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Clinical science

Lifelong experience of modified osteo-odonto-keratoprosthesis implantation over 50 years

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ABSTRACT

Aims The osteo-odonto-keratoprosthesis (OOKP) is a biological implant indicated for the treatment of eyes affected by corneal blindness, not amenable for keratoplasty. The purpose of the study is to report the long-term outcomes of patients undergone Falcinelli's modified OOKP (MOOKP).

Methods In this retrospective study, anatomical and functional survival rates were evaluated using Kaplan-Meier analysis, according to eye coverage (buccal mucosa vs skin). Best-corrected visual acuity (BCVA) was recorded before and after surgery along with intraoperative and postoperative complications.

Results 310 eyes of 269 patients affected by corneal blindness underwent MOOKP and were followed up for 15.9±12.0 years (up to 45 years). Anatomical survival rates for eyes covered by buccal mucosa were 85.1% at 20 years (number at risk (n)=81) and 82.3% at 45 years (n=10). Functional survival rates were 70.7% at 20 years (n=74) and 56.5% at 45 years (n=7). Anatomical and functional survival rates for eyes covered by skin were 58.9% (n=3) and 37.0% (n=3) at 20 years, respectively. Survival rates were significantly lower for eyes covered by skin (p<0.001). Postoperative BCVA at the last follow-up visit was significantly higher compared with baseline (0.88±1.08 LogMAR vs 2.49±0.38 LogMAR; p<0.001). The most threatening complications were glaucoma (n=70, 22.6%), endophthalmitis (n=24, 7.7%), retinal detachment (n=20, 6.4%), instability/tilting/expulsion of the optical cylinder and expulsion of the prosthesis (n=24, 7.7%).

Conclusions MOOKP showed excellent long-term anatomical and functional survival rates. Visual acuity significantly improved as soon as 3 months postoperatively and remained unchanged in about two-thirds of patients throughout the entire follow-up.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The osteo-odonto-keratoprosthesis (OOKP) is a biological implant that employs an osteo-dental lamina as haptic, with an optical acrylic cylinder at the centre, which replaces the cornea.

WHAT THIS STUDY ADDS

⇒ Anatomical survival rates for eyes covered by buccal mucosa were 85.1% at 20 years and 82.3% at 45 years. Functional success rates were 70.7% at 20 years and 56.5% at 45 years. Both survival rates were significantly lower for eyes covered by skin (always p<0.001).

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Modified OOKP showed excellent long-term anatomical and functional outcomes for the treatment of eyes affected by corneal blindness, not amenable to keratoplasty.

INTRODUCTION

Allograft corneal transplantation is the conventional approach for treating corneal blindness, able to achieve high survival rates when performed in wet, non-inflamed and avascular recipient beds. However, in case of severe ocular surface disease, dry eye or corneal neovascularisation, the risk of graft failure is high, often requiring repeated keratoplasty.[1 2] Implantation of a keratoprosthesis (KPro) is a possible solution for restoring vision in eyes affected by corneal diseases in which conventional keratoplasty or surgical reconstruction of the ocular surface may fail or cannot be feasible.[3] Depending on the haptic used to bind the artificial cornea to the eye, KPros are classified into biocompatible, biointegrated and biological.[4] The Boston Type 1 KPro belongs to the biocompatible type and is the most used worldwide; however, it is mainly indicated for eyes with adequate tear film and blink mechanism.[5] The osteo-odonto-keratoprosthesis (OOKP) is a biological KPro, first introduced by Strampelli in 1964.[6] This technique employs an osteo-dental lamina as a biological haptic, opportunely derived from an autologous monoradicular tooth. An optical acrylic cylinder at the centre of the lamina replaces the cornea. Several studies showed significantly better long-term results for OOKP compared with other KPros in ocular surface diseases characterised by severe dry eye and/or eyelids affections.[7–11] To improve anatomical and functional outcomes, Falcinelli *et al* made several advances to the original surgical technique, leading to the development of the so-called modified OOKP (MOOKP).[6 12 13] Falcinelli *et al* validated the MOOKP procedure, reporting positive results in 181 eyes after a follow-up period of up to 25 years.[6] Following this first report, further case series were published.[14–16]

The purpose of this study is to report the long-term anatomical and functional outcomes of a new

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cohort of patients who underwent MOOKP between 2000 and 2019 and to extend the follow-up period of the cohort that underwent surgery between 1973 and 1999, first evaluated by Falcinelli *et al*.[6]

MATERIALS AND METHODS

This retrospective study evaluated the outcomes of patients who underwent MOOKP between 1973 and 2019, followed up to 2023. Surgery was performed by two experienced surgeons (Giancarlo Falcinelli and Paolo Colliardo) at San Camillo Hospital (Rome, Italy) and at Pio XI Private Hospital (Rome, Italy).

