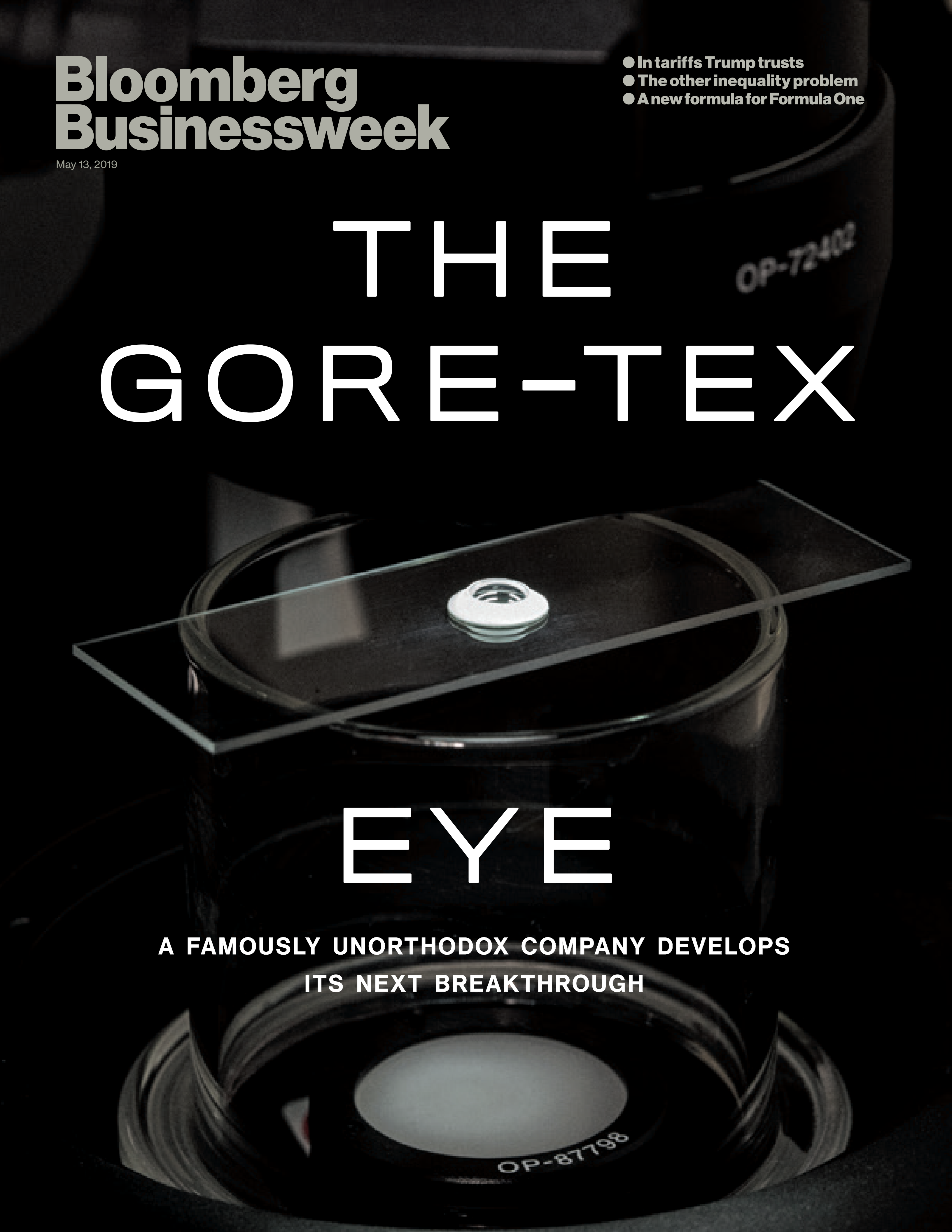
Bloomberg Businessweek

May 13, 2019

- In tariffs Trump trusts
- The other inequality problem
- A new formula for Formula One

THE GORE-TEX EYE

A FAMOUSLY UNORTHODOX COMPANY DEVELOPS ITS NEXT BREAKTHROUGH



They're Coming For Your Eyeballs

W.L. Gore, one of the world's most innovative companies, is hunting for new product lines—and reinventing itself in the process

By Drake Bennett
Photographs by Jeremy Liebman

▲ Gore cornea lens held over a Gore-Tex jacket

Scrubbed in and gowned, Esen Akpek perches on a stool over a surgical table, her blue-gloved hands miming the procedure she's about to perform. In front of her, fixed in the beam of her operating scope, the eye of an anesthetized female rabbit bulges through a slit in a surgical drape. A video screen mounted near Akpek's head shows the feed from the scope: the albino eye, lids pried open, glares out like the Eye of Sauron.

