**Objective:** To evaluate long-term anatomical and functional outcomes of a modified osteo-odonto-keratoprosthesis (OOKP) technique for treatment of corneal blindness from various etiologies.

**Methods:** Two-hundred three patients (224 eyes) underwent modified OOKP surgery between 1973 and 1999. Of the original cohort, 181 patients (98 men and 83 women; mean [SD], age 54.3 [15] years) in whom a standardized 2-step surgical procedure was performed were included in the study. Preoperative diagnoses were dry eye (n=70) due to ocular pemphigoid (n=39), Sjögren syndrome (n=11), trachoma (n=8), Stevens-Johnson syndrome (n=6), Lyell syndrome (n=6), and graft-vs-host disease (n=1) and congenital lid coloboma (n=1), severe corneal burns (n=68), bullous keratopathy (n=13), keratitis sequelae (n=15), and bullous keratopathy secondary to antiglaucoma surgery (n=15). Several innovations were made to the original Strampelli technique. Median follow-up duration was 12 years (range, 1-25 years).

**Results:** Anatomical complications leading to OOKP loss were found in 11 (6.07%) of 181 patients. Survival analysis estimated that 18 years after surgery, the probability of retaining an intact OOKP was 85% (95% confidence interval, 79.3%-90.7%). Pooling patient groups, mean (SD) best postoperative visual acuity was 0.76 (0.34). Mean (SD) final acuity at the end of follow-up declined slightly (0.69 [0.39]) but significantly ($P < .01$). In individual diagnostic groups, mean acuity decline reached statistical significance ($P < .05$) only in the pemphigoid (1 line), trachoma (1 line), and bullous keratopathy secondary to antiglaucoma surgery (2 lines) groups. Survival analysis estimated that 18 years after surgery, the probability of retaining best postoperative visual acuity (within 2 lines) was mean (SD) 55.5% (12.9%).

**Conclusion:** Modified OOKP surgery for corneal blindness of different etiologies may provide, in the long-term, anatomically stable corneal prosthesis as well as an effective, rehabilitating recovery in visual acuity.

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biological, biocompatible, or biointegrated haptic postoperative outcomes are in general not encouraging (eg, up to 39% of endophthalmitis incidence in patients with Stevens-Johnson syndrome), clinical studies suggest that in OOKP surgery, complications are less frequent. With the innovations recently implemented to the original Strampelli technique, the incidence of failures may be further reduced compared with other techniques. In addition, the percentage of patients with satisfactory visual recovery may be larger than that reported for other types of KPro.

Although OOKP surgery is now being used in different European centers with a reasonable rate of success in the short-term follow-up, systematic studies on the long-term anatomical and functional outcomes of the modified OOKP procedure have not yet been reported. The present study describes the long-term anatomical and functional results of the modified OOKP procedure, performed between 1973 and 1999 on a large series of patients with severe bilateral corneal blindness not treatable with corneal transplantation. Several innovations to the original Strampelli technique were made to improve the anatomical outcome. Data from different subgroups of the study population were statistically analyzed to evaluate the long-term stability and safety of OOKP surgery as well as the maintenance over time of the functional recovery.

The results indicate that modified OOKP surgery can provide favorable anatomical and functional results that are stable in the long-term and suggest a lower rate and severity of complications compared with those reported for other types of KPro.

### METHODS

Between 1973 and 1999, 203 patients (121 men and 82 women, 224 eyes) with various corneal diseases not treatable by penetrating keratoplasty underwent OOKP surgery. Of the original cohort, 181 patients (98 men and 83 women) who underwent surgery performed according to a standardized procedure were included in the current study. In the remaining 43 eyes, the surgical procedure had some nonstandard steps owing to individual anatomical conditions. For instance, in most of these cases, autologous oral mucosa was not available for implant and was replaced by autologous skin or mucous tissue from different anatomical districts (eg, vaginal mucosa). For these reasons, these 43 eyes were not included in the present study, although they underwent regular follow-up examination. Their results will be presented in a separate report. At the time of surgery, patients' age ranged between 20 and 83 years (mean [SD], 54.3 [15.5] years). All patients underwent full general and ophthalmic examination before surgery, including, whenever possible, intraocular pressure (IOP) estimated by a MacKay-Marg electronic tonometer, ophthalmic echography (to assess the anatomical integrity of the posterior segment and the status of the anterior segment), and visual evoked potentials to flash stimulation. Patients were enrolled in the study if they met the following inclusion criteria: preoperative visual acuity of 0.3 or less in both eyes or in the eye eligible for surgery, with an acuity of 0.1 or less in the fellow noneligible eye; no clinical signs of phthisis bulbi; no evidence of retinal detachment; and an IOP lower than 21 mm Hg, with or without hypotensive treatment. The patients eligible for surgery had been referred to one of us (Giancarlo Falcinelli) from other ophthalmic departments (in Italy, n=168; Western Europe, n=10; South America, n=3) and clinically followed up by us (Giovanni Falcinelli, M.T., and P.C.). Final selection was made by one of us (Giancarlo Falcinelli), who was experienced in corneal diseases and anterior segment surgery. In all patients included in the study, corneal disease was not considered treatable by standard corneal transplantation, mainly because of severe and diffuse corneal neovascularization associated with abnormalities of the ocular surface, eyelids, and bulbar or tarsal conjunctiva. In 34 (30%) of 181 patients, 1 or more corneal transplantation procedures had been performed with unfavorable results. Preoperative diagnoses, together with demographic data of patients, are reported in Table 1. A more detailed description of clinical diagnoses for each group is as follows. Dry eye syndrome was caused by ocular pemphigoid in 39 patients, by Stevens-Johnson syndrome in 11 patients, by Lyell syndrome or toxic epidermal necrolysis in 6 patients, by trachomatous chronic conjunctivitis in 8 patients, by Stevens-Johnson syndrome or erythema multiforme in 4 patients, and graft-vs-host disease and congenital lid coloboma in 1 patient each. Corneal burns were induced by accidental exposure to alkali and acids in 33 and 35 patients, respectively. The advanced stage of bullous keratopathy was present in 15 eyes, with fibrosis and corneal neovascularization. Sequelae of infective keratitis were present in 13 eyes with severe corneal opacities and marked superficial and deep neovascularization. Bullous keratopathy with fibrosis and