The study included eyes affected by corneal diseases in which keratoplasty was not possible or had already failed. Eligible eyes had preoperative decimal best-corrected visual acuity (BCVA) ≤0.3, with BCVA ≤0.1 in the fellow non-eligible eye. Patients affected by autoimmune diseases underwent MOOKP only when their general health status was deemed stable and an adequate control of the disease was possible during and after the surgical procedures.

Exclusion criteria were paediatric age (<17 years), phthisis bulbi, estimated intraocular pressure (IOP) ≥21 mm Hg, no light perception, untreated retinal detachment or other sight-threatening ocular diseases.

Preoperative evaluation

All patients underwent full general and ophthalmological examination. BCVA was assessed with a Snellen decimal chart. IOP was estimated by either MacKay-Marg electronic applanation tonometer (Berkeley Tonometer Company, USA) or digital palpation. B-scan ultrasonography was performed to examine both anterior and posterior segments. Since 1995, ultrasound biomicroscopy has also been used to assess the anterior segment. A biometry with A-scan ultrasonography allowed the calculation of the power of the polymethyl methacrylate optical cylinder for emmetropia or slight myopia. Electrofunctional tests were performed in selected patients to evaluate residual retinal function. Oral examination was performed to identify a suitable tooth. Orthopantomography and X-rays were executed until 2015; then, cone beam CT has become the favourite technique. A vital monoradicular tooth was selected, preferably a canine. If canines were not available, incisor teeth were chosen instead. If no tooth was suitable, one from a first-degree relative was used.

Surgery

Detailed description of the surgical technique was previously reported by Falcinelli *et al.*[6] Briefly, MOOKP includes two surgical stages, separated by approximately 12 weeks. The first stage involves the preparation of (a) the anterior surface of the eye and of (b) the osteo-dental-acrylic lamina (figure 1A,B). The anterior surface of the eye is covered by a flap of autologous buccal mucosa, collected from the cheek. If buccal mucosa was not available, transpalpebral skin, retroauricular skin or vaginal mucosa were used for eye coverage. The second surgical stage involves (a) the preparation of the anterior segment of the eye and (b) the implantation of the osteo-dental-acrylic lamina (figure 1C,D). If the eye has sufficiently deep conjunctival fornices, a cosmetic prosthesis can be applied 1 month postoperatively.

Postoperative treatment included systemic acetazolamide, as well as systemic and topical antibiotics and corticosteroids. In the case of a donated tooth, systemic cyclosporine was initiated 12 hours before surgery at a posology of 8 mg/kg/day (divided into two oral administrations). This daily dosage was maintained

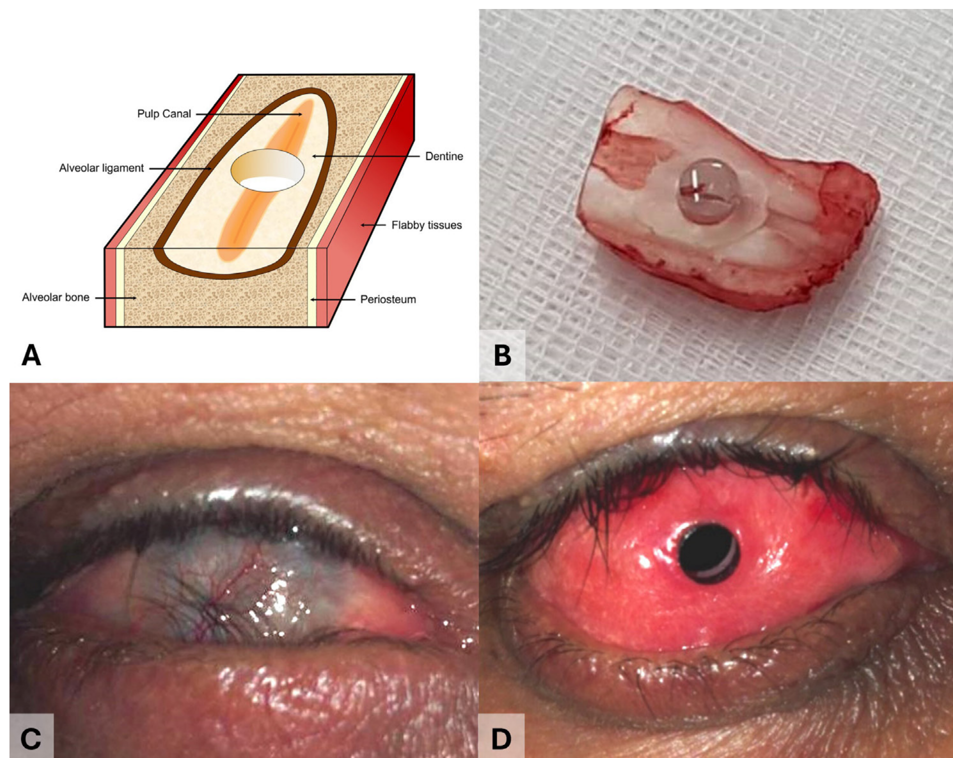

Figure 1 Osteo-odonto-keratoprosthesis implant. (A) Schematic representation of the osteo-dental lamina; (B) osteo-dental-acrylic lamina before implantation; (C) preoperative image of a patient affected by chemical burn; (D) postoperative result at 3 months of an eye implanted with the osteo-dental-acrylic lamina and covered by buccal mucosa.

