7th KPro Study Group meeting

Portoroz, Slovenia

Saturday October 3, 2009

EVER 2009

KPro's Today:
Corneal blindness defeated in adults;
Good results in Children

Organization:	GC Falcinelli, JM Parel and D Sweeney
Honorary Presidents:	E Alfonso, J Barraquer, C Dohlman
Meeting Presidents:	J Aquavella, G Grabner
Scientific Committee:	P Colliardo, B Duchense, G Falcinelli, M Fukuda, G Iyer, K Hille, V Perez, S Rao, J Stoiber, D Sweeney, M Taloni, A Temprano

EVER
European Association for Vision and Eye Research

Session 1
Chairman: C Dohlman
Moderator: K Hille and P Colliardo

8.15 Welcome
G Grabner
8.20 Meeting rationale
GC Falcinelli
8.25 History and the necessity for the KPro
C Liu

KPro Design, Surgical Techniques and Complications

8.35 The first Keratoprosthesis implantation in 1955
FM De la Paz, J Barraquer
8.45 Boston Keratoprosthesis Type 1 and 2
C Dohlman
8.55 Boston Type 1 in pediatric patients
J Aquavella
9.05 Modified OOKP
GC Falcinelli, P Colliardo
9.15 Barcelona OOKP and Tibial KPro
J Temprano
9.25 AlphaCor,Pintucci and Supradescemetic KPros
K Hille, J Stoiber
9.35 Discussion

Session 2
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Moderator: CG Falcinelli and J Aquavella

Clinical Results and Indications

11.00 How should we quantify the performance of KPro´s?
The Visual Acuity by Time –Index (VATI)
G Grabner
11.10 The Boston Type 1 and 2. The Autoimmune Challenge
J Chodosh
11.22 Boston I Keratoprosthesis in severe ocular surface disease
J Aquavella
11.32 Long-term functional and anatomical results of OOKP and tibial OKP. Barcelona experience
FM De la Paz ,J Barraquer
11.42 Tibial KPro
J Temprano
11.50 MOOKP
G Falcinelli, P Colliardo
12.00 AlphaCor, Pintucci, Supradescemetic
G Prosdocimo
12.10 Clinical decision paths in KPro Surgery
G Grabner
12.20 Discussion

Session 3
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13.45 How do get started with offering clinical service
M Fukuda
13.55 Inflammatory responses to KPro: can we control them?
VS Perez
14.05 The Indian Experience with MOOKP
G Iyer
14.15 Retinal detachment in MOOKP
P Colliardo, G Falcinelli
14.25 Dealing with Complications with MOOKP: Oculoplastic
A Gomaa
14.35 Glaucoma treathment in MOOKP
M Taloni, G Falcinelli
14.45 Tibial Bone KPro Technique and Longterm Results
A Temprano
14.55 Discussion

Session 4
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Moderator: M Fukuda and M Taloni

17.45 The Collagen Corneal Construct – an update
P Fagerholm
17.55 Eastern European and Russian devices
Z Zagorski
18.05 Glaucoma associated with KPros
K Hille
18.15 Improving the optics of KPros
C Hull (presented by C Liu)
18.25 The role of contact lenses in KPros
J Ciolino
18.35 Does imaging help with preventing extrusion?
A Gomaa
18.45 The clinical psychologist's role-a one year look back
A Busutti
18.55 Discussion
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Joint Meeting: KPro 1 session: design surgical techniques and complications

▪ 4121
History of and necessity for KPros

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(1) Sussex Eye Hospital, Brighton
(2) Tongdean Eye Clinic, Hove

The history of keratoprostheses goes back over 200 years. There was a resurgence in interest in the second half of the twentieth century as it was recognised that keratoplasty could not solve all types of corneal blindness. Many devices have been described but few have survived. Corneal transplantation is complicated by graft rejection and astigmatism. There is also a problem with adequate supply, and there is a risk of transmission of infection. There is a desire for an artificial cornea which surpasses cadaveric transplantation. There is much ongoing work, but the majority of clinical work on keratoprostheses are for corneal blindness not amenable to cadaveric grafts. These can be separated into two main groups. The wet blinking eye which have had multiple graft failures, and the dry eye with a keratinised ocular surface which may also have a deficiency in lid cover. The approaches to these are quite different.

▪ 4122
The first keratoprosthesis implantation 1n 1955

DE LA PAZ MF, BARRAQUER J
Centro de Oftalmología Barraquer, Barcelona

Purpose to describe the Barcelona experience with the different types of keratoprosthesis for end-stage cicatricial corneal disease.

Methods We present 6 cases showing various types of keratoprosthesis which we have used at the Barraquer Eye Center from the 1950´s up to the present.