### Table 1. Preoperative Diagnoses, Demographic Data, and Postoperative Follow-up Duration in the Different Groups of the Study Population

<table>
<thead>
<tr>
<th>Diagnostic Group</th>
<th>Sample Size</th>
<th>Age, y</th>
<th>No. of Men/Women</th>
<th>Duration of Blindness, y</th>
<th>Postoperative Follow-up, y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pemphigoid</td>
<td>39</td>
<td>64.3 (46-83)</td>
<td>15/24</td>
<td>5.52 (0.5-16)</td>
<td>10.4 (2-25)</td>
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<tr>
<td>Sjögren syndrome</td>
<td>11</td>
<td>62.5 (48-77)</td>
<td>1/10</td>
<td>4.63 (1-7)</td>
<td>12.09 (3-23)</td>
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<tr>
<td>Trachoma</td>
<td>8</td>
<td>62.4 (49-76)</td>
<td>5/3</td>
<td>9 (2-24)</td>
<td>10.6 (7-14)</td>
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<tr>
<td>Lyell syndrome</td>
<td>6</td>
<td>36 (28-45)</td>
<td>3/3</td>
<td>9.5 (4-16)</td>
<td>11.7 (5-23)</td>
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<tr>
<td>Steven-Johnson syndrome</td>
<td>4</td>
<td>42 (42-43)</td>
<td>2/2</td>
<td>13 (6-21)</td>
<td>9 (1-20)</td>
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<tr>
<td>Graft-vs-host disease</td>
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<td>52</td>
<td>1 Woman</td>
<td>1</td>
<td>6</td>
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<tr>
<td>Congenital lid coloboma</td>
<td>1</td>
<td>58</td>
<td>1 Woman</td>
<td>15</td>
<td>7</td>
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<tr>
<td>Corneal burns</td>
<td>68</td>
<td>46.4 (20-74)</td>
<td>48/20</td>
<td>9.5 (0.5-56)</td>
<td>8.7 (1-25)</td>
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<tr>
<td>Bullous keratopathy</td>
<td>13</td>
<td>67.5 (56-81)</td>
<td>4/9</td>
<td>5.1 (1-11)</td>
<td>8.6 (2-19)</td>
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<tr>
<td>Keratitis sequela</td>
<td>15</td>
<td>62.6 (49-76)</td>
<td>9/6</td>
<td>5.1 (1-12)</td>
<td>4.8 (1-9-13)</td>
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<tr>
<td>Bullous keratopathy secondary to glaucoma surgery</td>
<td>15</td>
<td>55 (28-80)</td>
<td>11/4</td>
<td>6.4 (1-27)</td>
<td>9.3 (1-4-18)</td>
</tr>
</tbody>
</table>

*Values are expressed as mean (range) unless otherwise indicated.
(corneal) neovascularization (15 eyes) was present in patients with repeated antiglaucoma surgeries (7 cases with congenital glaucoma). Figure 1 shows the preoperative anterior segment photographs taken from 2 patients with dry eye due to pemphigoid and chemical burn. In most patients, the disease causes serious complications at the level of the adnexa (symblepharon of varying severity, traumatic lid coloboma), anterior segment (corneal perforation or descemetocele, corneal thinning, anterior synechiae or absent anterior chamber, cataract), or posterior segment (vitreous hemorrhages, retinal detachment). None of these complications represented a criterion for exclusion from the present study. All complications were treated before OOKP surgery by surgical and/or medical treatment. Types of treatments performed for each complication are reported in Table 2. Preoperative glaucoma was present in 66 (36.5%) of 181 eyes. In all glaucomatous eyes, the disease was surgically (cyclodiastasis, a modified cyclodialysis procedure,19 or drainage valve) or pharmacologically treated (at the institution where surgery was performed or elsewhere) before OOKP surgery. In 24 glaucomatous eyes, additional glaucoma surgery was performed after OOKP surgery. Preoperative visual acuity of patients ranged from light perception only to 0.3. Light perception only was found preoperatively in 106 (58.6%) and hand motions in 47 (26%) of 181 eyes. Of the remaining 28 eyes, 25 had an acuity between counting fingers and 0.08 while in 3 eyes acuity ranged from 0.1 to 0.3. Disease duration, defined as the number of years in which corneal disease had effectively reduced visual acuity to the preoperative value, was mean (SD) 7.3 (8.9) years (range, 1-59 years). Informed consent was obtained from each patient after the aims and procedures of the study were fully explained. The study followed the tenets of the Declaration of Helsinki, and institutional review board approval was obtained.