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for 1 week postoperatively, after which it was gradually tapered to reach a target blood cyclosporine of 100 ng/mL.

Postoperative evaluation

Postoperative evaluation was performed every day for the first week, then after 2, 3, 4, 8, 12, 16, 20 and 24 weeks; afterwards, visits were scheduled every 6 months. BCVA was recorded starting from the third month after surgery. Slit lamp biomicroscopy and ultrasonography were respectively performed to examine the anterior and posterior segment. IOP was estimated by means of MacKay-Marg electronic applanation tonometer or digital palpation. When possible, Goldman perimetry and/or Humphrey 30-2 threshold test (Carl Zeiss Meditec, Dublin, California, USA) were performed 1 month and 6 months postoperatively. In case of glaucoma suspect, visual field tests were obtained every 3 months. Additionally, ophthalmoscopic examination of the optic disc, fundus photography and electrofunctional tests were performed for glaucoma assessment. During follow-up, the status of autoimmune diseases was monitored. When necessary, systemic treatments were tailored to ensure the stability of disease control and to reduce the risk of postoperative complications that could have an impact on surgical outcomes.

Statistical analysis

Anatomical and functional survival rates were drawn in Kaplan-Meier curves. We defined anatomic failure as any complication requiring MOOKP implant removal. BCVA measurements were converted to logarithm of the minimum angle of resolution (LogMAR). Functional failure was defined as a decimal BCVA <0.1. Data normality was assessed using Shapiro-Wilk and Kolmogorov-Smirnov tests. Parametric (paired or independent Student's t-tests) and non-parametric tests (Wilcoxon signed-rank or Mann-Whitney U tests) were used to compare continuous study variables, as appropriate. χ^2 test was used for the analysis of categoric variables. Log-rank test was used to compare Kaplan-Meier curves. Continuous variables were expressed as mean±SD. A p<0.05 was considered statistically significant. Data were entered into Microsoft Office Excel 365 (Microsoft, Redmond, Washington, USA) and analysed with GraphPad Prism (V.10.3.1; GraphPad Software, San Diego, California, USA).

RESULTS

Patients baseline characteristics

This study included 310 eyes of 269 patients (168 males, 101 females; age 53.6±16.0 years, range 17–87 years). Of these, 229 eyes belonged to the previous series originally evaluated by Falcinelli *et al*,[6] while the remaining 81 eyes belonged to the new cohort undergone surgery between 2000 and 2019.

The most common indications for MOOKP were chemical/physical injuries (n=109; 35.2%) and ocular pemphigoid (n=75; 24.2%). Table 1 shows detailed demographic data. Preoperative BCVA was 2.49±0.38 LogMAR (95% CI 2.44 to 2.53). Decimal BCVA was light perception in 204 eyes (65.8%), hand movement in 75 eyes (24.2%) and between 0.01 and 0.3 in the remaining 31 eyes (10.0%).

Surgical details

In most cases, the osteo-dental lamina was prepared using an autologous tooth, while in 26 eyes (8.4%) the tooth was donated by a first-degree relative. The mean dimensions of the osteo-dental lamina before implantation were 12.3±1.0 mm (range 10–16)×9.6±1.3 mm (range 6–14)×3.3±0.5 mm (range 2–4).

For eye coverage, autologous buccal mucosa was used in 278 eyes (89.7%), retroauricular skin in 16 eyes (5.2%), transpalpebral skin in 12 eyes (3.9%) and vaginal mucosa in 4 eyes (1.3%). There was no significant difference in mean preoperative BCVA between eyes covered by buccal mucosa and those covered by skin (p=0.31).

Postoperative results

The mean follow-up period was 15.9±12.0 years (95% CI 14.5 to 17.2), up to 45 years. Anatomical and functional Kaplan-Meier curves for eyes covered by buccal mucosa and skin are shown in figure 2A,B.

Anatomical survival probabilities for eyes covered by buccal mucosa were 93.0% at 10 years (number at risk (n=190), 85.1% at 20 years (n=81), 82.3% at 30 years (n=44) and 82.3% at 45 years (n=10). Functional success rates were 81.9% at 10 years (n=174), 70.7% at 20 years (n=74), 62.6% at 30 years (n=39) and 56.5% at 45 years (n=7).

Anatomical survival probabilities for eyes covered by skin were 64.3% at 5 years (n=19), 58.9% at 10 years (n=8) and 58.9% at 20 years (n=3). Functional success rates were 60.7% at 5 years (n=18), 37.0% at 10 years (n=6) and 37.0% at 20 years (n=3).

