

Realising market potential: HF and Design Thinking for novel ophthalmology patient interfaces

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SUMMARY

Breaking into a crowded space requires compelling differentiation. Our client wanted to enter the ophthalmic scanning market with a product which prioritises patient throughput to support the viability of optician businesses. We adopted a unique approach to design-thinking, prototyping and testing to explore novel patient interfaces to help achieve this challenging product requirement. The focus was not solely on enhancing ergonomics but moreover on supporting a robust business case - the surprising results may unlock significant commercial opportunity.

KEYWORDS

Medical devices, Ophthalmology, Commercial Opportunity, Design thinking, Formative Testing, Data analysis

Introduction

The demand for diagnostic technologies continues to grow as advances in medical science expand our ability to identify and treat disease. Within ophthalmology, this trend is particularly significant, as early detection has proven pivotal in managing a range of conditions, from glaucoma to age-related macular degeneration and diabetic retinopathy. Optical Coherence Tomography (OCT) has emerged as one of the cornerstone technologies in this field, offering high-resolution cross-sectional images of the retina that guide both diagnosis and treatment.

Despite the clinical value of OCT, improving access to this technology remains a pressing challenge. A wide variety of OCT systems have been developed, creating an increasingly saturated market where new entrants must offer meaningful differentiation to succeed. Recognising an opportunity, our client—a developer of premium multi-modal ophthalmic systems—approached us with a goal to enter the OCT market. Their vision centred on a device tailored to meet the needs of optician businesses by prioritising patient throughput and minimising attendant interaction, thus providing a competitive edge by supporting faster profitability.

This paper details the design and development process we undertook, emphasising the role of human factors engineering in shaping patient interfaces. By integrating design thinking, iterative prototyping, and innovating user testing, we explored novel interfaces to only enhance ergonomic comfort but also address the critical business case for optician practices. The insights gained offer a case study in how user-centred design can drive both clinical and commercial success.

Methodology

Medical product development follows a structured process to ensure devices are safe, effective, and meet user needs. It typically progresses from early exploration and concept generation, through

formal development stages governed by regulatory requirements, and ultimately to summative validation. Each phase builds on the previous, with early insights shaping later development.

The presented work fits into the front-end, pre-regulated phase, driven by design thinking principles. At this early stage, the focus was on exploring and validating concepts rather than adhering to formal design controls. The overarching goal was to provide the client with a 'reason to believe' that their commercial objectives could be achieved through innovative design and engineering solutions.

In this project, the client sought to differentiate their OCT system by maximising patient throughput—a key commercial requirement for optician businesses. To address this challenge, a two-part program was conducted: (a) an ideation and rapid prototyping phase to explore potential solutions, and (b) an in-depth evaluation of lead concepts to assess their compatibility with other product requirements. Although exploratory, the process incorporated elements of conventional Human Factors practice, such as task analysis and risk-based evaluation, ensuring meaningful and rigorous assessment.

The project tested the hypothesis that redesigning the user interface could reduce patient contact time while maintaining required standards of eye fixation and stability. These findings provided early confidence that the design could meet both clinical and commercial goals, offering a strong foundation for future development phases.

Although this program was an early-stage design-thinking exploration, a number of conventional Human Factors (HF) methods were selectively applied to ensure meaningful insights while maintaining agility in concept development. By balancing conventional HF methodologies with rapid, exploratory testing, the program maintained creative flexibility while ensuring design decisions were grounded in usability and anthropometric data.

Task Analysis & Risk Exploration

A high-level task analysis was conducted for multiple market-leading OCT systems to map out typical user workflows. Rather than a detailed step-by-step breakdown, this analysis remained abstract, focusing on identifying key operator and patient interactions that impact efficiency. The goal was to pinpoint areas where design innovations could streamline workflow and improve throughput.

While a formal uFMECA process was not followed—given the exploratory nature of this work—informal risk discussions were held with the client. These sessions explored 'pinch points' and usability challenges that could lead to negative clinical and business outcomes, helping to shape design priorities without constraining creativity.

Ideation and Prototyping

In understanding the conventional workflows and processes, the design thinking methodologies moved to focus on novel patient interfaces. Conventional OCT systems typically rely on an adjustable chin-and-headrest assembly, which can be time-consuming to adjust and uncomfortable for patients. This presented an opportunity for innovation. A range of alternative interface concepts, including 'goggle-style' and 'monocle-style' designs, were hypothesised and prototyped to varying degrees of fidelity using a various methods & materials.

Early Usability & Anthropometric Evaluations

A number of small-scale usability studies were conducted as part of iterative, fail-fast design sprints. These tests helped to stress-test interface concepts, and progress to the down-selection of two lead candidates for focussed evaluation. These internal studies leaned upon a diverse sample of

employees and relatives (including elderly and child participants) to before committing to the more structured formative assessment described in this paper.

With lead concepts selected, a digital anthropometric analysis was undertaken to determine the appropriate dimensions for the lead concepts to accommodate the target population, and assess whether individuals with extreme facial morphologies could use the interfaces comfortably without interference with the internal optics system.

This analysis processed first identified the key facial dimensions which would impact design and determined the corresponding anthropometric values from the PeopleSize [OpenErgonomics Ltd.] database (utilising 1st to 99th percentile values). Next, a number of digital personas were modelled within CharacterCreator3D [Real Illusion Inc.] embodying these anthropometric extremes. The digital personas were then imported into the system CAD model to evaluate fit and clearance to the lead concepts and system architecture.

Formalised Formative Testing

A formative study was planned involved 25 representative patients over 50 years old, representing a 'worst-case scenario' for usability. This demographic was prioritised based on early clinician insights, which indicated that elderly patients pose the greatest challenges for positioning and fixation during OCT scanning. As ophthalmic care needs increase with age, this group was identified as the largest sub-population that would routinely interact with the system.

