

Standards for Modified Osteodontokeratoprosthesis (OOKP) Surgery According to Strampelli and Falcinelli

The Rome–Vienna Protocol

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Purpose: To establish a time-proven “gold standard” in modified osteodontokeratoprosthesis (OOKP) surgery.

Methods: The OOKP is the procedure of choice for restoring sight in patients with corneal blindness caused by end-stage ocular surface disease not amenable to penetrating keratoplasty. Members of the OOKP Study Group met in Rome, Italy in 2001 and Vienna, Austria in 2002 to discuss indications and contraindications, patient selection, surgical technique, postoperative care, and recognition and management of complications of OOKP surgery according to Strampelli and modified by Falcinelli.

Results: Falcinelli’s modification of Strampelli’s technique of OOKP surgery remains the gold standard as far as visual and keratoprosthesis-retention results are concerned. The agreement on indications and contraindications, patient selection, surgical technique, postoperative care, and recognition and management of complications of this technique of OOKP surgery is summarized in the text of this manuscript.

Conclusion: This standard technique of modified OOKP surgery, where adequately performed, is capable of providing excellent anatomic and functional results even in the long term. In patients with corneal blindness untreatable by other approaches, we strongly recommend this technique for visual rehabilitation. Students of OOKP surgery should become familiar with the protocol described in this paper before subjecting the technique to further modifications.

Key Words: keratoprosthesis, osteodontokeratoprosthesis (OOKP), corneal blindness, surgical treatment

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In the last few years, interest in keratoprosthesis surgery has greatly increased because clinical results of standard ocular surface reconstruction procedures in very dry eyes are generally far from encouraging.¹ Nevertheless, the long-term fixation of alloplastic material on the surface of the eye for visual rehabilitation in cases of corneal blindness also seems to be largely unsolved. There had been many approaches to this problem over the past decades,^{2–10} but most studies report either on a short follow-up or a comparatively short-lived visual recovery in the majority of cases in clinical studies with longer follow-up. The technique with by far the best results and proven long-term follow-up is the osteodontokeratoprosthesis (OOKP) invented by Strampelli^{11–15} and modified over the years by Falcinelli.^{16,17} “The Role of the OOKP in Contemporary Ophthalmic Surgery” was the first international meeting organized by Falcinelli in Rome, after 20 years of good results, in October 1993. Those results were evaluated and confirmed by an independent study by Liu and Pagliarini.¹⁸ In the last few years several papers about OOKP were published.^{12–16,19–72} It seems, therefore, that lately the interest in this technique has increased as witnessed by the international attendance of the Introductory Course on OOKP in Brighton in November 2002. As a consequence, it is our hope that this method may be transferred to other surgical centers around the world.

In the fall of 2001 (Rome) and the spring of 2002 (Vienna), the few surgeons who still actively perform OOKP surgery convened with their collaborators and fellows to discuss the technique in detail and came to a consensus as to the current standard procedure of “modified” OOKP as developed by Falcinelli and co-workers over the years starting from the original Strampelli procedure. These meetings were suggested by G. C. Falcinelli after the fourth meeting KPro Study Group in Fort Lauderdale (May 4–5, 2001), because some recent clinical results that were obtained by some of the investigators, albeit in some cases with the personal collaboration of Falcinelli, were not considered to meet the usually high expectations of the group. In particular, the participants in this meeting were supposed to consider whether some innovations to Falcinelli’s original technique introduced in a few cases by some of the authors were to be considered helpful in improving the already good visual results documented for the “modified OOKP” or whether these changes carried a potential risk of increasing both the number and the severity of the comparatively few serious and vision-threatening complications of Falcinelli’s standard technique.

Therefore, the aim of this publication is to promote a “gold standard” technique that has gained acceptance from all participants of the Modified OOKP Teaching Group (senior members of the OOKP Study Group, Fig. 1) and to establish a firm basis for a surgical training course. It is evident that this article will and cannot be in itself a substitute for a course on OOKP or at least for visiting one of the centers of modified OOKP to get a thorough training in the surgical technique and direct personal advice about the intricacies of the method. Furthermore, this paper should serve as a starting point for future developments by providing a “gold standard” against which the results of all future work have to be measured.

Last but not least, the junior authors wish to honor G. C. Falcinelli, who trained them in OOKP surgery with utmost dedication and enthusiasm. Without him they would not have been inspired to study, practice, research, and also try to promote OOKP surgery as “true believers” in the technique.

PATIENTS AND METHODS

Principles of the Technique

The basic—ingenious—principle of OOKP is the use of a single rooted tooth and surrounding intact alveolar bone to fashion a plate as a carrier for a PMMA optical cylinder. The optical cylinder is cemented to the dentine, the central part of this “picture-frame” OOKP lamina. The dentine itself is coupled to the alveolar bone by the dentoalveolar ligament. The OOKP lamina is fixed by surrounding periosteum to the anterior corneal and scleral surface with sutures but is also covered and thereby protected by a thick buccal mucous membrane graft, which also serves to supply the living bone with nutrients (Fig. 2). Therefore, the biologic “behavior” of the implant is quite similar to that of a dental implant.

Patient Selection Criteria

Indications for keratoprotheses are all cases of severe damage to the ocular surface such as severe dry eye, limbal



FIGURE 1. The OOKP Teaching Group. From left to right: Günther Grabner, Konrad Hille, Giovanni Falcinelli, Paolo Colliardo, Christopher Liu, Padmanabha Pillai Syam, Josef Stoiber, and GianCarlo Falcinelli (sitting).

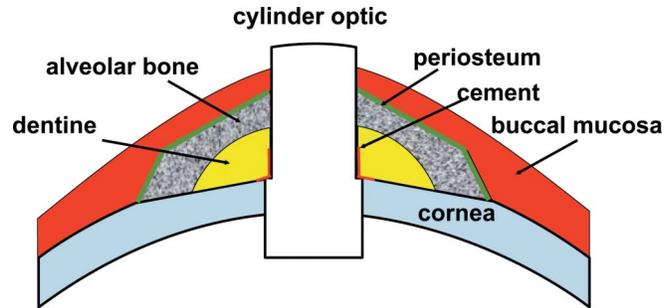


FIGURE 2. Schematic representation of the cross section of an OOKP.

stem cell insufficiency, and a densely vascularized cornea that cannot be treated with any reasonable expectation of medium- or long-term success by the other extensively published and well-tried methods, such as penetrating keratoplasty, lamellar grafts, and limbal stem cell transplantation (see Table 1).