Results We describe the first keratoprosthesis ever implanted in Spain, on a case of severe chemical burn on a young lady. We implanted a Dorzee acrylic keratoprosthesis in 1955. 5 years later she had extrusion of the prosthesis and superior retinal detachment. The second case describes the Dorzee-Barraquer-Cardona acrylic implant implanted in 1958 on a patient with end-stage glaucoma. Patient had good anatomical retention until his death in 1970. The third case describes the use of the Cardona keratoprosthesis in 1960. Patient had good anatomical and functional results for 8 years until suffering from an acute endophthalmitis. The fourth case demonstrates the expulsion of a Teflon-supported keratoprosthesis designed by Girard. The fifth case describes the first implantation of an osteo-odontokeratoprosthesis designed by Strampelli on a blast injury showing good results for 10 years. The last case shows our experience on the Boston keratoprosthesis which we started using in 2006. Finally, we present our technique of the osteo-odontokeratoprosthesis and a summary of our clinical results from 1970´s to the present.

Conclusion Our clinical experience for more than 50 years on the use of keratoprosthesis shows that while the surgical technique, design and post-operative treatment of both biological and non-biological keratoprosthesis have improved thru the years, the anatomical and functional success remains a challenge for the KPro surgeon.

▪ 4123
Boston keratoprosthesis

DOHLMAN CH
Cornea, Boston

Purpose To outline the present designs, recent outcomes and acceptance of the Boston devices. In addition, several areas of new developments will be briefly discussed.

Methods The Boston KPros implanted in Boston from 1990 to present provide the clinical basis for recent studies on materials, optics, drug delivery, intraocular pressure transducers, complications such as infections and retinal detachment, cost-effectiveness, outcome in the developing world, etc. The details are presented in accompanying posters.

Results More than 3000 Boston Keratoprostheses have so far been implanted worldwide. Recent outcome studies that have been published from centers outside Boston are particularly suitable for meta-analysis. For outcome of recent research in Boston, see posters.

Conclusion The Boston Keratoprostheses have shown clinical value but there is still a substantial gap to fill before having arrived at a simple, safe and inexpensive keratoprosthesis procedure for all corneal blindness, in all parts of the world.

▪ 4124
Boston type I in pediatric patients

AQUAVELLA J, CHAK G
Rochester

Purpose To present a retrospective review of keratoprosthetic implantation and retention in patients with congenital corneal opacities.

Methods Pediatric patients younger than seven years old, the average age of permanent visual loss from understimulation of the visual cortex, were selected from a single center Boston Type I keratoprosthesis database and categorized by 1) primary diagnosis, 2) short-term visual outcome, and 3) post-operative complications.

Results Seventeen patients, with an age range of 41 days up to 6 years, were selected from a database of over one hundred and forty patients. Six had a primary diagnosis of sclerocornea and eleven had Peter's anomaly. Visual outcome after one year improved in fourteen of the patients, with patients who previously could not detect light to subsequently being able to fixate and follow or even read allen cards. The remaining three patients showed no improvement in visual acuity but also no worsening from their baseline condition. In terms of post-operative complications of the optic, two had retroprosthetic membrane formation, and another patient required replacement of the keratoprosthesis due to phthisis and optic melting. From a retinal standpoint, four patients had retinal detachments. There were no cases of choroidal hemorrhaging or hypotony in these patients.

Conclusion Based on visual outcome, the Boston Type I keratoprosthesis is a safe and effective procedure for patients with congenital corneal opacities. With great retention, the artificial cornea is a viable option for prevention of amblyopia. Due to comorbidities such as congenital cataracts, congenital glaucoma, and retinal detachments, it is crucial to have glaucoma and vitreo-retinal surgeons on hand when managing and implanting keratoprosthesis in a pediatric population.

▪ 4125
Design, surgical technique and complications MOOKP

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(1) Osteo-Odonto-Keratoprosthesis Foundation, Rome
(2) PIO XI Clinic, Rome
(3) U.O.C. Oculistica Azienda Ospedaliera San Camillo-Forlanini, Rome

Purpose To describe design, surgical technique of the modified osteo-odonto-keratoprosthesis (MOOKP),originated from Strampelli's OOKP, with the modifications and the innovations made by Falcinelli, between these thoseones of the last years to the first stage of the procedure, never published.

Methods First stage:abstraction of the mono-rooted tooth with surrounding root and bone. Preparation of the lamina to which, in the dentine central part,the PMMA optic cylinder is glued.Burying of the lamina for 3 months (subcutaneoos pocket). New modification:opening of the A.C., complete removal of the iris, lens cryo-extraction,anterior vitrectomy.Intermediate stage: after 1 month covering of the eye surface by buccal mucosa. Final stage: after3 months implant of the lamina on the eye with insertion in A.C. of the cylinder after corneal trephining,covering with buccal mucosa previously detached.

Results MOOKP COMPLICATIONS-

1. Intraoperative, easy to be cured.
2. After the 1st stage and intermediate stage: all easily treatable.
3. After the prosthesis implant, more severe:
    a. Prosthesis complications which affect mainly the mucosa, easy to be cured, or the lamina and the cylinder, more rare, difficult to be cured.
    b. Eye complications: retinal detachment, not frequent and easily cured. Retroprosthetic membranes, very rare. Endophthalmites, very difficult to treat, fortunately rare.

