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hiips://doi.org/10.1007/s00417-020-04789-3

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A novel intraocular lens designed for sutureless scleral fixation: surgical series

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Received: 31 March 2020 / Revised: 18 May 2020 / Accepted: 1 June 2020

Abstract

Purpose To report a retrospective series of patients implanted with a novel hydrophilic acrylic single-piece intraocular lens (IOL) designed for sutureless scleral fixation (FIL-SSF Carlevale lens, Soleko, Italy) injectable through a 2.2-mm incision.

Methods Seventy-eight patients with minimum 6-month follow-up were divided into 6 groups: dropped nucleus, luxated IOL, trauma, aphakia, IOL exchange, and Marfan's syndrome. Surgery included peritomy and scleral flap creation at 3 and 9 o'clock position. The IOL was then injected and grasped with 25G forceps through a hole created 2 mm posterior to the limbus underneath the sculped scleral flap.

Results The study included 78 patients (mean age 71.9 ± 12.6 years) and average follow-up 10.2 ± 4.2 months. Average surgery duration was 69.4 ± 26.1 min and vision significantly improved from 0.86 ± 0.56 logMAR to 0.38 ± 0.42 logMAR at 6 months post-operative ($p < 0.001$). Intraoperative complications included corneal edema, retinal tears, and vitreous bleeding each in 2/78 patients (2.5%); 1/78 (1.3%) localized retinal detachment and 1/78 (1.3%) rupture of one T-shaped IOL harpoon. Post-operative complications included 4/78 (5.1%) cystoid macular edemas, 2/78 retinal tears, 2/78 retinal detachments, 2/78 developed ocular hypertension, and 1/78 corneal decompensation requiring DSAEK.

Conclusion The Carlevale lens is designed for sutureless intrascleral fixation and can be successfully used in a variety of indications including difficult trauma cases with good rehabilitation. An implant requires experience and delicate manipulation.

Keywords Aphakia · Intraocular lens · Pars plana vitrectomy · Sutureless intraocular lens · Scleral fixation

Introduction

The implant of an intraocular lens (IOL) is the mainstay of cataract surgery and secondary aphakia correction, often achieving substantial visual rehabilitation.

Whenever possible, elective in-the-bag IOL positioning offers unparalleled stability and optimal effective lens placement. In case of insufficient or non-existing capsular support [1], multiple alternative solutions have been deployed: anterior chamber IOLs [2], iris claw [3] and iris-sutured IOLs, sulcus IOLs [4], iris fixation [5], sutured scleral fixation [6], and sutureless scleral fixation [7].

Salvage procedures securing dislocated IOLs have also been developed as well as a few special IOLs designed specifically for scleral suturing [8]. In 2014, Yamane described a sutureless scleral fixation technique [9], based on the "entrapment" of the distal portion haptic underneath a lamellar scleral flap, allowing both secondary implant and salvage of specific IOL types [10] and countless variants followed ever since [11].

Electronic supplementary material The online version of this article (hiips://doi.org/10.1007/s00417-020-04789-3) contains supplementary material, which is available to authorized users.

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Published online: 11 June 2020

Drawbacks of most currently available scleral fixation lenses are their non-foldability and the need for suturing [12, 13], a difficult and time-consuming procedure. The Yamane technique, on the other hand, applies only to specific lens types and represents and off-label placement and securing of sulcus IOLs. Moreover, the intrascleral passage may stretch the haptics resulting in optic plate tilting or haptic severing.

The purpose of the present paper is to report a retrospective numerous series of patients implanted with a novel injectable intraocular lens specifically designed for sutureless intrascleral fixation for a variety of indications including complex trauma cases.

Materials and methods

Lens design

One of the authors (CC) designed a novel intraocular lens (IOL) specifically for sutureless scleral fixation (FIL-SSF, Carlevale Lens; Soleko Inc., Rome, Italy).

The Carlevale lens (Fig. 1) is a 6.5-mm-wide optic plate, 13.2-mm-long single-piece hydrophilic acrylic IOL featuring T-shaped harpoons protruding off the closed haptics in order to allow self-anchoring on the sclera without the need for sutures (Fig. 1). The haptics have a 5° anterior angulation with respect to the optic plate in order to guarantee a more physiologic effective lens placement, reduce pupillary bloc risk, and minimize iris chafing. The haptics have also two small asymmetric incisions (green arrows in Fig. 1a, front view of the schematic drawing) that allow surgeons to quickly check proper unfolding of the lens since they would be in a specular position if the lens were upside down.