**SURGICAL TECHNIQUE**

The surgical technique was developed from Strampelli,3 with several methodological changes and innovations introduced from the beginning of the present study. The surgical procedure, used in all patients included in the study, consisted of 2 fundamental steps separated by an average period of 12 weeks (range, 10-16 weeks).

**Modified OOKP Technique Step 1**

The first step included the preparation of (1) the bulbar anterior surface and (2) the osteodental-acrylic (ODA) complex. 1. Anterior bulbar surface preparation differed depending on the status of the conjunctiva: normal or with severe anatomical damage (advanced symblepharon or ankyloblepharon). In cases with normal conjunctiva, a 360° limbal peritomy was performed, and the conjunctiva was detached from the sclera by removing, if necessary, any scar tissue up to the insertion of the extraocular muscles recti. Recti were anchored with 5-0 silk threads to rotate the eyeball when needed. A lamellar keratotomy was subsequently performed starting from the limbus and involving the Bowman membrane. During keratotomy, any degenerative or scar tissue overlying the Bowman membrane was also removed. In cases with conjunctival damage, the tarsal surface was detached from the cornea (if no surgery for symblepharon or ankyloblepharon had been performed in advance), starting from a horizontal incision at the border between the 2 eyelids. Tissue separation proceeded up to the insertion of the recti, which were anchored as described earlier. A lamellar keratotomy was then performed. Anterior bulbar surface preparation was completed by covering the cornea and sclera, up to the muscle insertions, by a flap of oral mucosa from the cheek. The flap was removed by means of a surgical hemostat and was usually about 2 mm thick and

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**Figure 1.** Preoperative anterior segment photographs taken from 2 patients with dry eye due to pemphigoid (A) and chemical burn (B).

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**Table 2. Types of Procedures Performed for Each Complication Observed Before Performing a Modified OOKP Surgery**

<table>
<thead>
<tr>
<th>Preoperative Complication</th>
<th>Type of Treatment</th>
<th>No. of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symblepharon</td>
<td>Oral mucosa transplantation</td>
<td>10</td>
</tr>
<tr>
<td>Traumatic lid coloboma</td>
<td>Oculopalpebral plastic surgery</td>
<td>2</td>
</tr>
<tr>
<td>Corneal perforation</td>
<td>Penetrating tectonic keratoplast</td>
<td>5</td>
</tr>
<tr>
<td>Anterior synechiae</td>
<td>Synechotomy by spatula using viscoelastic or air</td>
<td>3</td>
</tr>
<tr>
<td>Cataract associated with anterior or posterior synechiae and elevated IOP</td>
<td>Synechotomy and preventive iris removal</td>
<td>3</td>
</tr>
<tr>
<td>Vitreous hemorrhage; retinal detachment</td>
<td>Vitreoretinal surgery with gas or silicone oil tamponade by means of Eckhard keratoprosthesis</td>
<td>2</td>
</tr>
</tbody>
</table>

*Abbreviations: IOP, intraocular pressure; OOKP, osteo-odontokeratoprosthesis.*
large enough to avoid any traction once in place. **Figure 2** shows examples of anterior bulbar surfaces covered by oral mucosa both intraoperatively (Figure 2A) and 1 month after OOKP surgical step 1 (Figure 2B). The mucosal flap was sutured (polyglactin 910 6-0 single stitches) to the sclera in correspondence to the insertion of the recti and at intermediate points between insertions, all at the same distance from the limbus. The previously detached conjunctiva was sutured to the peripheral border of the mucosal flap.

2. The ODA complex preparation proceeded as follows. A single-root tooth was chosen on the basis of preliminary clinical and radiological evaluation. Clinical evaluation was performed to determine the presence of degenerative or inflammatory processes of the root, alveolar bone, dentoalveolar ligament, and periodontium. Because it was available, a computed tomographic scan was performed to characterize some lesions that may have represented a contraindication to the use of a particular tooth. When, because of dental or periodontal diseases, the available osteodental lamina had a small surface (that did not allow the insertion of an optical cylinder having an anterior diameter large enough to provide a suitable visual field), 2 teeth with their roots were extracted to prepare 2 laminae, which were then glued by means of acrylic resin (Ivoclar, Schaan, Liechtenstein) and placed on the dentine surface to generate a single lamina with a larger surface. This procedure was performed in 5 patients. The most suitable tooth for the preparation of the osteodental lamina was the superior canine because it had the longest and largest root with the greatest quantity of alveolar bone. In the majority of patients, an autologous osteodental lamina was used. However, in some patients in whom the tooth was not available, a tooth from a first-degree relative with the highest number of compatible HLA antigen sites was used. Together with its surrounding bone and soft tissue, the chosen tooth was extracted by means of an oscillating surgical saw (Aesculap, Tuttlingen, Germany). After removing the tooth with its root, we obtained hemostasis, generally by diathermy. The small flap of mucosa detached from the labial surface on the root before cutting the bone was used to partially cover the dental arch cut to take out the root. The dental surgeon could put in an implant or use a prosthesis as the patient wished.

