

Development and research status of intelligent ophthalmology in China

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Abstract

• This paper analyzes the current status, technological developments, academic exchange platforms, and future challenges and solutions in the field of intelligent ophthalmology (IO) in China. In terms of technology, significant progress has been made in various areas, including diabetic retinopathy, fundus image analysis, quality assessment of medical artificial intelligence products, clinical research methods, technical evaluation, and industry standards. Researchers continually enhance the safety and standardization of IO technology by formulating a series of clinical application guidelines and standards. The establishment of domestic and international

academic exchange platforms provides extensive collaboration opportunities for professionals in various fields, and various academic journals serve as publication platforms for IO research. However, challenges such as technological innovation, data privacy and security, lagging regulations, and talent shortages still pose obstacles to future development. To address these issues, future efforts should focus on strengthening technological research and development, regulatory framework construction, talent cultivation, and increasing patient awareness and acceptance of new technologies. By comprehensively addressing these challenges, IO in China is poised to further lead the industry's development on a global scale, bringing more innovation and convenience to the field of ophthalmic healthcare.

• **KEYWORDS:** intelligent ophthalmology; image analysis; academic exchange

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INTRODUCTION

The field of intelligent ophthalmology (IO) is developing at a rapid pace due to the continuous innovation in medical technology, and this emerging force is transforming ophthalmic healthcare. The emergence of IO is not only driven by the innovative vitality of medical research in China and the concerted efforts of experts in the field but also benefits from the massive accumulation of ophthalmic medical data from a vast patient base and robust support from intelligent software and hardware technologies.

This paper discusses the developmental trajectory of IO in China, key technological innovations, the current status of clinical applications, the formulation of standards and regulations, the establishment of domestic and international academic exchange platforms, as well as the future challenges and prospects. This study aims to gain a thorough

understanding of the impact of IO on ophthalmic healthcare in China. Valuable insights and inspiration for the future development of this field will also be provided.

CONCEPT AND CONNOTATION OF INTELLIGENT OPHTHALMOLOGY

“Intelligent ophthalmology” refers to the profound integration and application of intelligent technology in the field of ophthalmology. This concept was initially proposed by Wei-Hua Yang and others from the Medical Artificial Intelligence Key Laboratory at Huzhou University in 2017. It has been continuously enriched and expanded during the establishment of the Intelligent Ophthalmology Group under the China Medicine Education Association. The core idea of IO is to combine a series of intelligent technologies, including artificial intelligence, with ophthalmology. By integrating advanced intelligent technologies, it aims to continuously improve the screening, diagnosis, treatment, monitoring, and prediction of ophthalmic diseases. The ultimate goal is to offer patients with eye diseases more accurate, faster, comprehensive, and personalized medical services.

IO involves the comprehensive analysis of ocular imaging data such as color fundus photography, optical coherence tomography, anterior segment images, corneal topography, visual field examinations, *etc.*, using next-generation information technologies like computer vision, big data analysis, machine learning, virtual reality, wearable devices, and 5G. Additionally, it can incorporate other relevant structured medical data to reveal the developmental patterns of ophthalmic diseases^[1-2].

In summary, IO aims to utilize advanced intelligent technologies to strengthen the management of various aspects of ophthalmic health throughout the entire lifecycle. This approach is designed to provide patients with a better medical experience and superior health assurance.

BIRTH AND SURGE OF INTELLIGENT OPHTHALMOLOGY IN CHINA

IO technology is the result of collaboration between medical institutions and intelligent technology professionals. This is because quality ophthalmic medical data and a team of professional ophthalmologists who provide data annotation are essential for the development of this technology. On the other hand, scientists committed to improving ophthalmic care are also necessary. Research in the field of IO in China has surged since 2017, with numerous outstanding technological achievements emerging, showing a significant annual increase in research since then. In 2017, the team led by Hao-Tian Lin at Zhongshan Ophthalmic Center (ZOC), Sun Yat-sen University, developed the CC-Cruiser, an artificial intelligence (AI) diagnostic and treatment decision platform for congenital cataracts. This marked the beginning of the current stage of

the surge in IO in China. The technology is utilized for the diagnosis, risk assessment, and treatment recommendations for congenital cataracts, which was featured as the cover article with the title “the Accelerating Power of Machine Learning” in the journal *Nature Biomedical Engineering*, making it the selected news for that issue^[3].