Conclusion Biological properties Strampelli's osteo-odonto lamina (OOL)with Falcinelli's surgical modifications make of MOOKP a KPro with best results, teorically without duration limits in the less and in the very severe cases of corneal and anterior oculare surfice alterations like the last stage of dray eye.

▪ 4126
Barcelona OOKP and tibial KPro

TEMPRANO J
Barcelona

We are using the second technique of the Strampelli OOKP since 1971.Preferably we use a tooth from the superior mandible to prepare the haptic part of the keratoprosthesis. The optic cylinder of 9 mm length, 0.4 mm diameter in the wider part and 3.5 mm in the narrow part is introduced into the prosthesis through the central opening previously prepared for this.

In 1988, trying to find a solution for patients without teeth, we decided to use another heterologous autotransplant, from the tibia. We obtained from the upper part of the medial area of the tibia a disk, 10 mm in diameter and 3 mm thick, and we performed in the center of the same an opening through which we introduced the optic cylinder similar to the one used in OOKP and fixed it to the bone.

The technique is similar for both techniques of keratoprosthesis, excepting the shaping of the support.

The first stage consists in cleaning the anterior portion of the eye, up to the muscle insertions and performing a superficial keratectomy to eliminate the epithelium. Subsequently we obtain from the lower lip of the same patient an oval fragment with a surface of 3 x 2 cm and total thickness including mucous and submucous tissue. This is sutured to the muscle insertations to cover the entire anterior pole of the eye. It is expected to revitalize the surface and will serve later to cover the keratoprosthesis.

The second stage consists in preparing the keratoprosthesis and once it has been completed it is introduced into a palpebral pocket in the inferior lid, so the prothesis will be covered by soft newly formed tissue which will later facilitate facilitate fixation with sutures. The prosthesis is left "in situ" for three months to make sure that it develops neither infection nor immune reaction.

The third stage is performed after three months. The mucosa is separated all over the cornea and an opening of 4.5 mm is performed in the center of the cornea. Previously the prosthesis has been taken out of the palpebral pocket, the wider portion of the optic cylinder is introduced in the anterior chamber, leaving the haptic part on the cornea anteriorly, which means we have a mesoprosthesis, which is then sutured to the eye and covered with the buccal mucosa.

Complications: During the first three months necrosis of the mucosa may develop, which means that a new mucosal graft must be applied or the third stage must be carried out as a transpalpebral procedure. Infection or resorption of the bone support of the prosthesis may also occur, in which case a new prosthesis must be constructed.

Late complications may include by order of frequency: Glaucoma, vitritis, retinal detachment, incipient extrusion of the prosthesis with intraocular infection and, finally, endophthalmitis with total expulsion of the prosthesis and phthisis bulbi.

▪ 4127
AlphaCor, Pintucci, Supradescemetic

STOIBER J (1), HILLE K
(1) Miami

Classically keratoprostheses are made from rigid materials such as PMMA. However, as the cornea is flexible, the materials for keratoprostheses should also be flexible.

Several different kinds of Keratoprostheses are available with a flexible haptic material, with the Pintucci keratoprosthesis being the most common. The haptic is made from Dacron felt that is well integrated into the rim of a PMMA cylinder, covered by buccal mucous on the corneal surface. As the Dacron may perforate through the mucous, palatine mucous coverage is recommended. Personal experience shows that the survival of the prosthesis is better if the Dacron is first covered by a donor cornea and then by mucous membrane. Nevertheless the risk of leakage will be higher than with an OOKP. The other complications are similar to those seen with an OOKP.

The AlpaCor KPro is FDA approved and is very close to a truly "artificial" cornea. It is a disc-prosthesis made from Poly(2-Hydroxyethyl Methacrylate(PHEMA)) and is implanted into a corneal pocket. The centre of the inner and outer lamella of the cornea has to be trephined, and therefore the level of the optic is lower than the cornel surface. In order to achieve a regular surface and a good retinal image, a contact lens has to be worn. A second limitation is that this implant is not suitable for patients with a dry eye or a herpetic history. Melting of the corneal stroma and staining in smokers have been reported.

To find a real substitution for a defective cornea, the idea of a flexible supradescemetic implant was promoted by several investigators. In theory, it reduces the extrusion pressure from the implant and facilitates a normal corneal surface. In addition, IOP measurement by applanation would be possible. Nevertheless this idea could not be implemented in therapy until now.

4221
How should we quantify the performance of KPro's? The Visual Acuity by Time –Index (VATI)

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Purpose To report a method of standardized data collection and reporting and statistical assessment that can be used for all KPro´s available on the market.
The database (will be presented) should be

- Usable for different types of KPro´s
- Easily adaptable to changes in technique
- Allow for complete entry of relevant data

Methods Visual Acuity data should be reported in different international surgical centres in a standardized manner: Best spectacle corrected VA, unless BCVA only possible with CL (> useful time of wear).A complete entry of all relevant data is possible in this database. The statistical analysis should be agreed upon by all centres.For Survival Time = Retention of KPro > the Kaplan-Meier methodFor Visual Acuity over the Course of Time > the Monte-Carlo method

Results A database will be demonstrated that can be used free of charge by all KPro centres interested. The VISUAL ACUITY BY TIME- INDEX (VAT- Index) will also be presented, whose theoretical basis published in: Journal of Theoretical Medicine, 2002 / 4, 183-190, W. Hitzl and G. Grabner „Application of the Monte Carlo Method for the Assessment of Long-term Success in Keratoprosthesis Surgery". Example of its use will be give, based in data, courtesy Barraquer Eye Clinic, Barcelona.