Eyes covered with skin showed significantly lower anatomical (χ^2=47.216; p<0.001) and functional (χ^2=29.790; p<0.001) survival probabilities compared with those covered by buccal mucosa.

Anatomical and functional Kaplan-Meier curves for eyes covered by buccal mucosa, stratified according to main surgical indications (n>30), are shown in figure 2D,E. Eyes affected by chemical/physical injuries had the best functional survival rate at 40 years (70.2%), followed by keratitis sequelae (48.7%), pemphigoid (44.3%) and end-stage bullous keratopathy (36.4%).

Kaplan-Meier curves to evaluate the survival of autografts (autologous tooth) versus allografts (tooth donated from a first-degree relative) in eyes covered by buccal mucosa are presented in figure 2F. A trend towards a significant difference was observed favouring autografts for both anatomical (χ^2=2.932; p=0.09) and functional survival rates (χ^2=3.285; p=0.07).

Of 310 eyes, 13 (4.2%) underwent repeat MOOKP due to failure of the first implant (9 covered by buccal mucosa, 3 by skin and 1 by vaginal mucosa). In eyes covered by buccal mucosa, the anatomical survival probability at 14 years was similar between first-time implants (86.7%) and repeat MOOKP (80.0%) (χ^2=0.599, p=0.44). However, the functional survival probability at 16 years was significantly higher for first-time implants (73.7%) compared with repeat MOOKP (25.9%) (χ^2=6.223, p=0.01).

At 3 months, BCVA was 0.26±0.50 LogMAR (95% CI 0.21 to 0.32) for eyes covered by buccal mucosa and 0.25±0.55 (95% CI 0.04 to 0.45) for those covered by skin, both significantly improved compared with baseline (always p<0.001). Decimal BCVA≥0.1 at 3 months remained unchanged in 169 out of 261 eyes covered by buccal mucosa (64.8%) for the entire duration of the follow-up, while 92 eyes (35.2%) experienced BCVA worsening, with a mean increase of 1.58±1.03 LogMAR (95% CI 1.45 to 1.70). Conversely, decimal BCVA ≥0.1 at 3 months lowered in 18 out of 27 eyes (66.7%) covered by skin, with a mean increase of 2.23±0.79 LogMAR (95% CI 1.94 to 2.52). The distribution of preoperative, 3-month postoperative and final decimal BCVA values is reported in table 2. The Kaplan-Meier curve in figure 2C shows the cumulative probability of retaining a BCVA within 0.2 decimal units of the 3-month

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Table 1 Demographic data for each diagnostic group, including sample size, age at surgery, low vision duration (calculated as the time between the onset of visual disability and the year of surgery), repeat MOOKP, tooth graft type and postoperative follow-up

