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Who checks the eye? Independent oversight of optical implants

Chiba Centre for Visual Science, Kiroshi Foundation, with Frothly

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Summary

Optical implants are three things at once. They are medical devices, placed in or on the eye by a surgeon. They are computers, which run software that is updated after they are fitted. And, increasingly, they are perception systems: software that decides what their wearers see, what is labelled, what is sharpened and what is left out.

This scoping study, carried out by the Foundation's Chiba Centre for Visual Science with Frothly between September 2021 and September 2023, asked who independently checks each of those three things, and what a sensible system of oversight would look like. We found that the first is checked carefully, the second partly, and the third hardly at all.

We make four recommendations: independent evaluation of perception software before release; firmware escrow for devices whose makers stop supporting them; wider adoption of open service interfaces; and secure, multi-year funding for independent registers of harm.

1. Why this study

About 2.6 million people wore an optical implant at the end of 2022, in the 23 countries where the largest maker sells them. Most were consumer devices, fitted to people with ordinary sight to give them more of it. A smaller number were medical devices, such as retinal implants for people blind from retinal disease, for whom the device is the difference between some sight and none.

The Foundation has a particular interest in the question, and a particular conflict. Its endowment is mostly invested in Kiroshi Opticals, which makes about three in five of the implants worn. It could not credibly answer the question by itself, which is why it asked Frothly, an independent institute with no shares and nothing to sell, to work with it. Frothly's staff wrote the sections on regulation and on other devices; Foundation staff wrote the sections on clinical practice and on discontinued devices. Both reviewed the whole.

2. What we did

We reviewed the regulation of optical implants in twelve countries: Japan, the United States, Canada, the United Kingdom, Germany, France, the Netherlands, Kenya, the Philippines, Viet Nam, Singapore and Australia. In each we read the medical device law, the guidance on software in medical devices and any rules on data and end of support.

We interviewed 64 people between March 2022 and May 2023: 18 staff of regulators, 14 staff of four implant makers, 19 clinicians and 13 wearers. Interviews were confidential, and quotations are not attributed.

We compared optical implants with three other kinds of device that run software after they are fitted or worn: insulin pumps, implanted cardiac devices and cochlear implants. Finally, we tested our draft recommendations at a two-day workshop in Chiba in March 2023 with 31 participants, including six wearers.

3. What is checked now

Table 1 summarises who checks each part of an optical implant in the twelve countries we reviewed.

Table 1. Who checks each part of an optical implant, twelve countries

Part of the implant	Checked by a regulator before sale	Checked after sale	Checked by nobody independent
Optics, materials and electronics	12 of 12	12 of 12	0 of 12
Surgical procedure	12 of 12	9 of 12	0 of 12
Firmware safety (power, heat, failure modes)	10 of 12	5 of 12	2 of 12
Perception software (what the wearer is shown)	1 of 12	0 of 12	11 of 12
Data the device keeps or sends	3 of 12	2 of 12	9 of 12
What happens when support ends	0 of 12	0 of 12	12 of 12

Every country checks the parts of an implant that resemble older medical devices. Almost none checks the software that decides what the wearer sees. Regulators we interviewed were candid about why: their rules treat perception software as a feature of the device rather than as a system that makes decisions, and they have no staff trained to evaluate it.

4. The gaps

- **Perception software.** A model that misses a kerb at dusk, or labels a white cane as an obstacle, can cause harm without any part of the device failing in the regulator's sense.
- **Data.** Implants see everyone their wearers look at. Rules on what devices may keep about those people are thin or absent.
- **End of support.** No country requires a maker to say, before sale, how long a device will be supported, or what happens to its software if the maker goes out of business.
- **Reports of harm.** Harm is reported to makers and, in some countries, regulators. Independent registers such as the Foundation's Independent Implant Register depend on voluntary reporting and on funding that can be withdrawn.

5. What other devices teach

Table 2. Oversight of software in four kinds of device

	Insulin pumps	Cardiac devices	Cochlear implants	Optical implants
Independent review of software before release	Partial	Yes, for therapy algorithms	Partial	No
Public register of faults	Regulator databases	Regulator databases	Regulator databases	One voluntary register
Rules on end of support	No	Some countries	No	No
Open service interface	No	No	No	One voluntary standard

The closest parallel is the cardiac device, where software that decides when to deliver therapy is reviewed by regulators as a decision-making system. Perception software in optical implants makes decisions of a similar kind, about what the wearer will see, and we see no principled reason to treat it differently.

6. Options

Table 3. Options considered

Option	For	Against	Indicative cost a year
Leave oversight to regulators	No new bodies	Regulators lack the staff and the remit	Nil
Makers evaluate their own software	Makers know their systems	Not independent	Borne by makers
Independent pre-release evaluation, published	Independent, public, repeatable	Depends on makers submitting voluntarily	¥150 million to ¥300 million
Licensing of perception software	Enforceable	Slow; unclear who would license	Unknown

7. Recommendations

1. Makers should submit the perception software in their implants to an independent evaluator before release, and the evaluator should publish what it finds.
2. Makers should place the firmware, source code and service documentation of every device with an independent escrow holder, to be released if support ends early or the maker ceases to exist.
3. Makers should adopt open service interfaces, so that any qualified clinic can maintain any implant.
4. Independent registers of harm should have funding set several years at a time, which cannot be reduced mid-term, and should report to bodies with no connection to any maker.

8. What happens next

Recommendations in a scoping study are cheap. We set out here what each would take, and who would have to act.

The first depends on makers. No law requires a maker to submit perception software for independent evaluation, and an evaluator can only evaluate what it is given. Frothly's Blackwall programme already evaluates frontier AI systems submitted voluntarily by laboratories, publishes everything it finds, and has agreed to accept submissions from implant makers on the same terms. At the Foundation's request as its largest shareholder, Kiroshi Opticals agreed on 30 October 2023 to submit future versions of its perception model. Other makers have not yet been asked.

The second and third can be achieved partly through standards. KF-OS 1 version 2.1, published in July 2023, already asks makers to publish a support plan and to name an escrow holder. Adoption is voluntary, and only makers who choose to conform will do so.

The fourth is within the Foundation’s own power. Its Independent Implant Register is funded by the Foundation alone. Its funding can be set for three years at a time and protected from reduction mid-term by a decision of the board, without anyone else’s agreement.

Annex A. Countries reviewed

Table A1. Regulation of optical implants in the twelve countries reviewed

Country	Implants approved	Software guidance	Data rules specific to implants	End-of-support rules
Japan	Yes	Yes	No	No
United States	Yes	Yes	No	No
Canada	Yes	Yes	No	No
United Kingdom	Yes	Yes	Draft	No
Germany	Yes	Yes	No	No
France	Yes	Yes	No	No
Netherlands	Yes	Yes	No	No
Kenya	Yes	No	No	No
Philippines	Yes	Partial	No	No
Viet Nam	Medical only	No	No	No
Singapore	Yes	Yes	Yes	No
Australia	Yes	Yes	No	No

Annex B. Interview guide

Interviews followed a common guide, adapted for each group. The questions for regulators were:

1. Which parts of an optical implant does your organisation review before it may be sold?
2. Do you review the software that decides what the wearer sees? If not, why not?
3. How do you learn of harm caused by implants after they are sold?
4. What happens, in your rules, when a maker stops supporting a device or ceases to exist?
5. What would you need in order to review perception software?

Wearers were asked about their device, how it had changed with updates, whom they asked for help when something went wrong, and what they would want from an independent body. Clinicians were asked about servicing devices from makers other than the one they had trained with, and about reporting harm.

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