Conclusion With the Kaplan-Meier method:

+ analysis is done quickly, uses all data available, hypotheses tests are available for comparisons and mean and median survival time can be computed
- no information about relation between time and best corrected visual acuity and the definition of terminal event is arbitrary to a certain extent.

Monte-Carlo method (VAT-index):

+ Method is based on a so-called non-parametric longitudinal model
+ Reliabel estimation of relation between time and best corrected visual acuity at any given time point (patient as well as surgeon is basically interested in this relation).
+ statistically valid analysis and better comparison of different KPro techniques
+ easy comparison of defined postoperative periods
+ comparison of different initial clinical findings and diseases possible
+ long-time follow-up of BCVA
- shorter follow-up time as compared with Kaplan-Meier method (e.g. with strict „80% data complete" criteria)

4222
The Boston keratoprosthesis in autoimmune disease

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Massachusetts Eye and Ear Infirmary, Boston

Purpose Patients with corneal blindness due to mucous membrane pemphigoid and Stevens Johnson syndrome who undergo corneal transplantation carry a poor prognosis for visual recovery. The Boston keratoprosthesis has been demonstrated to provide excellent retention rates and postoperative visual acuity in patients with corneal graft failure, however, poor visual outcomes still occur in patients with underlying autoimmune disease.

Methods We reviewed the current literature to determine the results of keratoprosthesis in patients with blinding autoimmune diseases.

Results Much of the published literature on keratoprosthesis fails to clearly differentiate outcomes on the basis of the underlying disorder. Based on available evidence, inflammation, retinal detachment, and glaucoma appear to be the most significant complications after keratoprosthesis in autoimmune patients, and a diagnosis of mucous membrane pemphigoid or Stevens Johnson Syndrome appears to be associated with a significantly higher complication rate than other preoperative conditions.

Conclusion Patients with autoimmune diseases carry the worst prognosis for success with keratoprosthesis. Improvement in clinical outcomes might be achieved with changes in keratoprosthesis design and material, perioperative therapy, and/or surgical technique. Possible approaches to complications after Boston keratoprosthesis in patients with underlying autoimmune diseases will be discussed.

4223
Boston keratoprosthesis in pediatric patients

AQUAVELLA J

ABSTRACT NOT PROVIDED

4224
Long-term functional and anatomical results of OOKP and tibial OKP: Barcelona experience

DE LA PAZ MF, BARRAQUER J
Barcelona

Purpose To report the long-term functional and anatomical results of OOKP and Tibial OKP performed at the Barraquer Eye Center from 1974-2006. Different factors like surgical technique, clinical diagnosis, age and post-operative complications are also analyzed and reported.

Methods A retrospective study on 330 eyes of 227 patients who underwent OOKP or tibia OKP was performed. Kaplan Meier survival curves and multivariate analysis using Cox regression model of the different variables mentioned are presented.

Results OOKP and Tibia OKP have comparable functional and anatomical results in the long-term. Best long-term functional and anatomical results are for patients with chemical burns, cicatricial trachoma and Stevens-Johnsons/Lyell syndrome. Thermal burns have a higher anatomical retention than other diagnostic categories. Younger patients have better visual prognosis and anatomical retention than older patients. Patients must be warned of the possibility of sight-threatening complications like extrusion of the prosthesis, retinal detachment and glaucoma.

Conclusion Our more than 35 years experience with biological keratoprosthesis using the OOKP and the tibia OKP shows that the two techniques are comparable. Certain variables like clinical diagnosis, age and post-operative complications affect the anatomical and functional results in the long-term.

Joint Meeting: KPro 2 session: Clinical results and indications

▪ 4225
Tibial KPro

TEMPRANO J
Barcelona

The clinical results, from the anatomical point of view, are very good, although in the cases of mucosynechial syndromes, which also affect the buccal mucosa, pemphigoids or necrolysing epidermosis (Lyell), the mucosa may retract or necrolyse. In these cases we use the transtarsal method.In elderly patients with osteoporosis the bone may be resorbed and it would be necessary to repeat the procedure using bone from a more favorable area of the tibia, which should be determined with local densitometry.As far as the functional results are concerned, these depend on the conditions of the retina and the optic nerve. If both are in good conditions and the ocular pressure is normal, 20/20 vision may be achieved, although the visual field will never be more then 30° maximum. Indications: We perform this type of keratoprosthesis in patients without suitable teeth, affected with:Physical caustications (metal burns, bomb explosions, fire burns, etc.)Chemical caustications, no matter whether the origin be alkali (worse prognosis because of the glaucoma which usually develops in these cases) or acids (lime, sulphuric acid, sodium hydroxide, etc).Important trauma where the eye had to be covered with skin because of extensive lid destruction.Advanced trachoma with total leucoma and extensive vascularization.Pemphigus and all mucosynechial syndromes which lead to total xerosisLyell's syndrome, epidermizing necrolysisCases of repeated failure of corneal transplantationsAnterior segment alterations due to complicated aphakia, bullous keratopathy affecting the entire cornea after previous failure of keratoplasty. Generally, total leucoma with important alterations of the limbus which would not permit survival of a corneal homotransplant.

