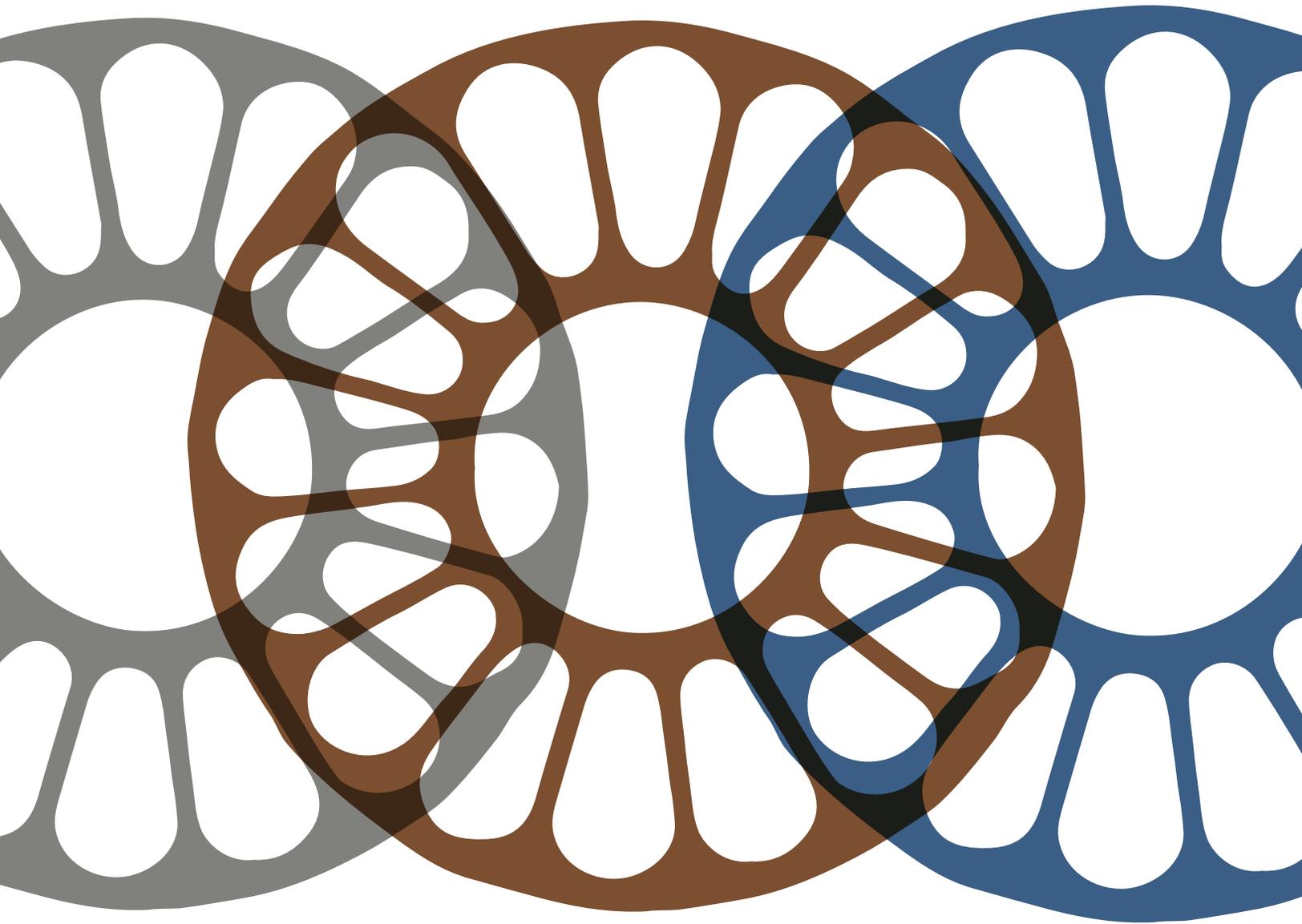


BOSTON KPro *news*

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The Future of Boston KPro

James Chodosh, MD, MPH

The year 2020 has been calamitous for all of us. Due to the COVID-19 pandemic and ensuing cessation of elective medical care in the U.S. and across the world, most Boston Keratoprosthesis (KPro) surgeries were delayed or cancelled. Our scheduled audits had to be completed online, and our workforce could only be on site briefly each week. Fortunately, we were able to retain all of our staff and are now back to work.