The osteodental block was freed from the soft tissue and epithelium, and from the half-root, an osteodental lamina was prepared. Figure 2C shows a typical osteodental hemilamina. The half-root was prepared by means of a diamond-edge mill saw (Cizeta srl, Bologna, Italy) and a supersonic trephine (Medicon Instruments, Tuttlingen, Germany). The pulp canal was opened and the dentine surface, which was to overlay the cornea, was smoothed. Excess alveolar bone was eliminated to suitably shape an approximately rectangular lamina of 9 to 10 mm (width) by 14.30 to 16 mm (length) with a thickness of 2.5 to 3.25 mm. Before removing the excess bone, its periosteum was detached and subsequently used as a flap to cover those surfaces of alveolar bone lacking periosteum. Periosteum was reattached by means of biological glue (Tissucol; Immuno, Pisa, Italy), which was also used to reattach any periosteum accidentally detached from the alveolar bone during the lamina preparation. The lamina’s surface, which was to be placed in contact with the cornea, was made in the centermost part (about two thirds of the lamina) of dentine surrounded in its periphery by a thin layer of cementum. The peripheral part (one third) of the lamina consisted of alveolar bone. The cementum and alveolar bone were connected to each other, as in the normal tooth histological structure, by the dentoalveolar ligament. The opposite surface of the lamina was made of alveolar bone. This was connected to the dentine by the dentoalveolar ligament and cementum. Of the 4 borders of the lamina, 2, parallel to the major axis, were made of bone covered by periosteum. The 2 shorter borders of the lamina corresponded to the apical and coronal parts of the tooth (apical and coronal borders of the lamina). The apical and coronal borders were made prevalently of bone and dentine, respectively. The lamina was then trephined approximately through its center, leaving an edge of dentine of 1 to 1.5 mm, so as to generate a hole of an average diameter of 3.70 mm (range, 3.3–4.0 mm) (Figure 2D). A schematic representation of the osteodental lamina is shown in...
Figure 2E. During the lamina preparation, tissues were frequently oxygenated by means of fresh blood (2-3 mL) taken from the patient.

A PMMA optical cylinder (Schalcon, Rome, Italy) was inserted into the hole and glued to the osteodental lamina by means of biocompatible acrylic resin (Figure 2F). The optical characteristics of the PMMA optical cylinder were as follows: mean intraocular diameter, 4.1 mm (range, 3.6-4.6 mm); mean extraocular diameter, 3.65 mm (range, 3.3-4.0 mm); the greater intraocular as compared with extraocular diameter created a step that allowed the cylinder to make tight contact not only with the inner hole surface but also with the posterior surface of the lamina dentine; in addition, this allowed the cylinder to be firmly kept in place at the required nodal point distance); mean length, 7.75 mm (range, 7.25-8.25 mm); mean radius of the convex extraocular surface, 16 mm; mean radius of the convex intraocular surface, 6.5 mm; refractive index, 1.49; and equivalent power, 50.8 diopters. These optic characteristics influence both the extent of postoperative peripheral visual field and the postoperative refractive status. For each patient, they were established to ensure the widest field and the refraction closest to emmetropic. The cylinder power was estimated preoperatively on the basis of echobiometry. The final choice of the remaining optical characteristics (length and diameter) was made at the intraoperative time of cylinder implantation and was constrained by the anatomical properties (thickness, total surface) of the osteodental lamina. The resulting ODA complex was temporarily inserted under the skin, just below the lower orbital rim, for an average period of 3 months (range, 2.5-4 months).

Modified OOKP Technique Step 2

The second step included the implantation of the ODA complex on the anterior bulbar surface. The ODA complex was removed from the subcutaneous pocket, and the surrounding soft tissue was trimmed. This soft connective tissue, which provides new vessels for the bone and peristeam, was usually adherent to the ODA complex, except for the surface of the lamina made of dentine. The latter was free from connection with any soft tissue. Once anatomical integrity of the ODA complex was verified, it was implanted on the anterior bulbar surface. First, the cheek mucosal graft covering the cornea was partially detached, from top to bottom, down to 1 to 2 mm over the lower limbus (Figure 3A), and 4 sutures in polyglactin 910 6-0, which were to be used to fixate the ODA complex once positioned, were predisposed at the limbus (at 6 and 12 o'clock) and approximately 1 to 2 mm from the limbus (at 3 and 9 o'clock). The cornea was trephined and a central full-thickness disc, of a diameter corresponding to the PMMA optical cylinder's intraocular diameter, was removed (Figure 3B). Thereafter, the iris was totally removed by performing a 360° iridodialysis under irrigation with balanced salt solution (Figure 3C). Usually, the ensuing bleeding ceased completely after 5 to 10 minutes. In some cases, where goniosynechia or anterior chamber membranes were present, an endodiathermy was performed. In phakic eyes, the lens (either clear or cataractous) was removed by intracapsular cryoextraction (Figure 3D) after enlargement of the corneal hole by 3 radial incisions. An open-sky anterior vitrectomy was then performed so that 1.5 to 1.8 mL of vitreous volume were removed. Corneal radial incisions were sutured with polyglactin 910 7-0 threads. Under suitable traction on the Flieringa ring, the posterior part of the PMMA optical cylinder was inserted, the ODA complex put in place over the cornea, and the borders of the lamina sutured, by at least 12 polyglactin 910 6-0 or 7-0 stitches, to the sclera and cornea. The ODA complex was put in place having its major axis horizontal (Figure 3E). Once the ODA complex was in place, air was injected by a 30-gauge needle (at the level of limbus) into the vitreous cavity to restore physiological IOP. The ODA complex was then covered by the flap of oral mucosa previously detached, after a hole had been trephined in the region of the flap corresponding to the PMMA optical cylinder (Figure 3F).
mucosal flap was finally sutured to the undetached oral mucosa, covering the sclera, by means of polyglactin 910 6-0 stitches.