Because some indications for keratoprotheses and ocular surface reconstruction with limbal stem cell transplantation seem to overlap, one has to consider advantages and disadvantages of both techniques. Ocular surface reconstruction by conventional means seems to be less destructive for the anterior segment, and the patients may obtain a large visual field in case of success. The disadvantages certainly are the lifelong need for systemic immunosuppression and the risk of rejection within a short time period.¹ The central visual acuity is also often inferior in patients with limbal stem cell transplantation as compared with those following OOKP because of remaining or recurring ocular surface problems.¹

From the long experience at the “Modified OOKP Centre” in Rome, visual acuity will be worse whenever multiple anterior segment surgeries have been performed in a patient before OOKP. Comparing the final visual outcome of 234 eyes in 212 patients after OOKP with or without previous perforating keratoplasty (mean follow-up from stage 2, 9.4 years; range 0.25 to 29 years), 19.5% of the patients receiving their OOKP after penetrating keratoplasty had no ambulatory vision in comparison to 7.5% of the patients receiving an

TABLE 1. Indications for OOKP

Bilateral blindness in severe cases of
Stevens-Johnson syndrome
Ocular cicatricial pemphigoid (stage 3 or 4)
Lyll syndrome
Epidermolysis bullosa acquisita
Trachoma (stage C0 according to WHO classification)
Chemical injury
Physical injury (fire, liquid aluminium, etc)
Loss of the lids (eg, Crouzon disease)
Vascularized corneas with complete stem cell loss and dryness following other causes (eg, other ocular surgeries, use of MMC)
Aniridia with severe corneal changes
Multiple failed penetrating keratoplasty
Corneal failure after vitrectomy with silicone oil filling that cannot be removed safely

OOKP only ($P \leq 0.025$). Reading visual acuity was found in 64.9% and 67.9%, respectively. If this is taken into account, it may make sense to perform an OOKP even in a patient with sufficient tear film, if there is a total loss of stem cells and the results will be disappointing with limbal stem cell allotransplantation only. Most regularly there will be some kind of surgical efforts in ocular surface reconstruction before an indication for an OOKP is seen because this is generally considered the very last and somewhat disfiguring resort—albeit often successful—to restore the visual acuity. In a patient with completely dry eyes and a keratinized epithelium, the survival rate of a corneal or stem cell transplantation is very close to nil. Some have performed a microsurgical salivary gland transfer,⁷³ but it is the opinion of the group that OOKP should be done in such cases without any prior attempt for ocular surface reconstruction.

It is felt that bilateral blindness with a visual acuity less than 1/20 in the better eye is mandatory before the procedure is attempted. In some exceptional cases (eg, Stevens-Johnson syndrome) vision can still be in the 2/10 range if the patient wishes to be operated on, especially in patients still active in the work process and well informed about both the potential risks and benefits of surgery. If both the retinal and optic nerve function of the eye with the lower visual acuity appears to be intact, surgery should be performed on this eye first. Experienced surgeons need not be deterred by patients with only one eye with visual potential.

Generally speaking, OOKP surgery should be carried out on only one eye, as the other eye can be considered a “spare eye” in case of the comparatively rare failure of the eye operated first. Should the second, “spare” eye be suffering from glaucoma, every effort has to be made to lower the intraocular pressure to preserve the vitality of the optic nerve. Surgery on the second eye may even help to monitor glaucomatous changes of the optic disc over time. Bilateral surgery was performed in many of those patients with good results (G. C. Falcinelli, personal communication).

Contraindications

In some patients an OOKP should not be performed because of the high risk of failure. Absolute contraindications are:

- Age below 17 years. Despite the fact that children will develop bilateral amblyopia if not treated, attempts at OOKP surgery did give very unsatisfying results: allografts (with the parents as donors) have been tried in two selected cases (the Salzburg group), but the laminae were found to be completely reabsorbed within months, possibly because of the high rate of turnover of bone during growth in this age group. One patient was lost to follow-up; the second retained light perception following penetrating keratoplasty and surgery for endophthalmitis. It is unknown whether additional attempts might yield more favorable results.
- In case of a phthitic eye, the risk for complications is very high, and a loss of the remaining perception of light is most often to be expected after such invasive surgery.
- In eyes with no light perception there remains no hope for restoring any visual acuity. Surgery will therefore only harm the patient.

- Eyes with detached retina (which cannot be reattached before OOKP) or other pathologies of the posterior segment that severely interfere with potential visual acuity should not be operated on either.
- Because a scleral shield with painted iris and a central opening to accommodate the optic can be provided, the majority of patients are willing to accept the postoperative cosmetic appearance. Nevertheless this problem has to be discussed with the patient and the relatives extensively prior to surgery.

Relative contraindications are:

- Mentally unstable patients may be boggled or confused by the surgery. Because at least two long operations in general anesthesia are required and a certain amount of complications have to be expected, it must be very carefully evaluated whether the patient is able to face all those problems. Similar problems may be encountered in patients with unrealistically high expectations.
- Patients who do not wish to or cannot come to follow-up visits. It is most important to inform both the patient and relatives in more than one extended discussion about all kinds of problems and complications that may occur and to identify an exceedingly well-informed patient. No questions or doubts should be left unanswered before the start of the surgical program.
- Defective light perception (which may signify a late-stage glaucoma) does not seem to constitute an absolute contraindication because of some surprising success in some of these patients. But the indication should be well considered, and the expectations of the patient should be tempered to quite a low level.

Preoperative Ophthalmological Assessment

To evaluate the potential success of an OOKP, some preoperative examinations are mandatory (Table 2). First of all, the potential visual acuity has to be evaluated. If the patient can discern hand movement or even has “finger counting” abilities, one can expect a good functional outcome. Accurate light projection is encouraging, but lack of accurate projection is not a bar to full visual rehabilitation, as the severely disturbed ocular surface may itself be a sufficient reason for the inaccuracy in projection. As a minimal

TABLE 2. Preoperative Assessment

Preoperative ophthalmological assessment	
VA (intact light perception)	Essential
Entoptic phenomena	Not mandatory
Electrodiagnosis (eg, positive flash-VEP)	Not mandatory
Ultrasonography (no pathologic findings)	Essential
A-scan biometry	Essential
Digital estimation of intraocular pressure	Essential
Examination for dry eye	Not mandatory
Preoperative oral assessment	
Orthopantomography	Essential
X-ray of tooth	Essential
Spiral CT	Not mandatory

requirement, the eye operated on should have a good perception of light.