▪ 4226
MOOKP clinical results and Indications

FALCINELLI G
Ophthalmology, Rome

Purpose To demonstrate which are the reasons that permit by the modified osteo-odonto-keratoprosthesis (Mookp) technique to obtain in 275 blind eyes,with a basic pathology where 42% of eyes were dry,and 32% had severe physical/chemical burns,excellent anatomical and functional results.

Methods Tables are shown which put into evidence the best visual acuity obtained in the 275 eyes affected by corneal blindness,operated by the Mookp technique from 1973 to 2008, with a 36 years causistry,with a very long follow-up.

Results 275 blind eyes. Best Visual Acuity recovered, between 10/10 and 5/10 in 80.25% of operated eyes, excellent for any working activity,(best visual acuity recovered), between 10/10 and 2/10 in 91,20%, useful for any activity.Final V.A., between 10/10 and 5/10 in 67,68%, and between 10/10 and 2/10 in 78,11%-

Conclusion The reasons for these excellent results are due to the biological properties of this Kpro invented by Strampelli and to the modifications made by Falcinelli. The indications for this technique are all those types of corneal blindness not treatable by penetrating keratoplasty.

▪ 4227
AlphaCor, Pintucci, Supradescemetic

PROSDOCIMO G
Conegliano Hospital - Ophth. Department, Conegliano

Purpose To report the long term results of a supradescemetic corneal implant to restore vision

Methods A Keralia "soft" keratoprosthesis was implanted in one eye of a seventy years old woman bilaterally blind and affected by a bilateral limbal stem cells deficiency.

Results After four years the implant is still insite, well tolerated.Thi initial visual recovery has been compromized , during the last year, by a progressive opacification of the superficial layer of the device.

Conclusion The Keralia supradescemtic implant seems well tolerated in the long term by the human eye.Problems related to the stability of the material should be solved in future.

▪ 4228
Clinical decision paths in KPro Surgery

GRABNER G, STOIBER J, HITZL W
Salzburg

Purpose To analyse the currently available methods for treating very severe anterior segment disease, such as stem cell transplantation with amniotic membrane transplantation, lamellar and penetrating keratoplasty techniques, and the different Kpro´s currently available, in regard to the initial clinical findings, the potential complications encountered and the surgical requirements needed for the different techniques.Factors considered are: uni- or bilaterality, limbal stem cell status, dry eye status and availability of healthy teeth.

Methods A systematic analysis of surgical options available for different stages of a variety of anterior segment diseases and currently published results of VA and complications

Results With a systematic approach it becomes clear that some popular reconstructive surgical techniques should be avoided in cases where a very low chance of success is to be expected (e.g. amniotic membrane and stem cell transplantation and /or PKP in very dry eyes –> these would have to be treated with OOKP).

Conclusion Following a simple the clinical decision path the anterior segment surgeon will be presented with standardized guidelines for treating those patients where conventional surgical procedures have to be avoided and replaced by rather rarely performed KPro techniques.

▪ 4322
How do we get started with offering MOOKP clinical service?

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(2) Department of Dental Surgery, Kinki University School of Medicine, Osaka
(3) Sussex Eye Hospital, Brighton

Modified osteo-odonto keratoprosthesis (MOOKP) is complicated two step surgery. Firstly, we must understand why it is effective for visual recovery of end-stage ocular surface diseases like Stevens- Johnson syndrome. MOOKP have a lot of advantages compared to other K-pros, for example the using auto tissue of canine tooth root and buccal mucous membrane, the tight adhesions between optical cylinder and canine tooth root, the adhesion between MOOKP lamina and sclera or cornea, the strong ocular surface by auto buccal mucous membrane, no inflammation on the back of optical cylinder and so on. However, the precise surgical techniques and proper instructions are necessary to succeed the very first case in newly set surgical center. In Japan, we successfully set up the MOOKP center and did perform 4 cases of MOOKP since 2003. We share our experience about it and point out our modification adjustable for Japanese patients.

▪ 4324
Inflammatory responses to KPro: can we control them?

PEREZ VS
Miami

ABSTRACT NOT PROVIDED

▪ 4325
Retinal detachment in Falcinelli's modified osteoodontokeratoprosthesis

COLLIARDO P (1, 2), FALCINELLI G (1, 2)
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(2) Osteoodontokeratoprosthesis Foundation, Rome

Purpose Aim is to evaluate the incidence, surgical treatment and outcomes of retinal detachment in eyes that had undergone Falcinelli's modified osteoodontokeratoprosthesis (MOOKP).