At the end of the procedure, the patient was kept in the supine position for 5 to 6 days until complete resorption of intravitreal air, verified by either ophthalmoscopy or echography. This event was usually associated with a subjective improvement of vision. Postoperative medical treatment included antibiotics, corticosteroids, and ocular hypotensive drugs (acetazolamide) administered systemically. Intraocular pressure was routinely controlled daily up to at least 10 days. One month after surgery, a cosmetic prosthesis covering the external ocular surface was usually applied. The final result obtained 3 months after surgery and the cosmetic prosthesis are shown in Figure 4.

FOLLOW-UP

Median duration of clinical follow-up was 12 years and ranged from 1 to 25 years. Clinical follow-up with routine ophthalmic examination was performed every month through the first 6 months after surgery and then every 6 months. At every examination, visual acuity, IOP (estimated by a MacKay-Marg tonometer17), echography, fundus appearance, and short-term and long-term anatomical complications were noted. Visual field testing (Goldmann perimetry and/or Humphrey 30-2 threshold test) was performed after 1 and 6 months from the end of the surgical procedure. Whenever required (clinically suspected glaucoma), repeated visual field testing was obtained every 3 months.

STATISTICAL ANALYSIS

One eye for each patient was included in the analysis. In cases in which both eyes underwent surgery, the results from one eye, chosen at random, were considered. Survival analysis was used to estimate the cumulative probability in an individual patient of retaining an intact KPro over the follow-up interval. A similar approach was used to determine the cumulative probability of retaining the best-corrected postoperative visual acuity over the follow-up. The incidence of postoperative complications was compared across the groups of the study population by means of cross-tabulation and χ² statistics. Assuming normal data distribution, best and final (ie, at the end of follow-up) postoperative visual acuities of patients were compared by paired t tests. Acuity results between patients with and without glaucoma were compared by independent t tests. In all the analyses, P<.05 was considered statistically significant.

RESULTS

ANATOMICAL RESULTS

The results of survival analysis showing the cumulative probability for an individual patient of retaining an intact osteodental lamina over the follow-up period are shown in Figure 5A. Eight years after surgery, the cumulative probability of retaining an intact lamina is more than 90%, with a narrow 95% confidence interval (88%-92%). Average probability is still greater than 80% 18 years after surgery (17 patients). No significant differences in the probability of retaining an intact osteodental lamina were found across the different diagnostic groups. All 4 patients not included in the logistic regression analysis (with a follow-up of 23 years) maintained an intact osteodental lamina, confirming the observed statistical trend.

The bar histogram in Figure 5B shows the percentage of anatomical complications found all patients over the follow-up period. Secondary glaucoma, which is currently considered the most frequent complication after OOKP surgery, was considered separately. Some complications specific for OOKP represent the etiologic factors responsible for the loss of the ODA complex. These include spontaneous resorption of the osteodental lamina in the region neighboring the PMMA optical cylinder and postoperative ulceration of oral mucosa in which treatment was ineffective because no timely treatment could have been performed. The latter case was the most frequent.

To obtain a complete healing in this complication, it is necessary to perform a good cleaning of the eroded area and its covering with the adjacent mucosa, already vascularized, by sliding. The exposed peripheral area (created by this sliding) is covered by a small free flap of mucosa taken from the mouth. For these delayed treatments, the eye that underwent OOKP surgery developed septic processes that eroded the osteodental lamina or involved the anterior chamber. This complication was considered in our Tables as a lamina reabsorption or endophthalmitis.

Complications have been also categorized as intraoperative (including both the first and the second surgical stages) and postoperative, divided into preimplantation and postimplantation of the ODA complex. Each com-
Complication is reported, together with its incidence, in Table 3 for the different diagnostic groups of the study population. The total incidence of complications did not vary significantly across the different diagnostic categories ($\chi^2 = 1.73; P = .18$). In total, there were 65 complications in 58 eyes. Ten were intraoperative complications, 13 were postoperative before the implantation, and 42 were postoperative after the implantation. All the intraoperative and postoperative preimplantation complications were successfully treated, whereas 12 of the postimplantation complications had a poor outcome, with or without treatment. The remaining 30 postimplantation complications were treated with success. Among the postoperative OOKP complications, endophthalmitis represented the most serious, although it was rare (Table 3).

We evaluated whether the anatomical conditions of the tooth, examined either preoperatively or intraoperatively, may have significantly predicted the occurrence of endophthalmitis. Preoperative poor tooth conditions were observed in 4 of 4 eyes with postoperative endophthalmitis. The same complication was not observed in any of the patients with a normal tooth condition.

