

Rayner Celebrates Anniversaries in 2009 and 2010

An interview with Donald J. Munro, Rayner's Chairman and Managing Director.

The parent company to Rayner Intraocular Lenses Ltd. (East Sussex, United Kingdom) was founded in 1910 under the name Reiner & Keeler. Thirty-nine years later, the first IOL, a product of Rayner Optical Company, was implanted. Celebrating this 60-year milestone, and in preparation for the company's 100-year anniversary in 2010, CRST Europe interviewed Donald J. Munro, Rayner's Chairman and Managing Director, to learn more about the company's history as well as its future direction in the industry.

CRST Europe: Rayner has a big anniversary in 2010. What do you have planned to celebrate?

Donald J. Munro: Actually, we have several things to celebrate. This year, 2009, is the 60th anniversary of Sir Harold Ridley's implantation of the first IOL, which was made for him in 1949 by Rayner Optical Company. So this is very significant for the company, as well as for me because I have been in the IOL business for 20 years.

The company was founded 99 years ago, long before the invention of the IOL, by an optician named John Baptiste Reiner. With Charles D. Keeler, he opened a shop called Reiner & Keeler in quite a prestigious location, Vere Street in the West End of London, in 1910.

Mr. Reiner started the company from that shop, and there are still family members related to him working in the company today. Rayner Intraocular Lenses, the IOL company, is part of a group of companies called the Rayner & Keeler Group, which also includes Rayner Opticians, a retail optical business. The group will celebrate its 100th anniversary next year with a variety of events. We plan to host events that will coincide as much as possible with those of the group.

The IOL business will also have its own dedicated marketing events to coincide with the 100th year. I imagine it will include a celebratory dinner with invited guests to commemorate the 60th anniversary of the invention of the IOL. We will have a number of seminars and celebratory events centering around November 29, the anniversary of Mr. Ridley's historic operation at St. Thomas' Hospital in London,

on the Thames—just opposite the Houses of Parliament.

In Brighton, where the company is based, we will also be celebrating the anniversary in conjunction with an award ceremony. This year, the company was honored to receive the Queen's Award for Enterprise, which we have never won before. The prestigious award recognizes sustained international trade in overseas markets and growing commercial success in international business (ie, business outside the United Kingdom). We had exceptional growth in the past 2 years, after we received US Food and Drug Administration (FDA) approval of our C-flex IOL in 2007.

There will be quite a fancy ceremony in Brighton connected with the bestowing of the Queen's Award. This summer, two representatives of our company went to Buckingham Palace for a reception where they met the Queen and members of the royal family. The Queen's representative in the county of Sussex will bestow the actual award on November 27, as close as we could get to the anniversary on the 29th.

CRST Europe: Is the invention of the IOL 60 years ago still relevant to ophthalmologists and to your company today?

Munro: Yes, it is. Let me relate a story that illustrates how it is relevant. I recently saw a case report from a surgeon in South Africa who is following a patient there. This woman had a traumatic cataract as a young girl, and she has a lens in her eye made by Rayner that was implanted by Dr. Edward Epstein in 1952. She was 12 or 13 years old when she was operated on. She is still in good health, her eye is still clear, and the IOL is still clear. When a little bit of history like that hits you, you think, my goodness, what we are doing today will go into someone's eye and it can last a lifetime.

Now think of that patient, with one of our lenses in her eye for almost 60 years, in context with our current technology. We have a close collaboration with Michael Amon, MD, a surgeon in Vienna, Austria, who performs a two-lens procedure using our new Sulcoflex IOLs. He has just implanted one of these lenses in a 2-year-old, as part of this *duet procedure*, as he calls it. I hope that child will have a long, happy life with

our lens. I hope he does as well as that patient in South Africa, and that people are talking about his healthy eye and his nice, clear IOL when he is in his 50s or 60s.

It is part of my job to talk about the history of the company, and I really do not tire of it. Sir Harold Ridley's story is well known, but it still fascinates people 60 years later—his observation during World War II that Perspex fragments seemed to be inert in the bodies of injured airmen; his subsequent determination to use that material to craft a replacement for the human lens; and the ultimate success of his endeavor, despite the initial hostility and censure of his colleagues.