The lens is foldable and can be injected via a dedicated disposable plunger injector and cartridge through a 2.2-mm corneal incision. Dioptric power ranges between − 5 and + 35 diopters and customized toric lenses are also available (cylinder power between up to 10 diopters, steps of 1 diopter). A-constant is 118.5.

Surgical technique

After exposure of the sclera along the horizontal meridian at 3 and 9 o'clock a 3.5 × 3.5 mm partial thickness scleral lamella is sculped with a 22.5° angled knife and carved with a crescent knife up to the limbus on both sides. A 25-G needle perforates the deep scleral lamella bed at 1.5 mm from the limbus at 3 and 9 o'clock and the Carlevale lens is injected through a 2.4-mm-wide corneal tunnel made at 12 o'clock hours after filling the anterior chamber (AC) with cohesive viscoelastic material.

As the IOL unfolds out of the cartridge tip in the anterior chamber, a 25-G serrated jaws forceps is introduced in the vitreous chamber through the 9 o'clock hole previously drilled through the deep scleral lamella (movie 1). The forceps gently grasp the distal haptic T-shaped harpoon and drives it out of the eye through the scleral hole and underneath the superficial scleral lamella. At this point in time, the IOL is completely released from the injector cartridge free to unfold and both the optic plate and proximal haptic rest in the anterior chamber over the iris plane. The serrated jaw forceps are now passed through the 3 o'clock deep scleral lamella hole in the vitreous chamber and anteriorly through the pupillary foramen to grasp the proximal haptic T-shaped harpoon and externalize it. In case of need, a second forceps, inserted through a clear cornea incision, offers the harpoon a second one passed through the deep scleral lamella with a "handshake" technique.

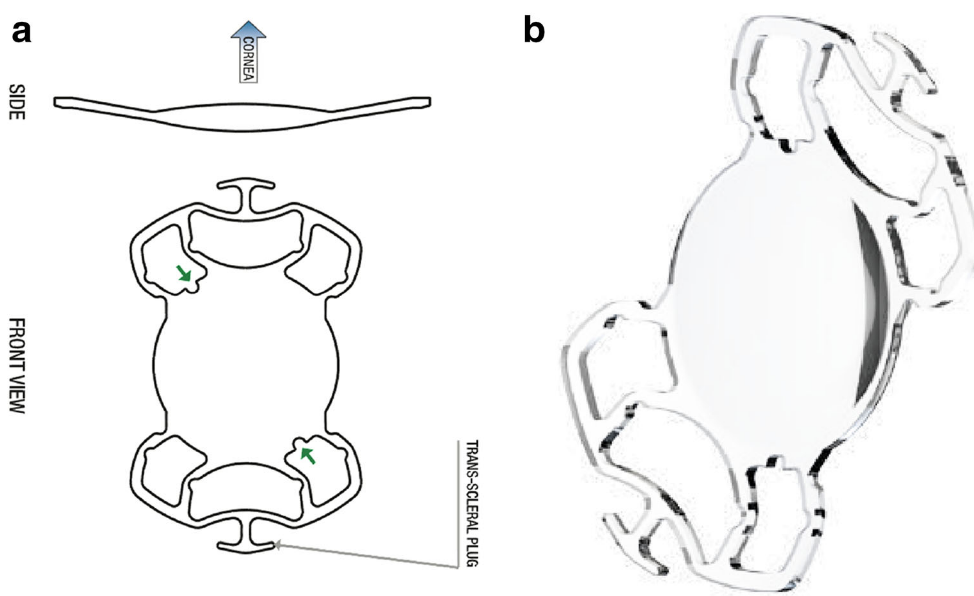

Fig. 1 **a** Schematic drawing front and side and **b** photo of the single-piece Soleko FIL-SSF "Carlevale lens." Note the posteriorly angled closed haptic design acting a spring and damper to adjust to slightly different sulcus width and the T-shaped harpoon to be placed underneath a scleral flap, counteracting the 4 points of sulcus contact. The green small arrows indicate asymmetric haptic incisions used to check the proper unfolding of the lens (they would be in specular position if the lens were upside down)

The superficial scleral lamella is folded back into place to cover the T-shaped harpoon without the need for suturing and the conjunctiva is sutured or cauterized back into place.