Table 3. Number and Percentage Incidence of Complications of Modified OOKP Surgery for the Different Diagnostic Groups of the Study Population*

<table>
<thead>
<tr>
<th>Complication</th>
<th>Pemphigoid</th>
<th>Sjögren Syndrome</th>
<th>Trachoma</th>
<th>Lyell Syndrome</th>
<th>Stevens-Johnson Syndrome</th>
<th>Graft-vs-Host Disease</th>
<th>Congenital Lid Coloboma</th>
<th>Corneal Burns</th>
<th>Bullous Keratopathy</th>
<th>Keratitis Sequela</th>
<th>Bullous Keratopathy Secondary to Glaucoma Surgery</th>
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<td>HeI</td>
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Abbreviations: CDI, choroidal detachment postoperative; CPI, corneal perforation intraoperative; DUL, dental unit loss; E, endophthalmitis; F, fistula; HeI, hemovitreous intraoperative; HeP, hemovitreous postoperative; LR, lamina resorption; MAPr, mucous alteration preimplantation; MF, mandibular fracture; MUPo, mucous ulcer postimplantation; OCE, optical cylinder extraction; RDPr, retinal detachment preimplantation; RDPr, retinal detachment postimplantation; and RLM, retrolentar membrane.

*Values are expressed as number (percentage) of patients.
The incidence of the postoperative complications significantly decreased \((\chi^2 P<0.05)\) as the time elapsed after surgery increased. The highest incidence of complications was observed within the first 18 months after surgery (7.5%), not considering glaucoma, and fell close to zero (0.2%) 10 years after surgery.

Sixty-six of 181 patients undergoing surgery had a preoperative primary or secondary glaucoma due to physical (fire, boiling water) or chemical burns. These patients were not considered when estimating the incidence of “true postoperative glaucoma.” The latter was considered when the following criteria were met: (1) absence of documented glaucomatous disease before surgery; (2) occurrence of glaucomatous disease (including persistent pathologic IOP elevation and significant optic disc and visual field changes) within 24 months from the second surgical step; and (3) any intraoperative complication (ie, iatrogenic damage to the aqueous veins during the various surgical steps) that may likely have led to a postoperative glaucoma. Postoperative glaucoma was diagnosed ex novo in 12 eyes, leading to an estimated incidence of 10.4% (95% confidence interval, 6%-14.8%; 12 of 115 cases without preoperative glaucoma).

**FUNCTIONAL RESULTS**

Mean postoperative best-corrected visual acuity and acuities measured at 1, 3, 5, 7, and 10 years of follow-up were reported in the different diagnostic groups of the study population are reported in Table 4. Mean best-corrected visual acuity varied from 0.41 (in the bullous keratopathy following glaucoma surgery group) to 0.8 (in the corneal burns and dry eye groups). Average final visual acuity at the end of clinical follow-up tended to decrease slightly (by 1 line) in all groups. However, this change reached statistical significance (by paired t tests) only in the pemphigoid, trachoma, and bullous keratopathy following glaucoma surgery groups \((P<0.05)\).

Results of survival analysis showing the cumulative probability for an individual patient of retaining the best-corrected postoperative visual acuity (ie, within 2 lines) at the end of follow-up. Error bars represent 95% confidence intervals.

Nine years after surgery, the cumulative probability of retaining the best-corrected postoperative acuity was more

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**Table 4. Best-Corrected Postoperative Visual Acuity (BVA) and Visual Acuities Measured at 1, 3, 5, 7, and 10 Years of Clinical Follow-up, for Each Diagnostic Group**

<table>
<thead>
<tr>
<th>Diagnostic Group</th>
<th>BVA 1y</th>
<th>BVA 3y</th>
<th>BVA 5y</th>
<th>BVA 7y</th>
<th>BVA 10y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pemphigoid</td>
<td>0.80 (0.31)</td>
<td>0.80 (0.31)</td>
<td>0.73 (0.36)</td>
<td>0.79 (0.33)</td>
<td>0.78 (0.32)</td>
</tr>
<tr>
<td>Sjögren syndrome</td>
<td>0.86 (0.20)</td>
<td>0.86 (0.20)</td>
<td>0.86 (0.20)</td>
<td>0.85 (0.20)</td>
<td>0.77 (0.22)</td>
</tr>
<tr>
<td>Trachoma</td>
<td>0.74 (0.37)</td>
<td>0.74 (0.37)</td>
<td>0.74 (0.37)</td>
<td>0.74 (0.37)</td>
<td>0.74 (0.37)</td>
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<tr>
<td>Lyell syndrome</td>
<td>0.83 (0.24)</td>
<td>0.83 (0.24)</td>
<td>0.83 (0.24)</td>
<td>0.83 (0.24)</td>
<td>0.90 (0.12)</td>
</tr>
<tr>
<td>Steven-Johnson syndrome</td>
<td>0.95 (0.10)</td>
<td>0.92 (0.08)</td>
<td>0.66 (0.47)</td>
<td>0.66 (0.47)</td>
<td>0.60 (0.50)</td>
</tr>
<tr>
<td>Graft-vs-host disease</td>
<td>1.0</td>
<td>1.0</td>
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<td>1.0</td>
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<tr>
<td>Congenital lid coloboma</td>
<td>0.1</td>
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<tr>
<td>Corneal burns</td>
<td>0.80 (0.33)</td>
<td>0.80 (0.33)</td>
<td>0.81 (0.32)</td>
<td>0.76 (0.36)</td>
<td>0.80 (0.35)</td>
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<tr>
<td>Bullous keratopathy</td>
<td>0.73 (0.42)</td>
<td>0.73 (0.42)</td>
<td>0.69 (0.44)</td>
<td>0.75 (0.41)</td>
<td>0.74 (0.42)</td>
</tr>
<tr>
<td>Keratitis sequelae</td>
<td>0.73 (0.39)</td>
<td>0.73 (0.39)</td>
<td>0.74 (0.38)</td>
<td>0.67 (0.42)</td>
<td>0.76 (0.40)</td>
</tr>
<tr>
<td>Bullous keratopathy secondary to glaucoma surgery</td>
<td>0.41 (0.28)</td>
<td>0.41 (0.28)</td>
<td>0.41 (0.28)</td>
<td>0.29 (0.22)</td>
<td>0.28 (0.23)</td>
</tr>
</tbody>
</table>

