LETTER TO THE EDITOR

When Your Patient Outlives the Start-Up That Created Their Medical Device

READ IT NOW

Imagine your life depends on a pacemaker that needs a new battery and the company that produced the battery went out of business. Luckily–your cardiologist assures you–the old machine can be taken out and replaced with a new pacemaker model. Of course, the cardiac pacemaker industry likely uses standardized batteries to avoid this situation. Other specialties such as ophthalmology, however, are not as lucky.

A major European newspaper recently published an article about a young man who had a type of mini-stimulator implanted in his upper jaw to treat cluster headaches.[1] The device has CE mark certification for cluster headaches and certain other forms of migraine. During a visit to the neurological clinic for a routine adjustment of stimulation parameters, the man learned that the device manufacturer had lost the confidence of its investors and gone bankrupt. The device was no longer supported, and spare parts were no longer available. The man resorted to an experimental antibody therapy, and he developed a wound-healing disorder.

In ophthalmology, as in any other field of medicine, there is a feeling of communal exhilaration when something new such as an IOL, innovative laser, or the latest MIGS device is introduced. Can the innovators of these and other products continue delivering over time, though? Can they keep up with consumer expectations? As Sheraz M. Daya, MD, FACP, FACS, FRCS(Ed), FRCOphth, and Tom Williamson, MD, MBChB, FRCS(Glas), FRCOphth and Williamson pointed out in their feature article, "From Innovation to Intervention," in the November/December 2022 issue of *CRST Europe*, "The journey begins, and the process progresses until suddenly there is a major setback. It feels like everything is going pear-shaped. The viability of the whole project is questioned."[2] (Scan the QR code to read the article.) This collective disappointment has not spared ophthalmology. Following is a sampling of products that were withdrawn recently.

WIOL-CF (Medicem). The bioanalogous extended depth of focus IOL showed exciting results for binocular UCVA, contrast sensitivity, and spectacle independence in a multicenter study in which our clinic participated. The lens material is unique; it is designed to absorb aqueous humor and expand to fill the capsular bag perfectly, imitating the geometry of the natural lens. In some eyes, however, the capsular bag was too large for the IOL. This caused the lens to dislocate inferonasally and disturbed some patients.

Beacon Aqueous Microshunt (MicroOptx). Inserted into the limbus, the Beacon shunt was designed to drain aqueous humor constantly and in a predefined quantity directly onto the surface of the eye. My clinic was the first European center to implant a Beacon, and we have implanted it in more than 20 eyes. The shunt successfully provided two benefits: (1) reliable IOP-lowering and (2) improved symptoms of dry eye disease by moisturizing the cornea. Some patients, however, experienced significant progressive endothelial cell loss.

CyPass Micro-Stent (Alcon). This device stands apart from the two previous examples. The stent was produced by a large company that reacted immediately and responsibly by voluntarily recalling the product. In the other two cases, the manufacturers were smaller/start-up companies. In "How to Proceed With an Idea," from the aforementioned November/December 2022 issue of *CRST Europe*, Timothy Page, MD, highlighted that the path from idea to innovation is usually taken by such start-ups since large companies "may not, however, want to become involved until they see that it has some market value or because they cannot manufacture the product. In the latter situation, you [the inventor] may need to partner with a smaller company for manufacturing."[3] (Scan the QR code to read Dr. Page's article.)

THE CORE PROBLEM

Start-ups come and go. They are the shining stars of the *Wall Street Journal* one day and history the next, when their product fails or their investors walk away. Unfortunately, our patients are left behind to live with a piece of medical engineering that did not fulfill the expectations. They begin a long journey when an ophthalmic device is implanted, and we must ensure they don't have to go it alone. They will need support–our support–long after the company that has produced the IOL, stent, or retina chip has gone out of business.

It may be worthwhile for the ophthalmology community to consider implementing a patient fund–perhaps one that is even made compulsory by lawmakers. If companies contributed to the fund in their most hopeful, early phase of innovation, it could help patients later if an intervention that might not be covered by insurance becomes necessary.

1. Feldwisch-Drentrup H. *Frankfurter Allgemeine*. When the neuroimplant is no longer supported. Updated August 29, 2022. Accessed February 1, 2023. https://www.faz.net/aktuell/wissen/medizin-ernaehrung/neuroimplantat-gesetze-schuetzen-nicht-vor-support-ausfall-18270806.html
2. Daya SM, Williamson T. Inventing and innovating. *Cataract & Refractive Surgery Today*. November/December 2022. Accessed January 30, 2023. https://crstodayeurope.com/articles/nov-dec-2022/inventing-and-innovating/?single=true
3. Page T. How to proceed with an idea. *Cataract & Refractive Surgery Today*. November/December 2022. Accessed January 30, 2023. https://crstodayeurope.com/articles/nov-dec-2022/how-to-proceed-with-an-idea/?single=true

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