Akpek is a professor of ophthalmology at the Johns Hopkins University School of Medicine in Baltimore. One of her specialties is corneal replacement, in which she substitutes the thin, transparent layer at the front of the eye with a donor or artificial one. Compared with the retina's specialized neural network or the iris's quicksilver diaphragm, the cornea is a simple piece of biological equipment. Its clarity allows light to enter the eye, and its curvature helps focus that light onto the retina, where it becomes the images we see. But the cornea's simplicity belies its importance. Damage to it, through disease or trauma, renders millions of people sightless—a 2017 study in the *Lancet Global Health* ranked this the fifth-leading cause of blindness. Today's operation is a test of a promising artificial cornea.

The procedure begins with Akpek suturing a thin metal ring to the veined, white sclera to hold the eye in place. With a custom stamp, she inks on a gunsightlike grid to guide the incision. Then, with a cylindrical blade and scalpels, she begins to excise the cornea. Occasionally she narrates the procedure. "I like this one," she says of a concave cutting tool—a "spoon thing," she calls it, in her Turkish-accented English. Onscreen her movements are decisive and quick; observed directly they're more twitches, the gestures of a ringmaster directing a flea circus.

It's a routine that normally doesn't have much of an audience, but Akpek's operating room is bustling. A chemical engineer named Anuraag Singh takes notes, asks questions, and suggests tweaks. A suspendered physicist named Thomas Schmiedel monitors an optical coherence tomography display showing a cross section of the cornea. From time to time Akpek will ask him to help orient her; at some moments he'll chime in unasked. Two other engineers mostly observe, speaking quietly.

All four men work for W.L. Gore & Associates Inc., the manufacturer best known for Gore-Tex, the waterproof membrane used in high-end outerwear. The company also makes air filters, headlight vents, heart stents, guitar strings, and more. Its membranes help batteries power electric cars. Its specially coated cables connect the electronics on the International Space Station. And it made the experimental implant Akpek is now folding, tacolike, with her tweezers and fitting into the rabbit's eye. If all goes well, the company will soon be making lots more of these. This is Gore's first foray into the eye, and success would provide a new market, a new mission, and, hopefully, new momentum.

In business school lecture halls and the "Management & Leadership" aisles of airport bookstores, Gore has long been lauded less for what it makes than for *how* it makes. Bestselling authors such as Jim Collins and Gary Hamel hail the privately held manufacturer as a paragon of organizational excellence—a workers' democracy where engineers unencumbered by shortsighted investors and middle managers perform feats of materials wizardry.

Yet Gore has lately entered corporate middle age, and it's proving vulnerable to the challenges presented by that stage of life. In the past decade, as the markets for its most successful products have matured, the company has reached "a stall point," as Jack Kramer, then its chief technology officer, put it in an interview last June. (He's since retired.) "We need a few big new things, a few big new spaces." To find these, one of the business world's favorite case studies is exploring what the business world has to teach it in turn.

In the late 1950s, Wilbert Lee Gore, a DuPont research chemist, became obsessed with a polymer called polytetrafluoroethylene. PTFE was by no means obscure: Discovered decades before at DuPont, it was commercialized in 1945 under the brand name Teflon. Renowned for its extraordinary slipperiness, it's also highly flexible, immune to ultraviolet radiation and extreme temperatures, minimally flammable, and chemically inert.

The carbon-fluorine bond is one of the strongest known to chemistry; in PTFE, a phalanx of fluorine atoms walls off a carbon spine. This structure prevents the polymer from reacting with other materials, whether it's an egg crisping in a nonstick pan or corrosive gas running through lined valves and pipes in the complex where the Manhattan Project enriched its uranium. "In a sense, it is the ultimate all-American material," Gore once said.

