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Special Report

# Real-world uptake of an innovative pupil expander device for cataract surgery: Implementation lessons learnt

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**Cataract surgery in the eyes, where the pupil does not dilate despite using eye drops, is fraught with vision-threatening complications. About 11 per cent of eyes undergoing cataract surgery have non-dilating, small pupils. The increasing prevalence of benign prostatic hyperplasia (BPH), hypertension, diabetes and medications used for the same are the contributing factors. The recent Food and Drug Administration (FDA) approval for the use of miotic agents in the treatment of presbyopia will lead to a further rise in the number of non-dilating pupils. While pharmacological agents and other methods have been used, mechanical pupil expander devices are the only fail safe option. However, available devices had a steep learning curve and limitations which made them difficult to use, unpredictable and unsafe. With its patented single plane, hexagonal, notches and flanges design, the US FDA registered B-HEX Pupil Expander (Med Invent Devices Pvt. Ltd., India) overcame these limitations and fulfilled an unmet need. The B-HEX is machinable, rapidly produced, consistent, easy to use, safe, and affordable. Despite such advantages, implementation hurdles have restricted its availability to healthcare systems worldwide. Peer acceptance has been steadily growing, with the B-HEX becoming the market leader in India, as evidenced by numerous publications, videos and papers presented at international conferences and comments from opinion leaders endorsing its use. However, impractical regulatory requirements and resource constraints remain a great impediment to the global distribution of this novel invention. This has denied many patients the benefits of a superior and more affordable option. Though value continues to be added to the B-HEX by maintaining a strong intellectual property portfolio with internationally granted Patents and Trademark, increasing its user base, and garnering support from key opinion leaders, only a collaboration with the right partner will help scale up the global reach and make it a leader in the global market.**

**Key words** Innovation implementation - pupil expander - non-dilating pupil - small pupil - cataract phaco

## Introduction

Cataract extraction is one of the most common surgeries performed on the human body[1]. Phacoemulsification (Phaco) with intraocular lens implantation is the standard of care. For a safe surgery, it is necessary to have a wide view of the cataractous lens. This is achieved by dilating the pupil with eye drops. Annually, 30 million eyes undergo cataract

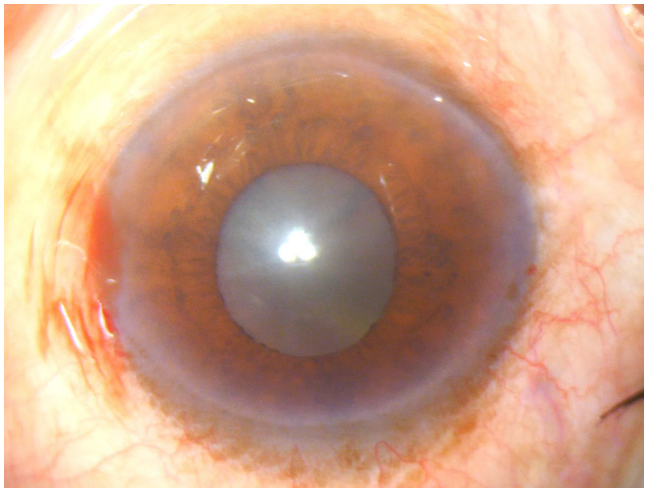

**Fig. 1.** A representative image showing a non-dilating small pupil that has not dilated beyond 4-5 mm despite the use of pupil-dilating eye drops.

surgery worldwide[2]. Of these, in about 11 per cent of eyes, the pupil does not dilate despite using dilating eye drops[3]. A non-dilating pupil can lead to serious vision-threatening complications. Reasons for non-dilatation include senile miosis, pseudoexfoliation syndrome (PXF/PXE), diabetes, intraoperative floppy iris syndrome (IFIS), uveitis, miotic treatment for glaucoma, trauma, and iridoschisis. IFIS is characterized by unpredictable progressive pupil constriction (intraoperative miosis) during surgery, which catches the surgeon by surprise[4]. Though initially associated with tamsulosin intake for prostate hypertrophy, risk factors for IFIS now include hypertension, finasteride, other alpha1-adrenergic receptor antagonists, angiotensin II receptor inhibitors, anti-hypertensive drugs, benzodiazepines, antipsychotics, and decreased dilated pupil diameter[5]. Thus, not only can many conditions lead to a non-dilating small pupil, this cannot even be predicted beforehand. Therefore, it is imperative that eye surgeons are equipped with the necessary knowledge, skills and devices for every cataract surgery.

