CPAG Summary Report for Clinical Panel

Keratoprosthesis for corneal blindness

The Benefits of the Proposition - Boston Keratoprosthesis Type 1 for corneal blindness			
No	*Metric*	*Grade of evidence*	*Summary from evidence review*
1.	Survival	Not measured	
2.	Progression free survival	Not measured	
3.	Mobility	Not measured	
4.	Self-care	Not measured	
5.	Usual activities	Not measured	
6.	Pain	Not measured	
7.	Anxiety / Depression	Not measured	
8.	Replacement of more toxic treatment	Not measured	
9.	Dependency on care giver / supporting independence	Not measured	
10.	Safety	Adverse events identified [B]	In a case series of 75 patients, one or more sight threatening complications occurred in 68% eyes (Goins et al 2016). These complications were managed by standard ophthalmological techniques.
11.	Delivery of intervention	Not measured	

Other health metrics determined by the evidence review			
No	Metric	Grade of evidence	Summary from evidence review
12	Visual acuity	Grade B	Visual acuity is a measure of how well someone can see. An acuity of 20/200, for example, means that a person can only see at 20 metres while a normal

			person can see at 200 metres. With this degree of poor vision, a person is eligible for registration as legally blind. In a study of 150 patients (158 eyes) who had Boston KPro implantation, only 9% of eyes had a visual acuity of 20/200 or better before operation, but after operation, 70% of eyes had visual acuity of 20/200 or better (Srikumaran 2014). Overall device retention rate was 67% at 7 years' follow up. This provides evidence of visual improvement after KPro implantation, given that, in patients eligible for this treatment, no spontaneous improvement in visual acuity would occur. The key limitation is that about a third of patients will have had the device removed at 7 years' follow up (Goins 2016) because of complications. These results should be interpreted with caution as they are based on a case series study therefore they do not provide evidence that KPro is any better or worse than other treatments for this outcome.
13	Quality of life	Grade B	The National Eye Institute Visual Functioning Questionnaire [NEI VFQ-25]) is a questionnaire measure completed by patients which asks about general vision, near and distance activities, social functioning, mental health, role difficulties, dependency, colour vision and peripheral vision A study of 24 patients (Cortina and Hallak 2015) who had Boston KPro reported substantial improvement in postoperative vision-related quality of life at 3 months and also after an average follow up of 16 months. Patient-reported visual function overall score was 43.1 at baseline versus 70.0

			at 3 months. This study shows that the improvements in visual acuity after KPro insertion are associated with substantial improvements in many important domains of quality of life including dependency, mental health, social health and role difficulties. The results were statistically significant (not due to chance) but lesser gains might be seen in routine practice. The other key limitations of this study is thesmall sample size and short duration of follow up.

The Benefits of the Proposition - KeraKlear Artificial Cornea keraprosthesis for corneal blindness			
No	*Metric*	*Grade of evidence*	*Summary from evidence review*
1.	Survival	Not measured	
2.	Progression free survival	Not measured	
3.	Mobility	Not measured	
4.	Self-care	Not measured	
5.	Usual activities	Not measured	
6.	Pain	Not measured	
7.	Anxiety / Depression	Not measured	
8.	Replacement of more toxic treatment	Not measured	
9.	Dependency on care giver / supporting independence	Not measured	
10.	Safety	Adverse events identified [C]	In a case series (Alio et al 2015), the KeraKlear Artificial Cornea was implanted within the cornea at one of two different depths.

			In 6/11 eyes implanted with a flap, severe complications were reported, including total cornea vascularisation of the cornea and extrusion of the KeraKlear Artificial Cornea. t.
11.	Delivery of intervention	Not measured	

Other health metrics determined by the evidence review			
No	Metric	Grade of evidence	Summary from evidence review
12	Anatomical outcomes (centration maintained within the intended position within the cornea)	Grade C	In a case series of the KeraKlear Artificial Cornea, followed up for up to 21 months, excellent anatomical outcomes (the device stayed within its intended position in the cornea) in 5/11 eyes with no complications. In six eyes there were complications as listed in point 10 above. Using a different operative technique, the anatomical outcome was excellent in all four eyes. These results should be interpreted with caution as they are based on a case series study.

The Benefits of the Proposition - Legeais BioKPro-III for corneal blindness			
No	*Metric*	*Grade of evidence*	*Summary from evidence review*
1.	Survival	Not measured	
2.	Progression free survival	Not measured	
3.	Mobility	Not measured	
4.	Self-care	Not measured	
5.	Usual activities	Not measured	
6.	Pain	Not measured	
7.	Anxiety / Depression	Not measured	
8.	Replacement of more toxic treatment	Not measured	
9.	Dependency on care giver /	Not measured	

	supporting independence		
10.	Safety	Adverse events identified [C]	One case series study with seven patients (Hollick et al 2006) followed up between 18-48 months reported retroprosthetic (behind the implant) membranes occurred in three patients and endophthalmitis (severe infection of the whole eye) in one.
11.	Delivery of intervention	Not measured	

Other health metrics determined by the evidence review			
No	Metric	Grade of evidence	Summary from evidence review
12	Time to device failure	Grade C	One case series study (Hollick et al 2006) reported keratoprosthesis failed in six of the seven patients because of extrusion of the implant from the eye occurring 2-28 months postoperatively. These results should be interpreted with caution as they are based on a case series study.
12	Visual acuity	Grade C	One case series study with seven patients (Hollick et al 2006) reported six patients could only perceive movement of a hand held directly in front of their eye, and one could only percieve light. The vision was the same or worse in the fellow eye. These results should be interpreted with caution as they are based on a case series study.