**NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE**

**INTERVENTIONAL PROCEDURES PROGRAMME**

# National Institute for Health and Clinical Excellence

## 391 – Corneal implants for keratoconus
## Comments table

**IPAC date: Friday 11th May 2007**

| Consultee name and organisation | Sect. no. | Comment no. | Comments | Response<br>Please respond to all comments |
|---|---|---|---|---|
| Individual Clinician | **1** | 1 | You need to specify whether you are recommending use purely in patients in whom corneal transplantation would have to be done otherwise (in other words all other options have failed) - or in all cases. | The overview states that the patient population in 5 of the 7 studies was either intolerant to contact lenses or unsatisfied with them. The other 2 studies did not define this. The Committee were not persuaded that the evidence was available to support this specification. |
| Individual Consultee | **1** | 2 | Thirteen months prior to my operation when I first discussed INTACS with my consultant I found very little information about the procedure in the UK.. Information on the safety and efficacy of the procedure should be made more readily available both to health care staff and patients. | The "Understanding NICE Guidance" (UNG) version of this guidance may be helpful when it is published. |
| Individual Clinician | **2** | 3 | 2.1.1 I believe that there is also some evidence for use in scarred corneas. 2.1.2 No mention of post-laser corneal ectasia | The literature search was generic to capture all indications, it was decided to consider only keratoconus. |

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| Individual Consultee | **2.1** | 4 | The quality of the patient's life should also be taken into consideration when assessing the indications for performing the procedure, especially in cases where level of keratoconus is not severe enough to warrant corneal grafts yet is not mild enough to continue management with spectacles or soft contact lenses. Similarly an intolerance to contact lenses should also be used in conjunction with the indications to assess suitability. | The overview states that the patient population in 5 of the 7 studies were either intolerant to contact lenses or unsatisfied with them. The other 2 studies did not define this. |
| The Keratoconus Self Help and Support Organisation | **2.1** | 5 | It may be helpful to include guidance on the minimum thickness of the cornea, in addition to the requirement for a clear central cornea, ie that the minimum thickness should be 450 micrometers, as in the US FDA guidance and as stated in a presentation on Intacs (corneal implants) given to the West Midlands KC Support Association by Vijay Savant, Corneal Fellow at the Birmingham Eye Centre | Only one study defined a minimum corneal thickness 400 µm. This is too much detail to include in the guidance. Opinions may vary and safe thickness may change with technological developments. |

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| The Keratoconus Self Help and Support Organisation | **2.1.3** | 6 | Para 2.1.3. omits the most common management option for moderate keratoconus, namely the whole range of contact lenses from corneal rgps, hybrid lenses, piggy backing options (a soft lens worn under a rigid lens) through to scleral lenses. As keratoconus progresses, fitting a lens which will give both adequate vision and comfort can become increasingly difficult. However, for the majority of patients in this group, spectacles can no longer correct the vision so they are completely dependent on contact lenses for functional sight. But within this group, some cannot tolerate contact lenses at all, others may become contact lens intolerant after years of constant contact lens wear, yet others can only tolerate their lenses for a limited number of hours a day, severely restricting their activities. For all these groups, Intacs offer an alternative management option which may restore functional vision with spectacles, or mean that contact lens wear will again be possible. | Current guidance mentions soft contact lenses only.<br>The Committee changed the first sentence in section 2.1.3 to read 'In mild to moderate keratoconus spectacles or a range of contact lenses contact lenses may help'. |
| Individual Consultee | **2.2** | 7 | No mention made of the fact that the procedure is fully reversible | The Committee added a section 2.2.3 which reads 'If required, the implant can be removed at a later date'. |
| Individual Consultee | **2.2** | 8 | These corneal implants are popularly referred to as ""INTACS"", a registered trade mark [I realise that you may wish to avoid using trademarks, but I think a layman searching the records will invariably use the INTACS name. | NICE's IP guidance avoids using trademarks or trade names such as INTACS. The table in the overview indicates which studies used INTACS and which used Ferrara rings. |
| Individual Consultee | **2.3** | 9 | Significant change in vision noticed 6 weeks post op. | Thank you for your comment. |

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| Individual | **2.3** | 10 | Corneal transplantation is not an ""inevitable next step"" for all patients. I have INTACS, but my condition is moderate and I would not consider transplants (and neither would my doctor) unless he condition became worse. | This section of the guidance represents the opinion of a Specialist Advisers. However, the Committee removed the words '…which would be the inevitable next step' to avoid confusion. |