## The growing unmet need

Combination mydriatics and local anaesthetics, viscomydriasis, pupil stretching, sphincterotomy, iris hooks and pupil expanders have been used to dilate a non-dilating pupil[5]. Of these, only mechanical devices like iris hooks & pupil expanders (pupil expansion devices) are fail safe. However, iris hooks require four additional incisions, increasing the risk of infection and leading to overstretching of the pupil margin, causing iris sphincter damage. These hooks move the pupil plane anteriorly, rendering the iris vulnerable to injury by instruments. Pupil expanders are resiliently flexible rings of fixed circumference which engage to the pupil margin and cause mechanical dilatation. The Malyugin ring, made from polypropylene suture[6], has scrolls, and the 'I-Ring', made of polyurethane[7], has pockets that engage to the pupil margin. The scrolls or pockets at the sides of these devices make them bulky and are a hindrance to smooth passage through slit corneal incisions used in phaco surgery. Engaging them to the pupil margin is challenging as the gaps in the scrolls and pockets at the sides are difficult to visualize through the operating microscope. Twisting unpredictably causing iris damage and breakage of the glued joint have been reported with the use of Malyugin ring[8]. With a steep learning curve and associated risks, there was an unmet need for a safe and easy pupil expander. Since the cost of these devices was also prohibitive, patients' safety and visual outcome were being compromised for the want of an easy to use and affordable device.

Incidence of non-dilating pupils is on the rise due to an alarming increase in the prevalence of benign prostatic hyperplasia (BPH)[9] and common use of alpha1-adrenergic receptor antagonists in its management[4]. Increasing prevalence of hypertension[10] and diabetes[11] are contributing too.

In 2021, the Food and Drug Administration (FDA) approved a miotic agent, pilocarpine 1.25 per cent drops, for the management of presbyopia[12]. This is expected to cause a significant increase in the number of non-dilating pupils when these patients undergo cataract surgery after a few years.

## The invention

The biplanar design of the scrolls or pockets was the principal limitation of existing devices. Also, the injector was used only to circumvent this problem and did not offer any convenience to the surgeon. In fact, the injector restricted direct control during engagement and release of the device to the pupil margin.

It was hypothesized that a thin and uniplanar device would overcome the limitations of existing pupil expanders. Nylon (polyamide) is resiliently flexible and springy in nature. Its thermoplastic properties allow it to be shaped desirably in a baking oven at home. Thus, the homemade 'Bhattacharjee Ring' was born[13]. It was made from nylon suture, with notches and flanges, all disposed in a single plane. It evolved from an open ring design to the closed ring hexagon. Conventionally, a pupil that does not dilate beyond 5 mm, is labelled as a non-dilating, small pupil (Fig. 1). Alternate flanges of

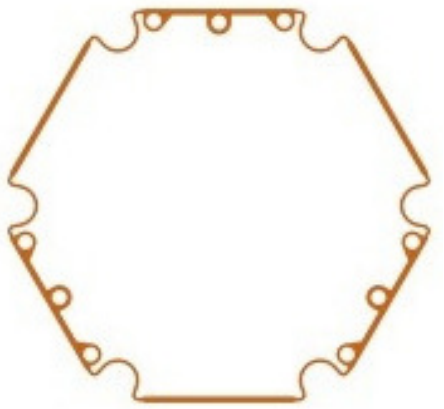

**Fig. 2.** The thin B-HEX Pupil Expander with notches and flanges disposed entirely in a single plane. Alternate flanges have 'tabs' which help in identification and holding during engagement to the pupil margin.

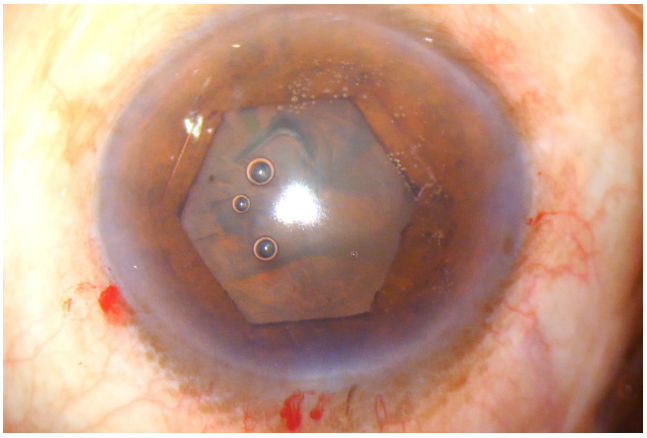

**Fig. 3.** A representative image showing the previously non-dilating pupil now expanded to a 5.5 mm hexagonal shape using the B-HEX Pupil Expander.