I have been in the IOL business since 1989, and I have seen IOL companies come and go. We are celebrating the fact that we are still around and have been making IOLs for every one of these past 60 years. We have people in the company who have been working with us for 25 and 30 years. We are part of a continuing tradition, and we are proud of our position and the perspective on the industry and the profession of ophthalmology that it affords us.

CRST Europe: Your award from the Queen is for your international business, so we should talk about that. Where do you stand with the US market?

Munro: We received US FDA approval for our platform model hydrophilic acrylic IOL, the C-flex, and that lens is currently being sold in the United States. We entered the US market last year with a pilot marketing approach in a small group of states, mostly in the southeast of the country, establishing our sales team and our customer base for the lens. We are not using a distributor but rather building a sales force; when we find sales people we think have the right pedigree for the job, we take them on. So far it is on a small scale, but we are pleased with the way it is going. Now we have to decide what other lenses to bring into that market.

CRST Europe: US surgeons do not have the body of experience with hydrophilic acrylic IOLs that European surgeons have had. Do you find that US surgeons are skeptical about hydrophilic IOLs?

Munro: Some may be initially hesitant to adopt hydrophilic IOLs. But remember, at one time, just about the whole ophthalmic world was hydrophilic-skeptic. Long before we got US FDA approval for the hydrophilic C-flex, we had no end of experience in the United Kingdom, Germany, India, South Africa, Australia, and all over the world, dealing with this issue: "Oh, your lens is hydrophilic, therefore I shouldn't use it." We are long past that stage in these other markets. So when we come to the United States and hear the same concerns, we are prepared—we have salesmen

who are well versed in answering surgeons' questions about the technology.

Few of our customers have come to foldable hydrophilic IOLs directly from rigid hydrophobic PMMA IOLs. Generally the way our business has increased over the past few years is through people converting from hydrophobic foldable acrylic to hydrophilic injectable IOLs.

We have not experienced the kinds of problems with our hydrophilic lenses that some other companies had 10 or 20 years ago. Before submitting our lenses for US FDA approval, we asked the noted IOL pathologist David J. Apple, MD, from Salt Lake City, Utah, to study them. David examined our lenses intensively, and he found nothing wrong with them. He helped us greatly in the work that led to improvements in our lens designs.

We've now had 11 years' experience with this material, which is enough experience for me to have confidence that that a 2-year-old, for instance, is still going to have a healthy eye and a clear lens 20, 30, and even 40 years from now.

So, yes, some American surgeons have asked us the questions you would expect regarding hydrophilic lenses. But US surgeons who have bought the lens commercially now have just under 1 year of experience with the lens. And beyond that, our investigators in the US clinical trial for FDA approval, like Michael Colvard, MD, FACS; Richard Hoffmann, MD; Mark Packer, MD, FACS; and Nick Mamalis, MD now have patients with 5 years of postoperative follow-up. The first lens was implanted in that US clinical study, in 2003, by Jim Davison, MD, in Marshalltown, Iowa. These patients have been followed closely, and their lenses are still clear. Our salesmen know this, and that is what they tell their customers.

CRST Europe: What is your market position in Europe?

Munro: It is difficult to sum up Europe as one place. Our acceptance varies from country to country. We have good positions in several European markets, including the United Kingdom, of course, but also Germany and Spain.

Beyond Europe, our company has a lot of reach. We sell very well in the Asia/Pacific Rim markets (China, Korea, Taiwan) and in southern Asia (India and Pakistan). We also sell well in Iran, the Middle East, South Africa, and Latin America. Our market shares in Latin America and Canada have recently grown as a consequence of our US FDA approval.

The only major market from which we are absent is Japan. When the moment is right, we would be pleased to start registering our lenses with the right corporate partner. One needs a strong Japanese partner to get through their regulatory system.

CRST Europe: Rayner has been one of the first companies

to combine advanced IOL technologies in one lens—for instance aspheric-toric-multifocal IOLs. Does this present manufacturing challenges for you? And does it present inventory challenges for surgeons?