Negative entoptic phenomena are also no contraindication for keratoprostheses because some patients do not recognize these phenomena. There are several patients reported with negative entoptic phenomena before surgery and a visual acuity of 20/20 after OOKP.

Flash-VEP and flash-ERG may be helpful to decide whether there is a retinal function left at all but will not help to predict the final visual acuity because the scars in the anterior segment will usually diminish the amplitude of VEP to a significant degree. In many patients there will be an intact light perception and hand movement, so that electrophysiological examinations will not be necessary in most cases.

Echography is mandatory to ascertain that there are no pathologic changes present in the posterior segment. A B-scan has to be done to detect retinal detachment, exudative maculopathy, and glaucomatous cupping of the disc and to search for prephthisis. An A-scan should be done if there is a possibility to choose the power of the optical cylinder for emmetropia or slight myopia. Ultrasound examination with high resolution (20 to 50 MHz, UBM) can be recommended to detect peripheral synechiae causing secondary angle-closure glaucoma.

Glaucoma is one of the most serious problems in OOKP. Therefore, all efforts should be undertaken to detect its presence very early on. In most cases IOP measurement with the Schiötz tonometer will not be very reliable. A rough estimation of the tension by digital palpation will be the only available method. All indirect clues such as the medical history of glaucoma, echographic signs of disc cupping, and anterior synechiae should be considered.

In addition a detailed general ophthalmic history and careful eye examination have to be performed. The lens status (phakic, aphakic, or pseudophakic) is to be considered to plan the surgical steps. If there was a corneal ulceration reported at some earlier stage of the disease process, the cornea might be very attenuated so that an additional lamellar corneal graft can become necessary.

The usual examinations for a dry eye state may help to decide against ocular surface reconstruction. Limbal stem cell transplantation will almost certainly fail, whereas OOKP gives very good results in dry eyes. Intact lids and conjunctival fornices do not quite have the pivotal role as in other types of ocular surface reconstruction. Whenever possible they should be surgically reconstructed to protect the buccal mucous membrane graft. Nevertheless, a complete closure of the lids is not mandatory. If there are no lids, OOKP implantation through the palpebral skin following removal of the tarsal plate ("transpalpebral" approach) has been performed, but with slightly poorer long-term results because of apparently more rapid bone absorption.

Preoperative Oral Assessment

The state of the buccal and labial mucous membrane should be evaluated, and an oral hygiene regimen is mandatory to diminish the risk of infection (Table 2). The presence of a vital single-rooted tooth can be checked at this stage by the

ophthalmologist. Further investigations should be done by an experienced oromaxillofacial surgeon.

Orthopantomography (OPG) will help in the selection of a suitable tooth; additionally, an x-ray of the individual tooth will make it possible to evaluate the length and girth of root, presence of caries, intact pulp, periodontal disease, the surrounding bone of the maxilla, and the space to the adjacent teeth. The root of the tooth should not have been treated previously. In the dentine canaliculi bacteria may be trapped. After removal of the root filling, the canaliculi will be reopened, and bacteria may regain their virulence, threatening the survival of the lamina. Pathologies of the dental crown itself (eg, fillings) are not a contradiction, but any signs of periodontal disease should certainly be taken into account. An additional spiral CT for the preoperative assessment of teeth and jawbone allows accurate description of anatomy and dimensions and seems helpful but is not necessary in every case.

If there is no vital single root available, it might be possible to obtain a root from a closely related donor. The long-term success, however, again seems to be slightly worse (G. C. Falcinelli, personal communication), and the use of immunosuppression in the recipient is certainly necessary. This will be discussed in an additional paper because it is not considered a standard procedure by the authors.

Surgical Technique

Stage 1: Preparation of the Globe, Buccal Mucous Membrane Graft (Stage 1a), and Preparation of the Osteodonto Lamina (Stage 1b)

Before implanting an OOKP in the eye, the globe has to be covered with buccal mucous membrane to serve as a biologic covering for the OOKP lamina, ie, for providing adequate blood supply to the bone, to protect the anterior surface of the haptic, and to act as a barrier against microbial invasion. This is usually performed together with the preparation of the lamina under a single general anesthetic. In cases when severe pathology of the anterior segment (such as extreme thinning of the recipients cornea) is expected and therefore an extensive prior revision and repair seems to be necessary, the "first stage" may be divided into two separate steps. If a significant risk of nonsurvival of the buccal mucous membrane graft (eg, because of extreme dryness of the eye or poor blood supply following previous injury) is present, it may be prudent to await survival of the mucous membrane graft before preparing the OOKP lamina, as the lamina may be reabsorbed if left under the orbicularis muscle for more than 3 or 4 months.

Preparation of the Mucous Membrane Covering

Mucous membrane as the "physiological" cover of the alveolar bone seems to be the best protection for the OOKP lamina. If sufficient buccal mucous membrane is not available, any other kind of mucous membrane, such as palatal, lip, and vaginal mucous membrane, can be used.

- Oral hygiene should start as soon as the decision is made to go ahead with OOKP surgery.
- Consider chlorhexidine and nystatin mouthwash a day or two before surgery.

- The oral cavity has to be cleaned with aqueous povidone-iodine to avoid infection at the time of surgery.
- The quantity of membrane removed should be sufficient to cover the anterior surface of the globe up to the insertions of the recti muscles (which amounts to a diameter of 3 to 4 cm).
- The parotid duct opening should be spared.
- After removal of the mucous membrane, a good haemostasis and closure with interrupted sutures may be advisable.
- Most of the submucosal fat should be evenly removed from the graft with curved scissors without excessively thinning the graft (Fig. 3).
- During preparation of the anterior ocular surface, the mucous membrane is stored either in an antibiotic solution such as cefuroxime or diluted aqueous povidone-iodine solution (5%).