In 2018, the team led by Ming-Guang He at ZOC successfully trained a technology for the automatic screening of visual-threatened diabetic retinopathy (DR), using over 100 000 fundus images. The diagnostic accuracy reached an impressive 95.5%, and the related research was published in *Diabetes Care*, receiving high recognition from the international peer community^[4]. In 2019, the team led by Hao-Tian Lin developed an ultra-widefield fundus photography AI system^[5]. The team led by Xiu-Lan Zhang introduced the first glaucoma AI mobile application, “IGlaucoma”^[6]. Wei-Hua Yang’s team developed intelligent diagnostic technology for central serous chorioretinopathy and other diseases^[7-8]. In 2022, the team led by Wen-Bin Wei at Beijing Tongren Hospital, Capital Medical University, developed the Retinal Artificial Intelligence Diagnosis System, which is capable of recognizing multiple diseases^[9]. Researchers from the Macau University of Science and Technology, Zhang Kang, and Xiu-Lan Zhang jointly developed a deep learning system based on color fundus photography to predict the onset and progression of glaucoma^[10]. In 2023, Hao-Tian Lin’s team used crystalline lens photographs to develop the LensAge Index as a deep learning-based biological age, used for self-monitoring of age-related diseases and mortality risks. The findings were published in *Nature Communications*^[11]. These technologies exceed the capabilities of human experts in terms of specificity, sensitivity, stability, and other aspects, providing possibilities for large-scale early screening of blinding eye diseases and precise diagnosis of challenging eye diseases.

The successful application of IO technology in clinical practice within medical institutions in China has demonstrated a robust development momentum. These technologies have gradually integrated into ophthalmic clinical practice, particularly providing new solutions for grassroots ophthalmology and population screening.

TECHNOLOGICAL TRANSFORMATION OF INTELLIGENT OPHTHALMOLOGY IN CHINA

IO has demonstrated significant value and potential in public eye health and population eye health management. To apply these advanced technologies to clinical practice, numerous research and development teams have actively led application development and clinical testing. They have collaborated with corporate entities to drive the commercial transformation of IO products. Simultaneously, the National Medical Products Administration (NMPA) places high importance on scientific

supervision and industrial development of AI medical devices, providing substantial support in product classification, standard formulation, and product evaluation.

Among the rapidly growing applications of AI in ophthalmology, intelligent diagnostic technology for DR gained early market recognition^[12]. In order to establish unified standards for AI-assisted ophthalmic disease screening, promote the clinical application of AI diagnostic systems, and elevate the level of ophthalmic disease diagnosis and treatment in China based on AI technology, Jin Yuan, in August 2019, led the IO Group in drafting and passing the “Guidelines for artificial intelligent diabetic retinopathy screening system based on fundus photography”^[13]. On August 10, 2020, the “Diabetic Retinopathy Fundus Image Assisted Diagnosis Software” from Shenzhen SiBright Co., Ltd. and the “Diabetic Retinopathy Fundus Image Assisted Diagnosis Software” from Shanghai EagleVision Medical Technology Co., Ltd. received approval from the NMPA and obtained Class III certificates^[14]. On August 19, 2022, Beijing Kangfuzi Health Technology Co., Ltd.’s “Fundus Lesion Fundus Image Assisted Diagnosis Software” officially received the first national multi-disease AI Class III certificate, as well as the first glaucoma AI Class III certificate in the country^[15]. In September 2022, led by Yan-Wu Xu, the Ocular Fundus Disease Group and the Expert Guidance Group for AI Research and Application of the Chinese Ophthalmological Society jointly drafted and released the “The standardized design and application guidelines: a primary-oriented artificial intelligence screening system of the lesion sign in the macular region based on fundus color photography”^[16]. These milestones not only mark the commencement of the commercialization transformation phase of IO technology in China but also indicate the gradual perfection of standardized datasets and clinical trial standards in related disease areas.

