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STEER

Osteo-odonto-keratoprosthesis

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The Wessex Institute
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Osteo-odonto-keratoprosthesis

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Conflict of Interest
None

NB:

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Osteo-odonto-keratoprosthesis

Question

1. What are the effects of osteo-odonto-keratoprosthesis in people with corneal opacities who are thought to be unsuitable for corneal transplant because of excessive risk of graft rejection?

Summary

The safety and/or efficacy of Osteo-Odonto-Keratoprosthesis as a treatment for severe corneal opacities cannot be determined at the present time due to a poor-quality evidence base. Given the extremely low level of evidence available for OOK the procedure should currently be regarded as experimental.

In his 1992 article, Ricci [2] states that "the development of an allogenic keratoprosthesis capable of lasting as long as an OOK but easier to implant and less traumatic for the patients would be valuable". In the intervening nine years, there may have been developments in suitable allogenic materials and investigating this possibility should be considered.

Background

Osteo-odonto-keratoprosthesis (OOK) is a method of corneal substitution, which uses a prosthesis composed of an acrylic optical cylinder mounted within a section of one of the patient's own teeth. Because the implant uses autologous tissue, it has been used in people who are at high risk of graft rejection following conventional transplantation.

We found one case series, which reported that OOK involves three consecutive operations over a period of six to twelve months, as follows:[1]

1. A strip of autologous oral mucosa is grafted to the cornea and sclera.

2. A monocuspidate tooth is removed along with the adjacent maxillary bone and a thin section is cut from the tooth. The optical cylinder is inserted through a hole made in the section. A pocket is created in the lower eyelid, into which the completed prosthesis is inserted and left for three months. During this time soft tissue grafts to the bone to which the tooth is attached.

3. Part of the oral mucosa is stripped from the cornea and sclera to create a space for final implantation of the prosthesis. The prosthesis is detached from the eyelid pocket and implanted, with the optical cylinder protruding through a hole in the mucosa.

Search Methods

Primary sources: Medline 1966 to date; Embase 1980 to date; Cochrane 2001 issue 1; NHS Centre for Research and Dissemination; Database of Abstracts of Reviews of Effectiveness; NHS Health Technology Assessment Database; NHS Economic Evaluation database; TRIPS database; Monash University database. Search date: June 2001.

Evidence found

We found no systematic reviews, controlled trials or cohort studies. Our search identified one uncontrolled series of moderate size and one article reporting histological outcomes only in three people who had undergone removal of the prosthesis.

The larger series reported visual acuity and complications at 30 days, 5 years and 10 years post-operatively in 85 people with corneal opacification predominantly due chemical burns. All participants were considered by the authors to be at high risk of rejection of corneal transplant and underwent OOK between 1966 and 1991.[1]

The second study, written by the same group of authors, reported on three people, who had undergone removal of a previously implanted prosthesis.

Quality of Evidence Found

All identified studies were uncontrolled and so may only usefully contribute to the evidence for efficacy of OOK if alternative management strategies yield uniform prognosis in similar patient groups. However, because of possible heterogeneity of the sample population in this series (see below), it is not clear that prognosis would have been uniform with alternative management.

The study stated that all 85 patients were included in the study at 5 and 10 years post-operatively. However, operations were conducted between 1966 and 1991 and the paper was accepted in 1993 and published in 1994. Thus, patients who had operations in 1991 were only available for a maximum of three years post-operative follow-up when the paper was published in 1994 and could not have had outcomes assessed 5 or 10 years post-operatively by 1994 as reported in the study. This discrepancy raises questions regarding the validity of outcomes reported.

Objective criteria used to select patients for OOK were not defined, and it was not clear whether selection criteria remained stable over the 25 year study period. Causes for corneal opacification varied considerably among included patients and this possible source of heterogeneity was not addressed. It was not clear why patients were considered at high risk of transplant rejection and whether evidence or consensus would support such a risk stratification. No details were given of methods used to select the sample from the total number of people receiving OOK and so the possibility of selection bias cannot be excluded.

It was not clear whether the study was prospective or retrospective. The study did not state whether the operations were conducted by the same surgeon or the same centre, and so the influence of surgeon and centre cannot be assessed. Change in visual acuity from baseline was not calculated, because no baseline assessment of visual acuity was reported. Subjective outcomes and overall functional ability or quality of life were not reported.

The article describing three cases is uncontrolled, subject to bias, lacks power and focusses on non-clinical outcomes in cases where the prosthesis had been explanted, either because substitution was needed, or because complications had occurred.[2] The study does not contribute to evidence for efficacy, but serves to illustrate reasons for OOK failure.

Study Results

At 5 years postoperatively, the larger case series found that 51% of the 85 patients had visual acuity exceeding 2/10 and 16.5% of patients exceeded 6/10. After ten years, 38% of the 85 patients had visual acuity exceeding 2/10 and 4.7% exceeded 6/10. The most common complication was secondary glaucoma, which occurred for the first time postoperatively in 28 patients (33%). Other complications included retinal detachment (3.5%), the

development of a retroprosthetic membrane (3.5%), and extrusion or necrosis of the implant (2.3%). The authors found no instances of intraocular infection or orbital cellulitis in the series.

The remaining article reported three cases where removal of the prosthesis was required. In the first case, the prosthesis was replaced by a prosthesis with a larger diameter cylinder after 20 years. In the second case, the prosthesis was removed because a mucosal ulcer and dense membrane developed behind the prosthesis after 15 years and in the final case, inflammation developed in tissues around the prosthesis after 12 years.[2]

Conclusions

The only evidence identified was from one case series and one article with three case reports describing the histology of three prostheses that had been removed. The case reports illustrate possible reaons for graft failure, but do not contribute substantively to evidence for efficacy.[2]

Significant flaws in the case series, including possible lack of validity of the reported outcomes and the lack of objective criteria defining patients at increased risk of corneal transplant rejection, make meaningful interpretation of the study impossible.[1] No information was presented on the potential risks of rejection of corneal transplant in the group of patients receiving OOK in the study, making it impossible to compare the outcomes from this procedure with conventional corneal transplant or other management strategies.

It is possible that advances in allogeneic transplant techniques have occurred since this series.[2] Controlled trials comparing OOK versus modern allogeneic techniques are needed in well defined patient groups.

References

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