Preparation of the Globe

Before the eye is covered with buccal mucous membrane:

- All corneal epithelium (including all remaining limbal stem cells) has to be thoroughly removed, and an intact Bowman membrane, if still present, also has to be removed.
- The conjunctiva has to be recessed with the superficial Tenon up to the recti muscles.
- Cautery should be reduced to a minimum so as not to destroy the episcleral vessels that will provide blood supply and drainage of aqueous humor.
- If the cornea is not vascularized, the eye should be covered with Tenon capsule because the mucous membrane would be too fragile to survive without vascularization and would become necrotic.
- The mucous membrane has to be fixed on the episclera either with interrupted or a running suture close to the muscle insertions and should not be overstretched.
- The edge of the mucous membrane should be fixed to the conjunctiva where possible (Fig. 4).
- Whenever a very thin cornea is present, a lamellar keratoplasty should be performed.

Preparation of the Lamina

The tooth with the largest available root should be used: upper canine, inferior canine, both upper incisors, first or second upper premolar (about 75% are single rooted), first and



FIGURE 4. Eye covered by buccal mucous membrane.

second inferior premolar, and inferior incisors, in descending order of usefulness.

- After dissection of the gingiva the root has to be removed with intact surrounding alveolar bone with a bone saw (Fig. 5).
- The periosteum on the alveolar bone should be preserved as much as possible so that it can be used to cover the bone of the implant later on. It can be reattached with fibrin glue if necessary.

The final size of the dentoalveolar lamina should be as large as possible. The ideal size is about 15 to 16 mm in length, 8–10 mm in the former labiopalatal dimension, and, after removal of half of the root, about 3.5 mm, but certainly, if at all possible, not less than 3 mm in thickness (Fig. 6).

There are some basic principles involved in preparing the haptic lamina from the dentoalveolar block that includes a significant part of the surrounding alveolar bone. Great care must be taken not to damage the dentoalveolar ligament. The explanation, therefore, should be done very smoothly. During preparation of the dentine the lamina always has to be grasped at the crown to minimize stressing the ligament. Vibrations and high temperature may also cause damage, so that the lamina to be implanted should constantly be irrigated with cooled saline during the grinding procedure and when drilling



FIGURE 3. Buccal mucous membrane prepared for transplantation.





FIGURE 5. Harvesting a canine tooth with a bone saw.

the opening. Before preparing the lamina the tooth has to be thoroughly cleaned from gingiva at the neck of the tooth (to avoid epithelial cysts) and extensively rinsed with aqueous povidone-iodine for some minutes to reduce bacterial contamination to an absolute minimum.

The next steps are:

- To remove half of the root from the former temporal or medial side of the alveolar bone with diamond-coated

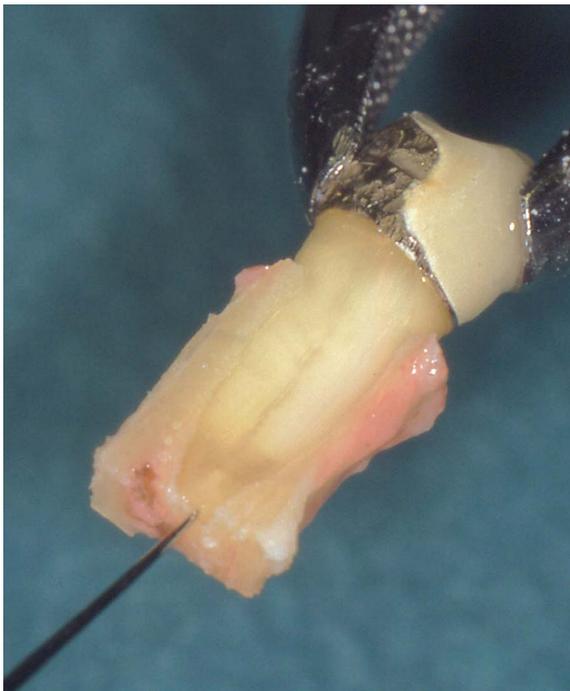


FIGURE 6. Appearance of the tooth after grinding off the upper half of the root down to the pulpal canal.

flywheel. The part of the block where less bone is available should be chosen as the starting side.

- The dental pulp canal has to be opened and all tissues removed to ensure watertight cementing of the optical cylinder.
- In principle the drilling of the opening for the cylinder should be centered on the dentine, but if there is very little bone tissue on one particular side of the dentine left, the cylinder should be placed slightly eccentric to the side where more bone is present. There should be at least 1 mm of dentine left to either side of the cylinder. Moreover as the dentine surface toward the apex becomes narrower, it is sometimes advisable (to get to a useful diameter of the cylinder) to decenter the opening toward the crown of the tooth. It must also be kept in mind that there should also be sufficient bone and dentine left between the opening and the lower border of the crown, so that the periphery of the posterior enlarged part of the optical cylinder will be surrounded by alveolar bone (Fig. 7). In any case a decentration of the optical cylinder in the lamina may cause problems with tilting when the lamina is sutured onto the eye but can sometimes be corrected during the implantation with differential tensioning of the sutures. Also, the thin rim left between the opening and the crown end of the lamina may make that area subject to accelerated bone and dentine resorption, putting the cylinder at risk for extrusion.

Because the monomer of the acrylic cement will shrink during polymerization, the optical cylinder should sit very snugly within the opening in the lamina. On the other hand, the surgeon should be able to insert the cylinder without applying too much force. It also has to be made sure that the drilling is absolutely perpendicular to the plane of dentine to avoid tilting of the cylinder and an eccentric visual field after stage 2 (Fig. 8).

The dimensions of the classic optical cylinder are as follows:

- The dioptric power can be calculated⁷⁴ and is about 50 to 60 diopters in an aphakic eye.
- The length of the anterior part should be from 5.75 mm to 6.0 mm, and the posterior part from 2.25 mm to 2.50 mm. That results in a total length from 8.0 mm to 8.25 mm.
- The diameter of the anterior part should be generally not more than 3.90 mm to leave at least about 1 mm dentine on all sides of the cylinder intact.
- To hold the cylinder in position during cementing, the diameter of the posterior part should be about 0.3 mm to 0.40 mm larger than the anterior part.
- The posterior cylinder should come to rest on the dentine only, and the acrylic cement should not come in contact with the alveolar bone so as not to interfere with the dentoalveolar ligament. The posterior cylinder should not be increased too much in diameter also (as the visual field extension is related to the cylinder's posterior diameter) to avoid a very large corneal trephination during the second step. Too large an opening in the cornea may lead to tilting of the optical cylinder, vessel ingrowth into the anterior chamber, retroprosthetic membrane formation, and unmanageable sequelae.