Meanwhile, ophthalmic experts have extensively explored IO technology from the perspectives of medical safety and clinical needs. In 2019, the team led by Hao-Tian Lin pioneered the world’s first artificial intelligence ophthalmology clinic. They collaborated with ophthalmology clinics at five different hospitals in different regions, completing a multi-center randomized controlled clinical study on CC-Cruiser. This validated the effectiveness and feasibility of CC-Cruiser in real-world clinical practice, and the results were published in *EClinicalMedicine*^[17]. In 2021, Hao-Tian Lin’s team collaborated with Airdoc, the Guangdong Medical Device Quality Supervision and Inspection Institute, and 18 other institutions, to complete the world’s first multi-disease AI real-world study in ophthalmology. The results were published in the top journal *The Lancet Digital Health*^[5].

These commercial transformations represent significant progress in the research and application of IO technology in the medical field in China. They also validate the safety and effectiveness of IO products, providing successful examples for the practical application and transformation of more IO technologies.

ESTABLISHMENT OF CLINICAL APPLICATION STANDARDS FOR INTELLIGENT OPHTHALMOLOGY IN CHINA

Unlike traditional medical devices, the commercial transformation in the field of IO involves the process from “research outcomes” to “commercial products”, where the re-establishment of clinical application standards and the improvement of approval processes are crucial. In early 2018, the National Institutes for Food and Drug Control initiated the quality evaluation and research work of medical artificial intelligence products. By drawing on domestic and international experiences in IO research and transformation and combining the principles of “Technical Review Guidance for Medical Device Software Registration”, “Technical Guidance for Registration of Mobile Medical Devices”, and “Technical Review Guidance for Registration of Medical Device Network Security”, the China National Institutes for Food and Drug Control established a standardized dataset of color fundus images containing 6327 cases. This dataset is also China’s earliest medical AI evaluation standard dataset.

Addressing the lack of standardized clinical research methods, technical evaluations, and industry norms in international IO, the Ophthalmic Imaging and Intelligent Medical Subcommittee of the China Medical Education Association, along with the Intelligent Medicine Professional Committee, reviewed and summarized relevant research in IO at home and abroad. They drafted and released multiple clinical standards. In September 2021, a group jointly led by Xiu-Lan Zhang, Yan-Wu Xu, and Wei-Hua Yang, and involving 27 units including ZOC, the Guangdong Medical Devices Quality Surveillance and Test Institute, the China Academy of Information and Communications Technology, Southern University of Science and Technology, and Shenzhen Eye Hospital, formulated China’s first group standard on data quality control for color fundus photography titled “Specification for Annotation and Quality Control of Color Fundus Photography (T/CAQI 166-2020)”. It was published in the *Chinese Journal of Experimental Ophthalmology* which is affiliated with the Chinese Medical Association and the English journal *Intelligent Medicine*^[18-19]. Additionally, the first guide on organizing publicly accessible ophthalmic image databases was published in December 2022 as “Guidelines for the use of global public databases on ophthalmic images (2022)”^[20]. In July 2023, the first expert consensus on the

ethical evaluation of IO clinical applications was published as “Expert consensus for ethics of clinical application of artificial intelligence in ophthalmology (2023)”^[21]. Along with this, several other guidelines were published, such as “Guidelines on clinical research evaluation of artificial intelligence in ophthalmology (2023)”^[1], “Guidelines for the application of artificial intelligence in the diagnosis of anterior segment diseases(2023)”^[22], “Guidelines for the application of artificial intelligence in the auxiliary diagnosis of retinopathy of prematurity (2023)”^[23], and “Guidelines for the application of artificial intelligence in thyroid-associated ophthalmopathy (2023)”^[24]. These guidelines provide guidance and standards for clinical researchers in the field of IO, promoting the standardization and normalization of clinical research in this area.