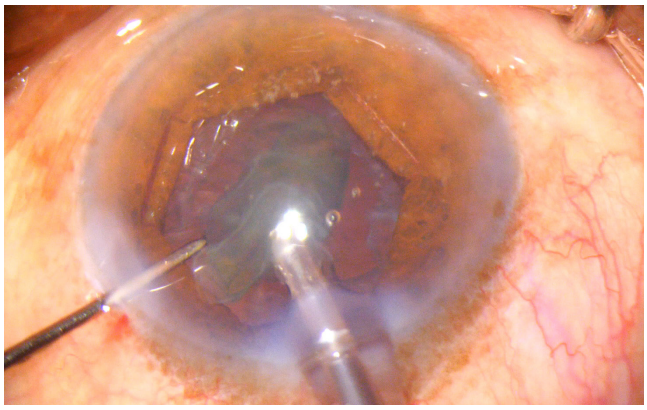

**Fig. 4**. Pupil showing safe Phaco surgery through a pupil expanded to an optimal size of 5.5 mm using a B-HEX Pupil Expander.

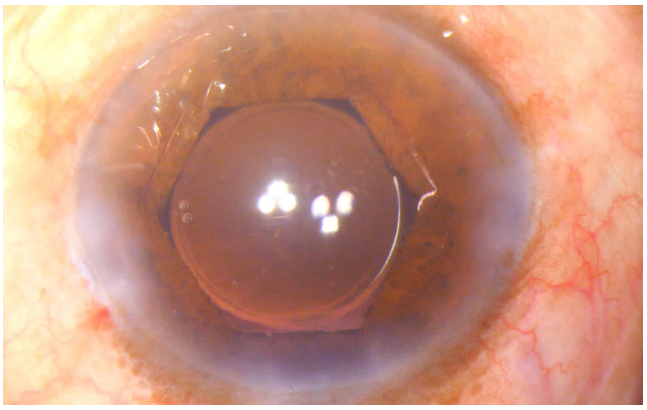

**Fig. 5.** Pupil showing that the 5.5 mm expanded pupil is adequate for safe implantation of the Intra Ocular Lens (IOL).

the 'B-HEX Pupil Expander' (Fig. 2) are tucked under the pupil margin. Figure 3 shows the alternate flanges of the B-HEX Pupil Expander tucked under the pupil margin to result in a hexagonal expanded pupil.

In 2013, the Indian Patent and Patent Cooperation Treaty (PCT) application was filed[14] and based on the inputs obtained from a large number of experts and opinion leaders, the commercial version, the B-HEX Pupil Expander (Med Invent Devices Pvt. Ltd., Kolkata) with a simple machinable design, made of polyimide, was launched in 2017[13]. By 2018, the patent was granted in all jurisdictions in which it had been filed, including India, USA, Europe, Canada, Japan, Australia, China and many other countries[14].

## Implementation hurdles

*Acceptance*: Resistance to change is a common reason for poor uptake of any new invention. The plausible reasons and remedies used in this context were: *(i)* the square pupil produced by the four iris hooks perceived as the best shape for a pupil expander. However, geometrical concepts and publications in peer-reviewed journals[8] ushered the understanding among the users that size for size; a hexagon is more efficacious, safe and practical than a square (Fig. 3) *(ii)* The Malyugin ring being the first mover, had the injector well accepted by its users. Nonetheless, research publications proved that the injector was only a means to an end, without offering any real advantage and the direct control provided by the 'B-HEX 23G Forceps' made usage easy and consistent *(iii)* The 5.5 mm pupillary expansion provided by the B-HEX appeared inadequate compared to the larger pupil expansion provided by iris hooks and the 7 mm version of the Malyugin ring. Practice documentations underline that a 5.5 mm pupil is optimal for safe phacoemulsification (Fig. 4) and Intra Ocular Lens (IOL) implantation (Fig. 5) and also preserves the integrity of the pupil sphincter (Fig.

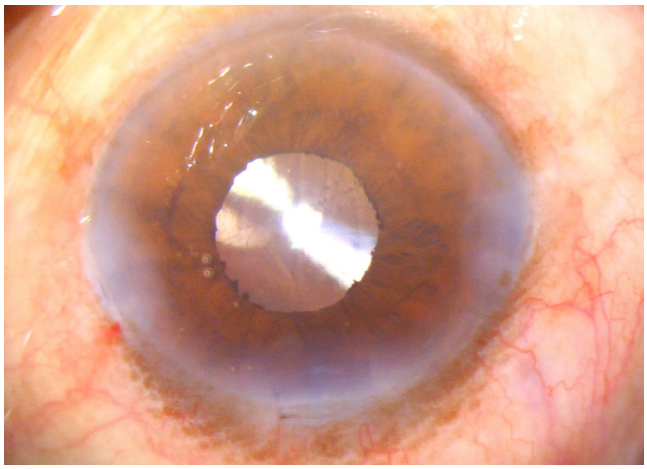

**Fig. 6.** Pupil showing the restored round shape after removal of the B-HEX Pupil Expander. This round pupil indicates that the pupil sphincter is undamaged and that its function is fully preserved.