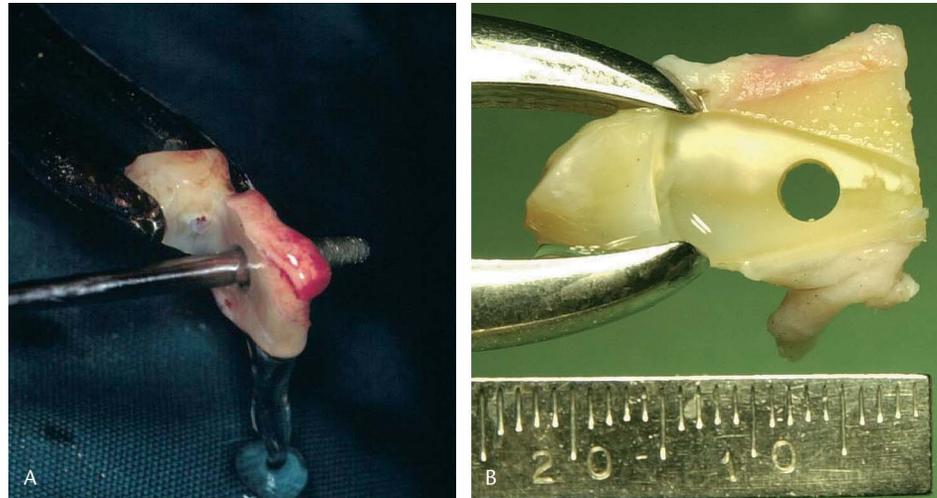


FIGURE 7. Left: Drilling of the opening through the lamina for the optical cylinder. Right: Measuring the opening in the lamina.

- Before cementing the optical cylinder to the dentine, the latter has to be completely dried by a flow of oxygen.
- Acrylic cement that has no apparent binding function (“overflow”) has to be cautiously removed with a knife. Toxic methyl-methacrylate monomer may still be present and cause toxicity especially for the alveolar ligament and the bone and has to be cautiously washed out.

After cutting off and thereby completely removing the crown of the tooth, the implant (Fig. 9) has to be inserted into a subcutaneous pouch for about 3 months to enhance revascularization of the implant, to promote growth of connective tissue and remaining periosteum, and to prevent and possibly detect infection from oral bacteria as well as to detect epithelial cysts.

The best location for this purpose seems to be the orbitozygomatic area, just inferior to the lower lid of the contralateral eye. The implant, called osteodontoacrylic lamina (OOAL), can readily be inspected, in general is not exposed to traumatic challenge, and, because the tissue of the face has an excellent blood supply, will also be well supplied with the essential nutrients. The implant should be inserted with the dentine facing the orbit and the bone toward the periorbital muscle.



FIGURE 8. The dentoalveolar lamina and the optic cylinder.

Stage 2: Implantation of the Osteodontoacrylamina

About 3 months after the preparation the OOAL, it should be implanted at the anterior surface of the globe under the mucosal membrane. At this point in time the implant will, as a rule, be completely covered by connective tissue. Leaving the lamina for a longer period of time in the submuscular bed can increase the risk for partial absorption.

- At first the lamina should be carefully explanted from its subcutaneous “storage space” to assess whether it is intact. Only a lamina in good condition without evident signs of absorption of the bone and dentine should be used.
- The connective tissue does not adhere to the dentine and has to be completely removed from the dentine surface that will be placed on the corneal surface.
- As soon as the lamina is cleaned off, most of the subcutaneous tissue is temporarily replaced in the submuscular pocket, or it can be stored in the patient’s own sterile blood (to be replaced in regular intervals) to avoid drying during the preparation of the globe.
- Next the buccal mucous membrane covering the surface of the cornea has to be partially lifted to create a large flap. A large base, just below the inferior limbus, should remain attached to retain an adequate blood supply.
- A Flieringa ring should be sutured to the sclera, and 2 traction sutures at 3- and 9-o’clock positions are prepared to lift the Flieringa ring at the time of the insertion of the lamina.
- As soon as the very center of the cornea is located, a trephination with the same diameter as the posterior part of the optical cylinder is performed. A marked decentration might cause a decentration of the visual field as well.
- The iris, lens, and anterior vitreous always have to be completely removed (and in some cases this has to be performed during the first stage of the procedure if alterations of these structures are evident or probable). Not adhering to this seemingly excessive procedure will always result in secondary glaucoma because of angle closure and in severe inflammatory membranes behind the optic cylinder. This step can be performed during the second

FIGURE 9. The implant before subcutaneous implantation for 3 months, view from the side and from the surface finally facing the cornea (2nd step), the dentine occupying the largest part of the surface.



stage by adding 3 radial corneal incisions. The iris can easily be removed by total iridodialysis. Bleeding from the base of the iris is generally not severe and should patiently be washed out by continuous irrigation until it stops. Lens extraction is always done “intracapsular” even when a clear lens is present. Especially in young patients, the zonular fibers have to be loosened very carefully and gently to avoid retinal detachment before removing the lens or pseudophakos, followed by an extended anterior vitrectomy.

- After watertight closure of the additional 3 corneal incisions, the prosthesis can be placed. It is recommended to preplace 4 vicryl sutures around the position of the prosthesis before inserting the cylinder into the cornea. The implant is placed with the dentine surface facing the cornea. As soon as the implant is in place, air is inflated by a 30-G needle from the limbus or through the cornea. The prosthesis is fixated with multiple interrupted sutures onto the corneoscleral surface with the inner part of the cylinder well centered and securely placed into the trephined opening. No connective tissue should be left between the posterior lamellar surface and the cornea.
- During fixation of the implant and pressurization of the globe with sterile air by a 30-G needle, the centration of the optic cylinder should be checked by indirect ophthalmoscopy and adjusted by suture tension.
- If the optic disc and both temporal vascular arcades are centered, sterile air should be inflated again by a 30-G needle to seal the cornea trephination. It is then mandatory that the patient should rest on his or her back for about 4 to 5 days after the operation.
- In a final step the buccal mucosa is placed back to cover the lamina after a central trephination for the anterior part of the cylinder and fixed to the sclera/conjunctiva by multiple interrupted sutures (Fig. 10).