Participants were recruited through a third-party agency specialising in medical Human Factors research. The study specifically included individuals with:

- Aged 50+, distributed across four age brackets (50–59, 60–69, 70–79, 80+ years).
- Self-reported or medically diagnosed upper back, neck, lower back, or mobility impairments.
- A balanced male-female ratio (~50:50) to reflect general patient demographics.
- A range of mobility restrictions, including two participants who required occasional or frequent wheelchair use.

Since the study's objective was to explore interface feasibility rather than evaluate clinical performance, vision status and prior OCT experience were not required for participation.

Ethnicity was not a formal recruitment factor, as incorporating additional demographic quotas would have significantly increased cost, complexity, and time constraints. While facial morphology is known to vary across ethnic groups, this study aimed to provide early validation of design feasibility rather than a fully representative solution. Although a digital anthropometric analysis (via PeopleSize and CharacterCreator3D) was conducted to refine interface dimensions, it did not influence participant selection. In later phases, broader demographic testing would be recommended to refine the interface further.

Within the elderly patient population, the most problematic cases for opticians and ophthalmologists typically involve:

- Limited neck and upper body flexibility, making it difficult to maintain the required scanning position.
- Difficulty achieving stable eye fixation, exacerbated by postural discomfort.
- Mobility impairments, increasing setup complexity and adjustment time.

To address these challenges, participants were selected to span a range of physical capabilities, ensuring the interface was tested under realistic, demanding conditions. While the primary focus

was on elderly users, limited testing with paediatric participants was also conducted in earlier fail-fast design cycles.

To facilitate representative testing, the team developed a functional rig with interchangeable interfaces and adjustable physical parameters, such as height and approach angle. The rig also incorporated a 4K camera (positioned off-axis via a prism) and an inline fixation target to measure patient stability. A custom machine vision application was developed to analyse patient stability during testing, addressing the client's requirement to evaluate the likely impact of interface designs on image quality and likelihood of needing re-scans.

The study evaluated three designs: Silicone Unibody Goggles, 3-Point Rigid Goggles, and the Conventional Head & Chin Rest as baseline to benchmark against. A randomised trial design captured both objective metrics (e.g., anthropometry, eye openness & movement) and subjective feedback (e.g., comfort ratings, interface preference).

Results

Rationale for Metrics & Evaluation Methods

This study aimed to assess whether novel patient interfaces could reduce patient 'chin time', thereby improving throughput without compromising usability or clinical performance. Three key evaluation areas were identified:

- **Setup Time** – The time required for a patient to self-seat in a comfortable and stable position. Since patient positioning contributes significantly to total chin time, this metric was critical in assessing efficiency. Patients were allowed to independently adjust their chair and table height to optimise their position. Setup time was measured as a single span from first interaction with the system to a self-reported 'ready' state.
- **Stability & Comfort in Use** – A user's ability to remain stable during scanning, while also maintaining subjective comfort. This was assessed using a 7-point labelled Likert scale, supplemented by qualitative participant feedback to capture individual experiences.
- **Eye and Head Fixation Stability** – Ensuring that novel interfaces did not compromise fixation quality, a key factor in scan integrity. Stability was quantified by tracking eye motion and head movement over a 30-second window while participants focused on a stationary fixation target. Machine vision methodologies were implemented in MATLAB, analysing point movement to determine variability.

Each metric was recorded for two novel interface designs and a benchmark chin-and-headrest system, tested across multiple inclination angles.

These methods provided structured, quantifiable evidence supporting a 'reason-to-believe' that novel designs could improve efficiency while maintaining usability and scan integrity.

1. Stability and Comfort

The Unibody Goggles were overwhelmingly preferred for comfort due to their softer, more supportive design. However, some participants noted tightness across the nose. Comparatively, the baseline design allows participants to rest into the interface, relieving neck pressure when positioned correctly, but setup was more complex and time-consuming.

Stability assessments using a custom MATLAB machine vision program revealed the Unibody Goggles achieved comparable eye fixation and lower overall head motion compared to the baseline. The 3-Point Goggles showed significantly greater motion and variability, indicating poorer stability. Furthermore, these performed poorly in maintaining 'eye openness', likely due to geometric issues.

Fixation analysis revealed the Unibody Goggles matched the Baseline in mean scores and standard deviations for net eye motion, demonstrating equivalence in visual fixation.

2. Effect of Tilt/Incline Angle

Participants preferred low tilt angles for Goggles interfaces (10–20°) however, higher angles (beyond 30° for Goggles and 10° for the Baseline) were deemed unacceptable due to discomfort, correlating strongly with reported back/neck pain. There were no significant differences in preferences by age, gender, or physical impairments.

3. Set-up time

Statistical analysis indicated no significant difference in setup times between the Unibody Goggles and 3-Point Goggles, but both outperformed the Baseline, which required more frequent camera focus adjustments, suggesting less positional repeatability. Self-adjustable interface height was universally appreciated, enabling participants to fine-tune their position for optimal comfort.

Key takeaways

1. **A Unique, Hypothesis-Driven Approach:** By prioritising a commercial imperative over pure ergonomics, the study demonstrated how novel patient interfaces can improve both efficiency and comfort in OCT systems.
2. **Design Thinking and Simulation Accelerated Development:** A design-thinking methodology, supported by human factors and ergonomic principles, leveraged simulation tools to validate concepts quickly and cost-effectively.
3. **Multidisciplinary, Data-Driven Collaboration:** Success hinged on a multi-disciplinary approach integrating expertise across optics, engineering, software, and human factors to develop and prove out a concept that balanced clinical and business needs.