Study design

We retrospectively reviewed the charts of all patients undergoing pars plana vitrectomy (PPV) and Carlevale lens implant for correction of primary or secondary aphakia of any origin and implanted with a Carlevale lens. All patients underwent complete pre-operative eye examination including distance and reading Snellen fraction and logMAR best-corrected visual acuity (BCVA), slit lamp examination of the anterior chamber, dilated fundus examination with 90-diopter lens and binocular indirect ophthalmoscope, B-scan ultrasound when there was no clear fundus view and Fourier-domain OCT imaging repeated at least on day 1, within the first week, at 1 month, 3 months, and 6 months. Patients with an incomplete chart or follow-up less than 6 months were excluded.

Patients were categorized into six groups according to surgical indication: 1, dropped nucleus and/or lens fragments; 2, dropped IOL; 3, traumas; 4, aphakia; 5, intraocular lens exchange; and 6, Marfan syndrome.

The study followed the tenets of the Helsinki declaration, patients gave consent, and the study received IRB approval.

Statistical analysis

All numeric variables were analyzed by means of ANOVA and p values less than 0.05 have been considered statistically significant. Paired sample T test was used to compare pre-op and post-op visual acuity and intraocular pressure.

Results

Overall, 83 patients met inclusion criteria; 5 were excluded due to incomplete chart and/or follow-up; and 78 (39 males and 39 females; 40 right eyes and 38 left eyes) were included in the study. The overall sample population mean age was 71.9 years (± 12.6) and average follow-up 10.2 months (± 4.2). The average duration of surgery for the entire sample was 69.4 min (± 26.1) and vision improved form an average 0.23 (± 0.20) Snellen acuity (0.86 ± 0.56 logMAR) to 0.54 (± 0.26) Snellen acuity (0.38 ± 0.42 logMAR). Visual acuity significantly improved throughout the sample population at 1, 3, and 6 months compared with pre-operative ($p < 0.0001$).

Marfan's syndrome patients were significantly younger than others while aphakic patients required a shorter surgery (Table 1). There was no any significant difference among groups in terms of pre-operative visual acuity and post-operative visual acuity at 1, 3, and 6 months although trauma eyes showed a trend towards lower acuities (Fig. 2).

Intraoperative complications included the development of hazy view due to corneal edema in 2/78 (2.5%, one trauma and one dropped nucleus) cases, 2 eyes suffered retinal tears treated by laser (2.5%), 2 patients bled in the vitreous chamber (2.5%), 1/78 (1.3%) developed a localized retinal detachment that was repaired during the same surgery, and in 1/78 (1.3%) cases, the T-shaped IOL harpoon ruptured when grasped with a serrated jaw 25-G forceps in an attempt to externalize it. The IOL needed replacement during the same surgery with no further complications.

Post-operative complications within the 10.2-month average follow-up included 4/78 cases of cystoid macular edema (5.1%; 2 eyes undergoing surgery after trauma, one complicated phaco with lens material in the vitreous chamber and one patient with IOL luxation in the vitreous chamber), 2 retinal tears (both after phacoemulsification complication), 2 retinal detachments requiring surgery (2.6%; one trauma and one complicated phacoemulsification), 2 ocular hypertension requiring drops, and 1/78 case (1.3%) each for corneal decompensation requiring DSAEK, mild vitreous chamber hemorrhage spontaneously resolved, and superficial scleral flap erosion sparing the conjunctiva that did not require intervention at the end of 6-month follow-up.

Discussion

Intraocular lens placement other than within the capsular bag always represents a suboptimal solution worth considering only if the bag is not viable.

The wide range of conditions requiring alternative IOL placement inspired innumerable and brilliant solutions justifying result variability of reported surgical series [5]. Alternatives to capsular bag placement include the anterior chamber (AC) [2], iris claw [14], iris suture [15], ciliary sulcus, and sutured and sutureless scleral fixation.