Munro: When we introduced our aspheric lenses, the C-flex Aspheric, we had to step up a level in our manufacturing technology. Again, when we started to make the multi-aspheric M-flex Multifocal we had to improve our game. But these were not challenges we had to spend years on before making a breakthrough. We have good people, and they put their minds to it, and we made the lenses.

In terms of production, we can get on with the job. That is the easy part—the more difficult part is getting the market to adopt these new technologies. When we introduced toric IOLs, many surgeons said “Why are you bothering? This is going to be a niche product.” Then a large American IOL company introduced toric IOLs. Now, at the ASCRS or ESCRS meetings, there are whole sessions devoted to toric lenses.

We introduced our combined multifocal-toric IOL, the M-flexT, in 2007, and I believe we were the first to offer this combination. But I suspect it will not be long before that big competitor IOL company, or another one, introduces a multifocal toric, and we will suddenly find that the market opens up further for us.

In comparison to these big companies, we remain a small pioneer in the IOL market. We don't necessarily have the resources to create markets for a new product. But when someone else catches on that a market can be created, we can move in on their coattails, so to speak. It's a curious position, being a pioneer regarding the technology and yet coming in later regarding the market. We have the advantage, when the larger company creates the market, that we already have the technology in hand.

Regarding inventory, we have to place some restrictions on what can be available overnight and what must be custom manufactured. Therefore, we have standard and premium ranges of toric IOLs. Surgeons do not often see a patient who needs a 10.00 D astigmatic correction. This would usually be a patient with a previous corneal graft or other corneal surgery. Surgeons accept that a company need not stock that kind of lens, knowing it will be called for only every 2 or 3 years. It is tolerable if they have to wait 6 or 8 weeks while we manufacture the lens.

We also custom-make high- and low-power lenses, although I kick myself periodically that we do not advertise enough the availability of this service. A few surgeons know us well, and know that Rayner is there with certain capabilities. In fact, they sometimes seem to enjoy stretching these capabilities.

In a way, this strategy is reaching full circle, customizing lenses specifically for a patient. For that child in South

Africa in 1952, the lens would have been hand-made by Rayner. Probably the chap who made it would have written the surgeon's name on the box, and definitely the patient's name, if he had that detail. That was real customized service, 1950s style.

I can see us coming back to a time when the surgical community is again going to demand that kind of customization from us: patient-specific lenses, made according to corneal topography and all the patient's biometrical details, fed in to make a lens that specifically matches the patient's eye. Although I can't see us writing the name on the box, I think we are coming back to that type of custom manufacturing, at least for selected patients in developed countries.

However, we cannot ignore that this kind of service is going to be available only in certain countries. There is a huge problem of untreated cataract blindness in the world today in Africa, Asia, and Latin America. Rayner is also involved on that front. I do not want this company to be categorized as making lenses only for people in the United States, Canada, the United Kingdom, and the rest of Europe. I want our lenses to be used everywhere.

CRST Europe: What is in the future for the company?

Munro: I see a good future for Rayner. We have a great team that can focus on bringing us forward in terms of increasing the market for toric, multifocal toric, and other lens technologies. I hope to see greater use of our Sulcoflex supplementary lenses, implanted in the sulcus as a secondary procedure or with the primary IOL in a duet procedure.

We also look forward to challenges making lenses for conditions other than cataract. We announced last year that we have a lens in development, not yet commercially available, for treating macular degeneration. The lens has a prism that deflects light onto healthy retina and away from unhealthy retina.

In addition to the team within Rayner, we also have a worldwide team of salesmen and distributors. We have relationships with some salesmen and distributors that go back to the 1980s. I want to build on that, and I expect that some of the distributors we have today will still be with us in 20 or 30 more years.

There will be a need for IOLs for a long time. Rayner should still be around at the 75th anniversary of the IOL, and why not the 100th? By that time, there may be other technologies for dealing with cataract, but until that day comes Rayner should have a role in the correction of aphakia at cataract surgery. ■

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