*Values are expressed as mean (SD) unless otherwise indicated.
than 70%, with a narrow 95% confidence interval (65%-75%). Average probability was still more than 50% 18 years after surgery (17 patients). All 4 patients not included in the logistic regression analysis (with a follow-up of 23 years) maintained their best-corrected postoperative acuity.

Visual acuity results over the follow-up period were also analyzed separately for the subgroup of patients having either preoperative or postoperative glaucoma (n=78). Specifically, we evaluated whether visual acuity results in the long-term follow-up were significantly poorer in patients with glaucoma compared with patients without glaucoma. The analysis was performed in a subgroup of patients having a clinical follow-up of 12 years. Ten of these patients had glaucoma, while 20 did not. In the former, mean (SD) final acuity was 0.45 (0.47), significantly lower (t test P<.05) than the best-corrected postoperative acuity (mean [SD], 0.71 [0.37]). In the latter, mean (SD) final acuity was 0.65 (0.26), also significantly lower (P<.05) than the mean (SD) best-corrected postoperative acuity (0.793 [0.26]). However, the drop in visual acuity observed at the end of follow-up was significantly greater (t test P<.05) in patients with glaucoma compared with patients without glaucoma.

THE MODIFIED OOKP PROCEDURE: RATIONALE FOR SURGICAL INNOVATIONS, RESULTS, AND COMPARISON WITH OTHER KPros

In the present study, the long-term anatomical and functional results of a modified OOKP procedure, developed from the original Strampelli technique, were evaluated in a large cohort of patients with different clinical types of severe corneal blindness untreatable with standard keratoplasty. As described in the “Methods” section, changes to the original Strampelli OOKP technique included (1) preparation of a large osteodental lamina, which, when needed, was obtained from the bonding of 2 different laminae (ie, from 2 different roots) by means of biocompatible acrylic resin, (2) emmetropization (even though sometimes incomplete owing to difficulties in preoperative measurements) through the PMMA optical cylinder, (3) total iris ablation, (4) intracapsular lens cryoextraction, (5) anterior open-sky vitrectomy, (6) lamellar keratectomy including the Bowman membrane (to allow a firmer adhesion of the mucosa to the cornea), (7) use of thicker cheek mucosa (to better vascularization to the lamina), (8) increased diameter of the PMMA optical cylinder, taking care to avoid too large a corneal hole, (9) use of impacted teeth, (10) use of a blood relation’s teeth in toothless patients, and (11) use of biological glue to reattach the periosteum. A large osteodental lamina obtained by joining 2 laminae allowed the preparation of a reasonably large hole for the PMMA optical cylinder placement while maintaining an amount of dentine and bone sufficient to prevent resorption of the osteodental lamina over time. We do not agree with authors who suggest reducing the lamina size to avoid a thinning of the mucosa. Total iris ablation and anterior vitrectomy prevented the development of inflammation and postinflammatory anterior and posterior synechiae, as well as angle-closure glaucoma. Intracapsular cryoextraction prevented the development of complicated cataract (with the consequent need of a third, complex surgical step) as well as the risk of phacoanaphylactic uveitis. The intracapsular procedure was considered preferable to the extracapsular since it minimized the risk of trabecular or anterior synechiae with the lens capsule and avoided the risk of incomplete removal of crystalline lens residuals, owing to their poor visualization through an opaque cornea, as well as the risk of secondary cataract. Antiglaucoma surgery effectively lowered IOP in cases of preoperative glaucoma and prevented the loss of visual function, as shown by the relatively preserved, although deteriorating over time, average final visual acuity in patients with glaucoma.

