is the combined clinical opinion that at the current time, only the Boston Keratoprosthesis has sufficient evidence to recommend it for commissioning by the NHS.