In summary, Chinese researchers in the field of IO are continually committed to establishing and improving relevant clinical application standards. The formulation of these standards and guidelines provides robust support for the clinical transformation of IO, offering clear guidance for its safe, efficient, and standardized application. Furthermore, it serves as a model for international collaboration and technological exchange.

DOMESTIC ACADEMIC EXCHANGE PLATFORMS IN INTELLIGENT OPHTHALMOLOGY IN CHINA

Currently, China has established a multi-level, multi-disciplinary academic exchange platform in the field of IO, providing ample space for collaboration and discussion in the academic community. These platforms provide ample space for collaboration and discussion in the academic community, strengthening communication among domestic and international experts and fostering the sharing of research outcomes and technological innovation.

In August 2018, the Zhejiang Society of Mathematical Medicine and the First People’s Hospital of Huzhou successfully hosted the first domestic IO summit, the “2018 Intelligent Ophthalmology Forum”, in Huzhou City, Zhejiang Province. This event formally created a vital platform for domestic IO exchanges. The forum received positive responses from the industry, prompting calls for the establishment of the Intelligent Ophthalmology Group. In October 2018, the Intelligent Ophthalmology Group was established under the leadership of ZOC and the Medical Artificial Intelligence Key Laboratory of Huzhou University, with strong support from the Intelligent Medicine Professional Committee of the China Medicine Education Association. The group gathered elite researchers engaged in IO research across China and successfully organized the first National Conference on Artificial Intelligence in Ophthalmology. This significant academic conference is held annually and has

become one of the most important academic events driving the exchange of cutting-edge knowledge and technology in IO. Subsequently, various IO forums flourished. Such as, Soochow University led the organization of the first International Summit on Ophthalmic Artificial Intelligence in January 2022. Several universities, medical institutions, and research organizations regularly hold academic seminars and forums on IO. These events invite renowned professors and scholars from both domestic and international arenas, with topics covering the development trends and challenges of innovation in Ophthalmology and artificial intelligence. They offer a platform for attendees to gain in-depth understanding, engage in extensive communication, mutual learning, and collaboration.

In addition, regarding the publication of research papers, several domestic and international academic journals and conferences, such as the *Chinese Journal of Ophthalmology*, *Chinese Journal of Experimental Ophthalmology*, *Chinese Journal of Ocular Fundus Diseases*, *International Eye Science (Guoji Yanke Zazhi)*, *Medical Imaging and Computer-Aided Diagnosis*, and *IEEE Transactions on Medical Imaging*, offer publication platforms for IO research. Numerous research articles, reviews, and papers related to IO have been published^[25-31]. It is worth mentioning that the *International Eye Science (Guoji Yanke Zazhi)* has a dedicated column for IO and regularly accepts related submissions^[32].

The construction of these academic exchange platforms not only promotes in-depth collaboration within the discipline but also provides crucial support for interdisciplinary research and applications in the field of IO. These platforms have facilitated closer clinical and research collaborations between the Chinese mainland and Hong Kong, Macao, and Taiwan in ophthalmology. They also provide platforms for professionals in the field of IO to share knowledge and discuss future development directions, promoting continuous innovation and progress in Chinese IO.

INTEGRATION AND EXCHANGE OF INTELLIGENT OPHTHALMOLOGY IN CHINA WITH THE INTERNATIONAL COMMUNITY

The field of IO in China has made significant progress in the integration and exchange with the international community, successfully facilitating the cross-border flow of knowledge and talent.

As the first ophthalmology journal from China to be indexed in SCI, the *International Journal of Ophthalmology* officially established the “Intelligent Ophthalmology” column in February 2023. Serving as a dedicated section that consistently accepts submissions related to IO, it has provided a platform for the global academic community to widely showcase and exchange research achievements in IO^[1,33].