Corneal endothelial damage [16], iris chafing [17], pupillary irregularity, and reduced mobility discouraged AC and iris-bound positioning whereas sulcus placement reduced long-term complications even in the absence of capsule remnants. Intraocular lenses with eyelets on the haptics have also been designed for this purpose, although suture erosion may threaten long-time stability and the implant may be lengthy and cumbersome [18].

In 2014, Yamane and colleagues introduced an original sutureless scleral fixation technique [19] that became popular due to time-sparing and ease of manipulation. Ever since, the sutureless sulcus scleral fixation option gained acceptance although mainly deployed through an off-label use of 3-piece IOLs intended for sulcus or bag placement.

The FIL-SSF Carlevale lens is specifically designed for intrascleral sutureless fixation (Fig. 1) [20]. The T-shaped harpoon and the 4 points of scleral sulcus counterpressure limit

Table 1 Sample population demographics and surgical details divided per group. *The difference between groups is significant at $p < 0.05$ level

	No.	M, F	Age*	Follow-up	Duration of surgery*	IOL power
Dropped nucleus	20	9,11	73.2 ± 10.7	11.1 ± 4.9	70.7 ± 30.7	18.7 ± 5.2
Dropped IOL	21	10, 11	75.5 ± 7.8	9.8 ± 3.3	64.1 ± 18.7	19.2 ± 6.3
Traumas	16	7, 9	69.0 ± 10.1	10.3 ± 4.3	86.6 ± 24.9	21.1 ± 2.6
Secondary implant: aphakia	9	6, 3	75.1 ± 9.9	9.3 ± 2.9	48.7 ± 24.6	21.4 ± 2.3
IOL exchange	7	3, 4	75.6 ± 5.8	7.6 ± 1.3	71.4 ± 22.6	17.6 ± 5.4
Marfan's syndrome	5	1, 4	49.6 ± 29.3	14.0 ± 5.6	65.0 ± 20.9	13.8 ± 5.4
Total	78	39, 39	71.9 ± 12.6	10.2 ± 4.1	69.4 ± 26.1	19.2 ± 4.9

tilting while the closed haptics angled posteriorly maintain the optic plate at a distance from the pupillary plain and minimize iris chafing, acting at the same time as a spring and allowing tolerance to slightly different sulcus-to-sulcus distance. The improvement of post-operative visual acuity compared with baseline was significant throughout the surgical series and for each group ($p < 0.001$ for all pairs; Table 2) while vision did not differ significantly among groups at any point in time (Table 2) despite a trend towards better visual outcome in secondary implants and dropped *nuclei* compared with Marfan's syndrome and IOL exchange patients.

Caution is imperative in evaluating such results since a selection bias may explain similar vision across groups as patients deemed eligible for scleral fixation IOLs (especially traumas) are obviously those with a relatively benign prognosis (at least in the surgeons' judgment) who eventually do achieve better results.

The average duration of surgery showed a significant difference between groups ($p < 0.05$): not surprisingly, traumas required almost twice as much time than secondary implants (Table 1) due to the surgical complexity beyond IOL fixation itself. We estimate the aphakic group better reflects Carlevale lens implant time alone (at least for the surgeons participating to present study) and was around 48.7 min (± 24.6). It should be noted that all surgeons elected to perform a 3-port "complete" PPV in an effort to reduce medium and long-term complications including retinal tears, detachment, and macular edema.

Intraoperative complications including retinal tears, bleeding, cornea edema, and retinal detachment do not seem to be directly related to IOL type while in one case, the haptic damaged most likely due to improper manipulation and the IOL needed replacement during the same procedure. Hydrophilic acrylic IOLs retain a great foldability and can be injected through very small incisions but mandate gentle manipulation as small-gauge forceps (25 G in our case) may exert significant pressure on haptic structures and tear them apart.