We continue to innovate to make the Boston KPro better, safer, and more user friendly. Last year, we received approval from the U.S. Food and Drug Administration for the Boston KPro Type I, Lucia design. Designed by Eleftherios Paschalis, PhD; John Graney; and me, this two-piece KPro has the traditional PMMA optic and titanium back plate components, but its design improves postoperative cosmesis and reduces costs. The petal-like slits in the back plate (Figure 1), an improvement over the previous design's circles, provide a more physiologic look and increase the overall corneal surface area in touch with aqueous humor. The Lucia back plate is less expensive to produce, which may help offset the ever-increasing regulatory costs of medical device registration and compliance. A critical next step, likely to be in place by the time this article publishes, is the addition of brown or blue to the back plate to mimic a natural eye color. This is accomplished by anodization, a process that oxidizes the titanium surface in a controlled fashion (Figure 2).

We are also considering reducing the available lens powers to two options: pseudophakic and aphakic, with the latter power set to the median axial length in past Boston KPros (23.5 mm). For recipients with a residual refractive error, this would make contact lens or spectacle correction necessary for best vision. Moving away from individual aphakic axial length choices will simplify production and allow us to move from a lathed to a molded front plate. Currently, the anterior refractive surface of the Boston KPro is spherical. The use of a mold would facilitate adding asphericity to the front surface, which would improve vision quality.

Finally, we are closer to a ready-to-use KPro that is preassembled, irradiated for sterilization, supplied at room temperature, and can be ordered in bulk.



Figure 1. KPro Type I, Lucia design *in situ*.

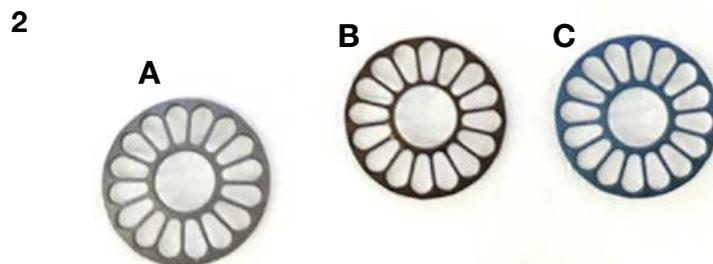


Figure 2. Lucia titanium: (A) nonanodized, (B) brown anodized, and (C) blue anodized.

Long-Term Glaucoma After Boston KPro

Claes Dohlman, MD, PhD; James Chodosh, MD, MPH; Larisa Gelfand, MEd; and Eleftherios Paschalis, PhD

Glaucoma is *the* most consequential and severe complication following Boston KPro surgery and is the main reason for the long-term visual attrition frequently reported from the “real world.”^{1,2} The eye with a KPro following alkali burn is particularly vulnerable. In this respect, KPro is not unique—the glaucoma complication is, to a lesser degree, shared with other corneal surgeries or traumas.³ The impact of glaucoma after such acute events, although well documented in the clinical literature, has most likely been underestimated by our profession due to its often delayed manifestation—frequently many years.

The glaucomatous damage after corneal surgery or trauma has invariably been blamed on elevated IOP (even if modest or even absent), often caused by the aqueous outflow obstruction during the recovery phase. However, recent animal experiments have pointed to the possibility of a very rapid, inflammatory (cytokine), IOP-independent pathway to glaucoma.³ Thus, inflammatory cytokines, especially tumor necrosis-alpha (TNF- α) that are generated anteriorly by the surgery, seem to rapidly diffuse posteriorly and, within hours or days, result in retinal damage, including apoptosis of the ganglion cells (the hallmark of glaucoma).⁴⁻⁶ Antibodies against TNF- α , such as infliximab (Remicade®), adalimumab (Humira®), are remarkably protective of the ganglion cells and promise great value prophylactically, if instituted promptly, against the later “time bomb” manifestation of glaucoma.^{3,4,7}

In addition, it has recently been shown that Boston KPro patients can have elevated TNF- α values in the blood years after the operation, which may indicate a need for sustained TNF- α antibody treatment to prevent glaucoma and other complications.⁸

To facilitate prolonged TNF- α antibody delivery to the eye, a drug-eluting device placed subconjunctivally in the eye has been designed.⁹ In rabbits with alkali burns to the cornea, it was demonstrated that use of such a device, loaded with only 85 μ g infliximab, significantly reduced ganglion cell apoptosis over a month.¹⁰

The full relevance of these insights are not yet entirely clear. We are continuing experimental work to determine the most effective and least toxic biologic drug, as well as optimal doses, delivery site, and duration of treatment. However, we suspect that KPro surgeons may already want to apply more prompt, powerful, and sustained anti-inflammatory medications postoperatively than have been customary in the past.⁶ The current mainstay are corticosteroids, but

their doses cannot be safely increased due to well-known complications, especially their effect on wound healing following corneal surgery. Therefore, powerful and relatively safe biologics will likely supplement them in the future.