In terms of international talent attraction, the field of IO in China has attracted a cohort of globally renowned scientists. In 2019, Kang Zhang, one of the 100 most influential figures in ophthalmology, joined the Faculty of Medicine, Macau University of Science and Technology on a full-time basis. In 2021, Wong Tien Yin, one of the world's most influential ophthalmologists, joined Tsinghua University full-time. These outstanding scientists are actively contributing to the development of IO in China while demonstrating the openness and friendliness of the field on a global scale.

To strengthen collaboration with the international community, the field of IO in China is committed to establishing high-level international cooperation and exchange platforms. Examples of such platforms include:

Since 2014, Yan-Wu Xu in collaboration with the Institute of High Performance Computing at the Agency for Science, Technology and Research in Singapore, including researchers such as Hua-Zhu Fu and Ya-Lin Zheng from the University of Liverpool, has been organizing the Ophthalmic Medical Image Analysis Workshop during the International Conference on Medical Image Computing and Computer Assisted Intervention. This workshop has been held successfully for 10 sessions. Concurrently, the team led by Yan-Wu Xu, in collaboration with the team led by Xiu-Lan Zhang, has established the iChallenge, a publicly available dataset of precisely annotated eye images representing various ocular diseases. Since its initial release in 2018, iChallenge has evolved into the world's largest publicly available dataset of precisely annotated eye images covering multiple disease types. It comprises 8 sub-datasets and is characterized by its diversity in diseases, imaging modalities, tasks, and annotations. In 2023, the Bench Council awarded this dataset the TOP100 Achievement Award in the Evaluation and Benchmarking category.

In November 2021, the "International Ophthalmology Submit 2021", jointly organized by Shantou University and The Chinese University of Hong Kong, was successfully held in Shantou, Guangdong.

In January 2022, Xiamen Ophthalmic Center successfully hosted a China-UK International Symposium focusing on eye disease screening and artificial intelligence.

In May 2023, the first China-Singapore Ophthalmic Artificial Intelligence Innovation Forum was grandly held in Beijing Shougang Park. The forum aimed to promote collaboration and exchange between China and Singapore in the fields of ophthalmology and artificial intelligence. It invited renowned professors and scholars from both domestic and international arenas, covering rich topics such as innovative applications and future development prospects of AI in ophthalmology.

In November 2023, the AIMS 2023 Conference, titled "New Journey of Medical AI: Interdisciplinary Integration, Intelligent Leadership", organized by the *New England Journal of Medicine* group, was successfully held in Shanghai, China, with simultaneous global bilingual live streaming.

These exchange platforms have attracted outstanding IO experts globally, showcasing China's remarkable achievements in IO while integrating advanced technologies and ideas from the international IO community. This academic fusion propels further development in ophthalmic medical technology, bringing more benefits to eye disease patients worldwide.

FUTURE CHALLENGES AND SOLUTIONS

While the rapid development of IO in China has achieved significant milestones, it also faces a series of challenges that require effective solutions to ensure sustainable growth.

In the field of bibliometrics research, Chinese researchers have been remarkably active, contributing a considerable number of research outputs. However, compared to developed countries such as Singapore and the United States, the influence and centrality of IO research in China still lag behind^[34-37].

Technologically, the prominent challenge lies in data privacy and security. With the exponential growth of medical data, it is crucial to ensure patient information privacy and data security. To address this challenge, possible approaches include establishing more robust data encryption and secure transmission mechanisms, defining clear data sharing standards, and further strengthening regulations and oversight to ensure comprehensive protection of patient privacy. Additionally, the lag in medical regulations is an urgent issue that requires attention. With the rapid development of IO, medical regulations must keep pace, establishing more efficient approval processes while setting clear technical standards to ensure the quality and safety of new technologies^[21,38].