DuPont, however, was only interested in manufacturing the compound, turning translucent crystals of raw fluorite into resins that other companies could process into miracle coatings. In 1958, Gore quit his job and became a DuPont customer himself. He and his wife, Genevieve, headquartered their new company in the basement of their home in the Delaware farm country near Wilmington. W.L. Gore's earliest products were PTFE-insulated wires and cables, some of which found their way aboard the first communications satellites and, in 1969, went to the moon with Neil Armstrong and Buzz Aldrin.

In October of that year, the Gore family made its own giant leap. Bill and Vieve's eldest son, Bob, a chemical engineer and the company's head of research, set out to see whether PTFE could be stretched to cover more surface area, making it more cost-effective. In a lab at the company's plant in Newark, Del., he heated rods of the cloudy polymer and pulled carefully at each end. Time after time, the fluorocarbon barely stretched before starting to break. Finally, near the end of another fruitless day, he took a sample from the oven and winged his arms back in a frustrated jerk.

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To his shock, the material didn't snap. It stretched, and in a way that seemed to defy physics. Hoping for a 50 percent extension, he'd achieved something closer to 1,000 percent. And the PTFE didn't stretch the way stretchy things normally do, thinning out as it elongated. It telescoped, retaining its thickness. The expansion was internal: Folded molecular chains were yanked straight, opening up billions of microscopic spaces throughout. It was as though Bob had taken a piece of string cheese and, with a tug, transformed it into a rope of Swiss 10 times as long.

The new, air-filled polymer, dubbed expanded PTFE, promised much more than savings. Lighter and yet stronger than regular PTFE, ePTFE and its tiny pores proved perfect for capturing both helpful and harmful substances. Many engineering problems are about letting certain things in while keeping others out, and Gore's researchers swiftly set to policing the world's structural borders. Within a few years the company was making Gore-Tex air purifier filters and then prosthetic blood vessels for bypass operations. The polymer's pores provided a space for the recipient's own cells to grow into, while its chemical inertness reduced the risk of inflammation and infection. ePTFE's flexibility and resilience allowed the grafts to survive for decades in the high-impact environment that is the human body.

▲ Akpek in an operating theater at Johns Hopkins

The first Gore-Tex "waterproof and breathable" rain gear went on sale in 1976. Veteran backcountry hikers and skiers, Bill and Vieve Gore had long been aware of the limitations of existing raincoats, whose impermeable fabrics reliably kept out rain and snow but just as reliably left wearers damp with trapped perspiration. The structure of ePTFE offered a solution: The pores, though minuscule, were still hundreds of times larger than the individual molecules that comprise water vapor. Even the smallest raindrop, on the other hand, contains trillions of water molecules bound together. That meant evaporating sweat could easily pass through ePTFE, while rain could not. Gore chose not to make most of the clothing incorporating its technology, instead selling the membrane to licensees, which turn it into North Face parkas and Patagonia ski shells. The agreements strictly mandate how Gore-Tex is incorporated into the final products, ensuring, for example, that its logo is always visible.

Over time, Gore engineers became mad rolfers of ePTFE, perfecting a set of esoteric techniques to tune its molecular structure and, thereby, its capabilities. They learned how to make it stronger, or thinner, or as pillowy as meringue. They combined it with other polymers to make a fabric that allowed hazmat suits to vent heat and perspiration. They adjusted its pore size so it could hold particles of mercury-trapping carbon for Gore-brand smokestack filters. They created stents and surgical patches, high-tension ropes for deep-water oil rigs, and premium dental floss (a silky tendril marketed as Glide). The company grew and grew, crossing $1 billion in revenue in 1996, $2 billion in 2007, and $3 billion in 2012. Today it's at $3.7 billion.

For all ePTFE's uncanny versatility, though, Gore's leaders and admirers tend to credit human, not molecular, structure for the company's success. Its unique organizational approach was first codified in 1976, when Bob Gore took over as chief executive officer and his parents distributed a now-legendary eight-and-a-half-page memo to everyone at the company. Written by Bill, it set out the precepts that had shaped "our Association" since its founding.

With its references to the psychologist Abraham Maslow's hierarchy of needs and the zoologist Konrad Lorenz's work on animal aggression, the memo was an unlikely piece of writing to have emerged from the mind of a chemical engineer. The 20th century corporation, Gore argued, was at odds with human nature. As a species, we're aggressive yet loyal, improvisational and curious; we self-organize, intuitively acting on the same social instincts that governed bands of paleolithic hunter-gatherers. But when organizations grow beyond a certain size—Gore pegged the number at about 150 people—the resulting command-and-control ▶

◀ measures begin to ossify, strangling our innate sociability and drive.