Postoperative Treatment

After the first stage the patient should receive systemic and local antibiotic therapy. Sometimes a scleral shield should be inserted to avoid shrinking of the fornices for a few days. If necessary, dapsone could be continued in an active stage of pemphigoid. After the second stage systemic and local antibiotics should be administered. Additional systemic corticosteroids are recommended to avoid intraocular inflammation, and mannitol with or without acetazolamide has to be administered as long as the intraocular pressure seems to be

elevated, as is frequently the case. Topical antibiotic therapy should be continued once daily on a lifelong regimen, perhaps with rotation of antibiotic every few months. Lubrication of the mucous membrane with balanced salt solution may be necessary in dry eyes. Cleaning of the optical cylinder should be done with a clean cotton-tipped stick. Juice from a fresh cut lemon is useful for removing deposits on the optical surface. “Lemon juice” from a bottle should be avoided. If lagophthalmos is present, the patient should use ointment at bedtime indefinitely. A scleral shield with a central opening for the anterior optical cylinder can be worn to achieve an aesthetic appearance and protect against dehydration (Fig. 11).

For the long-term follow-up, a patient with OOKP should ideally be examined at least every 3 months by an ophthalmologist experienced in following these cases. Visual acuity, a computerized visual field, and the estimation of the intraocular pressure by digital palpation should be done at every visit. The state of the buccal mucous membrane, the size of the lamina, the stability and protrusion of the optical cylinder, any change of refraction, and the appearance of the optic disc are all to be noted. To estimate the bone and dentine a spiral CT of the lamina with 3-D calculation should be done about every 1 to 2 years.

RESULTS

In a series of 234 patients with OOKP, Falcinelli reports anatomic success (no loss or explantation of the prosthesis) of



FIGURE 10. Eye with OOKP in place. The optic cylinder enters the eye through the cornea and is apparent at the surface of the buccal mucous membrane graft.

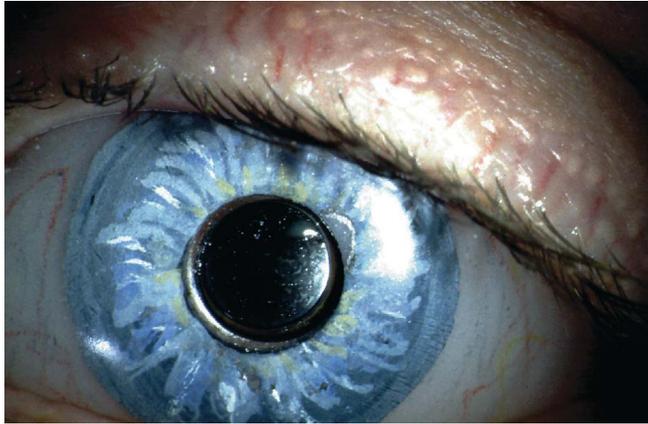


FIGURE 11. Patient with OOKP wearing a scleral shell. This will help cosmetic appearance as well as being effective against dehydration.

greater than 94% with a medium follow-up from stage II of 9.4 ± 5.7 years and up to 29 years (Table 3). In case of loss of follow-up, the last visit was taken as the endpoint.

In Figure 12 the anatomic survival of the OOKP is drawn up in a Kaplan-Meier curve. There is an anatomic success rate of 96.5% in about 5 years, 94.1% in 10 years, 88.8% in about 20 years with a maximum follow-up of 27 years.

Complications

Some of the complications mentioned below may occur rather frequently (eg, surface problems, ulcerations of the mucosa, and rise in IOP), and sometimes have to be dealt with immediately (exposure of the lamina, intraocular infection, retinal detachment). Knowledge of these problems and their treatment options is required not only by the surgeons them-

selves but also by the ophthalmologists caring for OOKP patients in their offices or outpatient clinics (see Table 4).

Perioperative Complications

Stage 1A (Preparation of the Mucous Membrane Covering)

There may be some bleeding from buccal vessels at the end of surgery in some rare cases requiring an oromaxillofacial surgeon for rapid management. There is always a risk of damage to the parotid duct present, but no serious complications have been seen to date by the group.

Stage 1B (Preparation of the Globe)

During preparation of the globe for mucous membrane transplantation, a perforation or leakage of the cornea may occur. If the eye cannot be adequately closed, a lamellar graft from a donor cornea should be performed.

In the early postoperative period following this stage, necrosis of the mucous membrane can occur (2%) and has to be repaired by a second graft. If an infection is suspected, antibiotics should be used following microbiological evaluation and sensitivity testing; all necrotic tissues have to be excised, and the eye covered with vascularized Tenon. To further prepare the eye a second mucosal graft will have to be performed.

Stage 1C (Preparation of the Lamina)

Intraoperative complications during harvesting of the dentoalveolar block have been reported, such as oromaxillary fistula formation, fracture of the mandible, and damage to adjacent teeth. It is imperative to look for such complications and to assure prompt treatment by the maxillofacial surgeon.

If excessive force is applied to the tooth, the dentine itself may break, or the dentoalveolar ligament may be

TABLE 3. Results: The Rome Series, 1973–2002 (232 Eyes in 212 Patients)

Indications		
Dry eye	96 (41.0%)	
Chemical burn	84 (35.9%)	
Sequel of infective keratitis	18 (7.7%)	
Corneal sequel of glaucoma surgery	17 (7.3%)	
Failed keratoplasty	19 (8.1%)	
Mean follow-up from stage 2 (years)	9.4 ± 5.7 (range 3 months to 29 years)	
Patients died/lost for follow-up	53 (25%)/39 (18.4%)	
Visual Acuity	Best Visual Acuity	Final Visual Acuity
10/10–8/10	158 (67.5%)	132 (56.4%)
7/10–5/10	25 (10.7%)	23 (9.8%)
4/10–2/10	27 (11.5%)	24 (10.3%)
1/10–3/50	10 (4.3%)	12 (5.1%)
2/50–1/50	6 (2.6%)	9 (3.8%)
HM	7 (3.0%)	8 (3.4%)
LP	1 (0.4%)	19 (8.1%)
No LP	0 (0%)	7 (3.0%)
Total	234 (100%)	234 (100%)
Anatomic success	220 (94%)	