There are still obstacles to overcome, including the cost of the biologics, lack of coverage by insurers, and regulations, but the latter should be less of a problem. These obstacles may force us to use inexpensive, well-tested steroids while we wait for affordable biologics.

If a patient is diagnosed with glaucoma preoperatively, the surgeon should consider a valved drainage device (Ahmed or similar) before or simultaneously with KPro implantation.² If the patient does not have a history of glaucoma, then pressure-lowering medication can be given prophylactically. Glaucoma drops may be impractical, but carbonic anhydrase inhibitors might be used to titrate the IOP down to a safe level, and keep it there for months.¹¹

Thus, it seems that more aggressive prophylactic anti-inflammatory medication is warranted following Boston KPro surgery, with emphasis on biologics, prompt initiation, and sustained delivery. In addition, prophylactic IOP-lowering medication, regardless of the initial pressure, may also have long-term protective effects against devastating glaucoma.

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Twelve Years in the Desert With Boston KPro

Roberto Pineda, MD

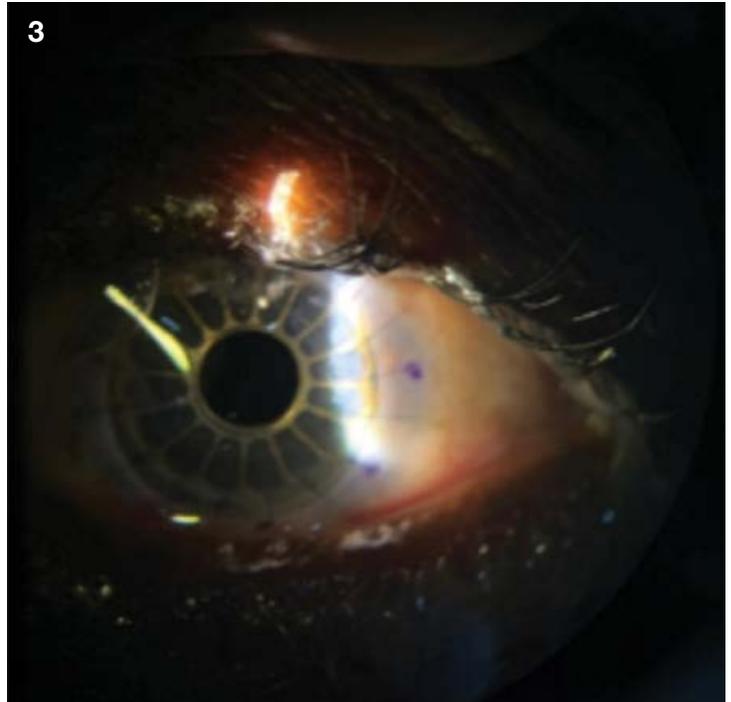
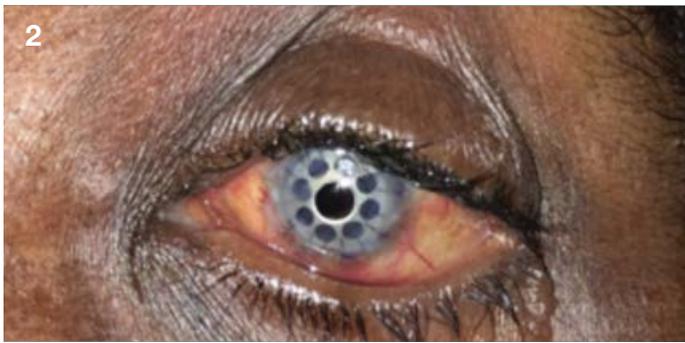


Figure. 1 A patient who received a Boston KPro with an autologous cornea as the carrier (2010).

Figure. 2 A patient with the Boston KPro Lucia design with a gamma-irradiated cornea (2017).

Figure. 3 A patient with the most recent Boston KPro Lucia design, which has an anodized backplate (2019).

This past February, I returned to Makkah Eye Complex, a tertiary eye center in Khartoum, North Sudan, supported by the Al Basar Foundation. The trip coincided with the Sudanese Ophthalmological Society's 21st Biennial International Scientific Conference, where I presented on my experience in Sudan over the past 12 years. The principal reason for my trip was to perform six Boston KPro surgeries.

In 2008, I introduced the device to my international colleagues after being invited by Dr. Khalid Al-Arfaj, a Saudi ophthalmologist who had completed a research fellowship at Mass. Eye and Ear. That year, we developed a guide for international ophthalmologists, which included criteria, screening tools, and recommendations for the selection and postoperative management of patients receiving Boston KPro implants. Most of these patients had advanced trachoma, limbal stem cell deficiency from severe vernal keratoconjunctivitis, or chemical injuries. The enthusiastic group of cornea specialists at the Makkah Eye Complex quickly learned to perform the surgery and manage patients postoperatively.