Methods Technological and surgical advancements allow to treat successfully a severe pathology as retinal detachment, even in eyes with keratoprosthesis (KPro). The autors accurately describe the surgical technique which usually uses an Eckardt or Landers temporary KPro, a pars plana vitrectomy and a gas or silicone oil tamponade, even if in selected cases it is possible to perform just a scleral buckling.

Results By the means of the described techniques good anatomical success and improvement in visual acuity have been obtained. Nine retinal detachments were successfully operated, one retinal detachment was unsuccessfully operated, four retinal detachments were judged to be inoperable for severe proliferative vitreoretinopathy because of late turning-up to clinical examination and lack of technology in the 70's.

Conclusion The autors point out that an accurate MOOKP procedure it is necessary for preventing the retinal detachment. An early diagnosis by echography performed at every clinical examination during the follow-up in patients with MOOKP and an appropriate surgical planning for each case are fundamental for a better anatomo-functional outcome.

▪ 4326
Tibial Bone KPro technique and long term results

TEMPRANO J
Barcelona

The operation is performed in three stages. The first stage consists in preparing the eye to receive and maintain the keratoprosthesis. For this purpose the anterior surface of the eye is cleaned and regularized, eliminating fibrous tissue and the entire epithelium. Subsequently we obtain a 2 x 3 cm graft of buccal mucosa from the inferior lip comprising the entire mucosal and submucosal thickness. The graft is sutured to cover the anterior pole of the eye to promote revitalization. The second stage consists in preparing the keratoprosthesis. A 10 mm disk of tibial bone from the superior part of the medial face of the tibia is obtained using a crown drill. The posterior part of the piece of bone obtained is then cut with a chisel to obtain a thickness of 3 mm. Subsequently the obtained disk of bone is cleaned and a central opening of 3.5 mm is performed to introduce in this opening a PMMA optic cylinder, 9 mm in length, 3.5 mm in diameter in its narrow portion, 4 mm in the wider portion. Fixation is achieved with cyanoacrylate. This is left to dry and then it is introduced into a palpebral pocket of the inferior lid of the patient. The pocket is closed with sutures and the piece is left in place for three months. For the third stage we remove the keratoprosthesis device from the palpebral pocket and if it is found to be in perfect conditions we dissect the buccal mucous membrane which is covering the cornea and perform a central window with a 4.5 mm trephine to remove the transparent or cataractous lens and perform a total iridectomy. The posterior portion of the optic cylinder is introduced into the anterior chamber. The prosthesis is sutured to the anterior pole of the eye with non-absorbible sutures. Finally the buccal mucosa is replaced, covering the entire area. One point of blepharorraphy is applied. Long term results. We started to use this technique in 1988 and after 21 years of experience we have 80% of anatomically perfect results. In 20 % of the cases the prosthesis extruded due to total or partial resorption of the bone. It has to be emphasized that these were cases without any other possibility of treatment. We did 143 cases during these years. The longest follow-up of a prosthesis "in situ" is 19 years. The earliest extrusion was after one year. The complications are the same as for OOKP (glaucoma, retinal detachment, vitritis, extrusion) The functional results depend on the conditions of the retina and the optic nerve. There were many cases with 20/20 vision. The mean value of retention of the prosthesis is 15 years.

■ **4327**

Management of oculoplastic problems in the OOKP eye

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OOKP surgery (either stage 1 or 2) can result in complex oculoplastic complications. The majority of these are mucous membrane graft-related, including graft thinning, ulceration and infection or overgrowth onto the anterior optical cylinder. However, lid malposition, forniceal shortening and widening of the palpebral aperture may also occur.Appropriate timely surgical intervention of these is crucial to protect the underlying OOKP lamina. In addition, correcting over-exposure of the globe aids in improved comfort for the patient. Adjustments of the lid and forniceal abnormalities can enhance comfort, cosmesis and prosthetic shell stability.Retrospective case note analysis of all patients treated 1996 – 2009 at the Sussex Eye Hospital, Brighton, UK, was performed. This study reports the prevalence and type of oculoplastic complications found and describes the surgical management for each.