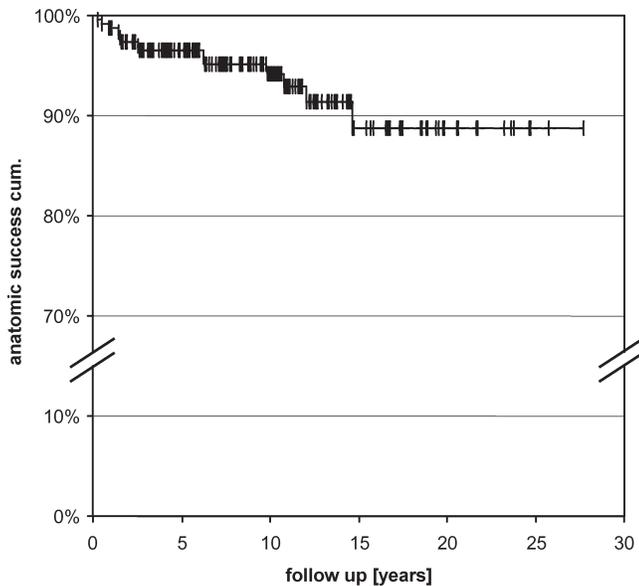


FIGURE 12. Kaplan-Meier survival analysis of the anatomic success of 234 OOKP. The small vertical lines represent the end of follow-up for each patient.

loosened during the preparation. If this happens a second tooth has to be prepared. Overheating from inadequate cooling (as mentioned above) may cause severe damage to the tissue followed by necrosis. Furthermore, a very thick, asymmetric overlying cortical bone should be removed at this point before drilling.

Stage 2

Conventionally the implant has first to be removed from its subcutaneous repository at the beginning of stage 2 to be carefully examined for

- Intact dentine
- Damage to the dentoalveolar ligament
- Possible absorption of the dentine and/or bone (1.5% of cases)
- Infection (2% of cases)
- An insufficient attachment of the optical cylinder to the haptic block by the acrylic cement

In this case the OOAL should not be implanted. It will be better to sacrifice a second tooth than to risk the eye. Epithelial cysts have to be removed completely if present.

During the preparation of the eye, intravitreal bleeding from the iris may become apparent. It should be removed by anterior vitrectomy as much as surgically feasible. But in general the amount of bleeding will be limited so that one can wait for spontaneous reabsorption within a few weeks. There also may be a risk for an expulsive hemorrhage, but this seems to be a rare occurrence. The risk may be lowered by ensuring low intraocular pressure before the globe is opened (intravenous mannitol) as well as low systemic blood pressure and low extraocular muscle and lid muscle tone (deep anesthesia with full paralysis).

In the early postoperative period intraocular pressure becomes high, probably from either a disturbance of the

aqueous veins, the detachment and replacement of the mucosal flap, or perhaps blockage of the chamber angle by air, blood, the remaining iris root, and vitreous prolapse. Therefore, the anterior vitreous is routinely, carefully, and extensively removed.

Systemic carbonic anhydrase inhibitors should also be administered, and if necessary mannitol for some days (6–8), until the ocular pressure returns to a more normal range.

Occasionally the intraocular pressure may be too low if the globe has not been adequately refilled with filtered air. This can lead to choroidal detachment and a late expulsive hemorrhage if additional air is not inflated.

Very rarely a tilted optical cylinder has to be recentered surgically at this stage also.

Late Postoperative Complications

Whereas the intraoperative, perioperative, and early postoperative complications are generally fairly easily dealt with, the most serious complications of OOKP are of late onset and will require experienced surgeons in most cases. In more than 8% we have to expect some kind of buccal mucous membrane alterations (Fig. 13). Mostly this is caused by:

- Insufficient thickness or vascularization of the primary buccal flap
- Inadequate pressure by a cosmetic shield
- Recurrence of the primary disease (eg, pemphigoid)
- Reabsorption of the underlying bone
- Injury during cleaning with an infection of the mucosa
- A bone spicule

In such a case the damaged part of the mucosa has to be surgically removed, any bone protrusion gently removed by grinding with a diamond burr, and a sliding flap performed with simultaneous replacement by a new mucous membrane graft in the periphery. Whenever mucous problems recur, one has to consider osteomyelitis, a fistulization between the cornea and the osteodental lamina, or reabsorption of the bone around the cylinder.

Endophthalmitis and Loss of the Cylinder/Lamina

Because OOKP uses an autologous fixation method, anatomic failure is relatively rare (Table 3, Fig. 12) and compares favorably with other reports.^{5,9,75–82}

Very rare is the fistulization at the optic cylinder/lamina interface. Whenever this is apparent, the lamina has to be explanted as soon as possible, the eye closed by a corneal graft, and a second tooth prepared.

In case of endophthalmitis, the prosthesis should be explanted immediately, a vitrectomy (plus intravitreal antibiotics) has to be performed by visualization with an Eckardt temporary keratoprosthesis. After removal of the infected mucosa, the eye has to be closed by a corneal graft covered by the residual mucous membrane and the patient treated with a regimen of systemic antibiotics. In some patients, this procedure, if adopted early, may be able to rescue the eye with restoration of vision after another keratoprosthesis.

Because the closure of the eye is watertight, the formation of a retroprosthetic membrane is a very rare event and not considered a significant problem in OOKP.