Diagnostic groups	Buccal mucosa					
	Sample size	Age at surgery (years)	Low vision duration (years)	Redo-MOOKP	Tooth graft type	Postoperative Follow-up (years)
	Eyes, patients (M/F)	Mean±SD (min/max)	Mean±SD (95% CI)	Eyes (%)	Autograft (%)/allograft (%)	Mean±SD (min/max)
All	278, 243 (154/89)	52.9±16 (17/87)	7±8.2 (6 to 7.9)	9 (3.2%)	260 (93.5%)/18 (6.5%)	16.7±12.2 (15.3/18.2)
Chemical/physical injury	102, 91 (80/11)	44.5±15 (18/74)	8±10.7 (5.9 to 10.1)	1 (1%)	101 (99%)/1 (1%)	21.4±13.9 (18.7/24.1)
Pemphigoid	66, 55 (28/27)	63.2±10.5 (40/83)	5.3±3.7 (4.4 to 6.2)	3 (4.5%)	58 (87.9%)/8 (12.1%)	13±8.9 (10.8/15.1)
End-stage bullous keratopathy	36, 34 (17/17)	57.1±16 (22/81)	5.6±5 (3.9 to 7.2)	1 (2.8%)	35 (97.2%)/1 (2.8%)	16±9.9 (12.8/19.2)
Keratitis-induced scarring and neovascularisation	35, 29 (17/12)	60.6±10.2 (36/87)	7.7±10 (4.4 to 11.1)	2 (5.7%)	33 (94.3%)/2 (5.7%)	12.3±9 (9.3/15.2)
Lyell syndrome	13, 11 (7/4)	38.5±15 (20/71)	6.8±4.4 (4.4 to 9.2)	1 (7.7%)	12 (92.3%)/1 (7.7%)	19±15.4 (10.6/27.4)
Sjögren syndrome	13, 12 (1/11)	61.8±10.1 (46/79)	4.3±1.8 (3.3 to 5.3)	1 (7.7%)	8 (61.5%)/5 (38.5%)	10.7±9.8 (5.3/16)
Steven-Johnson syndrome	10, 8 (3/5)	36.5±9.2 (17/51)	11.9±6 (8.2 to 15.6)	0 (0%)	10 (100%)/0 (0%)	18.8±10.8 (12.1/25.5)
Graft-versus-host disease	2, 2 (1/1)	49±3 (46/52)	10.5±9.5 (-2.7 to 23.7)	0 (0%)	2 (100%)/0 (0%)	12±3 (7.8/16.2)
Xeroderma pigmentosum	–	–	–	–	–	–
Congenital lid coloboma	1, 1 (0/1)	58±0 (58/58)	15±0	0 (0%)	1 (100%)/0 (0%)	13±0
Diagnostic groups	**Skin**					
	Sample size	Age at surgery (years)	Low Vision duration (years)	Redo-MOOKP	Tooth graft type	Postoperative follow-up (years)
	Eyes, patients (M/F)	Mean±SD (min/max)	Mean±SD (95% CI)	Eyes (%)	Autograft (%)/allograft (%)	Mean±SD (min/max)
All	28, 23 (14/9)	60.4±14.9 (26/83)	4.7±6.1 (2.4 to 6.9)	3 (10.7%)	20 (71.4%)/8 (28.6%)	7.8±6 (5.5/10)
Chemical/physical injury	6, 5 (4/1)	55.7±15.2 (36/72)	1.5±1 (0.7 to 2.3)	1 (16.7%)	5 (83.3%)/1 (16.7%)	5.5±4.4 (2/9)
Pemphigoid	8, 7 (4/3)	69.5±12.2 (41/83)	3.9±3.3 (1.6 to 6.2)	1 (12.5%)	4 (50%)/4 (50%)	8.9±6.4 (4.4/13.3)
End-stage bullous keratopathy	3, 2 (1/1)	69.3±3.7 (65/74)	4.3±0.9 (3.3 to 5.4)	0 (0%)	2 (66.7%)/1 (33.3%)	6.3±2.4 (3.7/9)
Keratitis-induced scarring and neovascularisation	2, 2 (0/2)	66±5 (61/71)	4±1 (2.6 to 5.4)	0 (0%)	1 (50%)/1 (50%)	12±9 (-0.5/24.5)
Lyell syndrome	1, 1 (1/0)	32±0 (32/32)	5±0	0 (0%)	1 (100%)/0 (0%)	20±0
Sjögren syndrome	–	–	–	–	–	–
Steven-Johnson syndrome	2, 2 (2/0)	61±5 (56/66)	20±14 (0.6 to 39.4)	0 (0%)	1 (50%)/1 (50%)	11.5±1.5 (9.4/13.6)
Graft-versus-host disease	4, 3 (1/2)	44±10.5 (26/52)	3±1.6 (1.5 to 4.5)	1 (25%)	4 (100%)/0 (0%)	5.8±4 (1.9/9.6)
Xeroderma pigmentosum	2, 1 (1/0)	66±1 (65/67)	6±1 (4.6 to 7.4)	0 (0%)	2 (100%)/0 (0%)	2.5±0.5 (1.8/3.2)
Congenital lid coloboma	–	–	–	–	–	–

online supplemental etable 1 contains additional data for eyes covered by vaginal mucosa.
MOOKP, modified osteo-odonto-keratoprosthesis.

postoperative value. The main causes for vision loss were glaucoma (n=40), endophthalmitis (n=21), retinal detachment (n=11) and expulsion/instability/tilting of the optical cylinder (n=11).

BCVA at the last follow-up visit was 0.88±1.08 LogMAR (95% CI 0.76 to 1.00), significantly worse than postoperative BCVA at 3 months (p<0.001). The mean visual gain, defined as the difference between postoperative BCVA at the last follow-up and preoperative BCVA, was significantly higher for eyes covered by buccal mucosa (−1.69±1.02 LogMAR (95% CI −1.81 to −1.57)) compared with those covered by skin (−0.87±1.16 LogMAR (95% CI −1.30 to −0.44); p<0.001).

Complications

Detailed report of intraoperative and postoperative complications is provided in table 3. Intraoperative complications (n=28, 9.0%) mainly involved damage to bones and oral structures while harvesting the dentoalveolar block and were successfully treated with the assistance of a maxillo-facial surgeon or a dentist.

The most threatening postoperative complication was endophthalmitis (n=24 eyes, 7.7%). Only four eyes (16.7%) affected by endophthalmitis were successfully managed with conservative treatments (topical and systemic medications). In 15 cases, the lamina was removed to perform vitrectomy, 4 eyes were not treated and 1 eye required enucleation. Instability (n=6, 1.9%), tilting (n=10, 3.2%) or expulsion of the optical cylinder (n=5, 1.6%), as well as expulsion of the prosthesis (n=3, 1.0%), determined anatomical failure in all cases except in 1 eye, successfully treated by bone cement injection. Endophthalmitis and optical cylinder misalignments were always associated with lamina resorption, which was confirmed after prosthesis explant. Overall, lamina resorption was reported in 40 eyes covered by buccal mucosa (14.4%) and in 8 eyes covered by skin (28.6%) (p=0.06). Another sight-threatening complication was retinal detachment (n=20, 6.4%).