Still, it was possible, he insisted, for a growing global business to run itself like a tribe. His vision was of a loose confederation of task forces that formed to take on different projects. For years after the memo was issued, the company would open a plant (the word it uses for all of its offices, even the few without manufacturing capabilities) whenever an existing one expanded past a couple of hundred workers. Associates didn't have assignments, they had "commitments." Bill called his model the lattice organization.

As Gore thrived, outsiders adopted similar approaches, to the point that corporations everywhere grew lousy with talk of flat management structures. And though it now counts 10,000 associates, Gore, too, has kept the faith. It does have bosses, including a CEO named Jason Field, and executives do make executive decisions. But Gore research teams still function like caucuses, with engineers signing on to projects that pique their interest and decisions still requiring consensus. Ideas live and die on collective enthusiasm; authority is temporary and contingent on the job at hand. The company routinely finds itself on lists of the best places to work, and its highly trained, eminently employable employees rarely leave—turnover in its North American offices is 2 percent. (By contrast, the Gore family itself has struggled with team dynamics, spending a decade embroiled in litigation after one of Bill and Vieve's five children, Susan, "adopted" her ex-husband in 2003 in an unsuccessful attempt to gain more company shares.)

But despite Gore's organizational flexibility, most of its firepower is focused on a single polymer. And competition is growing. A number of alternatives to Gore-Tex have made inroads into the market. A small materials manufacturer created eVent in 1999; fleece company Polartec LLC came out with NeoShell in 2010; Columbia Sportswear Co. released OutDry Extreme in 2016. And today an auto firm or appliance maker looking for a basic ePTFE membrane for one of its products can choose from a plethora of suppliers who will sell it for cheaper than Gore.

For a while, the company was leery of pursuing ambitious ideas that emerge from the lattice. The cornea implant actually dates to 2004, when Singh encountered a colleague, Gopalan Balaji, in the lunch line at a company event. Both are from India, a country plagued, like much of the developing world, by a lack of eye banks. Corneal blindness seemed to them like something Gore could and should tackle: The few artificial corneas on the market are difficult to implant and prone to complications. "There's millions of people outside the U.S. who are blind," Balaji told Singh. "We have unique materials. We have done this kind of work. What do you say?"

They recruited Schmiedel, an optics specialist, and reached out to Akpek at Hopkins. But the project fizzled. Like DuPont a half-century before, Gore's leadership didn't want to gamble on an unfamiliar new market, and the idea was shelved.

▲ Testing outdoor gear at a Gore lab in Elkton, Md.

Four years ago, under the direction of then-CEO Terri Kelly, Gore began looking for ways to take more chances. The company has traditionally advanced via intermittent, oblique leaps, hopping like a chess knight into new businesses with little apparent connection to its existing ones. It was an electronics manufacturer that decided to also be a medical-device company and then, for good measure, a fabrics business. "Historically, when we've created large jumps in growth it's usually by the addition of another division," says Greg ▶

Bloomberg Businessweek May 13, 2019

◀ Hannon, the executive Kelly ultimately tapped to lead her initiative. Hannon believed Gore had grown too conservative, too incremental—more king than knight.

There are good reasons for a large, well-known, profitable company to be more cautious than a startup. It has more money and jobs at stake, and more regulation to contend with. But even an unorthodox company needs to keep growing to ensure long-term success. And so Gore, aging star of the management circuit, decided to bring in a guru: the innovation theorist Steve Blank. An entrepreneur who first learned electronics as an Air Force mechanic in the Vietnam War, Blank is popular in Silicon Valley startup circles. His central idea is that small companies (and the big ones that increasingly ape them) shouldn't wait until they have a polished product to see if the world wants it. Instead, they should go to market early and often, with beta versions, with prototypes, even with mere concepts, and let the resulting customer feedback tell them what the product should be. If you've heard the term "lean startup," you've heard about Blank's ideas.

Blank addressed Gore's leadership in 2015, at a company plant in Phoenix. There was a sense among the executives there, he recalls, that the company had lost "that feel for how to take risks that great entrepreneurs know instinctually." He told Hannon about a program he'd helped start with the National Science Foundation to address researchers' chronic inability to turn technological breakthroughs into products. Scientists learned how to write rudimentary business plans, then were paired with experienced entrepreneurs. I-Corps, as it was called, became the germ of Gore's effort.