Simultaneously, the majority of IO research in China is confined to the Chinese population, severely lacking external validation of algorithms and models. Considering that the effectiveness and reliability of artificial intelligence algorithms may vary among different populations and regions, conducting cross-regional and cross-border validation and testing can enhance the universality and stability of the technology. Therefore, efforts should be directed towards establishing closer international cooperation mechanisms, strengthening international collaboration and data sharing, conducting cross-border validation and testing, promoting global exchange and sharing of IO technology, and collectively driving the advancement and development of the industry.

Talent shortage is also a potential issue in the development of IO. As the field requires interdisciplinary professionals, including doctors, engineers, and data scientists, efforts should be made to enhance training programs in relevant fields and

encourage more interdisciplinary research. The establishment of a “Smart Medicine” specialization in undergraduate and graduate training programs can expedite the cultivation of talents in intelligent healthcare. This can be achieved by adopting a model of interdisciplinary joint training that combines medicine with engineering, science, and humanities. In addition, attention needs to be paid to communication between medical professionals and patients, as well as patient acceptance of new technologies. Future efforts should actively advocate for patient involvement in medical decision-making, contributing to increased practical application and acceptance of IO technologies^[39-40].

Therefore, the future development of IO in China requires comprehensive support from various perspectives, including technological innovation, regulatory frameworks, talent cultivation, international academic exchange, and patient education. By actively addressing these challenges, IO technology is poised to better serve ophthalmic healthcare, providing patients with more accurate, faster, comprehensive, and personalized medical experiences.

REFLECTION AND PROSPECTS

The rise of IO in China signifies a transformative shift in the medical field. Its significant progress and robust support from national policies have positioned it at the forefront globally. However, as technology advances, a series of challenges and issues gradually arise, requiring comprehensive reflection and solutions.

First, despite significant achievements in IO research and development in China, there is still a lack of originality in algorithms. Strengthening original research in algorithms and enhancing the core competitiveness of technology are crucial directions for future development on the path of technological innovation. Additionally, challenges in clinical safety, data quality, and the interpretability of algorithm results require urgent resolution. Ensuring the safety and stability of IO technology in clinical environments is indispensable when introducing it into practical applications.

On the other hand, ethical and legal issues encountered in the practice of IO cannot be overlooked. With continuous technological development, relevant regulations and ethical frameworks need timely updates to ensure the full protection of patient rights^[41]. Furthermore, improving the interpretability of algorithmic results can enhance the acceptability of the technology in medical practice. This can help healthcare practitioners and patients understand the mechanism of the technology’s operation, eliminating potential doubts and mistrust.

The DR intelligent diagnostic software for fundus images has the most Class III certificates in the ophthalmology field among all auxiliary diagnostic software. Despite demonstrating

potential applications in grassroots ophthalmology and population screening, it has not yet been fully incorporated into relevant clinical screening guidelines in China. Given the significant differences in the development of IO across various levels of medical institutions, future development of IO technology will primarily occur in advanced-level medical institutions, while the promotion and application of the technology should be more focused on grassroots medical institutions.

Limiting factors such as other fee policies and patient acceptance, coupled with the difficulties in large-scale practical applications, indicate the challenges in translating IO research outcomes into clinical business practices. This issue requires in-depth research and close collaboration with the medical community and health management authorities to foster smoother implementation of IO technology in the healthcare sector.

In conclusion, despite significant progress in the development of IO in China, comprehensive and in-depth efforts are still needed in technological research and development, regulatory ethics, clinical practice, and other aspects. In the future, with the continuous improvement of IO research applications and increased societal awareness, it is believed that IO in China will embrace broader development prospects, bringing more innovation and convenience to the field of ophthalmic healthcare.

LIMITATIONS

This article has some limitations. First, it may not cover all the latest research and developments in the field comprehensively due to constraints on available literature and information. Additionally, due to the limited scope of the study, discussions on some details and specific aspects may be concise. Finally, the article lacks an in-depth examination of the differences between regions and institutions within the field of IO in China. These limitations affect the comprehensive understanding of IO in China, and future studies can delve more deeply into these aspects.

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