It has been reported that glaucoma is the most frequent complication of OOKP surgery. However, it is often difficult to establish whether glaucoma is caused by the surgery per se or instead is related to preexisting abnormalities of the anterior segment, involving trabecular meshwork and angle, induced by the original etiology (for instance, severe acid or alkali burns). According to the strict criteria described in the “Results” section, a true postoperative glaucoma was diagnosed in only a minority of patients (10.4%) in this study. On the basis of clinical examinations performed before OOKP surgery, it is reasonable to assume that most of the glaucomatous complications were preexisting. However, glaucoma detection is an important diagnostic challenge in these patients. In patients with OOKP, the diagnosis and monitoring of eventual glaucoma is done only by the morphofunctional study of the optic disc (visual field and ophthalmoscopy) in which it is impossible to measure exact IOP. Specific electrophysiological and psychophysical protocols have been published to help in the diagnosis of this complication. A drainage implant or, alternatively, a double-thread cyclodiastasis have been proven to effectively reduce IOP.

Anatomical outcomes showed that the present technique allowed the long-term maintenance of the visual prosthesis in the majority of patients. To our knowledge, the present follow-up is the longest ever reported in the literature for a KPro. While there is an increasing amount of reports illustrating new potential and promising approaches to KPro implantation (eg, the Chirila KPro), relatively few studies have reported long-term anatomical and functional results. Temprano described the results of a 15-year follow-up after implantation of a tibial self-graft KPro in 167 eyes, showing a rejection of the implant in 25% of cases. Lacombe, relatively few studies have reported long-term anatomical and functional results. Temprano described the results of a 15-year follow-up after implantation of a tibial self-graft KPro in 167 eyes, showing a rejection of the implant in 25% of cases. Lacombe, reporting the results of a 12-year follow-up of an all-PMMA prosthesis with a retrocorneal fixation haptic, found a rejection rate of 45%, mainly related to corneal necrosis attributed to epithelial cell downgrowth. Pintucci et al and Pintucci and Pintucci used a biointegrable KPro with a PMMA optical cylinder integrated with a tissue-colonizing Dacron. In their studies, 128 implanted eyes were followed up clinically for 20 years, but

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unfortunately, the anatomical and functional results were not specified in detail.

Functional results in the present group of patients confirmed the overall statistical trend observed for the anatomical outcome because postoperative best-corrected visual acuity was in general acceptably good and stable over the years. Functional outcomes were also reasonably good, as far as visual acuity was concerned, for glaucomatous eyes (mean final acuity, 0.4). So far, none of the case series in which other types of KPros were implanted reported long-term functional results comparable with those obtained by the present technique.

**BIOLOGICAL PROPERTIES OF THE OOKP**

Compared with case series reported in the literature, the modified OOKP technique may provide better long-term anatomical and functional results, although within the limitations imposed by a complex, demanding surgical approach with a relatively high rate of complications compared with other anterior segment surgical procedures. The superiority of the OOKP over other KPros may lie mostly in its biological properties, which can be summarized as follows:

1. The OOKP is a true heterotopic autograft made of living, long-lasting human tissue, unlike KPros that use biointegrated or biocolonizable tissues.  
2. The haptic is made of dentine, a hard tissue with a slow metabolic exchange, which may help to confer stability to the complex ODA lamina–PMMA optical cylinder structure through a tight and long-lasting contact (by means of acrylic resin) with the PMMA optical cylinder and provide protection against cylinder extrusion and fistulation. Cylinder extrusion was indeed observed in fewer than 2% of cases with dry eye and 6% of eyes with bullous keratopathy secondary to glaucoma surgery. Fistulation was found in fewer than 2% of dry eye cases. None of the eyes belonging to the other diagnostic categories had such complications.
3. The properties of dentine as an avascular tissue in contact with both the corneal surface and the optical PMMA cylinder may prevent or limit the frequency of formation of retroprosthetic membranes, which had a significant occurrence only in the keratitis and corneal burns diagnostic groups.
4. The tight, histologically demonstrated contact between the mucous epithelium and the components of the osteodental lamina (ie, the dentoalveolar ligament, bone, and dentine, which generate an “epithelial seal” to the anterior chamber) prevents leakage of the aqueous humor, infection, and tissular and neovascular proliferation, which are responsible for retroprosthetic membranes.
5. The living osteodental lamina may provide immune defense characteristics to the prosthesis, protecting against infections. Endophthalmitis was only observed in 2% of eyes with dry eye and corneal burns. Postoperative endophthalmitis was always associated with poor tooth conditions before surgery.
6. Long-term stability of the mucosal tissue covering the osteodental lamina was clinically demonstrated, providing protection and nutrition to the underlying bone.

Lamina resorption was indeed a relatively rare event in the present series, occurring in 7% of cases with keratitis and 2% of cases with dry eye.

**CONCLUSIONS**

Since the pioneering work of Strampelli, OOKP surgery has proven to be, over the years, the most effective approach to KPro implantation. While new, less invasive, and tissue engineering–based techniques will certainly be developed in the future to solve the problem of severe corneal blindness, the physician is still facing the problem of what is currently the most productive technique to treat such abnormalities. The innovation introduced to the original OOKP procedure may make the present surgical approach less prone to fatal complications (endophthalmitis or prosthesis extrusion) and more likely to achieve a better functional outcome compared with either the original technique or other proposed approaches. We recognize that this procedure routinely requires the extraction of at least 1 of the patient’s teeth, which has disadvantages compared with using synthetic materials. However, the findings of this study provide evidence of a long-term stability of the prosthesis with a level of visual rehabilitation that is currently unattainable with other KPro techniques.

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