When Kramer retired as CTO last year, Hannon replaced him, handing over leadership of the project to a biomedical engineer named Mike Vonesh. Based at Gore's Flagstaff, Ariz., plant, Vonesh is slim, with a Pepsodent smile, a gentle, unplaceable drawl, and special expertise in prostheses. The initiative he inherited from Hannon had I-Corps-style teams with "technical leads," "business leads," and external mentors. But it centered around a wholly internal venture capital market Gore had created. Its engineers would pitch their ideas to investment committees of colleagues with relevant technical, financial, and market expertise. The process was Darwinian: Concepts without clear market appeal were winnowed, while those that showed promise got additional funding rounds and more manpower.

"Most of our meetings we're around the table, all kind of hunched over, feeling, touching, poking at things"

▲ Testing fire gear in Elkton

The first two products to emerge from this bake-off were a thin insulation material intended to line women's dress shoes and a membrane that could dissipate heat from laptop and cellphone processors, allowing them to run more efficiently. Both used silica aerogels, a class of materials formed by replacing the water in a gel with air. They're extraordinary insulators but also extraordinarily fragile. The two Gore teams solved this problem by loading up a tough form of ePTFE with aerogel particles. The shoe insulation, Gore-Tex Thermium, is already on sale, and the electronics insulation has been rolled out in a line of Dell laptops.

Vonesh's "lean cohort" program—"I wish we had a better name," he apologizes—also inspired Balaji, Singh, and Schmiedel to dust off the cornea project and pitch it to an investment committee, which gave them seed funding. They used the money to conduct Blank-inspired interviews—almost 100 of them, with hospitals, insurance reps, ophthalmologists. They also created a prototype. "We didn't have the right design," Singh recalls. "We took Krazy Glue and cut pieces of ePTFE and stuck it all together."

▲ Schmiedel, Singh, and Balaji in Elkton

More important, though, they hit on the right materials. Asking around among his colleagues, Balaji had discovered a polymer Gore uses in its surgical patches—it's a fluorocarbon but it isn't ePTFE—that happens not only to be transparent but to bend light in the same way human cornea tissue does. And unlike the plastic used in existing corneal transplants, it has the softness and flexibility of eye tissue, as well. The Gore team melded the clear polymer with an outer ePTFE flange into which the eye's own tissue could grow.

Over the following months, in collaboration with Akpek, the team reworked and refined the design: the radius of curvature, the flange shape, the openings for nutrients. "We love putting prototypes and materials on the table," Singh says. A typical meeting would involve the surgeon and the engineers "all kind of hunched over: feeling, touching, poking at things." Schmiedel heat-molded the implants on a small steel press he'd built with Gore machinists, the piston tipped with optical glass. (The machining marks on steel would have left traces on the transparent polymer.) Akpek tried out the early iterations in "explanted" eyes—from rabbits, then pigs, then human donors—and once the team had a prototype it liked, it got funding for the in vivo rabbit study, which started in September 2017. Each time Akpek implanted a new rabbit, the Gore team would drive down to Baltimore to witness the procedure and, increasingly, to help. She took to calling them the bros.

The rabbit patients showed no signs of the complications associated with existing artificial implants, results that pleased Akpek tremendously. "Infection or melt happens more frequently with artificial corneas, and when it happens, it's bad," she says. "Overnight, that patient will go blind." The rabbits' immune systems hadn't attacked the implants, nor were there signs of glaucoma, another side effect of existing implants.

If all goes well, Akpek and the team will try out their implant in humans in 2020 and bring it to market in 2026. It will be a long and uncertain road, but the team is far enough along that they're preparing for a U.S. Food and Drug Administration trial and scaled-up production. Colleagues with more experience in those areas are beginning to join the effort.

"The big idea that I see large companies getting wrong and Gore getting right," Blank says, "is that innovation is not a point activity, it's an end-to-end process. You need a pipeline." He's already using Gore as a happy-ending case study for the other companies he advises.

For their part, the cornea bros are thinking about the next branch of the pipeline. The world is getting older, and a lot of eyes will need repairs in the coming years. Not surprisingly, Balaji hesitates to describe their new project in any detail, citing competitive fears. Besides, he says, "even if I did, it'll change tomorrow." Ⓑ

GORE