In later years, we shared modified versions of the Boston KPro and followed up with patients who had previously received a Boston KPro. Several of the Sudanese doctors published papers on their experiences with the device. In 2010, we published a paper in the *Archives of Ophthalmology* on using an ipsilateral autologous cornea as the carrier for the Boston KPro, a more sustainable method because of reduced costs (Figure 1). We also used gamma-irradiated corneal grafts. In 2017, we shared the Boston KPro's Lucia design, which was developed at a lower cost to allow for greater global access (Figure 2). In 2019, we introduced the most recent Boston KPro Lucia design with the anodized backplate (Figure 3).

Overall, the Sudan project has been successful. Some patients have experienced complications such as endophthalmitis, extrusion, and retinal detachments. However, the functional vision of many patients has been restored allowing them to see their families and pursue productive lives. I will continue to enthusiastically return to Sudan as part of my professional commitment to global ophthalmology.

Distinguished Boston KPro Surgeons



Wei Chen, MD, PhD

Dr. Chen is Vice-Chair and Professor of Ophthalmology at Wenzhou Medical University in China. He earned his MD from Wenzhou Medical University in 1998 and a PhD from Shanghai Fudan University in 2002. Dr. Chen was trained as postdoctoral research fellow at Schepens Eye Research Institute of Mass. Eye and Ear and the Ocular Surface Center at Baylor College of Medicine.

He established a Boston Kpro surgery center in the Eye Clinic of Boao Super Hospital, the only hospital in China that can legally use any FDA- or CE-approved medical device or pharmaceutical without approval from China. Along with Drs. Liqiang Wang and Yifei Huang, he has performed 26 Boston KPro Type II surgeries on patients with Stevens-Johnson syndrome and severe chemical burns using the autologous auricular cartilage reinforced technique. In 2018, he gave a lecture on *The Boston Keratoprosthesis Type II in the Management of Stevens-Johnson Syndrome* at the Asia Dry Eye Society meeting in Japan.



Ali Haider, MD

Dr. Haider, a cornea specialist based in Kentucky and Indiana, serves as President of Haider Eye Care, Louisville Cornea and Madison Eye Center. After finishing his fellowship under the mentorship of James Aquavella, MD, at the University of Rochester, he was appointed Director of the Cornea Division at the University of Louisville, where he served for three years. Since 2009, he has been heavily involved in using the Boston KPro to treat corneal blindness. In 2011, he founded World Sight, an organization that provides eye care to underserved areas in Africa, Asia, and the Middle East. Dr. Haider has taught and lectured about the Boston KPro around the world.



Bilal Faiz Khan, MD

Dr. Khan is Professor of Ophthalmology and Dean of Academic Affairs at United Medical and Dental College in Karachi, Pakistan. He is also the Chairman of the Department of Artificial Cornea. After graduating from the Aga Khan University in Pakistan, Dr. Khan completed a research fellowship on the Boston KPro under Dr. Claes Dohlman, followed by residency training and a Cornea, Refractive Surgery and External Disease Fellowship at Mass Eye and Ear. As a research fellow with Dr. Dohlman, he was involved in the designing and manufacturing of the Boston KPro, as well as setting up the initial large scale manufacturing process at the JG Machine Company.

Dr. Khan returned to Pakistan as the country's first cornea fellowship-trained specialist and was the first to start using the Boston KPro. His patients mostly present with acid burns, bomb blast injuries, and infections. As one of the few cornea specialists in the country, Dr. Khan also sees 350 patients with Stevens-Johnson syndrome, many of whom benefit from corneal reconstructive surgery. His research interest is in trying new ocular surface lubricants for the prevention of severe corneal abnormalities. He plans to use the Boston KPro Type II in severe dry eye patients. In the future, Dr. Khan hopes to teach more ophthalmologists about the Boston KPro.

Dr. Khan established the United Medical and Dental College nine years ago. Ranked among the top 15% of medical colleges in the country, the college has a strict merit-based

admission policy with no discrimination based on gender, religion, or ethnicity. As the name suggests, its mission is to bring students and faculty from diverse regions and backgrounds to a single, scientifically progressive educational environment.

Dr. Khan also established a free-of-cost 500-bed multidisciplinary tertiary care hospital, The Creek General Hospital in Karachi. The hospital offers both undergraduate and postgraduate training programs. With a patient load of over 125,000 per year, the hospital staff have treated over 700,000 patients free of cost since it opened eight years ago.



