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IOL Article for The Optician
By Dr Richard Young

Each year there are over 300,000 cataract operations in the UK alone, so an increasing number of practitioners have experience of advising and managing patients with developing cataract problems. In fact, many practitioners are becoming more involved, as members of a multi-disciplinary team, in the full process of pre - and post - surgical patient management.

Patients' preconceptions about cataract surgery are often very different from the contemporary reality. Some people continue to base their expectations on the old experience, when cataract surgery was still a major procedure and the lengthy recovery period involved adjusting to vision with thick, heavy, plus spectacle lenses. Today, the majority of cases involve relatively routine day treatments, performed under local anaesthetic, using modern intraocular lenses (IOLs) inserted through a small incision. The modern procedure provokes only minimal eye response and provides an immediate return to good vision. Over the last few decades there have been important developments taking place in this area of optics. Changes have happened so quickly that it may not always have been possible for practitioners – let alone their patients - to keep up to date or perhaps to really appreciate how far IOL materials, lens designs and surgical techniques have advanced. This article is an attempt to bridge the gap.

Early Materials and Industry Pioneers

As with contact lenses, it was PMMA material (polymethyl methacrylate) that enabled surgeons to develop the concept of the intraocular lens. Already in use in the 1930s as a spectacle lens material, PMMA's emergence as a candidate for use as an ophthalmic implantable lens stems from evaluation of injuries sustained by World War II Royal Air Force pilots. The British ophthalmic surgeon Harold Ridley (who later became Sir Harold Ridley) noted that after crashes, fragments of the aircrafts' PMMA canopies were tolerated very well within the eye, due to the inert behaviour of this material. His first implantation experiments were conducted in the 1940s. Ridley worked for many years to develop his ideas for an artificial lens and collaborated with the British company Rayners & Keeler to develop the first viable lens designs. Rayner Intraocular remains a major contributor in the global field of IOL design today.

The original Ridley IOL design was a posterior chamber implant. Through the 1950s and 1960s, his work and that of other ophthalmic surgeons continued, still using PMMA as the key IOL material. Names that stand out in this era include Benedetto Strampelli (Italy) and Peter Choyce (UK). Choyce's Mark I implant, based on the Strampelli IOL, was already innovative in that it was variable according to refraction. He went on to refine on a series of modifications, culminating in the Mark VII anterior chamber implant of the mid – 1970s. These were iris and lens capsule fixated designs. Meanwhile, Cornelius Binkhorst in the Netherlands had invented the iridocapsular lens designed to be 'embedded in the iridocapsular space following extra capsular cataract extraction', according to the first full review of IOL developments published in 'The Optician' in January 1975. The Binkhorst design dispensed with anterior fixation loops in an attempt to eliminate the problem of endothelial corneal dystrophy, caused by corneal touch, which was a problem with IOLs at the time.

By the mid 1970s, most IOL designs were still made primarily of PMMA. When ‘The Optician’ published its IOL review it also featured a new range of ‘temporary post-cataract spectacles’ developed for supply to hospital patients. PMMA is still used today in some parts of the world for the production of intraocular lenses, most commonly across Asia. PMMA does not absorb any water when placed in an aqueous environment and so retains its good refractive index. This material is cost-effective, offering lens stability and reliable optical performance. However, its rigidity means that the surgeon must make a relatively large incision (5mm) before the IOL can be implanted. This is more traumatic for the patients and they can be prone to more post-operative problems.

IOL Industry Developments

Despite the early popularity of PMMA, the limitations of this material were recognised. In the late 1960s there were some modest advances in cataract surgery techniques. As a result, there was increased investment in polymer material research, with for example the development of HEMA (poly 2-hydroxyethyl methacrylate). This benefited both the contact lens and intraocular lens industries.

When HEMA is placed in an aqueous solution, it absorbs a significant amount of water becoming a soft hydrogel material. This hydrated material has enjoyed a great deal of success as a soft contact lens material, as it is very flexible, yet tough enough to withstand daily handling. Unfortunately, the uptake of water lowers the refractive index, to a point where it is not suitable for use as an IOL material. However, if PMMA and HEMA monomers are combined then the water content of the resulting copolymer can be controlled by varying the levels of each monomer. Such copolymers have the potential for use in foldable IOLs, provided a balance is achieved between having sufficient water content to give the flexibility to allow a lens to be folded, as well as a low enough content to retain a high refractive index. This permits the lens design to remain thin enough to be folded and easily implanted into the eye.