Complications occurring during follow-up included 4/78 (5.1%) macular edema cases, a well-known drawback of any IOL-related surgery, especially after complicated cataract and 2/78 retinal detachments [20] (2.6%; one traumatic crystalline lens luxation and one trauma case). Very interestingly, pupillary capture, one of the most frequent complications of scleral fixation IOLs, never occurred in our series, most likely due to the peculiar IOL design. The Carlevale lens, in fact, has no round optic plate with protruding "J" or "C" shaped haptics

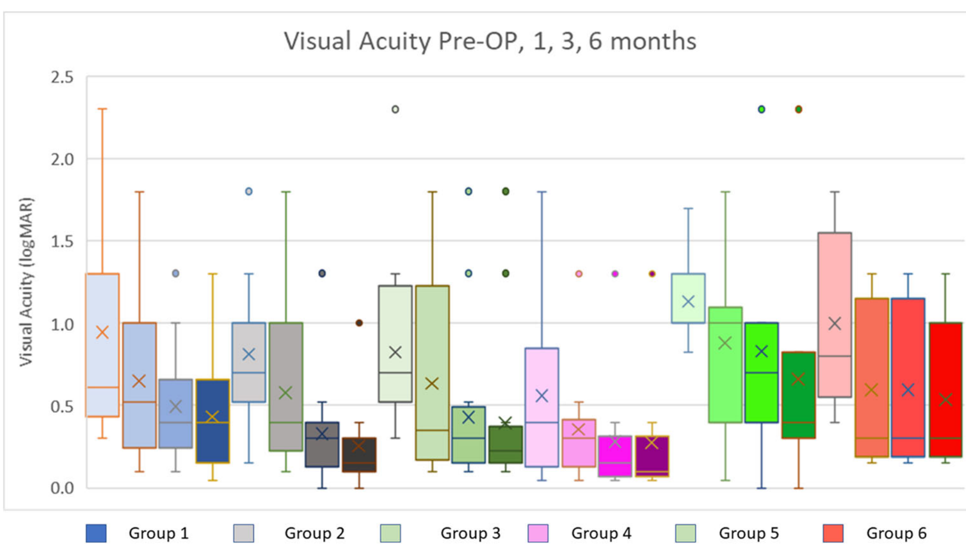

Fig. 2 Visual acuity of all groups at baseline, 1, 3, and 6 months post-op. Group 1: dropped nucleus and/or lens fragments; groups 2: dropped IOL; group 3: traumas; groups 4: aphakia; groups 5: Intraocular lens exchange; groups 6: Marfan syndrome

Table 2 Pre-operative best-corrected visual acuity (BCVA) and at 1, 3, and 6 months post-operative

	BCVA pre-op	BCVA 1 month	BCVA 3 months	BCVA 6 months
1. Dropped nucleus	0.21 ± 0.16	0.35 ± 0.24	0.40 ± 0.22	0.45 ± 0.24
2. Dropped IOL	0.24 ± 0.20	0.39 ± 0.25	0.57 ± 0.25	0.64 ± 0.24
3. Traumatic cataract	0.22 ± 0.22	0.40 ± 0.27	0.50 ± 0.24	0.54 ± 0.22
4. Secondary implant: aphakia	0.44 ± 0.30	0.56 ± 0.24	0.65 ± 0.26	0.66 ± 0.26
5. IOL exchange	0.09 ± 0.04	0.25 ± 0.29	0.30 ± 0.31	0.41 ± 0.29
6. Marfan's syndrome	0.15 ± 0.14	0.39 ± 0.27	0.39 ± 0.27	0.41 ± 0.25
Total	0.23 ± 020	0.39 ± 0.27	0.49 ± 0.27	0.54 ± 0.26

but is more comparable with "plate optic" designs and the closed haptics are wider than the optic plate, "protecting" its margin. This seems to prevent the iris from sliding posterior to the IOL together with the posterior angulation.

In no cases, the IOL unfolded upside down in the vitreous chamber: this has to do with the injection technique that mandates grasping the leading trans-scleral plug as it comes out of the injector while the optic place is still completely folded within the injector. This way, the optic plate unfolding is guided by the stability imposed on the leading plug timely grasped by the surgeon.

Veronese et al. [21] recently described a small series of 4 patients operated with the same FIL-SSF Carlevale lens with very good visual results while Barca et al. [22] reported the results of 32 patients, mainly dislocated IOL/bag with a very low incidence of complications. We present a much wider series of 78 patients encompassing a wider spectrum of indications including traumas and not surprisingly achieved worse average post-operative visual acuity while showing the many potential applications.