Pavel Stodulka, PhD, FEBOS-CR

Dr. Stodulka is a founder, chief surgeon, and CEO of Gemini Eye Clinics in the Czech Republic and Vienna, where he performs over 30,000 surgeries annually. An innovative surgeon, he was the first in his country to perform LASIK (1994), FemtoLASIK (2006), MICS (2001) and Femtocataract (2012); and the first in the world to implant a presbyopic diffractive phakic IOL (2014), perform CAPSULaser capsulotomy (2015), implant a hydrophobic version of the trifocal FineVision IOL (2016), and a presbyopic collagen corneal inlay that he designed (2018). Dr. Stodulka has been able to restore the vision of several patients, each blind for many years, with the Boston KPro. Among his patients was a man who was blind for over 53 years, the longest case of blindness ever cured in the Czech Republic.



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Translational Research



James Chodosh, MD, MPH
Surgery, Translational
Research



Roberto Pineda II, MD
Surgery, Clinical Research



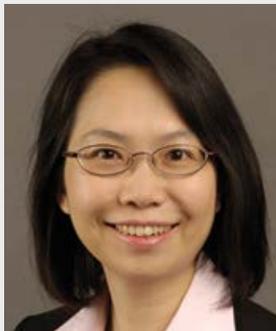
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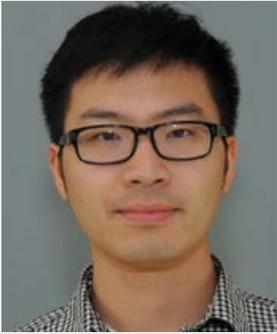


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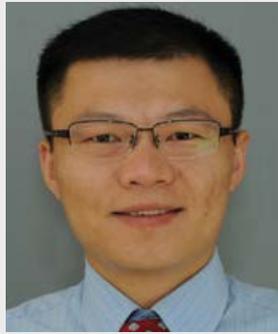


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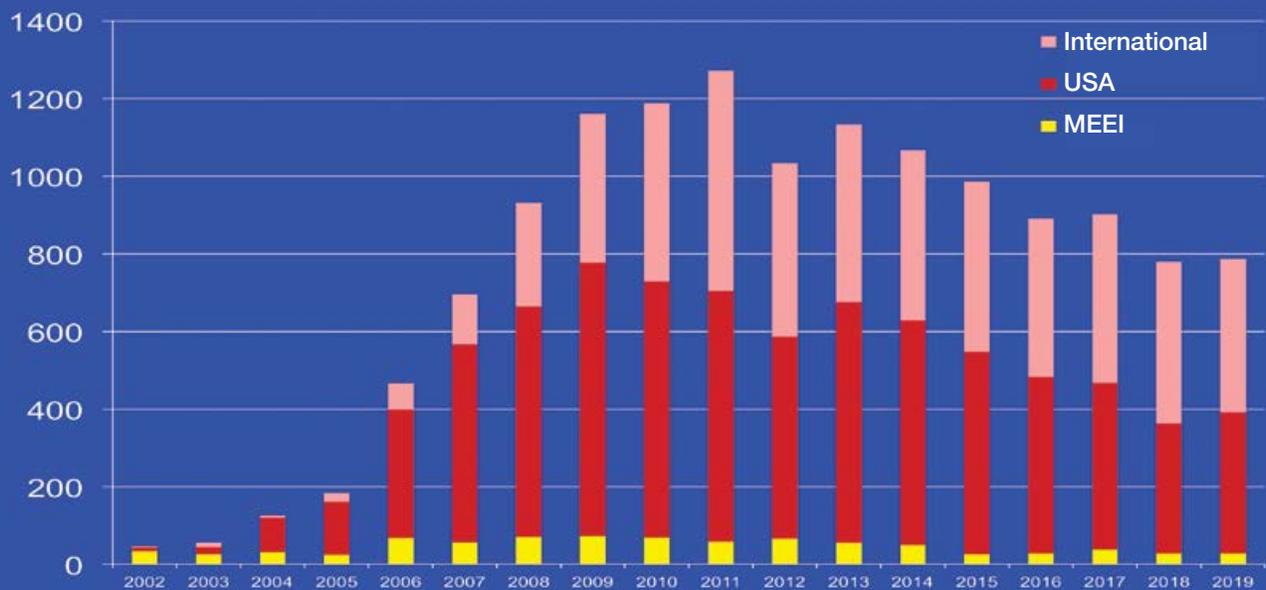
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Boston KPro Lucia Design



Boston KPro (about 15,000 implanted)





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