6). A larger pupil required a larger device which was unwieldy in the anterior chamber.

*Production*: Med Invent Devices Pvt. Ltd. is a startup incorporated in 2016 to commercialize the B-HEX pupil expander. Manufacturing the B-HEX ring requires high-precision LASER technology, which is unavailable in India. At times, import regulations and costs may appear restrictive for a startup. Since owning a manufacturing facility for a single medical device is not cost-effective, Med Invent Devices Pvt. Ltd. had to depend on medical device contract manufacturers for sustenance.

*Regulatory*: The regulatory landscape in most countries is often challenging towards a lean startup which owns intellectual property but does not have a manufacturing facility. The startup company owning the product must comply with the regulatory standards and financial commitments of a full-fledged manufacturing facility without owning one. However, the US FDA allows a company that develops specifications for a device that is distributed under the establishment's own name but performs no manufacturing to register as a 'Specification Developer'. The B-HEX Pupil Expander and B-HEX 23G Forceps have been US FDA-registered since 2020. This allowed exports to some countries. Complicated regulatory laws, prohibitive costs and long wait times have not allowed the B-HEX to be registered under agencies such as EU MDR (CE marking), MHRA (UK), PMDA (Japan), Health Canada, TGA (Australia), NMPA (China), ANVISA (Brazil) *etc*. This has restricted exports to a large direct market and to other indirect markets where these regulatory compliances are considered the standard.

*Marketing & sales*: Resource limitations typically restrict marketing and promotion spending. Maintaining a marketing and sales team on the payroll for a single product is not feasible. Hence, sales are typically managed by a startup and through a network of distributors who work on margins, as in Med Invent Devices Pvt. Ltd.

## Overcoming implementation hurdles

Strategically, value has been and continues to be added to the B-HEX Pupil Expander through clinical trials[15], patents[13], trademarks[16], regulatory approvals, commercialization, testimonials from opinion leaders and peers, *etc*. There has been significant traction, and the stage is set for a larger company to acquire the product and scale up.

With granted patents in India, USA, Canada, Japan, Germany, Italy, France, Spain, UK, Netherlands, Australia, China, Singapore, Korea, Hong Kong, Switzerland and Lichtenstein[13], and with a registered trademark in India, USA, 27 countries of the European Union, UK, Australia, Brazil, Japan, Korea, Singapore, Switzerland, Norway, Philippines, Canada, Israel, Russia, Greece, Turkey, Vietnam, Indonesia and Mexico[16], a large global market for single use disposable medical device in cataract surgery is available for the B-HEX Pupil Expander. However, its extensive usage[17-25] is what will determine its real-world uptake and successful implementation.

*Evidence of uptake*: The uptake of indigenous technology marketed by a startup may still be viable nationally. For instance, the Indian Railways, the Indian Army, and Central and State government hospitals are prominent institutional users of B-HEX. Additionally, private eye hospital chains like Sankara Nethralaya, LV Prasad Eye Institute, Aravind Eye Hospitals, Disha Eye Hospitals, Centre for Sight Eye Hospitals, Sharp Sight Eye Hospitals, Dr Agarwal's Eye Hospitals, Eye 7 Hospitals, ASG Eye Hospitals etc. are all regular users. Charitable hospitals, group practices, and individual eye surgeons form a significant part of the customer base and have also been open to incorporating this innovation into practice.

## Conclusions

Despite implementation hurdles, the B-HEX Pupil Expander is a success because an unmet need was

fulfilled, and users were willing to pay for it. It is also an example of how a frugal invention can be developed and patented by an individual private practitioner and then commercialized by a lean startup founded with limited resources. A collaboration with a government organization or private company is the next step to scale up and make it a global success.

Large corporates and the organized sector have deep pockets and unlimited resources to fulfill extensive regulatory requirements on medical devices. The lessons learnt from this mobilization of the B-HEX Pupil Expander for uptake suggest that though Government and private institutional hand holding schemes are available, there is a need for all stakeholders to understand that regulatory policies must have a provision for individual inventors and start up companies, so as to maximize the gains from innovations from these avenues. Lastly, over regulation should not obstruct the uptake and implementation of meaningful innovations.

***Disclosure regarding patients' consent*:** Patient's consent was obtained for collecting information and producing images with maintenance of privacy and confidentiality for use in research/ academic purposes.

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***Conflicts of Interest*:** The author Dr Suven Bhattacharjee is the inventor of the B-HEX Pupil Expander and the Founder & Director of Med Invent Devices Pvt. Ltd. He has assigned his patents to Med Invent Devices Pvt. Ltd. and gains financially from the company.

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