Trophic alteration of the buccal mucosa occurred in 44 eyes (14.2%). All cases were successfully managed through surgical advancement of the existing mucosal flap to cover the residual

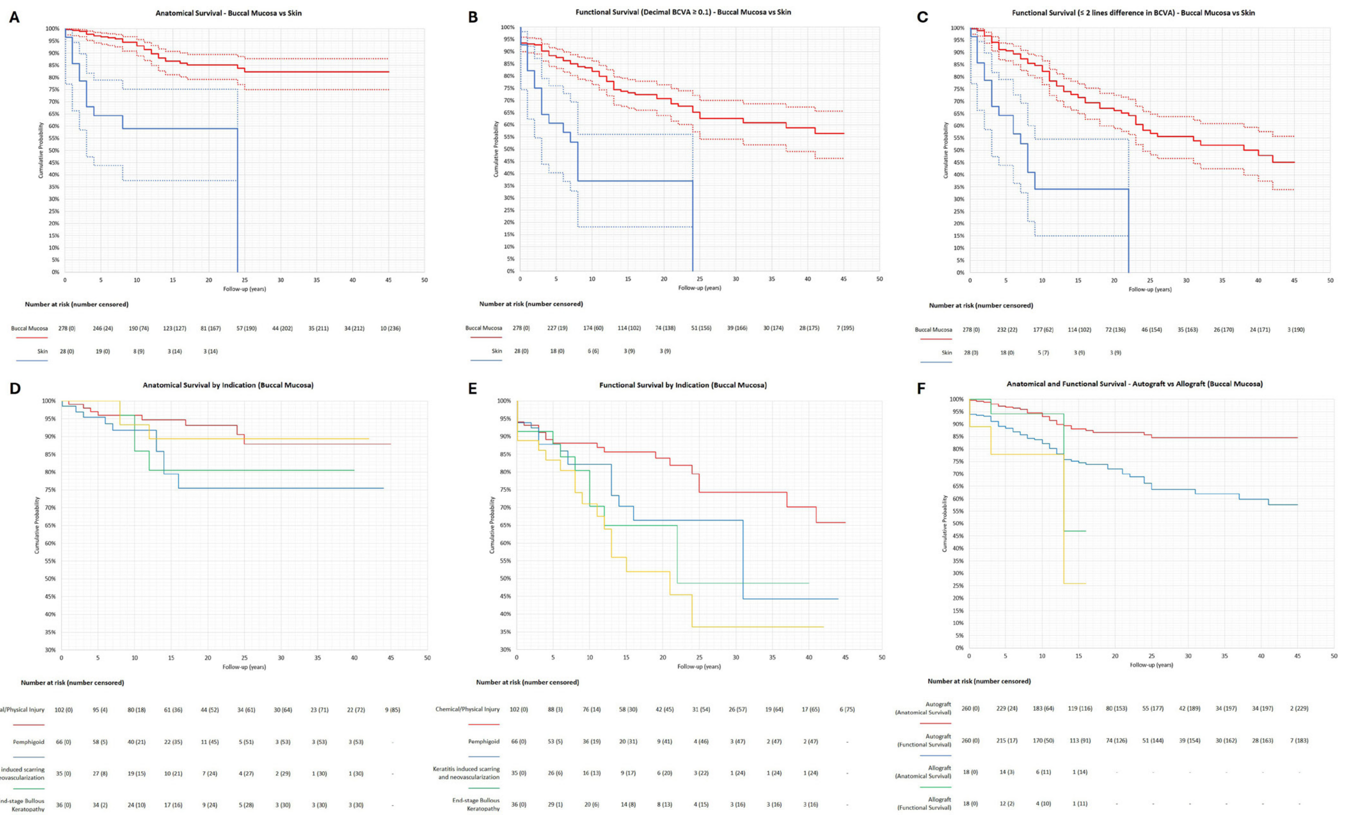

Figure 2 Kaplan-Meier analyses. (A) Anatomical survival probability, (B) functional survival probability and (C) cumulative probability of retaining a postoperative best-corrected visual acuity (BCVA) within 0.2 decimal units, for both eyes covered by buccal mucosa (red line) and by skin (blue line). The dashed lines represent 95% CIs. (D) Anatomical survival probability and (E) functional survival probability for eyes covered by buccal mucosa, according to the main indications for MOOKP (only groups with n>30 were reported). (F) Anatomical and functional survival probabilities for eyes covered by buccal mucosa, according to the tooth used for the implant (autograft vs allograft). MOOKP, modified osteo-odonto-keratoprosthesis.

mucosal defect. In case of extensive mucosal erosion leading to lamina exposure, transpalpebral skin was used to cover the lamina.