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| The Keratoconus Self Help and Support Organisation | **2.3** | 11 | As indicated at 2.1 for those patients with moderate KC who are or become contact lens intolerant or who have limited lens wear time, corneal implants offer the hope that vision may either be correctable with spectacles, or that contact lens tolerance will be much improved after the procedure. Keratoconus is usually diagnosed in the teens or early 20s ie affecting students and people of working age. The improvements in visual acuity and contact lens tolerance will therefore reduce the negative impact of KC on employment prospects, time taken off work when contact lens wear proves impossible, restore independence (eg by restoring driving vision) and improve mental well being which is often significantly affected when vision is poor. Many contact lens dependent people with KC currently report that their family and social life are significantly affected as they can only wear contact lenses during working hours.<br>Another group for which corneal implants may offer significant benefits are patients with Downs Syndrome (while the incidence of KC in the general population is 1 in 2000, the incidence is much higher in those with Downs). These patients often cannot manage contact lens wear, so the use of corneal implants may offer significant improvement in vision and quality of life for this group,<br>Corneal implants are not believed to stop the progression of KC, but do offer the prospect of more years of functional vision and do not interfere with subsequent transplant surgery, should this be needed (except in a very few cases of blood vessels growing into the Intacs tracks). A number of surgeons are using corneal implants in<br>conjunction with collagen cross linking (C3-R), a procedure designed to strengthen and thicken the cornea. NICE may want to consider whether the guidelines should cover this joint option which could increase the benefits of corneal implants. | The overview states that the patient population in 5 of the 7 studies were either intolerant to contact lenses or unsatisfied with them, the other 2 studies did not define this.<br><br>Patients with Downs Syndrome were not specifically excluded from the literature search but no studies were identified in this patient population. The guidance can equally apply to patients with Downs Syndrome and keratoconus. |

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| The Keratoconus Self Help and Support Organisation | **2.3.5** | 12 | We assume the rapid recovery time mentioned by the specialist advisors in para 2.3.5 refers to the physical recovery of the eye after the procedure. Improvements in visual acuity may take 6-12 months to be felt by the patient. This has been explained prior to the procedure to all the patients we know of who have had implants and has been acceptable to them, being comparable to the time taken for the benefits of corneal transplantation to be felt.<br><br>Long-term data on the efficacy of Intacs is not yet available. It will therefore be important to review this procedure 3-5 years down the line to ensure that there are no unanticipated lont-term drawbacks or side effects. We also recommend regular monitoring of those who have had corneal implants fitted and continuous research. | The Specialist Adviser's comment appears to be referring to operative rather than visual recovery.<br><br>The Committee agreed that there are few long term data available. The overview contained one study with mean follow up of 3 years, but most studies were to 1 year only. A sentence was inserted at the beginning of the safety section (in 2.3.1): 'Most efficacy data outcomes reported in the literature were up to 12 months' follow-up.' |
| Individual | **2.4** | 13 | Bacterial infection was experienced for one week post op. General discomfort experienced for six weeks post op, manifested as a feeling of grit in the eye; relieved upon removal of stitch. Halo"s ongoing. No mention of the possibility of light sensitivity to the eye, which has been experienced. | Safety data presented represent the most common or serious complications reported in the literature. One study reported 1 patient with photophobia. |

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| Individual | **2.4** | 14 | Need to be clear if this can be used in patients who have already had a corneal graft in the eye to be treated. Can a corneal graft be undertaken after an implant in the same eye? If there is a reduced chance of success of a graft after this procedure then this information should be required to be part of the consent process. | A sentence was added to section 2.5.1: 'The Committee noted that a previous implant is unlikely to impact the success of subsequent corneal implants.' |
| The Keratoconus Self Help and Support Organisation | **2.4** | 15 | The reversability of the procedure is important to stress. For the small group of patients who find vision is not improved or deteriorates, or for whom side effects such as halos or foreign body sensation prove unacceptable, the implants can be removed. According to the published studies, and the experience of the small number of patients known to us who have had this procedure, unwanted side effects are rare, and risks are less severe than in corneal tranplantation. | Noted, thank you. |
| The Keratoconus Self Help and Support Organisation | **General** | 16 | We have also drawn on the experiences of around 10 members who have posted their experience of the procedure on the discussion forum of our website (some of whom have independently contributed to the NICE consultation) | Noted, thank you. |