Contamac has developed an IOL material that achieves this balance of flexibility and refractive index. The CI26 material is named after the equilibrium water content of the copolymer. It combines the best properties of these two polymers so extensively used in the ophthalmic field. It has the stability and machining characteristics of PMMA and thanks to the inherent water content it also has the flexibility of HEMA. The refractive index is, however, much higher than that of HEMA and closer to that of PMMA.

Material producers have access to a wide variety of raw materials, offering different levels of quality and purity. The purest monomers are usually the most expensive, as might be expected. By using the highest purity HEMA available, the level of any impurities contained in the HEMA is kept to a minimum. Methacrylic acid is such an impurity and is always present in HEMA. Its presence has been suggested as a contributing factor in the post - implantation calcification and subsequent opacification of IOLs. Therefore, keeping its content to a minimum through use of the highest purity HEMA is crucial in material manufacture.

IOL Material Manufacture

Intraocular lens materials are produced by the polymerisation of liquid monomer components. This process requires heat to initiate the process and this is typically achieved by conducting the polymerisation in heated water baths. The polymerisation is an exothermic reaction, meaning it generates an amount of heat once started.
This heat build up can be significant and result in a measurable increase in bath temperature. At Contamac we have a unique bath design that includes a cooling facility for controlling precisely the bath temperature throughout the polymerisation reaction. This enables more consistent blanks to be produced since the heat build up can effect the polymerisation reaction.

Two essentially different methods exist in the manufacture of material for use in IOLs. These are generally referred to as rod polymerisation and button polymerisation.

In rod polymerisation, the liquid monomers are dispensed into plastic tubes, which are then capped and placed into a heated bath. The material then undergoes a heat initiated polymerisation reaction that usually takes several days. A relatively long polymerisation time is required since the mass of polymer being produced is quite large. If such a reaction is performed quickly, the resulting polymer can be inconsistent and contain regions of stress. A disadvantage of a rod based polymerisation process is that there is always some air trapped at the top of the rod after filling. Oxygen inhibits a free radical polymerisation reaction by reacting with radicals and causing it to terminate. This results in softer material at the end of the rod that usually has to be discarded.

The second form of polymerisation is the button polymerisation process. This is Contamac's preference. In polymerisation, the amount of material made at any one time, as well as the method selected, is also an important factor in ensuring the quality. Generally, homogeneous polymerisation is best achieved with accurate temperature control of the smallest possible unit of material. In a button polymerisation process each individual mould cavity produces a blank through a precisely controlled polymerisation. The mould design also prevents air being present during polymerisation, which inhibits this process. This type of polymerisation produces blanks that are free of stress and very consistent. Together with our insistence on maintaining the ideal balance of refractive index and flexibility, which is controlled by the water content of the material, our unique manufacturing process ensures finished products that have become the choice of discerning lens manufacturers worldwide.

Lens Designs and Surgical Procedures Today

Since the first cataract operations with implantation began, lens designs and surgical procedures have continuously advanced. Improved IOL materials have helped make these advances possible, while phacoemulsification has enabled the evolution of small incision surgery for cataract removal and replacement. Cataract surgery now involves a 1.5 - 3 mm incision and instead of eight or ten sutures, patients usually need none. IOL material improvements have led to flexible folded lenses that fit through the small incision and are unfurled once within the eye. These lenses restore good peripheral vision and depth perception with minimal distortion and magnification. Patients can go in for cataract surgery in the morning and be home by the end of the day. Good visual acuity returns almost immediately and people return to their normal activities within days, if not hours. There is no need for the unwieldy post - operative glasses of past times.

One consequence of the interactive advancement in IOL development and surgical technique has been that patients today need no longer wait for long periods, with diminishing vision, while cataracts 'ripen' or mature. When Ridley's original IOL work began in the 1940s, the number of cataract operations carried out annually in Britain was estimated at 30,000. Now, this has increased tenfold. The relative ease and precision of IOL surgery today has also made possible the expansion of crystalline lens removal beyond the boundaries of cataract into the new territory of clear lens exchange. This means pre-cataractous, but ageing lenses exchanged for IOLs, which have a variety of properties, from blue light filtering to simulated accommodation, built into their design.

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