Preoperative glaucoma was present in 126 eyes (40.6%), and it was medically or surgically treated before performing surgery to obtain an IOP <21 mm Hg. After MOOKP, glaucoma worsened

Table 2 Distributions of preoperative and postoperative values of decimal best-corrected visual acuity (BCVA) divided by eye covering

	Buccal mucosa			Skin		
Decimal BCVA	Preoperative	Postoperative (3 months)	Postoperative (last FU)	Preoperative	Postoperative (3 months)	Postoperative (last FU)
NLP	–	–	12 (4.5%)	–	–	3 (11.1%)
LP	181 (65.1%)	–	29 (11%)	20 (71.4%)	1 (3.6%)	10 (37%)
HM	67 (24.1%)	8 (2.9%)	14 (5.3%)	7 (25%)	–	3 (11.1%)
0.01	2 (0.7%)	–	–	–	–	–
0.02	19 (6.8%)	5 (1.8%)	7 (2.7%)	–	–	–
0.04	4 (1.4%)	1 (0.4%)	8 (3%)	1 (3.6%)	–	–
0.06	1 (0.4%)	3 (1.1%)	5 (1.9%)	–	–	–
0.1	1 (0.4%)	12 (4.3%)	12 (4.5%)	–	2 (7.1%)	2 (7.4%)
0.2	2 (0.7%)	19 (6.8%)	20 (7.6%)	–	–	–
0.3	1 (0.4%)	7 (2.5%)	9 (3.4%)	–	1 (3.6%)	1 (3.7%)
0.4	–	9 (3.2%)	8 (3%)	–	2 (7.1%)	–
0.5	–	10 (3.6%)	10 (3.8%)	–	1 (3.6%)	–
0.6	–	7 (2.5%)	6 (2.3%)	–	2 (7.1%)	1 (3.7%)
0.7	–	17 (6.1%)	12 (4.5%)	–	–	–
0.8	–	11 (4%)	11 (4.2%)	–	–	1 (3.7%)
0.9	–	17 (6.1%)	11 (4.2%)	–	3 (10.7%)	–
1.0	–	152 (54.7%)	102 (38.6%)	–	16 (57.1%)	6 (22.2%)

online supplemental etable 2 contains additional data for eyes covered by vaginal mucosa.
FU, follow up; HM, hand movement; LP, light perception; NLP, no light perception.

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Table 3 Complications divided into intraoperative, postoperative before prosthesis implant and postoperative after prosthesis implant

Complications	Buccal mucosa	Skin	Vaginal mucosa
Number of eyes	**278**	**28**	**4**
Intraoperative	25 (9%)	1 (3.6%)	2 (50%)
Oronasal fistula (into maxillary sinus)	3 (1.1%)	–	–
Fracture of the mandible	3 (1.1%)	–	–
Damage to teeth and oral structures	7 (2.5%)	–	–
Corneal perforation	4 (1.4%)	–	–
Retinal detachment	1 (0.4%)	–	1 (25%)
Choroidal detachment	1 (0.4%)	–	–
Vitreous haemorrhages	4 (1.4%)	1 (3.6%)	–
Scleral rupture	1 (0.4%)	–	1 (25%)
Capsular rupture	1 (0.4%)	–	–
Postoperative before prosthesis implant	16 (5.8%)	–	–
Lamina resorption	2 (0.7%)	–	–
Infection of lamina	6 (2.2%)	–	–
Trophic alteration of the buccal mucosa	6 (2.2%)	–	–
Retinal detachment	1 (0.4%)	–	–
Choroidal detachment	1 (0.4%)	–	–
Postoperative after prosthesis implant (trophic alteration of eye coverage)	32 (11.5%)	2 (7.1%)	–
Postoperative after prosthesis implant (lamina resorption)	38 (13.7%)	8 (28.6%)	2 (50%)
Instability of the optical cylinder	4 (1.4%)	2 (7.1%)	–
Tilting of the optical cylinder	7 (2.5%)	2 (7.1%)	1 (25%)
Expulsion of the optical cylinder	4 (1.4%)	1 (3.6%)	–
Expulsion of the prosthesis	2 (0.7%)	1 (3.6%)	–
Endophthalmitis	21 (7.6%)	2 (7.1%)	1 (25%)
Postoperative after prosthesis implant (eye)	37 (13.3%)	4 (14.3%)	–
Retinal detachment	14 (5%)	3 (10.7%)	–
Choroidal detachment	4 (1.4%)	–	–
Vitreous haemorrhages	12 (4.3%)	1 (3.6%)	–
Retroprosthetic membrane	5 (1.8%)	–	–
Uveitis, vitreitis	2 (0.7%)	–	–

online supplemental etable 3 contains a more detailed report of complications stratified by MOOKP indication.
Values are expressed as sample size (percentage).

in 43 out of 126 eyes (34.1%), while a new onset was reported in 27 out of 184 non-glaucomatous eyes (14.7%).