TABLE 4. Complications: The Rome Series, 1973–2002 (N = 234; Some Patients Have More Than 1 Complication)

Median Follow-up (years)	9.4 ± 5.7 (range 3 months to 29 years)
Intraoperative complications at stage 1 (A) (preparation of the mucous membrane)	
Damage to the parotid duct	0
Intraoperative complications at stage 1 (B) (preparation of the globe)	
Corneal perforation	4 (1.7%) (cured)
Scleral rupture	1 (0.4%) (cured)
Intraoperative complications at stage 1 (C) (preparation of tooth)	
Oronasal fistula (into maxillary sinus)	3 (1.3%) (cured)
Fracture of the mandible	2 (0.9%) (cured)
Damage to adjacent teeth and the oral structures	7 (3.0%) (cured)
Postoperative complications after stage 1 (B)	
Trophic alteration of the mucus	5 (2.1%) (cured by a new flap)
Rise in IOP	Almost in every operation, the first week after surgery
Choroidal detachment	1 (0.4%) (cured)
Retinal detachment	3 (1.3%) (cured)
Postoperative complications after stage 1 (C)	
Infection of lamina in pocket	4 (1.7%) (2 cured by antibiotics, 2 by a new lamina)
Absorption of lamina	3 (1.3%) (cured by a new lamina)
Perioperative complications at stage 2	
Expulsive hemorrhage	0
Choroidal detachment	2 (0.9%) (cured)
Hemorrhage into the vitreous	12 (5.1%) (11 cured)
Late postoperative complications after stage 2	
Buccal mucus alteration	19 (8.1%) (cured)
Glaucoma	67 (28.6%) 16 de novo; 48 relapse of previously controlled
Choroidal detachment	2 (0.9%) (cured)
Retinal detachment	10 (4.3%) (5 cured)
Endovitreal hemorrhages	12 (5.1%) (11 cured)
Endophthalmitis	11 (4.7%) (2 cured)
Uveitis/retroprosthetic membrane	4 (1.7%) (3 cured)
Retroprosthetic fistula	1 (0.4%) (cured)
Optic cylinder instability	2 (0.9%) (cured)
Expulsion of the optic cylinder	3 (1.3%) (2 cured)
Expulsion of the prosthesis	2 (0.9%) (1 cured)

Glaucoma

The most vision-threatening complication in OOKP is a primary or secondary glaucoma. About 50% of all patients with severe changes of the ocular surface requiring keratoprosthesis surgery have preexisting secondary glaucoma.^{37,83} Because of the extended interventions required in the anterior segment, the risk for secondary glaucoma following the surgery is about 7% de novo and 21% recurrence (Table 4). In other publications the total risk for glaucoma is about 75% of patients receiving a OOKP.^{37,38,45} In such patients conventional glaucoma surgery such as trabeculectomy will clearly not be possible nor offer any solution. The group first recommends drainage surgery using an aqueous shunt (such as a “Falcinelli posterior drainage tube,” an Ahmed valve, or a Baerveldt device to drain the aqueous humor into the posterior sub-Tenon space^{34,61,84}). The surgeon should have ample experience with this type of procedure before performing it on OOKP patients. Falcinelli developed a special “cyclodistasis” technique with “single or double thread” with good

results.³⁴ Endocyclolaser photocoagulation has been used with good results recently, but without long-term follow-up (C. Boscher, C. Forlini, G. C. Falcinelli personal communication), whereas transscleral cyclolaser seems to be less successful because of difficulties for controlled and correct application (G. Grabner, personal communication). Cyclocryocoagulation currently is not routinely recommended because of the significant risk of inflammation and phthisis. Glaucoma surgery can be done before or during stage 1 in severe preexisting glaucoma or at a later time period after stage 2. Simultaneous drainage tube implantation and stage 2 OOKP are not recommended because of the high risk of serious postoperative hypotony.

Retinal Detachment

The risk of retinal detachment is about 5% and remains an enormous challenge for any vitreoretinal surgeon. An encircling band may be useful but mostly has to be combined with vitreous surgery. There are different approaches

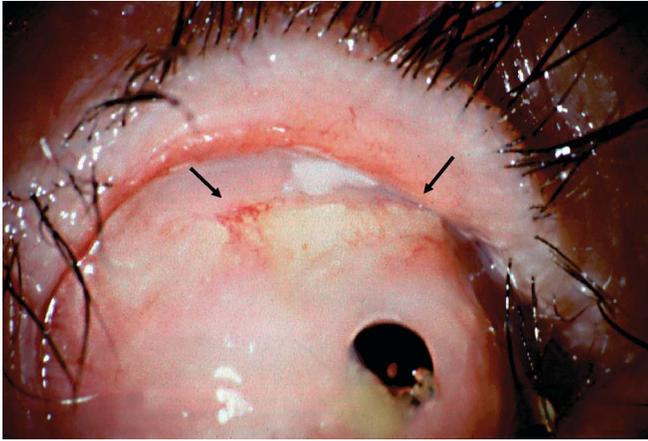


FIGURE 13. Eroded buccal mucous membrane that needs to be repaired rapidly by the use of a sliding mucous membrane flap.

depending on the experience of the surgeon and the availability of equipment:

- After removal of the OOKP lamina, visualization with the help of a temporary keratoprosthesis for vitrectomy and closure of the eye by a perforating keratoplasty. The lamina has to be replaced in the orbital/palpebral pocket until the retina is safely reattached for about 1 to 2 months.
- Leaving the lamina in place and visualization of the retina by:
 - a. endoscopic vitrectomy
 - b. the BIOM-system. By indentation of the ora serrata the complete peripheral retina can be visualized as shown on several occasions by one of the authors (Hille).
 - c. the use of a Barraquer coupling lens.⁸⁵ This may not allow a visualization of the peripheral retina similar to the BIOM, especially in OOKP patients, where the surface of the mucus may be more irregular than in other kinds of keratoprostheses.

With the lamina in place, the surgery may be more difficult but can be done in an adequate way. The advantage certainly is a much faster recovery of visual acuity, a better follow-up of the retinal status by the surgeon and the patient, and—last but not least—a reduced risk of damage to and absorption of the lamina.

CONCLUSIONS

It is the opinion of the authors that OOKP represents the keratoprosthesis with—by far—superior proven long-term results in comparison to other types of keratoprostheses.^{2–10} In the majority of the patients, the implant will remain anatomically and visually successful over many years and sometimes decades.^{3,17,18,37,45} Nevertheless it has to be pointed out that the surgery is extremely demanding and time consuming and places a great burden on the patients, the relatives, and the surgeon and his team as well as the referring ophthalmologists. The rewards will be very satisfying, however, and the patient may regain a quality of life that makes every effort for follow-up and treatment of unavoidable complications well worthwhile.

It is felt by the authors that OOKP surgery should be performed in only very few selected corneal centers worldwide that provide tertiary care, and by well-trained surgeons in close cooperation and consultation with the OOKP Teaching Group. This could ensure that more surgeons may gain enough experience with this complex technique in a sufficient number of patients to further spread and improve the method in the not too distant future.

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