

New IOL dedicated for scleral fixation

The lens design provides firm anchorage to the sclera without any sutures.

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A dedicated IOL for scleral fixation that requires no sutures remained stable over 8 years of follow-up and might be an ideal solution for pediatric cases as well as a secondary implant in aphakic eyes.

“Like many others, I wanted to find the best solution for fixating an IOL to the sclera, possibly without sutures. With the engineers of Soleko, I designed a lens with two small plugs on the haptics, which fold to penetrate into a thin scleral tunnel and then reopen to anchor the surrounding tissue,” **Carlo Carlevale, MD**, said.

The lens is made of a foldable acrylic material, has a wide diopter range and can be specifically customized to correct astigmatism.

“Compared with Scharioth’s and Agarwal’s techniques, this option has the advantage of better three-dimensional stability over time and refractive predictability because the lens is specifically designed for scleral fixation. The scleral plug is not subject to deformation, rupture or dislocation,” Carlevale said.



**Carlo
Carlevale**

Implantation technique

To prepare for insertion of the lens, two scleral flaps are created 180° apart. Scleral holes are made on the bed of the scleral flaps 1.5 mm from the limbus. The lens is then injected into the eye.

“We use 23-gauge or 25-gauge vitrectomy forceps to grab the plugs of the lens from the outside and drive them into position. The plugs are very supple, are smoothly driven through the tunnel and, once out of it, reopen immediately and fixate onto the sclera,” Carlevale said.

The scleral tunnel should be created with 23- to-25-gauge instruments because the plugs could be sucked down into a larger 20-gauge sclerotomy. Once the flaps are closed, the plugs are incarcerated within the sclera. At the end of the procedure, the conjunctiva is carefully repositioned and sutured to seal the flap.

Recently, Carlevale created an alternative, even easier technique.

“Two radial incisions are performed on the sclera 180° apart. Using a crescent knife, I create two pockets to the right and left of each incision. Then I perform a sclerotomy using a 23-gauge needle, and from there I grab the plug of the lens with the usual small-gauge forceps. Crocodile forceps are the best because they grasp the plug firmly. Using forceps, I secure the plug under the two pockets and seal everything with the conjunctiva,” he said.

With both techniques, if the scleral flap or the two scleral pockets are precisely delaminated, there is no need to apply sutures to the sclera, and only conjunctival sutures are needed.

“With this second technique, I have further reduced the surgical time by approximately 10 minutes, enhancing safety,” Carlevale said.

Results

Over 8 years, Carlevale has implanted about 30 of these lenses in complicated cataract cases or as a secondary procedure. Several of the cases were referred by colleagues. The lens is gradually gaining popularity and has been adopted by surgeons in Italy, Greece, France, Germany, Canada and Australia.

“What is special about it is that it hit the target immediately. The first prototype is almost what we are still using; there has been no need for many modifications. The size of the plug is just right for getting through the tunnel, for laying firmly on the sclera and for tight sealing the sclerotomy. It is big enough not to be sucked down into the hole and small enough to take up a minimal amount of space under the flap with no visible bulging on the surface,” Carlevale said.



Tommaso
Rossi

Tommaso Rossi, MD, has also implanted about 30 eyes with the Carlevale lens and has made it his lens of choice in all cases in which there is no capsular support, such as trauma cases, complicated surgery cases, Marfan syndrome cases and a few pediatric cases.

“Results are rewarding also because we can use small 2.2- to 2.4-mm incisions with no induction of astigmatism. Another advantage is that implantation is very fast,” Rossi said.

If the flaps are carefully developed, the appropriate instruments are used and the plug is well anchored to the sclera, this lens is a success, he said. Crocodile forceps secure a firm grasp, and 23-gauge forceps should be preferred because 25-gauge forceps are thin and may cut through the delicate material of the lens.

“The extreme suppleness of the material is at the same time a weakness and a strength of this implant. It makes it unfold and position very easily and smoothly, but at the same time it makes it vulnerable and calls for gentle handling,” he said.

Implantation in children

The supple material and the design of this lens make it adaptable for eyes of different sizes, including children's eyes, in which results are remarkable, Rossi said. One of his cases was an 8-year-old child with Marfan syndrome.



Sébastien
Guigou

"We achieved vision of near 20/25 in this child, which he had never had previously in his life," he said.

Sébastien Guigou, MD, implanted this lens in a boy with a large ocular injury caused by dog bites. [[See video.](#)]

"The sclera was in very poor condition. First, I had to repair a large wound of more than 1 cm, stop the hemorrhage, and at the stage of implanting the lens there were only some parts of the sclera that were not injured. The Carlevale lens, which does not need large flaps or sutures and is easy to fixate on a tiny area with its inbuilt anchorage system, gave us a chance that we would not have with other techniques. It can also be injected through a small incision, which was another big advantage in this case," he said.

The lens is now stable in the posterior chamber, and visual outcomes are excellent, with just 0.25 D of myopia.

Guigou is a retina specialist, and previously he implanted three-piece lenses using sutures in pediatric cases.

"It was long and cumbersome in small eyes, and I gratefully welcomed this new option, which makes surgery much easier and safer. For pediatric cases, it is just what we needed," he said.

He has also used the lens in one adult case and found it easy and fast to implant. –
by Michela Cimberle

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