4421
Biosynthetic corneas – evaluation in humans

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Collagen-based biosynthetic corneas, designed to mimic the extracellular matrix of the corneal stroma have been developed and extensively evaluated in animal models over the last 7 years. Human recombinant collagen type III (RHC III) was crosslinked with water-soluble carbodiimides and fabricated into optically transparent corneal substitutes for transplantation. Following study approval of the Medical Product Agency, Sweden and the Human Ethics Committee, University of Linköping, Sweden, a Phase I study was initiated. 10 patients who were scheduled for corneal grafting were enrolled into the study. Nine had keratoconus and one had a deep scar following Pseudomonas keratitis. A central 6 mm diameter deep lamellar button was excised and was replaced by a 6.25 mm diameter 500 µm thick construct. Six overlying sutures were used to anchor the graft. Topical 0.1% dexametasone and chloramphenicol was used for the first 1 month postoperatively. The sutures were removed after 5-7 weeks.The patients were followed clinically and evaluated for UCVA, BSCVA and VA with contact lenses. Corneal touch sensitivity (Cochet-Bonnet) and tear production (Schirmer) were tested. Photography, OCT (Visante), topography (Orbscan II) and in vivo confocal microscopy (Heidelberg) was documented. After 3 months all patients had stably epithelialized and implants were anchored by recipient keratocyte ingrowth. The mean BSCVA at 6 months (20/133) improved slightly at 12 months (20/90). The mean BCLCVA was 20/50 at 12 months and was notably better in younger patients (mean of 20/40 in the 5 youngest). One patient had BCLVA of 20/20 at 12 months.The mean central corneal thickness was stable between 3 and 12 months at about 400µm.The mean 5min Schirmer values were 20 ± 10mm in operated eyes and 17 ± 8 mm in fellow eyes. At 12 months the mean touch sensitivity was 25mm in operated eyes and 60mm in fellow eyes, which was the same as in penetrating grafts. In-vivo confocal microscopy revealed the ingrowth of corneal nerves at the subbasal epithelium.We have shown for the first time that bioengineered collagen-based corneal substitutes are fully compatible and promote regeneration of corneal cells. The 18 months follow-up results will be presented aswell.

4422
Keratoprosthesis surgery: Eastern European and Russian devices

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Purpose To present the development and current status of keratoprosthesis surgery in Eastern Europe.

Methods Collection of data from coauthors and other surgeons involved in k-pro surgery.

Results Large numbers of surgeries were performed in Filatov's Institute in Odessa (Ukraine), where over 1000 different types of devices developed by Puchkovskaya, Yakimienko and Golubenko were imlanted since 1966. The last model, s.c. "universal separable device" was implanted in over 750 with the best results (extrusion occured in about 2.5% cases). K-pro devices in Russia were mostly developed by S. FyodorovZ. Moroz, V. Zuyev, M. Krasnov, V. Volkov, R. Gundorova, N. Ushakov and V. Bedilo. Over 1500 surgeries sine 1969 resulted in the visual aquity improvement in 94% of cases. Haptics were made of titanium, stainless steel and also biocompatible materials (xenopericardium). In Poland about 100 surgeries were performed using mostly Russian and Ukrainian devices. The results were less favorable than in countries of origin. Small numbers were also implanted in other East European states.

Conclusion In former Soviet Union keratoprosthesis surgery was well developed in selected centers (Moscow, Odessa). Surgeons in these places have gained extraordinary experience performing hundredes of surgeries. The results presented by the authors were excellent, however they were less favorable in the hands of surgeons from other countries.

4423
Glaucoma associated with KPros

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Purpose Glaucoma is one of the most serious problems in Keratoprostheses. Already glaucoma is very frequent in patients with severe changes of the ocular surface requiring keratoprosthesis surgery. About 50% of those patients have pre-existing secondary glaucoma. Preoperatively all efforts should be done to detect its presence very early on. In KPro detection of glaucoma with traditional aids is difficult. 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 and examination of the visual field should be considered.

Methods The incidence of postoperative secondary glaucoma vary among the different kinds of prostheses according to the surgery affecting the anterior segment and the long term anatomic results. In Osteo-Odonto-Keratoprostheses (OOKP) the most vision threatening complication is a primary or secondary glaucoma, due to the extended interventions required in the anterior segment. In Boston Keratoprostheses the risk seems to be somehow less.

Results As the absorption of topical anti-glaucomatous medication will not reach the inner eye because of the anatomic barrier in KPro the only promising possibilities of treatment are systemic carbonic anhydrase inhibitors, different kinds of aqueous shunts and endo-cyclo-laserphotocoagulation.

Conclusion Glaucoma is still a mayor problem in KPro.PS: This lession will be presented at the KPro-Meeting!!

4424
Improving the optics of KPros

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Purpose The purpose of this talk is to review the clinically relevant optical and visual requirements of keratoprostheses.

Methods Modelling of designs using commerical and purpose-written optical design software as well as clinical measurments on a small number of patients implanted with the osteo-odonto keratprosthesis optical cylinder.

Results The important visual optical proerties of any keratoprosthesis optic are the foveal image quality (affecting the acuity) and the field of view. These fundamentally depend upon the pupil size, and the length and diameter of the optic since the power must be fixed to give emmetropia. The axial image quality can be changed by controlling the spherical aberration. However, maximising axial (foveal) image quality causes poorer off-axis image quality potentially reducing the effective visual field. Shorter, larger diameter optics help improve the visual field as well as consideration of off-axis image quality.

Conclusion The theoretical properties of keratoprosthesis optics must be balanced against other clinical requirements such as longterm complications and stability. The clinical requirements provide the constraints on the optical design. However, discussions can usefully happen between surgeons and those involved in the design of the optics to give the best possible visual rehabilitation.

▪ 4425
Glaucoma treathment in MOOKP

TALONI M, FALCINELLI G

Glaucoma is the most common complication following modified osteo-odonto-keratoprosthesis (MOOKP). Between 1973 and 2007, 266 eyes have been operated by the same surgeon (G.Falcinelli) with a modified osteo-odonto-keratoprosthesis.