DISCUSSION

Several KPro devices have been proposed to restore vision in eyes affected by corneal diseases in which conventional keratoplasty or surgical reconstruction of the ocular surface may fail or cannot be feasible. The Boston Type 1 KPro is the device of choice in eyes with normal blinking and tear secretion, while OOKP is indicated in end-stage ocular surface diseases characterised by severe dry eye and/or eyelid anomalies.[17 18]

The OOKP surgical technique was the first KPro to use a biological haptic. The MOOKP features several innovations: (1) total iris ablation; (2) lens cryoextraction; (3) anterior open-sky vitrectomy; (4) increased diameter of the optical cylinder; (5) dioptric power of the cylinder assessed by biometry; (6) lamellar keratectomy including Bowman membrane; (7) use of thicker cheek mucosa; (8) joining of two osteo-dental laminae; (9) use of teeth from blood relatives and (10) use of biological glue to reattach the periosteum.[19]

In this study, the long-term outcomes of 310 eyes that underwent MOOKP between 1973 and 2019 were examined. Kaplan-Meier analyses for eyes covered by buccal mucosa showed anatomical and functional survival rates higher than 80% and 55% at 45 years, respectively. At 3 months, decimal BCVA was 1.0 in more than half of the eyes. Postoperative BCVA ≥0.1 remained unchanged in almost two-thirds of the eyes for the entire duration of the follow-up.

In a recent paper, Ortiz-Morales *et al* reviewed the outcomes of 958 patients across 37 published case series.[20] The authors reported a mean anatomical success rate of 88.25% over a maximum follow-up of 30 years (median 3 years), with 78% of patients achieving a visual acuity ≥20/400. These positive results are aligned with those reported in our study, as we achieved an anatomical survival rate of 82.2% for eyes covered by buccal mucosa at 30 years, with 74.1% of eyes having a visual acuity ≥20/400 at the last visit.[20]

We reported significantly lower anatomical and functional survival rates for eyes covered by skin. This finding confirms the remarkable role of the buccal mucosa overlay, which is placed in contact with its alveolar bone and dentine, resembling the anatomical structure of the tooth neck inside the oral cavity.

As previously reported in literature for OOKP and other KPros, glaucoma was the most common complication.[6 15 21–23] It is thought to be favoured by the underlying conditions that cause corneal blindness, specifically the anatomical subversion of the iridocorneal angle, trabecular meshwork and episcleral venous system.[21]

Endophthalmitis was the most concerning postoperative complication. All patients must be treated with broad-spectrum systemic and topical antibiotics. Prosthesis explant, followed by vitrectomy, is usually required. Infected mucosa should be removed, and the eye must be closed with a corneal graft, covered by residual peripheral mucous membrane.[24]

Lamina resorption was confirmed in at least 14% of eyes covered by buccal mucosa, and 25% of eyes covered by skin. Similar rates have been shown in previous studies (Iyer *et al*, 23% (n=85),[25] Liu *et al* 19% (n=36)[26]; however, Avadhanam *et al* highlighted that the true incidence of this complication may be severely underestimated, as several authors have reported resorption only when leading to major complications.[27] Iyer *et al* proposed a grading system for laminar resorption, along with suggested management for each grade.[28] This classification ranges from early radiological signs without clinical findings (grades 1–2), to progressive stages with signs such as aqueous leakage or optical cylinder extrusion (grades 3–4), up to severe cases with endophthalmitis/panophthalmitis (grade 5).[28] Up to grade 3, it is possible to repair the lamina using bone morphogenetic protein and bone grafting. More advanced cases require lamina explant and repeat keratoprosthesis.[28]

Although mucosal complications other than trophic alterations can occur after MOOKP, including mucous membrane overgrowth, cyst formation, haematoma and dryness, no cases were found in our study.[29 30]

A limitation of the OOKP procedure consists in the need to harvest a healthy monoradicular tooth, precluding surgery for edentulous patients, even if it is possible to find a suitable donor.

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Osteo-keratoprosthesis (OKP) is a different biological KPro, designed by Temprano *et al*, which employs a cortical tibial bone lamina as haptic.[31] Angerer *et al* recently compared 78 eyes that underwent OOKP and 52 treated with OKP (maximum follow-up 25 years). OOKP had a better anatomic survival rate than OKP in the first 12 years after surgery.[32]

Although our study evaluates the outcomes of patients who underwent OOKP surgery with the longest follow-up ever reported, some limitations related to the retrospective nature and the long period of analysis should be mentioned, such as changes in surgical indications and technical refinements of surgery.

In conclusion, the MOOKP showed high anatomical and functional survival probabilities at 45 years (about 80% and 55%, respectively). Visual acuity significantly improved as soon as 3 months postoperatively and remained unchanged in about 65% of patients throughout the entire follow-up. These excellent results are possible thanks to the unique features of the osteo-dental haptic, which provides biological functions of immunological defence, repair and proliferation.

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