Although intrascleral sutureless fixation of the Carlevale lens required technical skill and a learning curve, it also proved its reliability and versatility both in posterior capsule ruptures and in much more complicated eyes such as the case reported in Fig. 3 where the surgeon elected to implant the IOL vertically (H6-H12) in a post-traumatic aniridic eye, in order to use the closed haptics design as an inferior iridectomy capable of maintaining silicone oil within the vitreous chamber with good results. There are obviously ways to correct aniridia but most of the time, those are not readily available for trauma eyes that may require silicone oil tamponade. The Carlevale lens allowed silicone oil confinement within posterior to the IOL optic plate, thanks to its specific design while waiting for more pragmatic, long-lasting, and cosmetically accepted solution that could not be arranged while repairing the trauma.

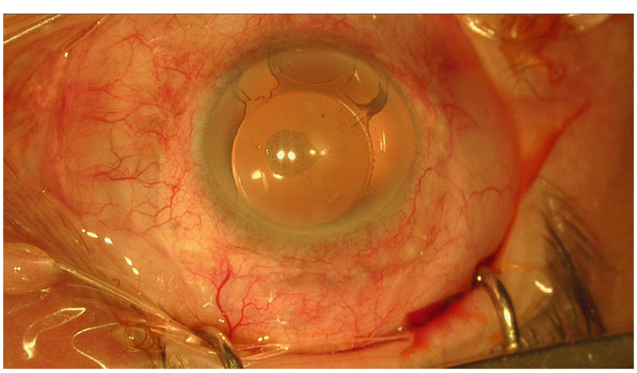

Fig. 3 Aniridic patient (post globe rupture) showing vertical placement of the lens in order to simulate inferior iridectomy

The long-term risk of scleral erosion is a very sensitive issue and deserves further study with longer follow-up as well as the development of iris dispersion syndrome and glaucoma. Veronese et al. [21] describe a different surgical technique leaving the trans-scleral plug deliberately underneath the conjunctiva with no further complications after 6.5 months of mean follow-up. We believe this technique is undoubtedly faster and easier but raises concerns at the long-term follow-up and risk of erosion and/or infection.

Post-surgical glaucoma onset deserves a separated consideration as a much longer follow-up would be needed, and the proteiform baseline diagnosis introduces multiple confounders. Iris pigment dispersion syndrome and vitrectomy itself in fact increase the risk of glaucoma.

The present study clearly suffers the pitfalls of retrospective series but gathers a reasonably large series of patients with lengthy follow-up, showing the expanded indications for this IOL specifically designed for sutureless intrascleral fixation. Although further study and larger series will clarify pitfalls and benefits, it is our opinion that the FIL-SSF lens represents an interesting solution after complicated cataract surgery in the absence of viable capsule remnants and even more interestingly allows safe and stable lens positioning in more complex procedures even in the presence of tamponades due to its scarce tendency to tilting. Hydrophilic acrylic material allows extremely gentle folding and unfolding through corneal tunnels up to 2.2 mm but mandates careful manipulation. A much longer follow-up and wider surgical series will permit a better clarification of important complications including tissue erosion and glaucoma.

Acknowledgments The authors would like to thank the Fondazione Roma for support.

Author contributions T. Rossi: manuscript writing and study design; D. Iannetta: data search, proof reading, and study design; V. Romano: data search and manuscript writing; C. Carlevale: manuscript writing and proof reading; M. Forlini: data search and proof reading; S. Telani: data search and proof reading; A. Imburgia: data search; A. Mularoni: manuscript writing and proof reading; L. Fontana: manuscript writing and proof reading; and G. Ripandelli: data search and proof reading.

Compliance with ethical standards

Conflict of interest All authors with the exception of Carlo Carlevale certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript. Carlo Carlevale receives speaker honorarium from Soleko srl but does not own stock in Soleko, neither is a member of any committee related to this IOL commercialization.

Statement of ethics Present research complies with the guidelines for human studies and was conducted ethically in accordance with the World Medical Association Declaration of Helsinki. Informed consent was obtained by patients involved in the study.

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