Before implantation, 94 patients had a preexisting glaucoma (36%).

Over 266 MOOKP's, 69 patients (26%) have to be treated for glaucoma (53 relapsed, 16 ex novo glaucoma). 28 patients were stabilized, 16 were slightly worse, 23 worsened, 3 had an absolute glaucoma.

Surgical approach applied was retroequatorial drainage for 12, double thread cyclodiastasis for 11, 3 transcleral photocoagulation, 1 diathermy of the ciliary body, 3 endo-cyclo photocoagulation, 1 Ahmed valve. The results will be discussed. But certainly an inaccurate surgical procedure can facilitate the onset of glaucoma after MOOKP.

▪ 4426
An antibiotic releasing contact lens

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Purpose To characterize a drug-eluting contact lens designed to release ciprofloxacin to the eye in a controlled manner for an extended period of time.

Methods Thin fiilms, containing ciprofloxacin or fluorescein encapsulated in PLGA (Poly[lactic-co-glycolic acid]), were coating by pHEMA (poly[hydroxyethyl methacrylate]) by ultraviolet light polymerization, creating prototype contact lenses. The films were characterized by scanning electron microscopy. Release studies were conducted in phosphate buffered saline at 37°C with continuous shaking. Ciprofloxacin eluted from the contact lens was studied in an antimicrobial assay to verify antimicrobial effectiveness.

Results Ciprofloxacin and fluorescein were released from the contact lenses in a controlled manner, demonstrating zero-order release kinetics under infinite sink conditions for over 4 weeks. The rate of drug release was controlled by modifying either the ratio of drug to PLGA or the molecular weight of the PLGA employed. Both the PLGA and the pHEMA affected release kinetics. Ciprofloxacin released from the contact lenses inhibited ciprofloxacin-sensitive Staphylococcus aureus at all time-points tested.

Conclusion A thin drug-PLGA film coated with pHEMA could potentially be used to create contact lenses which can serve as a platform for ocular delivery of antibiotics and other medications, with widespread therapeutic applications.

▪ 4427
Does imaging help with preventing extrusion?

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Both clinical and radiological methods can be used for early detection of resorption in OOKP patients; this is influential in preventing serious complications such as extrusion and endophthalmitis. Radiologically, use of either multidetector computed tomography (MDCT) or electron beam tomography (EBT) is valuable in identifying laminar resorption. A novel approach was recently adopted in Sussex Eye Hospital, using volume rendering software in processing previously obtained MDCT images, to calculate volume of the OOKP lamina rather than 2D measurements. We present the results of an observational retrospective case series study to illustrate the use of this approach. We describe how it can be used to calculate percentage change in volume of the lamina over time and how this can be correlated with clinical laminar resorption. We will also discuss further recommendations to build upon this advance.

▪ 4428
The clinical psychologist's role in the OOKP clinic. A one year review

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OOKP Surgery places complex Physical and Psychological demands on patients. Attention to Psychological factors is likely to facilitate good outcome and improve Quality of Life. This presentation outlines an innovative addition to the OOKP service at Sussex Eye Hospital, Brighton UK, incorporating a Clinical Psychologist as a member of the OOKP medical team. It will describe the first year's work including a study which has identified four subgroups of patients presenting for OOKP and the psychological needs of each group. The presentation describes how the service aims to address the particular psychological needs of these patient groups from assessment to psychological follow up. The presentation will also include a summary of a second Qualitative Interview study looking at patients' reports of their experiences of undergoing OOKP from a bio-psychosocial perspective.The National Health Service, UK seeks to use patient experience and feedback to shape clinical services and the implications of the outcomes of the research for the service will be discussed.

The indian experience with MOOKP

IYER G

Purpose To study the results of the Modified Osteo Odonto Keratoprosthesis (MOOKP) surgery in bilateral end stage ocular surface disorders.

Methods The MOOKP surgery is performed in 3 stages. Stage IA involves removal of the iris, lens, and anterior vitrectomy with a corneal transplant if indicated. Stage IB+IC usually performed simultaneously involves harvesting the buccal mucosa and transplanting it on to the ocular surface along with fashioning of the osteo odonto aerilic lamina (OOAL). Stage II involves transplanting the OOAL to the eye 3 months later.

Results The MOOKP surgery was completed in 50 eyes of 47 patients with a mean follow up of 15.38 months (range 1 month to 54 months). Anatomic success was achieved in 96% of the eyes. Functional success of visual acuity > 20/60 was noted in 66% of eyes. Complications included oroantral fistula (6%), trophic mucosal alterations (8%), lamina exposure (central-6%; peripheral-8%), mucus membrane overgrowth (2%), hypotony (2%), expulsion of optic cylinder(4%), endophthalmitis (2%), glaucoma (20%), sterile vitritis (6%) and retinal detachment (2%).

Conclusion MOOKP is the keratoprosthesis of choice in end stage bilateral ocular surface disorders in the Indian subcontinent. Complications do occur and have to be recognized and treated early